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Roadmap to Strengthen the U.S. Manufacturing Supply Chain via Digital Thread Technology

Prepared by Commonwealth Center for Advanced Manufacturing (CCAM)
Funded by the NIST Office of Advanced Manufacturing (NIST OAM)
NIST Advanced Manufacturing Technology Roadmap Program (MFGTech)

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Roadmap to Strengthen US Supply Chains via Digital Thread Technologies

CCAM
SOLVING ADVANCED MANUFACTURING CHALLENGES

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U.S. Department of Commerce
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Abstract

This work presents and catalyzes support for a technology roadmap to improve the resilience and capacity of the US manufacturing supply chain through Digital Thread technology. Risks to supply chain resilience and capacity are mapped against envisioned capabilities for Digital Thread technology in 4 industry sectors. The sectors are Aerospace and Defense, Energy, Agriculture/Food, and the Pharmaceutical, Biopharmaceutical, and Medical Device (PBMD).

Keywords

Artificial Intelligence, Augmented Reality, Capacity, Causal Analytics, Code of Federal Regulations, Digital Supply Network, Digital Thread, Digital Twin, FAIR, GS1, IIoT, Industrial Internet of Things, ISA-95, ISO, Machine Learning, MTConnect, OPC, PLM, Product Lifecycle Management, QIF, Quality Information Framework, Resilience, Smart Manufacturing Systems, SMS, STEP, Supply Chain, Traceability

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Executive Summary

On June 8, 2021, the White House announced key findings from the reviews directed as part of the February 2021 Executive Order on America's Supply Chains. The report revealed that structural weaknesses in domestic and international supply chains threaten America's economic and national security. The fragility of the modern supply chain has deep roots; strengthening it will require a reset in the design of supply chain networks to improve resilience[1] and capacity[2].

The promise of Digital Thread technology is to enable seamless access to, and association of, data throughout extended supply chains. The technology roadmap proposed, when implemented, focuses on strengthening Digital Thread technology to help organizations make efficient, effective, and timely use of the digital information collected and exchanged throughout their supply chains and envisioned digital supply networks. This will enable manufacturers and producers to align their diverse product and process capabilities, reduce costs, improve quality, and accelerate innovation and subsequent market penetration. Ultimately, these benefits are then transferrable to customers and consumers.

Digital Thread technology encompasses the systems and data that connect digital information about products throughout the entire product lifecycle, across all internal company organizations and external supply chain partners to provide a single source of truth. The technology can help to make supply chains more resilient and capable by providing increased visibility, improved collaboration, enhanced traceability, real-time insights, and capability for in-field performance improvements.

- **Increased visibility**: Digital Thread technology can provide a single, unified view of the entire supply chain, from raw materials to finished goods and transportation. This increased visibility can help to identify and mitigate risks and improve decision-making.
- **Improved collaboration**: Digital Thread technology can facilitate collaboration between different members of the supply chain (suppliers, producers, distributors, retailers, and service organizations). This collaboration ensures that everyone works from the same information and that problems can be identified and resolved quickly.
- **Enhanced traceability**: Digital Thread technology can track the movement of products throughout the supply chain, providing a complete history of each product for improved product safety, compliance, and recalls.
- **Real-time insights**: Digital Thread technology can provide real-time insights into the supply chain, inventory levels, lead times, demand signals, and transportation schedules. This real-time data is used to make better decisions and to improve the efficiency of the supply chain.
- **In-field performance improvements:** Digital Technology provides opportunities for new or improved data-enabled solutions for replacement parts that exceed product specifications.

[1] Resilience refers to the ability of a given supply chain to prepare for and adapt to unexpected events and to recover quickly to its pre-disruption state or a more desirable state.
[2] Capacity refers to the overall supply chain's ability to generate output over a pre-determined time.

The described technology roadmap will enable US manufacturers to rapidly identify supply-chain disruptions and quality issues, improve operational efficiency and effectiveness, and expand revenue opportunities by identifying a strategy to address barriers to adoption and rapid implementation of Digital Thread technology.

The roadmap primarily covers four (4) selected industry segments: Aerospace & Defense, Agriculture/Food, Energy, and Pharmaceutical, Biopharmaceutical Sciences & Medical Devices (PBMD). The unique needs, risks, challenges, and proposed research for each of these segments are addressed individually in section **Error! Reference source not found.**, 5, 6 and 7 respectively.

Highlights of the identified challenges to improving supply chain resilience and capacity include:

- Recognizing disruptions in the supply chain takes too long. This is made worse by gaps in digital threads that prevent the seamless exchange of timely and reliable information.
- There is a lack of clear vision about what systems to connect and how to connect them.
- Accessing and associating product lifecycle data across internal and external supply chain boundaries is challenging because suppliers and producers employ different data formats, different semantics, and different integration architectures.
- Organizational and geographical data silos create barriers to Digital Thread realization.
- The quality and timeliness of data are often unknown, resulting in decisions made on out-of-date or incorrect information.
- There is a lack of trust between organizations both internally and externally regarding issues such as IP protection, data ownership, and potential economic or national security information exposure.
- The landscape for data standards, semantics, and integration architectures is murky. Data is often copied from system to system and loses clarity and context. Standards-based implementations are sometimes incomplete, and conformance is not always verified.
- Manufacturers struggle to meet cost and schedule objectives while simultaneously satisfying supply chain connectivity requirements. This is especially true for small-medium businesses that do not have the resources for expensive data integration projects.
- There is insufficient collaboration between public and private stakeholders.

The developed roadmap focuses on strengthening Digital Thread technology that makes efficient, effective, and timely use of the digital information collected and exchanged throughout manufacturing supply chains and digital supply networks. The roadmap proposes a Digital Thread technology framework customizable for each of the four industry sectors and includes specific project recommendations that address several **key areas for Digital Thread technology development**. The areas of proposed research and technology development include:

- **Standardization and semantic data modeling**
- Methods for improved **integration and interoperability**
- **Data security and privacy**
- **Architecture issues** related to data collection/ingestion, storage, transfer and retrieval in both inter-organization and intra-organization contexts. These include scalability, performance, real-time data streaming, and edge/fog/cloud computing issues.

- Methods for **improved data analytics and decision-making**. Includes machine learning (ML) and artificial intelligence (AI) and methods for enhanced lifecycle traceability.
- **Human factors issues** including human-centric design (interfaces and visualization techniques), workforce development, challenges associated with cross-disciplinary and cross-cultural international collaboration, and ethical and social implications of increased data collection and sharing.

The **key recommendations** per industry are as follows:

Aerospace and Defense

- Perform additional research in applications of Digital Thread towards product lifecycle management and expand into larger assemblies and datasets
- Target digital supply networks and escrow models as solutions to be deployed in the industry at scale with focus on improved TDP management and support for predictive and causal analytics

Agriculture/Food

- Split research efforts between digitization of agricultural practices and improving traceability of products toward reducing the costs of regulatory compliance
- Target digital supply networks and scalable XaaS systems as solutions to be deployed in the industry at scale

Energy

- Focus research on the adoption of a Digital Thread framework for the energy sector, applying it towards increasing capacity and traceability of critical materials
- Target digital supply networks and virtual power plants as solutions to be deployed in the industry at scale.

Pharmaceutical, Biopharmaceutical Sciences, and Medical Devices

- Focus research towards reducing the costs of regulatory compliance using the traceability provided by Digital Thread technology of materials.
- Target digital supply networks and a common digital strategy for regulatory compliance as solutions to be deployed in the industry at scale

To support these objectives, the roadmap recommends funding workforce training and development and a cross-industry Digital Thread technology program featuring centers of excellence for Digital Thread technology and supply chain research.

Digital Thread technology can benefit all US industries, and cooperation is imperative to reach the necessary consensus for highly functional, composable, interoperable, secure, and cost-effective standards-based technology solutions to meet our nation’s supply chain challenges.

How to use this roadmap

This roadmap has been developed primarily to help the NIST OAM focus future research and development investment. However, it is also valuable to US manufacturers and producers and government entities wishing to improve organizational outcomes by addressing challenges with supply chain resilience and capacity via Digital Thread technology.

It is not necessary to read the entire roadmap to benefit from it. Each section is summarized below. We suggest reviewing sections 1 through 3 and then focusing on the information in section 4, 5, 6, or 7 that is most relevant to the reader. The program and recommendations proposed in section 8 are designed to pull together research and development efforts on Digital Thread technology in way that can benefit all US industries.

> **Section 1** provides background on the study, defines the over-arching goal of this work and describes its six core objectives and methodology.
>
> **Section 2** highlights the need for improved supply chain resilience and capacity and summarizes Digital Thread technology, its benefits, supply chain context, requirements, characteristics, and underlying technologies.
>
> **Section 3** provides an overview of the current situation regarding supply chain resilience and capacity, digital threads and digital twins. This section also summarizes challenges and threats to Digital Thread adoption and in current Digital Thread technology.
>
> **Sections 4, 5, 6, and 7** focus on the opportunities to use Digital Thread technology to address supply chain resilience and capacity in each of the four industry segments examined in this roadmap.
>
> > **Section 4** Aerospace and Defense
> >
> > **Section 5** Energy
> >
> > **Section 6** Agriculture/Food
> >
> > **Section 7** Pharmaceutical, Biopharma Sciences and Medical Devices (PBMD)
>
> **Section 8** summarizes recommendations in the context of a cross-industry Digital Thread technology program. The proposed program would focus investment on a standards-based Digital Thread technology framework in support of targeted solutions with significant benefit to US supply chain resilience and capacity. The program would also include funding for workforce development and training and for inter-industry centers of excellence.
>
> The **Appendices** describe the roadmap development process, background information on some of the existing research in the aerospace and defense industries, an overview of guidelines and regulatory concerns in the PBMD sector, and tables of relevant standards, working groups, and abbreviations used throughout the document.

1. Study Background

On June 8, 2021, the White House announced key findings from the reviews directed as part of the February 2021 Executive Order on America's Supply Chains [1]. The report revealed that structural weaknesses in both domestic and international supply chains threaten America's economic and national security [2]. The fragility of the modern supply chain has deep roots; strengthening it will require a reset in the design of supply chain networks to improve resilience and capacity. Soon after, on June 17, 2021, the NIST Office of Advanced Manufacturing (OAM) announced the Advanced Manufacturing Technology Roadmap (MFGTech) Program of which this document is a part. The emphasis of the MFGTech program is on technology roadmapping in areas of critical interest to the nation, including technology areas appropriate for potential future Manufacturing USA institutes [3].

1.1. Partners and Collaborators

The focus of the road mapping effort generated considerable support from partners and collaborators, and CCAM has been fortunate to gather a very strong team of major US manufacturers and other organizations. The project team is led by the Commonwealth Center for Advanced Manufacturing (CCAM) and Principal Investigator Eric Holterman, P.E. The team includes key contributors and globally recognized experts from four of the key industry segments identified in the Executive Order on "America's Supply Chains" as well as experts on supply-chain, cybersecurity and small-medium manufacturing enterprises. The four industry segments in focus are aerospace and defense, pharmaceutical & medical devices, energy, and agriculture.

Core Team members include:

- Commonwealth Center for Advanced Manufacturing (CCAM)
- BR&L Consulting (BR&L)
- CIMdata
- GENEDGE
- Open Applications Group, Inc. (OAGi)
- MTConnect Institute (MTCI)
- Procegence
- Thistle Blue Consulting
- Virginia Commonwealth University (VCU)
- Virginia State University (VSU)

Unfunded collaborators from private industry were critical to the success of this project by providing their expertise, perspectives, experiences, access to facilities, expanding the breadth of collaboration, and – most importantly – helping to define the desired future state(s), challenges to achievement, and future research and technology infrastructure investment which inform the technology roadmap for strengthening the US Manufacturing Supply Chain via Digital Thread Technology. A complete list of collaborating organizations can be found in the *Acknowledgements* section of this document.

1.2. Goal and Objectives

The goal of this work is to ***Develop and catalyze support for a technology roadmap to improve the resilience and capacity of the US manufacturing supply chain through Digital Thread technology***[3].

The technology roadmap proposed is aligned with the goals and objectives described in the October 2018 Strategy for American Leadership in Advanced Manufacturing (SALAM) [4]. The roadmap supports all three of the primary goals in the 2018 document and addresses most of the individual objectives. The work is also aligned with the 2021 executive orders to address the fragility of critical supply chains and increase their resilience and capacity. Four key industry segments are addressed along with the cross-cutting considerations of cybersecurity and potential impacts on small-medium manufacturers.

The digitalization of manufacturing continues to grow in ways that will permanently change the way companies conduct business. The drivers for this change are dramatic technological advances and lower costs for computing power, sensing, data storage, and software. It is now possible for vast amounts of data across the supply chain to be gathered in near real-time to perform advanced analytics, generate new insights, and execute more effective decisions. The challenge is that to fully realize the value of the data, it should be easy to collect, access, exchange, and associate with other data while being timely, reliable, and contextual.

The roadmap is a tangible, actionable, industry-driven document which describes a clear strategic path to fully realize the benefits of Digital Thread technology, especially in the context of supply chain resilience and capacity.

The six (6) objectives supporting the project goal are:

1. ***Identify risks to supply chain resilience*** which can be mitigated by strengthening and leveraging Digital Thread technology.
    a. Supply chain resilience refers to the ability of a given supply chain to prepare for and adapt to unexpected events; to quickly adjust to sudden disruptive changes that negatively affect supply chain performance; to continue functioning during a disruption (sometimes referred to as "robustness"); and to recover quickly to its pre-disruption state or a more desirable state [5].
2. ***Identify risks to supply chain capacity*** which might be mitigated by strengthening and leveraging Digital Thread technology.
    a. Supply chain capacity refers to the capability to produce output for a specific period. Supply chain capacity is composed of:
        i. Supplier Capacity – Including tier 2, 3 and 4 suppliers.
        ii. Production Capacity – Including manufacturers' abilities to meet internal and external requirements, regulations, and specifications for production of goods and services.

[3] Note use of the term "Digital Thread technology" and not *the* Digital Thread, digital fabric, digital web, or other similar terms. While each of these terms is in use, the authors chose the term "Digital Thread technology" because we feel it best captures the interconnected nature of several research domains which can be leveraged to provide increased visibility, improved collaboration, enhanced traceability, real-time insights, and capability for in-field performance improvements to address supply chain challenges. This topic is discussed in more detail in section 2.

    iii. Transport and Distribution Capacity – Including time spent in cargo, storage handling, staging, and inspection facilities as well as actual transport and load/unload activities.

3. ***Clarify the target future state(s)*** of Digital Thread technology in the context of value/supply chain resilience and capacity for key industry sectors.
    a. Digital Thread technology should enable manufacturers to seamlessly collect, access, associate, and share timely and reliable contextual data from various sources throughout their value and supply chains.
4. ***Identify weaknesses, gaps, and challenges*** of Digital Thread technology which must be overcome for manufacturers to maximize value from advanced manufacturing investments and reduce risk to supply chain resilience and capacity.
    a. Digital Thread technology continues to evolve, however, challenges to realizing the vision of simple access and association of contextual data throughout the extended supply chain remain numerous.
5. ***Identify and prioritize potential research*** projects and ***workforce development and training*** initiatives which address challenges to achieving the desired future state(s).
    a. Harnessing Digital Thread technology is critical to achieving maximum value from our technology investments since it weaves through all processes and interfaces throughout the extended supply chain. It is the glue connecting the ***S***uppliers, process ***I***nputs (e.g. raw material), physical and virtual ***P***rocesses, process ***O***utputs (e.g. products and byproducts), and ***C***ustomers of processes across every industry (***SIPOC***). Developing a clear strategy for research and development of Digital Thread technology along with initiatives to provide for workforce development and training on the technology will accelerate our ability to achieve all goals.
6. ***Catalyze development and support*** for a technology infrastructure to help US manufacturers improve the resilience and capacity of their supply chains through full realization and exploitation of Digital Thread technology.
    a. Effective implementation and successful deployment are essential for research & development projects to benefit industry. Manufacturing USA Institutes help to address the risks associated with these projects by bringing together member organizations from manufacturers of all sizes, academia, and government to work on major projects and train people on advanced manufacturing skills. This roadmap will strengthen and inform the existing Manufacturing USA institutes by providing a tangible, actionable, technology roadmap which identifies and organizes high-priority projects to address challenges.

1.3. Methodology

Developing a roadmap that addresses many manufacturing companies, industries, and roles within supply chains required participation from numerous organizations. It also required the use of various methods of information gathering and analysis which are more fully described in Appendix A. Several key principles guided the work:

1. Background study and information gathering to inform and guide the roadmap activity.
2. Formation of a core team made up of CCAM researchers, contractors, and selected experts from the core member organizations representing multiple industry segments and the interests of small and medium manufacturers.
3. The core team defined the overall roadmap elements, outlined key topics for deeper investigation, coordinated working sessions and regular meetings between the working groups, and synthesized results into a cohesive roadmap.
4. The core team was supported by working groups aligned with the different industry segments. Each working group investigated key topics, conducted interviews and surveys, defined key benefits, challenges, and opportunities for each individual topic, and supported integration into the overall roadmap.

Details of the methodology are described more fully in Appendix A.

2. Supply Chain Resilience and Capacity and Digital Thread technology

2.1. Highlighting the Need for Improved Supply Chain Resilience and Capacity

Selected excerpts from the June 2021 100-day Reviews under Executive Order 14017, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-based Growth [6]:

"The COVID-19 pandemic and resulting economic dislocation revealed long-standing vulnerabilities in our supply chains. The pandemic's drastic impacts on demand patterns for a range of medical products including essential medicines wreaked havoc on the U.S. healthcare system. As the world shifted to work and learn from home, it created a global semiconductor chip shortage impacting automotive, industrial, and communications products, among others. In February, extreme weather events—exacerbated by climate change—further exacerbated these shortages. In recent months the strong U.S. economic rebound and shifting demand patterns have strained supply chains in other key products, such as lumber, and increased strain on U.S. transportation and shipping networks.

…

Small failures at even one point in supply chains can impact America's security, jobs, families, and communities.

…

More secure and resilient supply chains are essential for our national security, our economic security, and our technological leadership.

National security experts, including the Department of Defense, have consistently argued that the nation's underlying commercial industrial foundations are central to our security.

…

Our economic security—steady employment and smooth operations of critical industries—also requires secure and resilient supply chains.

…

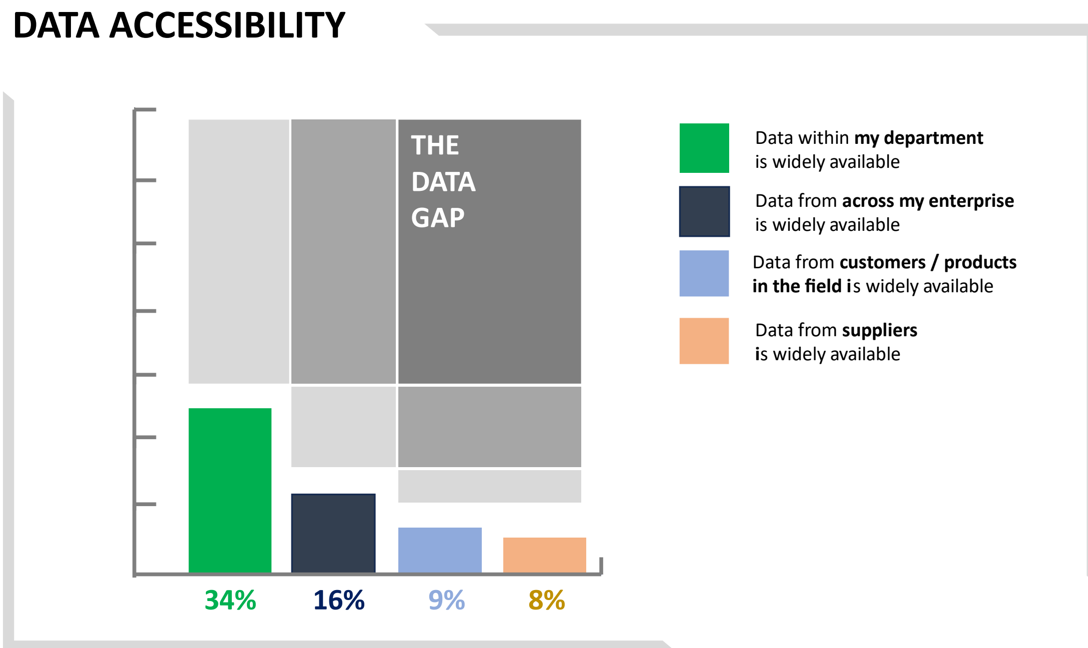
A resilient supply chain is one that recovers quickly from an unexpected event. Our private sector and public policy approach to domestic production, which for years, prioritized efficiency and low costs over security, sustainability, and resilience, has resulted in the supply chain risks identified in this report."

2.2. Digital Thread Technology

Digital Thread technology describes the systems and data that connect digital information about products thought the entire product lifecycle, across all internal company organizations and external supply chain partners to provide a single source of truth. The term 'Digital Thread' was first used in the Global Horizons 2013 [7] report by the USAF Global Science and Technology Vision Task. NIST also has a Digital Thread in Manufacturing project [8].

US Manufacturers of all sizes and across all industry segments struggle to access data across the supply chain. As the PTC survey [9] shows in Figure 1, there is currently a tremendous gap between the perceived value of data and the companies' ability to recognize that value.

The PTC survey only investigated companies' ability to *access* data from various sources. The data gap would likely be even wider if manufacturers were asked about their ability to *seamlessly* *collect, access, associate, and share timely and reliable contextual data* from various sources throughout their value and supply chains.



Question: Please select the option which best describes your organization's ability to access data from various sources through it's enterprise systems.
Survey conducted in 2021, n=150

Figure 1: Responses to recent survey on State of Digital Thread describing organizations' ability to access data.

The concept of Digital Threads is to use digital technologies, standards, and training to transform the ability of manufacturers and producers to increase throughput and efficiently meet standards for quality and conformance (capacity) while simultaneously providing unprecedented visibility to their supply chain networks and the ability to quickly respond to potential disruptions and quality issues (resilience).

The ISO/TC184/SC4/WG15 working group on Digital Manufacturing offers the following description of Digital Thread in the working draft of ISO standard 23247-5 [10]:

A Digital Thread is the *connected communication mechanism for contextualized life cycle data* with support of the following aspects:

— The connected communication is enabled by standards and technologies
— The communicated data spans the entire life cycle
— The data is contextualized for clear and extendable interpretation
— The contextualized communication enables data traceability

This connected communication mechanism ensures the seamless flow of data and provides integrated access to up-to-date and consistent manufacturing information across traditionally isolated processes. By linking data across various stages, manufacturers and producers can get the right data at the right place at the right time which significantly improves decision making and operational efficiency.

2.2.1. Digital Thread Technology Benefits

Investments in Digital Thread technology provide value throughout the lifecycles of products as well as services. By providing increased visibility, improved collaboration, enhanced traceability, real-time insights, and capability for in-field performance improvements, Digital Thread technology can help US supply chains become more resilient and capable.

- **Increased visibility**: Digital Thread technology can provide a single, unified view of the entire supply chain, from raw materials to finished goods and transportation. This increased visibility can help to identify and mitigate risks and improve decision-making.
- **Improved collaboration**: Digital Thread technology can facilitate collaboration between different members of the supply chain (suppliers, producers, distributors, retailers, and service organizations). This collaboration ensures that everyone works from the same information and that problems can be identified and resolved quickly.
- **Enhanced traceability**: Digital Thread technology can track the movement of products throughout the supply chain, providing a complete history of each product for improved product safety, compliance, and recalls.
- **Real-time insights**: Digital Thread technology can provide real-time insights into the supply chain, inventory levels, lead times, demand signals, and transportation schedules. This real-time data is used to make better decisions and to improve the efficiency of the supply chain.
- **In-field performance improvements:** Digital Technology provides opportunity for new or improved data-enabled solutions for replacement parts that exceed product specifications.

2.2.2. Digital Thread Technology in the Context of Supply Chain

Digital Threads tie together multiple different activities within a manufacturing organization and across companies in the upstream and downstream supply chains. These activities are defined, in general, in ISO/DPAS 24644-1:2023 – Mass Customization Value Chain – Framework [11]. See Figure 2. These activities range from user interactions that define product demands, through R&D, marketing & sales, sourcing & planning, production, logistics (transportation), and service. Organizations often (usually) employ multiple digital systems that must be integrated to allow for the exchange of accurate and timely information.

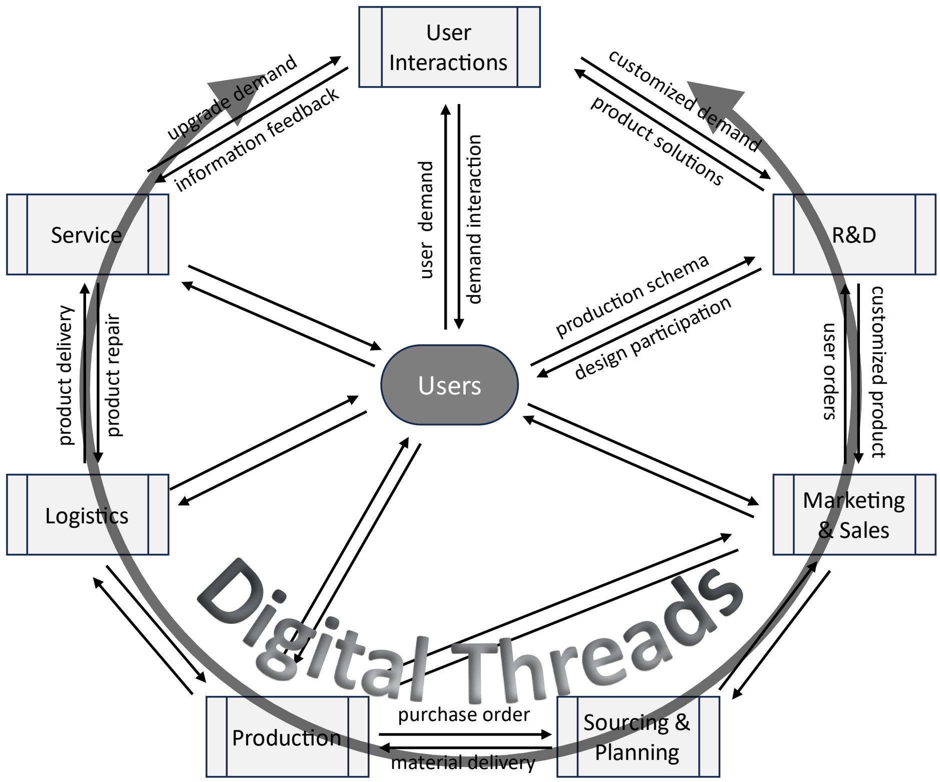


Figure 2: Derived from ISO/DPAS 24644-1:202(E) – Mass Customization Value Chain – Framework

Since Digital Threads must carry many different types of information, across a wide variety of systems, it is better to look at the specific subsets of activities that must regularly exchange information. The types of exchanged information between the different activity sets are illustrated in Figure 3.

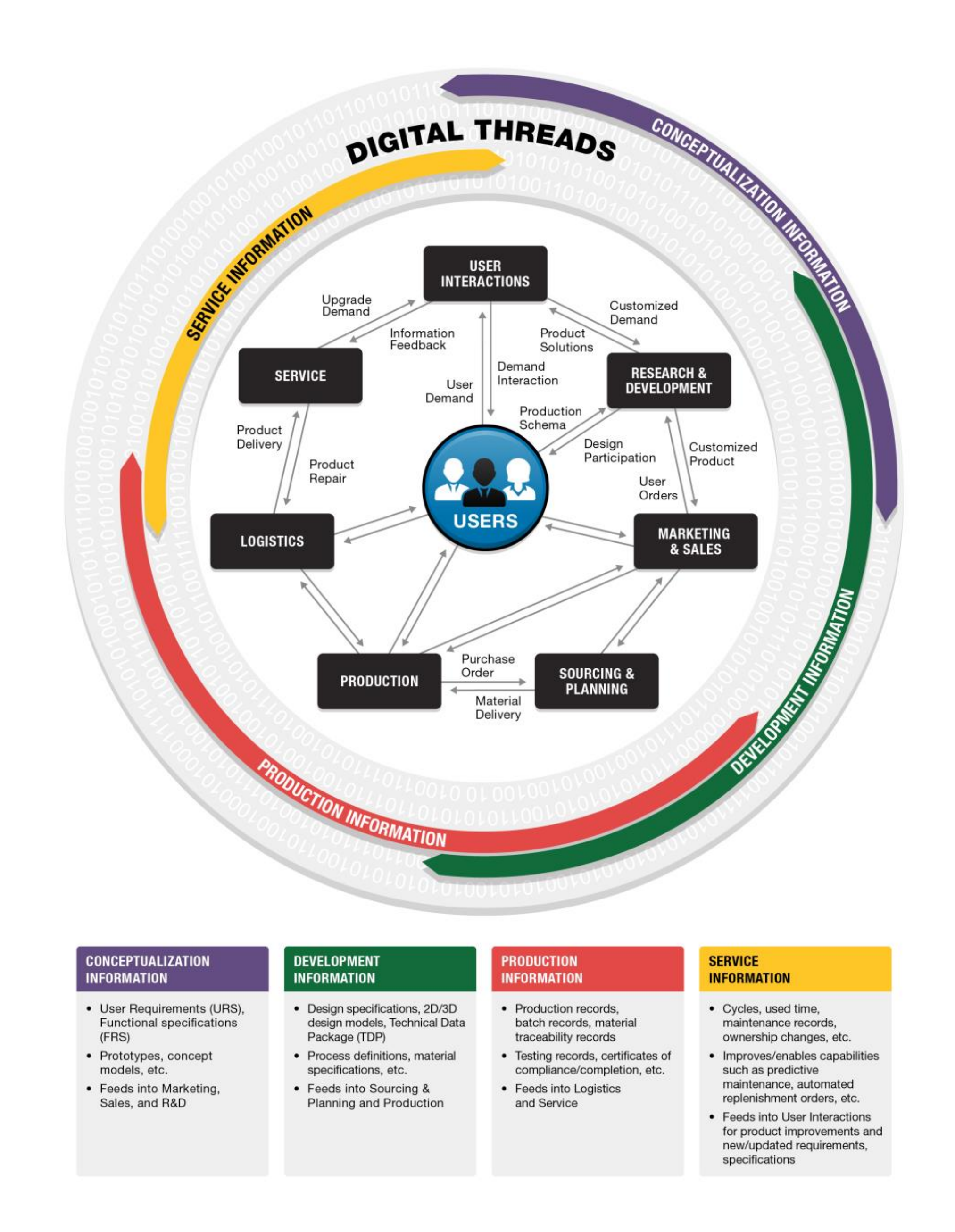


Figure 3: Activity Specific Information in Digital Threads

- **Conceptualization Information**
  - Customer/User Requirements, functional specifications, prototypes, concept models, …
  - Feeds into R&D and Marketing & Sales
- **Development Information**
  - Design specifications, 2D / 3D design models, technical data packages (TDP), process definitions, material specifications, …
  - Feeds into Production and Sourcing & Planning.

- **Production Information**
    - Production records, batch records, material traceability records, in-line testing records, quality testing records, equipment maintenance records, …
    - Feeds into Logistics and Service
- **Service Information**
    - Cycles, used time, maintenance reports, ownership changes, replacement part records, …
    - Feeds into User Interactions for new requirements, updated specifications, and product improvements
    - Improves or enables new data-relevant business models, such as predictive maintenance with AI, automated maintenance orders, automated replenishment orders.

2.2.3. Digital Thread Requirements and Characteristics

ISO/TC184/SC4 WG15 is the International Standards Organization group developing a 6-part standard for "Digital twin framework for manufacturing." The 5th part of this standard deals specifically with "Digital Thread for Digital Twin." The requirements listed below are from a recent draft version of the proposed standard and may change somewhat in the published version, however, they are an excellent reference for requirements to be considered for Digital Threads. From ISO NP Draft 23247-5:2023, Digital Twin Framework for Manufacturing — Part 5: Digital Thread for Digital Twin [10]:

- **Continuity**: A Digital Thread is a seamless, end-to-end connection that links all data related to a product or process, from design to production to maintenance.
- **Traceability**: A Digital Thread provides traceability of all data related to a product or process. This allows stakeholders to track the lineage of the data, understand its origin, and ensure data integrity.
- **Connectivity**: A Digital Thread provides connectivity across different systems and data sources, enabling seamless and efficient data sharing.
- **Granularity**: A Digital Thread provides granular data, with detailed information about each stage of a product or process.
- **Accessibility**: A Digital Thread provides easy access to data, allowing stakeholders to access the information they need quickly and efficiently.
- **Integration**: A Digital Thread integrates data from different sources, allowing stakeholders to view and analyze data in a unified way.
- **Real-time updates**: A Digital Thread allows for real-time updates of data, providing stakeholders with up-to-date information about the product or process.
- **Standardization**: A Digital Thread follows standardized processes and protocols, ensuring consistency and interoperability across different systems and data sources.
- **Security**: A Digital Thread provides secure data storage and transmission, ensuring that sensitive information is protected from unauthorized access or tampering.
- **Maintenance**: A Digital Thread must ensure that contextual links are not broken within individual systems/tools.

Characteristic measures of Digital Threads include:

- **Fidelity** of data within the Digital Thread and transfer of data between activities:

  Includes accuracy, completeness, numerical resolution, consistency in representation, and level of protection from unauthorized access, alterations or accidental corruption

- **Freshnes**s of data in the Digital Thread:

  Includes frequency of updates of individual data nodes and latency between instantiation or modification of the data and its availability to users, other organizations, and other data entities.

- **Depth** of support for standardize processes, protocols, and data representation:

  Includes identification of standards related to specific implementations or use cases, minimum acceptable levels of implementation, support for model-based definitions, and verification of correct implementations

- **Scope** of activities supported by the Digital Thread:

  Digital Threads are use-case specific. Use cases may vary across different industries and may also share commonalities based on classifications such as commodity production or LMHV (Low-Mix-High-Volume) vs HMLV (High-Mix-Low-Volume). Digital Threads to improve real-time visibility and decision support use cases will differ from Digital Threads supporting simulation, change management, predictive maintenance, and causal analytics use cases.

2.3. Digital Thread Technologies

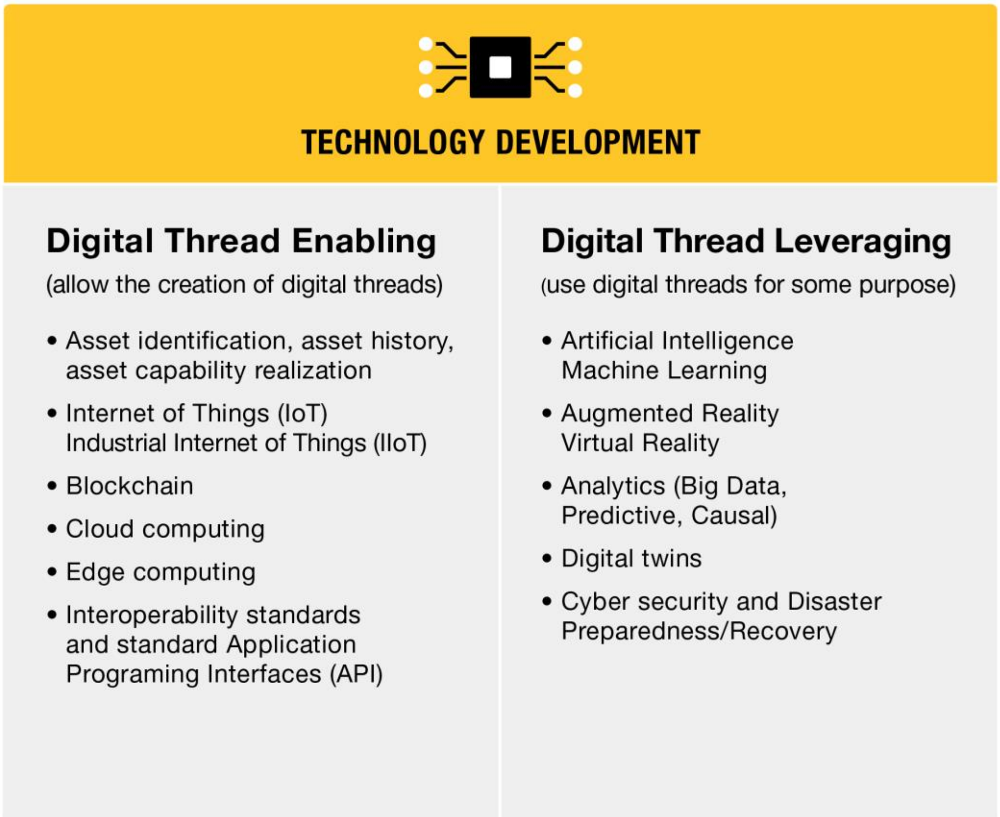


Figure 4: Technologies that Enable or Leverage Digital Threads

To realize the benefits of Digital Threads, further research in several technology areas is essential. Key areas where new research can make a significant impact fall into two categories, technologies that *enable* Digital Threads, and technologies that *leverage* Digital Threads.

Technologies that *enable* digital threads include:

- **Asset Identification, history, and capability representation**
  - Enhance interoperability between automated systems
- **Block Chain**
  - Address cybersecurity issues associated with sharing of decentralized, secure, transparent, immutable records between multiple parties
- **Cloud Computing**
  - Enable data integration and sharing
  - Improve performance and scalability of Digital Thread technologies
  - Reduce development, deployment, and operations costs of digital systems
- **Digital Twins** (virtual representations of physical objects or systems)
  - Digital Twin and Digital Thread research are complementary
  - Provide more precise and comprehensive data for Digital Threads

  - Improve ability to simulate systems and gain actionable insights at all stages of product lifecycle through entire supply chain and digital supply network
- **Edge Computing**
  - Enable real-time analytics and decision support
  - Improve efficiency and data utility through compression/thinning and validation of data at point of collection or ingestion
  - Improve security: provide data encryption, validation, and malware detection services
  - Enable distributed computing for improved efficiency, scalability, and speed
- **Interoperability Standards and standard application programming interfaces (API)**
  - Improve capability and productivity, reduce costs and time-to-market, and enhance re-usability of digital investments by encouraging the development of truly interoperable and composable applications which leverage standardized Ontologies, information models, and data models
  - Enhance the flexibility and agility of digital investments making them more resilient and potentially longer-lasting and easier to update
  - Enable cost-effective, scalable data sharing and collaboration
    - between organizations
    - between processes
    - between (smart) assets/things
- **Internet of Things (IoT) and Industrial Internet of Things (IIoT)**
  - Expand real-time monitoring and control opportunities
  - Expand the quantity and quality of data to support Digital Thread technology
  - Reduce the complexity of device integration
  - Enhance interoperability between (smart) assets/things and other entities
  - Enhance asset identification, history, and capability representation

Technologies that *leverage* digital threads include:

- **Artificial Intelligence (AI) and Machine Learning (ML)**
  - Enhance decision support, analysis and causal analytics
  - Automate connections/relationships/associations between data
  - Automate data extraction and validation of unstructured data
  - Analyze real-time and near real-time data streams to detect security issues, data and process anomalies, and verify processes execute as expected
  - Improve predictive maintenance and predictive analytics capabilities
- **Augmented Reality (AR) and Virtual Reality (VR)**
  - Provide intuitive interfaces, visualization techniques, and context-aware dashboards for more human-centric designs
  - Improve methods to condense complex data streams into actionable insights
- **Big Data Analytics** – storage, processing, and analysis methods
  - Support better decisions, data analysis/reporting, and causal analytics
  - Optimize processes

    - Enhance traceability and visibility
    - Manage highly variable or unstructured data
    - Improve training of AI/ML systems
- **Cybersecurity** and disaster preparedness
    - Protect data from unauthorized access or tampering at rest and in transit
    - Protect intellectual property (IP) and provide for data privacy
    - Provide regulatory compliance
    - Build trust between supply chain and digital supply network participants
    - Protect data from unplanned events

Cybersecurity is also a key enabler of digital threads and must be built-in to ensure the safety, protection, and privacy of the linked data.

The combination and integration of these technologies contribute to the seamless flow of information, collaboration, and improved decision-making across the entire product lifecycle. The specifics of adoption will vary based on industry, use case, and organizational requirements.

3. Current Situation Overview

3.1. Risks to Supply Chain Resilience and Capacity

The USA's private sector and public policy approach to domestic production, which for years, prioritized efficiency and low costs over security, sustainability, and resilience, has resulted in the supply chain risks identified in the 100-day reviews and subsequent supply chain reports from DOD, DOE, USDA, HHS, and others [12], [13], [14], [15]. Specific threats to the supply chains of each of the four industry segments discussed in this roadmap are listed in these industry-specific supply chain reports and examined more fully in sections 4 (Aerospace and Defense), 5 (Energy), 6 (Agriculture/Food), and 7 (Pharmaceutical, Biopharmaceutical Sciences and Medical Devices).

A summary of the **freight and logistics threats** described in the Supply Chain Assessment of the Transportation Industrial Base: Freight and Logistics February 2022 [16] is listed below. These threats are relevant to any industry reliant on freight and logistics (transportation) including all four industry sectors examined in this roadmap:

- Degraded transportation infrastructure support
- Low levels of climate resilience (for example, storm surge at coastal airports).
- Bottlenecks and physical infrastructure constraints (ports, terminals, etc.)
- Ripple effects across supply chains and transportation modes
- Lack of real-time information
- Proprietary private data
- Inadequate level of detail for publicly accessible data
- Increasing cybersecurity threats
- Increasing opportunities for theft due to multiple transportation stops
- Increased e-commerce adding stress to "last mile" deliveries
- Regulations and restrictions
- Spatial mismatch, where available chassis and containers may not be positioned where they are needed most
- Container dwell times susceptible to delay and congestion
- Flexibility in response. Disruption responses can require waivers and regulatory flexibility

Please refer to the industry-specific supply chain reports referenced previously and sections 4, 5, 6, and 7 of this document for additional supply chain risks identified in the context of the individual industry segments.

3.2. Digital Twins and Digital Threads

Digital Twin and *Digital Thread* have often incorrectly been used interchangeably in literature and modern conversation [17]. The term "Digital Twin" likely began with NASA in 2010 [18], although forms of digital twins have existed in modeling, simulation, process monitoring, and command and control domains for decades. A Digital Twin is fundamentally a digital representation, in software or data, of a process, machine, part, or design. Digital Twins do not necessarily need to have a 3D model associated with them. Still, it has become common practice to do so in discrete manufacturing, construction, and large-scale assembly. Digital Twins in the process and continuous process manufacturing industries are usually more process-focused and might be based on physical, chemical, or biological first principles models.

Digital Threads add elements of traceability to physical objects [19]. Started by the United States Air Force in 2013 [7], the concept has been used with Digital Twins in many works [17], [20]. Given that the goal of Digital Threads is to be able to trace products and processes from their conceptual stages up through retirement, it is difficult or possibly impossible to have a Digital Thread without a Digital Twin existing in some form or capacity. Similarly, the creation of Digital Twins often relies on design data present in Digital Threads or other types of interconnected data that specify requirements, capabilities, or condition. Ultimately, Digital Twins and Digital Threads are each necessary in realizing the potential of the other for use in simulation, decision-making, reconditioning, and many other activities.

With the development of Digital Twins real-time remote monitoring and simulation can become native pieces of the physical entities and environments the twins embody [21], [22], [23]. Digital Threads greatly enhance the utility of Digital Twins by connecting and contextualizing data. This includes design data such as CAD models, process data for any operation that may have gone into producing it, shipping and receiving data, or data from its usage. One such example would be a manufactured airfoil. Data from a milling process, thermal spray process, quality checks, and flights that the assembled aircraft has flown may all be contained in the Digital Threads for the airfoil [21].

Digital Threads and Digital Twins continue to expand throughout the life of an entity. Just as Digital Threads carry information throughout the life cycle, Digital Twins can carry information about the “as-is” as well as the “as-designed” state of products and processes. For a part consumer, a Digital Twin would be the manufactured part after acquiring it from a manufacturer. Still, later, the Digital Twin may also carry information relating to the acquired wear on the part after continued usage.

Digital Twins are often created at design time or even the conceptual stages of a part or process design and are extremely valuable for simulation or emulation purposes before a physical part or process exists [19]. At the same time, while Digital Threads exist through all phases of a product or process lifecycle and are necessary for the conceptualization and development of Digital Twins, they often find more use in the production and service stages of the entity’s life cycle (including transportation and logistics). An analyst might seek to understand the reasoning behind a product’s performance, to seek improvement, or improve supply chain capacity or resilience. Digital Threads can help manufacturers better fit their products to their environments and use cases, service and maintenance personnel more reliably predict failure, and managers understand where and what products are doing at any time [23].

Today, the data that composes Digital Threads is too often fragmented, incomplete, inaccessible, or otherwise hard to use. Users need Digital Threads which are organized and accessible in ways that allow both human beings and virtual entities, such as digital twins and AI systems, to greatly reduce the cost, time, and effort necessary to answer questions of who, what, when, where, how, why in the contexts of both correct and incorrect system behaviors.

3.3. Challenges to Digital Thread Technology Adoption

The following table is a summary list of the challenges facing broader adoption of Digital Thread technology to address supply chain issues.

ID	Challenge	Description
1	The value proposition for Digital Threads is not clearly defined	While there is a subjective sense that Digital Thread technology would be helpful, there is in some industries a concern that any long-term benefits do not outweigh the short-term expense. For example, this is especially true for small-medium businesses that do not have resources for expensive data collection or integration. Digital Thread implementations are usually competing with other funding priorities with more immediate value propositions.
2	Closed systems limit data exchange	Many commercial systems do not provide standard ways to access the important information needed for Digital Threads. This is a bigger problem when dealing with information from suppliers and/or partners, who themselves may not have easy access to data from their commercial systems.
3	Operational silos hinder connectivity	Organizational and geographical data silos create barriers to sharing information across different stages in a product's lifecycle. For example, support and service organizations may not even be aware of, or have access to, design information to aid in repairs and troubleshooting.
4	Internal security policies limit data sharing	Internal IT security policies and procedures can prevent access to critical information for Digital Thread technology. For example, database access may be restricted to only one department or group of individuals, even though most of the database information could be shared.
5	Lack of a comprehensive vision for interconnected systems	There is a lack of a clear and comprehensive vision of what systems to connect and how to connect them. These systems and the data contained often cross organizational boundaries. If the Digital Thread technology strategy is not supported by upper-level management then there are gaps in Digital Threads which limit the usefulness and value propositions.
6	Uncertainty in availability and usability of standards delays adoption	In some industries the standards landscape is murky. There is the use of different data formats, semantics, and architectures by tools used in different lifecycle stages. Even within a stage (concept, design…) there can be multiple competing standards, with none supported by all tools. In addition, standards-based implementations are sometimes incomplete and conformance is not always verified.
7	There is a lack of trust across organizations for the protection of Intellectual Property (IP) and confidential business information.	There is no mechanism or certification agency to test for the protection of IP information by trusted partners. This leads to an unwillingness to share proprietary data. This lack of trust can occur internally between organizations and externally between supply chain partners.
8	Data integrity and validation are missing from exchange processes	Data often is transferred from system to system with loss of clarity and context. This leads to misunderstanding, multiple sources of truth, and duplicated efforts to re-validate received data after every exchange. For pharmaceuticals and other highly regulated industries, this prevents a successful audit and leads to warning letters for violation.
9	Lack of data governance across organizations	With few, if any, data governance policies and procedures in place, the integrity of information across different organizations means that incorrect or out of data information may be used. This is a major problem in piecemeal integration of tools, and leads to redesign, rework, and missing requirements. Like #8, this leads to data integrity issues, potential quality issues, audit failures.
10	Lack of technical expertise and capability	There is a lack of IT and OT expertise in many small and medium businesses, and in Tier 2 and 3 suppliers. The businesses and their suppliers must rely on

		commercial systems to provide the exchange or integration capability, without a clear understanding of the data and meta data needed for the most useful Digital Threads. Fragmented digital ecosystems are common, making these integrations even more challenging. Reliance on a 3rd party service consultants is cost-prohibitive for many companies.
11	Lack of technical expertise and capability (continued)	As digital systems and data management needs increase in complexity, more investment is needed for advanced training and support for additional data/system requirements
12	Sharing of partial Digital Thread information	Information needs to be shared, but only selected elements, and it must be protected from non-authorized internal and external access. There is also the question of who "owns" the Digital Thread data for any fielded system.
13	Lack of public/private collaboration	Insufficient collaboration between public and private stakeholders.
14	Loss of information in handoffs between organizational units	One of the identified challenges is the loss critical information in handoffs from design to production, production to deployment, and deployment to maintenance.
15	Disconnect between IT & OT	IT and OT teams report into different organizational leaders, creating misalignment around motivations/incentives, goals, objectives and KPIs, creating incongruence in funding priorities.
16	Lack of harmonization for global regulatory and technical standards	Supply chains are very rarely restricted to one continent, and most often, the products are exported globally. This creates confusion and duplicative work for companies submitting regulatory filings with intention for global distribution as well as traceability.

3.4. Threats to Digital Thread Technology Adoption

Threats to Digital Thread technology adoption include:

- Cost: Defined value propositions and value adds for manufacturers, producers, and suppliers might outweigh the investment to implement.
- Competing business priorities for investments
- Lack of defined standardization for data formats, open API connectivity, and seamless data transfer from point to point
- Security protections and intellectual property concerns threatening data sharing.
- Workforce development: There will be a need for new types of employees trained in both engineering and data analytics, and engineers with an understanding of manufacturing, processes, and controls and trained in traditional IT concepts like information modeling and composable systems.

3.5. Gaps in Digital Thread Technology

Just as the use cases for Digital Thread technology vary by industry, the gaps between the current state of Digital Thread technology and its desired state also vary by industry. These industry-sector-specific gaps are explored in sections 4, 5, 6, and 7. Listed below are gaps that are common to many, if not most, existing Digital Threads:

- Continuity
    - Resilient links between data items within a digital thread that can resist data loss from switching data formats

    - Sufficient abstractions over data items to permit interoperability between Digital Threads
- Traceability
    - Bi-directional connections to entity data stored in the Digital Thread and related entities such as those sharing a process
- Connectivity
    - Security concerns increase in response to the increased number of servers, each a potential attack site, in decentralized, interconnected solutions.
    - Data lifecycle management practices for digital threads, especially the large ones, need definition. Can and should a digital thread be partially archived?
    - Fault tolerance designs for decentralized Digital Threads to handle potentially intermittent availability of storage servers.
- Data Accessibility
    - Many products in the field cannot provide real-time telemetry data.
    - Customers want to keep their data private, i.e. government.
- Integration
    - Users of Digital Threads should have seamless access to them regardless of if they are stored and connected in a centralized or decentralized manner.
    - Scalable decentralized design patterns to promote horizontal scaling to Digital Thread solutions
- Data Privacy
    - Restriction of data is necessary to protect IP, customers, producers, and suppliers
    - Built-in trust between stakeholders building and utilizing Digital Threads
- Data Security
    - Consumers of a Digital Thread entity with the intent of spying on company processes should not be able to access private data such as process data.

The next four sections (4, 5, 6, 7) will dive deeper into the industry-sector-specific opportunities to apply Digital Thread technology in the context of supply chains for Aerospace and Defense, Agriculture/Food, Energy, and Pharmaceutical, Biopharmaceutical Sciences and Medical Devices (PBMD).

4. Digital Thread Technology in the Aerospace and Defense Industry

The Aerospace and Defense (A&D) industry can be considered the home industry of Digital Thread technology research. Since the United States Air Force coined the term in 2013, there have been numerous research projects and attempts to bring Digital Thread technology into not only the A&D industry but also other industries, such as Agriculture, Energy, and Pharmaceutical [24]. Despite this, it can be said many in the industry do not have a coherent definition of Digital Threads or Digital Thread technology; on the other hand, there is a general understanding of what digital threads are and what they do within the industry [25]. According to interviews conducted during this roadmapping effort, adopting Digital Thread technology is underway at many large OEMs but inconsistent across the industry. That said, a maturity model for Digital Thread technology does not yet exist, and the scope of Digital Thread implementations currently underway is sometimes unclear.

One application of Digital Thread technology in A&D supply chains which receives significant attention is the management of technical data packages (TDP). TDPs are collections of information used for defining products [26]. Traditionally, when manufacturing of a product is outsourced to suppliers, the TDP is transferred to the supplier to provide the definition, requirements, configuration, and other core information regarding the product [27]. This is analogous in some ways to the beginning of a product's documented Digital Thread although Digital Threads can also spawned at the product conceptualization stage. However, complications with TDP management arise due to suppliers' varying ability to construct, maintain, and utilize Digital Thread technology. There are numerous research thrusts underway to address this challenge. ISO 10303-243 or STEP AP243 is one example. The standard leverages other ISO 10303 standards to provide a business model to enable collaborative systems engineering, modeling and simulation for complex product development in model-based enterprises [28].

4.1. Risks to Supply Chain Resilience and Capacity Addressable by Strengthening and Leveraging Digital Thread Technology

Supply chain resilience refers to the ability of a given supply chain to prepare for and adapt to unexpected events; to quickly adjust to sudden disruptive changes that negatively affect supply chain performance; to continue functioning during a disruption (sometimes referred to as "robustness"); and to recover quickly to its pre-disruption state or a more desirable state. Supply chain capacity refers to an entity's capability to produce output for a specific period. According to the Department of Homeland Security, failure to manufacture equipment or provide material to A&D would have debilitating effects on security, national economic security, national public health or safety, or any combination [29]. The underlying causes of market disruptions in critical materials supply chains impacting A&D among other industries are not new, but the impact has grown more intense [14]. The Department of Defense has performed extensive work documenting the risks to its supply chains, primarily from the perspective of critical materials. Materials like lithium are critical for many consumer, clean energy, and construction applications. Additionally, critical materials enable the United States' unique combat capabilities. According to the DOD report on defense-critical supply chains, the $90 billion industry enables more than $3.3 trillion in domestic value-added industry sectors. Despite the importance of these materials, America has relied on importing them, even in wartime [2]. America is 100% reliant on imports for 15 of 49 critical minerals core to the A&D supply chain, such as titanium sponge [30].

The risks to aerospace and defense supply chains include:

- **Lack of information** on national suppliers and friendly international suppliers

  Without detailed information on suppliers, organizations may not be aware of potential risks or disruptions in their supply chains. They can also hinder a company's ability to quickly switch to alternative suppliers when needed. Furthermore, it has been shown that international trade positively influences the growth of the A&D industry, and even after a supplier is identified, it can take upwards of 10 years to onboard them into the supply chain due to the certification process [30].

- **Nonstandard TDP** by 2nd, 3rd and lower tier suppliers

  Non-standard formats can lead to misinterpretations and errors in data handling, causing delays, scrapped work, or worse. Incompatible formats reduce interoperability, slowing processes and making adapting to changes or disruptions difficult. This risk is rooted in varying levels of industrial knowledge in suppliers [30].

- **Vendor control of detailed technical data**

  "Black box" solutions encourage vendor lock-in, whether it's good for the customer or not, while also making it difficult to adapt to product and process changes or disruptions.

- **Lack of visibility** into the supply chain

  Especially in the case of DoD, visibility is hampered by the reliance on OEMs to track the capacity of lower-tier suppliers and the risks and threats to supply chains associated with these lower tiers. Visibility is further eroded by system-level manufacturers who simply seek the lowest-cost producer and are source-agnostic. Without sufficient visibility, organizations have limited ability to make proactive decisions to limit supply chain risks, including stockouts and/or overstocks of unnecessary/outdated/non-qualified material, predict potential disruptions, and detect and respond effectively to disruptions and changes in demand. This, in conjunction with the lack of stability, predictability, and transparency in federal funding, leads to difficulty in growing and maintaining the supply chain [31].

- **Lack of visibility** into manufacturing workforce supply and demand

  Sufficiently representative and detailed data are not yet available to understand and assess the changing workforce needs of the Defense Industrial Base (DIB). The lack of definitive data on what labor skills are needed in the next 5 to 10 years, along with workforce development programs to address the needs, is also a problem for private industry

- **Created and Exploited Vulnerabilities**, such as Cybersecurity threats
  Sensitive information of individuals and organizations and national security interests are at constant risk from cybersecurity attacks. Disruptions to operations, financial losses, data breaches, and the introduction of counterfeit goods or substandard products entering US supply chains all represent risks to national security, personal safety and privacy, and corporate profits. While there have been government efforts to reduce cybersecurity threats, it will remain an ongoing risk [32], [33].

- **Concentration of supply**

A significant portion of strategic and critical materials production is in only one or a few countries. The lack of supplied diversity creates a single-point disruption risk [34].

- **Lack of Investment Capital**
  Many suppliers to A&D supply chains fall into the SMM category. Despite the ongoing fourth industrial revolution, these manufacturers often have difficulty digitizing their processes due to lack of a clear path forward, financial capital, and understanding of how to integrate and use digital systems in their established workflows.
- **Limited Supplier Capacity**
  Supplier capacity is often limited by sole source production as far as 3rd or 4th-tier subcontractors, which currently provide little to no insight to the ultimate customer (e.g. DoD) as to the actual capacity of the manufacturer for a specific part. In the case of a small manufacturer producing a flight-critical component, there may be no excess capacity to ramp up production. Further, some small manufacturers may have no consistent promise of demand for a particular part and, therefore, will prioritize the manufacture of other products, which can result in an apparent lack of capacity or result in the small manufacturer exiting the marketplace.
- **Limited Production Capacity**

  Production capacity requires a trained workforce and the ability to scale production across multiple vendors and locations. This is especially important in terms of production longevity given the long operational lifetimes in aerospace and defense. Understanding which manufacturers are producing the most critical components, how many manufacturers are producing each component, and which are the greatest potential points of failure to ensure production capacity while maintaining adherence to operational requirements remains challenging.
- **Transport and Distribution Challenges**
  Transportation and distribution capacity in the Aerospace sector is often confounded by specialized production in specific geographic areas which can limit the ability to get parts effectively shipped long distances in a timely manner. One approach to this challenge is to have small lots of parts produced at many different facilities nationwide or worldwide and ultimately shipped to various points of need (flexible, distributed manufacturing), but this is logistically complex. In the case of expedited need or limited storage capacities for parts, an optimized logistics pipeline is highly desirable.

4.2. Target Future State of Digital Thread Technology in the Context of Value/Supply Chain Resilience and Capacity

A resilient and capacious supply chain should exhibit several key behaviors including:

- Rapid detection, response, and recovery. Supply chains need to be able to quickly detect, respond to, and recover from changed conditions. These may include changes within the control of manufacturers (i.e. production/quality/logistics control issues) as well as changes outside of their control (i.e. man-made disasters, cyber-attacks and exploitation of supply chain vulnerabilities).
- End-to-end, data-driven, supply chain control. Supply chain integration, transparency, and visibility are necessary conditions for enhanced resilience. Being able to easily

access information about raw materials, semi-finished goods, and finished products starting from “suppliers’ suppliers” to “customers’ customers”.

- Collaboration of private and public supply chain stakeholders.

Digital thread technology should enable manufacturers to seamlessly collect, access, associate, and share timely and reliable contextual data from various sources throughout their value and supply chains. This section aims to clarify the benefits and characteristics of digital thread technology and how it should (or could) be applied in tangible ways to realize maximum benefit. The envisioned future state of Digital Thread technology integrated into supply chains would encompass the following characteristics:

- Facilitate collaboration between organizations using homogeneous or heterogenous sets of standards within their organizations in an interoperable manner
- Allow organizations to benefit from Digital Thread technology embedded in the supply chain, allowing them to access relevant data on demand through loosely coupled and federated services
- Integrate into supply chains in a standardized and ubiquitous manner while remaining easy to use
- Facilitate the construction of complex systems within the A&D industry by simplifying the manufacturing, delivery, and maintenance of core systems within time and financial budgets
- Facilitate the reliable flow of data across the aerospace and defense sector for each system being produced or maintained so that each stakeholder can get a timely 360-degree picture of the operational pipelines required to meet mission needs
- In the case of any adverse occurrence, from short-term supply disruptions to longer-term disruptions resulting in facilities and entire regions being inaccessible, the integrated Digital Thread technology should provide a means of detecting the time to impact and enable early mitigation actions, such as identifying substitute suppliers, to minimize any degradation to readiness. To realize this, the Digital Thread technology must have an understanding and visibility of suppliers and their capabilities.
- In the event of surge demands, such as during conflict, the Digital Thread should provide observability to production pipelines to enable a more streamlined scaling process by connecting procurement and maintenance operations into the supply network. This connectivity will enable earlier actions to find adequate and possibly alternative sources for key parts.
- Seamlessly provide access spanning organizations to the right and relevant data to key parties on-demand and in time to enable analytics of prior and current production to assess and predict gaps and shortfalls in production before they cause an operational impact in a safe, private, and secure manner to protect IP and personnel
- Evolve to detect, respond to, and recover from ever-changing threats to the supply chain. These can include cyber-attacks and abrupt material unavailability, as demonstrated by COVID-19. Alternatively, it could be an unintended change within the suppliers, such as a process falling out of certification.
- Monitor the health and safety of products in the field created through the supply chain. In maintaining the thread beyond the manufacturing lifecycle, problems within the supply

chain that show symptoms late can be identified, traced back to their root causes, and fixed promptly [35].

- Seamless integration between the digital systems of OEMs and those of the SMMs that are often not as extensive and well-featured as their OEM counterparts.
- Dynamically adapt to changes in supplier performance that are negatively affecting the supply chain. This can involve switching to an alternate supplier until the cause of error in the original supplier is identified and alleviated or simply switching machine tools running a job within the same facility.
- Contain sufficient redundancy and fallback mechanisms to allow the Digital Thread to function alongside the supply chain even when subsections of the supply chain become unavailable
- Allow suppliers to easily identify subcontracting opportunities based on their capabilities, as the digital thread indicates capability requirements for prospective suppliers
- Enable downstreaming of part requirements from the OEM to tier 2, 3, 4, etc. suppliers based on the part's intent. For example, Digital Thread technology should inform a tier 4 supplier that the material should be tested for specific properties based on what the product being manufactured is and what conditions it will be subjected to.
- Provide a foundation to quantify the long-term performance of each manufacturer of a single part, as well as the performance of a manufacturer portfolio across all parts and supporting comparative analytics between manufacturers of the same part (where applicable)
- Enable cost savings for manufacturers by reducing the effort required to manage TDPs, track part compliance, prove long-term compliance, and report on operational practices due to a common foundation.
- Provide a foundation for vendors to build Digital Thread technology that integrates with existing and emerging manufacturing processes and machinery to achieve interoperability with a lowered barrier to entry.
- Provide a point of integration for vendors to conform with, ensuring a high degree of interoperability without specific vendor-to-vendor integrations.
- Introduce a means of optimized supplier scheduling based on the needs and criticality of consumers.
- Qualify or requalify machine tool performance using the production history of the machine tool.
- Enable rapid assessment and responsive re-prioritization and shaping of the supply chain to enable alternative manufacturing pipelines during event-driven disruptions and demand surges.
- Enable traceability to raw materials in the event of contaminated or non-conforming feedstocks.
- Enable planning for augmented maintenance regimes to manage risk from marginally acceptable parts produced under surge or disruption conditions.

Finally, DoD recently made seven recommendations regarding the supply of critical materials. The envisioned future state for Digital Thread technology supports these recommendations in tangible ways to help make them achievable.

1. Develop and Foster Sustainable Standards for Strategic and Critical Material-Intensive Industries
2. Expand Sustainable Domestic Production and Processing Capacity, Including Recovery from Secondary and Unconventional Sources and Recycling
3. Deploy the DPA and Other Programs
4. Convene Industry Stakeholders to Expand Production.
5. Promote Interagency Research & Development to Support Sustainable Production and a Technically Skilled Workforce
6. Strengthen U.S. Stockpiles [32]
7. Work with Allies and Partners to Strengthen Global Supply Chain Transparency

4.3. Weaknesses, Gaps, and Challenges of Digital Thread Technology

Digital thread technology continues to evolve; however, numerous challenges remain in realizing the vision of simple access and association of contextual data throughout the extended supply chain. Subsection 3.5 summarizes most of the gaps in Digital Thread technology relevant to aerospace and defense. Similarly, sections 3.3 and 3.4 list many challenges to the widespread adoption of Digital Thread technology in the sector. This subsection highlights a few additional industry-specific weaknesses, gaps, and challenges impeding the implementation of Digital Thread technology into the A&D supply chain.

The Air Force Research Laboratory (AFRL) conducted a workshop in October 2022 to identify use cases for digital thread in the defense and aerospace sector in the context of TDP. Several gaps were identified which inhibit the realization of digital thread use cases for TDP:

- There isn’t a robust solution for mapping and tracing data from neutral CAD formats to other life cycle data at scale.
- The marking, visualization, and validation methods of information stored in TDPs are not standardized.
- Data composing a digital thread may come from different sources and, as a result, follow different formats, standards, name conventions, etc. With the notable exception of STEP for translating proprietary CAD formats, there are currently few, if any, good tools to translate other kinds of TDP to universal machine-readable formats without information loss. Because of this, data is lost in translation, resulting in gaps in Digital Threads.

In their paper titled *Is Digital Thread/Digital Twin Affordable? A Systemic Assessment of the Cost of DoD’s Latest Manhattan Project*, West et al. [36] investigates the affordability of developing, implementing, and maintaining Digital Thread and Digital Twin systems. Three highlighted challenges in realizing these systems are:

- amassing the computational power,
- growing a workforce with the required expertise to use, develop, and maintain the systems,
- and managing the cost of Digital Twin and Digital Thread.

The working group focused on aerospace and defense in the context of this roadmapping effort found several key barriers towards broader adoption of Digital Thread concepts, including:

- **Intellectual Property**: Because of the industry's proprietary nature, sharing key manufacturing data beyond what is within technical data packages is difficult, if not impossible.
- **System Interoperability**: Major enterprise software system providers (e.g., ERP, MES, PLM) are not designed to interoperate with other systems without significant effort and cost. A nearly universal concern is the lack of openness and dependence on third-party connectors for connectivity and data interchange with PLM solutions. The perception is that interoperability and openness have improved but are fragile, and there are emerging signs of potential backsliding.
- **Benefits**: Lack of defined, measurable benefits at all tiers of the supply chain, especially for small and mid-sized suppliers
- **Commitment**: Lack of commitment from company senior management to enable capabilities or invest in solutions
- **Standards**: Lack of industry standards, international standards, national standards, or system/solution standards related to data representation and exchanges of Digital Thread information
- **Real-Time Data**: Lack of consistent, real-time, or near real-time supplier and production data from different systems
- **Skillset**: Lack of investment for advanced training and support for additional data/system requirements. New types of employees will need to be trained in engineering and data analytics and engineers will need a cross-discipline understanding of manufacturing, processes, and controls and traditionally IT-centric concepts including information modeling and composability.
- **Cost:** Defined value propositions and value adds for manufacturers and suppliers might outweigh the implementation investment. The cost of curation needed to maintain the digital library and manage the quality of shared information is significant.
- **Competing business priorities** for investments

The government, namely the DoD, has also highlighted a list of challenges to Digital Thread deployment at scale within the A&D industry [1], [6], [14]:

- **Transparency**

  Individual strategic and critical materials markets often contain incomplete information on trade flows, production, prices, or inventories [32].
- **Asymmetric Information**

  Because of the small dollar value and overall product volumes of strategic and critical materials, the number of market participants is also small. This leads to asymmetric market information where one part of the market has better or more information than the other part of the market.
- **Diminished Domestic Manufacturing Capacity**

  The global share of U.S. manufacturing in global and domestic GDP has declined. As a high-wage country, the United States needs to develop a cost-competitive manufacturing capacity. Working towards reducing dependency on adversarial foreign sources [37], [38].

- **Uneven Access to Investment Capital**

  Annual manufacturing investment growth averages below the overall GDP growth rate. This is due in part to limited venture capitalist interest, high cost of capital compared to Europe and Asia, and outsourcing of manufacturing to other countries.

- **Modernization Divide between Small and Large Manufacturers**

  Despite the being in the beginning of the fourth industrial revolution, many SMMs are not utilizing the new technologies. The penetration of new automation, digitization, and cybersecurity technologies into the nation's 300,000 SMMs is unknown.

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4.4. Potential Research Projects and Workforce Development and Training Initiatives

Harnessing digital thread technology is critical to achieving maximum value from our technology investments since it weaves through all processes and interfaces throughout the extended supply chain. It is the glue connecting manufacturing processes together and with their suppliers, process inputs (e.g. raw material), process outputs (e.g. products and byproducts), and their customers. Developing a clear strategy for research and development of digital thread technology along with initiatives to provide for workforce development and training on the technology will accelerate our nation's ability to achieve all 3 goals and most of the objectives outlined in the previously referenced *Strategy for American Leadership in Advanced Manufacturing* (see note 4).

4.4.1. Research Projects

There has been some progress made to date in application of Digital Thread technology to the aerospace and defense industries, but there is still a great deal of research and development to be done for broader adoption of the technology and for expanded benefits to be realized. Furthering research on Digital Thread technologies should build upon existing work and leverage existing standards to the extent practical. Key areas for continued research in the defense space should focus on the following 4 aspects:

- **Limited, single part or component trial**

  Pilot effort which provides a targeted implementation project to use digital thread technology across a limited set of parts or components manufactured by a single prime manufacturer and a known set of subcontractors. This type of effort will enable the investigation into the necessary data to be collected, assess the mechanisms for long-term storage and transport of the digital thread data across the parties and to the final defense customer. Several of these pilot projects in specific aerospace, naval, and ground platforms would provide a good foundation for proving out the commonalities and differences across the manufacturing pipelines. Each of these projects should produce a working digital thread capability including technical data packages (TDPs), test and quality results, acceptance data and a set of project findings useable for further development of the capabilities in the pilot.

- **Complex component supply chain**

  For a specific effort, a single known complex component with multiple different manufacturers and subcontractors with a goal of identifying and piloting a more complex digital thread that would effectively be at a scale of several "limited" pilots that are interconnected. The complex supply chain implementation would provide a similar set of outcomes, at a larger scale with an expectation of more data, more parties involved and will serve as to demonstrate the opportunities to scale up the use of digital threads while also identifying risks and limitations that will need to be addressed before broader adoption at scale.

- **Full-lifecycle demonstration**

  For a single platform, demonstrate the use of a digital thread from extending a "limited" pilot to augmenting the digital thread to include inspection, maintenance / repair, demobilization and retirement. This level of demonstration would provide enhancement to the digital thread data to include all actions to the lifecycle of a component and to the parts within that component to demonstrate end-to-end traceability.

- **Cross-Approach trial**

  For a single part with existing specifications and quality constraints based on a manufacturing process and manufacturer, transition manufacture to a different manufacturer and/or to a different manufacturing process (e.g. forging to AM) leveraging digital thread technologies to account for both the commonality and any differences in characteristic information that would be required to provide proof of conformance and lifecycle quality traceability. This form of pilot project will assist in developing an understanding of the differences in data tracking required for the same part under different manufacturing processes and assist in preparing the supply chain for supplier diversification and crisis surge implications. This form of complex supply chain variability are expected to significantly benefit from the use of digital threads.

Digital Thread technology research thrusts are already underway in several areas and should be continued in the context of the aspects described above. These include:

- **Management of expanded Technical Data Packages (TDP)**

  The scope of TDP as defined by MIL-STD-31000B is limited. As can be seen by Figure 5, the current standard only addresses "Product Design" information. Research is needed to:

  - expand standards for data representation and systems interoperability,
  - develop widely accessible services for secure data collection and information exchange within digital supply networks,
  - develop new architectures, applications, interfaces, analytic techniques, and cybersecurity systems,

  Several branches of the military have sponsored multiple projects in this domain. Ultimately, Technical Data Packages should be based on specific use-cases with the ability to draw on all the types of data shown in the diagram below in standardized, interoperable ways to support improved analytics and decision-making.

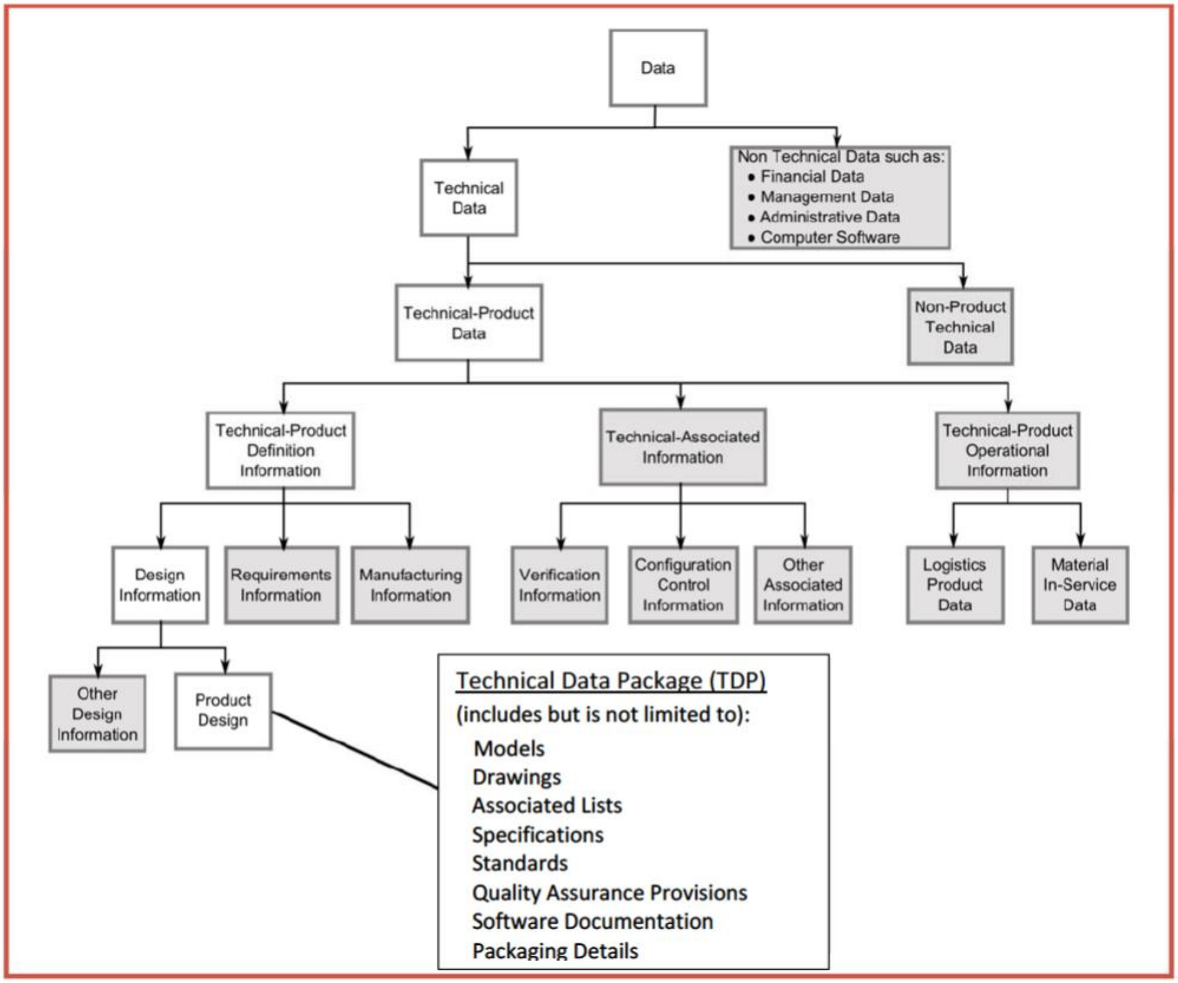

Figure 5: TDP Relationships (from MIL-STD-31000B)

- **Frameworks for predictive analytics and causal analytics**

  The use cases for Digital Threads in the context of analytics are many. Real-world solutions already exist for many predictive maintenance use cases, however, moving beyond classic predictive maintenance use cases such as tool wear, vibration monitoring and infrared monitoring will require further development of standardized representations for assets, asset availability, asset capability, requirements, and asset history along with improvements and wider adoption of information models like MTConnect to promote standardized representation of manufacturing data and increase interoperability between IIoT entities. Other analytics use cases include change management and causal analytics. The change management use case focuses on identifying possible impacts from proposed changes to parts, processes, or system inputs. Causal analytics seeks to identify and possibly predict the potential causes of part or system failure.

- **Open standards-based association of data throughout the product lifecycle**

  NIST, in conjunction with partners AMT, CCAM, DMSC, the MTConnect Institute, STEP Tools, and many others has sponsored several projects to enable open standards-based association of data between the design (conceptualization), planning (development), manufacturing (production), and service stages for high value discrete parts. Most of the focus to date has been on product definition standards (in alignment with MIL-STD-31000B), however, significant work has also been demonstrated for other types of information including requirements information and manufacturing and quality information.

- **Information models for part and process qualification**
  The goal of this effort is to enable automated collection of digitally signed, verifiable data in standardized formats to meet part and process qualification requirements and regulatory approval requirements. Qualification of parts and processes requires collection and collation of vast amounts of data including raw material inputs, supplier data, certifications of conformance to purchase and performance specifications, quality control data, and regulatory compliance data. In many industries, including discrete part manufacturing for aerospace and defense, standardized information models already exist (e.g. MTConnect and OPC UA companion specifications) or can be expanded to automate the association of raw/native data with the semantics of these standardized models. Broader use of standardized information models will promote interoperability, lowering the costs in currency and time of integrating new equipment and processes as well as the costs associated with collecting, collating, and retrieving the data for part and process qualification. Pilot projects in this space should focus on extending the adoption rates of standardized information models and promoting those which satisfy specific use cases for interoperability and part and process qualification.

4.4.2. Workforce Development and Training

A key enabler for Digital Thread adoption and sustainable use with the defense supply chain (for US, NATO and foreign military sales interests) [39] is ensuring the workforce understands the value of digital threads and can leverage the technologies that supply the core digital thread information.

Workforce training should include extensions to existing educational programs with:

- foundational computer and technology use for all (core skills)
- specialized technology use in the applied fields of manufacturing such as expanding hands-on use of CAD/CAM and additive manufacturing tools
- specialized education on data handling for manufacturing as it relates to the digital thread and supply chains as a feedstock/component consumer and as a component supplier to down-stream manufacturers

Additional areas of training include workforce augmentation training and continuous learning for those already in the workforce and those looking to transition from other industries. Finally, the incentives should be there to attract skilled workers in other technology related fields to augment the manufacturing space.

4.5. Development and Support for Digital Thread Technology Infrastructure

To support digital thread technology across the aerospace and defense industries, a set of foundational capabilities and understanding will be required. This will include supporting some level of harmonization across existing industry standards and an onramp for existing vendor solutions to integrate with the emerging capabilities. The digital thread capabilities will include more than a single solution or single vendor implementation and will instead rely on a host of capabilities that are loosely coupled and rely on both networked and air-gapped data transfers while accommodating small vendors whose transition to technology solutions will be delayed by varying amounts of time. This will overall result in a technological journey that will require cooperation, understanding and a myriad of capabilities built by industry and government partners over time.

It should be expected that isolated pockets of the industrial base will build out capabilities early, which will serve as exemplars for others to evolve toward. This level of multi-party technology evolution is complex and aligns most closely with how open-source standards, software and communities of practice work. Key technological challenges will include addressing short and long-term data storage and data transition between responsible parties as the logistics of which parties are ultimately responsible for longer-term disposition of data is elucidated. While use of cloud technologies will go a long way in assisting with data volumes and reliable retention of data, the stewardship responsibilities are still an open question. Other technological challenges will include areas around cyber security to protect data, non-repudiation and general chains of custody to ensure data integrity is maintained throughout the data lifecycle, and the general set of acceptable protocols used to locate, access, secure and transfer data between parties. It is expected that a large part of the user-facing interactions with digital threads will happen over web technologies, but there will additionally be the need to support autonomous producers and consumers of data that are not web based and will have different demands in terms of data volumes, rates and latency requirements.

Funding is recommended for cross-industry centers of excellence focused on Digital Thread technology which would be responsible for the Digital Thread technology program described in this section and section 8 and provide support to multiple industry sectors on their Digital Thread journeys. Potential COEs for this concept include existing Manufacturing USA institutes as well as academic institutions, national labs, and public/private entities like CCAM.

Figure 6: Aerospace and Defense Sector Activities, outlines a research program for Digital Thread technology which incorporates the aerospace and defense pilot programs described above and adds proposed “solutions” designed to focus the research on obtainable five-year goals. Please see section 8 for more detail on this proposed approach.

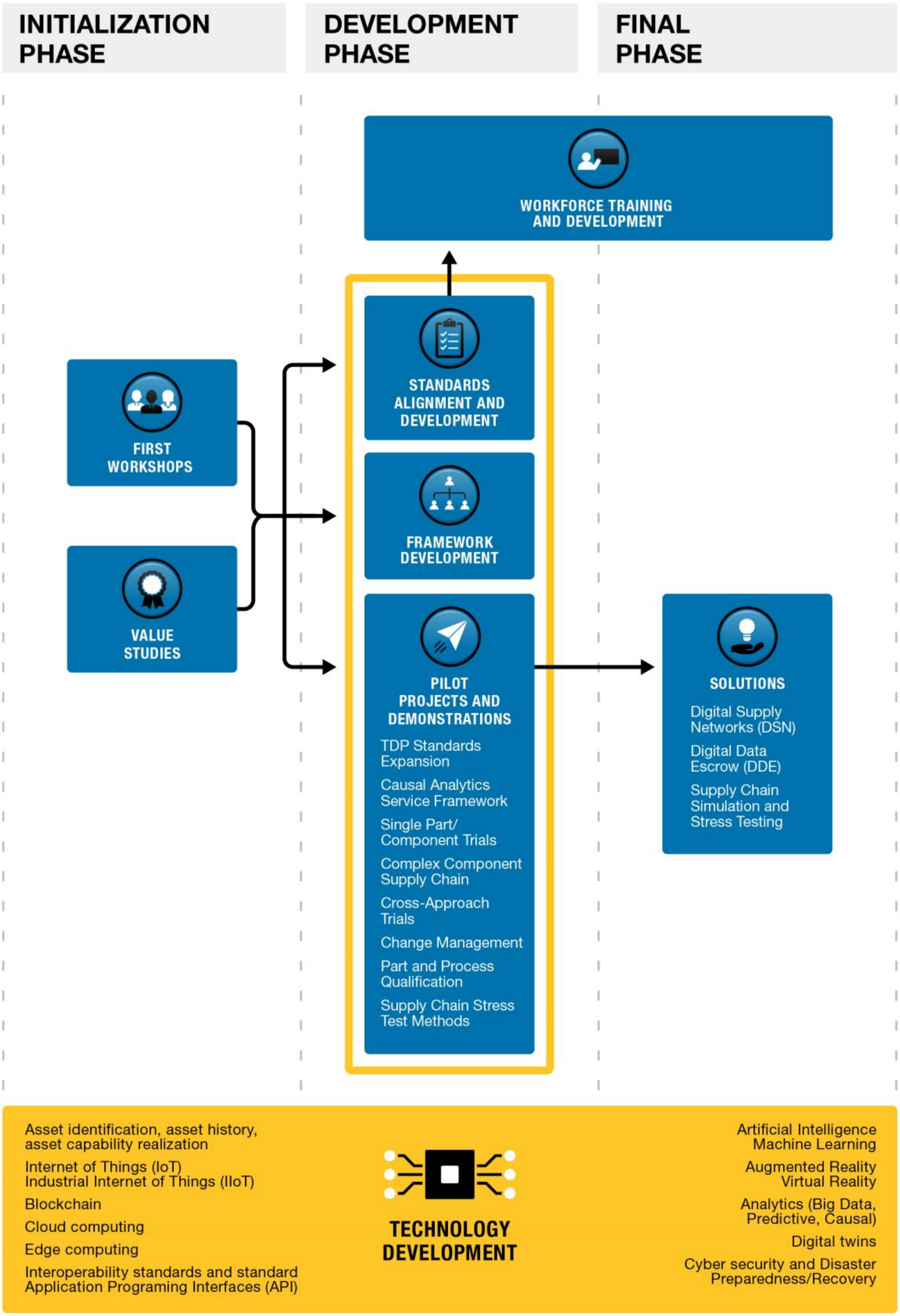

Figure 6: Aerospace and Defense Sector Activities

5. Digital Thread Technology in the Agriculture Industry

This section addresses supply chains for agricultural commodities and food products within the United States. It does not address United States imports or exports.

Digital Thread technology is significantly underutilized in the United States agriculture industry [12]. Additionally, their potential usefulness is under-researched. This is largely due to the lack of awareness of the positive impact Digital Thread technology would have on producers and consumers within the supply chain, affordability of the technologies by farmers, research funding available to advance the technologies in an agricultural context, and development funding for agriculture-centered solutions. Despite these impediments, effectively applied Digital Thread technology can improve agricultural supply chains, thereby decreasing costs, reducing risks, and increasing the opportunities for farmer profitability.

It is not surprising that knowledge of Digital Thread technology and its implementations vary widely by industry. In agriculture, Digital Thread implementations are understood to be of "track and trace" data which track crop inputs from manufacturers to fields and food products from field to consumers. There are efforts underway in the agriculture industry to introduce the most basic forms of Digital Thread technology to reduce the need for manual paperwork trails, especially for recalls and regulatory-compliance audits.

Most agriculture-industry executives interviewed for this roadmap viewed the current state of a Digital Thread approach as fragmented across the industry. Some referenced current US government initiatives (e.g., USDA Climate-Smart Commodities program, NRCS Environmental Quality Improvement Program) as having potential to subsidize adoption of such approaches. However, since these programs rely upon subsidies to aid in transitioning companies, farmers, and manufacturers, the value of such efforts may diminish when the subsidies end.

5.1. Mitigating Risks to Supply Chain Resilience and Capacity through Digital Thread Technology

There are numerous risks to supply chain resilience and capacity in the agriculture industry. Many of them are hard to predict or currently outside the ability of humans to control or even sufficiently mitigate. Agriculture industry parties can use Digital Thread technology to improve mitigation of, and potentially eliminate, many risks to supply chain resilience and capacity. Supply chain resilience refers to a supply chain's ability to return to normal operations following a disruption. Supply chain capacity refers to the throughput of the supply chain or the ability for the supply chain to handle current and projected demand.

Environmental issues impacting supply chain resilience and capacity in the agriculture industry include climate, weather, sustainability practices, pest management, and disease management. Climate change is having a significant impact on the agriculture industry. Variations in weather, temperature, and water availability all have significant effects on produce yield. Sustainability issues include soil health degradation due to intense farming practices rendering farmlands less productive, and reduced biodiversity rendering ecosystems unstable. Lastly, pests and diseases can reduce the quality of livestock and produce, which is a challenge to detect and to trace detected issues to specific resource units (e.g., rail cars, grain silos, fruit packages) at various steps within the supply chain.

Economic influences impacting agricultural supply chains include labor shortages, agriculture commodity-market volatility, technology availability, regulatory compliance, government policy, and consumer trends. Labor shortages are a consequence of an aging workforce and lack of interest in younger generations to work in the agriculture industry. This, combined with the economic pressure from market volatility and high debt for young and small-scale farmers, leads to perceptions of farming as a less attractive career than alternatives. Furthermore, while many industries can confidently estimate the benefits of adopting new technologies, the agriculture industry tends to experience mixed results, leading to farmers being intrigued by - but leery of - vendor technology claims. While larger farms tend to be capable of adopting new technologies, smaller farms have trouble making what are frequently large financial investments for the advantages brought by technological innovations. Changing or increasing regulations often leads to more work and increased costs to comply with state and federal regulations. Government policies, including those that address agricultural subsidies and other forms of support are subject to shifting political conditions. Lastly, consumer trends are pushing towards locally sourced produce, organic produce, transparent and ethical practices, and non-GMO produce which are often lower yield and available only in smaller quantities due to transportation and logistics challenges.

5.1.1. Understanding Risks to Supply Chain Resilience and Capacity

The risks to supply chain resilience and capacity in the agriculture industry come from a wide range of factors, each of which can be positively influenced by the introduction or improvement of Digital Thread technology. Risks to supply chain resilience and capacity include, but are not limited to:

1. **Transportation infrastructure**: The aging transportation infrastructure in the United States is expected to present increasing supply chain challenges. See section 3.1for additional freight and logistics-related threats.
2. **Cybersecurity threats**: While cybersecurity incidents in agriculture are not as frequently reported as those of banks and hospitals, cybersecurity incidents over the last few years have put parts of the food supply at risk. For example, equipment manufacturers are working together on standards and best practices to ensure that autonomous operations of agriculture equipment are not compromised by cybersecurity breaches.
3. **Food-safety related recalls**: Food safety recalls can disrupt distribution channels, erode consumer confidence, and change consumer demand.
4. **Changing relationship of growers and retail chains**: There is a trend toward erosion of traditional wholesalers toward direct marketing contracts between growers and retail chains due to increased centralization of food procurement systems.
5. **Concentration in food retail**: Increasing concentration in food retailing, especially among the largest grocery retailers, presents new challenges to the agriculture industry.
6. **Logistics consolidation**: Consolidated distribution infrastructure in freight rail and ocean shipping, all of which require consistency and timeliness due to the perishable nature of specialty crops is changing the nature of supply chains.

7. **Poor quality, untimely, or incomplete data regarding environmental factors**: Areas include soil composition, weather, and the local ecosystem as well as how these factors change throughout the lifecycle of livestock and pose risks to agricultural operations.
8. **Produce transport regulations**: The USDA and the FDA impose regulations to ensure the safety of food products being transported between or within states. Some states, such as California, impose quarantine laws to prevent the spread of pests and diseases such as fruit flies.
9. **Unstable climate**: The rapidly changing climate impacts temperature, weather, seasons, and ecosystems, each of which impacts the growth and patterns of produce. These factors also impact market demand for products.
10. **Severe weather events attributable to climate change**: Severe weather events are increasing in frequency and severity with an increasingly devastating effect on agricultural production.
11. **Pests and diseases**: Waves of pests such as some species of bugs and rodents negatively impact produce yield. Additionally, diseases can be introduced by contact with disease-carrying organisms or genetic variations. Each of these negatively impacts the resilience and capacity of agricultural supply chains by removing the infected supplier from the chain, and potentially removing other suppliers from the chain due to contamination.
12. **Farm-management practices**: While crop rotation introduces its own risks due to higher market variability, labor requirements, and potential pest/disease carry over. Conventional tillage can lead to soil erosion and no-till farming can lead to dependence on herbicides.
13. **Consumer preferences**: Consumer preferences can complicate supply chains as demand for produce with specific characteristics or production processes requires identification and segregation throughout the supply chain in ways not well supported by today's technologies.
14. **Loss of land**: Rising land prices makes expanding difficult when combined with the financial issues plaguing many farmers. Additionally, increasing urbanization reduces the amount of land available for agricultural practices.
15. **Restricted importation**: In general, the USDA and FDA ensure that produce meets safety guidelines when being transported within or between states. Produce quality requirements add additional labor costs and processing time to farmers. Additionally, some states, such as California, restrict the transport of produce such as raw milk across state lines, certain fruits and vegetables, and any other produce that may carry diseases or spread pests such as fruit flies.

The USDA Agri-Food Supply Chain Assessment, February 2022 [40] also identifies the following risks:

- Aging transportation infrastructure
- Cybersecurity threats
- Animal disease outbreaks that affect supply and disrupt supply chains
- Food-safety-related recalls that can disrupt marketing channels

- Erosion of traditional wholesalers toward direct marketing contracts between growers and retail chains due to increased centralization of food procurement systems
- Increasing concentration in food retailing, especially among the largest grocery retailers
- Consolidated distribution infrastructure in freight rail and ocean shipping, all of which are required consistently and timely due to the perishable nature of specialty crops

By addressing these risks to supply chain resilience, American agricultural supply chains can be made more resilient and capable of increasing capacity. Other supply chain issues, such as the lack of digital integration in farming practices and management of premium-value produce, can also be addressed.

5.2. Role of Digital Thread Technology

Digital Thread technology can be pivotal in making supply chains more resilient, capable, and adaptive. Digital thread technologies, at their core, provide traceability to operations and entities. In the context of supply chains, which are analogous to Digital Threads in terms of structure, Digital Thread technology provides the capability to entities within supply chains to follow how products are being developed or used throughout the supply chain to improve decision making. Like other industries where IIoT technologies are rapidly transforming digital architectures to cloud-hybrid architectures where computation exists everywhere from the cloud to the edge, Digital Thread technology integrated into the agriculture supply chain must also be deployed from the cloud to the edge to maximize the benefits of the technologies.

Data sources include farm equipment, farm management information systems, food processors, retailers, distributors, manufacturers, service providers, weather data providers, testing labs and more. Digital Thread technology should be employed as close to the processes that produce data as possible (e.g., to collect telemetry data). Farmers should collect information regarding all processes and conditions under which plants and livestock are produced. For example, for grain silos, the information provided by telemetry should include temperature, humidity, luminosity, and other information known to impact the condition of the grain being stored. Food processors should provide data regarding the conditions under which processing takes place and data from or regarding the process itself. Lastly, retailers should provide data on how products are stored and sold.

5.3. Target Future State(s) of Digital Thread Technology in the Context of Value/Supply Chain Resilience and Capacity

To realize the full set of additional capabilities within agricultural supply chains, there is a minimal set that must be realized in Digital Threads prior to their integration into the agricultural supply chain. This minimal set of capabilities includes:

- Continuity: A Digital Thread is a seamless, end-to-end connection that links all data related to a product or process, from design to production to maintenance – or in an agriculture context, from planning to consumption. In the agriculture industry data would seamlessly flow from manufacturer to distributor to retailer to farmers or application service providers. Data would seamlessly flow from combines to grain carts to trucks to grain elevators to rail cars or barge systems to food processors. Data would seamlessly flow among various types of farm equipment, in-cab displays, and OEM clouds.

- Traceability: A Digital Thread provides traceability of all data related to a product or process. This allows stakeholders to track the lineage of the data, understand its origin, and ensure data integrity. In the agriculture industry, traceability is mostly discussed in the context of crop inputs (i.e., seed, crop nutrition products, and crop protection products). However, it can be considered in the context of harvested product from field to consumer purchase. Traceability is likely to be the capability that most resonates with agriculture industry stakeholders and is the capability that all other capabilities in some way contribute to make possible. For crop inputs the target future state is knowing the location, custodian, and owner of each container (e.g., a package of herbicide, a bag of seed, a bulk container of fertilizer) at any time. For crop outputs, the target future state is knowing the history of the product and its production from field prep to planting to growing to harvesting to transport to processing. Compelling financial justification for investing in improving traceability will be available to all parties in the agriculture industry.
- Connectivity: A Digital Thread connects different systems and data sources, enabling seamless and efficient data sharing. The target future state is simply sufficient bandwidth throughout the vast geographic range of agricultural operations.
- Standardization: A Digital Thread follows standardized processes and protocols, ensuring consistency and interoperability across different systems and data sources. The agriculture industry has a rich ecosystem of standards development with non-profit standards organizations like AgGateway, the Agriculture Industry Electronics Foundation (AEF), the Association of Agricultural and Biological Engineers (ASABE), and the Open Applications Group (OAGi, an AgGateway partner). Furthermore, leaders in these organizations are well placed and highly engaged in ISO leadership positions. That said, the development of standards, guidelines, best practices, and tools is critical to enabling Digital Thread technology. The target future state is one where these organizations and others continue their positive trajectory in their standards-related resource production.
- Security: A Digital Thread provides secure data storage and transmission, protecting sensitive information from unauthorized access or tampering. Farmers regard the data produced by the equipment and other systems on their farm as “their data”, i.e., something they “own”. They recognize that it has value to themselves and many other parties. The target future state is that the agriculture industry will have technical, legal, and social systems in place that enable farmers to control “their data” in a way that delivers value to them and controls to whom and in what ways it may be of value to others.

In addition to the minimal set of Digital Thread capabilities, there are additional capabilities that would work towards greatly improving the resilience and capacity of agricultural supply chains. These capabilities include:

- Granularity: A Digital Thread provides granular data, with detailed information about each stage of a product or process. The agriculture industry is already going in this direction. The target future state is that this trajectory continues.

- Real-time updates: A Digital Thread allows for real-time data updates, providing stakeholders with up-to-date information about the product or process. The agriculture industry is already going in this direction. The target future state is that this trajectory continues.
- Accessibility: A Digital Thread provides easy access to data, allowing stakeholders to access the information they need quickly and efficiently. The agriculture industry is already moving in this direction. The target future state is that this trajectory continues.
- Maintenance: A Digital Thread must ensure that contextual links are not broken within individual systems/tools. This is a direction that the agriculture industry is working hard to address. The target future state is that they succeed.
- Integration: A Digital Thread integrates data from different sources, allowing stakeholders to view and analyze data in a unified way. The agriculture industry is already inclined in this direction. The target future state is that this inclination continues and is enabled by the capabilities of the technologies described in section 2.3.

By adding both sets of capabilities to current Digital Threads, they will be much better equipped to handle the rising challenges to the agriculture industry and its supply chains. However, for Digital Threads to acquire the identified capabilities necessary for minimal or full integration into agricultural supply chains, several gaps need to be addressed.

5.4. Weaknesses, Gaps, and Challenges of Digital Thread Technology

The previous section lists Digital Thread capabilities, describes them, and discusses their target future state. This section points out the gaps and challenges in achieving that future state.

- Continuity: In the agriculture industry there are many disconnects in data flow. One example is the disconnect from input supply chain to field operations. Another disconnect is multiple pieces of equipment in typical grain harvesting, which include combine, grain cart, truck, elevator, and rail car or barge. Improved standards, technology, and connectivity will contribute to addressing these challenges.
- Traceability: One of the biggest challenges to traceability is the financial incentives to improve. Most parties in the agriculture industry will claim that traceability improvements are worthwhile, but investments do not support the claims.
- Connectivity: Bandwidth is a major challenge in the agriculture industry. Technology leaders are working with the Federal Communications Commission on identifying ways to improve rural broadband service.
- Standardization: At least three standardization challenges are present in the agriculture industry. First, awareness. There are myriad standards that would be useful to implementers if they only knew about their existence. Second, competition with government-funded initiatives. Often the US government awards grants to initiatives that look to “start from scratch” and “do things the right way” while ignoring existing standards. The result is often “standards” or open-source reference implementations that offer the attraction of “free”, but without the overall industry

input or organizational infrastructure for its ongoing development and maintenance. Third, poor assumptions by startups or established-company initiatives. Executives in startups or established companies kicking off an initiative often wrongly assume, “We don’t have time for standards”, or “Our project has unique requirements”.

- Security: The industry lacks technical, legal, and social systems which enable farmers to control “their data” in a way that delivers value to them and controls to whom and in what ways it may be of value to others.
- Granularity: If the gaps in the minimal set of capabilities are addressed, granularity capabilities will rapidly improve. One major challenge for the agriculture industry is that many inputs and produce are in bulk, which by nature is not conducive to granularity.
- Real-time updates: Gaps with this capability would likely be mostly addressed by improving connectivity.
- Accessibility: Gaps with this capability would likely be mostly addressed by improving connectivity.
- Maintenance: Gaps related to this capability are difficult to distinguish from gaps in other capabilities. With respect to physical connections (e.g., a tractor to a sprayer), AEF has ongoing processes in place for continual improvement.
- Integration: Integration gaps are not systematic across the industry except perhaps with accounting and R&D systems. As other capabilities improve – especially standards – integration should improve.

5.5. Potential Research Projects and Workforce Development and Training Initiatives

To reduce or eliminate the gaps between the current state of Digital Thread technology and the target future state identified in Section 1.2, research projects are necessary to prototype and develop the tools, technologies, capabilities, and workforce skills before they are put into practice within the agriculture industry. Furthermore, the workforce needs to develop skills to enable them to make full use of the technology and the productivity benefits they provide. Research and development of Digital Thread technology-based tools and the development and training of the work force must be carefully choreographed.

5.5.1. Research Projects

- Optimized crop selection – Optimized crop selection based on weather, ecosystem, market demand, soil, pH, and nutrient levels to maximize profit or yield. Additionally, optimization of crop rotation planning and cover crop selection can be introduced to maintain soil and environmental health while still providing sufficient, or potentially increased profit or yield over the total time span.
- Precision agriculture – Variable-rate application of crop nutrients, crop-protection products, and water to fit the needs of plants within a field while minimizing waste and environmental impact. Combined with understanding of environmental effects such as weather forecasts, water usage can be optimized, ensuring that crops are

sufficiently irrigated. This capability is especially useful in locations at risk for droughts or where water access is scarce.

- Integrated pest management – using comprehensive knowledge of local pests, local diseases, and the surrounding ecosystem, detailed threat assessment and mitigation plans can be generated with respect to migration and seasonal patterns. This can include threats from outside the localized environment such as the global market and weather.
- Sustainable farming – Improved understanding of soil and pest conditions would allow farmers to optimize chemical usage, which is the foundation to sustainable farming and reduced environmental impact. An understanding of soil erosion risks and moisture levels and better tillage practices could be developed that could reduce soil erosion and improve water retention.
- Yield prediction and management – Using detailed data regarding weather and soil, yield maps could be created that estimate the yield at the plant level (aspirational, but in sight the idea of digital twin for a plant). A better understanding of yield for each crop would allow farmers to better allocate labor and machinery to maximize the profitability of farming operations.
- Data management – Research on technical, legal, and social frameworks for data rights management (sometimes referred to as "data sharing") in the agriculture industry is severely lacking. Tremendous potential can be unlocked once those with the data are willing to provide access by those capable of using it for the benefit of all involved.
- Grain traceability – Some promising NIST-funded research has been carried out in collaboration with Kansas State University and with AgGateway's support. While grain traceability is a tough challenge, continued research along a Digital Thread technology axis would likely produce resources complementary to completed and current research.

5.5.2. Workforce Development and Training

Workforce development and training in agriculture for Digital Thread technology should be accomplished by incorporating Digital Thread technology topics into existing programs. Examples include adding Digital Thread technology topics to:

- university courses
- continuing education programs
- university extension programs
- standards organization webinars and in-person training events

Topics could be featured as Digital Thread technology or could be featured as capabilities of Digital Threads.

Incorporating Digital Thread technology topics into existing programs may increase interest in the agriculture industry, in part due to higher wages.

5.6. Development and Support for Digital Thread Technology Infrastructure

In agriculture, a key enabler of the application of Digital Thread technology would be a semantic infrastructure. A semantic infrastructure in this context is a system for managing controlled vocabularies and the correspondence of entries. Types of controlled vocabularies include code lists (e.g., country codes, currency codes, crop definitions, days of the week, units of measure, soil characteristics), identifier schemes (e.g., GTIN, GLN, VIN), and standardized information models. The agriculture industry has myriad controlled vocabularies and many other data patterns that would be best served using a controlled vocabulary. Additionally, having information about how an entry in one list corresponds to an entry in another list would be invaluable (e.g., #2 Yellow Corn in one list corresponds with a specialization of Yellow Corn in another list). Unfortunately, there is no funded coordinated effort today to develop a semantic infrastructure. A NIST-funded project to address this need would likely be one that could be straightforwardly transferred to an industry-supported ongoing set of services.

One note regarding the scope of semantic infrastructure. In some contexts, a semantic infrastructure may refer to the development and implementation of a rigorous domain ontology with instance data expressed as RDF triples over which inferencing is done. That is not what is proposed here. This proposal is limited to controlled vocabulary management.

Figure 7: Agriculture/Food Sector Activities, outlines a research program for Digital Thread technology which incorporates the agriculture pilot programs described above and adds proposed “solutions” designed to focus the research on obtainable five-year goals. Please see section 8 for more detail on this proposed approach.

Funding is recommended for cross-industry centers of excellence focused on Digital Thread technology which would be responsible for the Digital Thread technology program described in this section and further developed in section 8 and provide support to multiple industry sectors on their Digital Thread journeys.

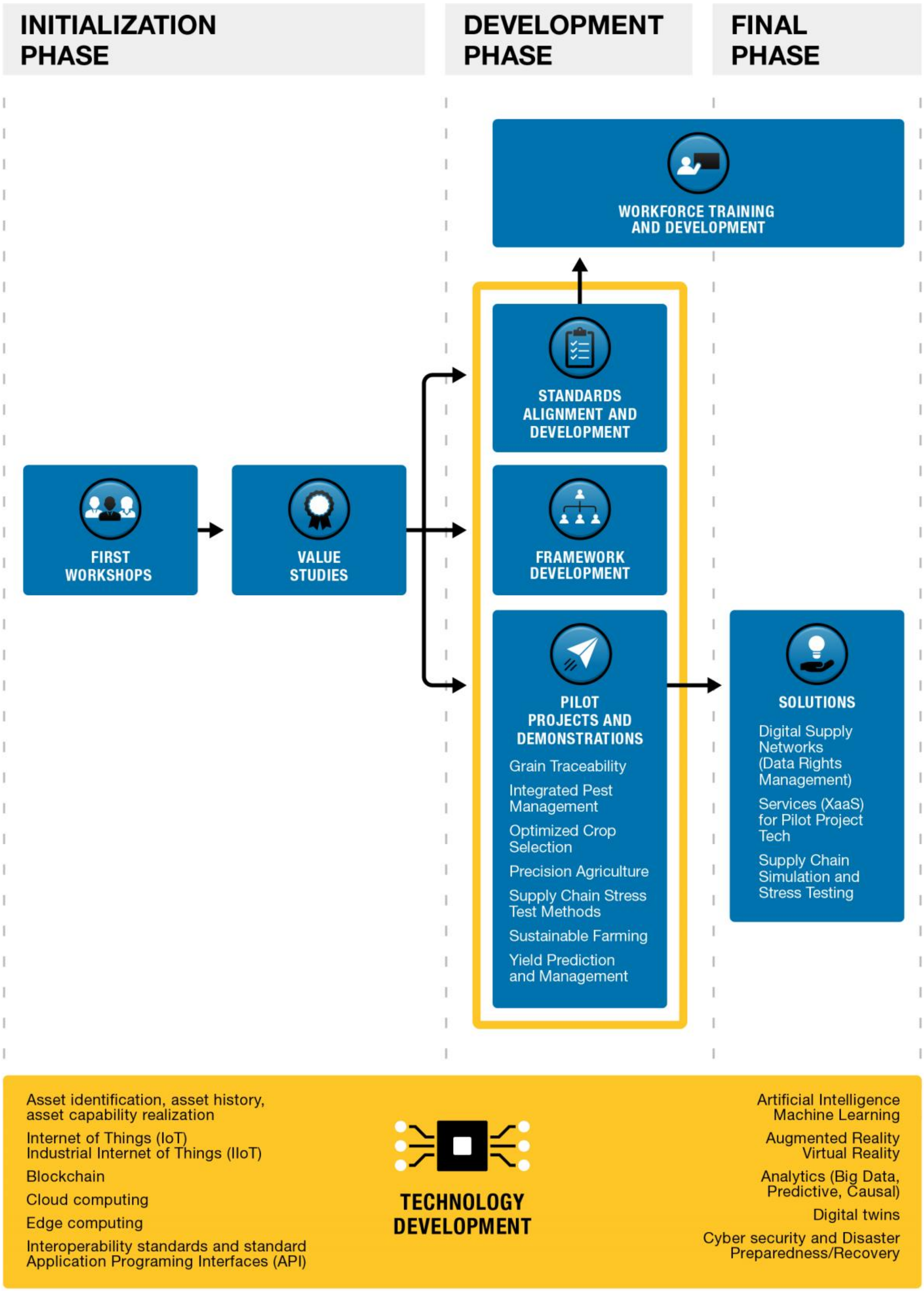

Figure 7: Agriculture/Food Sector Activities

6. Digital Thread Technology in the Energy Industry

In February 2022, the U.S. Department of Energy (DOE) published "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition [13]"—the first comprehensive U.S. government plan to build an Energy Sector Industrial Base (ESIB). The strategy examines technologies and crosscutting topics for analysis in response to Executive Order 14017 on America's Supply Chains [6] and is part of a whole of government approach to chart a course for revitalizing the U.S. economy and domestic manufacturing by securing the country's most critical supply chains.

Digital Thread technology will play a key role in helping to address the findings and opportunities identified in the DOE report for a "robust clean energy transition." In addition, improved linkages of information (Digital Threads) throughout our existing energy supply networks, regardless of their age, will help minimize power disruptions and maintain the competitiveness of the US energy infrastructure as the country continues to work towards clean energy and net zero goals.

In this section of the Digital Thread roadmap report, risks to energy supply chain resilience and capacity are examined from the perspectives of raw material supply, equipment production and delivery, construction, power generation, energy storage, transmission, distribution, and retirement, disposal, and replacement of energy-related assets, waste, and by-products.

After enumerating supply chain risks, Digital Thread technology's role in an "ideal future state" for the energy industry is explored. That exercise will help to identify gaps and weaknesses in Digital Thread technology and help to identify the opportunities for future research.

6.1. Risks to Supply Chain Resilience and Capacity in the Energy Sector

6.1.1. Supply Chain Resilience

Supply chain resilience refers to the ability of a given supply chain to prepare for and adapt to unexpected events; to quickly adjust to sudden disruptive changes that negatively affect supply chain performance; to continue functioning during a disruption (sometimes referred to as "robustness"); and to recover quickly to its pre-disruption state or a more desirable state. A resilient supply chain should exhibit several key behaviors including:

- Rapid detection, response, and recovery. Supply chains need to be able to quickly detect, respond to, and recover from changed conditions. These may include changes within the control of manufacturers and producers (i.e. production/quality/logistics control issues) as well as changes outside of their control (i.e. man-made disasters, cyber-attacks and exploitation of supply chain vulnerabilities).
- End-to-end, data-driven, supply chain control. Supply chain integration, transparency, and visibility are necessary for enhanced resilience. This implies being able to easily access information about energy generation, transmission, and distribution, and the availability of distributed energy resources (DERs) and energy storage, as well as raw materials, physical assets, and human resources from "suppliers' suppliers" to "customers' customers."

- Collaboration of private and public supply chain stakeholders. Collaboration between public and private entities is critical to enhance information sharing which can reduce risk, provide threat intelligence and spread best practices. By working together, public and private entities can also pool resources to improve overall risk management, identify threats, enable efficient, coordinated responses to supply chain disruptions, and increase the overall adaptability and flexibility of the nation's energy sector.

6.1.2. Supply Chain Capacity

We define supply chain capacity as the capability of an entity to produce output for a specific period of time. For the Energy Sector Industrial Base (ESIB), supply chain capacity is composed of:

- Supplier capacity for equipment and raw materials used in equipment – includes tier 2, 3, and 4 suppliers
- Transportation and distribution capacity for equipment and raw materials – includes time spent in cargo, storage handling, staging, and inspection facilities as well as actual transport and load/unload and construction activities
- Construction, installation and commissioning of equipment.
  Construction of energy-related infrastructure is highly regulated and highly specialized. While construction might not be considered a "supply chain" activity, it is included here because of its profound effect on energy supply capacity and the cost and schedule risks associated with "megaprojects" such as construction of nuclear power plants [41].
- Supplier capacity for fuels and other energy-producing resources
- Transportation and distribution capacity for fuels and other energy production resources
- Power generation capacity – including producers' abilities to meet internal and external requirements, regulations, and specifications as well as demand
- Energy storage, transmission, and distribution capacity
- End-of-life energy-related waste management capacity

6.1.3. Risks to Supply Chain Resilience and Capacity

The February 2022 DOE one-year energy supply chain review report highlighted fifteen "risks and vulnerabilities" to the US Energy supply chain. These are divided into seven "common" and eight "technology-specific" risks and vulnerabilities:

Common risks identified in the February 2022 DOE supply chain review:

1. **Availability of raw materials:** Many clean technologies use rare earth elements, minor metals, and precious metals as key constituents [13]. Extraction and production of many of these materials are concentrated in a few countries where political instability, trade restrictions or disputes, and regional conflicts could disrupt supply chains.

2. **Declining US manufacturing capabilities:** Since the year 2000, the US has experienced significant declines in manufacturing capability and employment in the manufacturing sector [42]. Disruptions due to COVID-19 clarified weaknesses in U.S. manufacturing by exposing supply chain risks and vulnerabilities in multiple sectors.
3. **Insecure foreign supply chains:** DOE assessments show supply chains of multiple energy technologies are highly dependent on insecure foreign sources [13]. Oil and gas have a long history of insecure supply chains due to geographic resource constraints which have only recently been reduced in the US. Similarly, many of the limited sources of materials for clean energy production are considered "insecure" with histories of human rights violations and limited respect for privacy and intellectual property.
4. **Lack of sufficient demand to support the domestic supply of some clean energy technologies:** Supply chain investments usually have a long payoff period, and uncertainty in future demand is a challenge in scaling up investment in supply chains in the United States.
5. **End-of-life waste management:** Some materials used in energy production are hazardous; others have significant value but are difficult and expensive to collect, process, and recover.
6. **Mismatch in demand and supply of the US workforce across multiple sectors:** Successfully rebuilding domestic supply chains will depend on the employers' ability to attract and retain a skilled, trained, and diverse workforce at all levels of manufacturing, power generation, and distribution.
7. **Limited visibility to supply chains and inadequate databases and analytic tools:** The DOE review identified limitations in current data and analytical tools to assess and understand holistic and interdependent supply chains in the context of the "Energy Sector Industrial Base [13] (ESIB)."

The 2022 DOE supply chain review also identified **key technology-specific risks** and methods to address each:

8. **Hydrogen and captured CO2:** Improve infrastructure to support market growth. Existing infrastructure for Hydrogen and captured CO2 delivery and storage is needed to support market growth.
9. **Fuel cells and electrolyzers:** Re-envision electricity resources and markets. The DOE proposes utility reforms that place value on services provided by integrated hydrogen systems. Suggested approaches include state and local government authorization of innovative or direct utility ownership to help address
10. **Land-based wind turbines:** Address logistical needs. Land-based wind components are approaching or exceeding road and rail size limits. As wind components get larger and wind deployment increases, remaining routes are likely to become increasingly congested, and complying with disparate permit requirements more difficult and costly—unless addressed with smart policy interventions.
11. **Offshore wind turbines:** Upgrading port and vessel infrastructure. The business case for investments in specialized port infrastructure and Jones Act-compliant specialized maritime vessels is challenged by lack of certainty in near-term offshore wind demand. DOE proposes strong policy interventions.

12. **Electric grid, hydropower, and nuclear components:** Modernizing aged/outdated infrastructure. As it has for many years, DOE urges strategic policy actions to support modernizing these systems without creating additional pressure on existing supply chains.
13. **Hydropower:** Improving access to large capital and other incentives. Obtaining financing for new hydropower projects and rehabilitation of existing facilities is challenging since most hydropower projects require large investments with long payoff periods. DOE proposes expanded tax credits for environmental improvements, enhancements to improve grid resilience, and dam safety improvements.
14. **Semiconductors:** Accelerating focus on energy efficiency gains. Most semiconductor-related supply chain risks are identified in the Department of Commerce supply chain report. DOE identified an additional vulnerability in the slowing of energy efficiency gains in each successive generation of semiconductors and is developing an R&D roadmap to aggressively tackle the issue.
15. **Grid-scale energy storage:** Developing commercial variety to meet broad system requirements. DOE sponsors R&D dedicated to alternatives to lithium-ion batteries (e.g., flow batteries) manufactured with abundant materials (e.g., low-cobalt alternatives) for grid-scale energy storage solutions.

The risks and vulnerabilities listed in the DOE report are targeted mostly towards renewable energy solutions in the supply chain context. The identified risks also tend to be ones which government can help address through policies and regulations.

Additional risks to existing and emerging energy supply chains identified by participants in this project are listed below. Some of these are also covered by risk 12 above (where DOE recognizes the risks associated with aging infrastructure). Some of these risks may be more localized and/or may be beyond the control of government in whole or part.

These **additional risks to supply chain resilience and capacity** include:

16. **Cybersecurity threats:** Like many industries, the energy industry is a target for constant cyber-attacks. Organizations expend significant resources to continuously assess the threat landscape, enhance IT/OT controls, monitor IT/OT systems, and develop plans for threat response, training, and disaster recovery.
17. **Physical threats:** Power plants, refineries and chemical plants with a fixed location typically have very strong security on premises. Pump stations, compressor stations and especially pipelines are more difficult to guard [43].
18. **Limited financial and technical resources at public power entities:** Public power generates 10% of all electricity in the U.S. and distributes — or sells at the retail level — 15% of all power flowing to homes and businesses [43]. While there are many benefits to this system, public power entities may have resource limitations which could impact their reliability and ability to invest in infrastructure and technology upgrades.
19. **Shift from hydrocarbon to electrification:** This shift will place significant strain on the aging electrical grid while simultaneously forcing the industry to manage the intermittent nature of many renewable energy sources, the complexities of integrating new

technologies, high initial costs, volatile markets for raw materials, and an uncertain policy and regulatory environment.

20. **Demand forecasting complexity and uncertainty:** Demand forecasting is notoriously difficult for reasons that include weather and climate change, economic and social factors, technological advancements, the integration of DERs (Distributed Energy Resources), and data quality and availability [43].
21. **Megaproject nature of adding capacity:** To meet future energy needs, a significant number of new large-scale generation facilities will need to be constructed. Many of these projects will exceed $1B and are classified as megaprojects. Data cited by Ritter and Rhoades indicates that only 35% of megaprojects are completed within 25% of planned schedule and budget [41].
22. **Data management:** Huge amounts of data associated with facility design, construction, and operation are the norm. Many operators struggle to make the mix of paper documents, digital documents, system monitoring data, maintenance reports, and other types of data Findable, Accessible, Interoperable, and Reuseable (FAIR data principles) creating risks to both resilience and capacity.
23. **Weather, climate change, natural disasters, and wildlife:** Severe weather is the biggest cause of power outages. Climate change causes an increase in extreme weather events (including natural disasters), more variation in temperatures creating stress on the grid, and sea level rise and possible flooding of energy facilities. Animals coming in contact with equipment is also a common cause of power disruptions.
24. **Technology failures:** While new technologies for generating power, storing energy, and operating energy infrastructure have significant benefits, they often increase complexity of the overall system. This additional complexity creates risk due to flaws in the technology, poor integration and testing, lack of interoperability, or human error.
25. **Inconsistent federal policy:** After the Trump administration worked to eliminate barriers for fossil fuels, the Biden administration has put significant incentives in place to help renewables grow. The changes in the regulatory environment can make long-term forecasting and public-private cooperation difficult for companies in all stages of the energy stream [43].

6.2. Current and Target Future States of Digital Thread Technology in the Context of Value/Supply Chain Resilience and Capacity

Digital Thread technology should enable organizations to seamlessly collect, access, associate, and share timely and reliable contextual data from various sources throughout their value and supply chains. In this section, current understandings and implementations of Digital Thread technology in the energy sector are explored along with how existing and envisioned Digital Thread technology could be used to mitigate previously identified risks and realize maximum benefit. This information is used to help identify weaknesses, gaps, and challenges in current Digital Thread technology to inform future activities and the overall roadmap.

6.2.1. Current Understanding of Digital Thread Technology

Digital Thread and the related nomenclature are not in common use across the energy sector. To date, there is little in the way of Digital Thread deployment. When addressed it is still considered largely a research topic and mainly the purview of government and private sector laboratories. The current energy system in the U.S. is in a large state of transition, with a high level of focus on deploying newer low-carbon technologies to market (i.e., renewables and energy storage) and re-shoring critical enabling technologies for more established energy systems (i.e., semiconductors and material processing). As a result, supply chain digitalization technologies often receive limited development and deployment funding. Digital Thread discussions that occur are often in the context of Digital Twin implementation.

6.2.2. Current State of Digital Thread Technology

During meetings, interviews, discussions, and background research, little was found to suggest any significant implementation of Digital Thread technology into production environments in the energy sector. Most work done to date is via U.S. national labs or under R&D grant funding as demonstration programs and generally represents a subset or "mini threads" tying together very discrete data sets (such as Digital Twin demonstration projects). Despite the critical energy system supply chain challenges experienced during the pandemic shut-downs, Digital Thread has not yet emerged as an acknowledged enabling technology to improve supply chain resilience and capacity within the energy sector.

It should be noted that Digital Thread in this context is separate from Digital Twin approaches that have recently gained traction in the energy sector. We have identified Digital Twin being demonstrated in such areas as nuclear reactor design, offshore wind turbines, and hydropower, and it was noted that offshore oil and gas platforms are evaluating the technology to enable required inspections via unmanned systems. Additionally, it was reported that larger industrial players and utilities are beginning to understand the Digital Twin value proposition and are moving towards implementation.

Digital and AI technology is also becoming more critical in the management of the grid, particularly with the deployment of smart meters and new approaches to Smart Grid and Virtual Power Plants (VPP). Given resiliency challenges due to system failures or extreme weather events, there is a premium in the application of digital technologies in today's utilities to collect and analyze in real-time system issues and optimization opportunities. In some cases, supply chain challenges and delays have led to increased use of data to better manage grid assets – although in many cases smaller utilities do not have adequate expertise to analyze the large data pools now enabled via smart metering and other systems. Larger utilities have more readily embraced the application of real-time operational data to reduce risk and enable efficiency, although challenges still exist.

It was observed that Digital Thread technology has the highest potential value in capital-intensive system deployments, such as nuclear or hydropower plant construction. In these cases, the cost of supply chain issues is amplified during the construction process, as avoidable issues can lead to expensive "stop-work" conditions.

6.2.3. Target Future State of Digital Thread Technology

Given the highly fragmented supply chain in the energy sector, the application of Digital Thread technology could help improve supplier collaboration, reduce supply chain disruptions and their resulting impacts, and provide more overall awareness of supply chain performance and potential constraints. The desired outcome would be increased uptime and reduced costs. However, this fragmented nature also makes Digital Threads difficult to achieve at scale, particularly given concerns over data security with international suppliers.

Traceability of key energy assets is one significant benefit area for the energy sector. This includes everything from tracking and predicting the operational performance of key grid components such as transformers (that may degrade more quickly under high load or in high-temperature environments), to the design and development of capital-intensive generation systems such as nuclear power plants (including newer advanced and modular reactor designs), hydropower, and offshore wind turbines. In all these cases, accessing and using data related to product life cycle and having traceability to historical performance can help improve overall system performance and readiness.

Additionally, new considerations for circularity and recyclability of energy system assets are driving increased need for access to full product lifecycle data. Examples include energy storage systems (batteries) and wind turbine blades. An effective Digital Thread that allows seamless connection of serial number specific data across the product lifecycle could help address circularity requirements for critical energy system components.

Technological advancements towards Distributed Energy Resources (DER), Smart Grids, and Virtual Power Plants (VPP), along with the deployments of Advanced Grid Integration (AGI) smart meters are increasing the opportunities for digitalization of the electricity grid. Potential improvements include the application of Artificial Intelligence (AI) algorithms that can better manage real-time grid loads and disruptions in demand or supply. The successful deployment of AI and related digitalization technologies will need to leverage a robust, consistent, and trusted data set of the components and subsystems on the grid.

Further development of Digital Thread technology could be a key enabler for the development of this trusted data set.

In the envisioned future state, Digital Thread technology is the key to realize robust, automated causal analytics. When disruptions occur, the data should not only describe “who, what, when, and where” but also “how” and even “why.” Future systems will include improved capabilities to predict potential disruptions before they occur and provide guidance for appropriate corrective actions.

Digital thread technology should also enable future capabilities such as:

- **Digital supply networks (DSN):** Suppliers can access standardized technical data packages (TDP) containing single source of truth for product and process definition information. Suppliers would submit “as-produced” data for traceability, configuration control, product and process qualification and verification. Logistics and in-service data are also present and refreshed in a timely manner. The data would conform to standardized information models and vocabularies to foster interoperability, AI and analytics, and seamless data exchange. Data storage and representation must follow FAIR data principles while respecting organizations' intellectual property and personal privacy.

- **Automated regulatory and QA/supplier compliance:** Organizations can verify regulatory, quality, and supplier compliance through automated systems which accept digitally signed, verifiable data in standardized formats. Just as important, digital agents can review data in the context of existing or proposed regulations and specifications to warn owners and operators of potential non-compliance.
- **Change management:** Digital Thread technology can be used to identify and document the impacts of proposed/actual changes.
- **Predictive analytics:** Predictive models are improved by connecting data from all stages of a product's lifecycle in a timely and accessible way to identify complex patterns and improve forecasts, schedule and perform as-needed maintenance, and avoid disruptions.

6.3. Weaknesses, Gaps, and Challenges of Digital Thread Technology

Digital thread technology continues to evolve, however, challenges to realizing the vision of simple access and association of contextual data throughout the extended supply chain remain numerous. Gaps in Digital Thread technology and barriers to adoption include:

- Limited understanding of the potential value or cost benefit of deploying Digital Thread technology.
- Lack of a heterogeneous data structure or data source to support deployment
- Inconsistent digital expertise along the supply chain
- No clear value proposition for suppliers who must provide the data to support Digital Thread – i.e., "what's in it for them"
- Implementation costs that must include development, deployment, and management of Digital Thread technology
- Concerns over digital data security, given both the international nature of the supply chain and concerns over domestic energy security. This concern is amplified in technology areas that may have defense implications, such as nuclear reactor design and deployment. (It was noted by one participant that Digital Thread technology could help resolve this industry challenge by enabling more transparency across the supply chain.)
- Investment prioritization focused on deploying emerging low-carbon technologies and re-shoring critical suppliers, resulting in a decreased focus on increased supply chain technology development.
- Government bureaucracy and red tape, particularly given the highly regulated nature of energy utilities and related data management and technology deployment considerations
- A fragmented supply chain and a utility sector that does not have natural "integrators," in contrast to sectors such as aerospace that rely on a few key prime contractors and a highly consolidated supply base.

- Cultural issues, such as resistance to the open architectures needed to enable wide deployment of Digital Thread technology, and distrust of machine-generated data over traditional forecasting and planning tools.

Given the nascent nature of Digital Thread technology in the energy sector, there are a number of threats that may derail large-scale deployment initiatives. These include:

- Unclear value proposition and competing capital demands, leading to insufficient funding to develop, demonstrate, and deploy Digital Thread technology
- Insufficient investment in the needed ecosystem and infrastructure, such as open architectures and standards for data sharing
- Lack of digital expertise at utilities and across the energy supply chain
- Data security regulations and related concerns that limit the ability to share data effectively
- Potential issues related to data ownership and access, considering proprietary information, intellectual property, as well as data monetization business models
- Lack of a value proposition for all participants in the value chain, leading to adoption resistance and incomplete or erroneous data sources
- Cultural resistance to move away from individual supplier-centric systems (including custom spreadsheets and home-grown solutions) to a more unified and robust heterogenous set of master data

6.4. Potential Research Projects and Workforce Development and Training Initiatives

Harnessing digital thread technology is critical to achieving maximum value from our technology investments since it weaves through all processes and interfaces throughout the extended supply chain. It is the glue connecting all aspects of equipment manufacturing and energy production, storage, transmission and delivery together. It connects suppliers, process inputs (e.g. raw material), actual processes, process outputs (e.g. products and byproducts), and their customers. Developing a clear strategy for research and development of digital thread technology and supporting initiatives to provide for workforce development and training on the technology will accelerate our ability to achieve the goals and objectives outlined in the *Strategy for American Leadership in Advanced Manufacturing*. Proposed R&D will also support the 2022 DOE report on *America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition* by promoting adoption and implementation of traceability standards to improve global supply chain mapping capabilities, instill integrity of product custody, promote social responsibility, and support carbon foot-printing of energy supply chains [13].

DOE identified four strategic opportunities in the most recent *Supply Chains Progress Report* (published August 2023) [44]. These opportunities include:

- Securing critical materials
- Expanding energy sector manufacturing
- Growing the domestic clean energy workforce
- Building out supply chain capabilities

The proposed programs that follow are aligned with these four opportunities and also address many of the risks to supply chain resilience and capacity enumerated earlier.

6.4.1. Securing Critical Materials through Adoption and Expansion of ISO 23664:2021

The proposed program promotes the use of ISO standard 23664:2021 [45] and will explore expansion of the standard. This standard deals with the *Traceability of rare earths in the supply chain from mine to separated products.* In the envisioned future state, producers and processors of rare earths would conform to the standards and recommendations of the standard. The proposed research would focus on leveraging common information models and data representations to satisfy traceability requirements and promote interoperability with other digital systems while enabling secure data sharing throughout the supply chain. The result should be a single, unified view of the entire supply chain which complies with pertinent data security and privacy requirements.

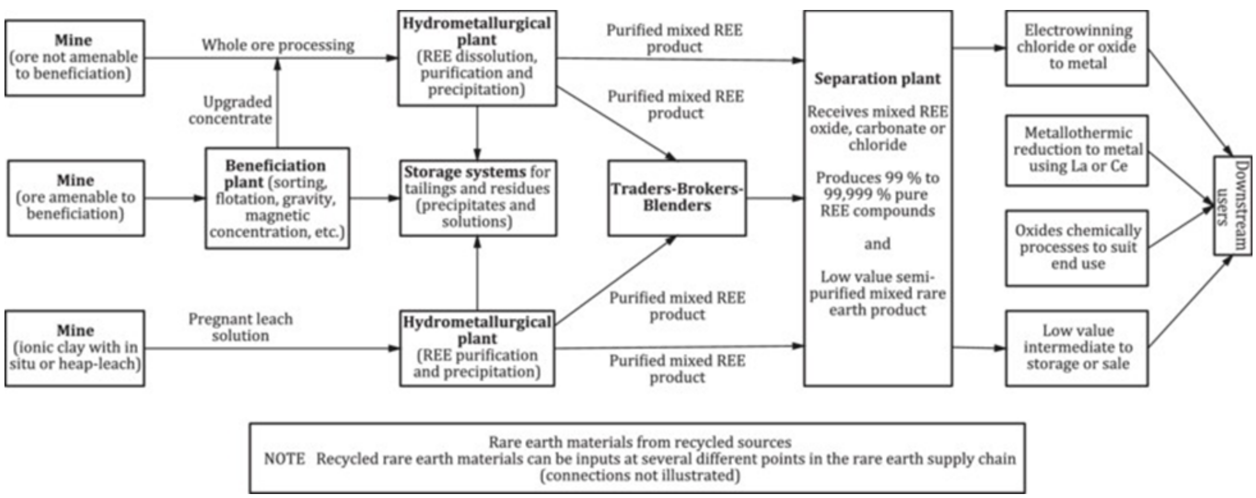

Figure 8: Rare Earth Metals Traceability (from ISO standard 23664:2021)

6.4.2. Expanding Energy Sector Manufacturing Capacity through Digital Supply Networks

The proposed program is expected to improve collaboration between suppliers, contractors, and owner/operators in the context of energy-related “megaprojects” (e.g. hydro and nuclear power plants) as well as other projects focused on battery manufacturing, semiconductors, and renewable power. The program will design and build prototype digital supply network infrastructure delivered on cloud-based services. Participants in the program would access standardized technical data packages containing product definition information and submit “as-produced” data conforming to standards and information models of interest for traceability, configuration control, product and process qualification and verification. Existing standardized information models and vocabulary would be leveraged and possibly expanded to support this effort. Ideally, logistics and in-service operational information for the manufactured products would also be available to provide real-time insights and enable predictive capabilities and in-field performance improvements. Access to data in the DSN must conform to FAIR data principles while protecting sensitive information of individual organizations and personally identifiable information.

6.4.3. Growing the Domestic Clean Energy Workforce through Digital Thread Technology

The proposed program leverages Digital Thread technology and digitalization in general as the prime mover to grow the domestic clean energy workforce. The envisioned future state is one where the ability to integrate systems is merely a building block to enable interoperability and the creation of composable systems. Composable systems are designed with modular components that can be easily combined and reconfigured to enhance the system's flexibility, scalability, and adaptability. To achieve this goal, the US must educate and train engineers and scientists in what have traditionally been IT-centric concepts. Courses on information modeling, systems modeling, and composable systems concepts are key. As systems become more interoperable and ultimately composable, automation opportunities increase. Workers at all levels ultimately benefit from better working conditions and higher wages associated with the increased automation of less desirable jobs.

6.4.4. Building out Supply Chain Capabilities through Digital Thread Technology

The proposed program addresses the DOE Office of Manufacturing & Energy Supply Chains (MESC) need to aggregate supply chain data and create real-time "live" tooling which will enable economic analysis as well as analytics focused on addressing supply chain risks and other strategic opportunities. We propose leveraging open standards for information models, semantics, vocabulary, data exchange and data representation to establish a consistent framework, that supports data validation and sharing, addresses and overcomes data gaps, and helps to identify future research needs. Efforts should be made to assemble public (federal, state, and local) and private, historical, and near-real-time raw data, including data that covers environmental and social vectors. The government has a role to play in coordinating data collection (through voluntary or compulsory reporting), while protecting the sensitive information of individual persons and organizations (such as costs and production volumes) [46].

6.4.5. Enabling the future of the Smart Grid and Virtual Power Plants (VPP) through a Digital Thread Framework

This program envisions and endeavors to realize a future state in which contextual data is seamlessly collected, accessed, associated, and shared timely and reliably throughout the supply chains associated with smart grids and virtual power plants.

Background:

With a move towards increased electrification of building, transport, and industrial systems there is an accelerating need for electrical generation capacity. Historically, increased demand has been addressed by investing in centralized power plants and associated transmission and distribution assets. With the deployment of Distributed Energy Resources (DER) and an increased ability to perform demand response and utilize localized energy storage, the construction of new centralized plants can be minimized by better management at the local level. This implementation requires networking a variety of energy generation and demand systems from a wide variety of suppliers, and being able to rapidly adapt as new resources are brought on line. Such an implementation is referred to as a Virtual Power Plant (VPP).

Current challenges with developing, deploying, and maintaining current electricity generation, transmission, and distribution resources are significant – and the implementation of VPPs adds an additional layer of supply chain management complexity. A VPP brings several new supply chain participants into what has typically been a tightly controlled ecosystem; different providers rely on diverse data security approaches and are not always interoperable. Ownership of these new assets is highly distributed, and there are additional intermediaries such as power system aggregators.

Description:

The program proposes Digital Thread technology as enabling technology for VPPs, supporting existing grid assets and accelerating the deployment of this technology solution.

As what is considered "the grid" has expanded to include systems typically considered "behind the meter," the number of critical components and suppliers has expanded exponentially. By creating a standardized digital thread framework, the broader energy supply chain can be brought together to standardize performance and communication protocols and harmonize operations. Utilizing Digital Thread technology as a framework, utilities could better understand what new assets are coming onto the grid and how they can be most effectively utilized given local conditions. Digital Thread technology could also address cyber security concerns over new distributed resources potentially accessing critical energy system data.

The build-out of traditional generation as well as transmission and grid systems could be enabled by Digital Thread technology as well. By digitally linking the supply chain and relevant part data across the project, the utility can significantly improve insight into the supply chain. By linking programmatic schedules with development, test, and production status across the value chain, construction managers can significantly improve insight into potential delivery delays and part conformance issues. This enables the Engineering, Procurement, and Construction contractor (EPC) to realign schedules, reassign assets, and minimize the overall impact on the construction project.

Additionally, the implementation of Digital Thread technology can help improve the resilience of the existing grid as well as enable highly distributed VPP assets. One example is the management of transformers that are subject to long lead times and will degrade at different rates in the field due to environmental temperature extremes and utilization during peak demand periods. Digital Thread technology could be deployed to better track unit performance in the field, correlate with detailed product history data, and more effectively utilize assets with an overall extension of average life of fielded components – both traditional and VPP assets. Advanced algorithms and/or AI could be utilized to track asset performance over time (bringing in development and test data) and provide prognostics for early insight into replacement demand as aligned with supply chain lead times.

Digital Thread technology could be utilized to improve the resilience of the electricity system and shorten or eliminate time to repair critical components. Many energy generation and grid assets are in remote locations and difficult to access (e.g., offshore wind turbines, offshore platforms, remote community energy systems), and scheduled inspections and repair orders frequently rely on human interaction with multiple handoffs. This results in a potentially significant time lag from system failure to corrective action via maintenance visit and order of critical replacement parts. By digitally connecting fielded systems and critical components across the supply chain, prognostics and health monitoring systems could assess performance and automatically trigger replacement part order and field service orders. With a robust and secure Digital Thread infrastructure, this could conceivably be done in a fully automated manner, eliminating human-in-the-loop and associated handoffs and processing time. This would reduce time to repair and increase overall uptime of the fielded systems

6.5. Development and Support for Digital Thread-enabling Technology Infrastructure

The recommendations in this roadmap are meant to strengthen and inform both new and existing research on supply chains, Digital Thread technology and other digitalization efforts. Effective implementation and successful deployment are essential for research & development projects to benefit industry. The NIST Office of Advanced Manufacturing (OAM), NIST Laboratory programs, Manufacturing USA Institutes, National Laboratories, the DOE Office of Manufacturing and Energy Supply Chains (MESC), and public/private research institutes such as CCAM should work with manufacturers and producers of all sizes to develop specific scopes of work to further develop the research and development projects described herein, make policy recommendations and implement workforce and training recommendations. Funding is recommended for cross-industry centers of excellence focused on Digital Thread technology which would be responsible for the Digital Thread technology program described herein and provide support to multiple industry sectors on their Digital Thread journeys.

Figure 9: Energy Sector Activities, outlines a research program for Digital Thread technology which incorporates the proposed energy sector projects described above in the context of proposed “solutions.” The solutions are intended to focus the research on outcomes valuable to the energy sector supply chain with obtainable five-year goals. Please see section 8 for more detail on this proposed approach.

Funding is recommended for cross-industry centers of excellence focused on Digital Thread technology which would be responsible for the Digital Thread technology program described in this section and further developed in section 8 and provide support to multiple industry sectors on their Digital Thread journeys.

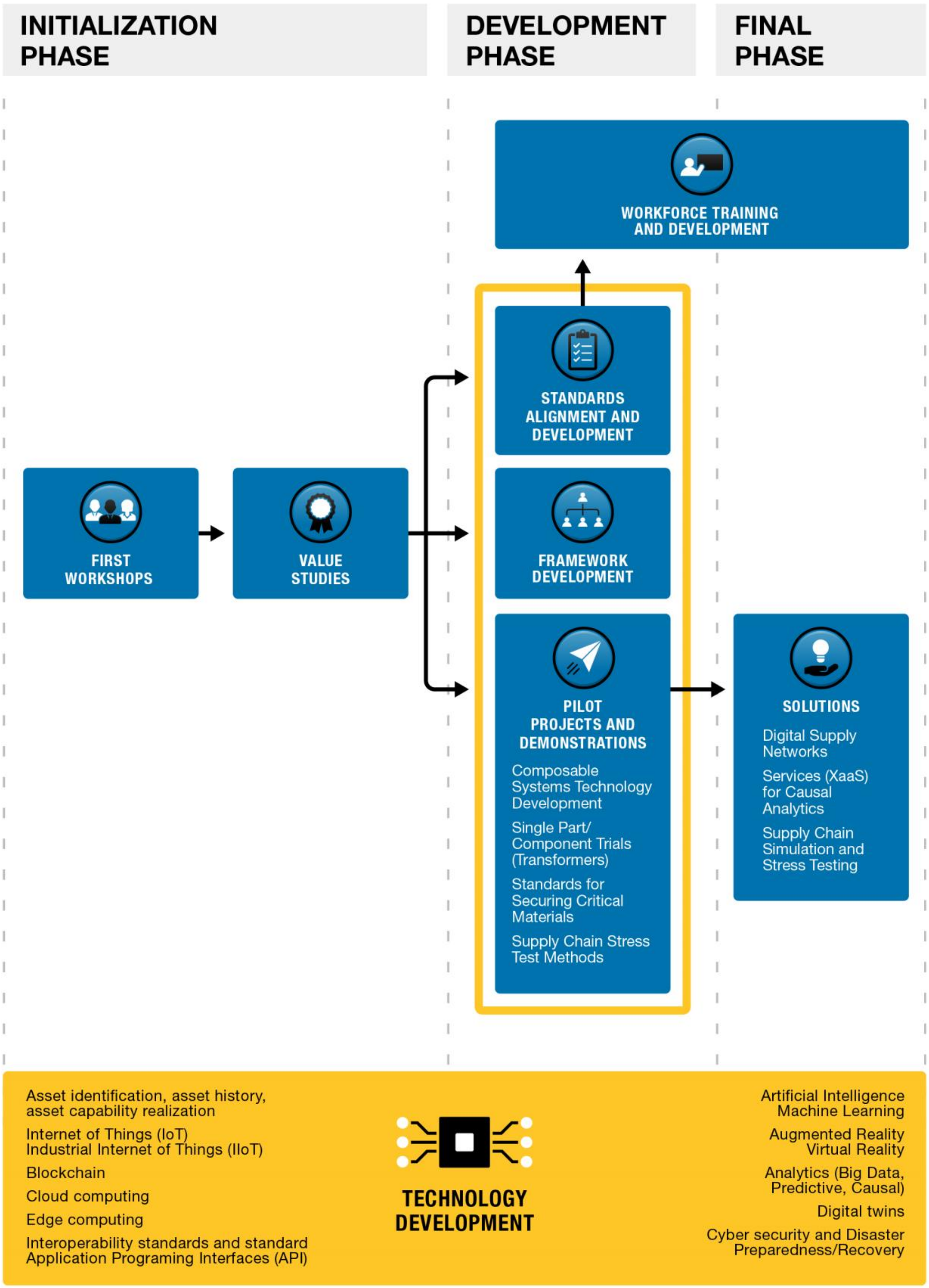

Figure 9: Energy Sector Activities

7. Digital Thread Technology in the Pharmaceutical, Biopharmaceutical Sciences and Medical Device (PBMD) Industries

Building resiliency and capacity of the Pharmaceutical, Biopharmaceutical Sciences and Medical Device (PBMD) supply chains involves an array of factors across the product lifecycle. As is the case with many other industries, the traditional supply chain is more of a network than it is linear, and gaps in digital technology and in their implementation exist at each node. Pharma and Medical Device companies share commonality in their current business initiatives regarding their supply networks and in the desired outcomes they are striving to achieve, with digitalization remaining a key factor in their success.

Companies are at varying stages of self-reported maturity relative to end-to-end digitalization of their supply networks, but their respective digital ecosystems, rife with fragmented legacy systems, tend to be unique. Individual sites within a company often have different ecosystems than other sites as well. These situations have made it difficult for solution providers to deliver technologies that will satisfy the overall needs of the industry, as tailored customizations and integrations are more common than not. In turn, PBMD companies have remained skeptical of the Digital Thread technology solutions available. These gaps in current technology, along with a shortage in workforce expertise and a lack of harmonized global technical standards and regulations, make digital transformation of the supply chain, and the realization of true Digital Threads from raw material to the end customer, a significant, ongoing challenge. Achieving this desired end state will require improvements and efficiency gains at each node of the supply network, not just in manufacturing. To be successful, stakeholders across the organization need a common language with goals and KPIs fully aligned.

For this portion of the Digital Thread technology roadmapping effort, surveys, interviews with PBMD SMEs, and a workshop with SMEs from multiple industries were used to assess participants' understandings of Digital Thread technology, opportunities for its application in the context of supply chain resilience and capacity, gaps in the technology, and challenges and threats to overcome for widespread adoption and realization of envisioned benefits. Interviewees were provided three documents in advance to set the theme and expectations of each interview:

1) An overview of the NIST-sponsored effort being managed by CCAM,
2) the set of questions to be asked of each participant, and
3) a "level-set" briefing on the meaning and objective of Digital Thread technology.

Core team members also conducted literature reviews of previous research, market and industry reports, government regulations, and guidance, and technical standards and drew on their own expertise and experiences working in industry, academia, government, industry working groups and worldwide standards organizations to identify headwinds and tailwinds, regulations, technical standards, gaps in Digital Thread technology, state of the industry, existing projects and recommended areas of future research.

From the information obtained from these activities, it can be said that Digital Thread technology implementations currently exist within PBMD supply chains of all stages of a product's lifecycle. However, they are fragmented with disparate systems and terminology for the conceptualization (pre-clinical phases), manufacturing (clinical trials, scale-up and full production), distribution and service (patient incident tracking and serialization track and trace) stages of product lifecycles. Bringing a drug to market involves multiple partners across multiple continents, and the lack of harmonization of regulations further hinders development of a resilient and capacious supply chain.

Though its adoption varies across different organizations and regions, many companies in the pharmaceutical industry are moving to a “Pharma 4.0” maturity model-based framework for adapting digital strategies, including Digital Thread technology. The term Pharma 4.0 was coined by the International Society for Pharmaceutical Engineers (ISPE) to envision a digitally mature pharmaceutical industry [47]. When asked to choose which digitalization framework resonates the most, ~40% of the participants from the survey indicated they were most familiar with Industry 4.0 (the remaining 60% chose either Digital Thread, Factory of the Future, Smart Facility or that they were not familiar with these frameworks). This suggests there is a long way to go for universal adoption of any specific framework for digitalization of the supply chain in the PBMD industries.

This section addresses the application of Digital Thread technology in the PBMD industries to address risks to supply chain resilience and capacity [15]. Subsections 7.1 and 7.2 identify the risks to supply chain resilience and capacity, respectively. Subsection 7.3 identifies the target future state for the sector with the envisioned adoption and integration of Digital Thread technology. Subsection 7.4 highlights the weaknesses, gaps, and challenges to reaching the identified target future state. Next, subsection 7.5 provides a selection of research projects to advance the development of Digital Thread technology to benefit the PBMD sector. Finally, subsection 7.5.5 provides a plan for integrating Digital Thread technology into the industry and training the existing workforce to use the newly integrated technologies.

7.1. Risks to Supply Chain Resilience Addressable by Digital Thread Technology

Supply chain resilience refers to the ability of a given supply chain to prepare for and adapt to unexpected events; to quickly adjust to sudden disruptive changes that negatively affect supply chain performance; to continue functioning during a disruption (sometimes referred to as “robustness”); and to recover quickly to its pre-disruption state or a more desirable state. The key industry challenge to strengthening PBMD supply chain resiliency is understanding tier 2, tier 3, and tier 4 suppliers’ resiliency. A resilient supply chain will be resilient from failures at any tier. For example, from the lowest supplier-level, such as those creating bulk plastic, to the makers of plastic films, to the makers of sterilized dispensing bags using the film, to bags filled with a medication, through transportation and distributer systems to patients. A resilient supply chain will provide the information to become quickly aware of supply chain problems and provide the information to assess possible solutions.

Four key risks within PBMD supply chains addressable by Digital Thread technology are examined.

1. **Production Disruptions** of raw materials, APIs, and secondary production material
2. **Difficulty in sharing IP** and other corporate data securely, safely, and legally so that suppliers and producers can be dynamically introduced to supply chains and ramped up and validated
3. **Ability to Detect and Recover** from accidental or blatant attacks on the supply chain.

4. **Complexity of Global Supply Chains** and the associated risks of not having access to suppliers from a region or visibility to their operations and capability due to issues rooted in politics, safety, etc.

Production Disruptions of raw materials, APIs, and secondary production material

PBMD supply chains can be characterized by two different classes of products: generics and branded. Generics often have multiple producers and comparatively resilient supply chains due to competitive pressure (such as aspirin, various antibiotics, creams, and ointments). Some generics, however, only have a single producer (such as Adapalene Cream and Rifaximan tablets) and a single production site. In a resilient supply chain, producers would have visibility of alternate production capacity through knowledge of potential outsourcing partners and their ability to set up manufacturing, validate the processes, ramp up production, and deliver products regardless of being branded or generic. For example, a recent tornado hit a Pfizer facility in Rocky Mount, North Carolina, that makes nearly one-fourth of the sterile injectable medications Pfizer supplies to U.S. hospitals [48]. A resilient supply chain would provide the information needed to handle this kind of disruption by providing visibility into alternate production sourcing and visibility into alternate material availabilities.

Difficulty in sharing IP

The second addressable risk, the secure, safe, and legal sharing of IP and other corporate data, is a major inhibitor to PBMD supply chain resilience. For example, the production of branded (patent-protected) products usually has a single source of raw, intermediate, and production materials. Additionally, patent-protected products generally have a single or few production sites, often dedicated to single products. This causes a drug shortage when there is increased demand, such as for Ozempic [49]. Additionally, product definitions, identifiers of all the materials needed for production of a product, ultimately identify how to create their branded products. Their inability to be minimally, safely, and legally shared inhibits the identification of alternate suppliers when production needs to be ramped up.

Ability to Detect and Recover from both accidental and blatant attacks on the supply chain

A resilient supply chain should be capable of detecting and recovering from both accidental and blatant attacks. The insertion of counterfeit drugs into the PBMD supply chain is one example. There are increasing regulatory requirements to track and trace all produced medications due to the prevalence of counterfeit products and to simplify recalls of scarce medications. By inserting counterfeit drugs into PBMD supply chains, batches of products can be affected, causing widespread damage to production devices and consumers within the supply chain. Furthermore, scoped recalls of distributed products are difficult without identifying or localizing the cause. The introduction could be at production, in distribution warehouses, in transportation, or even at the end pharmacy or store, each of which differs regarding effective strategies for combating the attack [50]. Instead of mass recalls, targeted recalls can save millions of dollars in costs while still protecting consumers. There were a total of 466 drug recalls between 2009 and 2019, with over half the recall classified as Class I, where the product in question can cause serious health problems or death [51]. This capability also provides the means to handle emergencies such as natural disasters (such as earthquakes or tornadoes) or man-made disasters (such as plant fires or explosions) that impact production or supply chain deliveries.

Complexity of Global Supply Chains

Outsourcing of biopharma development and/or manufacturing to CMO/CDMOs around the globe has doubled in the last 13 years [52]. This is adding complexity to the supply network and increasing the demand for an improved means to seamlessly and securely share production and process data and act on it. The supply chain for a simple small molecule pharmaceutical product can involve 22 first-tier suppliers (from API to primary and secondary packaging) and hundreds of second and third-tier suppliers [53], all of which must have validated products and processes. This is a major risk in managing a resilient supply chain. Digital thread technology has the potential to manage this complexity across possibly hundreds of suppliers and to handle unexpected supply chain issues at any tier of production.

The survey conducted by Procegence as part of this project also identified the following supply chain risks:

- There is a very limited domestic capacity to make essential medicine active pharmaceutical ingredients (APIs) [54].
- For many materials, there is a single, foreign source of supply [54].
- There has been limited private investment in domestic API manufacturing capacity [54].
- Real-time information about needs and shortages is not easily accessible [50].
- Outsourcing of biopharmaceutical development and/or manufacture to CMO/CDMOs around the globe has doubled in the last 13 years, adding complexity to the supply network [55].
- Most generic medicines are manufactured outside the US, and this is significant because 90% of US prescriptions are filled with lower-cost, generic medicines [55].
- The strategic national stockpile of medical supplies was never designed to address long-term storage, however, finished medicines have an average shelf life of only two years, requiring continual supply chain replenishment [54].

7.2. Risks to Supply Chain Capacity Addressable by Digital Thread Technology

The key industry challenge to strengthening PBMD supply chain capacity, or the capability of entities within the supply chain to produce output for a specific period, is to understand tier 2, tier 3, and tier 4 suppliers' available capacity. It is important to understand not just the available capacity, but also the confidence factors in capacity margin (room for unexpected demand or demand growth). A capacious supply chain will be able to provide how much a supplier at each tier can produce, within current supply constraints and possibly running extra shifts assuming they have access to the necessary human and material resources.

Three key risks to supply chain capacity in PBMD supply chains are examined:

1. **Seasonal demand** and the challenges it presents
2. **Lack of sufficient safety stock**, causing significant challenges when demand surges
3. **Slow time-to-market** of new PBMD technologies and drugs and long lead times to construct, qualify, and ramp new production capacity even for existing drugs using proven technology

Seasonal demand

Most PBMD production is made to stocking levels. Regulatory agencies often set the amount of required stock based on expected near-term or seasonal demand for brand drugs. Generic drugs usually have stock levels based on the expiration dates of the product and estimated demand. The average overall equipment utilization (OEE) in the PBMD industry is about 35%, meaning that there is often sufficient internal capacity to scale up production. However, the utilization rate varies widely. For example, asthma inhalers run at over 95% utilization throughout the pollen and flu season but are otherwise much lower, while seasonal vaccine production runs at 10% during much of the year. When final production capacity can be rapidly expended (as seen in the production of Covid-19 testing kits and Covid-19 vaccine production), the capacity is usually limited by the production materials, especially those consumed or used and discarded during production. Digital threads that cover the entire supply chain are independent of supplier tiers, therefore, they can be used to identify qualified alternate suppliers should the primary supplier's capacity be insufficient to meet surge demand. For example, while production of Covid vaccines could be ramped up, the ability to source glass vials, and even the glass for the vials, was a limiting factor in distribution [56], [57].

Lack of sufficient safety stock

Sometimes errors occur that are not caught in production, and products must be recalled. While the FDA does require that manufacturers maintain safety stocks for expected situations, the safety stocks do not provide capacity in the case of natural or man-made disasters that impact production sites and supply chain failures, or in the case where the safety stock itself must be withdrawn. A capacious supply chain provides the ability to maintain safety stock levels when unexpected events occur.

Slow time-to-market

In the PBMD supply chain, capacity is also a measure of the ability to bring the product to the patients. The gating factors on this are often regulatory approval and the time, effort, and expense involved to scale from single site production to global production. As the recent COVID "Warp Speed" project demonstrated, regulatory approval can slow time to availability by over 75%. To scale production, every stage requires a technology transfer and demonstrated proof that knowledge, expertise, documentation, and production processes have been correctly transferred to the new production environment. Technology transfer can add years to the process, which can be far longer than the time required to gain regulatory approval. Clinical trials are another significant factor in the timeline of bringing drugs to market. Between 2008 and 2013 [58], clinical trials took about 90 months for completion. Even more staggering is that only ±10% of drugs approved for clinical trials make it through Phase 3 and are granted regulatory approval [59]. Up-front improvements in candidate screening using modeling, simulation, AI, and ML could have an enormous impact on these timelines and success rates, especially when built on digital threads contextualizing the lifecycle data.

Additional supply chain risks and operational challenges identified by the project team and addressable by Digital Thread technology include:

- A bipartisan bill, Mapping America's Pharmaceutical Supply (MAPS) Act [50], was introduced in July 2023, calling the lack of visibility across the pharmaceutical value chain a matter of both health and national security risks. An estimated 80% of the world's

Active Pharmaceutical Ingredients (APIs) come from China, India, and a handful of other foreign countries.

- Most production processes are batched instead of continuous, which is often both financially and environmentally costly.
- Real-time information about needs and shortages is not easily accessible, which prevents all parties from working together to address supply-and-demand challenges and manage inventories. Medical device companies maintain limited inventory and manufacture on an on-demand basis. “Brand” pharmaceutical manufacturers maintain a reliable inventory since they are the sole producers of their products. This is different from generic medicines which, in general, are kept at lower inventory.
- Many drugs, APIs, and biologics must be constantly stored at specific temperatures. In cases of transportation delays, exposure to temperatures outside this range for an extended period will ruin the quality of these products.
- Outsourcing of biopharmaceutical development and/or manufacture to contract manufacturing organizations and contract development and manufacturing organizations (CMO/CDMOs) around the globe has doubled in the last 13 years, adding complexity to supply networks that demands improved means to seamlessly share data and act on it.
- The diversity of therapeutic modalities in the pipeline has increased dramatically over the years with the proportionally decreased opportunity for blockbuster drugs. This creates an additional need for manufacturing agility due to the need for many different production lines to accommodate smaller batch sizes.
- Inflation rates have come down since the spike witnessed in 2021-22, but they are still not at pre-COVID-19 pandemic levels. This, coupled with the rollout of the Inflation Reduction Act and Medicare’s negotiation of “high-cost single-source brand-name drugs,” is forcing drug companies to identify other ways to protect their margins by improving efficiencies.
- Clinical trials are protracted and do not have a high rate of successful candidates. Patient-centered and decentralized clinical trials are becoming increasingly popular because they improve patient compliance, may even improve recruitment of more representative patient populations, and can also save time. These approaches require digital health technologies and/or remote sample collections, demanding robust traceability and data transfer.
- Pharmaceuticals and medical device industries are highly regulated and there are existing mandated traceability and quality measures on APIs, drug products, and manufacturing. Most of the data inventory and batch records are digital and traceable from starting material to final packaged products.

7.3. Target Future State of Digital Thread Technology in the Context of Value/Supply Chain Resilience and Capacity

Ideally, the introduction of Digital Thread technology into the PBMD supply chain will address each of the risks identified in subsections 7.1 and 7.2. The target future state with respect to Digital Thread technology integrating into PBMD supply chains to address resilience and capacity should:

- Ensure that within a supply chain, there is a process to securely, safely, and legally share IP so that alternate suppliers or producers can be ramped up and validated in the case of long-term disruptions, such as through CMOs.
- Utilize a digital thread to identify suppliers of the materials and identify alternate qualified suppliers while protecting information within the product definition.
- Communicate needs and shortages using real-time information to suppliers and producers to permit decision-making bodies to make informed production decisions [50].
- Determine, in a quick and efficient manner, if a medication is real or counterfeit and where in the supply chain the counterfeit was introduced.
- Determine the effective scope of recalls in the case of product quality problems discovered after product release by identifying not just the unique lot number of the recalled products, but ideally down to the individual saleable product.
- Provide visibility into the supply chain for the availability of raw materials, intermediate materials (APIs – Active Pharmaceutical Ingredients), and secondary production material, such as sterilized bags, cotton swabs, glass containers, reagents, packaging materials, etc.) available at suppliers.
- Provide location and status of materials in-transit and insight into potential disruptions due to storage and transportation of drugs, APIs, and biologics outside specific temperature ranges during shipment.
- Inform manufacturers and distributors of disruptions to material procurement, such problems arising from train derailment, and potential recovery options such as reordering or procurement from alternate suppliers.
- Enable traceability of the transportation and distribution portions of the supply chain for final products and production materials to simplify the recall process in the case of counterfeits introduced in scarce medicines.
- Facilitate faster regulatory approval and technology transfer of production definitions to allow quicker submissions, approvals, and technology transfers and speed up the time-to-market of new drugs and technologies.
- Enable consistent product manufacturing through proper recipe management facilitated though Digital Thread technology including process optimization and documentation across the multitude of handoffs and transfers to ensure products are being made correctly and consistently every time.
- Create, manage, and automate the documentation for design history files (DHF), design master records (DMR), and with FDA regulations, the device history records (DHR) used throughout the lifecycle of medical devices from concept through development to production to service.
- Enable integration between the production systems of CMOs and their partners, thereby allowing seamless transfer of necessary information to carry production data to characterize manufactured products.
- Share complete product information available from the raw material to process to final product through to its eventual use by a patient. This will enable process improvement, information sharing across departments, incidents and recalls analysis, sensitivity

determination of supply chain disruptions, and regulatory documentation generation needed for every lifecycle stage of PBMD products.

Manifesting end-to-end digitalization enables efficiency and increases productivity while paving the way for systematic and continuous improvement. Making data accessible and connected throughout the product lifecycle increases visibility across the ecosystem and enables traceability that is impossible with paper-based and siloed datasets. By being able to more efficiently track and trace sources of product failure (due to process, equipment, or material), companies are better equipped to handle incidents and product recalls. The benefit of complete, accessible, Digital Threads is that traceability and linkage of large and distributed datasets can introduce new processes that (1) increase the efficiency of currently existing methodologies and (2) develop new methodologies for increasing product efficiency.

The desired end-state in the PBMD industries is to have complete product information available including the conceptualization and product and process development stages, procurement and supply of process inputs (raw materials), through the production process to final product, and eventual distribution and use by a patient. This complete product data is needed for improving processes, sharing information across organizations, analyzing incidents and recalls, determining sensitivity to supply chain disruptions, and for the generation of regulatory documentation needed for every lifecycle stage.

7.4. Weaknesses, Gaps, and Challenges of Digital Thread Technology

While there are many obvious benefits to incorporating Digital Thread technology in PBMD supply chains and realizing the target state, there are several weaknesses in the technology, gaps between the current and target states, and challenges to overcoming the identified gaps and weaknesses. Challenges and weaknesses range from ideological challenges, such as corporations and individuals not wanting to change what already works, to technological challenges, such as technologies not supporting the desired use cases. The gaps within the industry can be consolidated into six major points:

1. Lack of harmonization of and between standards, terminology, file types, and regulations (interoperability)
2. Difficulty in seamlessly integrating new technologies into digitally fragmented ecosystems (interoperability)
3. ERP-esque solutions not offering a full justification for migration from paper/spreadsheets (capability)
4. Slow progress in adopting new technologies past the proof of concept or pilot phase due to difficulty, complexity, and misaligned expectations (complexity)
5. Inaccessible technologies due to high prices, implementation difficulty, or integration difficulty (cost)
6. Insufficient assurance that data is properly firewalled among partners within the digital thread (privacy and security)

Many PBMD companies remain hindered by siloed, high latency, and paper-based processes. Moving from paper-based to electronic systems is strongly desired, but the cost of adoption is high in terms of time and overall expense of required revalidation. In the PBMD industries, the culture of “if it isn’t broke don’t fix it” is stronger than in many other industries because of regulatory requirements. There are ongoing initiatives in the FDA to change this mindset and to help simplify the implementation of digital technologies. Although the FDA and other regulatory agencies encourage and promote the advancement of the pharma industry and better tools and techniques for quality monitoring and control, the resistance has been from the industry in adoption and modernization.

Fragmented digital ecosystems and lack of congruency between IT and OT add additional barriers to the adoption of Digital Thread technology. Many companies are dealing with legacy systems and different vendor solutions across sites, often due to what was in place at the time of a given acquisition, and the task of reconciling this quagmire across the enterprise is incredibly daunting. IT and OT teams have different reporting lines, goals and KPIs, often resulting in a misalignment of priorities. Building the necessary bridge between these two worlds requires top-down investment and support. Automating the collection of data is not a barrier, nor is representing the data in standard formats with meta data. The barrier is in aggregating and contextualizing these data (and their myriad file types and formats) across the 20+ year product lifecycle to inform better decision-making within and among all the partners that collaborate to bring medicines and medical devices to market.

Although the development and deployment of standardized tools and solutions across the board would be very helpful for universal adaptation of the digitalization practices, the solution and tools require customization based on the needs of individual companies regarding production methods, modalities, product type and dosage. The concept of “one-solution-fits-all" has created a resistance in industry to adaptation, as standardized software and dashboards often do not fulfill diverse expectations of different companies.

The primary threat to achieving future benefits is cultural resistance to changing existing policies and procedures, especially those that would require revalidation. Another potential threat is frequent corporate executive level changeovers that would interrupt progress towards end-to-end digitalization as priorities are repeatedly revisited. Time must be allowed for pilot studies to play out so that ROI can be accurately assessed, and if investment is curtailed too early, any skepticism that may have been present at the start will just be reinforced. This ties back to cultural resistance.

To gain perspective into the current state of digital integration in the PBMD industry, the interviewed SMEs were asked what stage their organizations were in with regards to digitalization of their supply chains. The choices presented were based on Strategic Objective 3, “Underpinned by end-to-end digitization,” described as “A fully digitized supply chain, to support effective commerce, quality and R&D data exchange”), in BioPhorum’s Maturity Capability Model as follows:

- Stage 0: Not considering standardizing processes with digital technologies yet [Stage 0 is not in BioPhorum’s model]
- Stage 1: Mainly paper, spreadsheets, pdfs; standardized processes are not yet agreed upon companywide, but good coordination at some sites
- Stage 2: Digital platforms at the local level; supply chain partners are being engaged to evolve eData transfer processes.
- Stage 3: Globally standardized processes across the company with some implementations across the broader supply chain

- Stage 4: Globally standardized processes are being consistently implemented with suppliers and partners enterprise wide.
- Stage 5: Globally standardized processes with suppliers and partners are fully integrated; patient is at the forefront; an example to other companies.

Participants selected Stages 1, 2 or 3, with the majority selecting Stage 2. When asked in what timeframe they felt their organizations would realize end-to-end digitalization of their supply chains, 38% said within 5 years and 46% selected between 5-10 years. The remaining participants stated it would take their organizations >10 years or that they did not think end-to-end digitalization of the supply chain was feasible for their organization.

7.5. Potential Digital Thread Technology Research Projects and Workforce Development and Training Initiatives

7.5.1. Removal of Data Silos

Challenge: It is difficult to find, access, and associate data across fragmented digital ecosystems to seamlessly integrate new technologies.

Use Case: Create fully connected, accessible Digital Threads that can be leveraged for improved visibility to the supply chain, predict and respond quickly to potential disruptions, and more effectively support overall business needs

In general, the PBMD industries are familiar with the concept of Digital Thread and its implementations. Digital Threads exist in multiple primary forms, with different data systems spread across the product lifecycle (discovery, process development and optimization, electronic laboratory notebooks and pre-clinical work, clinical production, clinical trial tracking, current good manufacturing practice (CGMP) and related standard operating procedures (SOPs), recipe management, tech transfer and production scale-up, production and post-market surveillance; traceability of inbound and outbound materials/products, ERP/logistics, planning & scheduling, maintenance, distribution). The resulting data silos lack connectivity across functions at each stage of the product lifecycle and corresponding portions of the supply chains.

While most experts in the PBMD industries view the current state of a Digital Thread technology approach as mature, most also believe that data is fragmented for the different product lifecycle stages with limited to no integration or interoperability across stages. This leaves organizations without the ability to truly harness the power of data. Digital Thread technology can improve access to data and interoperability across siloed systems and enable a shift from reactive to proactive approaches across the entire lifecycle with the end patient at the center.

7.5.2. A Common Digital Strategy

Challenge: Lack of a comprehensive vision for interconnected systems and disconnects between IT and OT systems

Use Cases: Accelerate and enable opportunities for continuous improvement, foster collaboration between organizations, and reduce costs associated with regulatory compliance

Though its adoption varies across different organizations and regions, many companies in the pharmaceutical industry are moving to a “Pharma 4.0” maturity model-based framework for adapting digital strategies, including Digital Thread technology. Pharma 4.0 is a framework, and not an architecture, so it does not provide integration models for the different lifecycle stages. ISPE is now collaborating with BioPhorum on their Digital Technology Roadmap, another framework that builds upon the BioPhorum Digital Plant Maturity Model [60]. This partnership serves as an example of organizations aligning around a common goal for universal terminology, assessments, and next steps. However, there is a long way to go for universal adoption of any specific framework for digitalization of the supply chain in the PBMD industries.

Fragmented digital ecosystems and lack of congruency between IT and OT add additional barriers to the adoption of Digital Thread technology across the supply chain. Many companies are dealing with legacy systems and different vendor solutions across sites, often due to what was in place at the time of a given acquisition, and the task of reconciling this quagmire across the enterprise is incredibly daunting. IT and OT teams have different reporting lines, goals and KPIs, often resulting in a misalignment of priorities. Building the necessary bridge between these two worlds requires top-down investment and support. Automating the collection of data is not a barrier, nor is representing the raw data in standard formats. The barrier is in aggregating and contextualizing these data (and their myriad file types and formats) across the 20+ year product lifecycle to inform better decision-making within and among all the partners that collaborate to bring medicines to market.

7.5.3. Regulatory Agency Support

Challenge: Regulatory compliance is cumbersome and expensive

Use Case: Reduce costs associated with regulatory compliance and simplify the implementation of digital technologies

Many PBMD companies today remain hindered by siloed, high latency and paper-based processes. Moving from paper-based to electronic systems is strongly desired, but the cost of adoption is high in terms of time and overall expense of required revalidation. In the PBMD industries, the culture of “if it isn’t broke don’t fix it” is much stronger than in other industries because of regulatory requirements. There are ongoing initiatives in the FDA to change this mindset and to help simplify the implementation of digital technologies. Although the FDA and other regulatory agencies encourage and promote advancement of the pharma industry and better tools and techniques for quality monitoring and control, the resistance has been from the industry in adoption and modernization due to agency auditing inconsistencies.

A standardized data format for produced product Digital Threads and associated inputs, supported by the regulatory agencies, would provide the supply chain visibility that is currently lacking in most regulatory bodies. Note that the FDA is working on this problem in the context of the Drug Supply Chain Security Act (DSCSA) and in September 2023 provided guidance recommending use of the GS1 EPCIS standard for compliance with the DSCSA [61], [62]. However, the guidance at this time is minimal, and companies have wide leeway to populate the data structures defined in the EPCIS as they see fit vs adhering to the GS1 Core Business Vocabulary (CBV) or another semantic standard. Development of methods to easily adapt legacy systems to support industry-wide adoption and interoperability of standardized information models would make the information obtained through the DSCSA more FAIR (findable, accessible, interoperable, reuseable) and actionable.

The medical device industry uses Digital Threads to create, manage, and automate the documentation for the design history file (DHF), design master record (DMR), and with FDA regulations, the device history record (DHR). These documents describe the lifecycle of a medical device from concept through development to production. They do not usually cover conceptualization and post-production data, and this is an area for improvement opportunities.

7.5.4. Accelerating Regulatory Submissions for New Product Development and Product Introductions

Challenge: New medications and devices expand internal supply chains and require new ways to quickly validate systems.

Use Case: Make it easier/faster/cheaper to manage product and process information across the stages of development; R&D, clinical Phase 1, Phase 2, Phase 3, and commercial production.

Digital Thread technology can support new product development and introduction processes with two main applications: regulatory submissions and process development and technology transfers from lab scale to commercial production. These steps can be challenging because of reliance on manual processes for process optimization instead of using digital tools for modeling and simulation, an inability to share data in real-time and inaccuracy of data due to human error. These inefficiencies negatively impact critical milestones in drug commercialization such as:

- Regulatory submissions
    - Investigational New Drug applications (IND) for approval to move a drug to the clinical phase
    - New Drug Applications (NDA) or Biologic License Agreement (BLA) to gain approval to market, distribute and sell the new medicine.
- Annual Product Quality Reviews (APQR) for the monitoring of ongoing production
    - Scaling up manufacturing, including tech transfer and recipe management,
    - From R&D labs to small scale manufacturing, i.e., for clinical studies,
    - From small scale manufacturing to large commercial production, and
    - From single site commercial production to global production with or without contract manufacturing organizations.

As was previously observed, each of these steps requires proof that demonstrates that knowledge, expertise, documentation, and production processes have been correctly transferred to a new production environment, potentially adding years to the process. There is a tremendous corporate desire to increase efficiencies and overcome these hurdles to bring new products to the market as fast as possible during their patent protected lifetime. Delays of months in getting a new product to market can cost a company hundreds of millions of dollars in lost revenue due to the limited patent lifetimes of new drugs. Digital thread technologies have been demonstrated on a limited scale with most pharmaceutical and biotechnology companies and have demonstrated reductions in gaining regulatory approval.[4]

[4] Digital Health Technologies (DHTs) for Drug Development, December 26, 2023 - Digital Health Technologies (DHTs) for Drug Development

7.5.5. Standardized Data Representations

Challenge: It is difficult to associate life cycle data across supply chain boundaries.

Use Case: Make it easier/faster/cheaper to associate life cycle data across supply chain boundaries: raw material suppliers, API suppliers, production material suppliers, delivery system, and final dispensing systems.

Standardization of data representations for the pharmaceutical, biotech, and medical device industries is required. These includes 3-D CAD models of medical devices and ancillary equipment (bags, vials, …). The representations also must include the process models (chemical and biological) and product models (chemical and physical) needed for both simulation and technology transfer.

The lack of standardized data representation means that currently determining supply chain alternatives is a manual process or involves information loss as formats are converted from one vendor’s system to another.

Fragmented digital ecosystems and lack of congruency between IT and OT add additional barriers to the adoption of Digital Thread technology. Many companies are dealing with legacy systems and different vendor solutions across sites, often due to what was in place at the time of a given acquisition, and the task of reconciling this quagmire across the enterprise is incredibly daunting. IT and OT teams have different reporting lines, goals and KPIs, often resulting in a misalignment of priorities. Building the necessary bridge between these two worlds requires top-down investment and support. Automating the collection of data is not a barrier, nor is representing the data in standard formats with meta data. The barrier is in aggregating and contextualizing these data (and their myriad file types and formats) across the 20+ year product lifecycle to inform better decision-making within and among all the partners that collaborate to bring medicines to market.

Although development and deployment of standardized tools and solution across the board would be very helpful for universal adaptation of the digitalization practices, the solution and tools require customization based on the needs of individual companies, with regards to production methods, modalities, product type and dosage. The concept of “one-solution-fits-all” has created a resistance in industry to adaptation, as standardized software and dashboards do not currently fulfill diverse expectations of different companies. Data standardization should not enforce a specific software architecture solution.

7.5.6. Continuous Improvements and Change Management

Challenge: Continuous improvements of validated systems require validated integration of multiple data sources.

Use Case: Make it easier to identify if a proposed improvement will operate within the product design space documented in a digital thread.

Implementing Digital Thread technology enables efficiency and increases productivity while paving the way for systematic continuous improvement. Digital Threads make data accessible and connected throughout the product lifecycle. It is not uncommon for knowledge workers in the development and delivery ecosystem to spend 30% or more of their time just looking for information. Digital Threads provide the framework to capture relevant information and make it quickly available. This enables traceability that is impossible with paper-based and siloed datasets. By being able to more efficiently track and trace sources of product failure (due to process, equipment, or material), companies are better equipped to handle incidents and product recalls.

7.5.7. Targeted Recalls

Challenge: Product recalls are expensive and can cause customer loss of confidence in medications.

Make it easier to identify targeted recalls through serialization and product/process Digital Thread integration.

The benefit of a complete digital thread that includes complete serialization information is that a more targeted recall approach can be implemented, saving time, money, and effort, while also doing what is best for the patient population.

7.5.8. Complete Product Information for Modeling and Simulation

Challenge: Product and production data stored in multiple siloed modeling and simulation systems with problems of data loss, accessibility, and data validation.

Use Case: Support development of robust product and process modeling data standards for modeling and simulation and fund

Digital Thread technology and associated digital twins are used for process optimization using digital tools for modeling and simulation instead of manual processes in the end state. Digital Thread technology will also provide the ability to share data in real time across different simulation systems, without the inaccuracy of data due to human errors and lost data due to translation from one system format to another system format. The models and simulations provide the ability to quickly determine possible viable alternatives to raw materials, secondary materials, and production processes in the case of internal or external supply chain failures.

7.5.9. Intellectual Property Protection

Challenge: Consumers of a Digital Thread entity with the intent of stealing proprietary processes should not be able to access the information.

Use Case: Develop red and blue teams to perform controlled attacks and defenses of Digital Thread supply chain systems.

Security concerns rise when increase the number of servers, or sites from attack, in decentralized solutions. With multiple organizations involved, such as contract manufacturing organizations, contract development organizations, and contract packaging organizations, it is a challenge to keep IP secure.

7.6. Development and Support for Digital Thread-enabling Technology Infrastructure in the PBMD Sector

The recommendations in this roadmap are meant to strengthen and inform both new and existing research on supply chains, Digital Thread technology and other digitalization efforts. Multiple offices within FDA including the Office of Digital Transformation, the FDA Emerging Technology Program (ETP), and the Center for Drug Evaluation and Research (CDER), along with public-private partnerships such as BioFab USA, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), other Manufacturing USA Institutes, the Drug Supply Chain Consortium, and the Advanced Pharmaceutical Manufacturing (APM) Tech Hub at CCAM should work with other PBMD industry organizations, and manufacturers and producers of all sizes to develop specific scopes of work that further develop the research and development projects described herein, make policy recommendations and implement workforce and training recommendations.

Figure 10: Pharmaceutical, Biopharma and Medical Devices Sector Activities, outlines a research program for Digital Thread technology which incorporates the proposed PBMD sector projects described above in the context of proposed “solutions.” The solutions are intended to focus the research on outcomes valuable to the energy sector supply chain with obtainable five-year goals. Please see section 8 for more detail on this proposed approach.

Funding is recommended for cross-industry centers of excellence focused on Digital Thread technology which would be responsible for the Digital Thread technology program described in this section and further developed in section 8 and provide support to multiple industry sectors on their Digital Thread journeys.

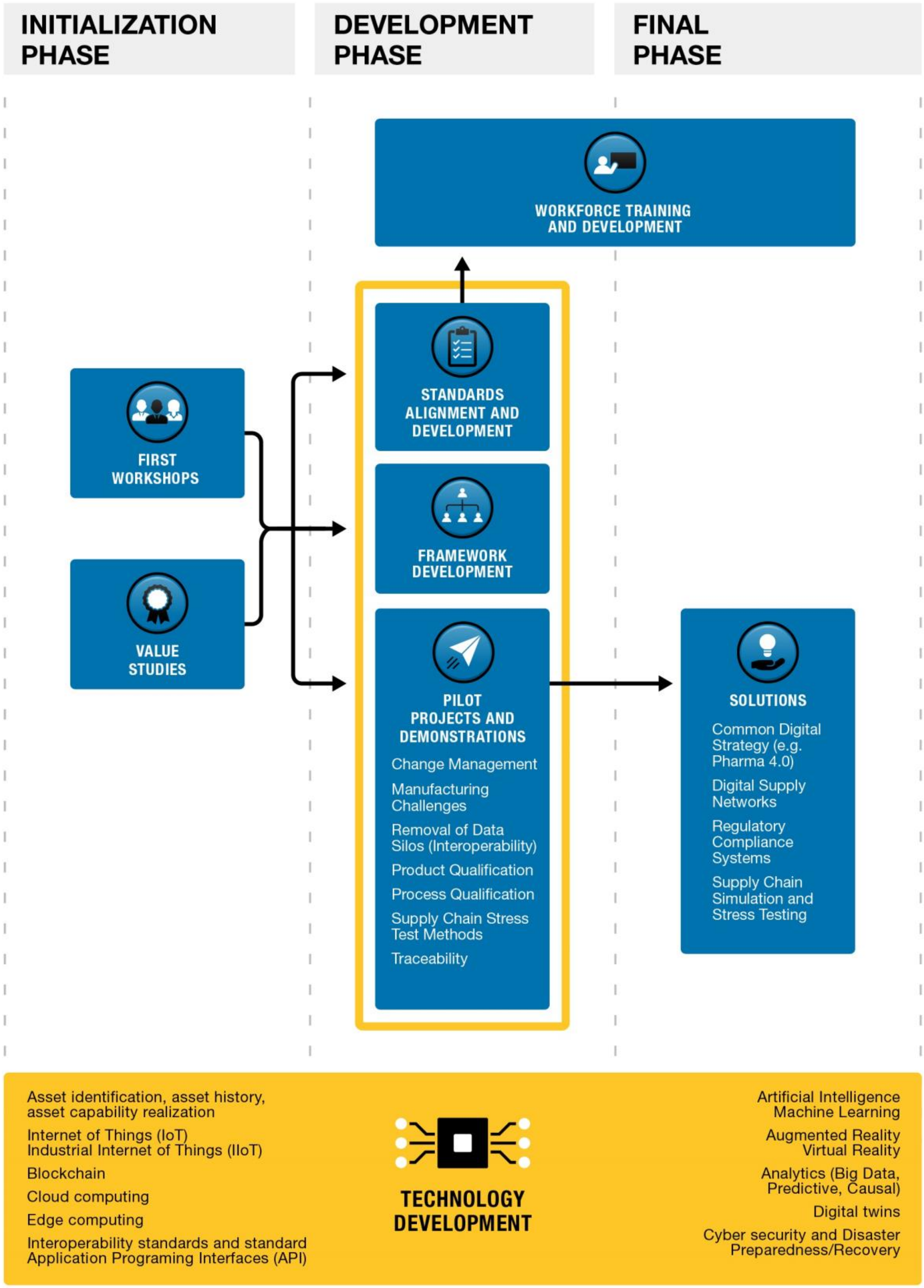

Figure 10: Pharmaceutical, Biopharma and Medical Devices Sector Activities

8. Program to Improve Supply Chain Resilience and Capacity through a Digital Thread Technology Framework and Standards Development

This section outlines a proposed program for developing Digital Thread technology that multiple industry sectors can leverage to realize benefits. The proposed research can be sponsored through numerous avenues including DOD, DOE, FDA, and NIST - as well as private industry - and realized through existing organizations such as Manufacturing USA, our national labs, CCAM, the Advanced Pharmaceutical Tech Hub (APM), and similar institutions with capability to develop convergent testbeds for industry that leverage common architectures to test, validate, and mature technologies to a targeted readiness level. Designation of "Centers of Excellence" for Digital Thread technology with centers representing different industry sectors would also be valuable.

The program proposes focused investment in specific "solutions" rooted in Digital Thread technology to address supply chain resilience and capacity issues presented previously in this roadmap. A standards-based Digital Thread technology framework is proposed to enable composable, interoperable, and secure solutions that can cost-effectively address many use cases across multiple industry sectors.

As has been discussed, different industries are at different stages of readiness for general implementations of Digital Thread technology. Each industry and organization will have different starting points and future states with differing characteristics. Even so, the program presented here can be adopted and adapted by different industry sectors and sponsoring entities to support efforts and guide investments in research and development on Digital Thread technology.

8.1. Summary of Proposed Research Projects

The projects identified in sections 4, 5, 6, and 7 are summarized below. Please refer to those sections for more information.

Aerospace and Defense
Limited, Single Part or Component Trial
Complex Component Supply Chain
Full-Lifecycle Demonstration
Cross-Approach Trial
Management of Expanded TDP
Frameworks for Predictive Analytics and Causal Analytics
Open-standards-based Association of Data Through the Product Lifecycle
Information Models for Part and Process Qualification

Summary of Proposed Research Projects (cont)

Agriculture
Optimized Crop Selection
Precision Agriculture
Integrated Pest Management
Sustainable Farming
Yield Prediction and Management
Data Management
Grain Traceability

Energy
Securing Critical Materials Through Adoption and Expansion of ISA 23664:2021
Expanding Energy Sector Manufacturing Capacity through Digital Supply Networks
Growing the domestic Clean Energy Workforce Through Digital Thread Technology
Building out Supply Chain Capabilities through Digital Thread Technology
Enabling Virtual Power Plants (VPP) through a Digital Thread Framework

Pharmaceutical, Biosciences, and Medical Devices
Removal of Data Silos
A Common Digital Strategy
Regulatory Agency Support
Accelerating Regulatory Submissions for new Product Development and Introductions
Standardized Data Representations
Continuous Improvements and Change Management
Targeted Recalls
Complete Product Information for Modeling and Simulation
Intellectual Property Protection

8.2. Digital Thread Technology-based Solutions

Digital-Thread technology-based "solutions" are proposed for each industry sector to focus investment on use cases that can most benefit supply chain resilience and capacity. The proposed work would have clear endpoints based on attainable deliverables that offer significant value. The solutions examined here are distilled from the research projects proposed previously in industry-specific sections 4, 5, 6, and 7. Developing complete, scalable, solutions that satisfy fully developed needs and requirements for multiple use cases will also force gaps and weaknesses in Digital Thread technology to be addressed. Since ***Digital Supply Networks*** (DSN) are relevant for all four industry sectors examined in this roadmap, the proposed DSN solution is emphasized.

Digital Supply Network Solution

The solution will develop requirements, capabilities, and frameworks necessary to deliver, adopt, and support digital services for supply networks usable by multiple industry sectors. The efforts towards this program should be cross-industry. By focusing research efforts of the overall Digital Thread technology program on overcoming the challenges and barriers to adoption of fully specified, fully functional, cost-effective, and secure DSNs - with robust traceability, information sharing, AI, and analytics capabilities - many of the challenges, gaps, and weaknesses of Digital Thread technology in the context of supply chain resilience and capacity can be overcome. Suppliers within the envisioned DSNs can access standardized technical data packages (TDP) containing single sources of truth for product and process definition information. Suppliers would submit “as-produced” data for traceability, configuration control, product and process qualification and verification. Logistics and in-service data are also present and timely refreshed. The data would conform to standardized information models and vocabularies to foster interoperability, AI and analytics, and seamless data exchange. Data storage and representation must follow FAIR data principles while respecting organizations’ intellectual property and personal privacy. Emphasis should be on composability, secure data representation, retrieval, and exchange standards, and methods and frameworks necessary to achieve cost-effective, low-code interoperability between commercially available enterprise-level software and XaaS (everything as a Service) solutions for connecting and managing Digital Supply Networks. The increased visibility, improved collaboration, enhanced traceability, real-time insights, and capability for in-field performance improvements provided by DSNs will greatly improve the resilience and capacity of US supply chains.

Other potential solutions that will focus investment in Digital Thread technology and strengthen US supply chains include:

- **Aerospace and Defense** - Digital Data Escrow Model

  This solution would develop the standards by which an escrow program could be initiated to maintain, in an exchangeable format, product information that could be used for long lifetime products when they have become obsolete, or the original vendor is no longer supporting or even in business. The solution should include the regulatory rules for controlling access to relevant parts of the information by contractually authorized users while maintaining necessary privacy and security measures to also protect human and business interests.

- **Agriculture/Food** - Scalable XaaS for Agriculture (everything as a service)

  This solution would extend the pilot project research proposed in section 5.5 using cloud-based services built on standardized semantic infrastructure to make the solutions accessible and affordable for small and medium-sized producers as well as larger organizations. The solution can include services for optimized crop selection, precision agriculture, integrated pest management, sustainable farming, yield prediction and management, data management, and perhaps even grain traceability.

- **Energy** - Virtual Power Plants

  This solution proposes Digital Thread technology as enabling technology for VPPs, supporting existing grid assets as well as accelerating the deployment of VPPs and associated DERs into the energy grid and is discussed more thoroughly in section 6.4.5. The solution should emphasize standards for interoperable entities and the creation of composable systems that can be brought together to standardize performance and communication protocols and harmonize operations. Utilizing Digital Thread technology as a framework, utilities could better understand what new assets are coming onto the grid and how they can be most effectively utilized given local conditions. The proposed solution would also address cybersecurity concerns over new distributed resources potentially accessing critical energy system data.

- **PBMD** – Common Digital Strategy for Regulatory Compliance

  This proposed solution supports ongoing initiatives in the FDA to help simplify the adoption and implementation of digital technologies and facilitate efficient regulatory compliance. The solution should deliver standardized data representations for produced product Digital Threads and associated inputs, supported by the regulatory agencies and interoperable with existing enterprise-level commercial software solutions commonly used in the PBMD sector. The solution should leverage existing standards where possible, especially with respect to the Drug Supply Chain Security Act (DSCSA), e.g. GS1 EPCIS. The solution should also support and extend the work in the PBMD pilot projects to accelerate regulatory submissions for new product development (through the KASA initiative [63]), product introductions, and CPV (Continued Process Verification), reduce costs of regulatory compliance associated with continuous improvements, support improved intellectual property protections, and ultimately provide additional supply chain visibility that is lacking in most regulatory bodies.

8.3. Digital Thread Technology Program Activities

The primary activities of the proposed program include:

1. Workshops
2. Value Studies
3. Technology Development
4. Standards Alignment and Development
5. Framework Development
6. Pilot Projects and Demonstrations
7. Supply Chain Stress Test Method Development
8. Supply Chain Simulations and Stress Testing
9. Framework Evaluation Based on Proposed Solutions

These activities are not sequential and will feed back upon each other. Consideration should be given to funding the *Digital Supply Network*, *Digital Data Escrow Model*, and possibly other *focal point solutions* as either a single program or complementary programs with durations of five years. In this scenario *Framework Development* becomes the overall driver of the programs with periodic review and input by sponsoring entities within DOD, DOE, FDA, NIST, or elsewhere. *Annual Conferences and Periodic Workshops* provide opportunities to share progress, provide training, and communicate about the ongoing work. Program leaders and workshop participants will cooperate to identify the industry-specific needs and opportunities for *Standards Alignment and Development* and industry-specific use cases where additional *Pilot Projects and Demonstrations* are needed. All industries will benefit from Digital Thread *Technology Development* in the areas listed previously in section 2.3. Note that the research projects and programs described in this roadmap will not necessarily be prime movers for most of the technology areas listed in section 2.3. Instead, researchers would seek to focus these technologies to support specific use cases for the benefit of the Digital Thread *Framework Development*. Investments should focus on how the Digital Thread enabling and leveraging technologies can address specific challenges, opportunities, and gaps and deliver the promised benefits of increased visibility, improved collaboration, enhanced traceability, real-time insights, and capability for in-field performance improvements.

The roadmap also identifies the need for better Supply Chain Stress Test Methods to perform Supply Chain Simulations and Stress Testing. If desired, this could be a stand-alone program funded independently from the Framework Development aspect described previously or rolled into one large program. Regardless, the efforts to improve stress testing should be kept separate and distinct from other activities.

Industries are at different stages of Digital Thread maturity. In a broad sense, Digital Thread Maturity has yet to be defined. However, within a given industry, the stage of Digital Thread maturity can be quantified by the number of core and extra capabilities realized by digital thread implementations. The evolution of implementation depends upon several factors including:

- Knowledge regarding terminologies surrounding Digital Thread as a concept.
- Understanding of the application of Digital Thread to a business's specific operational environment.
- Awareness of Digital Thread data collection and analysis requirements to generate value-added informatics.
- Resources for investment in workforce education and technology to implement data collection and analysis capabilities.

The diagrams below describe one possible scenario, however, actual implementation timelines will depend on outputs from the *First Workshops* and *Value Studies* activities and the availability of funding and other resources.

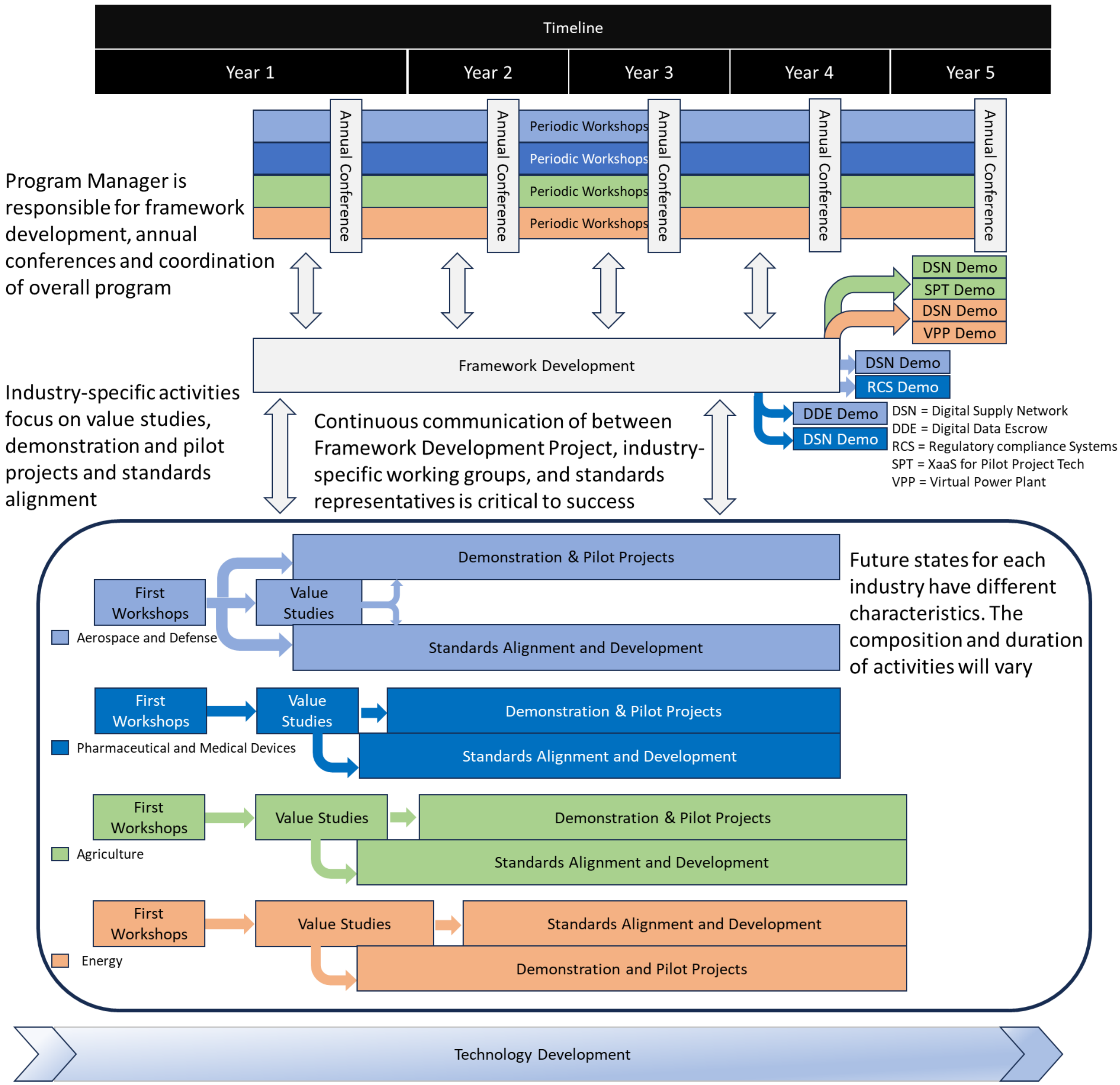

Figure 11: Digital Thread Technology Program Activities

Within the scope of the proposed program, the following activities should be carried out:

1. Workshops and Annual Conferences –
    a. First Workshops: These are industry-specific 1½ day workshops for participants to agree on common definitions and exchange concepts and methods for evaluating and improving supply chain maturity using Digital Thread technology. Organizational structure for the industry-specific portion of the program should also be established.

   b. Periodic Workshops: These are also industry-specific activities to support overall program development and provide opportunities for engagement. Early-phase workshops should focus on supporting value studies. Mid-phase workshops will address industry-specific use-cases, pilot projects, and standards alignment work that brings value to the framework development. Late-phase workshops will focus on the industry-specific needs for Digital Supply Network and other end-state solutions.
   c. Annual conferences: These are multi-day events to provide opportunities for cross-industry engagement, expert-led learning, and training on supply chain stress assessment methods and Digital Thread technology. Progress on standards alignment and development, pilot projects, framework development, and stress testing will be presented along with invited speakers on topics of interest for supply chain maturity and Digital Thread technology. The conferences would also include training to learn from supply chain and Digital Thread technology experts how organizations can realize more value from emerging standards, methods and technologies.
2. Digital Thread Value Studies: These projects will enumerate, score, and prioritize different industry-specific use cases and identify specific resource or technology gaps for each use case. These projects will compile reports on existing studies and charter new studies to document use cases and demonstrate the value of Digital Thread technology in both external supply chains and internal capability and capacity improvements. Industries that have been studying and performing digital thread maturity for several years can draw on existing research to complete much of this stage. Industries that have not previously expressed production and supply chain challenges in terms of Digital Thread technology may need to expend more effort to determine the value it provides and identify the best use cases to focus resources. The results of the value studies will feed into workforce development and training, standards alignment and development, and framework development efforts.
3. Digital Thread Technology Development: The Digital Thread technology program should focus on identifying, leveraging, and adapting existing technologies to fit Digital Thread use cases and requirements for the future state wherever possible. By clearly defining the requirements for fully featured Digital Supply Networks and other end-state solutions that require full featured Digital Thread technology, gaps in technology funding can be identified. So, while most Digital Thread enabling and leveraging technology development is envisioned to remain outside of this program, it may still be advantageous to fund some development of these technologies within the Digital Thread Technology Program. Technology development can and should be contributed to and utilized by all industries to realize their respective Digital Thread use cases.
4. Standards Alignment and Development: This program leverages the work performed in the pilot and demonstration projects, framework development, workforce training and development, and value studies to develop and align standards related to Digital Thread technology. The standards identified in this program fall into two categories. The first are the industry standards for overall digitalization of specific industries. These should look toward standardizing the use of digital threads within their respective industries. The second is the cross-industry standards, which, as the name implies, includes standards regarding application of Digital Thread technology independent of industry. The purpose of each of these types of standards is to promote interoperability between Digital Thread technology in various industries. In doing so, future research on applications of Digital Thread technology

and the nesting of threads from different industries to realize ideas such as digital product passports become much more feasible. Work performed in this activity will subsequently drive framework and development, workforce training and development, and pilot projects and demonstration activities. Existing standards should be leveraged wherever possible. One example is the possible use of the GS1 EPCIS and CBV standards to improve visibility across supply chains in almost all industries as was recently recommended by the FDA in the context of the Drugs Supply Chain Security Act (DCSA).

5. Framework Development: The framework development will occur in parallel with the pilot and demonstration projects, and standards alignment and development. In doing so, the framework development can be influenced by the adaptation of new technologies and the development of emerging Digital Thread standards that govern Digital Thread technology within the industry sector or more generally. Framework development will continue until it has been validated by the ongoing pilot and demonstration projects and is ready for realizing high-level use cases, e.g. digital supply networks and other end-state solutions.

6. Digital Thread Value Pilot and Demonstration Projects: The pilot and demonstration projects will be ongoing efforts to validate the framework development in parallel. They begin after the value studies have been completed for each industry and should look to demonstrate each use case resulting from the value study completed prior. The requirements of the pilot and demonstration projects for each industry should inform the technology development program about the requirements of Digital Thread technology. Many of the research programs and projects identified in the sector-specific sections of this document are expected to become pilot and demonstration projects. Convergent testbeds at CCAM and similar institutions able to perform research and host demonstrations on live equipment would be valuable. These testbeds should leverage common and emerging architectures and incorporate the Digital Thread framework to test, validate, and mature technologies to targeted readiness levels.

7. Supply Chain Stress Test Evaluations Rules: These would define the evaluation rules that companies could use to determine their risk to supply chain disruptions, using the company's actual supply chain information (tiers, lead times, typical backlog supply, and Digital Thread information etc.), (similar to the banking industry's stress testing rules) [64], [65], [66].

8. Supply Chain Disruption Simulation: These would provide a tool for companies, using Digital Thread information, to simulate supply chain disruptions and to determine if they have the policies and procedures in place to quickly detect and resolve supply chain disruption issues [67], [68], [69].

9. Framework Evaluation: The evaluation of the developed framework would be performed in the context of the proposed Digital Thread technology-based solutions designed to focus investment by satisfying requirements for multiple use cases in different industry sectors. Several of the proposed solutions are described in section 8.2. Since Digital Supply Networks (DSN) are relevant for all four industry sectors examined in this roadmap, and many others, the framework must at a minimum enable fully specified, fully functional, cost-effective, secure DSNs with robust traceability, information sharing, AI, and analytics capabilities. Evaluation should focus on composability, re-useability, secure data representation, retrieval, and exchange standards, and achieving cost-effective, low-code interoperability between commercially available enterprise-level software and XaaS (everything as a Service) solutions for connecting and managing DSNs.

8.4. Workforce Development and Training

Workforce development and training in Digital Thread technology should be accomplished by incorporating Digital Thread technology topics into existing programs and supported with materials developed through the proposed Digital Thread technology program.

Examples include adding Digital Thread technology topics to:

- University courses

  Courses on the individual technologies identified in section 2.3 which enable and leverage Digital Threads already exist at the university level (e.g. the CCAM-developed course on IIoT). However, courses which teach concepts like Digital Thread, digital twin, and mode-based enterprise are rare or non-existent. The US must also educate and train engineers and scientists in what have traditionally been IT-centric concepts. Some have even suggested that a new category of engineers with IT/OT skills is needed. Understandings of information models, systems modeling, and composable systems concepts are key enablers for development and scalable adoption of Digital Thread technology. Encourage fluency with query tools like SQL, GraphQL, and data analytics software.

- Community college and continuing education programs

  A key enabler for Digital Thread adoption and sustainable use is ensuring the workforce understands the value of digital threads and can leverage the technologies that supply the core digital thread information. Workforce training should include extensions to existing educational programs with:

  - foundational computer and technology use for all (core skills)
  - specialized technology use in the applied fields of manufacturing such as expanding hands-on use of CAD/CAM and additive manufacturing tools
  - specialized education on data handling for manufacturing as it relates to the digital thread and supply chains as a feedstock/component consumer and as a component supplier to down-stream manufacturers
  - Additional areas of training include workforce augmentation training and continuous learning for those already in the workforce and those looking to transition from other industries. Incentives may be needed to attract skilled workers in other technology related fields to augment the manufacturing space.

- University extension programs
  Particularly as it relates to Digital Thread technology in the Agriculture/Food sector. Focus on providing education and training which encourages digitization of agricultural practices to improve traceability of products. Include training on digital tools that support optimized crop selection, precision agriculture, integrated pest management, sustainable farming, and yield prediction and management.

- Online courses and training materials and workshops

  The Digital Thread Technology program would publish research and develop training to educate organizations and practitioners on methods and technologies to realize benefits from the work. Emphasis should be given to providing tools and training which enable smaller manufacturers and producers to adopt Digital Thread technology in the context of large supply networks.

- Standards organization webinars and in-person training events

  Topics could be featured as Digital Thread technology or as capabilities of Digital Threads.

As systems become more interoperable and ultimately composable, automation opportunities increase. Workers at all levels ultimately benefit from better working conditions and higher wages associated with the increased automation of less desirable jobs.

8.5. Centers of Excellence for Digital Thread Technology

Finally, funding for "Centers of Excellence" for Digital Thread technology and supply chain research that crosses industry sector boundaries is strongly encouraged. Digital Thread technology can benefit all US industries and cooperation is imperative to reach the necessary consensus for highly functional, composable, interoperable, secure and cost-effective standards-based technology solutions to meet our nation's supply chain challenges.

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Appendix A. Roadmap Development

The purpose of this work is to achieve the goals and objectives previously described. The project was executed at CCAM in Prince George, Virginia and at other locations throughout the US.

CCAM managed the project and worked closely with other members of the Core Team and all working groups to engage and interact with our collaborators from industry, other research institutions, standards organizations, and academia to perform the work. By the end of the project, the Core Team included CCAM, Virginia Commonwealth University (VCU), Virginia State University (VSU), GENEDGE, the Open Applications Group, Inc. (OAGi), BR&L Consulting (BR&L), Procegence, Thistle Blue LLC, the MTConnect Institute (MTCI) and the SecureAmerica Institute (SAI). Organizations were added to the Core Team as needed.

A.1. Participants

The Core Team addressed aspects of the roadmap which are common to manufacturers and suppliers in key industry segments as well as to small-medium manufacturers. Other working groups, each lead by a Core Team member, addressed the specific concerns of the key industry segments, small-medium manufacturers, and the cross-cutting cybersecurity issues.

Several Working Groups were used in the execution of the project, as listed in the Table below.

Core Activities Team	**CCAM**	**All orgs in this table**
Defense	CCAM	CIMdata + MTCI
Transportation	VSU	CCAM + MTCI
Pharmaceutical and Bio-Medical Devices	Procegence + VCU	BR&L + CCAM
Energy	Thistle Blue LLC Consulting	BR&L
Agriculture Commodities and Food Production	OAGi	CCAM
Small-Medium Manufacturers (SMM)	GENEDGE	MTCI
Cybersecurity concerns	CCAM	BR&L + VCU

A.2. Methodology

The effective development of a roadmap that addresses challenges across many manufacturing companies, industries, and roles within supply chains required participation from many organizations as well as various methods of information gathering and analysis. The project approach used several key principles:

1. Background study and information gathering to inform and guide the roadmap activity.
2. Core team formation to define overall roadmap elements, outline key topics for deeper investigation, and synthesize results into a cohesive roadmap.
3. Working groups to investigate those key topics, define key benefits, challenges, and opportunities for the individual topic, and support integration into the overall roadmap.
4. Cross-pollination of each Working Group, especially with the Core Roadmap Working Group.

A.3. Working Groups

Working groups were established throughout the project on an as-needed basis. These Working Groups focused on topics that were identified, selected, and outlined in the following categories:

- Core activities common to all manufacturers including cybersecurity and trust elements,
- Industry-focused activities specific to one or more industry segments.
- Activities specific to small-medium manufacturers.

A.4. Methods

The realities of the ongoing COVID-19 pandemic and the uncertainties of its future impact upon travel and face-to-face group interactions required a multi-pronged and multi-faceted approach. Activities included conducting interviews, performing site visits, hosting and facilitating collaborative work sessions, carrying out substantive literature reviews, presentations by project participants and external subject matter experts, and conducting surveys incorporating the Delphi technique [70] which included subject matter experts who were not otherwise participating actively in the roadmapping effort. The Delphi technique is a widely used and accepted method for achieving convergence of opinion without having to bring all parties together for meetings.

A.5. Task Descriptions

The work was divided into three phases plus an ongoing reporting and dissemination component. CCAM lead activities unless otherwise stated.

A.5.1. Task 1 – Initiate

This phase included overall project planning and preparation to execute the work. The following activities occurred:

1. Planning meetings: Met with project sponsors to review refine the project goals, objectives, planned activities, and other organizational elements based on input and guidance from project sponsors.
2. Communicate expectations: Worked with other members of the Core Team, and key collaborators to update the project plan and RACI matrix so that all working groups clearly understand the objectives, associated activities, and key deliverables.
3. Expand collaboration: All project participants worked to expand the pool of collaborators to enhance the quality, magnitude, and adequacy of industry representation for each of the working groups and for the project as a whole. The effort was led by the team leader for each working group with emphasis on engagement throughout the value chain.
4. Literature reviews: Literature reviews were performed to support the activities of each working group with the assistance of Core Team members and other key collaborators. These reviews examined the objectives in the contexts of the key industry segments, cybersecurity, and SMMs to inform roadmap development and the activities of each working group.

5. Technology and communication tools: Leveraged secure collaboration tools to facilitate coordination of activity and dissemination of information about the work both during and after the period of performance.
6. Develop Survey #1: The Core Team developed surveys to address the six objectives.
7. Kick-off meeting: CCAM led a meeting of all project participants and collaborators to communicate the motivation for the work and potential impacts. We reviewed and received input on the overall project plan, goals/objectives, tasks, and deliverables. The intent was to develop a mutual understanding of expectations for each working group and all project participants. Leaders of each working group then conducted similar break-out sessions with their partners and collaborators and then Survey #1 will be distributed.
8. Generate Interim Deliverables: The deliverables for the activities of the Initiate Phase:
    a. Documentation of the artifacts created or presented during meetings/interviews
    b. Updated project plan including RACI matrix to reflect sponsor input
    c. Updated table of project participants and collaborators showing members of each working group
    d. Actionable output from literature reviews (e.g. examples of risks, gaps, challenges)
    e. Technology and communication tools established

A.5.2. Task 2 – Gather

The activities in this phase were informed by the first four project objectives. Each planned activity was addressed in the context of supply chain resilience and capacity reflecting the viewpoints which are common to all manufacturers as well as those which are specific to key industry segments and the concerns of SMMs. The objectives focused on in this phase are summarized below:

- Objectives #1 and #2: Identify risks to supply chain resilience and capacity
- Objective #3: Clarify the target future state(s) of Digital Thread technology
- Objective #4: Identify weaknesses, gaps, and challenges of Digital Thread technology

To achieve these objectives, the following activities were used:

1. Survey #2: Core Team compiled results of Survey #1 and prepared and distribute Survey #2.
2. Literature reviews: Additional literature reviews were performed.
3. Baseline supply chain resilience and capacity risks: Members of the Core Team reviewed the supply chain reports published by the federal government and other sources to identify risks to supply chain resilience and capacity with Digital Thread aspects including cybersecurity concerns. Activities included leveraging their previous and existing work, conducting interviews, hosting, and facilitating collaborative work sessions, and reviewing the output of the previous literature reviews and surveys.
4. Identify specific risks: Each working group shared their findings with industry collaborators and worked to refine in the contexts of each.

5. Clarify target future state(s):
    a. Data and Information Exchange: CCAM engaged with the working groups to prepare additional interview and engagement protocols, plan agendas, engage presenters, conduct interviews and meetings, and develop other materials to facilitate clarification of the target future state(s) of Digital Thread technology. Additional materials included Lean-focused process improvement methodologies to assist in building future state maps based on current state maps and materials using different methodologies to aid in development of a shared vision for the future state. During this activity, project participants and external subject-matter experts were given opportunities to share their visions and use cases for how Digital Thread technology could be optimally leveraged to increase value throughout the extended supply chain. The Core Team worked with key collaborators to identify the application domains and value mechanisms for Digital Thread technology. Project participants were challenged to clarify the features and characteristics of Digital Threads necessary to maximize value to supply chain resilience and capacity for various use cases in different domains and industry sectors.
6. Identify weaknesses, gaps, and challenges:
    a. Data and Information Exchange: In this activity, project participants were asked to identify weaknesses, gaps, and challenges in the Digital Thread by comparing the current state of Digital Thread technology with the desired future state developed in the previous task. As was done previously, CCAM engaged with the working groups to plan agendas, engage presenters, prepare interview and engagement protocols, conduct interviews and develop other materials to facilitate the achievement of the objective. Project participants & other subject-matter experts will be given opportunities to share their perspectives with specific use case examples.
    b. Workshop and interviews: Multiple virtual and face to face interviews were conducted through a series of meetings and joint events hosted by project participants to assess understandings of Digital Thread technology, its envisioned benefits and identify weaknesses, gaps, and challenges. An in-person workshop was held at CCAM to support the overall effort. The workshop included exercises to classify and prioritize the different items in the contexts of different industry sectors and SMMs.
7. Generated Interim Deliverables: The deliverables for the activities of the Gather Phase:
    a. Documentation of the artifacts created and presented during the meetings, interviews, and workshop
    b. Output from literature reviews and other activities from the Gather Phase to inform the Define Phase and development of the final deliverable.

A.5.3 Task 3 – Define

The activities in this phase were informed by project objectives #5 and #6 and the overall project goal. As before, each activity was addressed in the contexts of supply chain resilience and capacity and in the viewpoints which are common to all manufacturers vs those which may be specific to key industry segments and/or the concerns of small-medium manufacturers. The objectives associated with project activities in this phase are summarized below:

- Objective 5: Identify and prioritize potential research projects and workforce development and training initiatives
- Objective 6: Catalyze development and support for a technology infrastructure to enable full realization and exploitation of Digital Thread technology.
- Project Goal: Deliver technology roadmap

To achieve these objectives, the following activities were performed:

1. Establish research thrusts: Core Team participants worked together and with key collaborators on the project to analyze the findings from the Gather Phase and identify distinct areas of research necessary to address risks, weaknesses, gaps, and challenges described in objectives #1, #2, and #4 and achieve the future state described by objective #3.

2. Form new working groups: New working groups were formed at this stage to define and focus on aspects of the work necessary to close the gap between current and future states.

3. Literature reviews: CCAM and other Core Team participants performed additional literature reviews to insure the proposed future work builds on and extends existing research where possible.

4. Workforce development and training initiatives: The Core Team worked to identify aspects of Digital Thread technology which will require additional capabilities and/or capacity from the US manufacturing workforce. The developed initiatives were based upon Goal #2 of the Strategy for American Leadership in Advanced Manufacturing (SALAM) to “Educate, Train, and Connect the Manufacturing Workforce” and informed by the risks, gaps, and challenges identified in conjunction with objectives #1, #2, and #4 and the anticipated needs associated with the future state vision of objective #3. The initiatives identified initiatives are intended to align with the strategic objectives described in the SALAM:

    a. Attract and grow tomorrow’s manufacturing workforce
    b. Update and expand career and technical education pathways
    c. Promote apprenticeship and access to industry-recognized credentials
    d. Match skilled workers with the industries that need them

5. Synthesize Inputs & Develop Recommendations: In this subtask, CCAM and the Core Team synthesized Core and Working Group outputs into a cohesive program and developed the recommendations included in the final output of this project.

6. Generate Interim Deliverables:

    a. Documentation of the artifacts created or presented during meetings/interviews
    b. Internal reports from each sector compiling the findings and outputs related to objectives 3-6

       These reports were for internal consumption by the team and project sponsors to facilitate work on the final deliverable technology roadmap and are not public-facing documents.

    c. Output from literature reviews and other activities in the Define Phase which informed development of the final deliverable.

7. Write Technology Roadmap: The Core Team incorporated the outputs of all previous activities on this project into a tangible, actionable document which represents the interests of US industry and the nation to describe a clear strategic path to realize the benefits of Digital Thread technology, especially in the contexts of supply chain resilience and capacity

A.5.4. Task 4 – Reporting and Dissemination

The project culminates in the release of a well-defined Roadmap identifying key objectives and challenges, mapping the technology gaps and pathways to address each, and recommending approaches to have a lasting impact.

A full documentation package is intended to support the Roadmap and its dissemination, including:

- Technology Roadmap
- Recommendations for implementing the Roadmap
- White Paper for formal publication the explains the roadmapping process, results, the Roadmap, and recommendations for implementation
- Formal press release
- Key talking points for collaborators (for interviews and verbal communications)
- Presentation materials for project collaborators to present to colleagues, partners, & customers
- Documentation of the roadmap process & outcomes, incl. survey & workshop results, contributor inputs, Working Group output (such as industry-specific challenges/recommendations), etc.

The project team will continue to communicate the Roadmap and final reporting with a comprehensive approach:

- A workshop will be held at CCAM for stakeholders, collaborators, and other interested parties to share the process undertaken, progress, and results, with participants engaged in future planning exercises. The documentation package will be shared and provided to collaborators.
- The White Paper will be submitted to NIST for publication
- The Roadmap, Recommendations, and White Paper will be made available online
- CCAM and the Core team will work with project sponsors to release results to the public, through social media, national news media, and local/regional news organizations.

Contributors to the project will work with their network of collaborators to disseminate the outcomes of the project and encourage implementation of the recommendations, including the conference presentations and other interactive work sessions.

Appendix B. List of Symbols, Abbreviations, and Acronyms

Abbreviation	Title/Definition
AI	Artificial Intelligence
ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available – ensures data quality, reliability, and compliance with regulations
AM	Additive Manufacturing
AML	Automation Markup Language
AMPAC	Ampac Fine Chemicals
AMT	Association for Manufacturing Technology
ANSI	American National Standards Institute
API	Active pharmaceutical ingredient
APM	Advanced Pharmaceuticals Manufacturing
APQR	Annual Product Quality Reviews
AR	Augmented Reality
ARM	Advanced Robotics for Manufacturing Institute – Manufacturing USA institute
ASTM	American Society for Testing Materials
A&D	Aerospace and Defense
BLA	Biologic License Agreement
BR&L	BR&L Consulting
CBRNE	Chemical, Biological, Radiological, Nuclear, and Explosive
CCAC	Commonwealth Center for Advanced Computing
CCAM	Commonwealth Center for Advanced Manufacturing
CDER	Center for Drug Evaluation and Research
CDMO	Contract Development and Manufacturing Organization
CESMII	Clean Energy Smart Manufacturing Innovation Institute – Manufacturing USA institute
CFR	Code of Federal Regulations
CIM	Computer integrated manufacturing
CMMS	Computerized maintenance management system
CMO	Contract Manufacturing Organization
CGMP	Current Good Manufacturing Practice
CPP	Critical Process Parameter
CQA	Critical Quality Attribute
CYMANII	Cybersecurity Manufacturing Innovation Institute – Manufacturing USA institute
DCIM	Data Center Infrastructure Management
DDE	Digital Data Escrow
DHF	Design History File
DHR	Device History Record
DIB	Defense Industrial Base
DIN	German Institute for Standardization
DMR	Design Master Record
DMSC	Dimensional Metrology Standards Consortium
DQSA	Drug Quality and Security Act
DSCSA	Drug Supply Chain Security Act
DSN	Digital supply network
DTh	Digital Thread
DTw	Digital Twin
ERP	Enterprise Resource Planning

ESIB	Energy Sector Industrial Base
ETP	FDA Emerging Technology Program
FAIR	Findable, Accessible, Interoperable, Reusable – guidelines for data management
FDA	Food and Drug Administration
FMC	Flexible manufacturing cell
FPGA	Field Programmable Gate Arrays
FSMA	Food Safety Modernization Act
G-Code	Geometric Code
GD&T	Geometric Dimensioning and Tolerancing
GENEDGE	GENEDGE Alliance
GM	General Motors
GS1	Global authority for unique identification of products and companies - Barcode Standards
H.E.	Holterman Engineering
HTTP	Hypertext Transfer Protocol
HMLV	High Mix Low Volume production
IaaS	Infrastructure as a Service
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – International standards/guidelines for Pharmaceutical industry
ICT	Information and communications technology
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IIoT	Industrial Internet of Things
IND	Investigational New Drug
IoT	Internet of Things
IP	Intellectual Property
IPC	Association Connecting Electronics Industries – electronics industry standards and guidelines
ISA	International Society of Automation
ISO	International Organization for Standardization
ISPE	International Society for Pharmaceutical Engineers
ISV	Independent software vendor
IT	Information Technology
JSON	Javascript Object Notation
KASA	Knowledge-aided Assessment & Structured Application
KPI	Key Performance Indicator
KPP	Key Performance Parameter
LMHV	Low Mix High Volume production
M4All	Medicines for All
MEP	Manufacturing Extension Partnership
MESA	Manufacturing Enterprise Solutions Association
MFGTech	NIST Advanced Manufacturing Technology Roadmap program
MIMOSA	Mimosa Networks
ML	Machine Learning
MOM	Manufacturing Operations Management
MRPII	Manufacturing Resource Planning
MTC	Machine Tool Connect
MTCI	MTConnect Institute
MXD	Manufacturing times Digital – Manufacturing USA institute
NDA	New Drug Application

NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
NIST	National Institute of Standards and Technology
NOFO	Notice of Funding Opportunity
NRCS	Natural Resources Conservation Service
OAGi	Open Applications Group, Inc.
OAGIS	Open Applications Group Integration Specification (now ConnectSpec)
OASIS	Organization for the Advancement of Structures Information Standards
OAM	NIST Office of Advanced Manufacturing
OEM	Original equipment manufacturer
ONR	Office of Naval Research
OT	Operational Technology
PaaS	Platform as a Service
PBMD	Pharmaceutical, Biopharmaceutical Sciences, and Medical Devices
PDES	International industry, government, and university consortium standards for product data exchange in the Digital Enterprise (Product Data Exchange Using STEP)
PI	Principal Investigator
PLM	Product Lifecycle Management
PMI	Product and Manufacturing Information
QbD	Quality by Design
QIF	Quality Information Framework
RACI	Responsible, accountable, consulted and informed
RFID	Radio-frequency identification
SaaS	System as a Service
SAI	SecureAmerica Institute
SALAM	Strategy for American Leadership in Advanced Manufacturing
SC4	ISO/TC 184/SC4 INTERNATIONAL Data Committee
SCADA	Supervisory control and data acquisition
SIPOC	Six Sigma process mapping methodology - Suppliers, Inputs, Process, Outputs, Customers
SME	Subject Matter Expert
SMIP	Smart Manufacturing Innovation Platform
SMM	Small-medium manufacturers
SMS	Smart Manufacturing Systems
SOP	Standard Operating Procedure
SOW	Statement of Work
SPC	Statistical Process Control
STEP	Standard for the Exchange of Product model data
STL	Standard Tessellation Language
VCU	Virginia Commonwealth University
VR	Virtual Reality
VSU	Virginia State University
WEF	World Economic Forum
XaaS	Everything as a Service (includes SaaS, Paas, IaaS, etc)
XML	Extensible Markup Language

Appendix C. Digital Thread Technology Research in Aerospace and Defense

The most prominent works towards realizing Digital Threads in the discrete industries are based on the ISO 10303 standard, known more formally as STEP (Standard for the Exchange of Product model data). To this end, Kwon et al. extended the initial work done in the area by proposing an automated pipeline utilizing knowledge graphs for STEP and QIF files [71]. To realize Digital Twins for Additive Manufacturing (AM) processes, Bonnard et al. developed the Hierarchical Object-Oriented Model (HOOM) [72] for storing additional information regarding a printing process in a singular file after identifying that the lack of a STEP file equivalent is holding AM processing back from the realization of Industry 4.0 paradigms such as Digital Thread. Within the HOOM, data from 7 stages of the product lifecycle can be stored in a singular file ((1) AM Project Information, (2) part description, (3) machine description, (4) manufacturing parameters setting, (5) numerical control program, (6) manufacturing, and (7) validation and post-production).

Toward the modeling and communication of Digital Twin information, there are investigations exploring the use of Automation ML language, an open XML standard for modeling engineering plant information, to model and communicate Digital Twin information [73]. West et al. [36] investigates the affordability of developing, implementing, and maintaining Digital Thread and twin systems.

In 2015, Feeney et al. published a work expressing the capacity in which the STEP tolerance standard can enable smart manufacturing systems [74]. A link is built between the as-designed data present in CAD/CAM stages and the STEP standard. This link can be leveraged by including STEP in the digital workflow. Gaska et al. employs a system-based approach for simplifying multiple DTh containing lifecycle data using the system of systems approach [75]. This approach identifies a primary system and uses the remaining as enabling systems.

In 2016, Hedberg et al. evaluated the ability of Digital Thread technology to support model-based manufacturing and inspection [76]. In doing so, it was discovered that leveraging Digital Threads in model-based manufacturing could reduce the cycle time by 74.8%.

In 2017, Bernstein et al. worked towards creating links between existing information silos across the product life cycle, including manufacturing data in MTConnect data and quality data in QIF files to aid in lifecycle decision-making [77]. A case study was then performed on this concept using the NIST SMS Test Bed data. In this study, an enhanced digital representation of a part was created to illustrate how the feed rate changes at various parts of the NC program in accordance with the cutting geometry. Helu et al. presented an architecture for integrating heterogeneous manufacturing systems to create a Digital Thread [78]. The architecture provides segregated access to internal and external clients to protect sensitive information such as intellectual property. The thread was assembled using STEP, G-Code, MTConnect, and QIF data. It was used in a case study to identify problems in the manufacturing chain related to the feed rate.

In 2018, Bone et al. presented a discussion on the feasibility of supporting frameworks to enable DTh, specifically, can current technology support the cross-domain artifact sharing necessary for Digital Thread [79]. This work presents a working and detailed framework that can visualize decision tables based on digital data such as Geometric Dimensioning and Tolerancing (GD&T).

Hallmann et at. presented a methodology for mapping GD&T and other PMI between STEP and STL (Standard Tessellation Language) models [80]. The primary use case for this methodology is when design files are not available in STEP format. This is often the case for additive manufacturing processes that prefer STL files versus STEP files to store 3D geometries. Hedberg et al. [81] presented a standards and technology roadmap for scalable distributed manufacturing systems. The four immediate areas of need are identified as (1) cyber-infrastructure integration, (2) physical-infrastructure integration, (3) modeling and simulation, and (4) analytics and data science for manufacturing. The most notable area of need in the context of this review is area one. This area refers to a manufacturing system's ability to leverage data standards such as STEP, MTConnect, and QIF (an XML based quality information framework), as well as other manufacturing systems, to create Digital Threads.

In 2020, Bonham et al. [82] worked towards the development of Digital Threads for the additive manufacturing of customized kayaks, where three key lessons were identified, (1) a process model of physical and digital flow should be developed early, (2) data to be shared and processing of data to perform tasks should be separated, and an ad-hoc digital application to involve new stakeholders should be developed. This system was tested by remotely 3D printing a kayak in which a client designed a kayak, and parties such as couriers and manufacturers could read, write, and limit access to Digital Thread data. This system worked with PLM and integrated access control on various data so that each party involved in the kayak production could limit which other parties could view or write data.

In 2024, Standfield et al. [83] continued development of digital thread research based on the STEP AP242, MTConnect, and QIF standards to perform spatial and temporal alignment of shape aspects described at design time (STEP AP242) with temporal data collected during the manufacturing process (MTConnect) and with data gathered during QA testing (QIF). The work relied on the use of UUID (Universally Unique Identifiers) to identify and associated shape aspects with other kinds of data in a similar way to what may be proposed in future ISO standards.

Martinez et al. [84] presented a flexible and open simulation environment that works towards implementing Digital Threads. In this work, Digital Thread technology is used to share information using HTTP and JSON in a cyber-physical system linking the design and simulated manufacturing steps.

Appendix D. Aerospace and Defense Sector Interview Summary

Surveys, interviews, and workshops were conducted by members of the core project team across all industry sectors. An example from the aerospace and defense sector is include here. Interviewees were provided three documents in advance to set the theme and expectation of the meeting:

- An overview of the NIST-Sponsored effort being managed by CCAM
- The set of questions to be asked of each participant
- A "level-set" briefing on the meaning and objective of Digital Thread

Interviews were scheduled between April and November 2023 and included representatives from companies, academics, and government & national lab researchers. A series of questions were asked of the participants in groups of 3-4 industry representatives regarding their industry perspective, their company's perspective, or their personal perspective on such topics as:

- Are you familiar with the term Digital Thread?
- What is your definition or understanding of the term Digital Thread?
- What is the current state of implementing Digital Thread technology and concepts?
- Where in the supply chain are Digital Thread technologies/concepts being implemented?
- What are the current roadblocks/impediments to adoption of Digital Thread technology?
- What is your hoped-for future state and future benefits from a Digital Thread approach?
- Where are the gaps preventing Digital Thread from achieving the future state in five to ten years?

As expected, the knowledge of Digital Threads and their implementations vary widely by industry. In the case of aerospace and defense, Digital Thread implementations are most prevalent in the Conceptualization and Development product lifecycle stages. They are also significant in Production but are rare in later lifecycle stages of Service.

A summary of responses from group interviews and incorporating data from the CIMData A&D PLM Action Group Digital Thread Collaborative Research Report, August 2023 [25] follow.

D.1 Question: Understanding Digital Thread in A&D

In general, the group had heard the term Digital Thread being used in connection with manufacturing processes. Some participants indicated they were active with outside organizations involved in setting guidelines or standards for Digital Thread technology.

With a few significant exceptions, most of the participants had no definitive definition of the term "Digital Thread." Several maintained that the issue with Digital Thread is that it is not well understood as a term or even as a concept. Some of the responses were:

- The concept of Digital Thread is more closely related to data interoperability and standardization than some kind of technological advancement.
- Most spoke of Digital Thread in terms of the flow of data and the interconnections between manufacturing systems and other business systems such as ERP, CRM (Customer Relationship Management), and IMS (Inventory Management System).

- One organization said that Digital Thread should provide for access of data across the ecosystem. It implies security, authentication, and utilized in conjunction with approved boundaries and approved analysis.
- Other terms mentioned during this part of the interview were “Digital Rope” and “Digital Web” to indicate multiple threads of information coming together, rather than a single thread.
- Participants were careful to differentiate the term Digital Thread from “Digital Twin” in that a “Digital Twin” focused more on the model-based design and engineering.

CIMdata’s analysis clearly indicates that Digital Thread investment within the ecosystem of industrial users, their customers, suppliers, and solution providers is poised for rapid growth. Initial implementations of targeted Digital Thread solutions have provided proof points of value and essential learnings. New rounds of investment are ramping up, guided by these early achievements and with expectations driven by the value potential revealed.

CIMdata’s analysis also shows that the conceptual understanding of Digital Thread within industry overall is immature. Nearly half of companies surveyed do not have a commonly accepted definition of Digital Thread. However, there is a broadly shared perception of what Digital Thread technology does and what a Digital Thread is. The most prominent characteristics of what a Digital Thread is and what it does relate to “establishing traceability of product information.”

D.2 Current State of Industry Adoption of Digital Thread in A&D

Most participants viewed the current state of a Digital Thread within the aerospace and defense industry as fragmented and inconsistent. Within their own organizations, the general response was one of “under consideration,” although a few large OEMs (Original Equipment Manufacturers) do have significant efforts already underway. Additional comments made included:

- Digital Thread was recognized as a strategy for most of the organizations according to the participants.
- One organization mentioned the establishment of an office within the company focused on digital transformation, of which Digital Thread is a component.
- Another organization said there is usually a proof of concept to validate the use case with constraints.
- Most recognized the importance of Digital Thread in reducing costs and improving ability to respond to emerging threats.
- One organization said they have a keen interest in establishing international standards for interoperability to define how Digital Threads are used in the supply chain, and it is a challenge.
- Digital Thread implementations are most prevalent in the Concept and Development product lifecycle stages in conjunction with Digital Twin development. They are also significant in Production but are rare in later lifecycle stages of Utilization, Support and Retirement.

Most of the participants viewed Digital Thread as encompassing all of a company's systems, not just manufacturing but also including warehousing, inventory control, purchasing, and quality control. Some of the participants mentioned that they viewed Digital Thread as more of a marketing term and less of a reference to actual capability, with some current capabilities as covered under the new definition.

D.3 Question: Barriers to Adoption of Digital Thread in A&D

The aerospace and defense group found several key barriers towards broader adoption of Digital Thread concepts including:

- Intellectual Property: Because of the proprietary nature of the industry, sharing key manufacturing data beyond what is within Technical Data Packages is difficult if not impossible.
- System Interoperability: Major enterprise software system providers (e.g., ERP, MES, PLM) are not designed to interoperate with other systems without significant effort and cost. A nearly universal concern is lack of openness and dependence on 3rd party connectors for connectivity and data interchange with the PLM solutions. The perception is that interoperability and openness have improved but are fragile and there are emerging signs of potential backsliding.
- Benefits: Lack of defined, measurable benefits at all tiers of the supply chain, especially for small and mid-sized suppliers.
- Commitment: Lack of commitment from company senior management to enable capabilities or invest in solutions.
- Standards: Lack of industry standards, international standards, national standards, or system/solution standards.
- Real-Time Data: Lack of consistent, real-time or near real-time supplier and production data from different systems.
- Skillset: Lack of needed investment for advanced training and support for additional data/system requirements.
- Data Management: One respondent mentioned the "cost of curation" needed to maintain the digital library and manage the quality of the information being shared.

D.4 Question: Future Benefits for Digital Thread in A&D

The overall desired end-state for Digital Thread focused on potential benefits including:

- Standardized, exchangeable data across different systems (FAIR).
- The ability to retain and recall production data to perform causality assessments for part failure (causal analytics).
- Reduced costs to manufacture and improved time from order to delivery.
- Scalable systems that can handle rapid increases in demand in response to emerging needs.
- Flexibility in supply chain sourcing through open data standards.

Other benefits desired by the group included:

- Hybrid manufacturing with human workforce enabled by autonomous manufacturing.
- Improved efficiencies through real-time data analysis, possibly with integration of AI tools.

D.5 Question: Expected Status of Digital Thread in A&D

When asked about where they see Digital Thread technology and the resulting benefits in five to ten years, most interviewees were pessimistic about achieving progress towards a Digital Thread solution within their organization within five years.

Some mentioned the unique nature of the USA defense supply chain where OEM and Tier 1 suppliers must work with a diverse manufacturing base, including smaller companies without the resources to upgrade to Digital Thread solutions. Some mentioned progress in system API development and in data standardization to facilitate data exchange.

For the ten-year timeframe, there was a split in the view of Digital Thread implementation within the industry. Some saw opportunities for change coming with industry solution providers and upstart companies working on new capabilities. Others were more pessimistic, seeing the benefits as more focused on the larger manufacturers and not reaching down through the supply chain to benefit smaller suppliers. One respondent mentioned a need for a major event to drive rapid adoption of new technologies.

D.6 Question: Threats to Achieving Future Benefits in A&D

Several barriers were identified by the group as potentially delaying or derailing adoption of Digital Thread concepts or technologies in future states, including:

- Cost. Defined value propositions and value adds for manufacturers and suppliers might outweigh the investment to implement.
- Competing business priorities for investments.
- Lack of defined standardization in data format, open API connectivity, and seamless transfer of data from point to point.
- Security protections and intellectual property concerns threatening data sharing.
- There will be a need for new types of employees trained in both engineering and data analytics, and engineers with an understanding of manufacturing, processes, and controls.

Appendix E. Overview of Guidelines and Regulations in the PBMD Sector

Related pharmaceutical and medical device standards and guidance include:

- FDA guidance document "Data Integrity and Compliance with Drug CGMP"
- FDA 21 CFR Part 11
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q8(R2), ICH Q9(R1), ICH Q10, ICH Q12
- ASTM E2500-20
- IEC 61512-4:2009 Batch Production Records
- IEC 61513-3 General and Site Recipes
- IEC/62264-4:2015 Enterprise Control System Integration

The FDA's guidance document, "Data Integrity and Compliance with Drug CGMP", underscores the criticality of data integrity within the pharmaceutical industry, aligning with the ALCOA+ principles—Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, and Enduring [54]. It provides comprehensive guidance for manufacturers to ensure compliance with Current Good Manufacturing Practice (CGMP) regulations. Emphasizing the importance of meticulous record-keeping and robust quality systems, the document catalogs the need for accurate, complete, and reliable data throughout the manufacturing lifecycle to guarantee product quality and patient safety.

FDA CFR Part 11 outlines regulations for electronic records and electronic signatures in industries governed by the FDA. It establishes criteria for ensuring the authenticity, integrity, and reliability of electronic records and signatures used in the context of FDA-regulated activities.

Some of the requirements specified in Part 11 include: validation to provide proof that the data in a computer system can be trusted, rendering records to ensure that all electronic records are provided in a readable format that humans (not just computers) can understand, document storage & record retention procedures to safeguard documentation and keep it available as long as needed, system access controls to ensure that only the right people have access to each computer system, and audit trails to provide a complete history of all electronic records automatically captured by a computer system. All of these are considered requirements for pharmaceutical and medical devices Digital Threads.

ICH Q8(R2) and ICH Q9(R1) focus on Quality Risk Management, essentially pushing for adoption of risk-based assessment and QbD (Quality by Design) principles. Inherent in this guidance is documentation when warranted based on ultimate level of risk to the patient and is a means for achieving greater efficiencies.

ICH Q10 defines technology transfer as a stage of the product development life cycle:

"The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach, and ongoing continual improvement." (Guidance for Industry, Q10 Pharmaceutical Quality System (3.1.2))

In practice this means passing on all the information required for the receiving site to be able to replicate the manufacture of the product, at the required quality and scale in a safe manner, and in a way that complies with regulatory requirements. Specifically, this product knowledge transfer should include a detailed and robust process description and its experimentally derived critical quality attributes (CQAs) and critical process parameters (CPPs).

ICH Q12 defines post approval change management, product life cycle management, and pharmaceutical quality systems which are all reliant on data, traceability, and management of records.

ASTM E2500-20 is the "Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment" [55]. This document provides guidance to ensure that manufacturing systems and equipment are fit for their intended use, properly qualified, and compliant with regulatory requirements. The guide supports, and is consistent with, the framework described in ICH Q8, ICH Q9, ICH Q10, and ICH Q11, and is designed to conform with FDA, EU, and other international regulations.

Some other related guidelines and regulations include:

- 21 CFR Part 4 - medical device requirements for combination products
- 21 CFR Part 314 - For FDA approval to market a new drug.
- 21 CFR Part 210 - CGMP in Manufacturing Processing, packing, or Holding of Drugs.
- 21 CFR Part 211 - CGMP for Finished Pharmaceuticals.
- 21 CFR Part 212 - CGMP for Positron Emission Tomography Drugs.
- 21 CFR Part 600 - Biological Products: General.
- FDA Office of Pharmaceutical Quality; includes Quality Management Maturity framework
- FDA's Computer Software Assurance (CSA) for Production and Quality System Software ties into FDA 21 CFR part 820 (Quality System Regulation)
- ISO 13485: Quality Management System for Medical Device Manufacturing

Appendix F. Related Standards

The following are some of the current standards dealing with Digital Threads, Digital Twins, communications, exchange of product information, and exchange of design information. This list is not exhaustive.

F.1 Standards Governing Design and Implementation Representations

IEC 62814 and AutomationML	An open standard for the exchange of engineering data across the entire lifecycle of manufacturing systems, including digital representations of machines, equipment, and production processes. https://www.automation.com/en-us/articles/2016-1/opc-releases-automationml-for-opc-ua-spec
ASME Y14.41	Establishes requirements for model-based definitions in CAD software and among those who use CAD software to create product definitions. https://www.asme.org/codes-standards/find-codes-standards/y14-41-digital-product-definition-data-practices
ISO 10303 (STEP):	STEP (Standard for the Exchange of Product Data) provides a comprehensive framework for exchanging and representing product data throughout the manufacturing process. https://www.iso.org/standard/72237.html
ISO 16792:2021	Standardizes technical product documentation and digital product definitions. https://www.iso.org/standard/73871.html
OSLC (Open Services for Lifecycle Collaboration)	A set of open standards for integrating tools and data across the entire product development lifecycle, including digital representations of requirements, design data, and testing data. https://open-services.net/resources/oslc-primer/
Requirements Interchange Format (ReqIF)	Provides standards-based exchange of requirements authored in different Requirements Management (RM) tools; almost all RM and SysML modeling tools today support ReqIF import and export. https://www.omg.org/reqif/

F.2 Standards Governing Physical Entities

IEC-62832-1:2020	Defines the general principles of the Digital Factory framework (DF framework), which is a set of model elements (DF reference model) and rules for modelling production systems.
IEEE 2888.1	Defines the vocabulary, requirements, metrics, data formats and APIs for acquiring information from sensors, enabling definition of interfaces between the cyber world and physical world.
IEEE 2888.2	Defines the vocabulary, requirements, metrics, data formats and APIs for describing characteristics of, setting up parameters for, and commanding actuators enabling definition of interfaces between the cyber world and physical world. These actuators shall be defined either in cyber or physical world.
ITU-T Y.4473	Specifies the SensorThings application programming interface (API) which provides an open standard-based and geospatial-enabled framework to interconnect Internet of things (IoT) devices, data and applications over the Web.
ISO 13399	Defines an open standard for cutting tool data representation and exchange. It allows for consistent and standardized representation of cutting tool information, facilitating efficient data exchange and tool management in Digital Thread manufacturing. https://www.iso.org/obp/ui/#iso:std:iso:ts:13399:-3:ed-3:v1:en

F.3 Standards Governing Virtual Entities

IEC 63278-1	Defines the Asset Administration Shell of Industry 4.0 which can be used to implement PnP (Plug and Produce) capability in industrial field devices.
IEC 62714-1 (AML)	Automation Markup Language. A solution for data exchange focusing on the domain of automation engineering.
IEEE P2806.1	Defines the connectivity requirements of digital representations for physical objects in factory environments. Based on heterogeneous data, the connectivity requirements include high-speed protocol conversion, unified data modeling and data access interfaces to meet the interoperability and interaction requirements between physical objects and the corresponding digital representations.
IPC 2551-2020 International Standard for Digital Twins	Part of the IPC Factory of the Future standards establishing the IPC Digital Twin, which is comprised of the Digital Twin Product, Digital Twin Manufacturing and Digital Twin Lifecycle frameworks.

F.4 Standards Governing Representation of Data

IEC 62264 (ISA 95)	This international standard provides models and terminology for the integration of enterprise and control systems. It supports interoperability and information exchange between business systems (such as Enterprise Resource Planning) and control systems (such as Supervisory Control and Data Acquisition) in Digital Thread manufacturing. https://www.iso.org/standard/57308.html
IEC 61987	Deals with data structures and elements in process equipment catalogs pertaining to industrial process measurement and control.
IEC 61360	A series of standard documents defining a general-purpose vocabulary in terms of a reference dictionary published by the International Electrotechnical Commission.
ISO/IEC Guide 77	Provides recommendations for standardization committees for the description of products and their properties for the creation of computer processable product libraries, catalogues, and reference dictionaries.
ISO 13584	An international standard that describes the representation and exchange of product information using a data modeling methodology called EXPRESS. The standard is titled "Industrial automation systems and integration - Parts library" and provides guidelines for organizing and structuring product information in a standardized format.
IEC 62541 (OPC UA (Unified Architecture))	An open standard for industrial interoperability developed by the OPC Foundation and IEC. It provides numerous information models for exchanging data between different devices and systems in the manufacturing environment. https://opcfoundation.org/about/opc-technologies/opc-ua/
ISO 14306 (MTConnect)	An open standard designed to foster greater interoperability between manufacturing equipment, devices, and software applications using a protocol-agnostic SysML-based information model. It enables the exchange of data in real-time for improving productivity, analytics, and optimization. https://www.iso.org/standard/62770.html
ISO/IEC 19514 (OMG SysML)	General-purpose modeling language for systems engineering which helps to ensure traceability between requirements, design, and verification artifacts.
ISO 23247 Automation systems and integration — Digital Twin	A four-part standard for Digital Twins for manufacturing that defines overview & general principles, a reference architecture, digital representation, and technical requirements for information exchange between entities within the reference architecture.
ISO 29002	A series of international standards that provide guidelines for the classification and description of products and services. The standards in the ISO 29002 series are titled "Industrial automation systems and integration - Exchange of characteristic data" and focus on the exchange of information related to product characteristics.
ISO 8000: ISO 8000-	A series of standards that focus on data quality. It provides guidelines and specifications

1:2022	for data quality management, ensuring accurate, reliable, and standardized data across different systems and processes. https://www.iso.org/standard/81745.html
ISO/IEC AWI 30172 Digital Twin	Use cases for Digital Twins, under development.
ISO/IEC AWI 30173 Digital Twin	Concepts and terminology for Digital Twins, under development
MIL-STD-31000B	This standard defines the requirements for a technical data package (TDP) and its related TDP data management products. https://quicksearch.dla.mil/qsDocDetails.aspx?ident_number=276980

F.5 Standards Governing Connections

IEC 61784	An international standard series that defines the communication profiles and network architectures for industrial automation systems.
IEC 62541 (OPC UA (Unified Architecture))	An open standard for industrial interoperability developed by the OPC Foundation and IEC. It provides a secure and reliable communication framework for exchanging data between different devices and systems in the manufacturing environment. https://opcfoundation.org/about/opc-technologies/opc-ua/
IEC 62657	An international standard that describes the methodology for assessing the data quality of measurement processes.
IEEE 1451.4	This standard series defines a smart transducer interface for sensors and actuators. It enables plug-and-play interoperability between transducers and systems, simplifying integration and data exchange in Digital Thread manufacturing. https://standards.ieee.org/wp-content/uploads/import/documents/tutorials/1451d4.pdf
IEEE 2888.3	Intended to provide standardized guidance to researchers and industry workers who wish to implement a CPS (Cyber-Physical System) or DTS (Digital Twin System). This standard defines the vocabulary, requirements, metrics, data formats and APIs for setting up parameters for and communicating with digital objects to provide synchronization & interaction with physical objects.
IIRA (Industrial Internet Reference Architecture)	The Industrial Internet Reference Architecture is a framework developed by the Industrial Internet Consortium (IIC). It focuses on enabling connectivity, interoperability, and security in industrial systems, including those related to Digital Thread manufacturing technologies. Link: https://www.iiconsortium.org/iira/
ITU-T Y.3090	Recommendation that describes the requirements and architecture of a Digital Twin Network (DTN)
ITU-X SG.DTN	Recommendation that describes the security guidelines for a DTN
ISO 14306 (MTConnect)	An open standard designed to foster greater interoperability between manufacturing equipment, devices, and software applications. It enables the exchange of data in real-time for improving productivity, analytics, and optimization. https://www.iso.org/standard/62770.html

F.6 Standards Governing Services

IEEE 1671	Specifies a framework for the automatic test markup language (ATML) family of standards. ATML allows automatic test system (ATS) and test information to be exchanged in a common format adhering to the extensible markup language (XML) standard.
ISO 17359	An international standard that provides guidelines for the implementation of electronic data interchange (EDI) in the transport and logistics industry.
ISO 20242-3	Defines a service interface for the communication with virtual devices comprising capabilities of software modules and physical devices, accessed via resource

	management services as defined in ISO 20242-2
ISO 23952 (QIF)	Quality Information Framework. XML-based standard which facilitates consistent quality information exchange throughout the product lifecycle across diverse systems and processes in manufacturing and machining. https://qifstandards.org/overview/
DSCSA	The FDA's Drugs Supply Chain Security Act aims to introduce a set of standards to ensure traceability of pharmaceutical supply chains thorough electronic data exchange.
DQSA	The Drug Quality and Security Act aims to introduce a set of standards to enable traceability at the package-level post-distribution.
GS1 EPCIS and CBV	EPCIS is GS1's flagship data sharing standard for enabling visibility within organizations as well as across an entire supply chain of trading partners. The US FDA recommends its use for compliance with the Drug Supply Chain Security Act (DSCSA). The Core Business Vocabulary (CBV) is a companion standard which provides definitions of data values that may be used to populate the data structures defined in the EPCIS standard

Appendix G. Industry Working Groups

G.1 Aerospace and Defense Working Groups

Some of the groups working on Digital Threads, Digital Twins, and exchange of product information.

Organization	Description
Aerospace & Defense PLM Action Group	The work done by the Aerospace & Defense PLM Action Group supports the digital thread by promoting standardization, defining requirements, and exploring practical applications of the digital thread in the aerospace and defense industry. https://www.cimdata.com/en/aerospace-and-defense
Clean Energy Smart Manufacturing Institute (CESMII)	CESMII is a public-private partnership that aims to accelerate the adoption of smart manufacturing technologies in the United States. The CESMII Smart Innovation Platform (SMIP) provides a standardized, secure, interoperable, and scalable infrastructure built on the concept of Profiles to contextually describe sensors, equipment, and processes, and the ability to create semantics for data. https://www.cesmii.org/
Commonwealth Center for Advanced Manufacturing (CCAM)	CCAM is a public-private applied research center that bridges the gap between fundamental research and product development, accelerating the translation of innovative research from the laboratory to commercial use. CCAM researchers work with members, subject matter experts, and program sponsors to advance digital thread technologies to solve manufacturing challenges and build process intelligence. https://ccam-va.com
Digital Twin Consortium	Digital Twin Consortium drives the awareness, adoption, interoperability, and development of Digital Twin technology. Through a collaborative partnership with industry, academia, and government expertise, the Consortium is dedicated to the overall development of Digital Twins. https://www.digitaltwinconsortium.org/
Direct Digital Manufacturing Advisory Team	https://www.sme.org/engage/communities/direct-digital-manufacturing-group/
DOD Joint Additive Manufacturing Working Group	https://www.dodmantech.mil/Manufacturing-Collaborations/Joint-Additive-Manufacturing-Working-Group/
Industrial Internet Consortium (IIC)	The IIC is a global organization that focuses on accelerating the adoption of the Industrial Internet of Things (IIoT). They have several working groups focused on developing standards for Digital Thread technology such as semantic interoperability and testbeds. https://www.iiconsortium.org/
Industrial Ontologies Foundry (IOF)	The Industrial Ontologies Foundry (IOF) has been formed to create a suite of interoperable ontologies that would serve as a foundation for data and information interoperability in all areas of manufacturing. https://spec.industrialontologies.org/iof/
International Data Spaces Association (IDSA)	The IDSA is a nonprofit association that focuses on developing a secure and trustworthy data sharing ecosystem for industrial data. They have several working groups focused on developing standards for Digital Thread technology such as data sovereignty and data semantics.
ISO/ TC 184/AG2 – Digital Twin	evaluate concepts & terminology utilization for Digital Twin across the scope of TC 184 and create a Digital Twin roadmap for industrial systems
ISO/IEC JTC 1/SC 42	This is a joint technical committee between the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) that focuses on artificial intelligence (AI) and machine learning. They have several working groups focused on developing standards for Digital Thread technology such as data quality and ethics.

	https://www.iso.org/committee/6794475.html
Manufacturing times Digital (MxD)	MxD is a public-private partnership focused on advancing digital manufacturing and design. They have several working groups focused on developing standards for Digital Thread technology such as cybersecurity and supply chain interoperability. https://www.mxdusa.org/
MESA International	Manufacturing Enterprise Solutions Association International is a global nonprofit providing education, networking and best practice sharing around Smart Manufacturing and Industry 4.0. MESA's community includes
MIMOSA	MIMOSA is a 501 (c) 6 not-for-profit industry trade association dedicated to developing and encouraging the adoption of open, supplier-neutral IT and IM standards enabling interoperability and digital transformation for asset lifecycle management spanning plants, platforms, and facilities.
NDIA Cybersecurity for Advanced Manufacturing Joint Working Group (CFAM JWG)	A joint working group under the National Defense Industry Association
NIST (National Institute of Standards and Technology)	NIST, a part of the U.S. Department of Commerce, is actively involved in promoting standards and technology development in manufacturing. They have various initiatives related to Digital Thread technology, including the Smart Manufacturing Systems (SMS) Test Bed and the Digital Thread for Smart Manufacturing (DTSM) project
OAGi (Open Applications Group)	The Open Applications Group is an international consortium that develops and promotes open standards for business interoperability. They have been involved in creating standards for various domains, including manufacturing and supply chain, which are relevant to Digital Thread technology.
Object Management Group (OMG)	The OMG is an international standards consortium that focuses on developing object-oriented technologies. They have several working groups focused on developing standards for Digital Thread technology such as model-driven architecture and industrial internet of things.
Open Process Automation (OPA)	The Open Process Automation Forum, initiated by The Open Group, is working on developing open standards for process automation systems. These standards aim to create a vendor-neutral and interoperable framework for integrating process automation components and improving system flexibility and scalability. It applies the OPC UA, AutomationML, Redfish, and IEC standards in a comprehensive automation framework.
PDES (Product Data Exchange Using STEP)	PDES, Inc. is an international industry, government, and university consortium committed to accelerating the development and implementation of standards for product data exchange in the Digital Enterprise
W3C (World Wide Web Consortium)	The W3C is an international community that develops open standards for the World Wide Web. While not specific to manufacturing, their work on semantic web technologies, data representation standards (e.g., RDF, JSON-LD), and web services (e.g., REST, WebSockets) can be leveraged in Digital Thread manufacturing.
RAMI 4.0 (Reference Architecture Model Industrie 4.0)	Although not a specific organization, the RAMI 4.0 reference architecture has been widely adopted in the context of Industry 4.0, which encompasses Digital Thread manufacturing technologies. It provides a conceptual framework for organizing and integrating different layers and components within manufacturing systems. https://www.isa.org/intech-home/2019/march-april/features/rami-4-0-reference-architectural-model-for-industr

G.2 Agriculture Working Groups

Some of the groups working on Digital Threads, Digital Twins, and exchange of product information.

Organization	Description
AgGateway	AgGateway is a global, non-profit organization focused on the Agriculture and related industries whose members develop standards and other resources so that companies can rapidly access information. https://aggateway.org/
Commonwealth Center for Advanced Manufacturing (CCAM)	CCAM is a public-private applied research center that bridges the gap between fundamental research and product development, accelerating the translation of innovative research from the laboratory to commercial use. CCAM researchers work with members, subject matter experts, and program sponsors to advance digital thread technologies to solve manufacturing challenges and build process intelligence. https://ccam-va.com
Digital Twin Consortium	Digital Twin Consortium drives the awareness, adoption, interoperability, and development of Digital Twin technology. Through a collaborative partnership with industry, academia, and government expertise, the Consortium is dedicated to the overall development of Digital Twins. https://www.digitaltwinconsortium.org/
International Data Spaces Association (IDSA)	The IDSA is a nonprofit association that focuses on developing a secure and trustworthy data sharing ecosystem for industrial data. They have several working groups focused on developing standards for Digital Thread technology such as data sovereignty and data semantics.
ISO/IEC JTC 1/SC 42	This is a joint technical committee between the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) that focuses on artificial intelligence (AI) and machine learning. They have several working groups focused on developing standards for Digital Thread technology such as data quality and ethics. https://www.iso.org/committee/6794475.html
MIMOSA	MIMOSA is a 501 (c) 6 not-for-profit industry trade association dedicated to developing and encouraging the adoption of open, supplier-neutral IT and IM standards enabling interoperability and digital transformation for asset lifecycle management spanning plants, platforms, and facilities.
NIST (National Institute of Standards and Technology)	NIST, a part of the U.S. Department of Commerce, is actively involved in promoting standards and technology development in manufacturing. They have various initiatives related to Digital Thread technology, including the Smart Manufacturing Systems (SMS) Test Bed and the Digital Thread for Smart Manufacturing (DTSM) project
OAGi (Open Applications Group)	The Open Applications Group is an international consortium that develops and promotes open standards for business interoperability. They have been involved in creating standards for various domains, including manufacturing and supply chain, which are relevant to Digital Thread technology.
Object Management Group (OMG)	The OMG is an international standards consortium that focuses on developing object-oriented technologies. They have several working groups focused on developing standards for Digital Thread technology such as model-driven architecture and industrial internet of things.
W3C (World Wide Web Consortium)	The W3C is an international community that develops open standards for the World Wide Web. While not specific to manufacturing, their work on semantic web technologies, data representation standards (e.g., RDF, JSON-LD), and web services (e.g., REST, WebSockets) can be leveraged in Digital Thread manufacturing.

G.3 Energy Working Groups

Some of the groups working on Digital Threads, Digital Twins, and exchange of product information.

Organization	Description
Clean Energy Smart Manufacturing Institute (CESMII)	CESMII is a public-private partnership that aims to accelerate the adoption of smart manufacturing technologies in the United States. The CESMII Smart Innovation Platform (SMIP) provides a standardized, secure, interoperable, and scalable infrastructure built on the concept of Profiles to contextually describe sensors, equipment, and processes, and the ability to create semantics for data. https://www.cesmii.org/
Commonwealth Center for Advanced Manufacturing (CCAM)	CCAM is a public-private applied research center that bridges the gap between fundamental research and product development, accelerating the translation of innovative research from the laboratory to commercial use. CCAM researchers work with members, subject matter experts, and program sponsors to advance digital thread technologies to solve manufacturing challenges and build process intelligence. https://ccam-va.com
Digital Twin Consortium	Digital Twin Consortium drives the awareness, adoption, interoperability, and development of Digital Twin technology. Through a collaborative partnership with industry, academia, and government expertise, the Consortium is dedicated to the overall development of Digital Twins. https://www.digitaltwinconsortium.org/
Industrial Internet Consortium (IIC)	The IIC is a global organization that focuses on accelerating the adoption of the Industrial Internet of Things (IIoT). They have several working groups focused on developing standards for Digital Thread technology such as semantic interoperability and testbeds. https://www.iiconsortium.org/
International Data Spaces Association (IDSA)	The IDSA is a nonprofit association that focuses on developing a secure and trustworthy data sharing ecosystem for industrial data. They have several working groups focused on developing standards for Digital Thread technology such as data sovereignty and data semantics.
ISO/ TC 184/AG2 – Digital Twin	evaluate concepts & terminology utilization for Digital Twin across the scope of TC 184 and create a Digital Twin roadmap for industrial systems
ISO/IEC JTC 1/SC 42	This is a joint technical committee between the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) that focuses on artificial intelligence (AI) and machine learning. They have several working groups focused on developing standards for Digital Thread technology such as data quality and ethics. https://www.iso.org/committee/6794475.html
MIMOSA	MIMOSA is a 501 (c) 6 not-for-profit industry trade association dedicated to developing and encouraging the adoption of open, supplier-neutral IT and IM standards enabling interoperability and digital transformation for asset lifecycle management spanning plants, platforms, and facilities.
NIST (National Institute of Standards and Technology)	NIST, a part of the U.S. Department of Commerce, is actively involved in promoting standards and technology development in manufacturing. They have various initiatives related to Digital Thread technology, including the Smart Manufacturing Systems (SMS) Test Bed and the Digital Thread for Smart Manufacturing (DTSM) project
OAGi (Open Applications Group)	The Open Applications Group is an international consortium that develops and promotes open standards for business interoperability. They have been involved in creating standards for various domains, including manufacturing and supply chain, which are relevant to Digital Thread technology.
Object Management Group (OMG)	The OMG is an international standards consortium that focuses on developing object-oriented technologies. They have several working groups focused on developing standards for Digital Thread technology such as model-driven

	architecture and industrial internet of things.
W3C (World Wide Web Consortium)	The W3C is an international community that develops open standards for the World Wide Web. While not specific to manufacturing, their work on semantic web technologies, data representation standards (e.g., RDF, JSON-LD), and web services (e.g., REST, WebSockets) can be leveraged in Digital Thread manufacturing.
RAMI 4.0 (Reference Architecture Model Industrie 4.0)	Although not a specific organization, the RAMI 4.0 reference architecture has been widely adopted in the context of Industry 4.0, which encompasses Digital Thread manufacturing technologies. It provides a conceptual framework for organizing and integrating different layers and components within manufacturing systems. https://www.isa.org/intech-home/2019/march-april/features/rami-4-0-reference-architectural-model-for-industr

G.4 Pharmaceutical, Biopharmaceutical, and Medical Devices Working Groups

Some of the groups working on Digital Threads, Digital Twins, and the exchange of product information on external and internal supply chains are:

Organization	Description
BioPhorum	BioPhorum consists of ten forums leading more than 110 industry-changing initiatives with the help of 7,500 active subject matter experts. It brings leaders and subject matter experts together to collaborate on challenges in existing and emerging topics that affect the whole industry including change notification, cybersecurity, extractables and leachables, forecast and demand planning, knowledge management, single-use systems, and sterile filtration. https://www.biophorum.com/download/a-vision-for-the-biopharmaceutical-industrys-inbound-supply-chain/
Commonwealth Center for Advanced Manufacturing (CCAM)	CCAM is a public-private applied research center that bridges the gap between fundamental research and product development, accelerating the translation of innovative research from the laboratory to commercial use. CCAM researchers work with members, subject matter experts, and program sponsors to advance digital thread technologies to solve manufacturing challenges and build process intelligence. https://ccam-va.com
Digital Twin Consortium	Digital Twin Consortium drives the awareness, adoption, interoperability, and development of Digital Twin technology. Through a collaborative partnership with industry, academia, and government expertise, the Consortium is dedicated to the overall development of Digital Twins. https://www.digitaltwinconsortium.org/
Industrial Internet Consortium (IIC)	The IIC is a global organization that focuses on accelerating the adoption of the Industrial Internet of Things (IIoT). They have several working groups focused on developing standards for Digital Thread technology such as semantic interoperability and testbeds. https://www.iiconsortium.org/
Industrial Ontologies Foundry (IOF)	The Industrial Ontologies Foundry (IOF) has been formed to create a suite of interoperable ontologies that would serve as a foundation for data and information interoperability in all areas of manufacturing. https://spec.industrialontologies.org/iof/
International Data Spaces Association (IDSA)	The IDSA is a nonprofit association that focuses on developing a secure and trustworthy data sharing ecosystem for industrial data. They have several working groups focused on developing standards for Digital Thread technology such as data sovereignty and data semantics.
International Society for Pharmaceutical Engineering (ISPE)	ISPE is the global industry leader in connecting pharmaceutical knowledge to deliver manufacturing and supply chain innovation, operational excellence and regulatory insights to enhance industry efforts to develop, manufacture and reliably deliver quality medicines to patients.

	https://ispe.org/initiatives/pharma-4.0
ISO/ TC 184/AG2 – Digital Twin	evaluate concepts & terminology utilization for Digital Twin across the scope of TC 184 and create a Digital Twin roadmap for industrial systems
ISO/IEC JTC 1/SC 42	This is a joint technical committee between the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) that focuses on artificial intelligence (AI) and machine learning. They have several working groups focused on developing standards for Digital Thread technology such as data quality and ethics. https://www.iso.org/committee/6794475.html
MESA International	Manufacturing Enterprise Solutions Association International is a global nonprofit providing education, networking and best practice sharing around Smart Manufacturing and Industry 4.0. MESA's community includes
MIMOSA	MIMOSA is a 501 (c) 6 not-for-profit industry trade association dedicated to developing and encouraging the adoption of open, supplier-neutral IT and IM standards enabling interoperability and digital transformation for asset lifecycle management spanning plants, platforms, and facilities.
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OAGi (Open Applications Group)	The Open Applications Group is an international consortium that develops and promotes open standards for business interoperability. They have been involved in creating standards for various domains, including manufacturing and supply chain, which are relevant to Digital Thread technology.
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Open Process Automation (OPA)	The Open Process Automation Forum, initiated by The Open Group, is working on developing open standards for process automation systems. These standards aim to create a vendor-neutral and interoperable framework for integrating process automation components and improving system flexibility and scalability. It applies the OPC UA, AutomationML, Redfish, and IEC standards in a comprehensive automation framework.
W3C (World Wide Web Consortium)	The W3C is an international community that develops open standards for the World Wide Web. While not specific to manufacturing, their work on semantic web technologies, data representation standards (e.g., RDF, JSON-LD), and web services (e.g., REST, WebSockets) can be leveraged in Digital Thread manufacturing.
RAMI 4.0 (Reference Architecture Model Industrie 4.0)	Although not a specific organization, the RAMI 4.0 reference architecture has been widely adopted in the context of Industry 4.0, which encompasses Digital Thread manufacturing technologies. It provides a conceptual framework for organizing and integrating different layers and components within manufacturing systems. https://www.isa.org/intech-home/2019/march-april/features/rami-4-0-reference-architectural-model-for-industr

Appendix H. Change Log

REQUIRED IF UPDATE OR REVISION. If this report is an update, revision, or new edition of a previously published report, briefly state changes made and the date of changes.

Date	Type of Edit	Change	Location
Aug 9, 2024	Update	Updated figures and edited for clarity	All figures