

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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CENTER *for* **MEDICAL**
INTEROPERABILITY

March 15, 2019

Mr. Alex Thai
National Coordination Office
National Science Foundation
2415 Eisenhower Avenue
Alexandria, VA 22314
sent electronically via: HITRD-RFI@NITRD.gov

RE: Request for Information on Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care, 2019-02519

Dear Mr. Thai:

Thank you for you for the opportunity to respond to the request for information on actions on interoperability of medical device, data, and platforms to enhance patient care. This is a topic that the Center for Medical interoperability (CMI) was founded to address. CMI is a non-profit 501(c)3 organization with a mission to accelerate the seamless exchange of information to improve healthcare for all. Modeled after centralized labs from other industries, CMI serves as a cooperative research and development lab as well as a test and certification resource to address healthcare industry technical challenges. CMI's CEO-level board of directors identify healthcare industry technology problems that, when solved, will benefit the public good and the healthcare industry. CMI membership is limited to health systems, individuals, and self-insured corporations, but we work with a variety of stakeholders, including medical device manufacturers, electronic health record (EHR) vendors, standards development organizations, and others, to design and engineer the technical infrastructure that will enable the comprehensive interoperability, data liquidity, and trust needed to deliver person-centered medical care.

In the following pages please find a detailed response outlining CMI work which includes an executive summary and responses to the four questions.

Sincerely,

*/*signed*/*

Ed Cantwell, President and CEO
Center for Medical Interoperability

Executive Summary

The healthcare industry is at an inflection point and its leaders face many challenges, including evolving business and care models, adapting to outcomes-based payment mechanisms, coordinating care across disparate delivery sites and entities, leveraging data analytics, and engaging individuals in their care. To successfully navigate these transitions, hospitals and health systems need a firm grasp on the technical underpinnings that enable their industry.

The ability to share information across multiple technologies - especially among medical devices at the point of care - is essential to the sustainability of the U.S. healthcare system. Our healthcare system's current inability to seamlessly share and trust information contributes to a chaotic environment that's not conducive to patient care. This lack of interoperability increases the potential for adverse drug events, medication ordering errors, transcription errors, redundant testing, inadequate monitoring, and miscommunication—all of which adversely impact patients and caregivers. Missing symptom, test, and relevant diagnostic data can result in clinical errors and diminished patient outcomes. Additionally, when information does not flow automatically, healthcare professionals are forced to manually enter data or troubleshoot the technology instead of spending time with patients.

The Center for Medical Interoperability (CMI) is a non-profit 501(c)3 organization with a mission to accelerate the seamless exchange of information to improve healthcare for all. CMI agrees with the National Science Foundation (NSF) thesis in this request which states that “while healthcare systems are rife with medical devices and the data they produce, to date, these devices are not interoperable and cannot effectively interact with each other and the broader healthcare ecosystem.” We also agree that the benefits of allowing the access and flow of that data are profound. An analysis conducted by the West Health Institute in 2013 estimated that achieving medical device interoperability among even a portion of acute care medical modalities can eliminate more than \$30 Billion of waste annually in the healthcare system.¹ Interoperability enables a vast set of new capabilities and processes which only amplify and compound its cumulative impact over time.

Unless disparate technologies used in care become interoperable, the nation will not succeed in providing better individual care, managing population health, or lowering costs. Some health systems and provider networks may be able to afford proprietary middleware to integrate technologies on an ad-hoc basis, but this is largely cost prohibitive to provider systems with limited resources. If we do not make interoperability accessible and affordable to the entire system, we risk further handicapping a significant portion of providers, namely those who serve vulnerable and hard-to-reach populations where health disparities are most profound.

¹ West Health Institute (2013) The Value of Medical Device Interoperability: Improving patient care with more than \$30 billion in annual health care savings. Available at http://patientsafety movement.org/wp-content/uploads/2016/02/Resources_Reports_Value_of_Medical_Device_Interoperability.pdf.

In response to this request, we will discuss CMI's work with a broad set of stakeholders and our collaborative approach to drive market change as a centralized lab for the healthcare industry. We will also discuss CMI's technical progress to date and our recently published foundational specifications for device identity, connectivity, secure update, provisioning flow and certificate policy. We also address the specific Request for Information (RFI) questions with a summary outlined here:

- **For Question 1, we share CMI's Vision and Technical Approach**
 - CMI's vision for addressing interoperability issues between medical devices, data, and platforms
 - CMI's initial steps, including our technical approach and foundational specifications for medical device interoperability
 - Summary of an exemplary use case for sepsis surveillance and early intervention that illustrates the power of interoperability to help solve a critical problem facing our nation

- **For Question 2, we describe Contributions to CMI**
 - The collaborative nature of our approach, highlighting the work of many contributors, including health system leaders, clinical experts and technical architects
 - Medical device vendor community involvement and their contributions, including the process by which companies participate in CMI specification development workgroups
 - Previous and current industry efforts that CMI is leveraging, including the many standards referenced and incorporated into our specifications

- **For Question 3, we discuss how CMI is Addressing Challenges**
 - The net result of historical barriers and impediments to interoperability
 - CMI's centralized lab approach and the broad deployment of a trust platform as a solution for overcoming barriers and supporting economic industry incentives that are aligned with the goals of patients and providers

- **For Question 4, we highlight CMI's Alignment with Federal Vision**
 - Rationale for the viability and necessity of the NSF RFI-proposed Future State for medical device, data, and platform interoperability
 - Key principles of the CMI Interoperability Maturity Model that guide our technical work

Making the transformation to a fully data liquid health technology ecosystem requires, at its foundation, interoperability of medical devices at the point of care. A typical patient in the intensive care unit is connected to between six and twelve medical devices, such as vital sign monitors, ventilators, infusion pumps, electrocardiographs, and defibrillators. Despite being located inches apart, these technologies generally do not communicate with or rely on one another in any way. If they do, it is usually because they are part of a proprietary product suite. This lack of interoperability makes it

difficult and costly to share data and is a significant impediment to achieving better quality of care, increased efficiency, and lower costs.

Many factors contribute to the lack of interoperability: misaligned incentives, limited adoption of standards, proprietary equipment and solutions, impracticality of government mandates, and the financial and operational complexities associated with migrating long-established legacy proprietary systems to a modern open platform-based technology architecture. Despite efforts from the vendor community, volunteers, and policymakers, it has been difficult to advance interoperability without a forum where the users and suppliers of medical technologies can jointly explore solutions. CMI was created as a place to work on solving these problems by aligning market demand with a centralized technical lab to drive market change.

Question 1: CMI Vision

What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your key use cases and pain points?

CMI Technical Approach- Interoperability and Trust

Achieving interoperability in healthcare is not a matter of having the right technology inventions. The basic required technologies have been in existence for many years and have been widely deployed in many other industries. It is about developing consensus around and selecting the right technology architectures that match the goals of the industry. What the healthcare needs includes more than just interoperability—it needs trust.

To truly become a learning health system, healthcare needs more than point-to-point interoperability solutions. It needs to ensure that data is not only available, computable and interoperable but that it is exchanged safely, securely, privately and in a trusted manner. Trust is truly a condition precedent for interoperability, and it encompasses much more than the cybersecurity issues that are often discussed. The dimensions of trust include key aspects of reliability, data governance and provenance, neutrality, auditability, information relevance, and several other system characteristics, both technical and non-technical. In order for interoperability initiatives to deliver the same types of economic advantages at scale that are enjoyed by other modern industries, US healthcare must adopt a trust platform approach.

CMI's technical efforts are focused on working with our members and the technology supplier community to embrace a trusted platform approach. The complex workflow requirements needed to make dynamic information useful for clinical decision support

and business operations demands the ability to orchestrate and contextualize data flows in real-time. The trust platform must also support full data liquidity, meaning that data and information must flow to the right person (or device or application) at the right place and at the right time, unimpeded by information blocking practices, to optimally care for the individual. Most importantly, the platform must provide a foundation of trust for all ecosystem participants that interact with it. This trusted platform approach enables an interoperable architecture design, technology selection and specification, reference implementation development, and testing for interoperability and certification.

CMI is leading an industry-wide effort to align health systems and their technology suppliers around a trust and interoperability platform reference architecture that will provide the capabilities needed to transform the industry. Our work is organized around three orchestrated technical campaigns:

Trusted Infrastructure and Medical Devices

The first campaign provides a solid technology foundation to protect against growing cybersecurity threats and to ensure reliable operation of medical devices and gateways, systems, and applications. The currently available specifications address issues of basic device *operability* by defining specific requirements for secure wired and wireless connectivity, both for devices and for the hospital infrastructure, and by defining interoperable mechanisms for device provisioning and management. They further address cybersecurity issues by defining requirements for medical device identity, authentication, support for authorization, data encryption, and automated secure software update. The campaign defines a beginning set of trust services that are provided by the platform to establish and maintain technical trust among the connected infrastructure components, systems, and applications. Other dimensions of trust are being addressed coincidentally through the other technical campaigns.

Connect Everything

Building upon the foundation of trusted infrastructure and medical devices, CMI specifies syntactic and semantic interfaces needed to seamlessly and securely connect medical devices and gateways with enterprise applications through a neutral, non-proprietary set of platform services for trust and data liquidity. Replacing the legacy device driver model that supports one-off integration with plug-and-play interoperability addresses technical and economic barriers that impede the free-flow of data within the healthcare enterprise. The semantic aspects of the campaign are being addressed based on a prioritized list of clinical data needs. Vitals data for physiological monitoring were addressed first and current efforts are focusing on ventilation and anesthesia.

Interoperability Platform Architecture

As described above, CMI is leading the design of vendor-neutral interoperability platform architecture to support the strategic goal of enabling interoperability, data liquidity, and trust across the healthcare enterprise. The platform envisions

open and interoperable interfaces that are modular, scalable, services-based, and secure, affording health systems greater control over the data they need to optimally provide care.

CMI is delivering these capabilities to the industry in the form of specifications, software reference implementations, and a robust interoperability testing and certification program.

The CMI testing and certification lab is a center of excellence for interoperability and trust. It develops and demonstrates architectures and interfaces needed to deliver interoperability, data liquidity, and technical trust at scale. The CMI Interoperability Testing and Certification Program validates that medical devices and gateways and components that implement platform services (e.g., software or hardware components) are compliant to the CMI's interoperability specifications. Conformance to the specifications provides a consistent technical approach to interoperability while also building a stronger foundation for cybersecurity and trust.

Initial Specifications

CMI has recently published an initial set of specifications that focus on the domains of Acute Care treatment and Point-of-Care systems – the intersection of medicine and technology that presents the greatest benefit to patient outcomes and experience, holds the most significant clinical and operational improvement potential for providers, and represents the most powerful example of safety, quality and economic impact for the nation. Medical device and technology vendors are provided with an excellent opportunity to develop plug-and-play interoperability solutions that have a direct impact on patient care and a provider community that is eager to adopt.

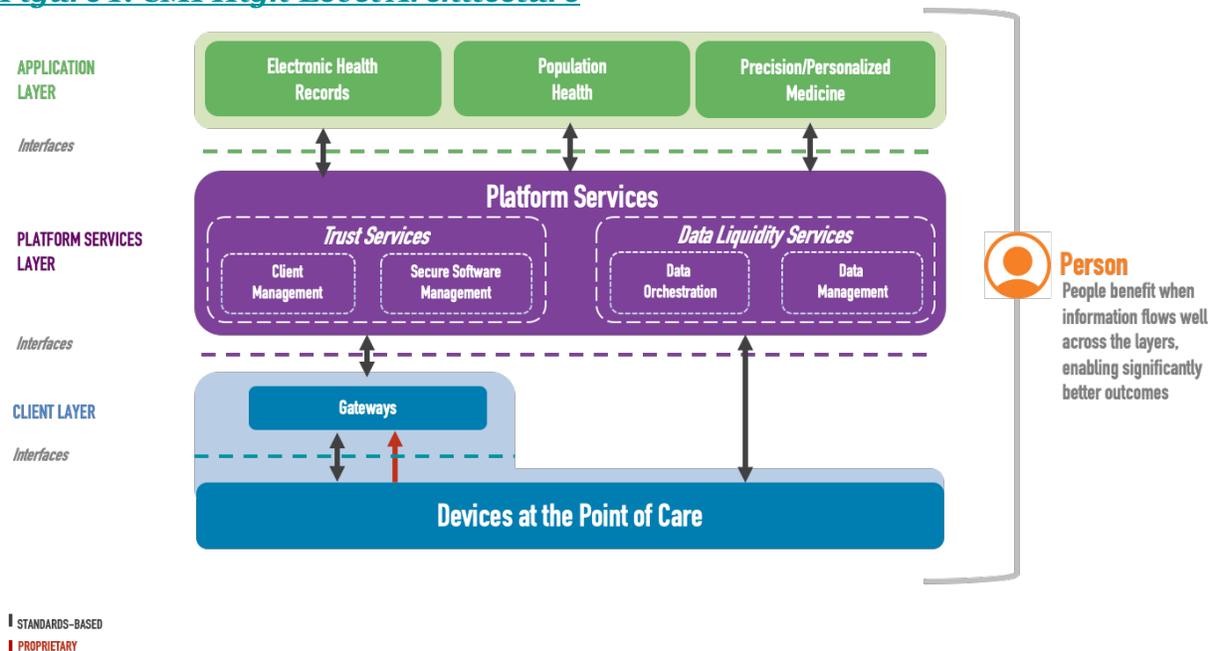
**[CMI Specifications can be accessed online:
www.medicalinteroperability.org/specifications](http://www.medicalinteroperability.org/specifications)**

The CMI's strategy to achieve interoperability, trust and data liquidity among medical devices and systems includes multiple stages of development from foundational requirements to building platform services and reference architectures to facilitate interoperability at scale.

CMI's first set of specifications has focused on enabling interoperability between the Client and Platform Services layers (Figure 1) and includes:

- Requirements for operational communications between the client and platform services for trust and data liquidity to enable secure and seamless interoperability e.g., identity and authentication requirements, provisioning flows, and secure software update
- Clinical data communications between the client and the platform enabled via an Internet Protocol (IP) network

Figure 1: CMI High-Level Architecture



Technical detail of CMI’s initial specifications is summarized as follows:

Foundational

- Initiatives independent of clinical data communications that are considered critical for secure interoperability, such as a trust model that specifies identifiers and identities for connected components, mechanisms to enable secure connectivity to wired and wireless networks, provisioning flows for automated participation in operational networks, profiles for automated and interoperable participation, a framework to remotely update software in a secure and interoperable manner (for instance, to enable quick, automated, responses to cybersecurity threats), and requirements to ensure architectural resiliency when unexpected conditions are encountered (e.g., errors in provisioning flows, or while sending clinical data).

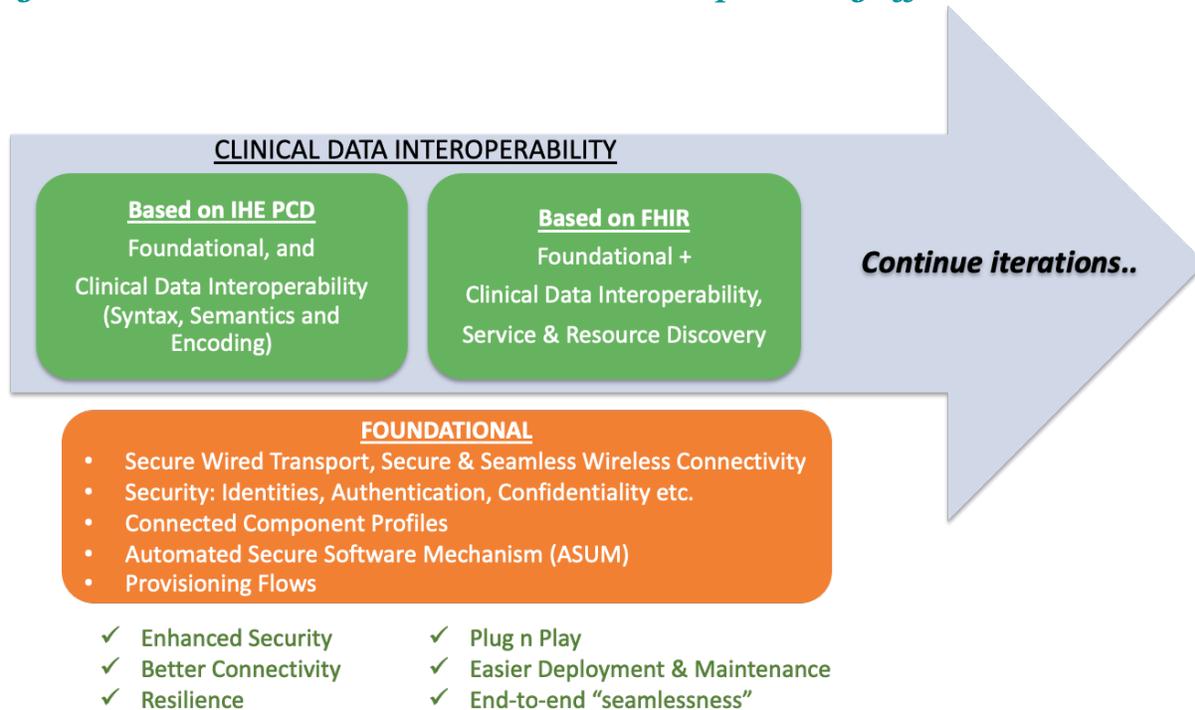
Clinical Data Interoperability

- Data communications between the client and platform services related to patient care; this is based on existing standards such as Integrating the Healthcare Enterprise – Patient Care Devices (IHE PCD) and Fast Healthcare Interoperability Resources (FHIR), extended as required to utilize the foundational elements such as the trust model.

Figure 2 visually illustrates the topics above. Both Foundational and Clinical Data Interoperability efforts aim to comply with the interoperability tenants and leverage CMI’s iterative Interoperability Maturity Model (see response to Question 4) approach. The current scope includes the foundational elements and clinical data interoperability based on IHE PCD to provide a straightforward path for vendor product

implementation. FHIR based medical device and gateway interfaces for clinical data interoperability are contemplated but not yet specified, as the standards are still maturing.

Figure 2: Foundational and Clinical Data Interoperability Efforts



Importance of Trusted Infrastructure

Identity, authentication, encryption, and integrity verification are integral to enabling interoperability and trust. They are also critical to addressing cybersecurity threats. The CMI’s specifications address this architecturally via a trust model that includes key elements such as digital identities for connected components, mutual authentication for communications, and mechanisms for integrity and confidentiality.

Digital identities provide a clear and consistent way to identify and authenticate infrastructure elements: clients, platform services, applications etc. To provide a basis for secure interoperability, these identities must be attestable by an ecosystem root of trust. CMI will establish this root of trust through the use of a managed Public Key Infrastructure (PKI) that we will operate on behalf of the health systems and their technology suppliers. Digital certificates will be issued for infrastructure elements that have passed CMI certification tests, thus validating their conformance with the applicable CMI interoperability specifications while also providing a foundation for secure operation. The identities embedded in the digital certificates have associated identifiers for recognition and credentials for authentication. While identifiers and associated identities may be publicly shared, the authentication credentials are private. It is to be noted that authentication neither implies nor assumes authorization, which is separate and will need to be handled by health systems. Where appropriate, mechanisms for authorization are provided.

Example Use Case: Sepsis Surveillance

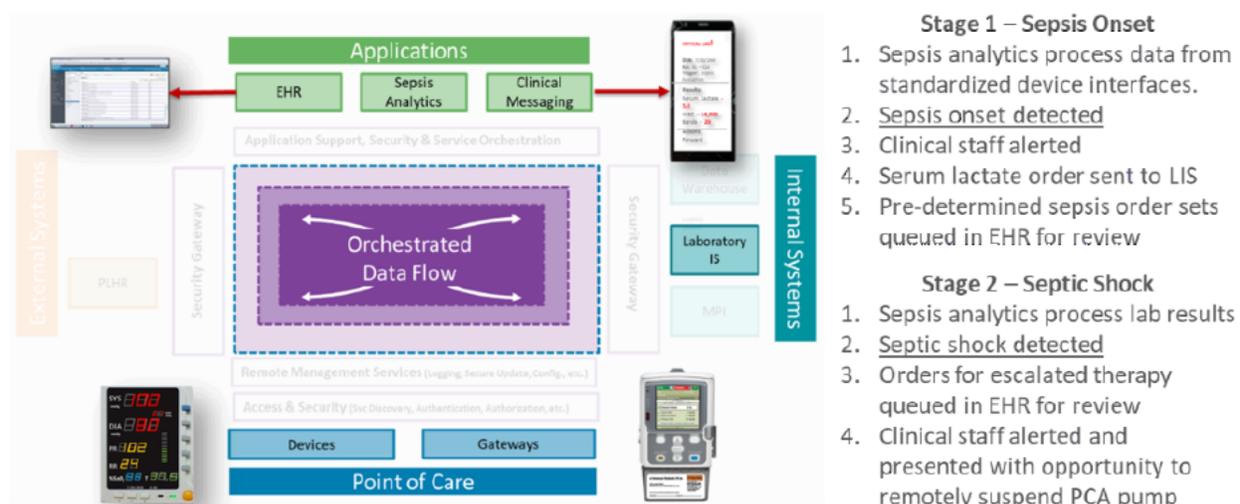
Patient data generated during a hospital visit holds great promise for improving patient care through risk monitoring and timely interventions, but that promise cannot be fully realized without the trusted and seamless exchange of data. The current states of sepsis detection and intervention exemplify this issue.

Sepsis is one of the greatest challenges in US hospitals, accounting for 270,000 deaths and \$27 billion each year.² The sepsis disease process is well understood, but intervention guidelines are only effective when implemented early in the onset of sepsis. Despite advances in technology, education, staffing models, and workflows, the identification and intervention in severe sepsis and septic shock remains unchanged, and the death rate for sepsis has not improved significantly. One of the greatest technical challenges for any sepsis intervention program is access to trusted and timely data about the patient and the ability to scale the program.

Trusted Platform Proof-of-Concept – Sepsis Surveillance

To demonstrate the principles of a trusted platform architecture, CMI has worked with its members to develop a proof of concept for early recognition of and response to sepsis—that is scalable. The demonstration environment in our lab includes a physiologic monitor, clinical and analytic applications, a mobile alerting system, a surrogate lab system, and a surrogate patient-controlled analgesia (PCA) pump (Figure 3). These components exchange data through a trust platform at the episode of care, allowing them to work together to detect the onset of sepsis and patient deterioration—as it is happening—which allows the care team to intervene early enough to avert a potentially fatal trajectory.

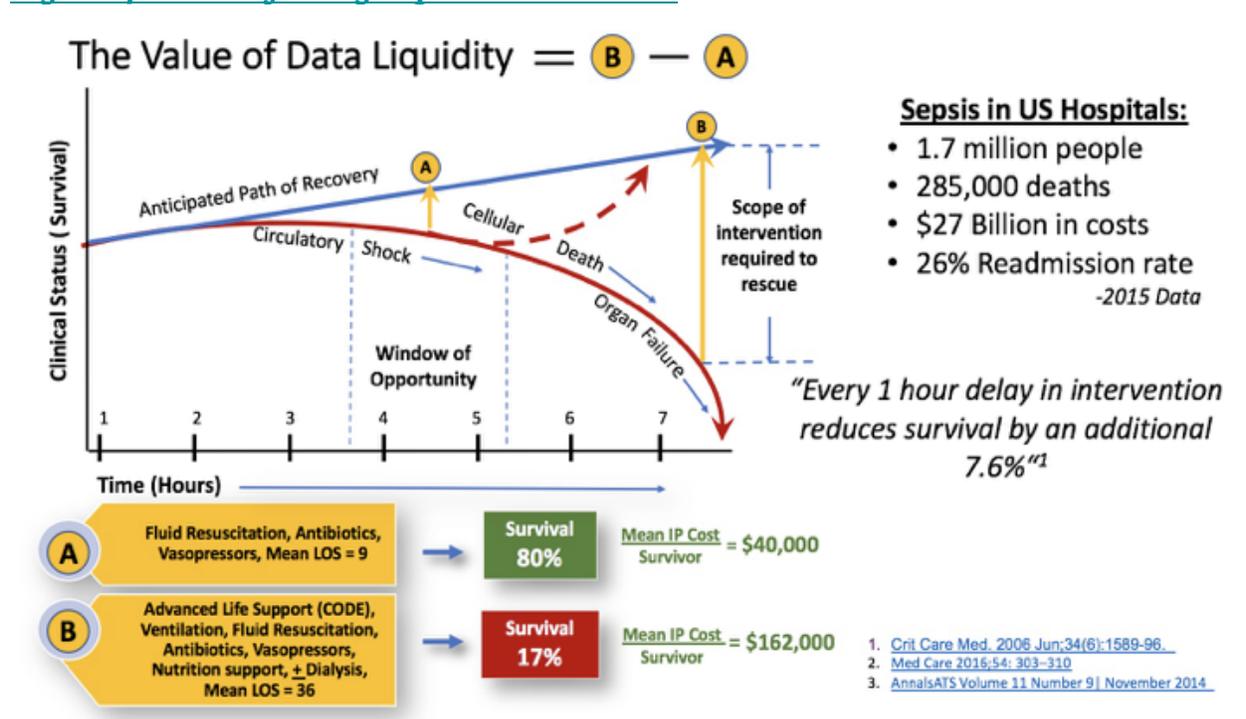
Figure 3: CMI Sepsis Surveillance Demonstration Model



² SL, et al. Outcomes and Resource Use of Sepsis-associated Stays by Presence on Admission, Severity, and Hospital Type. Med Care. 2016 Mar;54(3):303-10.

The ability to detect and identify shock at a very early stage coupled with an algorithmic-driven succession of events to diagnose and prompt treatment is not only lifesaving but limits a long, uncomfortable recovery from multi-organ failure and extended hospitalization at enormous cost. The benefits of achieving this type of advanced situational awareness are summarized below.

Figure 4: Value of Early Sepsis Intervention



Question 2: Contributions to CMI

Who are the relevant parties and their contributions to your interoperability solution?

CMI membership is limited to health systems, individuals, and self-insured corporations, but we work with a variety of stakeholders, including medical device manufacturers, electronic health record (EHR) vendors, standards development organizations, and others, to design and engineer the technical infrastructure that will enable comprehensive interoperability, data liquidity, and the trust needed to deliver person-centered medical care. CMI's Technical Advisory Committee (TAC) oversees our efforts to reduce technical complexity, and input from our Clinical Transformation

Advisory Committee (CTAC) ensures that solutions are useful, safe and satisfying for patients and their care teams.

Health System Members

CMI's Board of Directors consists of the leading executives of some of the largest health systems in the United States. Our board represents the diversity of healthcare and is unified by the desire to ensure information is readily available for everyone to be able to make the best decisions. The Board of Directors includes:

- Michael M. E. Johns, MD, Chairman Emeritus
- Mike Schatzlein, MD. Chairman Emeritus
- Nancy Howell Agee, President and CEO, Carilion Clinic
- Jeffrey Balser, MD, PhD, Chairman of CMI Board, President and CEO, Vanderbilt University Medical Center & Dean, Vanderbilt University School of Medicine
- William Carpenter, III, Chairman and CEO LifePoint Health
- Dick Green, PhD, Retired President and CEO, CableLabs
- Dean Harrison, Chairman-elect of CMI Board, President and CEO, Northwestern Memorial HealthCare
- R. Milton Johnson, Chairman and CEO, Hospital Corporation of America
- Thomas Priselac, President and CEO, Cedars-Sinai Health System
- Jon Pryor, MD, MBA, CEO, Hennepin Healthcare System
- William Roper, MD, MPH, CEO, UNC Health Care System & Dean, School of Medicine and Vice Chancellor for Medical Affairs, UNC
- Wayne Smith, Chairman, President and CEO, Community Health Systems
- Karen Springer, President and CEO, Saint Thomas Health &, Senior Vice President, Tennessee Market Executive, Ascension Health
- Veterans Administration Liaison

CMI engages health system leaders, technical, and clinical experts at all of our member organizations. The Technical Advisory Committee (TAC) oversees the CMI's technical portfolio and prioritizes the work to be completed by the CMI's technical staff. The TAC is appointed by the Board of Directors and consists of technical leadership from member organizations. The Clinical Transformation Advisory Committee (CTAC) is responsible for creating a clinical transformation roadmap, developing and prioritizing scalable, high-value use cases, and promoting data liquidity across healthcare. CTAC input guides our technical work, providing requirements for the platform architecture, to ensure that interoperable solutions are safe, useful and satisfying for patients and their care teams.

Vendor Engagement

Healthcare technology solution vendors contribute to the CMI efforts in multiple ways. CMI is vendor-neutral, and all technology solution providers are welcome to participate. In order to protect the work itself and those contributing, all participating vendors execute an Intellectual Property Rights Contribution and License agreement. Vendors can engage in technical working groups, participate in testing events, and contribute technology to CMI's physical lab.

Technical working groups are convened to address various technical aspects of medical interoperability. CMI technical working groups are currently focusing on the following topics: architecture and requirements, security, connectivity, semantics and testing. The output of the technical working groups takes the form of interoperability specifications for how modalities interface with one another along with testing procedures to assure correct implementation of the specifications. Vendors demonstrate their conformance to the interoperability architecture by adoption of these technical specifications and participating in interoperability testing and certification events. CMI has completed five interoperability testing events with the vendor community since April 2017.

CMI’s Current Vendor Participants:

- | | | |
|----------------------|--------------------------|----------------------------|
| - Acuity Engine | - Forescout Technologies | - Neuroflow Solutions |
| - Airstrip | - GE Healthcare | - Orion Health |
| - Amplion | - Healthspek | - Philips |
| - B. Braun Medical | - Infor | - Redox |
| - Becton Dickinson | - Innovision Medical | - RTI |
| - Bridge Connector | - Interoptex | - Stasis Labs |
| - CableLabs | - ITPA Group | - Texas Instruments |
| - Caresyntax | - Laird Technologies | - Transformative AI |
| - Cerner Corporation | - Masimo | - vTitan |
| - Commerce Kitchen | - Medal | - ZOLL Medical Corporation |
| - CyberMDX | - MEDHOST Inc. | - 86Borders |
| - DGMS Labs | - Mindray | |
| - Draeger Inc. | | |

Industry Collaboration

As part of the specification work of the CMI, we leverage the efforts of many standards development bodies and aim to enhance adoption of standards and ensure usability by end users in accordance with CMI defined specifications. The following list identifies some of the major standards bodies and federal agencies whose documents are referenced in our specifications:

- HL7 (Health Level Seven International)
- ISO (International Organization for Standardization)
- IEEE (Institute of Electrical and Electronics Engineers)
- IETF (Internet Engineering Task Force)
- IHE (Integrating the Healthcare Enterprise)
- ITU (International Telecommunication Union)
- OWASP (Open Web Application Security Project)
- WFA (Wi-Fi Alliance)
- NIST (National Institute of Standards and Technology)
- FCC (Federal Communications Commission)
- FDA (Food and Drug Administration)

We also recognize and applaud other initiatives to advance interoperability outside the episode of care and we continue to explore ways to strengthen and coordinate our efforts. The following are examples of organizations that are focused on improving the exchange of information between care settings: Carequality, Commonwell Health Alliance, Direct Trust, and the Sequoia Project. The following efforts are focused on connected medical devices outside of the clinical setting: The Personal Connected Health Alliance and University of New Hampshire's InterOperability Lab.

In addition, interoperability has risen to a high level of priority for government and regulators. Key provisions of the 21st Century Cures Act are being implemented. The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) recently released proposals related to interoperability, patient access, information blocking, and the ONC Health IT certification program. The Office of Civil Rights (OCR) is also considering potential changes to Health Insurance Portability and Accountability Act (HIPAA) and other privacy rules. We know that achieving our goal of trusted comprehensive interoperability and data liquidity will require coordination with many stakeholder groups. We welcome opportunities for public-private coordination to ensure the work we are doing can benefit all stakeholders, especially the individual.

Question 3: CMI Addressing Challenges

What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

Challenges to Advancing Interoperability

The healthcare industry in the United States has been unable to demonstrate organized strides toward interoperability. Conflicting priorities and misaligned incentives have resulted in a fragmented ecosystem that lacks a unified, scalable platform. Vendors compete on point solution effectiveness, driven by the need for profitability and competitive advantage in an environment where every installation is unique. In the absence of widely deployed, standardized, neutral platform architecture, proprietary software and hardware solutions have become common across the ecosystem. The resulting procurement "vendor-lock" and clinical reliance on proven (although proprietary) workflow solutions perpetuates a closed technical culture that resists a transition to interoperability.

Ecosystem regulators and influencers have provided guidance, incentives, and penalties to encourage healthcare information technology adoption but have not applied equal pressure to drive the requirement for interoperability of that technology. This has resulted in the prevalence of proprietary technology where *intra*-operability of

organization-specific solutions is paramount. While many advocacy groups have formed to address these challenges and promote the advancement of interoperability, the ecosystem, has lacked any sort of unifying leader with the independent technical resources and strength of commitment from the provider community to guide the market toward interoperability.

The healthcare industry manages a plethora of information in the form of patient records, medical images, medical device data, patient bills, prescriptions, insurance claims, and research data. Providers and other healthcare organizations are not only required to store data but are also required to process and maintain this data using various data management strategies and solutions. Providers are required to make this data available on demand and across boundaries, and at the same time to focus on their core function of delivering patient care.

Generally, hospitals and other healthcare providers use various systems for different aspects of services they provide, which are often unable to communicate with each other or do so with substantial effort and investment. In such cases, healthcare integration is recognized as one of the most effective tools for providing a framework for the exchange, integration, sharing, and retrieval of electronic health information with advanced security. Thus, driven by information needs, technologies from the healthcare integration market are increasingly being adopted by healthcare organizations to mobilize the healthcare information across or within the organization.

In order to glue together these disparate, dysfunctional and sometimes barely operable systems, the market has created products (integration/interface engines, device integration software, media integration solutions, and other integration tools) and services (implementation, support and maintenance, and training) to support some level of communication across systems.

Addressing Barriers and Challenges to Interoperability

In large and complex industries, like media, telecommunications, banking, power, and healthcare, a high degree of interoperability is not only advantageous and desirable, it is essential. Outside of healthcare, a common practice of those industries is to drive the adoption of interoperable systems by aligning their technology procurement requirements and processes with the interoperability specification and certification testing activities of a centralized industry lab. It is a proven model that has benefitted these industries with massive technology scale and significant operating efficiencies. The resulting consumer benefits are obvious and ubiquitous – mobile phones, automated teller machines, the electrical power grid, high speed internet service, high definition television. In healthcare, the purchasers of technology have not driven widescale conformance to industry-standard specifications that enable interoperability and, therefore, there is no baseline platform infrastructure from which to achieve technical scale and the benefits that result. In the absence of such an infrastructure, technology suppliers have been forced to establish and define their own proprietary solutions, which they have embraced as product differentiators. This has resulted in a medical device marketplace where suppliers are competing on price and method of data

presentation in physical product components instead of competing on what is valuable to patients and providers -- better health outcomes at lower cost.

Although many technology vendors understand and desire interoperability for business and altruistic reasons, out of necessity, they have developed significant revenue streams that result from the lack of interoperability. The supplier community faces an innovator's dilemma. There is also potential business risk for a vendor to open its interfaces to be leveraged by competitors without the guarantee of reciprocation. It is a very difficult problem for the vendors to solve alone and they need the market – specifically, the technology buyers – to resolve the conflict.

This situation is not unique to healthcare. The same dynamic has played out in many other industries over the past few decades. The role of a centralized lab is to organize the technology design and selection process in a way that efficiently aligns the industry around an interoperable architecture. This approach fulfills the buyer needs for interoperability while preserving the technology supplier's ability to differentiate their products and compete. It is, by nature, a collaborative and vendor-neutral process.

In addition to creating market demand for interoperability, a centralized lab approach for healthcare is needed to address shared technical challenges and bring order to the process of developing, procuring, and deploying medical technologies and systems. With a centralized lab approach and better procurement practices that facilitate the acquisition of a fully interoperable digital infrastructure—electronic health record (EHR) systems, medical devices, and mobile technology—healthcare systems will advance much more rapidly into the healthcare environment of the future.³

CMI is filling the centralized lab role for the healthcare industry. In the CMI approach, members of the buyer community (health systems and provider networks, self-insured employers and individuals) work with the vendor ecosystem to establish interoperability requirements that guide technical activities conducted in the test and certification lab. The lab, in turn, facilitates the development of standards-based architectures, interoperable interface specifications, and associated reference implementations. The lab also oversees protocols for testing and certifying that solutions comply with the mutually established requirements and specifications. This process enables healthcare organizations to have confidence that the solutions they purchase will be interoperable. Both buyers and suppliers of healthcare technology stand to benefit when the marketplace shifts to support products and solutions that better serve the needs of patients and providers. Incremental and partial interoperability initiatives will fail to develop the critical mass needed to tip market forces toward a positive industry transformation.

³ Pronovost P, Johns MME, Palmer S, Karney M, et al, eds. *Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care*. Washington, DC: National Academy of Medicine; 2018. ISBN: 9781947103122.

Question 4: CMI Alignment with Federal Vision

Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.

Future Vision is Viable and Necessary

We applaud NSF for thinking beyond initiatives that produce incremental improvement in favor of supporting the creation of a modern data interoperability infrastructure that supports long-term success. We believe that the NSF vision for a medical device, data, and platform interoperability end state is viable. Many other large and highly complex industries have already achieved very high degrees of interoperability and data liquidity, demonstrating viability of the interoperability vision in different contexts. There is no reason to believe that it couldn't be achieved in healthcare. That doesn't mean that achieving the vision will be easy. There are many challenges to overcome, and the solutions must address the needs of the many ecosystem stakeholders. We believe that **it is not only viable to achieve the vision of interoperability but necessary** if we expect our health systems to operate effectively and keep pace with the changes of the digital age.

Planning for this future vision and being able to prioritize the right activities will necessitate strategic design and a long-term view. CMI's work and mission is guided by a set of overarching principles as well as an Interoperability Maturity Model (IMM) to enable data liquidity in healthcare. We discuss these important principles below.

CMI's Overarching Principles

CMI follows a set of overarching principles that provide a framework for achieving interoperability and trust among healthcare technologies across the full continuum of care.

- **Data Liquidity**

CMI understands that the success of future value-based and learning health systems will depend largely upon their capacity to support a data liquid environment. Once vital data is freed from previously controlled data system siloes and allowed to flow when and where it is needed, it can be contextualized and turned into valuable information that can then be analyzed to become useful and computable knowledge and wisdom.

- **Comprehensive Interoperability**

Most, if not all, federal interoperability efforts to date have been focused on network-based exchange of electronic medical record (EMR) data. While CMI is a strong advocate of these efforts, it believes that data liquidity and interoperability should not stop at the network level. It should be pervasive and comprehensive. We applaud the vision of this RFI to address interoperability of medical devices, platforms, and data at the point of care. Comprehensive interoperability constitutes more than HIE or system-to-system data sharing; it refers to the

ability to seamlessly and automatically deliver data when and where needed, safely and securely, and without political, technical, or financial blocking.

- **Trust**

CMI considers trust to be a condition precedent for comprehensive interoperability and data liquidity. Trust mechanisms form the technical foundation for every interoperability specification that CMI is developing. CMI is also providing a Trusted Wireless Health reference architecture for hospitals as a foundational step to address the many challenges related to the use of the unlicensed Wi-Fi bands for consumer, enterprise and medical devices.

- **Connectivity**

Data liquidity calls for all medical technologies to communicate using standards-based interfaces without imposing undue financial burden on the health system. Today, the adoption of standards-based interfaces is poor, at best, due to the gaps in standards and low levels of adoption by vendors and health systems. CMI works with industry vendors to develop syntactic and semantic interface specifications needed by health systems to seamlessly and securely connect their medical devices with their enterprise applications through a neutral, non-proprietary interoperability platform.

- **Person-Centric Access**

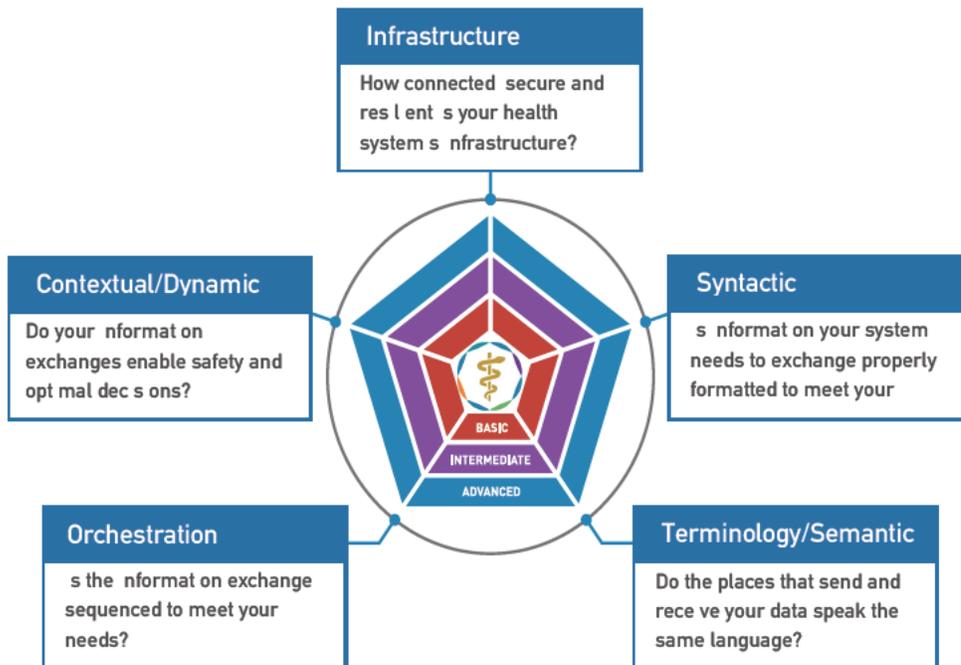
Only a trusted, neutral and secure personal longitudinal record supported by a digital identity can provide an appropriate level of utility and control that individuals will require in order to benefit from true interoperability. CMI supports the creation of secure personal identification algorithms or identifiers to support private data transmission, person-centric aggregation of longitudinal health data, and standardization of APIs and network sharing approaches that include a secure path for patient access to full data sets.

CMI Interoperability Maturity Model

Interoperability, like security, is not a specific state but a continuum of levels of achievement. It ranges from complete inability to exchange even a single data point to ubiquitous data liquidity. Building on the basic concept of interoperability, one can further specify that plug-and-play interoperability is the ability of two or more systems to appropriately, seamlessly and interchangeably share and use information in real time.

CMI has developed an Interoperability Maturity Model (IMM) to plan and evaluate the levels of plug-and-play interoperability that devices, systems and/or clinical domains are able to achieve. The IMM identifies capabilities around five dimensions that must be included in order to provide a clinically useful functional component of plug and play interoperability: infrastructure, syntactic, terminology/semantic, orchestration, and contextual/dynamic (Figure 5).

Figure 5: CMI Interoperability Maturity Model



Attributes of Interoperable Technology

Interoperability refers to the ability of connected components such as medical devices and care applications to seamlessly exchange and make use of information. The following characteristics are deemed as critical for interoperability:

- **Plug-and-Play:** one can attach a client (medical device or a gateway) or system without requiring manual configuration of either side of the connection.
- **One-to-Many:** a client or system certified as being conformant with a set of specifications is now plug-and-play with similarly certified clients, systems, or both.
- **Two-Way:** data communicated between connected components can flow in both directions.
- **Trusted:** achieved when stakeholders are confident that interoperable systems are enabled to behave in a secure, safe, and reliable manner without unexpected behavior or failure conditions when built and tested according to specifications.
- **Standards-Based:** applying technical and health domain open standardized solutions to the overall medical interoperability reference architecture, interface specifications, and testing.

The intended result of the efforts to improve interoperability is to achieve a state of data liquidity, an environment where data securely and seamlessly flows throughout the healthcare system. When patients and providers have dynamic access to trusted digital

health data, the entire health system benefits through improved clinical outcomes, reduced clinician burden and person-centered care.

Conclusion

The National Science Foundation (NSF), through the Networking and Information Technology Research and Development (NITRD), has established a vision for Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care. Through this request for information, NSF is seeking input from the market regarding the feasibility and practical implications of the vision. The Center for Medical Interoperability was formed out of a need and a mission to achieve the vision that NSF has described. We hope that our response shows how CMI is taking practical steps to advance the industry towards this important vision. We believe that to resolve longstanding interoperability issues, the healthcare industry must adopt a trusted architecture that supports the free flow of information on a vendor-neutral, non-proprietary platform.

In our response we have:

- Outlined CMI's technical approach
- Provided a summary of CMI's initial specifications
- Described an exemplary use case for Sepsis Surveillance
- Highlighted the leadership from CMI's health system members
- Demonstrated how vendors contribute to CMI's technical efforts
- Stressed the ongoing need for industry collaboration
- Showed how CMI's centralized lab model can address industry challenges
- Concluded that the NSF vision is viable and necessary
- Outlined key trust platform principles and an Interoperability Maturity Model

CMI feels strongly that the platform requirements must be driven by the purchasers and users of health information technology. Hospitals, health systems, and other large purchasers of healthcare technology and services should collectively align on the principles and technical interfaces of a trusted platform architecture for data exchange. Benefits can be realized by all stakeholders. Right now, vendors often compete on the way that they present and process their information within their proprietary solutions. When the industry adopts a common platform for interoperability, it will allow technology vendors to simplify and decouple their proprietary products by leveraging the signals that natively come from not only their products, but from all others as well.

Healthcare delivery and its technology infrastructure are approaching a critical juncture. Standards development and EHR adoption over the past decades have laid a fertile

ground for an era of data liquidity where key information flows across the care continuum – and across the life cycle – help clinicians to make better decisions at the right time for the right person. In the marketplace, it is also a critical time to ensure that competition among healthcare providers and technology vendors is focused on quality and value, rather than on exclusivity and proprietorship of data.

It is time to devote the nation's resources and attention to solving the issue that will make it possible to create the thriving patient-centric healthcare system that we all envision. We recognize that this is a complex ecosystem problem that will require collaboration among all the key stakeholders to solve. The Center for Medical Interoperability stands ready to assist the National Science Foundation and other federal agencies with the process to progress from the current state of healthcare systems with limited interoperability to the future state of healthcare systems with fully interoperable systems. The learning healthcare system that we envision is not possible without interoperability, and we have an obligation to improve healthcare so future generations will have better lives. The time is now to realize the true potential of health information technology.