

HITRD RFI Responses, March 15, 2019

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

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Response to Request for Information

Action on Interoperability of Medical Devices, Data, and Platforms To Enhance Patient Care

March 15, 2019

Spiritus Partners, Inc.

Princeton, NJ 08540

www.spirituspartners.com



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1 – Background Information

Name of the individual(s) or organization(s) filing the comment

Robert V. Clint, Chief Technology Officer, Spiritus Partners, Inc. [REDACTED]

Description of the individual(s) or organization(s) mission and/or expertise

Mr. Clint has more than three decades of experience in data architecture, data integration, enterprise solutions, big data and data analytics, distributed ledger technology. He is co-founder (with CEO Susan R. Ramonat) and CTO of Spiritus Partners (Princeton, NJ).

Spiritus is dedicated to helping health systems, medical device manufacturers, and 3rd party service providers overcome data, systems, and organizational silos and gain greater assurance about the performance, safety and condition of medical devices. The platform offers traceability, verifiability and tamper-proof evidence and analytics to support improved patient safety and clinical outcomes – upstream through the supply chain and downstream to the point of care and throughout a device's lifecycle.

By design, the Spiritus solution is strongly aligned with pertinent FDA and EU MDR guidance and regulations. These include use of unique device identifiers (UDI), GS1 and HL7 FHIR standards, quality management systems, post-market surveillance and adverse event management requirements, and cybersecurity risk management. Our solution is also closely aligned with relevant privacy and data protection regimes in the US, EU and Canada.

Non-proprietary public-private partnership work within the past three years with Federal, State, or local governments that is relevant to applied research on interoperability on data, platforms, and medical devices

Scotland

With the benefit of two grants from the Scottish Government valued in excess of £450,000 (\$585,000), Spiritus has been conducting an 18-month pilot program of its solution and capabilities with the National Health Service (NHS) in Scotland.

The primary grant supporting this pilot was awarded in April 2017 by The Data Lab, (<https://www.thedatalab.com>). The Data Lab is a Scottish government-funded innovation center promoting use of data analytics to advance the country's economic and social interests, including healthcare and life sciences among other sectors.

Under the auspices of the grant, Spiritus has partnered with NHS National Services Scotland (NSS), select regional boards in Edinburgh, Glasgow and Aberdeen, and Edinburgh Napier University to develop, demonstrate and prove out its platform for tracking, tracing, and registering comprehensive chain of custody, data provenance, and digital service histories for medical devices and equipment. A case study is



under development by Spiritus, NHS NSS and Edinburgh Napier for publication in late 2019.

In recent months, Spiritus has been in discussions with various NHS executive, medical, clinical engineering, procurement, and technology leaders, as well as the Scottish Government's Medical Device policy team, about implementing its platform at one of its largest boards for which patient safety and clinical outcomes issues have been particularly challenging, with knock-on effects for costs and financial stability. Such an implementation would be a precursor for a "Once for Scotland" roll-out across its 14 regional and 7 specialist boards.

United States

With the NHS Scotland pilot now drawing to a successful conclusion, Spiritus is currently negotiating a live trial and strategic relationship with a prominent health system in the United States known for pioneering innovations with emerging technologies.

The proposed trial will focus on implant tracking and recall management of a cardiac implantable and may involve several of the world's largest medical device manufacturers.

Follow-on projects could include but not be limited to (1) other implants, in particular connected, software-enabled cardiovascular, orthopaedic and/or neurological devices; (2) rolling stock such as infusion pumps, beds, patient monitors and ventilators; and (3) home-based devices and equipment such as dialysis machines, bariatric beds, and closed-loop diabetes systems.

Canada

The company is also in early discussions with a leading hospital in Ontario, Canada about developing a Canadian solution. Potential use cases include implant tracking and recall management, clinical asset management, sterile services and device reprocessing, infection control, and clinical/built-environment management.

Notably, the Medical Device Bureau, Canada's medicines and devices regulator, has expressed strong interest in the Spiritus platform and its potential participation in any Canada-based projects.

RFI Questions – Quick Reference

- 1. Q:** 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?
A: See section 4.2 Spiritus Platform
- 2. Q:** Who are the relevant parties and their contributions to your interoperability solution?
A: See Section 1 – Background Information



- 3. Q:** What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?
A: See section 5 – Challenges and Impediments
- 4. Q:** 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.
A: See section 4.2 – Spiritus Platform

Before we dive into the concepts presented in the RFI, some foundational concepts need to be explained.



2 - Definitions

2.1 - Data Interoperability

Data and device interoperability methods for data collection, storage, and transformation to enable safe and secure data interoperability for clinical IoT and healthcare. Technical Interoperability is defined to be the ability of two or more information and communication technology applications to accept data from each other and perform a given task, in an appropriate, accurate, and satisfactory manner, without the need for extra operator intervention.

Of primary concern is whether the technology will use the data, or just pass the data through to another technology. Potential actions include examining, analyzing, adding to, subtracting from, encrypting, or reporting out on the data. When the technology simply passes data to another technology, it acts fundamentally as a data tunnel, for which the veracity and provenance of the data must still be maintained.

Interoperability must be considered at all levels of technology – hardware, software, firmware, and such service layers as online communications. It must also include the human element as it manifests itself in clinical practices, defined protocols and manual processes or workaround.

Considerations of the impact that clinical IoT data and device interoperability has on health systems, medical device manufacturers, 3rd party service providers, home health care providers, clinics, diagnostic laboratories, outpatient clinics, home health care providers, and clinical researchers. It must also take into consideration the mandates, interests, guidance and regulations of such government agencies as the FDA, HHS, CDC, CMS, VA, Defense Health Agency (DHA), FCC, DHS, and state-based health departments in the US, and corresponding entities in other countries, as well as WHO.

2.2 - Data Validation

Validation of data consumed and produced by medical devices requires consistent, reliable, extensible, and reproducible structures, methods, processes, and concepts for the validation of data generated and/or managed by the Internet of Medical Things (IoMT). Device manufacturers should adhere to these and thus enable IoMT assets to harmonize, exchange, interoperate, and integrate IoMT data streams and repositories with other operational and analytical data streams, across their enterprises and extended networks.

Clinical Data Validation involves identifying, and potentially remediating, discrepancies and/or flaws across eight characteristics of “good clinical data”:

- **Attributable:** Sources of the data are known and recorded
- **Legible:** Data are human or machine readable
- **Timely:** Source data are recorded when they are generated



- **Original:** All data come from the original source - Copies and transformations of the data are accurate and complete, do not overwrite original data, and are traceable back to original data
- **Accurate:** Data are correct, given the context of their use
- **Enduring:** Data are available for the entire time they are required to be kept
- **Complete:** All pertinent and contextual data, including metadata, transactional and detail, are included
- **Consistent:** All data is characterized by use of consistent, non-contradictory terms

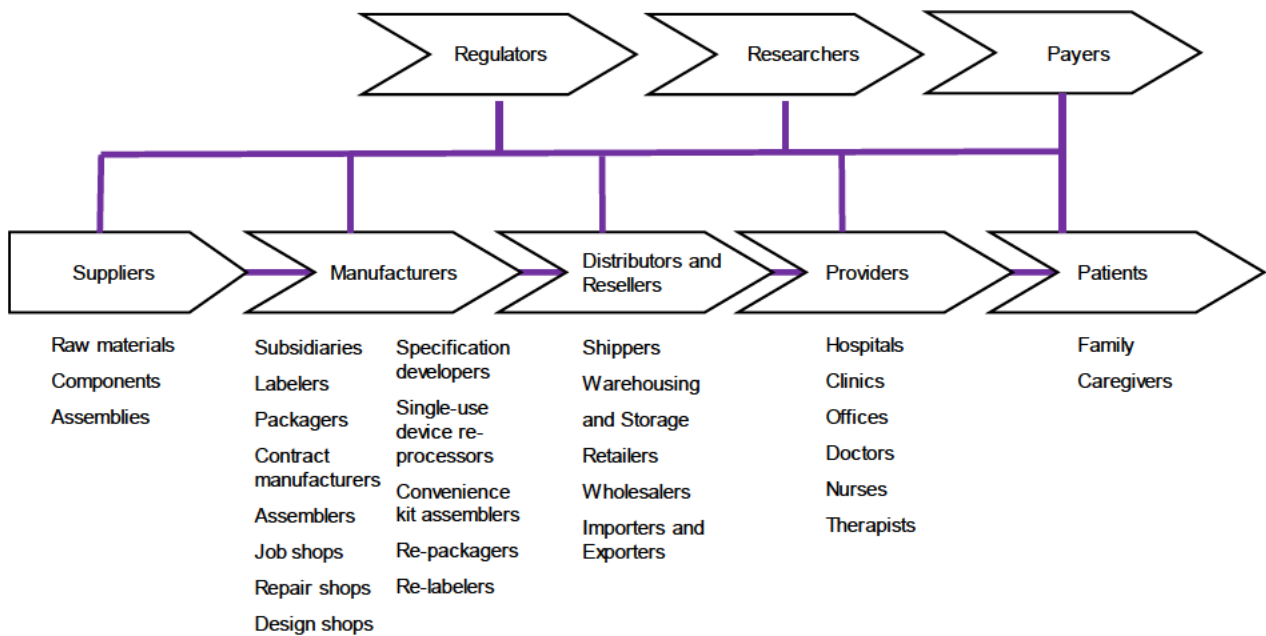
IoMT data must be validated using appropriate, existing industry standards – including such well-known and mature standards as HL7, LOINC, SNOMED, RxNorm, and SOLOR.



3 - Current Ecosystem

The current state of interoperability of connected medical devices and equipment and their data is siloed, patchy, and inconsistent. Standards-based protocols like HL7-FHIR enable well-formed healthcare data messages to be exchanged. Various industry standards such as LOINC, SNOMED, RxNorm, and SOLOR allow the semantics of the data to be harmonized and validated. However, their adoption is by no means uniform. Connected devices themselves are not computationally capable to manage the burdens of data validation, translation, and standards-based formatting on their own.

Further, the ecosystem of players who create, distribute, service, configure, employ, and benefit from such devices and equipment is complex and multi-faceted:



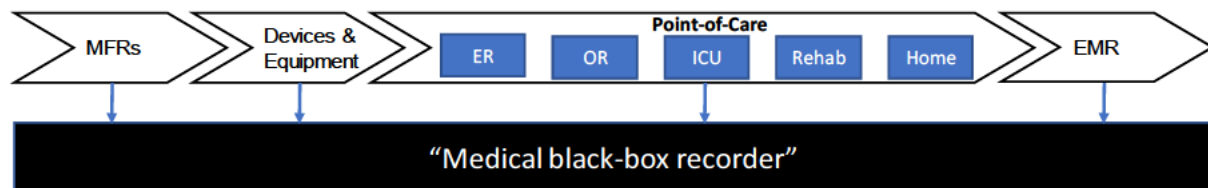
Working across such a diverse ecosystem requires flexibility and adaptability – in processes, technologies, and approaches. Heavily proprietary solutions tend to create new silos of information, an undesired by-product of current technology approaches and commercial models.

Arguably, the healthcare ecosystem has one of the most ossified collections of information silos of any sector. A new approach is needed to realize the benefits of medical device innovation. As such, the FDA’s concept of a “medical black-box recorder” hints at what we consider the most viable approach.



4 - HITRD Future State Vision

The vision described in the RFI depicts the familiar fragmented ecosystem of players and devices, interoperating and producing joined-up datasets capable of providing valuable insights to disease processes, device efficacy, clinical outcomes, and a whole range of as-yet unattainable analytics through the use of an integration layer, expressed in your vision as a “medical black-box recorder”:



4.1 Medical Black Box Recorder

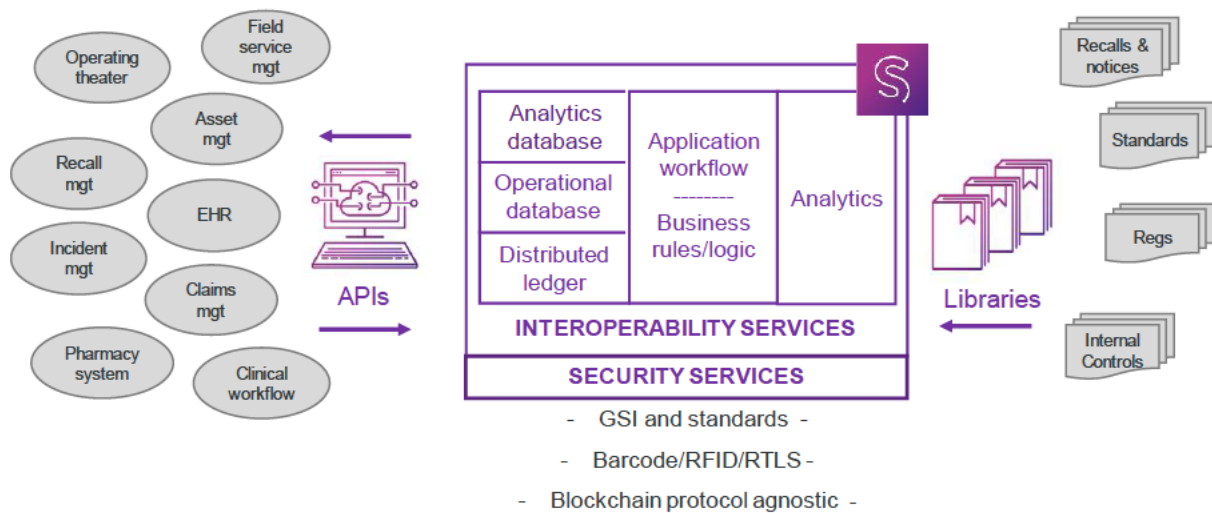
The term “black box”, however, conjures images of inaccessibility and imperviousness, in some ways the opposite of what we feel the proper solution should be. We believe the “medical black-box recorder” concept would leverage technologies and techniques that have been in use for decades in the development of data analytics environments.

Until recently these circumstances required design, construction, layering and maintenance of multiple custom databases on top of one another. Fortunately, the recent emergence of distributed ledger technology (DLT/blockchain) promises to help us solve this intractable problem.

4.2 Spiritus Platform – A Future State Vision

At Spiritus we have worked hard over the last three years to crystallize our vision for DLT/blockchain’s application, demonstrating its feasibility and value in addressing this problem in healthcare. Fortunately, the technology has matured significantly in this time, with major IT players such as the Linux Foundation, IBM, Intel, Microsoft, and SAP undertaking major programs across industry sectors. Indeed, viable use cases have made it through successful trials and moved into production in financial services, food safety, supply chain management and healthcare. Examples in healthcare include provider directories, credentials verification, and claims processing, along with promising work on pharmaceutical track and trace and early investigations for clinical trials. As such, it is our belief that a new standard of interoperability has been made possible.

We have built a DLT-enabled medical device tracking and tracing platform, capable of establishing a modern, joined-up digital service history for connected medical devices. You can think of the “black-box” above as the Spiritus platform – a new form of “connective tissue” for healthcare ecosystems.



The diagram above illustrates several key design decisions that make this platform a solid fit for these requirements:

- **API enabled** – The entire Spiritus platform is API enabled. This allows us to be woven seamlessly into any technology-enabled environment, including those that are fragmented across multiple providers and versions of legacy systems.
- **Standards-driven** – We support standards natively, from GS1 standards driving the adoption of UDIs, to Global Location Numbers (GLNs) and EPCIS events. Our APIs can also directly connect to HL7 FHIR Resources for interchange of healthcare data.
- **DLT protocol agnostic** – Because DLT technology is evolving rapidly, we have insulated our platform from the underlying DLT protocol, once again using APIs. We currently run on either Hyperledger Fabric or Ethereum. Importantly, we are committed to future-proofing our solution and routinely engage with and evaluate other players in the field for fit and appropriateness.
- **Tracking protocol agnostic** – Our platform accommodates multiple methods for identifying and tracking the movements of devices and equipment – whether accomplished through barcode scanning, passive or active RFID, Real-Time Location Services (RTLS), Bluetooth Low-Energy (BLE) or other means. Regardless of method, we can ingest and harmonize the data generated and provide the critical chain-of-custody, data provenance, and digital service history.
- **Controls and standards libraries** – Our platform enables pertinent controls and standards to be attached to transaction records of events which occur during the lifecycle of devices and equipment.



These could include ISO standards for quality management or cybersecurity, manufacturer guidance, and or a health system's internal requirements for such matters as calibration, inspection and testing, maintenance and upkeep, and reuse/reprocessing, decontamination and sterilization.

- **Enterprise-grade privacy and security** – Due to the sensitive nature of Protected Health Information (PHI), it is imperative that a solution to your future state adheres to the highest achievable standards for privacy and security protection. By design and through continuous evaluation and testing, we seek to meet and/or exceed provisions of relevant privacy and data protection regimes and such cybersecurity frameworks as ISO 27001 and NIST for confidentiality, integrity and availability.

To do so, we use sophisticated encryption, cryptography, identity and access management (IAM), networking and communications, and asset management techniques. We also maintain an ISO 27001-aligned risk register subject to regular technology and executive management updates and reviews. Risk mitigation decisions and action plans are subsequently reflected in our product and development roadmaps.

4.3 Machine to machine connectivity and interoperability

Though our platform has not yet evolved to support machine-to-machine connectivity and interoperability of devices and equipment, such capabilities are part of our platform vision and roadmap. Indeed, it has been designed to support evolution for such use cases.

We can also currently support integration with EHR/EMR systems. The integration enables connecting device UDIs with clinical procedure data, linking to patients, and providing the missing links to providing real-world evidence for post-market surveillance.

Such a solution architecture will naturally enable superior post-market surveillance and adverse event management, as well as collection, aggregation, and analysis of post-market signals including litigation, claims, domain/geographic registries, recalls, and medical literature.

Imagine a longitudinal database of every event during the lifecycle of a medical device – in some cases, lasting a decade or more. Such a datastore would enable correlation of a wide array of post-market signals with device failures, patient injuries, and other adverse events and sharply reduce unnecessary harms.

While improving patient safety and clinical outcomes, it could also allow health systems to reduce overstocking and undertake evidence-based, value-driven procurement. In concert, we foresee improved manufacturer/clinician partnerships



focused on delivering evidence-based care and sharply reducing cycle times from incident occurrence and adverse event pattern recognition to timely issuance of recall notices and their execution in the field.

Correlation of these signals across device types and geographies with patient demographics and co-morbidities, device configurations, component materials, use patterns, and patient pathways will make possible tremendous advances in device design and formulation, clinical treatment, and patient outcomes and satisfaction.

With the pace of device connectivity, software-enablement, interoperability and algorithms accelerating and such innovations as remote robotic surgery, drug-device combinations, and widespread 3D or 4D printing just over the horizon, such data would be invaluable. The path would exist for weaving key data directly into the clinical data flow, bypassing current data integration, extract, download, and re-entry schemes, and enabling better validation of clinical data and device identity.



5 – Challenges and Impediments

Of course, in every solution roadmap, there are plenty of potential bumps to face along to road. For a solution such as the one envisioned here, these include establishing the appropriate consortium of ecosystem players, (re)building a sufficient historical record of lifecycle events to realize the potential of that network of players, and assessing and mitigating the quality of the data available with which to create that history.

5.1 – Establishing the Consortium

For a DLT solution to achieve its true potential, it requires a network of distributed parties, all collaborating and contributing to a shared ledger. In our case, many of these players will be actual or perceived competitors, unwilling to risk sharing data for any reason lest it be seen by a rival, and potentially erode a competitive advantage. The challenge here is to:

- a) build a credible value proposition, based on definable metrics that can be quantified and proven (i.e., for manufacturers, the ability to shorten recall timeframes, reduce the enormous costs of adverse events, and so on),
- b) overcome “fear of the unknown” – while DLT currently enjoys enormous hype, with hype comes doubt, and with doubt come roadblocks. It is critical to explore fears and concerns and address them thoroughly – whether commercially or technologically. It will be important to develop a governance framework that provides a means for oversight, monitoring and decision-making that is fairly grounded and changes over time with the network’s growth and technology’s evolution.
- c) build “skin in the game”, achievable by understanding which consortium players favor which value metrics, and making sure they are not only measured but accurately and honestly reported, in a timely manner

One way to accelerate the consortium-building process is to target existing collaboration networks or consortiums where you already achieved a level of collaboration – these may be supply chain networks, HIE partnerships, or other existing partnerships.

5.2 – Rebuilding History

Collecting the data needed to establish an accurate and useful historical baseline of lifecycle events for medical devices often requires reaching into multiple systems, databases, and often backups to extract appropriate transaction data. This is no small task, but here again the experience of building analytics platforms is instructive.

There are two primary approaches to this task – 1) full history capture, and 2) selecting a Synch Point and moving forward from there.



- 1) Full history – Full history builds are by far the most challenging, because they often require going back to data created over multiple versions of multiple systems, which may have differing and even conflicting schemas, translation rules, and storage media, and present dramatically different data quality challenges. If you need full history, the best advice is to start with the most current, easily accessible data, and then build history backwards in stages. As with any system/data migration, you will reach a point where the return on the conversion investment no longer makes business sense.
- 2) Synch Point – More pragmatic is to select a valuable and achievable synch point in history, recover the data to that point, and focus most of the consortium energy on creating value as a network as you move forward. Generally, this is a far less expensive undertaking than Full History. It gets you to steady state much more quickly, and increases buy-in among members by reducing effort and cost.

5.3 – Data Quality

Data/systems migrations notoriously suffer from data quality issues. It is imperative that the consortium be aware of the risks, plan for the necessary mitigations, allocate resources and time for it, and make every effort to make the needed changes at their source, so that they don't recur as subsequent data refreshes are executed. This will need to become part of the overall consortium governance structure and responsibilities, as discussed below.

5.4 – Governance of the Network

Because DLT-centric solutions are so new, the supporting policies, procedures, and controls have not yet caught up. Nevertheless, it is imperative to spend time thinking about consortium governance at the outset, and to put in place your best guess/estimate/ideas about how that will be done. DLT solutions (by definition) introduce new trust models to the consortium participants. Knowing that your model(s) will likely need to change and adapt over time needs to be part of the initial governance charter.

Too, it is important to ensure that everyone has a “seat at the governance table” – because nothing erodes trust faster than being on the outside looking in. These consortiums are new to almost everyone, so be prepared to take time to understand fears and concerns, respond to everyone's concerns fully and equally, and build in mechanisms for feedback, suggestions, and improvements – because this is all new.



6 – About Spiritus Partners

Founder-funded and organized in early 2016, Spiritus is working with health systems, device manufacturers and 3rd party service providers to create a cross-enterprise ecosystem to selectively share vital data and analysis about medical devices at the point of care. We're helping forward-thinking organizations collaborate in new ways to answer the tough questions with greater certainty and speed, improving patient safety and clinical outcomes in a value-based care setting.

Headquartered in Princeton, NJ, we've established a development center in Edinburgh, Scotland, where the Spiritus team joins a community of top-flight talent, world-class universities, and government-sponsored innovation centers deeply committed to developing cutting-edge advances in healthcare and life sciences.

For more information about Spiritus and our work in Scotland, see www.spirituspartners.com.