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

SIERRA NEVADA CORPORATION

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Prepared for:

Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation, Health Information Technology Research and Development Interagency Working Group (NITRD IWG)

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1.0 MEDICAL DEVICE INTEGRATION AND INTEROPERABILITY BACKROUND

SNC's eHealth and Remote Monitoring Experience

- Over 10 years of integrating medical devices
- Independent Army Study Results - Interoperability between MEDEVAC and Receiving Medical Treatment Facility significantly reduce time between patient handoff and definitive care
- Automatically captures patient data from medical devices
- Systems are interoperable with existing communications infrastructure, and fielded medical devices

SNC's partnership with the U.S. Army, and Industry extends over 10 years including proof of concept and advanced development programs, as shown in Figure 1. The vast experience, and unique technologies developed through this partnership are applied to delivering integrated solutions that improves warfighter patient outcomes, and long-term healthcare outcomes through integrated solutions that leverage existing technology, and medical devices to automatically collects patient/treatment data, and communicates to the receiving medical treatment facility without any additional burden on the care provider.

SNC's latest Army prototype, MEDHUB, includes six (6) Food and Drug Administration (FDA) Cleared Sensors, Tactical Display, patient data hub, novel wireless drug rack sensor, novel wireless tourniquet sensor, and Android based medical application that automatically collects, displays, and translates patient data to their electronic patient care record, ahead of the patient to the receiving medical treatment facility's ICU/ER big board, and finally into the patient's electronic health record.

See Army's YouTube Link for additional information on the program:
https://www.youtube.com/watch?v=OFMEad-BcnI

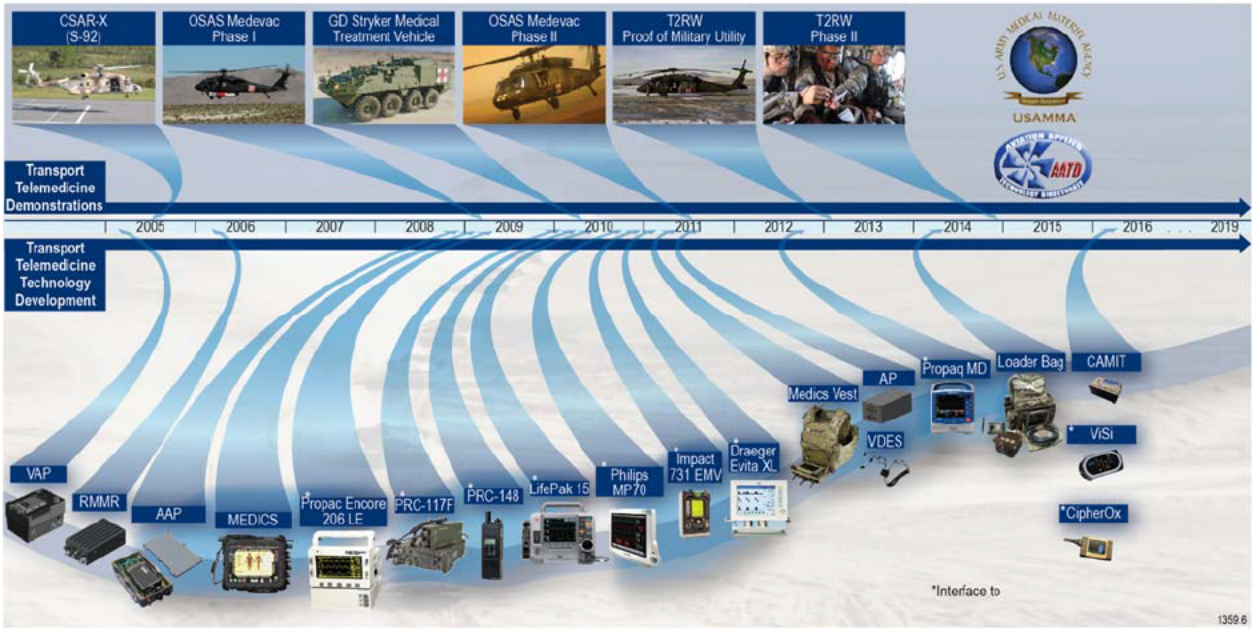

Figure 1. Medical Device Integration Experience

1.1 MEDICAL DEVICE INTEROPERABILITY VISION, PAIN POINTS, AND PLAN

SNC provides integrated eHealth & Remote Monitoring solutions that automatically capture, store and communicate critical, real-time patient status and treatment information from the point of care, throughout transport, to the receiving medical treatment facility. Our novel approach allows care providers to focus on patient vs. documentation. Receiving clinicians can prepare and reduce the time to definitive care; and remote clinical specialists can provide tele-mentoring and consults to remote care facilities during prolonged field care.

1.1.1 Use Cases

SNC's eHealth & Remote Monitoring solutions are adaptable and scalable to successfully handle a wide variety of pre-hospital care use cases including: medical evacuation, casualty evacuation, aeromedical evacuation, critical care air transport, disaster recovery, prolonged field care and mass casualty use cases. Our carry-on systems are customizable to achieve the care provider's goals, while also addressing the mobile air or ground platform certification requirements. Our pre-hospital use cases can easily be transitioned into fixed facilities including clinics, Emergency Rooms, and Intensive Care Units.

- **Pain Points**
  - **Medical Device Communication Interface -** Medical Devices do not have a common interface for communications. They range from USB, Ethernet, Serial, or are not available except for device manufactures to perform routine maintenance (i.e. calibrations), troubleshooting, and loading SW/firmware updates.
  - **FDA Regulatory Compliance** – Small Business IOT start ups cannot afford to be compliant with medical device regulations.
  - **HIPAA Regulatory Compliance** – HIPAA restricts interoperability of electronic patient health information between care providers.
  - **Communication Quality of Service** – Military, and rural environments often present inadequate communications infrastructure to enable remote monitoring/control of medical devices.
  - **ROI –** Medical Device Manufacturers are not incentivized to have open architectures with other competitors, so all have proprietary interfaces for data/communications.
  - **Security –** For DoD, traumatic patient injury often occurs in theatre, so data must flow across multiple network domains, i.e. from classified networks to unclassified networks where medical care providers communications infrastructure exists. In addition, medical devices are often procured as COTs, so DoD Cyber Security standards and controls are often not implemented.
- **Patient Data Access System Solution**
  - **HW and Wireless Interface –** An access point, can provide the I/O translation required to integrate all commercial types of medical device I/O inputs, and securely stream to a common I/O output, tailored to identified data consumers.

- **FDA Regulatory –** Common platform to conduct patient risk assessments, as data passes from point of care to remote care providers. No need to regulate the entire system if the end points are already cleared FDA Devices.
- **HIPAA Regulatory –** Ensured data integrity including Encryption, and logging of patient data transactions. Compliant with commercial data protection best-practices and portability.
- **Security –** Meets Risk Management Framework DoD 8500.01/8510.01 and CNSSI 1253 security controls. Security controls are enhanced throughout the product lifecycle of the program to mitigate vulnerabilities. The Access Point acts as an added layer of security between the network and patient medical devices.

1.2 RELEVANT PARTIES AND CONTIBUTORS

Sierra Nevada Corporation is a prime integrator for its customers. As a result, we have established relationships with industry, academia, and government run labs as required by their customer's use cases and unique requirements. Over the last 10 years, SNC has formed and maintained relationships with Zoll, Masimo, Phillips, AthenaGTX, Army Institute of Surgical Research, Army Applied Research Lab, Office of Naval Research, Army Medical Research and Material Command, Denver Children's Hospital, and Womack Medical Center to name a few.

Each organization is working on parts of the solution including remote monitoring, remote medical device control, telementoring, prolonged field care, care provider decision assist algorithms, and autonomous care.

1.3 INTEROPERABILITY CHALLENGES AND IMPEDIMENTS

The top interoperability challenges and impediments SNC has experienced over the years are:

1. **Communications Quality of Service and Availability** – For DoD, medical applications typically receive the lowest priority to the Operational Commanders. Quality of service required for real-time patient monitoring, and remote control of medical devices is not guaranteed. SNC's patient data access system continually monitors the network availability, manages data, and enables care provider applications based on quality of service.
2. **Medical Device Certification –** Interoperability between medical devices for active patient monitoring, remote control and automated control is heavily regulated to provide safe solutions to patients; therefore, SNC recommends the crawl, walk, and run approach for interoperability. Start with unregulated Patient situational awareness solutions, and grow into remote patient monitoring and medical device control with full transparency with FDA regulators.
3. **Care Provider Credentialing and Compensation –** Remote monitoring of patients, which is a key driver for medical device interoperability, is a relatively new market. As a result, the care providers willing and trained to provide high quality consultations are limited. As you start talking about remote control of medical devices, the challenge grows because the care provider is taking on more and more liability. To solve this issue, industry,

major hospital systems, and the insurance companies will need to be involved to define a solution.

1.4 INTEROPERABILITY END STATE VIABILITY

SNC has demonstrated that technology is, and has been available to provide a viable solution to many of the future vision capabilities mentioned in this RFI. For example, our solutions automatically pulls patient data from medical devices, data is time synchronized to that patient's electronic patient care report, and then that data is stored and managed for inclusion in the patient Electronic Care Record. SNC is excited to learn, and contribute more as the NITRD Health Information Technology Research and Development Interagency Working Group Progresses.