

HITRD RFI Responses, March 15, 2019

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

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**Society for Technology
in Anesthesia**

March 15, 2019

Alex Thai
Technical Coordinator
National Coordination Office (NCO) for Networking and Information Technology R&D
2415 Eisenhower Avenue
Alexandria, VA 22314
Submitted by email to HITRD-RFI@nitrd.gov

Dear Mr. Thai,

Re: RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

The Society for Technology in Anesthesia (STA) appreciates the opportunity to provide information on this very important topic. STA was founded in 1998 to bring together clinicians, researchers, engineers, manufacturers, and members of governmental agencies to advance the state-of-the-art of technology for patient care in anesthesia and other high-acuity care settings. Over twenty years ago, the Society identified limitations in medical device interoperability as the source of foundational barriers to building “smarter”, fully Integrated Clinical Environments (ICEs) that could provide cockpits and data dashboards; comprehensive data access to accelerate clinical research, medical device development and regulatory approval; and enable device-device-app communication for closed loop control of medication, fluids, and lung ventilation, among other promising applications.

STA has held many workshops over the past few years on medical device interoperability. A STA consensus framework on medical device data availability was published in *Capturing Essential Information to Achieve Safe Interoperability* (Anesth Analg. 2017 Jan;124(1):83-94). In response to this RFI, we offer this general framework for the consideration by HIRTD:

Medical device interoperability (MDI) general framework:

The following data must be made available through the medical device Electronic Data Interface (EDI):



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1. All data displayed to the medical device operator. (Note—This requirement excludes proprietary manufacturer data that is not normally displayed to the operator/clinician.)
2. The state, and change in state, of any operator-adjustable setting (eg., alarm settings, signal averaging time, and computation constants).
3. Important device attributes, such as software and firmware revisions, time of last clock update, and equipment maintenance–related data.

Note that the MDI Framework is silent on the use of a specific standard or data format, although data interface standards-compliance is assumed. The key points are that data is openly available, and that both measured data and meta data availability are ensured.

Sincerely,

*/*signed*/*

Brian Rothman, M.D.
President, Society for Technology in Anesthesia