



June 6, 2024

**A Collaborative Community to  
Advance the Development and Adoption of  
Smart and Autonomous Medical Systems (SaAMS)**

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SaAMS Collaborative Community: <https://mdpnp.mgh.harvard.edu/saams-cc/>  
Symposium Agenda: [mdpnp.mgh.harvard.edu/saams-symposium-2024/](https://mdpnp.mgh.harvard.edu/saams-symposium-2024/)

## What are Smart and Autonomous Medical Systems (SaAMS)?

- SaAMS describe medical systems in which apps connect to medical devices to deliver transformative patient-care solutions safely and efficiently.
- SaAMS may use sophisticated algorithms that interact with interoperable medical devices to perform tasks that improve patient safety or care efficiency, make decisions, automate processes, enhance vigilance, personalize patient and user experiences, advance healthcare equity, and solve historically intractable problems.
- SaAMS algorithms may be based on artificial intelligence (AI) to adapt to new information, make predictions, and operate autonomously.
- *Solutions to long-standing gaps in clinical technology effectiveness and patient safety will benefit from SaAMS-based technologies.*

## Examples of SaAMS:

- Automated closed loop control of intravenous anesthesia (ACLIVA)
- Closed-loop vasopressor therapy for blood pressure management
- Closed-loop IV fluid administration
- Control of Infusion Pumps (via external data interface)
- Remote control of Lung Ventilators (via external data interface)
- Stop/pause infusion of medication with an interlock to prevent harm (e.g. Patient Controlled Analgesia - PCA)
- AI-based predictive clinical analytics
- Smart alarms that improve sensitivity to clinically significant events and enhance specificity to reduce non-actionable alarms and reduce alarm fatigue

*Integration of actuators, sensors, platforms, and smart clinical algorithms are foundational components of these SaAMS.*




There have been many historical challenges to successful SaAMS development which can be addressed through a Collaborative Community.

# The Benefits of a Collaborative Community

- A Collaborative Community can address challenging medical technology needs and regulatory science gaps that no single manufacturer or other entity may be able to accomplish alone.
- This includes identifying and advancing key enabling device features and clinical system capabilities that address complex engineering and clinical challenges
- A collaborative community can bring together many of the various development entities to address the challenges of developing SaAMS.
  - E.g. Baseline information developed with community experts for completeness – in contrast to a small group from within a single company
- MGH has formed a Collaborative Community, **as defined by the FDA, “to achieve common outcomes, solve shared challenges, and leverage collective opportunities”** to advance the maturity, adoption, and clinical use of SaAMS to improve patient care.

# Collaborative Communities: Addressing Health Care Challenges Together

In the medical device ecosystem, collaborative communities bring together stakeholders to achieve common outcomes, solve shared challenges, and leverage collective opportunities. At the FDA, the Center for Devices and Radiological Health (CDRH) believes collaborative communities can contribute to improvements in areas affecting patients and health care in the United States. Accordingly, participation in collaborative communities was one of CDRH's [strategic priorities for 2018-2020](#).

- [OpenOximetry Collaborative Community](#) 
- [The Implantable Brain Computer Interface Collaborative Community \(iBCI-CC\)](#) 
- [Smart and Autonomous Medical Systems \(SaAMS\) Collaborative Community](#) 



*Excerpted from FDA Collab Community Page [https://bit.ly/FDA\\_CC\\_SaAMS](https://bit.ly/FDA_CC_SaAMS)*

## What can the SaAMS Collaborative Community deliver?

Deliverables are focused on **pre-competitive** evidence to support the safety and efficacy of SaAMS

- Concept(s) of operation of SaAMS systems including descriptions of clinical scenarios to assure conceptual interoperability
- Description of system components, architecture, and the requisite device data and control commands to assure safe operation, and to support re-use of sensors and actuators (aligned with Medical Device Interface Data Sheets – MDIDS *DOI: 10.1213/ANE.0000000000004251*)
- Use-case specific best practices
- Safety Assurance Case(s) and a shared risk model
- Considerations for implementation in Integrated Clinical Environments (ICE: AAMI 2700-1) on platforms with interoperable, actuators, sensors, and smart clinical algorithms
- Data logging / black box recorder requirements for quality assurance (AAMI 2700-2-1)
- Test methods – failure modes, fallback state(s), interoperability, communication degradation
- White papers, presentations, publications, content for inclusion in industry consensus standards

## Some Benefits of the SaAMS Collaborative Community

- Access to pre-competitive risk management information
  - Avoids starting risk-analysis from scratch
  - Build on reasonably mature and robust information; instantiate for specific applications
  - Customize for intended use and hardware platform
- Medical device manufacturers & innovators can incorporate SaAMS information into their own product-development process
  - Prospective clinical applications for SaAMS
  - Clinical ramifications of using SaAMS
- Include input from expert clinicians, researchers, and manufacturers

# Formation of the SaAMS Collaborative Community

- 2010 Follow-on to **FDA Interoperability Workshop**, MGH MD PnP Program-led 20-organization (including FDA) collaboration “Medical Device Interoperability Safety Working Group”. Developed “Mock” Pre-submission for medical device interoperability. Provided foundation for FDA Guidance on interoperability (2018).
- 2020 MGH SaAMS Lab established to provide publicly-accessible medical device and system engineering services to accelerate the development and adoption of innovative medical device and digital health technologies and platforms. Based at the Massachusetts General Hospital Department of Anesthesia, Critical Care, and Pain Medicine, MD PnP Program\*.
- 2020 SaAMS **public collaboration initiative** proposed at Society for Technology in Anesthesia annual meeting
- 2023 MGH SaAMS [Center](#) for Smart and Autonomous Medical Systems (SaAMS) established at MGH
- 2023 **SaAMS Collaborative Community program established** at MGH Center for SaAMS and MD PnP Program.
- 2023 SaAMS Collaborative Community [webpage](#) and sign-up form were created. <https://bit.ly/SaAMS>
- January **2024 SaAMS panel and breakout session** at Society for Technology in Anesthesia meeting. Over 40 clinician and medical device manufactures signed up to participate in Collaborative Community using public sign-up page.
- January 2024 SaAMS Collaborative Community panel presentation and breakout session at annual **Society of Critical Care Medicine** meeting. SCCM is identifying participation pathway.
- February 2024: **American Society of Anesthesiologists** membership pending Executive Committee approval.
- March 2024 **Anesthesia Patient Safety Foundation** membership pending Board approval.
- April 30, 2024 – **FDA formalizes membership in MGH SaAMS Collaborative Community.**
- June 3, 2024 - **U.S. Army's Telemedicine & Advanced Technology Research Center (TATRC)** formalized participation

\* MD PnP - Medical Device “Plug-and-Play” Interoperability & Cybersecurity research program, based at MGH Dept. of Anesthesia, Critical Care, and Pain Medicine. PI – Julian M Goldman, MD



# Who is participating in the SaAMS Collaborative Community?

- Participants in the MGH SaAMS Collaborative Community include a wide range of experts:
  - manufacturers
  - clinicians
  - engineers
  - researchers
  - government agencies
  - Societies (medical, engineering, regulatory, etc.)



<https://bit.ly/SaAMS>



U.S. Army  
Telemedicine & Advanced Technology  
Research Center



Industry members will be announced shortly

## **It is anticipated that the SaAMS CC will begin with the following projects**

1. ACLIVA – identification and documentation of current barriers to advancing Automated Closed Loop IV Anesthesia
2. Externally controllable IV infusion pumps – current barriers to marketing
3. Risk management and safety considerations for SaAMS - safety requirements and test methods
4. Test bench/test bed for verification and regulatory support
5. Cybersecurity applicable to SaAMS – strategic assessment and pathway to advancement

## SaAMS projects may spawn work streams such as:

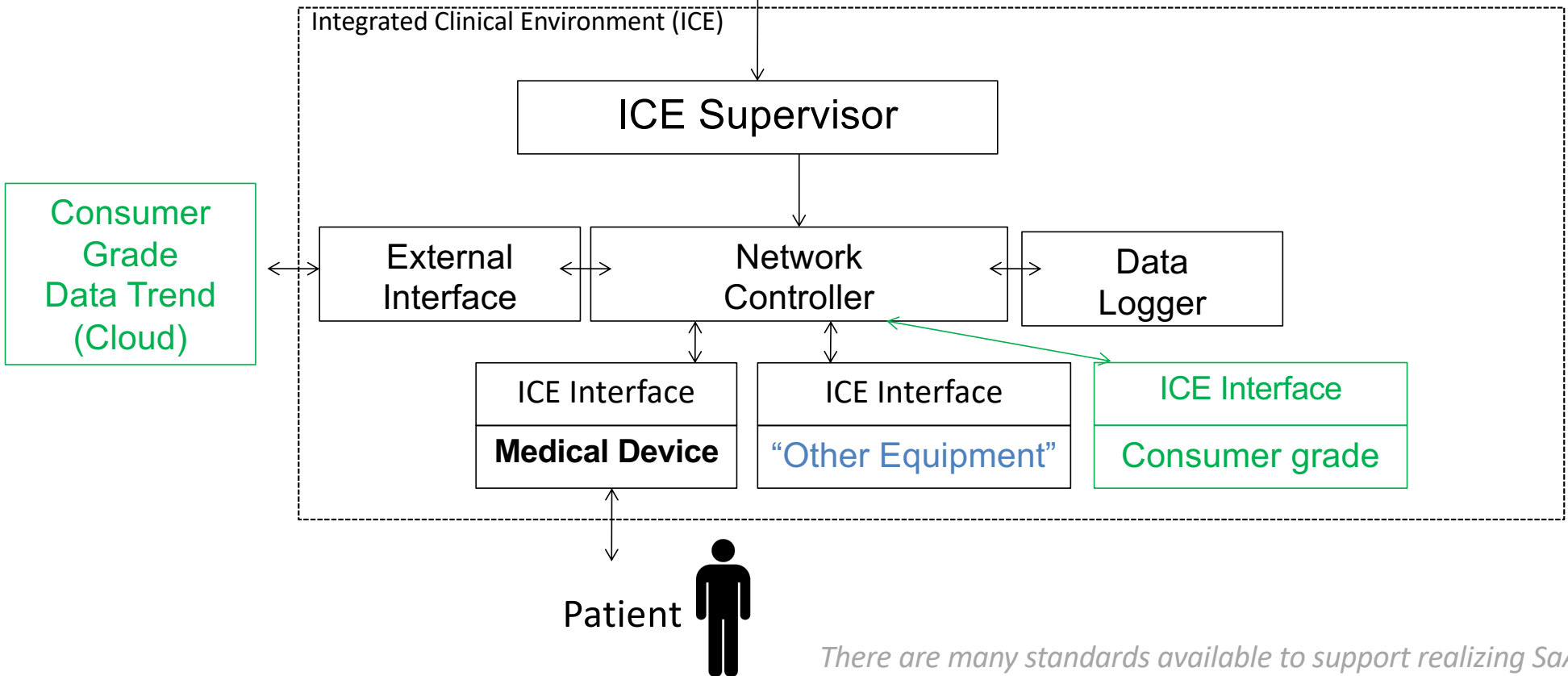
- Medical Device Informatics related to medical device command and control:
  - Selection and analysis of data communication patterns and quality of service requirements for reliable medical device control
  - Nomenclature to support interoperability of IV pump control commands
  - Requirements to achieve functional safety of networked systems that require high levels of safety and reliability for SaAMS
- Hardware-in-the-loop testbeds for ACLIVA device interface, component, and system testing
- Guidelines and test methods for demonstrating equivalency for interoperable sensors, actuators, and applications

Example: Application of ICE architecture to deploy SaAMS, demonstrating “medical grade” and “consumer grade” devices connected in the patient environment, and connected through the cloud.

## Integrated Clinical Environment AAMI 2700-1 (2019)



Clinician



*There are many standards available to support realizing SaAMS*