

MGH Medical Device Plug-and-Play (MD PnP) Interoperability and Cybersecurity program

Program Overview

The Medical Device Plug-and-Play Interoperability and Cybersecurity (MD PnP) Program, founded in 2004 at the Massachusetts General Hospital is recognized as a leader in enabling healthcare technology transformation to improve patient safety and clinical outcomes.

Our team of clinicians, computer scientists, and biomedical engineers collaborate with a global network of experts to define, develop, and demonstrate next-generation medical system capabilities to improve care delivery and serve as a foundation for next-generation Smart and Autonomous Medical Systems (SaAMS).

The MD PnP Lab in Cambridge, Massachusetts provides a sophisticated sandbox environment, including a wide range of medical devices, a highly configurable network infrastructure, and rich simulation and testing tools. This vendor-neutral environment is used to expedite the design, testing, and deployment of innovative solutions. The program has its roots in the MGH Operating Room



of the Future project, where rapid technology assessment and deployment was essential to achieving the project's mission.

The MD PnP Program has served a variety of commercial, academic, and governmental collaborators for the development and assessment of medical devices, digital health solutions, and hospital IT systems related to safety, security, and



interoperability. For example, the program supported national medical technology responses to Ebola Virus Disease in 2014 and the COVID19 Public Health Emergency, with an emphasis on virtual critical care and remote medical device control.

We have been accomplishing our programmatic mission with over \$30M of support from governmental agencies (NIH, NSF, DoD, DHS, FDA, NIST) and commercial entities, and through pre-competitive research collaborations with the US Food and Drug Administration (FDA) and other government agencies.

Lab Facilities

The MD PnP Program is located at 65 Landsdowne St. in Cambridge, MA. Our custom-built 3200-sq. ft. lab suite comprises four distinct labs for biomedical electronics, interoperability, cybersecurity, and EHR integration. Our lab suite is equipped with numerous medical devices,

patient simulators, testbeds, and supporting medical (hospital) facility infrastructure. The lab is designed to be highly configurable, so that diverse clinical-care settings can be simulated to support a wide range of use cases and technology solutions.

MD PnP Program Capabilities and Services

The MD PnP program has established a wide range of lab capabilities to provide world-class services to collaborators across the digital healthcare ecosystem:

1. Clinical System Integration and Interoperability Assessment and Testing

• Apply systematic analysis and testing for evaluating health technology as it relates to clinical workflow, cybersecurity, systems safety, and interoperability, to support care delivery. This can facilitate deployment and de-risk innovative digital health technologies.

2. Cybersecurity Risk assessment

• Product lifecycle assessment - analysis of hazard, risks, and operational viability of risk-control measures.

3. Pre-Deployment Evaluation and Testing

• Performance assessment and testing for early detection, evaluation, and mitigation of clinical integration issues in a simulated hospital setting.

4. Technology assessment

- Hazard identification, usability gap identification of device/system.
- Identification and documentation of pre-clinical deployment considerations.

5. Medical system engineering

Evaluate concept of operations / system requirements to assure safety and inform product development, focusing on device informatics.

6. Medical IoT

Provide controlled, representative, hospital and or novel healthcare environments for testing of medical IoT and wireless technologies.

Web Resources:

MGH Program web site: <u>https://mdpnp.mgh.harvard.edu/</u> Projects and Themes page: <u>https://mdpnp.mgh.harvard.edu/projects-themes/</u> Program services page <u>https://mdpnp.mgh.harvard.edu/services/</u>

Joint Warfighter Medical - *Enhancing Healthcare Through Interoperability* <u>https://cdmrp.health.mil/jwmrp/research_highlights/20goldman_highlight.aspx</u>

US DoD Virtual Critical Care demonstrations:

December 2021: <u>https://vimeo.com/channels/tideremotecontrol/658588736</u> November 2022: <u>https://vimeo.com/channels/tideremotecontrol/784432343</u>

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