European Commission

MedSecurance

Advanced Security-for-safety Assurance for Medical IoT

The MedSecurance project will develop novel methodologies, infrastructures, and technologies that enable an effective, harmonious and continuous development and evolution of secure Internet of Medical Things (IoMT). The project advances knowledge and understanding for decision-making in diverse IoMT security threat landscapes based on different system and component level interactions and interdependencies, and will provide scalable and verifiable secure system engineering management solutions that capture, communicate, and act on these complexities in order to improve cyberdefence while automating cybersecurity assurance.

AT A GLANCE

Project Title
Advanced Security-for safety Assurance for Medical IoT

Project Coordinator
Unparallel Innovation (PT)

Partners
BioAssist (EL)
CEA (FR)
Doccla (SE)
European Federation for Medical Informatics (CH)
European University of Cyprus (CY)
Hospital Garcia de Orta (PT)
Hygeia Hospital (EL)
Polytechnical University of Catalonia (ES)
STAB VIDA (PT)
The Open Group (UK)
University of Birmingham (UK)
University of Warwick (UK)

Duration
01.2023 – 12.2025

Total Cost
7.507.172 €

EU Contribution
4.792.358 €

Programme
HORIZON-HLTH-2022-IND-13-01 / Enhancing cybersecurity of connected medical devices

Further Information
www.MedSecurance.org

Context and Motivation

The health industry is a key driver for growth in the EU and has the capacity to provide technologies that benefit both patients and providers of healthcare services. The value chains involve a broad variety of actors from supply, demand and regulatory constituencies. In addition, the pathways for innovation in healthcare technologies are often long and complex. The development of novel healthcare technologies often encounter market barriers due to highly demanding quality and security requirements (e.g. clinical performance, safety, data privacy and cybersecurity) and market specificities (e.g. strong regulation, pricing and reimbursement issues). In addition, the growing concern for environmental issues is putting increased pressure on the healthcare industry. These combined challenges create a pressing need for research and innovation integrating various EU stakeholders to achieve innovative digital health technologies.

Escalating Threats

Innovations in medical device software development practices and tools provide the most promising solutions to address the complexity of increasingly connected medical devices and the escalating threat environment in which they operate. However, substantial technological challenges remain in achieving interoperability, dependability and trustworthiness at scale within the diverse commercial EU medical device market.

Project Approach

MedSecurance ambitions will be achieved through five objectives addressing the evolving security challenges of today's connected medical devices:

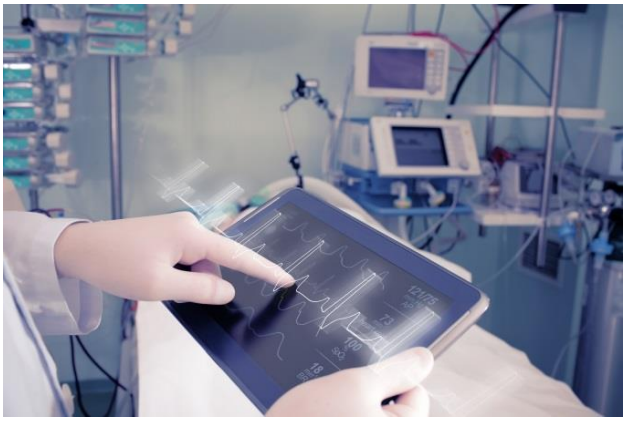
- Systematic review, concept, and gap analysis of security approaches for the Internet of Medical Things (IoMT)
- Development of harmonised tools and methods for the unification of automated security and safety assurance for certification of IoMT
- Development of a Security Assurance Automation Toolbox that accelerates and lowers IoMT certification costs
- Verification and Validation of the methods and tools by industry
- Updated regulatory recommendations, industry access and engagement of stakeholders

MedSecurance will develop an Assurance Toolkit with a number of innovative tools for healthcare architectures that will allow security to become an integral part of the development of European digital health services.

Solution

The MedSecurance concept has three methodological pillars as its foundation:

- **Security analysis discipline** – to assure that the threats are effectively countered, MedSecurance will apply well-proven standard security description references and data for analysing threats, vulnerabilities, weaknesses and attack patterns and disciplines for deriving an actionable set of objectives and requirements.
- **Techniques and tools to automate development of a Certification Assurance Artefact** – effective techniques and tools are essential to cost-effectively achieve compelling and repeatable assurance results. Analysis on design and implementation artefacts will generate evidence required to support the certification arguments.
- **Guidance and standards to achieve industry-wide interoperability with safety and security** – using standards to implement security and safety by design as a basis for industry-wide secure interoperability. Standards are essential for commercial success in any inter-operation endeavour as they enable multiple vendors to achieve interoperability without exponential effort.



Key advances and innoviations will be addressed through research and development tasks in the following technology areas:

- Threat, vulnerability and risk analysis for IoMT
- Architecture and design modelling and analysis for IoMT
- Formal methods for critical IoMT requirements
- Ontologies for interoperability and to support security and safety of IoMT
- Security and safety by design with support for composition
- Automated certification assurance artefacts for IoMT

Expected Impact

The European medical technology market was estimated to be roughly €140 billion in 2020, with Europe representing 27% of the worldwide market, and is forecast to grow at a CAGR of 7.5% through 2026. The three major medical device user categories are Hospitals, Clinics and Home Care Settings -- each of which is represented by the three Use Cases included in the MedSecurance project. MedSecurance will deliver to Europe's healthcare industry substantial benefits in the following areas:

- New measures to identify and address cybersecurity risks and gaps
- Risk benefit analysis and decision making capabilities for IoMT cybersecurity
- New methodologies and a assurance toolbox for ensuring IoMT cybersecurity
- New guidance covering challenges posed by connected medical devices
- Maintaining the performance of connected medical devices while enhancing safety, security, data confidentiality, integrity and availability

MedSecurance will lower the development costs and deliver greater assurance of the security, safety, and dependability of connected medical devices for a wide range of healthcare applications.

The MedSecurance project has received funding from the European Union's Horizon Europe Research and Innovation Programme under grant agreement No. 101095448.