PRESS RELEASE

Bringing benefits to patients and public health through efficient and effective safety-certified upgrades for AI-enabled medical devices

Paris, 27 January 2021- The PENTA project, Vivaldy (VerIfication and Validation of Ai-enabLeD sYstems) aims to allow medical devices such as those used in the analysis of medical images and in minimally invasive surgery to be upgraded more easily and frequently, but with full safety certification. This will bring improved quality of care, help patients better engage with their care, and allow healthcare systems to adapt quicker to fast-changing public health challenges. In technical terms, its goal is to develop efficient re-verification and re-validation and effective regulatory approval guidelines for the incremental upgrade of class II[1], AI-enhanced Cyber Physical Systems (CPSs) in the professional healthcare domain.

Many of today's medical devices incorporate CPS – systems that interact both with computing capabilities built into the product and directly with the physical world (e.g. a monitoring system that reacts to sensors on the body). Often, these devices also include Artificial Intelligence (AI) which enhances their utility. For instance, AI helps doctors spot critical diagnostic information in scans, while CPS and AI in X-ray systems guide doctors during extremely precise minimally invasive procedures.

Given that patient safety is always paramount, these devices require lengthy certification by relevant authorities. However, CPS and AI are rapidly evolving fields and there are currently no guidelines to allow for frequent incremental upgrades so such medical devices can keep pace with the latest advances. The Vivaldy project seeks to solve this issue by developing techniques that enable upgrades to be implemented and re-certified more efficiently. Major system upgrades could happen once a year instead of every three years, and module and/or AI upgrades every six months instead of once a year.

To achieve these ambitions, the project partners bring expertise in medical devices, medical imaging analysis, visualization and simulations, software verification and impact analysis, and AI in medical applications. They aim to create a 'DevOps[2]' approach to verification and validation which involves integrating product development and the ability to deliver frequent upgrades into a single engineering approach.

Besides patient and healthcare provider benefits, the project will increase the competitiveness of European players in huge and growing global healthcare markets. The worldwide diagnostic imaging market is expected to

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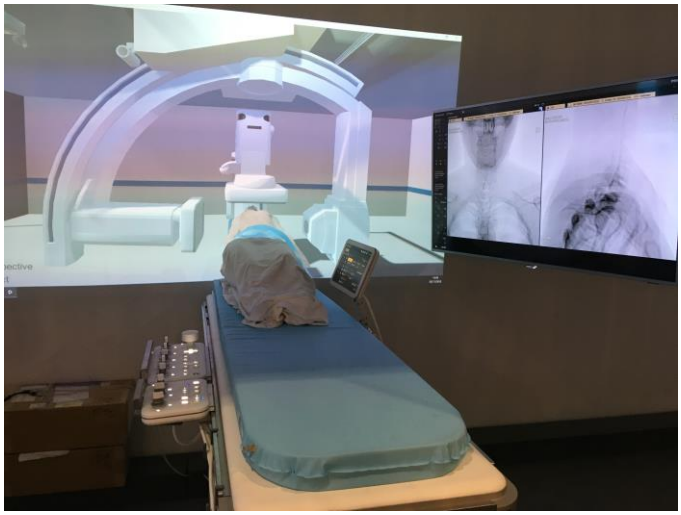
[1] The FDA classifies medical devices based on (a) their intended use and (b) upon their potential harm to a patient. Clinical decision support systems (i.e. systems that provide recommendation to a healthcare professional on a health condition) are generally classified as class II medical devices and must comply with stringent patient-safety requirements.

[2] DevOps integrates the two worlds of development and operations, using automated development, deployment, and infrastructure monitoring. It's an organizational shift in which, instead of distributed siloed groups performing functions separately, cross-functional teams work on continuous operational feature deliveries. This approach helps de-liver value faster and continuously, reducing problems due to miscommunication between team members and accelerating problem resolution

reach USD 36.4 billion by 2021, at a CAGR of 6.6% from 2016 to 2021[3]; while the global interventional radiology market, covering the complete spectrum of medical imaging systems, is anticipated to reach USD 22.9 billion by 2024, registering a CAGR of 5.8% over the period between 2016 and 2024[4]. In addition, the Vivaldy project will establish user groups with industry, regulators, researchers, and end-users to bring its results not only to healthcare but also to other safety-critical areas such as the automotive industry.



Virtual Test Platform- Copyright: Philips

About the PENTA programme

PENTA is a EUREKA cluster whose purpose is to catalyse research, development and innovation in areas of micro and nanoelectronics enabled systems and applications. Guided by the Electronic Components & Systems (ECS) Strategic Research and Innovation Agenda (SRIA) four technology layers, four cross-sectional technologies and six ECS key application areas, the PENTA programme enables the development of electronic solutions to help drive the digital economy through the formation of collaborative ecosystems along the ECS value chain. This creates the opportunity for rapid competitive exploitation and a strong impact on European societal challenges. PENTA supports SMEs, large corporations, research organisations and universities to work together in project consortia by facilitating access to funding, fostering collaborative work and creating consortia in areas of mutual industrial and National interest.

PENTA is managed by the Industry Association AENEAS

More on PENTA: http://www.penta-eureka.eu
More on AENEAS: https://aeneas-office.org

About the Vivaldy project:

Vivaldy is a RD&I project consortium involving 8 partners from 2 countries. The project partners are: Barco (Project leader), icometrix, Philips Medical Systems Nederland BV, TNO-ESI, TU Delft, Verum Software Tools BV, VITO NV, and Unit040. National funding support is provided by Belgium and the Netherlands.

About Vivaldy: https://www.vivaldy-penta.eu/

[3] Markets and markets – Diagnostic Imaging Market, February 2017
[4] http://www.transparencymarketresearch.com/interventional-radiology-market.html