PROJECT PROFILE

19021

Efficient re-verification and re-validation to enable rapid dissemination of innovations for AI-enhanced CPS in professional healthcare

[Vivaldy]

The Vivaldy (VerIfication and Validation of Ai-enabLeD sYstems) project is developing efficient re-verification & re-validation strategies and effective regulatory approval guidelines for the incremental upgrade of class II[1], AI-enhanced CPSs in the professional healthcare domain. Based on a 'DevOps' approach, it will enable rapid incremental dissemination of innovations, increasing the frequency of major system upgrades from every three years to once a year, and module and/or AI upgrades from once a year to every six months. This will lead to better responses to fast-changing public health challenges, along with improved patient engagement and quality of care, while ensuring patient safety remains paramount.

Increasingly, products of all kinds – from consumer appliances to medical devices – are becoming intelligent, connected, and linked to the physical world. They incorporate Cyber Physical Systems (CPS) which interact directly both with embedded intelligence and with the real-world physical environment. Today, advanced CPS are characterized by frequent incremental upgrades (software, hardware and modules) after the initial product release, and by the addition of Artificial Intelligence (AI) to enhance their utility. This poses challenges in applications such as professional healthcare. With patient safety of paramount concern, class II medical devices must undergo certification to demonstrate that they comply with stringent safety requirements. However, there are currently no regulatory guidelines for incremental upgrades. This limits the ability of such devices to be upgraded rapidly to respond quickly to emerging public health challenges and to benefit from evolving advances in CPS and AI. Moreover, if upgrades are carried out, the evidential value of the initial verification and validation (V&V) required for certification is rapidly lost.

Enabling a DevOps approach to re-verification and re-validation

The Vivaldy project will address these issues by developing efficient, model-based (virtual) re-verification and re-validation techniques for rapidly evolving and AI-based CPSs. It will research practical guidelines, supporting tools and methodologies for the re-verification, re-validation and certification of three distinct kinds of incremental upgrades for healthcare class II CPSs in a 'DevOps oriented' total product lifecycle approach: (i) hardware upgrade, (ii) component upgrade and (iii) software/AI upgrade.

'DevOps' is set of practices that combines software development and IT operations in order to shorten the systems development life cycle and provide for continuous delivery of high-quality software. Regulatory authorities such as the FDA (US), Notified Bodies (EU) and the CFDA (China) recognize the advantage of a DevOps release cycle for (AI-enhanced) healthcare to achieve the goals of faster public health responses and improved patient engagement and quality of care. The Vivaldy project will enable this paradigm shift by offering a total solution and guidelines for the transitioning from today's product-oriented development cycles to a DevOps driven, upgrade-oriented development cycle for professional healthcare solutions.

Five key innovation areas will be addressed:

1. Analysis of field-obtained user/usage data for re-training and incremental upgrade of AI components for clinical decision support; and secondly, for selection of the most significant verification and validation (V&V) activities to safeguard patient safety;
2. Hardware upgrade strategy for efficient re-V&V while improving the effectiveness, reliability and safety of CPSs for clinicians and patients after the upgrade;
3. Change-based impact analysis combining patient risk-based analyses with analysis of potential impacts on functionality, reliability and patient's or clinician's safety of individual upgrades to minimize overall V&V effort for certification;
4. Integration and test framework combining virtual (simulation models / digital twins) and physical testing for V&V without compromising on product safety for patients and clinicians;
5. Guidelines for regulatory approval addressing the current lack of incremental upgrade guidelines in conjunction with a relevant user group.

[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.

KEY APPLICATION AREAS

- Healthcare
- Digital Industry

ESSENTIAL CAPABILITIES

- Systems and Components Architecture, Design & Integration
- Safety, security and reliability

PARTNERS

Barco
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Philips Medical Systems Nederland BV
TNO-ESI
TU Delft
Verum Software Tools BV
VITO NV
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KEY PROJECT DATES

01 February 2020 to 31 January 2023

The results will be proven on four industrial use cases each targeting a specific type of upgrade ranging from hardware and components to AI applications. In addition, the project consortium will involve regulatory authorities and partners active in other safety-critical industry domains in order to benefit from developments in various fields.

Shared vision

The partners in the Vivaldy consortium bring expertise from a wide range of relevant fields including medical devices, medical imaging analysis, visualization and simulations, software verification and impact analysis, and AI in medical applications. They will leverage this joint expertise to enable the necessary paradigm shift from today's development-centric engineering towards an approach that considers the development and operational phases of CPS in an integrated way.

Commercial opportunities and markets

The initial target for the Vivaldy project is the healthcare market which requires systems and solutions that must remain fit for purpose over a long lifecycle. In particular, the project will lead to exploitable results in minimally invasive diagnosis and treatment, AI-enhanced clinical decision support systems and visualization solutions. Its outcomes will support rapid, cost-efficient re-verification, re-validation, and certification of incremental CPS upgrades that will allow the industry to respond more quickly and efficiently to the needs of its customers. In many cases, this will provide a competitive edge for medical device makers in the huge global healthcare market.

Worldwide, healthcare expenditure is currently estimated at USD7.6 trillion and its growth will continue to be greater than that of GDP, reaching double the rate in some countries[2]. Within the EU, healthcare including health & wellness represents up to 25% of the economy. In the areas of diagnostic imaging and interventional radiology, where Vivaldy's results have major potential, markets are growing significantly. The worldwide diagnostic imaging market is expected to reach USD36.4 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 USD22.9 billion by 2024, registering a CAGR of 5.8% over the period between 2016 and 2024[4]. Much of this growth derives from ageing populations, and the rise of chronic diseases, often resulting from lifestyle changes. In addition, AI is expected to bring important productivity gains in healthcare and AI applications could potentially create growth in the AI health market that could reach USD 6.6 billion by 2021 – a CAGR of 40%[5].

At the end of the project, the Vivaldy partners anticipate that its resulting innovations will be introduced step by step into product development processes. Consequently, AI-enhanced CPS medical devices that can be incrementally upgraded could be introduced on the market within three to four years. In the long term, through its interaction with the scientific community, industry, end-users, policymakers, regulatory and standardization bodies in various market segments, Vivaldy will help enable regulatory approval of AI-enhanced and incrementally upgradeable products in other safety-critical areas such as the automotive industry.

2 World Economic Forum, Value in Healthcare, Insight Report April 2017
3 Markets and markets – Diagnostic Imaging Market, February 2017
4 http://www.transparencymarketresearch.com/interventional-radiology-market.html
5 Frost and Sullivan, Cognitive Computing and Artificial Intelligence Systems in Healthcare, Dec 2015.

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