

SUMMARY PAGE

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TITLE OF RCA Project:

Evidence-based arguments to support assurance and qualification of medical devices

FDA Office/Center: Center for Devices and Radiological Health

FDA Principal Investigator: Mr. Paul Jones

Collaborator Organization: Gdańsk University of Technology (GUT), Gdańsk, Poland

Collaborator Principal Investigator(s): Prof. Janusz Górski

TERM OF RCA: Five (5) years from the effective date

ABSTRACT OF THE RESEARCH PLAN:

Software has become ubiquitous in devices and accounts for approximately 25% of adverse events recorded in FDA's Maude data base. It continues to grow in complexity as it takes on the role of many health care professional and physiological functions.

GUT is actively involved in researching evidence-based arguments and their applications in demonstrating both assurance and conformance in various application domains, including health, railways, automotive, oil & gas and others. Research results produced a mature tool, called NOR-STA that supports development, assessment and maintenance of argumentation structures and the related evidence.

Collaborative research issues to be explored include methods of structuring and assessing assurance cases, methods of integrating assurance cases with the results of hazard analysis (like hazard tables) and system models, developing modular assurance cases that follow system – component decomposition, and applying evidence based arguments to demonstrate conformity with reference safety and security standards.

This research applies to regulators, third parties, and manufacturers because it provides a means of improving the communication of large volumes of complex information between the stakeholders.

