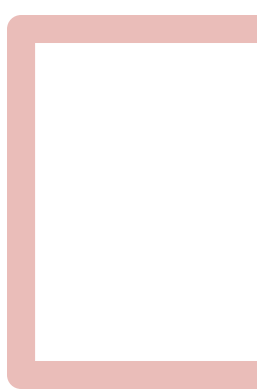


Regulatory and Standardization Challenges for Connected and Intelligent Medical Devices



Session Aim

- Share details of the **BSI-UCL collaboration** project with stakeholders of the medical devices industry
- Obtain **stakeholders' inputs** in 3 main areas:
 - Regulatory and standardization
 - Safety and security
 - Innovation and trends



Rules of Engagement for Breakout Session



Use Q&A feature to type inputs



Notes will be taken



BSI will be recording the session



Except for Zoom usernames, no personally identifiable data will be collected

SPEAKERS



Natalia Maj
Project Manager



Jiehui Song
Head of Policy
Communications

The STEaPP Project Team



Malla Tedroff
Head of Industry
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Dr Irina Brass
STEaPP Project Lead





Student Research Programme

- BSI publishes around 2,500 standards annually
- Research is often incorporated into the standards development process including postgraduate level
- The Student Research Programme matches postgraduate research projects with a BSI research need
- Find out more at bsigroup.com/SRP



bsi.

Matthew Chiles
Educational
Development

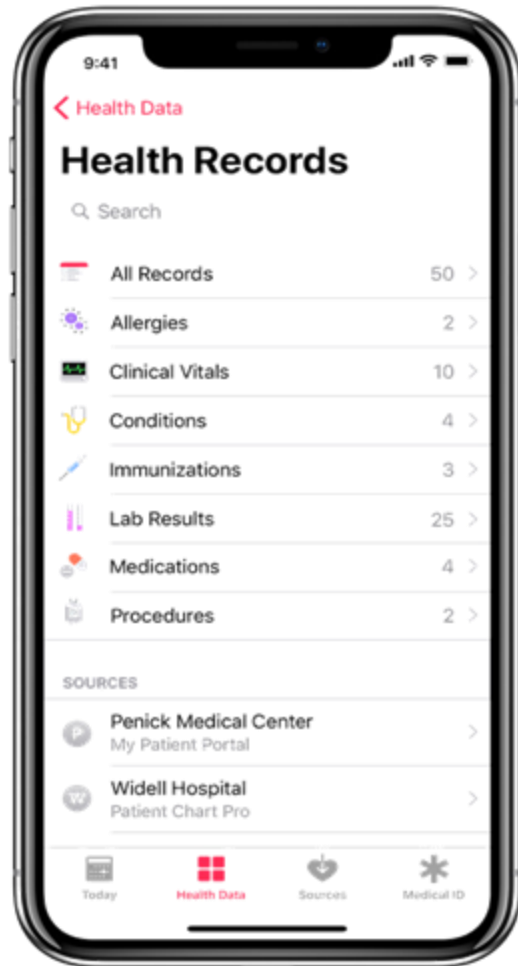
Gill Jackson
Research and
Insight Manager

Paul Sim
Medical Devices
Knowledge Manager

Rob Turpin
Head of Sector
(Healthcare)



Connected and Intelligent Medical Devices



- Medical devices are **highly regulated**, with numerous **standardization initiatives**
- Increasing connectivity to computer networks may introduce new challenges to the protection of **patient safety** and **device security**.
- New digital technologies **disrupt** the **established regulatory frameworks**
- Hypothesis - standards may offer **stability** and **predictability**

Project Aim



The **purpose** of this project is to:

- Analyse the role of **global standards** in addressing security of intelligent and connected medical devices
- Understand **cyber risks** across the entire supply chain
- Investigate the problems between **organisational boundaries**
- Explore the main **trends and innovations** emerging in the field of intelligent and connected medical devices

Research Methodology



INTERVIEWS



SURVEY



INDUSTRY
MEETINGS



LITERATURE
REVIEW



HORIZON
SCANNING





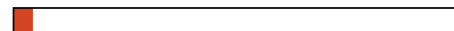
DEPARTMENT OF SCIENCE,
TECHNOLOGY, ENGINEERING AND
PUBLIC POLICY

Welcome to the University College London (UCL) - British Standards Institution (BSI) survey on the innovation journey and standards in the field on connected and intelligent medical devices.

This is a final research project of Master of Public Administration candidates at the UCL's Department of Science, Technology Engineering and Public Policy. The project is conducted in collaboration with BSI Knowledge Solutions. The project's duration is from February 2020 to September 2020. The purpose is to examine standardisation and regulatory challenges relating to the increased use of connected and smart medical devices. We are particularly interested in safety and security of connected and smart medical devices across the supply chain – the scope extends to standalone software and software incorporated into a physical medical device.

BSI is the UK's National Standards Body responsible for developing and publishing national and international standards. BSI consults with academic and industry experts, government bodies, trade associations and consumer groups to understand good practice and gain expert consensus in order to create standards.

This survey contains 19 questions and should take around 15 mins to complete.



Survey progress: 4%



Methodology Example: Survey



Break-out session structure

Regulation and
Standardization

Safety and Security

Innovation and Trends

Regulation and Standardization

- Do you see any regulatory gaps emerging in the field of intelligent and connected medical devices?
- Has the new Medical Device Regulation or the In Vitro Device Regulation had any impact on your work?
- How important are standards in this area in clarifying regulatory objectives?

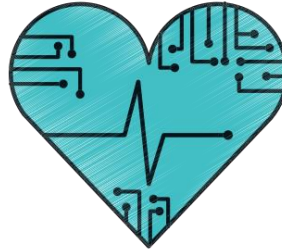


Safety and Security

- What do you think are the main security challenges across the supply chain for intelligent, connected medical devices?
- What do you think are the main problems for patient safety created by intelligent, connected medical devices?



Innovation and Trends



- What are the main trends and innovations you see emerging in the field of intelligent and connected medical devices?
- What are the key challenges or risks that these trends and innovations may create?
- How do you think regulations and standards could help to address these challenges?



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LINKEDIN

<https://bit.ly/3bqtDE9>



WEBSITE

<https://www.ucl.ac.uk/steapp/>

GET INVOLVED



● ● ● **THANK YOU !**

bsi.