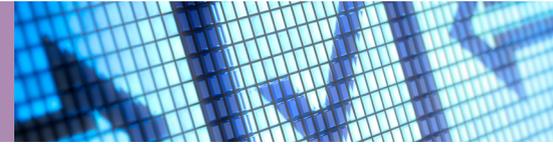


An Overview of the Regulatory Environment for Connected Health



Executive Summary

The regulatory environment is a critical aspect of all healthcare technologies for example, contact lenses, crutches, wound care, pregnancy tests, stents and medical device software. This report presents an overview of regulations associated with the medical device sector to inform Connected Health practitioners on relevant regulatory guidance. It identifies the importance of European and international standards and regulations. The concept of improved connectivity is a welcomed shift in healthcare but it does not just support greater efficiency; it transforms how we do things and even what can be done, how we exploit smart grids and Connected Health using embedded sensor networks.

Improved technology is enabling innovative collaboration and new types of partnerships, particularly between healthcare providers, governments and citizens. However, there can bring about both benefits and potential threats, social and economic alike and regulations play a central role to ensure safe and quality care continues to be the primary objective of Connected Health.

Commercial Opportunities for Industry

Developing processes to examine and align healthcare technology, mobile app development and Connected Health regulation should become another key future research focus within ARCH and industry partners. Overall, streamlining the process of understanding a regulatory environment to identify various bottlenecks can provide significant support to propel the Connected Health research and development agenda in Ireland. This also presents an opportunity to lead research in regulatory support services and develop methods to streamline regulatory decision-support. This could also potentially support quality management systems (QMS) and decision-making processes through a regulatory roadmap in Connected Health.

Connected Health can support the delivery of high-quality healthcare, and building on the concept of 'connectedness', can enable more accurate diagnosis and treatment through personalised care pathways and patient empowerment. In addition, we need to develop processes to support companies implement QMS knowledge systems within the Connected Health domain.

Companies with a commercial interest in these connected health opportunities or who are interested in collaborating with ARCH should contact the Project Co-ordinator on info@arch.ie or call 01 7165400.

Project Lead

Dr Noel Carroll
e: noel.carroll@lero.ie

Collaborators

S3 Group, Vitalograph, Novartis

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Data

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Report

**ARCH Industry Members have full access to this report*



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