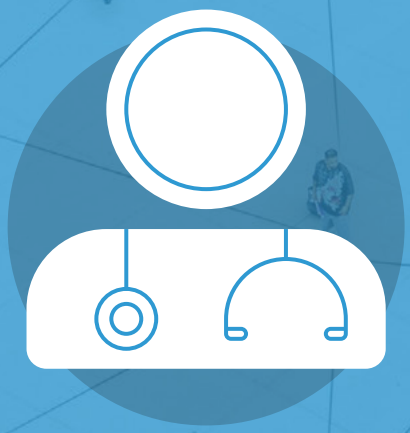

A Method of Justifying Confidence in the Safety of Digital Health Interventions

ETHOS blog from our Director

ETHOS

A Method of Justifying Confidence in the Safety of Digital Health Interventions

As co-founder of ETHOS, safety engineer, clinical safety specialist and all round digital health geek I spend most of my personal time researching elements of my PhD. I am studying at the University of Warwick's Institute of Digital Healthcare. Any time I have left is spent as project lead with the International Standards Organisation and an expert panel member with the BSI.

Digital health is a significant area of interest for me, not just a job. At ETHOS we like to share published papers and interesting contributions to the industry and this one concerns digital health interventions (DHIs).

DHIs enable improvements in health strategy and address health system challenges. The World Health Organization provides a formal classification for DHIs. However, safety claims, about such interventions, vary in quality and are often vague. Modes of communication between technical, clinical experts and stakeholders can be equally vague. By combining the DHIs with a method of safety analysis and justification, we postulate a level of confidence in the safety of digital technology. Confidence can result from the application of the framework to the DHI, using some well-defined health system challenges.

The framework and derived safety justifications can be applied to any DHI. It can serve as a guideline for health strategy, regulatory and standards based compliance.

A link to the full paper is here:

pubmed.ncbi.nlm.nih.gov/32604630/

The exponential growth, diversity of DHIs and associated regulatory positioning are some of the biggest challenges to the industry. Policy makers, manufacturers, health organizations and digital technology users (healthcare professionals and patients). This is one of our biggest challenge areas requiring further development and maturity of approach.

For more information about ETHOS safety and innovation work please find us on:

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