Prof. Dr. Stephen Gilbert



Head of the Group Medical Device Regulatory Science, Else-Kröner-Fresenius Center of Digital Health, Technical University Dresden

Role in LiSyM-Cancer

- Partner in DEEP-HCC
- Support and mentoring for LiSyM-Cancer on the quality requirements for medical devices, IVDR requirements and the AI Act
- Scanning of the LiSyM Cancer Implementation and Approval Landscape
- Prioritization of projects based on the LiSyM cancer implementation and approval
- Development of a regulatory strategy for the prioritized LiSyM cancer implementation projects

Expertise

- Medical Device Regulatory and Certification policy and strategy expert
- Regulatory requirements, especially for software as a medical device and artificial intelligence in medical devices
- Innovative approaches to regulation of healthcare of the future

Degrees

- 2005 – 2008, Doctor of Philosophy (Ph.D.), Computational Biology University of Leeds

Professional Experience

- Since 2022, Head of Medical Device Regulatory Science, Else-Kröner-Fresenius Center of Digital Health, Technical University Dresden
- 2019 – 2022, Clinical Evaluation Director, Ada Health, Berlin, Germany
- 2017 – 2019, Manager - Clinical Evaluation/Regulatory Affairs team at BIOTRONIK SE & Co. KG, Clinical Evaluation/Regulatory Affairs team at BIOTRONIK SE & Co. KG
- 2014 – 2017, Senior Post-doctoral Research, Max Delbrück Center for Molecular Medicine Berlin, Germany
- 2012 – 2014, Independent Post-doctoral Research Scientist, L'Institut de Rythmologie et Modélisation Cardiaque, Bordeaux Area, France
- 2008 – 2012, Senior Independent Research Fellow, University of Leeds

Publications

2025-07-18	Overcoming regulatory barriers to the implementation of AI agents in healthcare. *Nat Med*
2025-07-17	The barriers for uptake of artificial intelligence in hepatology and how to overcome them *Journal of Hepatology*