# Laws for a Genie: governance and evidence frameworks for large language model-based chatbots in medicine

##### Keynote Speech

The debate for how to regulate LLMs is one of the hottest topics of 2023 and has been addressed in speeches and articles by the German Health Minister, the CEOs of Google, OpenAI and Nuance, the FDA Commissioner and debated in the EU parliament and the US Congress. Some propose that LLMs will soon be the linkers/glue for interoperability in the management of health data and health delivery, managing the transformation of health data, its conversion to and from structured data, between ontologies, the magic wand resolving health software and data interoperability questions, and the massive data synchronisation challenges in healthcare. Indeed, products offering some of these use cases are already on healthcare markets. There is great medical potential for Large Language Model (LLM)-based generative chat tools, such as ChatGPT or Google’s MedPaLM. However, LLM’s underlying approach has no model of medical “ground truth”, which is dangerous in medicine [1]. Chat interfaced LLMs have already provided harmful medical responses and have already been used unethically in ‘experiments’ on patients without consent. Almost every medical LLM use case requires regulatory control in the EU and US – some developers and understand this well, but others are either unaware or decide to ignore this to the risk of patients. In the US their lack of explainability disqualifies them from being ‘non devices’. LLMs with explainability, low bias, predictability, correctness, and verifiable outputs do not currently exist, and they are not exempted from current (or future) governance approaches. I will address the limited scenarios where LLMs could find application under current frameworks, and we explore the development of frameworks that preserve patient safety.

## Speaker

| Stephen Gilbert | Stephen Gilbert is Professor of Medical Device Regulatory Science at the Else Kröner Fresenius Center for Digital Health, Technische Universität Dresden where he teaches and conducts research on regulatory science with a team of colleagues. He worked in senior MedTech and Digital Heath roles in industry for 5 years, before returning to academia in 2022.  His research goal are to advance the regulatory science of software as a medical device and AI-enabled medical devices. Innovative digital approaches to healthcare must be accompanied by innovative approaches in regulation to ensure speed to market, to maximum access of patients to life saving treatments whilst ensuring safety on market. My main research interests are in: (i) data sharing and the European Health Data Space; (ii) approaches to market approval of adaptive AI enabled medical devices; (iii) drug<->digital/AI-enabled medical device product realisation; (iv) digital/virtual twins: as an organising concept of the future of healthcare. |
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