

## Translational Imaging Center, Bern: Ongoing Projects

Lecture series with speakers from Bern organized by the Translational Imaging Center @ sitem-insel in Bern on current projects at our center

# How the EU MDR and its Swiss implementation affect human research: the example of academic MR studies

**Prof. em. Christoph Boesch, PhD**

Universität & Inselspital Bern, Magnetic Resonance in Medicine Group

**Wednesday, November 5<sup>th</sup> 2025, 16:00**

Several defective medical devices have caused serious harm to patients, prompting the European Union to introduce the Medical Device Regulation (EU-MDR). Although well-intentioned, the MDR contains inherent weaknesses that create excessive administrative complexity. Large manufacturers can manage this burden through dedicated compliance departments or external consultants, but academic researchers often lack the resources and expertise to navigate these requirements, resulting in significant delays - particularly in MR research.

In 2024, the ESMRMB established the EU-MDR Working Group to identify key challenges and explore possible solutions. Some issues lie beyond the influence of the MR community, as the MDR is primarily designed for CE-conformity assessments rather than for academic research. Even clearly safe modifications, such as adding a few new lines of sequence code to an MRI protocol, can trigger lengthy regulatory procedures.

Other challenges, however, can be addressed within the MR community itself. Regulators and researchers often “speak different languages,” and dedicated MR expertise is largely absent among authorities, who must oversee thousands of different types of medical devices. A concise “MR Essentials” guide could help bridge this gap. Conversely, MR researchers often lack familiarity with regulatory terminology and hypothesis-driven study design, both of which can and should be strengthened. This presentation will summarize the current findings of the working group and outline potential solutions that can be implemented at the level of the MR research community.

**The lecture will be held as in-person meeting at Inselspital, Anna Seiler Haus (ASH), Konferenzraum U1\_006, followed by an Apéro.** In addition, the talk is broadcast via zoom @:

<https://unibe-ch.zoom.us/j/61954796127?pwd=b25nSWVlVl9PWlV4Vlp3NXpMdjRQdz09>

Spread the word to anybody potentially interested (for further info: [bernd.jung@insel.ch](mailto:bernd.jung@insel.ch)).