11.30 - 13.00 @Balcony Room

From Data Return by Design to Ethical Secondary Use: A Scalable Approach to the Governance of Clinical Trial Data

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Health research and health data are crucial components in the "One Health" approach. With the recent adoption of the European Health Data Space (EHDS), new opportunities and challenges have emerged in the realm of health data governance. To navigate this evolving landscape, it is essential to implement structured, ethically sound, and legally compliant approaches. A core principle gaining traction is: start small, but start — engaging patients and stakeholders early, and learning together while adapting to shifting EU and global regulatory frameworks. This incremental approach allows for the development of scalable and responsible solutions informed by real-world experience.

In the clinical trial domain, the FACILITATE project has pioneered a patient-centric, "by design" model for responsible data governance. Through a repeated, dialogue-based process, the project has co-created a framework for the Return of Individual Participant Data (RoIPD)—going beyond access to general trial results to prioritize patient autonomy. This model offers adaptable, minimum guidelines for sponsors to support flexible implementation and promote broader adoption and interoperability. Another challenge is in the field of clinical trial data is its secondary use for future research. The principles and methodology developed by FACILITATE are promising to inform the secondary use of clinical trial data—ensuring ethical integrity, regulatory compliance, and public trust while unlocking the potential of data for meaningful research.

This session will discuss the following questions from academic, regulatory, patient, and industry perspectives:

- What does RoIPD "by design" mean, why is it important, and how can it be effectively implemented, considering the perspectives of ongoing industry initiatives, regulatory expectations, and the patient's voice?
- What ethical, legal and regulatory challenges in data return and secondary use?
- How can the same patient-centric principles can apply to broader secondary use of clinical trial data?
- What are practical strategies to test and refine solutions for responsible secondary use?