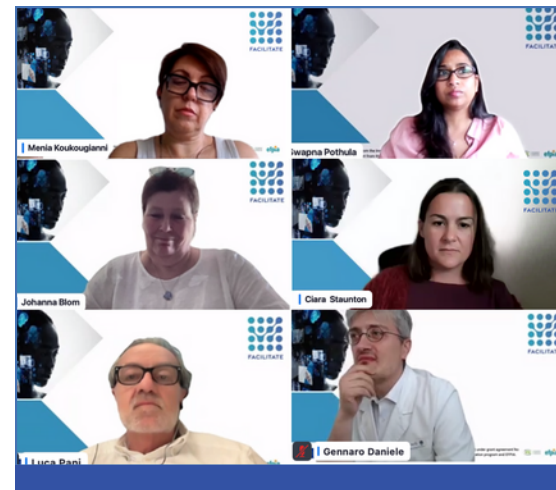# Let's FACILITATE

Newsletter

THE RETURN OF DATA IS BY DESIGN

The FACILITATE webinar **Return of Individual Participant Data (RoIPD) by Design. Where do we stand?**, held on 25 June, is now available online.   It was a rich and engaged discussion, which involved 186 attendees - patients, companies, researchers, CROs, health institutions and regulators - from 35 countries. The interactive conversation of the stakeholders virtual roundtable focused on the three fundamental concepts that define RoPID: patient-centric, flexible, and by design. Watch the webinar to learn more about the meaning of these new features.

Watch the webinar

ALL WE NEED IS TRUST

How can we truly put patients first when it comes to health data? Professor Johanna Blom, Coordinator of the FACILITATE project and Professor of Psychobiology at the University of Modena and Reggio Emilia (UNIMORE), shares her vision in this interview released to mark the 19th European Patients' Rights Day, 15th of May
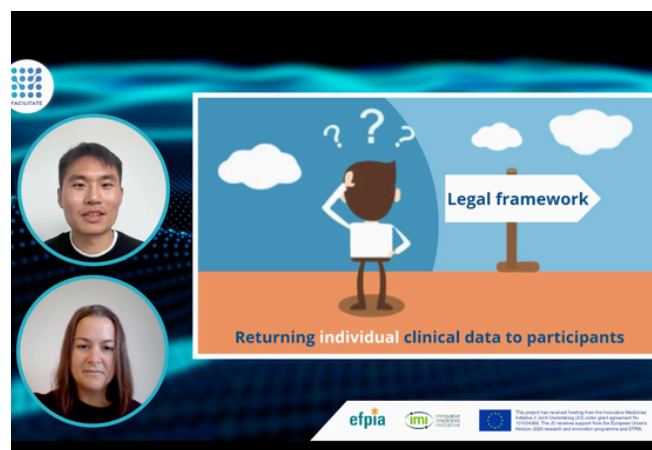
Watch the interview

THE LEGAL SIDE OF DATA RETURN

The videopodcast dedicated to the **role of the legal and ethical framework** of FACILITATE is online! Wenkai Li, legal researcher at Vrije Universiteit Brussel, and Ciara Staunton, legal and ethical researcher at UNIMORE, go deep into the legal challenges of returning individual clinical data to participants, a topic that's at the core of our patient-centric project.

The idea behind: simpler, clearer, and more consistent access to the individual data of clinical trial by participants. A process not easy, because of different systems, rules, attitudes and needs that make returning individual data very challenging. The analogy of the colouring book clarifies what is meant by legal and ethical framework in FACILITATE: law is the outline that gives the boundaries, the structure, while ethical principles are the colours that bring the picture to life.

Watch the videopodcast

A VERY SOCIAL ALLIANCE

Don't miss this animated video based on the opinion paper **The nexus of social alliances and Diverse Moral Domains**, where Professor Johanna Blom advocates for a social alliance as a primary objective in the clinical research setting. Blom explains how integrating transparency in sharing clinical trial data enhances trust, contributes to shared decision-making processes, and fosters a more participatory clinical research paradigm. The social alliance, as the authors envision it, represents voluntary collaborations between multiple entities with distinct structural nuances and requires mutual interdependence, authentic interest in others' well-being, and a commitment to support structures.

Watch the video

A TRUST TO BE BUILT

We are glad to share the new publication **Building trust in clinical research:** a systems approach to ethical engagement and sustainable outcomes, authored by Johanna Blom and colleagues of UNIMORE. This paper highlights how trust and trustworthiness are essential to the success of clinical research, influencing participant engagement, data integrity, and overall study outcomes.

The authors distinguish "trust in clinical research," referring to confidence in the ethical, procedural, and operational integrity of research processes, from "trust of clinical research," referring to confidence in the reliability, relevance, and societal value of its outcomes but also participant trust, emerging through direct engagement in the research process, and public trust, formed through broader social narratives and institutional reputation.

Building trust in clinical research: a systems approach to ethical engagement and sustainable outcomes

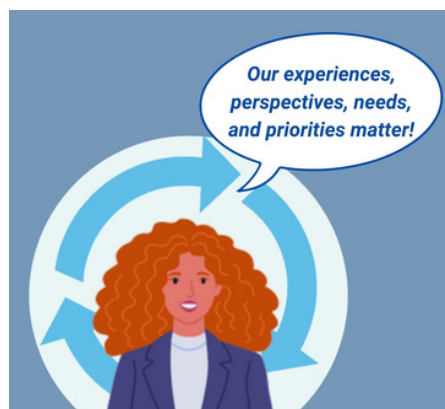Johanna M. C. Blom[1,2*†]   Veronica Rivi[1]   Fabio Tascedda[2,3,4]

Luca Pani[1,2,5†]

Read the full article

FACILITATE *Glossary* Patient-Focused Drug Development

A TERM, ITS PROPER MEANING

Do you know what "**Patient-focused drug development**" is? Enter the world of our patient-centric project and understand the meaning of terms related to the return of individual clinical trial data to participants with the support of FACILITATE **glossary.**

Go to glossary

Patient-Focused Drug Development is
a systematic approach that integrates **patients' experiences, perspectives, needs, and priorities** into the drug development and evaluation process.

Our experiences, perspectives, needs, and priorities matter!

Patient-Focused Drug Development aims
to move beyond traditional clinical trial endpoints and consider what **truly matters to patients** in their daily lives when living with a specific disease.