European Network of Trusted Research Environments

EOSC-ENTRUST workshop:

"Support of IPD meta-analyses through trusted research environments (TREs)"

Date & Time: 15 January 2025, 14h00-16h00 CET

Scope

As part of the EOSC-ENTRUST (European Network of TRUSTed research environments, https://eosc-entrust.eu/) project, funded by Horizon Europe (3 years, March 2024 - February 2027) and coordinated by ELIXIR, the workshop aims to explore opportunities and address challenges for improving meta-analysis of clinical trial data through faster, safer and more comprehensive data sharing within federated Trusted Research Environments (TREs). As part of a task led by ECRIN in collaboration with the University of Oslo, Health Data Research UK and the University of Dundee, the workshop will focus on enabling secure, legally and ethically compliant cross-border re-use of clinical research data.

Expected Outcomes

1. Identify and formalise the essential requirements for TREs to enhance individual participant data (IPD) meta-analysis capabilities.
2. Insights gathered during the workshop will contribute to the development of a European network of TREs dedicated to managing sensitive data securely and efficiently.
3. Outcomes will support the joint development of a common blueprint for federated data access and analysis, promoting interoperability across Europe.

Format

Two-hour virtual workshop consisting of a series of short presentations covering the EOSC-ENTRUST project, meta-analysis requirements, federated analysis, and TREs. The presentations will be followed by an interactive panel discussion designed to foster participant engagement.

Participants

The workshop will bring together experts from a range of key domains, including meta-analysis, statistics, data sharing, TREs, data repositories, e-infrastructures, federated analysis, legal and ethical frameworks, Health Technology Assessment (HTA), data standards, and representatives from DG-SANTE.

Please note

The workshop will be recorded for minute-taking purposes and internal use only.

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Programme

14:00 - 14:15	**Welcome, tour de table and setting up the scene** *Moderated by ECRIN Team*
14:15 - 15:05	**Presentations + Q&A**
14:15 - 14:25	**EOSC-ENTRUST and role of drivers** *Jan-Willem Boiten, Ligature & Health-RI*
14:25 - 14:35	**Requirements and challenges of IPD meta-analyses** *Matthias Briel, Cochrane & Basel Institute of Clinical Epidemiology*
14:35 - 14:50	**Pros & cons of federated analysis** *Blaise Thomson, Bitfount*
14:50 - 15:05	**Challenges for a federated approach of TREs** *Rob Baxter, DARE UK at HDR UK*
15:05 - 15:50	**Panel discussion with input from all participants**
	Panelists: Irini Kessissoglou, DG-SANTE, EC Martin Posch, SHARE CTD, MedUni Vienna Frank Hulstaert, KCE Irene Schlünder, BBMRI Barbara Bierer, Vivli
15:50 – 16:00	**Wrap – up and conclusions**

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Background information on Individual patient data (IPD) meta-analysis

IPD meta-analysis is a specific type of systematic review. Rather than extracting summary (aggregate) data from study publications or from investigators, the original research data are sought directly from the researchers responsible for each study. These data can then be re-analysed centrally and combined, if appropriate, in meta-analyses. IPD meta-analyses of clinical trial data enhance analytical potential, yielding more robust and reliable evidence[1,2].

There are many hurdles for IPD meta-analyses, including the findability, the accessibility and the re-usability of datasets. This is reflected in the low data sharing rates for IPD meta-analyses, which has been demonstrated in several studies and is still observed despite the various data sharing initiatives and platforms[3]. This situation is going to be improved by the new and forthcoming regulation (EHDS), better provision of Trusted Research Environments (TRE) for data analysis, and further developments of federated approaches and analyses.

The ongoing EU Horizon Europe funded EOSC-ENTRUST project (https://eosc-entrust.eu/) aims to create a European network of TREs for sensitive data and to drive European interoperability by joint development of a common blueprint for federated data access and analysis to support the development of the European Open Science Cloud (EOSC). EOSC-ENTRUST brings together providers of operational TREs from 15 European countries with a shared goal to implement, validate and promote their capabilities through a common European framework using shared standards and common legal, operational and technical language. EOSC-ENTRUST has identified four use cases, or drivers, as prototypes for federated, multinational use of TREs in research practice across scientific domains and user communities. Each driver highlights and validates specific aspects of the TRE functionality and represents different sectors (e.g. health, social sciences, public/private collaborations) which require secure and reliable sharing and analysing of sensitive data.

ECRIN together with HDR-UK and the University of Dundee oversees driver 3, “Enabling secure transnational re-use of clinical research data in a legally and ethically compliant manner”. In this use case, ECRIN has partnered with the University of Oslo (UiO) to design and operate a TRE adapted to the specific needs of the clinical research community and aiming to promote clinical research data sharing and reuse. This TRE will serve as a use case for establishing minimum requirements for clinical research data sharing (legal, operational, technical) and exploring interoperability requirements across different TREs that focus on clinical research and health. In this context, specific use cases have been designed, dealing with the requirements to support **IPD meta-analyses** based on an infrastructure of federated TREs.

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[1] Stewart LA, Tierney JF. To IPD or not to IPD? Advantages and disadvantages of systematic reviews using individual patient data. Eval Health Prof. 2002 Mar;25(1):76-97. doi: 10.1177/0163278702025001006. PMID: 11868447.

[2] https://methods.cochrane.org/ipdma/about-ipd-meta-analyses

[3] Ohmann C, Moher D, Siebert M, et alStatus, use and impact of sharing individual participant data from clinical trials: a scoping review.BMJ Open 2021;11:e049228. doi: 10.1136/bmjopen-2021-049228

The planned workshop is dedicated to the exploration of the options and challenges to improve IPD meta-analyses through quicker, safer, more efficient and more complete data sharing based upon federated TREs. Experts from different fields (meta-analysis, statistics, data sharing, TRE, repositories, infrastructures, HTA, data standards and ethical/legal aspects) will discuss the relevant issues. The objective is to define the requirements for a secure computational environment that supports IPD meta-analyses significantly better than is currently the case.