Together, for more equitable health

Once again IHI-FACILITATE project had a prominent space among the efforts devoted to responsible data sharing at the Drug Information Association (DIA) Global Annual Meeting hosted in San Diego from June 16-20, 2024.

On Wednesday, June 19, the project was introduced by Jean Stimola-Sposaro, MSJ, Human Advocate for Equity in Access and Informed Decision Making at Bristol Myers Squibb (BMS), as one of the most interesting initiatives that are working together with TransCelerate (https://www.transceleratebiopharmainc.com) to problem solve on the topics of clinical trial data return and reuse.

During her speech in the panel “Patient-Centric Approaches in Summaries and Individual Participant Data Return”, Stimola-Sposaro pointed out how FACILITATE is placing the patient at the core of all intersecting disciplines, with its joint purpose dedicated to improving study participants access to their individual health data generated during the study and conduct a

landscape assessment regarding the reuse of clinical trial data and its potential impact on scientific innovation and health equity.

FACILITATE's goals fitted perfectly within the panel's objectives, which were mainly:

- reflect on the concepts of inequality, equality, equity, and justice
- understand the broad scope and role of global industry collaborations with patients as enablers of scientific innovation, health equity, access, and inclusion
- discuss the value of linked patient-generated health data and the research and development of high quality, safe and effective new treatments
- illustrate the impact of advancing clinical study data sharing on the patient experience, increased understanding of patient safety, product effectiveness and evidence generation
- highlight patient-centric approaches and solutions developed to increase global commitments to the return of individual participant data and aggregate lay summaries, why it matters and what is changing
- identify how implementing risk based flexible/personalized approaches impacts essential informed decision making, trust in the research enterprise, scientific advancement, public health and the convergence of clinical care and clinical research.

Stimola-Sposaro continued by showing how clinical studies cannot be conducted without the people who choose to participate and how participants would like data they contribute returned to them during and after participation in clinical studies.
This is supported by data from a survey conducted in collaboration with the Center for Information and Study on Clinical Research Participation (CISCRP), that shows how 83% of participants want access to their own data/results and 80% of participants want access to overall results of the study.

After having illustrated some examples of Individual Participant Data Return, Stimola-Sposaro highlighted how these are different from the actual Layperson Summary Aggregate Results Return, the summary of the results of the clinical study written in plain language. She concluded with the hope that access to one's individual data will foster the establishment of a state of mind in which patients feel valued and respected for their contributions to clinical study.

This is FACILITATE's main take-home message: providing participants in clinical trials with the option to receive their individual data empowers them to be an equal partner and informed decision-maker in Europe.