

SHARE-CTD - Sharing and re-using clinical trial data to maximise impact

Data from clinical trials are a rich source of clinical information, highly structured and clearly explained by the accompanying protocols. Responsible sharing of such data holds incredible promises to increase value and decrease waste in medical research. It is built on principles (ethical, scientific), governance structures, skills, and operation infrastructure. Clinical trial data sharing (CTDS) is an emerging activity in academia as well as in the pharmaceutical industry. Both communities develop models for organising and performing CTDS. Thereby, several issues gain relevance: enhancing data sharing with researchers, improving public access to clinical study information, sharing results with patients participating in clinical trials, certifying procedures for sharing clinical trial information, and reaffirming commitments to publish clinical trial results. We see a developing field of professional activities that need well educated experts to define and implement best practices. Training such a new generation of experts in CTDS requires specific teachings with a focus on clinical trial transparency and reproducible research practices. It should include topics such as clinical trials regulations, ethical, legal, and social issues, informatics, data science, biostatistics, and meta-research, as well as domain expertise across different medical fields. In order to gain a deep understanding of this developing field, research activities should be based on meta-research approaches. Those activities focus on research on best practices for CTDS, developing methods to make efficient use of shared data (e.g. methods to augment randomised clinical trials, perform independent participant data meta-analysis, or estimate personalised treatment effects) and measuring CTDS impact.

Coordinator: Ludwig-Maximilians-Universitaet Muenchen

Beneficiary: Università degli Studi di Padova

UNIPD Supervisor: Ioana Alina Cristea

Department: Department of general Psychology

Total Contribution: € 259 437,60

Project Duration in months:

Find out more: https://cordis.europa.eu/projects/en