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CHAIR OF BIOMETRY AND BIOINFORMATICS
PETTENKOFER SCHOOL OF PUBLIC HEALTH

How and why to teach young medical scientists about clinical trials data sharing?

The SHARE-CTD project

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Conflicts of interest

I receive funds from the

- EU (MSCA-DN),
- German Research Agency (DFG),
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- German Ministry of Education and Science (BMBF).

SHARE-CTD

Cooperate to share and gain

- **Nine medical schools** from six European countries
- **Twelve partners** covering a wide range of data sharing activities.

Funded by
the European Union

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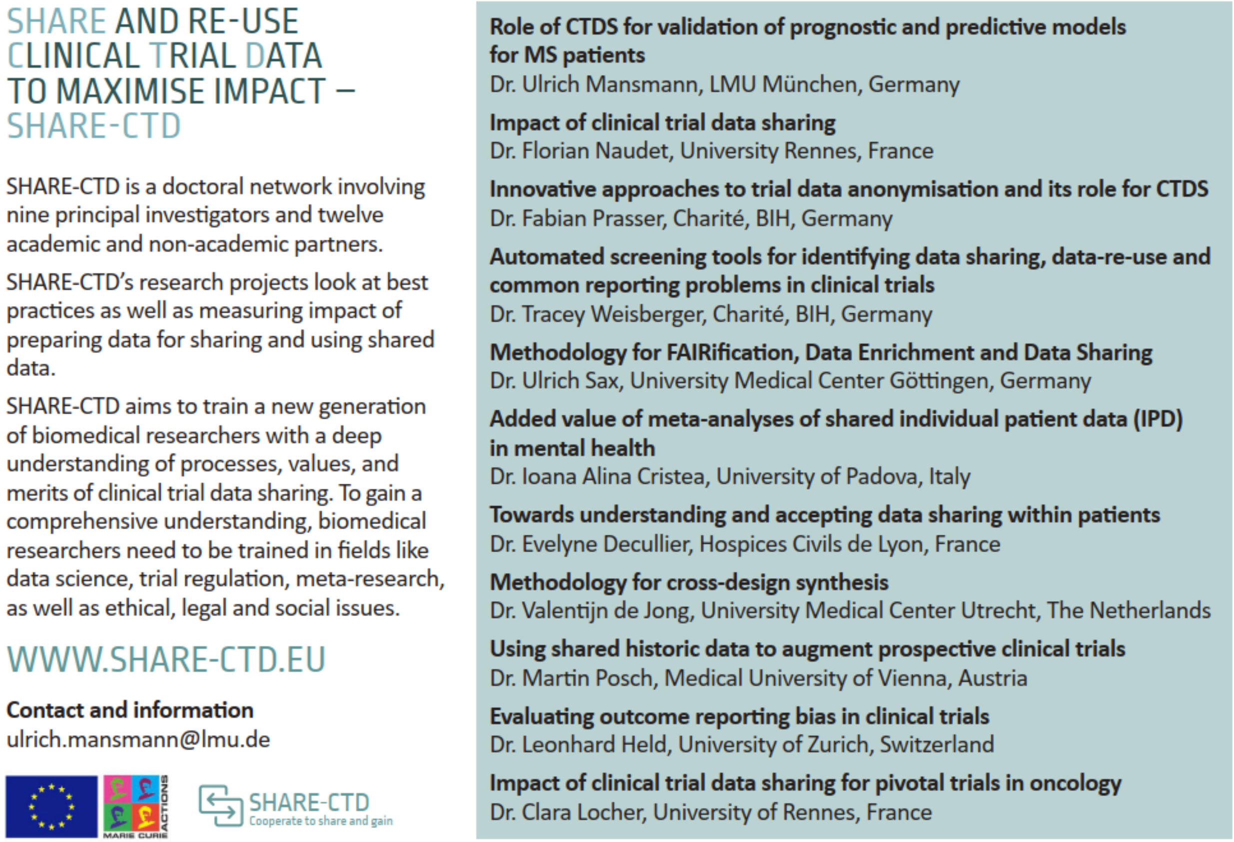
LMU Ludwig-Maximilians-Universität München
Università degli Studi di Padova
Universität Zürich
Universitätsmedizin Göttingen UMG
UMC Utrecht
BIH Berlin Institute of Health @Charité
HCL Hospices Civils de Lyon
Université de Rennes
Medizinische Universität Wien



SHARE AND RE-USE CLINICAL TRIAL DATA TO MAXIMISE IMPACT – SHARE-CTD

SHARE-CTD is a doctoral network involving nine principal investigators and twelve academic and non-academic partners.

SHARE-CTD's research projects look at best practices as well as measuring impact of preparing data for sharing and using shared data.

SHARE-CTD aims to train a new generation of biomedical researchers with a deep understanding of processes, values, and merits of clinical trial data sharing. To gain a comprehensive understanding, biomedical researchers need to be trained in fields like data science, trial regulation, meta-research, as well as ethical, legal and social issues.

WWW.SHARE-CTD.EU

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SHARE-CTD
Cooperate to share and gain

Role of CTDS for validation of prognostic and predictive models for MS patients
Dr. Ulrich Mansmann, LMU München, Germany

Impact of clinical trial data sharing
Dr. Florian Naudet, University Rennes, France

Innovative approaches to trial data anonymisation and its role for CTDS
Dr. Fabian Prasser, Charité, BIH, Germany

Automated screening tools for identifying data sharing, data-re-use and common reporting problems in clinical trials
Dr. Tracey Weisberger, Charité, BIH, Germany

Methodology for FAIRification, Data Enrichment and Data Sharing
Dr. Ulrich Sax, University Medical Center Göttingen, Germany

Added value of meta-analyses of shared individual patient data (IPD) in mental health
Dr. Ioana Alina Cristea, University of Padova, Italy

Towards understanding and accepting data sharing within patients
Dr. Evelyne Decullier, Hospices Civils de Lyon, France

Methodology for cross-design synthesis
Dr. Valentijn de Jong, University Medical Center Utrecht, The Netherlands

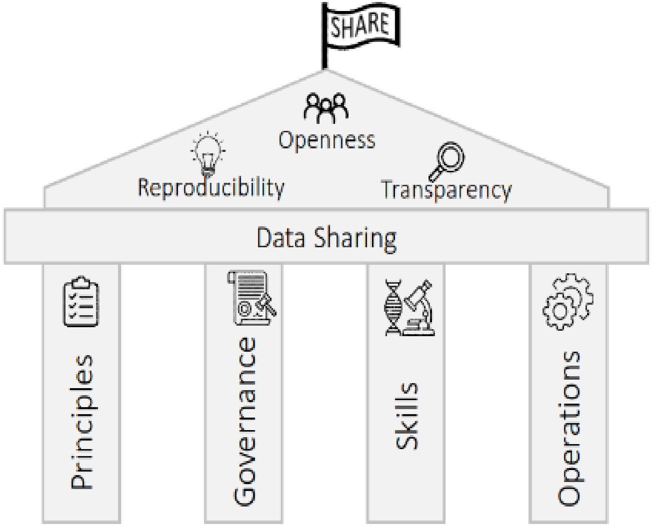
Using shared historic data to augment prospective clinical trials
Dr. Martin Posch, Medical University of Vienna, Austria

Evaluating outcome reporting bias in clinical trials
Dr. Leonhard Held, University of Zurich, Switzerland

Impact of clinical trial data sharing for pivotal trials in oncology
Dr. Clara Locher, University of Rennes, France

- **Eleven** individual scientific projects and
- **Six** joint projects (group papers)

Four pillars of data sharing and three specific foci



- Impact
- Practices
- Competences

https://pubmed.ncbi.nlm.nih.gov/36732626/

The State of Open Data November 2023 (Springer Nature Report)

- Support is not making the way to those who need it;
- One size does not fit all;
- Challenging stereotypes;
- Credit is an ongoing issue;
- AI awareness hasn’t translated to action.

Support is not reaching those who need it: Role models and roadmaps in different areas

- **Roadmaps for industry**: Infrastructure, big data agenda
- **Academic prospects**: Data Champions, Centers for Data Competencies, Biostatistic Units, Clinical Study Centers
- **Funders**: Promoting, reviewing, crediting
- **Journals**: Promoting, crediting, business models
- **Agencies**: Initiating and using clinical trial data sharing (CTDS)

take the stage as architect of a brighter scientific future

Six European academic medical research systems
Example Germany – stakeholder for academic CTDS

- NFDI
- DZ..(..HK, ..L, ..I, ..NE, ..KJ, ..PG)
- MII
- Specific medical societies
- AWMF: Working Group of the Scientific Medical Societies (Umbrella organization)

What SHARE-CTD can do: Collect ideas, set impulses, participate on opinion building, get in touch with stakeholders in different systems, provide synopses.

One size does not fit all: Why clinical trial data sharing (CTDS) ?

- **Data of high quality**;
- Well defined by a **PICO**;
- **Data with a rich set of metadata**: Protocol, DMP, DVP, SAP, Data dictionary, annotated CRFs, ….
- **Sharing platforms** are established and developing;
- Using the **multiversity of clinical trial data** for further research.

Our approach: Research, theory, practice, and communication

Understand challenges, leverages, and barriers to CTDS

Four pillars of data sharing:
Principles, Governance, Skills, Operations

Best practices: Sharing and using CTD

Meta-reserach to demonstrate relevance of CTDS

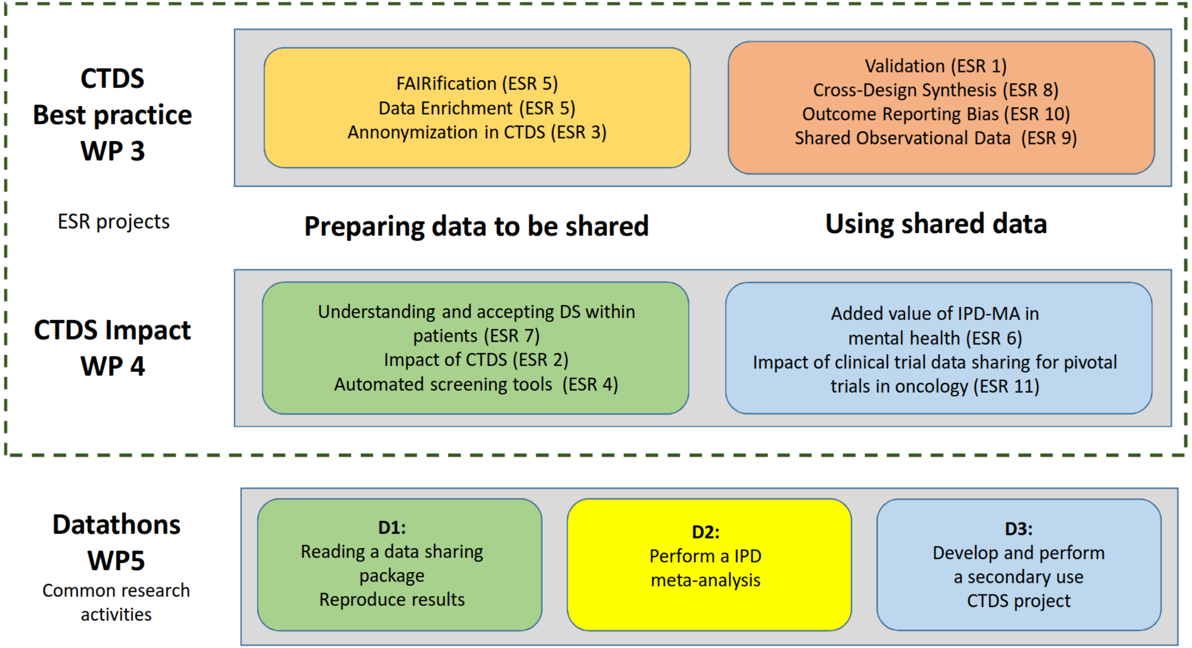
Strengthen sklills for collaborative and reproducible research

Use advanced methodology on CTDS

We are not frontrunners and thus can pair up with many consortia and projects that focus comparable intentions

CTDS: Clinical trial data sharing

Our approach: Research, theory, practice, and communication



CTDS
Best practice
WP 3

FAIRification (ESR 5)
Data Enrichment (ESR 5)
Annonymization in CTDS (ESR 3)

Validation (ESR 1)
Cross-Design Synthesis (ESR 8)
Outcome Reporting Bias (ESR 10)
Shared Observational Data (ESR 9)

ESR projects

Preparing data to be shared

Using shared data

CTDS Impact
WP 4

Understanding and accepting DS within patients (ESR 7)
Impact of CTDS (ESR 2)
Automated screening tools (ESR 4)

Added value of IPD-MA in mental health (ESR 6)
Impact of clinical trial data sharing for pivotal trials in oncology (ESR 11)

Datathons
WP5
Common research activities

D1:
Reading a data sharing package
Reproduce results

D2:
Perform a IPD meta-analysis

D3:
Develop and perform a secondary use CTDS project

Joint projects

- **Datathons**: Participants utilise the data provided to develop and answer topic-driven questions or to develop innovative approaches to analyse the data
- **Policies**: High grade convincing evidence on the value of CTDS for all stakeholders involved in therapeutic research
- **Communication**: Project webpage (share-ctd.eu), blog and social media, audio podcast, webinar series

We do not want to see all our DCs ending up in well functioning industrial data sharing infrastructures

- **Horrifying prospects** in the German academic system: Underfinanced and reluctant development
- **Challenging stereotypes**: we hope to meet an academic environments in which all members develop increasing enthusiasm and engagement into open science issues.

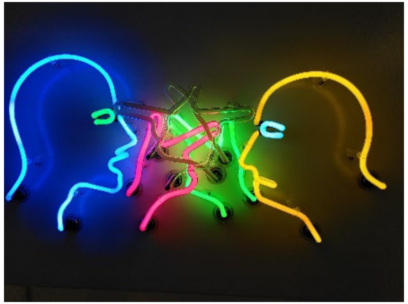
Using AI instruments

- Improve metadata
- Improve Data quality
- Improve proposals
- Help searching for papers and data

Leaving the closed circle of academia

- Enabling affordable citizen science: Issues related to adverse events and complications.

Research Integrity: Micro and macro level effects



- Improve your own working methods through intensive engagement with the fundamentals of research findings that are extremely relevant to your own work
- Establishing re- and sensitivity analyses as a counter-model to the current process of evidence production in medicine.
- The issue of robust results.

Many thanks for your attention

A landscape as seen from above

Additional slides

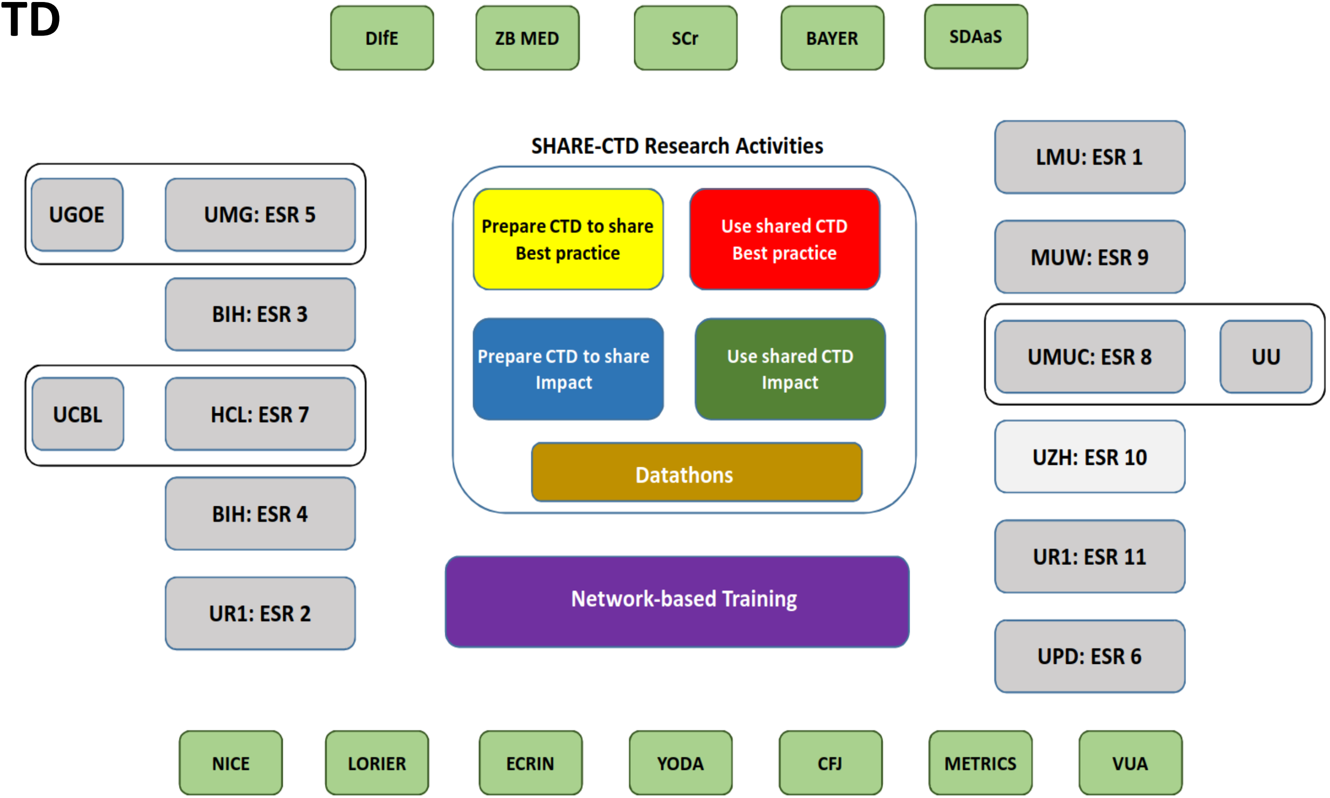
Responsible Data Sharing and Scientific integrity

- To understand what was done:
  Independent Sensitivity and re-analyses
- Exploring untapped information:
  Secondary analyses and IPD Meta-Analyses
- Leaving the closed circles of academia:
  Enabling affordable citizen science
- Scientific obligations:
  Maximize value and reduce waste

Best practices need specific infrastructures and a well trained research community

- Preparing data to be shared
- Establishing and using infrastructures to share data
- Reusing data to be shared: Designs and methodologies
- How to implement the new vision - Role models and road maps

The SHARE-CTD network



DIfE
ZB MED
SCr
BAYER
SDAaS

SHARE-CTD Research Activities

Prepare CTD to share Best practice
Use shared CTD Best practice
Prepare CTD to share Impact
Use shared CTD Impact
Datathons

Network-based Training

UGOE
UMG: ESR 5
BIH: ESR 3
UCBL
HCL: ESR 7
BIH: ESR 4
UR1: ESR 2

LMU: ESR 1
MUW: ESR 9
UMUC: ESR 8
UU
UZH: ESR 10
UR1: ESR 11
UPD: ESR 6

NICE
LORIER
ECRIN
YODA
CFJ
METRICS
VUA

Why to train young medical scientists on data sharing?

- Lack of data related skills;
- Not knowing what opportunities communication with data experts offers them for their research;
- Searching for and finding good data promotes your own research as well as the search for relevant literature;
- Making your own research data and methods accessible increases the thoroughness, transparency, and credibility of someone’s work.

The ubiquity of data and the related epistemic gap

- Data Science overtakes medicine: The self learning health care system