# The AUDiCT Project: Analysing and Understanding the Digital Transformation of Clinical Trials

Recent years have seen a dramatic uptick in the use of connected digital tools ("Digital Health Technologies") in clinical trials broadly, as well as in medical specialty areas such as Neurology (2). To date, most research documenting these trends has focused on the use of just one database of clinical trials, the U.S. clinical trial registry, ClinicalTrials.gov. These studies have provided compelling early evidence of how digital tools are being used to support biomedical research and have shed light on where new categories of medical products, such as digital therapeutics (3) are being developed. Yet there are challenges with existing data sources: While many are publicly available, they are not fit-for-purpose for studying digital technologies, nor are any existing databases mergeable. This project will address both of these challenges by building and publishing a novel, fit-for-purpose database to be used as the basis for an academic research project and manuscript.

Project Goals
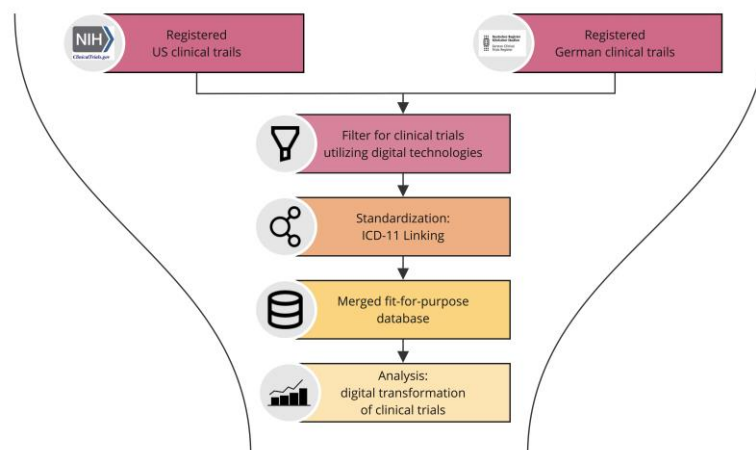
1 – Digital Clinical Trials Database

We will develop and publish what we believe to be the first transatlantic database of clinical trials using digital health technologies. This comprehensive database will integrate data from multiple registries (ClinialTrials.gov and the German Clinical Trial Register), addressing existing limitations and providing a valuable resource for studying the digital transformation of clinical research.

2 – ICD-11 Linking

We will enhance the database with research-relevant features, specifically by linking clinical trials to their corresponding ICD-11 codes. This will facilitate targeted research on disease-specific digital health interventions.

3 – Analysis and Manuscript

We will utilize then novel database to co-author a manuscript, with the objective of publishing a peer-reviewed article. Based on the group's interests, the article will explore key aspects of the digital transformation in clinical research, such as the adoption of digital health technologies, their impact on trial efficiency and outcomes, and/or emerging trends in digital therapeutics. Specific expertise or interests of the team will shape the specific research question(s).

Your Learning Opportunities

- Hands-on work with clinical trials data
- Building up a new database that serves as research resource
- Work in an interdisciplinary team
- Learn about and work with international clinical coding standards (particularly ICD-11)

Your Skills:

- **Interest in digital health technologies:** Enthusiasm for the application of digital technologies in medicine
- **Programming skills:** Good programming skills and interest in working with/ creation of databases
- **Research:** Enthusiasm for conducting research, including publication of results
- **Desirable (but not required):** Experience in building, documenting, and maintaining research-grade databases.

Further Information and reading material:
https://tinyurl.com/AUDiCT-Project

If you are as excited as we are or have any questions feel free to contact us:

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References:

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(2) Masanneck, L., Gieseler, P., Gordon, W.J., Meuth, S.G. and Stern, A.D., 2023. Evidence from ClinicalTrials. gov on the growth of Digital Health Technologies in neurology trials. npj Digital Medicine, 6(1), p.23.
(3) Masanneck, L. and Stern, A.D., 2024. Tracing Digital Therapeutics Research Across Medical Specialties: Evidence from ClinicalTrials. gov. Clinical Pharmacology & Therapeutics.