Novel Approaches to Sharing Data and Specimens in Alzheimer's Disease Clinical Trials

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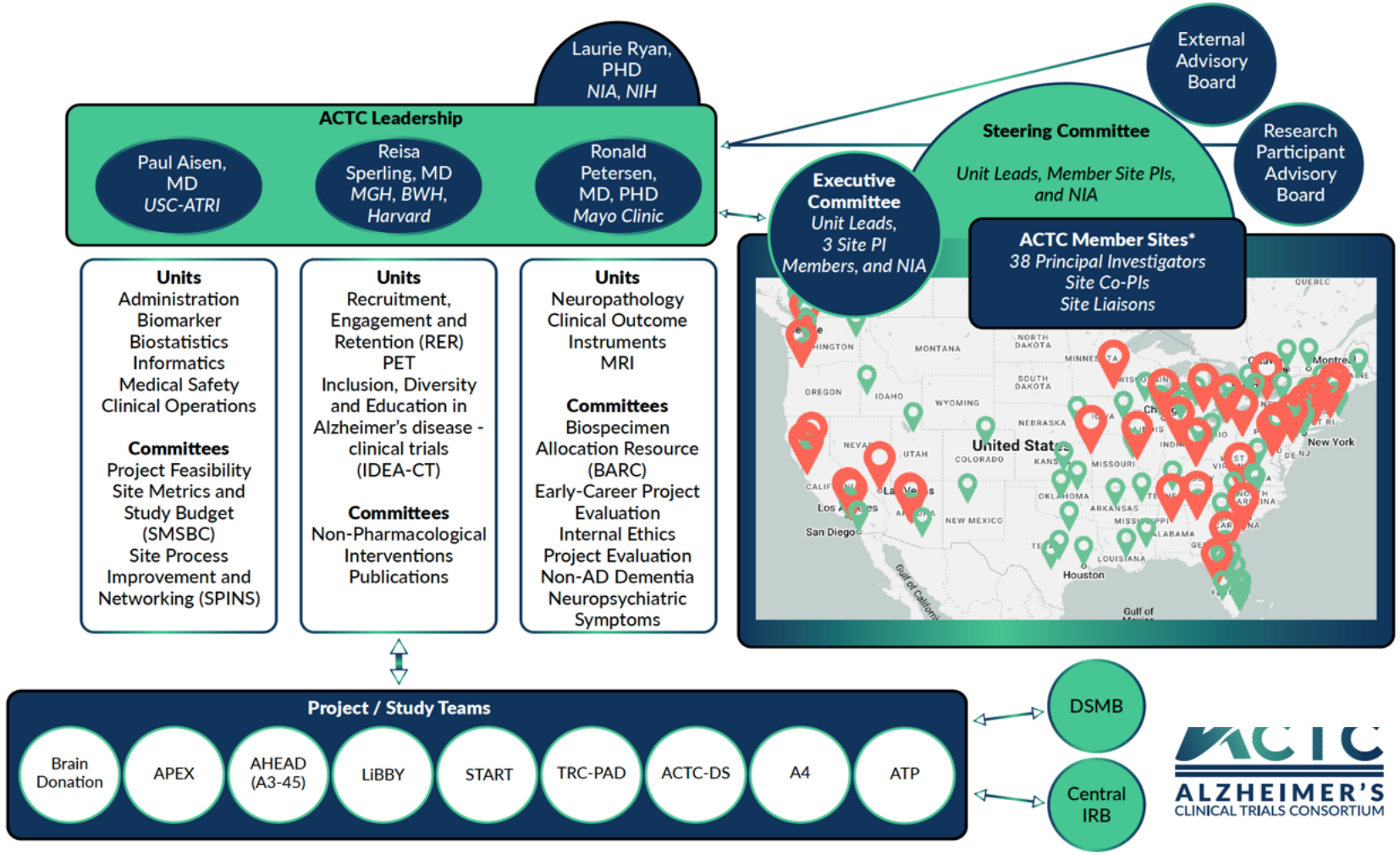
ACTC
ALZHEIMER'S CLINICAL TRIALS CONSORTIUM

Disclosures

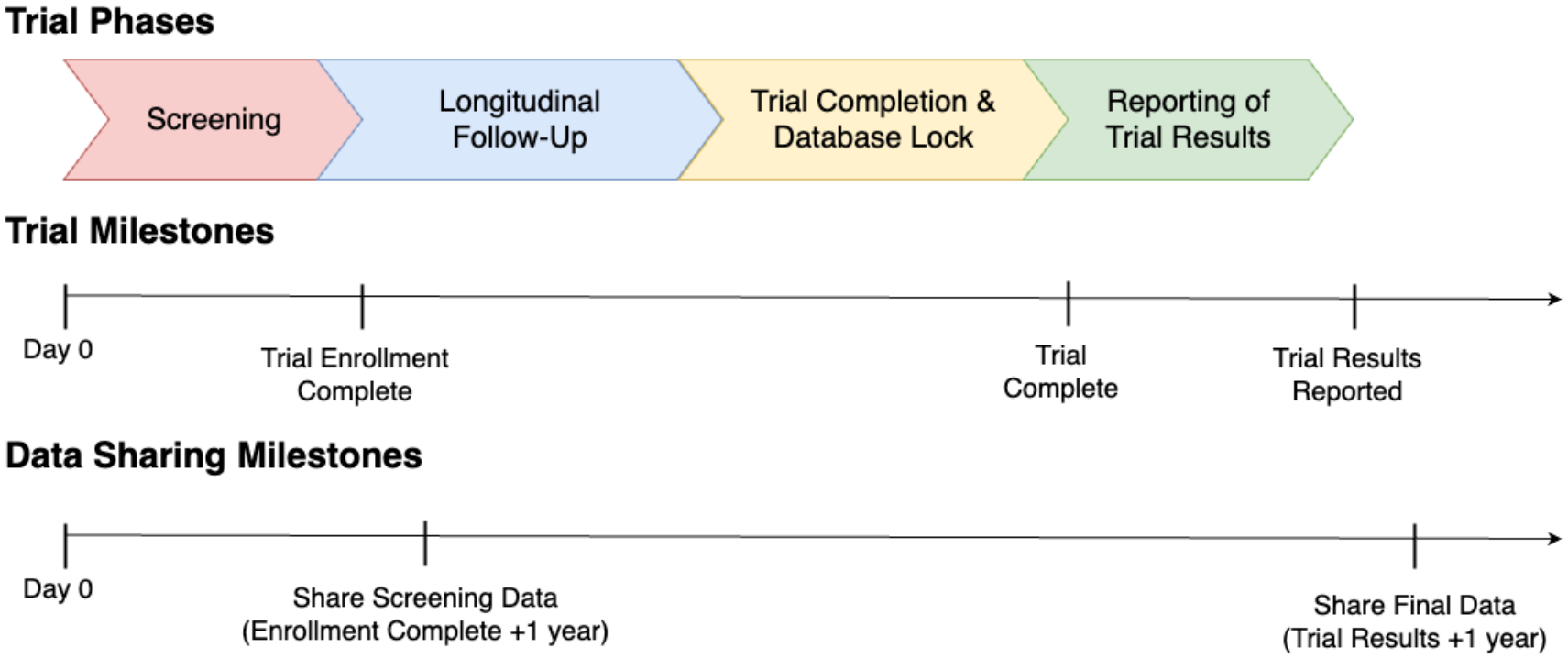
- Nothing to disclose

ACTC: Accelerating ADRD Clinical Trials



ACTC: Commitment to Open Science

- Broad and timely trial data and resource sharing that protects participant privacy and trial integrity
  - Aligned with NIA, FAIR, and CAP expectations and principles



ACTC shares:

- De-identified data
- Software
- Instruments
- Anonymized biospecimens
- Expertise on trial design
- Documentation

Case: Sharing A4 Trial Data

- Study cohort
  - 6,945 screens, 1,147 enrolled participants
  - Preclinical AD based on Amyloid PET measures
  - Experimental Groups: Solanezumab vs. Placebo
  - Ages 65-85
  - 4.5-year follow-up
  - LEARN observational sister study
  - For more details:
    - https://clinicaltrials.gov/study/NCT02008357

- Data was shared in two stages:
  1. Screening dataset (2018)
  2. Final study dataset – Placebo/Treatment Arms (2024)

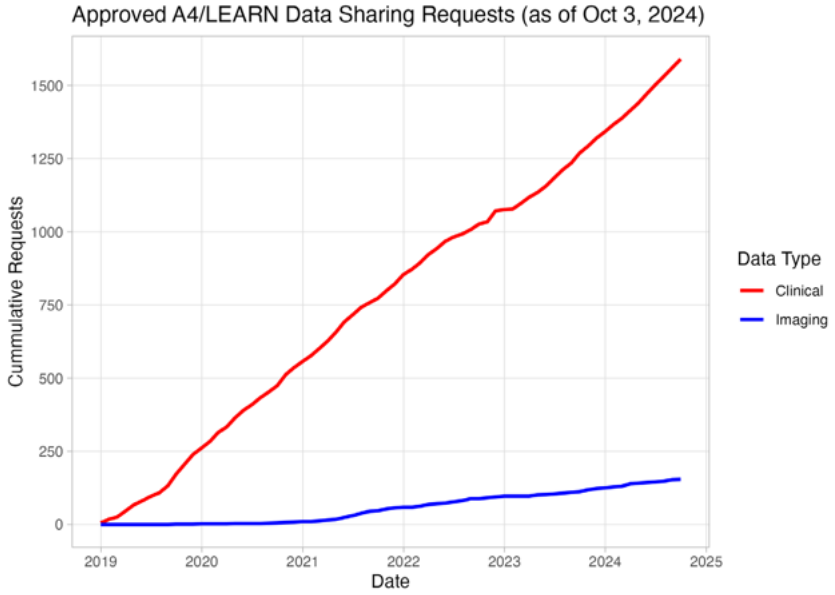
The A4 Study
NOW IS THE TIME

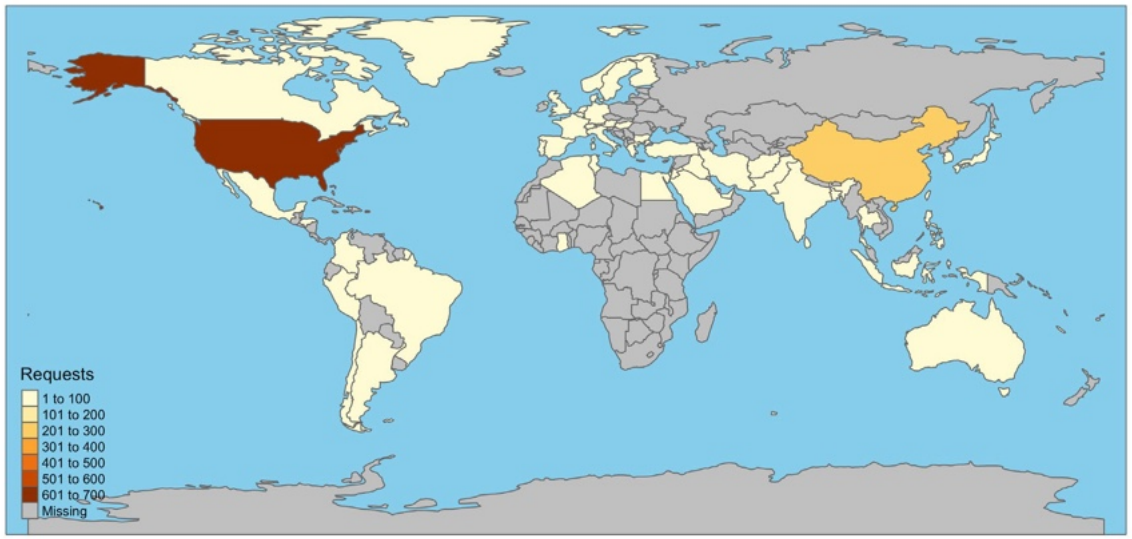
Data shared:
- Clinical
- Cognitive
- Labs
- Biomarker
- Neuroimaging
  - MRI, Amyloid PET, Tau PET
- GWAS

Stage1: A4 Screening Data (as of Oct 3, 2024)

- A4 data and biospecimen sharing has been <u>successful</u>
  - Data shared via **GAAIN/LONI IDA**
  - Data and biospecimen sharing committee established
  - **1,590 (91.6%)** approved requests for clinical and biomarker data
    - Investigators from **>60** countries
  - **154** approved requests included imaging data
  - **>974k** image series downloaded
  - **>2000** aliquots of SC plasma shared worldwide
  - **5** R01s funded using A4 SC plasma
  - **73** Peer-reviewed publications (Source: Google Scholar)

- Opportunities for improvement
  - Data preparation
  - Measuring impact and assessing needs
  - User support
  - Sample sharing
  - Biomarker data sharing

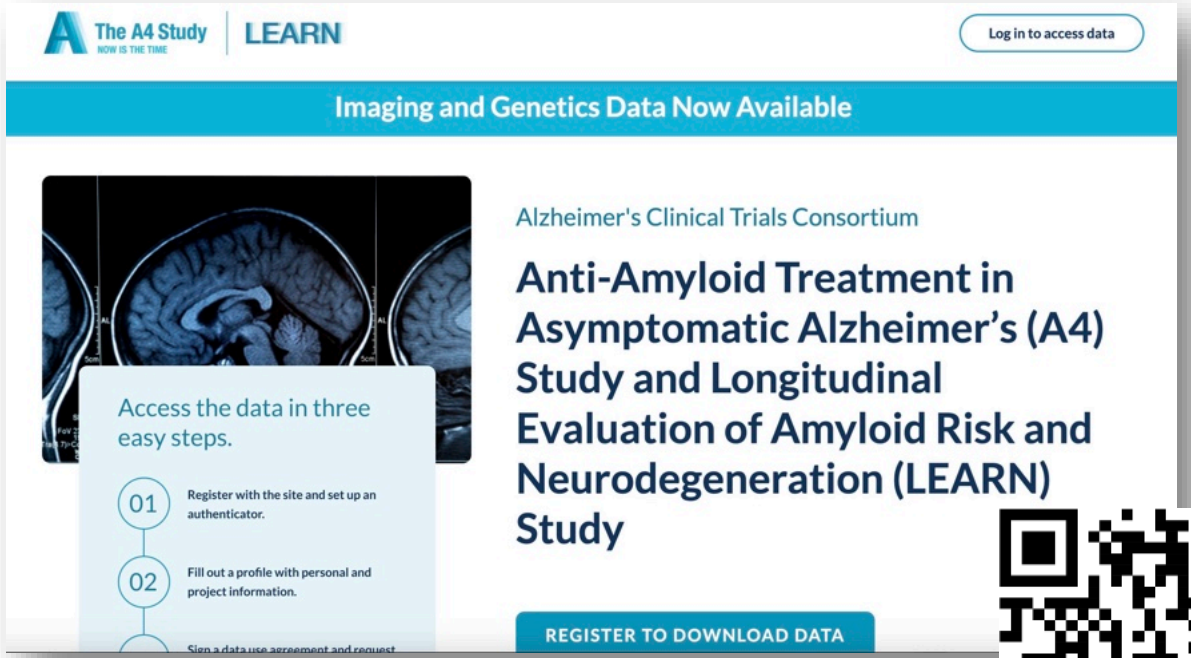




Stage2: A4 Final Study Data (as of Oct 3, 2024)

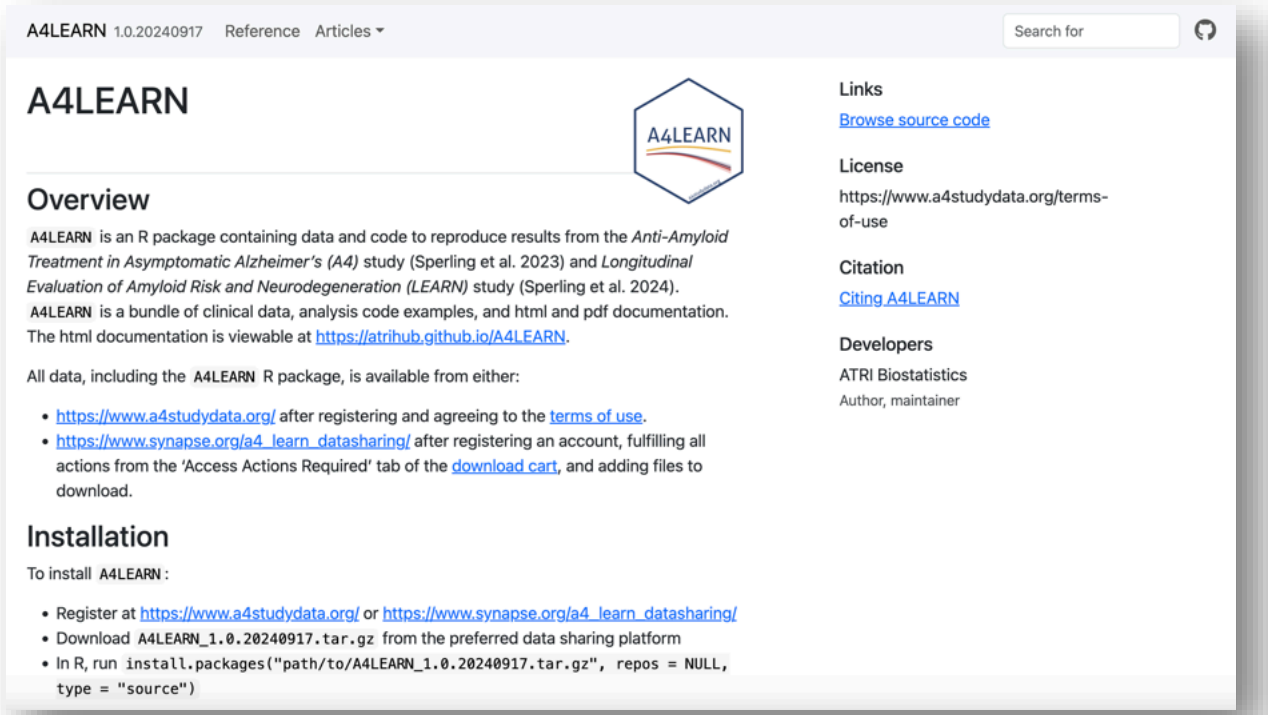
- **A4/LEARN Final Study Data Available for Download Now!**
  - >84k longitudinal participant visits
  - >15k longitudinal image studies (MRI, Amyloid PET, Tau PET)
- **>150** approved requests
  - Investigators from **18** countries
- Lessons learned (JPAD A4 Special Issue):
  - *Maximizing the Utility of Alzheimer's Disease Trial Data: Sharing of Baseline A4 and LEARN Data (Jimenez-Maggiora et al., 2024)* 10.14283/jpad.2024.120

- Omni-platform approach:
  - **GRIP:** www.a4studydata.org
  - **Synapse:** www.synapse.org/a4_learn_datasharing
  - **GAAIN/LONI IDA:** Coming soon!



Using R to Improve Data Usability

- R package to reproduce A4/LEARN primary results is included with the data set
- Vignettes allow investigators to learn how data is structured
- Documentation is integrated into R console for easy reference



This work is being led by Michael Donohue, PhD and ATRI Biostatistics

This application is being developed in collaboration with Gates Ventures

Next Steps

- Extend ACTC tools and infrastructure to support open science and trial data and resource sharing
  - Enable **precise requests** for data, documentation, images, and biospecimens based on demographic, genetic, and other specifications
  - Develop **privacy-protecting methods** for an increasing set of data types
  - Provide open-source **data analysis, exploration, and visualization tools**
  - Improve **data usability** using AI-enabled data exploration via natural language prompts
- Ensure trial data findability, accessibility, and interoperability with the broader ADRD data ecosystem
- Promote secondary use of trial data and resources to drive precision medicine approaches to accelerate ADRD prevention and therapeutic development

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Thank you!