ClinicalTrials.gov

STATS 418: Final Project Proposal

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Background

- **Clinical Trial:** A research study in which one or more **human subjects** are prospectively assigned to one or more **interventions** to evaluate the effects of those interventions on **health-related biomedical** or **behavioral** outcomes

- **ClinicalTrials.gov** is a publicly accessible, online database provided by the **US National Library of Medicine (NLM)** and the **US National Institutes of Health (NIH)**

- Provide information on clinical trials from around the **world**

Data

- Provides access to:
  - **Study metadata:** (logistics)
    - Company/Sponsor
    - Objective
    - Intervention
  - **Results summaries:** (science)
    - Outcomes
    - Participant flow
    - Demographics
    - Adverse events

- Technical Specs:
  - **RESTful API**
  - Defined using **OpenAPI** specifications
    - YAML specification doc.
  - Data refreshed **Monday-Friday by 9:00 AM EST**
  - Retrieve data as **JSON** or **XML** (legacy)

Model

- **Adverse event (AE):** Unexpected and undesired medical occurrence

- **Serious Adverse Event (SAE):** An AE that leads to death, is life-threatening, requires hospitalization, or results in persistent disability

- Explore relationships between **AEs**:
  - Sponsors
  - Type of trial
  - Regions
  - *etc.*