Less Blood, Less Burden: A Patient-Centered Approach to Trials

Faculty Advisor: Professor **Retsef** Levi
Takeda team: **Ophelia** Mok, **Reese** Kelso, **Maria Camila** Marenco


Malcolm Gaynor **Hunter** Sporn

MIT MANAGEMENT BUSINESS ANALYTICS

PROBLEM STATEMENT

Our mission is to **limit patient burden** in clinical trials.

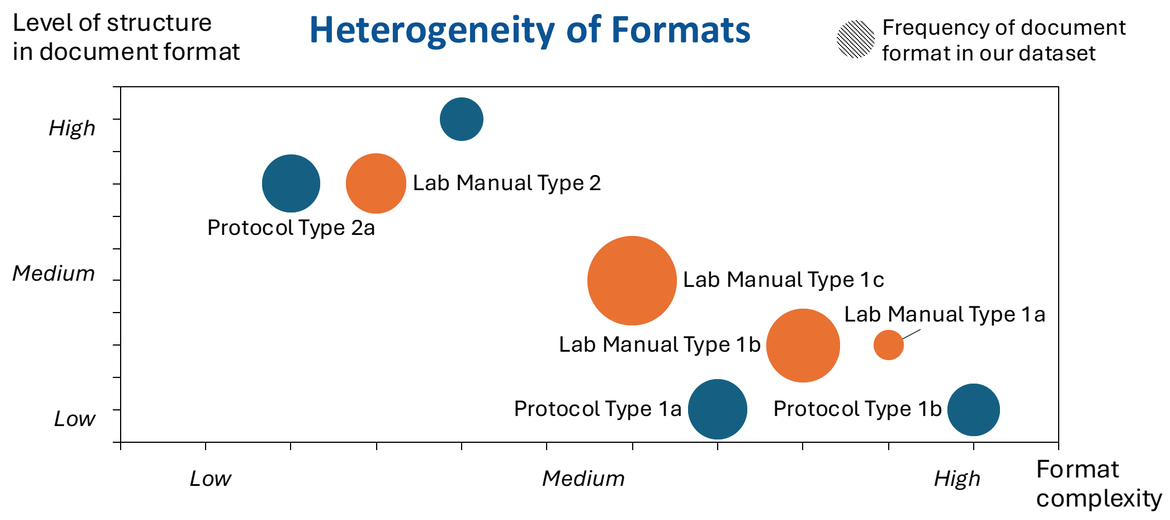
We **automate the extraction** of blood draw data from clinical trial documents to populate a database and develop a tool offering **warnings and recommendations** when trials approach regulatory limits or become overly burdensome.

North Star - Putting patients first

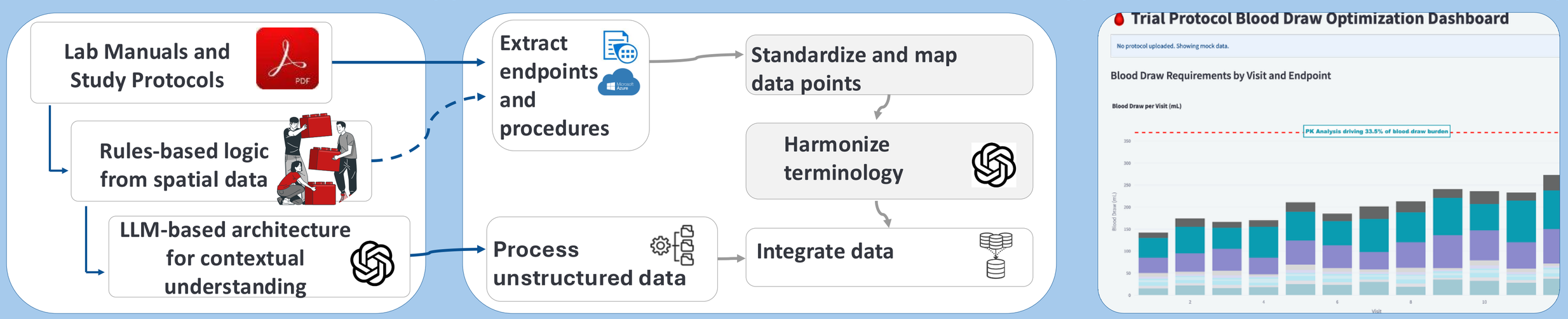
Facilitate **informed clinical trial decision making**, limiting patient burden and **decreasing the risk of costly clinical trial pauses** due to patient dropout or regulatory noncompliance

DATA

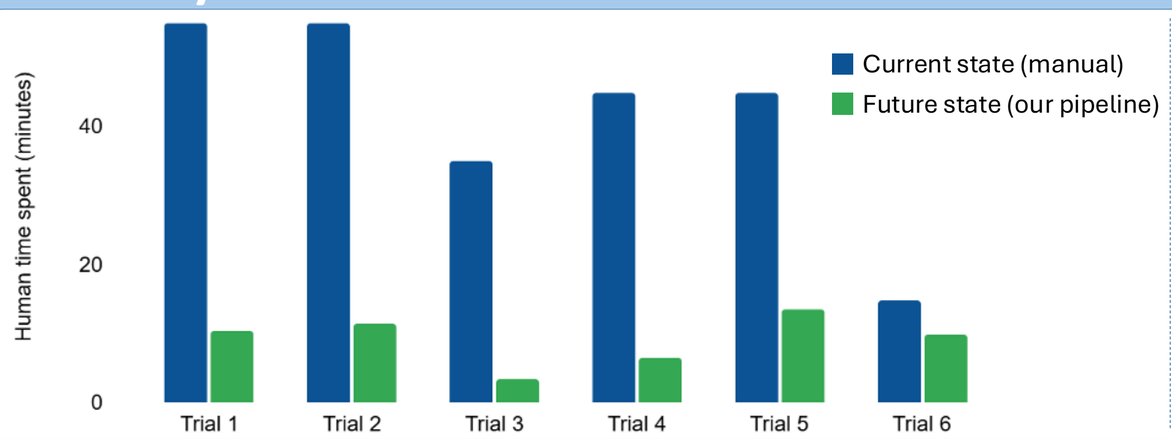
Our dataset includes several **document types**, each with a different structure. Data extraction for each document type (represented by a bubble below) required a distinct technical architecture that incorporated **spatial relationships** and **domain-specific logic**.



METHODOLOGY



Efficiency Gains



Time to extract endpoints from clinical trial protocols

Our fit-for-purpose approach to extracting data not only supports derivation of critical insights but also yields significant **gains in workflow efficiency**. For just clinical trial protocols, our pipeline reduces the human **time investment for endpoint** extraction to as little as 1 minute per page; today, an average protocol would consume up to a **full hour in time**.

BUSINESS IMPACT

Project Context

2,000
Patients being recruited for Takeda clinical trials in 2024

$600K to $8M
Cost of delaying a clinical trial by just one day[1]

72%
Trials in industry are delayed by at least one month[2]

2 solutions to address a key **root cause** of clinical trial interruptions

1. Best-in-class **digital repository** of blood draw needs from past trials
2. Tool leveraging our repository & algorithm to **improve trial** designs

Next Steps

1. **Test and update** the blood volume database and automated extraction pipeline to include **competitor trials** for comparisons and baselining.
2. **Expand dashboard functionalities**, including integrating generalized **patient burden scoring** metrics for procedures outside of blood draws.
3. **Integrate direct comparisons** to similar trial blood draw procedures and patient burden metrics within the dashboard.

1. According to the Association of Clinical Research Professionals (ACRP), delays in clinical trials can cost between $600,000 to $8 million per day, depending on the therapeutic area, trial phase, and market potential 2. According to industry research