Weill Cornell Medicine

EmulatRx: A Multi-Agent System for Intelligent Clinical Trial Design

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Background & Unmet Need

- Randomized controlled trials (RCTs) remain the gold standard for evaluating the efficacy and safety of medical interventions
- However, the costs, logistical complexities, and ethical considerations of conducting a full RCT have led researchers to seek alternative methods for generating robust causal evidence
- Trial emulation, wherein a target clinical trial is simulated as closely as possible using real world data (RWD), provides an alternative method for producing causal evidence and streamlining clinical trial planning
- While trial emulation can generate causal data, each step in the pipeline requires careful domain expertise and rigorous quality checks to ensure valid results
- **Unmet Need:** Methods for streamlining trial emulation to optimize clinical trial design serve as an alternative for generating robust causal evidence

Technology Overview

- **The Technology:** EmulatRx is a multiagent system which allows insights to be extracted from RWD to perform target trial emulation
- EmulatRx is comprised of distinct computational nodes—a “Supervisor,” “Trialist,” “Clinician,” “Informatician,” and “Statistician”—each handling specialized tasks
- EmulatRx’s multiagent design can address common obstacles in using RWD, such as missing data, sample size limitations, and covariate imbalances
- **PoC Data:** In a PoC study, EmulatRx emulated a historical trial evaluating the effectiveness of corticosteroids in managing sepsis within the ICU using the MIMIC-IV database
- EmulatRx identified and relaxed eligibility criteria to maximize the sample size, addressed missing key variables, and refined potential covariates
- The average treatment effect and hazard ratio identified were consistent with the actual RCT

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Patents:
Provisional Patent

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Cornell Reference:
D-11405

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Technology Applications

- Post-market studies for real world effectiveness
- Identification of label expansion opportunities
- Clinical trial planning and design
- Adaptive trial evaluation and design
- Drug repurposing hypothesis generation
- Post-market pharmacovigilance studies

Technology Advantages

- Adheres to standard frameworks to ensure compatibility with heterogenous data sources
- Provides a log of results to enable detailed auditing and reproducibility of results
- Distributed processing enables high scalability
- Integrates standard APIs and GPUs for reduced computing requirements

Supporting Data / Figures

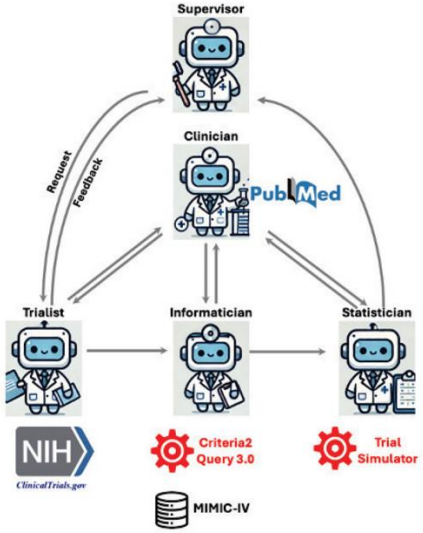

Figure 1: Schematic of EmulatRx multi-agent framework.

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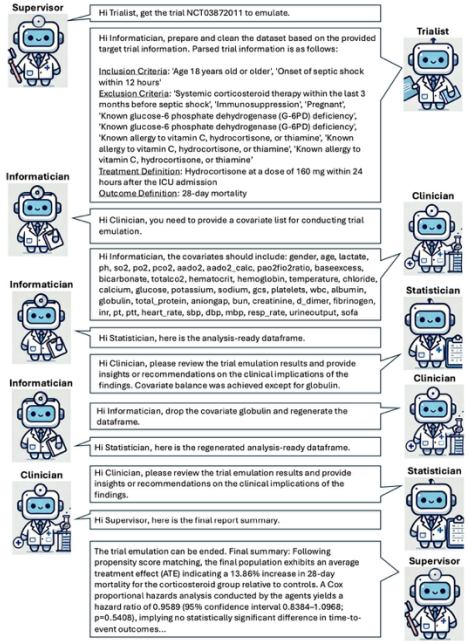

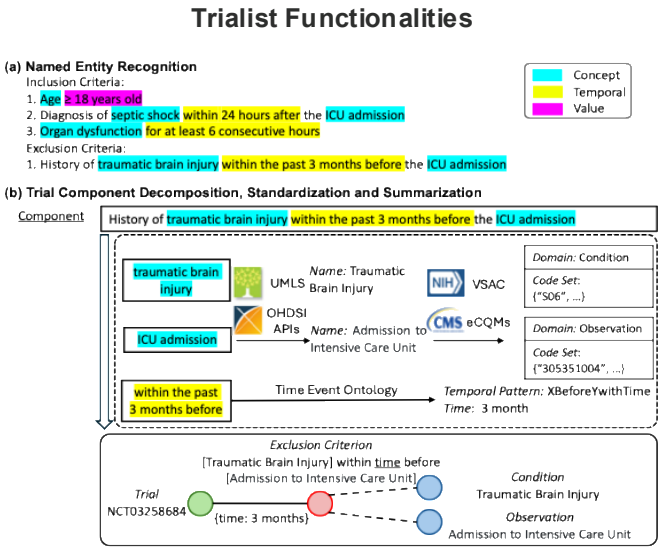

Figure 2: Left: Example of a conversation between agents to coordinate trial emulation **Right:** Example of functionalities of the 'trialist' agent.

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