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A Post-Marketing Drug Evaluation Framework Based on Real-World Electronic Health Records Data

Yu Wang

Associate researcher

Zhejiang Laboratory, China

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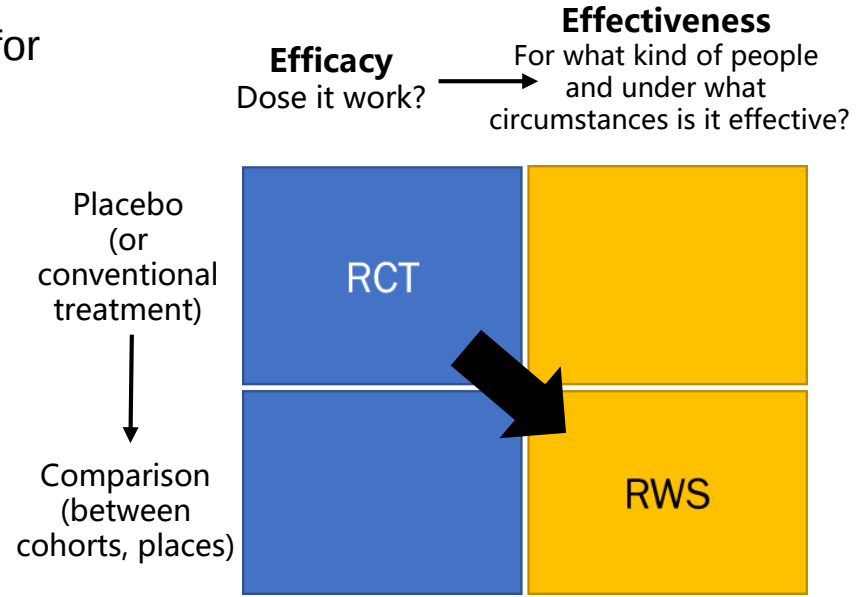
Background

- **Post-marketing drug evaluation** is crucial for rational use and cost control.

- **Randomized controlled trials (RCTs)** vs **Real-world studies (RWSs)**

- **Real-world data (RWD)** → **Real-world evidence (RWE)**



Background

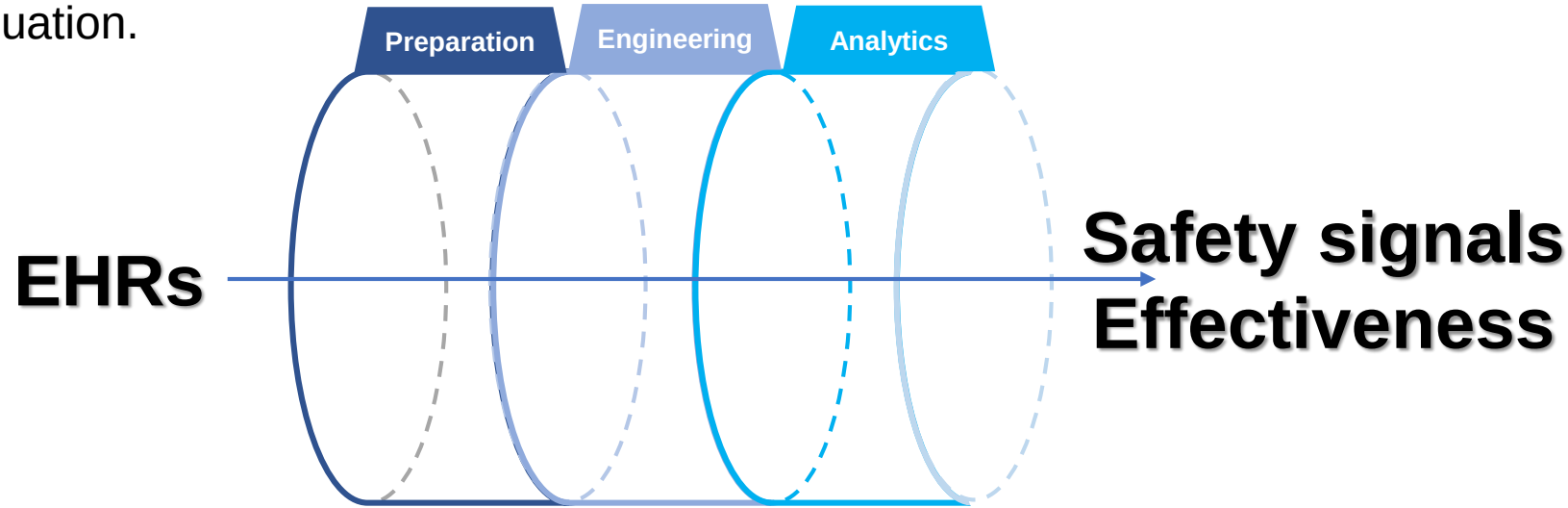
- **Claims data** are the main real-world data source for post-marketing drug evaluation (e.g., **Sentinel Initiative, EU-ADR, AsPEN**)
  - Limitations:
    - Lack of clinical detail.
    - Inaccurate measurement of confounding variables.
- **Electronic health record (EHR)** data offer advantages:
  - More clinical detail available
  - Enhances post-marketing drug evaluation
- However, there is a gap between researches and real-world practice:
  - Few studies on a unified framework for post-marketing drug evaluation using EHR data.

Sentinel Initiative

OHDSI Atlas

Aim

- Proposes a framework using large-scale EHR data for post-marketing drug evaluation.



Methods: the post-marketing drug evaluation framework

- **Drug Evaluation Data Model (DEDM)** :

  Data Preparation

- **Drug Evaluation Pipeline (DEP)** :

  Data engineering

- **Drug Evaluation Applications** :

  Data Analytics

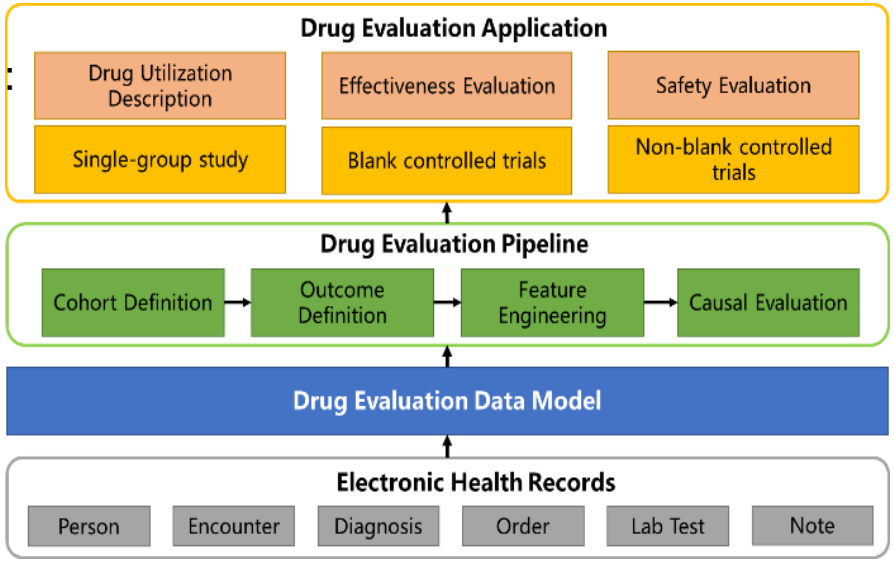


Figure 2. Overview of the post-marketing drug evaluation framework based on EHRs.

Drug Evaluation Data Model

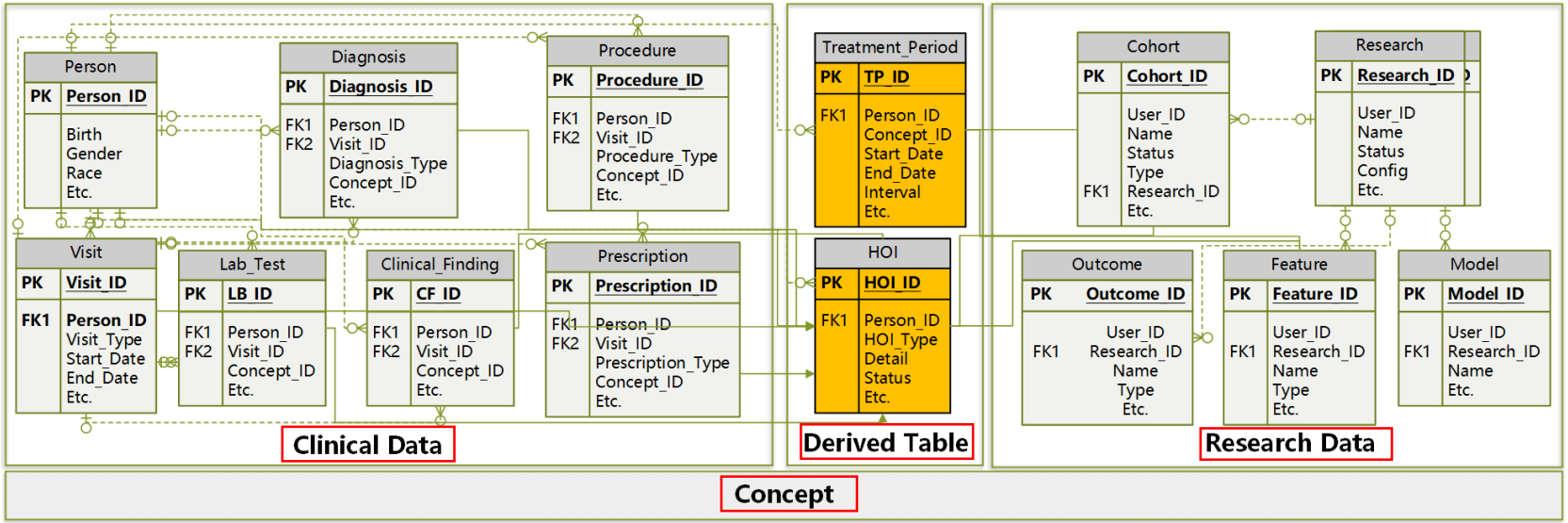
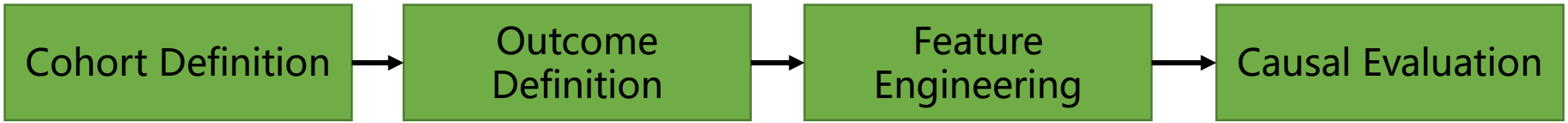


Figure 3. Entity-relation diagram of drug evaluation data model.

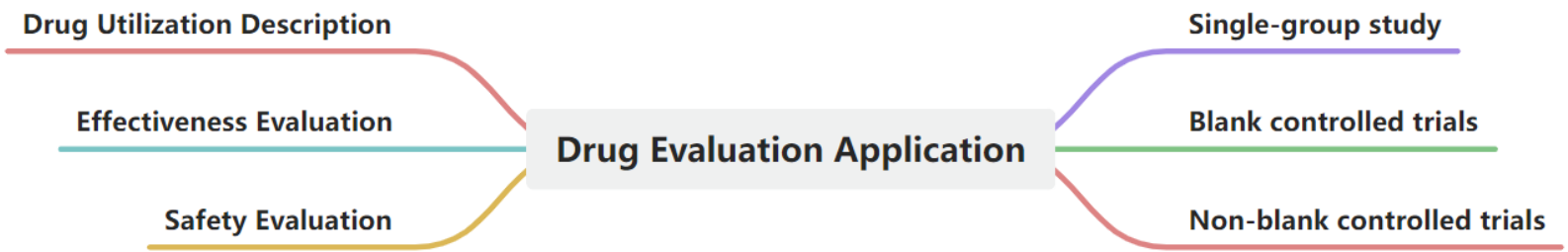
Drug Evaluation Pipeline

1. **Cohort definition:** Define eligibility criteria and screen results
2. **Outcome definition:** Identify study outcomes based on user-defined clinical events or pre-defined outcomes in the HOI table.
3. **Feature Engineering:** Calculate confounding variables, along with outcome events and features.
4. **Causal estimation:** Causal comparing outcomes between groups.



Drug Evaluation Application

- DEDM and DEP support various clinical trial paradigms.
- Enables users to perform drug evaluation applications.



Results - Allergic reactions to cefodizime and ceftriaxone

Research objective: Safety analysis

Research paradigms: Controlled trials

Cohort Definition

- Patients on cefdizime vs ceftriaxone
- First prescription in 2010.1-2020.5
- No other prescription of Cephalosporins in 3 days

Outcome Definition

- Anti-allergy prescriptions in 3 days after first prescription of cefdizime or ceftriaxone

Features Engineering

- Age, gender, primary diagnosis, Other combined medications with a clear risk of allergic reactions, etc

Causal Evaluation

- Propensity score matching
- chi square test

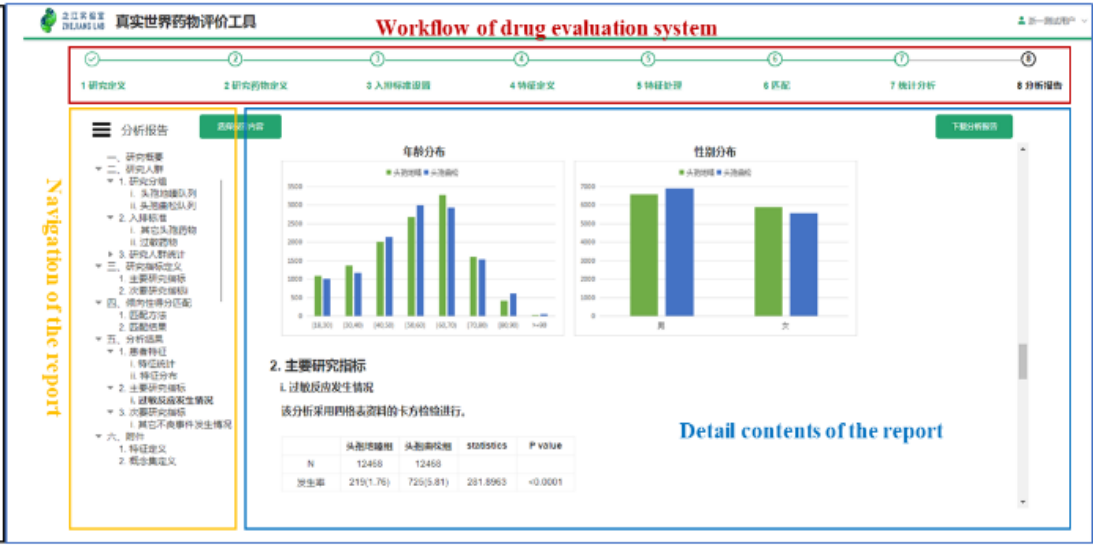


Figure 4. Entity-relation diagram of drug evaluation data model.

Discussion and conclusions

- Proposed **a framework for post-marketing drug evaluation** using real-world EHR data.
- Benefits of **a tailored data model and unified pipeline**
  - Comprehensive pipeline covering data conversion, customized cohort construction, confounder selection, and causality assessment.
  - Applicable across various post-marketing scenarios.
  - Enables easy and automated generation of evaluation reports.

Conclusion

- Challenges:
  - Mapping EHR data to standardized concepts for effective analysis.
  - Ongoing optimization of term mapping algorithm.
- Further improvements and integration of additional paradigms are necessary for wider applicability.

Acknowledgments

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Thank You!