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Common Data Model for Interoperability of Observational Health Data: Bulgarian Diabetes Register Pharmacology Case Study

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Main Topics

1. Introduction
2. Objectives
3. Methods and Materials
4. Results
5. Discussion
6. Conclusion

1. Introduction

The need for a Pharmacology case study for diabetes treatment.

Assessment of expenses for prescribed drugs:

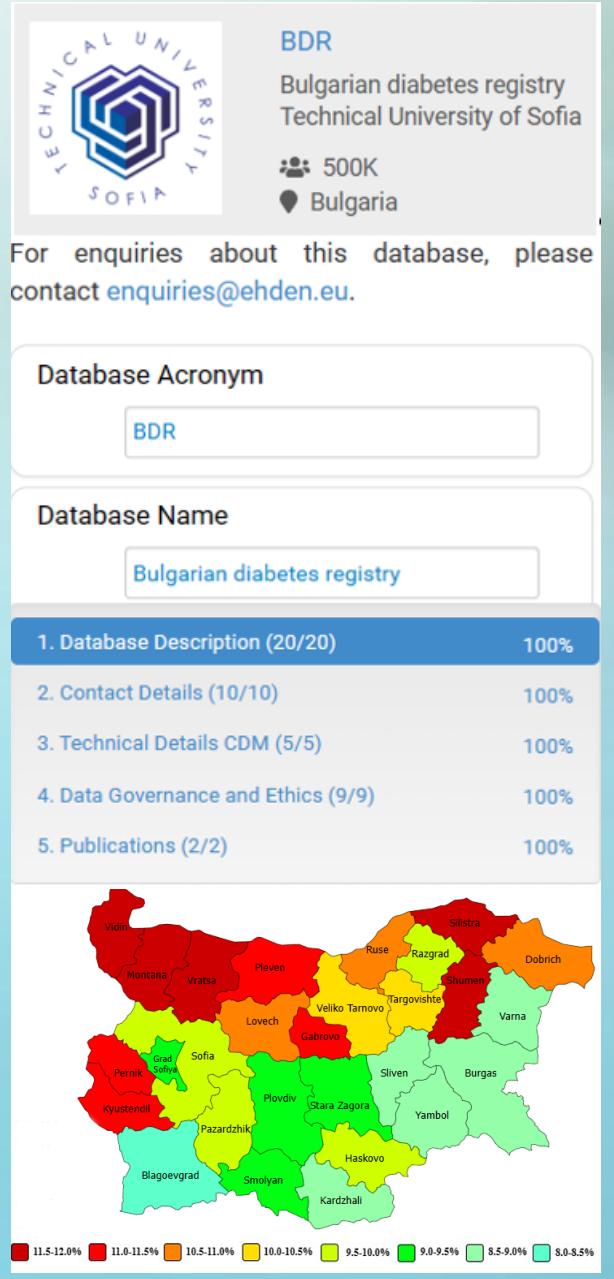
- provides evidence for regulatory decision making
- identifies trends in using different classes of drugs

Requires patient-centric approach for data analysis:

- outpatient records are collected for disparate and heterogenous data sources
- serious interoperability issues

Solution:

- employ a Common Data Model for representation of observational health data
- Map to a CDM all the outpatient records (**6,887,876**) issued in Bulgaria to patients with diabetes (**501,065**)
- the BDR published in the EHDEN Portal allows sharing EHR data across clinicians, patients and communities



2.Objectives

- What is the share **of modern drugs for treatment of diabetes** in the Total costs?
- What is the share of costs for drugs prescribed for **treatment of diabetes comorbidities** (*cardiovascular*, *nervous system*, *ophthalmological disorders disorders* etc)?
- What are the **relative shares of costs** for treatment of these disorders with respect to the overall expenses for treatment of diabetes comorbidities?
- What is the **average yearly cost for prescribed drugs** for diabetes treatment and **how it relates similar expenses in other EU countries**?

3. Methods and Materials

Code	Drug class	International Nonproprietary Name (INN)
T1	Insulin	Insulin unique analogues and combination regimens
T2	Sulfonylureas	Glyburide, Glipizide, Glimepiride, Gliclazide, Tolbutamide,Chlorpropamide, Tolazamide
T3	Biguanides	Metformin
T4	Alpha-Glucosidase Inhibitors	Acarbose, Miglitol, Voglibose
T5	Thiazolidinediones	Troglitazone, Rosiglitazone, Pioglitazone
T6	Incretin-Dependent Therapies	Incretin , Exenatide, Liraglutide, Dulaglutide, Albiglutide",Lixisenatide, Semaglutide, Sitagliptin, Saxagliptin, Linagliptin,Alogliptin
T7	Meglitinides	Nateglinide, Repaglinide
T8	Sodium-Glucose Cotransporter Type 2 Inhibitors	Canagliflozin,Apagliflozin,Empagliflozin, Ertugliflozin
T9	Statin-Dependent therapies	Simvastatin, Lovastatin, Ravastatin , Fluvastatin, Atorvastatin, Cerivastatin, Rosuvastatin, Ppitavastatin

Table 1. Drug classes for treatment of Diabetes

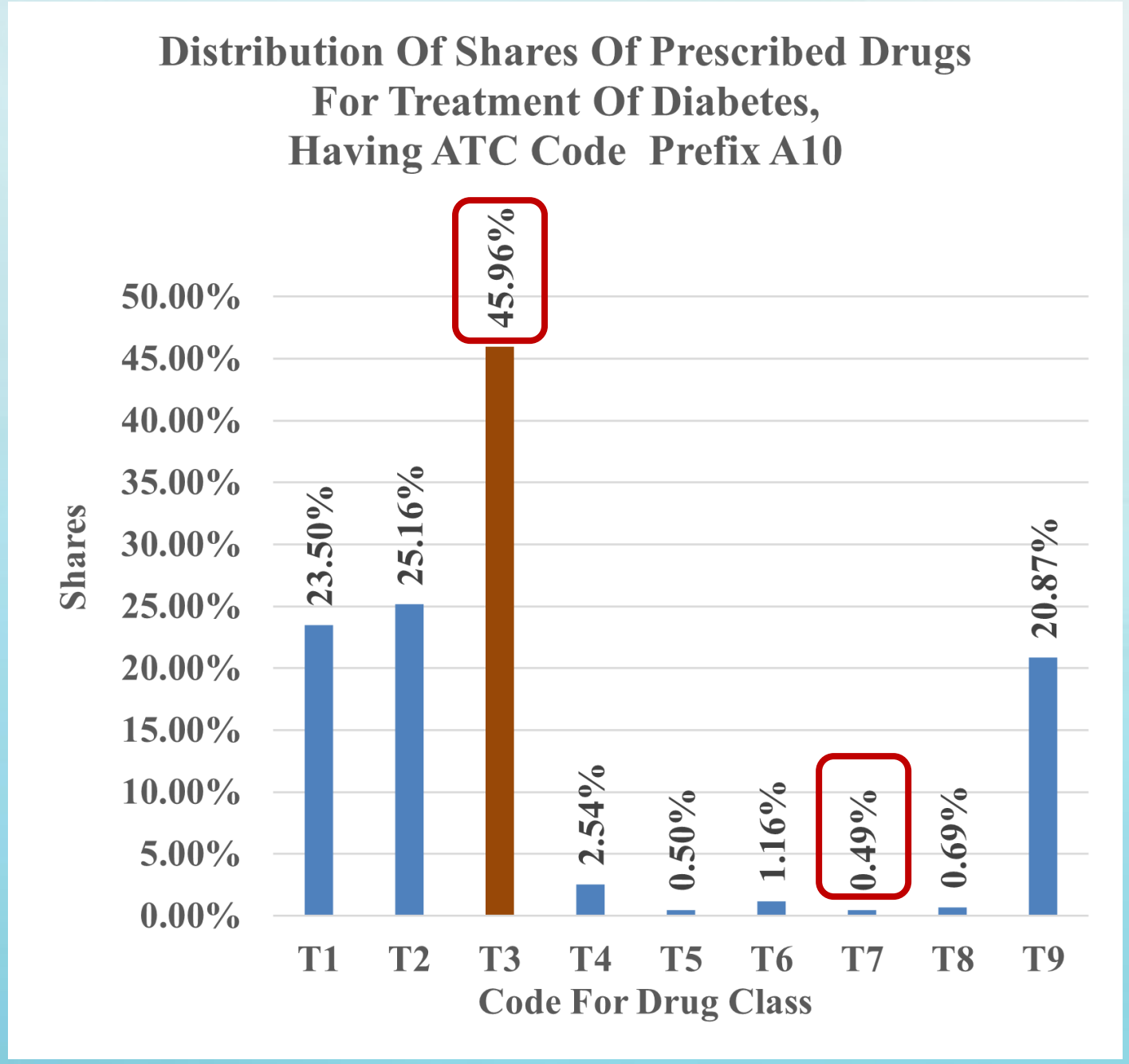
Code	Drug class for comorbidity treatment	ATC code prefix
A	Cardiovascular drugs	C01, C03, C07, C08, C09, C10
A1	Antithrombotic agents	B01
N	Nervous system disorders	N01-N07
G	Urological disorders	G04
S	Ophthalmolotical disorders	S01
L	Endocrine disorders	L02
M	Ttreatment of bone diseases	M05
R	Asthma drug categories	R03

Table 2. Drug classes for Diabetes comorbidity treatment

The costs are evaluated both at **patient- centric level** and at **high level** in terms of **cost distributions** among the drug classes in each one of the two groups **using** a **OHDSI OMOP CDM** database (**BDR**) .

4. Results

- ✓ The Bulgarian Diabetes Register is **a public Common Data Model** implementation allowing to overcome poor interoperability issues.
- ✓ It contains the **latest and complete dataset of outpatient records of 501,065 distinct patients** with diabetes in **Bulgaria in 2018**. **Compared** to data from **312,223 diabetic patients in Italy (2014)**
- ✓ The **pharmacology case study** reports **new results for better assessment of the cost burden** created by prescribing drugs for diabetes.
- ✓ **Two major groups of drugs are considered**-drugs for treatment of diabetes and **related comorbidities**.
- ✓ **Novel drug diabetes therapies are just evolving** in 2018, while the **Metformin prescriptions prevail** significantly.
- ✓ **The costs are evaluated both at patient- centric level and at high level** in terms of cost distributions among the drug classes in each group.
- ✓ **Average *675 euros yearly per diabetic patient expenses for prescribed drugs in Bulgaria in 2018***, *compared to* ***average 1,044 euros yearly per diabetic patient in Italy in 2014 .***



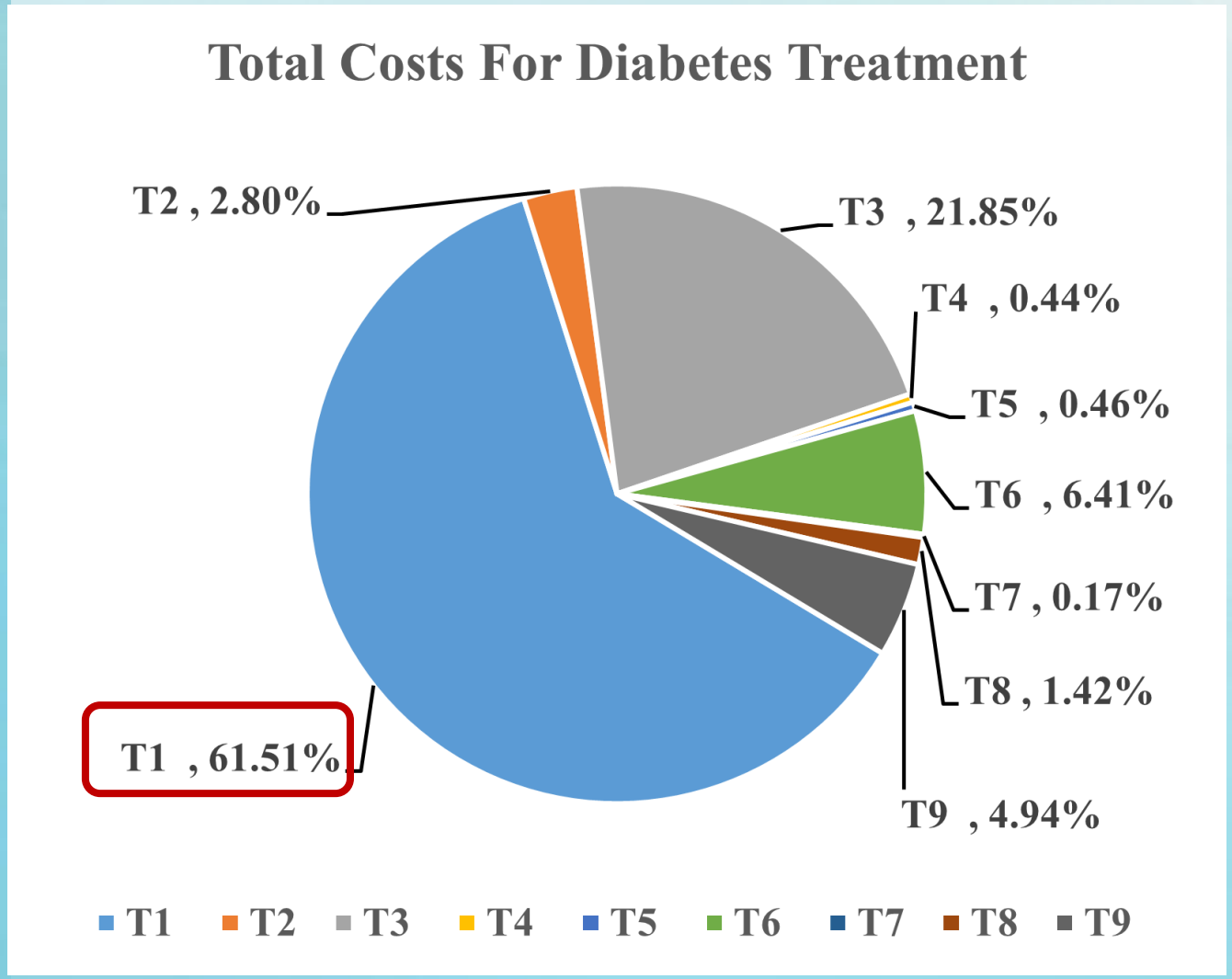
Shares of prescriptions for diabetes treatment

Notes

Biguanides (T3 class), *Metformin* drugs are the **most frequently prescribed**

Modern classes of drugs (T8 class) *Sodium-Glucose Cotransporter Type 2 Inhibitors*, are among **the least frequently prescribed** in 2018.

Other rarely prescribed drugs are (**T5 & T7 class**), Thiazolidinediones and Meglitinides because **they have undesirable side effects**.

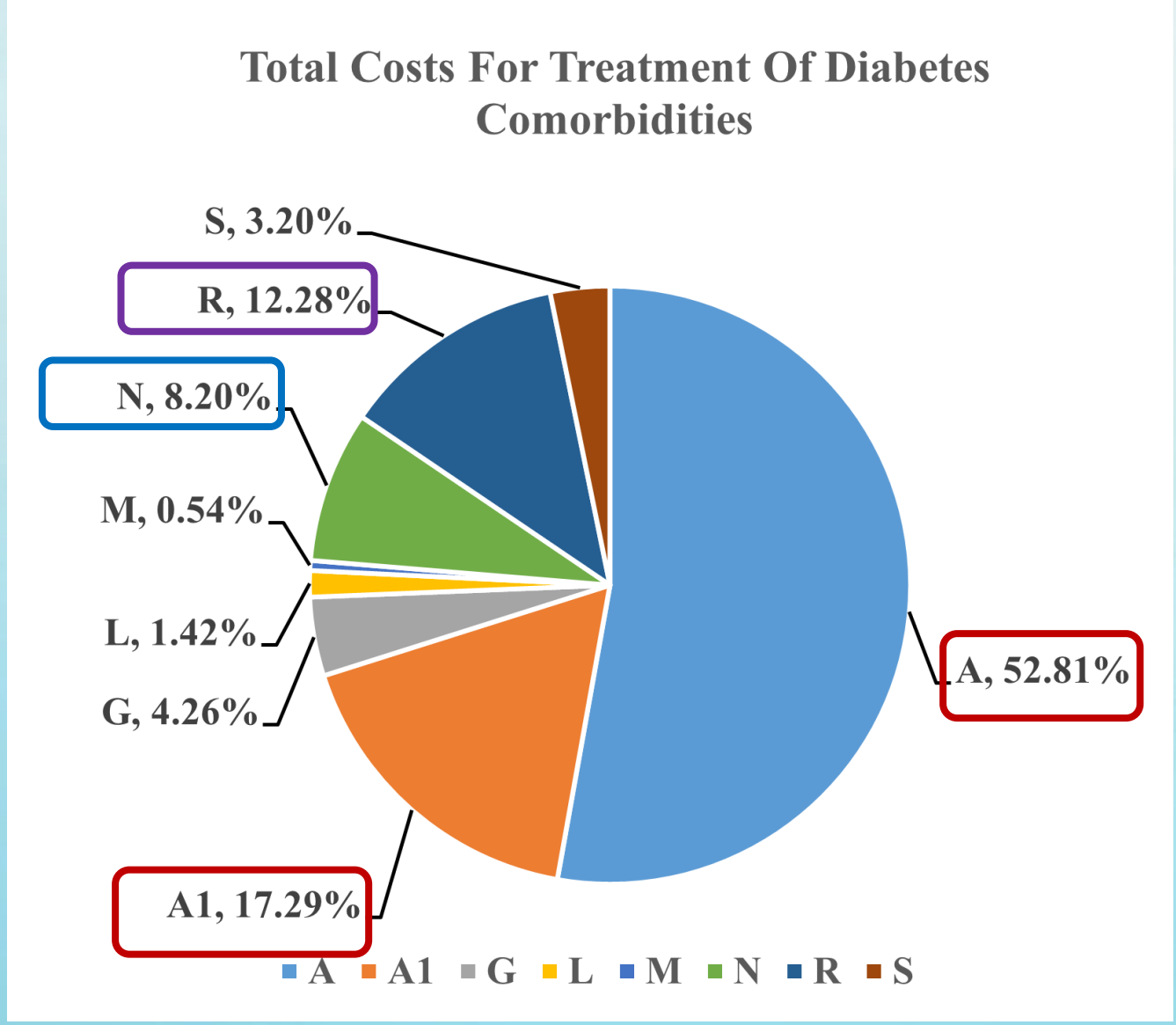


Total costs of drugs for diabetes treatment

Notes

The **largest share** of expenses is attributed to the **insulin** (T1 class) drugs, although it is the third most prescribed class of drugs.

Besides**,** the **average pri**ce in Bulgaria for the **insulin drug** class has been **about 60 euros** against **16 euros for the Metformin drug** class in 2018.



Total costs of drugs for treatment of diabetes comorbidities

Notes

Drugs for **cardiovascular disorders** and
drugs with **antithrombotic agents** (coded A and A1)
together have the greatest weight (**70.10%**) in the Total Costs for **treatment of comorbidities.**

5. Discussion

Novel results:

- ✓ **Nationally-representative observational health data** of patients with diabetes in Bulgaria from 2018 mapped to an OMOP CDM in the BDR(**501,065 distinct patients)**.
- ✓ **Population-based pharmacology studies** of the drug cost burden for treatment of socially significant diseases like diabetes are **rarely public available**.
- ✓ Public access to the BDR enables **transparency in accessing data** and **verifying the integrity and consistency** of the pharmacology case study results
- ✓ The reported results **confirm public data** for the shares on expenses on distinct drug classes used for diabetes treatment established in Italy (**312,223 patients**) .
- ✓ The pharmacology study results are **consistent with data in official governmental financial reports** for diabetic's drugs reimbursement expenses.

6. Conclusion and Future Work

- ✓ This paper provides results from a **population-based study** of the burden of pharmacology costs for treatment of diabetes in Bulgaria (**501,065 distinct patients** with diabetes).
- ✓ **Popular CDM are critically analyzed** in relation to the objectives of this study.
- ✓ The study **uses observational health data from heterogenous, disparate datasets** that is transformed to OMOP CDM and persisted in the BDR.
- ✓ The **results indicate the trends and effects** in using different classes of drugs for diabetes treatment in comparison with public data from other countries.
- ✓ The results allow to **conclude that the shares on expenses per drug classes used for diabetes treatment in Bulgaria are similar to those established in other EU countries (***average* ***675 euros yearly per diabetic patient*** *expenses for prescribed drugs*).
- ✓ The study provides **evidence that the treatment of comorbidities accompanying the diabetes illness is almost as expensive as the treatment of the diabetes itself**.
- ✓ The pharmacology case study **makes public lot of new and rarely found** in the literature evidence-based results **that are useful** for regulatory decision making as well as for drug suppliers in planning their market strategies.
- ✓ The inherent interoperability of the OMOP CDM allows extending the research work to **data analysis across a federated network of OMOP CDM databases by participating in the MegaStudy** entitled "*Studying Drug shortages in Europe: A Multinational, Multidatabase Network Study*" as EHDEN Data partner.

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Thank you for your attention!

Questions?

Comments?