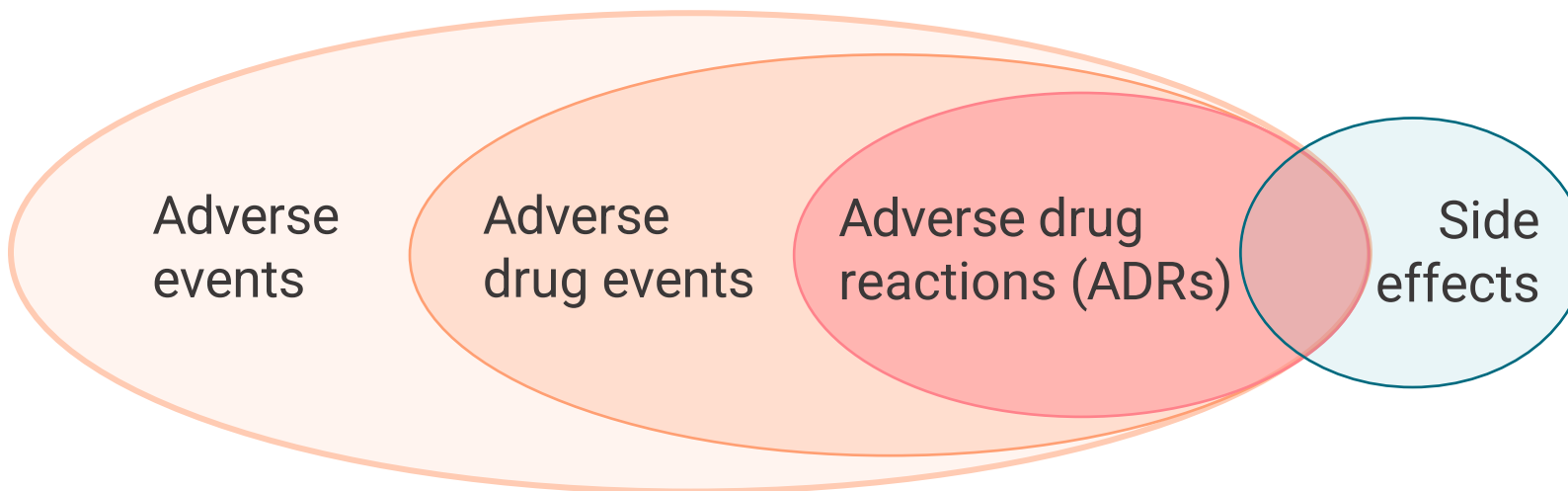


ADVERSE REACTIONS OF WORLD-WIDE APPROVED DRUGS

P. Savosina, D. Druzhilovskiy

Institute of Biomedical Chemistry, Moscow, Russia



Due, A. (2023) *Euro Jnl Phil Sc.* 13, 16.
 DOI: [10.1007/s13194-023-00519-8](https://doi.org/10.1007/s13194-023-00519-8).

SIDE EFFECTS

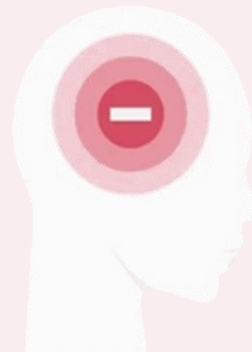
Promethazine → HNA* inhibition
 Latanoprost → Eyelash growth
 Levodopa → Creative awakening

↓
 Drug repositioning
 «First-in-class» development



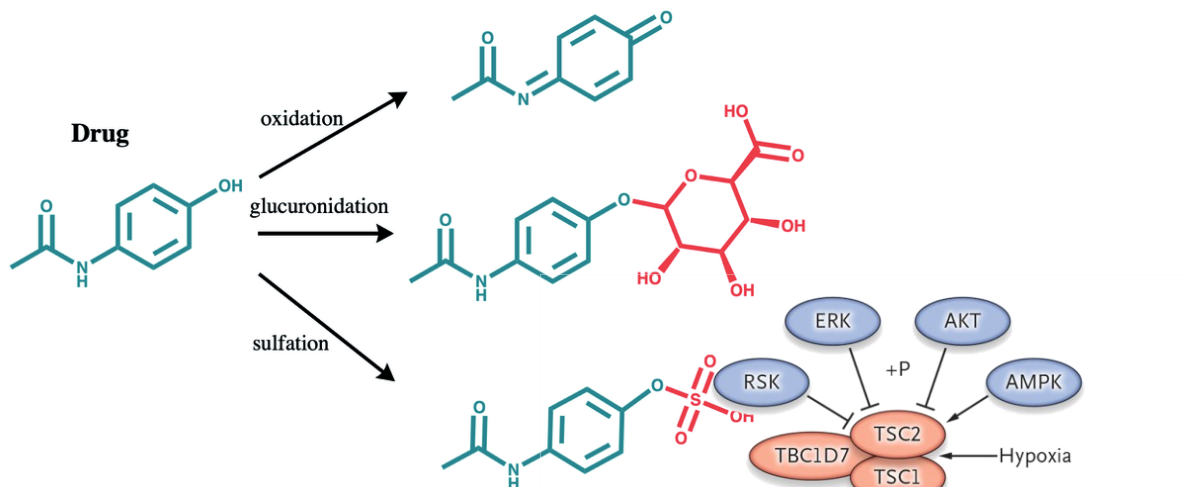
Rimonabant → Suicidal thoughts
 Atorvastatin → Cataract
 Tadalafil → Deafness

↓
 Drug development termination
 Disability/death
 Drug withdrawn

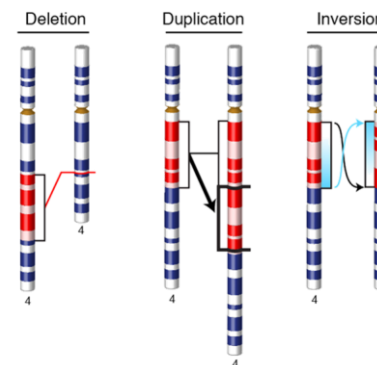
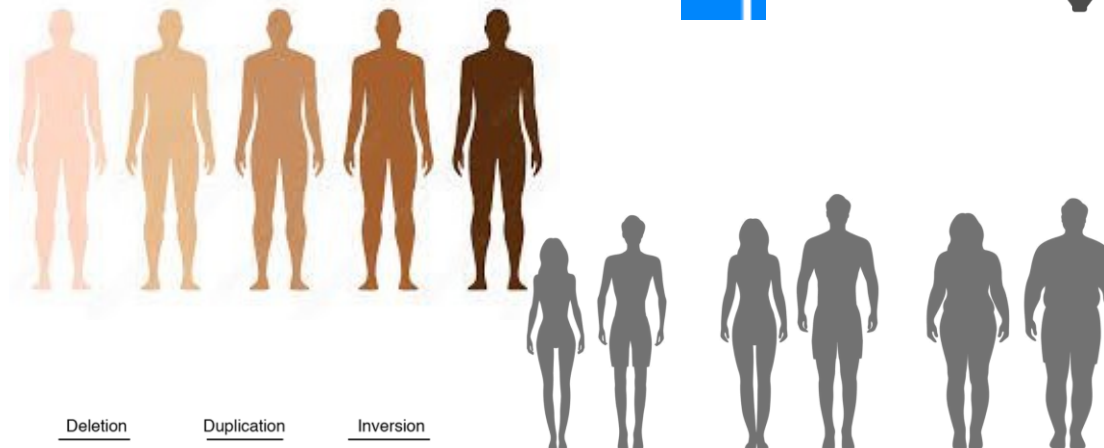
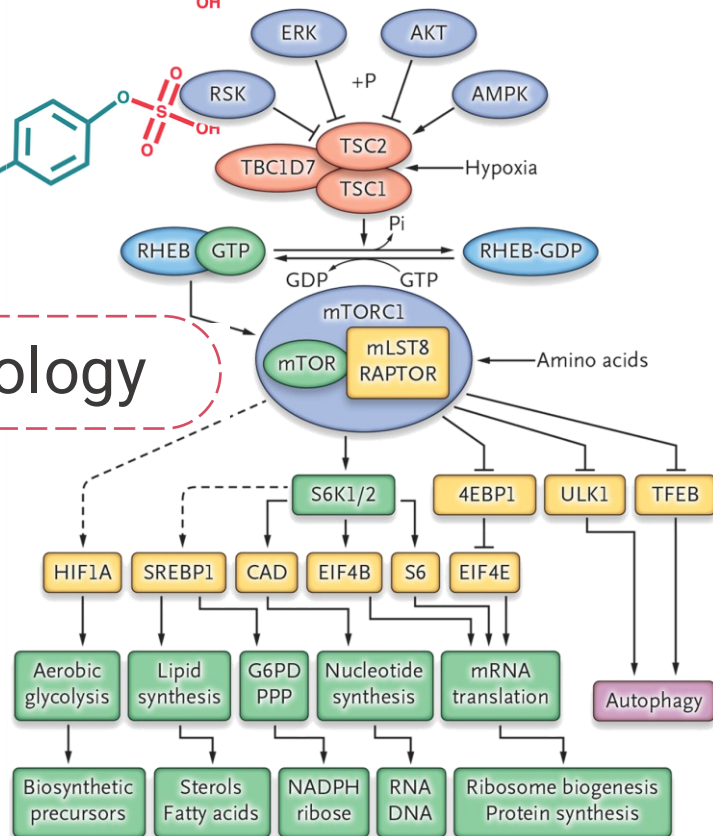


*HNA - Higher nervous activity

Drug Metabolites



Drugs' pharmacology



Patients' individual characteristics



SIDER 4.1 : Side Effect Resource

Please note that we have no funding to further develop SIDER. The data in SIDER is from 2015 and therefore out of date!

OnSIDES

Our fine-tuned language model achieves an F1 score of 0.90, AUROC of 0.92, and AUPR of 0.95 at extracting effects from the ADVERSE REACTIONS section of the FDA drug label. For the BOXED WARNINGS section, the model achieves an F1 score of 0.71, AUROC of 0.85, and AUPR of 0.72. For the WARNINGS AND PRECUATIONS section, the model achieves an F1 score of 0.68, AUROC of 0.66, and AUPR of 0.68. Compared against the reference standard using the

VigiAccess



World Health
Organization

Pharmacovigilance

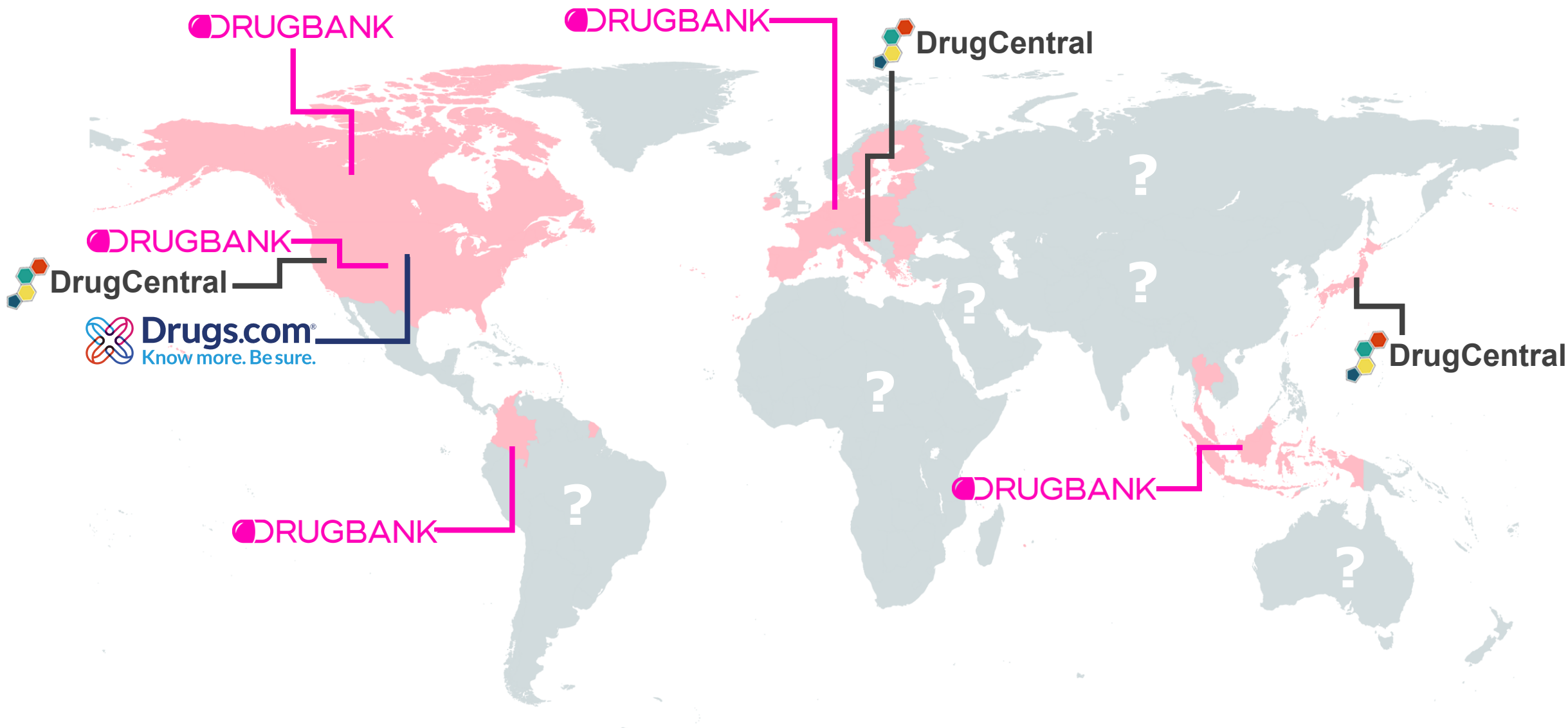


EAEU

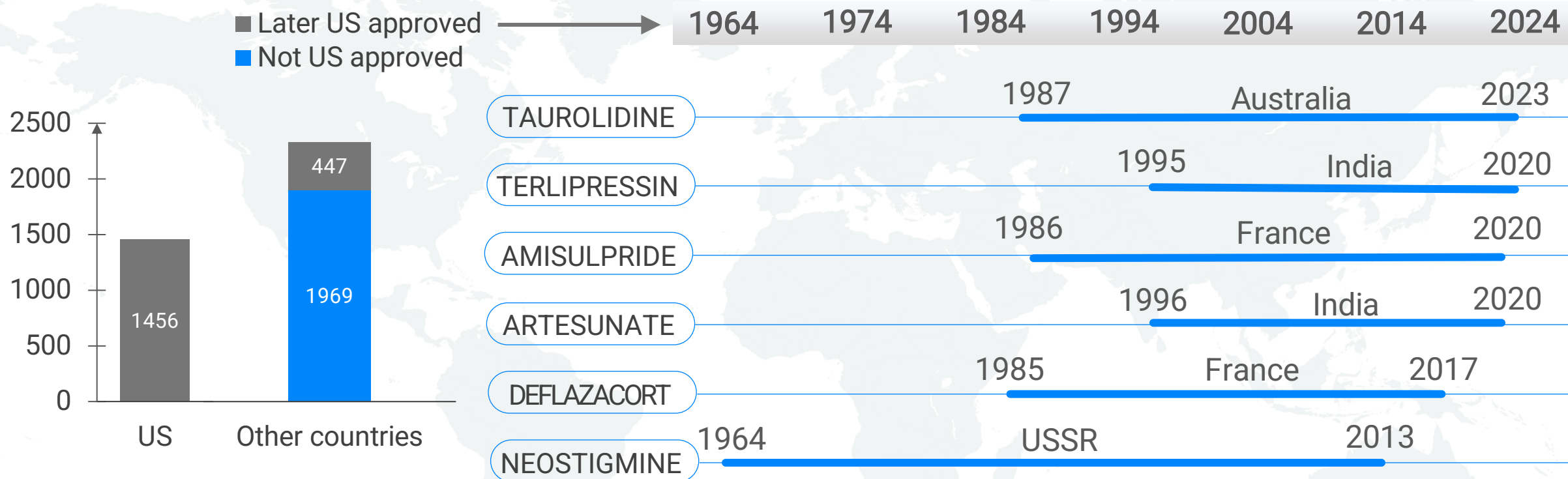
DATABASE OF ADVERSE
DRUG REACTION

EudraVigilance

FDA FAERS

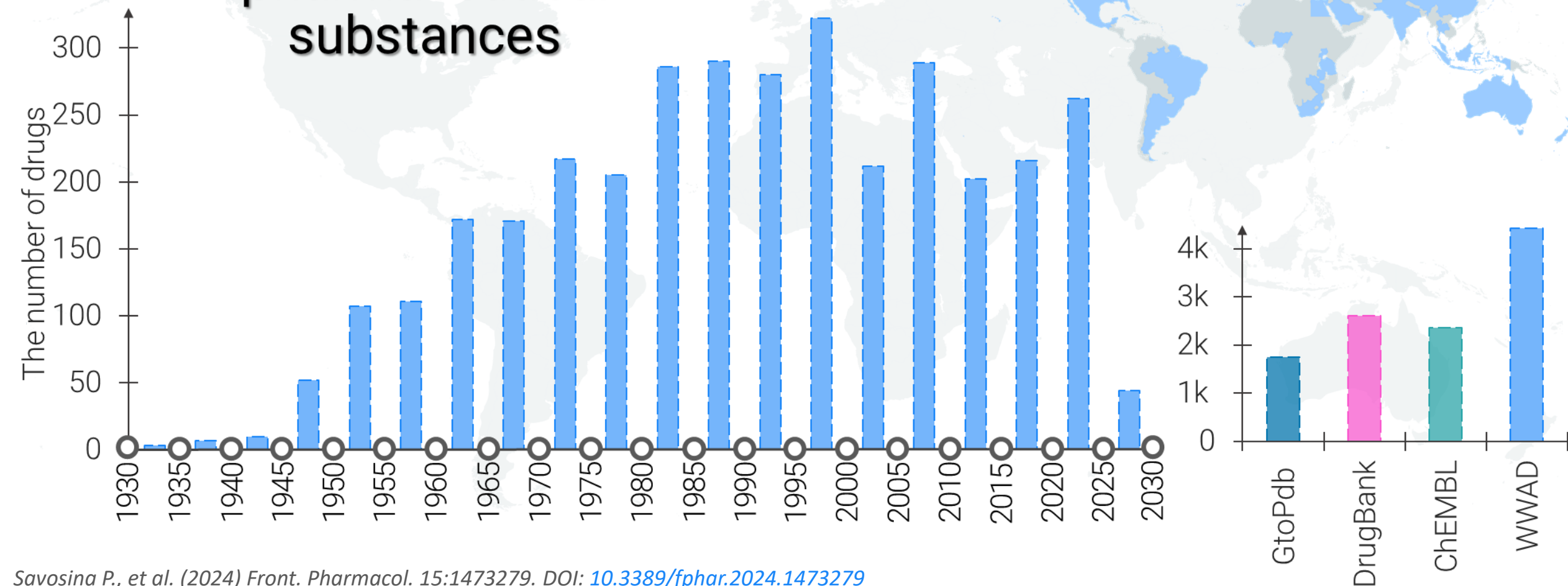


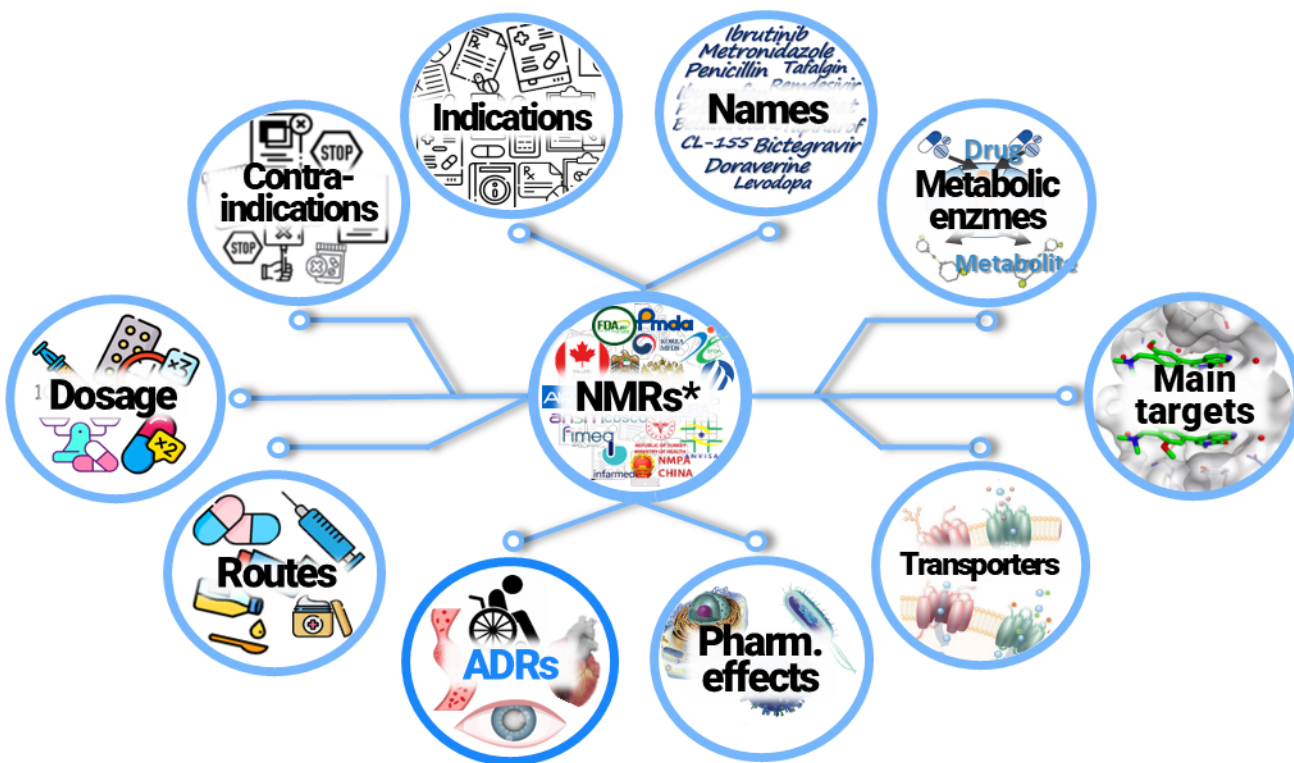
■ Later US approved
 ■ Not US approved



4 557
pharmaceutical
substances

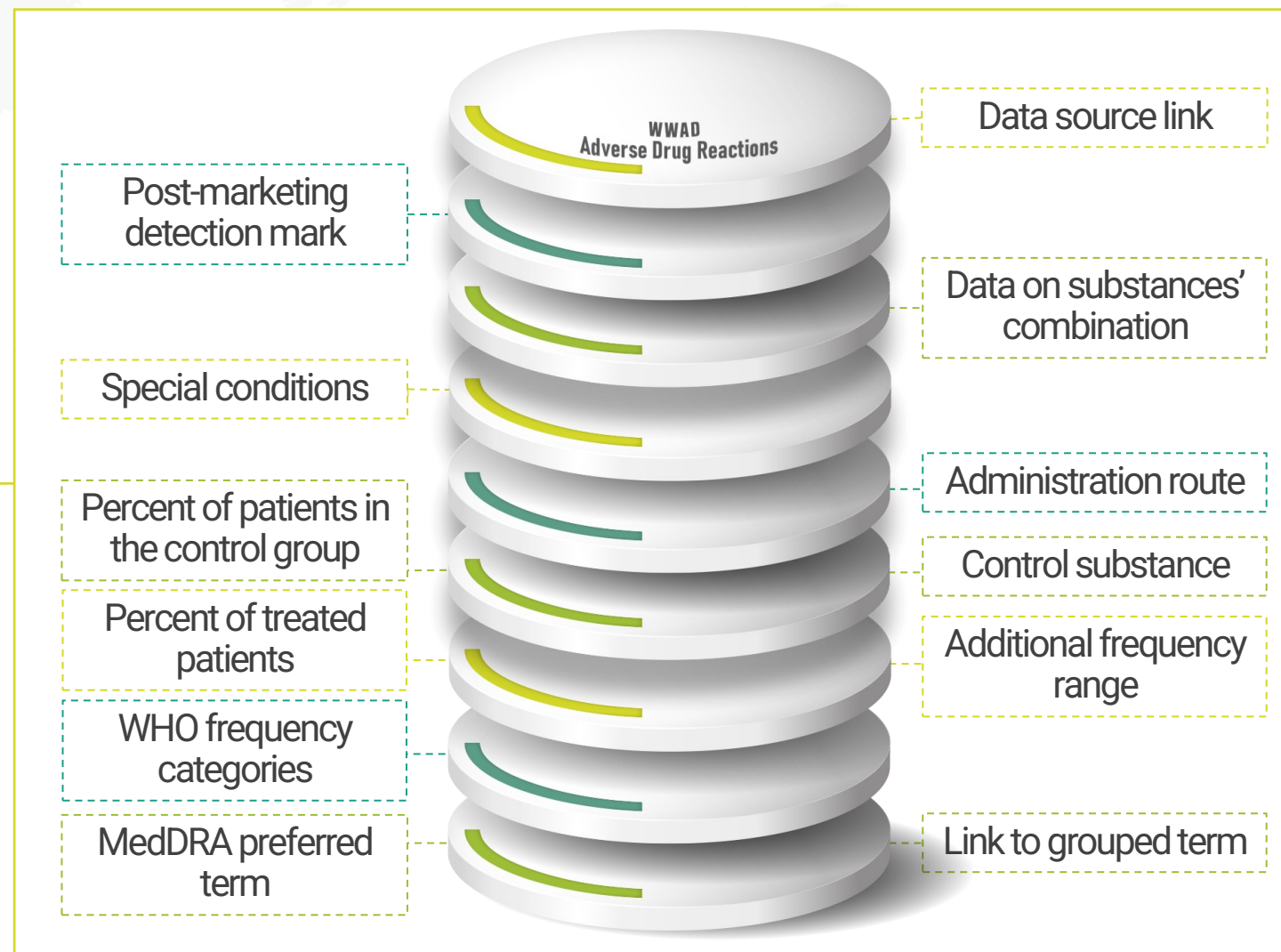
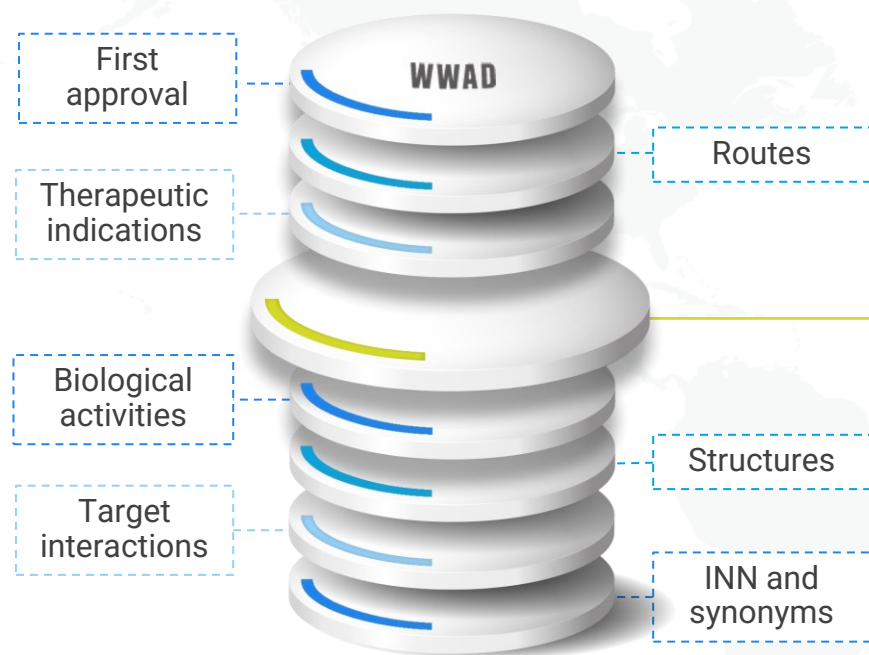
90 countries





- FDA Drug Label
- Instructions for Medical Use
- Summary of Product Characteristics
- PMDA Review Report
- European Public Assessment Report





2 306
pharmaceutical
substances

4 587
MedDRA
preferred terms

36
administration
routes

120 193
records

20 144
records with
percent of patients

11 781
records control
group data

■ The number of active substances

 SIDER 4.1

1 430 -----> > 2300

■ Additional information

administration route, conditions, etc. -----> no

 SIDER 4.1

 OnSIDES

■ National diversity

1 country -----> > 30 NMR

 OnSIDES

■ Data quality

manual curation -----> text-mining

 SIDER 4.1

 OnSIDES

■ Time range

before 2015 -----> to date

 SIDER 4.1

■ Data standardization

ready for ML -----> required

 SIDER 4.1

 OnSIDES

■ Control group data

no -----> > 11 000 records

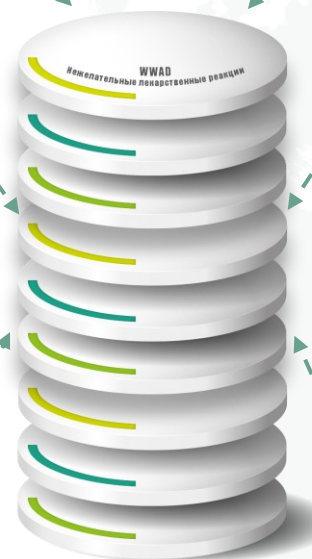
 OnSIDES

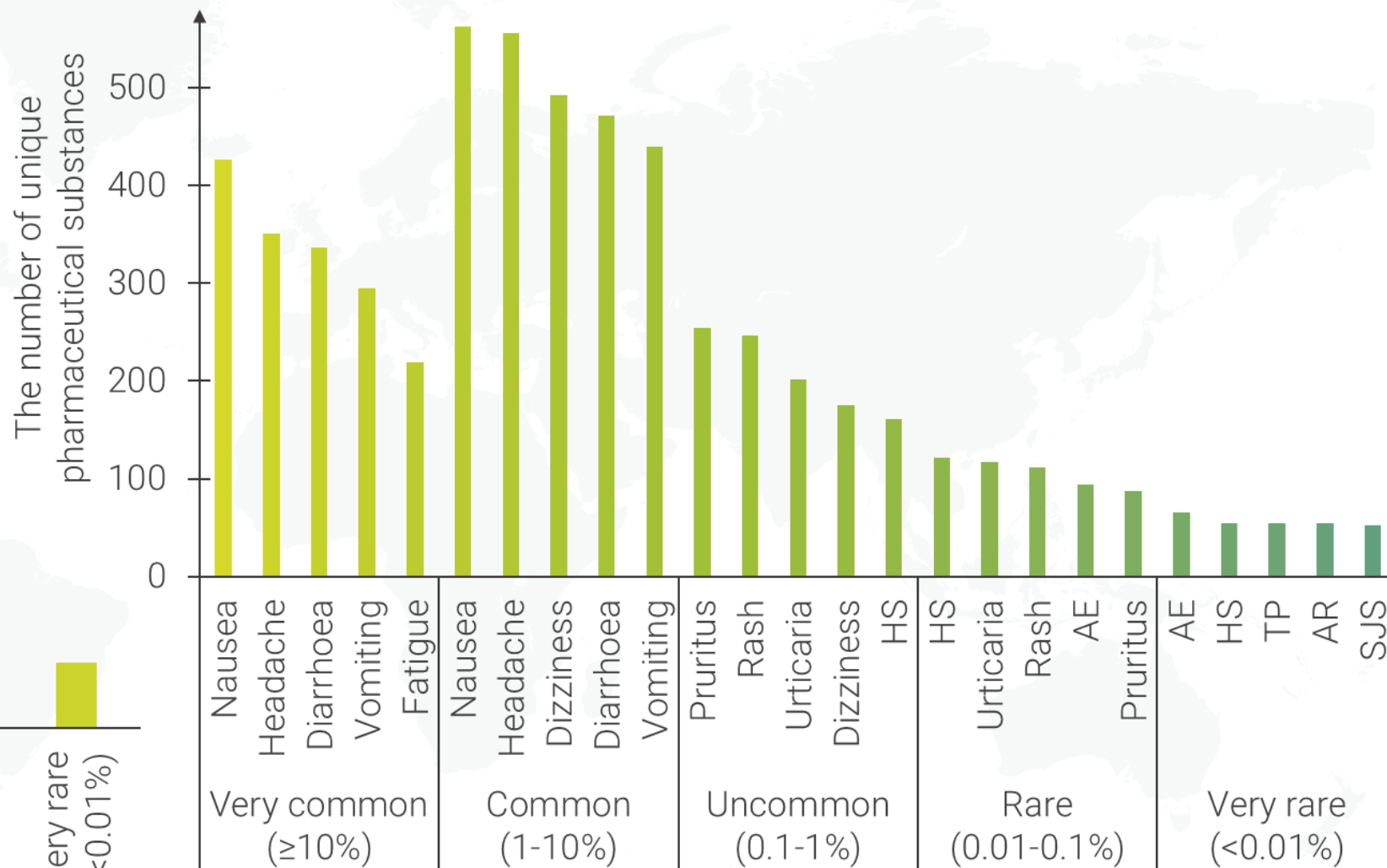
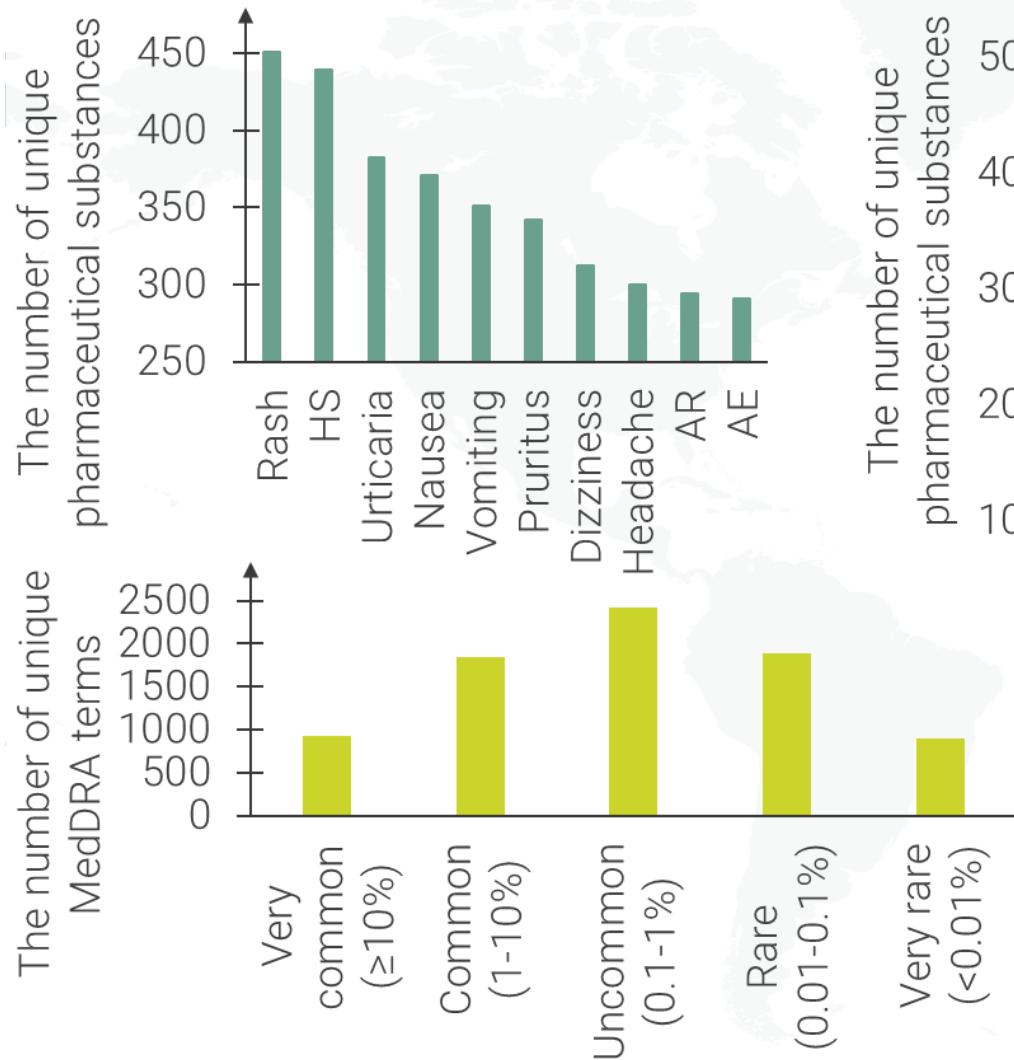
■ Integration with other data

WWAD -----> no

 SIDER 4.1

 OnSIDES





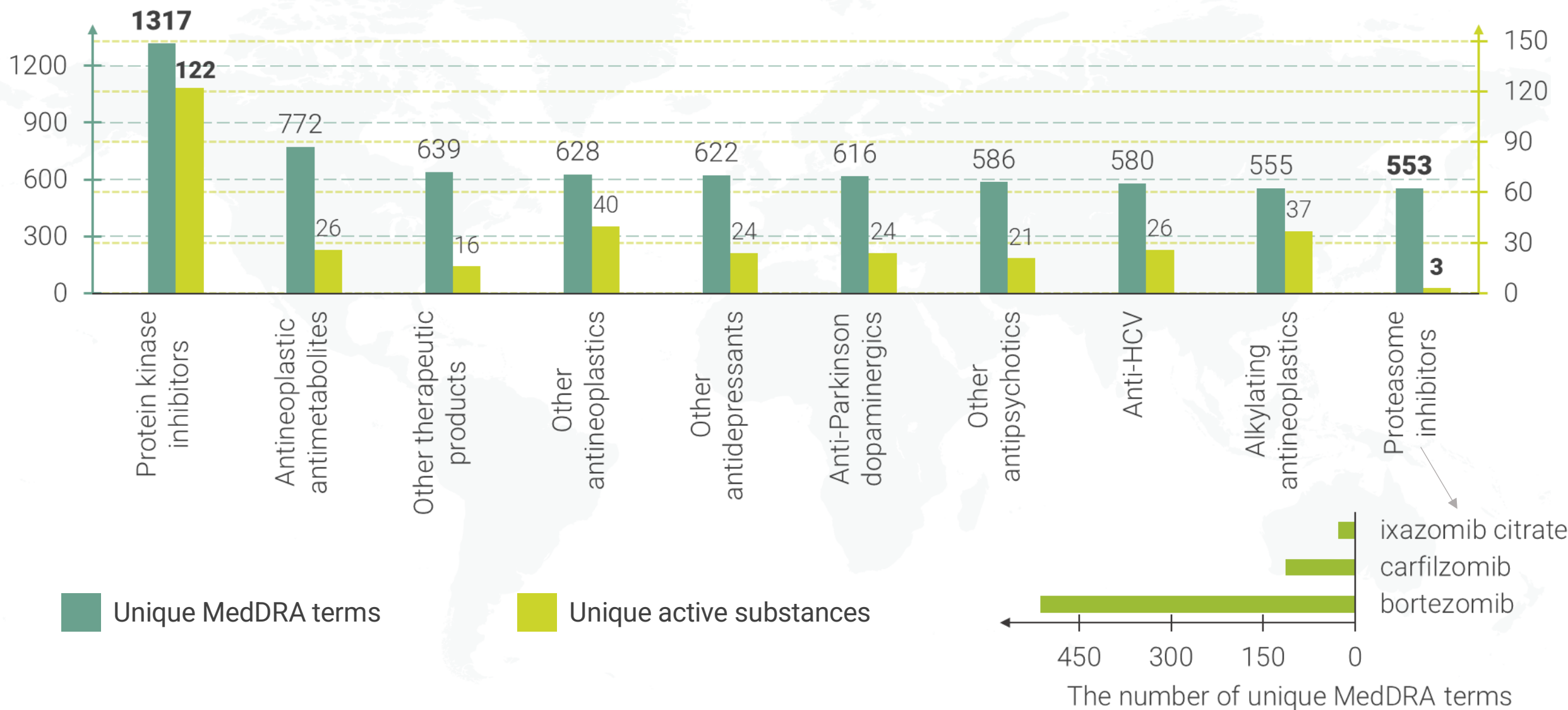
HS – Hypersensitivity

AR – Anaphylactic reaction

AE – Angioedema

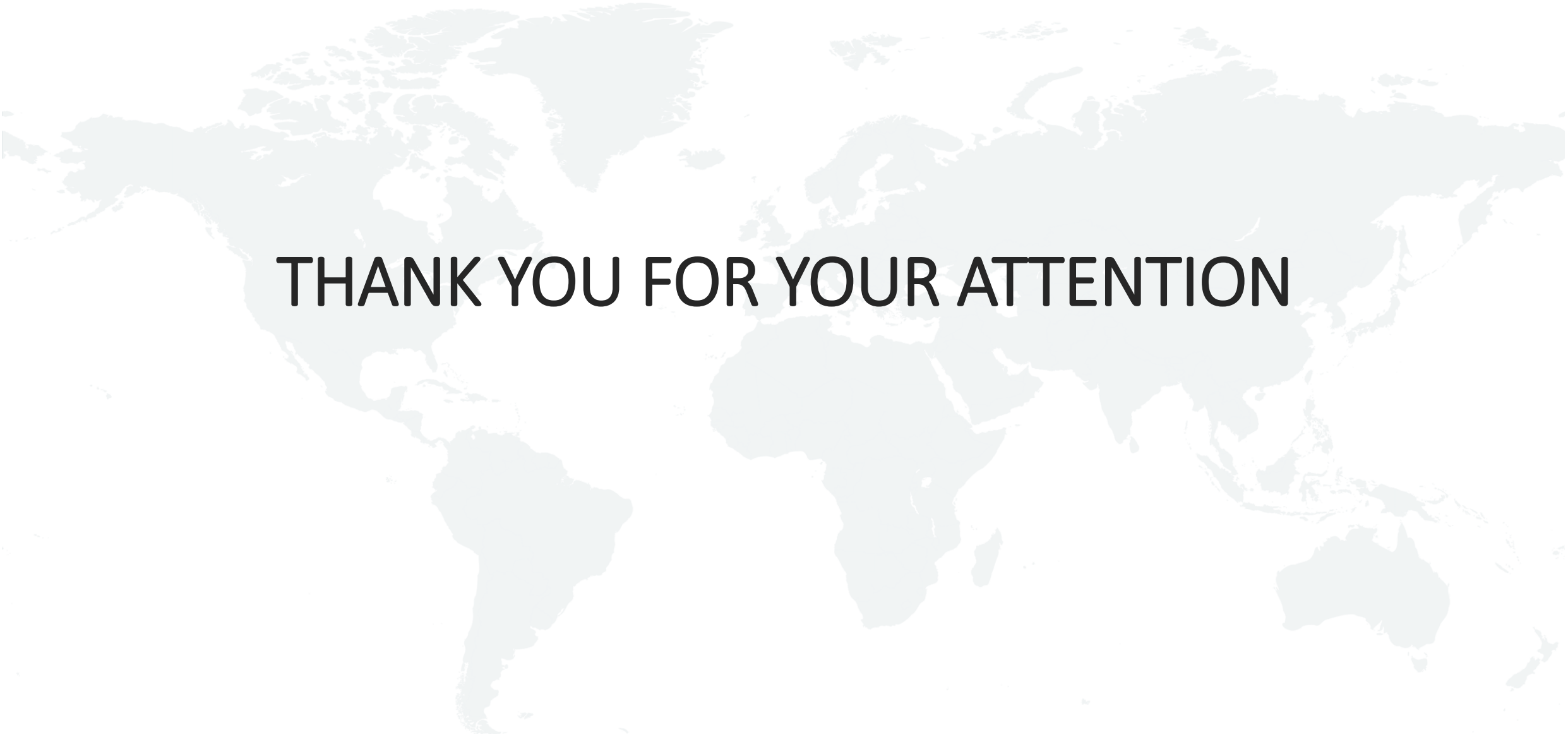
TP – Thrombocytopenia

SJS – Stevens–Johnson syndrome





Grant № 25-25-00106



THANK YOU FOR YOUR ATTENTION