PODR Datasources

This document contains a list of datasources that are/will be loaded into PODR.

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# Background

There are huge amounts of Real World Data available, PODR collects this open data from different organization and countries and integrates it in one place.

PODR gives the users the ability to view data from different countries, agencies and departments that is related without having to go search through the internet.

NIHPO’s process of the data will improve the user experience when working with this data but the raw data will remain unmodified.

# ES\_AEMPS\_Nomenclator

Dataset Name: Nomenclator for prescription

url: https://cima.aemps.es/cima/publico/home.html

Description: Nomenclator for Prescription is a medicine database intended to provide core prescription information to the care information services. Nomenclator for Prescription applies to all medicinal products that have been authorised and marketed, financed and unfunded, data relating to their identification and technical information

# EU\_EMA

Dataset Name: EMA Medicines

url: https://www.ema.europa.eu/en/medicines/download-medicine-data

Description: European Medicines Agency's (EMA) medicine-related data published

# EU\_EudraCT

Dataset Name: European Union Drug Regulating Authorities Clinical Trials Database

url: https://eudract.ema.europa.eu/

Description: EudraCT (European Union Drug Regulating Authorities Clinical Trials Database) is the European database for all interventional clinical trials on medicinal products authorized in the European Union (EEA) and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP) from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC. Protocol and results information on interventional clinical trials are made publicly available through the European Union Clinical Trials Register since September 2011.

# US\_FDA\_AERS

Dataset Name: FDA Adverse Event Reporting System (FAERS)

url: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-adverse-event-reporting-system-faers

Description: FDA Adverse Event Reporting System supports the FDA's post-marketing safety surveillance program for all marketed drug and therapeutic biologic products. It contains adverse event reports FDA has received from manufacturers as required by regulation along with reports received directly from consumers and healthcare professionals.

# US\_FDA\_DRUGS

Dataset Name: FDA Drugs@FDA

url: https://www.fda.gov/drugs/drug-approvals-and-databases/about-drugsfda

Description: Drugs@FDA includes most of the drug products approved since 1939. The majority of patient information, labels, approval letters, reviews, and other information are available for drug products approved since 1998.

# US\_FDA\_BMIS

Dataset Name: FDA Bioresearch Monitoring Information System (BMIS)

url: https://www.fda.gov/drugs/drug-approvals-and-databases/bioresearch-monitoring-information-system-bmis

Description: In order to foster transparency and encourage information sharing within the clinical research community, FDA’s Center for Drug Evaluation and Research (CDER) maintains a bioresearch monitoring Web site that makes clinical research information available to the public. This Web site contains information that identifies clinical investigators, contract research organizations, and institutional review boards involved in the conduct of Investigational New Drug (IND) studies with human investigational drugs and therapeutic biologics. This information is extracted from IND-related documents submitted to the agency and made available to the public as the Bioresearch Monitoring Information System (BMIS) at http://www.accessdata.fda.gov/scripts/cder/bmis/

# US\_FDA\_IIG

Dataset Name: Inactive Ingredients Database Download

url: https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-database-download

Description: The Inactive Ingredients files are supplied as comma delimited text and Excel files. The size of each unzipped file is less than 2 MB.  
We update the database quarterly, by the tenth working day of April, July, October, and January.

# US\_FDA\_OrangeBook

Dataset Name: FDA Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book

url: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

Description: The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

# US\_FDA\_CLIIL

Dataset Name: Clinical Investigator Inspection List (CLIIL)

url: https://www.fda.gov/drugs/drug-approvals-and-databases/clinical-investigator-inspection-list-cliil

Description: The Clinical Investigator Inspection List (CLIIL) contains names, addresses, and other pertinent information gathered from inspections of clinical investigators who have performed studies with investigational new drugs. The list contains information on inspections that have been closed since July 1977.

# US\_FDA\_NDC

Dataset Name: FDA National Drug Code Directory

url: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Description: The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

# US\_FDA\_POSTMARKETING

Dataset Name: Postmarketing Requirements and Commitments: Downloadable Database File

url: https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-downloadable-database-file

Description: Postmarketing Requirements and Commitments database.

# US\_FDA\_510K

Dataset Name: FDA

url: https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

Description: Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance

# US\_FDA\_REMS

Dataset Name: Approved Risk Evaluation and Mitigation Strategies (REMS)

url: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page

Description: Currently, there are 63 REMS.

57 [90%] include "elements to assure safe use' (ETASU). REMS with ETASU typically require clinicians or health care settings to become certified prior to prescribing and to participate in additional REMS activities, such as training, patient counseling, and monitoring.

4 [6%] include only a "communication plan" REMS element which is informational in nature. These communication plans are typically composed of letters, websites, and fact sheets describing the specific safety risks identified in the REMS.

1 [2%] include only the "medication guide" REMS element. Even products that do not have "medication guide" REMS elements may have medication guides as part of their labeling.

1 [2%] include the "communication plan" AND "medication guide" REMS elements only.

# US\_FDA\_PCC

Dataset Name: FDA National Drug Code Directory

url: https://www.fda.gov/medical-devices/classify-your-medical-device/download-product-code-classification-files

Description: The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.

# US\_FDA\_WDD3PL

Dataset Name: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers

url: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/annual-reporting-prescription-drug-wholesale-distributors-and-third-party-logistics-providers

Description: The Drug Supply Chain Security Act (DSCSA) requires wholesale distributors and third-party logistics providers to report licensure and other information to FDA annually under sections 503(e)(2) and 584 Federal Food, Drug, and Cosmetic Act. FDA recently published a draft guidance, Identifying Trading Partners Under the Drug Supply Chain Security Act (DSCSA), to clarify whether entities are engaged in activities that require licensure and annual reporting.

# US\_FDA\_DECRS

Dataset Name: Drug Establishments Current Registration Site

url: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site

Description: The drug establishments current registration site is a publication of currently registered establishments which manufacture, prepare, propagate, compound or process drugs that are distributed in the U.S. or offered for import to the U.S.

# US\_HHS\_CMS\_PUF

Dataset Name: CMS Medicare Provider Utilization and Payment Data

url: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data

Description: These Medicare Provider Utilization and Payment Data files include information for common inpatient and outpatient services, all physician and other supplier procedures and services, and all Part D prescriptions. Providers determine what they will charge for items, services, and procedures provided to patients and these charges are the amount that providers bill for an item, service, or procedure.

# US\_CMS\_OPEN\_PAYMENTS

Dataset Name: CMS Open Payments Dataset

url: https://openpaymentsdata.cms.gov/

Description: Record of Open Payments for payments made by drug and medical device companies to physicians and teaching hospitals

# US\_CMS\_MTC

Dataset Name: CMS Medicare Provider and Supplier Taxonomy Crosswalk

url: https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-provider-and-supplier-taxonomy-crosswalk

Description: The Medicare Provider and Supplier Taxonomy Crosswalk dataset lists the providers and suppliers eligible to enroll in Medicare programs with the proper healthcare provider taxonomy code. This data includes the Medicare speciality codes, if available, provider/supplier type description, taxonomy code, and the taxonomy description

# US\_CMS\_NPI

Dataset Name: CMS National Plan and Provider Enumeration System

url: https://www.cms.gov/regulations-and-guidance/administrative-simplification/nationalprovidentstand

Description: The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. The NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about healthcare providers, such as the state in which they live or their medical specialty. The NPI must be used in lieu of legacy provider identifiers in the HIPAA standards transactions.

# US\_NIH\_RxNorm

Dataset Name: RxNorm Files

url: https://www.nlm.nih.gov/research/umls/rxnorm/index.html

Description: RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, and Gold Standard Drug Database. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.

# US\_NIH\_CDISC

Dataset Name: CDISC Terminology

url: https://www.cdisc.org/standards/terminology/controlled-terminology

Description: Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you WHAT to collect; it tells you IF you collected a particular data item, how you should submit it in your electronic dataset.

# US\_NLM\_MeSH

Dataset Name: NIH Medical Subject Headings

url: https://www.nlm.nih.gov/mesh/meshhome.html

Description: The Medical Subject Headings (MeSH) thesaurus is a controlled and hierarchically-organized vocabulary produced by the National Library of Medicine. It is used for indexing, cataloging, and searching of biomedical and health-related information. MeSH includes the subject headings appearing in MEDLINE/PubMed, the NLM Catalog, and other NLM databases

# US\_NLM\_**PubMed**

Dataset Name: NLM Medical Publications

url: https://pubmed.ncbi.nlm.nih.gov/

Description: PubMed® comprises more than 33 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full text content from PubMed Central and publisher web sites.

# US\_NLM\_**ChemID**

Dataset Name: NLM Chemical Database

url: https://chem.nlm.nih.gov/chemidplus/

Description: ChemID provides access to the structure and nomenclature authority files used for the identification of chemical substances cited in National Library of Medicine (NLM) databases. ChemIDplus also has structure searching and direct links to resources at NLM, federal agencies, U.S. states, and scientific sites. The database contains more than 400,000 chemical records, of which over 300,000 include chemical structures.

# US\_NLM\_SNOMEDCT

Dataset Name: SNOMED CT United States Edition

url: https://www.nlm.nih.gov/healthit/snomedct/us\_edition.html

Description: The US Edition is a standalone release that combines the content of both the US Extension and the International releases of SNOMED CT. NLM distributes the US Edition of SNOMED CT

# US\_ClinicalTrials

Dataset Name: Clinical Trials

url: https://clinicaltrials.gov

Description: ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions

# US\_Spendings

Dataset Name: USA Spendings

url: https://www.usaspending.gov/

Description: Track how federal money is spent in communities across America and beyond. Learn more about government spending through interactive tools that explore elements of the federal budget, such as federal loan, grant, and contract data.

# LOINC

Dataset Name: LOINC terms

url: https://loinc.org/

Description: An export of all of the LOINC terms that are in the complete table with a subset of the fields that are both crucial for defining each LOINC term and whose structure is anticipated to be stable over the long-run

# **WHO\_ICTRP**

Dataset Name: WHO International Clinical Trials Registry Platform (ICTRP)

url: https://www.who.int/clinical-trials-registry-platform

Description: The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.