PHUSE Open Data Repository ("PODR") :: Launch

 Comments: Jose.Lacal@NIHPO.com

Agenda

- About Jose C. Lacal
- PODR’s Objectives
- NIHPO Platform Overview
- Enriched Open Data
- Instance of NIHPO Platform
- Planned Initial Datasets
- Live Demo
- Q&A, Feedback

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About Jose C. Lacal

- 1994-1996: Internet Service Provider in Mexico
- 1996-1999: Siemens Telecom (Voice over IP)
- 2000-2007: Motorola (Mobiles, tele-medicine)
- 2007-2012: Analytics for tracking Medicare fraud
- 2012-2014: Data Mining of EU and US Open Data
- 2014-2019: Stryker (Data Mining, cybersecurity)
- 2020- Principal Sales Engineer at SaaS company

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PHUSE Open Data Repository ("PODR") - Objectives

- Increase member engagement in WGs, events.
- "From Zero to Analysis" in under five minutes.
- Accelerate discovery of solutions to challenges.
- Learn new tools (Jupyter, Python); Best Practices.
- Members quickly launch collaborative research.
- Make data analytics accessible to all user levels.
- Members will not need any IT involvement.

NIHPO Platform Overview 01

Literature	Clinical Trials	Regulatory Approval	Adverse Events	Vendor Payments	Medicare Payments	Federal Payments

U.S. Department of Health & Human Services

NIH U.S. National Library of Medicine

NIH U.S. National Library of Medicine

ClinicalTrials.gov

EU Clinical Trials Register

FDA U.S. FOOD & DRUG ADMINISTRATION

Drugs@FDA: FDA Approved Drug Products

FDA U.S. FOOD & DRUG ADMINISTRATION

Medical Devices

510(k) Clearances

FDA U.S. FOOD & DRUG ADMINISTRATION

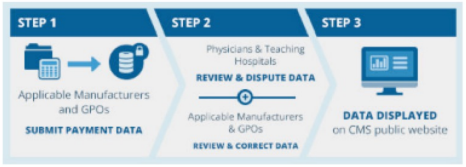
Medical Devices

Premarket Approval (PMA)

FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files

MAUDE - Manufacturer and User Facility Device Experience

How Open Payments Works



- Medicare Provider Utilization and Payment Data: Physician and Other Supplier
- Medicare Provider Utilization and Payment Data: Inpatient
- Medicare Provider Utilization and Payment Data: Outpatient
- Medicare Provider Utilization and Payment Data: Part D Prescriber
- Medicare Provider Utilization and Payment Data: Referring Durable Medical Equipment, Prosthetics, Orthotics and Supplies
- Medicare Provider Utilization and Payment Data: Home Health Agencies
- Medicare Provider Utilization and Payment Data: Skilled Nursing Facilities
- Medicare Provider Utilization and Payment Data: Hospice Providers

USASPENDING.gov

FY 2018 OBLIGATED AMOUNT

$6.6 Trillion

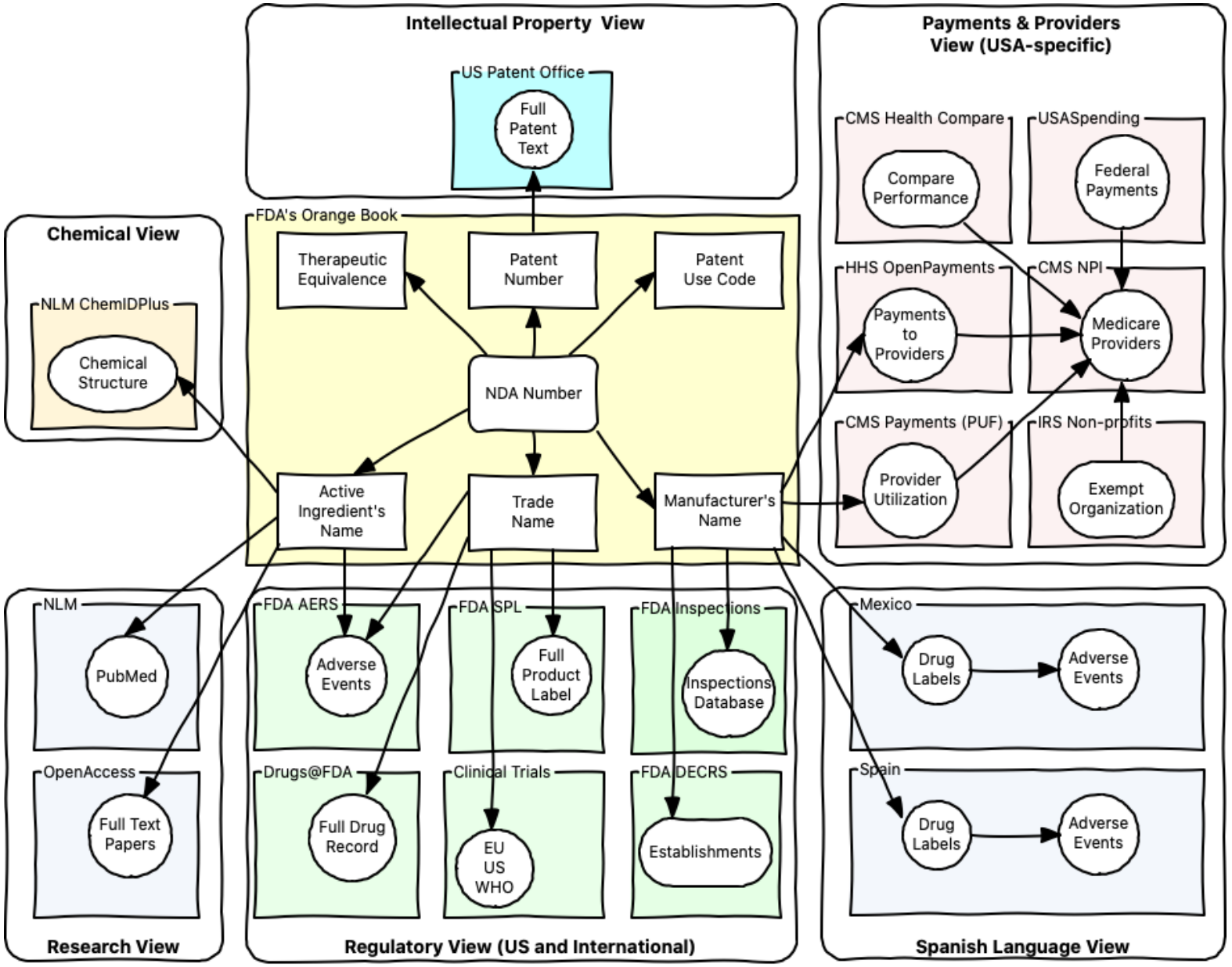
Data as of September 30, 2018

Chemical Compound

PubChem

Using Open Data would allow a PHUSE user to trace a drug's entire lifecycle:
* starting with chemical compounds (NLM's PubChem)
* through clinical trials (ClinicalTrials.gov, WHO's ITPR)
* documentation on regulatory pathway (IND, NDA, etc.)
* reported adverse events (FDA's FAERS)
* manufacturer payments to providers (HHS' OpenPayments)
* Medicare reimbursement data (CMS' Provider Utilization and Payment Data)

NIHPO Platform Overview 02



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Enriched Open Data

- Open Data is Everywhere
- Not cleanly defined
- Different formats:
  FDA AERS has 04 formats
- Changes often
- Harmonized names

BAYER

'BAYER PHARMACEUTICALS CORPORATION'
'BAYER GERMANY'
'BAYER HEALTHCARE LLC'
'BAYER HEALTHCARE PHARMACEUTICALS IN'
'BAYER HEALTHCARE PHARMACEUTICALS'
'BAYER PHARAMCEUTICALS CORPORATION'
'BAYER PHARMACEUTICAL CORPORATION'
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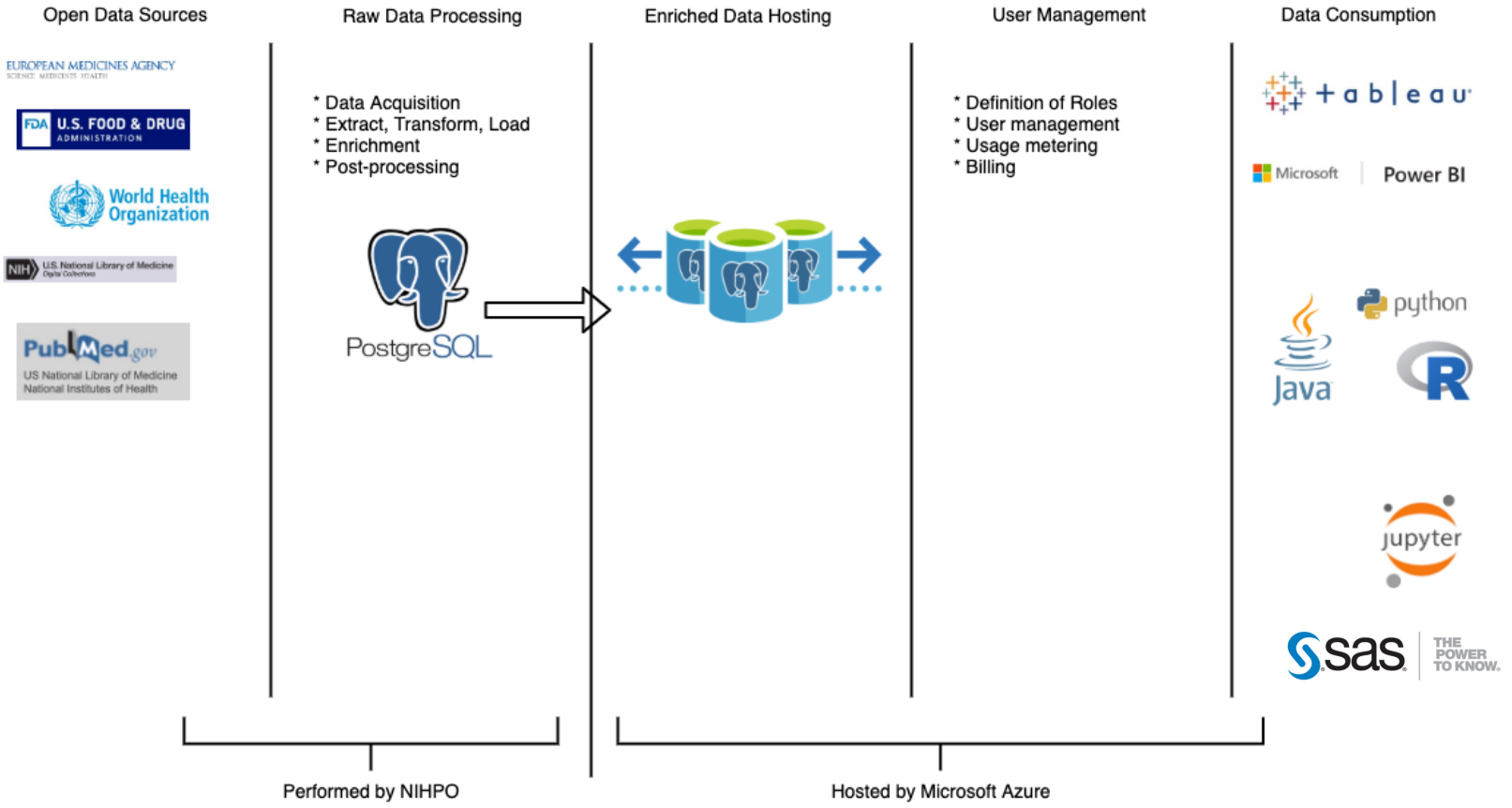
Instance of NIHPO Platform



NIHPO has developed proprietary software that enriches the raw data provided by the government and international agencies. This enrichment process includes:
* structuring each dataset into a single format across time
* harmonizing manufacturers' and drug names (for example the names "Stryker" and "Striker" and "Stryker, Inc" need to be harmonized into a single "stryker" value)
* cross-referencing sources with other sources

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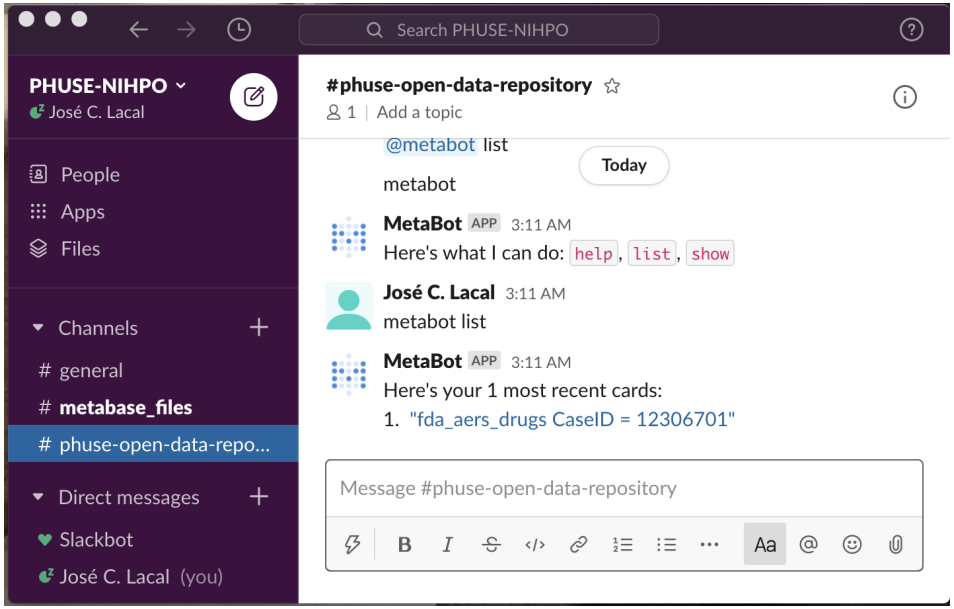
Planned Initial Datasets

Dataset	Description
EU - EMA	European Medicines Agency's (EMA) medicine-related data.
EU - EudraCT	EudraCT (EU's Drug Regulating Authorities Clinical Trials Database)
CMS - NPI	The National Provider Identifier (NPI).
CMS - PUF	Medicare Provider Utilization and Payment Data files: Part D prescriptions.
ClinicalTrials.gov	ClinicalTrials.gov: privately, publicly funded clinical studies worldwide.
FDA - AERS	Adverse Event Reporting System - FDA's post-marketing safety surveillance.
FDA - BMIS	Bioresearch Monitoring Information System (BMIS).
FDA - Drugs@FDA	Drugs@FDA - Prescription brand-name, generics, biologics, OTC.
FDA - NDC	FDA - National Drug Code (NDC)
FDA - Orange Book	Approved Drug Products with Therapeutic Equivalence Evaluations.
HHS - Open Payments	Payments, transfers of value to physicians and teaching hospitals.
NLM - ChemID	Access to structure, nomenclature for identification of chemical substances.
NLM - MeSH	Medical Subject Headings (MeSH) appearing in MEDLINE/PubMed.
NLM - PubMed	Over 30 million citations for biomedical literature from MEDLINE.
USASpending	Tracks federal spending to see how money is used across America.
WHO - ICTRP	International Clinical Trials Registry Platform

Live Demo

Q&A, Feedback 01



- Desired level of support?
- Desired Documentation?
- Are datasets good start?
- Intended Use Cases: Google questionnaire.
- New Use Cases? Please send.
- Test volunteers? ==>> Jose.Lacal@PHUSE.eu

Q&A, Feedback 02 - Documents

- ClinicalTrials: Provided documents
- EU EMA:
  - Decision
  - Safety Update
- EU EudraCT:
  - Results' HTML / Protocols' HTML
  - Pediatrics :: study_summary_document
- FDA Drugs@FDA:
  - Application Docs

Contact

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