Mapping of Existing Disease-Specific Data Sources in Latin America for the Conduct of Real-World Studies

A. Bergamasco[1], Teigna Arredondo-Bisono[1], Gerardo Machnicki[2], Camilo Obando [3], Julio Azzael Hernandez-Moran [2], Alan Andryc [4], Xiaoying Wu [4], Louis Pozzo[5], Surendranath Gutta [6], Y. Moride [1,7]

1. YOLARX Consultants, Paris, France; 2. Janssen LATAM, Buenos Aires, Argentina ;
3. Janssen LATAM, Panama City, Panama. 4. Janssen Pharmaceutical Research & Development, Philadelphia, United States; 5. Janssen Pharmaceuticals, New Jersey, United States;
6. Janssen Data Sciences, New Jersey, United States and 7. YOLARX Consultants, Montreal, Canada

This project was funded by Janssen LATAM.

BACKGROUND

- Safety and cost-effectiveness assessment of new drugs increasingly require the collection of disease-specific variables in the real-world practice setting.
- Given the importance of having fit-for-purpose data sources, while ensuring efficiencies in preventing duplication of data collection, absence of a central repository of longitudinal and disease-specific data sources in Latin America (LATAM) represents a major challenge.

OBJECTIVES

- Identify and characterize existing real-world data (RWD) sources in Latin America for 19 diseases of interest in 5 disease areas: hematology/oncology; immunology; infectious diseases; metabolic diseases; and central nervous system;
- Determine the usefulness of identified data sources for observational research.

METHODS

1. Identification of required data elements for each disease of interest

2. Independent systematic literature reviews for all diseases of interest
(Medline, Embase, LILACS/Bireme)

ABSTRACT SCREENING

3. Pragmatic search of web sources

4. Follow-up questionnaire to database custodians tailored to data source applicability
(Linkage possibilities and access policy of identified sources)

IN-DEPTH REVIEW

5. Extraction of information on standardized matrix of characteristics

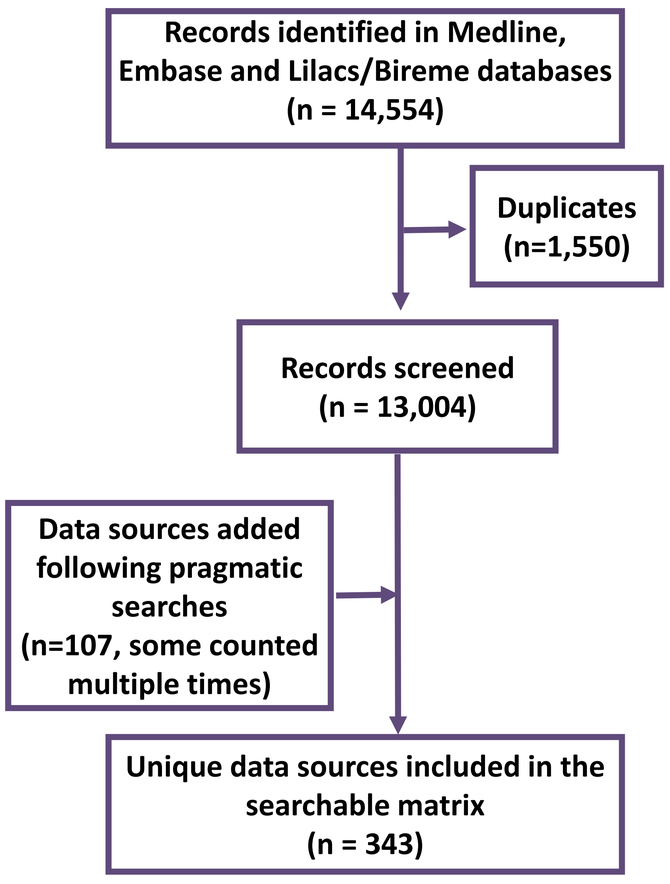
6. Assessment of database usefulness

Table 1. Criteria for the assessment of usefulness of data sources

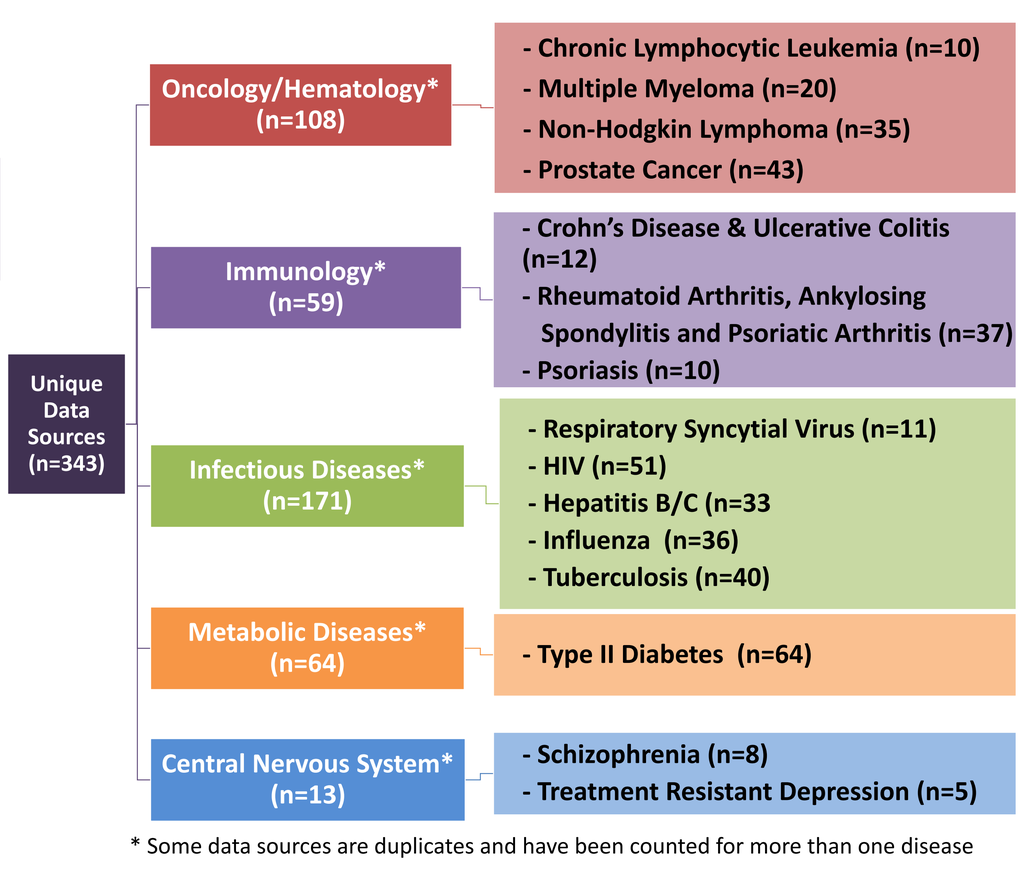
Type of Study	Required Characteristics or Data
Prevalence	- Cross-sectional data
Incidence	- Longitudinal data
Drug utilization	- Prescription or drug dispensing - Longitudinal data
Natural history of the disease	- Clinical outcomes - Longitudinal data
Safety and effectiveness	- Patient characteristics: ○ Socio-demographic ○ Medical history ○ Comorbidity - Disease characteristics and symptoms - Treatments - Clinical outcomes & Death - Longitudinal data
Healthcare utilization	- Drugs, visits, tests, hospitalizations - Longitudinal data
Economic evaluation	- Same as above, with cost data
Outcomes research	- Quality of life measures, work productivity, etc. - Patient questionnaire

RESULTS

Quorum Chart of Literature Review

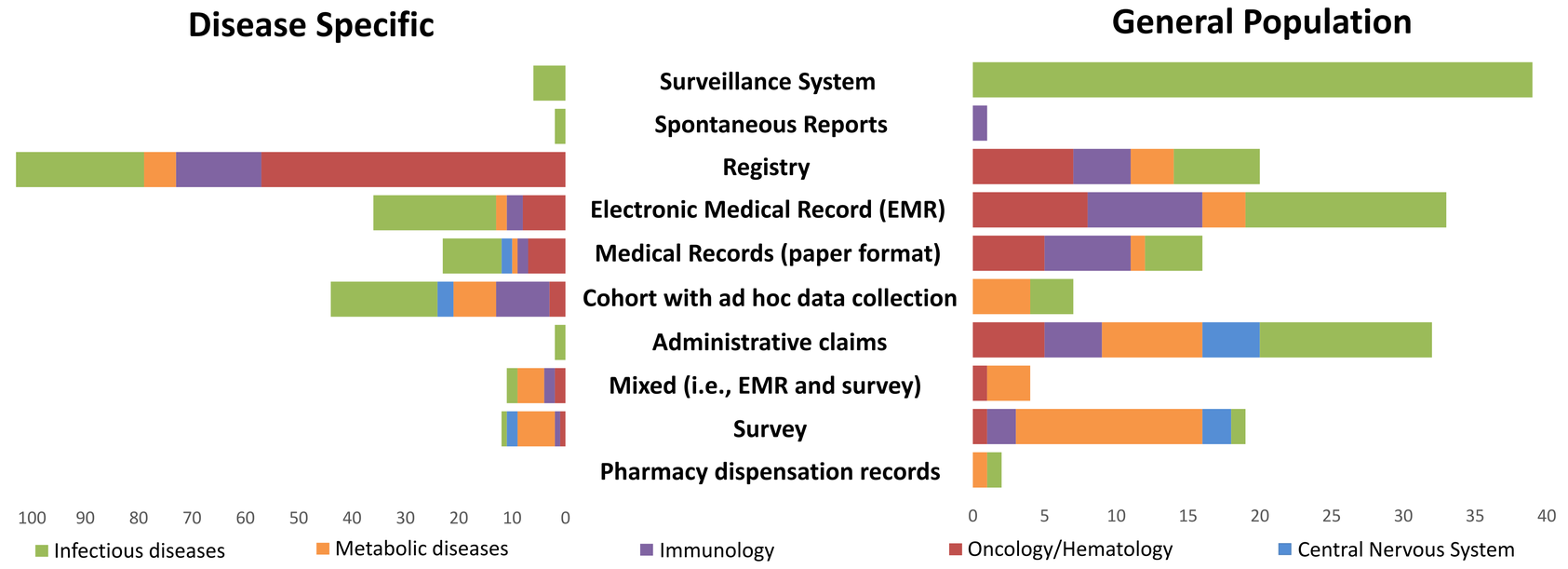


Number of Data Sources per Disease Area (DA)



* Some data sources are duplicates and have been counted for more than one disease

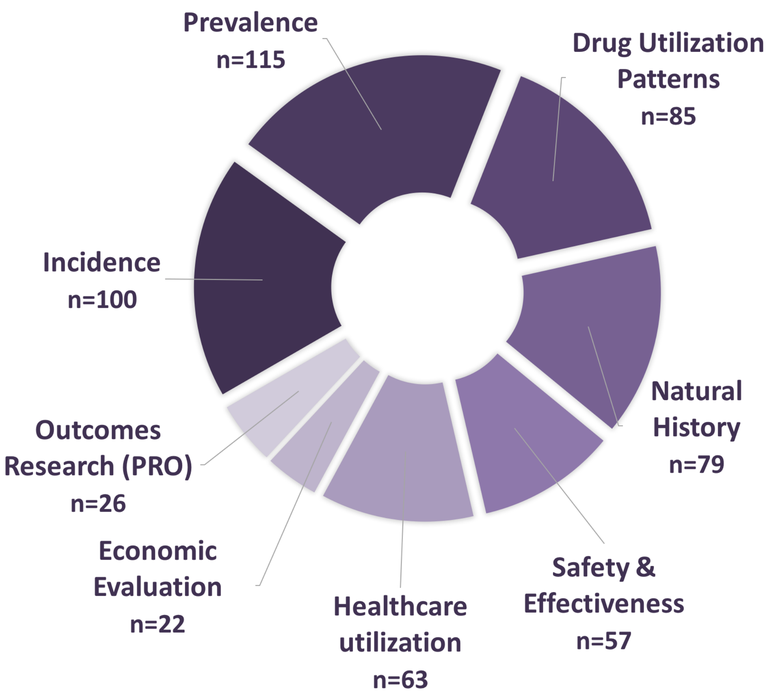
Type of Data Sources Identified



Number of Data Sources Shortlisted (all DA)

Usefulness of Shortlisted Data Sources

- Comparing data available in selected data sources against criteria presented in **Table 1**, their usefulness for different types of RW studies was qualitatively evaluated.



- Most data sources include longitudinal data; hence can be used for incidence (n=100) or prevalence studies (n=115).
- However, only a limited number of data sources is adapted for outcomes research (n=26) or economic evaluation (n=22).

CONCLUSION

- This project contributed to the development of a repository of available RWD sources in Latin America
- Almost all identified data sources include details regarding treatment patterns (i.e., daily dose, medication history) and clinical characteristics (i.e., symptoms, medical history, clinical outcomes).
- However, most lack information on PROs and costs. Therefore, use of additional data sources (i.e., patients interviews, administrative claims data) will be key to collect patients' experience and identify unmet needs or treatment gaps.

32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management (2016), Dublin, Ireland