

Optimizing RWE Design and Conduct by Leveraging Computable Operational Definition (CODef) Indication Libraries: Development, Verification and Value

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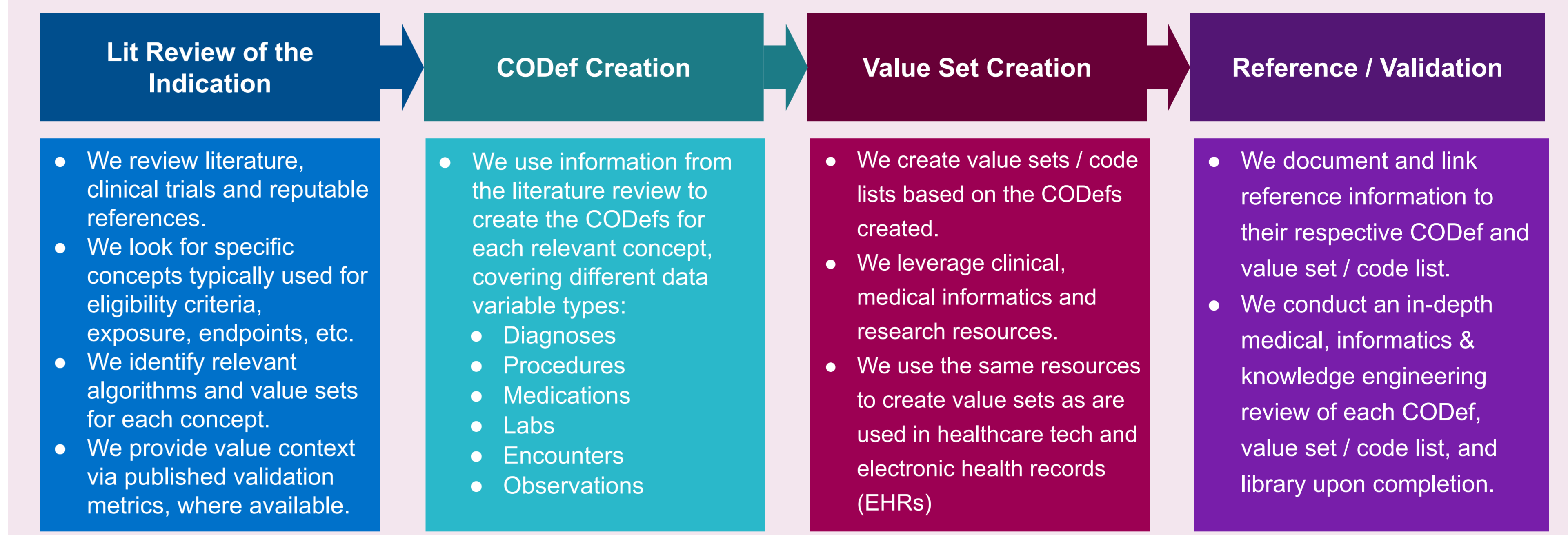
Why is this important?

- Real-world evidence (RWE) involves the interpretation of study elements into conceptual and operational definitions, including up-to-date code lists.
- CODefs maximize comparability and consistency across data sources in global RWE.
- Thoughtful CODef selection has a direct impact on study results as indicated by FDA Guidances *

| Objective: To support the optimization of real-world evidence (RWE) design and conduct via direct selection of CODefs from pre-curated indication-specific libraries.

How did we perform this research?

- A rigorous process was used to develop each indication specific library



*Online Poster



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Indication-specific CODef Libraries for this Project

- Each concept will have multiple CODef implementations. The number of CODefs per library ranged from 86-252 and the number of concepts per library ranged from 45-74 (averaging 1.9 – 3.4 CODefs/concept) [Figure 1]

- The libraries utilized international code systems including >35,000 individual codes. [Figure 2]

Code systems include:

- > ICD-10-CM
- > ICD-9-CM
- > ICD-10-WHO
- > SNOMED CT
- > CPT
- > ICD-10-PCS
- > ATC
- > RxNorm
- > NDC
- > HCPCS
- > SNOMED CT UK
- > READ2
- > CPRD Aurum Medical
- > CPRD Aurum Product
- > OPCS
- > Classification Commune des Actes Médicaux
- > UCD Medication
- > CIP Medication
- > MedDRA

Figure 1. Number of CODefs and concepts across five of the indication libraries

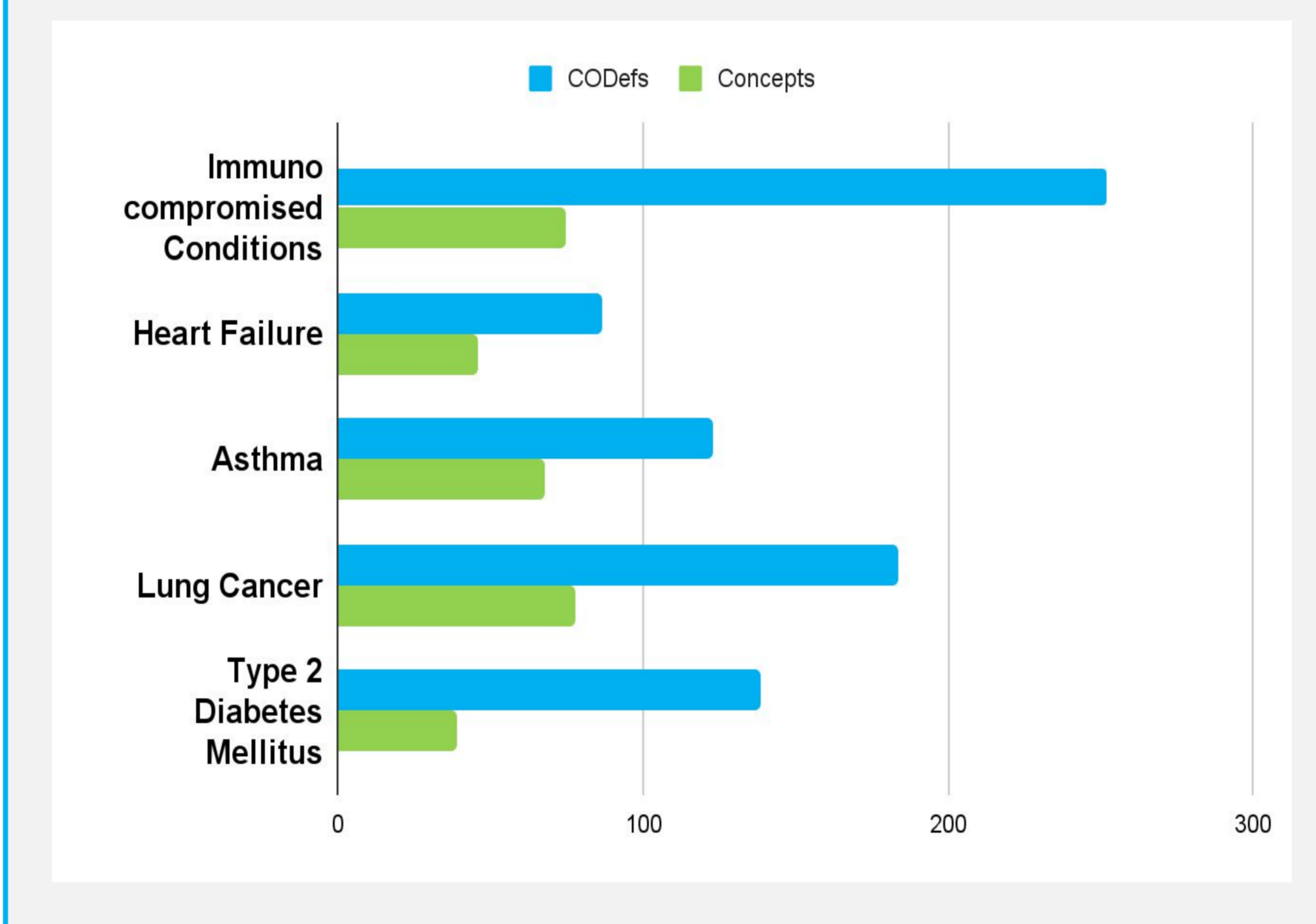
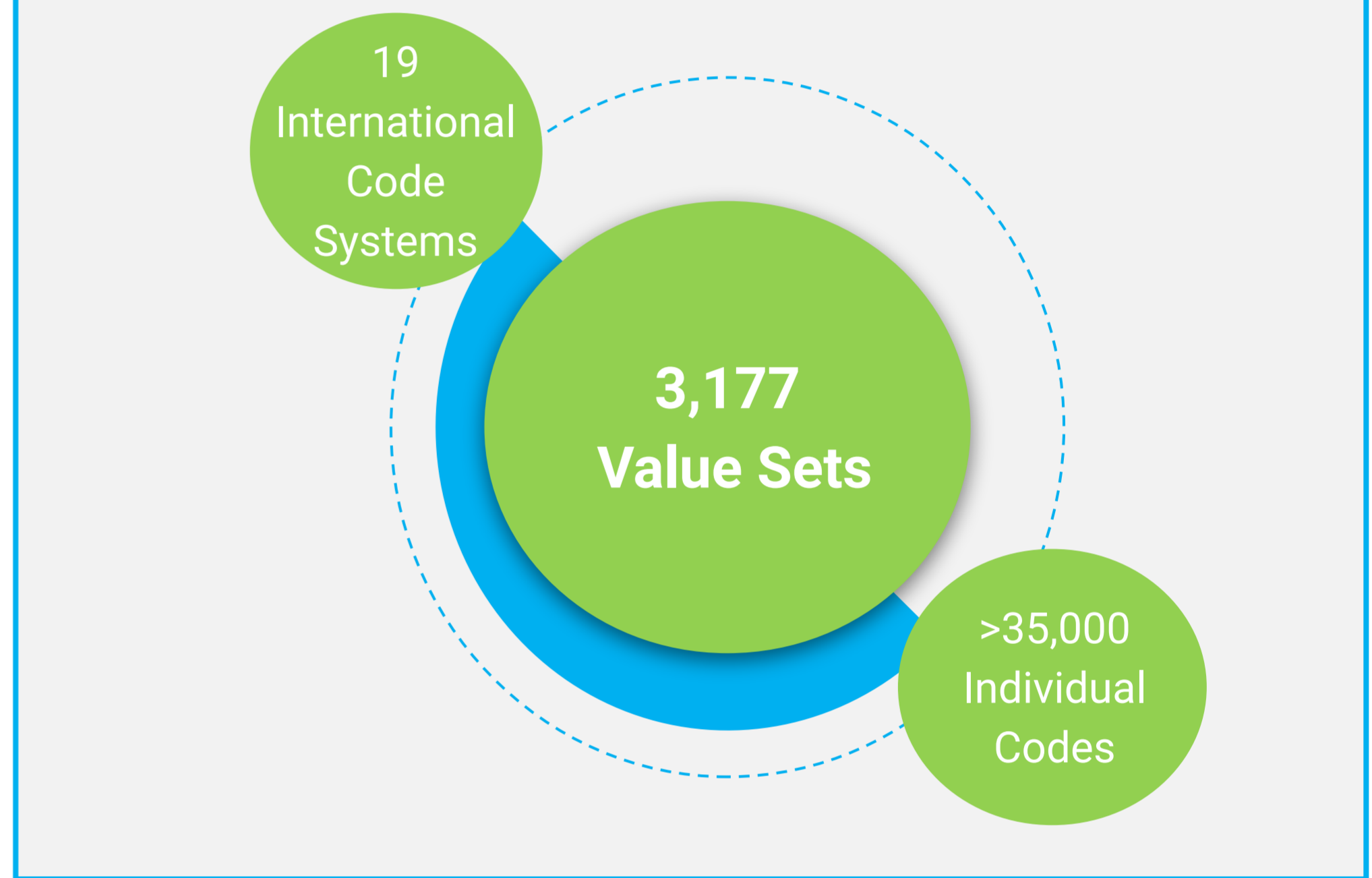


Figure 2.



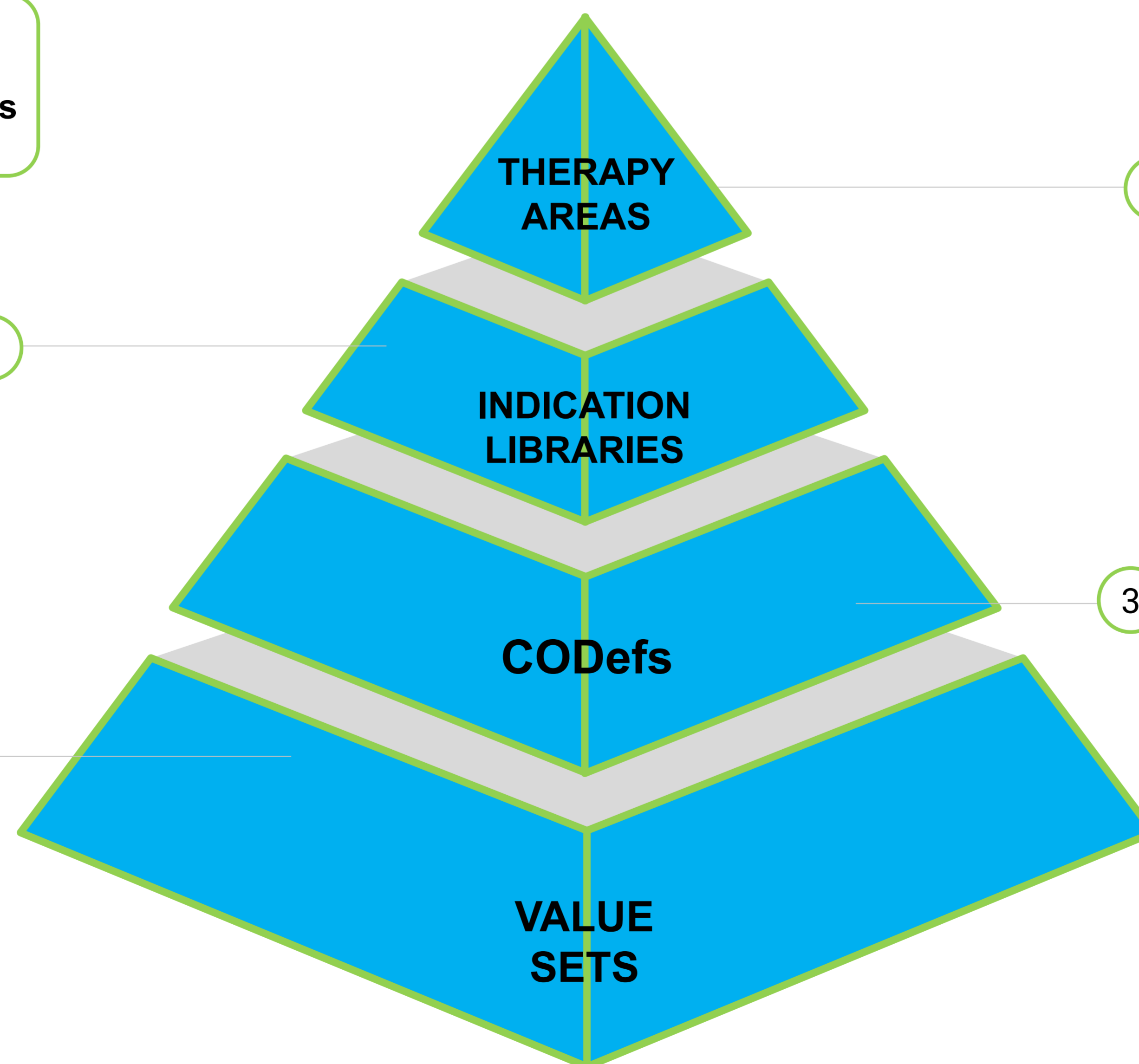
Value sets using the most appropriate set of standard codes maximized the relevancy and usefulness of each CODef for Real World Evidence, across global geographic regions.

Current Coverage

To-date 21 RWE studies have been modelled using CODefs from these libraries

We created a total of 24 indication specific libraries within the therapy areas

A total of 3,177 value sets were created to build the CODefs



There are 10 therapy areas covered by our indication libraries including:

- > Cardiovascular
- > General
- > Infectious Disease
- > Metabolics
- > Oncology: Solid Tumors
- > Oncology: Hematologic Malignancies
- > Renal
- > Respiratory
- > Safety
- > Transplant

There is a total of 1,768 distinct CODefs across all indication libraries

SO WHAT?

| Pre-curated indication-specific libraries of CODefs provide significant value to RWE.

| Researchers can select the most appropriate CODef from a library, saving time while ensuring consistency within studies and across the industry.

* FDA Guidance: Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products. July 2024. <https://tinyurl.com/fda-guidance-july-2024>.
 FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. December 2023. <https://tinyurl.com/fda-guidance-dec-2023>.