

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

Jared H. W. Kamauu,¹ Michael Buck,¹ David Thompson,² Amanda R. Shields,³ Megan Somerday,³ Allise G. Kamauu,¹ Craig G. Parker,¹ Scott L. DuVall,⁴ Aaron W. C. Kamauu¹

¹Navidence Inc., Cottonwood Heights, Utah, USA; ²Rubidoux Research, Boston, Massachusetts, USA; ³Navidence LLC, Chapel Hill, North Carolina, USA; ⁴VA Informatics and Computing Infrastructure, VA Salt Lake City Health Care System, Salt Lake City, Utah, USA

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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.

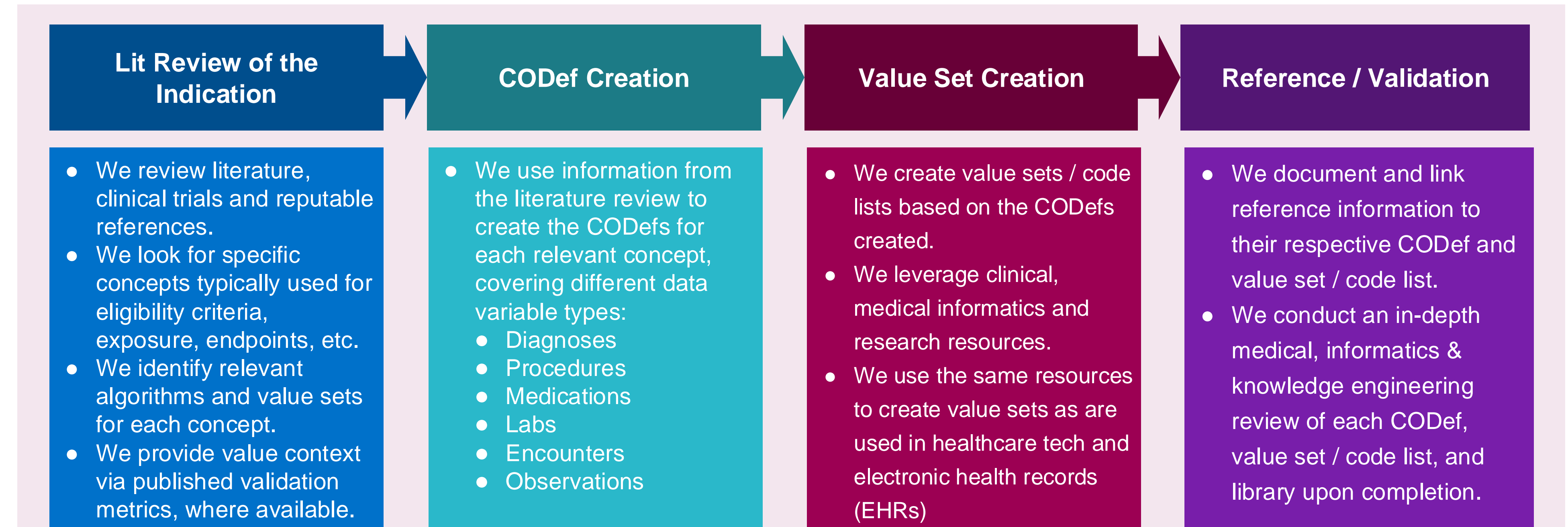
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How did we perform this research?

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



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

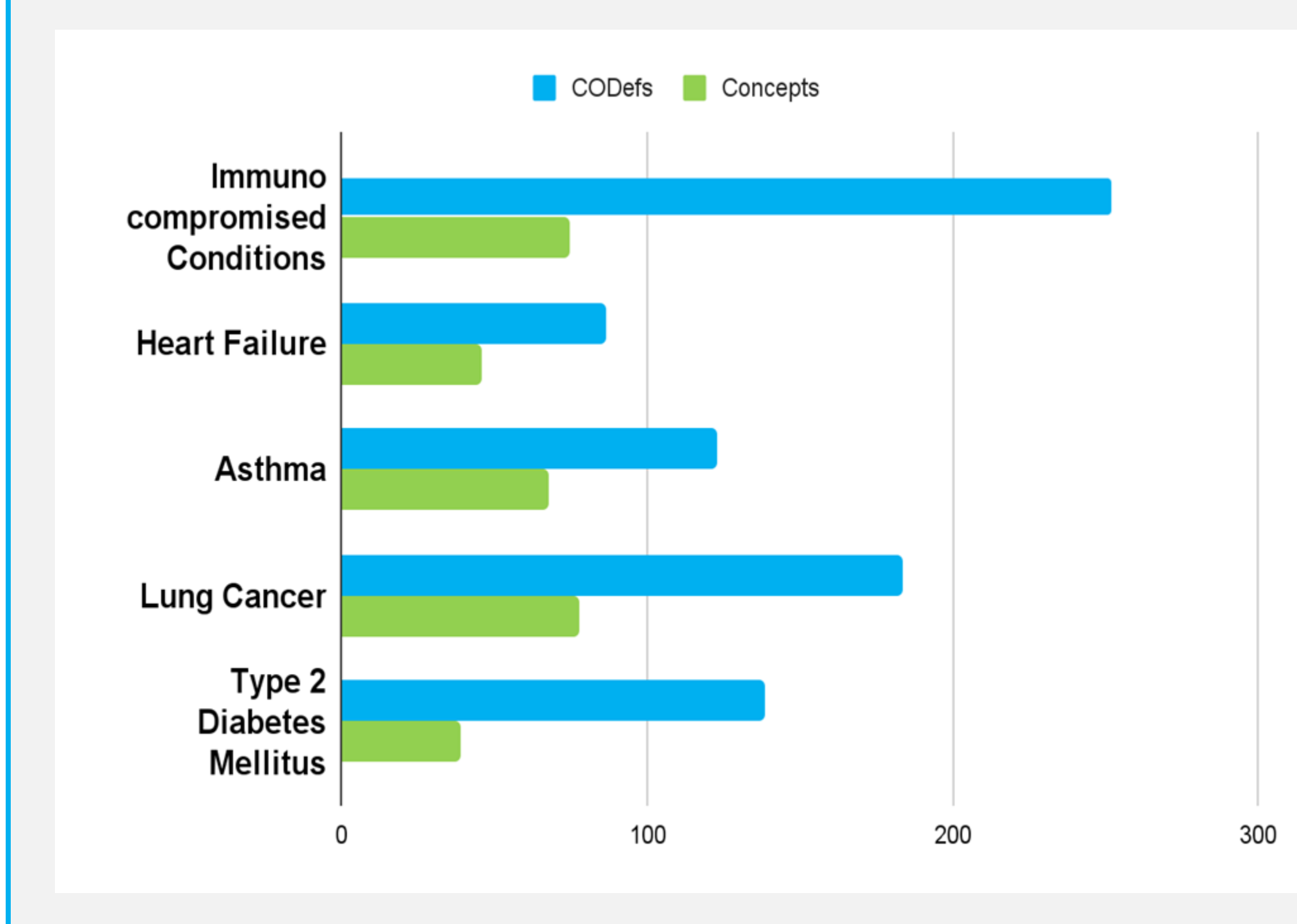
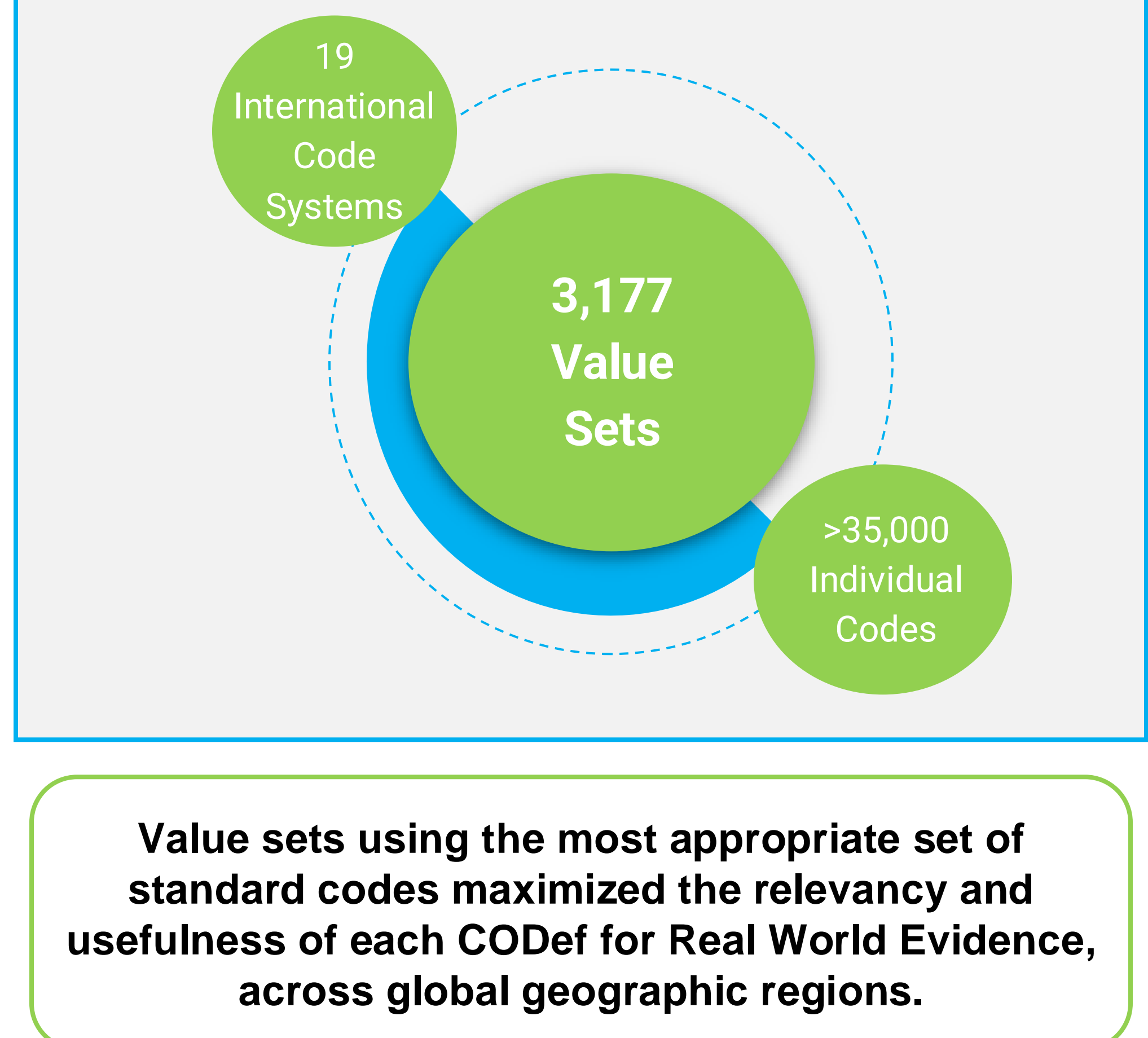


Figure 2.

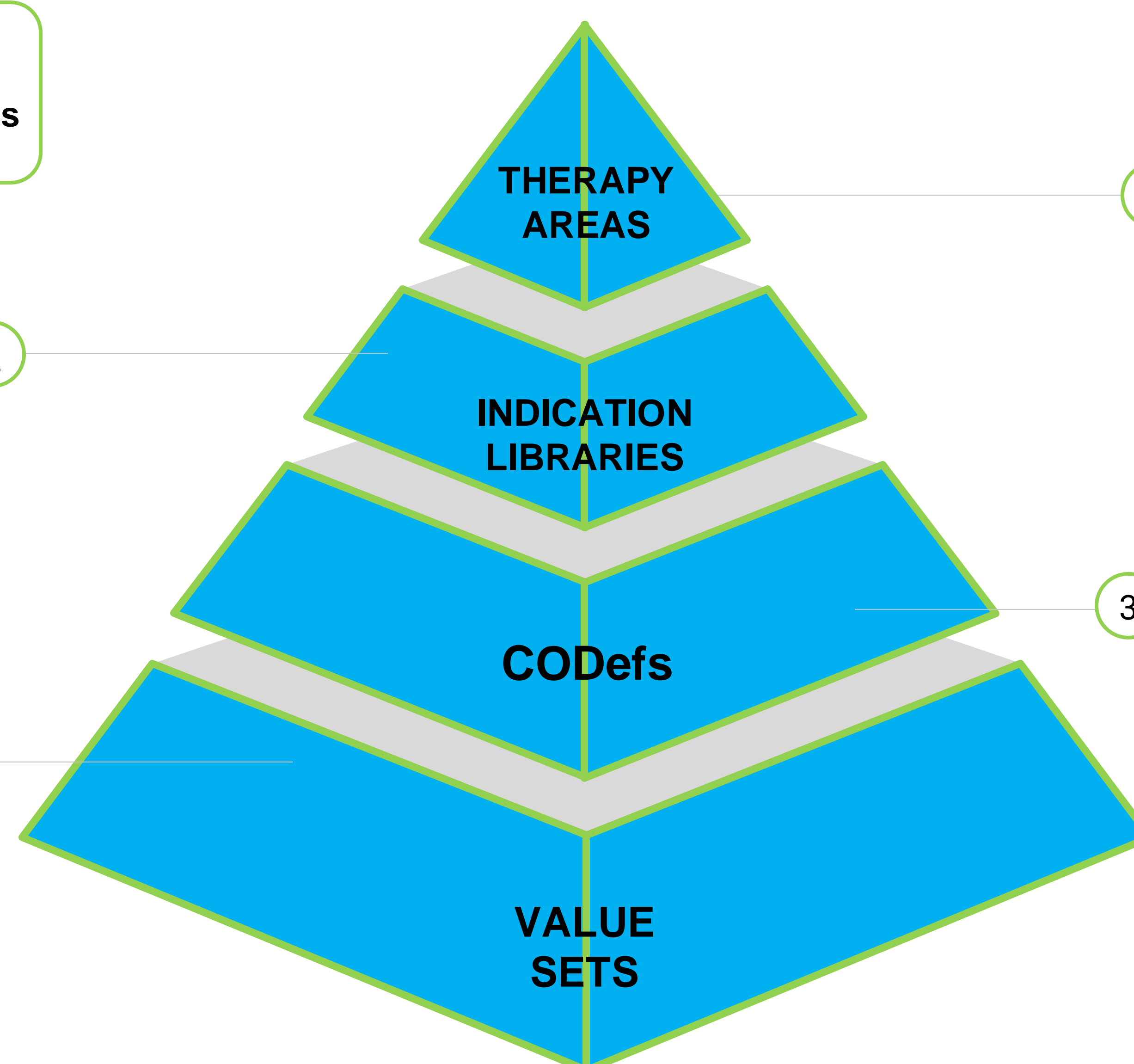


Current Coverage

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.**