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 realworld evidence (RWE) design and conduct via direct selection of CODefs from pre-curated indication-specific libraries.

*Online Poster



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How did we perform this research?

A rigorous process was used to develop each indication specific library Lit Review of the **CODef Creation Value Set Creation** Reference / Validation Indication • We review literature, We use information from We create value sets / code We document and link clinical trials and reputable the literature review to lists based on the CODefs reference information to create the CODefs for references. created. their respective CODef and • We look for specific each relevant concept, We leverage clinical, value set / code list. concepts typically used for covering different data medical informatics and eligibility criteria, variable types: We conduct an in-depth exposure, endpoints, etc. Diagnoses research resources medical, informatics & Procedures We identify relevant We use the same resources knowledge engineering algorithms and value sets Medications to create value sets as are review of each CODef, Labs for each concept. used in healthcare tech and We provide value context Encounters value set / code list, and electronic health records via published validation Observations library upon completion. metrics, where available.

(EHRs)

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
- > SNOMED CT UK
- > ICD-9-CM
- ➤ READ2
- > ICD-10-WHO
- > CPRD Aurum Medical > CPRD Aurum Product

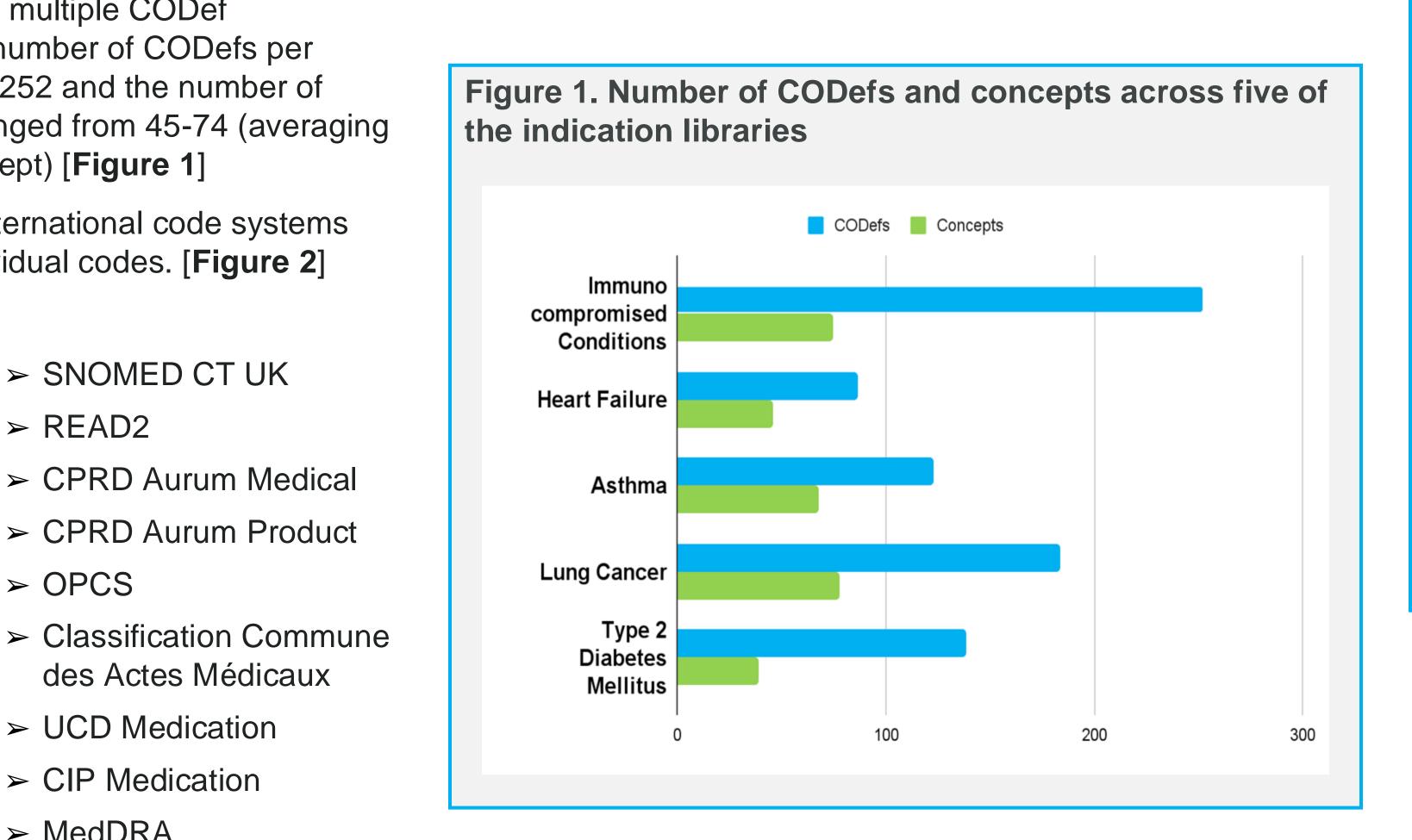
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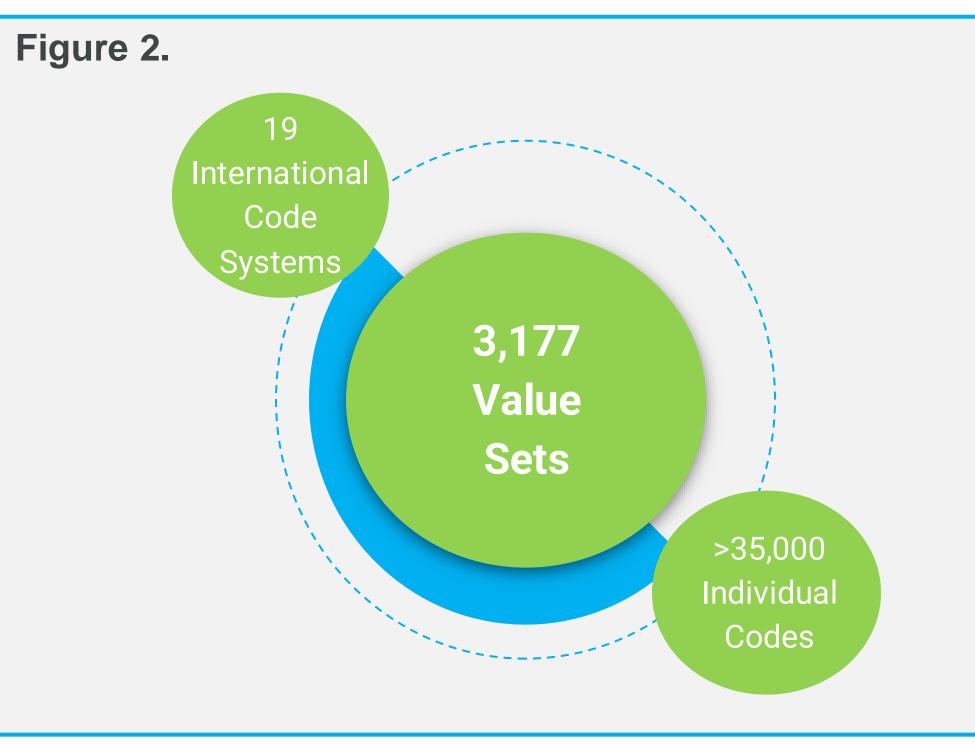
- > SNOMED CT ➤ CPT
 - > OPCS
- > ICD-10-PCS
- > ATC
- > NDC

- > RxNorm
 - > CIP Medication

> UCD Medication

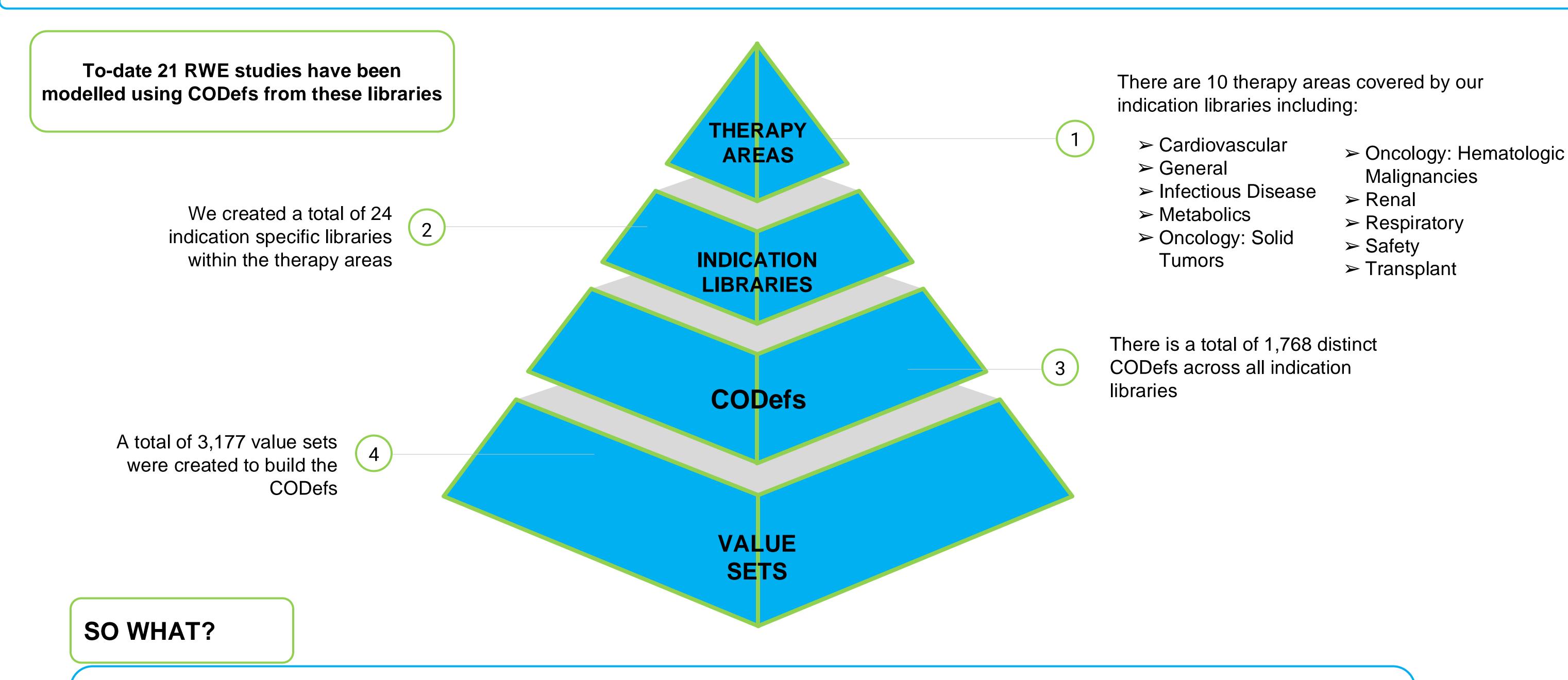
> MedDRA > HCPCS





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



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.



