



The Clinical Data
Science Conference

US 2024

25-28 February

Bethesda North Marriott Hotel
& Conference Center



Walter Reed National
Military Medical Center

Usage of OMOP-CDM along with CDISC in Clinical Trials: Challenges and Opportunities

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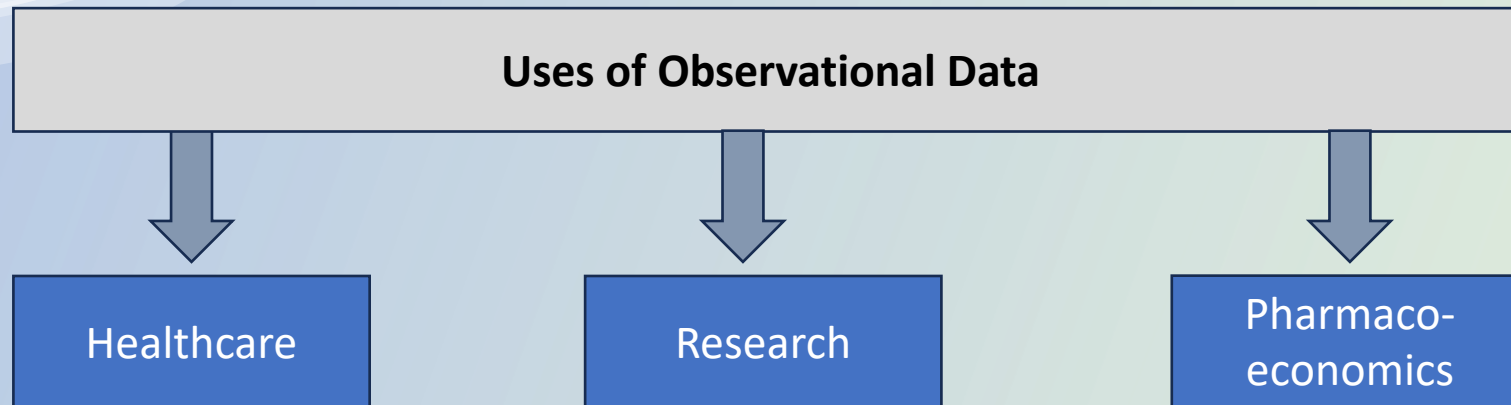
Usage of OMOP-CDM along with CDISC in Clinical Trials: Challenges and Opportunities

Disclaimer

The content of this presentation is for knowledge sharing and information purpose only. The content is developed through research. The information presented here represents the work of authors and should not be considered in general as a views of author's organization.

Introduction- Observational Data

Observational Data- Collection of Information about what happens to patient while receiving healthcare?



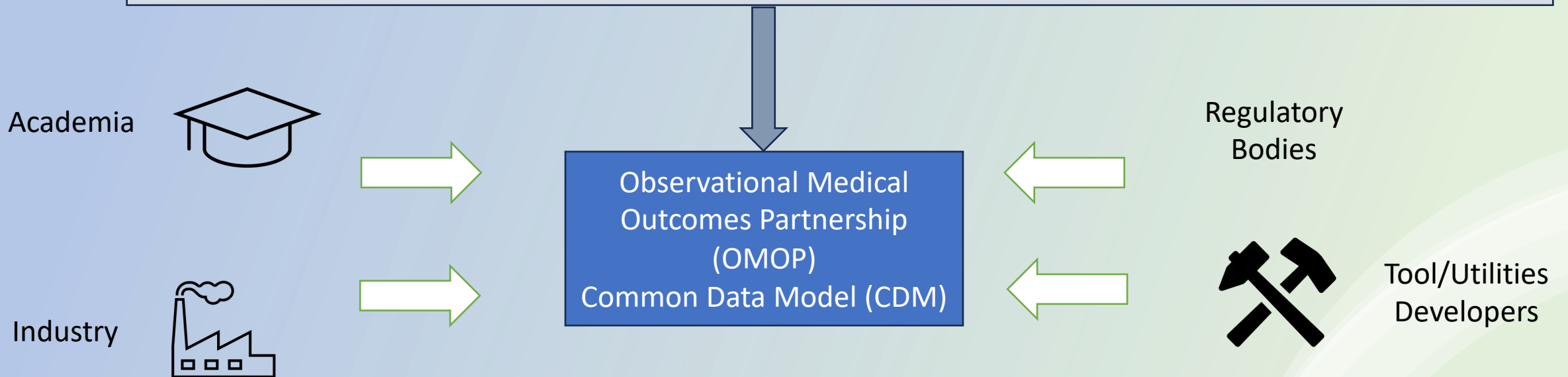
How and where is it used in Clinical Studies?



What is OMOP-CDM?

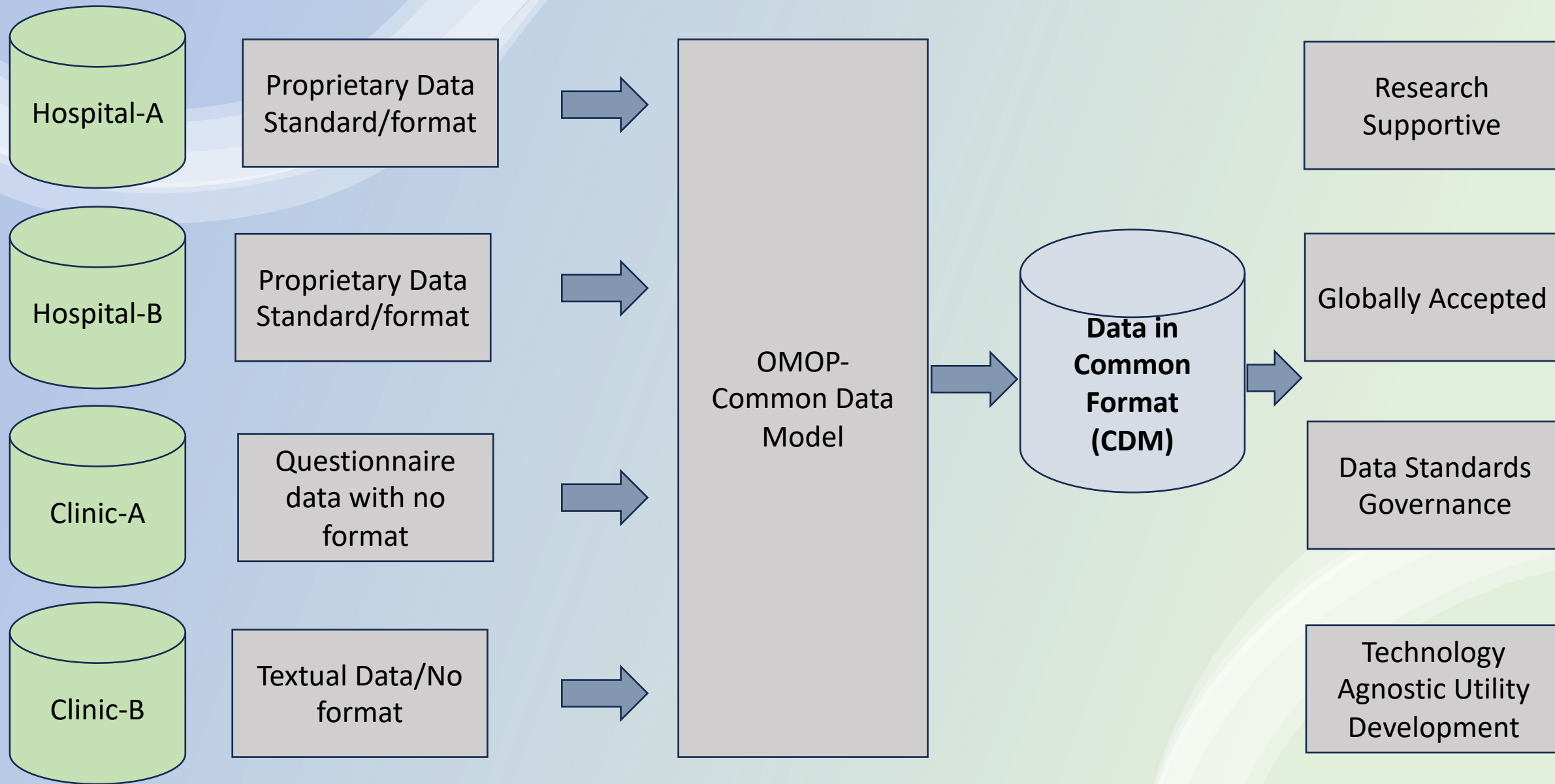
The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source. OHDSI has established an international network of researchers and observational health databases with a central coordinating center housed at Columbia University.

Mission: To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.

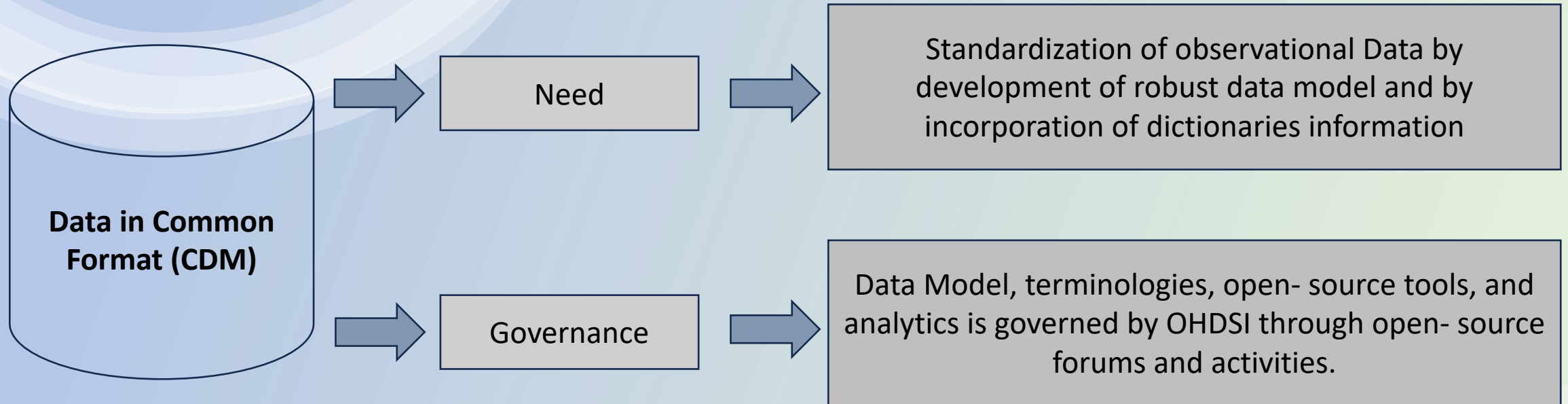


[Source: OHDSI – Observational Health Data Sciences and Informatics](#)

What is OMOP-CDM?- Data Model

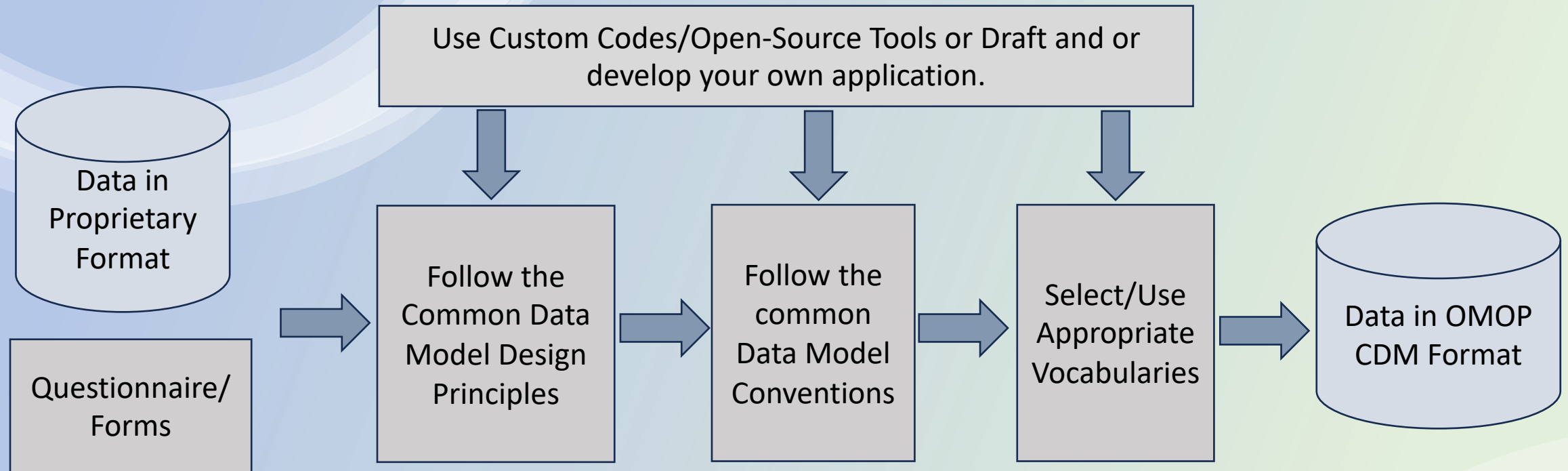


OMOP CDM – More Info



- Continued clinical research with help of research tools developed by academia and by industry
- Medical research in terms of development of new biomarkers, phenotypes, and other outcomes measures
- Continued global adaption

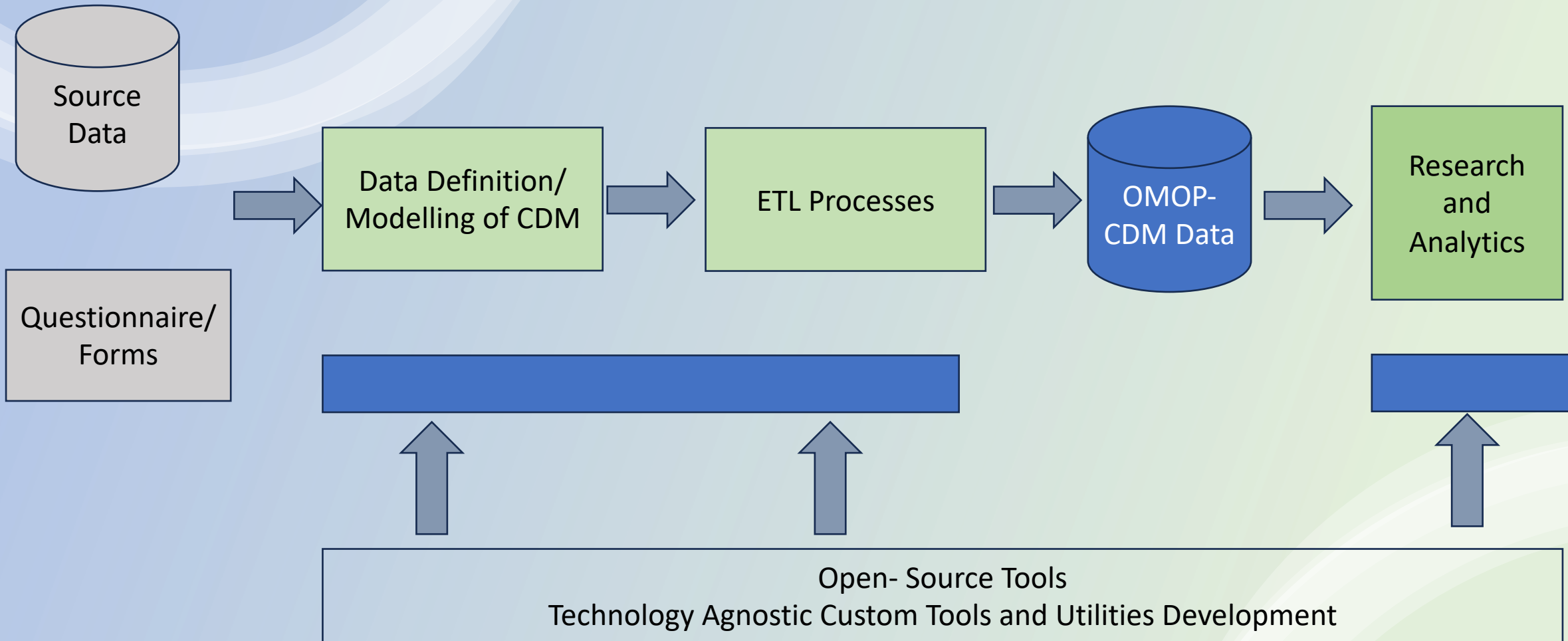
OMOP CDM – How to set-up?



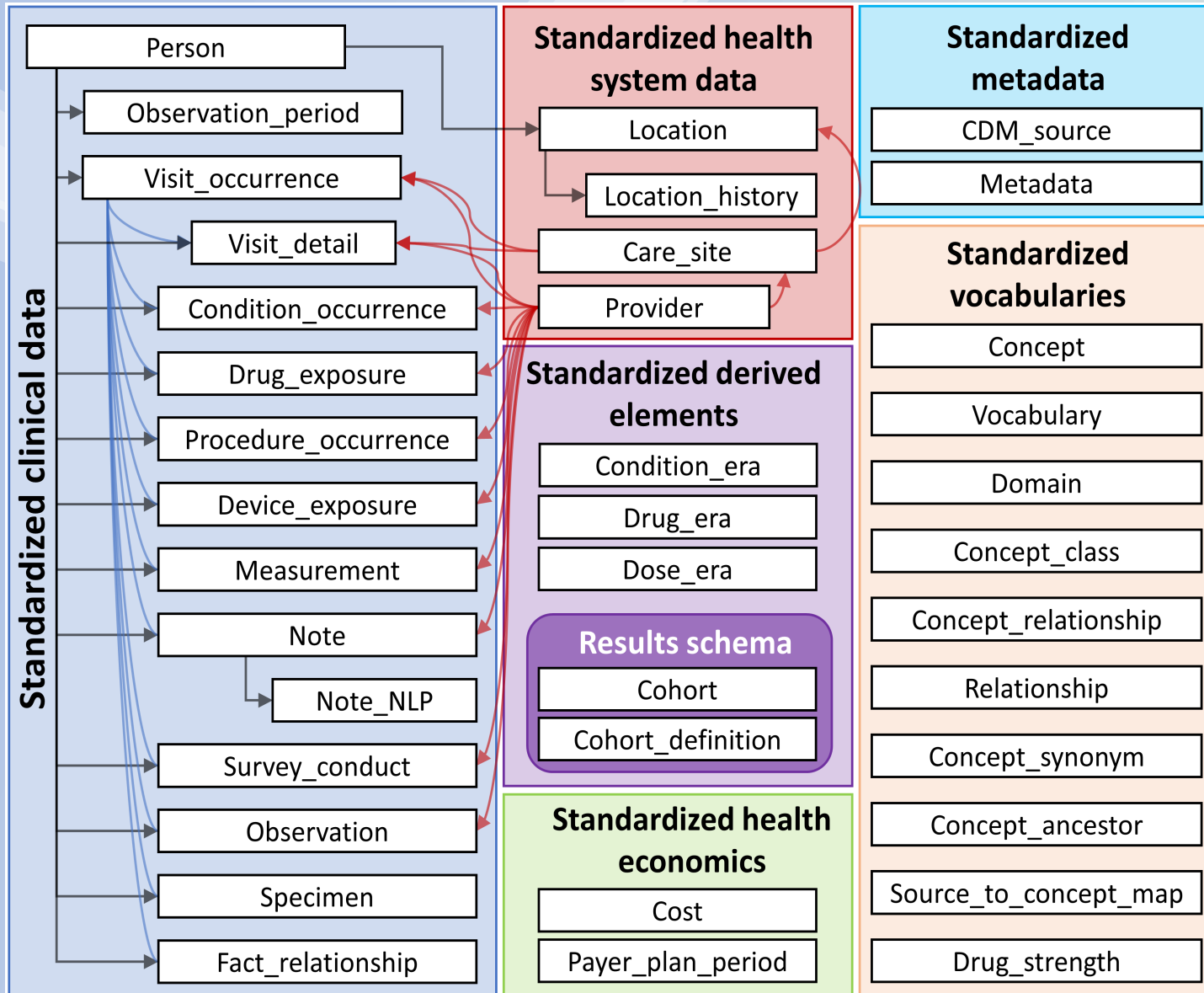
How to ensure that the designed CDM is of good quality?:

Key indicators include Data security, Scalability of model, backward compatibility of the model, Optimum use of standardized vocabularies, and adherence to CDM domain design

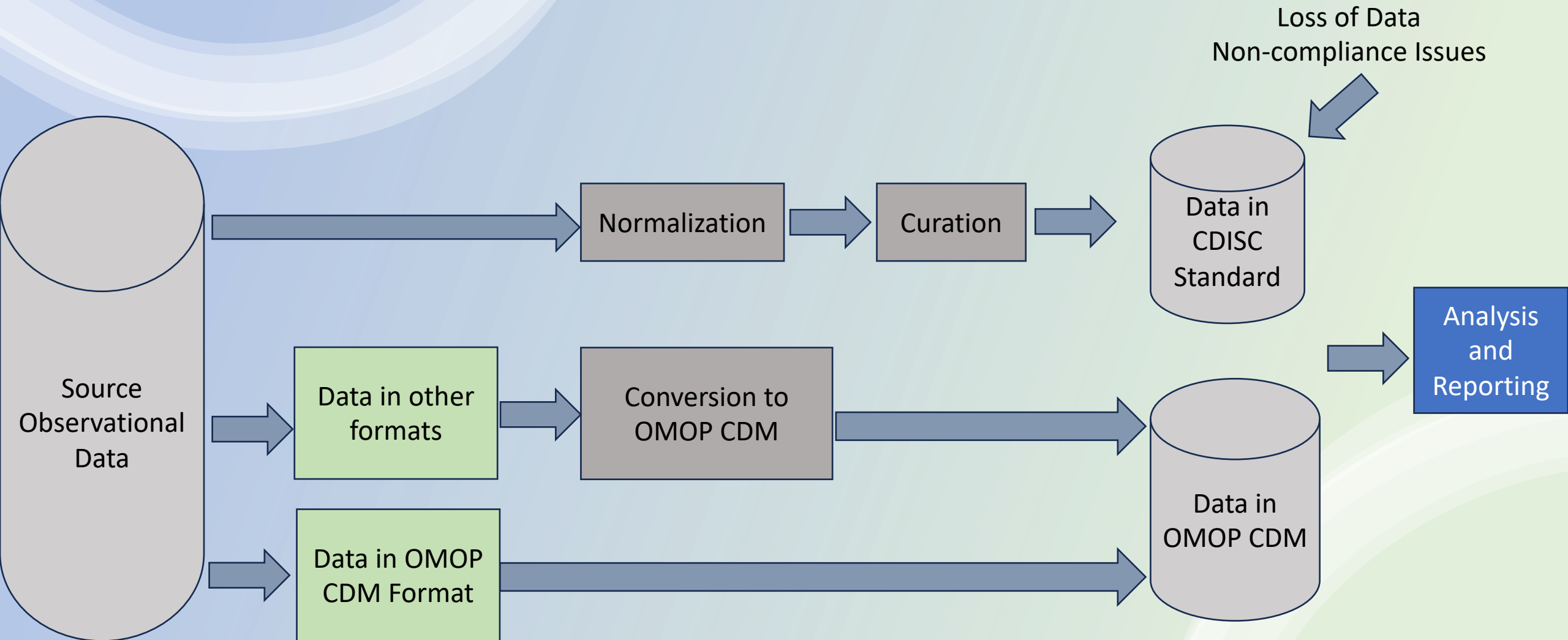
OMOP CDM – Data Curation Process



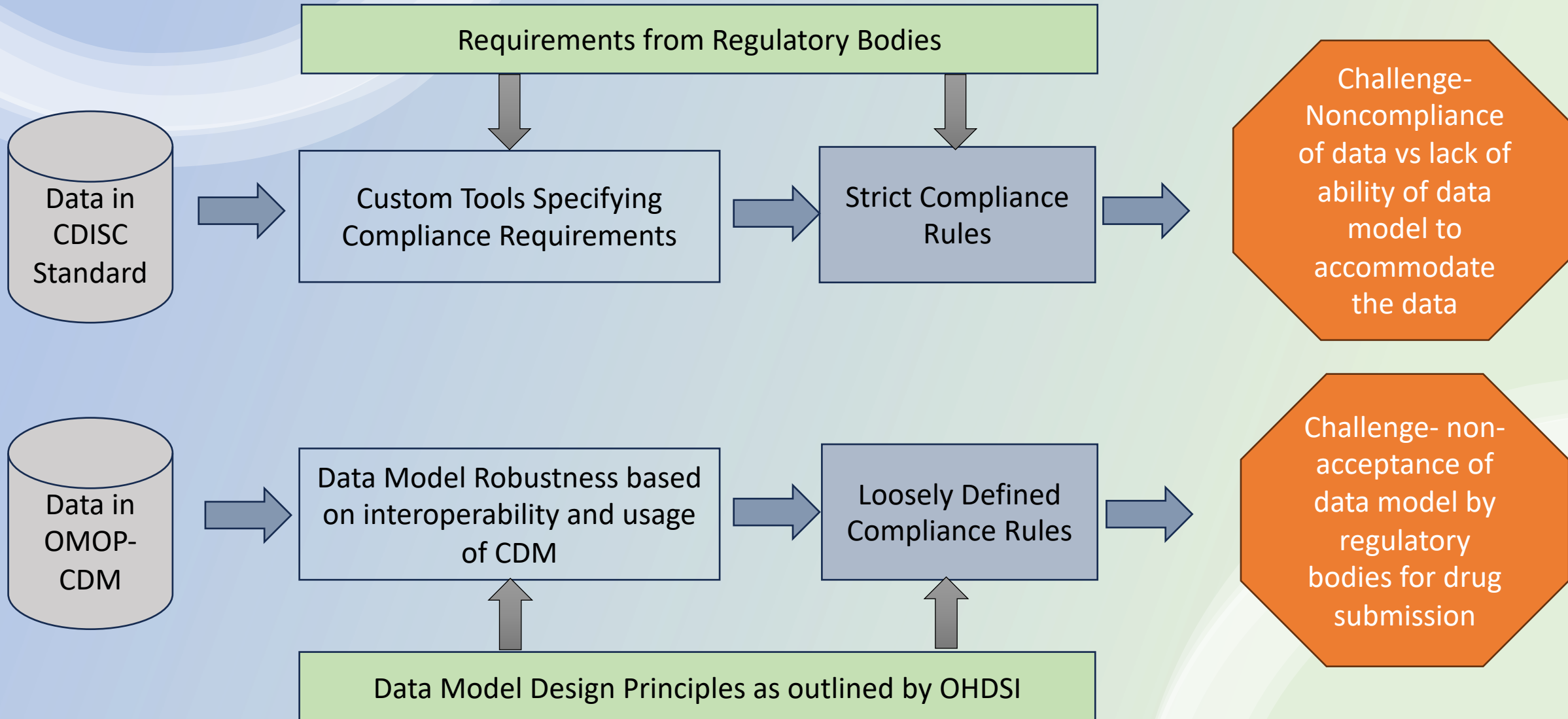
OMOP CDM – Table Structure



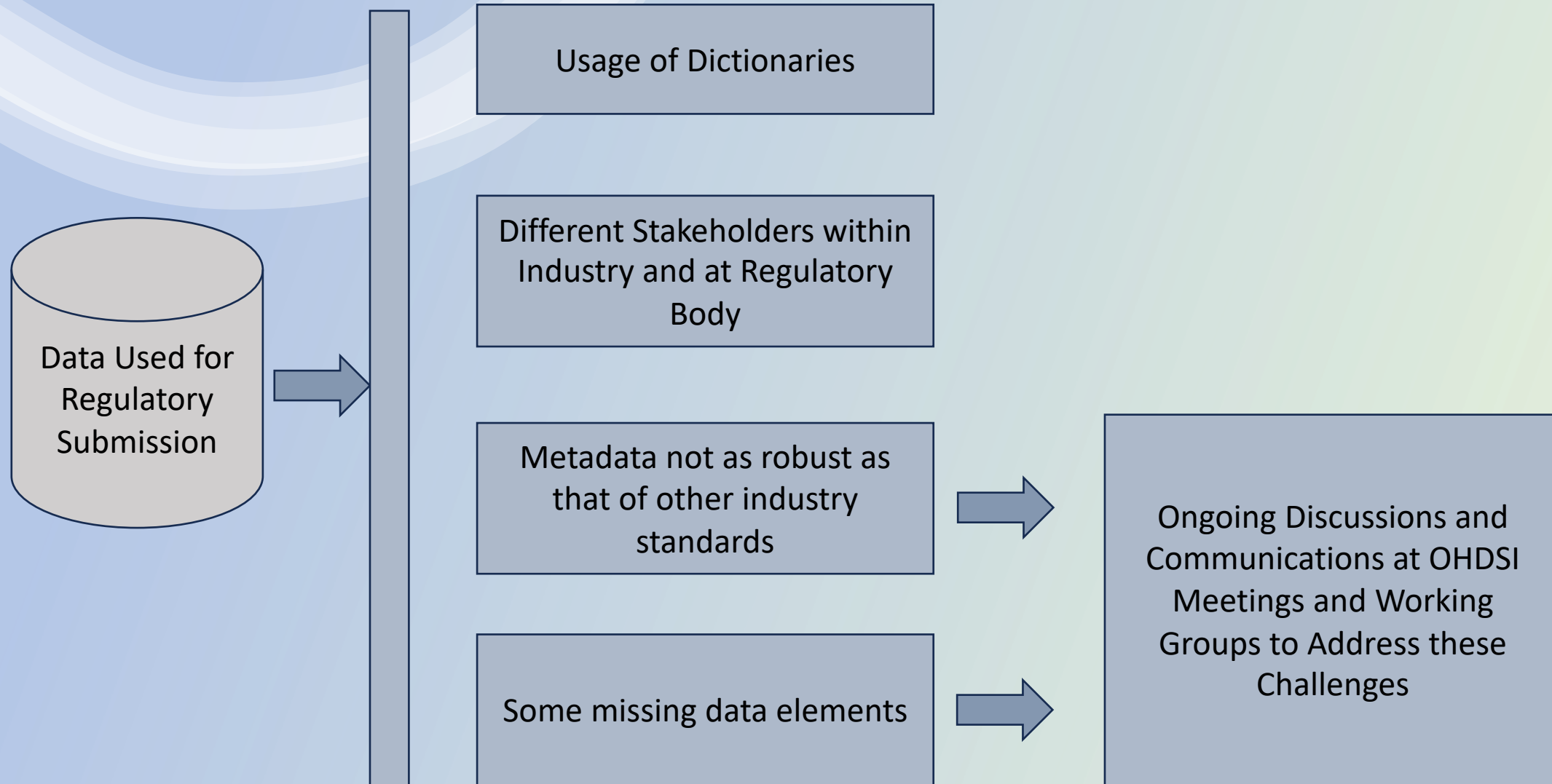
Observational Data- Traceability and Provenance Aspects



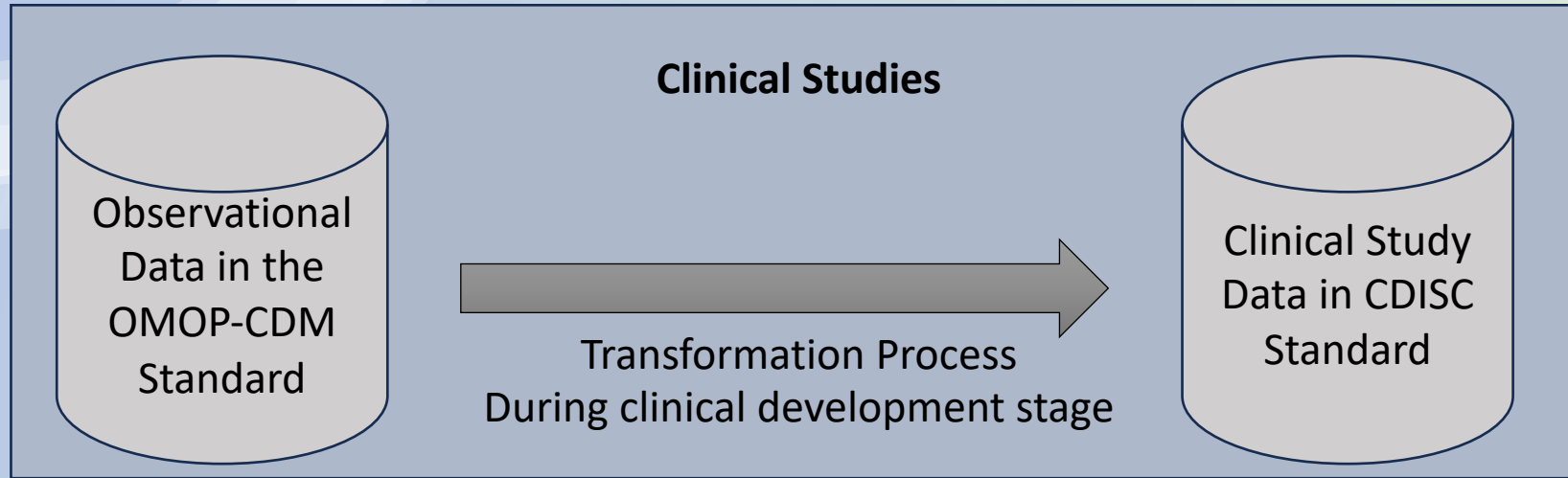
Data Standards Compliance Aspects



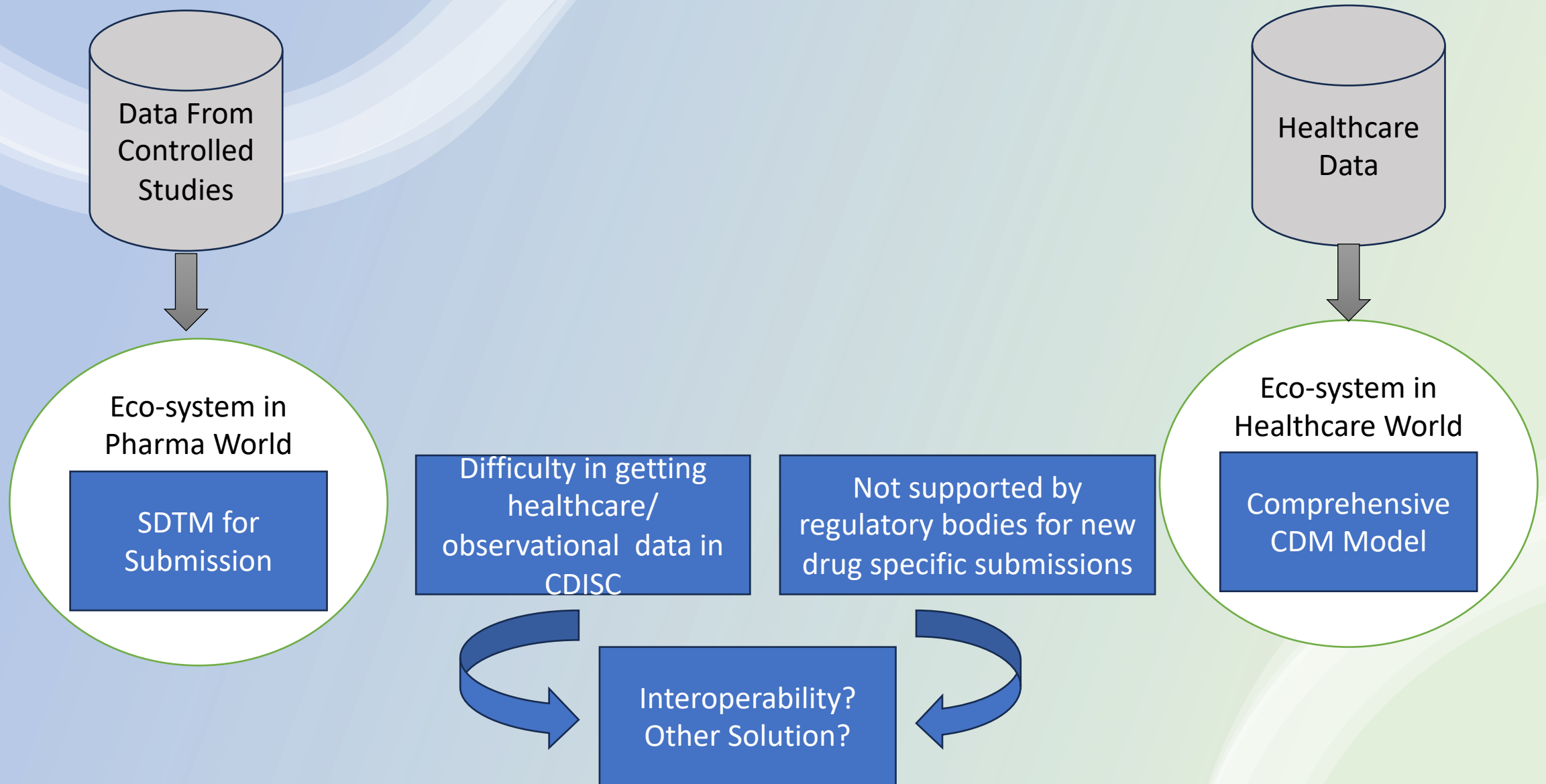
Challenges with OMOP and Efforts from OHDSI



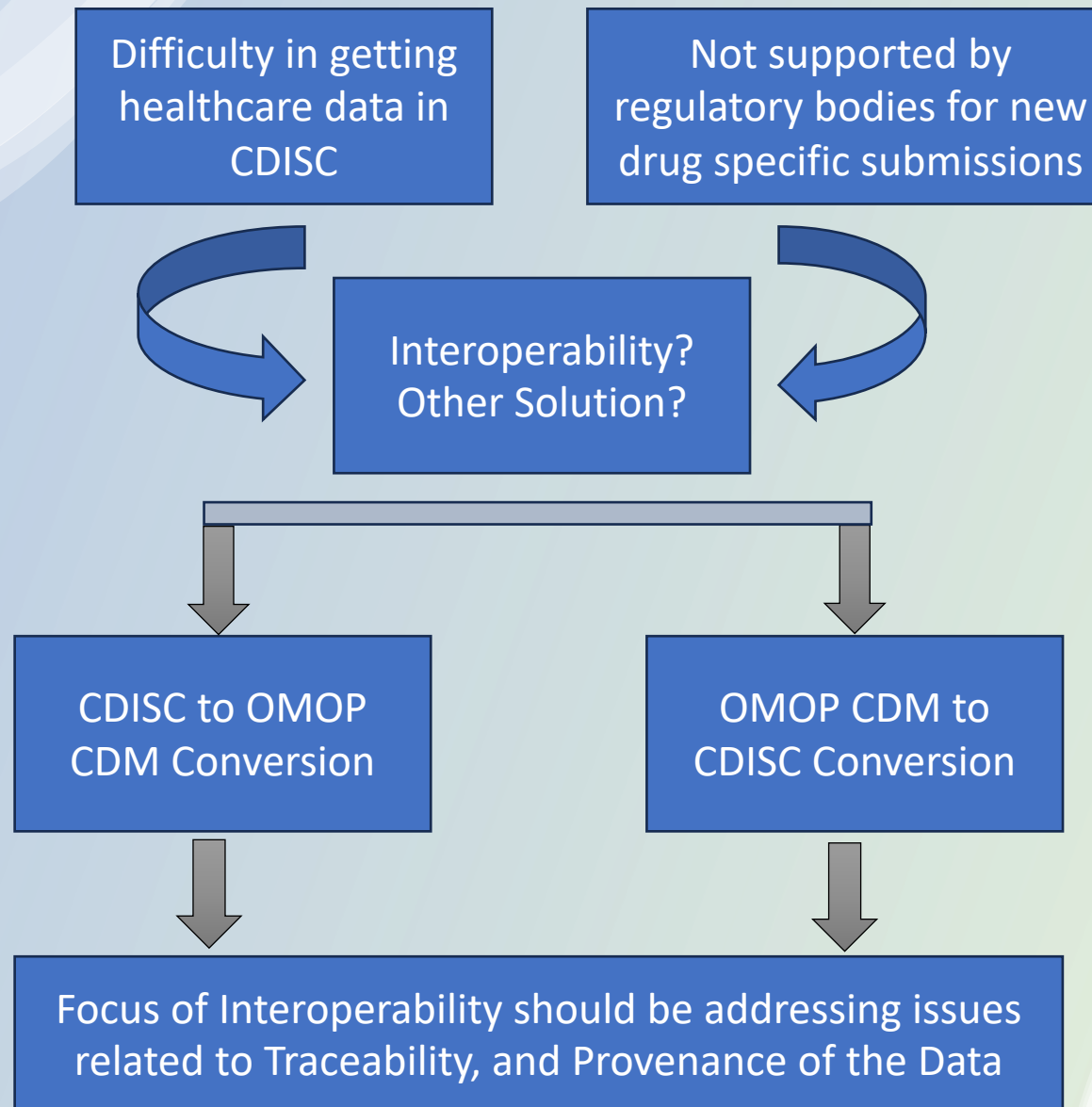
How Industry is Using OMOP-CDM?



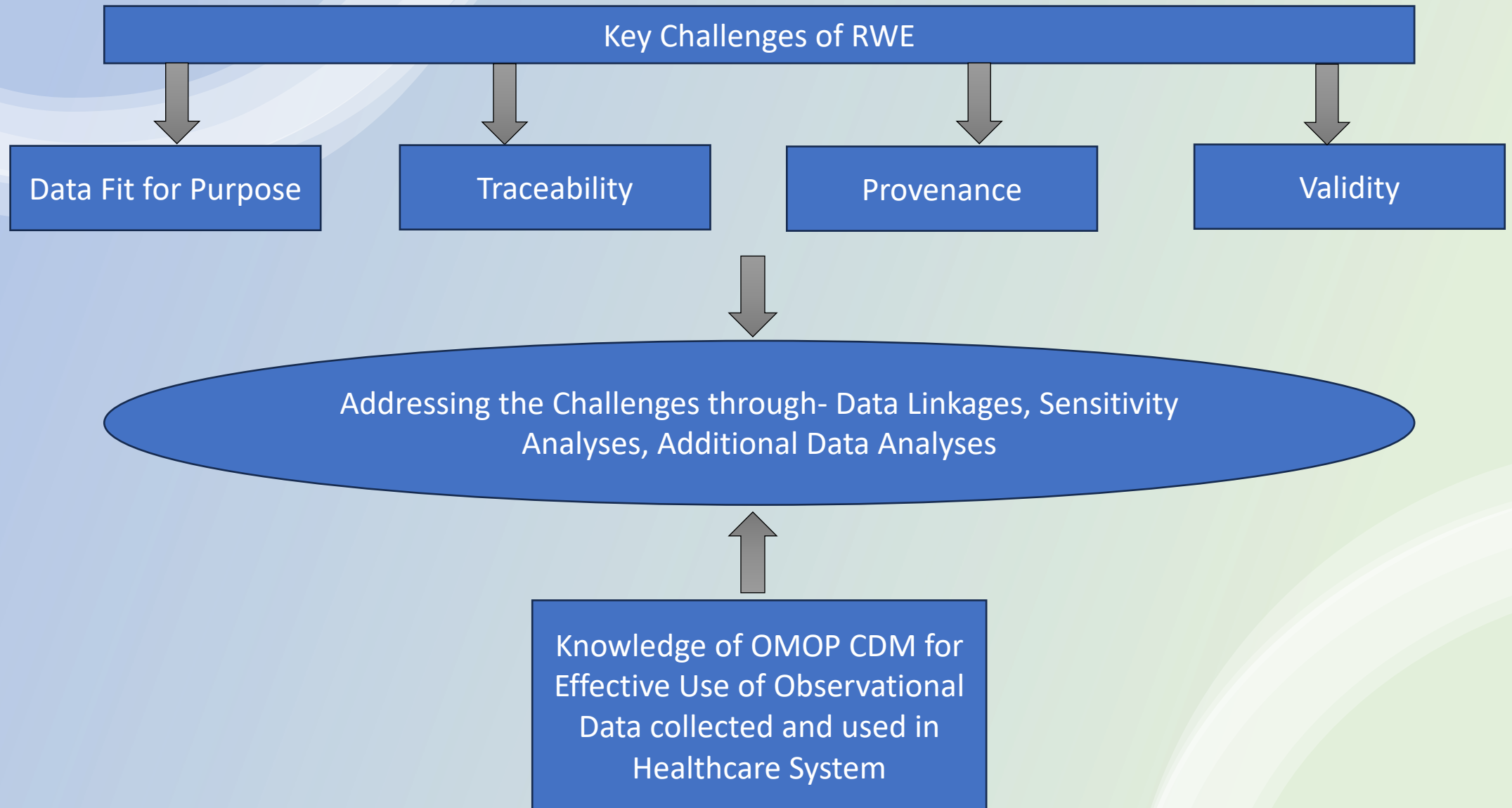
Can Regulatory Bodies Accept OMOP CDM?



Can Regulatory Bodies Accept OMOP CDM?



Why is it Important to Know OMOP CDM- RWE Perspective



Acknowledgement and Recommendation

We are thankful to all industry colleagues who shared the knowledge and experiences of Real-World Data usage and of generating Real World Evidence.

Our special thanks to our colleagues from PHUSE Real World Evidence Working group for their passion about RWD Usage. It would not have been possible to initiate research and analysis in RWE space without their collaborative spirit to bring innovative solutions to our industry!

We strongly recommend joining PHUSE RWE Working group to learn more about the current practices, processes, and industry initiatives.

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References:

- 1) Observational Health Data Sciences and Informatics, [OHDSI – Observational Health Data Sciences and Informatics](#)
- 2) Clinical Data Standards Interchange Consortium, <https://www.cdisc.org/>
- 3) OMOP-CDM Data Standards, <https://ohdsi.org/data-standardization/>
- 4) Data Standards for Drug and Biological Product Submission Containing Real- World Data, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data>
- 5) SNOMED International, <https://www.snomed.org/>
- 6) Medical Dictionary for Regulatory Activities, MedDRA, <https://www.meddra.org/>
- 7) Leveraging the OMOP CDM V5 for CDISC SDTM RCT Data, by Joshua R., et. all, <https://www.ohdsi.org/web/wiki/lib/exe/fetch.php?media=projects:workgroups:shyft-ohdsi-poster.pdf>