

Operationalizing a multi-country OMOP-based analytical pipeline to characterize finerenone initiators in the FINEROD study

Background: Real-world evidence generation across countries and data types requires standardized data models, portable analytics, and documented operational workflows. As part of the FOUNTAIN¹ platform, the FINEROD study implemented an OMOP Common Data Model (CDM) approach using OHDSI² and DARWIN-EU³ tools to characterize patients initiating finerenone in multiple claims and EHR databases in Japan and the United States. In this work we emphasize methodological and operational design, the analytical package structure, and lessons learned to support reproducible, upscalable multi-database studies.

Methods: The FINEROD study is a single-arm, observational, descriptive study of finerenone initiators conducted so far in two Japanese databases (MDV, RWD Co.) and four US databases (MarketScan, Optum Claims, Optum EHR, HealthVerity), all mapped to the OMOP CDM. Index was defined as the first prescription/dispensation for finerenone. Visual representation of the target cohort design can be seen in Figure 1.

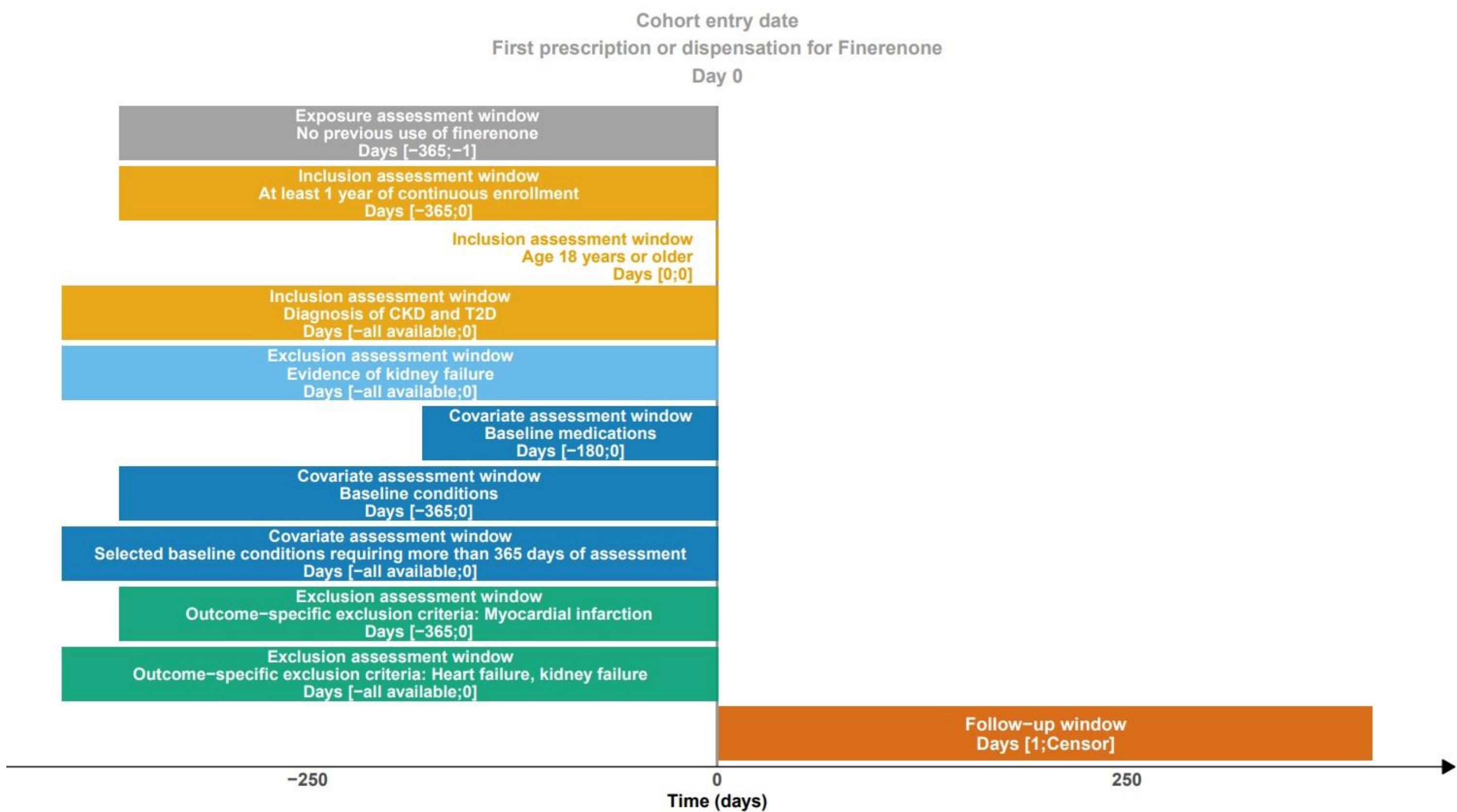


Figure 1. Variable assessment windows relative to the study index date for finerenone initiation

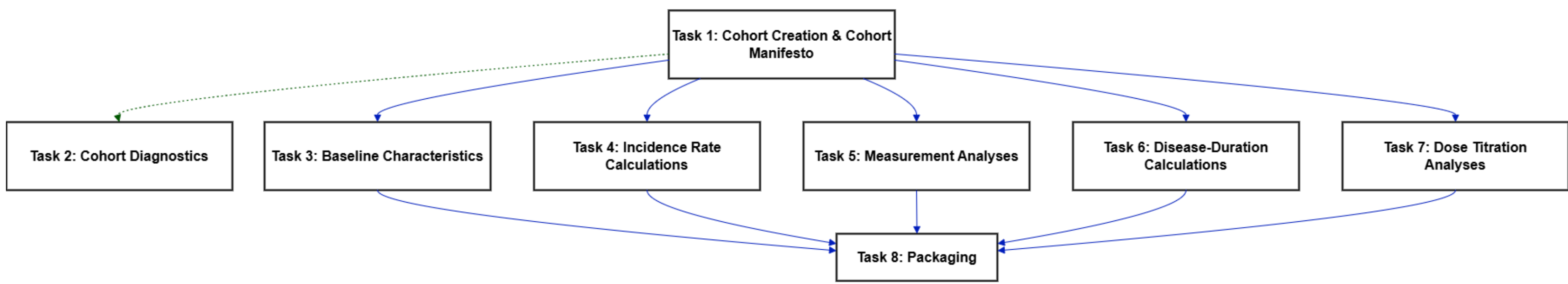


Figure 2. Task flow of FINEROD study

Methods (cont.): The analytical implementation followed an R-based study package structured into modular tasks (Figure 2):

- Task 1: Cohort creation and cohort manifesto (ATLAS-derived JSON import);
- Task 2: Cohort diagnostics (incidence, attrition, concept set checks);
- Task 3: Baseline characteristics (standardized covariates);
- Task 4: Incidence rate calculations for pre-specified cardiovascular and kidney outcomes;
- Task 5: Measurement analyses (UACR and relative change at 4 months, lab value thresholds);
- Task 6: Disease-duration calculations (time from first evidence of both CKD and T2D);
- Task 7: Dose titration analyses (10mg to 20 mg up-titration; 20mg to 10 mg down-titration);
- Task 8: Packaging: aggregate and zip results, provenance metadata.

Most tasks used OHDSI and DARWIN-EU R packages whereas measurement, disease-duration and titration tasks retained database-specific SQL for efficiency, seamlessly integrated into the analytical package using R code. Emphasis was placed on automated cohort diagnostics, standardized output templates, and documentation to ease reuse and upscaling.

Results: Aiming for multi-database execution, the analytical package was successfully executed across six OMOP CDM databases with the same cohort definitions and task flow. There were several standardized deliverables produced per database, such as a cohort manifesto, cohort diagnostics report, baseline characteristics table, incidence-rate tables, UACR measurement summaries and relative-change outputs, disease-duration outputs, titration summaries, and a zipped results package containing metadata and provenance. The modular approach using a task-based design allowed re-running individual tasks (e.g., only diagnostics or only measurement analyses) without reprocessing earlier steps. Using Atlas JSONs for cohort definitions and versioned R package releases ensured that cohorts and results could be recreated deterministically in additional OMOP-compliant sites, ensuring portability and reproducibility. Some gaps that were identified and addressed included heterogeneity in lab availability and coding between claims and EHR databases, which required harmonization rules, and local SQL stubs isolated database-specific logic to minimize changes when adding new data partners.

Conclusion: FINEROD demonstrates a practical, reproducible approach to multi-country characterization studies using OHDSI and DARWIN-EU tools. This approach minimizes incremental effort for expanding to new databases or geographies and provides a template for future OMOP-based multi-database studies. The analytical package allows studies to be scaled up efficiently to integrate new databases and routine data refreshes.

References:

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