Facilitating Global Understanding of Tixagevimab/Cilgavimab Use: Leveraging OMOP Common Data Model for Harmonized Data Extraction and Federated Network Creation

**Background:** Tixagevimab + Cilgavimab is a combination monoclonal antibody used for the prevention and treatment of COVID-19 in patients at high risk of severe disease due to immunocompromise, inadequate response to vaccination or comorbid conditions. The U.S. Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for pre-exposure prophylaxis (PrEP), while the European Medicines Agency (EMA) granted a EUA covering use for both PrEP and treatment, though approved indications and deployment strategies varied between local authorities.

Graticule is leveraging the OMOP Common Data Model (CDM) to support harmonized data extraction and consistent analyses in multiple regions as part of an effort to understand Tixagevimab + Cilgavimab use globally. A single, foundational CDM is particularly beneficial for this effort as the creation of federated network, leaving data in situ, is being explored. This approach depends on the ability to translate computable standards-based operational definitions fluidly across data partners. Our methods and preliminary results are presented.

**Methods**

Clear conceptual definitions and computable operational definitions were developed for each study element. Computable operational definitions included algorithms and value sets that were most often identified via literature review or through publicly available repositories (e.g., CMS, VSAC), minimizing the need for de novo creation.

1. Original public resources for each operational definition were reviewed to identify existing vocabulary mappings (e.g. where both ICD-9-CM and ICD-10-CM codes were indicated). These mappings were accepted & referenced.
2. Where the original reference did not indicate mappings, other publicly available resources were reviewed for relevant concept mappings analogous to the original intent, these were used & referenced.
3. Where no pre-existing mappings were identified, automated cross-walking methods were used (e.g., CMS general equivalence mappings). Otherwise manually curated mappings were used as necessary.

These computational operational definitions were deployed in the OMOP-compliant N3C (National COVID Cohort Collaborative) dataset in the US. Definitions were then adapted to account for differences in approved indications in European countries. Standardized definitions using commonly used vocabularies in the US like ICD-10-CM, SNOMED, RxNorm, HCPCS, and LOINC vocabularies from the condition occurrence, drug exposure, procedure, and measurement domains were translated into standard vocabularies used in the EU like ICD-9-CM and ATC using the following decision hierarchy:

- 1 Procedure Record from Solid Organ Transplant Procedures any time in the past
- 1 Diagnosis Record from Solid Organ Transplant Diagnoses (any time in the past AND any encounter type AND any diagnosis position)

**Components of a computable operational definition:**
- Data variable
- Quantity / magnitude
- Target value, concept or code list / value set
- Time period qualifier
- Other qualifiers based on the data variable or type of operational definition

**Expression to describe how the components relate to each other**

**Results & Conclusions**

**Result:** 64 core computable operational definitions utilizing 66 distinct value set groupings were reviewed. Value set groupings each represent a particular clinical concept. These 66 value set groupings collectively contain 181 distinct value sets across 12 standard vocabularies: ICD-10-CM, ICD-9-CM, SNOMED, ICD-10-PCS, ICD-9-Proc, CPT, HCPCS, CVX, LOINC, RxNorm, NDC, and ATC.

The mapped computable operational definitions were then used to collect descriptive feasibility metrics in an OMOP-compliant environment with consistent results across initial sites.

**Conclusion:** Computable operational definitions can be standardized while retaining original concept meaning. Such definitions, deployed in OMOP CDM environments, can support a federated approach that can provide insight on drug uptake and can contribute to robust real-world evidence generation in the United States and Europe.

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**Limitation:** Work is ongoing. Final results may differ from preliminary exploration.

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