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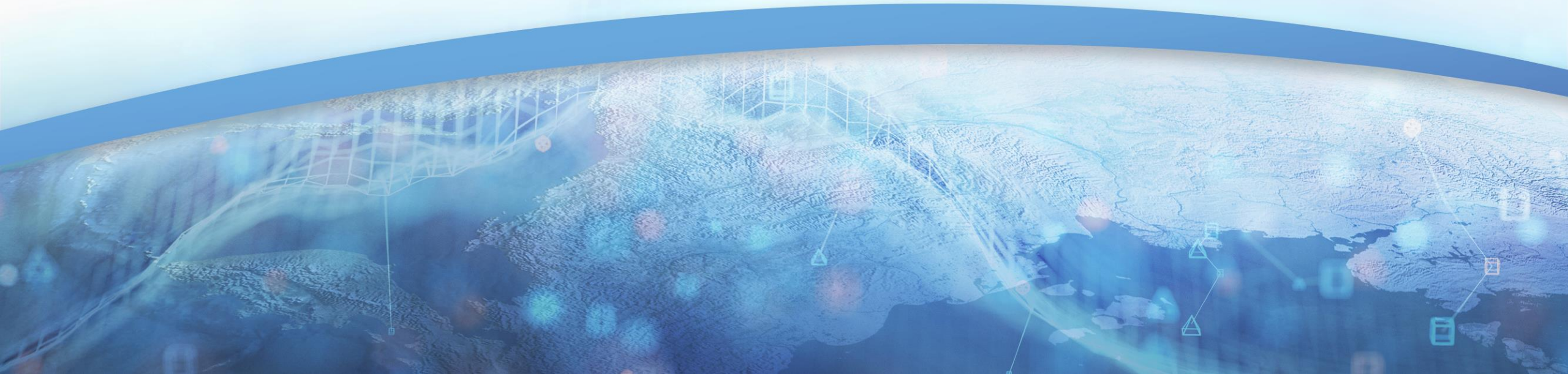
International COVID-19 Data Alliance

COVID-19 Enriched Summary Level Data Dictionary



COVID-19 Data Flow: From Common Data Elements to Standard Tools

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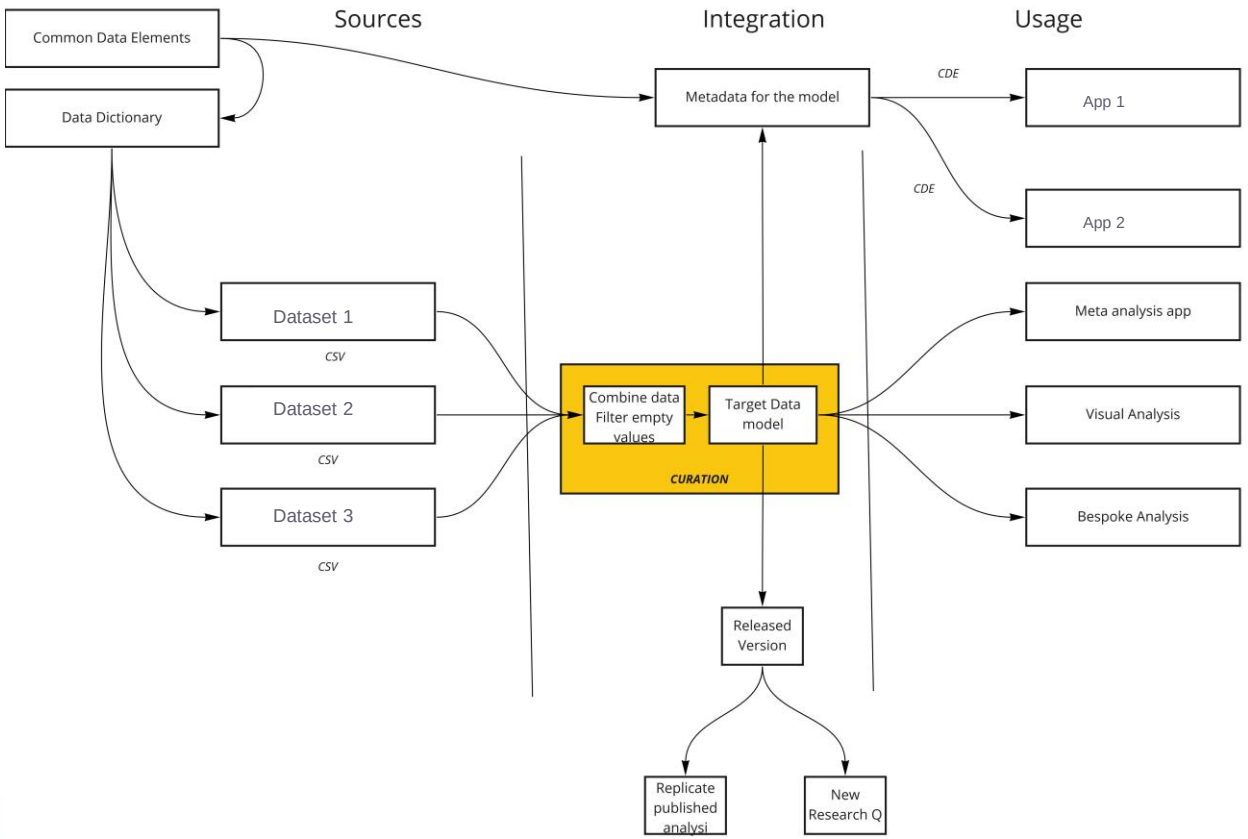
- **A Data Model** that enables harmonization of trial data across trials and facilitates assessment of key questions of interest in a structured format**.**
  - Common data elements
  - Enriched data dictionary with harmonized endpoint(s) and assessments
- **Curated data** for easy of use and to prepare bespoke data sets.
- **Standard tools** to visualize and describe the trials, to provide meta-analyses, and network meta-analyses etc
- **Data Model** can be bridged to other data sources to simplify data curation and analysis across data sources.



COVID-19 Enriched Summary Level Data Dictionary - Clinical Variables General Structure

Study specific information,

- Abstracted from the trial summary domain of SDMT.

Baseline Variables,

- Set of subgroups that can be investigate across trials;
  - Patient Demographics, co-morbidities (risk factors that may impact disease progression or treatment response)

Efficacy Endpoints of interest

- Reconstituted to common definitions using established data dictionary

Safety endpoints

- Patient exposure, retention rates and medications introduced post entry to the trial

COVID-19 Enriched Summary Level Data Dictionary - List of Clinical Variables

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Study Information

- Study name
- Study design
- Treatment arms (inc duration and dosing)
- Countries
- Inclusion/exclusion criteria
- Dates of First/last patient, first public release of information, link to any publications

Baseline Variables

- Age (by fixed intervals), Sex, race, ethnicity
- Comorbidities at the time of entry to the trial
- Meds at entry
- COVID19 disease severity at presentation

Efficacy Endpoints*

Number of patients and/or time to and/or duration

- 8-point scale
- NEWS and NEWS2 score
- Improvement based on 8-point scale and NEWS and NEWS2 Score
- Mechanical ventilation
- Oxygen use
- Non-invasive Ventilation/High-Flow Oxygen Use
- Mechanical Ventilation/ECMO
- Hospitalization
- Fever
- Viral clearance
- CRP
- D-dimer
- Serum ferritin
- Discharge/Ready for Discharge

Safety Endpoints*

Number of patients with

- Aes Overall
- Specifically overall
  - Cardiac
  - Gastrointestinal
  - infections and infestations
  - Metabolism
  - Renal
  - respiratory
- CTC Grade 4 AEs
- SAEs

Time to

- CTC Grade 4 AE
- Death

Exposure and Retention*

- Number of patients remaining in the trial
- Number of patients remaining on study drug

Efficacy, safety and exposure endpoints

- Baseline, Day 3, 7, 14/15, 28/29 and latest follow up time of the trial.
- By subgroups such as demog, lab based, and comorbidities

Standard tools

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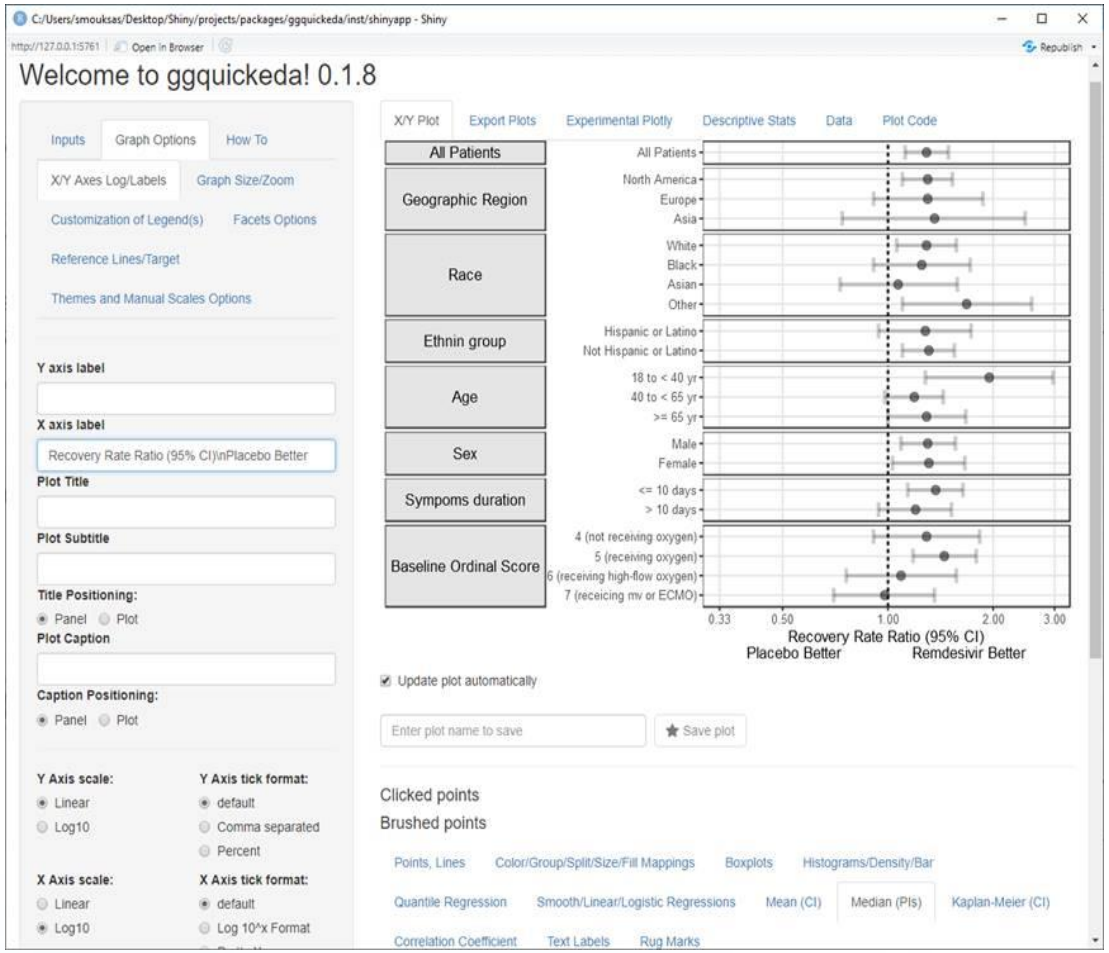
Visualization App

- The visualization app is designed to provide an analysts with an easy to use and a powerful tool to describe and visualize trials.
- It can work as a collaboration tool for real time exploration of data
- Features includes;
  - scatter plots, dotplots, boxplots, barplots, histograms, densities and summary statistics tables
  - data manipulations such as categorize/cut, merge factor levels, recode/reorder categories, combine variables, etc
  - summary/regression functions such as Smooth/Linear/Logistic Regressions, Mean Confidence Intervals, Median Prediction Intervals, Kaplan-Meier curves, Correlation Coefficient



Meta-Analysis App

- The meta analysis app is designed to provide an analysts with simple steps to walk through a meta analysis.
- It is assumed that the user has some amount of statistical training.
- There are two simple steps:
  - Select studies that have a common treatment and outcome of interest
  - Specify a meta analysis by selecting subgroups to analyze and specifying various meta-analysis parameters
- The results from selected studies are analysed and output is provided in the form of plots and tables.
- By default, a study-level meta analysis is shown.
- Subgroup analyses can be performed by selecting subgroup variables to analyse.
- The analyst can also select which time point to look at, as well as specifying several meta analysis parameters.