COVID-19 Enriched Summary Level Data Dictionary
COVID-19 Data Flow: From Common Data Elements to Standard Tools

- **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.
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

**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
Visualizațion 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
The meta analysis app is designed to provide an analyst 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 analyzed 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 analyze.

The analyst can also select which time point to look at, as well as specifying several meta analysis parameters.