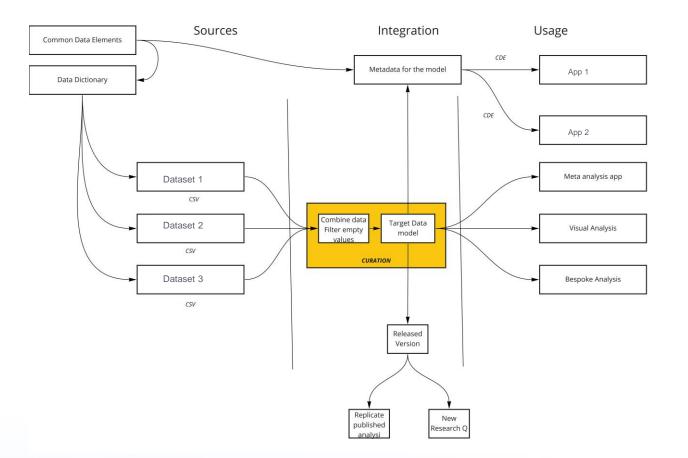


## **COVID-19 Enriched Summary Level** Data Dictionary

### **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.



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



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#### 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**



#### Exposure and Retention\*

- Number of patients remaining in the trial
- Number of patients remaining on study drug
- **Study Information Safety Endpoints\* Baseline Variables Efficacy Endpoints\*** Age (by fixed intervals), Number of patients with Number of patients and/or • Study name • Sex, race, ethnicity time to and/or duration Aes Overall Study design Comorbidities at the time Treatment arms Specifically overall 8-point scale of entry to the trial **NEWS and NEWS2** Cardiac (inc duration and Gastrointestinal dosing) Meds at entry • score Countries COVID19 disease Improvement based on 8infections and severity at presentation infestations Inclusion/exclusion point scale and NEWS criteria and NEWS2 Score Metabolism Dates of First/last Renal Mechanical ventilation • • patient, first public respiratory Oxygen use • CTC Grade 4 AEs Non-invasive release of • SAEs information, link to Ventilation/High-Flow any publications **Oxygen Use** Time to Mechanical CTC Grade 4 AE • Ventilation/ECMO Death Hospitalization • Fever • Viral clearance **CRP** • Efficacy, safety and exposure endpoints **D**-dimer • Baseline, Day 3, 7, 14/15, 28/29 and latest Serum ferritin • follow up time of the trial. **Discharge/Ready for** •
- By subgroups such as demog, lab based, and comorbidities

COVID-19 ALLIANCE

Discharge

| 4

# **Standard tools**



### **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



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		Age	40 to < 65 yr >= 65 yr		
X axis label			Male		
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Plot Subtitle			4 (not receiving oxygen)		
TOT SUBLICE		Baseline Ordinal Score	5 (receiving oxygen)	-	
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Log10	Log 10 <sup>*</sup> x Format	Correlation Coefficient	Text Labels Rug Marks	s	

## **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.

