

## COVID-19 Evidence Accelerator

### Parallel Analysis – Project Topic 1

Original Key Question: *How can real-world data improve our initial understanding of safety and effectiveness of therapies used for COVID-19?*

#### Specific Scenario for Project Topic 1:

**Among hospitalized patients with COVID-19, describe the following for hydroxychloroquine +/- azithromycin vs control?**

- *Characterize COVID-19 patient populations treated with hydroxychloroquine +/- azithromycin vs control*
- *Characterize hydroxychloroquine +/- azithromycin treatment (e.g., timing in COVID-19 illness trajectory; monotherapy vs co-prescription; dose)*
- *Characterize safety signals with hydroxychloroquine +/- azithromycin vs control, including by subpopulations (e.g., age, diabetes, COPD)*
- *Describe comparative effectiveness of hydroxychloroquine +/- azithromycin vs control on key outcomes (see below)*
- *Identify potential predictors of treatment safety and effectiveness*
- *Validate COVID-19 risk stratification score*

Example outcome measures - ranked in in order of when these could likely be assessed.

Outcome Measures	Timeframe	Output	Data Submission
Safety / SAEs	As reported	Cardiotoxicity rates, other SAE occurrence	Regular intervals
Clinical status	Within 14 days from admission	Death; Hospitalized with or without ventilation; with or without O2; Not hospitalized	Submit data at designated patient threshold or specified # of events
Time on ventilator	Time between admission and discharge	Total days with ventilation	
Admission to intensive care	Time between admission and discharge	Transfer from regular care to ICU during admission	
Duration of hospital admission	Time between admission and discharge	Total days admitted to the hospital	
In hospital mortality	Time between admission and discharge	All-cause mortality during admission	
Mortality at 30 and 90 days	Follow-up at 30 and 90 days	All-cause mortality assessed at 30 and 90 days	

\*\*When possible, use COVID-19 common data elements and/or contribute to improving the list