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Supplementary information

Trends in COVID-19 therapeutic clinical trials

In the format provided by the authors

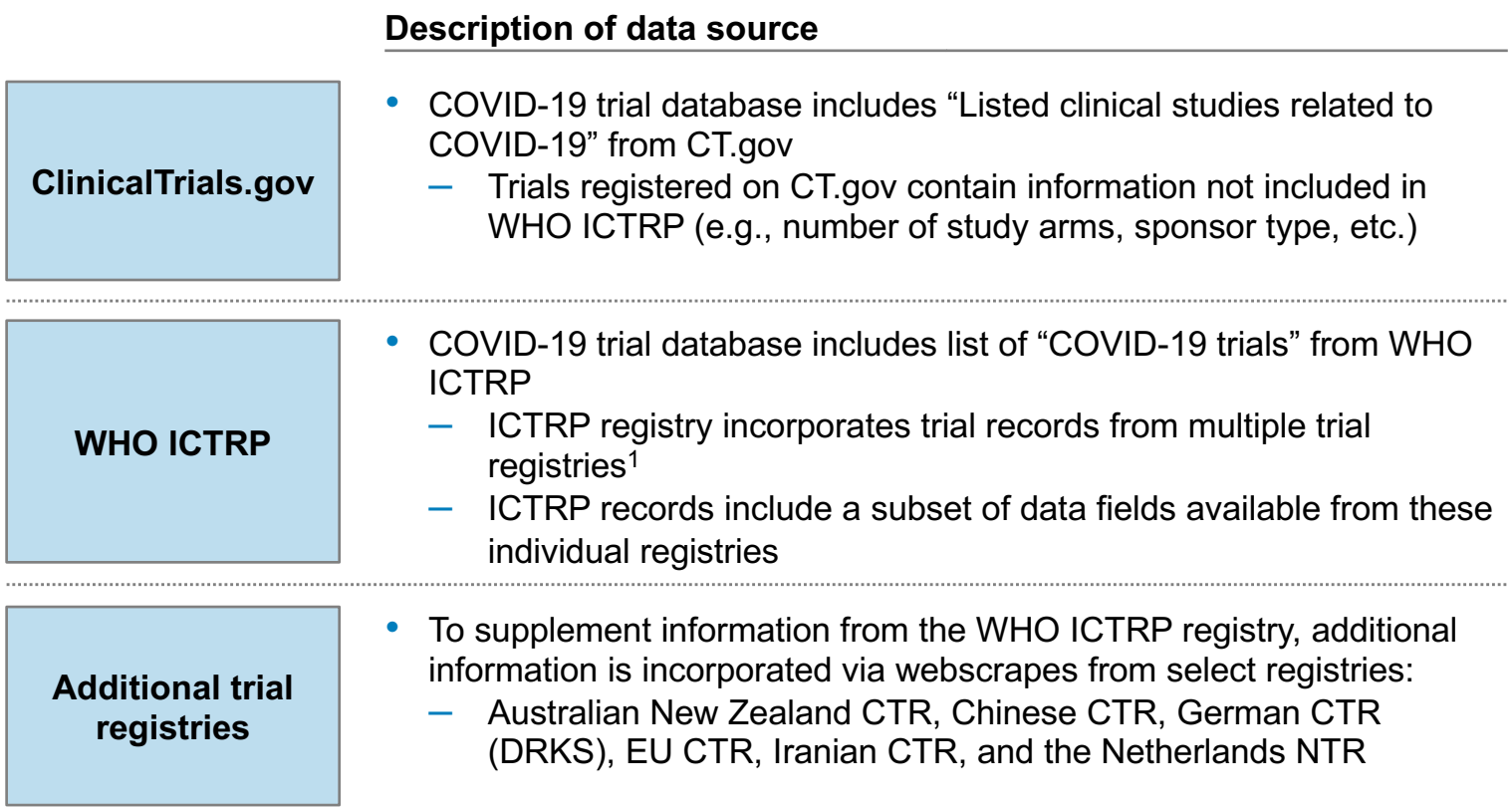

Figure S1: The COVID-19 trial database incorporates data from CT.gov, WHO, and select additional clinical trial registries

1 ICTRP registry includes a subset of data fields from Australian New Zealand CTR, Chinese CTR, ClinicalTrials.gov, EU CTR, ISRCTN, Netherlands NTR, Brazilian CTR, Indian CTR, Korean CTR, Cuban CTR, German CTR, Iranian CTR, Japan CTR, Pan African CTR, Sri Lanka CTR, Thai CTR, and Peruvian CTR.

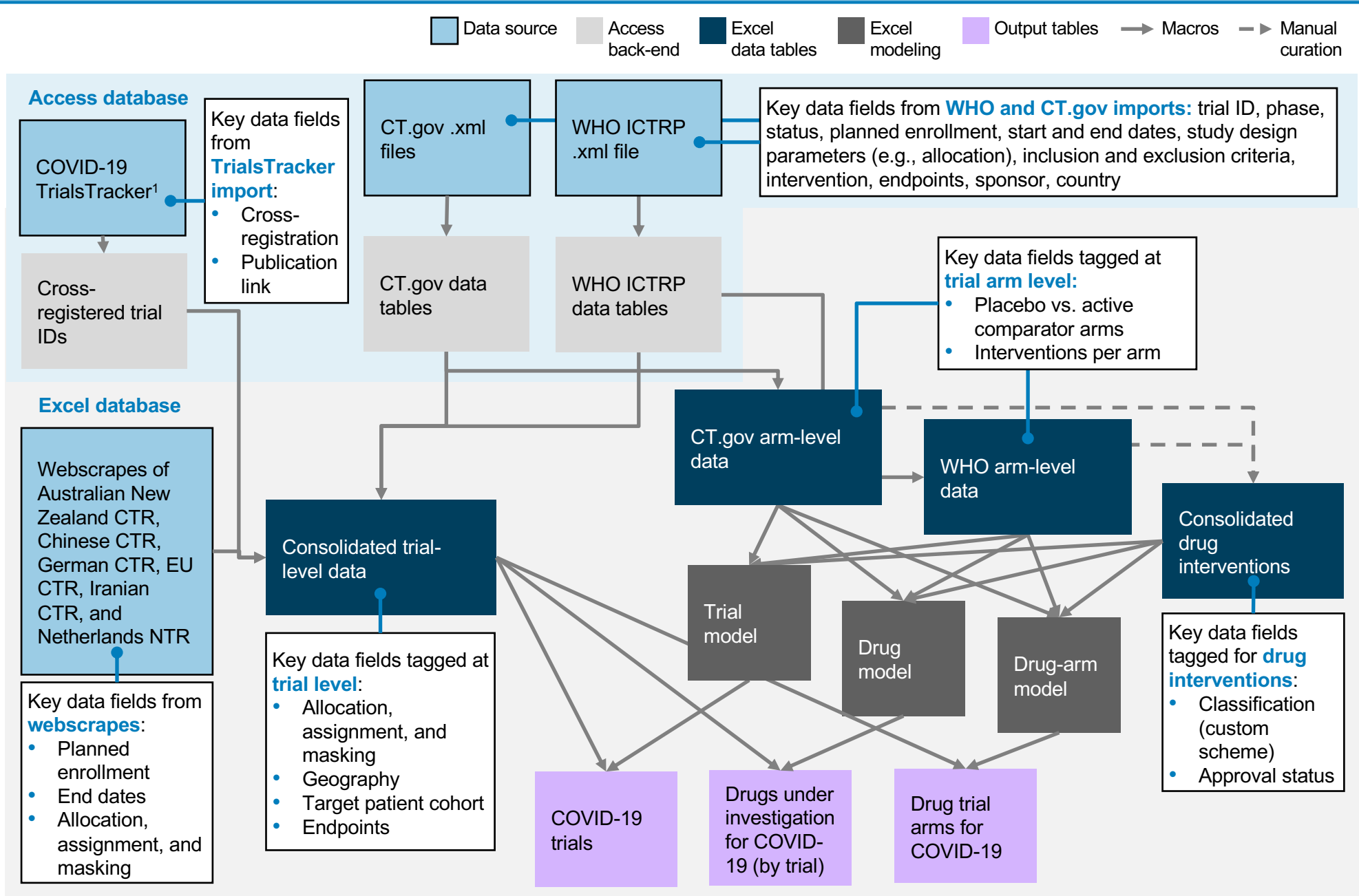

Figure S2: Data model

1 http://covid19.trialstracker.net/index.html

Table S1: Summary of key data fields

Intervention

Intervention
Drug name
Therapeutic class

Study type
Observational
Interventional (drug, non-drug)

Trial design

Allocation
Randomized
Non-randomized

Assignment
Parallel assignment
Factorial assignment
Sequential assignment
Single group assignment

Masking
Blinded (single, double)
Open label

Severity
Uninfected
Exposed
Infected without symptoms
Mild
Moderate
Severe
Critical
Recovered

Patient journey
Pre-exposure prophylaxis
Post-exposure prophylaxis
Asymptomatic
Early mild
Hospitalized LRI
Ventilated ICU
Recovered

Endpoint (not exhaustive)
Mortality
Clinical recovery
Organ failure
ICU utilization/status
Hospitalization status

Evidence generation
Link to publication

Enrollment

Phase
0, 1, 1/2, 2, 2/3, 3, 4

Status
Active e.g., recruiting etc.
Cancelled e.g., withdrawn etc.

Planned enrollment
Enrollment for trial
Enrollment for each study arm

Study dates
Start date
Primary end date

Operations

Sponsor
Lead sponsor
Sponsor type (Available only for CT.gov)

Country
Lead country
US involvement e.g., at least 1 trial site in the US

Trial site
Number of trial sites

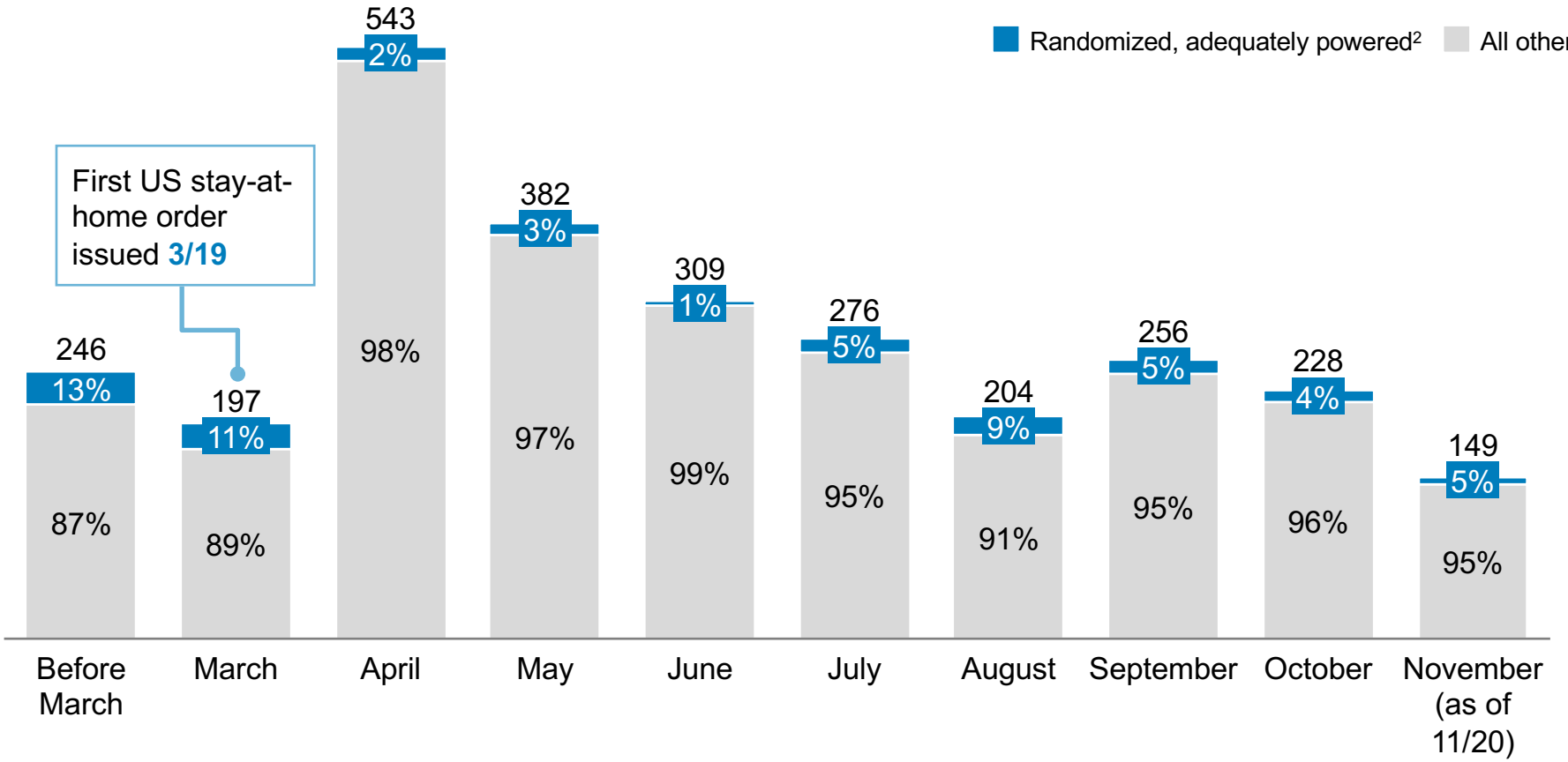

Figure S3: The total number of trial arms[1] started and randomized, adequately powered per month

1 Corresponds to number of global investigational trials recruiting or completed. Excludes trials that have been terminated (or equivalent). Separates out multi-arm trials into distinct counts, including arms testing the same intervention in different doses or durations. May not be fully comprehensive. Excludes Traditional Chinese Medicine and vaccine trials. Placebo arms are not included in arm counts.
2 Randomized, adequately powered trials are defined as randomized controlled trials in Phase 2 or beyond with expected enrollment of 250+ per arm for ventilated ICU, 500+ for hospitalized LRI, 1,000+ for early mild or asymptomatic, and 5,000+ for post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).

Source: Clinicaltrials.gov accessed 11/20/2020 and WHO clinical trial registry accessed 11/20/2020

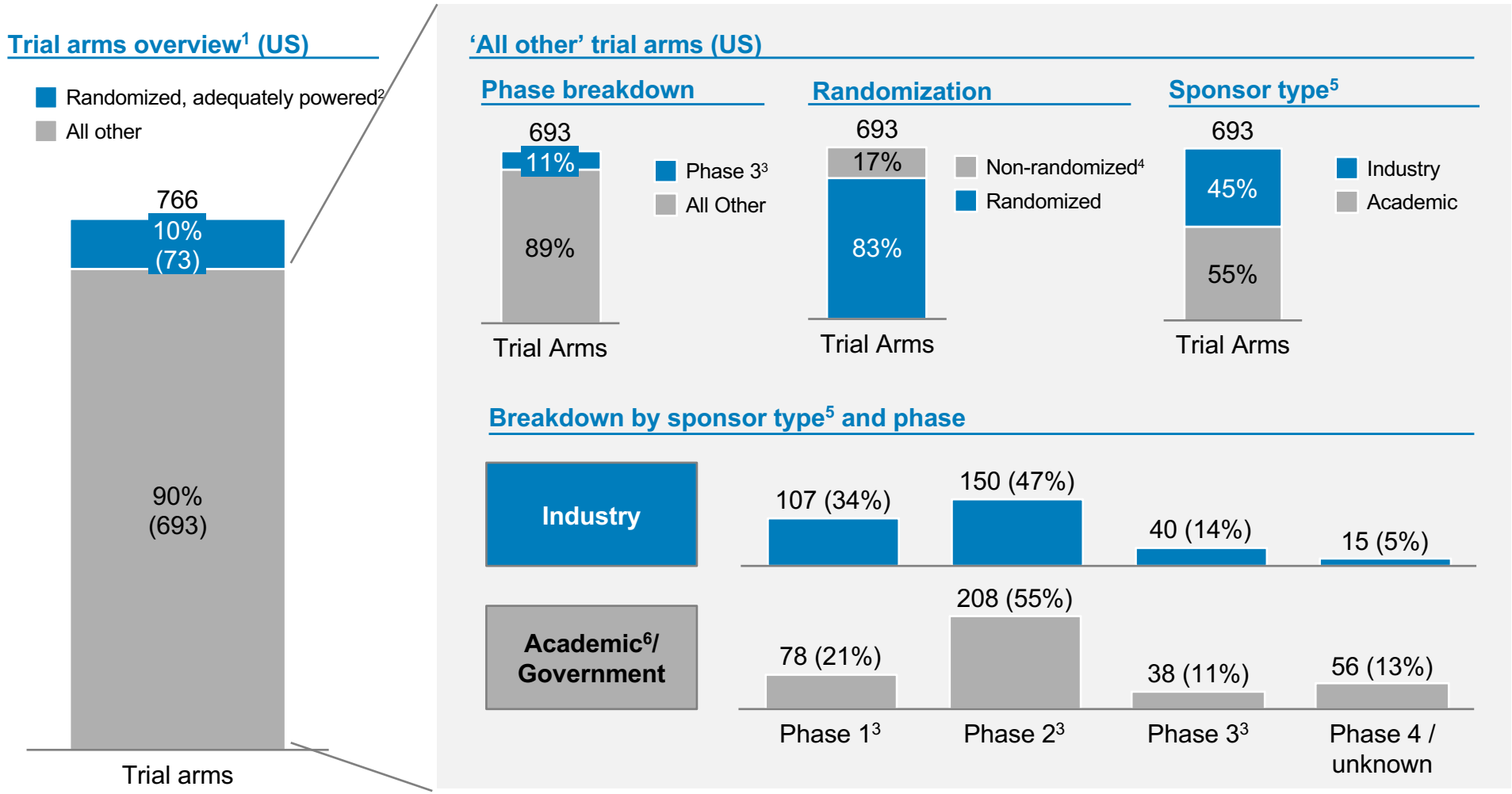

Figure S4: Characteristics of non- 'randomized, adequately powered' trial arms (US)

1 Corresponds to number of global investigational trials recruiting or completed. Excludes trials that have been terminated (or equivalent). Separates out multi-arm trials into distinct counts, including arms testing the same intervention in different doses or durations. May not be fully comprehensive. Excludes Traditional Chinese Medicine and vaccine trials.
2 Randomized, adequately powered trials are defined as randomized controlled trials in Phase 2 or beyond with expected enrollment of 250+ per arm for ventilated ICU, 500+ for hospitalized LRI, 1,000+ for early mild or asymptomatic, and 5,000+ for post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).
3 Multi-phase trials grouped with earliest phase involved: Ph 1/2 trials grouped with Ph 1 trials, Ph 2/3 trials grouped with Ph 2 trials, Ph 3/4 trials grouped with Ph 3 trials.
4 Includes trials with unknown randomization design.
5 If multiple sponsors are involved, trial is categorized by lead sponsor type.

Source: Clinicaltrials.gov accessed 11/20/2020 and WHO clinical trial registry accessed 11/20/2020

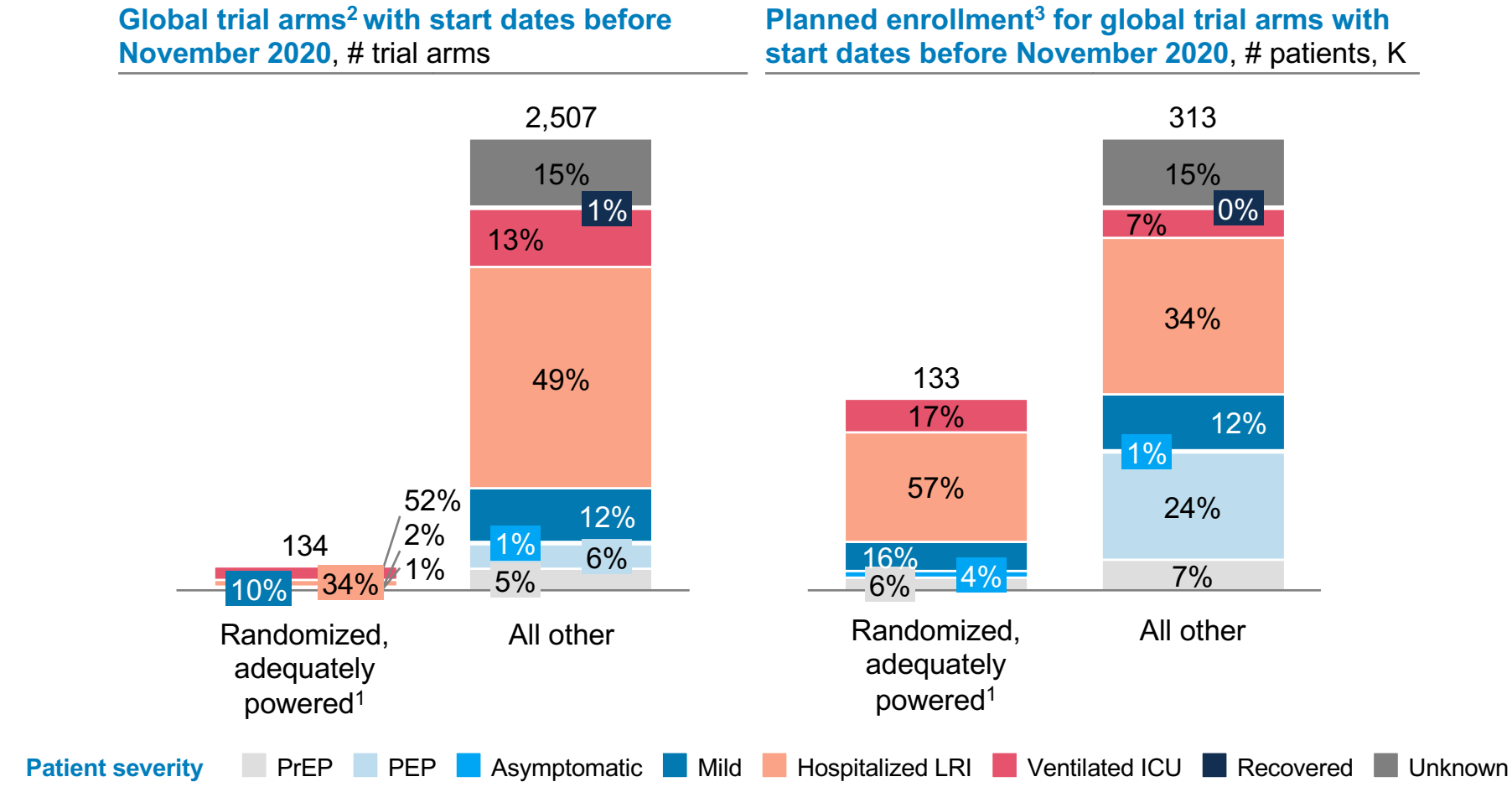

Figure S5: Randomized, adequately powered trial arms[1] and target patient enrollment for trials started before November 2020

1 Randomized, adequately powered trials are defined as randomized controlled trials in Phase 2 or beyond with expected enrollment of 250+ per arm for ventilated ICU, 500+ for hospitalized LRI, 1,000+ for early mild or asymptomatic, and 5,000+ for post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).
2 Corresponds to number of global investigational trials recruiting or completed. Excludes trials that have been terminated (or equivalent). Separates out multi-arm trials into distinct counts, including arms testing the same intervention in different doses or durations. May not be fully comprehensive. Excludes Traditional Chinese Medicine and vaccine trials.
3 Planned enrollment defined as enrollment per arm estimated from total enrollment by assuming even distribution of patients across all arms. It is not reflective of actual enrollment. Total planned enrollment does not include planned enrollment in placebo arms.

Source: Clinicaltrials.gov accessed 11/20/2020 and WHO clinical trial registry accessed 11/20/2020