Median Accrual Rate Common Metric
First Submission due in August 2021, reporting 2020 Calendar year data

Inclusion Criteria

- All *clinical trials* accruing participants at any point in Calendar Year 2020.
  A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (May include placebo or control) to evaluate the effects of those intervention on health related or biomedical or behavioral outcomes.
- Behavioral health studies meeting the clinical trials definition are included
- Any funding source (NIH, Industry, etc.)
- Clinical trials with recruitment on hold but not closed

Exclusion Criteria

- Exclude any clinical trials for which informed consent is not required
- Exclude trials with an initial targeted number of participants is less than 5
- Exclude trials not open to accrual during year (2020)
- Exclude multisite trials using competitive enrollment
- Report only accrual rates at your site for multi-site trials

Required Data Elements for each Trial

- **Number of Participants Targeted** - Sample size power calculation (lesser of all estimates)
- **Number of Participants Accrued** – Number of participants that signed consent form and passed all screening requirements on December 31 or end of trial recruitment . Participants who withdraw or lost to follow-up are conceded accrued.
- **Number of calendar days elapsed since open to recruitment**. (December 31 or end of trial recruitment)
- **Number of calendar days the trial will be open to recruitment**. Planned number of days open to recruitment (requires enrollment open date and planned enrollment end date)

Accrual Rate Formula

$$Accural\ Rate = \frac{\left(\frac{\#\ of\ Particpants\ Accrued}{\#\ of\ Participants\ Targeted}\right) \times 100}{\left(\frac{\#\ of\ Days\ Open\ to\ Accural\ during\ year}{\#\ of\ Days\ Trial\ will\ be\ open\ to\ accural\ during\ year}\right) \times 100}$$

Data Collection and Sampling

- Data can be obtained from a Clinical Trials Management System, or a combination of investigator survey and information on record, such as from the IRB.
- Hubs can opt or a random or non-random sample of eligible trials. Criteria must be specified in the Turn the Curve Plan (TTC)
- TTC must specify the number of trials included in calculating the median, and the number of trials open to accrual but not accruing any subjects
- It is expected that over the next 3-5 years the requested reporting will be segmented by gender, unrepresented minority status and other less represented community categories.