

## CTEP Operational Efficiency Working Group (OEWG)

### Absolute Deadline

#### Policy and Procedure

Version date: September 1, 2019

**Policy:** All studies that are not activated (i.e., open to patient enrollment) by the OEWG absolute deadline will automatically have their status changed to “OEWG Terminated.” The absolute deadlines are:

Phase 1, 1/2 and 2 LOIs: 400 calendar days from OEWG start date to protocol activation (i.e., opening to patient enrollment)

Phase 2 Concepts: 450 calendar days from OEWG start date to protocol activation (i.e., opening to patient enrollment)

Phase 3 Concepts: 540 calendar days from OEWG start date to protocol activation (i.e., opening to patient enrollment)

#### **Procedure:**

- CTEP and the lead organization will work collaboratively throughout the protocol development process to achieve the OEWG deadline.
- CTEP will send reminders to the lead organization 120, 90, 60 and 30 calendar days prior to the Absolute Deadline.
- The day after the Absolute Deadline has been reached
  - The trial is terminated
  - A letter is sent from PIO to the lead organization informing them that the trial has been terminated due to exceeding the absolute deadline.

If the site can demonstrate that the trial activated before the Absolute deadline was reached, CTEP will change the protocol status from “OEWG Terminated” to “Active.”