## CTEP Operational Efficiency Working Group (OEWG) Policy and Procedure for Determining the OEWG Start Date <u>Version Date</u>: September 1, 2019

<u>Goal:</u> To define the official OEWG Start Date for studies included in the CTEP OEWG process based on document type and the required review process for the document.

The OEWG Start Date will be used to calculate the absolute deadline for all studies included in the CTEP OEWG process.

## **Policies/Definitions:**

**OEWG Start Date:** The baseline date from which the absolute timeline is calculated.

- 1. For all LOIs, the OEWG Start Date is the date of initial CTEP review (either Investigational Drug Branch or Protocol Review Committee review, as appropriate).
- 2. For all <u>Concepts reviewed by a Steering Committee</u>, the OEWG Start Date will be the date of the initial, actual Steering Committee review, regardless of the actual submission date. (Please note that the secure Timeline Reports website will use the planned Steering Committee date as the OEWG Start Date until the actual Steering Committee date is entered.)
- 3. For all <u>Concepts that do not yet have a Steering Committee</u>, the OEWG Start Date will be the date of the initial, actual Concept Review Meeting (for phase 3 Concepts) or the initial, actual Protocol Review Committee review (for NCTN phase 2 Concepts).