**MCC PROGRESS REPORT GUIDE:**

**PROCESS**

1. A Clinical Trial Progress Report should be completed for each open site that was initiated on or before the date of data capture.
2. Please keep the following in mind when completing the forms:

-        The site information should reflect the site’s status on the date of data capture.

-        The “Date commenced” cannot be prior to MCC approval. If the SIV was done prior to MCC approval, then the “Date commenced” is the MCC approval date.   If a re-initiation visit was done after MCC approval   then the “Date commenced” is the re-initiation visit date.

-        The “Expected date of completion” is the (expected) Site Closure Visit (SCV) date.

-        For “Sponsor approved” protocol non-compliance, record only Sponsor approved waivers/protocol deviations/violations. May be attached separately (**complete list required**).

-        For “Non-Sponsor approved” protocol non-compliance, record only waivers/protocol deviations/violations NOT approved by Sponsor. May be attached separately (**complete list required**).

-        All SAEs and drug related AEs have to be completed on the applicable forms (Attachments 1 and 2). These are attached to each individual site-specific progress report.

1. Line Managers should review the reports before it is sent to the sites. A checklist that you can use for this purpose is available on the QSSA Team Site.
2. The PI, or the sub-investigator on behalf of the PI, should review the report and complete the “Summary of Progress to Date” (page 3 of template) section before it is signed and returned to the Monitor.
3. Monitor signs
4. Manager signs
5. CTA/CRA do final check