To our Sponsors, Principal Investigators and Clinical Trial Study Teams: please refer to the table below for study documentation requirements to be received for DMC review at least **five business days** prior to a call [as well as data formats].

Please send all documentation directly to CFF DSMB Portal Administrator/Project Manager, Ms. Leslie Hargrove, lkhargrove@email.arizona.edu. As well as a copy to your specific CFF DMC Study Coordinator.

DMC and Study Team Initial, Organizational (new) study review:

|  |  |
| --- | --- |
|  | **The role of your CRO is to**:* Generate statistical analysis plan mock-ups (see below)
* Prepare Open (blinded) and Closed (unblinded) reports for interim analyses
* Attend the closed portion of interim analysis calls to assist the DMC with any questions or discussion items.
 |
|  | **Statistical analysis plan in mock-up form**:Tables, charts, graphs, box-plots, summaries, spaghetti plots, open reports, closed reports, SAE summaries, etc, *applicable to your study design.*Closed reports should either identify treatment groups, or a separate document identifying treatment groups should be sent.Reports should be transmitted to the DMC Database Administrator in PDF format, and should be condensed. The DMC should receive only one PDF file for tables, one for listings, and one for figures. |
|  | Protocol |
|  | Draft DMC Charter |
|  | Investigator’s Brochure |
|  | Informed Consent models |
|  | Sponsor’s Power-point presentation study summary |
|  | Data Analysis Mock-up sets (please see above description) |

DMC and Study Team **Interim Analyses** Requirements:

|  |  |
| --- | --- |
|  | Sponsor Power-point slide presentation including recruitment and summary of the open report (see examples on next page) |
|  | Summary of Open Report by blinded statistician |
|  | Open Report Data Sets *(One PDF file each for: tables, listings, figures. May send additional files as needed.)* |
|  | Closed session summary report |
|  | Closed Report Files *(One PDF file each for: tables, listings, figures. Identify treatment groups, or put them in a separate file. May send**additional reports as needed.)* |
|  | Unblinded Study Team Statistician presentation and Q&A |

Examples:

* Enrollment updates;
* Demographics;
* Participant disposition – withdrawal, drop-out rate;
* Protocol violations or deviations;

In the Appendix [found in charter template] please identify the following:

**APPENDIX:**

|  |  |  |
| --- | --- | --- |
| **Study Team:** | **Institution or University** | **Email address and phone #s** |
| Principal Investigator |  |  |
| Co-PI |  |  |
| Medical Monitor |  |  |
| Clinical Trial Manager |  |  |
| Blinded Statistician |  |  |
| Trial Master File Manager Very important to identify immediately |  |  |
| **Contract Research Org:** |  |  |
| Blinded StatisticianOpen Reports |  |  |
| Unblinded StatisticianClosed Reports |  |  |