Appendix D

**CT.gov Results Reporting Guidelines**

This checklist is to provide guidance on how results should be reported.

Before starting you need access to all data.

Remember: data is required to be reported within 1 year after the final subject meets his/her primary endpoint. CT.gov and the FDAA law do NOT care about publication. Additionally, reporting results should be in such a way that a non-researcher can understand.

Note: Any red **ERROR** must be addressed or changed; any blue **NOTE**: is only a suggestion. A red \* is a field that must be completed. Click on **Edit** to enter or change data.

Click on ***Save*** for all entries

|  |  |  |  |
| --- | --- | --- | --- |
| **Check if completed** | **Data field** | **Guidance** | **Comments** |
|  |  | Open the record |  |
|  | Under Protocol status | Select Study Status |  |
|  | Record Verification | Change to current month and year |  |
|  | Overall Recruitment Status | Change to appropriate category; Completed would be appropriate if the study is over and results are being reported |  |
|  | Primary Completion Date | Date and month enter month and year last subject met primary endpoint |  |
|  | Under Study Design |  |  |
|  | Enrollment: Number of subjects | Enter number | Enter actual number enrolled |
|  | Type | Change to actual |  |
|  | | | |
|  | Participant flow | Select arms of study |  |
|  | Started | Number of subjects signing consent |  |
|  | Completed | Number of subject meeting primary endpoint |  |
|  | Not completed | Enter number that failed to meet primary endpoint and secondary endpoint | Categorize by reason |
| Demographics | | | |
|  | Age, gender, ethnicity | Answer appropriately |  |
| Results |  |  |  |
|  | Outcome endpoints:  Number analyzed | Enter number | Number o f subjects meeting the endpoint |
|  | Outcome measure data table: measure type | Answer | Select the most appropriate |
|  | Outcome measure data table: measure dispersion | Based on measure type selected |  |
|  | Outcome measure: unit of measure | Enter appropriate |  |
| Adverse events | | | |
|  | Risk | Number of subjects that COULD have experienced the AE | Usually the total number of subjects enrolled unless the study is designed |
|  | affected | Number of subjects that DID experience the event |  |
| References | | | |
|  | References | Enter either key references that support the protocol, and or enter references that report the results (not required) | NOTE: references that report the results will NOT substitute for entering the outcome measure results |
| Approving and releasing | | | |
|  | Approve | Must be completed by the PI |  |
|  | Release | Must be completed by the PI |  |
| After releasing and approving, CT.gov may take about 15 to 30 days to respond. Either CT.gov will approve the record or generate **Review Comments.** | | | |
|  | Open review comments and address all questions |  |  |
|  | Approve | Must be completed by the PI |  |
|  | Release | Must be completed by the PI |  |
|  |  |  |  |
|  |  |  |  |