CVM eSubmitter Changes

Table: Configuration Change Request Details

CCR Number	ESUB-077
Title	Revised INAD Effectiveness and Target Animal Safety Technical Sections for I-P-EF and I-P-TS submission types
Business Owner	ONADE
Change Type	Enhancement
Components	I-P-EF and I-P-TS templates
Severity	High
Application Release	Version 1.11.00 – 8/15/2018

I. Introduction

The changes to the INAD Effectiveness and Target Animal Safety Technical Sections for I-P-EF and I-P-TS submission types described within this document are in support of industry feedback.

II. Change Description

The changes are listed per section of the template and reflect both I-P-EF and I-P-TS templates, unless otherwise noted.

A. 1.0 General Information

The general information section changes are as follows:

- Replaced the two-optional single file attachment questions for cover letter and submission content with a single required multi-file attachment question requesting a submission summary and/or cover letter to remove confusion about what is being requested.
- Replaced the multi-line text submission summary question with a single line text question requiring a brief description of the information included within the submission. Also, included a hint describing the purpose of the summary text.

B. 2.0 Product Description

No changes to the product description section.

C. 3.0 Effectiveness Data/Information (Target Animal Safety Data/Information for I-P-TS)

The effectiveness data/information section for I-P-EF and target animal safety data/information for I-P-TS changes are as follows:

- Added a new question to collect the study number. Along with the study type, the study number is carried over into the header of the subsequent nodes/screens and report output to clearly identify the associated study for the information collected.
- Moved the question collecting the status of whether an Electronic Data Capture (EDC) system was used in the study from the subsection under Standard of Conduct

up to the section 3.0 to better manage how EDC questions are asked across the subsequent nodes/screens.

- Added a new question asking if the study had been submitted previously, when the submission is in response to a previous CVM technical section incomplete letter. This allows both new studies to be added, as well as updates to a previously submitted study. Previously, only updates could be submitted.
- Added hints to the study number and study description questions.
- Removed the question on describing how the attributes of ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) were maintained for any non-EDC collected data during the internal handling of the files through the submission of data files to CVM.
- Removed the sub-section specific to collecting analytical reports.

D. 3.1 Final Study Report (FSR)

The final study report section change is as follows:

- Added links to GLP and GCP FSR references for additional guidance.

E. 3.2 Protocol

The protocol section changes are as follows:

- Added a new question to collect the status of whether the sponsor received concurrence by CVM on their protocol before requesting the associated CVM submission number.
- Added a new question asking if the signed protocol is included within the FSR. If responding with yes, the sponsor is requested to provide a page number within the FSR. If responding with no, the sponsor is requested to attach the protocol or reference where in the submission the protocol is located.

F. 3.3 Test and Control Article Characterization

The test and control article characterization section changes are as follows:

- Replaced the yes/no question asking if the test article used for the study utilized the final formulation to be marketed for the product with a new question asking to identify if the formulation used for the study is one of the following options:
    - Proposed final formulation
        - If selected, the lot number(s) and certificate of analysis (COAs) for the test article are requested.
    - Currently marketed/approved formulation
        - If selected, the lot number(s) for the test article are requested.
    - Change from the currently marketed/approved formulation
        - If selected, the lot number(s) and certificate of analysis (COAs) for the test article are requested.
    - Other
        - If selected, the composition of the formulation utilized and lot number(s) for the test article are requested.

G. 3.4 Protocol Amendments and/or Protocol Deviations (not included for Target Animal Safety Data/Information for I-P-TS)

The protocol amendments and/or protocol deviations section changes are as follows:

- Replaced the reference to Study Amendments with Protocol Amendments.
- Replaced the file attachment question when responding to whether protocol amendments are included/implemented in the study with a series of new questions to simplify the process of referencing where protocol amendments are located within the submission:
    - Added a new question to collect whether the protocol amendments are included within the FSR?
        - If yes, where in the FSR (i.e., page number)?
        - If no, attach the protocol amendments or reference where in the submission they are located.
- Replaced the file attachment question when responding to whether protocol deviations are included/implemented in the study with a series of new questions to simplify the process of referencing where protocol deviations are located within the submission:
    - Added a new question to collect whether the protocol deviations are included within the FSR?
        - If yes, where in the FSR (i.e., page number)?
        - If no, attach the protocol deviations or reference where in the submission they are located.

H. 3.5 Standard of Conduct

The standard of conduct section changes are as follows:

- Added links to GLP and GCP FSR references for additional guidance.
- Added a new question to attach the GLP compliance statement to address 21 CFR 514.1(b)(12)(iii) for a study conducted under the FDA GLP standard or comparator standard (e.g., OECD GLP).
- Removed the question asking to include the differences between the Standard of Conduct denoted and the standards utilized in this study.
- Moved the question collecting the status of whether an Electronic Data Capture (EDC) system was used in the study from the subsection under Standard of Conduct up to section 3.0 to better manage how EDC questions are asked across the subsequent nodes/screens.

I. 3.6 Electronic Data Capture (EDC) Systems

The Electronic Data Capture (EDC) Systems section change is as follows:

- Moved the section out to be at the same structural level as the other study sections, instead of as a sub-section to the standard of conduct section.

J. 3.7 ReadMe File

The ReadMe file section changes are as follows:

- Added a link referencing GFI #197 for additional guidance.
- Replaced the multi-file attachment question with a single-file attachment question.

K. 3.8 Data Files

The data files section changes are as follows:

- Added a new question to collect a brief description of the data collected within the referenced data set.
- Adjusted how the question that collects whether an EDC is used for the data files included is shown within this section. Previously, the question was always shown regardless of the response to if an EDC systems was used to collect data for the study in section 3.0. Now, the EDC question in this section is only presented when responding yes to the EDC question in section 3.0.
- Added a link referencing GFI #197 for additional guidance on attaching data files.

L. 3.9 Program Files

The program files section changes are as follows:

- Added a link referencing GFI #197 for additional guidance.
- Adjusted the hint text for attaching program files.

M. 3.10 Contributing Scientist Reports (not included for Target Animal Safety Data/Information for I-P-TS)

The contributing scientist reports section changes are as follows:

- Added hint text to the contributing scientist reports included question.
- Replaced the file attachment question when responding to whether contributing scientist reports are included in the study with a series of new questions to simplify the process of referencing where contributing scientist reports are located within the submission:
    - Added a new question to collect whether the contributing scientist reports are included within the FSR?
        - If yes, where in the FSR (i.e., page number)?
        - If no, attach the contributing scientist reports.

N. 3.11 Records of Communication

The records of communication section changes are as follows:

- Added hint text to the records of communication included question.
- Added a new question to collect a reference to where in the submission records of communication are located (i.e., file name and page number) when not attached as files to simplify the process of referencing records of communication within the submission.

O. 3.12 Other Study Related Information

The other study related information section change is as follows:

- Added hint text to the other study related information attachment question.

P. 4.0 Labeling, Freedom of Information (FOI), Further Information

No change to the labeling, Freedom of Information (FOI), and further information section.

Q. 5.0 Comments

No change to the comments section.