1. BACKGROUND:

This procedure applies to all DF/HCC studies that require RIO EDC developed Electronic Case Report Forms (eCRFs), principally Investigator Sponsored Trials (ISTs.)

2. ASSOCIATED DF/HCC POLICIES:

2.1. DATA-101 Section 5.2.1

3. PROCEDURE:

3.1. Pre-Meeting Preparation

3.1.1. The Designer prepares sample eCRFs and the Protocol Feedback Form and updates the status in Salesforce.

3.1.1.1. Sample eCRFs are sourced individually from InForm library and/or or created specifically for this protocol.

3.1.1.2. The Protocol Feedback Form contains questions and comments about eCRF requirements, with specific references to the protocol.

3.1.2. The Designer emails the annotated sample forms and Protocol Feedback Form to the Biostatistician, PI, and Study Team Representative (study stakeholders) for review, copying the Customer Experience Specialist.

3.1.3. Study stakeholders complete pre-meeting requirements as instructed in the introductory email within five business days.

3.1.3.1. Salesforce sends a reminder email to study stakeholders five business days after the Protocol Feedback Form has been marked as complete by the Designer.

3.1.3.2. Pre-meeting requirements includes emailing available PIM times to the Customer Experience Specialist.

3.1.4. The Customer Experience Specialist reviews available meeting times and schedules the PIM.

3.1.5. After the Protocol Feedback Form is completed by the Study Team and Biostatistician, the Designer may elect to cancel the PIM if all requirements are clearly indicated and there are no remaining questions for discussion.

3.2. **Project Initiation Meeting**

3.2.1. The Biostatistician, Designer, PI, a representative from the Study Team, and the Customer Experience Specialist attend the PIM.

3.2.1.1. The goal of this meeting is to bring the key stakeholders together and get all questions answered related to the eCRF build.

3.2.2. The sample forms prepared by the Designer are reviewed at the PIM.

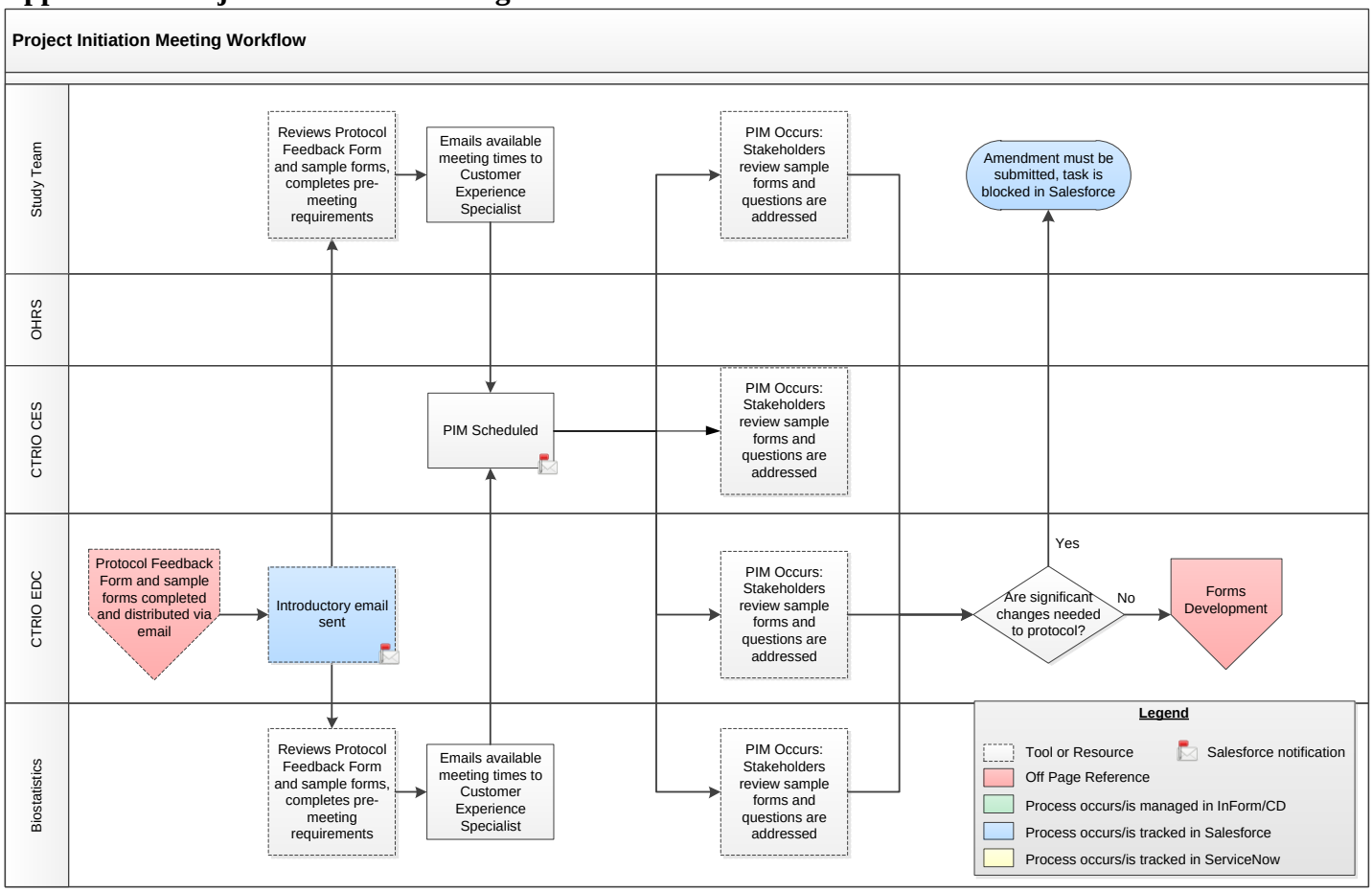
3.2.2.1. The forms are reviewed alongside the Protocol Feedback Form and all comments and questions are resolved and recorded in the Protocol Feedback Form.

3.2.3. If, during the PIM, a protocol is identified as needing significant changes (e.g. additional treatment visit, additional quality of life measures, additional primary endpoint, etc.), changes are captured in the Protocol Feedback Form, the PIM ends, and the status of the task is updated to "blocked" in Salesforce until an amendment is submitted and approved. After the amendment is approved, the process restarts at Pre-Meeting Preparation.

3.2.3.1. Minor protocol changes will not require an amendment, but all changes must be captured on the Protocol Feedback Form to be used in downstream processes.

3.2.4. If the PIM discussion does not result in any significant changes to the protocol, the PIM ends after all forms have been reviewed and agreed upon by the Biostatistician, Designer, PI or proxy, and Study Team reviewer, and the study proceeds to eCRF build.

Appendix 1: Project Initiation Meeting Workflow



Appendix 2: Protocol Feedback Form

Protocol Feedback Form

The Protocol Feedback Form below should be prepared by the Designer for the Study Team and Biostatistician. The form should be used to answer questions such as:

- *Is the form required per protocol? Will the data captured on the form be used for analysis? It is not necessary to capture all data points collected on trial if they will not be used for research purposes. (For example, a Pregnancy form is not usually required even if pregnancy is tested on study* **since the test is done for safety/eligibility and the data will not be analyzed.)**
- *Is the visit necessary for the study? Do any forms need to be removed from the visit? Do any forms need to be added to the visit? Does the order of the forms in the visit need to be changed?*

The first three rows below include examples that could be included by the Designer. The response column on the right is used by the Study Team Representative and Biostatistician and is discussed during the Project Initiation Meeting (PIM).

#	Form Name	Protocol Reference	Designer Question or Comment	Response
1	*Lab Hematology*	*Section x.x p xx and SOE on p xx*	• *Please verify all fields, units, lengths of results (xx.x vs xxx.x, etc.).* • *Do we need both Absolute and differentials?*	
2	*Medical History and Medical Conditions*		• *Are there any disease-specific medical conditions that should be listed here along with the standard options?*	
3	*Date of Visit*		• *What is approximate maximum length of treatment for each course (in years)?*	
			•	

Appendix 3: PIM Agenda Template

Protocol: <##-####>
Date: <MM/DD/YYYY>
Time: <HH:mm AM/PM>
Location: <LOCATION>
Attendees: <ATTENDEES>

Meeting Agenda

I. Introductions
   i. *PI or Proxy*
   ii. *Study Team member*
   iii. *Biostatistician*
   iv. *Designer*
   v. *Customer Experience Specialist*

II. Annotated forms review
   i. *Review sample forms prepared by Designer and address any and all questions that arise*
   ii. *Record comments and required forms updates in the Protocol Feedback Form throughout the review*

III. Protocol Feedback Form review

Review any outstanding questions on the Protocol Feedback Form and ensure all meeting details captured on the form before adjourning.