

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 5.2.2

3. PROCEDURE:

3.1. Initial Build and Study Team Review

3.1.1. After the study is approved for EDC build following the PIM, the assigned Designer uses the protocol and completed Protocol Feedback Form to build the eCRF in the InForm development tool, Central Designer.

3.1.1.1. This includes building the study structure, attaching forms to visits, developing edit checks (when not included in libraries), adding global conditions, and creating a rules specification document.

3.1.1.2. During eCRF build, the Designer performs unit testing on the eCRF.

3.1.1.2.1. Unit testing is a preliminary QA done by the Designer to check for any issues with the forms prior to sending them for Final eCRF Signoff. This includes field attributes (e.g. alpha-numeric conventions, ranges, acceptable formats, ability to include free text where applicable, edit check performance, etc.).

3.1.1.2.2. Please see Appendix 2 for Unit Testing Guidelines.

3.1.2. The Designer will send annotated forms to the Study Team for their review before sending the eCRFs to PI and Biostatistician Final Signoff.

3.1.2.1. The Study Team will provide their comments and the Designer will implement changes in an iterative process until forms are ready for PI and Biostatistician Final Signoff.

3.2. PI and Biostatistician Final Signoff

3.2.1. The Designer updates the status of the eCRF in Salesforce after the forms have been created, triggering an automatic email from Salesforce to the PI and Biostatistician asking for their review and final signoff.

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Forms Development

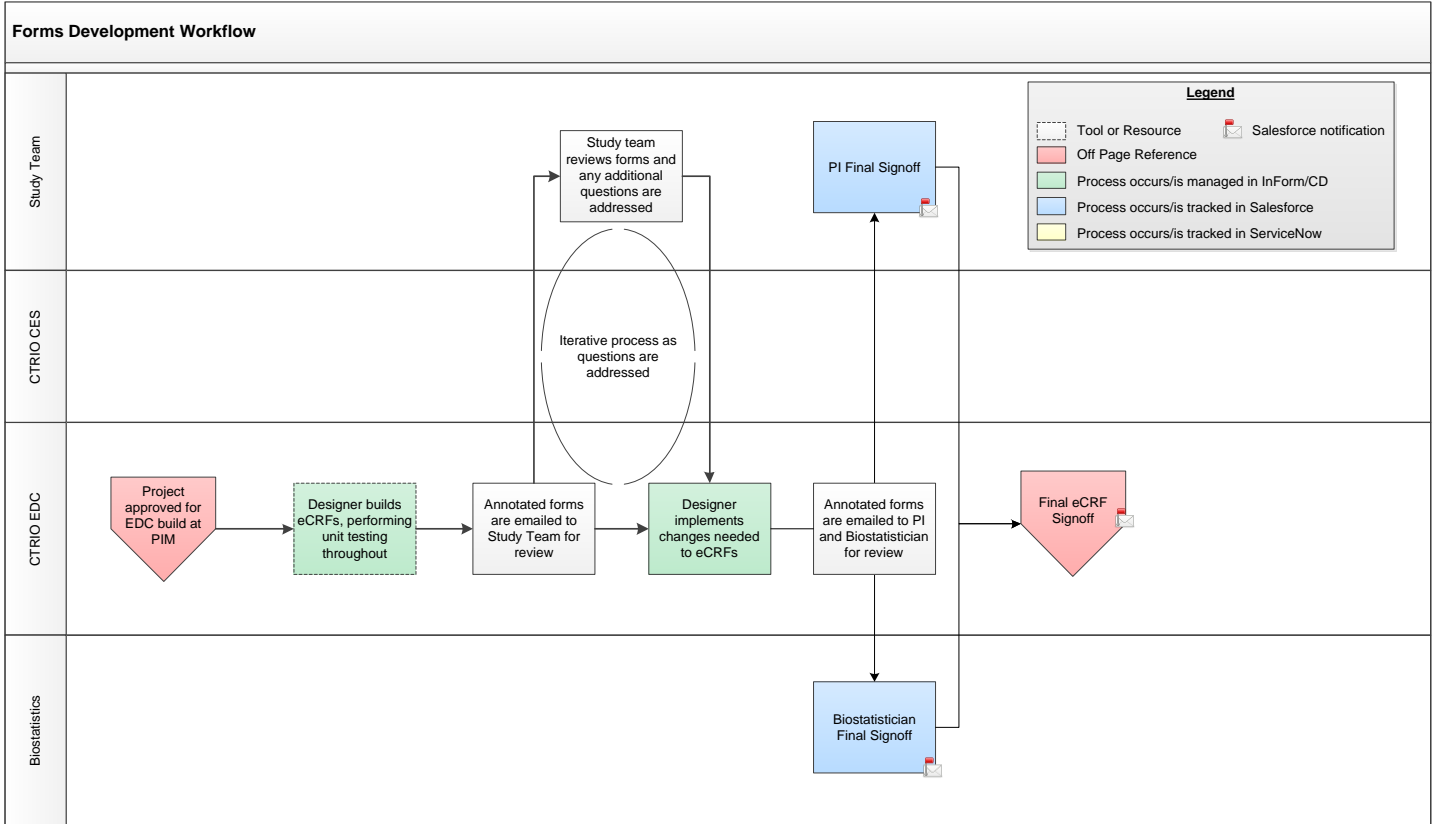
- 3.2.2. The Designer emails the annotated forms to the PI and Biostatistician for review.
- 3.2.3. The Study Team and Biostatistician review the forms and reply to the auto-generated Salesforce email with their final approval.
 - 3.2.3.1. If there are any questions, the reviewers correspond with the Designer or whomever else needed to address all questions and comments before providing their approval. Approval should only be provided after all changes have been made to the forms and consensus is reached.
 - 3.2.3.2. The Designer is notified when a response has been sent by the PI and Biostatistician and monitors email responses in Salesforce to identify when approval has been received.
- 3.2.4. Once approval has been received, the Designer updates the task in Salesforce to indicate that PI and Biostatistician final review is complete. Salesforce automatically moves the study to Final eCRF Signoff.
 - 3.2.4.1. Salesforce sends an automatic notification to the Study Team indicating that the eCRF is ready for Final eCRF Signoff.

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Appendix 1: Forms Development Workflow



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Appendix 2: Unit Testing Checklist



Unit Testing
Checklist.doc

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