

## 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 5.2.3

## 3. PROCEDURE:

### 3.1. Pre-Production Rules

- 3.1.1. EDC Manager assigns pre-production rule specifications to RIO staff member.
- 3.1.2. Assigned RIO staff completes the pre-production rule specifications document and updates the status of the task in Salesforce, triggering an automatic notification to the Rules Developer (Contractor).
- 3.1.3. The Rules Developer (Contractor) follows the specifications document and develops the pre-production rules in InForm Central Designer.
- 3.1.4. The Rules Developer (Contractor) updates the status of the task in Salesforce, triggering an automatic notification to the Tester that the pre-production rules are complete.

### 3.2. Final RIO Testing

- 3.2.1. The Tester completes eCRF testing, including a protocol compliance review and a pre-production rules test.
  - 3.2.1.1. To ensure protocol compliance, the Tester reviews the spelling, content, and study structure. The Tester uses the protocol and the Protocol Feedback Form as the source for compliance review.
- 3.2.2. The Tester fills out the testing review form and updates the status of the task in Salesforce, triggering a notification to the Designer that the review is complete.
  - 3.2.2.1. The Tester uploads the testing review form to Salesforce.

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**Maintained by:** Research Informatics for Operations (RIO)

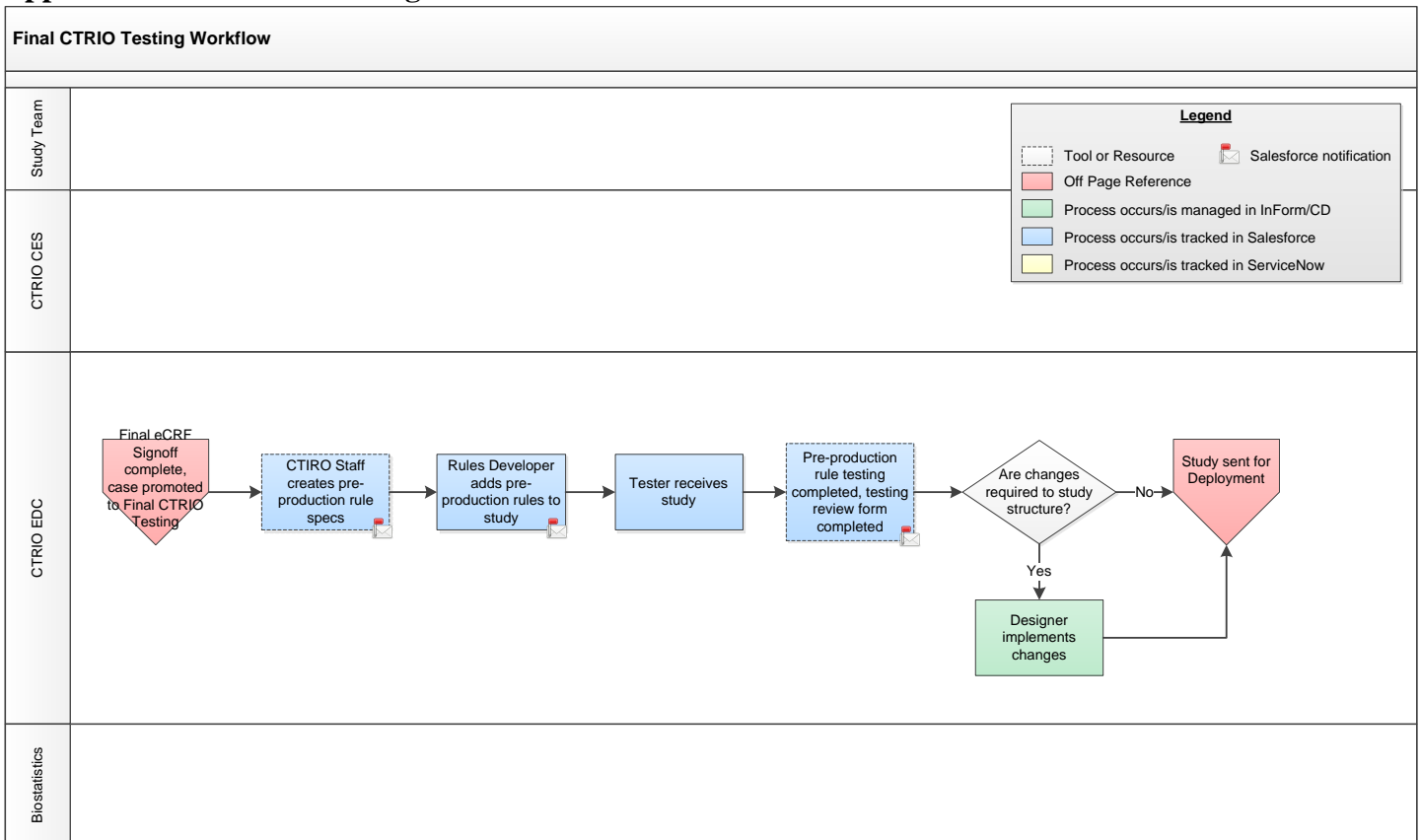
### 3.3. Forms Updates

3.3.1. If there are significant issues with the structure of the study, the original study Designer updates the forms, and the process starts again, beginning with Pre-Production Rules step 3.1.1., above.

3.3.2. If there are minor issues, the original study Designer updates the eCRFs accordingly.

3.3.2.1. Once minor eCRF issues are addressed, the original study Designer updates the status in Salesforce, indicating that the eCRF is ready for Deployment.

### Appendix 1: Final RIO Testing Workflow



## Appendix 2: Pre-Production Rules Specification Document



Pre-Production Rules  
and Specifications Ter

## Appendix 3: Testing Review Form

### XX/XX/XXXX Final RIO Testing

#	Tester Comments/Findings	Designer (initials; date fixed; comments)	Tester (re-tested; P/F)
1			
2			