PP11: Robust Test Data

Introduction

Problem Statement
- Inadequate test cases to fully test coding assumptions upfront
- Inadequate coding / lack of robustness of code
- Code re-work / updates during re-delivery cycles
- Delayed time to stable code

Solution
- Develop solid logical test cases before coding commences

Return on Investment
- Increase robustness of code
- Reduction in re-work time
- Programming can start earlier

Process

Prerequisites
- Final Study Protocol
- Final approved CRF version
- Final Annotated (database annotations) CRF
- Final Database Specifications
- Other associated guidelines e.g. CRF completion guidelines

Example

Example Table

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Sponsor 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICON Study Number</td>
<td>12345678</td>
</tr>
<tr>
<td>EDC System</td>
<td>Train</td>
</tr>
<tr>
<td>Test Environment</td>
<td>TRAIN</td>
</tr>
<tr>
<td>Reserved Test Site</td>
<td>T1235</td>
</tr>
<tr>
<td>Number of Subjects</td>
<td>10</td>
</tr>
<tr>
<td>Test Case 1</td>
<td>Completed</td>
</tr>
<tr>
<td>Test Case 2</td>
<td>Screen Failure</td>
</tr>
<tr>
<td>Test Case 3</td>
<td>Screen Failure</td>
</tr>
<tr>
<td>Test Case 4</td>
<td>Screen Failure</td>
</tr>
<tr>
<td>Test Case 5</td>
<td>Discontinued</td>
</tr>
<tr>
<td>Test Case 6</td>
<td>Enrolled</td>
</tr>
<tr>
<td>Test Case 7</td>
<td>Completed</td>
</tr>
</tbody>
</table>

Considerations

There is an art to defining good test cases
- Keep focus on the goal i.e. robust programs, less re-work
- Avoid introducing illogical test cases that 'break' the programs or cause unnecessary 'coding-around'
- But do give consideration to logical test cases, that may not be per protocol or deviate from the eCRF completion guidelines

Assess investment versus benefit to the study
- This process may benefit studies with a first reporting event after a small number of subjects are enrolled
- But may not be of benefit for studies with more generous time to the first reporting event
- If beneficial, start the process as soon as prerequisites are in place
- Cross functional team should meet to discuss plans and test cases as soon as possible around eCRF live
- Define and enter the test data available at the same time as the SDTM specification is being written and finalized

Jennie McGuirk
Director of Statistical Programming
Jennie.Mcguirk@iconplc.com

Ramesh Ayyappath
Director of Statistical Programming
Ramesh.Ayyappath@iconplc.com

Debra Anderson
Director of Data Management
Debra.Anderson@iconplc.com

© 2018 ICON plc. All rights reserved.