Test Harnessing – An Automated Model Based Testing Approach

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Agenda

Introduction

Business Overview

Model Based Testing (MBT) for Test Harnessing

Conclusion
Testing Challenges for Life-Science Software Product Vendor

- Stringent timeline for compliance to regulatory changes
- Meeting GxP guidelines for Computer System Validation (CSV)
  - Installation Qualification
  - Operation Qualification
  - Performance Qualification
  - Up-to-date test documentation for Audit Compliance of Regulatory Authority
- Domain knowledge for testers
- Reuse of test artifacts
- Generation of Automated Test Scripts and maintenance
agXchange IRT™ is a software product from Aris Global Software that enables pharmaceutical company in global collection of drug safety data, assessment and tracking.

ARISg™ is a software product from Aris Global Software that enables pharmaceutical company in maintaining critical drug safety data and reporting adverse events periodically to authority as per regulatory guidelines.

- Validate the products in conformance to the “intended use”
- Maintain signed copy of test execution evidences for audit purpose
- Develop and maintain automated test scripts for regression testing

<table>
<thead>
<tr>
<th>Engineering Metrics</th>
<th>ARISg</th>
<th>IRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of Java Packages</td>
<td>527</td>
<td>162</td>
</tr>
<tr>
<td>Lines of Code(LOC)</td>
<td>585,036</td>
<td>318,830</td>
</tr>
<tr>
<td>No. of Classes</td>
<td>3,789</td>
<td>957</td>
</tr>
</tbody>
</table>
MBT Approach for Test Harnessing

Step 1 • Business Process Model

Step 2 • UML Model

Step 3 • Test Generation

Step 4 • Manual Execution

Step 5 • Key-word scripting

Step 6 • Automated Test Execution
Case Study-Business Process Model

To PMDA Distribution

Start Japanese Workflow

JapaneseDataEntry

JapaneseReview

PMDDistribution

PendingAck

EndJWF

JapaneseEndProcess

FromJWFtoJWF

FromJWFtoJWF

JWFEnd

JWFStart

JWFEnd

JWFStart

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# Case Study - UML Model Metrics

<table>
<thead>
<tr>
<th>Model Elements</th>
<th>No. of Components</th>
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<tbody>
<tr>
<td>BPM diagrams</td>
<td>8</td>
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<tr>
<td>Classes</td>
<td>67</td>
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<tr>
<td>Operations</td>
<td>755</td>
</tr>
<tr>
<td>Enumeration</td>
<td>44</td>
</tr>
<tr>
<td>Associations</td>
<td>70</td>
</tr>
</tbody>
</table>
Business scenarios definition and information

Integration_NewCase_NonJapan_CT_Significant_Not_Reportable

Process: Main Business Process

Tags:

Key stages:
- Create Adverse Event
- @AIM: PQ Create Adverse event from fax with Index data
- Edit receipt item
- @AIM: PQ Edit AE CT case
- Duplicate search
- @AIM: PQ Duplicate search for new
- Assess receipt item
- @AIM: PQ Assess New CT cases
- Assess receipt item
- @AIM: PQ Assess Medical review
- Dispose Case
- @AIM: PQ Disposition
- DataEntry
- @AIM: Non-Japan CT Case Data Entry
- CaseReview
- @AIM: Non-Japan CT Case Review
- QualityReview

Business sequence:
- StartMainWF
- IRT
- Start agXchange IRT
- Adverse event
- Start Adverse Event
- Create Adverse Event
- @AIM: PQ Create Adverse event from fax with Index data
- Edit receipt item
- @AIM: PQ Edit AE CT case

1 story will be generated
Case Study - Test Case Generation

Test detail

Steps

- Default model instance
- Initialized model instance

- AdverseEvent_SUT_instance.Create_Adverse_Event(PQ_Create_AE_from_fax_medium)
- Low Level Operations_instance.PQ_Create_AE_Fax_INDEXdata()
- Observations_instance.Verify_PQ_Create_AE_Fax_INDEXdata()
- AdverseEvent_SUT_instance.Edit_receit_item(PQ_EDIT_AE_CT)
- AdverseEvent_SUT_instance.Duplicate_search(PQ_DIP_SRCH_FOR_NEWCASE)
- AdverseEvent_SUTInstance_Assess_receipt_item(PQ_DA_new_CT, NA, NA, NA, NA)
- AdverseEvent_SUT_instance.Assess_Designation(PQ_DA_Medical_review, NA, NA, NA, NA)
- AdverseEvent_SUT_instance.Dispose_Case(PQ_DISPOSITION)
- DataEntry_instance.DataEntry(NI_CT)
- CaseReview_instance.CaseReview(NI_CT)
- QCReview_instance.QualityReview(NI_CT)
- MedReview_instance.MedicalReview(NI_CT_EXIT)

Point of view

Selected tags

1: Console
### Auto-Generated Test Script – for Manual Execution

<table>
<thead>
<tr>
<th>Step No</th>
<th>Procedure Steps</th>
<th>Test Data</th>
<th>Expected Results</th>
<th>Actual Results</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.198</td>
<td>Enter the Login credentials of the Medical Reviewer User and Click on Login button. &quot;PS&quot;</td>
<td></td>
<td>The ARISg Home page with the Workflow Status window is displayed.</td>
<td></td>
<td>Pass:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pass with Exceptions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fail:</td>
</tr>
<tr>
<td>1.1.199</td>
<td>Click the Filter button and Enter AER no as specified in the test data column and click Refresh button in Workflow Status window. &quot;PS&quot; Note: Ensure that the Work in progress option is selected.</td>
<td>AER No: &lt; Case created at Step no: &gt;</td>
<td>The case is displayed in the list box with the activity as 'Medical Review'.</td>
<td></td>
<td>Pass:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pass with Exceptions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fail:</td>
</tr>
<tr>
<td>1.1.200</td>
<td>Verify the Activity due date, Case due date and Submission due date for the case selected as specified in the test data column. &quot;PS&quot;</td>
<td>Activity due date: LRD+2days  Case due date: LRD+8days  Submission due date: LRD+9days</td>
<td>The case is displayed in the list box with the activity as 'Medical Review' and the Activity due date, Case due date and Submission due date is displayed.</td>
<td></td>
<td>Pass:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pass with Exceptions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fail:</td>
</tr>
</tbody>
</table>

**Comments:**

**Comment Form Number:**

**Initials:** ___________________________  **Date (DD-MON-YYYY):** ___________________________
<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Automated Test Case Document</td>
<td>Project Name</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Template Version 1.0.26 Mar-2013(Do not edit/delete)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3</td>
<td>Test Case ID</td>
<td>Case Description</td>
<td>Test Procedure</td>
<td>Test Object</td>
<td>Test Value</td>
<td>Expected_Result</td>
<td>Test Status</td>
<td>Remarks</td>
<td>Error Log Ref. No.</td>
<td>Person Tested</td>
<td>Test Date</td>
</tr>
<tr>
<td>3</td>
<td>TCC-053</td>
<td>Click on Sign of link &quot;PS&quot;</td>
<td>AppName_QCRevSignOff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Enter the Login credentials of the Medical Reviewer User and Click on Login button. PS Click the filter button and Enter AER no as specified in the test data column and click Refresh button in Workflow Status window. PS Note Ensure that the Work in progress option is selected. #testdata# AER No. &lt; Case created at Step no. &gt; #endtestdata#</td>
<td>AppName_VFSearchMedRev</td>
<td></td>
<td></td>
<td>The User is logged off and the Login page is displayed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>TCC-060</td>
<td>Verify the Activity due date, Case due date and Submission due date for the case selected as specified in the test data column. PS #testdata# Activity due date: LRD+2days Case due date: LRD+9days Submission due date: LRD+9days #endtestdata#</td>
<td>AppName__MedRevDueDate</td>
<td></td>
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<td>3</td>
<td>TCC-061</td>
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<td>Rp_dueDate=NULCT_DUEDATE</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td>Scope</td>
<td>Planned Test Design effort w/o MBT</td>
<td>Actual Test Design effort w/ MBT</td>
<td>Test Effort saving</td>
<td>Remarks</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Safety Suite of product</td>
<td>Computer System Validation (CSV)</td>
<td>128 days</td>
<td>55 days</td>
<td>57%</td>
<td>The same models is used to generate other test scripts based on customer business process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory</td>
<td>New Features &amp; Regulatory change</td>
<td>91 days</td>
<td>48 days</td>
<td>47%</td>
<td>In addition to this, the same models will be used for CSV script generation and key-word based automated test script generation</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Business Impact**

- Test productivity improvements of nearly 25% (considering the test design effort along with automation test design effort is approx 50% of the total test effort) where ever MBT approach has been adopted in test strategy
- Identification of more defects in beta testing due to quick business scenario creation and execution
- Meeting the compressed release deadline without compromising on testing
- Reusable assets creation for future releases
- Quick design of test scripts based on SMEs inputs
A comprehensive test strategy involving ‘Right’ MBT approach and Automation helps in achieving

- Harnessing test generation and publication of test scripts for functional testing
- Harnessing test generation and publication of test scripts based on business scenario
- Publishing Key-word based test scripts ready for Automated Test Execution
- Easy maintenance of automated test scripts
Q & A?
Thank you!
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