USING WORKFLOWS TO STANDARDIZE BUSINESS PROCESSES AND
BEST PRACTICES IN PHARMACEUTICAL PROGRAMMING

JULIE MADOX, SAS
MARK LAMCREHT, SAS
AGENDA

• What are business process, workflows, and workflow management system?
• 2 use cases of workflows related to clinical trials
• Workflows in SAS Drug Development: control and automated SAS execution
• Summary and outlook
• A business process: a collection of activities designed to produce a specific output for a particular objective.
• Clinical trials and business processes
• Possibly involving both human and system interactions
• Captured in SOP’s
WORKFLOWS ENACTED IN WORKFLOW MANAGEMENT SYSTEM

- An abstraction of business process activities
- Balances control with flexibility
- A series of connected steps, asynchronous or parallel
- Each step consists of an activity that is assigned to
  - An individual
  - A group of persons
  - An automated computer program

- Workflow management system?
  - Computer system -> “BPM” software
  - Used before in CTMS
  - SAS Drug Development
USE CASE 1
PROGRAMMING - DEV/TEST/PROD

Program specification

Principal Programmer

Send for acceptance testing

Quality Control Programmer

Ready for production

Project Lead

Reject and send back

Reject and send back

Approve SAS program for production
USE CASE 2

WORKFLOW GOVERNING EXCHANGE OF DATA BETWEEN SPONSOR AND CRO

Clinical data collection and operations

Exchange area:
- study specifications (define.xml)
- incoming SDTM, ADaM data and metadata

Data Standards Library (eCRF, CDISC, protocol, visit schedule)

Adherence checks Quality Reporting

Explore Biostat Submission

CLINICAL REPOSITORY

SAS Drug Development
SET-UP IN SDD  WORKFLOWS IN SAS DRUG DEVELOPMENT (1/2)

• Definitions
  • SAS Workflow Services
  • Workflow management system in SDD : surfaces as work items = set of tasks
    • Individuals can create their own work items or work items can be created by lead programmers for a specific project or analysis
  • A workflow contains one or more tasks and is defined using SAS Workflow Studio
  • Work item can have descriptions, due dates for tasks, assignees, messages to send out, attachments (specification documents)
  • Work items can be reassigned
• Visual lay-out created by a business user
• Translation of visual layout in workflow template
• Workflow template can be uploaded in SDD
• Workflow template can now be instantiated in the context of trials, projects, analyses, ...
• Instance started: parameters resolved
  • User-application launch
  • Signal-driven launch
  • Services-driven launch (third-party software)
ASYNCHRONOUS  DEV/TEST/PROD WORKFLOW

• Asynchronous workflow, one task active at a time
• Dev/Test/Prod tasks can be assigned to an individual or a group
• Transitions from task to task depends on selected Status
  • Submit for Test
  • Read for Prod
  • Failed Test – Code Issue
  • Approve
  • Deny – Test Issue
• Synchronous workflow, multiple tasks active at a time
  • Develop Program
  • Develop Validation Program
• Transitions from task to task depends on the selected Completion Status
  • If Results Differ, both Develop Program and Develop Validation Program tasks are re-activated
Automated Tasks

Exchange of Data between CRO and Sponsor

**Upload Data Task** - Performed by an individual, or member of a group

- **Data Upload**
- **Data Ready for Validation**
- **Make Corrections**
- **Failed Validation**
- **Notify Failed Validation**
- **Check Run Job Status**
- **SAS Errors**
- **Success**
- **Notify Successful Data Upload**
- **Run Job**

**Decision to send Notifications based on Results of Validation Code**

**Execute Validation Code and Send notifications based on validation results** – Automated, Performed by the Workflow Management System
IN SAS DRUG DEVELOPMENT

NEW WORK ITEM

- Select from list of registered workflows
- Add Attachments for Work Item
IN SAS DRUG DEVELOPMENT

WORK ITEM TASK ASSIGNMENT

- Select individuals or groups to assign user-based tasks
- Enter Task Description
- Define Due date, Priority, Complexity
• Automated Tasks assigned to System
For a system notification task
- Select notification recipients, individuals or groups
- Enter the Subject and Message text
- Set a message priority
EXECUTE JOB TASK

- For a Job Execution task
  - Select SAS job to be executed
  - Enter job parameter values
• Tasks can be re-assigned
• Work Item workflows can be stopped and restarted
  • Upon stop, all tasks associated with the work item, are removed from individuals task list
  • Upon restart, tasks are re-sent to individuals
**IN SAS DRUG DEVELOPMENT**

**TRACKING WORKFLOW PROGRESS**

- Workflow metadata collected as the work item progresses
- Date Task Started/Completed
- Comments on completion status
- Number of times task repeated

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<thead>
<tr>
<th>Name</th>
<th>Due Date</th>
<th>Assigned To</th>
<th>Priority</th>
<th>Complexity</th>
<th>Date Started</th>
<th>Date Ended</th>
<th>Comment</th>
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<td>Sep 12, 2012</td>
<td>CRO User</td>
<td>Medium</td>
<td>Medium</td>
<td>Sep 12, 2012 10:36 AM</td>
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<td>Data has been uploaded</td>
</tr>
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<td>System</td>
<td></td>
<td></td>
<td>Sep 12, 2012 10:46 AM</td>
<td>Sep 12, 2012 10:46 AM</td>
<td>Completed job loadADSL job by System</td>
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<tr>
<td>Notify Successf...</td>
<td>Sep 12, 2012</td>
<td>System</td>
<td></td>
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<td>Sep 12, 2012 10:46 AM</td>
<td>Sep 12, 2012 10:46 AM</td>
<td>Notification sent by System</td>
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<tr>
<td>Approve for Prod...</td>
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<td>Project Lead 1</td>
<td>High</td>
<td>Medium</td>
<td>Sep 12, 2012 12:42 PM</td>
<td>Sep 12, 2012 12:44 PM</td>
<td>Validation failed, please correct and re-submit data</td>
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<tr>
<td>Dev</td>
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<td>CRO User</td>
<td>Medium</td>
<td>Medium</td>
<td>Sep 12, 2012 12:45 PM</td>
<td>Sep 12, 2012 12:47 PM</td>
<td>Corrections made, data re-uploaded</td>
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<tr>
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<td>Sep 12, 2012</td>
<td>System</td>
<td></td>
<td></td>
<td>Sep 12, 2012 12:47 PM</td>
<td>Sep 12, 2012 12:47 PM</td>
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<tr>
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<td>Sep 12, 2012 12:48 PM</td>
<td>Validation passed, data moved to production</td>
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</table>
SUMMARY

• SAS Drug Development introduces workflow management into clinical trial data management and analysis
• Even partially automated processes are more efficient than completely manual processes
• Data standards lead to process standards
• Secondary advantages
  • Metrics and follow-up on inefficiencies and bottlenecks
  • CRO – sponsor collaboration
  • Programming
  • Overall reporting on workflows
• SAS Drug Development 4.1 remains the premier statistical computing environment