

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

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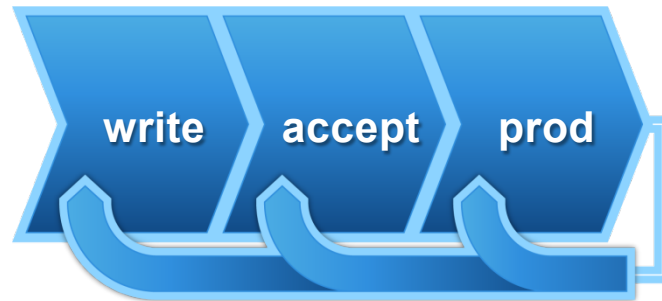


AGENDA

- 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

DEFINITION | BUSINESS PROCESSES

- 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

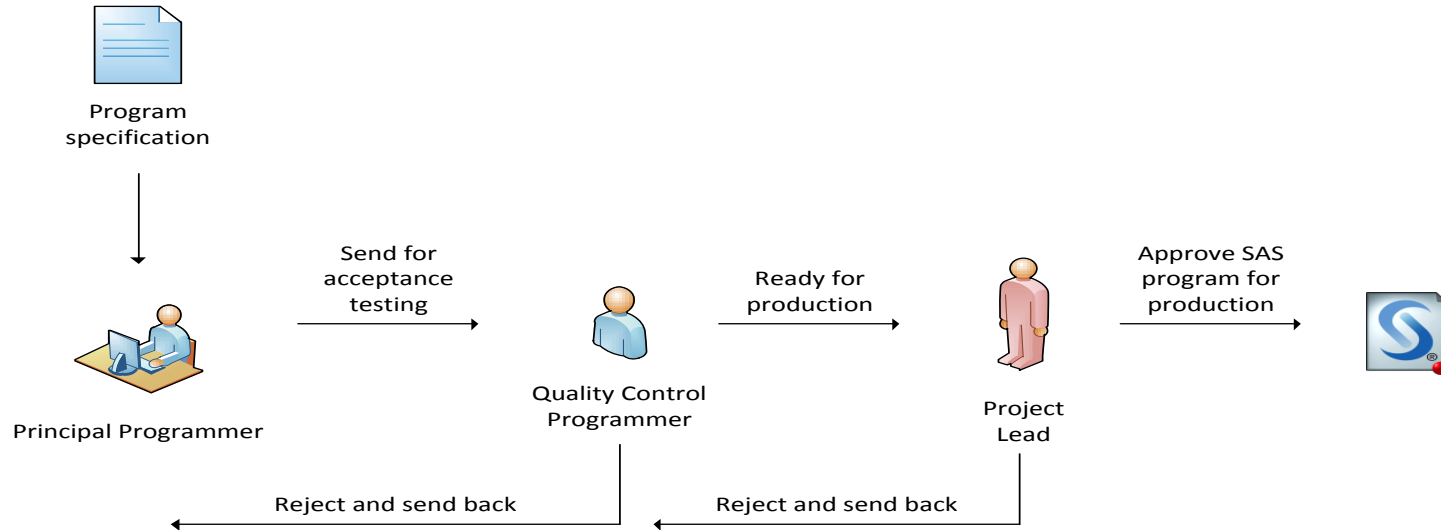


WORKFLOWS

WORKFLOWS ENACTED IN WORKFLOW MANAGEMENT SYSTEM

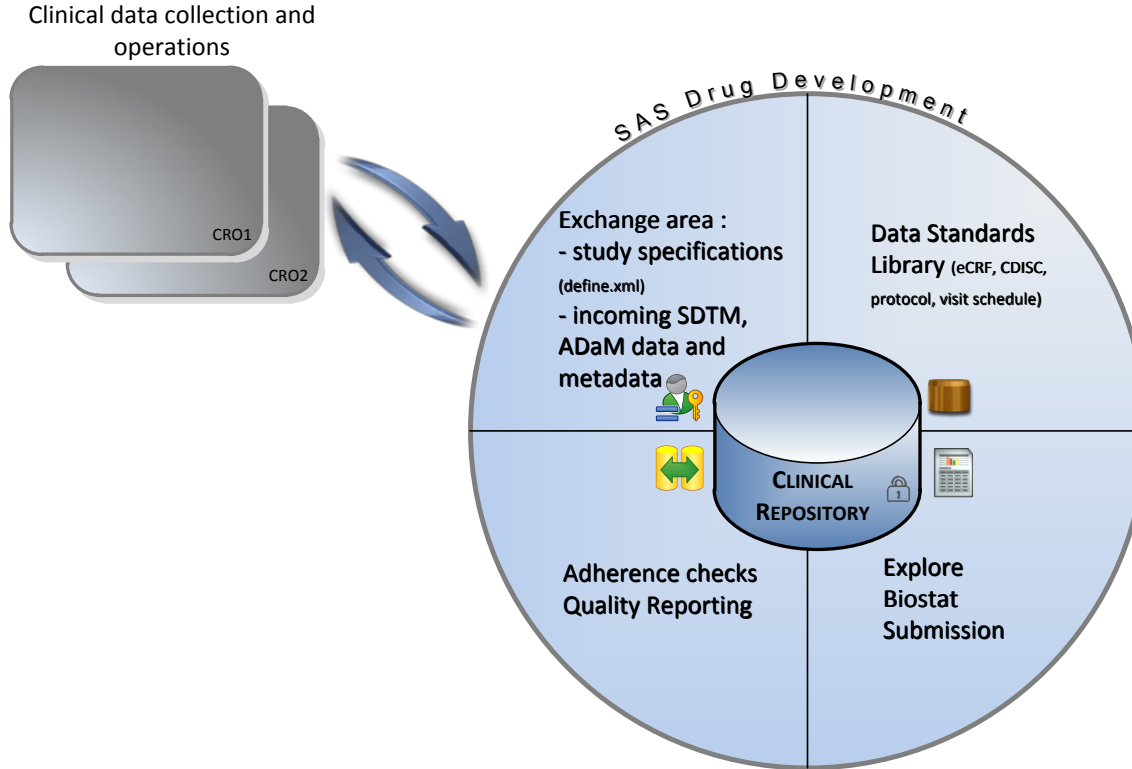
- An abstraction of business process activities
- Balances control with flexibility
- A series of connected steps, asynchronous or parallel
- Each step consists of an activity that is assigned to
 - An individual
 - A group of persons
 - An automated computer program
- Workflow management system ?
 - Computer system -> “BPM” software
 - Used before in CTMS
 - SAS Drug Development

USE CASE 1 PROGRAMMING - DEV/TEST/PROD



USE CASE 2

WORKFLOW GOVERNING EXCHANGE OF DATA BETWEEN SPONSOR AND CRO



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

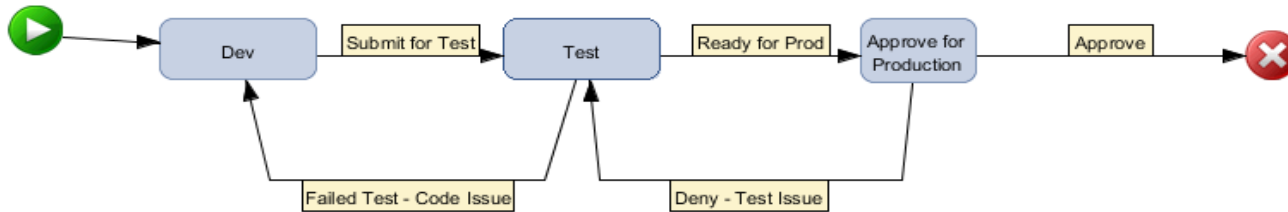
- Definitions
 - SAS Workflow Services
 - Workflow management system in SDD : surfaces as ***work items*** = set of tasks
 - Individuals can create their own work items or work items can be created by lead programmers for a specific project or analysis
 - A ***workflow*** contains one or more tasks and 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**

SET-UP IN SDD | WORKFLOWS IN SAS DRUG DEVELOPMENT (2/2)

- 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)

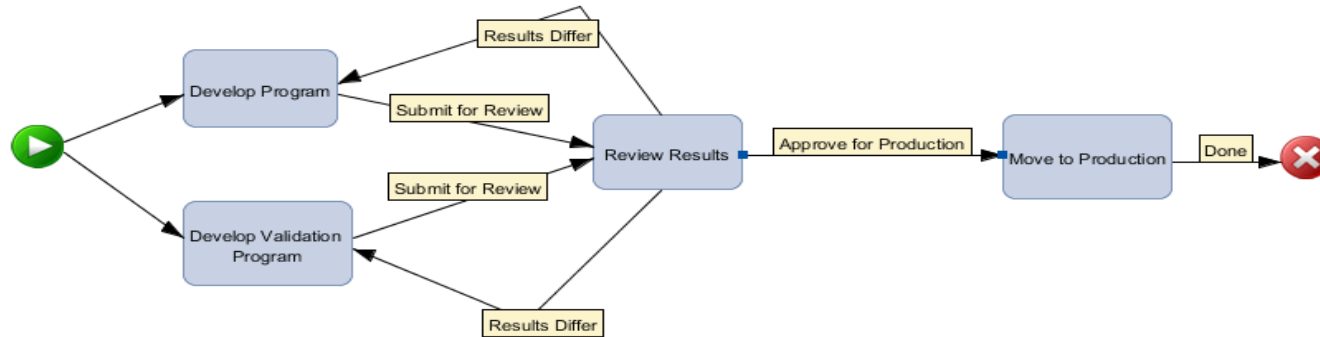
ASYNCHRONOUS DEV/TEST/PROD WORKFLOW

- 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



PARALLEL DOUBLE PROGRAMMING WORKFLOW

- 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

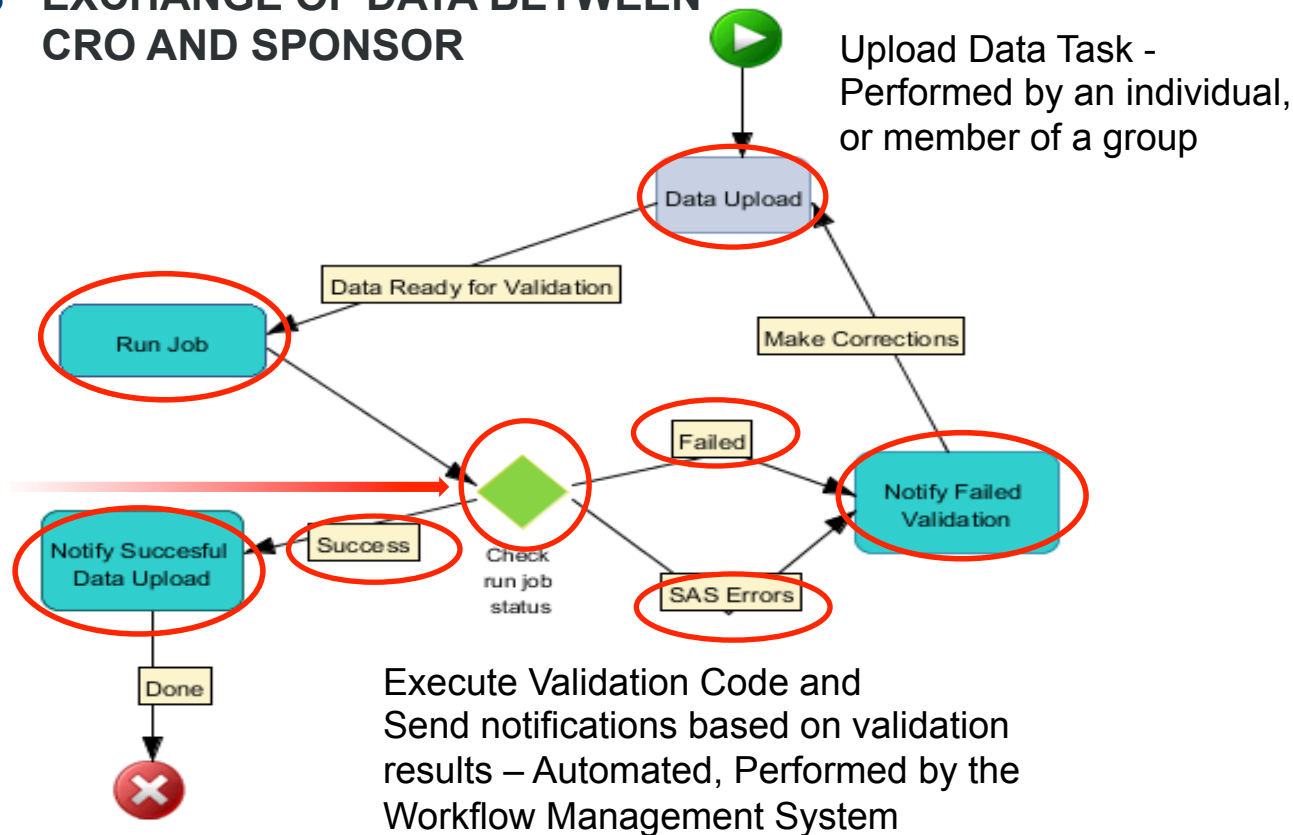


AUTOMATED TASKS

WORKFLOW

EXCHANGE OF DATA BETWEEN CRO AND SPONSOR

Decision to send
Notifications based on
Results of Validation
Code



- Select from list of registered workflows
- Add Attachments for Work Item

New Work Item

General	Workflow: DevTestProd			
Flow	Tasks:	AcceptReject		
Attachments		AutomatedNotificationJob		
		AutomatedRunJob		
		AutomatedTasks		
		DevRunJobApprove		
		DevTestProd		

Order	Complexity	Due Date	Type	Assigned To
1	Medium			Unassigned
2	Medium			Unassigned
3	Medium			Unassigned

Task Properties [X]

Name:

Description:

Priority:

Complexity:

Due date:

Type:

Assigned to:

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Select Assignee...

Unassigned

Analysis Lead 1

Select Assignee [X]

Available:

- ▶ All Analysis Leads
- ▶ All Programmers
- ▶ All QC Programmers
- Analysis Lead 1
- Programmer 1
- Project Lead 1
- QC Programmer 1

Select Cancel

- Select individuals or groups to assign user-based tasks
- Enter Task Description
- Define Due date, Priority, Complexity

- Automated Tasks assigned to System



Workflow: DevRunJobApprove

Tasks:

Order	Name	Active	Priority	Complexity	Due Date	Type	Assigned To
1	Dev		Medium	Medium	Sep 12, 2012		CRO User
2	Run Job						System
3.1	Notify Successful Job ...						System
3.2	Fix Run Job Failure		High	Medium			CRO User
4	Approve for Production		High	Medium			Project Lead 1

- For a system notification task
 - Select notification recipients , individuals or groups
 - Enter the Subject and Message text
 - Set a message priority

The screenshot shows the 'Task Properties' dialog box with the 'Notification' tab selected. The 'To:' field contains two recipients: 'CRO User' and 'Project Lead 1'. The 'Priority:' dropdown is set to 'High'. The 'Subject:' field contains 'Data Validation Reports'. The 'Message:' field contains the text: 'The uploaded study data does not pass validation. Please review validation report and make corrections, and then re-upload the data.'

Task Properties	
General	To: CRO User
Notification	Project Lead 1
	Priority: High
	Subject: Data Validation Reports
	Message: The uploaded study data does not pass validation. Please review validation report and make corrections, and then re-upload the data.

- For a Job Execution task
 - Select SAS job to be executed
 - Enter job parameter values

Task Properties

General

Job Details

Job name:

Version: Latest

Location: /QAGPharma/PainXD-Study101/Create Study Data/Files/Programs/Dev/

Description: Load data into the ADSL dataset

Parameters:

Label	Value
Project Name	PainXD-Study101

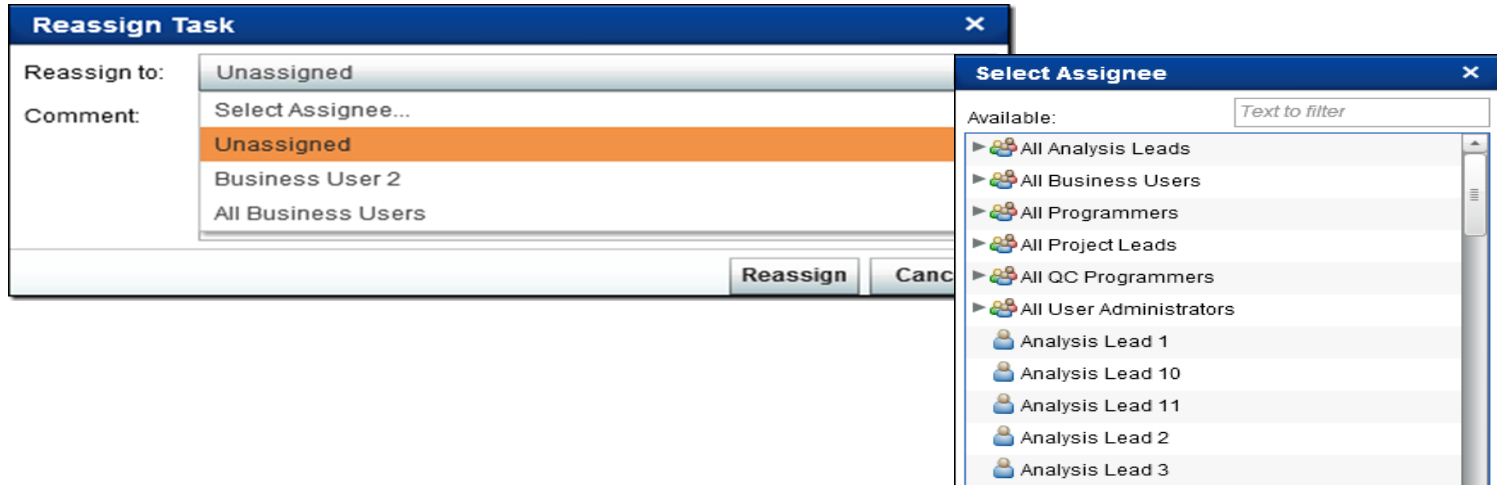
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OK Cancel

IN SAS DRUG DEVELOPMENT

WORKFLOW / TASK MANAGEMENT

- 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



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

	Name	Due Date	Assigned To	Priority	Complexity	Date Started	Date Ended	Comment
General	Dev	Sep 12, 2012	CRO User	Medium	Medium	Sep 12, 2012 10:36 AM	Sep 12, 2012 10:46 AM	Data has been uploaded
Flow	Run Job		System			Sep 12, 2012 10:46 AM	Sep 12, 2012 10:46 AM	Completed job loadADSL.job by System
Active Tasks	Notify Successf...		System			Sep 12, 2012 10:46 AM	Sep 12, 2012 10:46 AM	Notification sent by System
Completed Tasks	Approve for Prod...		Project Lead 1	High	Medium	Sep 12, 2012 12:42 PM	Sep 12, 2012 12:44 PM	Validation failed, please correct and resubmit data
Attachments	Dev	Sep 12, 2012	CRO User	Medium	Medium	Sep 12, 2012 12:45 PM	Sep 12, 2012 12:47 PM	Corrections made, data re-uploaded
Event Subscriptions	Run Job		System			Sep 12, 2012 12:47 PM	Sep 12, 2012 12:47 PM	Completed job loadADSL.job by System
Audit	Notify Successf...		System			Sep 12, 2012 12:47 PM	Sep 12, 2012 12:47 PM	Notification sent by System
	Approve for Prod...		Project Lead 1	High	Medium	Sep 12, 2012 12:45 PM	Sep 12, 2012 12:48 PM	Validation passed , data moved to production

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

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