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How Process Flow Standardized our Process

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ABSTRACT

Managing business process takes a lot of tedious work. Especially in Pharmaceutical industry, with the collaboration between Sponsors and CROs, the tasks are becoming more distributed and complex. Pharmaceutical companies require a comprehensive approach to meet their business requirement. It is crucial to make the entire process of the clinical studies in an orderly and consistent way. Workflow definitions encapsulate a combination of automated and manual activities that can be used to manage business process in organizations.

This paper utilizes several typical examples to illustrate how workflow in SAS® Life Science Analytics Framework handle business processes in task allocation, clinical data management and statistical analysis. It describes how business processes are modeled, developed, deployed and managed throughout their entire life cycle. Let's take a look at the examples that will give you the agility to optimize your workflow designs.

INTRODUCTION

Business process modeling is the first activity for a workflow, let's see the modeling first. Business process modeling is a key capability that helps capture what matters to businesses, such as business events and situations, and the corresponding response actions. To create a new business model, we can follow below iterative steps, see Figure 1. It includes the capturing and collaboration on process design, as well as the simulation and analysis on the models in order to optimize them for reduced risk and increased flexibility.

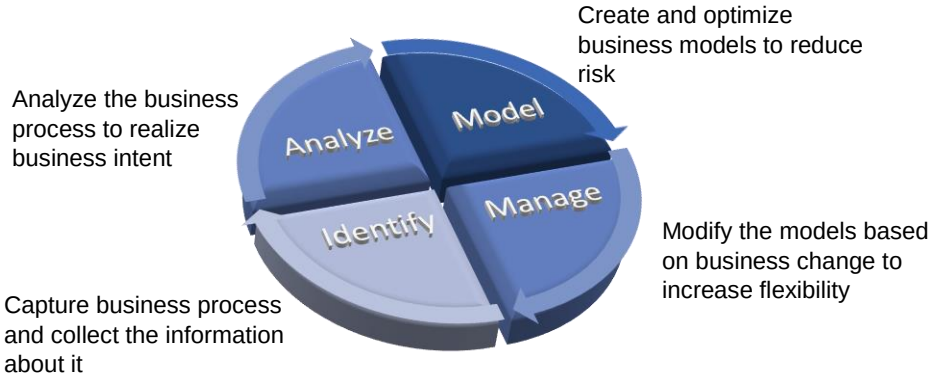


Figure 1 Modeling business process steps

In LSAF, any BPMN 2.0 modelling application can be used to create the business process template. In our use cases, we create template by using Camunda Modeler, a third party BPMN tool for process modeling. There are detailed instruction about how to create a new model in my previous paper, please referred it if needed. There is no more explained here.

WORKFLOW IN SAS LSAF

Base on the current status of the research, SAS understand that organizations require a comprehensive approach to meeting their strategic business requirements. In practice the process is seldom linear, with many aspects of the process taking place in parallel, each step of the process from target identification through to product registration is designed to resolve a specific process. This understanding drives our business innovation and optimization approach. Here LSAF workflow comes.

Workflow Definition

What is workflow? Taken from the Wikipedia definition, “A workflow at its simplest is the movement of documents and/or tasks through a work process. More specifically, workflow is the operational aspect of a work procedure: how tasks are structured, who performs them, what their relative order is, how they are synchronized, how information flows to support the tasks and how tasks are being tracked”.

In SAS® LSAF, Workflow contains two parts: Process Flow Definition and Process Flow. The following is an outline of a general LSAF workflow:

1. Process Flow Definition
    a. A process flow definition represents an executable business process, which consists of one or more tasks, gateways, and transitions between these activities.
    b. A process flow definition serves as a template for a process flow. A process flow definition life is an XML file that is defined in the Business Process Model and Notation 2.0 format
2. Process Flow
    a. A process flow is an instance of a process flow definition. Examples of process flows include tables, figures, listing, data transformations, and any other work products that need to be delivered. The work to perform follows the business process that is defined in the process flow definition.

Workflow Lifecycle in LSAF

Each process defined in third party tool is stored as a workflow template in XML format. These templates can be opened from or saved to a local file system. In addition, LSAF workflow supports persistence and versioning of the workflow templates using SAS® LSAF Repository. Finally, user can activate the workflow templates, which results in uploading the specified version as a formal workflow definition via LSAF workflow for instantiation.

The following figure illustrates the lifecycle of a workflow from its creation to its instantiation in LSAF.

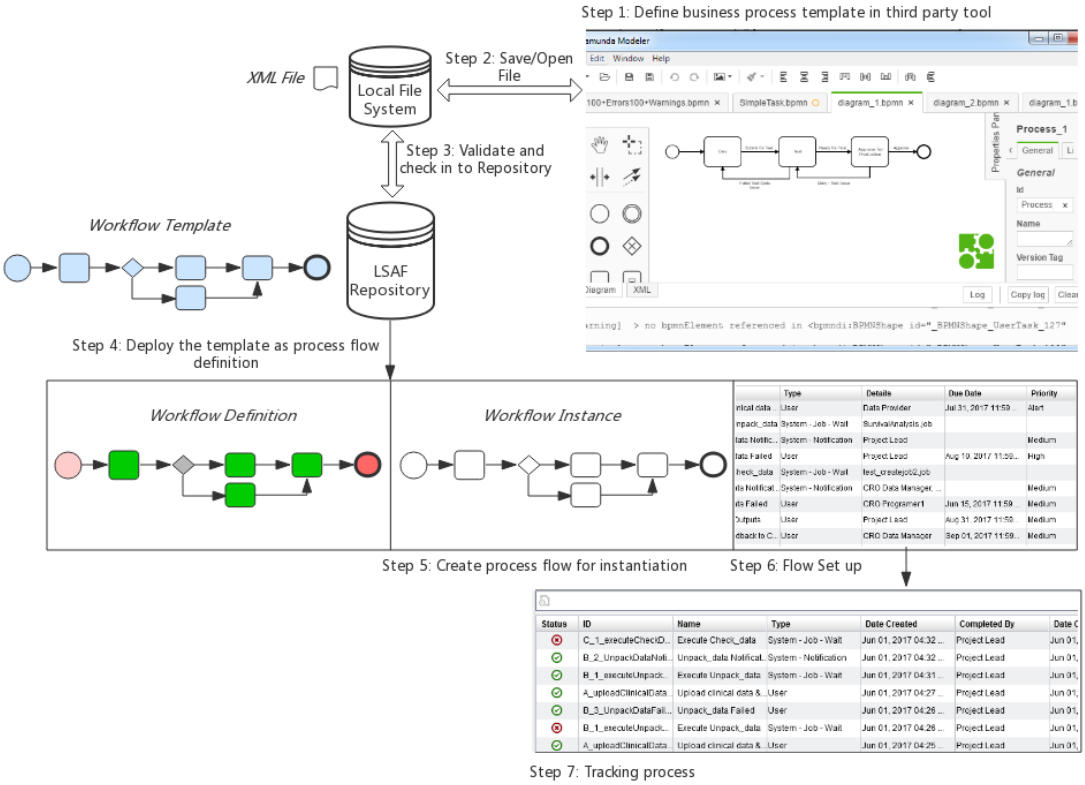


Figure 2 Workflow Lifecycle

PHARMACEUTICAL PROCESSES IN PRACTICE

After having an understanding of the lifecycle of workflow in LSAF, next let's take a look at a few use cases for workflow design that may give you the agility to react, scale and adapt when your business needs change.

This paper provides examples and focuses on the continuous process improvement. Below I describe three use cases where workflows have been applied in task allocation, statistical programming and clinical data management. All these use cases show how common business processes are translated into workflows and will be used later as examples to discuss aspects of workflows in SAS® LSAF.

Use case 1: Statistical Analysis/Programming: DEV/TEST/PROD

One of the important process in clinical study is develop and test the statistical programs, see Figure 3. The statistical SAS program is deeply embedded in the practices of the clinical programming team. The example below illustrates the development and validation of statistical program. The source programmer is the programmer whose program outputs will be eventually used in production. The validation programmer will check whether the source outputs and validation outputs are the same, whether the source output meet specification requirement and whether the log is free of error. If validation is failed, comments are sent back to the source programmer to make modification. After a program passes validation, it will be moved on to a statistician for review. The statistician will check the inferential statistics portion and send comments if there are errors. Once the statistician is satisfied that the program produces the expected results, the program can be promoted and considered as part of the production environment.

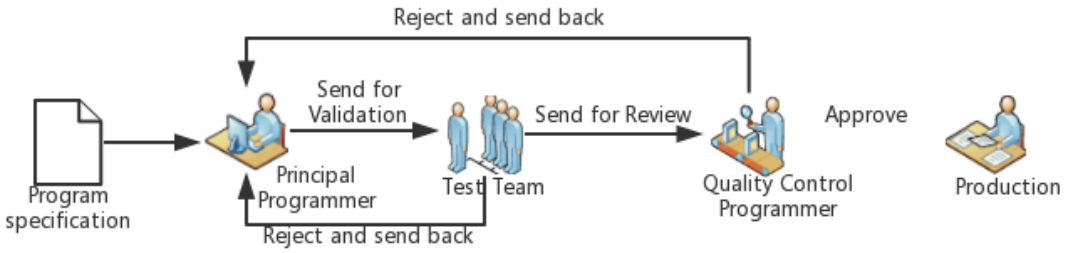


Figure 3 Statistical program validation process

Figure 4 below shows the definition for this use case. In this use case, this workflow consists a signal event that once the source data is uploaded to the target location, the activity for developer will start. The usage of signal event makes the entire process more convenient.

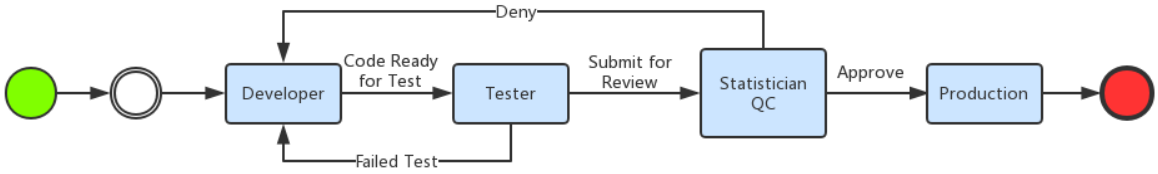


Figure 4 Workflow for Statistical program validation

Use case 2: Clinical Data Management/Governing exchange of data between Sponsor and CRO

One of the transformations and changes pharmaceutical companies are faced with is to renew definition of clinical data operations, data management and submission-driven activities including collaboration with contract research organization (CRO). Figure 5 below, describes this business process. The pharmaceutical sponsor is collaborate with a CRO partner for the clinical study. When done, the CRO will unpack the clinical date and Metadata to repository.

Once successful, the pharmaceutical programmer will run a series of validation programs to check whether the data provided by CRO is consistent with the specification. When the validation passed, the report will be sent to project lead to evaluate. If project lead is satisfied with the generated study metadata, it can be released to production. Or the CRO will receive feedback that alerts them for the correction of the study metadata and re-upload the data.

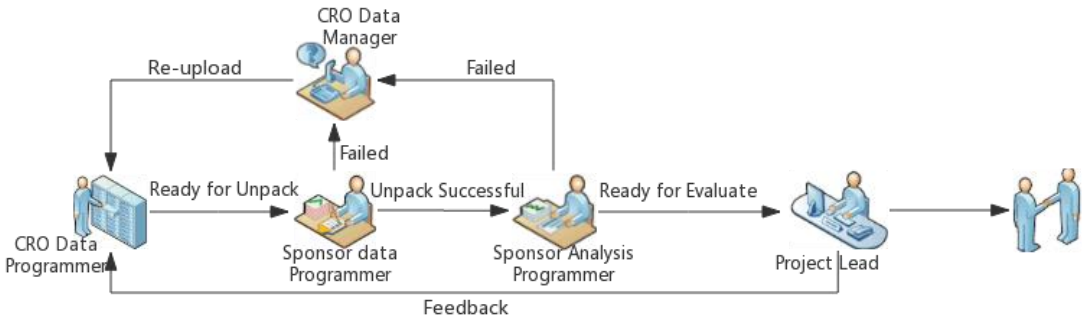


Figure 5 Data exchange process between sponsor and CRO

Figure 6 shows the model of data exchange between Sponsor and CRO. This workflow is an example of a more complex template because it consists of both user-based manual tasks and automated SAS job execution, plus automated notifications. We use automated task to execute the unpack data, validation and notification which reduces the number of participation and error. And it also contains a decision point – gateway, which is used to control the divergence and convergence of sequence flow in a process.

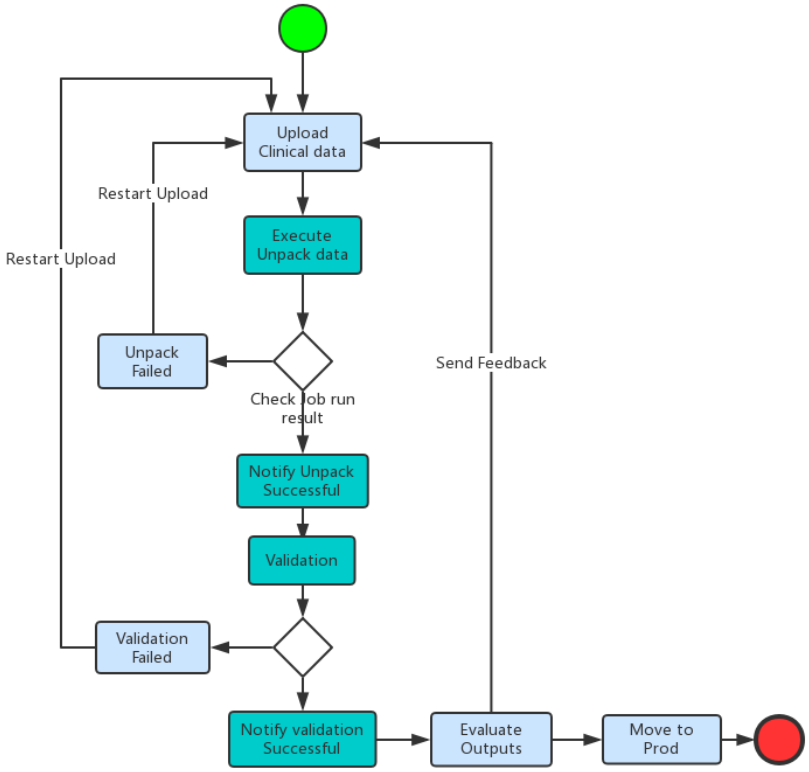


Figure 6 Workflow for Data Exchange between Sponsor and CRO

Use case 3: Task Allocation

The drug discovery and development process is long, costly and complex process, with risk of failure at every step. It requires the close interaction and coordinated collaboration of a large number of individuals and groups from different departments, see figure 7 below. It is only the successful interaction and cooperation of all these professionals that can culminate the registration and marketing of a new medicine.

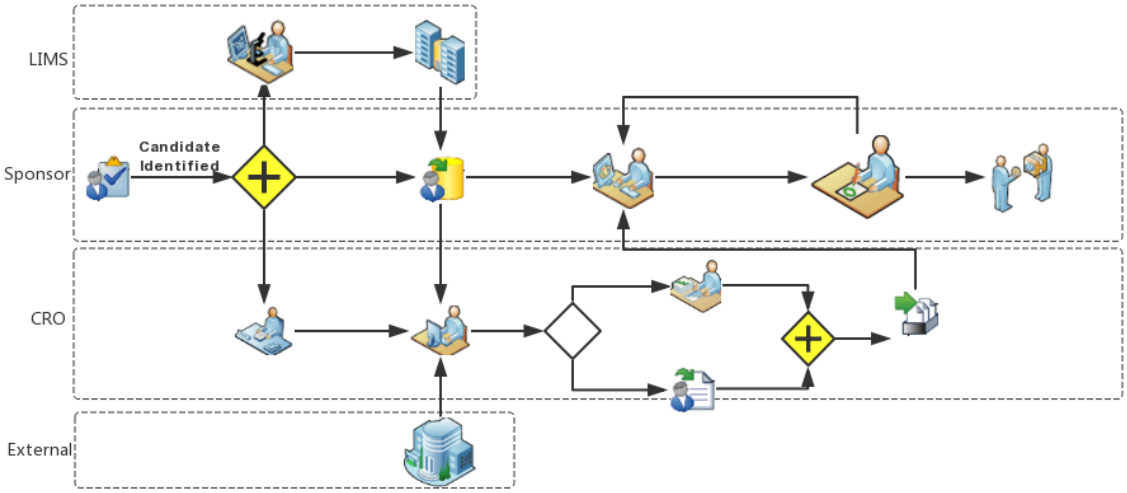


Figure 7 Task allocation process

The example below illustrates the workflow of communication of organizations during drug development. From the figure we can see that the task allocation is well-regulated and orchestrated – by way of Pool, which is a graphical container for partitioning a set of activities in a collaboration. All tasks or activities are assigned to roles that are meaningful to people in the business. It makes the entire process be streamline and easy to locate issues and adopt changes.

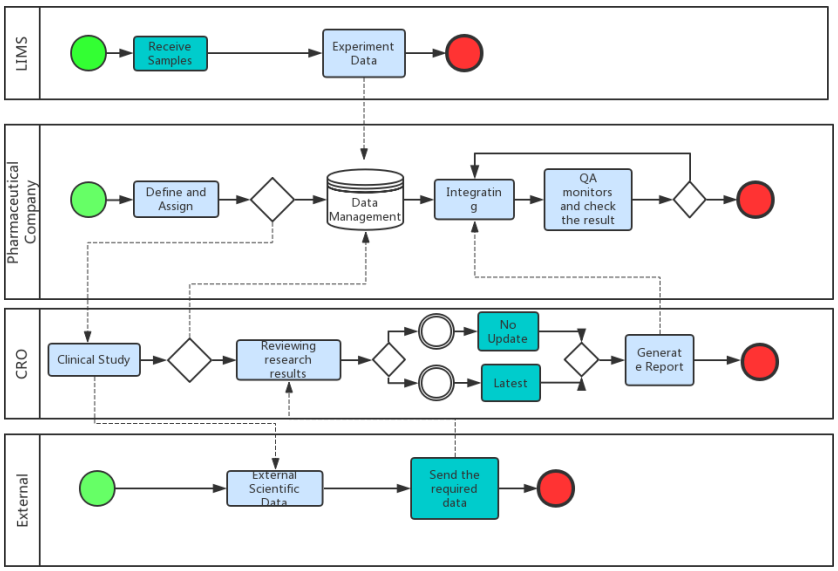


Figure 8 Workflow for Task Allocation during Drug Development

HOW PROCESS FLOW IN LSAF STANDARDIZED OUR PROCESS

In LSAF, the workflow management system surfaces workflows to the user as process flow. A process flow describes a unit of work that needs to be accomplished. For example, a process flow can be defined to write code for a safety report. A process flow is defined using a process flow definition which captures the tasks and flow describing a best practice. Next, let's take use case 2 for example to see how process flow in LSAF handle the business process. I will follow the lifecycle in figure 2 to describe the process.

Step 1 & 2 – Create process template

To handle a business process in LSAF, firstly, process designer should define the business process template in the Business Process Model and Notation 2.0 format, see figure 1 for detailed steps.

Step 3 & 4 - Process Flow Definition

Below is the general steps to use a process flow definition:

1. Create the workflow template in an application outside of SAS® Life Science Analytics Framework.
2. Upload the process flow definition file to the workspace.
3. Validate the process flow definition file to review whether there is warning or error before store it in repository, see Figure 9. If the validation is not passed, we should correct it in the template tool according to the errors in the validation result.
4. Check the process flow definition file to Repository if there are no errors.
5. Deploy the process flow definition so that it is available for creating process flows.

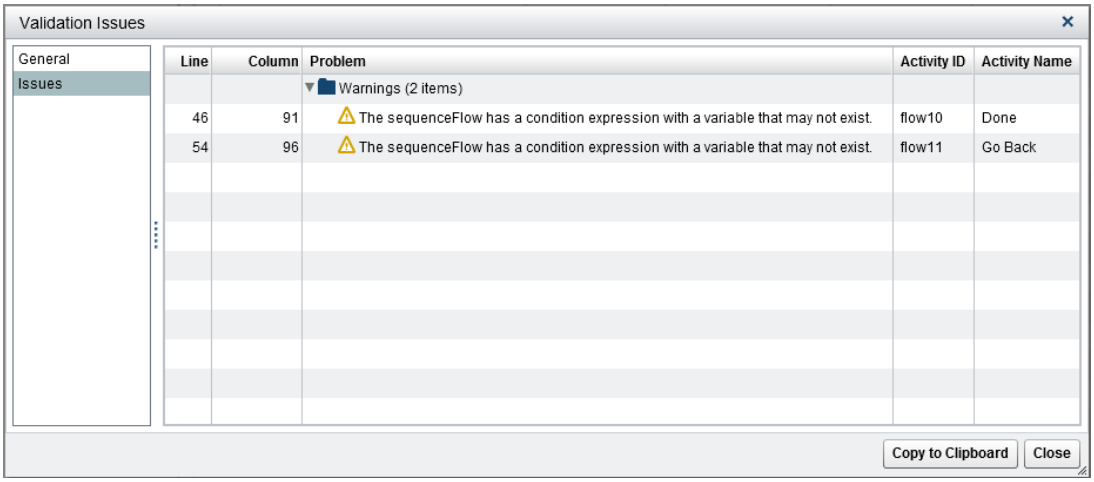


Figure 9 Validation PFD File

After deployed the PFD, all the users who was authorized the relevant privileges can view the process flow definition and check the entire process as a diagram view. See figure 10 below which is the PFD for use case 2. In diagram view, you can view information about each object, a task, event, gateway or sequence flow which is accurately reflects the process as described in use case 2.

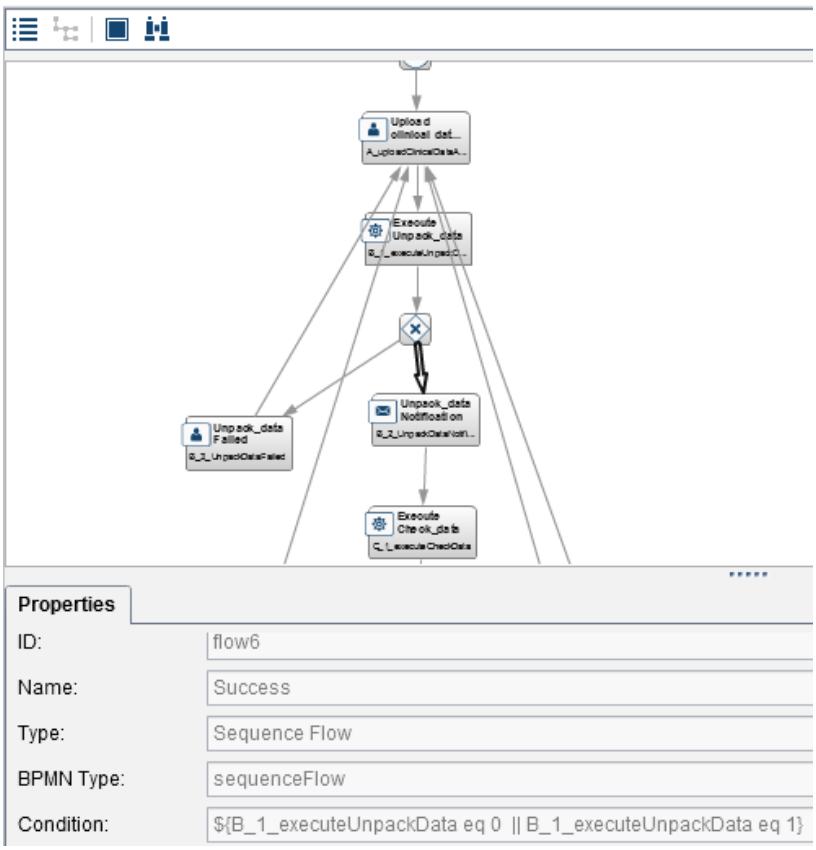


Figure 10 Diagram View of a PFD

Step 5- Process Flow

As I mentioned in the first section, process flow is an instance of a process flow definition. After the process flow definitions are available, next project manager can create process flow by using the appropriate PFD.

This is the step for process flow creating. We should select the appropriate PFD, for example in use case 2, the workflow describes the data exchange between Sponsor and CRO. The PFD selection determines the flow and order of the tasks for the process flow. Figure 11 shows the PFD selection.

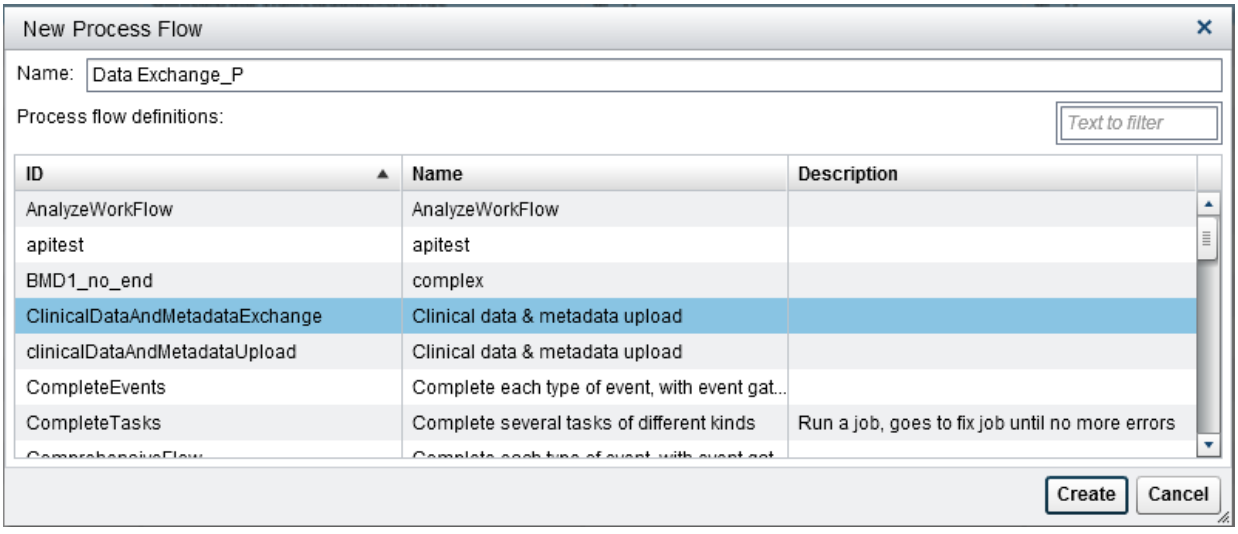


Figure 11 New Process Flow

After the creation, the process flow appears on a new tab. The general information page is shown. It contains the tasks, attachments, subscriptions and the flow. The flow is the list of tasks, gateway, and events needed to complete the process. If you select to see the diagram view, you will found the work to be perform follows the business process that is defined in the process flow definition.

Step 6 - Flow Setup

When a process flow is created, before it is activated, the project manager need to set up the user tasks, system tasks, and events with assignees and specific details to perform the tasks in this business process. The flow setup of the process flow specifies the values that the properties of a flow element have when the flow element is instantiated. The remaining steps depend on the type of element that you are editing: user task, job task, notification task, events.

Set up Tasks

A task is part of a process flow. It represents work that is performed within a process flow. There are two types of tasks: user tasks and system tasks.

- A user task is a task that is performed by a user. A user task can be assigned to a user account or contain a list of candidates (user accounts and user groups) who can claim the task.
- LSAF provides two types of System tasks which run automatically when triggered by SAS® Life Science Analytics Framework – Notification task and Execute Job task.

User Task: Assign Task

The user task has many properties. Here are the significant properties:

- Due date
- Actual hours
- Type
- Priority
- Complexity
- Assign to
- Candidates

According to the time distribution of the project, the project manager can set the appropriate properties for all the team members. Then the team or the assignment can prioritize their work due to the Due date, Priority and Complexity that set by the manager.

Once a process flow is activated, the tasks assigned to a particular user or each user who is a candidate, will appear in his individual Task list. Figure12 below shows CRO data manager's task list, including the task properties. The user can prioritize tasks by the priority and due date. Or simply select the process flow link to open the process flow which describing the work to be done.

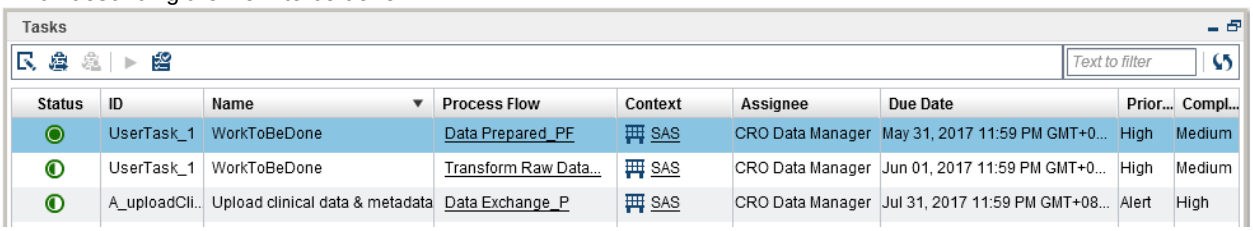


Figure 12 Task list for an individual

Automated tasks in Process Flow

In addition to tasks which are performed manually by an individual, SAS® LSAF provides two types of tasks which are automated. These automated tasks are a Notification task and a Job task. Automated tasks are assigned to the system, and will not appear in the task list of any of the users included in the workflow. Figure 5 above illustrates how the automated notification and job execution tasks can be incorporated. In this example, the automated job task is executed and depending on the results of the execution an automated message is sent to the appropriate recipients.

System- Job Task: Specify Job Details

In this use case, sponsor data programmer and sponsor analysis programmer develop the SAS code for the unpack data and validation data. Once this type of task is triggered, it will execute a SAS Job and return the execution status of the job to the process flow.

System- Notification Tasks: Specify Notification Details

As CRO data manager, I need to know whether the uploaded data pass the validation. Figure 13 below shows the properties for a notification task. It includes the recipient who will receive the notification as well as the content of the message. If the data validation failed, the CRO data manager and Data provider will receive this notification to arrange the recheck work.

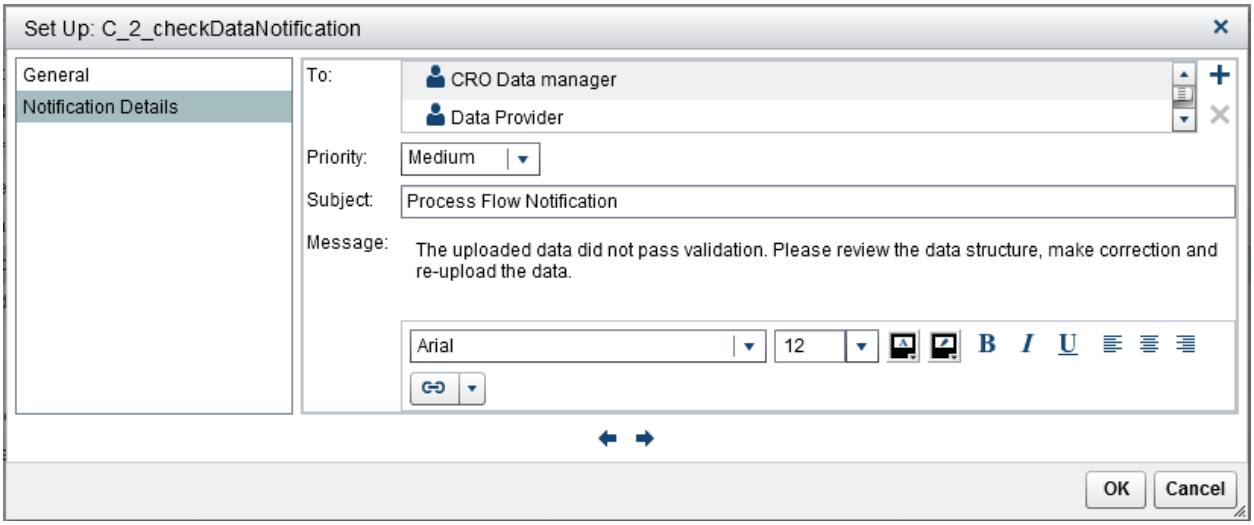


Figure 13 Notification task property

In a notification task message, you can include completion information about the tasks in the process flow. Here is the general form of the expression: **`${variable}`**. This expression in the message subject or body is replaced by the value returned by the evaluation of variable. Here are the valid expression for variable:

Expression	Description
jobTaskID.completionStatus	The status of a completed job.
completionDataFormPropId	The value of a property in a completed user task.
processVarFormPropId	The value of a process data variable.

Table 1: Valid expression for notification task

Step 7 - Tracking process

Once completed the setup, the process flow can be activated. Figure 14 below shows all the status of a process flow. It includes these statuses: Active, Completed, Suspended, and Not Started.

	Data Prepared_PF	SAS	SimpleTask	Project Lead	Project Lead	May 20, 2017 05:30 PM GMT+0800
	DataAnalysis	SAS	AnalyzeWorkFlow	Sherry	Sherry	May 19, 2017 03:21 PM GMT+0800
	DataAnalysis1	SAS	AnalyzeWorkFlow	Sherry	Sherry	May 19, 2017 03:37 PM GMT+0800
	Demo_1	SAS	AnalyzeWorkFlow	Project Lead	Project Lead	May 23, 2017 04:13 PM GMT+0800
	Demo_2	SAS	myProcess	Project Lead	Project Lead	May 20, 2017 05:24 PM GMT+0800
	Demo_3	SAS	SimpleTask	Project Lead	Project Lead	May 20, 2017 05:24 PM GMT+0800

Figure 14 Status of Process Flow

To view the details for each process flow, project manager can select the one he wants to check and then drill into the list of tasks. A process flow lists tasks that are currently running and that have completed. As a process flow runs, the tasks move from the current tasks list to the completed tasks list.

Manage the Current Task

The list of current tasks contains the tasks that are running in a specific context. It displays tasks that are active or in a suspended state. The list of tasks that user sees is based on the user's role in the process flow or on the privileges granted at the context of the process flow.

View the Completed Tasks

After all tasks in a process flow are completed, the process flow is automatically completed. When a process flow is completed, certain information about it is read-only.

ABOUT PROCESS FLOW OPTIMIZATION

With the three use cases I described above, we see that efficient and flexible process flows are critical to the success of any data management project, especially as data volumes and complexity increase. The following sections describe some tips help you improve the performance of process flow development.

Step-by-step build

When you build process flow definitions, build by validations as you build up complexity. For example, build a process subsection, and then test and validate it. Then, add additional elements, which you can test and validate as you go. This step-by-step process of progressively building avoid the chain reaction.

Splitting workflows

If you split a linear workflow into multiple, digestible modules, for example of use case3, we split the process into 4 pools which gain a number of key efficiencies that can make a big difference:

- Flexibility to adapt to changing business needs
- Rapid error resolution to debug a single module rather than an entire workflow
- More efficient testing to examine individual modules, and quickly identify and resolve potential issues

Add Sub-Process

If the process contain large amount of tasks, group elements together into a sub-process can help organize and reuse business logic. A sub-process is a process contained within a parent process that can be used to refactor a larger process into smaller components. Using sub-processes improves readability of the workflow definition and promotes consistent reuse of process logic within the organization.

Upfront Input & Output

It's always a good idea to consider input and output at the beginning of the workflow design process. This can help you avoid needing to make major adjustments to your entire workflow later in the process. Also, take into consideration and allow time for any interruptions or variations that might not fit within the standard process, such as offline collaboration.

BENEFIT OF USING LSAF WORKFLOW

As described above, many business processes can be managed by using workflows. Table below summarizes the benefits from different perspective.

Organization	Project manager	Employee
Reducing errors	Facilitate resource management	Get assignment from system
Reducing costs	Improve visibility and real-time report	Eliminating repetitive and manual processes
Shortened project durations	Scalability	Improving communication
Increased productivity	Measure and monitor performance	Enhanced responsiveness

Table 2: LSAF Workflow benefits

CONCLUSION

Many people may ask about the “right” process flow definition, but it’s not really the right or wrong model. Which one to choose is not the issue; it's about creating the model that best fits your business needs and that is flexible to edit to fit the change environment and another business requirement.

Workflow in SAS® Life Science Analyze Framework provides the ability to deploy, manage and track the entire pharmaceutical process during drug discovery and development. This paper describes the benefits of using workflow to improve the efficiency and flexibility by several use cases. In conclusion, follow the steps I mentioned above to create a streamlined process and manage it in LSAF to achieve ongoing continuous improvement, and it is very easy to deal with the changing environment.

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