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How to customize your business process more effectively by BPMN with SAS® LSAF

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ABSTRACT

As we all know, new drug development process in pharmaceutical industry is perennial, complex and disjointed. Within every organization there are common business processes designed to meet objectives. However, the process are cross-functional, human interaction increase complexity. The need of change may come from almost anywhere, both inside and outside that may cause a series of cost on management. Therefore, how to effectively customize and optimize your business process throughout the entire life cycle becomes very important.

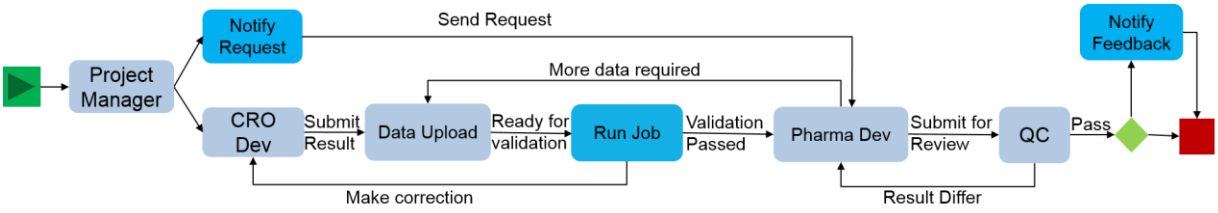
This paper presents BPMN (Business Process Model and Notation) compliant workflow in SAS LSAF (Life Science Analytics Framework), a powerful and flexible feature that can help you design, manage and monitor your processes. It allows customers the ability to manage the creation, modification and deployment of any templates they want. Meanwhile, it is readily understandable by all business users, from the business analysts that create drafts of the process, to the technical developers that will perform the process, and finally, to the business people who will manage and monitor the process. In this paper I will introduce how to customize or optimize your business process by BPMN with SAS LSAF.

INTRODUCTION

Display 1 below is a topology graph to describe one use case where workflow was applied in clinical study. It shows a simplified process in real research life cycle. It will be used later as example to be translated into BPMN compliant workflow by SAS LSAF and discuss more detailed aspects about BPMN and workflow.

Use Case: Sample Data Analysis Process of Pharmaceutical Company and CRO

A pharmaceutical company is collaborate with a contract research organization (CRO) partner for the clinical study. Display 1 illustrates the data development and validation between pharmaceutical company and CRO, and also handle customers' requirement. The outputs from CRO's programmer will be used by the pharmaceutical company's programmer to do the internal research. The validation programmer will check whether the output format meet specification requirement. If validation is failed, comments are sent back to the source programmer to make modification. After the data passes the validation, it will be moved to a Quality control researcher (QC) for review. The researcher will check the inferential statistics portion and send comments if there are errors. Once the QC is satisfied that the program produces the expected results, the program can be promoted and considered as part of the production environment that is applicable for the study.



Display 1. Workflow for data analysis between pharmaceutical company and CRO

What is BPMN

Business process model and notation (BPMN) is an established standardized graphical notation for process modeling and automation. It ensures that XML language designed for the execution of business processes can be visualized with a business-oriented notation. A BPMN model in the current version 2.0 can be directly executed by a BPMN engine without translating the business model into other languages for execution and systems integration. The aim of modeling is to illustrate a complete process, enabling managers, consultants and staff to improve the flow and streamline the process. The focus of the improvements is on "change" actions that make the customer service and experience better, and on reducing wasted time and effort.

Why Use LSAF Workflow?

SAS Life Science Analytics Framework provides an integrated system for managing, analyzing, reporting, and reviewing clinical research information. Of these, a new feature - BPMN2.0 compliant workflow, is a BPM system

which sustain a high level of confidence about the accuracy and flexibility for the clinical research. It aids project management oversight, and support process:

- Align with BPMN2.0 standard, it is easy to understand.
- More flexible. Customers can define and manage any process templates they want. It is better control and deployment of resources.
- Support multiple analyses, including interim and final analyses, with different team members, access rights and context-specific privileges.
- Assign tasks and track progress for each analysis activity and deliverable to improve overall project performance, and provide instant insight into the status of analysis and reporting activities for a single study or your entire portfolio.
- Automate activities in your clinical process using process orchestration capabilities, such as automatic job initiation and event notifications.

HOW TO APPLY A BUSINESS PROCESS MODEL INTO REAL WORLD AND EXECUTE IT

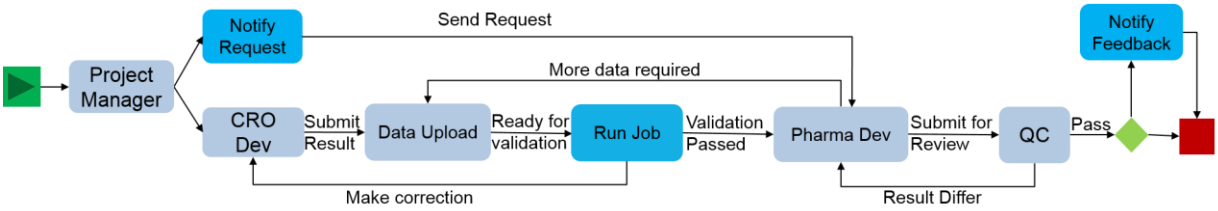
In this section, I will give you a brief introduction about how organizations can use BPMN in concert with LSAF to provide the foundation for scalable, repeatable and automated processes which are secure and manageable. A well-designed and executed template make the process more efficiency.

Using the modeling scenario from above display 1, the main steps is as below:

1. Analyze the entire process to classify the roles and the main relationships.
2. Define BPMN file for execution in Camunda Modeler
3. Import to LSAF as PFD
4. Create the corresponding PF
5. Set proper value for each element

1. Analyze the entire process to classify the roles and the main relationships

Take the topology graph which described the use case for example. The company is to work with a CRO. For the result of the cooperation to be efficient it is necessary that the company and the CRO to work together in harmony. To create a successful business process model, it has to be defined and understood how, from who, to who, in which conditions communication and reporting related to CRO and company.



Pharmaceutical company:

- Project manager: Define and assign all trial-related duties and functions to conduct the study. Serves as a primary resource and point of communication for the customer and project team.
- Analysis programmer: Write procedures to integrate new research results with previously generated data.
- Quality control researchers: To ensure that the appropriate assays are developed, validated, and in place to support the manufacturing program.
- Validation programmer: Review the format of the report and finish the validating. Comparing research results with plan to ensure that the developmental studies are being conducted as designed and described in the study protocol.

CRO:

- Clinical Programmers: Conduct relative studies and create appropriate written procedures.

- Data Management: Review the technical reports to ensure that the data are analytically acceptable and correctly. Then upload the data into the study location.

When we figure out the responsibility for each role, we can know the relationship between them clearly. As described in the topology graph, it has a specific direction between each role.

2. Define BPMN File for Execution in the Camunda Modeler

From the use case, we can see the business process template consists of a set of elements that are performed together in an organization environment. Distribution and coordination of work among people or systems is an important task of the process. BPMN provides a set of notation categories so that the reader of a BPMN diagram can easily recognize the basic types of elements and understand the diagram. Within the basic categories of elements, additional variation and information can be added to support the requirements for complexity without dramatically changing the basic look and feel of the diagram.

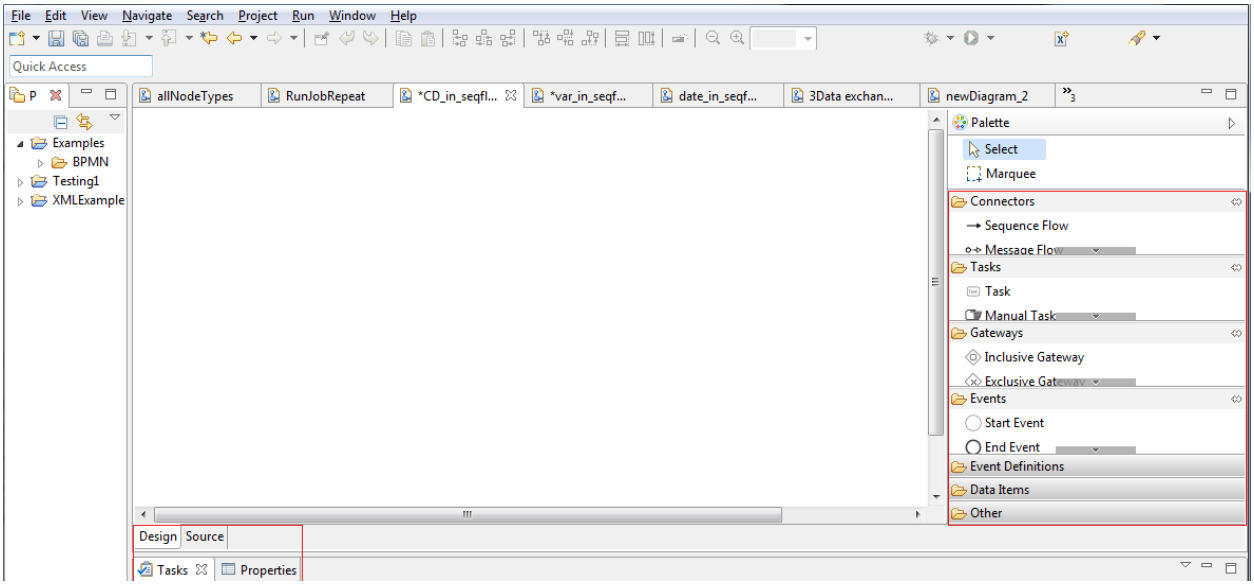
Basic BPMN Elements

A.1 in Annex section shows the basic elements of BPMN. It consists of the following basic building blocks:

- Flow objects: The main graphical elements to define the behavior of a Business Process. There are three flow objects: Events, Activities, and Gateways
- Connecting objects: Connecting the flow objects to each other or other information. Mainly comprising arrows. These indicate sequence flow, message flow, and associations
- Swim lanes: There are two ways of grouping the primary modeling elements through Swim lanes: Pools and Lanes
- Artifacts: Used to provide additional information about the process. There are two standardized Artifacts: Group and Text Annotations
- Data: Provide information about what activities require to be performed and what they produce.

Tools for Business Process Modeling using the BPMN

Any BPMN 2.0 modelling application can be used to create the process flow definition XML file, containing the process flow definition that will be deployed. We create template with Camunda Modeler, a third party BPMN tool for process modeling (See Display 2). It allows you to model files located directly on your local file system. It fully matches the applicable compliance points as stated in the International Standard and supports the required BPMN packages. Such as BPMN core elements; Process diagrams which include the elements defined in the Process, Activities and Data; Collaboration diagrams which include Pools and Message Flow; Conversation diagrams which include conversations.



Display 2. An overview of Camunda Modeler

BPMN model in Camunda Modeler

The next step is to define a BPMN 2.0 model in Camunda Modeler for the use case. Two types of Activities are used in this use case: Tasks, and Call Activity. There are different types of Tasks identified within BPMN to separate the types of inherent behavior that Tasks might represent (See more details in Display 3). For the use case, there are activities that need people performs the task. So I defined User type task for these activities; also, for some repeated activities, using Call Activity to perform will be more flexible. Call Activity allows the inclusion of re-usable and automatic task in the diagram. There are three types of Call Activity in LSAF.

- System - Notification
- System - Wait Job
- System - No Wait Job

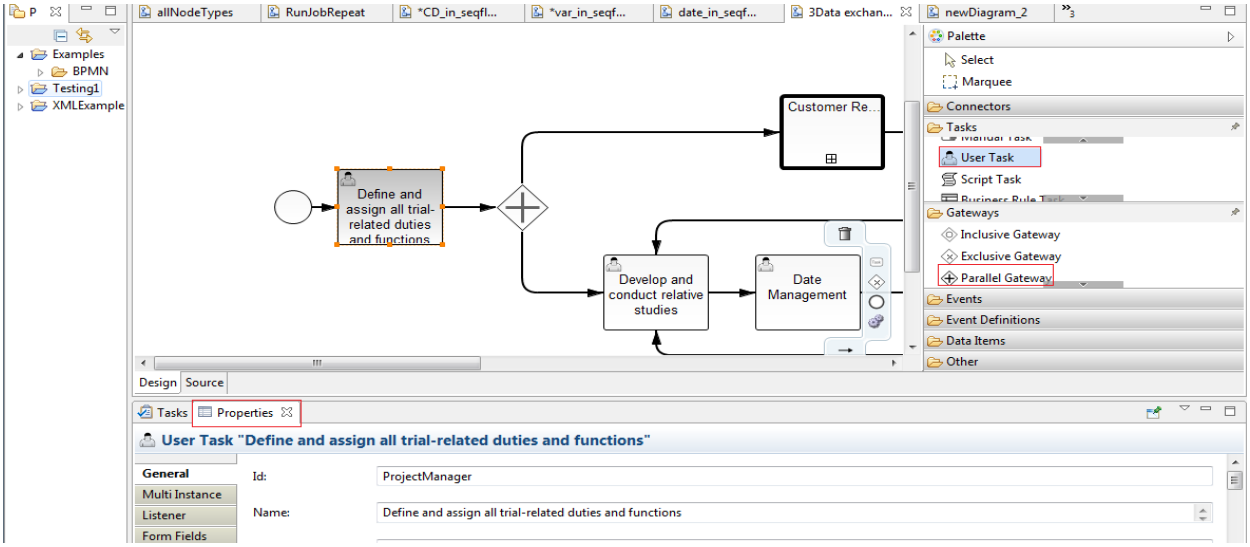
For example, project manager and QC can handle customers' requirement by using Notification type to send email automatically; and validator can handle the repeated validation by using Job type.

Camunda Modeler contains two general tab for the definition: Design tab and Source tab. In Design tab, you can drag and drop the desired elements to complete your design; you can also write XML language in Source Tab to complete your design. If some properties that the tool does not support the implementation via its UI, you can set and modify them directly in the XML. The advantage of doing it inside from Source tab is, if you make a mistake, like a missing tag, you will get an error when you switch back to the Design tab.

Design Tab

Select create a PFD in a project or in the external. Then add the appropriate elements from the palette in Design tab by dragging and dropping them onto the diagram canvas, or select the activities or connections by click the icons which around the element.

Let's take Project Manager for example. It is an activity that should be performed by an individual, so we select User Task for it from the palette and add it onto the canvas. Then set properties for this user task if needed. Due to the nature of the project manager, next step is create a new parallel gateway and connect it to this item: one is for handling customer's requirement and the other is for CRO. After complete this step, the definition for project manager is completed (Display 3). And so forth for other role. Appropriate types and values should be set depending on the use of each activity.



Display 3. Definition for project manager in Camunda Modeler

Source Tab: Configure properties for Execution

The BPMN file we defined in the Design tab is stored in the format of XML. There is a mapping between the graphics and XML elements. Variables can be used to add data to process runtime state or more variable scopes. In our template, the flow takes different paths depending on the use of the process. So we should define specific variables to make decisions, then the variable can be used in conditions to control the flow.

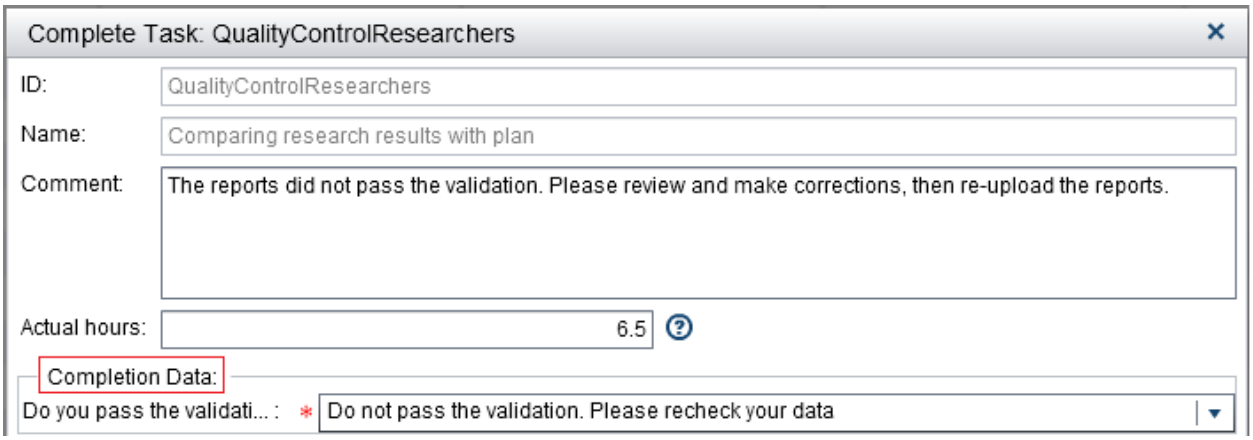
I set completion data which is a LSAF term referring to the display of user task form properties on the Edit Task (Display 4) to control the flow for user task. Once you define it, it can be entered once a task becomes current. This

allows for the user to enter the information at any point in the life of the task, rather than just when user wishes to complete the task.

```
<bpmn2:extensionElements>

<activiti:formProperty id="rerun" name="Do you pass the validation or not" required="true" type="enum" default="yes">

<activiti:value id="yes" name="Complete process flow"/>

<activiti:value id="no" name="Do not pass the validation. Please recheck your data"/>

</activiti:formProperty>
```

Then I defined the condition expression to control the flow direction for the sequence flow. A sequence flow is represented in XML as a regular sequence flow.

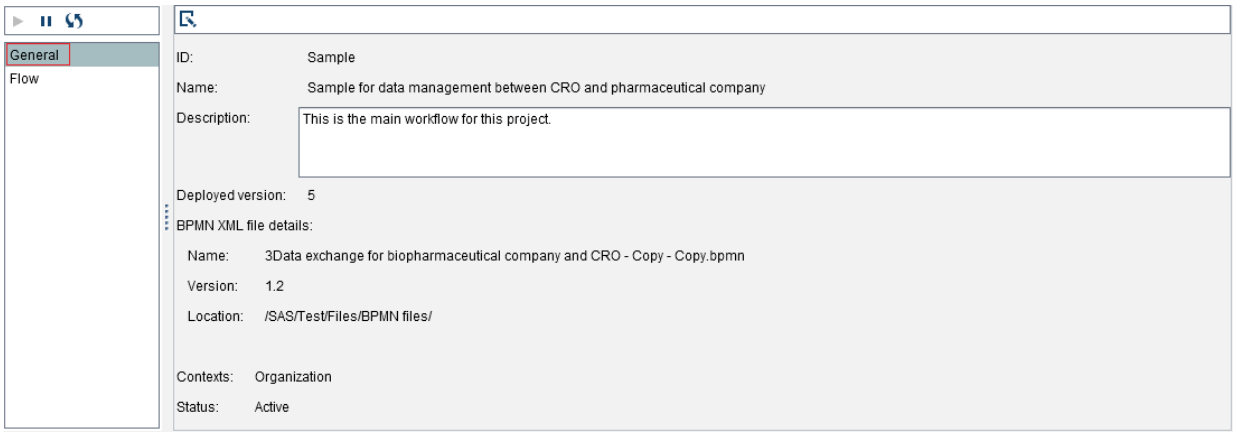
```
<bpmn2:sequenceFlow id="SequenceFlow_14" name="" sourceRef="QualityControlResearchers"
 targetRef="AnalysisProgrammer" >

        <bpmn2:conditionExpression xsi:type="bpmn2:tFormalExpression"><![CDATA[${reupload == "yes"}]]></bpmn2:conditionExpression>

</bpmn2:sequenceFlow>
```



Display 4. Completion Data in LSAF

3. Import to LSAF as PFD

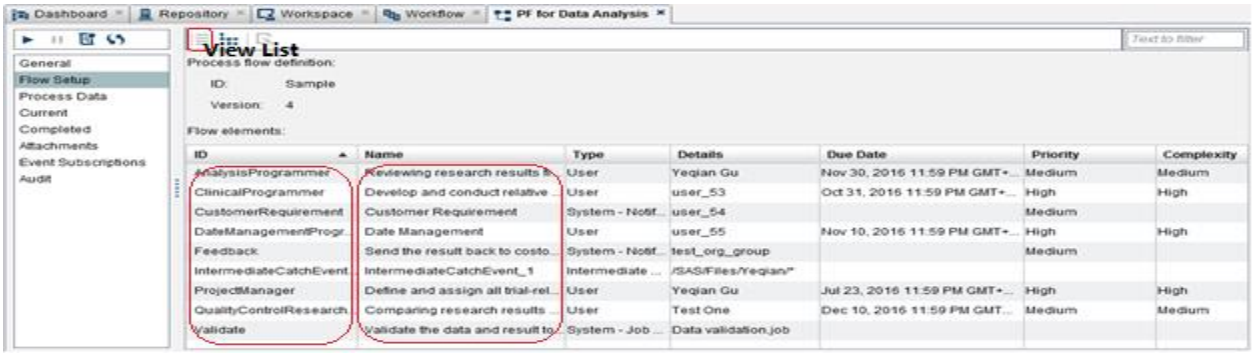
After create the desired template, then we can deploy it in LSAF. Templates are used to create instances of workflow are called 'Process Flow Definition' (PFD) in LSAF. Deploy a PFD that has been loaded into the Repository. The General information window is shown (Display 5). The user can edit the properties for this PFD. In Flow section, user can see the flow elements in list view and diagram view to get the whole outline just as Display 5 and Display 6.



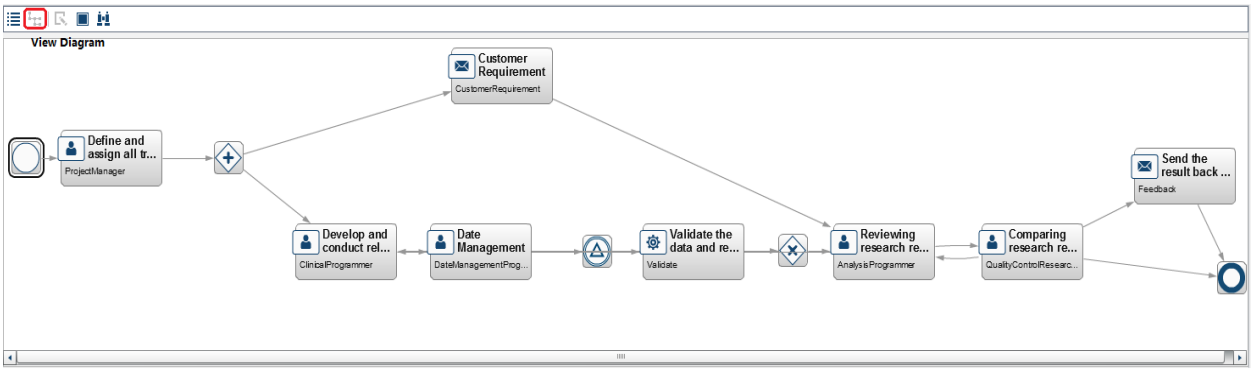
Display 5. General information for a PFD

4. Create the corresponding PF

In LSAF, an instance create from the previously deployed PFD which is named Process Flow (PF). For the example we used, the process flow describes a unit of work for CRO and pharmaceutical companies that needs to be accomplished. It captures the tasks and flow describing a best practice. There are List view (Display 6) and Diagram view (Display 7) for the tasks. User can see all the tasks for each role and also can see the detailed diagram in LSAF. All kinds of roles to do collaborative works together in the same process, enabling better control and deployment resources as well as the streamlining of clinical process.



Display 6. Process Flow Properties in List view



Display 7. Process Flow Properties in Diagram view

5. Set proper value for each element

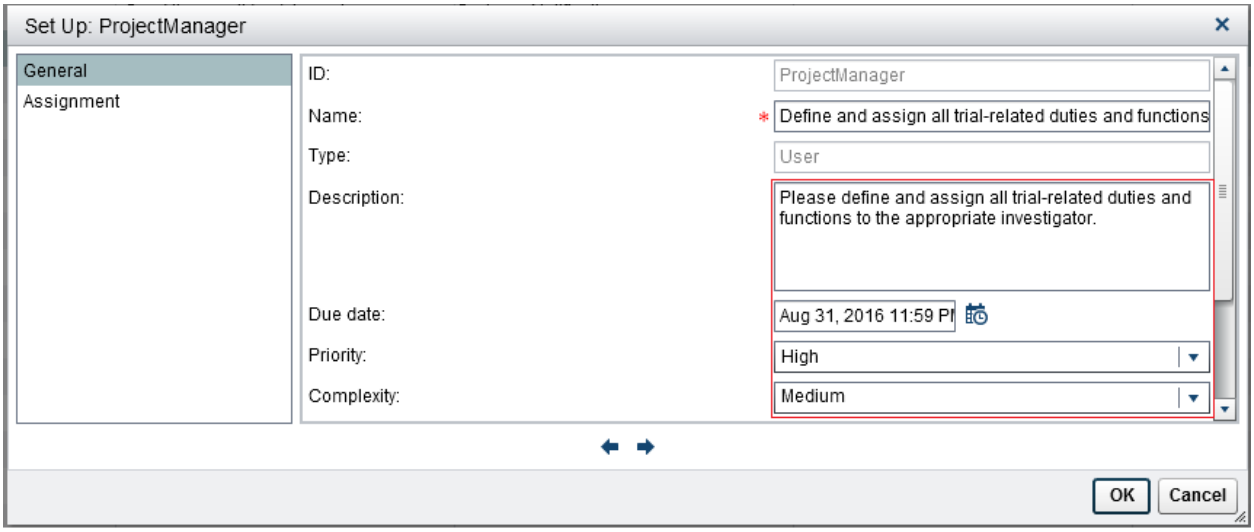
Let's see the properties for a PF. It contains General, Flow Setup, Process Data, Current, Completed, Attachments, Event Subscriptions and Audit. All of these properties can be modified by user to satisfy the requirement.

Flow setup

Each of the task attributes in a Process Flow can be modified by the user who is assigned the task or the owner if the task is no assigned. We used 3 types of tasks in our template: User, System-Notification, and System-Job.

User type

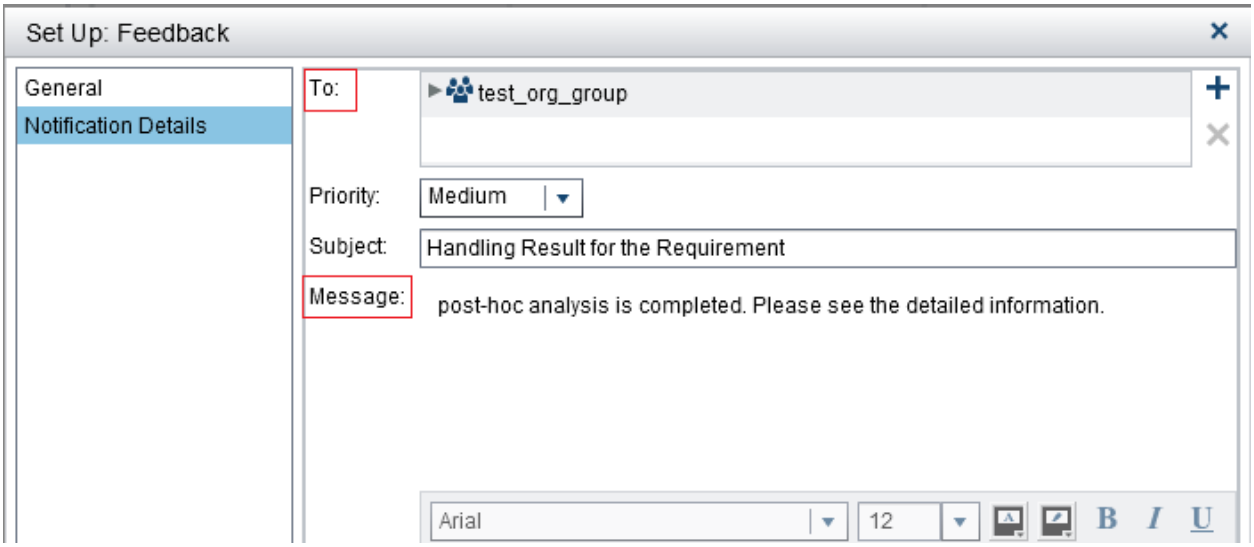
As a project manager, you need to define and assign all trial-related duties and functions to the appropriate investigator. Display 8 shows the properties of a user type task within a process flow. In the Set Up dialog, user can define the Description, Due date, Priority, Complexity and assign the task. The Description field of a task may be sufficient to detail the work to be accomplished for the assignee. Once a PF is activated, the tasks assigned to a particular user will appear in his individual task list. Project manager can reassign tasks to other team members when the assigned resource is absent or if the workload becomes too heavy for the assigned resource. Any task in a process flow which is not assigned will appear in the Task list of the PF owner or the candidates.



Display 8. Set Up task

System - Notification Type

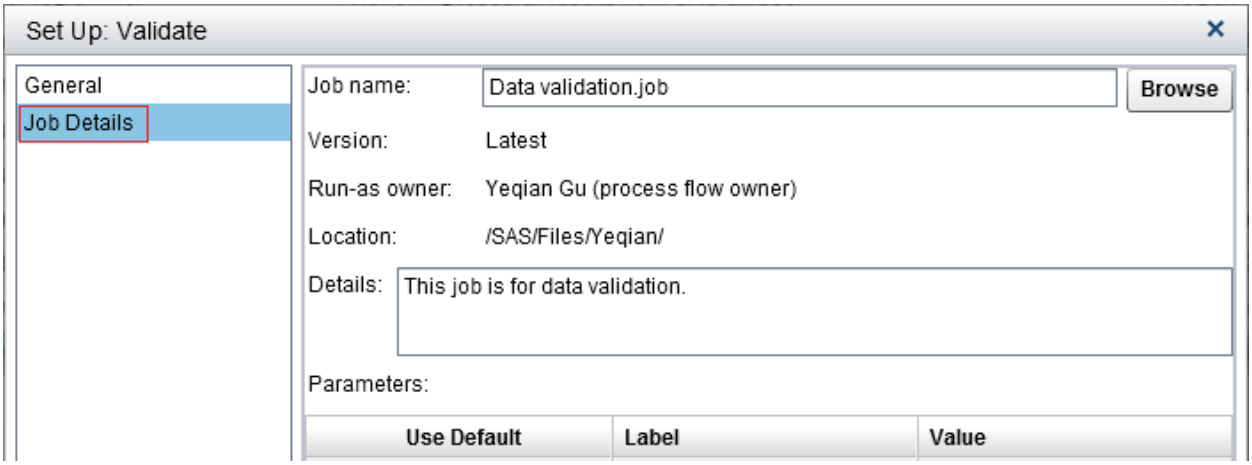
As a Quality Control researcher, you need to give feedback to the customer. Display 9 shows the properties for a notification task. The properties for this task include the list of users who should receive the notification as well as the content of the message.



Display 9. System-Notification task

System - Job Type

As a validator, you need to check the data once it is uploaded or updated. So you need an automate Job task to execute. A System Job task will execute a LSAF Job and return the execution status to the appropriate role. Display 10 shows the properties for a job task. The job task will execute a LSAF job and return the execution status of the job to the PF. It includes the job and parameters in the job.



Display 10. System-Job task

Process Data

LSAF provide the ability to control the flow using decisions based on information given by the user creating a process. This allows a modeler to create on flow that could take different paths depending on the use of the process. The modeler also uses 'Form Property' definition on 'Start Event' node type to specify these variables. The data entered is not confined to process creation time. This data can be provided at any time in the life of the process.

Current/Completed/Event Subscription/Audit

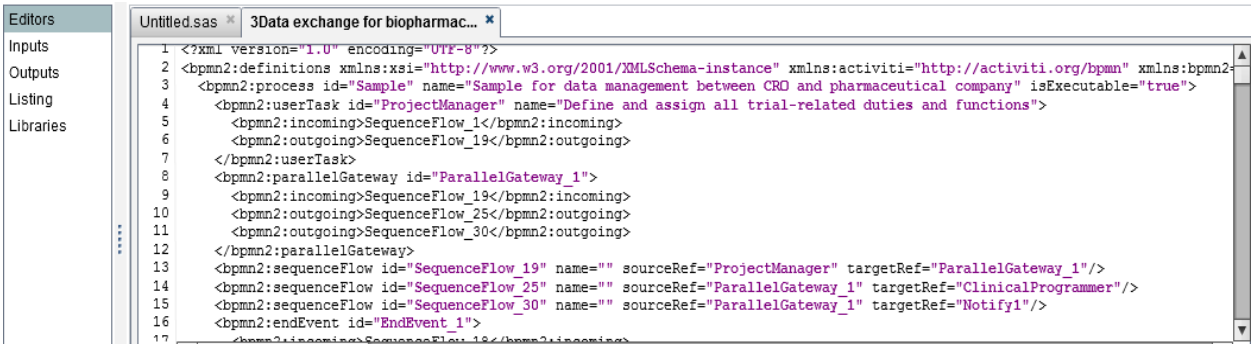
As a project manager, you can monitor the entire progress to ensure the research studies are conducted. Once a process flow is activated in LSAF, the progress of the PF can be readily tracked by checking the Current and Completed (Display 8). LSAF allows pharmaceutical organizations to reduce their interactions with CRO in the change of the context or some actions performed apply to the collaboration. It provides a traceable and auditable record for the outcome of the process. Whilst user can subscribe to available process flow and task events and be notified when those event occur. So workflow capabilities provides immediate and ongoing insight to the project progress.

Status	ID	Name	Type	Date Created	Completed By	Date Completed
✓	QualityControlResearc...	Comparing researc...	User	Jul 23, 2016 06:34 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:36 PM GMT+0800
✓	AnalysisProgrammer	Reviewing research..	User	Jul 23, 2016 06:32 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:34 PM GMT+0800
✓	IntermediateCatchEven...	IntermediateCatchE..	Intermediate Event -...	Jul 23, 2016 06:33 PM GMT+0...	<system>	Jul 23, 2016 06:33 PM GMT+0800
✓	DateManagementProg...	Date Management	User	Jul 23, 2016 06:33 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:33 PM GMT+0800
✓	ClinicalProgrammer	Develop and condu...	User	Jul 23, 2016 06:32 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:33 PM GMT+0800
✓	CustomerRequirement	Customer Require...	System - Notification	Jul 23, 2016 06:32 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:32 PM GMT+0800
✓	ProjectManager	Define and assign ...	User	Jul 23, 2016 06:31 PM GMT+0...	Yeqian Gu	Jul 23, 2016 06:32 PM GMT+0800

Display 11. Completed tasks for PF

Edit BPMN File

As beginning part mentioned, it is more flexible to handle the change actions. If you want to enrich the BPMN file with execution attributes, add objects or removed some. For example, it was unavoidable for team members to change during the project. Then you should add or remove some tasks. Then you can check out the BPMN2.0 XML file from your Repository to Workspace, and open it using SAS Session Editor. Then modify it with your new required process. Of course, it can also be modified in Camunda Modeler.

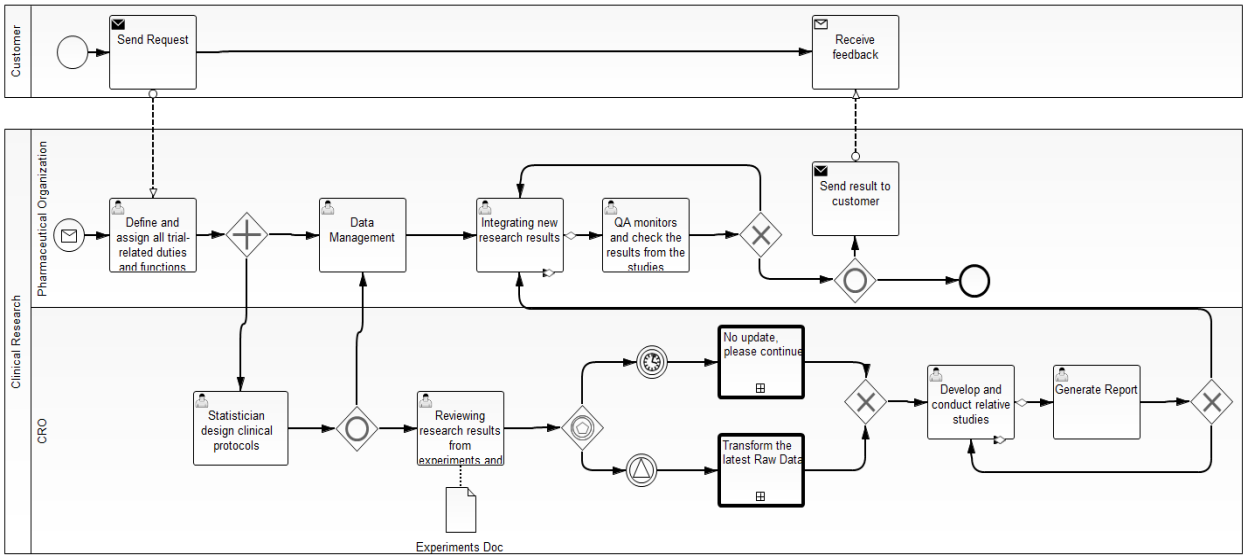


Display 12. Edit BPMN file in SAS Session Editor

EXTENDED BPMN MODELING ELEMENTS

There is a more extensive list of the Business Process concepts that could be depicted through a business process modeling notation. A.2 in Annex part shows some frequently used extended elements. But the extended elements are much, much more than that. Actually, in our template, we've already used some of them.

For the templated we used, we can design it with more detailed information which will use more extended elements. Display 13 shows a more abundant elements during the business process. It is simple and understandable, while at the same time being able to handle the complexity inherent to Business Process. Users can monitoring the status of research studies in each stage to ensure that they are being conducted according to the timeline and critical path in the development plan.



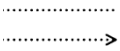
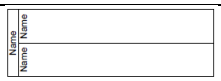
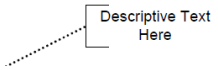
Display 13. More detailed Process by using abundant BPMN elements

CONCLUSION

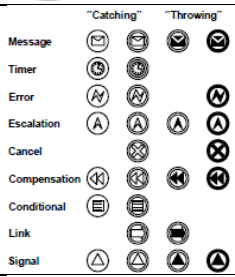
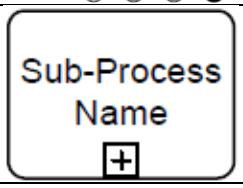
BPMN provides organizations with the capability of understanding their business procedures in a graphical notation and give organizations the ability to communicate these procedures in a standard manner. SAS delivers BPMN compliant workflow capabilities that aid project management oversight, and support process enablement to automate activities in your clinical process. It is a flexible function to customize and modify users' business process. By providing immediate access and ongoing insight onto project progress, SAS workflow enables your organization to better control the deployment of resources. In addition, clinical research and development processes and tasks are streamlined and flexible.

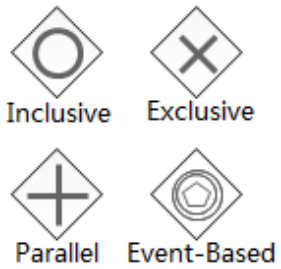
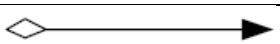
ANNEX

A.1 Basic Modeling Elements of BPMN

Element	Description	Notation
Event	An Event is something that happens during the course of process	
Activity	A generic term for work that company performs	
Gateway	Used to control the divergence and convergence of sequence flows in process	
Sequence Flow	Show the order that activities will be performed in a process	
Message Flow	Show the flow of messages between two participants that are prepared to send and receive them	
Association	Used to link information	
Pool	The graphical representation of a participant in a collaboration	
Lane	Sub-partition within a process	
Group	Grouping of graphical elements that are within the same category	
Text Annotation	It is a mechanism for a modeler to provide additional text information for the reader of a BPMN diagram	
Data Object	Provide information about what activities require to be performed	
Message	Depict the contents of a communication between two participants	

A.2 Frequently used Extended Modeling Elements of BPMN

Element	Description	Notation
Intermediate	As the name implies, it occurs between a Start event and an End event. It will affect the flow of the process.	
Type Dimension (Message, Timer, Error, Cancel, Signal, Terminate, etc.)	The Start and some Intermediate Events have triggers that define the cause for the Event. There are multiple ways that these events may define a result that is a consequence flow path ending.	
Collapsed Sub-Process	The details of the Sub-Process are not visible in the Diagram. A plus sign in the lower center of the shape indicates that the Activity is a Sub-Process and has a lower-level of detail	

Gateway Control Types	The types of control include: • Inclusive Gateway decision and merging • Exclusive Gateway decision and merging • Parallel Gateway forking and joining • Event-based can start a new instance	
Conditional flow	A Sequence Flow can have a condition Expression that are evaluated at runtime to determine whether or not the sequence flow will be used.	

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New Drug Approval Process: Accelerating Global Registrations
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