ABSTRACT
As a beginner lead programmer, the traditional focus is to work with given programming team, study statistician, study data manager to deliver outputs per given timelines. Eventually the experienced lead would engage in timeline discussion, resource discussion, and CRO management. This traditional approach has its limitation in terms of perception of success, burned bridges with other functional groups, lack of communication, and lack of satisfaction in some areas etc. This paper takes holistic view of stakeholder management and how to use available processes, tools and techniques to ensure whole success – tangible and intangible. We will learn about creating Stakeholder Management Plan which will include following four processes, their inputs, tools and techniques and outputs.
1. Identify Stakeholders
2. Plan Stakeholder Management
3. Manage Stakeholder Engagement
4. Control Stakeholder Engagement
This paper is intended for a lead SAS programmer. However, contents are useful to SAS programmers at any level.

INTRODUCTION
According to Project Management Institute, Project Stakeholder Management includes the processes required to identify the people, groups, or organizations that could impact or be impacted by the project, to analyze stakeholder expectations and their impact on the project, and to develop appropriate management strategies for effectively engaging stakeholders in project decisions and execution. Stakeholder management also focuses on continuous communication with stakeholders to understand their needs and expectations, addressing issues as they occur, managing conflicting interests and fostering appropriate stakeholder management in project decisions and activities. Stakeholder satisfaction should be managed as a key project objective. Figure 1 provides overview of each stakeholder management process, their inputs, tools and techniques, and outputs.

As a lead programmer, it is understandable that typical work day does not circle around 100% project management. However, there are certain positions available in the industry to require just that. It is up to individual lead how much formal or informal emphasize they want to give to this knowledge area of stakeholder management within the whole project management framework.

Overall idea here is to understand this new approach, its importance, its reliability, awareness of available tools and techniques to accomplish what you want to achieve. Imagine a box full of tools; it is up to you which tool you want to use, when and how.

As you become more experienced with this new approach, compare the results with your expectation and make adjustment accordingly.

Also it is important to understand limitation of available tools. It is recommended to have discussion with your manager about this new approach. After all, your manager is one of the key stakeholders.

PROCESS 1: IDENTIFY STAKEHOLDERS
Identify stakeholders is the process of identifying the people, groups, or organization that could impact or be impacted by a decision, activity, or outcome of the project, analyzing and documenting relevant information regarding their interest, involvement, interdependencies, influence and potential impact on project success. The key benefit of this process is that allows the lead to identify the appropriate focus for each stakeholder. The input, tools and techniques, and outputs are depicted in Figure 2.
1.1 IDENTIFY STAKEHOLDERS: INPUTS

Project charter is a formal or informal document or goal provided by your manager which includes high level timelines, assigned resources, CRO, list of groups or departments participating in your study, types of deliverables.
Procurement documents include master service agreement, statement of work for contractors, CRO, key software contracts e.g. SAS, Pinnacle 21 or at least summary of key details related to your projects.

Enterprise environmental factors refer to conditions not under control of project team that influence, constrain or direct the project. E.g. Organization culture, Geographic distribution of resources, Industry and government standards, Existing human resources, Company work authorization system.

Organization process assets are the SOPs, guidelines, knowledge base, templates specific to your organization. It also includes lesson learned and stakeholder register from previous projects.

1.2 IDENTIFY STAKEHOLDERS: TOOLS AND TECHNIQUES

Stakeholder analysis is a technique of systematically gathering and analyzing quantitative and qualitative information to determine whose interest should be taken into account throughout the project. It identifies the interests, influence, and expectations of the stakeholders and relates to the purpose of the project. It also helps to identify stakeholder relationships that can be leveraged to build coalitions and potential partnership to enhance the project’s chance of success. E.g. Leveraging strong relationship with medical monitors to influence resource needs with your manager, leveraging strong biometrics relationship to streamline scope and bargain timeline with medical monitors, leveraging strong relationship with medical monitors to gather potential requests earlier to plan resources and allow more time for your team complete the deliverables.

Stakeholder analysis generally follows the steps as described below:

- Identify all potential project stakeholders and relevant information, such as their roles, departments, interests, knowledge, expectations, and influence levels. Key stakeholders are usually easy to identify. They include anyone in a decision-making or management role who is impacted by the project outcome.
- Analyze the potential impact or support each stakeholder could generate, and classify them so as to define an appropriate strategy.
- Assess how key stakeholders are likely to react or respond in various situations, in order to plan how to influence them to enhance their support and mitigate potential negative impact.

Stakeholder analysis generally follows the steps as described below. According to the Project Management Institute, Stakeholder classification models such as Power/Interest grid, Power/Influence grid group the stakeholders based on their level of authority and their level of interest or influence in the project as indicated in Figure 3.
1.3 IDENTIFY STAKEHOLDERS: OUTPUTS

Stakeholder register is the main output of Identify Stakeholders process. This contains all details related to the identified stakeholders including, but not related to identification information (Name, Organization position, role in the project, contact information), assessment information (main expectation, potential influence in the project) and classification (internal or external, supporter or resister).

For a lead programmer, stakeholder register may contain list from following indicated in Figure 4.

PROCESS 2: PLAN STAKEHOLDER MANAGEMENT

Plan stakeholder management is the process of developing appropriate management strategies to effectively engage stakeholders throughout the project life cycle, based on the analysis of their needs, interests and potential impact on project success. The input, tools and techniques, and outputs are depicted in Figure 5.

2.1 PLAN STAKEHOLDER MANAGEMENT: INPUTS

Potential inputs to the process include project management plan (detailed study deliverables timelines, resource assignments on specific tasks, acquisition of resources, communication plan etc.), stakeholder register, enterprise environmental factors and organization process assets.
2.2 PLAN STAKEHOLDER MANAGEMENT: TOOLS AND TECHNIQUES

Expert judgement, meetings and analytical techniques are tools and techniques used in this process. The current engagement level of all stakeholders needs to be compared to the planned engagement levels required for successful project completion. Stakeholder engagement throughout the lifecycle is critical for project success. Analytical techniques can be used to classify stakeholder engagement levels as follows:
Stakeholder Management: How to be an effective lead SAS® programmer, continued

- Unaware: Unaware of project or impacts. E.g. Programming infrastructure group in process of making macro changes unaware of your project’s timelines and potential impact of their work. IT support staff on vacation without backup unaware of unblinding activity of your study.

- Resistant: Aware of project, resistant to change. E.g. Medical monitor resistant to make change to their past process of using draft TLFs for data cleaning activity. Medical monitor who moved from a large pharmaceutical company to a startup pharmaceutical is resistant to idea that production of validated TLFs is more than pushing a button.

- Neutral: Aware of the project, yet neither supportive nor resistant. E.g. Head of programming wanted all study teams to use available servers without assigning a specific server to the study team with ongoing unblinding activity.

- Supportive: Aware of project and potential impacts and supportive to change. E.g. Your manager is willing to provide more resources to counter potential timeline reduction and/or increased scope.

- Leading: Aware of project, actively engaged in ensuring the project is a success. E.g. Medical monitor or other stakeholder with high influence asks head of programming to provide more resources to the lead programmer.

Stakeholder Engagement Matrix as shown in Figure 6, can be used to document current (C) and desired (D) engagement level. Through this analytical process, actions and communication plan should be developed to close gap between current and desired level of engagement.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Unaware</th>
<th>Resistant</th>
<th>Neutral</th>
<th>Supportive</th>
<th>Leading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Manager</td>
<td></td>
<td></td>
<td>C D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT Support Staff</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Statistician</td>
<td></td>
<td></td>
<td>C D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Manager</td>
<td></td>
<td></td>
<td>C D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Monitor</td>
<td>C</td>
<td></td>
<td>D</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 6. Stakeholder Engagement Assessment Matrix

2.3 PLAN STAKEHOLDER MANAGEMENT: OUTPUTS

Stakeholder management plan and project documents updates are output of this process. The lead should be aware of sensitive nature of the stakeholder management plan and should take appropriate measures. E.g. Information on stakeholders who are resistant to the project could be damaging and due consideration should be given to distribution of such information.

PROCESS 3: MANAGE STAKEHOLDER ENGAGEMENT

Manage stakeholder engagement is the process of communicating and working with stakeholders to meet their needs/expectations, address issues as they occur, and foster appropriate stakeholder engagement in project activities throughout the project life cycle. The input, tools and techniques, and outputs are depicted in Figure 7.

3.1 MANAGE STAKEHOLDER ENGAGEMENT: INPUTS

Stakeholder management plan, change log, organization process assets are potential input to this process. Another input to the process is communication management plan which documents stakeholder communication requirement, communication channel, format, escalation process. E.g. Escalation for weekly biometrics study team may be to the meeting of each head within biometrics.
3.2 MANAGE STAKEHOLDER ENGAGEMENT: TOOLS AND TECHNIQUES

Communication methods, interpersonal skills, and management skills are potential tools and techniques used by the lead. E.g. building trust, active listening, facilitating consensus towards project objectives, influencing people to support the project, negotiating agreement to support project needs.

Figure 7. Process 3: Manage Stakeholder Engagement

3.3 MANAGE STAKEHOLDER ENGAGEMENT: OUTPUTS

Potential outputs for this process are issue log, change requests, project management plan updates, project documents updates, organization process assets updates. It is important to maintain issue log with new issues as they occur and documenting resolution of old issue. These well documented outputs may very well become input for your next project or for the project of your colleague.

PROCESS 4: CONTROL STAKEHOLDER ENGAGEMENT

Control stakeholder engagement is the process of monitoring overall project stakeholder relationships and adjusting strategies and plans for engaging stakeholders. The input, tools and techniques, and outputs are depicted in Figure 8. The key benefit of this process is that it will maintain or increase efficiency and effectiveness of stakeholder engagement activities as the project evolve and its environment changes.

4.1 MANAGE STAKEHOLDER ENGAGEMENT: INPUTS

Project management plan, issue log, work performance data, project documents are input to the process.

4.2 MANAGE STAKEHOLDER ENGAGEMENT: TOOLS AND TECHNIQUES

Information management systems, expert judgement, meetings are tools and techniques used in the process.

4.3 MANAGE STAKEHOLDER ENGAGEMENT: OUTPUTS

Work performance information, change requests, project management plan updates, project documents updates, organization process assets updates are output to the process.
4 Control Stakeholder Engagement

**.1 Inputs**
- .1 Project management plan
- .2 Issue log
- .3 Work performance data
- .4 Project documents

**.2 Tools & Techniques**
- .1 Information management systems
- .2 Expert judgement
- .3 Meetings

**.3 Outputs**
- .1 Work performance information
- .2 Change requests
- .3 Project management plan updates
- .4 Project documents update
- .5 Organizational process assets updates

Figure 8. Process 4: Control Stakeholder Engagement

**CONCLUSION**

This new approach of looking through glass of stakeholder management will ensure the traditional success of delivering quality outputs within specified timelines. In addition, it will open up a whole new world of project and personal success in terms of meeting or exceeding expectation of people you work with, constructive work relationship, effective communication, pleasant work environment, higher influence and impact on the organization and career enhancement.

**REFERENCES**


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