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Something Old, Something New: A little programming management can go a long way

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ABSTRACT

We propose a statistical programming project tracking tool that will help manage and track programming progress, deliverables, and timelines at the study level. The tool can be used across studies to prepare aggregate reports for upper management and can be updated to fit the needs of any statistical programming organization or team.

INTRODUCTION

Have you ever found yourself searching tirelessly for documents as the lead programmer of a study when the previous study lead had already left? Or maybe you were in the shoes of a manager who wished for easier access to the status of the projects that your direct reports lead? Statistical programmers in the pharmaceutical and medical device industry work on interdisciplinary and cross-functional teams. A successful statistical programmer must not only have proficient programming knowledge, but also have strong organizational and communication skills. We should be keeping track of not only what we as programmers are doing but also what others on the study team and project are doing.

We propose a project management and tracking tool to help manage ourselves, others, deliverables, and timelines at the study level. The tool includes but is not limited to study contact information, location of study files (i.e. raw datasets, SDTM, ADaM, mock-ups), ongoing, completed and future deliverables, study highlights and risk management. A summary of study highlights can be pulled across the multiple study tracker files and be presented as an aggregate report to upper management, such as the head of programming. The tool we present can be updated to fit the needs of any statistical programming organization or team.

STUDY TRACKER TOOL

The four main components to the proposed study tracker tool include:

I. Study team contact information

II. Study files management

III. Study highlights & deliverables (ongoing, completed, future)

IV. Risk management

The tracker tool we propose is in an excel workbook format, with each of the four aforementioned components managed in separate excel worksheets. The project tracking tool can be housed in an organization's shared server or on a secure file sharing storage and collaboration software.

STUDY TEAM CONTACT INFORMATION

A crucial part of managing any project or task is to be aware of the members of the project team, the stakeholders and what their roles are in the team. This section of the tracking tool (see **Figure 1**) contains all details related to identifying the study itself (study names, compound names) and the different team members including the study team members' names, role in the project (statistician, data manager, project manager, etc.), and contact information (phone, email). Not only is it important to identify these key members at the beginning of any study, but throughout the study, this list must be managed and updated to reflect any transitions in the team.

<<Study Name>>			
<<Other study name(s) and study number(s)>>			
<<Compound Name and Compound Number>>			
	Contact Names	**Phone**	**Email**
Statistician			
DM			
PM			
CRO Name (if applicable)			
CRO Contact (if applicable)			
Clin pharm & DMPK / Clinical Science			
Safety			
Medical Monitor / Clinician			
Regulatory lead			
Clinical lead			
Medical Writer			

Figure 1. Study team contact information

STUDY FILES MANAGEMENT

Each organization and each project may have a file directory structure that is organized slightly differently. When working individually or with team members on project work, it is more efficient to have easy access to all pertinent study documents at your fingertips. This section contains file locations (can use hyperlinks) along with version and status of the programming or programming-related documents. See **Figure 2**.

Study file information in this section can include but are not limited to study protocol, statistical analysis plan (SAP), case report forms (CRF), mockup/shells, raw data, ADaM, SDTM, TLF, define-xml, and reviewer's guide locations.

	File Location (Link)	Version	Status
Protocol	[Study Name] Protocol	v1.0	Final
SAP	Study_01_SAP	v1.3	Final
CRF	Study_01_aCRF	v1.0	Final
Mockup/Shells (TLFs)	Study_01_Shells	v1.2	Final
Rawdata	Study_01_rawdata	8-Sep-17	Final
ADaM	Study_01_ADaM	8-Sep-17	Final
SDTM Link	Study_01_SDTM	8-Sep-17	Final
TLF Link	Study_01_TLF	21-Sep-17	Final
ADaM Define-xml	Study_01_adam_define	6-Dec-17	Draft
ADaM Reviewer's Guide	Study_01_ADRG	6-Dec-17	Draft
SDTM Define-xml	Study_01_sdtm_define	1-Dec-17	Draft
SDTM Reviewer's Guide	Study_01_SDRG	1-Dec-17	Draft

Hyperlink address:
<<Study 01 SDRG File Pathname>>

Figure 2. Study files – This section includes individual file location information as well as the document version number (or date) and status. In the highlighted example, "Study_01_SDRG" is hyperlinked to the Study 01 SDTM Reviewer's Guide file pathname and we can see that the most current version of the SDTM Reviewer's Guide is a draft from December 1, 2017.

STUDY HIGHLIGHTS AND DELIVERABLES

Another important part of managing any project involves managing project deliverables, highlights and activities.

Study	Deliverable	Owner	Start_Date	End_Date	Duration (Days)	Status	Follow-up / Comments
Study 04	SAP for Study 04 - has SAP been finalized yet?	Biostats	7/24/2017	12/1/2017	127	Completed	CRO will initiate SAP
Study 04	Received draft SAP and shells 12/1 - provide comments to CRO by next Friday, 12/8	Biostats	12/1/2017	12/8/2017	7	Completed	Provide 1st draft comments by 12/8/2017
Study 04	Received 1st draft SDTM datasets from CRO 11/22 - provide SDTM comments by 12/11/2017	Programming	11/22/2017	12/11/2017	19	Completed	Provided comments by 12/11/2017 - Done.
Study 04	Received 2nd draft SDTM 2/14/2018; comments need to be sent back 2/23/2018	Programming	2/14/2018	2/23/2018	9	Completed	SDTM comments sent back to CRO 2/23/2018 - Done.
Study 04	Received 1st draft ADaM; comments to be sent back 2/26/2018	Programming	2/14/2018	2/26/2018	12	Completed	ADaM comments sent back to CRO 2/26/2018 - Done.
Study 04	Received 3rd draft SDTM and 2nd draft ADaM from CRO - provide comments	Programming	3/6/2018	3/13/2018	7	Completed	Provide consolidated ADaM and SDTM comments for -04 study to CRO 3/13 - Done.
Study 04	Final SDTM datasets received; need to send email to CRO requested OpenCDISC report	Programming	3/28/2018	4/4/2018	6	Ongoing	
Study 04	Expect 3rd draft ADaM + TLF (safety and PK) April 6, 2018; need to provide PK content-related comments by April 13, 2018	Biostats, Programming	4/6/2018	4/13/2018	7	Future	Send to team for review

Figure 3. Study highlights and deliverables

This section (see **Figure 3**) includes but is not limited to the following: the specific study highlight or deliverable, the owner of the document (either the department or team or individual who owns the file), dates associated with the deliverable (start and end dates along with duration of the deliverable), status of the deliverable (whether it is an ongoing, completed or future item) and any additional comments.

RISK MANAGEMENT

Risk events may impact resource selection and availability, and so any risk updates should be carefully managed as well. Risk management involves risk identification, risk analysis, response planning and controlling risk on a project. This section of the project management tracking tool involves determining which risks may affect the project and documentation of prioritizing risks and determining the degree to which the risks affect the project. It can also include the options and steps taken to reduce these risks.

The example in **Figure 4** details a risk register with *qualitative analysis*. The identified risks are described in as much detail as possible under the *Risk* column. The probability (or likelihood) of the occurrence of the risk is estimated by assignment of "high", "medium", or "low" probability; the impact (or consequence) of the risk is estimated by assignment of critical "high", "medium", "low" or "critical" impact. The impact and probability assignment rules are specified by the organization or study team in advance of the project and may differ across studies. Responses to the occurrence of the risk are documented under the *Risk Mitigating Actions* column.

Date	Study	Risk	Owner	Deadline	Impact	Probability	Risk Mitigating Actions	Comments/concerns
3/12/2018	Study 04	PK results were sent to CRO on Monday, March 12, which is later than anticipated or planned; PK parameters will now be available March 21	ClinPharm, DPMK	3/21/2018	Medium	High	CRO will need to adapt timelines	Affects availability of PK TLFs (will now be available April 6)
3/15/2018	Study 04	Bank holiday 3/15, 3/16 in Hungary, update at site S01 cannot be performed before 3/19	DM	3/19/2018	High	High	Clarification of responsibilities (PM)	DBL will be delayed by a couple of days (**estimate now is the DB lock on Fri 23rd at the latest)**

Figure 4. Risk register

MANAGEMENT SUMMARY

A high-level summary of study highlights can be pulled across the multiple study tracker files and be presented as an aggregate report to upper management, such as the head of programming. The

summary report can be built according to the needs of upper management or the organization. For instance, one could build a report to include only any ongoing or future tasks that are due or any risks that have significant or critical impact on any of the projects.

The two-page summary that we propose pulls the relevant study highlights and deliverables status and timelines from each study as well as presenting any critical risks that upper management should be aware of.

AGGREGATE STUDY HIGHLIGHTS AND TIMELINES

The aggregate study highlights and timelines provide an overview of the status and timelines of the different study highlights and deliverables. We used the HIGHLOW plot statement as part of the SAS® Statistical Graphics (SG) procedures and Graph Template Language (GTL) to create a visual overview of ongoing, completed and future study deliverables (see **Figure 5**, see **Appendix** for SAS® program code). Each study deliverable is represented by a horizontal bar in the plot on the right-hand side of the figure. We use the *LowLabel* and *HighLabel* to display the start date and end date, respectively, of the study deliverable. The graph below uses the colors green, red, and light blue to classify ongoing, completed and future deliverables.

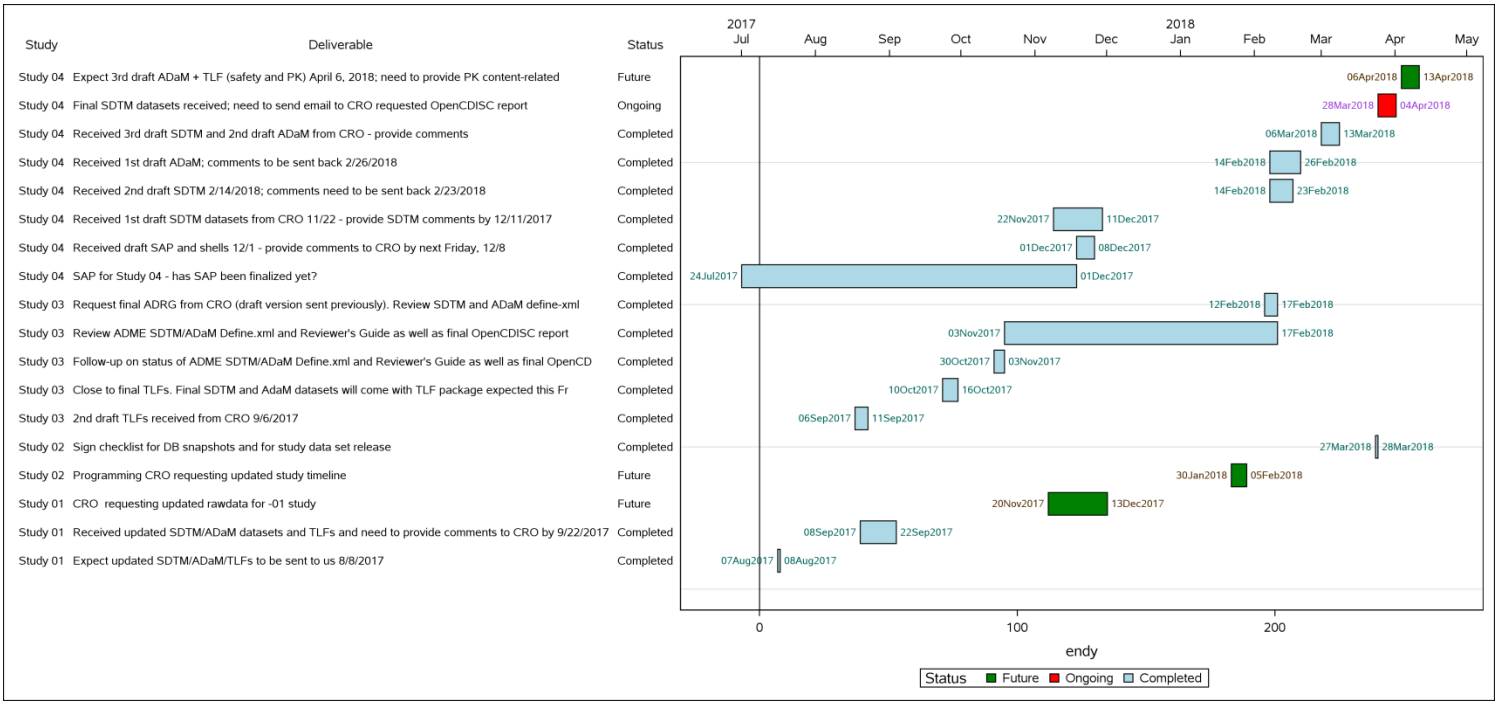

Figure 5. Aggregate study highlights and timelines

AGGREGATE RISK SUMMARY REPORT

The aggregate risk summary report provides an overview of the risks for all the studies. The report can be tailored to report certain degrees of impact to study or probability of risk. For instance, a report can be built to only show the risks that have high or critical impact on the studies (see **Figure 6**).

Study	Lead Programmer	Risk	Impact	Probability	Risk Mitigating Actions	Comments/Concerns
Study 01	Jack Sparrow	Resource needs for upcoming deliverables	High	High	Work with management to identify resources including hiring	
Study 01	Jack Sparrow	TLF Mock ups have not been reviewed by all stakeholders	High	Medium	Work with Project manager and statistician to develop TLF approval process which includes all critical stakeholders	
Study 02	Elsa of Arendelle	After study unblinding, TLF log may contain error when using unblinded data for first time to deliver outputs in 24 hours	High	Medium	Create a team of unblinded programmer which could run ouputs on unblinded data to find out issues earlier	
Study 02	Elsa of Arendelle	Uncoded AE terms for interim analysis	Critical	High	Periodic review of critical raw data	
Study 02	Elsa of Arendelle	Missing lab ranges	Critical	High	Periodic review of critical raw data	

Figure 6. Aggregate risk summary report

ADDITIONAL AGGREGATE REPORT SECTIONS

Additional aggregate reports can be created depending on the needs of the specific department or organization. An example of an additional aggregate report section would be to include additional resources, such as people, needed for each study deliverable so that upper management may have a better idea of resource allocation. Another example would be an overview of the file locations for each of the study trackers.

CONCLUSION

With the successful implementation of this proposed project management tracking tool for statistical programming teams, the lead programmer in the aforementioned scenario where the previous lead programmer of a study has left may now experience a smoother transition period. For the manager who wishes for easier access to the status of the projects that his/her direct reports lead, the high-level summary of study highlights and also risks analysis and response planning can be a useful and powerful tool.

The primary output of this proposed tracking tool is the initial entry to the specific excel workbook. As with any management and tracking tool, the tool should be reviewed and updated on a regular basis, as contact information, study deliverables, and tasks may change or new ones may become available or identified throughout the course of the project. The tool we present can be updated to the fit the needs of any statistical programming organization or team.

APPENDIX

The program below uses the HIGHLOW plot statement in SG Procedures and GTL to create an aggregate study highlights and timelines chart. The ***full*** data set includes the highlights and deliverables section from each of the individual study trackers. We use the parameter *y* instead of *x* to create horizontal bar segments as seen in **Figure 5.** We use the LowLabel and HighLabel to display the start date (low=stdy) and end date (high=endy) of each study deliverable.

```
data status;
      length status $9 xs 4 ys 4;
      input status $ xs ys;
      datalines;
Future        -100 -100
Ongoing       -100 -100
Completed     -100 -100
      ;
run;

*Full data;
data full;
      set status deliverables;
run;

*Define Attribute Map;
data attrmap;
      retain id 'Status';
      input value $1-9 fillcolor $11-19;
      datalines;
Future    green
Ongoing   red
Completed lightblue
      ;
run;

*Highlow Map;
ods listing gpath='<PATHNAME>' image dpi=400;
ods graphics / reset width=15in height=7in
imagename="Aggregate_Timeline" noscale;

title "Aggregate Study Highlights and Timelines";

proc sgplot data=full dattrmap=attrmap;
      format Start Date date9.;
      refline 0 / axis=x lineattrs=(color=black);
      highlow y=seqno low=stdy high=endy / type= bar group=status
                  lineattrs=(color=black pattern=solid) barwidth=0.8
                  lowlabel=Start Date highlabel=End Date attrid=Status;
      scatter y=seqno x=Start Date / x2axis markerattrs=(size=0);
      yaxistable Study Deliverable status / position=left
                  valueattrs=(size=8pt);
      yaxis grid display=(nolabel) offsetmax=0.02
                  values=(-10 to 250 by 10);
      x2axis display=(nolabel) offsetmax=0.02 ;
      yaxis grid display=(noticks novalues nolabel);
run;
```

```
ods  all  close;
ods listing;
```

REFERENCES

A Guide to the Project Management Body of Knowledge (PMBOK Guide®). Newtown Square, PA: Project Management Institute, Inc.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

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