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Managing Transitions So Your Life Is Easier

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ABSTRACT

Transitions can be a very troublesome time for everyone involved; managers, programmers and clients. It seems like a very simple thing to manage, however people still struggle with programming transitions, leaving a huge knowledge gap when a programmer departs the team. Effectively managing the information flow during a transition makes life much simpler, for both the transitioner and the transitionee.

The most common programming complaint from programmers taking over code is that there are chunks of code that do things that we aren't quite sure they should be, and sometimes code that we have no idea what it is actually doing. In this paper, we will lay out an effective transition plan, which can be applied to single program codes, full studies, and used across multiple roles - management, programming and statistics.

INTRODUCTION

Transitions impact everyone; whether on the management, programming, or statistical side of a project, and regardless of whether the transition is a planned or unplanned event, time and time again, we see teams struggle to cover this.

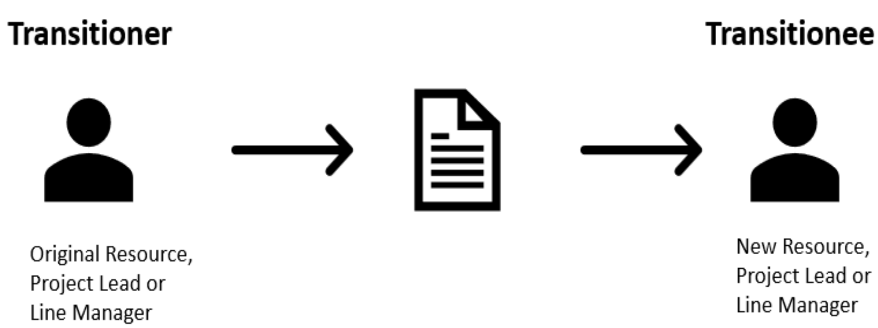
From a management perspective, you want to know that your team will continue on the project with no impact to quality, deliverables, and timelines; from a programming and statistical support perspective there is key information you need to ensure that you can complete the tasks that are transitioned to you.

Having a well-documented transition process that covers these roles for either an individual study, or a suite of studies will help ensure transitions stay in the "business as usual" state. This paper covers a transition process plan that can be used by an oversight project lead, a programmer, or a statistician.

TRANSITIONS – PLANNED OR OTHERWISE!

Obviously, a planned transition, a known leave of absence, for example, is easier to manage than an unplanned transition, such as a sudden unexpected long-term, or undefined, leave. Regardless of the transition being a planned or unplanned event, you need to document a current project snapshot.

The type of transition determines who the author is for the transition document. For a planned transition this would be the person doing the current role, for an unplanned transition, this would likely fall to the project lead, client oversight, or a line manager. In some planned cases, a transitionee may not be identified before the deadline date. This is a more unusual situation, however in these instances the transition of knowledge would be made to the project lead, or persons manager, who would then transition that knowledge to the appropriate person, once they were identified.



Different roles within the project will require different focus and information, but the key information that needs to be transferred will be the same.

TRANSITION PLAN CONTENT

A transition plan should be able to give you all the pertinent information regarding a specific study, and an immediate snapshot of the completed and outstanding tasks that were assigned to the transitioner. By documenting all the necessary information, in a consistent format, and walking through this information with the transitionee we can mitigate some of the inefficiencies and miscommunications that typically arise during these moments.

In the following sub-sections, we will go through the pertinent information that should be transferred and the reasoning behind including these specifics.

FIRST THINGS FIRST

The very first section of the transition document, should be able to give you an immediate overview of project, what role is transitioning and a quick highlight of the study status. As someone transitioning onto an ongoing study, getting this information helps bring you up to speed faster and gives you an immediate understanding of any urgency that needs to be associated with the study.

1. Role

This will be the role that is being transitioned; this paper focuses on the main biometrics roles we support; oversight for a suite of studies, project lead, project programmer and project statistician. It would be fairly easy to modify our examples from our transition document to account for other roles, just ensure that you capture the specific tasks related to that role.

2. Transition From and To

This is really collected for an audit trail history, the information from the transitioner is marked as passed to the transitionee, with a date noted for the final date of knowledge transfer discussion. Should this be an unplanned transfer, the transitionee may be an intermediate step, and will then pass along the information when the correct transitionee is identified.

3. Basic Project Information

It is very important to know the base project information, similar to when you start working on a study, you need to know the client, study number and the directory path that you will be working in. This also helps ensure that project directory access is requested and granted, and timesheets codes are set up.

4. Project Synopsis

The project synopsis is the next step up from the previous level of information. Now we document the premise of the study – usually the SAP synopsis is the perfect descriptor to use here. If the SAP has not yet been developed, please use the protocol to craft a synopsis indicating the phase, study type, treatment, and therapeutic area.

5. Current Deliverable Status

The current status is very helpful to ascertain an understanding of completeness of a study.

Are we in start-up mode; at SAP draft; draft TFL deliverables; interim analysis 3; or approaching final deliverables and database lock? Knowing this helps get an inkling to the scope of project work completed, and outstanding, and gives you the enough information to make sound strategic decisions.

6. Next Deliverable Date

This is to document the next upcoming deliverable date, it could be an internal or an external delivery, and the scope could be varied. This is one of the reasons why it is so important to document transitioning tasks, we need to know the dates and the scope of that deliverable, so we can prioritize our activities and evaluate the time to deliverable versus the outstanding project workload.

Client:	ClientA
Study Number:	StudyB
Directory Location:	ClientA/Project99/StudyB/

Study Description	A randomized, double blind, dose escalation study for patients with X disease, using DrugY in combination with DrugZ.
Current Status:	Programming of SDTM and ADaM datasets in progress, no TLF work started. Mapping specifications for SDTM and ADaM are signed off. Dataset programming around 65% complete.
Next Deliverable:	17th Feb 2021, SDTM and ADaM to client for review prior to TLF prog start.

KEY DOCUMENTS

This section of the transition document is extremely important, around 90% of the information in this section should have been covered during the project kick-off meeting. This information should be collated and distributed to study team members as they join the team, so regardless of type of transition, this should be known information to everyone on the project team.

Having this information stored in a central location in the study directory is not only useful for role transitions, but when any new team member joins, the lead can very quickly send out this list for onboarding reading/training before starting onto project work.

Directory links should always go to the base level directory. For example, the link for the protocol should open the directory at the /protocol level – it should not open a named protocol file, as if there are amendments those could be missed in the link updates.

Should more than one version of the file exist, please note the name of the most current file. There should be a note on any items that are in development, and a comment on their current status.

This list below will cover the majority of items that should be provided as reference documents for most roles within the biostatistics and programming group.

1. Timelines Location
2. Protocol
3. SAP
4. aCRF
5. SDTM Specs
6. ADaM Specs
7. Issue Log
8. Minutes
9. Project Tracker
10. Project Specific Training / Kickoff information
11. Review Comments

Important Documents	
Timelines	ClientA/Project99/StudyB/Docs/Timelines/Timelines.xls
Protocol	ClientA/Project99/StudyB/Docs/Protocol/ "ProtV2.pdf"
SAP	ClientA/Project99/StudyB/Docs/SAP/ "SAPV1.pdf"
aCRF	ClientA/Project99/StudyB/Docs/SDTM/aCRF/aCRF_10JAN2020.doc
SDTM Specs	ClientA/Project99/StudyB/Docs/SDTM/SDTM_Mapping_Final_20DEC2019.xls
ADaM Specs	ClientA/Project99/StudyB/Docs/ADaM/ADaM_Mapping_Final_3JAN2020.xls
Issue Log	ClientA/Project99/StudyB/Docs/Issue_Log.xls
Minutes	ClientA/Project99/StudyB/Docs/Meetings/Minutes/ "Team_Meeting_18JAN2021.doc"
Project Tracker	ClientA/Project99/StudyB/Docs/Project_Tracker.xls
Project Specific Training / Kickoff	ClientA/Project99/StudyB/Docs/Training DrugY.ppt, Client KO Meeting 20OCT2019.doc.
Review Comments	ClientA/Project99/StudyB/Docs/ **No files yet.**

NUMBERS SNAPSHOT

This is a great overview for the scope of the study – useful to management, programming, and statisticians for very different reasons. This information is usually available in your project tracking dashboard (if you do not have one of those – that is a subject for another day!).

From a management perspective, you can see at a glance the size of the study and use this to help work out resource allocations based on set timelines and ensure consistency of service.

From a programming perspective, you see the size of the study and number of outputs required, even if you are not responsible for them all.

From a statistical perspective, depending on when you transfer into the study this gives you an idea of how many mocks you are developing, an idea of how long programming will need, the number of items you will be checking and, if applicable, time needed for a senior review.

Study Number Overview Snapshot					
Type	**Total**	**Topline Tier1**	**Topline Tier2**	**Topline Tier3**	**% Complete**
SDTM	36				55%
ADaM	17				10%
Tables	235	125	85	25	0%
Listings	71	46	14	11	0%
Figures	42	5	37	0	0%
Ad-hoc	N/A	N/A	N/A	N/A	N/A
% Complete		0%	0%	0%	

ASSIGNMENTS/RESPONSIBILITIES

Assigned tasks on a study will differ whether the transition is for a programmer or a statistician, however having sections for specific and non-specific tasks on a transition document is useful for both roles. In some companies, statisticians are either production or validation for efficacy datasets, and key endpoint deliverables.

Specific Subset Overview of Assigned Programming

As useful as it is to get a view of the entire scope of a study, when it boils down to individual transition tasks, the newly assigned transitionee is typically most interested in the specific subset of work that they are now responsible for. This overview is a less detailed snapshot than the project tracker which we would suggest is screenshot and added into the transition document for all project tasks assigned to the transitioner.

The total number of assigned items, whether production or validation, is broken into categories and documented, along with the number of items that have reached completion in regard to the next programming/validation step.

In the example shown below, we see a total of 7 assigned datasets tasks across SDTM and ADaM, with 6 of these tasks programmed. The comments field gives an overview of validation/programming completeness.

Current Study Assigned Programming Status		
Type	**Programmed/Total**	**Comments**
SDTM	3 / 3	All 3 SDTM completed validation, P21 report checked.
ADaM	3 / 4	ADSL and ADEX programmed, in val. V_ADLB ready and v_ADVS in progress.
T	0 / 20	t-ae prog in progress
L	0 / 40	No output programming started
F	N/A	N/A
Ad-hoc	N/A	N/A

As you see can see from the numbers above, 0 of the assigned outputs have been programmed, as our example is from a study just moving through start-up. If you had 40 individual programs to name and document, or a large number of output programs, it would be perfectly acceptable to document this using the numbers overview format, shown below, and then list the program name details in the "Individual Task Descriptions" section

L	35 / 40	35 prod programmed. 20 passed val. 15 awaiting val, 5 to program, see study tracker for program details.

Non-standard Assignments

This section of the transition document came into play when we realized that it is not just the biostatistical programming tasks that we need to ensure are transitioned.

This is a wonderful area to make note of any other tasks that need to be transitioned that are being undertaken either for the client or the internal team; it might be that there is an upcoming monthly team meeting that now needs a minute taker, or that the client has requested an update on the team percent completes that is due next week, or that we have a "sister" study that can be used for some similar program codes.

Any Other Deliverables / Initiatives / Responsibilities / Guidance Information
ADaM specs for ADCM to finish review after client modification – see comments log,
Monthly meeting agenda to produce for FEB2021.
Please note STUDY X is a sister study and can be looked at for program code adaptation

Individual Task Descriptions

This section provides in-depth detail on the individual tasks that being transitioned, it details whether the work is production or validation, lists the program name, the status of the program, and additional details, such as name of programmer on the opposite side of the programming, questions that are outstanding on items, and if a single program creates multiple outputs.

This task list should correlate with the assigned numbers above, however, should one program create multiple outputs, please be aware that total numbers will not have a one-to-one relationship with the number of tasks in the tracker.

Study Tracker Assignments/Responsibilities ClientA/Project99/StudyB/Docs/Project_Tracker.xls			
Type	Program name	Status	Comments
PROD	dm.sas	Completed	Passed val.
PROD	ae.sas	Completed	Passed val.
VAL	lb.sas	Completed	Passed val.
PROD	adsl.sas	Ready	In validation (Validator : ASmith)
PROD	adex.sas	Ready	In validation (Validator : ASmith)
VAL	v_adlb.sas	Ready	Awaiting ADLB (Prod: ASmith)
VAL	v_advs.sas	In progress	Code 75%, awaiting stat feedback on Q. ADVS ready to check (Prod: ASmith)
PROD	t_ae	In progress	Will produce all 20 tables assigned
PROD	** Listings**	Not started	** See tracker at end for full assignment info*

* Please see screen shot of tracker items at end of template.

KEY PEOPLE AND MEETING INFORMATION

Lastly, we document the team members, both on the client and internal sides. We also document the meetings, along with the location of the templates for the meeting agenda and minutes, if applicable. Depending on the transition role, this may be of a higher or lower importance to you.

If you are the project lead or oversight, you may be required to communicate regularly and attend these meetings, as a study programmer you may only be required to attend certain ones. Regardless of role, it is useful to know the client and internal team, along with their roles in the project, for better understanding during team discussions.

Templates				
Meeting Agenda:				
Meeting Minutes:				
Key Team members – Introduction completed ☐				
Client:				
Name	Title	Role	Email	Phone
Name	Title	Role	Email	Phone
Internal:				
Name	Title	Role	Email	Phone
Name	Title	Role	Email	Phone

Team Meetings – Invites forwarded ☐			
Client:			
Weekly Team Meeting	<Date/freq>	Attendees:	
Meeting x	<date>	Attendees:	
Internal:			
Weekly Team Meeting	<date /freq>	Attendees:	
Meeting x	<date>	Attendees:	

CONCLUSION

A key component for managing change and transitions is communication, by building a clear framework for pertinent information during a transition, you facilitate an effective exchange of information across roles. This results in a cohesive transfer of knowledge, and reduces the time spent ramping up on projects and minimizes the risks to the timeline and deliverables.

Transitions are common in any organization, and it is imperative to learn how to navigate the transfer of knowledge in order to keep credibility and confidence with the client, and your internal teams. As with any task, input in equals input out, the more you support and promote effective transition plans, the more your team will value these, buy in on the process and reap the benefits.

CONTACT INFORMATION

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

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