Role Transition for a Programmer: tips and tricks to make it more efficient

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ABSTRACT:

When the time comes for a programmer to transition into a new project, either within their current organization or at another, it is in the interest of both the current programmer and future programmer to ensure a smooth transition. This paper gives guidance on key points to be considered and pitfalls to be avoided as a programmer for internal or external transition. An example of transition plan will be presented and will cover responsibilities (Ongoing and upcoming work assignments), list the daily tasks, timelines, team members, expectations, and instructions to name a few. These attributes need to be tuned to ensure maximum synergies with minimal disruption in daily routines. Close insight of current programmer's work and projects is required so that successor is confident to complete the project successfully. Methods for effective transition management are discussed and lessons learned documented, which would immensely help all lead programmers.

INTRODUCTION:

In the world of statistical programming within the pharmaceutical industry, programmers have shifted roles, especially for the permanent staff that was originally hired to do statistical programming "hands-on". The lead programmer is responsible for managing and coordinating the requests for statistical analysis of clinical data, understanding ongoing and upcoming projects, planning and forecasting resource needs, tracking projects, evaluating workload and coordination of role based associates. Programmers are also expected to possess strong statistical and analytical skills, have in-depth knowledge about the molecules and the clinical data they support, contribute to process improvements to increase efficiencies, and ensure compliance with company policies and procedures. If a programmer transitioned into a new project, within the organization or at another, they are expected to ensure a smooth transition without disruption in project quality, with speed and in a timely manner.

Transition is an essential part of the project planning process. A Transition Plan is a comprehensive list of objectives, assignments, and itineraries that are needed to fulfill the delivery of a project solution. Transition plans require a great deal of preparation and research before they are executed. This paper presents a range of suggestions from which programmer may select ideas that would be useful in their particular context. It is not expected that every suggestion outlined here will be an appropriate solution or incorporated in every pharmaceutical company's transition-planning process.

ROLE TRANSITION PROCESS

When a role transition takes place, the following information will be very helpful for both incumbent and successor. Three important stakeholders required: Project Manager (PM), Outgoing Statistical Programmer (OSP) and Incoming Statistical Programmer (ISP).

Figure 1: Below shows the end-to-end process of Role Transition:

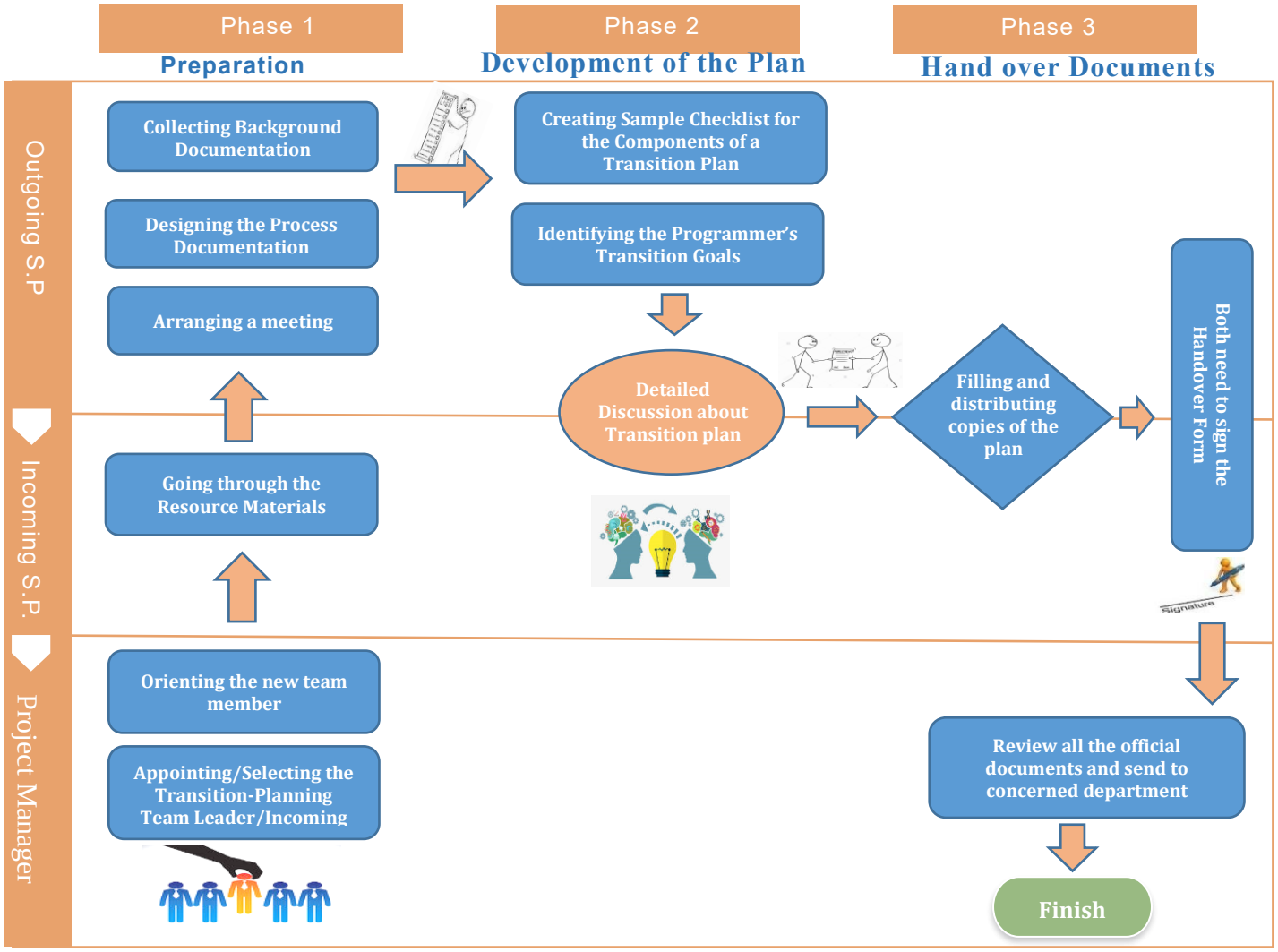
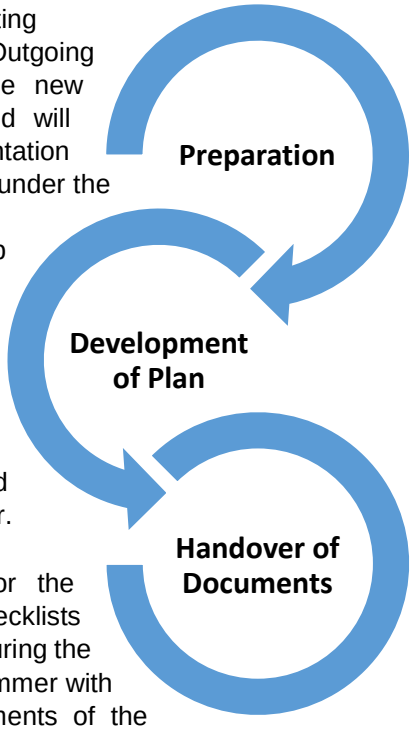


Table 1. Transition Check List Items:

1. Project Access & Documents	2. Project Programming details	3. Project timelines
• Working directory • List of documents ✓ SOPs ✓ Protocol ✓ CRF and CRF completion guidelines ✓ Data Quality Plan ✓ Data Transfer Specification ✓ Statistical Analysis Plan ✓ Table Figure Listings shell ✓ Programming Datasets Specification -SDTM / ADaM ✓ Tracking file ✓ Project Summary Report ✓ Case report tabulation files	• Macros • Metadata • Standard guidelines with version ✓ SDTMIG ✓ ADAMIG ✓ Pinnacle 21 ✓ MedDRA ✓ WHODD ✓ CTCAE ✓ Etc... • Issue Tracker	• Study-level deliverables • DMC / IA / CSR • Development /Validation status of datasets &TFLs (detail information can keep in assignment tracker)
4. Stakeholder's contacts	**5. Miscellaneous**	
• Statistics team • Data Management team • Programming team • Medical writer • Global Clinical Lead • Brand Safety Lead • Regulatory Manager • PK Sciences team • Clinical Team	• Decision happened mails • Important meeting recording links • Minutes Of Meetings mails or documents of respective study • Acceptance check sheet(if any)	

Three important phases with each stakeholders responsibilities:

- Phase I – Preparation
    - Project Manager takes part in the role of selecting and appointing Incoming statistical programmer to take over from the Outgoing statistical programmer. Project Manager will introduce the new Incoming statistical programmer during CTT meetings and will distribute new contact details to all the required parties. Orientation and distribution of orientation documents of the ISP also falls under the Project Manager's responsibilities.
    - Outgoing statistical programmer is responsible for setting up the role transition meeting with Incoming statistical programmer. This person is responsible for collecting background documentation and designing all the transition documents required to handle the role transition to the Incoming statistical programmer.
    - Incoming statistical programmer is responsible for reviewing and familiarizing themselves with all the orientation and resource material provided by Outgoing statistical programmer.
- Phase II – Development of Plan
    - Outgoing statistical programmer creates the checklist for the handover documents as well as the transition plan. These checklists are described in detail in next section. A detailed discussion during the role transition meeting is held with Incoming statistical programmer with regards to the checklists and all relevant resource documents of the Transition Plan.
- Phase III – Handover of Documents
    - Both Outgoing statistical programmer and Incoming statistical programmer are required to complete and distribute copies of the transition plan to required parties. Both Outgoing statistical programmer and Incoming statistical programmer needs to sign off on the handover form before sending to project manager.
    - Project Manager reviews and approves all the relevant documents after the transition has taken place. These documents are then distributed to the concerned departments.



Checklist Item 1: Project Access & Documents

This is first on the list because it is the most critical to a smooth transition. In any complex system, there is a huge amount of context that cannot be transferred via static documentation. It is invaluable to have someone around who understands why the process is the way it is, knows the occasional workarounds that were needed, can quickly get to the root of a problem, knows what stakeholders can quickly answer questions, etc. Give the Guidance to get the access to all working environments. Which consist of above-mentioned list of documents. This person can also provide the path, status and responsible stakeholder contact of respective documents listed. Below example format can be used to give more information of the documents.

Study	Document Name	Description	Location	Status	Responsible	Remarks
ABCXX2201	SAP	Statistical Analysis Plan	XXX/XX/abc	Draft	Statistician Name	

Checklist Item 2: **Project Programming details**

Some pieces of a project, such as the environmental setup, study level macro utilization, metadata and versions of standard guidelines require very detailed instructions that are not performed very often. If these details are not documented, the information could be lost. Worse yet, if some subtle piece of the setup information is missed or lost, the environment may appear to work correctly, but behaves differently than expected due to missing components or data.

Documentation is great, but it is difficult to keep up to date. To overcome these difficulties, there should be a read me file for each study, which consist of all the data related issues, programming challenges, and which macro is getting used for which task and what are the versions using for standard guidelines documents. If a study is at DMC stage, which programs needs to be updated for cutoff date after DMC.

Checklist Item 3: **Project timelines**

Provide the milestones of the project with predefined timelines along with the status of the deliverable. Multiple deliverables like DMC, IA, CSR, DSUR, PSUR etc. could form part of the study. Make sure to provide the information about upcoming events and current status. This includes FPFV, LPLV, DMC, IA, Final delivery, CSR dry run, DBL final delivery etc. List out the all activities of the study. If DMC is ongoing at time of transition, provide the resource gap (if any) for next millstone (either it's for IA or CSR). If your project has external dependencies, then it is a good idea to document those. This will ease the determination of any unfinished work, latest changes made to the project, who were involved and a huge amount of context as to how the study is performing.

Checklist Item 4: **Stakeholder's contacts**

It is always good to have contact information of team members who are involved in the study with their roles either it can be directly or indirectly. Therefore, whenever input is required, the team members can be reached to avoid any delays in the study. In addition, this will provide an idea of working hours, since these members may be working in different locations around the world.

Checklist Item 5: **Miscellaneous**

Finally, important emails and meeting recording links need to be incorporated in transition. This can provide information on future tasks and will contain decision-making proofs. Minutes of meetings need to be handed over to successor.

CONCLUSION:

Current trends of statistical programming activities place a greater burden on the management of analysis and reporting projects. This burden should not be carried by the lead programmer alone as project quality, timeliness and cost cannot be compromised. This is the premise for bringing in a programming transition checklist document to increase team efficiency and reduce project risks.

These five pitfalls are not the only potential dangers lurking in the shadows for the successor, but are recurring themes. Whether new to the role or more experienced, if a successor develops an awareness of these situations, it will be empowering and help in proactive decisions that will contribute to the project's satisfaction.

DISCLAIMER

The contents of this paper are the work of the authors and do not necessarily represent the opinions, recommendations or practices of Novartis Healthcare Private Limited.

ABBREVIATIONS

ADAM	Analysis Data Model
CSR	Clinical Summary Report
CTCAE	Common Terminology Criteria for Adverse Events
CTT	Clinical Trial Team
DMC	Data Monitoring Committee
FPFV	First Patient First Visit
IA	Interim Analysis
ISP	Incoming Statistical Programmer
LPLV	Last Patient Last Visit
OSP	Outgoing Statistical Programmer
PM	Project Manager
SDTM	Standard Data Tabulation Model
SOP	Standard Operation Procedure
WHODD	World Health Organization Drug Dictionary

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