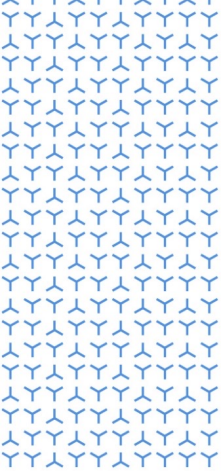




Role Transition for a Programmer: tips and tricks to make it more efficient

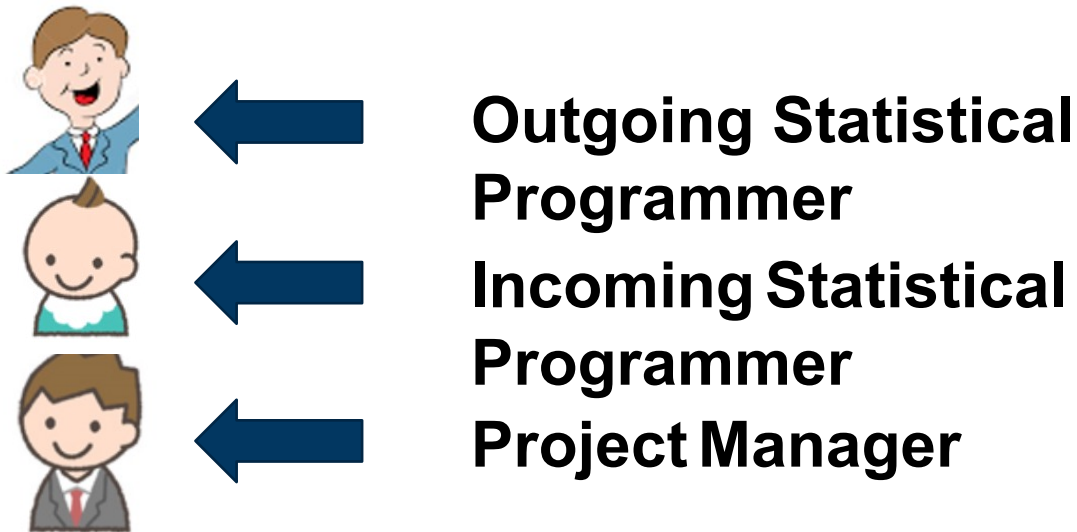
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Disclaimer

- 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.
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Target audience



- **All the statistical programmers either he is outgoing S.P. or Incoming S.P. and Project Manager**

Outline

- **Introduction**
- **Phases of Role Transition Process :**
 - ✓ Phase 1-Preparation
 - ✓ Phase 2-Development of the Plan
 - ✓ Phase 3-Hand over Documents
- **Transition Check List Items:**
 - ✓ Project Access & Documents
 - ✓ Project Programming details
 - ✓ Project timelines
 - ✓ Stakeholder's contacts
 - ✓ Miscellaneous
- **Conclusion**

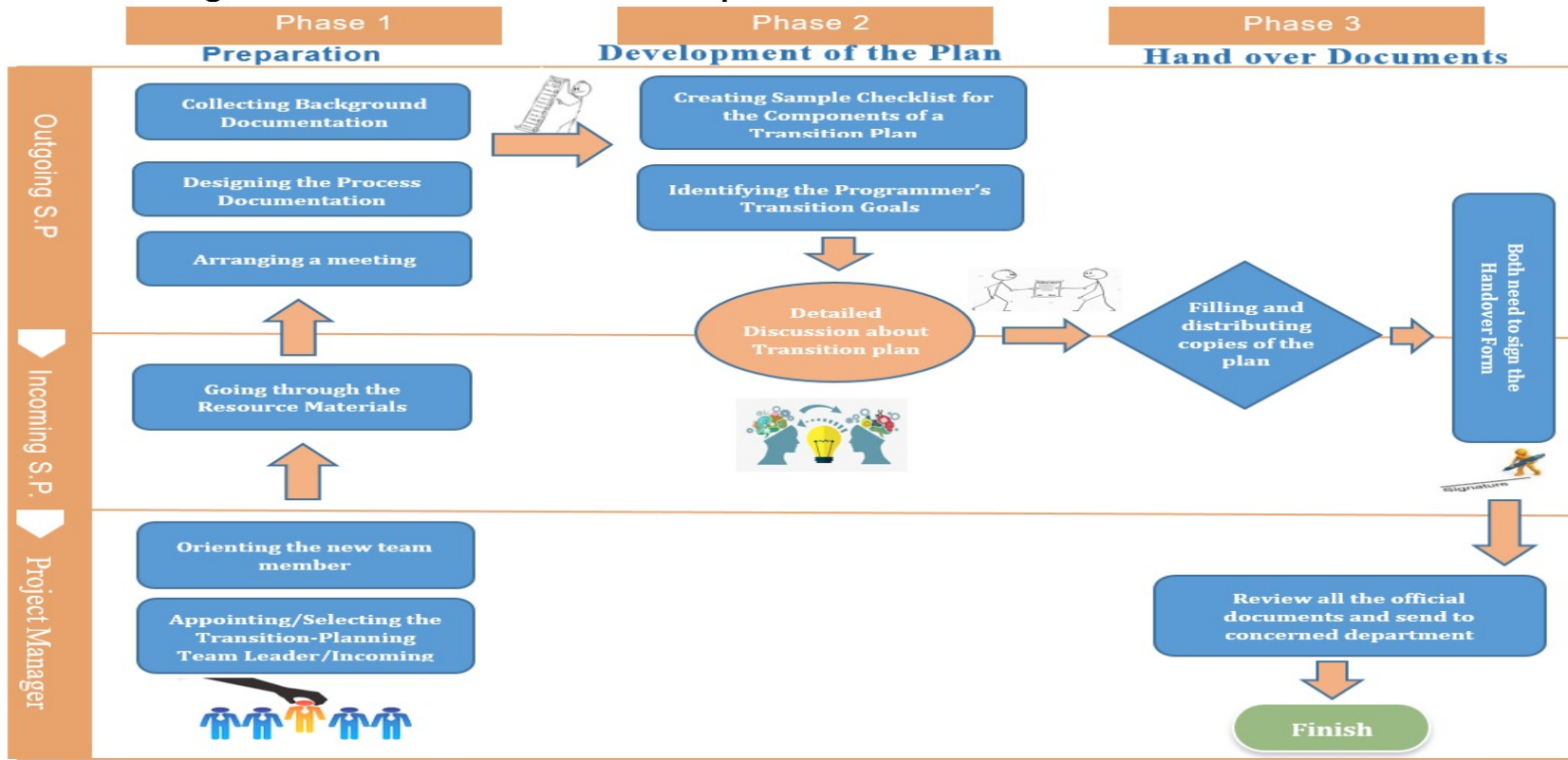
Objectives

- Guidance on considerations and pitfalls to be avoided for internal or external transition.
- Suggestions of select ideas that would be useful in their particular context.
- It will cover responsibilities like
 - ✓ Ongoing work assignment & future assignments
 - ✓ List the daily tasks
 - ✓ Timelines, team members
 - ✓ Expectations & instructions
- Methods for effective transition management.

Introduction

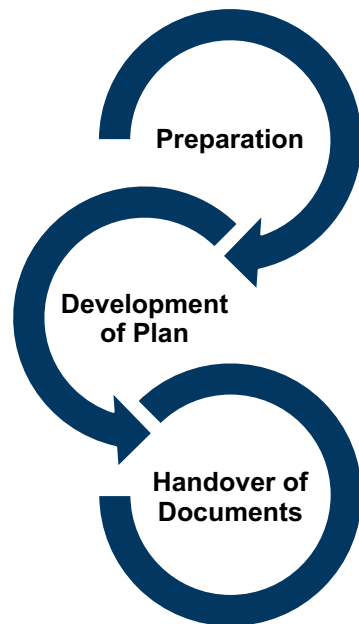
- The lead programmer is now responsible for:
 - Managing and coordinating the requests for statistical analysis
 - Understanding ongoing and upcoming projects
 - Planning and forecasting resource needs
 - Tracking projects
 - Evaluating workload and coordinating an increasing number of role based workers
- Either programmer transitions into a new project within their current organization or at another.
- A Transition Plan is a comprehensive list of objectives, assignments and itineraries.
- Transition plans require a great deal of preparation and research before they are executed.

ROLE TRANSITION PROCESS FLOW



ROLE TRANSITION PROCESS

- Phase I – Preparation
 - Select and prepare ISP.
 - Setup the Role Transition Meeting.
- Phase II – Development of Plan
 - Create checklist and Transition Plan.
 - Run the Role Transition Meeting.
- Phase III – Hand over Documents
 - Complete and distribute Transition.
 - Sign off on the Handover Form.
 - Hand over documents to PM.



Transition Checklist Item 1:

Project Access & Documents

- Ensure access to all working directories.
- Compile list of documents.
- Confirm status and location of documents.
- Confirm document responsibilities.
- Confirm owners of documents.

- 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

Transition Checklist Item 2: Project Programming Details

- Compile list of Macros.
- Confirm status and location of macros.
- Ensure use of metadata.
- Confirm status and location of metadata.
- Review use of standard guidelines for study.
- Ensure Issues Tracker is setup.
- Confirm status and location of Issues Tracker.

- Macros
- Metadata
- Standard guidelines with version
 - ✓ SDTMIG
 - ✓ ADAMIG
 - ✓ Pinnacle 21
 - ✓ MedDRA
 - ✓ WHODD
 - ✓ CTCAE
 - ✓ Etc...
- Issue Tracker

Transition Checklist Item 3: Project Timelines

- Confirm all study level deliverables and how and when these deliverables take place.
- Confirm status of all datasets, TFLS and any other deliverables.

- Study-level deliverables
- DMC / IA / CSR
- Development /Validation status of datasets &TFLs (detail information can keep in assignment tracker)

Transition Checklist Item 4: Stakeholder's Contacts

- Ensure you have received all contact details required.
- Make sure that your contact details are distributed to all concerned parties.

- Statistics team
- Data Management team
- Programming team
- Medical writer
- Global Clinical Lead
- Brand Safety Lead
- Regulatory Manager
- PK Sciences team
- Clinical Team

Transition Checklist Item 5: Miscellaneous

- All important information, emails, recordings, minutes, lesson learned etc. is required.

- Decision happened mails
- Important meeting recording links
- Minutes Of Meetings mails or documents of respective study
- Acceptance check sheet(if any)

Conclusion

- Current trends place a greater burden on management of analysis and reporting projects.
- Project quality, timeliness and cost cannot be compromised.
- All the information given is not a complete set and is based on recurring themes and personal experience.
- Whether new to the role or more experienced it will be empowering and proactive.

End

ANY
QUESTIONS

