
How to Set-up a Project/Study in Statistical Programming – Experiences, Best Practices and Recommendations

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Agenda

- Background
- Scope
- Key Focus Areas
- Future Plans
- Q&A



Background

- Project Leads for new projects in two different sites
- Questions, Questions, Questions !!
- End-to-end guidance across sites but project variability
- Variety of tools, systems and best practices across sites and projects

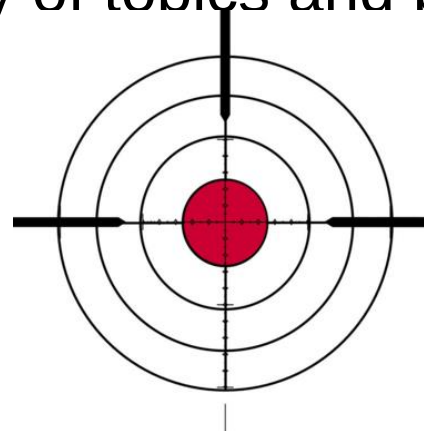


Ultimate aim

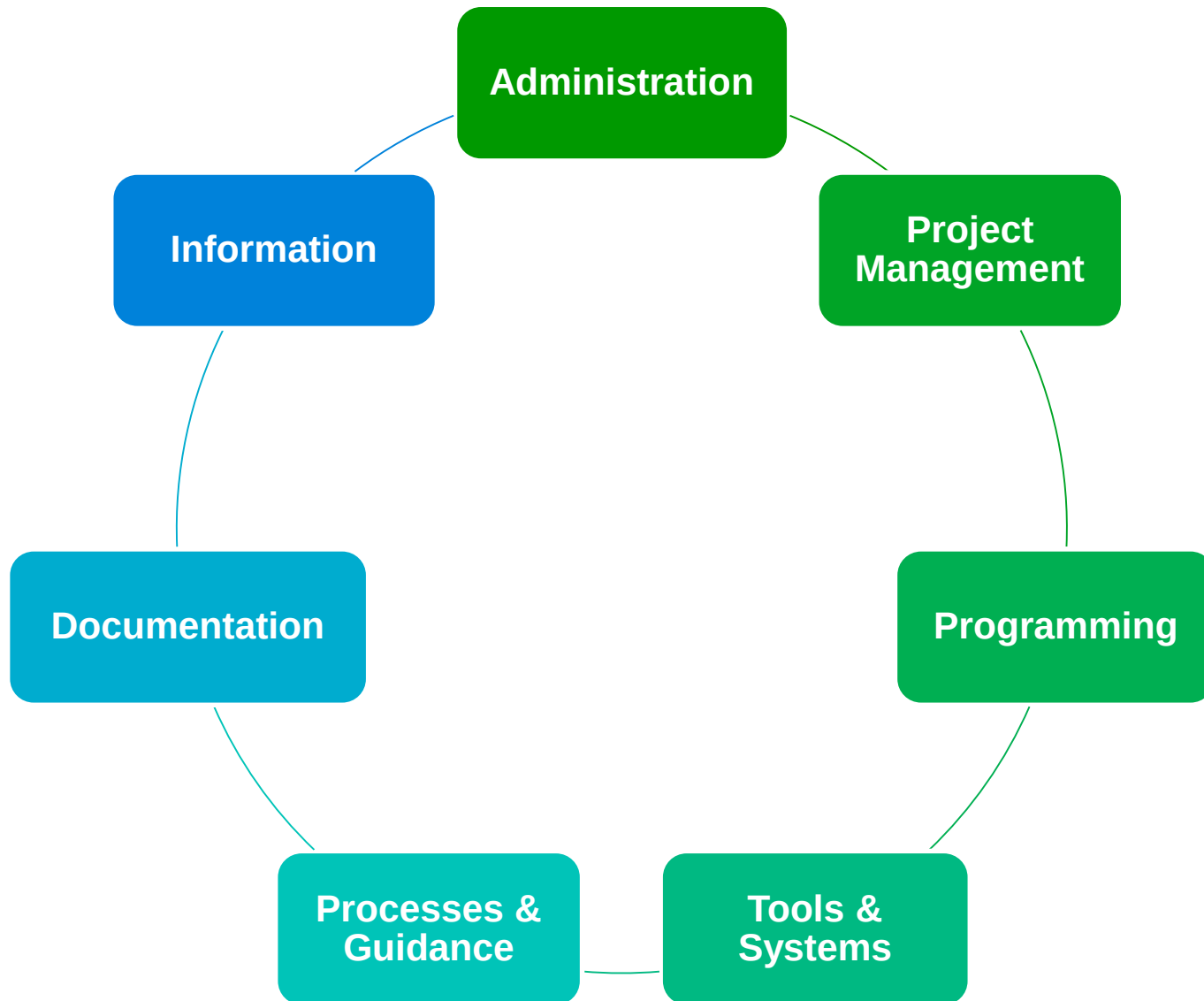
→ Create best practices reference for teams and move a step closer towards a more harmonised, standardised approach

Scope

- Informal best practices reference document, particularly for leads setting up a new project/study
- Based on experiences of the authors in setting up/ leading a number of different drug projects in different therapeutic areas (TAs)
- Not meant to be a final or exhaustive list of topics
- The document covers a broad array of topics and provides recommendations where possible



Key Focus Areas



Key Focus Areas – Administration

- Administrative considerations including :
 - On-boarding new project / study team members
 - SOPs / Guidances
 - Distribution Lists
 - E-mail rules
 - TA/Disease Background & Updates for Team Members
 - Back-ups for team members, Other Functions & wider team Members
 - Resourcing



Key Focus Areas – Project Management

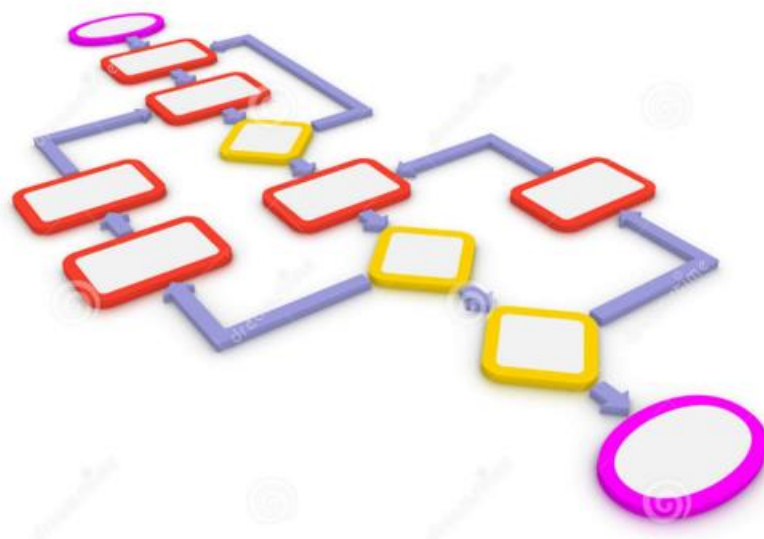
- Project Tracking and Management Tools
- Project Area set up
- Reporting Event Calendar/Tracker for current tasks
- Reporting event metadata and strategy
- 2nd line QC tracking
- Platform for discussions (e.g. Internal Discussion Platform or email)
/ Communication Strategy



- Information flow (from study leads to project lead)
- Execution of regular reporting events
- Debriefs and Lessons Learnt, Feedback

Key Focus Areas – Programming

- Program / TLG Naming Conventions
- Project & Programming Principles
- Data Cut Rules Implementation
- Agreement on autoexecs
- Titles & Footnotes Handling
- Dependencies of Datasets and Programs
- Medical Dictionaries
- How / Where to store Meta-Data
- Blinding



Key Focus Areas – Programming

- Handling of Table Shells / Dummy Outputs
- Best use of in-house reporting tool
- Catalogue for non-standard Templates and Outputs
- Rules for Log-Checking (Programs/Outputs)
- Post-Release Revisions
- Re-use of existing datasets/code for ad-hocs?
- Master/Program - Template for the Project
- Promotion to production environment clarity (e.g. on behalf of someone)

Key Focus Areas – Tools & Systems

- Directory Setup, Hierarchy, Naming conventions
- Use of Utility scripts and features
- New Reporting environments
- Supporting tools
- New tools : SPOTFIRE, R, Document Repository



Key Focus Areas – Processes and Guidance

- Ad-hoc Request Handling
- Filing Strategy, HA interactions, E-sub considerations
- Statistical Analysis Plan - process, authoring, review
- Kick off Meetings (with the rest of biometrics)
- Data Quality Issues
- Meetings & Discussions
- IDMC & IDCC
- Trial Master File



Key Focus Areas – Documentation

- Programming Plan/ Catalogue (Meta Information)
- Study Documentation – Statistical Analysis Plans, STUDY INFO sheets, COOKBOOKS
- Logs - Decisions, Actions, SAP update, Data Quality
- Meeting Minutes – Departmental, Project, Study



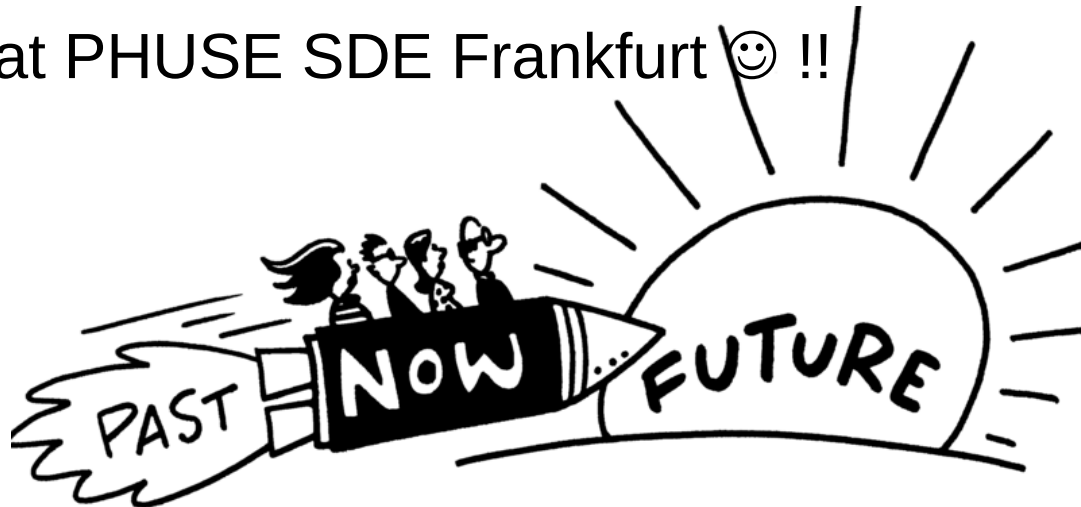
Key Focus Areas – Information

- Key supplementary information
- Understanding the Experiment/Study
- Understanding the Medical Review Plan
- Data Flow
- Teams & Committees
- Statistical interpretations & study specific data
- Useful Tools Information



Future Plans

- Integrate this document into a wider study-life-cycle guidance
- Governance model
- Look for collaboration across the department to keep it live
- Continue to enhance the document
- Present at PHUSE SDE Frankfurt 😊 !!



Q & A

Roche



Doing now what patients need next