
A Standardized Collaborative Approach for Statistical Programming Project Information

Strategy in Programming (SP10)



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Agenda

- Introduction
- Background & Rationale
- Key Concepts
- Additional Considerations
- Recommended Content and Useful Functionality
- Conclusion - Q&A

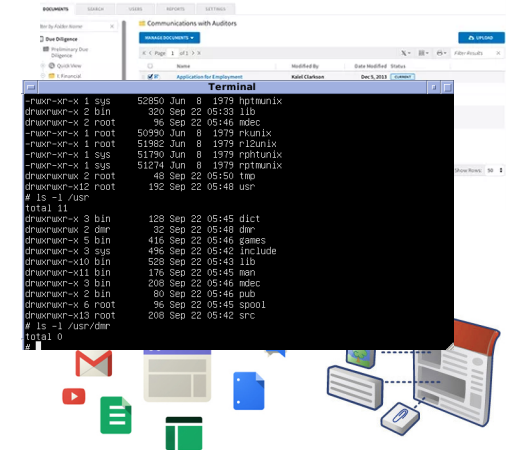


Introduction

Statistical programming **project information areas** are usually subjective to what the lead statistical programmer inherited, is familiar with or preferred look of a tool.

This can be difficult for new or existing statistical programmers to **access, manage, share** or even **find information**.

We need to be more **agile** and **efficient** - spending time searching for information, obtaining access or updating information should be **easy** and **intuitive**.



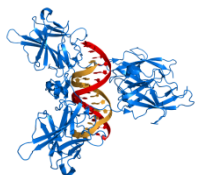
Background and Rationale



Improve **agility** for
molecule **transition**
between sites and resource
changes between molecules



Complex programming
landscape and
stakeholders



Increased **combination**
studies



F.A.I.R. Data

Findable

Accessible

Interoperable

Reusable

Key Concepts

Standardized

- Consistent look/feel of project level information within the project and between projects
- Allows users to navigate easily between study and project information quickly without having to familiarize themselves with a different information landscape



Key Concepts

Collaborative

- Crowdsourced information creates higher levels of engagement, less maintenance by the owner and improve accuracy
- Share the work



A standardized and collaborative approach will create an ideal “one-stop-shop” for statistical programmers

Additional Considerations



Accessible

- limited restrictions within the organization
- links to sensitive areas



Intuitive

- easy to navigate and build capabilities
- leverage existing user strengths



Supported, Secure and Stable

- long term support and secure
- upgrades with minimal down-time

Recommended Content and Useful Functionality

Content may be statistical programming specific or Biometric end-to-end

- **Project** specific information may include:
 - Molecule strategy
 - Planned filings, ICSD, DSURs
 - List of project lead names and info of key stakeholders
- **Study** specific information may include:
 - Links to study documentation, outputs, QC, code area
 - Key deliverables, milestone, project management
 - List of key stakeholders



The contents should be enough to serve as an ongoing transition portal should there be any resourcing changes or desire to share information

Recommended Content and Useful Functionality

Some important **functionality** you may want to consider:

- Integration with other tools/websites
- Embed links to key documents
- Macros
- Import/export
- Search feature
- Render documents or multimedia
- Mobile application
- Project management



**When applied all of these functional capabilities help
create an efficient “one-stop shop”**

Conclusion

- Primary difficulties establishing this framework may be around the organizations **tools available** and **change mindset**
- Direct impact can include increased **agility** and **collaboration, filing readiness, transparency** and **big picture**
- Less obvious impact can include more **meaningful conversations** with managers and stakeholders

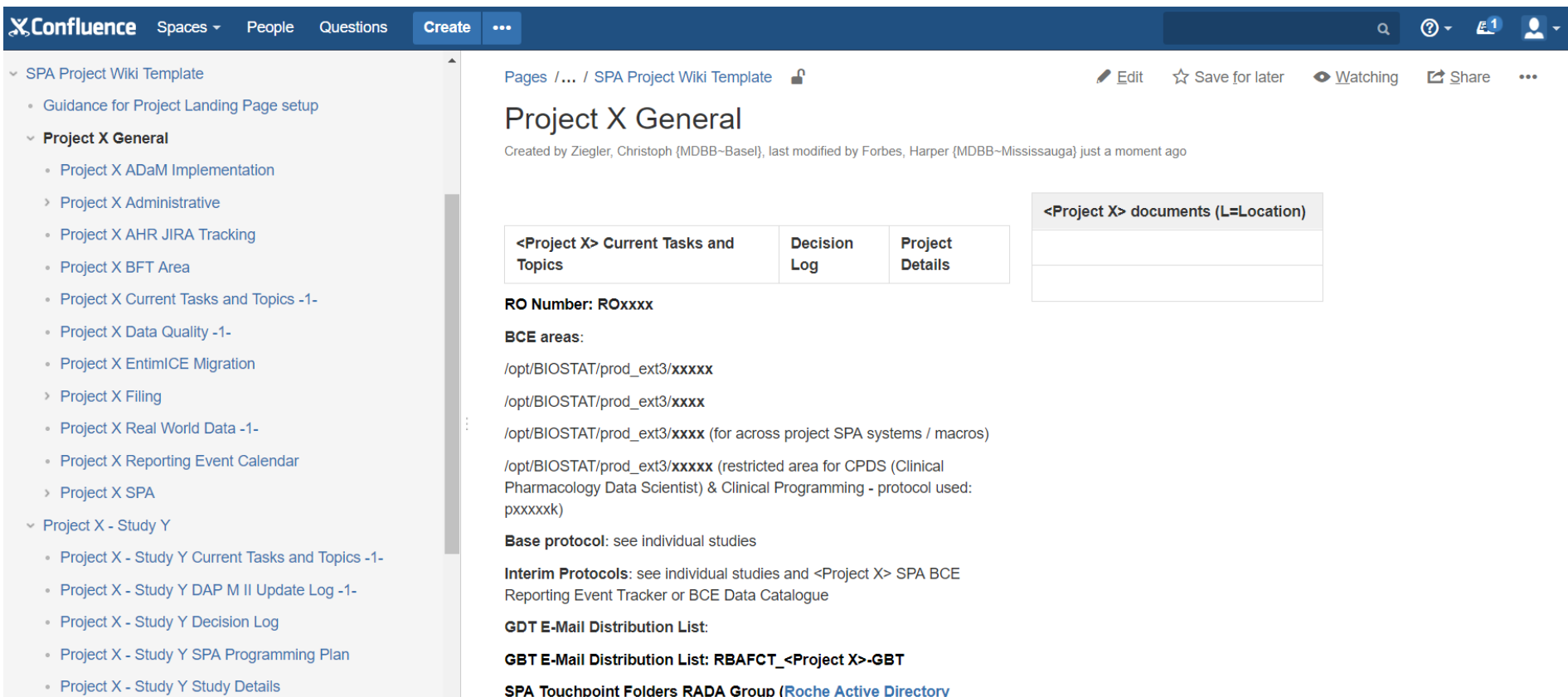




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Backup Slides

Sample Project Information Area (using Atlassian Confluence)



The screenshot displays the Atlassian Confluence interface. The top navigation bar includes 'Confluence', 'Spaces', 'People', 'Questions', 'Create', and a search icon. The left sidebar shows a tree view of the 'SPA Project Wiki Template' with sections like 'Guidance for Project Landing Page setup', 'Project X General' (expanded), and 'Project X - Study Y'. The main content area is titled 'Project X General' and includes a breadcrumb 'Pages / ... / SPA Project Wiki Template'. Below the title, it states 'Created by Ziegler, Christoph (MDBB-Basel), last modified by Forbes, Harper (MDBB-Mississauga) just a moment ago'. The content is organized into three columns: '<Project X> Current Tasks and Topics', 'Decision Log', and 'Project Details'. The 'Current Tasks and Topics' column contains text about RO Number, BCE areas, and Base protocol. The 'Project Details' column has a table titled '<Project X> documents (L=Location)'. The 'Decision Log' column is currently empty.

Project X General
Created by Ziegler, Christoph (MDBB-Basel), last modified by Forbes, Harper (MDBB-Mississauga) just a moment ago

<Project X> Current Tasks and Topics	Decision Log	Project Details				
RO Number: ROxxxx BCE areas: /opt/BIOSTAT/prod_ext3/xxxxx /opt/BIOSTAT/prod_ext3/xxxx /opt/BIOSTAT/prod_ext3/xxxx (for across project SPA systems / macros) /opt/BIOSTAT/prod_ext3/xxxxx (restricted area for CPDS (Clinical Pharmacology Data Scientist) & Clinical Programming - protocol used: pxxxxxk) Base protocol: see individual studies Interim Protocols: see individual studies and <Project X> SPA BCE Reporting Event Tracker or BCE Data Catalogue GDT E-Mail Distribution List: GBT E-Mail Distribution List: RBAFCT_<Project X>-GBT SPA Touchpoint Folders RADA Group (Roche Active Directory)		<table border="1"> <thead> <tr> <th><Project X> documents (L=Location)</th> </tr> </thead> <tbody> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </tbody> </table>	<Project X> documents (L=Location)			
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