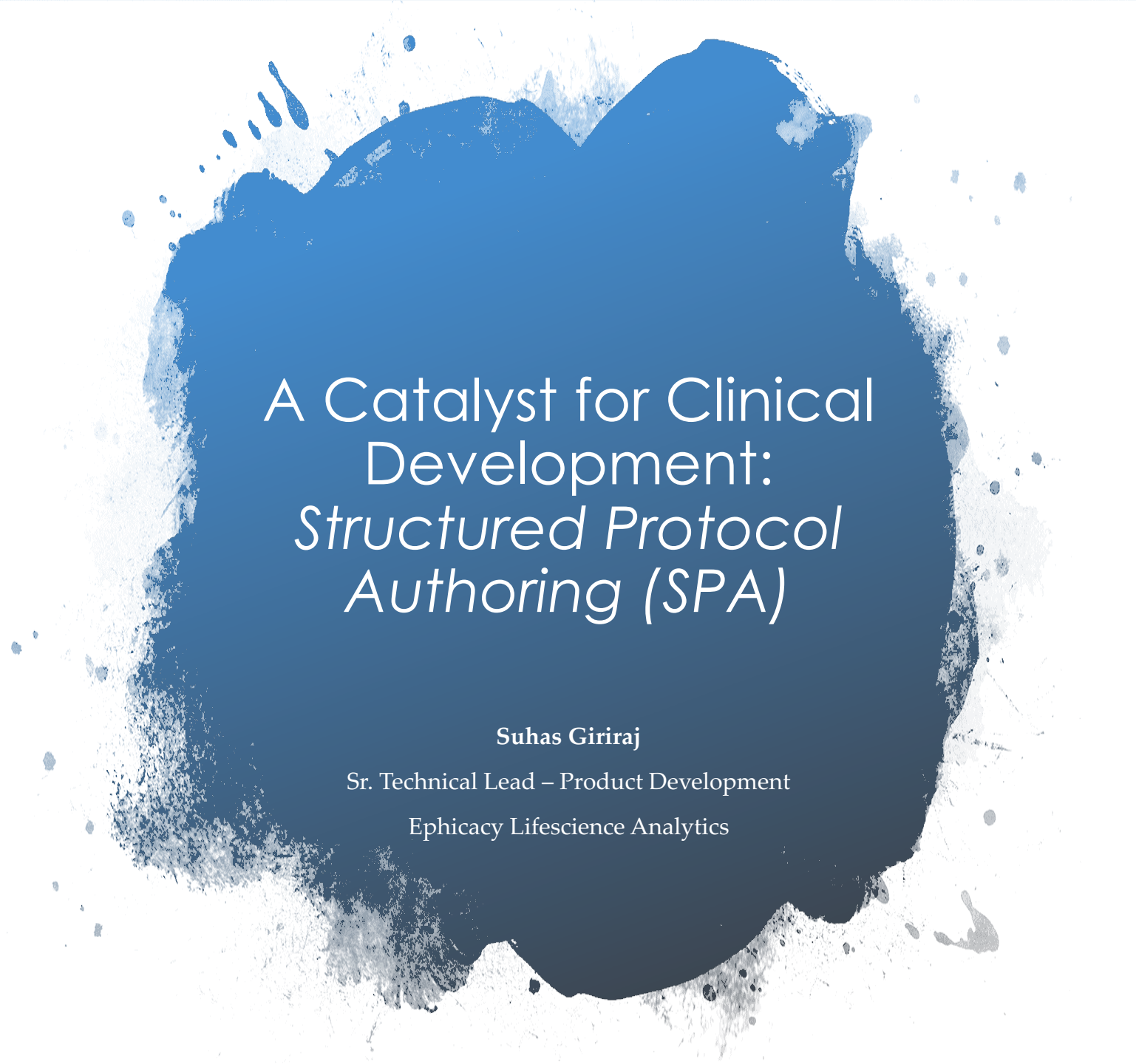




A Catalyst for Clinical Development: *Structured Protocol Authoring (SPA)*

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About me



Suhas Giriraj

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- I live in Bengaluru, the IT hub of India!
- Working as Senior Technical Lead and a full stack developer at Efficacy Lifescience Analytics Pvt. Ltd from past 5 years.
- 10+ years experience in software development, mostly on Ruby and ReactJS.
- Have been developing cloud-based applications for pharmaceutical companies from past 5 years.
- Contributor of Metadata Repository(MDR) and Statistical Computing Environment(SCE) product developments. Currently leading the product development for SPA.
- Love to ride bike and explore new places and food.

Abstract

In the clinical domain, Clinical Development Plan (CDP) provides an overview of the drug development strategy for all indications and describes the plan for the clinical studies to be carried out.

A tool christened **Structured Protocol Authoring (SPA)** is a cloud-based SaaS application for collaboration space, allowing better and easier input from stakeholders aiding in developing a robust protocol.

This tool is used to capture protocols in machine-readable form, saving time by promoting reuse of protocol elements from standards or past studies, configuring CDP structure and document templates, thus improve quality and preventing amendments through comparison against benchmarks and competitor studies; being in sync with medical writing with familiar Microsoft Office Online and visualizations in powerful layouts views(Gantt charts or tables).

SPA's audit trail feature captures every change made in structured study design and CDPs. It ensures regulatory compliance making it the most powerful SaaS footprint in the biopharmaceutical industry.

Current Challenges in Planning Clinical Development



Planning and forecasting techniques are neither sophisticated nor scientific.



Frequently unable to tie project forecasts to historical data.



No systems in place to archive and track past projects and activities.



Intensive process resources and tough data comparisons.



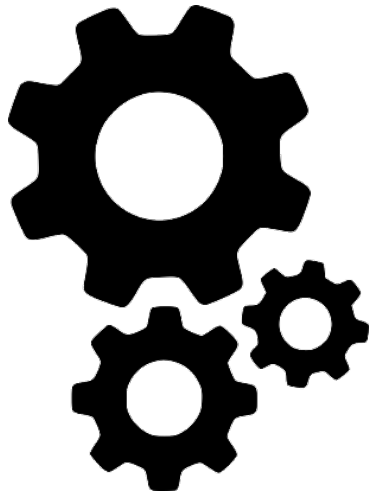
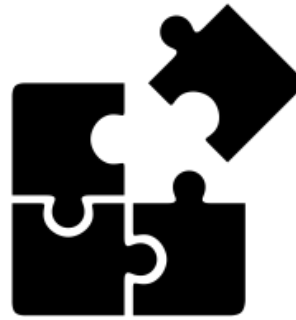
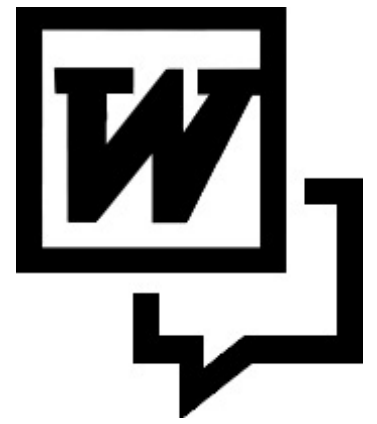
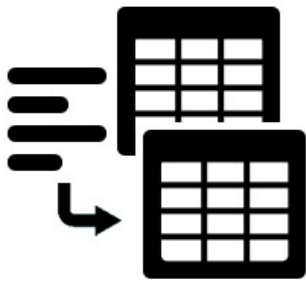
Lack of a centralized repository - leading confusion in operations and project management, this leads to inaccurate budget planning.



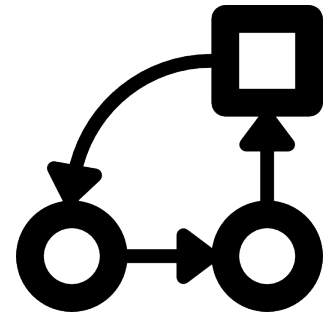
Time-consuming - It can take weeks or even months to create a clinical study plan and budget.



No security and audit trail of changes to data.



Structured Protocol
Authoring(SPA)





Introduction to SPA

A **cloud-based SaaS application** for collaborative Clinical Trial Protocol Authoring and Structured Study Design environment that provides standard templates, libraries and powerful search tools along with familiar editing using Microsoft Word.

Who are the users?

Typically they are **medical writers**, **global clinical leads** or **physicians** with elevated roles allowing them to create and update CDPs as well as studies and export them as documents.



Capture Protocols in machine-readable form



Reuse protocol elements from approved or past studies



Configure CDP structure and doc templates



Allow advanced comparison against benchmark studies



Sync with medical writing in Microsoft Office Online



Use protocols to drive study-level metadata planning & build or to export in Microsoft Excel or Word format



Audit trail - all changes made on SPA, along with who made the changes and when the changes were made.



Saving time and budget of sponsors with more accuracy

Why SPA?

SPA Capabilities



Capture Protocols in machine-readable form

- Capture various aspects of the clinical development plan as discrete database elements but presented and edited in familiar ways



Reuse protocol elements from approved or past studies

- Inherit many of the protocol elements from already approved protocols
- Populate the rest so that they can be thoroughly reviewed
- Allow advanced searching to find elements and reuse.



Configure CDP structure and doc templates

- The CDP Structure option allows the administrator to configure the sections of the Program Level Overview.
- And define one or more CDP and Study Protocol MS Word Templates in the system.

SPA Capabilities (cont.)



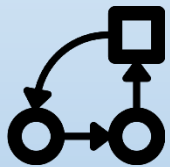
Allow advanced comparison against benchmark studies

- Compare a benchmark study to the currently selected one, and to choose protocol elements from the benchmark to add to the new study being built, visually distinguish between added/missing/common elements.



Sync with medical writing in Microsoft Office Online

- Use integrated Microsoft Office Online to engage Medical Writers in the review and revision tools that they find familiar.



Use protocols to drive study-level metadata planning & build or to export in Microsoft Excel or Word format

- Integrate with existing collaboration, approval, reporting, and archiving processes because of powerful extensible export formats
Example: XLSX workbook containing CDISC Trial Design Matrix.

Migrating to SPA

- Basic training needed for users to move from conventional systems to SPA.
- Requires subscription to SPA SaaS application and only authenticated users can operate in the application. (Single Sign On or SPA account)
- Requires internet to connect to cloud servers online.
- Runs on popular browsers like IE11+, Firefox, Chrome and Safari.
- More customized and advanced feature updates in every new version.

Conclusion

- Leading biopharmaceutical businesses and medical devices show that greater yields on the research and development assets are achieved through optimizing the study planning.
- The ability to perform what-if scenario planning quickly and accurately as well as higher visibility to the operational and financial plan for a study.
- Benefits have been gained dramatically from abbreviated planning cycle times, faster delivery rates, lower costs and yet maintaining study feasibility.



Questions?



Thank you