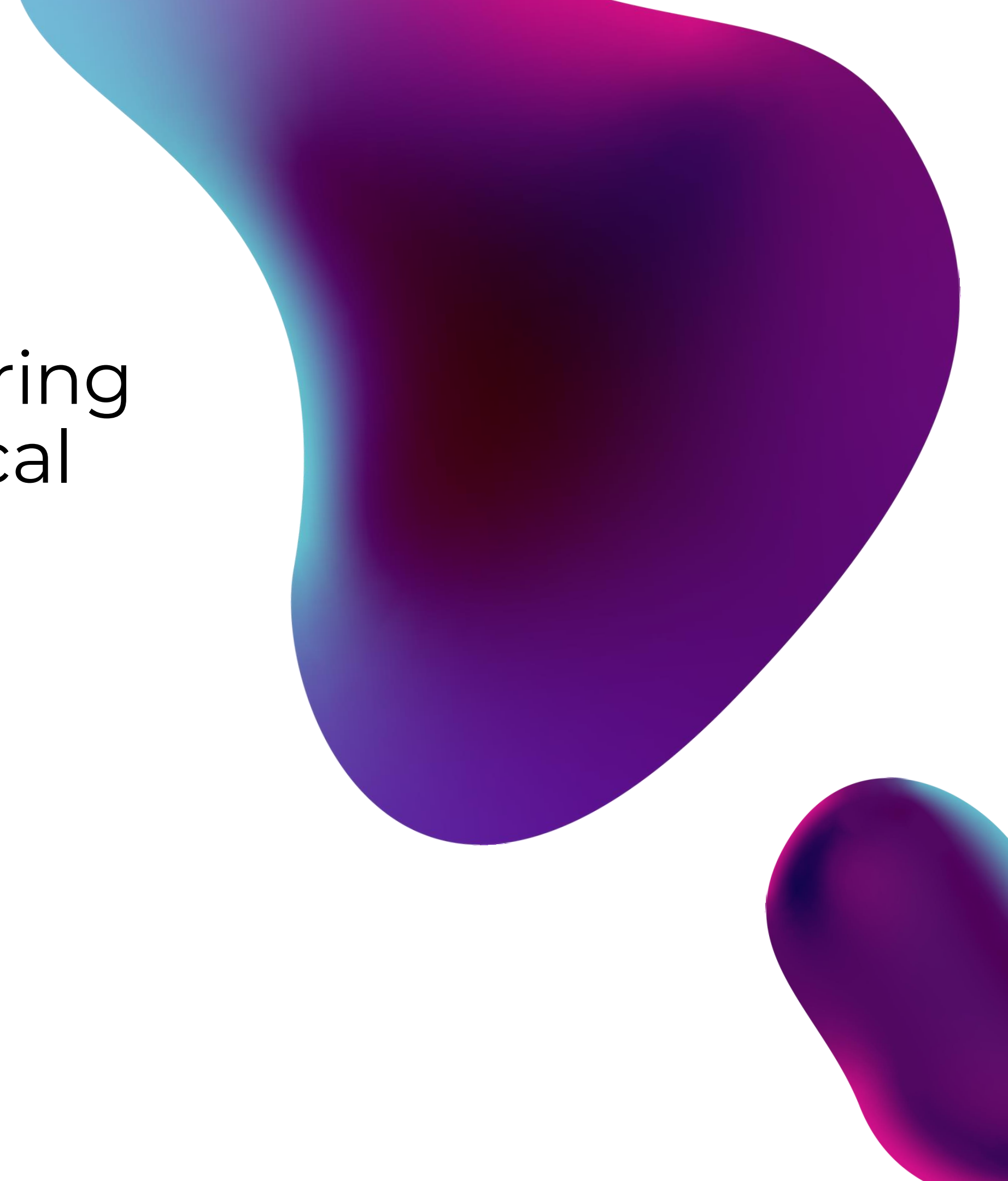




Structured Protocol Authoring (SPA): A Catalyst for Clinical Development

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About Suhas Giriraj

A full-stack programmer and Ruby enthusiast for the past 14 years. An IT engineering graduate from Bengaluru City, The Silicon Valley of India.

- Leads the product development team at Efficacy Life Sciences, Bengaluru.
- Developing cloud-based applications for pharmaceutical companies for the past 8 years.
- Actively contributed to building Metadata Repository (MDR) and Statistical Computing Environment (SCE) applications. Currently drives the product development for Structured Protocol Authoring (SPA) and MDR products.
- Suhas is passionate about seeing and capturing the world through his lenses, traveling, and exploring various cuisines.

The background features a dark purple gradient with several large, organic, fluid-like shapes in shades of purple and blue. These shapes are positioned on the left side of the frame, creating a modern, abstract aesthetic.

Current Challenges in Planning Clinical Development



No data integrity



Lost or duplicate work



Cannot archive or track past studies



Intensive resources and tough data comparisons.



Lack of a centralised repository



Time-consuming



No security and audit trail

Introduction to SPA

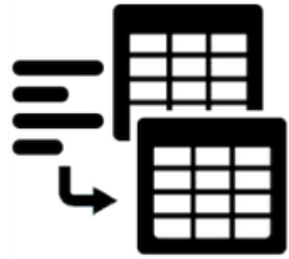
A cloud-based SaaS web application for collaborative Clinical Trial Protocol Authoring and structured study design environment.

Who are the users?

- Medical experts
- Medical writer
- Global clinical leads
- Data managers



SPA Capabilities



Capture Protocols in
machine-readable form



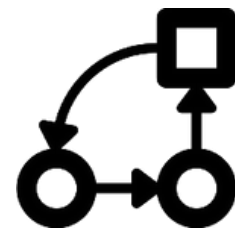
Compare studies



Reuse
elements



Collaborative
real-time
editing with MS
word



Build CRF or
export study
design / protocol



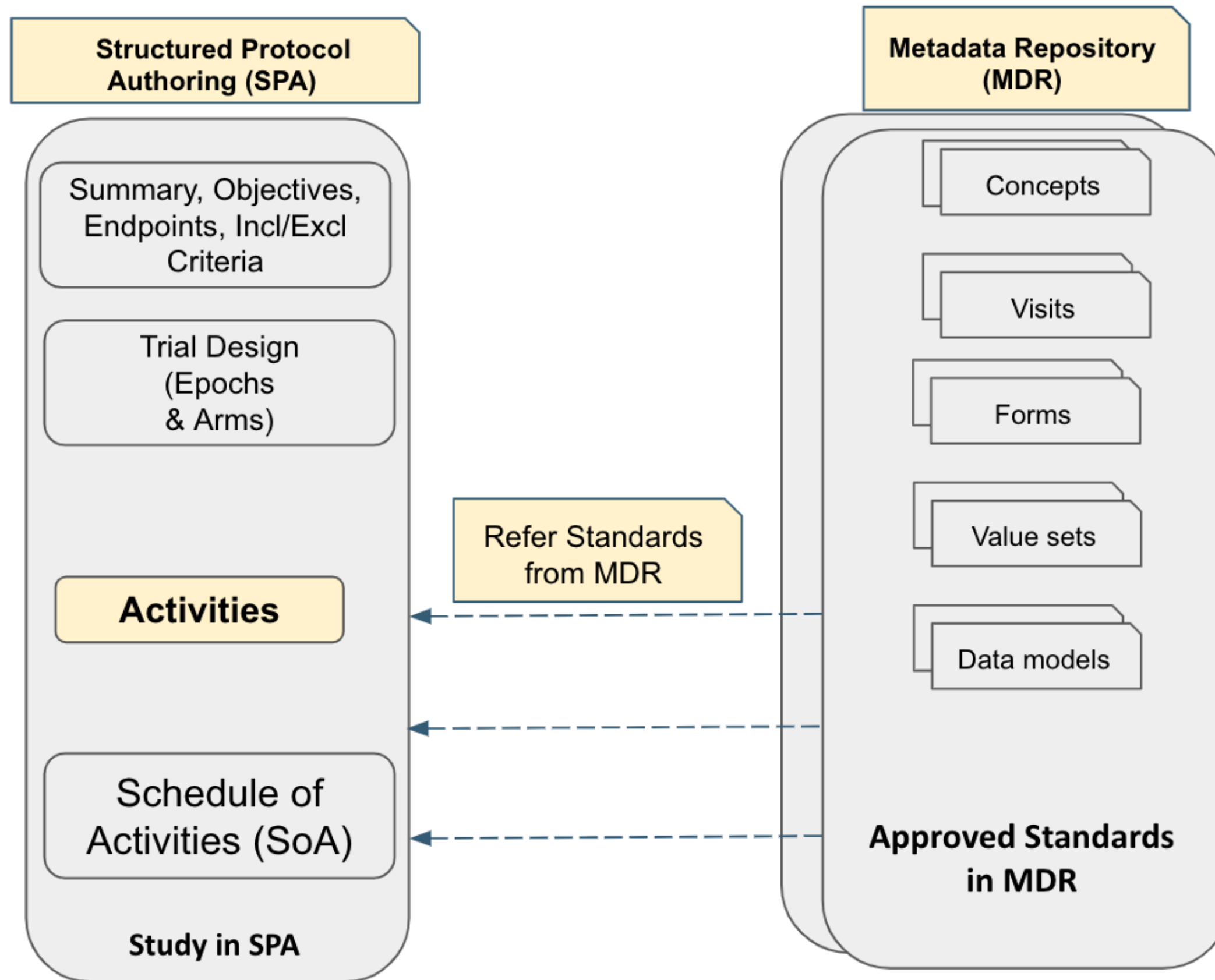
Company /
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templates



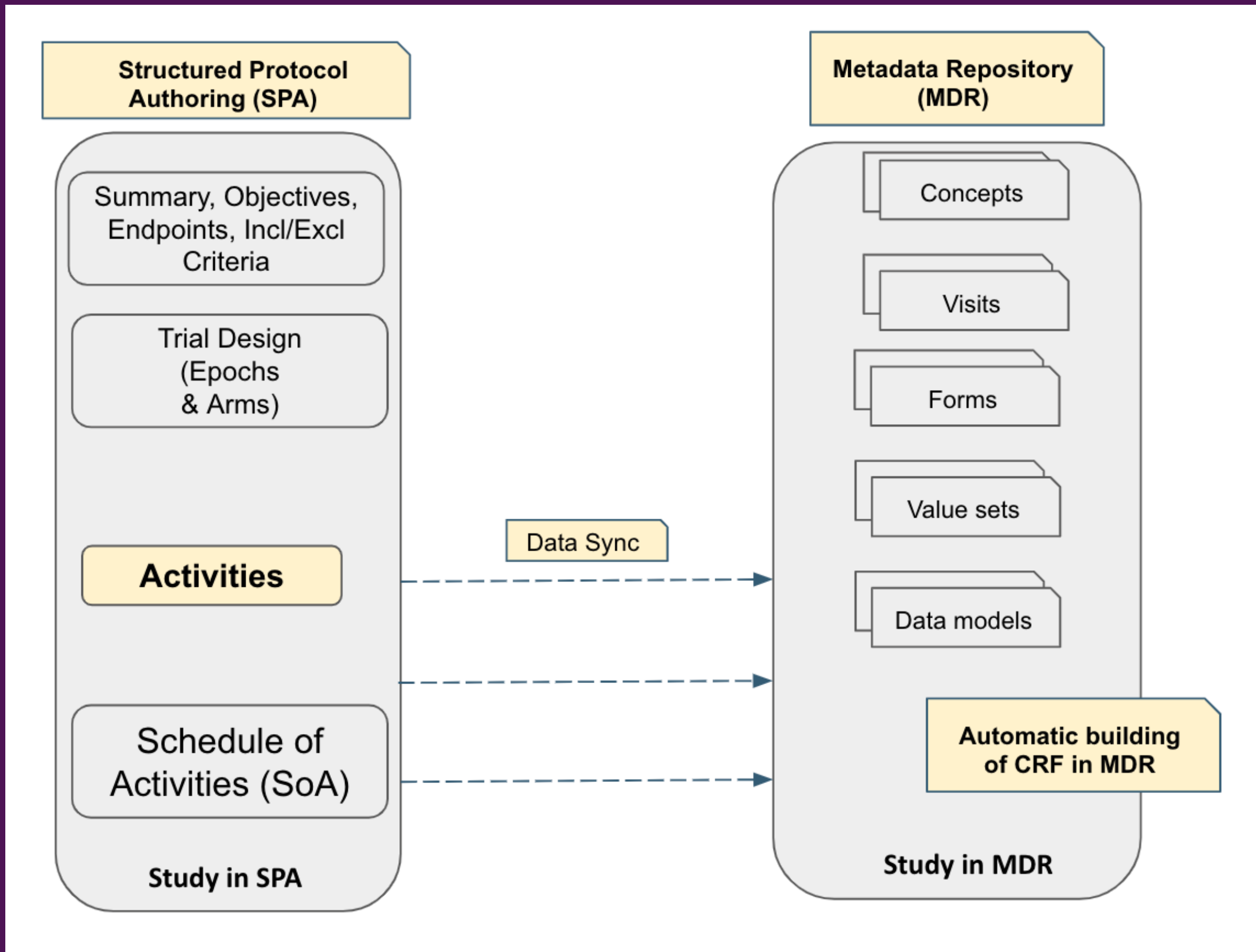
Audit trail



Saves budget
and time of
sponsors



SPA utilizes approved standard libraries from MDR to build Activities



CRF studies are automatically built into MDR using SPA APIs



Conclusion

- Faster build time of study protocols or CRFs
- Improved productivity of medical writers by reduced cycle times due to collaborative editing.
- Consistent and data accuracy

"Discontent is a catalyst for change."

–Mike Murdock

Thank you

Questions

