

Nonclinical Protocol Automation



Project Scope

Determine the feasibility of transforming the BioCelerate Nonclinical Protocol Template into a dynamic Microsoft Word document where filling in the template allows output of all fields for machine readability. Determine the feasibility of expanding the OpenStudyBuilder system for nonclinical study usage. Explore the output and API functionality of this system. Based upon conclusions from the above, work with one or both groups to complete a pilot for creating a few model study designs for demonstration of protocol automation.

Problem Statement

The industry is very interested in developing an automation of protocol development to a final protocol for nonclinical studies. Currently, this is mainly managed using manual document authoring based on company-specific templates.

Problem Impact

The benefit for industry with an automation of protocol:

- Easier to implement standard structure and format of protocol document.
- Ability to electronically transfer protocol designs between sponsors and CROs during study initiation.
- Trial design domains that become part of the SEND study submission could come from this system and at the time of protocol conceptualisation instead of at the end of a study, which would lead to more accuracy, efficiency and completeness of contents.

Relationship to previous projects

- OpenStudyBuilder: a CDISC Open Source Alliance Project to automate clinical protocol development.
- Related to the BioCelerate nonclinical study template project (which is a shared common template but a nonautomated approach to protocol development).

Stakeholders

- Software providers, sponsors, CROs
- CDISC
- OpenStudyBuilder project team
- BioCelerate
- FDA and other regulatory agencies

| Project Leads | Email |
|------------------------------------------------|--------------------------------------------------------------------|
| Bob Friedman, <i>Xybion</i> | bfriedman@xybion.com |
| Alex Pearce, <i>PHUSE</i> Project Assistant | Alexandra@phuse.global |

CURRENT STATUS Q1 2024

- Project Closing out
- Leads producing a white paper on what was researched

Objectives & Deliverables

Feasibility trial of the Nonclinical Protocol Template from a dynamic Microsoft Word document

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Feasibility trial of the OpenStudyBuilder system for nonclinical study usage. This is done by comparing its clinical study abilities to the needs for nonclinical studies and by exploring the output and API functionality of this system

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| Create three example study designs using one or both of these approaches | Q 2 2 0 24 |
| Prepare Phase I results as a CSS meeting presentation | Q 3 2 0 24 |
| Presentation of lessons learned and project status at the CSS meeting | Q 4 2 0 24 |