PP01 Standardizing schematics for the subject ID across the industry

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ABSTRACT

To address key issues with the current Subject ID schema resulting from a growing company drug pipeline, a cross-functional team was assembled to pressure test potential solutions. Solutions brought forward were only those that were workable and did not add to site/user burden. The new Subject ID schema included program, phase and study identifiers and an alpha character to accommodate subject rescreening. An additional numeric character was added to the site number to identify the country of enrollment. Prior to the system wide launch, the new Subject ID schema was pressure tested using historic study data and piloted in a real study to assess performance. The project took approximately 8 months from kick-off to official launch. As of October 2021, 20 new studies have adopted to the new schema.

OBJECTIVES

To address issues with the current Subject ID schema assigned to subject in Biogen clinical studies. These include:

- ✓ Subject ID duplication (the same subject ID used at the same site, for two different active studies)
- ✓ Inability to identify rescreened subjects
- ✓ Lack of consistency in the use of the Subject ID schema across partnership and portfolio
- ✓ Subject IDs not easily identifiable by program, phase, study or country

To define the process for implementing and maintaining the new Subject ID schema, including defining team member roles and responsibilities.

METHODOLOGY

A cross-functional team was assembled to review current Subject ID schema issues and propose potential solutions. Representatives included team members from Global Clinical Operations, Analytical Data Systems, Clinical Drug Supply, Research & Development IT, CRO, Central Lab and IXRT Partners. A project plan was developed including frequent check-in meetings with the project sponsor and leadership team to ensure alignment prior to moving to the next project phase.

The team met bi-weekly to review ongoing stakeholder feedback and pressure test potential solutions against the current systems requiring a subject ID identifier. Systems tested included EDC, CTMS, LIMS and IXRT. Solutions brought forward were only those that were workable and did not add to site/user burden. Workable solutions were defined as those that addressed all key issues and accommodated a growing company pipeline. The team agreed on a proposed schema which was presented to leadership team for final endorsement. The endorsed Subject ID schema was presented to both the Global Clinical Operations and Analytical Data Systems leadership teams for alignment prior to implementation.

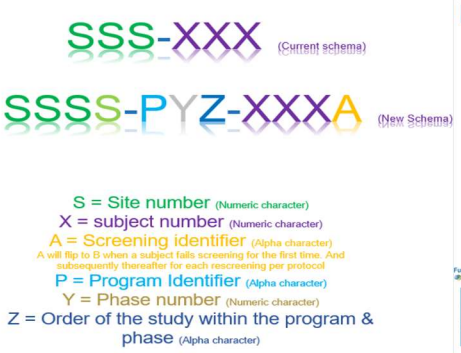
RESULTS

Focusing on the key issues initially identified from ongoing studies and stakeholder feedback, three potential subject ID schemas were brought forward as potential solutions.

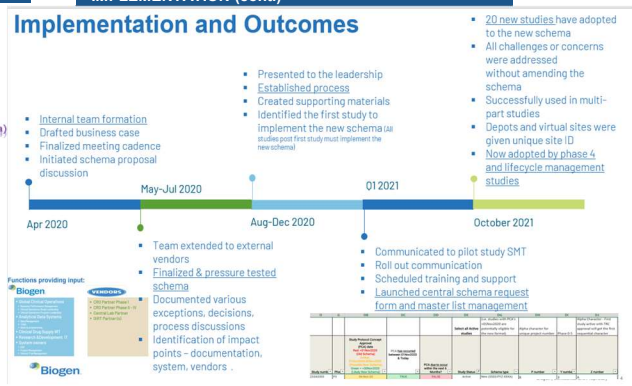
Additional criteria were incorporated to help move one of the three proposed Subject ID schemas forward. They included:

- ✓ Limiting the number of additional characters required
- ✓ Ensuring the new schema does not deviate extensively from the existing schema

RESULTS (cont.)



IMPLEMENTATION (cont.)



IMPLEMENTATION

Prior to the system wide launch, the new Subject ID schema was pressure tested using historic study data and piloted in a real study to assess performance. Following the successful pilot, study teams that had recently received study approval in the previous 6 months were contacted and trained as part of the implementation plan. Hyper care was provided to studies that were part of the initial launch to resolve any issues or provide clarification. Studies considered out of scope included those that were already enrolling subjects, studies that had the protocol concept already approved or studies that had already finalized and approved study specifications. The team also identified a target date after which all new studies would implement the new Subject ID schema. This was communicated to the Global Clinical Operations organization as part of the communication plan developed. The team also developed standard training material. A central subject ID schema master list tracker is developed to track and manage unique subject ID allocation per study. A central team within GCO is responsible to manage the master list. The team continues collecting post launch feedback.

CONCLUSION

The team was able to successfully implement a new Subject ID schema addressing the key issues associated with a growing company pipeline. The project took approximately 8 months from kick-off to official launch. As of October 2021, 20 new studies have adopted to the new schema. All Implementation challenges or concerns were addressed without a requirement to amend the schema. The schematic was also successfully used in multi-part studies and sites with multiple locations. As part of the ongoing maintenance required, specific country identifier are generated as required.

The same schema was adopted by groups running phase 4 and lifecycle management studies.

REFERENCES & ACKNOWLDGEMENT

We referred to “PharmaSUG 2019 - Paper DS-146 - Considerations When Representing Multiple Subject Enrollments in SDTM” CDISC white paper on schematics and data standardization.

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