

Adverse Event Collection and Reporting Improvement Project

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BACKGROUND

Adverse event collection was completed on a paper-based system to capture all required elements on events experienced by patients enrolled in a clinical trial. Several deficiencies were identified with this system:

- Variation in AE collection templates across teams (i.e., headers, attributions, signature sections)
- Lack of consensus on AE collection method (i.e., paper logs, MD email correspondence, fillable PDFs in eReg platform)
- Need for multiple source document maintenance requiring duplicate entry between research systems resulting in delayed reporting efforts
- Extended time from AE identification to EDC entry resulting in delayed entry of safety data impacting Sponsor's ability to conduct ongoing analysis
- Increased number of queries and delayed response time due to necessary modifications or additions to source record
- Lack of centralized/transparent location of documentation to support staff coverage and continuity in the event of extended absences or transitions

SOLUTIONS and METHODS

A pilot was conducted consisting of several collection methods (i.e., paper, customized smart phrase, EPIC based module). Feedback from all stakeholders was analyzed to support the selection of a single system moving forward: **EPIC AE Activity Log** module. Over the next four months, a working group was established with representation from all teams, including Investigator leadership. The group was responsible for developing policy, work instructions and mapping department workflows to support implementation. Research IT systems leadership was engaged to provide support in automating and using existing technology to optimize efficiency. The team communicated their progress with formal presentations at department meetings. Additional focused feedback was solicited from protocol Sponsor partners.

GOAL: Establish a single, centralized system and implement a process that supports AE collection and entry into the EDC system while reducing duplication of entry, allowing real-time documentation and Investigator attribution, and supporting Direct Data Connections (DDC) in the future.

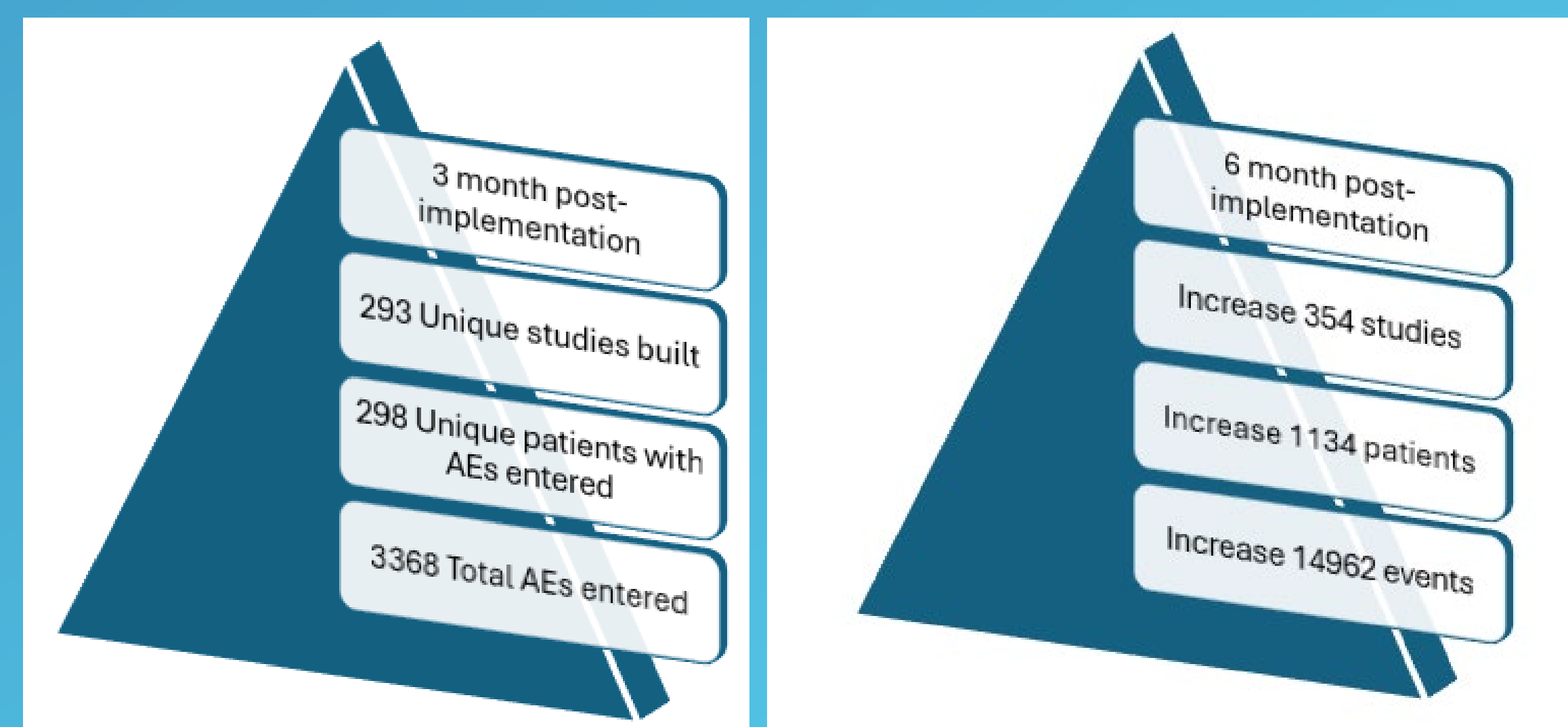
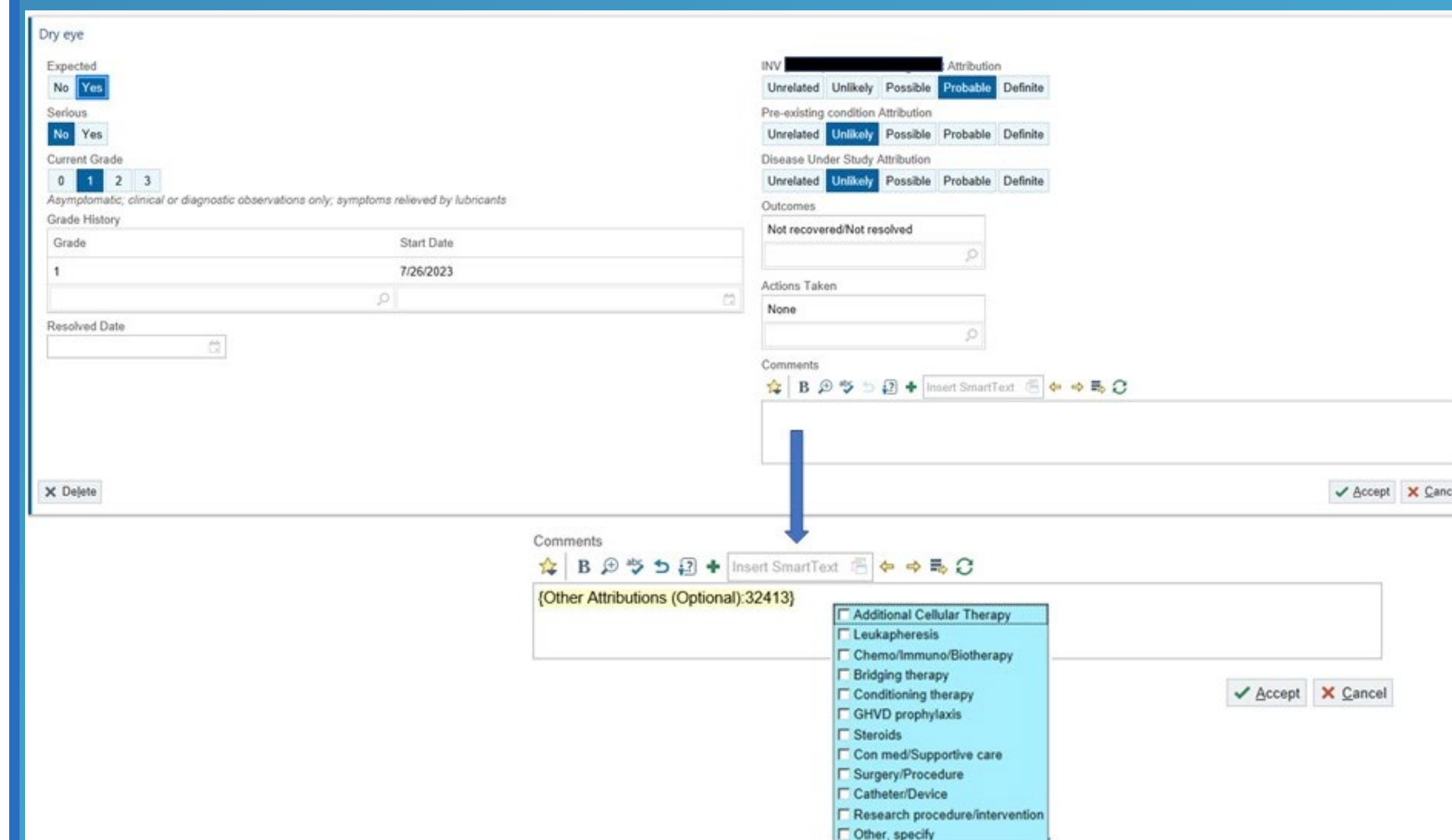


Table 1

OUTCOMES

Upon finalization of supporting documents and tools, the implementation of the EPIC AE Activity Log module, across the therapeutic trial portfolio, at two campuses and eight network locations, was launched. Resources, such as identified team super-users, were available to assist the research staff and to meet with Investigators to reinforce the use of this new tool, ensure adherence and provide valuable feedback. A focus group convened at three months and six months post launch to assess utilization, compliance, and address user responses from these first 24 weeks. (Table 1) Feedback from data coordinators supported that the utilization resulted in increased speed of AE entry into the EDC as result of a single, centralized platform. In addition, the group communicated system reports that reflect adoption and utilization metrics. These reports, for example, provide the ability to analyze aging AE attributions and investigator sign-off, which in turn helps to identify where targeted follow-up or more one-on-one training is needed.

KEY LESSONS LEARNED

1. Consistent and thorough communication between all individuals involved in AE collection cycle
2. Flexible approach, when appropriate, regarding AE entry and responsibility workflow
3. Sensitivity to clinic operations, research staff space allocation, and equipment functionality
4. Balance time and effort between retired processes and the transition to newly implemented system

FUTURE DIRECTIONS

1. Incorporate additional reporting tools of key quality metrics
2. Reinforce user engagement and solicit continued feedback
3. Pilot DDC opportunities
4. Expand use of AE module to all COH enterprise locations