The Impact of Implementing a Global Research Subject Database to Prevent Dual Enrollment in Early and Late Pain Clinical Trials

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Background

Enrollment in subjective disease states and in particular pain clinical trials can present unique and considerable challenges to research sites, pharmaceutical companies and CROs:

- The research subject's failure to admit to simultaneous participation in more than one clinical trial and jumping from one trial to another without allowing sufficient time to lapse between treatments compromises: 1) the health of the subjects, 2) data quality and 3) efficacy and placebo rates of the investigational compound.
- The issue of dual enrollment in clinical trials is widespread, especially in the pain clinical trials. When a research subject combines multiple investigational products or alternatively does not actually take the study product and provides false data, this often leads to altered efficacy rates, placebo rates, and potential for increased adverse events to screening for the clinical trial.

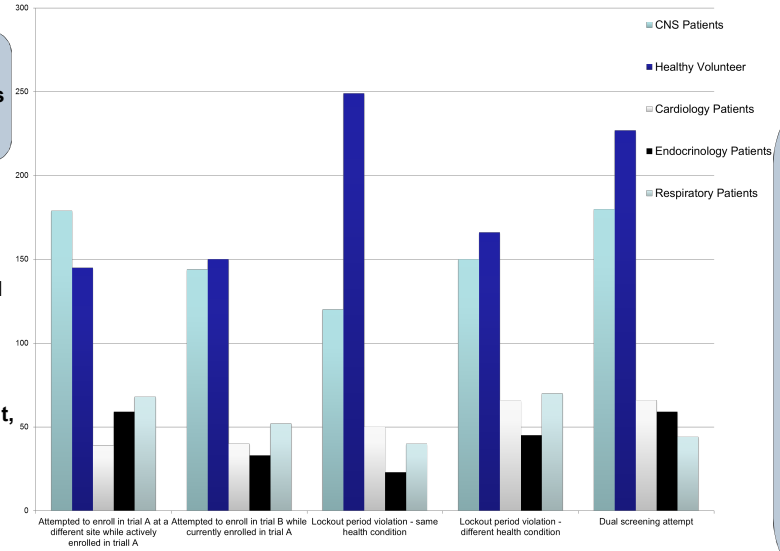
Objective

To develop a system to prevent dual enrollment in clinical trials to ultimately improve safety and data quality in clinical trials

Methods

- Using a proprietary HIPAA compliant de-identified research subject clinical trials registry database system, Verified Clinical Trials has successfully performed XXXX total verifications and multiple security alerts over the past 2 years in North America.
- Both early phase and late phase trials were incorporated in to the Verified Clinical Trials system. * Following informed consent, each subject is verified and several different types of security alerts are completed just prior to screening for the clinical trial.

Report for pain Events*	Number of Subjects (N=17,859)
Previously enrolled in the same protocol	11
Subject is currently randomized in a protocol	138
Subject is still within the lockout period	359
Compound Exposure	278
Compound half-life did not expire	2
In-Screening at a different site	196
In-Screening at the same site	702
Biologic compound	0
Attempted protocol violations	9%



Results

A significant number of subjects attempting to screen in clinical trials were found to be problematic:

- 4% of the subjects attempted dual enrollment across all phases of clinical research and all disease states.
- A much higher incidence was seen in early phase trials where stipends were higher and in certain disease states such as healthy volunteers, pain, pain and other subjective conditions.
- Attempted dual enrollment was successfully thwarted with the database registry.
- Furthermore, overall costs were reduced by stopping the attempted dual enrollment prior to screening and preventing costly screenings:
- The system detected 7% attempted enrollment during their lockout period across all phases of clinical research with similar statistics across early and late phase trials.
- 5% attempted to screen while actively screening at another clinical trial center.

Conclusions

- Dual enrollment is a serious problem that can be costly to the research site, pharmaceutical company and most importantly harmful to patients. pain clinical trials are inherently prone to increased attempted dual enrollment with significant safety and data quality ramifications
- By tracking the dual screening activity, Verified Clinical Trials was able to alert pain research centers; thus allowing them to be pro-active with finding qualified alternates to meet their enrollment and dosing numbers
- 99.8% of research subjects accepted the verification system at screening and the added security and safety measures of a clinical trials research subject database system had very little, if no impact on successful screening and enrollment in pain clinical trials.