Category: Clinical Trial Operations – Work in Progress

We Have 99 Problems But a Participant Withdraw is No Longer One

S. Bigelow, C. Galasso, J. Ventimiglia, L. Casetta, C. Zuccaro, J. Mancini

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

One of the essential components of clinical research is accurate and timely reporting of a participant's status, which includes the research participant's decision to discontinue treatment or withdraw themselves completely from a clinical trial. Through the evolution of the clinical research program at the Karmanos Cancer Institute (KCI), the terminology used by investigators and clinical trials staff to document a participant's decision to discontinue treatment has evolved into categorizing them as a "withdraw." Source documentation reflecting a participant withdrawal subsequently requires a different pathway for reporting versus a participant's decision to discontinue from the primary intervention. The Clinical Trials Office (CTO) identified this as an area of opportunity for us to: 1) Understand and educate the clinical research team on the accurate terminology to define a participant's decision to discontinue treatment or withdraw from study; 2) Increase accurate documentation, standardization, and reporting consistency for participant-initiated discontinuations/withdrawals; 3) Increase participant comprehension of the outcome of their decision.

2. Goals

Resources from OHRP, FDA, GCP, and collaborating institutional review boards were reviewed to guide the documentation process and establish definitions for use throughout this initiative. Collectively understanding the definitions of the applicable terminology was essential. A subsequent goal was to generate a template for real-time use by the clinical research nurses (CRN), which can be recorded in the medical record, to accurately document the participant's decision. Creation of a CTO Policy and Workflow was also required.

3. Solutions and Methods

Participants enrolled on a clinical trial may discontinue and/or withdraw participation at any time. It is the responsibility of the investigator and research team to confirm the details of the participant's request. The CTO implemented a policy and workflow to guide the clinical research team to accurately document the participant's decision, in real time. The utilized template includes pre-defined questions that allow the CRN and participant to determine the subsequent course of action. The completed template is recorded as a clinical document in real time in our cancer center's electronic health record (EHR) and is accessible to the applicable clinical research team and sponsor/CRO representatives for monitoring purposes. Furthermore, this policy provides definitions of a participant withdrawal and discontinuation, which can now be provided as a source for education of various members of the research team.

4. Outcomes

A positive change that has occurred is the increase of source documentation in the participant's EHR, which outlines a clear decision by the research participant. This initiative has eliminated subsequent follow-up between the CRN and CTO study coordinators to determine and report the participant's

decision. Additionally, the standardized definitions within the policy promotes consistent documentation in our cancer center's Clinical Trials Management System. This policy was implemented in October 2020, and over the last six months, 13 participants discontinued treatment or withdrew from study. We were able to capture 85 percent compliance utilizing this standardized process and template.

5. Lessons Learned

Instances of participant-initiated discontinuation or withdrawal continue to be evaluated for compliance. Education to the treating physicians, non-physician providers, and clinical research team regarding proper documentation and terminology for discontinuations and withdrawals is ongoing.