Improving Efficiency and Time Management During the Site Selection Process: A Collaborative Approach

Leanne Lujan, BS, CCRP; Brett Johnson, BS, CCRC; Sally Fairbairn, BS, CCRP; Elizabeth Constantz, BS, CCRP; Janna Espinosa, BA, CCRP; Jessica Moehle, BS, CCRP; Theresa L. Werner, MD; Susan Sharry, BS, CCRP

Huntsman Cancer Institute at the University of Utah

BACKGROUND

Cancer centers receive multiple requests for information from sponsors and their contract research organizations (CROs) to assess a site's feasibility to conduct a clinical trial. This involves assessments in many areas:

- Site logistics
- Technical capabilities
- Accrual potential
- Activation timelines
- Administrative infrastructure
- Site-specific standard operating procedures

Gathering information in these areas requires lengthy questionnaires, access to portals, multiple email conversations, and meetings in addition to required pre-site selection visits (PSSVs). The requests for information and required questionnaires are extensive, time-consuming, and in many cases duplicative.

METHOD

- Our goal is to streamline communication during the site selection process to work more efficiently and collaboratively with our sponsors/CROs as well as ensure accuracy and consistency of information provided during the site selection process.
- By creating and maintaining a comprehensive document with site-specific information and answers to frequently asked questions for our sponsors/CROs, we expect to improve efficiencies for all parties by reducing the time it takes to confirm site selection.

RESULTS

We created a comprehensive new study start-up packet to give sponsors/CROs as soon as site selection discussions commence. The packet includes the following:

- Site-specific study start-up requirements
- Activation timelines
- Technical capabilities
- Answers to frequently asked questions

We provide this comprehensive document to our sponsors and CROs to help them assess the feasibility of conducting clinical research at HCI in a more efficient manner.

TABLE OF CONTENTS

Table of Contents for the site-specific study start-up packet.

CONCLUSIONS

- The feedback from sponsors and CROs has been positive. Most state they are able to complete the majority of their site selection reports with the data provided in our site-specific study start-up packet prior to the PSSV.
- Time with the principal investigator and site study staff during the PSSV can now be spent more productively, addressing questions and discussing study-specific recruitment strategies and protocol requirements.
- Site selection timelines appear to have improved, especially in our Phase I experimental therapeutics space, where rapid site selection is necessary, primarily for participation in dose escalation.
- Internal reports from management as well as sponsors and their CROs have confirmed that providing the study start-up packet prior to the PSSV allows for transparency, which improves communication and the sponsor/site relationship overall.

FUTURE PLANS

- Create and implement sponsor/CRO surveys to confirm feedback received to date and measure satisfaction
- Begin discussion with CROs/sponsors regarding creation of databases to capture site-specific study start-up requirements, activation timelines, technical capabilities, and answers to frequently asked questions
- Continue to update the New Study Start-up Documents as clinical research requirements and site specific processes evolve