

Implementing Foundational Clinical Research Training in Initial Onboarding

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1. Background

OHSU Knight Cancer Institute provides specific clinical research onboarding aimed at preparing new clinical research staff for roles in coordination, regulatory management, and data management across both solid and hematologic research teams. The training, provided by two full-time clinical research trainers, consists of 1:1 and/or small group sessions covering ~50 topics related to research operations and processes. The target timeline for an individual's onboarding completion is 150 days, achieved by attending 1-2 training sessions per week.

After receiving feedback, reassessment of the program was needed to address the following concerns:

- Lengthy onboarding duration
- Insufficient role preparedness
- Training inconsistencies due to differences in team-specific processes
- Inadequate alignment between training timelines and practical application

2. Goals

Implementation of Foundational Training, which consists of three key pillars:

- Building essential clinical research knowledge
- Teaching resourcefulness and self-sufficiency
- Standardizing the training process across all research teams

3. Solutions and Methods

To address onboarding concerns, a systematic revision of the training program was initiated in August 2023 by a Working Group (WG) of Clinical Research leaders. The WG identified key topics and restructured the curriculum to better support the foundational training. Developed content is reviewed by disease team managers and the Clinical Research Quality and Administration (CRQA) team to ensure alignment with best practices and institutional policies. The finalized content is presented at a Continuing Education Series (CES) session, which is recorded and available on the Education and Onboarding landing page for easy access. In the final step, the content is entered into an on-demand e-Learning module that is vetted by the Education Team before publishing, ensuring consistent and accessible training materials for clinical research staff.

4. Outcomes

The identified overarching topics include clinical research terminology, general cancer education, protocol comprehension, data integrity, patient safety, and oversight.

Currently, this project is 55 percent completed, with 38 percent of content in progress of development, and 7 percent in need of development. To expedite onboarding, the finalized e-learning modules (30-45 minutes each) have been assigned to current trainees one week before their corresponding trainer-led discussions. In the trainer-led discussions, the trainers review content from modules including exercises, competency checks, and Knight Cancer-specific standards and processes. Early feedback indicates staff like the more streamlined approach.

5. Learned and Future Directions

Although not an initial goal, the on-demand e-learning modules have been valuable in addressing key Data and Safety Monitoring Committee (DSMC) audit findings. These modules have also been assigned to at least one investigator and incorporated into onboarding new fellows.

With the final topics in content development, the WG will establish the order for assigning Foundational Training Topics and developing assignments focused on team processes. For example, an AE assignment will include reviewing the AE collection and review process with their manager or onboarding coach.

Looking ahead, the Foundational Training will continue to evolve, expanding on fundamental topics in alignment with the Joint Task Force Core Competency Framework.

Figure

