SIV On-Demand: Online Site Initiation Visits for Investigator-Initiated Trials (IITs)

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1. Background
Scheduling a site initiation visit (SIV) can be challenging due to the coordination of multiple schedules and can result in delayed study activation. Additionally, it is difficult to assess comprehension of critical study processes and it can be challenge to record and collect/maintain a log of participants. Finally, often study processes are embedded in a longer presentation that also contains standard GCP and local SOP information which can dilute important study operational information. To address all of these, the University of Florida Health Cancer Center (UFHCC) Project Management Office (PMO) developed an "on-demand" style site initiation visit process for investigator-initiated trials (IITs).

2. Goals
- Increase efficiency of SIV scheduling and completion
- Improve documentation of SIV attendees
- Enhance understanding of critical study operations with a goal of reducing later protocol deviations

3. Solutions and Methods
Canvas was identified as a promising alternative to live SIVs because it is accessible to all UF staff, allows for automatic tracking of training for each study team member, has the option for "quizzes" that can ensure understanding, and serves as a central resource for new study staff and re-training through the life of the study.

Each study is created as a training module within a larger Canvas "SIV" course, which serves as a portal to access each study. Trainings are created via PowerPoint presentations and recorded by the project manager to be posted in the associated study module. The protocol training is separated into two presentations: one that includes general clinical trial SOPs and GCP and a separate module specific to protocol-specific study operations. A three-question quiz is created by PMO and administered for coordinators as knowledge checks on the most important information from the protocol training presentation.

Once the study module is accessible, a deadline is provided to the study team for completion and an optional meeting time with the PI is set up to discuss any study questions following the SIV. The study module, containing all the training presentations, is active through the life of the study for ease of new staff training. A report using the New Analytics feature can serve as a SIV training log including participants who have viewed the SIV and date of their training. Quiz scores from coordinators are also accessible to identify where special attention may be required for the project manager.

4. Outcomes
PMO developed its first SIV Canvas course in Fall 2021. Since that time, three other IITs have successfully utilized this process.

5. Lessons Learned and Future Directions

Areas for future improvement include being able to post different trainings for different study roles and assign them accordingly. While our current framework does not accommodate this, we are exploring other ways to structure the course so we might implement improvements. Additionally, we'd like to collect metrics on how many times each participant attended the training and track how long they were engaged with each session.