Development of a Competence-Based Quality Assurance Program

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BACKGROUND

Coordinator turnover is a challenge that plagues many cancer centers, including the Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO). The ability recruit experienced staff is limited. Trials are increasing in complexity and there are many regulations. We have developed a robust comprehensive training program, however, volume of information and retention issues plague our staff. To mitigate this, we are in the development process of a competence-based quality assurance (QA) program.

METHOD

- The QA program consists of three phases:
  1. A computer-based, proctored exam mapped to topics covered in the training program and GCP principles. The exam administered at the 3-month mark. Retraining and additional mentoring for identified deficiencies.
  2. Task-based competence assessments conducted by senior staff who have previously demonstrated competence. New staff are only allowed to complete tasks autonomously after demonstrated competence.
  3. Five charts will be QA reviewed for new employees for months 3-6 and then two charts per month thereafter. These checks will confirm adherence to best practices and standard policies.

OUTCOME

We are still in the early development of the program. We anticipate the following four benefits:

1. Create a paradigm shift to proactive quality assurance away from reactive corrective actions.
2. Identify retention gaps to address with re-training and added mentoring.
3. Highlight needed modification to the training program.
4. Provide professional development opportunities for mentors.

EXAM
Computer-based, open-book, proctored exam mapped to training topics and GCP

TASK-BASED ASSESSMENTS
Demonstrated competence before completing tasks autonomously

QA CHART REVIEWS
Five charts reviewed for the first 3-6 months; two charts each month thereafter

CONCLUSIONS

- Development is still ongoing.
- Drafting competence-based exam questions has already led to some modifications to the training program.

LESSONS LEARNED

- Dedicating staffing resources for a project this large has been challenging.
- Administrative burden for tracking will be large.

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