Category: Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

Introducing a Quality Management System Into the Mayo Clinic Cancer Center Clinical Research Office

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1. Background

The Mayo Clinic Cancer Center (MCCC) clinical research office (CRO) serves the clinical investigators and research participants across the MCCC's academic medical centers in Arizona, Florida, and Minnesota, as well as throughout the Mayo Clinic Health System in Minnesota and Wisconsin. This organizational complexity and wide geographic distribution of staff contributed to a lack of standardization of training programs and core business processes. While numerous processes and procedures were developed, the utilization of these by CRO staff was inconsistent and ineffective.

A robust quality management system (QMS) was needed to achieve a manageable and sustainable infrastructure for the CRO training, process, and procedure materials. The QMS must be specific and optimized to the needs of the CRO to ensure that it is effective and provides value to the staff. The QMS would cover the following quality system essentials (QSE): organization and leadership; customer focus; personnel and training; standard operating procedures; documents and records; monitoring and assessments; and event management.

Development and implementation of these QSEs would ensure effective training of CRO staff. The definition of core business processes, their inputs and outputs, and key performance and quality metrics, will enable better management of operational performance. Once implemented, the cycle of monitoring and continuous improvement will be engaged.

Recommendation was for the MCCC CRO to establish and maintain a stable and living QMS.

2. Goals

The goal is to create a culture of quality for the CRO, an optimized QMS to support the performance and management of core business processes, and their supporting documentation, as well as a system of continuous improvement.

3. Solutions and Methods

- Define governance and oversight for the QMS
- Establish a quality management coordinator (QMC) to be responsible for the development and management of the MCCC QMS
- Define MCCC QMS elements based on ISO 9000/9001 quality management principles
- Train CRO managers and supervisors on QMS
- Perform current state assessment of existing documentation to determine necessary changes-250 (i.e., archive, update, gap)
- Define core business functions using Supplies Input Process Outcomes Customers/Requirements (SIPOC/R) methodology
- Establish document control aligned with Mayo Clinic policies
- Develop/revise core business process documentation (i.e., process, procedure, form, training)
- Develop and deliver training
- Develop performance metrics and define maintenance/action plan

- Focus on continuous improvement using metrics to guide education, and documentation

4. Outcomes

- Started implementing QMS:
  - Established awareness, vision, and importance of QMS within MCCC leadership
  - Designated a QMC
  - Confirm subject matter experts
  - Start creation of core business processes
  - Create and reestablish a desire to engage in QMS
  - Develop training

5. Lessons Learned and Future Directions

Creating a culture of quality, and competencies in quality management for our managers, supervisors, and staff is essential. Having an effective system and oversight structure is essential for maintaining a QMS.

Our future direction is to continue to mature the QMS and use a change management approach to revision of processes and procedures. We will continue to engage the staff to reinforce the quality management principles and enhance adoption and learning. A dashboard of key performance indicators will be developed in alignment with the core business processes.

Figure: