Category: Regulatory – Work in Progress

Supporting Virtual Clinical Trials: How the Generation of DOAs in PIMS has Enabled Clinical Trial Compliance in a Remote World

P. Lim

Memorial Sloan Kettering Cancer Center

1. Background

There are various regulatory documents needed to be collected, approved, signed, and stored to open and continue research studies at Memorial Sloan Kettering (MSK). If regulatory standards are not upheld, this can cause delays, remediations with patients, and adverse consequences for sponsors and the institution. Some of these documents have been digitized and automatically maintained in an internal MSK platform called the protocol information management system (PIMS), but others require upkeep through paper and manual processes. We describe a continuation of this type of work done to one of these critical, paper documents, the study-specific delegation of authority (DOA) log.
All therapeutic and some non-therapeutic studies require a DOA. It details applicable staff, the specialized tasks each are given authority to do, and the timeframe in which each have these capabilities for a study. This log must be approved and signed by the principal investigator (PI) of a study before any research can be done and continually maintained during its lifecycle.

Previously, this was a manual process requiring staff to create the document offline, have PIs sign through a wet signature in person or through fax and email, and then upload into the PIMS eReg binder. This required ample attention, time, and effort to maintain compliance as staff reorganization is a frequent occurrence. This was further exacerbated due to the pandemic, solidifying the need to provide virtual means for log management.

2. Goals

1. Compliance
2. Time saved
3. Efficiencies

However, the ultimate goal is to allow resources to shift effort away from unnecessary procedures and towards patient care, while also increasing the overall ability for continued compliance.

3. Solutions and Methods

Created a workflow within PIMS that allows staff to initiate, manage, and store study specific DOAs, providing the ability to process everything electronically. The method follows the below:

1. Initiate DOA, pulling in staff based on the face sheet and those tied to the specific service
2. Update DOA details directly in tool, while system provides suggested inputs throughout
3. Send notice to PI to sign off on changes
4. After PI approval, eSignature automatically added, DOA document created, and stored in eReg binder

4. Outcomes

1. Standardized the DOA process across MSK for new studies
2. Removed the constraint on wet signatures, fax, email, and offline creation of documents by providing one coherent workflow within one tool.
3. Decreased time spent on DOA maintenance and increased overall efficiency

Category: Regulatory – Work in Progress

5. Lessons Learned and Future Directions

There are many pieces to ensuring that a study is compliant and maintained well. However, in an ever-changing world that is rapidly going virtual, there need to be better efficiencies to meet the demands of cancer research, offering in return more space for innovation and growth.

There are hopes to extend the functionality to retrospectively update all study specific DOAs for existing studies as well. As this is limited to only MSK studies, future enhancements are planned to allow externally generated studies and external users to also be maintained through this process. The overall roadmap would be to continue optimizing workflows and documents that follow inefficient, manual, and paper processes.