Developing an Automated Deviation Reporting and Electronic PI Attestation Process
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Background
Providing clear and consistent documentation of Principal Investigator (PI) oversight throughout a clinical trial is an important element for trial management. Timely evaluation of protocol deviations is one way in which a study site can demonstrate effective PI oversight. In addition, effective protocol deviation management can help to improve protocol execution and minimize further deviations within a clinical trial.

Solution or Methods Implemented
• Developed resources for study staff on DOTs to utilize when reporting deviations and/or discussing deviations in team meetings
  o Training Documentation for both study staff and PIs on process
  o Templates for deviation reporting within CTMS
• Designed and implemented an electronic system to export documented deviations from CTMS into PI Attestation application
  o Piloted with 2 DOTs prior to roll-out to entire CTO
  o PI Attestation application used to supplement DOT meetings during which deviations are addressed and discussed
• Created features within PI Attestation application to view both CTMS documentation and PI determination in order to facilitate reconciliation
• Developed reports with PI Attestation application so that deviation outcomes and PI oversight could be reviewed at a site level

Outcome
• Roll-out of new deviation documentation across entire (CTO)
  o Now have 100% deviation attestation occurring via electronic PI attestation application
• Including 45 PIs across all DOTs
• Audit trail of PI review for all deviations reported within CTMS and pulled into PI attestation application
  o Including determination by PI for major vs. minor deviations
  o Reports can be reviewed by PI, protocol, DOT or site level

Lessons Learned & Future Directions
Lessons learned:
• Determining what deviation template should contain earlier within process rather than later
• Developing a more effective method to reach out and train PIs in larger settings
• Creating a back-up paper process in case of technology issues

Future directions:
• Rolling out to teams outside of the CTO that operate under the Cancer Center

Figure 1. Process for Deviation Reporting

- DOT documents deviation in CTMS in real-time
- DOT creates report weekly
- Deviation report routes to PI automatically
- PI reviews report and attests to deviations
- DOT reviews at Disease Team Meeting
- Deviations can be reviewed at site level

Metrics & Goals to be Achieved
- Establish a standardized method in which all Disease-Oriented Teams (DOTs) would report and review protocol deviations within the Clinical Trials Office (CTO)
- Develop an electronic process by which PIs could review and sign-off on deviations for each protocol, utilizing existing deviation entry process into the Clinical Trial Management System (CTMS)
- Create a reconciliation process to confirm that deviations are documented consistently between both the electronic PI Attestation application and the CTMS
- Provide a mechanism which will allow the Data Safety Monitoring Committee (DSMC) to review deviations across CTO, as well as confirm PI oversight