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 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.

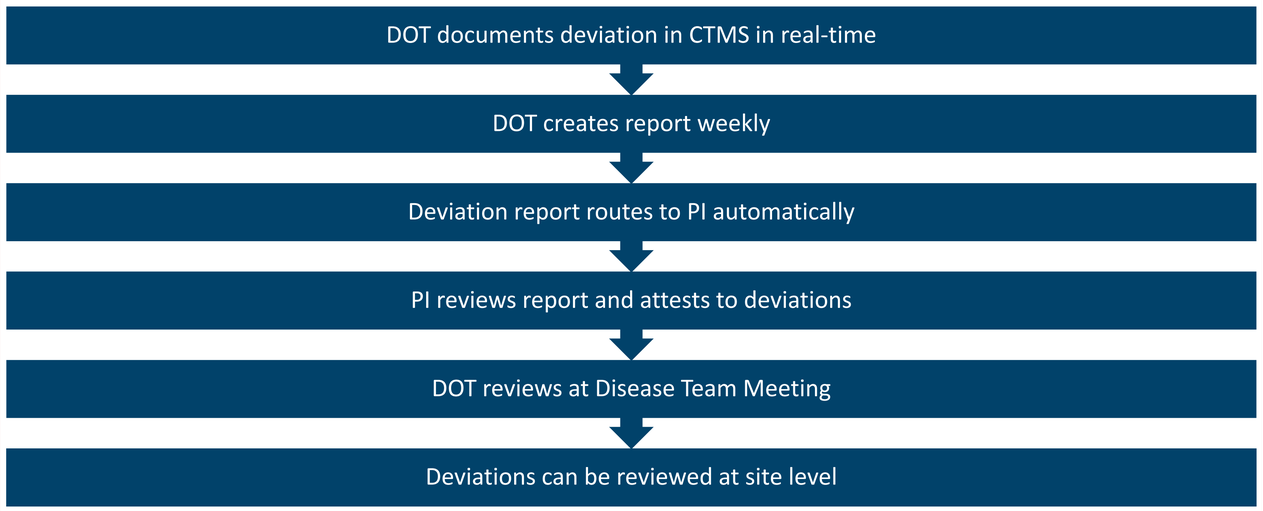
Metrics & Goals to be Achieved

- Establish a standardized method in which all Disease-Orientated Teams (DOTs) would report and review protocols 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

Solution or Methods Implemented

- Developed resources for study staff on DOTs to utilize when reporting deviations and/or discussing deviations in team meetings
  - Training Documentation for both study staff and PIs on process
  - Templates for deviation reporting within CTMS
- Designed and implemented an electronic system to export documented deviations from CTMS into PI Attestation application
  - Piloted with 2 DOTs prior to roll-out to entire CTO
  - 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

Figure 1. Process for Deviation Reporting



Outcome

- Roll-out of new deviation documentation across entire (CTO)
  - 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
  - Including determination by PI for major vs. minor deviations
  - 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