Greetings to the PHS Community

The CLINICAL TRIALS OFFICE (CTO) celebrated its one- year anniversary on August 1 from our new space on the 7th floor at Assembly Row! **Please note our new address:** 399 Revolution Drive, Suite 760, Somerville, MA 02145. Telephone: 857-282-1862 Fax: 857-282-5786.

Much has happened in the past 12 months that we want to share with our colleagues here at PHS and at our affiliated Hospitals.



Clinical Trials Office Staff Photo

- The CTO continues to experience growth. From FY15 Q2 to FY16 Q2 the CTO saw a 31% growth rate in clinical trial agreements. Our investigators continue to be busy and productive.
- DocuSign is now available. In an effort to speed the execution of CDA's, contracts and amendments for PHS PIs and sponsors, the CTO has implemented electronic signature technology. Please watch for these documents from our office.
- We have hired a Director of the OnCore Clinical Trials Management System as well as two OnCore CTMS analysts to work at MGH and BWH to support PIs and their staffs. Hardware and OnCore software have been installed, and Insight and EPIC integration are underway. Super User training occurred in late July with a planned roll out in late October/early November for Neurology and Neurosurgery at BWH and Emergency Medicine and the Neuroendocrine Unit at MGH. Stay tuned for future updates.

OnCore: Phase I Functionalities and Interfaces

Clinical Trial Management

- Protocol and Subject Lifecycle Management
- Calendar and Schedule of Events
- Financial Management Sponsor Invoicing and Payment Reconciliation
- Reporting

Integrations

- Standard integrations available with Epic (PeC team)
 - Demographics pull from Epic to OnCore
 - · Subject-protocol link pushed from OnCore to Epic
- Integrations with Insight/eIRB (Partners Research Applications Team)
 - Protocol detail from Insight to OnCore
- Active Directory



- CTA and other agreement turnaround times have improved from a mean of 120 days to 90-100 days.
 Our goal remains continued turnaround time reduction. The CTO office has been reorganized to include additional Agreement Associates to expedite turnaround times bringing our staffing level to 25 FTEs.
- New Service initiatives by the CTO. Development of a CTO Advisory Committee has helped to identify operational areas of concern and process bottlenecks. We have developed a quarterly questionnaire to be sent to both PIs and sponsors. Our customers have provided enthusiastic responses and helpful suggestions including usage of Master Service Agreements for sponsors and Contract Research Organizations to decrease turnaround times. We currently have MSAs executed for 28 companies and numerous others in negotiation.

To all of our colleagues, we thank you for your support during our first year of operation and look forward to continuing to provide timely service and clinical trial expertise to your teams from our new location.

For further information about the CTO, please contact:

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To visit our website:

https://partnershealthcare.sharepoint.com/sites/phrmResources/ep/Pages/Partners-Clinical-Trials-Office-(CTO).aspx