Creation of a Clinical Trials Business Office: 
Operations and Compliance Considerations, 
Lessons Learned

Fernando Vallés & Draco Forte

June 1st, 2015

Overview

• Challenges and Lessons learned during the reorganization of the Clinical Trials Business Office:
  
  (a) Scope of Clinical Trials Business Office and getting institutional buy-in;
  
  (b) Integration of technology into administrative processes and compliance considerations.

Introduction & Background

• Boston Children’s Hospital (BCH) is a 395-bed comprehensive center for pediatric health care.
  
  • BCH sees approximately 25,000 inpatient admissions each year;
    — 200+ specialized clinical programs schedule 557,000 visits annually;
    — Performed more than 26,500 surgical procedures;
    — 158,700 radiological examinations.
  
  • Our team of physicians and nurses has been recognized by a number of independent organizations for overall excellence.
Introduction & Background

- BCH has long been a major site for clinical trials in a number of areas,
  - including muscular dystrophy, through our Neuromuscular Program,
    Cystic Fibrosis, through our CF Center, and metabolic disorders.
- As a leading academic research hospital, Boston Children’s is also a pioneer in developing cutting-edge treatment modalities for the rarest of disorders.

Scope of Clinical Trials Business Office

- The Clinical Trials Business Office (CTBO) provides end-to-end professional services to investigators interested in conducting clinical research at BCH.
- CTBO Oversees:
  - Contract and budget development;
  - Negotiation of industry-sponsored and investigator-initiated studies;
  - Insurance coverage determination;
  - Other services.

Clinical Trials Business Office

- Obtaining institutional buy-in;
- Perseverance;
- Getting the right group to assist in making necessary changes;
- Process and change take time.
Clinical Trials Business Office: Institutional buy-in

- Informing direct supervisor of challenges and weak points;
- Proposing issues to those above you;
- Forming alliances with other people within institution to assist in the cause for change.

Clinical Trials Business Office: Perseverance

- Once leadership has seen the issues, the important thing is to continue to push for the importance of change;
- Continue to use others within circle of influence to keep the issue alive and to continue to show reasons why change will be the best for the institution.

Clinical Trials Business Office: Bringing in the right group

- Once leadership has decided to make the necessary changes, the right outside group is needed to fully assess the concerns;
- Important to make sure that outside group understand the need for change;
- There always has to be someone internally that stays on top of the outside group.
Clinical Trials Business Office: Process & change take time.

- Implementation of new process and the creation of a new office takes time;
- Staff challenges;
- Making sure other groups don’t feel that new office has received preferential treatment;
- Continue to keep the momentum going.

Integration of Technology--Invoicing

- Assessment of current-state processes
  - Key personnel interview and process mapping
- Identification of business and compliance issues
  - Timely distribution of invoices
  - Invoice tracking and accounts receivable
- Consensus on solutions
  - Use of existing clinical trial management system
  - Electronic Funds Transfer

Integration of Technology- Billing

- Assessment of current-state processes
  - Key personnel interview and process mapping
- Identification of business and compliance issues
  - Large bill hold work queue
  - Varying methods to determine standard of care
- Consensus on solutions
  - Medicare Coverage Analysis
    - Utilization of CTMS
  - Electronic Health Record Research Billing Functionality
Integration of Technology - Lessons Learned

• Understand and Document Processes
  – Ensures common language
  – Mitigates brain-drain
  – Ensures automated solution(s) fit organizational need

• Secure Dedicated Resources for the Life-Span of the Project
  – Consistency in execution of work plan
  – Buy-in and commitment of committee members & staff
  – $$$

• Project Management 101
  – Consensus on work plan
  – Regular Updates and Issues log
  – Change control process

• Patience

Questions