Clinical Trials Office's short and long-term goals

September 11, 2019

Objectives

1. Review BMC's Clinical Trials Office current initiatives

2. Discuss how BMC can catalyze diversifying data collection across all patient populations
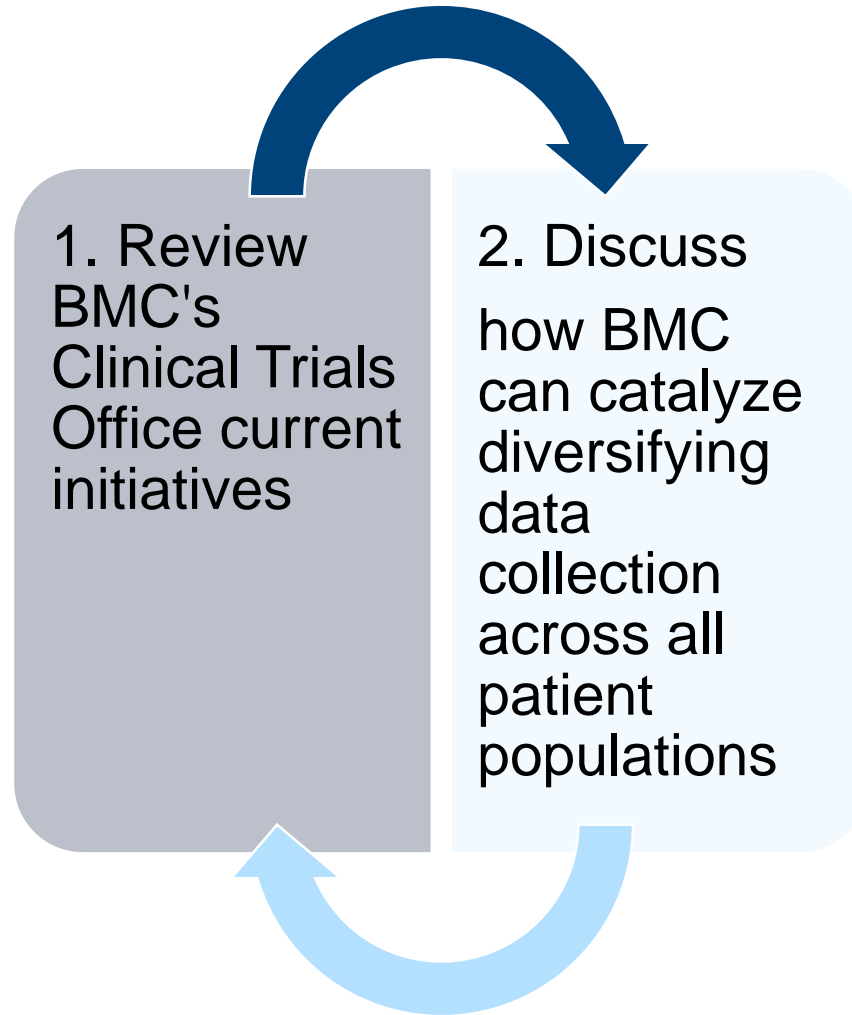
Mission

Welcome! We're here to help support your clinical and human research.

BMC Clinical Trial Office (CTO) serves as a central resource for principal investigators, study staff and departments involved in clinical research and for sponsors seeking to conduct clinical trials at Boston Medical Center. Our CTO pre-award and post-award team(s) supports and advances BMC's mission by providing leadership and expertise in research, finance, and administration. In fulfilling this mission, the CTO's primary functions are to:

- Review, negotiate, and approve of protocols that are projected to be IRB: approved, expedited, or exempt AND industry or internally funded (Clinical Trial Agreement, CDA, NDA)

- Support Grants & Contracts on protocols that include human subjects (government agency, subaward, foundation award, Boston University)

- Oversee document harmonization before final approvals: Informed Consent, Contract, Budget, and Medicare Coverage Analysis

- Ensure accurate clinical research: billing process, charge routing, and pricing

- Coordinate, educate, and train on clinical research requirements within research community and clinical departments

- Monitor and provide oversight of clinical trial account finances

Leadership initiatives

— Drafting an annual strategic plan 2019-2020

— Collaborating with ancillary service departments who support clinical research protocols
  - 7/15/19- IRB, Investigational Pharmacy Service, Lab Services, Clinical Research Resources Office
  - 9/10/19- BMC Marketing, Radiology, Research Compliance, Cancer Care Administration, and GCRU

— Emphasizing that CTO is central point of contact for all BMC clinical research pricing, i.e. departments should not be providing researchers projected clinical procedure rates

— Hosting monthly and bi-weekly research billing working groups

— Reviewing and providing feedback on clinical research related guidelines and policies

— Informing BMC leadership on a variety of clinical research related issues and successes

— Engaging in department discussions on areas of improvement for CTO

Re-design CTO pre & post award workflows

— Define CTO roles and responsibilities within Research Operations and departments providing clinical research
  - Provide high level scope determination
  - Design research protocol workflow
  - Develop ease and efficiency of projects routing through Res Ops with clear understanding of ownership

— Provide excellent customer service for our clients in pre & post award workflows: BMC/BU departments performing clinical research
  - Streamline tasks
  - Increase efficiency
  - Centralize financial oversight and mitigate risk
  - Encourage continued education for CTO staff

Research Operations scope summary

Grant & Contracts scope
1. Government agency or foundation funded
2. All basic science, regardless of sponsor type
3. All material transfer agreement (MTAs)
4. All data transfer/use agreements (DTAs, DUAs)
5. All subawards

Clinical trials office scope
1. Industry or internally funded AND IRB: expedited, full-board review, or exempt
2. All non-disclosure agreements (NDAs)
3. All confidential disclosure agreements (CDA)

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Research Operations service intake processes

Research Operations agreement intake process		
Research Ops lead	Grants & Contracts	Clinical Trials Office
Agreement type	MTAs, DTAs, DUAs, subawards	CDAs and NDAs
Department action	Email grants.admin@bmc.org	Email CTO@bmc.org

Research Operations software system data entry flow		
Research Ops lead	Grants & Contracts	Clinical Trials Office
Protocol funding source and type of research	1. Government agency or foundation 2. All basic science	1.Industry or internally AND IRB: expedited, full-board review, or exempt
Department action	Create InfoEd record	Create Velos record

Department Research Operation workflow
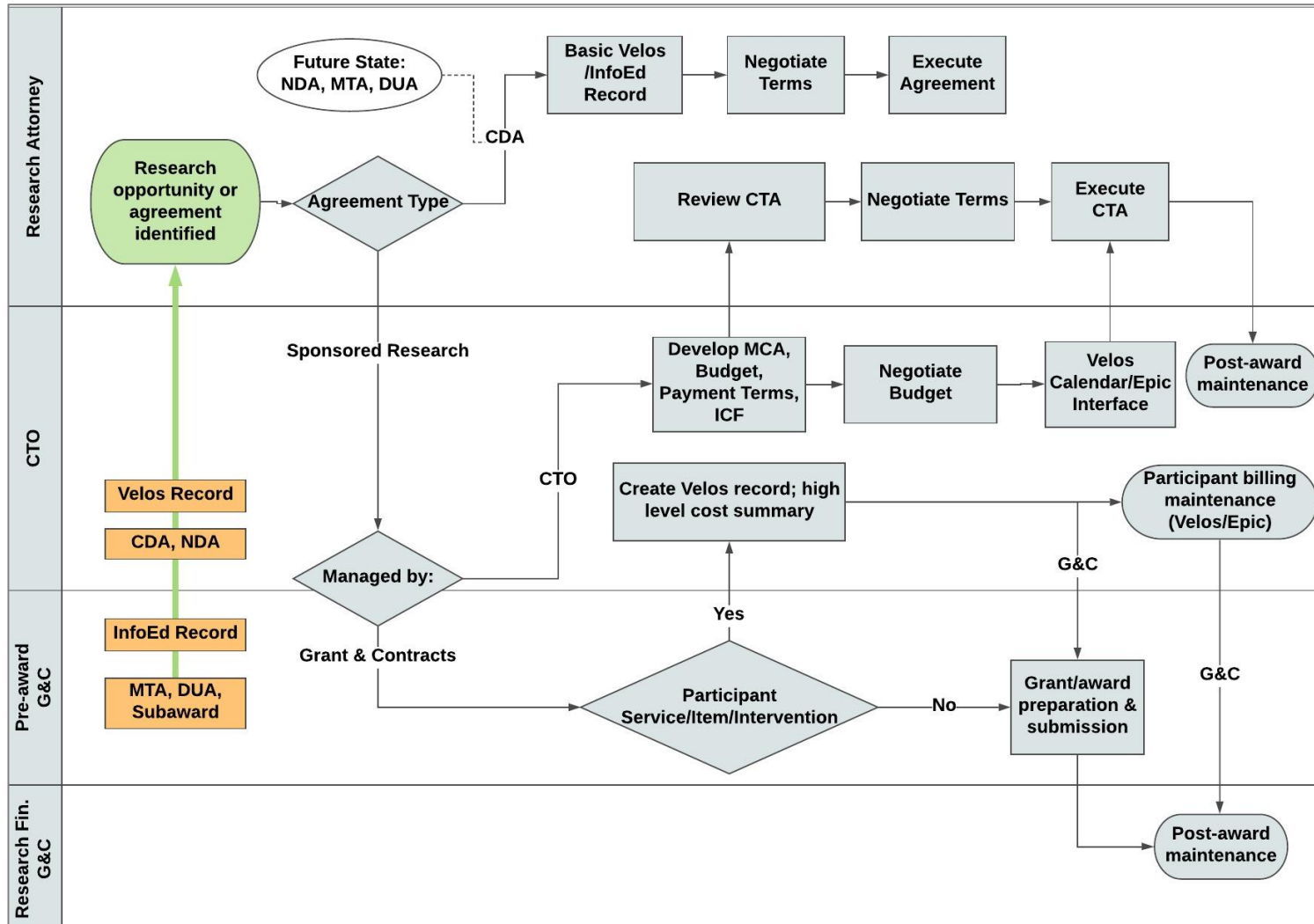
New CTO initiatives: pre-award

1. Reorganize CTO study folders by sponsor, allowing for review of all department contracts and budgets before negotiations commence

2. Improve communications with study teams
   - update CTO website
   - develop standard study initiation letter
   - collaborate on all CTFA lead processes

3. Use Velos beyond previous definition- all work to be managed by CTO and Research Attorneys will have a Velos record
   - CTFA will aid in execution of CDAs and NDAs

4. Serve as primary liaison between the sponsor, the study team, the Research Attorneys, and Ancillary Services = CTFA

5. Provide review of the Injury and Cost language in the Informed Consent = CTFA

6. Review and negotiate payment terms with the sponsor = CTFA

7. Lead kick-off meeting for new clinical research protocols = CTFA

New CTO initiatives: post-award

1. Focusing on outstanding AR

2. Identifying and developing short/long-term solutions for research billing issues and audit

3. Brainstorming ways to improve monthly research department meetings

Outstanding AR April – Aug 2019 summary

- $154k reduction in open AR over 120 days since project implementation
- Goal: to receive payment at 61-90 days = improve fiscal health

Open AR - CY 19

Over 120 AR - CY 19
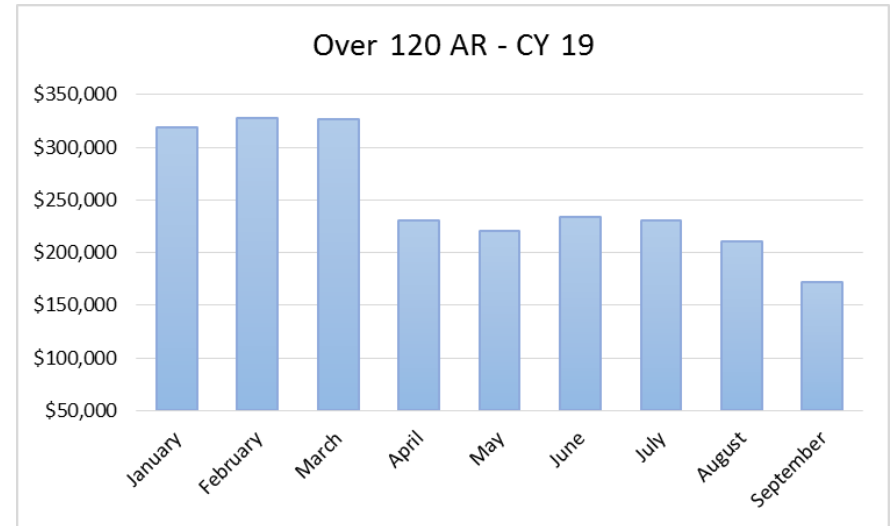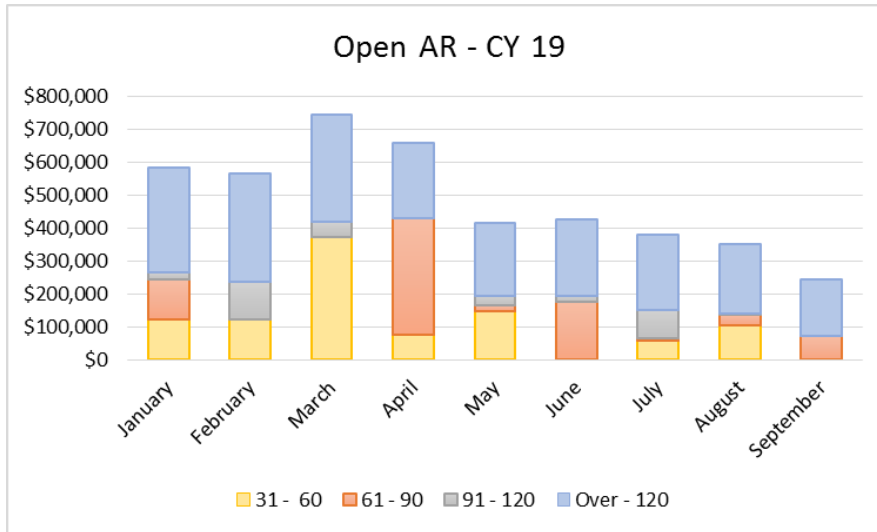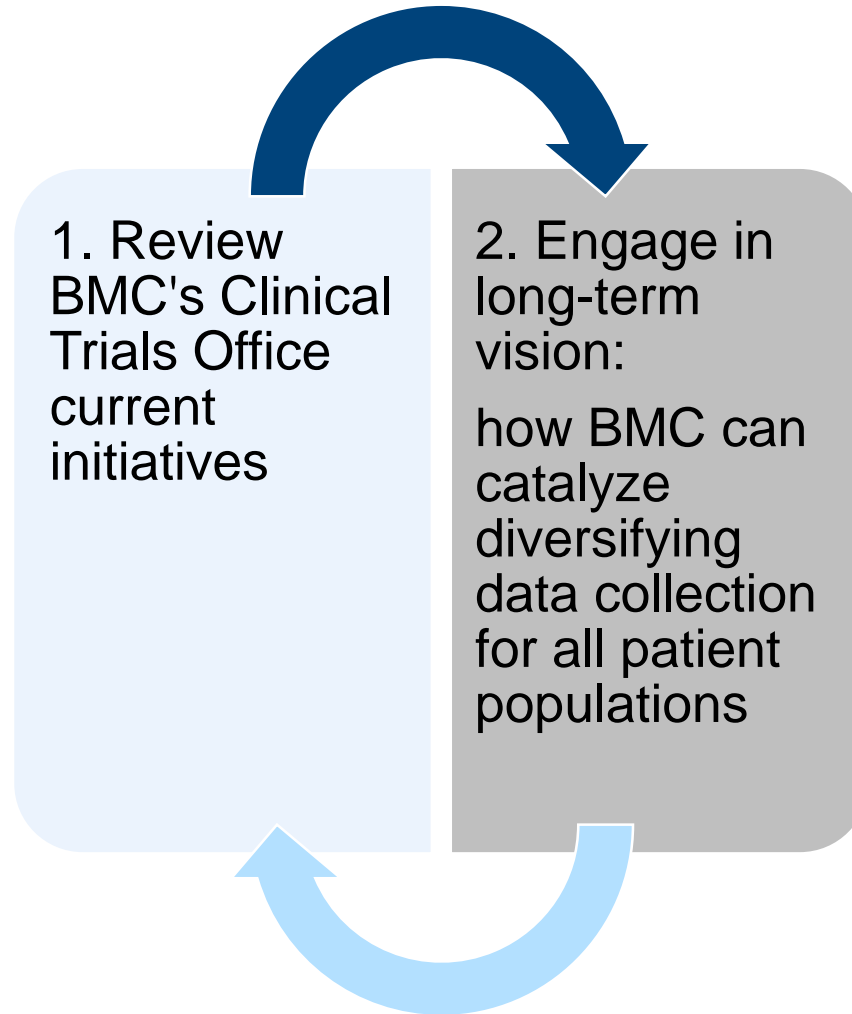
Research billing update

- Manage working group bi-weekly and leadership meeting monthly
  - pt status between Epic and Velos- CTO to complete 100% pt status review in Velos and Epic
  - professional billing
  - claims logic and coding

- Complete research-related denial audit
  - 36 encounters to review with denial code "Experimental/Investigational"
  - Reviewing 100% of claims in two steps:

    step 1: accurate charge routing, confirmed 100% accuracy

    step 2: claims processing accuracy, if research related, then review insurance requirements

- Request review of 100% of "research-related, bill to insurance" claims

- Secure Epic project to begin Oct 2019 to address
  - final status change requirements to relieve manual review
  - automatic claims processing requirements to relieve manual review
  - Medicare Advantage Plan billing and research

Monthly research department meetings

Welcome suggestions on improved process, draft brainstormed ideas below

- Provide one email from Research Operations to department admins containing:
  - CTO and G&C account balance reports
  - CTO invoicing/milestone checklist per study

- Improve agenda
  - Include pre-award for statuses G&C and CTO
  - Discuss lessons learned in pre and post award
  - Review financial analysis reports
  - Review invoices/milestones met
  - Discuss outstanding AR (>120 days)
  - Review CTO projects effort allocation by personnel and study
  - Discuss newly awarded accounts, and allocation of related expenses
  - FFRs and final invoices
  - Send standard follow-up email with action items listed and deadlines for completion

Objectives

1. Review BMC's Clinical Trials Office current initiatives

2. Engage in long-term vision:

how BMC can catalyze diversifying data collection for all patient populations

The future of clinical research at BMC

CTO workflow

Increase clinical research opportunities across all BMC patients- through efficiency workflows

Data collection and analysis

Develop database of sponsors to include: contract payment terms, budgets, and experience

Velos

Advance Velos software to mirror and replace manual efforts

The future of clinical research at BMC, cont.

Epic

- Move research fee schedule rates for HB and PB to generate out of Epic, manual journal entry remains for CTO to charge study fund
- Review Coverage with Evidence Development logic and assess process improvement

Financial projections

Provide departments with monthly financial projections for Active accounts

The nature of research

Look into my crystal ball, if I could only predict the future…….

Contact information and Questions

Questions, comments, feedback

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Other Research Operations resources:
Website: https://www.bmc.org/research-operations
Contact list: http://www.bmc.org/sites/default/files/Research/documents/Combined_Assignment_List.xlsx
CTO inbox: CTO@bmc.org
G&C inbox: grants.admin@bmc.org