



Inaugural Research Town Hall Meeting

November 28, 2023



Agenda

- Welcome & Research Enterprise Overview- Megan
- Research year in review – Tina
- Sponsored Programs Administration (SPA)- Chris
- Research Finance– Tyler
- Center for Clinical Research Advancement (CCRA) – Johanna
 - Clinical Trials Office– Mike
 - Clinical Research Network FY 23 Metrics- Ryan

*Notes: we will record the session and make the slides available

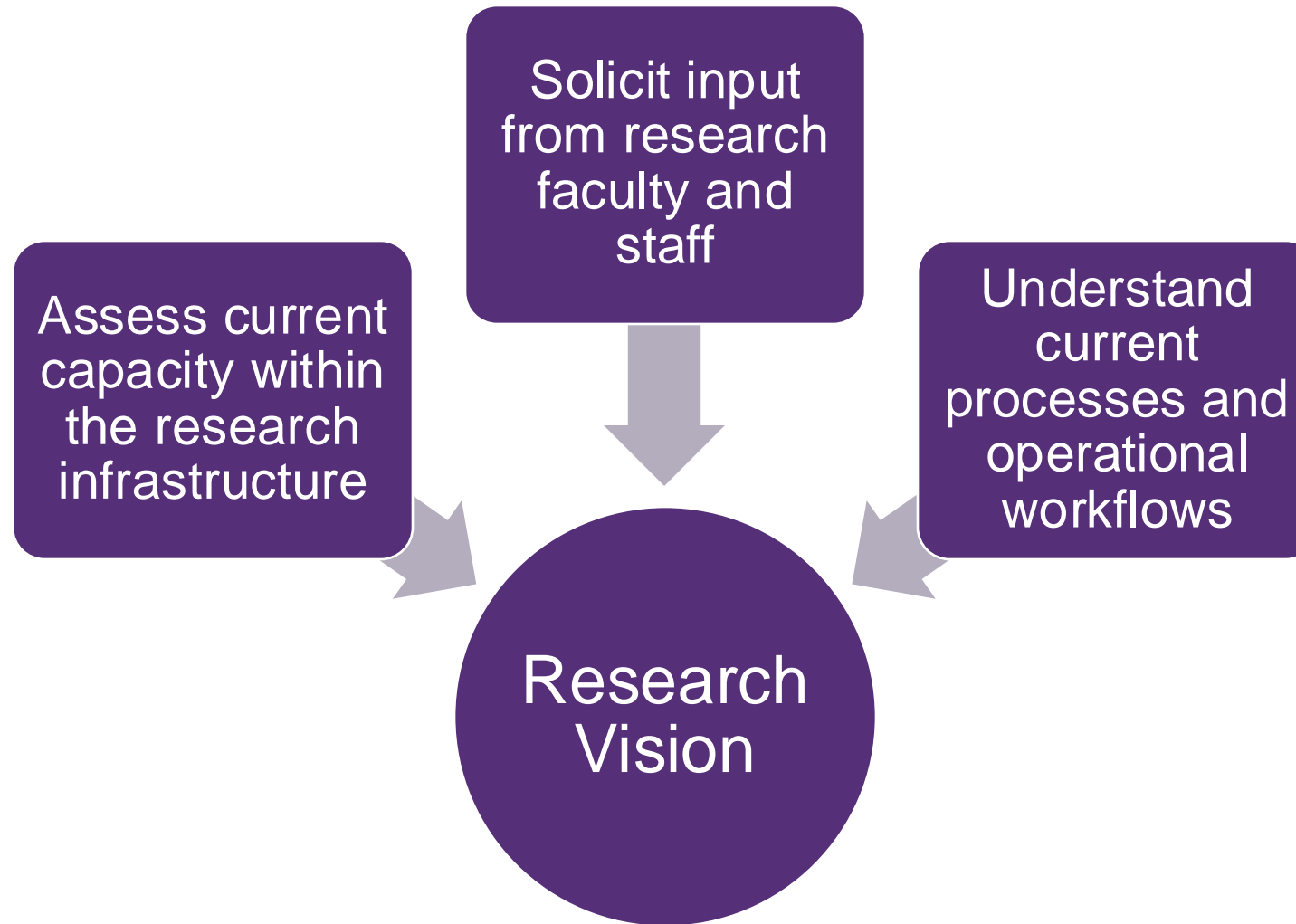
Research Town Hall Meetings: Welcome to our Inaugural Meeting

- **Purpose:** Bring together the BMC research to ensure people are aware of research happenings and to build community
- This meeting will be an intro to the Research Enterprise and Res Ops
- **Future Meetings:**
 - 3-4 times per year, hybrid, will move times during the day
 - Future meetings will highlight the work of different researchers/research teams
 - Future meetings will include networking opportunities

Make sure that you are receiving our emails/newsletter

- If you need to get added to the DG, email Alexandra.Zhang@bmc.org

Our research vision and developing strategic plan are informed by a rigorous process of discovery and preparation to engage stakeholders across the health system





Research Enterprise Mission & Vision

Mission

BMC is a **world-class, interdisciplinary research institution centered on equity**, which guides the science we conduct across the full spectrum of scientific discovery, and in how we conduct it.

We believe that expanding the opportunity to participate in research – as a member of a research team; as a participant; and as an interested member of the community - is core to providing inclusive, innovative, accessible, equitable, and exceptional healthcare for all.

Vision

Building upon our long history of partnering with our community, our vision is to **advance equity-driven research to tackle our patients' and the nation's toughest health challenges**, creating a reproducible national model that advances health equity for all.



Research Enterprise Values

Engagement

We actively engage all stakeholders to elicit input and diverse perspectives

Transparency and Clear Communication

We strive for open and frequent communication to achieve full transparency in our work and to provide high levels of service to the research community

Accountability

To support effective teamwork and partnerships, we hold ourselves accountable for our individual and collective contributions and responsibilities

Respect and Kindness

We assume the best intentions of everyone and treat each other with respect and kindness

Service Excellence

We strive to provide excellent service to the BMC research community through our deep expertise, attitude of continual learning, responsiveness, and pride in our work

Knowledge sharing

We are committed to sharing our learnings and knowledge – both our scientific discovery resulting from research, and our learnings about how we apply a research equity approach

Research Enterprise Goals

#1: SUSTAINABLE RESEARCH INFRASTRUCTURE	#2: INNOVATION AND PARTNERSHIPS	#3: ADVANCING SCIENTIFIC DISCOVERY	#4: EXCEPTIONAL RESEARCH FACULTY AND STAFF
<p>Strengthen and expand a sustainable research infrastructure that supports our investigators and fosters growth of federal and other extramurally sponsored studies</p>	<p>Accelerate growth of biopharma and PI-initiated research, IP and TT, and industry partnerships in strategic areas that match our expertise, capacity, priorities, and expand our comprehensive portfolio</p>	<p>Expand funded work in high-impact, cross-cutting areas where we are poised to have outsized impact, with a focus on health equity</p>	<p>Facilitate recruitment and retention of a diverse, productive, and professionally vital research faculty and staff</p>

Focused Research Operations strategies will facilitate achieving our goal

Early strategies and accomplishments:

- New 1.0 FTE (Asa Lopatin, JD) for agreements, with new more transparent processes and significant decreases in time to execution
- 2 new FTEs in the Clinical Data Warehouse for Research, with reduced time to receive data
- Changes in Sponsored Programs to assign individual to specific Sections/Departments
- IDC policy nearing finalization
- Central feasibility assessment creation
- Research Ops Advisory Council created and meets monthly
- Approved to create (Q3) a methods core and a scientific writing core
- 3000 square feet of a clinical research unit to open on Yawkey 6 in 11/24

We are exploring and identifying BMC's opportunity areas for scientific growth

Early Strategies:

- **Map areas of faculty expertise** that are cross-Departmental
- Understand areas of **growth and priority for NIH** and other funders (Huron)
- Partner with our Health Equity Research **CAB** to understand their areas of priority
- Learn about similar approaches from **peer institutions**
- **ARPA-H participation**

Investing in our faculty and staff will promote recruitment and retention of a diverse cadre of research scientists and professionals

Early Strategies:

- Annual **bridge funding** RFA released, and 6 early career investigators funded
- **Pilot RFP** for BMC investigators coming early 2024
- **T32 pre and post doctoral** get togethers
- **Onboarding packet** for new researchers being created
- First ever **BMC Speed Mentoring** Event!
- Establish **research town halls** to highlight science and initiatives (11/28)
- Promote **ASCEND program** to train community members to become research team members

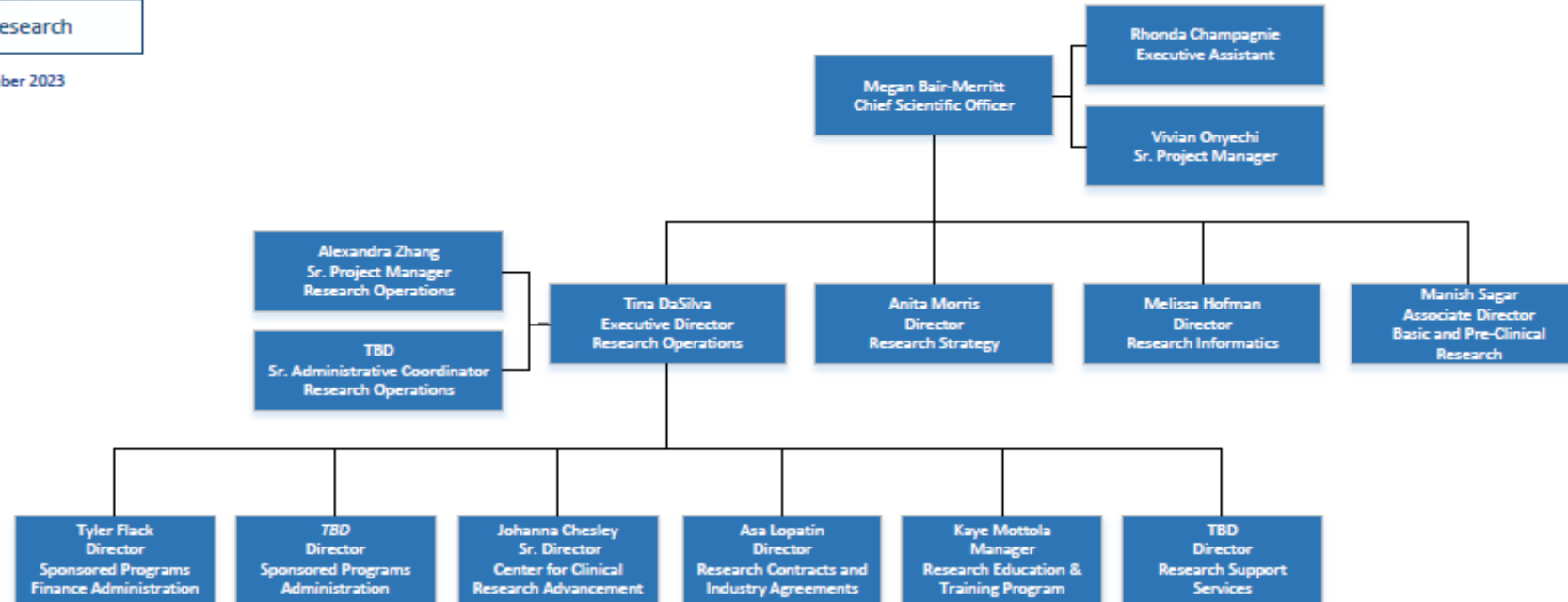
Office of Research Organizational Structure



EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Office of Research

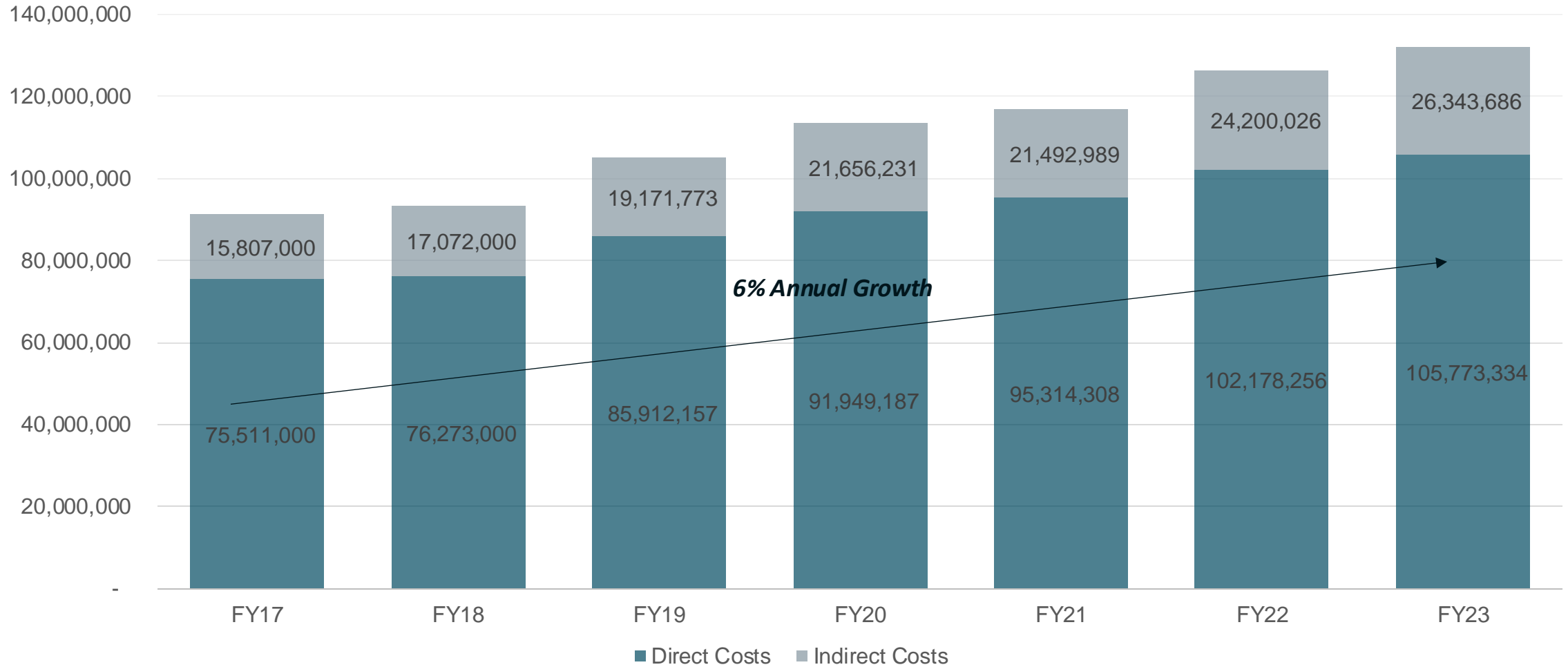
Updated: November 2023



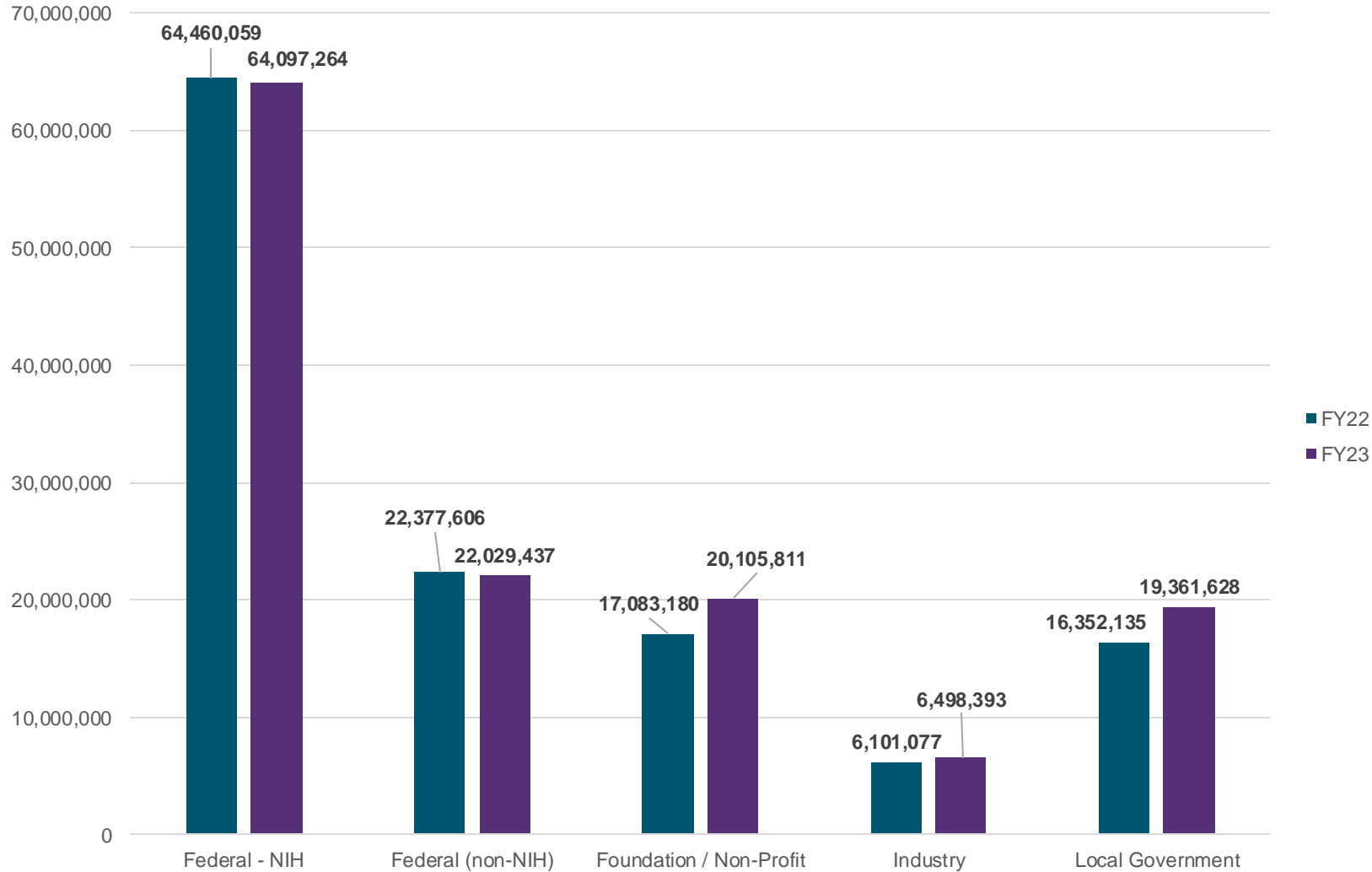


FY23 Metrics

Sponsored Program Expenditures FY23



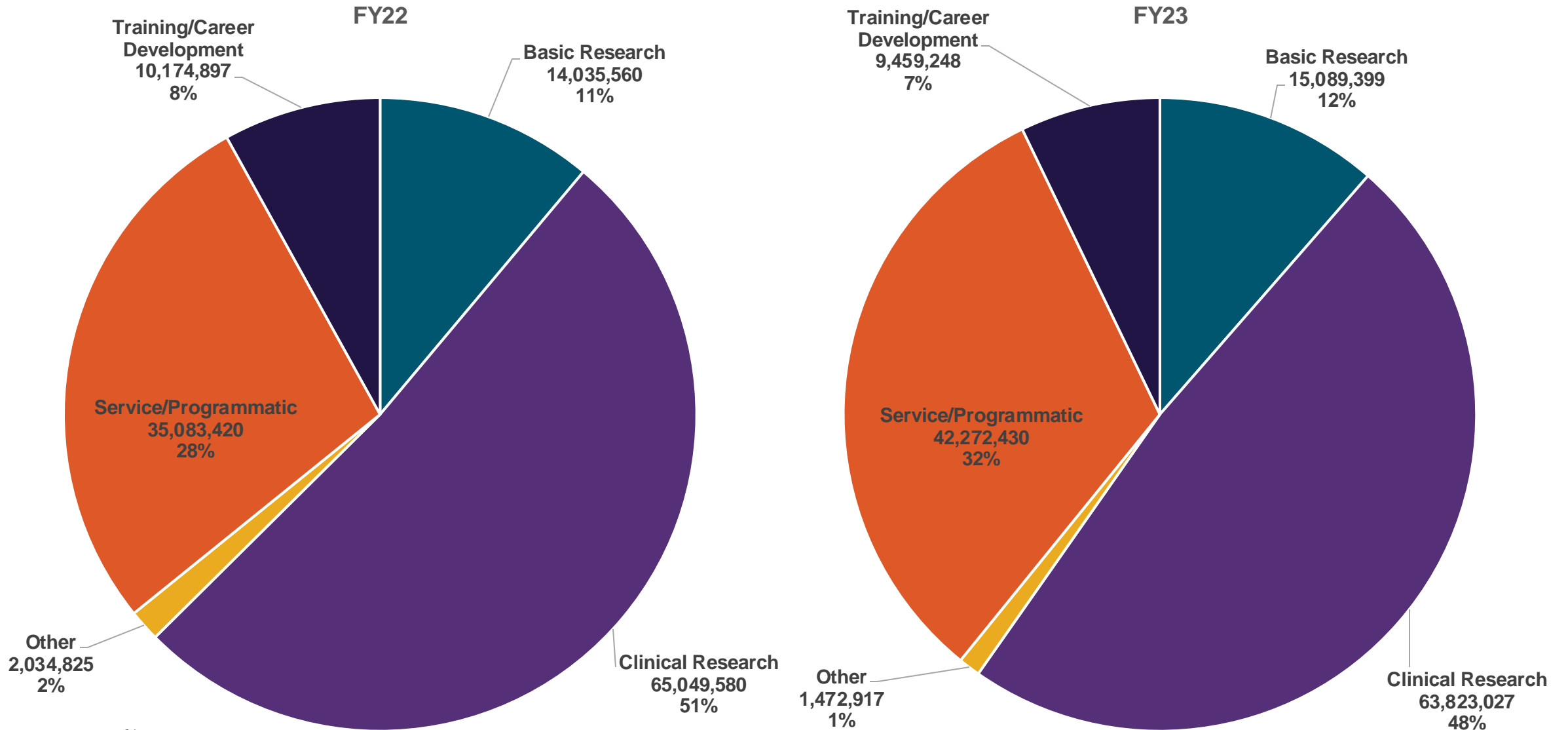
Sponsored Program Expenditures FY23 by Source



- Increase in local government attributable to Mass and Cass Housing Grant from Boston City
- Federal sources include direct and sub awards to BMC

Foreign sources not represented on graph – FY22 4,225 and FY23 24,488

Sponsored Program Expenditures FY23 by Program Type



"Other" includes equipment and quality improvement grants and contracts

FY24: Looking Ahead....

Agreements

- **Refine Agreements workflow**
- **Eliminate Redundancies**
- **Reduce multiple points of entry**
- **Identify system solution**

Research Metrics Dashboard

- **Continue to work with Research Informatics and Research Information Systems to launch Research Metrics Dashboard**

Data Integrity

- **Enforce Data Integrity Procedures**

InfoEd

- **Test InfoEd S2S capabilities**

Space Survey

- **Identify space tracking tool**

CTMS

- **Evaluate CTMS solutions**

SPA

- **Support onboarding of SPA director**



Sponsored Programs Administration (SPA)

Sponsored Programs Administration Fast Facts



We are

- First point of contact for individuals with questions related to sponsored research at BMC



We regularly work with

- Foundation Relations & Government Grants (FRGG)
- Research Finance (RF)
- Research Information Systems (RIS)
- Research Contracts and Industry Agreements (RCIA) and the Office of the General Counsel (OGC)
- Clinical Trial Office (CTO)
- Research Compliance Office



We provide

- Guidance and advice in interpreting sponsor guidelines, institutional policy
- Award management, incoming award reviews and acceptance and outgoing subaward issuance
- Research-related services, including incoming and outgoing Material Transfer Agreements (MTAs) and Data Use/Sharing/Transfer Agreements (DUAs)



We strive to

- Provide a positive experience for all individuals who require our assistance
- Respond to inquiries and requests within a reasonable amount of time
- Restore trust and confidence, and forge stronger relationships with, Departments and investigators
- Improve the efficiency and delivery of SPA services to its primary customers

Selected Accomplishments in FY 2023

- Created a uniform sub-out request process – issuance to execution time reduced from weeks/months to fewer than 21 days from submission of request
- Eliminated over 95% of mismatches of subs-out and POs that affect financial operations
- Hired an experienced GCA with extensive InfoEd knowledge to fill one of two vacated roles
- Submitted 430 proposals and processed 110 new incoming awards (excluding existing subawards)*
- Launched proposal routing
- Prioritized processing of incoming award agreements and MTA and DUA requests
- Restructured the department from a functional service model to portfolio-based research management

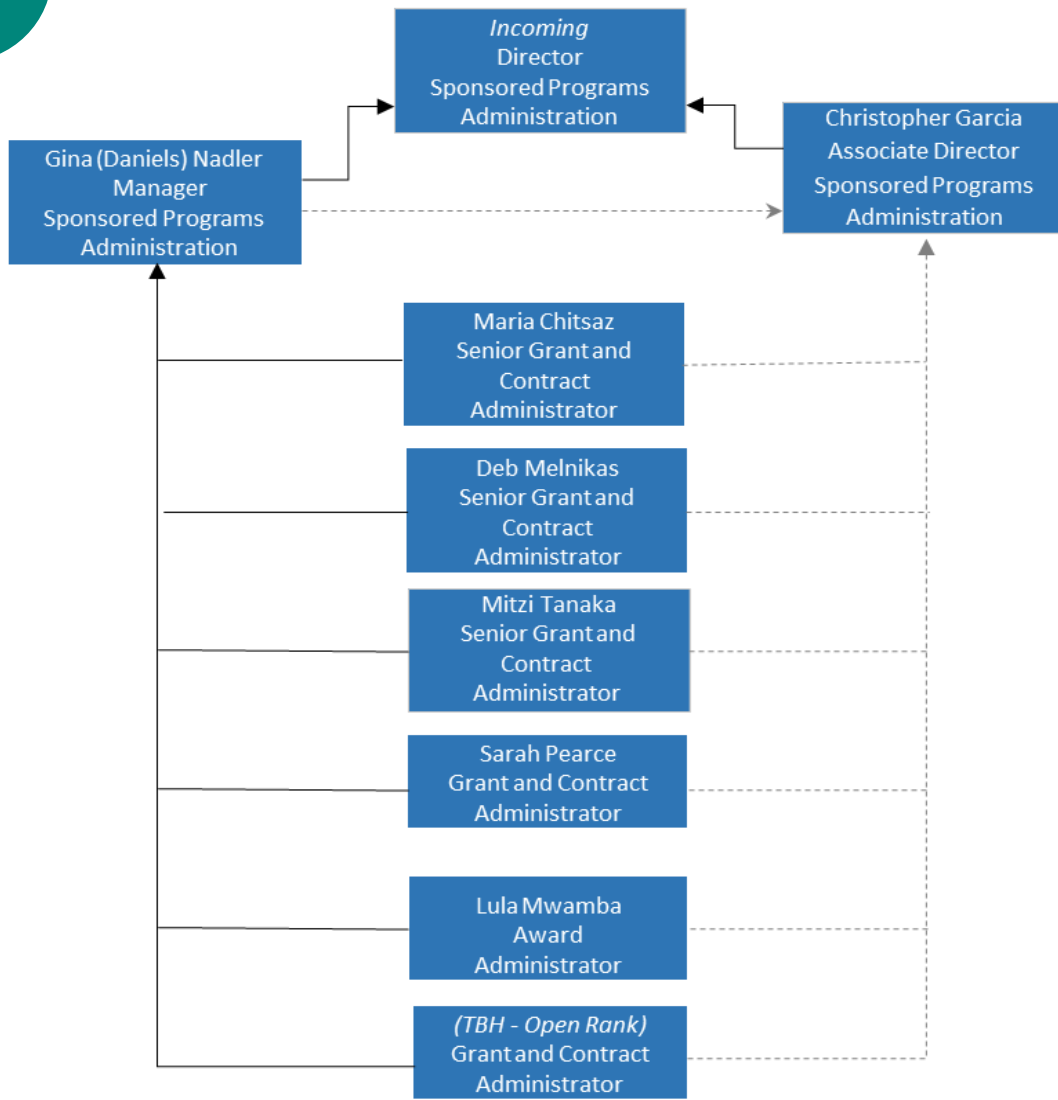
What You Need to Know About the New SPA Structure

- **Restructuring SPA means that...**
 - GCAs are no longer “pre-award” or “non-financial post-award” specialists; each is now a generalist and comprehensive research administrator responsible for “cradle-to-grave” management of projects.
- **Each Department is assigned a GCA for “one-stop shop” award administration to establish...**
 - project continuity (award/project history, context, special circumstances)
 - consistent and reliable service and to Departments by having a single contact person
 - sustainable and dependable coverage in the absence of a Department’s primary GCA.
- **November and December 2023 will be intensive cross-training months, so SPA thanks you in advance for your patience and understanding.**

FY24: Focus Areas

- **Define and establish the role of Sponsored Programs Administration within the BMC research enterprise.**
 - Clearly identify the roles and responsibilities of SPA and work with Leadership to determine the appropriate home(s) for some of SPA's inherited activities.
- **Identify areas for improvement and implement efficiencies where able to: processing incoming award agreements, MTA and DUA requests to expedite turnaround times.**
- **Continue to train/cross-train SPA personnel to gain the knowledge and expertise required to provide effective and uniform service to all the Departments.**
- **Position SPA to be a forward-looking operation (vs. how things have “historically” been done) by maintaining a robust technical infrastructure, applying current and best practices in research administration and continuing to advance BMC’s mission of health equity for all.**

Current SPA Structure and General Overview of Personnel Responsibilities



Effective 01/02/2024

Lula Mwamba Award Administrator

- Manages Grants.Admin@bmc.org mailbox
- Processes actions (awards, modifications, etc.)
- Prepares awards for account setups and changes

Maria Chitsaz, Deb Melnikas Sarah Pearce, Mitzi Tanaka Grant & Contract Administrators

- Main contact for each Department
- Responds to or redirects inquiries
- Reviews and submits proposals
- Communicates with sponsors
- Reviews incoming awards and negotiates terms and conditions
- Reviews progress reports, assists with award transfers, etc.
- Issues subcontracts-out, reviews and drafts MTAs and DUAs
- Closes out completed projects

Gina (Daniels) Nadler Manager of SPA

- Manages GCA and AA personnel
- Oversees compliance reporting
- Provides expertise and manages city and state contracts
- Provides GCA and SPA leadership backup as needed

Christopher Garcia Associate Director, SPA

- Serves as backup to the Director
- Oversees SPA operations
- Helps resolve escalated issues
- Authorized signatory for routine documents and agreements

Incoming Director of SPA

- Provides Department Leadership
- BMC's Primary Authorized Organizational Representative
- Works with RO Leadership on new initiatives and policies

Department GCA Assignments (check [here](#) for periodic updates)

Maria Chitsaz

- Cancer Research Center
- Cardiothoracic Surgery
- Dental Clinic / Dentistry
- Neurology/Neurosurgery
- Ophthalmology
- Oral Surgery
- Otolaryngology
- Pediatric Dental
- Psychiatry
- Radiation Oncology
- Surgical Oncology
- Vascular Surgery
- Department of Medicine
 - Calcium Signaling Unit / Ion Channel
 - Cardiology
 - Genetics Program
 - Hematology/Medical Oncology
 - Hypertension
 - Myocardial Biology
 - Vascular Biology
 - Vasculitis Center

Debra (Deb) Melnikas

- Administration
- Boston Healthnet
- Boston Urban Asthma Coalition
- CTSI & Development
- LWAHP (p/k/a ELAHP)
- Executive Offices, Finance & IT
- Volunteer Services & Social Work
- Department of Pediatrics
 - Administration
 - Adolescent Clinic
 - Ambulatory
 - Community Nutrition / Nutrition
 - Developmental & Behavioral
 - Emergency & Emergency Dept.
 - Endocrinology
 - Gastroenterology
 - General & Primary Care
 - Genetics
 - Growth and Development
 - Hematology/Oncology
 - Infectious Diseases
 - Intensive Care Program
 - Neonatology / Newborn Care
 - Neurology / SIDS Program
 - Pulmonary
 - Residence Education Program
 - Project Health
 - Reach Out and Read Program

Sarah Pearce

- Adult immunization
- Colon and Rectal Surgery
- Dermatology
- Developmental Therapeutics
- Epidemiology Bioscience
- Gastrointestinal Surgery
- Pathology & Laboratory Medicine
- Pharmacy
- TB Trials Consortium
- Urology
- Department of Medicine
 - Biomolecular Medicine Unit
 - Clinical Epidemiology Research & Training
 - CReM
 - Endocrinology, Diabetes, Nutrition
 - Gastroenterology
 - Immunobiology
 - Infectious Diseases
 - Medical Information Systems Unit
 - Molecular Medicine
 - ❖ Molecular Genetics Unit
 - ❖ Obesity Center
 - Nephrology
 - Pulmonary, Allergy & Critical Care
 - Rheumatology

Mitzi Tanaka

- Clinical Trial Office
- Critical Care Surgery
- Emergency Medical Services
- Emergency Medicine
- Family Medicine
- Nursing
- Obstetrics & Gynecology
- Occupational Health
- Orthopedics/Orthopedic Surgery
- Pediatric Orthopedic Surgery
- Plastic Surgery
- Podiatry
- Quality Improvement & Patient Safety
- Radiology
- Surgery – General & Transplant Trauma Surgery
- Department of Medicine
 - Anesthesiology
 - Community Medicine Unit
 - Digital Imaging Microscopy Center
 - General Internal Medicine
 - Geriatrics
 - Preventative Medicine & Epidemiology
 - Women's Health Unit

Some Reminders and Central Contact Information

Please remember to remind your sponsors to send all award notices communications, and other requests that require institutional action to, and for all other general inquiries, contact:

Grants.Admin@bmc.org

To request an outgoing subaward to an external collaborator, please complete the form found at: <https://bmc.tfaforms.net/170>, and for any questions regarding the status of outgoing subcontracts, contact:

Subaward@bmc.org

To request an outgoing MTA or DUA, please download and complete the intake questionnaire from [this site](#) and send it to:

DUA.MTARequest@bmc.org

During the open application period for the NIH Loan Repayment Program (LRP), please send all communications and questions, for faster response times to:

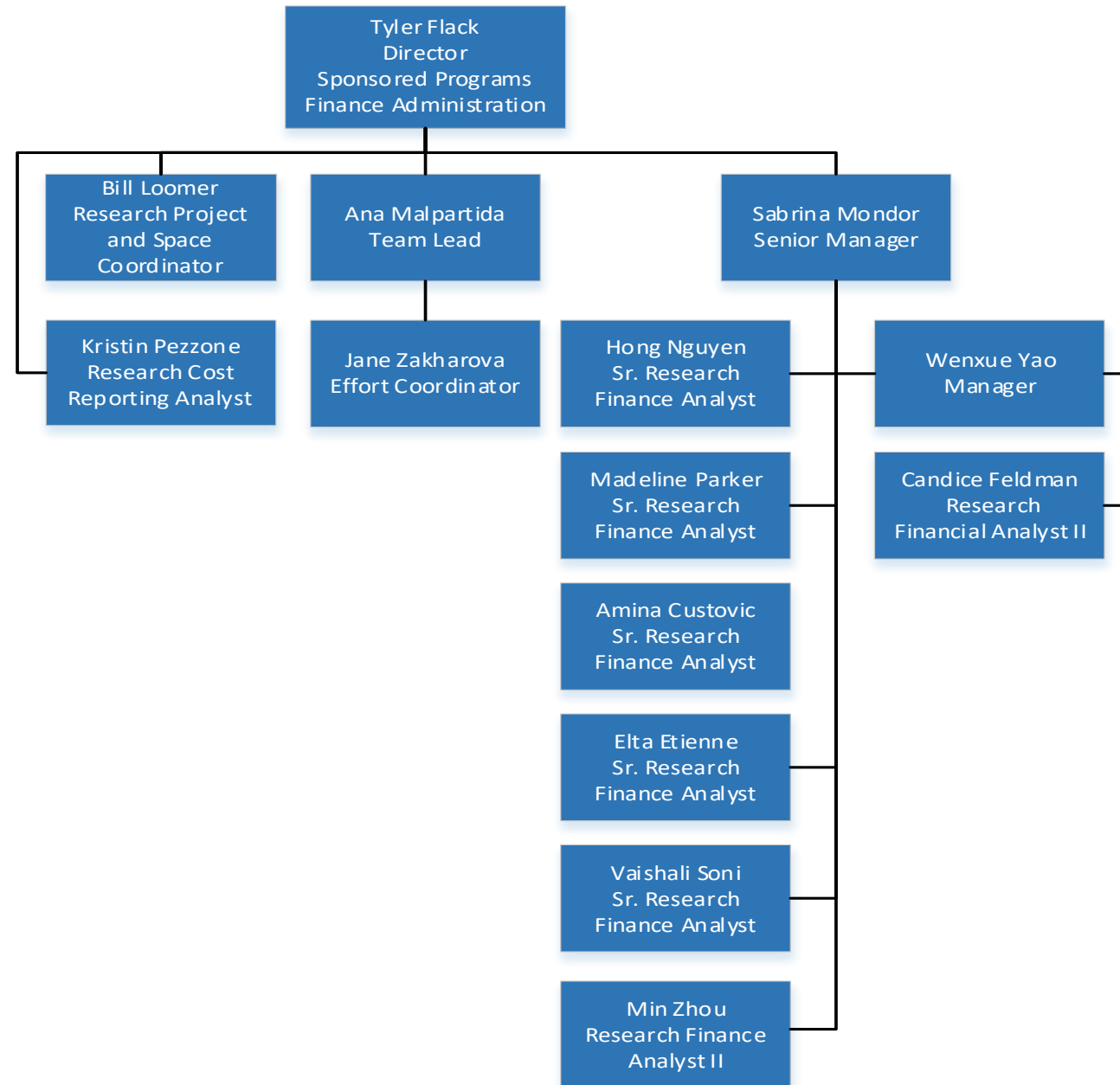
LRP@bmc.org



Research Finance

Research Finance Overview

- Financial Portfolio Management for all grants and contracts, excluding industry funded clinical trials
 - Financial Reporting to Sponsors
 - Invoicing and Federal Draws
 - Financial Closeout
 - Accounts Receivables
- Effort Reporting and Salary Allocation Support and Approvals
- Single Audit
- Financial Reporting (Institutional)
- Subrecipient Invoice Payment
- IDC and Fringe Rate Proposals and Negotiations
- Research Equipment Tagging and Database Management
- Space Survey and Utilization Reporting

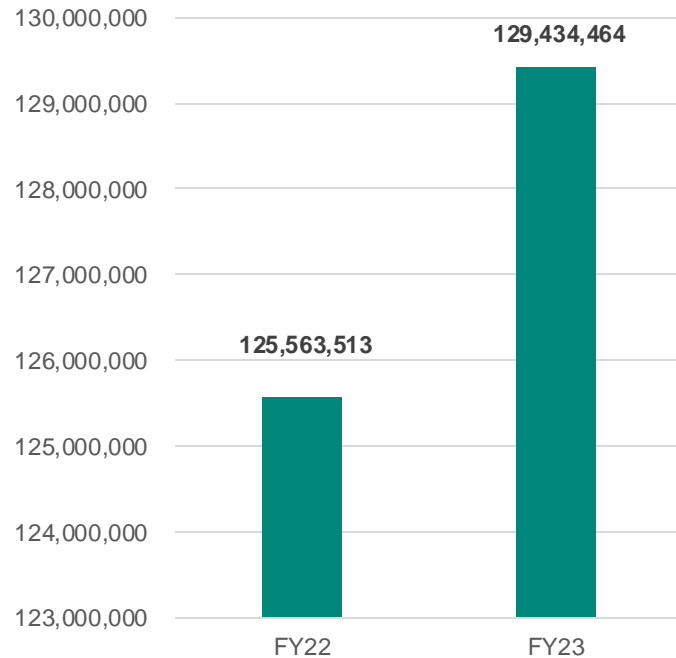


Research Finance Contacts

	Primary Contact	Back-up Contacts
Financial Portfolio Management	Portfolio Contacts List	Sabrina.Mondor@bmc.org
Financial Reporting (Institutional)	Kristin.Pezzone@bmc.org	Tyler.Flack@bmc.org
Audits and Site Visits	William.Loomer@bmc.org	Tyler.Flack@bmc.org
Effort Reporting	EffortReporting@bmc.org	Ana.Malpartida@bmc.org Jane.Zakharova@bmc.org
Space Survey	William.Loomer@bmc.org	Tyler.Flack@bmc.org
Research Equipment Management	William.Loomer@bmc.org	Tyler.Flack@bmc.org
Salary Allocation Support	Ana.Malpartida@bmc.org	Jane.Zakharova@bmc.org

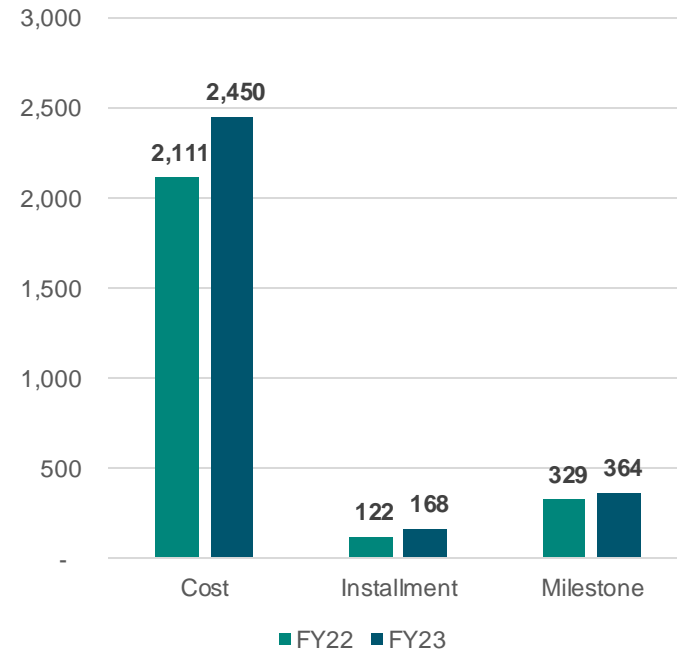
FY23 Year in Review – Volume Metrics

RF Portfolio Expenditures



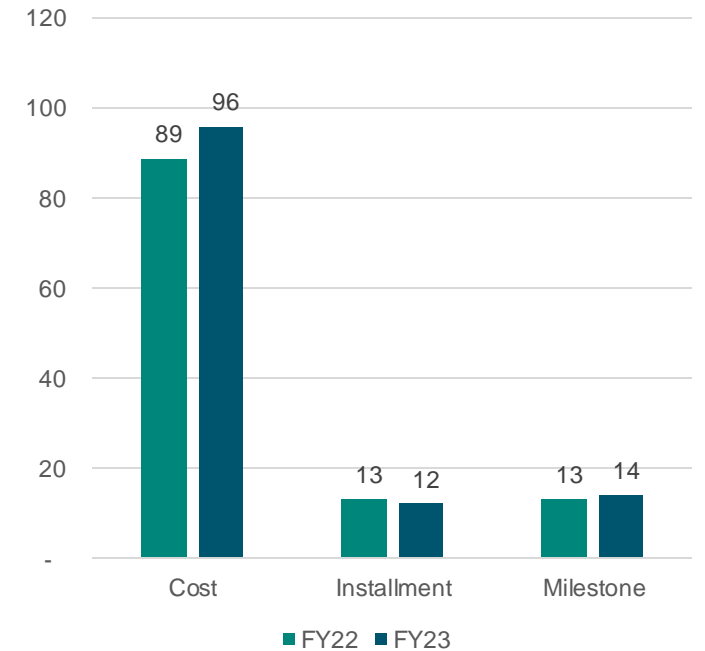
Expenditures in RF portfolio increased by approx. \$4M in FY23

Invoicing - Count



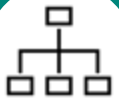
Total invoices produced by RF increased by 16% in FY23

Invoicing \$s in Millions



Total dollars invoiced by RF increased by 6% in FY23

Research Finance Key Accomplishments FY23



Staffing

- Filled three open positions, team fully staffed
- Added one new position dedicated to city and state contracts



Audits

- Filed FY23 Single Audit (annual audit of federal programs)
- No findings for FY23



Effort Reporting

- Two roles in Research Finance dedicated to salary allocation and effort reporting support and training




Invoicing

- Initiated new internal invoicing processes improving timeliness and accuracy of monthly invoices



Website

- Drafted over 20 new pages for Research Operations website redesign to improve transparency and access to information on business processes – **COMING SOON**



Center for Clinical Research Advancement (CCRA)

Center for Clinical Research Advancement

Transforming discovery and innovation *with and for all people*

- ❖ Our transformative approach fosters multi-directional collaboration uniting investigators and community partners, participants and support staff, sponsors and academic colleagues to collectively advance medicine.
- ❖ We challenge traditional scientific inquiry by scrutinizing the systemic practices within clinical research operations, identifying hidden biases, unveiling new tools, and reconfiguring operational methods.



Clinical Trial Office (CTO)

- Oversees the CT agreement & budget negotiations
- Supports all BUMC clinical researchers performing research at BMC with: coverage analysis, budgeting, research charge master, business operation systems (Epic research billing, CTMS, & Participant Reimbursement)
- Monitors post-award financial health of clinical trials.



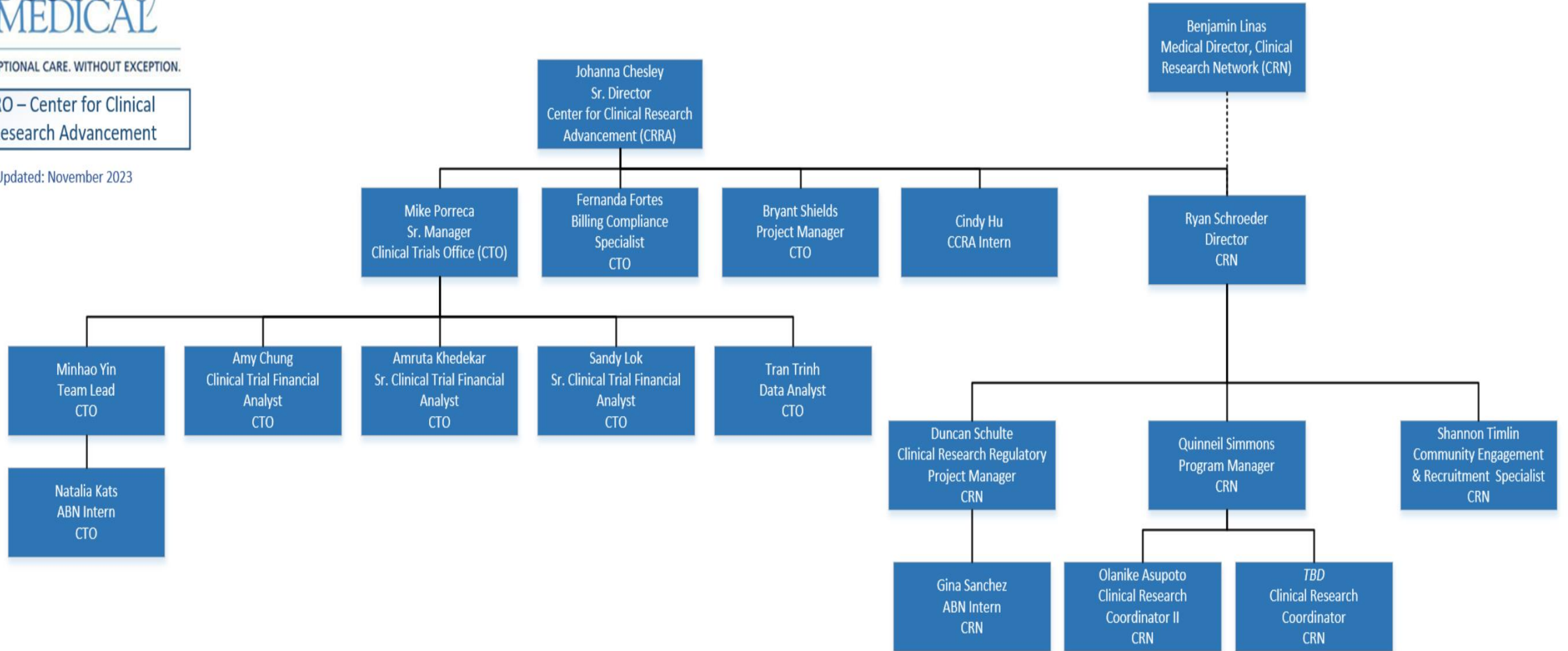
Clinical Research Network (CRN)

- Offers full-service staffing solutions for institutionally prioritized and under resourced studies infused by community-engaged values
- Serves researchers and our surrounding communities by re-thinking clinical research engagement practices and co-designing appropriate interventions

Foster community advisement | Promote financial sustainability | Optimize systems and practices

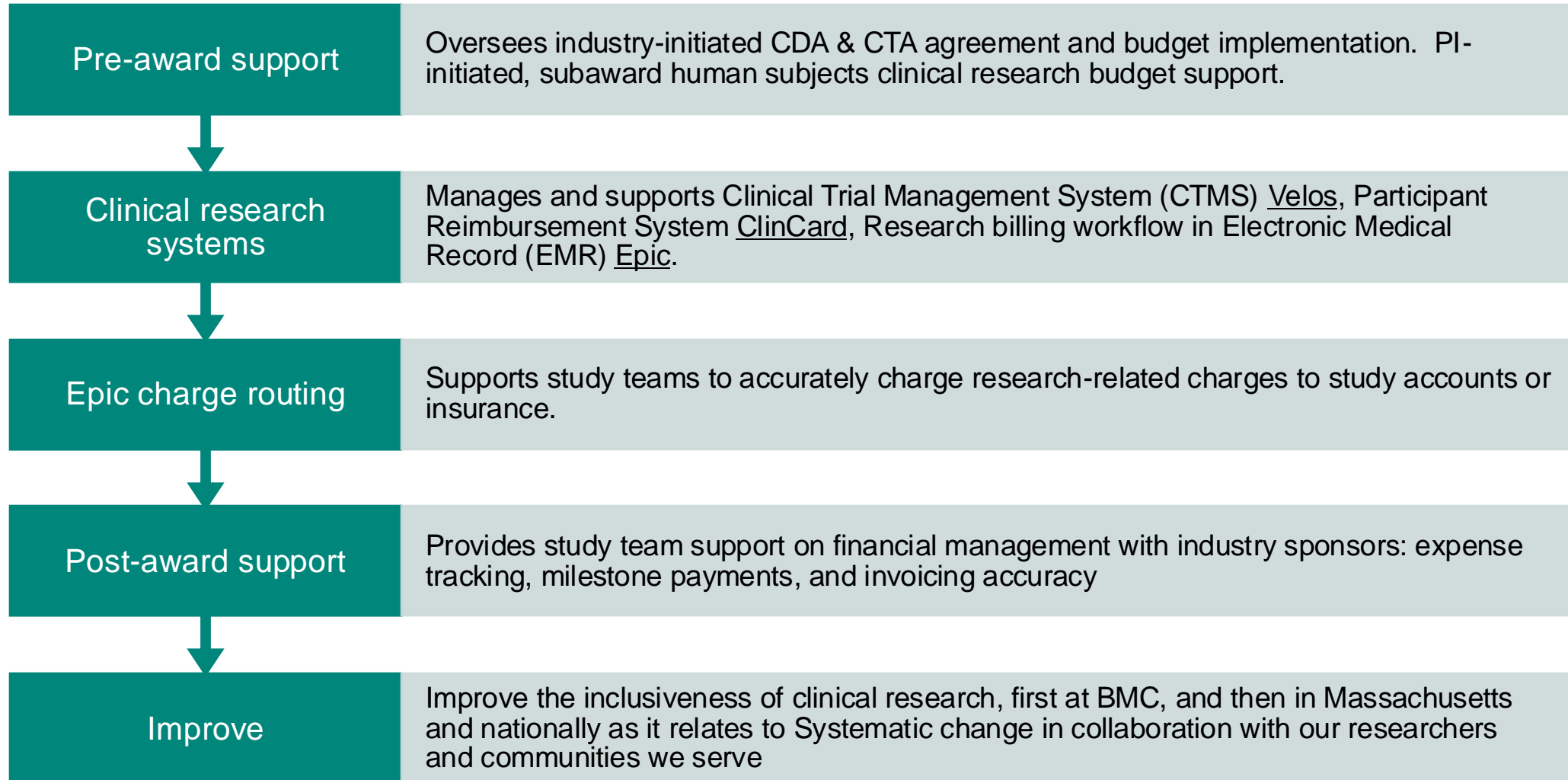
RO – Center for Clinical Research Advancement

Updated: November 2023



Clinical Trial Office

Promoting clinical research financial stability with efficiency driven by a customer service focused approach

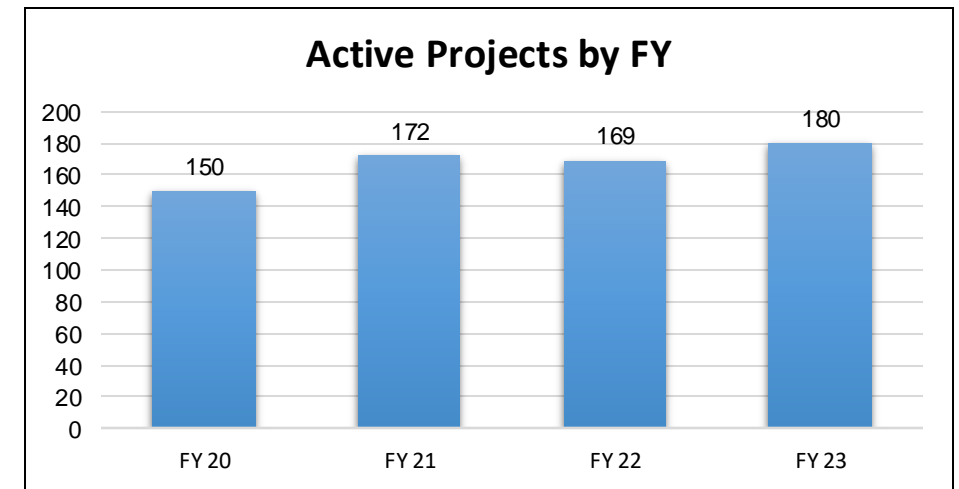
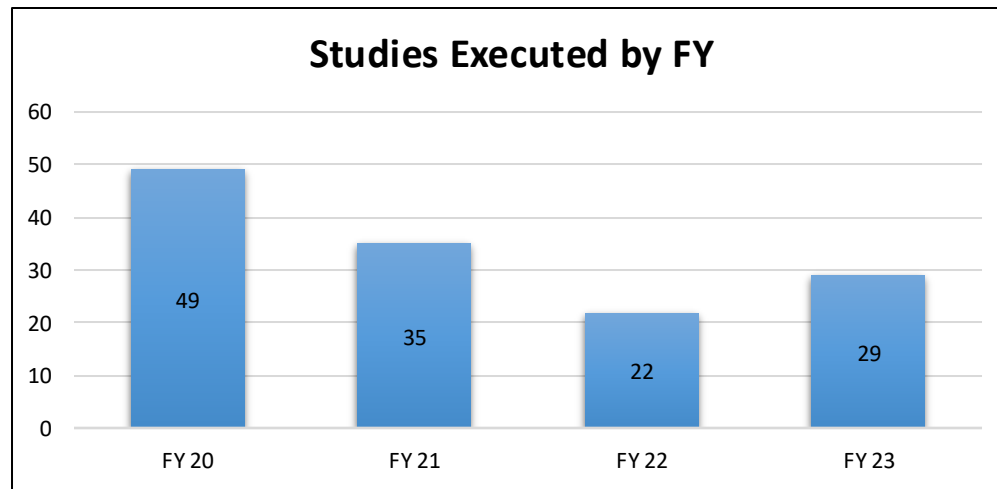
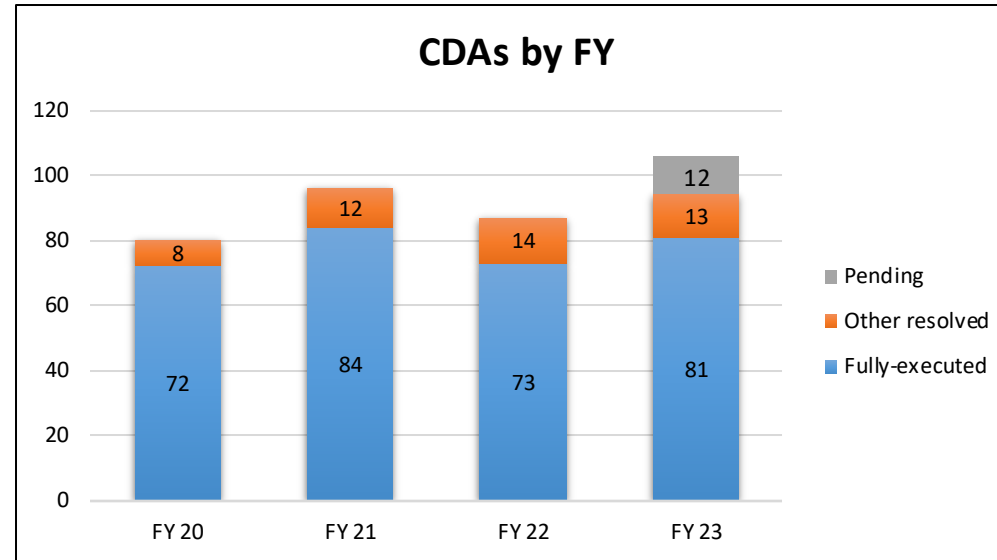


CTO Contacts

	Entry Point	Back-up Contacts
Clinical Trial Financial Portfolio Management	Portfolio Contacts List	CTO@bmc.org ; Michael.Porreca@bmc.org
New Industry Clinical Trial	CTO Intake Form	CTO@bmc.org ; Minhao.yin@bmc.org
New CDA/NDA	CDA/NDA Intake Form	CTO@bmc.org ; Sandy.Lok@bmc.org
ClinCard	Setup/Pickup Request	CTO@bmc.org ; Tran.Trinh@bmc.org

CTO Pre & Post-Award Portfolio

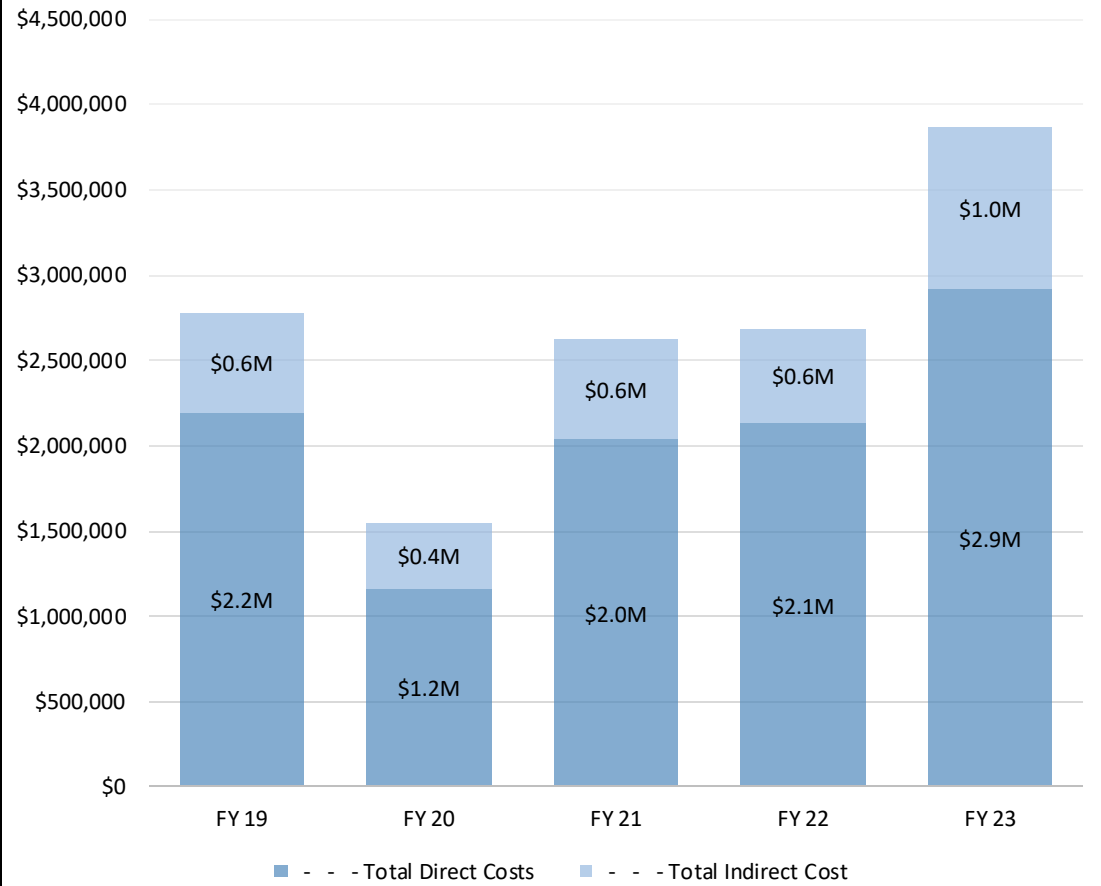
(FY 23 is 10/1/22 → 9/30/23)



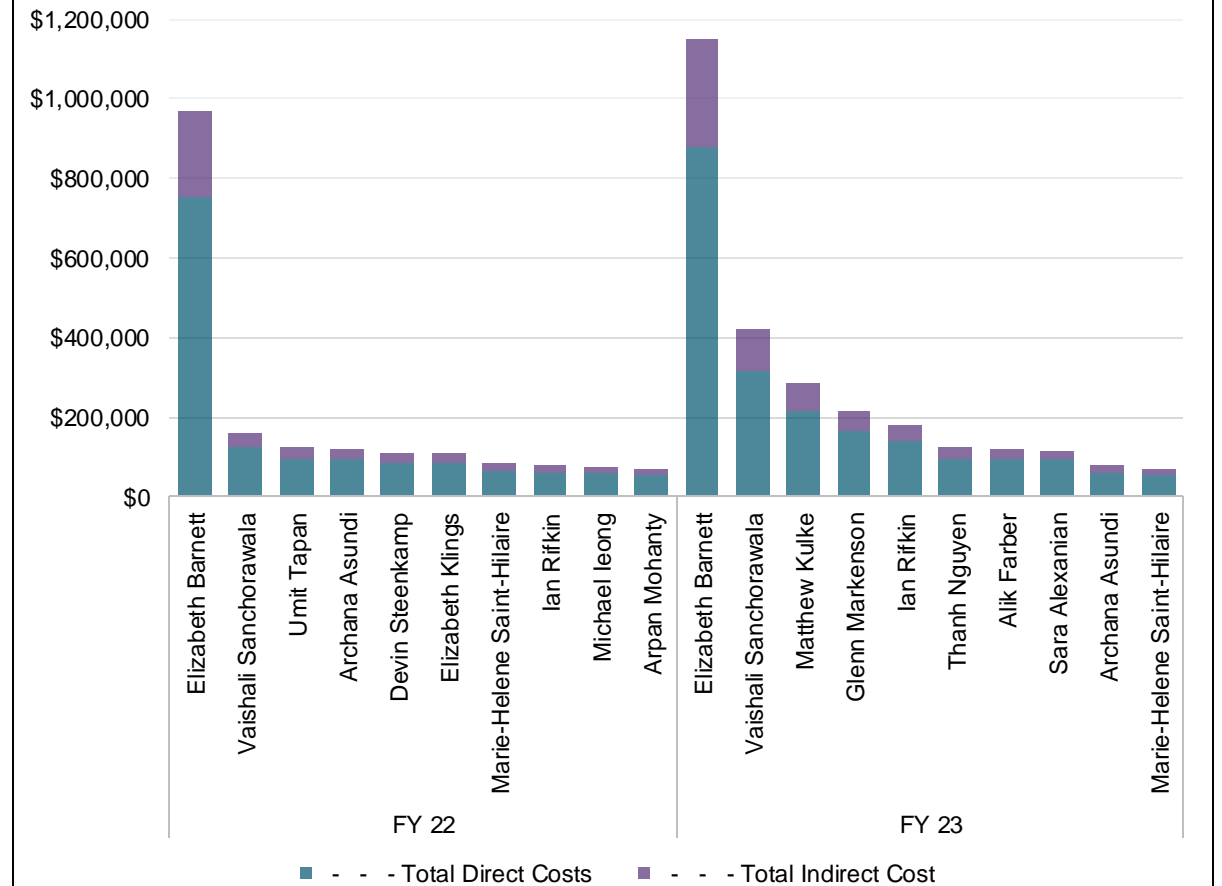
CTO Portfolio Study Expenses

(FY 23 is 10/1/22 → 9/30/23)

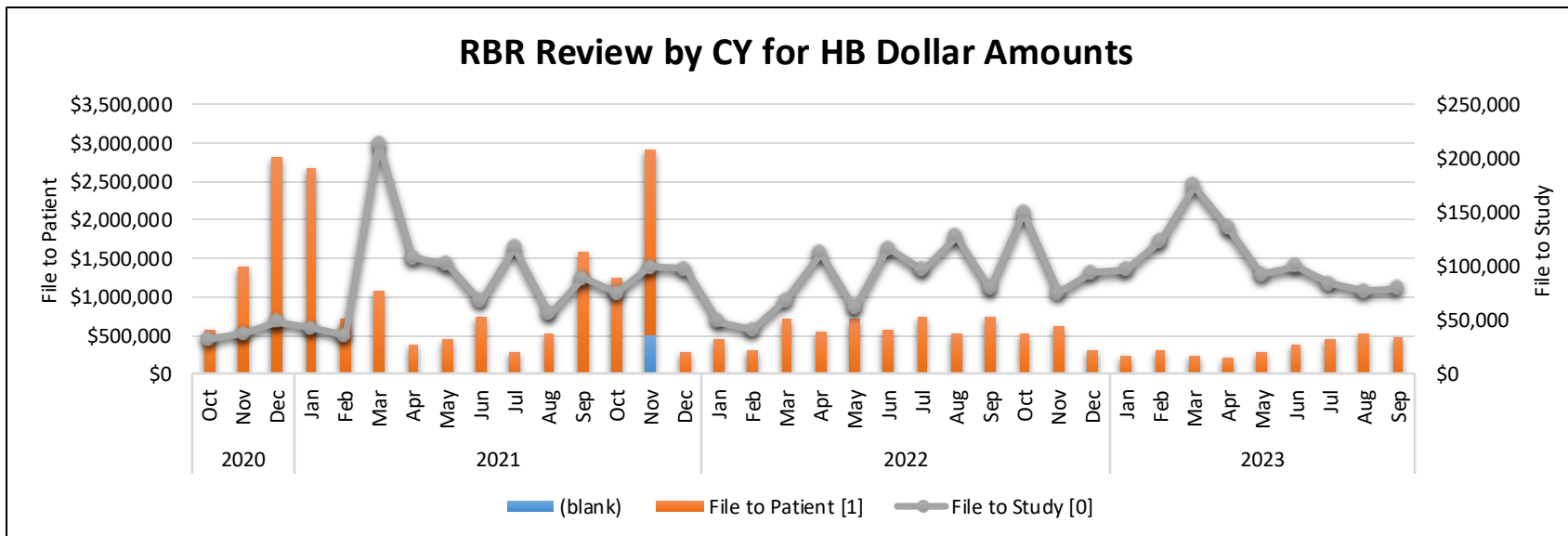
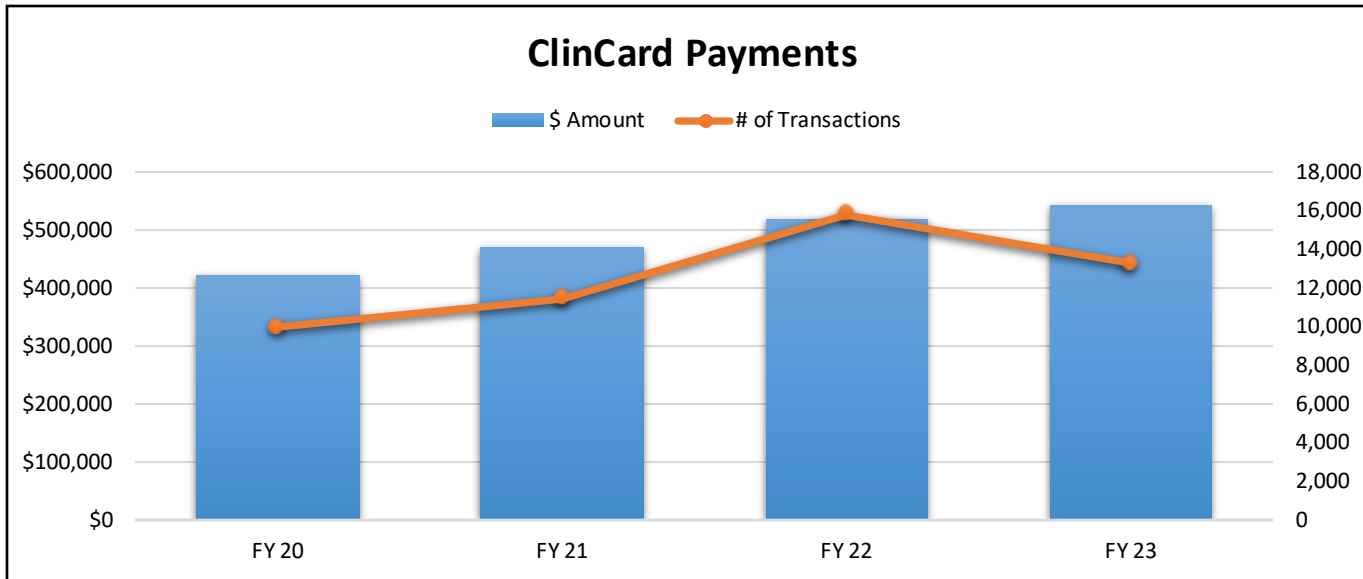
Expenditures by FY (Direct + IDC)



Top 10 Expenditures by PI/FY (Direct + IDC)

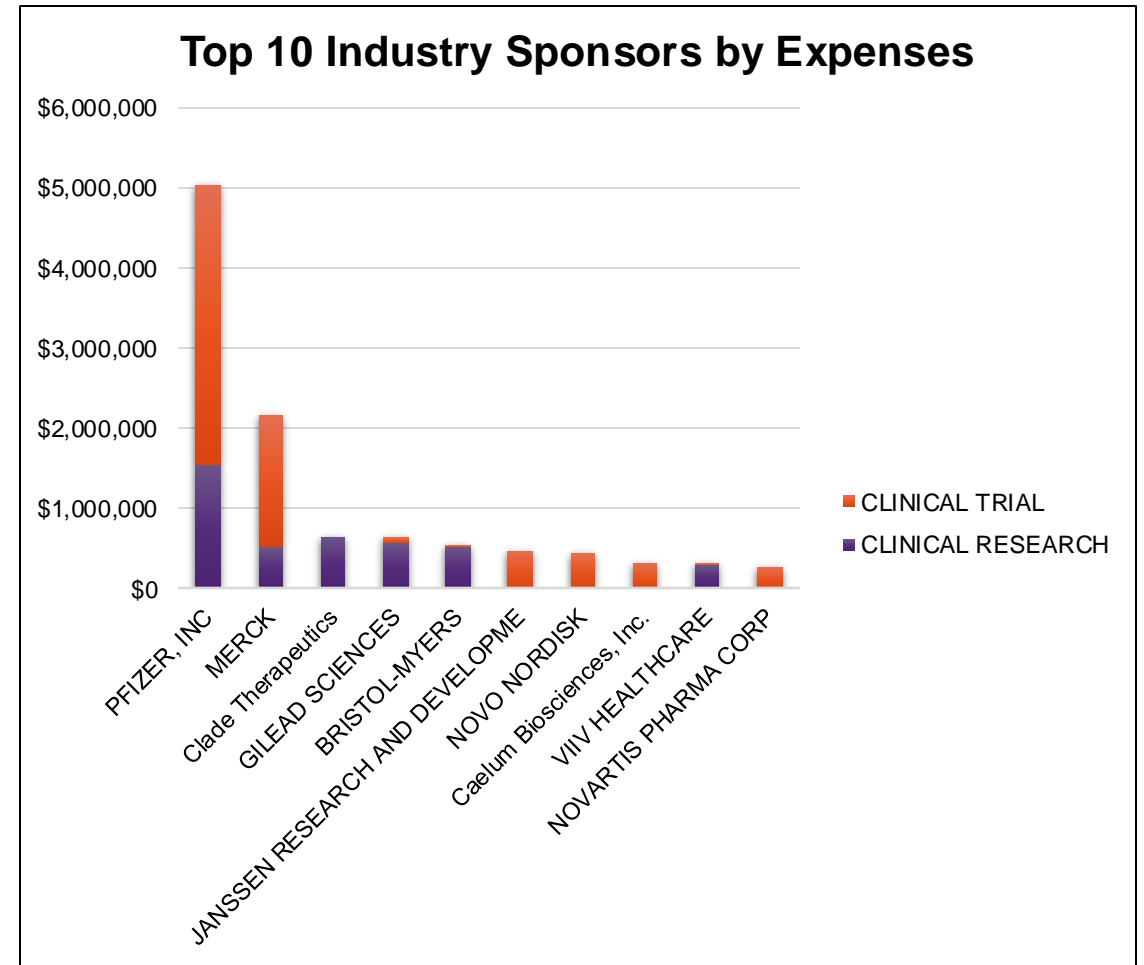
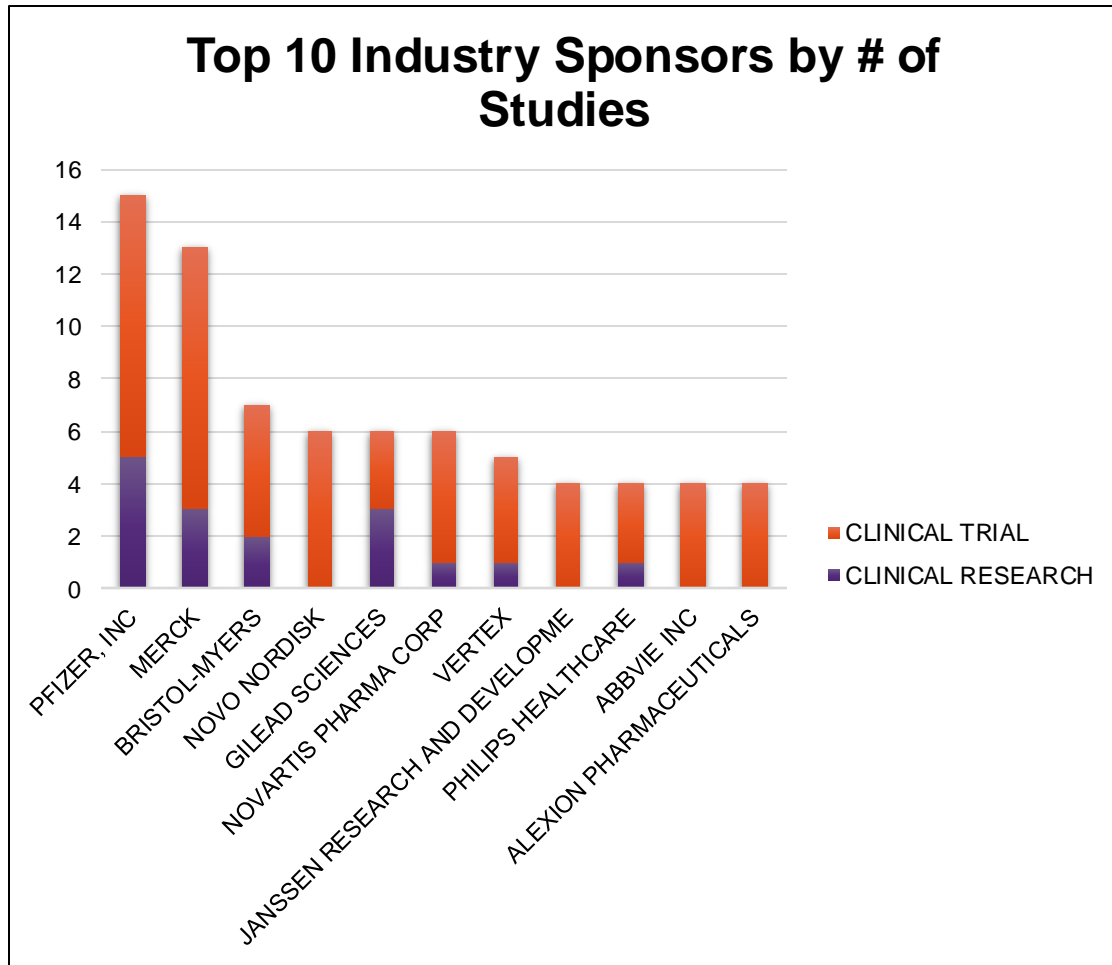


CTO responsibilities and oversight



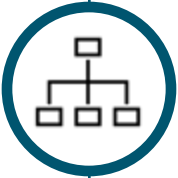



Industry Sponsor Breakdown

All data in Infor (excludes projects that were inactive 10/1/2021)



- 72% of our clinical trials under enroll by 50% or less
- 13% of our clinical trials never enroll a participant

CCRA/CTO Key Accomplishments FY23

 CCRA Structure	<ul style="list-style-type: none">▪ Finalized re-branding for CTO and CRN▪ Hosted 2 interns▪ Supporting operational research study questions
 Process Improvement	<ul style="list-style-type: none">▪ CTO managed contract workflow efficiencies▪ Internal CTO Manual Developed▪ Velos Upgrade
 Infrastructure building	<ul style="list-style-type: none">▪ Embed research into clinical structure – JCRU▪ Website Development- coming soon!
 Policy updates	<ul style="list-style-type: none">▪ Participant Reimbursement▪ Coverage analysis▪ Use of CTMS▪ Human Subjects Research

CLINICAL RESEARCH NETWORK

CRN Intake Form

Community Engagement

Facilitate bi-directional dialogue between the community and our researchers to improve trust and co-create future research



CENTER FOR CLINICAL RESEARCH ADVANCEMENT

Optimized Budgeting

Utilize costing and negotiation expertise in CRN to increase study funding and remove financial barriers to diverse participation



Research Staffing

Provide highly experienced staffing for under-resourced PIs and studies of strategic importance



Rapid Activation

Focused, senior level resources to rapidly activate our most important studies



Build Infrastructure

CRN will share and implement best practices broadly to improve research infrastructure at BMC



Our goal is to integrate traditional clinical trial metrics of high performance with inclusive values and intentionality to reach and include all people in every phase of the clinical research lifecycle.

Clinical Research Network Services - Contacts

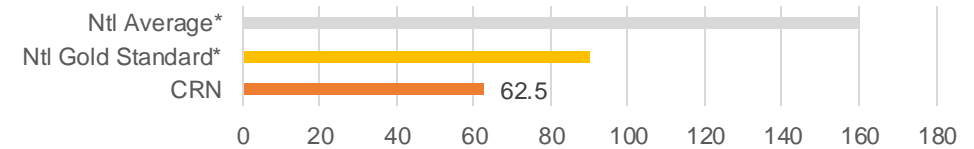
	Primary Contact
Community Engagement	Shannon.Timlin@bmc.org
Financial Budgeting and Management	Quinneil.Simmons@bmc.org
Regulatory Management & New Study Feasibility	Duncan.Schulte@bmc.org
Clinical Research Coordination	Olanike.Asupoto@bmc.org
Program Oversight	Ryan.Schroeder@bmc.org
CRN Intake	CRN Intake Form

FY23 CRN Study Staffing Service Metrics

FY23 Enrollment Goals vs Actual (goal is to avg. 70%)

Study	Goal	Actual	%	Years Remaining
ACTIV 1	20	20	100%	Closed in FY23
ACTIV 2	15	11	73%	Closed in FY23
ACTIV 4a	10	5	50%	Closed in FY23
ACTIV 5	15	11	73%	Closed in FY23
ACTIV 6	20	11	55%	Closed in FY23
Pfizer Paxlovid	15	2	13.3%	1
Vertex CKD	2	1	50%	2
RECOVER-Vital	25	27 verbal interest		1
RECOVER-Neuro	20	15 verbal interest		1
TEVA	8	pending		0.25
Total Avg:			59.2%	

CRN Rapid Activation (calendar days) Goal of 60 days (N=5)



FY23 Pipeline Growth (goal 2-3 new trials): **+1100%**

(full service – all CRN staffing / CE Only – Community Engagement Support)

- Vertex CKD (Nephrology) (full service)
- NIH PTSD (Psych) (CE Only)
- Merck HPV (Peds) (full service)
- Novartis C3GP (Nephrology) (full service)
- RECOVER-Vital (GIM) (full service)
- Pfizer RSV (Peds) (CE Only)
- Novo Nordisk (Internal Med)
- RECOVER-Neuro (Neuro)
- Nanobiosym Saliva (GIM)
- Novartis LNP023 (Nephrology)
- Teva (Endocrinology)

CRRO Internal Audit Results (Quality/Compliance)



CRN FY23 Community Engagement Metrics

CRN's goal is to improve awareness, understanding, and trust in research through outreach & education, building authentic community partnerships, empowering our community members to shape research priorities at BMC, and ensuring fair and just access to research for all.

KPI(s) for Community Engagement "Reach":

Community Events Attended FY23: **26**

CRN Organized & Led Events: **3**

Event Attendees: **1600**

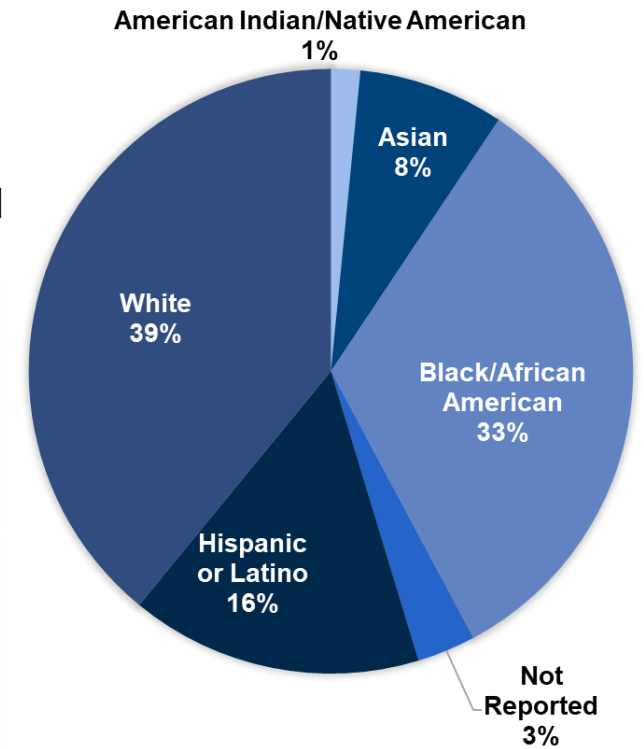
Neighborhoods: Dorchester, Mattapan, Roxbury, Roslindale

CRN Community Partnerships: **21**

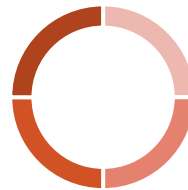


64
pts enrolled

Demographics Across CRN Managed Trials



CRN Dept Outreach



- Nephrology
- Pediatrics
- Family Medicine
- Psychiatry

CRN Dept Portfolio



- Nephrology
- Pediatrics
- Family Medicine
- Psychiatry
- IM
- Neuro
- GIM
- Endo

FY23 CRN Infrastructure Process Improvement

As an incubator for inclusive, high quality clinical trial practices across the BMC research enterprise, the CRN's goal is to improve diverse participation in research by building inclusive infrastructure within BMC and our communities



SOP Project: Create standardized guidance for clinical research conduct that spans BMC and BU to improve compliance and reduce institutional risk.

- **15** SOPs Launched in Jan 2023
- CRN partnered with CRRO on **5** Training Seminars
- **200+** BMC/BU Researchers trained in CITI Modules to date



Interpreter Services Research Training – CRN, MA-CEAL, and Interpreter Services created an educational program that has trained **46** medical interpreters and is expanding to **Tufts Medical Center** and **Dana Farber** as local partners with the goal of improving language diversity in research.



JCRU – CRN has been delegated the role of operationally leading JCRU planning and upon launch, oversee operations.



CRN Advisory Committee – Guiding transparent assignment of CRN resources, the advisory committee is led by hospital and community engagement leadership. **11** new studies were reviewed in FY23.



CHC/BHN Fee Schedules & Guidance Toolkit – CRN is leading a project to optimize research collaboration with **11** BHN CHCs s by developing a standardized fee schedule and costing guidance.



Partnerships – CRN is investing in our BMC CE partnerships by hosting standing cross functional meetings between **CRN, MA-CEAL, CTSI** and **CE & External Affairs**, and building systems to share partnership and event information across teams.

Contact Information



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