BMC Research Town Hall Meeting

March 19th, 2024

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Agenda

- Welcome & Research Enterprise Overview- Megan
- Research Compliance– Jami Wood
- BMC Research Informatics- Melissa Hofman
- Research Contracts & Industry Agreements – Asa Lopatin
- Research Service Center- Doug Rockwell

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

Research Town Hall Meetings

- **Purpose**: Bring together the BMC research to ensure people are aware of research happenings and to build community
- This meeting is a "part 2" for introducing groups central to the Research Enterprise
- **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

Announcements

- Welcome to Jennifer Kennedy, Director of Sponsored Programs Admin
- Welcome to Research Foundations and Government Grants group
- Welcome to Mike Fischer
- Check out our new landing page (website still a work in progress): https://www.bmc.org/research
- We received 31 applications for pilot awards!!
- Stay tuned for Learning Health System scholar application
- Stay tuned for the next Bridge Funding announcement
- THANK YOU to all who provided commentary for our IDC policy
  - Analyzing themes
  - Planning on having some IDC related info sessions
  - Will post FAQs/responses

Research Compliance

Jami Wood, MBA, CHC, CRC

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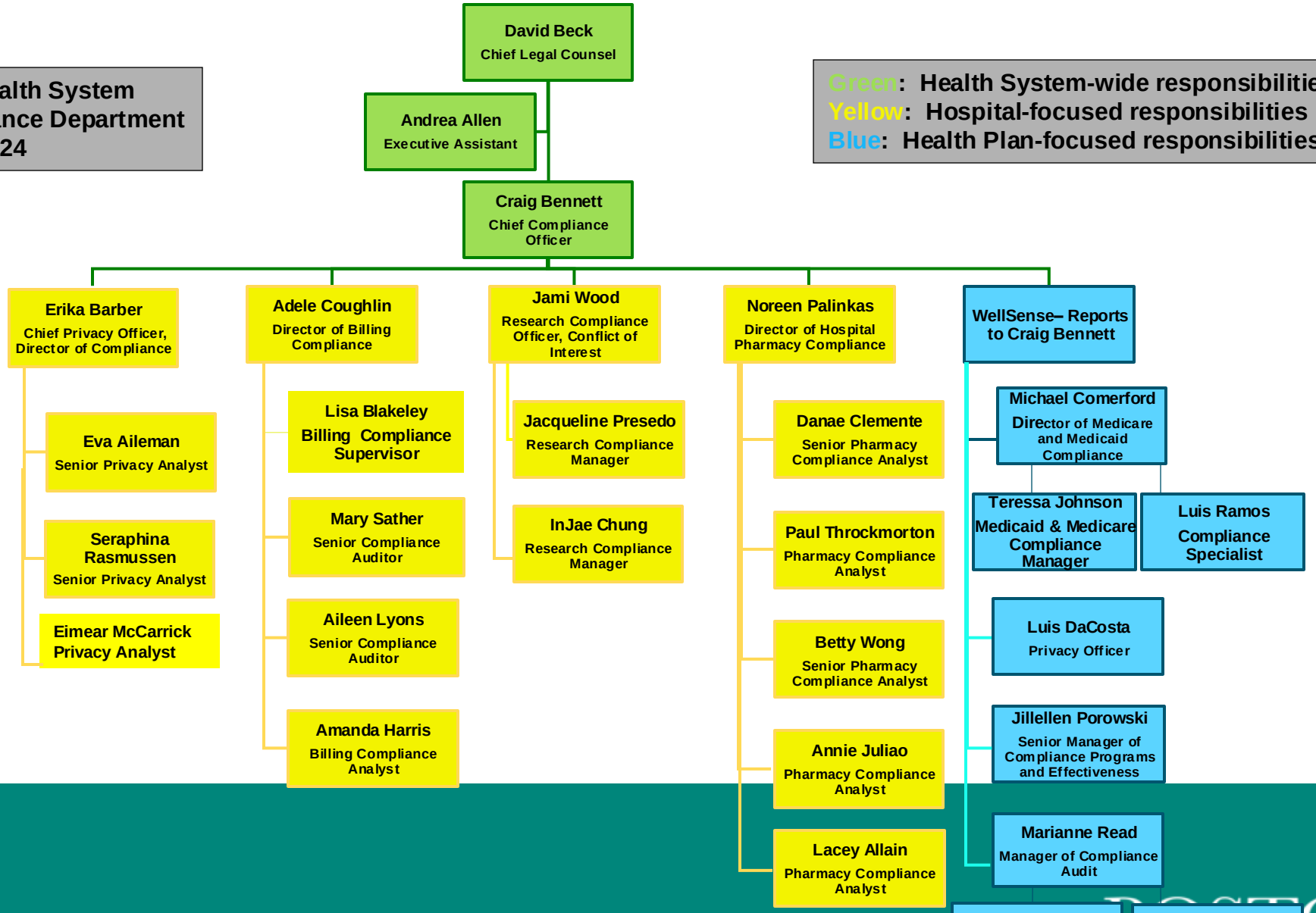
BMC Health System Compliance Department 02/01/2024

Green: Health System-wide responsibilities
Yellow: Hospital-focused responsibilities
Blue: Health Plan-focused responsibilities



Areas Covered by Research Compliance Program

Data Acquisition, Management, Sharing and Ownership	Accurate & proper collection, management, storage and sharing of data in accordance with confidentiality, privacy & security requirements
Conflict of Interest & Commitment	Review and management of outside relationships or interests to ensure real or perceived conflicts do adversely influence research
Research Misconduct	Prevent and address issues of fabrication, falsification and plagiarism
Human Subjects Protections	Ethical conduct of research with human subjects ensuring the rights, safety and welfare of subjects are protected
Research Involving Animals	Humane care and use of animals involved in research
Export Controls	Compliance with laws and regulations governing the shipment or transfer of items, software, data, technology etc., whether occurring in the US or abroad
Publication Practices & Responsible Authorship	Accurate and timely registration of studies and reporting of research findings and results
Clinical Trials Billing	Assurance of proper coding, billing and claims management in billing for items/services received by research participants

Research Compliance Responsibilities

- Coordinate the compliance efforts of a diverse research enterprise.
- Conduct risk assessments to find, evaluate and minimize operational and organizational risks.
- Perform compliance reviews to identify gaps in policies, processes and controls.
- Develop and/or deliver targeted education and training.
- Respond to deviations and incidents of noncompliance in research, e.g. privacy, animal welfare concerns, late clinicaltrials.gov registrations, HRPP reportable events and new information (RENI) etc.

Compliance Workplan and Elements of an Effective Compliance Plan

- Our Compliance Workplan is part of having an effective Compliance Program
- The Workplan requires compliance with the seven elements of effective compliance programs
- The Hospital includes an additional element: Monitoring our 340B pharmacy program

Research Compliance

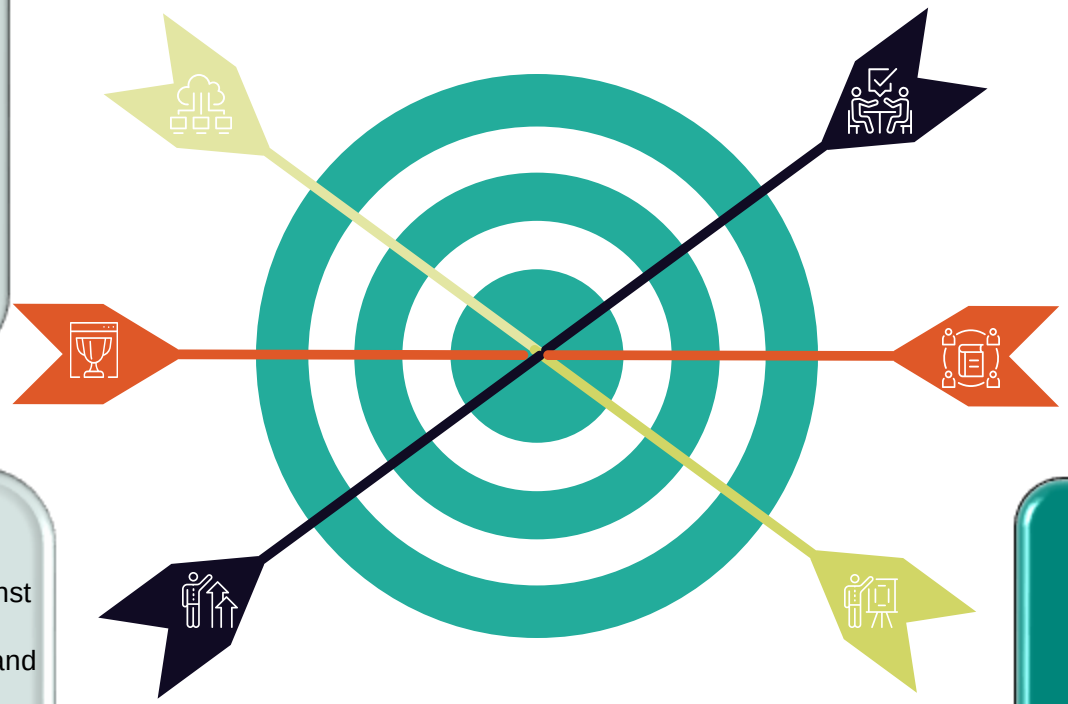
ACCOMPLISHMENTS - YEAR IN REVIEW 2023

Compliance Achievements

- Implemented Institutional Conflict of Interest in the Conduct of Research policy.
- Updated HRPP policy & procedures to include enforcement for noncompliance with COI requirements on research studies.

Compliance Oversight

- Clinical Trials Billing audit completed.
- Audited COI disclosures against Open Payments, identifying areas for targeted education and training.
- Audited ClinCard payment process and procedures; ***92%*** accuracy rate in making payments to research participants.



Collaborations

- Co-led effort with Research Technology Program to validate DocuSign as 21 CFR 11 compliant for electronic signatures.
- Co-managed externship program with Privacy Team; externs have led many of the ***10*** DEI sessions presented to Legal, Risk and Compliance staff.

Compliance Operations

- Achieved ***97%*** completion rate for annual Conflict of Interest Survey.
- Achieved ***80%*** completion rate for annual IRS 990 Survey.
- Most recent IRS 990 survey launched on ***2/29/24***.
- Upcoming annual COI survey is planned for ***April 2024***.

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Upcoming Initiatives – 2024

- Collaborate with Research Finance:
  - Audit of Cost Transfer policies, process & sample transactions
  - Audit of Procurement activities for Single Audit readiness
- Collaborate with Clinical Trial Operations:
  - Develop and implement an appropriate Clinical Trials billing monitoring program
- Collaborate with Office of Human Research Affairs:
  - On the review and, as necessary, remediation from COI Management Plan review findings from Clinical Research Resources Office Quality Assurance Review reports
- Conduct program needs assessment of Export Controls Program
- Implement more frequent, targeted COI education as well as continued monitoring of Open Payments and BMC COI disclosures
- Collaborate with Sponsored Programs Administration:
  - On the baseline compliance review of Reported Foreign Affiliations in Other Support & Biosketch forms

Upcoming 2024 Conflict of Interest Survey

Annual Disclosure of Outside Interests: Launch planned for 1st week of April 2024

Audience:

- Trustees, Officers, Directors & Senior Management
- WellSense Health Plan employees
- Providers
- Investigators & Key Research Personnel
- Office of the General Counsel and Compliance Department
- Members of committees who may influence purchasing or formulary decisions
- Supply Chain and Value Analysis Team

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Other Contact Information

Compliance Department
DG-ComplianceHelp@BMC.org

Compliance Hotline (800-586-2627)

Research Compliance
DG-Research_Compliance@BMC.org
COI-Compliance@BMC.org

https://hub.bmc.org/departments/compliance/research-compliance

617-638-7954
Jami.Wood@bmc.org

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BMC Research Informatics
& the Clinical Data Warehouse for Research (CDW-R)

Melissa Hofman, MSIS

Director, Research Informatics

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BMC Research Informatics

BMC Research Informatics

BMC Research Informatics serves as a centralized entity to support the BUMC research community in **research data strategy and infrastructure** by leading optimization efforts to **improve data quality** and implementing **innovative strategies to leverage research-quality data** that support the institution's broad research goals.

Supporting the BUMC research community in research data strategy and infrastructure

Research Data Infrastructure

Design and develop optimal data workflows, curation, storage, and extraction.

System Environments

Collaborate with BMC Research Technology Program (RTP) on IT and system environments, Epic research functionality, software integrations, and vendor management.

Informatics

Translate research data needs into innovative solutions and systematic data systems, optimizing efforts to improve data quality and implementing innovative strategies to leverage research-quality data (natural language processing, phenotyping, algorithms, pivoting data, Epic smart tools).

Research Data Services Administration

Develop and maintain analyst standard operating procedures, data documentation, and core facility billing policies and practices.

Increase data literacy among BUMC research community through training, education, and resources on research clinical data collection, documentation, manipulation, transformation, and use.

BMC Research Informatics Scope of Work

Research Data

Facilitate researcher access to EHR, CHC, claims, and external data sources.

Manage the *BMC Research Data Warehouse (CDW-R)*, a Research Core Facility that supports provide data sets extractions, recruitment lists, cohort lists, and simple counts information to BUMC research teams.

Research Data Governance

Collaborate with IRB, regulatory, compliance, privacy, legal, and operations to develop and document permissible research data access policies and ensure streamlined, appropriate research data access workflows.

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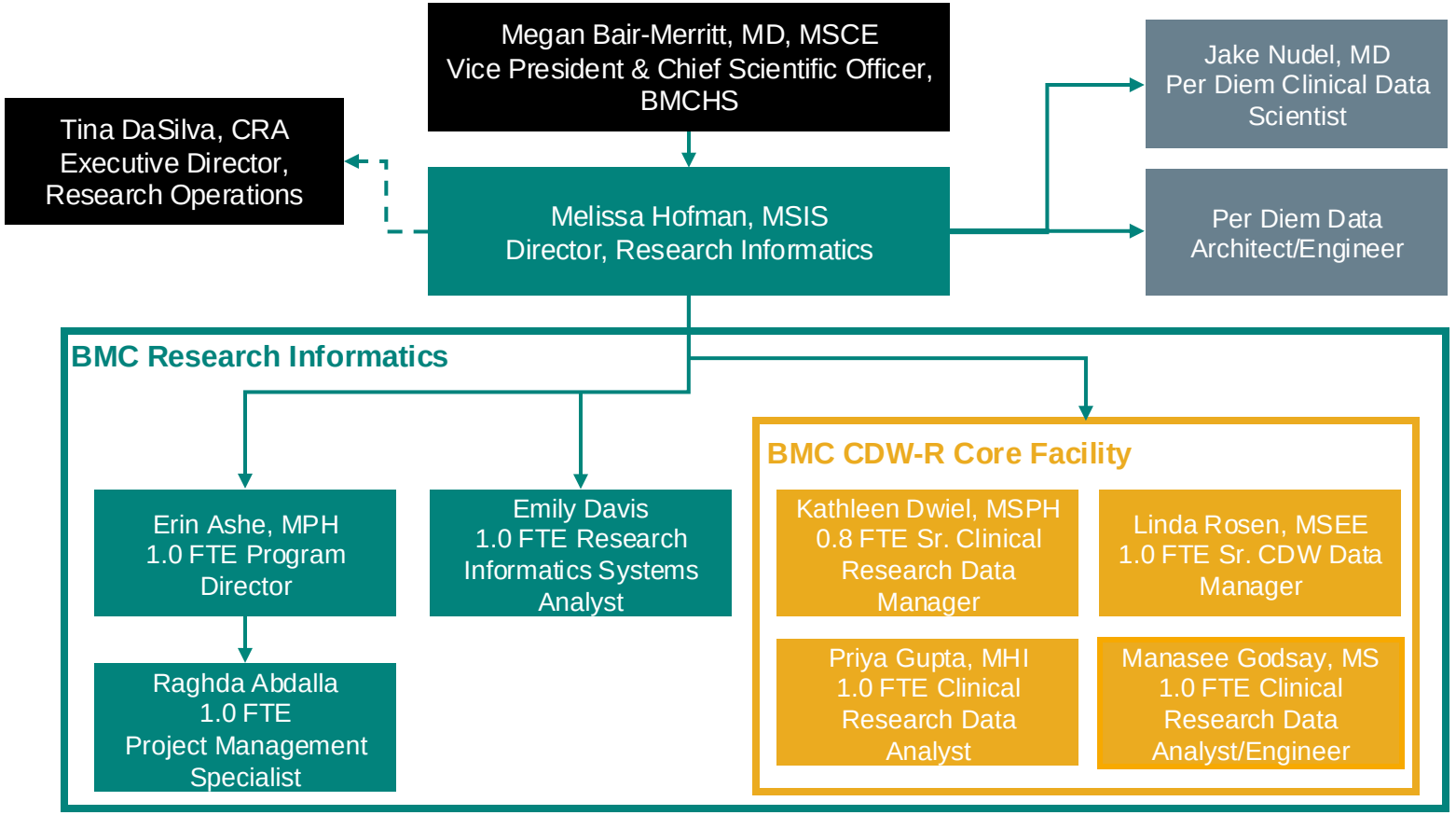
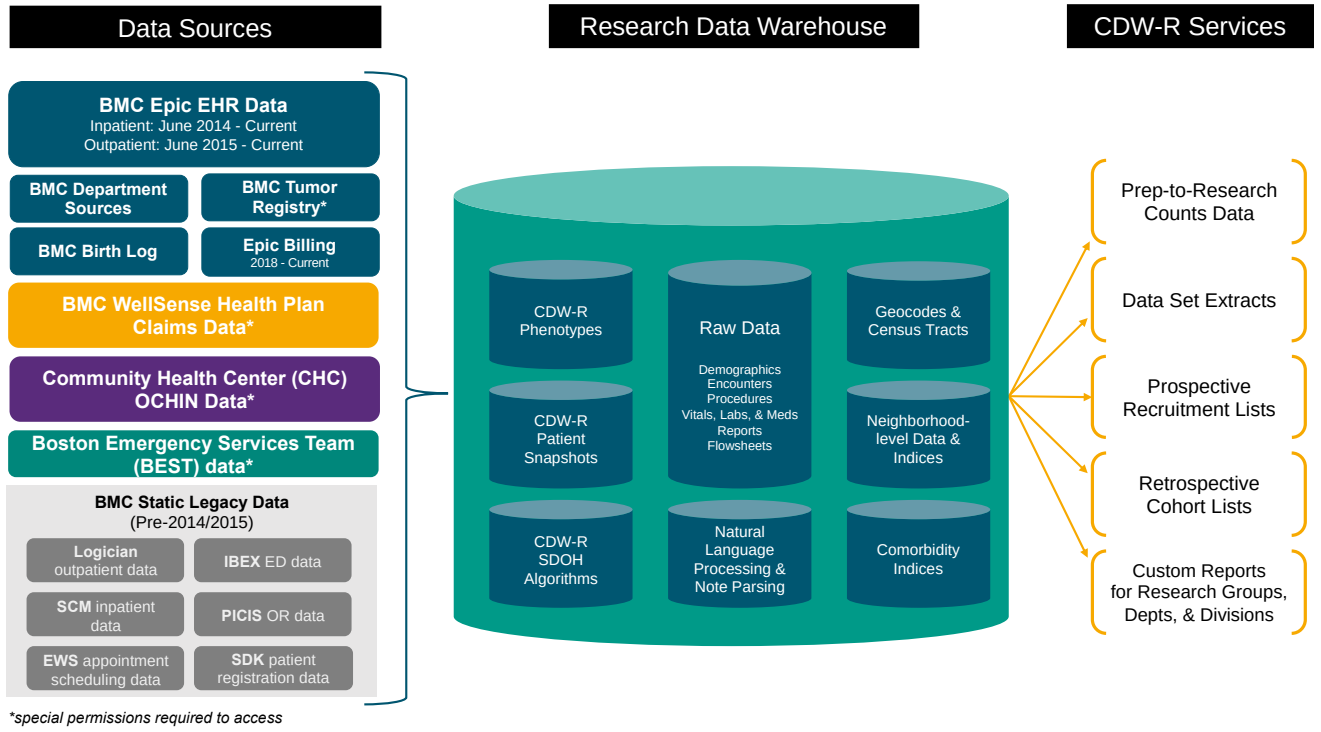
BMC Research Informatics



BMC Clinical Data Warehouse for Research (CDW-R)

BMC Clinical Data Warehouse for Research (CDW-R) – Research Core Facility

- Centralized resource to **access patient-level and population-level data for research.**
- CDW-R analysts **extract and link data** from various health system data streams:
  - BMC Epic electronic health record (EHR) data.
  - Historical data from legacy clinical systems.
  - Community Health Center (CHC) OCHIN EHR data.
  - BMC WellSense Health Plan claims data.
- CDW-R develops **algorithms and phenotypes for identifying patients, characteristics, and conditions** – improving data capture and consistency.
- CDW-R collaborates with Departments, Divisions, and research groups to **increase research infrastructure** and **better leverage data for research.**



https://www.bmc.org/research/clinical-data-warehouse-cdw

The CDW-R operates as a BMC Research Core Facility/Shared Service. There is an hourly fee for data extraction services.

CDW-R Core Facility Services

Simple Counts

Provide aggregate counts for study planning, feasibility analysis, and grant/proposal submission.

Recruitment/Cohort Lists

MRN, DOB, name, contact information, demographics, upcoming appointments, cohort inclusion criteria.
(as permitted by IRB protocol)

Data Extracts

Data extracted from the data warehouse for your study cohort, organized for data management and provided in excel files.
(mitigating need for manual chart review)

Custom Reports

Recurring data extractions, automatic prospective reports, and patient snapshots

Linked Data Extracts

Data extracted from the data warehouse linked to community health center (CHC) data, claims data, and other external data.

Department- or Division-wide Efforts

Describe specific patient populations, establish efficient recruitment strategies, and increase infrastructure to better leverage data for research.

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Research Informatics
FY24 Accomplishments & Goals

BMC Research Informatics – FY24 Accomplishments

Department Staffing

- Hired per diem Clinical Data Scientist
- Hired per diem Clinical Research Data Architect/Engineer.
- Hired full-time project management specialist role
- Hired 4th CDW-R data analyst

Resource Development

- BMC CY2023 Patient Snapshot
- New “Basic vs. Clinical Research” resource
- Clinical Trials (Velos) Patient Overview Report for CTO
- New ‘CDW-R Tip Sheet’
- BMC CDW-R THRIVE data guide – research recommendations
- Updated guidance for using, sharing, and securing CDW-R data

Research Data Infrastructure

- Incorporated Minority Health Social Vulnerability Index (SVI) data into Research Data Warehouse (a compliment to the CDC/ATSDR SVI data)

Data Request Workflow Optimization

- Launched new ‘Simple Counts’ request form
- Launched new quote for CDW-R services request form
- Launched Calendly for researchers to schedule CDW-R consultations

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BMC Research Informatics: FY24 Priorities

1

Continued to support CSO Office & Research Operations in research systems and data needs

2

FY24 Data Migration & Infrastructure Improvement Project

FY24 Data Migration & Infrastructure Improvement Project

BMC Health System is undertaking several data warehouse infrastructure improvement efforts leading up to Fall 2024.

- **Data Migration Outcomes and Benefits**
  - Streamline the data request to provision process
  - Leverage more secure and efficient technologies for data provisioning
  - Increase use of automation and AI to handle complex data requests
  - Standardize variables and improve documentation both internally and externally

This one-time data migration project requires a short-term impact – a 'downtime' – on the CDW-R team's ability to engage with new research data set extraction requests.
Information on the CDW-R downtime and its impacts are detailed on our website.

For more information…

Visit our website
https://www.bmc.org/research/clinical-data-warehouse-cdw

Email us
cdw@bmc.org

Research Contracts & Industry Agreements (RCIA)

Asa Lopatin

Director, Research Contracts and Industry Agreements

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RCIA Team Functions

Contract Negotiation and Execution
Draft, review, and negotiate contracts related to BMC research and research-adjacent programs.

Education, Training, and Consultations
Develop and implement training and guidance resources pertaining to relevant terms and conditions, legal/regulatory requirements, BMC policies and processes, and structure of research collaborations.

Systems and Process Improvement
Provide transparency and customer service to BMC researchers and research administrators.

Activities to Date

- Starting in Fall 2023, collected information on relevant policies, SOPs, templates, systems, institutional stakeholders, customer feedback.
- Transition majority of contract negotiations in Research Operations to RCIA portfolio, including:
  - Data Transfer and Use Agreements
  - Material Transfer Agreements
  - Non-Funded Collaboration Agreements
  - License Agreements
  - Limited Service and Programmatic Agreements
  - Industry-Sponsored and BMC Investigator-Initiated Clinical Trial Agreements
- Advise and consult researchers regarding administrative requirements for pending and in-progress research projects
- Begin developing foundation for streamlined intake process and agreement tracker to promote transparency, efficiency

Priority: Managing Contracts Efficiently and Transparently

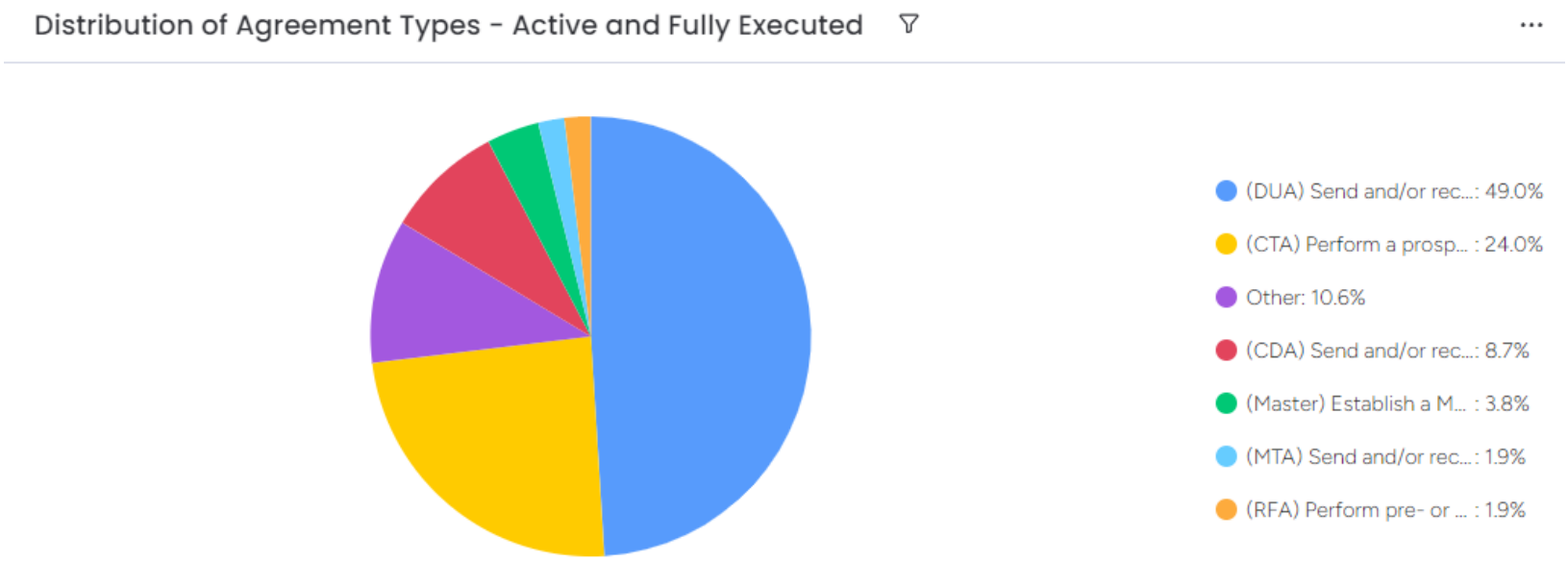
Balancing Compliance and Efficiency
RCIA is tasked with satisfying the dueling priorities of executing research agreements as quickly as possible while protecting the institution's interests, shielding BMC from liability, and doing right by our patients.

Improving Transparency
Eliminating the "black box" that is common in research administration by prioritizing responsiveness, both internally and externally, and taking a collaborative approach to working with BMC researchers.

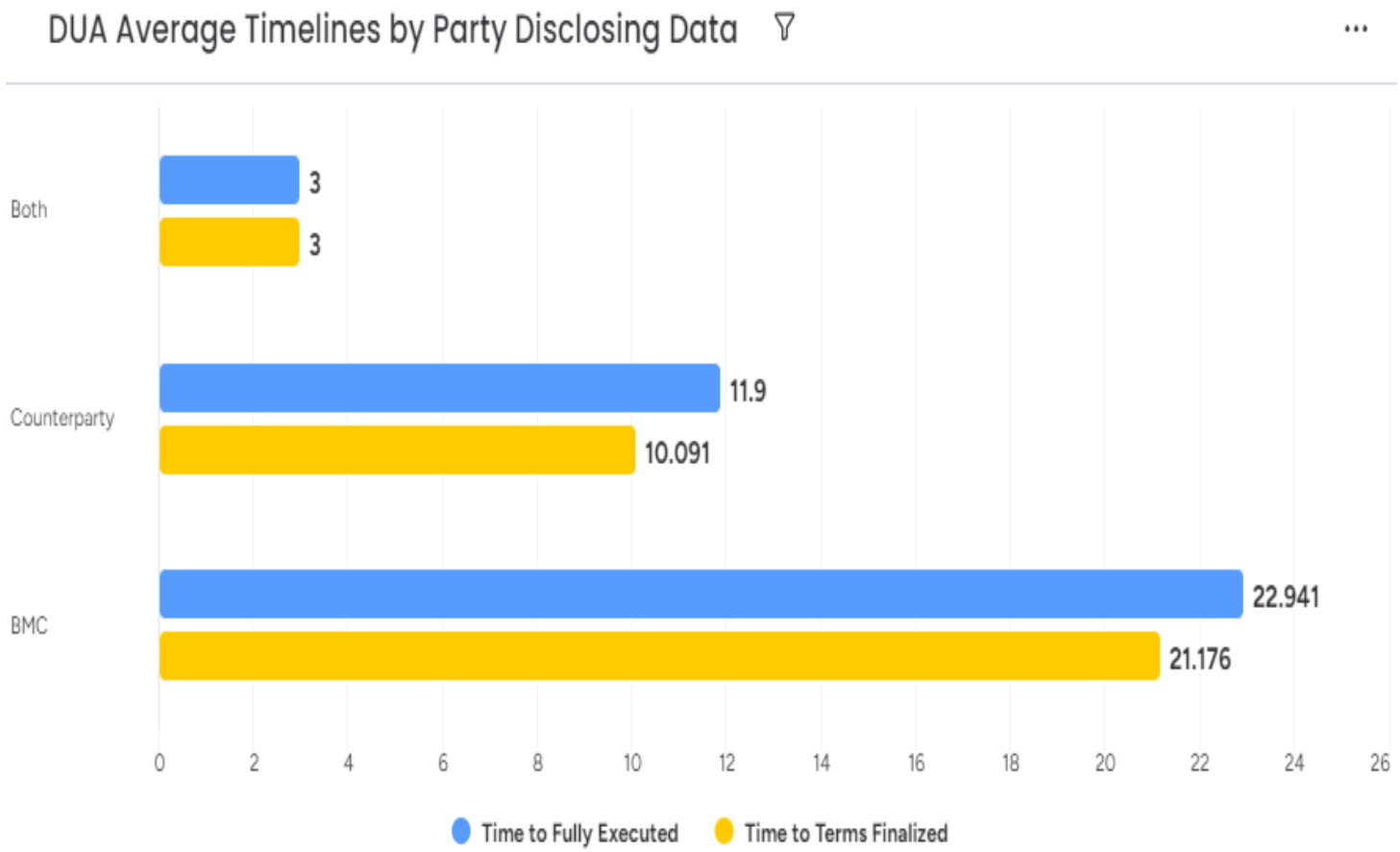
Investing in Systems, Resources, and Relationships
Leveraging increased transparency to identify opportunities to for continued improvement, training, and education.

Consolidating and Standardizing Intake and Workflow Tracking

By collecting more detailed data during the agreement request process and tracking review and negotiation timelines in a standardized manner, RCIA can better understand where additional resources need to be devoted.



Reducing Negotiation Timelines



On average, it takes nearly twice as long to execute an outgoing DUA as it does to execute an incoming DUA.

Detailed records allow us to identify potential causes as well as opportunities for proactive investments and process improvements.

Where processes can be modified, we will have the information to do so strategically. Where they can't, we can develop appropriate training materials.

Initiatives for 2024

Consolidate Agreement Request Intake Processes
Standardize request process for agreements handled by RCIA to reduce confusion caused by large number of discrete forms and workflows.

Refine Tracker for Negotiations and Active Agreements
Continue to evaluate available options and build system capable of providing accessible updates and meaningful data.

Expand Training and Guidance Resources
Identify priorities for additional training opportunities, reference materials, and strategic partnerships.

Thank you!

Asa Lopatin, JD, Director, Research Contracts & Industry Agreements

Asa.Lopatin@bmc.org

Research Service Centers

Douglas Rockwell

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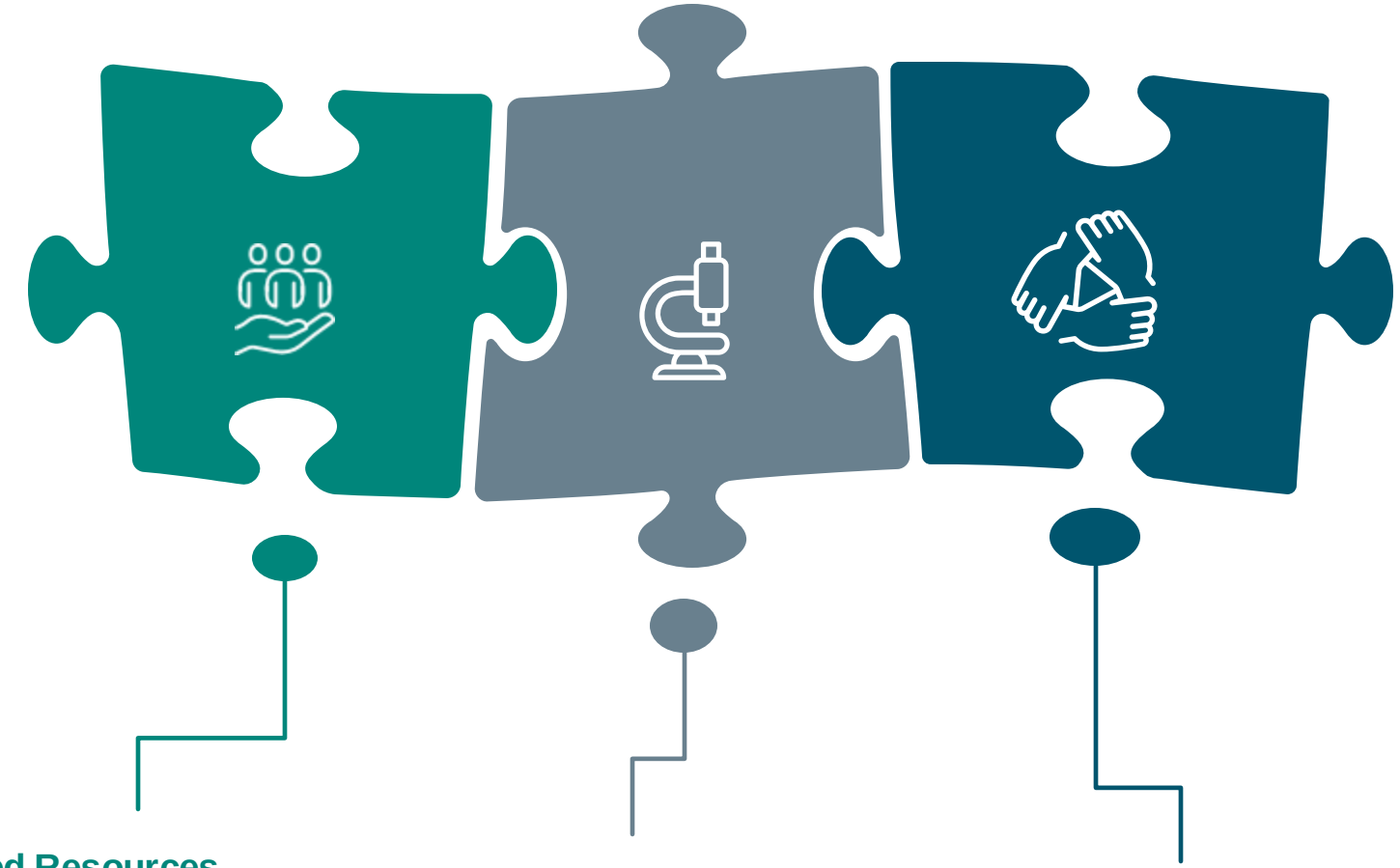
Research Service Centers



Shared Resources

BU Shared Services

Core Facilities

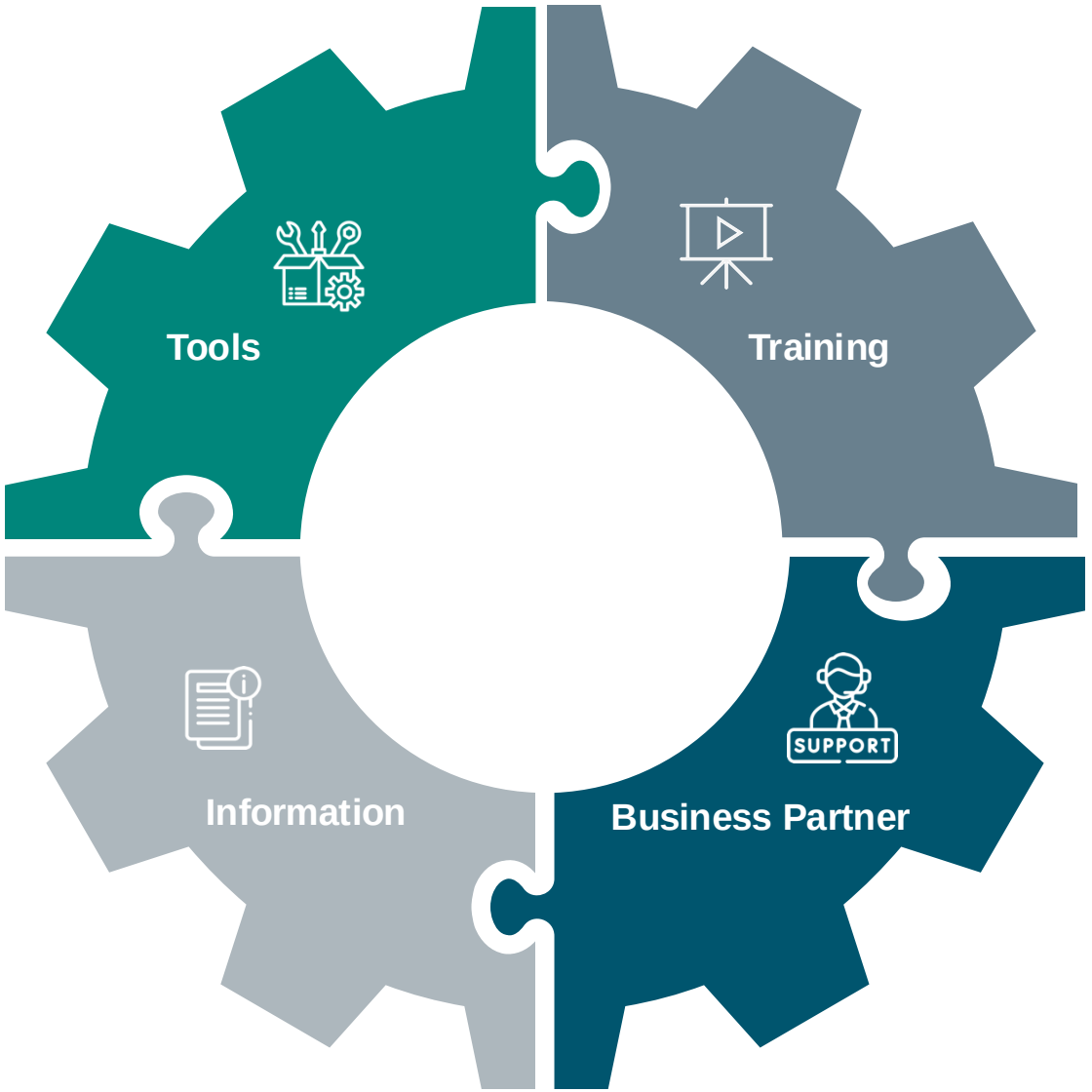
BMC Clinical Data Warehouse (CDW) for Research

Laboratory and Biorepository Research Services Core

Radiology Core

Sponsored Programs Support Services

Sponsored Programs Support Services

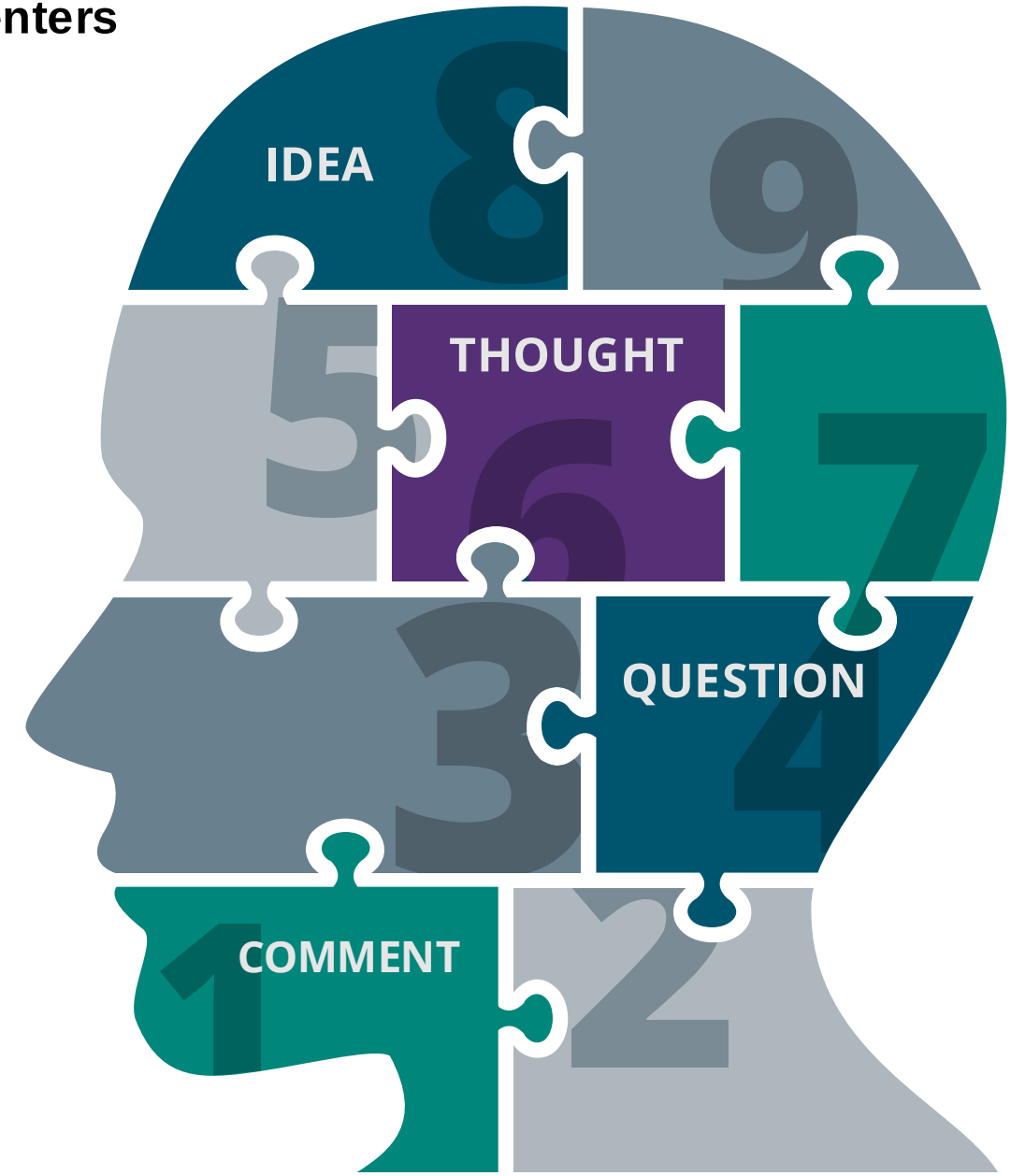


Sponsored Programs Support Services

FINANCIAL SUPPORT

- JIT
- Account financial oversight
- Budget and Cost monitoring & tracking
- Salary allocations
- Payments
- Purchasing
- Job Posting

Research Service Centers



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