ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE

Building Bridges in the Bronx and Beyond

Responses to 2024 EAC Recommendations

EINSTEIN Albert Einstein College of Medicine

Montefiore

ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE

Building Bridges in the Bronx and Beyond

Overview

Jessica Kahn, MD, MPH

Mimi Kim, ScD

EINSTEIN Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **The EAC would like to hear more next year about the relationship between the medical school's executive team and the CTSA….It would be helpful to have a sense next year of the role of the ICTR in all of the new institutes and centers, and how these are integrated into the ICTR strategic plan.**

  - We discussed this suggestion with Drs. Tomer and Keller to ensure that there are close synergies between the ICTR and Einstein institutes and centers.
  - Dr. Kim has been tapped to lead the Data Science Institute which will foster even closer alignment between the institute's missions and objectives and ICTR strategic goals. The new institute will also draw on ICTR modules to build programs and expertise; these developments will in turn bolster ICTR resources and activities.
  - Dr. Kahn created a Basic, Clinical, and Translational Research (BCTR) Leadership Council involving leaders of centers and institutes that is focusing on developing cross-institute/center strategic synergies and efficient leveraging of resources across the entities.

Responses to EAC Recommendations

- **The EAC would like to hear more about strategic relationships and strategic joint projects; e.g. what programs and collaborations the ICTR is leading versus engaging in as participant, etc.**
  - ➢ Clarifying these strategic relationships has been a focus in 2025 and we have asked each module to describe the role of the ICTR (leader, collaborator, etc.) in their 2025 EAC presentations.

Responses to EAC Recommendations

- **The EAC would like to stress the importance of institutional support for faculty recruitment to build learning healthcare system, health equity research, and data sciences in translational research and science…The EAC suggests Einstein-Montefiore Leadership consider an annual collaborative fund that is directed toward partial support of faculty who are seriously engaged with the CTSA (e.g. >25% effort) to ensure that they are dual faculty.**
  - There is institutional commitment in the Einstein Strategic Plan to build LHS, health equity, and data science research programs, with the intent that recruited faculty in these areas will have the opportunity to engage with and contribute to the ICTR. We have been actively discussing with Department Chairs whether recruitment packages can include support for ICTR roles. We also have a new philanthropic gift to the ICTR that will include targeted effort in the ICTR for a faculty member with expertise in implementation science.
  - The new Dissemination and Implementation Science/LHS lead (Dr. Rikin) has institutional support.

Responses to EAC Recommendations

- **To complement the excellent progress in the individual modules, the EAC would like to hear more next year about increased collaboration and engagement between modules. The EAC would like to hear more about an integrated strategy in different elements and modules.**

  - This was a focus of 2025. A primary goal of our ICTR retreat in July 2025 and Continuous Quality Improvement project for our Element B Strategic Management Module was to find ways to increase cross-module interactions as well as develop integrated strategies for jointly advancing shared goals/initiatives and the overall mission of the ICTR.
  - The EAC will hear about these collaborations in the overview and core/module presentations.

Responses to EAC Recommendations

- **The volume of requests for BERD continues to rise and there may be a need for more prioritization, more resources to respond to requests, and strategic deployment of resources.**
  - ➢ This will be discussed in the BERD presentation.

Responses to EAC Recommendations

- **There will be a need to increase volume in the Clinical Research Center and to focus on sustainability.**

  - We instituted biweekly strategy meetings involving ICTR and Office of Clinical Trials leadership to increase volume in the CRC. We developed and implemented a multi-pronged approach to accomplish this and have had success so far. This will be discussed in the CRR presentation.

Responses to EAC Recommendations

- **There was a focus on progress toward implementing initiatives and processes across the modules, but less of a focus on metrics, milestones, formative and summative outcomes.**

  - This has been a focus of 2025; the Evaluation/CQI team collaborated with all modules to link module objectives with ICTR strategic goals, and to create tables that link module objectives, initiatives, outcomes, and metrics. These were reviewed at the 2025 ICTR retreat. Developing overall metrics for the ICTR was also a focus of the ICTR retreat. More on this effort will be presented during the CQI/Evaluation presentation.

ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Learning Health System and Implementation Science

Sharon Rikin, MD, MS

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **“There are a number of good projects, but the module seems to be project-specific and focused on engagement in the projects of others instead of ICTR-driven initiatives. It was not clear where ICTR is the leader or initiator on these projects.”**

  - We have prioritized the following to shift from an individual / project-based IS/LHS module to a system-based, ICTR-driven IS/LHS module
    - **Capacity building** through training and pilot programs: EQUIP, Kwok, PCORI Health System Implementation Initiatives
    - **Facilitating collaboration** through defining membership in IS/LHS working group (member, investigator, consultant) and identifying areas of research strength
    - **Facilitating IS/LHS research** through toolkits and studios designed to support use of research methods, informatics, and stakeholder engagement

Responses to EAC Recommendations

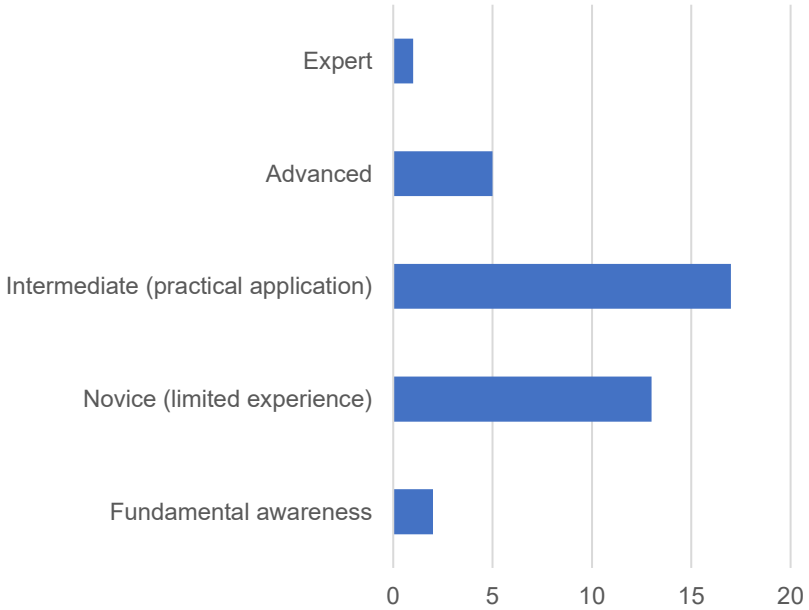
- **"It was not clear what the overall framework was. Consider clarifying which LHS framework or frameworks serve as a guide or roadmap for this module. Consider a learning collaborative similar to the 'NIH collaboratory.' The EAC encourages Drs. Rinke and Gong to collaborate with the CTSA implementation science working group on these issues."**

  - The D&I/LHS module leader, Dr. Rikin, is convening a LHS committee
    - This committee will: define the Montefiore-Einstein LHS framework, uses, and structure to facilitate IS/LHS research (e.g., studios, research review committees, etc.).
  - Dr. Rikin has joined the CTSA Implementation Science working group.

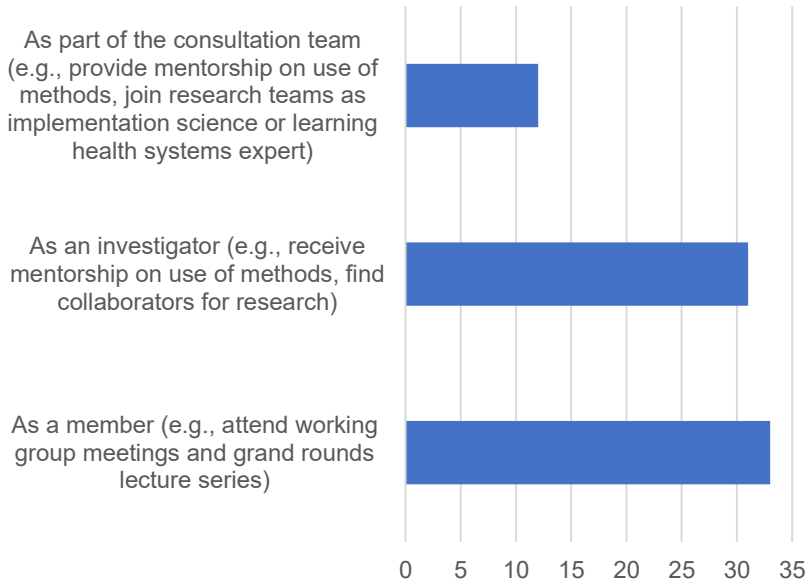
Responses to EAC Recommendations

- **"The EAC understands the challenge of participation in an implementation science working group and grand rounds and recommends crowdsourcing strategies to engage and generate ideas "**
  - ➢ D&I/LHS Lead conducted a needs assessment of current Implementation Science working group participants through interviews, group meetings, and a survey (N=39). Results are below.

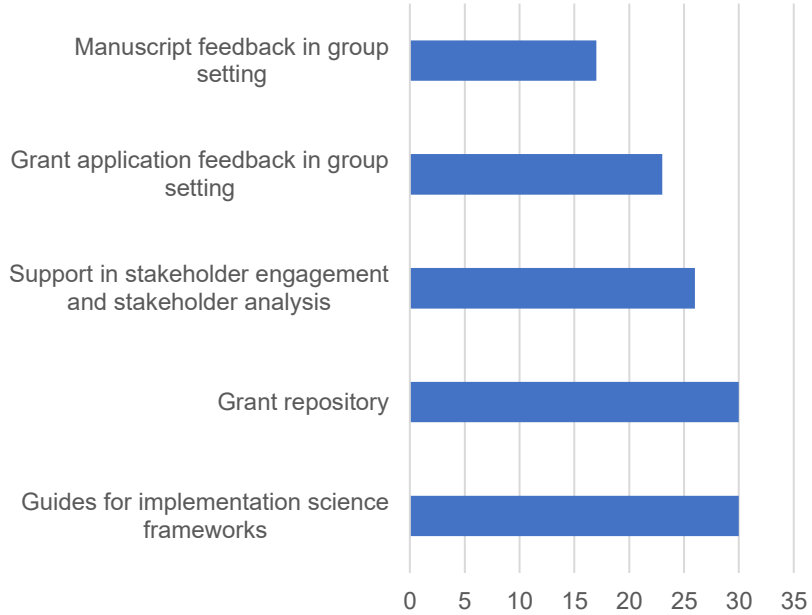
What is your experience with implementation science methodology?



How would you like to engage with the Implementation Science and Learning Health Systems Collaborative?



What resources would be helpful for your research?



Responses to EAC Recommendations

- **“Consider meeting with health system leaders to find out what their priorities are, using existing meetings. Including the community to see how the research process works, especially through the CCC, could help support involvement and engagement.”**

  - We convened a **LHS Advisory Board** of health system leaders to identify priority areas for LHS research aligned with the ICTR and NCATS mission. This Board includes leadership responsible for community engagement.
  - We will convene a **LHS Research Committee** which includes ad hoc representation from community members to facilitate patient/family/community stakeholder engagement when appropriate.

ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE

Building Bridges in the Bronx and Beyond

Community Collaborative Core

Hector Perez, MD

Damara Gutnick, MD

EINSTEIN Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **“What is the integrated strategy, how do the initiatives align, and why have specific initiatives been chosen? What are the common elements across all of the different initiatives?.... How can other modules access the CCC to work together?”**
  - After the transition to new CCC leadership, the director and associate director worked to align core goals with ICTR strategic priorities
  - An ICTR-wide CQI review was conducted which redefined core goals, activities, and metrics to promote cross-module collaborations
  - The CCC leaders developed a strategic plan to better integrate CE across all ICTR programs and progress activities towards the redefined goals:
    1. Accelerate CTS research to address the significant burden of conditions that affect all populations in the Bronx.
    2. Ensure equitable community-academic partnerships.
    3. Build sustainable stakeholder engagement.
    4. Strengthen a skilled, multidisciplinary workforce to lead CE initiatives.

Responses to EAC Recommendations

- **"The EAC was intrigued by the community engagement tracker and would like to hear more about it next year. This is an initiative that would be valuable to disseminate. This is an opportunity to collaborate with the data science group and figure out how to use NLP to scan advertisements of and descriptions of events, to get them into the database so that we can cross-reference code words and standardize data entry."**
  - The new CCC leaders have continued to develop the CE tracker. Currently the tracker has 36 active users, tracking 150+ community and faith-based organizations.
  - The CCC leaders presented the CE Tracker in October 2025 at the Fall CTSA Meeting, initiating collaborations with Duke and AAMC.
  - <u>Next steps:</u>
    - Internal collaborations to build dashboards for institutional stakeholders and researchers
    - Refine system through ongoing CQI with new users

- **"Acceleration of CTS research through community engagement was not well-articulated. What would acceleration look like? The EAC would like to hear more about this next year."**
  - We redefined goals, outcomes, and metrics for all CCC activities. Acceleration of CTS research is defined by meeting our metrics in view of our goals. In addition, our new Element E project is focused on community-engaged research.

Responses to EAC Recommendations

- **"The ICTR should assess whether the ICTR CCC is adequately staffed, especially with investigators who can mentor junior faculty. What is the pipeline for developing investigators and mentors? What metrics can be used to assess staffing and resource adequacy?"**

  - We reorganized leadership this year and recruited Dr. Dana Watnick as Director for the new qualitative and mixed methods core.
  - We prioritized mentorship as a CCC goal with planned initiatives:
    - Developing a CE working group and CE conference, to better integrate and invest in a community of CE investigators and potential mentors in the CCC.
    - Metrics tracking of consultations, publications and grants as outcomes of mentored relationships.

- **"The EAC recommends focusing on metrics, measures and outcomes in the third year and the impact on community health. Some of these measures may need to be less focused on impact and more on the upstream progress measures such as capacity, connectivity, and trust."**

  - We re-evaluated all CCC goals, outcomes and metrics.
  - We launched a 360 community evaluation framework to assess trust and capacity.
  - We plan to leverage the CE Tracker to measure community connectivity and engagement.

Responses to EAC Recommendations

- **“The EAC recommends increased integration of community engagement across all ICTR programs. More attention is needed toward an integrated strategy.”**

➢ We strengthened/will continue to strengthen CE integration throughout the ICTR and across Einstein-Montefiore in the following ways:

- Partner with clinical stakeholders, BERD and HI to develop infrastructure to catalyze and support new social determinants of health research.
- Develop communication plan to promote CCC services through institutional channels emphasizing Montefiore Einstein Centers of Excellence (ME Comprehensive Cancer Center, CFAR, etc.).
- Develop infrastructure to get feedback and assess needs of existing CE researchers to determine gaps in current offered services.
- Create a CE Working group to promote CE faculty, disseminate existing work, and catalyze new collaborations across the institution
- Plan a CE Conference to integrate and create networking opportunities between researchers and community organizations and community members.
- Partner with Montefiore’s Community Health Needs Assessment team to disseminate information on community health needs to catalyze new research within community priority areas.
- Develop a new micro-grant program to accelerate small CE projects within community priority areas.

Responses to EAC Recommendations

- **“Clarification of terminology will be helpful. For example, defining for the community what health equity means will drive optimal collaboration across institutions and the community. Clarification as to whether the ICTR is working on the following will be helpful: community engaged research vs. patient-partnered research vs. community engagement vs. patient engagement vs. clinical advocacy engagement vs. organizational engagement, as would clarification of the definition of community. ”**
  - We adopted a broad, inclusive definition of health equity to align with evolving national priorities which allows for the CCC and the ICTR to be more responsive to all research projects and missions encompassing a greater variety of community perspectives
  - ICTR supports a spectrum of engagement from community-informed to community-led research
  - CCC goal to promote all collaboration, regardless of type of research (patient-partnered, advocacy-based or institutional.

Responses to EAC Recommendations

- **"CTSAs should consider how do communities, as systems, operate and to then merge those systems to ultimately improve the health holistically of an individual as well as a population."**
  - ➢ As part of our new strategic plan, we will integrate the expertise of social network analysts and system scientists to explore the feasibility of conducting studies of communities as systems.

- **"As the ICTR adds more requirements for research teams (e.g. TS, health equity, community engagement and partnership) the time from start-up to completion of projects may be increased, itself a TS barrier."**
  - ➢ Maintaining high-quality CE while reducing barriers is integrated within the core's goal to accelerate TS by streamlining processes, such as:
    - Compensation mechanisms for community members
    - New CE Element E project developing AI-driven tools to improve recruitment efficiency.
- **"Consider a social network analysis so that the breadth and depth of connectivity are clear."**
  - ➢ See above response.

ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

BERD

Melissa Fazzari, PhD

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

"The volume of requests for BERD continues to rise and there may be a need for more prioritization, more resources to respond to requests, and strategic deployment of resources."

Response: BERD has explored several avenues to address and prioritize increasing demand for support

- **Engage medical and graduate students** to help with more routine consulting projects under the guidance of BERD statisticians. This model is already applied by the Office of Medical Student Research (Reider) and the Division of Biostatistics. Utilizing this resource will allow BERD consulting requests to be training opportunities in areas such as data management, data cleaning and transformation, statistical testing, and statistical modeling.
- **Revised and launched a centralized ICTR request portal** to streamline project intake, prioritize requests, and generate usage summaries.
- **Align with new Data Science Institute.** The Institute will initiate recruitment in key areas like Bioinformatics that will further increase BERD capacity in areas where we need more expertise.
- Continuing to increase **statistical self-sufficiency of investigators** through BERD House training material in statistics, data science, machine learning, R coding, and study design; R workshops; Data Science lecture series (DS 101)

Responses to EAC Recommendations

"Some consideration should be given to the approach for measuring the added utility of the joint BERD/Informatics support for EHR based projects."

"We would like to hear more about combined BERD and HI metrics next year."

Response: Given our pre-existing individual pipelines, BERD and Informatics are exploring the best ways to collaborate on EHR-based projects. In 2025, we focused on continuing to expand joint BERD/Informatics training opportunities.

Evaluation and measurement of the added utility of these collaborations is a goal for 2026 (*demand, user feedback, productivity*)

- BERD and HI leadership in the new **Data Science Institute**
- Data Science 101 lecture series **with EHR session developed jointly with HI**
- Several BERD faculty members will be trained as **super-users in Epic Cosmos and data scientists to facilitate researcher access to the EHR data and expert Data Scientists**

Responses to EAC Recommendations

- **"The EAC would be interested to see a collaboration between BERD and the Community Collaborative Core in EHR training. We would suggest incorporating DEI in training."**

Response: BERD will continue to explore opportunities for collaboration with the CCC, particularly in EHR training.

- Dr. Mimi Kim – gave an overview on **Research Methodology to the CCC Community Advisory Council**
- Collaboration with Community Collaborative Core and Informatics to **develop novel analytic methods in the analysis of social determinants of health** is already planned. This will expand BERD's ability to evaluate how neighborhood, socioeconomic, and structural factors influence clinical outcomes and will facilitate research that promotes *health for all.*
- **Data Science 101 lecture series (Fall, 2025)** contained a lecture on EHR analysis that will, in part, focus on health equity, building unbiased and fair models, social determinants of health, and considerations about race/ethnicity in modeling and analysis. *We will expand this training in collaboration with HI, WFD and CCC to include case studies using de-identified EHR + SDOH data.*

Responses to EAC Recommendations

"In the coming year, many projects are planned and the EAC did not have a good sense of how they were going to be integrated into the total operational work. What is the strategic focus?"

Response: In 2025, BERD's strategic focus will be training and workforce development centered around our online BERD House resource ("*rising tide lifts all boats*").

- **Collaboration with workforce development**
  - Lecture (February 2025) – Introduction to Study Design for **research coordinators**
  - Other lectures are planned in 2026
- **Data Science 101 lecture series**
  - Initial series given in Fall, 2025
  - **R workshops -** Expanded to include **Machine Learning in R** (Spring, 2026)

This will have a large impact on the ICTR's and BERD's mission of advancing TS by alleviating analytic bottlenecks and equipping current and future researchers with the statistics and coding skills that are essential for rigorous and reproducible research.

Responses to EAC Recommendations

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

"The EAC noted that a new TS pilot project was just awarded to senior BERD statisticians on this topic and would like to hear more about this in a year."

Response:

BERD statisticians, Drs. Tao Wang and Xiaonan Xue, are PIs on the project, ***A Novel Data Science Framework for EHR-Based Health Research***, which is a translational science pilot project awarded in 2024 to address missing data in electronic health records-based research by applying AI to mine the clinical notes to impute the missing information.

2025 Update: This study is still underway, but pathological reports from unstructured EHR for patients in the cohort have now been extracted from clinical notes, key words to identify clinical variables such as tumor stage have been generated and the **large language model (Ollama) has been tested on a subset of observations.**

ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Health Informatics Core

Pavel Goriacko, PharmD, MPH
Erin Henninger, MPH

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **“A large number of individual projects were presented, and it was not clear how they are prioritized. The EAC had difficulty discerning the HI governance structure, and how the HI leadership prioritizes resources and integration with other cores.”**

  - We formed a new governance committee to streamline the prioritization of HI projects and align them with our strategic goals.

Responses to EAC Recommendations

- **“A significant concern of the EAC is that many of the projects were characterized in the way that they are an “end” – with less emphasis that these are a “means” to a TS goal; e.g. to improving outcomes. For example, the HI core created synthetic datasets, but it was unclear if researchers are using them and what was their impact.”**
- **“It was unclear from leadership which ICTR and institutional goals the HI activities and projects aligned with.”**
  - We have conducted an alignment of HI projects, activities, and metrics with the broader ICTR strategic goals.
  - In our presentation this year, we’ll be more explicit about how HI projects supported translational science and research.

Responses to EAC Recommendations

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

- **“The EAC perceives a need for improved governance and prioritization for HI projects, including access to data collection tools other than ATLAS (e.g. EPIC Cosmos, TriNetX).”**

  - We have created a new governance committee to review and prioritize HI projects.
  - We are extending our repertoire of data collection tools, with the current rollout of Epic Cosmos and more streamlined querying of INSIGHT (PCORnet CRN) data for feasibility.

Responses to EAC Recommendations

- **“While HI has made progress over the past year with AI models, we would encourage more thought on how such models can be applied to TS, and consideration of collaboration with the Pilot Funding Program.”**
  - We are evaluating opportunities for applying AI models to translational science, including an ICTR collaboration on the future Element E project application on "Utilizing Artificial Intelligence to Reduce Barriers to Community-Engaged Translational Research”.
  - We are collaborating with the Pilot Projects program on reviewing letters of intent and applications to identify projects which can benefit from additional informatics services, including our AI models.

Responses to EAC Recommendations

- **“Given the overall ICTR focus on HE, the EAC felt that much greater clarity was needed into how HE was incorporated into HI training and projects. For example, algorithmic bias was addressed by a talk by Dr. Fazzari on AI/ML to Einstein alumni, but formal training materials or courses were not evident. This is a growth opportunity and should be addressed for the next year.”**

- **“The EAC strongly encourages the HI to collaborate more with the CCC, and to expand on how community data (e.g. social determinants of health, geospatial data, etc.) can be used to advance CCC projects.”**

  - We have made it a goal to collaborate with CCC on making community and social determinants of health data more accessible to the researchers; this is a goal for year 4.

ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE

Building Bridges in the Bronx and Beyond

Workforce Development

Aileen McGinn, PhD

EINSTEIN Albert Einstein College of Medicine

Montefiore

Response to EAC Recommendations

The EAC strongly supports the recommendation of the K12 EAC to track the careers of graduates from each of the programs, and for the ICTR to present those data at future meetings.

- Up until recently we have followed-up with out graduates through a variety of time-consuming mechanisms such as:
  - Periodical internet and LinkedIn searches
  - Biannual newsletters (CRTP)
  - Graduate school tracking (PCI)
  - Personal communication

- This has worked relatively well, and we have up-to-date email address, current position, and NIH funding, etc. on >80% of graduates

- Currently overhauling evaluation system for all educational programs
  - Assess how many are engaged in CTR, total publications, grants received, new positions, etc.
  - Using annual assessments, implementing a more automated system such as Flight Tracker

Response to EAC Recommendation

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

The EAC would like to know what methods are used to assess each offering on a yearly basis. If participants fill out surveys, how have the data been used to make adjustments in the programs?

CRTP (Director: A. McGinn, PhD)

- **Course Evaluations**
  - Weekly reflections for each class to help address issues in a timely fashion
  - Anonymous end of semester evaluations are reviewed by the Director. Feedback is distributed to faculty and Director meets with any instructor where the evaluations indicate issues with teaching

- **Program evaluations**
  - CRAI Social Capital (entry, end of year 1, end of year 2)
  - Career Outcomes Expectations (entry, end of year 1, end of year 2)
  - Work-life Balance (entry, end of year 1, end of year 2)
  - Mentor Appraisal (6 months, end of year 1, end of year 2)
  - Exit Interview Focus Group conducted by Claudia and summarized for Director (end of year 2)

Response to EAC Recommendation

Continued from prior slide

PCI (Director: D. Hosgood, PhD)

- Regular **WIP sessions** to assess if each trainee is progressing on their research; feedback provided
- **Scientific Advisory Committee** meets at least annually
  - Provides critical feedback on the research plan, to assess experimental progress, and to advise the student when to write/defend the Thesis
  - Charged with aiding the student in moving efficiently towards the PhD degree, while at the same time maximizing the significance and impact of the thesis research
- **Associate Director for Student Support**: S. de Olivera, PhD
  - Oversees and manages trainees use of the IDP
  - Monitors and assesses the effectiveness of mentoring teams to advance trainee's learning

K (Director: D. Rastogi, MD, MS)

- Regular **WIP sessions** to assess if each trainee is progressing on their research; feedback provided
- **Scholarly Oversight Committees**
- **Associate Director for Scholar Support**: S. Suadicani, PhD
  - Discuss Individual Development Plan (IDP) and mentorship
  - Provide space to discuss and assess need for support in general or specific to each scholar

Response to EAC Recommendation

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Are any survey questions designed as institutional climate assessments to assess whether trainees feel that Einstein provides an inclusive environment?

- **CRTP Scholars** (via CRAI survey at entry, end of first year and end of second year)
  - To what extent are you and your work colleagues at Einstein-Montefiore willing to help each other out?
  - To what extent are you and your work colleagues at other institutions willing to help each other out?
  - Relative to your colleagues who are NOT currently in the CRTP, how well networked are you in your field?

- Working with T and K leadership to **develop entry and exit surveys** to capture this information going forward

- **Developing** more robust survey questions to address inclusivity

Response to EAC Recommendation

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

The coordinator resources are tremendous as is the curriculum. EAC would like to see metrics on coordinator recruitment/retention/career ladder.

- Coordinator recruitment/retention/career ladder has been historically challenging to track
- Different hiring processes at Albert Einstein College of Medicine and Montefiore Medical Center
- Wide range of job titles for those who operate in a coordinator capacity at the institution
  - ~5-10 at Albert Einstein College of Medicine alone
- Working with our Clinical Research Management System (Velos CRMS) team to identify job titles of system users who are listed as study or regulatory coordinators on an active study
  - Allow us to identify majority of the coordinator job titles across the institution
  - Will then leverage to request further detail from both respective Human Resource departments.

ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

CQI and Evaluation

Ariel Fishman, PhD
David Lounsbury, PhD
Claudia Lechuga, MS

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

"The EAC would like the module to consider whether the addition of CQI on top of regular evaluation is creating challenges with respect to staffing and bandwidth."

- Our CQI & evaluation strategy is a decentralized and centralized **partnership.**
  - **Module leaders** bring their subject/content expertise (decentralized).
  - **CQI team** brings their methodological support (centralized).
    - Moving from *Prove* to *Improve*: CQI serves *facilitators/partners/enablement*, not evaluation as *auditors.*

      "We don't make a lot of the products you buy;

      We make a lot of the products you buy better." - *BASF corporate slogan (1990s)*
- We redistributed Director of Evaluation's (Claudia L) responsibilities to other staff. She is a *member* of the CQI team.

Responses to EAC Recommendations

"The EAC would like to see the impact of CQI connecting different modules across the ICTR and groups across the institution."

- We conducted a CQI project (new!) with the SM module (June-October 2025).

  Focus: How can we advance cross-unit collaboration?

  Analyze: Developed new *Goals-Activities-Metrics* tracking database.

  Change:
  - Used DB to visualize connections between modules (in support of retreat planning).
  - Identified and prioritized **15** collaboration opportunities, 7 of which were already in progress (but not framed that way).

  Evaluate: Collaborations are developed and in progress!

New Collaborations Across ICTR

(As seeded at retreat and SM's CQI process)

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Collaboration	Modules	ICTR Strategic Goal Alignment
New		
1. Incorporate into WFD programs (including CRTP, TRANSCEND, K12, T32?) application of translational science principles to current/future work	WFD, K12, T32, Pilots	Goal 1 (TS) and Goal 4 (Workforce)
2. Improve HI, BERD and CCC components of applications for WFD programs and pilots by reviewing applications by HI, CCC and BERD teams (with option to review all protocols that request ICTR services by HI in the future)	WFD, K12, T32, HI, BERD, CCC, Pilots	Goal 1(TS) and Goal 4 (Workforce)
3. Improve accessibility of CRC and recruitment of PWD in research	Element E, CRC	Goal 1 (TS) and Goal 3 (Resources)
4. Incorporate into WFD programs (CRTP, K12, T32?) lessons learned about engagement and awareness of barriers to research for those LWD	WFD, K12, T32, Element E	Goal 1 (TS) and Goal 4 (Workforce)
5. Facilitate Research with SDoH	BERD, CCC	Goal 2 (CSE)
6. Increase the use of social needs screening data in research through a consultation program to assist researchers with identifying data and analyzing them	CCC, BERD, HI	Goal 2 (CSE)
7. Research coordinator training – incorporate cultural competency	CCC, CRC	Goal 2 (CSE) and Goal 3 (Resources)
8. Support pathway programs	CCC, WFD	Goal 4 (Workforce)

Ongoing Collaborations Across ICTR

(As seeded at retreat and SM's CQI process)

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Ongoing		
9. Strategy to increase utilization of CRC, BARC, BioR	SM, CRR	Goal 3 (Resources)
10. Launch qualitative/mixed methods core and manage consultations	SM, CCC	Goal 3 (Resources)
11. Develop supports for Epic Cosmos rollout	BERD, CCC, SM	Goal 3 (Resources)
12. Develop new masters, certificate programs (long-term)	SM, WFD, BERD, HI, D&I/LHS	Goal 4 (Workforce)
13. Develop data science training and ultimately certificate program	BERD, WFD	Goal 4 (Workforce)
14. Facilitation of cross-module collaborations	SM with all modules	Goal 1 (TS)
15. Development of metrics and dashboards for ICTR modules and overall	SM, CQI, HI, and all modules	Goal 1 (TS)

ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE

Building Bridges in the Bronx and Beyond

CTS Pilot Project Program

Sofiya Milman, MD, MS

Sylvia Suadicani, PhD

EINSTEIN Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **“The EAC recommends regional collaborations around using checklist language, screening, and actual administrative tools used when working with pilot awardees and in town halls. ”**

➢ TRANSIT

  - We have developed a new scoring system based on TS principles to better assess TS potential and focus of the project
  - If validated in 2026 cycle, we will disseminate the tool to other hubs

Responses to EAC Recommendations

- **“The EAC recommends considering a follow-up publication to the hub’s TS challenges paper (2023).”**
  - ➢ A follow-up paper is planed in which we will discuss outcomes from approaches that we implemented to facilitate TS at our institution including:
    - 1:1 TS consultation requirement
    - Introduction of LOI + optional consultation
    - Self assessment of project TS focus using TRANSIT tool
    - Implementation of TRANSIT scoring system in the pilot project review
    - TS seminars:
      - Presentations by TS pilot awardees to the research community to increase awareness about TS.
      - Presentations about TS to K and TRANSCEND scholars
      - TS Informational Town Hall

Responses to EAC Recommendations

- **“Understanding the outcomes of the TS educational initiatives would be helpful; e.g. town hall, seminar and consultation attendees (N), as well as increase in knowledge or other outcomes.”**

  - Quantitative analysis completed that will be shared at the EAC meeting and includes:
    - Comparison of outcomes from Y1, Y2, and Y3
    - # of responsive applications
    - Increase in awareness and understanding of TS and its goals measured using a brief survey at the TS Town Hall and TS Seminars

Responses to EAC Recommendations

- **"The EAC would be interested to see plans for evaluating in the coming year the differences between using the letter of interest vs. the pre-application meetings with the TS two-question approach. Is it possible to get qualitative data?"**

  - **<u>Quantitative data collected that assesses</u>**:
    - Number of requested pre-application meetings vs. number of LOIs
    - Number of responsive applications discussed in pre-application meetings and number of responsive LOIs
    - Total number of submitted applications per number of meetings and number of LOIs

  - **<u>Qualitative Data</u>** – will consult with CQI Team about collecting these data

Responses to EAC Recommendations

- **“Consider reaching out to basic scientists who are developing techniques and technology platforms that are generalizable, or to core facility leaders. They may not recognize that their activities are aligned with TS.”**
  - TS Pilots have a strong record of engagement and support of basic science projects
  - Collected data from the TS works in progress, seminars, and town hall re: % of basic scientists who have attended, number of basic scientist/clinician collaborations in proposals
  - Plan to engage Core Directors (e.g., John Grealy, Steven Almo) to discuss how the technology developed in their Cores can be used to advance TS research and lead to collaborations

Responses to EAC Recommendations

- **“Consider providing opportunities to foster team formation in this regard, improving how pilots may bring together T1 focused work with TS further along the translational spectrum.”**

- ➢ Plan to inform SPARC awardees about TS pilot funding opportunities to expand their collaboration
- ➢ Plan to present about TS to CRTP, K, and TRANSCEND scholars
- ➢ Plan to engage the core directors who can disseminate information to their users

ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Clinical Research Resource

Matthew Abramowitz, MD, MS

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Responses to EAC Recommendations

- **“Extending the sharing to external users would likely further enhance utilization and provide a firmer base for justifying the significant fixed expenses for maintaining the biorepository. Similarly, offering space in the biorepository to scientists in other institutions could provide additional financial support.”**
  - Medium term goal is to expand access to shared repository to external CTSAs (and possibly academic institutions in general) after internal sharing has been established.
    - Will need mechanisms in place for review of external protocols, billing/payment
  - Will accept requests from external users to use biorepository storage but will not actively advertise due to liability issues.

Responses to EAC Recommendations

- **“The EAC recommends using the Clinical Research Center as an internal CQI project to find ways to increase utilization.”**

  - The CQI project is underway: examining challenges to CRC use
    - ICTR CQI area of focus: CRC utilization
    - Distributed survey to clinical investigators
    - Offering expanded after-hours and Saturday service
    - Outreach to increase awareness among potential users and administrators
    - Increasing number of industry-sponsored studies at Einstein-Montefiore
    - Collaboration with HIC to enhance trial recruitment

Responses to EAC Recommendations

- **“The EAC supports CRC collaboration with the cancer program to do phase 1 investigator-initiated clinical trials and increasing industry studies.”**

  - We have explored this but encountered the following obstacles to collaboration
    - Cancer center has robust clinic- and infusion center-based clinical research program
    - Studies are embedded in infusion center infrastructure and require nursing chemotherapy administration
    - Inpatient studies require off-hour nursing support, e.g. overnight blood collection
    - Patient and IP transport to CRC is a challenge
    - MDs would need to come to Van Etten to conduct study visits
  - Opportunities we are discussing
    - Future studies with oral agents
    - Potential collaboration for expanding cancer-focused biorepository

Responses to EAC Recommendations

- **“The CRC should consider trying to obtain outcome data by surveying the research participants.”**

- Currently surveying CRC users (members of study teams)
- Consider survey of research participants’ experience in the CRC
  - When surveying research participants about their experiences, how do we distinguish between the activities and impact of CRC staff and those of study teams?

Responses to EAC Recommendations

- **"The EAC recommends both a careful analysis of potential money-saving actions that can still support the existing volume, as well as outreach to stimulate utilization, including providing assistance to investigators in developing protocols. Senior ICTR leadership may also want to consider meeting with basic science faculty to ascertain their interest in conducting human subjects research if provided with appropriate medical support."**

  - Comprehensive strategy implemented this year to increase utilization and impact
    - Expanded outreach efforts
    - Investigator education during study feasibility phase
    - Revised pricing structure
    - Collaboration with other Einstein centers
    - Survey of clinical and translational investigators to identify needs
  - Consideration of limiting activities to one campus
  - Reduced staffing
  - Protocol development consultation service for junior investigators
  - Fostering collaborations between basic science and clinical faculty
    - Basic science faculty unlikely to pursue human subjects research unless advancing a specific project
    - Typically are not interested in learning about clinical research infrastructure
    - Will benefit from initiatives (e.g. internal funding opportunities) to foster basic-clinical collaborations