SECTION B.2 - ACCOMPLISHMENTS

OVERALL

B.2.1 Progress of Overall Program: We summarize below the major accomplishments, outcomes and innovations in Year 3 of the award by module, specifying which ICTR UM1 strategic goals each support, followed by challenges/plans for resolution and institutional support. *The UM1 strategic goals are as follows, each of which contributes to our vision of furthering translational science (TS) innovations and health for all*:

1. Catalyze and support research to advance TS
2. Facilitate community and stakeholder engagement throughout the translational process
3. Create/implement state-of-the-art scientific resources, services, informatics capabilities to facilitate clinical and translational research (CTR)
4. Develop/maintain skilled, multidisciplinary translational workforce to support and lead high-quality CTR
5. Partner with CTSA hubs and the consortium to accelerate translational research (TR) and respond to public health emergencies

Strategic Management (*supports strategic goals 1, 2, 3, 4, 5*)

Leadership. The ICTR has undergone several leadership transitions over the past year, including new directors and/or associate directors for Community and Stakeholder Engagement (CSE), Dissemination and Implementation (D&I), Health Informatics (HI), and the practice-based research network: this has required intentional onboarding efforts but has infused new expertise, capacity, and enthusiasm into the ICTR leadership team. In this award year, we have implemented several organizational development projects to improve ICTR effectiveness, efficiency, productivity, impact, communication, and team engagement. These included an ICTR-wide retreat in July 2025: multiple objectives were met including development of 15 cross-module collaborations, about half of which have launched, and a process to define overall ICTR metrics that measure TS innovations and health for all. We also launched a new online resource and seminars for researchers to navigate new federal directives.

External and Internal Advisory Committees (EAC, IAC). We held the 2025 IAC meeting in May 2025 and the EAC meeting in November 2025 which have led to transformative changes (see IAC and EAC summaries).

D&I/Learning Health Systems (LHS). Dr. Sharon Rikin, Associate Dean for Institutional Quality Improvement, assumed leadership from Dr. Rinke in 2025 and has implemented several new capacity-building and workforce development initiatives. She convened a LHS Advisory Board comprised of senior health system leaders to identify priority areas for LHS research and implementation initiatives to enhance the impact and sustainability of ICTR-supported research. She launched the Shiu Y. Kwok Pilot Grants, funded by a new philanthropic gift to the ICTR, which provides pilot funding and intensive mentorship studios to drive innovation, implementation, and impact. She reconceptualized the Implementation Science (IS) working group that meets monthly to support D&I/LHS research, conducting a needs assessment which led to valuable data that will drive the group's work. Former D&I director Dr. Rinke was awarded funding from the Patient Centered Outcomes Research Institute (PCORI) Health System Implementation Initiative (HSII), a cohort of 42 U.S. health systems, to promote the uptake of high-priority evidence from PCORI-funded research into clinical care, and Dr. Rikin is leading a new project entitled "Addressing Hypertension in Adults." The ICTR continues to support our practice-based research network (PBRN), the New York City Research and Improvement Networking Group (NYC-RING). Dr. Andrew Telzak, a graduate of our CTSA-supported Clinical Research Training Program, is the medical director and has facilitated clinical research and implementation science projects through NYC RING that are funded by the NIH, CDC and foundations. The PBRN has 7 active research studies. Dr. Jonathan Ross became associate director this year: he is an Associate Professor of Medicine who conducts implementation science research and received a Masters in Clinical Research Methods through the ICTR. An American Cancer Society grant led by Dr. Dean Hosgood, ICTR T32 PI, includes 24 NYC RING primary care sites to increase lung cancer screening in the Bronx through the implementation of a centralized screening unit. Dr. Rikin continues to lead the EQUIP+ Center for Learning Health System (LHS) Science, a collaboration with Columbia and Cornell funded by AHRQ (1P30HS029763). The objectives are to build and coordinate a robust LHS infrastructure that provides vital research resources, didactics, and mentoring to embedded LHS scientists and meets their individual training and research project needs.

Response to public health emergencies. We are prepared to transition to a virtual leadership structure and rapidly realign activities to assist response efforts, and underwent a succession planning process for all senior and module leaders this year.

CQI: The CQI team continues to utilize the innovative FACE (Focus, Analyze, Change Planning, and Evaluate) framework to guide its CQI activities, resulting in multiple improvement projects with measurable impact. They disseminated this approach in a second manuscript published in JCTS (Fishman et al., Evaluation means making CQI collaborative (E = MC2): Lessons learned from implementing a new continuous quality improvement process at the Einstein-Montefiore CTSA hub). This year the CQI team implemented an innovative, ICTR-wide process to facilitate cross-module collaborations described later in the RPPR.

Training and Outreach (*supports strategic goals 1, 2, 3, 4, 5*)
Workforce Development: We continue to innovate in our flagship two-year Clinical Research Training Program, adding an elective this year in collaboration with Health Informatics, *Real World Data for Clinical and Translational Research*. Current scholars published 30 manuscripts this year. The Einstein Discover Research Program, a collaboration between the ICTR, the Montefiore-Einstein Comprehensive Cancer Center, and Lehman College of the City University of New York, enables students at Lehman to obtain a Master of Science by conducting research at Einstein as a foundation for their Master's thesis. The first students in this program successfully defended their theses in 2024. Building on the success of this program, we submitted an R25 ("Bronx-MEETS") that was funded in 2025 to develop and incorporate translational science education into the Einstein Discover program. Bronx-MEETS offers a ten-week summer curriculum in translational science that integrates undergraduates and master's students into a hands-on research and multilevel mentoring network. The program's design includes a Continuous Quality Improvement framework that uses feedback from participants and mentors to refine both curriculum content and mentorship models. Together, the Discover and Bronx-MEETS programs now form a cohesive pipeline that connects students from the Bronx community to graduate opportunities in translational research. The ICTR submitted a grant to support mentorship through this program entitled "Shaping Professional Advancement through Research mentoring and Knowledge (SPARK)" and it was funded by the LifeSci NYC Initiative. The Translational Science Career Enhancement and Networking Development Program (TRANSCEND) to support K awardees has been reconfigured so that it coincides with K12 Scholar meetings to increase networking among these junior faculty. The Reach for the First R01 program has led to successful federal funding in approximately 30% of the 28 participants to date. The ICTR's clinical research coordinator training program was also enhanced by offering a combination of online courses, in-person workshops, a research coordinator working group, and research coordinator forum: 169 learners participated in 2025 representing ~58% of the coordinator workforce.

Community and Stakeholder Engagement Research. The CCC, under new leadership (Drs. Perez and Gutnick), has implemented significant improvements to its community engagement service provision processes including: development of a Community Engagement Research Implementation Toolkit (comprised of a best practices guide, tool to connect researchers to community based organizations, and an evidence-based tool evaluating perspectives from community members about research participation), expansion of the Community Engagement Tracker which is an interactive tool to track community engagement in research, facilitation of the Community Advisory Council, expansion of language translation services for research, provision of qualitative analysis software, development of new collaborations with the Montefiore Community Health Worker Institute, continued consultations, and cross-institutional collaborations to support community-engaged research. The team was invited to present the community engagement tracker to the CTSA Collaboration and Engagement Enterprise Committee. The CCC also launched a new qualitative and mixed-methods core led by Dr. Watnick in the fall of 2025. The CCC has been integrally involved in multiple grant submissions, and has disseminated its innovative work through presentations (including the CTSA fall program meeting) and publications.

CTS Resources and Pilots (*supports strategic goals 1, 2, 3, 4, 5*)
Resources and services (BERD, CRC, BARC, BioR).
BERD**:** In addition to continued development of E-M's Data Science Hub and the online biostatistics resource, BERD House, BERD continued to expand data science resources in year 3. These included launching a Data Science 101 Lunch and Learn series, leading training opportunities in R coding and machine learning, and participation in the launch of Epic Cosmos to facilitate researcher access to over 300 million patient records. BERD faculty contributed to nearly 70 peer-reviewed publications and multiple funded grants, several of which focused on translational science methods. BERD faculty also led an ICTR pilot award to address missing data

in electronic health record research using artificial intelligence. Dr. Mimi Kim, ICTR Associate Director, launched the Data Science Institute this year, a component of the Einstein Strategic Plan, to increase data science expertise, resources, and educational programs; this will considerably strengthen data science support and training capabilities in the ICTR as well as in the broader Einstein community. Several BERD faculty are involved as leaders of the DSI. Joint ICTR/DSI efforts include the Data Science 101 series, a high performance computing workshop, EHR data access resources, and methodologic training for clinical research coordinators, the CCC community advisory board, and the broader Einstein community.

The Clinical Research Resource (CRR), under the direction of Dr. Matthew Abramowitz and Zoe Tsagaris, has developed a pool of research and nurse study coordinators to assist in the start-up, execution, and close-out of clinical research studies. The Clinical Research Center expanded hours and equipment, including a new body composition assessor, and conducted a needs assessment survey and extensive outreach to increase use. The Biomarker and Biorepository Core (BBC) is a critical resource to investigators who can access assays and storage for human specimens. The CRR has made progress toward establishing a set of shared biospecimens that will be available for use by all E-M investigators and in collaboration with HI, has made excellent progress in BBC patient samples with clinical data from the EHR, so that clinical metadata and patient outcomes are linked to these specimens, and has also linked the database with ATLAS and created a new user-searchable cohort in ATLAS. The Hub Liaison Team has developed resources and supports to enhance recruitment of diverse study participants and a comprehensive online Research Project Navigation Tool. The Regulatory Knowledge and Support Resource (RKSR) has developed multiple resources to support regulatory education, compliance, and ethics including IND and IDE toolkits for E-M.

CTS Pilot. The ICTR Pilot Project Program provides support to researchers to design and conduct innovative TS studies and funds TS projects that have the greatest potential to overcome major translational roadblocks. In year 3, we received 23 letters of intent (LOIs) of which 12 aligned with TS and were invited to submit a full application. We introduced a new TS scoring system for applications, the Translational Science Indicator Tool (TRANSIT) and all reviewers scored each application on 7 NCATS TS principles. All funded projects are highly innovative and have potential to overcome TS roadblocks: 1) Community-Based Virtual Group Reminiscence Therapy to Improve Loneliness and Apathy in Community-Dwelling Older Adults (PI: Mirnova Ceide, MD, MS), 2) Bridging the Gap: Assessing Digital Health Literacy and Readiness for Behavioral Change in Emergency Department Populations (PI: Carlo Lutz, MD), 3) Predicting population-specific genetic disease risks in biobank-scale data (PI: Srilakshmi Raj, PhD), and 4) Finding Neoantigens Using an mRNA Translational-Based Approach (PI: Kamini Singh, PhD). Current awardees published several high-impact manuscripts, submitted grants based on their work, and filed a patent. The pilot program also expanded its educational and mentorship program to educate our academic health center about translational science through consultations, educational materials, a TS Town Hall, and TS seminars.

Data Science (Health Informatics) (*supports strategic goals 1, 3, 4, 5*)
The ICTR Health Informatics Core (HI), under new interim leadership (Drs. Goriacko and Henninger), has supported 718 projects over the past year and responded to 251 service requests, most of which utilized self-service platforms supported by HI including Atlas and REDCap. Innovative automated recruitment services developed by HIC matched patients to 36 cancer trials. HI contributed to 21 publications in high-impact journals and closely collaborates with multiple CTSA HI cores, including with the Tufts and NYU CTSAs to develop free online self-training modules on real world evidence and cohort-based studies. HI also established an AI Governance Committee in collaboration with the M-E Center for Bioethics, IRB, and others. HI has developed several innovations and unique capabilities including the ALBERT LLM Ensemble, a clinical trial matching platform, an AI transparency platform, and automated OMOP concept mapping. At this year's OHDSI symposium, two of our HI team members were selected as Best Community Contribution finalists for their submissions: Advancing Learning Health Systems Through Integrated Machine Learning Operations: A Novel Extension of the OHDSI Research Infrastructure (led by Boudewijn Aasman) and Automated OMOP Concept Mapping Using Multi-Agent Large Language Models and Graph-Enhanced Semantic Retrieval (led by Adil Ahmed). We have an open search for a new director of HI who will serve as Chief Research Informatics Officer at Montefiore-Einstein.

Element E (*supports strategic goals 1, 2, 3, 5*)
The Element E team has completed measurement of knowledge, attitudes, and perceptions of researchers related to engaging people with disabilities in research and designed an eLearning module for investigators which is now being evaluated in a randomized controlled trial. A manuscript based on this work is being

revised for JCTS (Bonuck K et al. Researchers' Roadblocks to Including People with Intellectual and Developmental Disabilities in Research) and the eModule will be used in a toolkit being developed by the CTSA working group, Engaging Individuals with Disabilities in Research.

Partnerships, collaborations, facilitation of multi-site research (*supports strategic goals 1, 2, 3, 4, 5*)
See above for examples of our many collaborations with other CTSA hubs and institutions. In addition, we continue to support the engagement of our research community with the Trial Innovation Network. This year we have expressed interest in three upcoming trial opportunities and were selected as a participating site for two others (VPS RCT and COMBO AC) which are pending funding. M-E is a participating site of the Optimizing the use of Ketamine to Reduce Chronic Postsurgical Pain (HEAL KALPAS) trial led by Dr. Jing Wang at New York University School of Medicine, which achieved its enrollment target of 750 participants this year (DOI: 10.1186/s13063-023-07884-y). Health informatics has supported these study teams using eConsent via REDCap and Twilio SMS service for follow-up and participant retention. The Community and Stakeholder Engagement module team has participated in several successful collaborations to increase community engagement in translational research and increase generalizability of research; e.g. Einstein-Rockefeller-CUNY Center for AIDS Research (P30AI124414, NIAID), Montefiore Einstein Comprehensive Cancer Center, National Center for Engagement in Diabetes Equity Research: National CEDER (1U2CDK137135-01, NIDDK), Hispanic Community Health Study – Study of Latinos (HCHS/SOL) 4th contract renewal (N01HC65235, NHLBI), and Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR) at Montefiore Einstein (RM1DA055437, NIDA). HI closely collaborates with 5 other NYC based CTSA-Informatics cores (Columbia, Mt. Sinai, Cornell, NYU, Rockefeller) and the INSIGHT Clinical Data Network. Additionally, HI works with Tufts and NYU CTSI to develop training materials on RWE, EHR-based research, and the OMOP-CDM. Additional engagements are shown in the **Table**:

Service on CTSA EACs and other boards
EACs: Clinical and Translational Science Collaborative of Northern Ohio (Dr. Kahn), Rockefeller EAC (Dr. Kim), Rutgers University (Dr. McGinn).
Columbia's Irving Institute Translational Science Leadership Committee (Dr. Milman)
Board of Biostats4you, a website hosted by the University of Minnesota (Dr. Fazzari)

CTSA national engagement
Steering committee: Dr. Kim
Enterprise Committees: Drs. Kahn (Integration Across the Lifespan), Kim, Fazzari and Goriacko (BIDS), Perez (Community Engagement), Goriacko (Informatics), McGinn (WFD), Archer-Dyer (Community Engagement) and Ms. Lindquist (BIDS), Sack (WFD), and Lechuga (Community Engagement)
Special Interest Groups: Drs. Kim, Fazzari (BERD), C. Lechuga (Evaluation)
Working groups: Drs. Kahn (Pediatric Clinical Trials), Bonuck (Engaging Individuals with Disability), Goriacko (Real World Data WFD), Rikin (LHS), Fazzari and Kim (BERD)
Consortium groups: Drs. Kahn (PI), Kim (PI), Hosgood (T32), Rastogi (K12); Ms. Alfieri (Administrators), Sack (Communicators), Castro (Administrators and QA/QC), Marte (Administrators).
Fall CTSA meeting planning committee: Dr. Kahn
AIM-AHEAD: Ms. Lechuga

Challenges encountered and plans for resolution: 1) Meeting the ever-growing demand for data science training and EHR research support. Plans for resolution include: expanding online content (e.g. BERD House, HI resources), expanding coding, data science, and machine learning content into training programs, collaborating with the Data Science Institute to develop a Data Science certificate program, and providing more methodological support for access to EHR data enclaves given the launch of resources such as Epic Cosmos. 2) Increasing collaboration and coordination among ICTR modules and cores, especially to better integrate Community Collaborative Core expertise and resources into the other ICTR components to ensure their activities and outcomes align with the perspectives and priorities of patients, communities and ICTR partners. Plans for resolution include implementing the cross-module collaborations that were developed during this award period. 3) Increasing visibility of the ICTR. Plans include ICTR open houses on both campuses, departmental presentations, additional marketing materials, a new community engagement symposium, and continuing our TS town hall, TS seminar series, and monthly newsletter.

Institutional support: The ICTR receives significant institutional support for ICTR initiatives that are not covered by the CTSA grant, including funding for a full-time Program Manager to support NYC RING; a full-time research coordinator to spearhead the coordinator pool to assist investigators who do not have access to

study staff within their departments; faculty to support education, training, and career development programs; funding to support student stipends for the pathway program with Lehman College; and personnel to support the Health Informatics Core, Biomarker and Biorepository Core and Clinical Research Units. Dr. Yaron Tomer, who was named the Marilyn and Stanley M. Katz Dean of the Albert Einstein College of Medicine in October 2023, has demonstrated strong and continued commitment to the ICTR. Dr. Tomer appointed Dr. Marla Keller, former Senior Associate Dean of Clinical and Translational Research and ICTR PI, as Executive Dean in 2024 and Dr. Jessica Kahn was recruited to serve in both of those positions in October 2024. The ICTR received a $1 million gift (to be distributed over 4 years) from an anonymous donor during this award period which will allow us to expand our reach and impact even further through additional support for each module's initiatives.

ELEMENT B: STRATEGIC MANAGEMENT

EVALUATION REPORT:

Conceptual Framework and Objectives: Over the past year, the ICTR's internal efforts have continued to be grounded in a conceptual framework that orients evaluation around *improving* rather than merely *proving* the performance of our modules. Our Continuous Quality Improvement (CQI) process remains anchored on three key components: (1) Logic Models outlining goals and associated mechanisms of each module; (2) development of metrics to evaluate opportunities for improvement; and (3) application of a structured model for improvement. Building on this foundation, we have continued to empower module leaders to drive improvement efforts, advancing change based on data-driven insights while fostering collaboration and cross-pollination of ideas across the ICTR. Our approach was published in *Journal of Clinical and Translational Science* (Fishman et al., 2024).

The CQI team has benefited from continuity with no staff turnover. It has been led since its inception by Ariel Fishman, David Lounsbury, and Claudia Lechuga. The Team's FACE—Focus, Analyze, Change Planning, and Evaluate—orients the management of its CQI activities not only to advance systematic improvement across all ICTR modules but also to foster cross-pollination of ideas. Through this framework, the team supports module leaders on **Focusing** on projects aligned with the ICTR's goals, **Analyzing** relevant data, designing and implementing targeted **Changes**, and **Evaluating** outcomes to guide subsequent improvement cycles. Regular convenings ensure that insights from individual projects cross-pollinate between modules and inform broader institutional efforts, reinforcing CQI as a dynamic, collaborative process that builds organizational learning and accelerates progress toward the ICTR's strategic goals.

In 2025, we published a second article in *JCTS* describing lessons learned from implementing our CQI process. Through reflective inquiry, we examined our collective experiences launching the ICTR's CQI program and our efforts to embed it as a core element of strategic management. We shared key lessons from implementation, including the importance of establishing a common understanding of CQI's purpose and scope; centralizing CQI coordination while preserving module-level autonomy; creating structures that foster collaboration and cross-pollination of ideas; and applying CQI principles to improve the CQI process itself. We also examined strategies for addressing misconceptions about CQI that emerged during implementation, emphasizing how trust, leadership support, and iterative learning have been critical to building a sustainable culture of continuous improvement across the ICTR.

Based on feedback from our external advisory committee, we have also expanded our conceptual framework to encompass facilitating collaborations between ICTR modules and potentially across the institution. Thus far, our efforts have outlined areas of alignment between modules and overall ICTR goals, identified areas of potential cross-module collaboration around current goals and activities, and initiated steps towards early collaboration activities.

Milestones, metrics, and data collected. At the conclusion of every FACE meeting, we administer feedback surveys to assess CQI objectives both quantitatively and qualitatively. Presenters and attendees rate their agreement on a Likert scale with statements such as whether the CQI team encouraged active decision-making and created a collaborative experience, and whether the team helped modules accomplish their goals—serving as a proximal measure of CQI project effectiveness. Satisfaction with the CQI team's performance has remained consistently high, exceeding 84% since the program's launch. Qualitative feedback collected on the survey remains positive. Open-ended comments from module leaders in 2025 – particularly ones who are new to the ICTR – included statements such as, "This is a good example of progressing to a focused project that would otherwise may not have received the dedicated attention and support outside of a

CQI process" and "I think it is a great opportunity to learn what other modules are doing to keep abreast of new initiatives and potentially follow-up afterwards off line." These comments highlight the collaborative spirit and practical merits of the CQI process, underscoring its utility in fostering shared learning, collective problem-solving, and cross-module collaboration, while ensuring that the process remains participant-centered and productive.

Specific changes implemented:

Feedback from last years' RPPR and EAC resulted in some recent modifications: the CQI team extended its focus beyond module specific projects towards CQI-engagement ICTR-wide and the CQI team added Strategic Management as a module unto itself, which allows CQI principles to address ICTR-wide priorities and to model the process for broader institutional improvement.

Strategic Management's first CQI project focused on expanding cross-module collaboration. To begin, the CQI team convened with module leaders beginning February 2025 to revisit, revise and aggregate their own modules' goals, activities and metrics over the subsequent few months. We catalogued this information into a database to identify areas where multiple modules engage(d) in activities that advance the same ICTR goals (overall and sub). At the ICTR retreat in July 2025, modules engaged in a series of activities designed to 1) share widely within the ICTR each modules' goals and activities, 2) center module leader-driven identification of their modules' goal alignment with ICTR-wide goals, and 3) facilitate module leader-driven identification and prioritization of

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		
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)

cross-module collaboration opportunities. The CQI team worked with module leaders in the subsequent months to further revisit their module goals and activities (if changed post-retreat) and facilitate and catalog cross-module activities. Efforts for the facilitation, tracking and analysis of these activities (8 new, 7 ongoing; see **Figure**) and new collaborations are currently underway.

DISSEMINATION AND IMPLEMENTATION SCIENCE (IS) / LEARNING HEALTH SYSTEMS (LHS)

Goals:
1. Research Infrastructure: Build implementation science and LHS research infrastructure
2. Education and Consultations: Enhance capacity to perform IS/LHS research
3. Operations: Alignment of research with health system priorities
4. Innovations and Projects: Stimulate and support research in priority areas

Highlights, Milestones and Challenges

- Leadership Transition & Strategic Integration: Leadership of the module transitioned from Dr. Michael Rinke, the Chief Quality Officer for Montefiore Einstein, to Dr. Sharon Rikin, the Associate Dean for Institutional Quality Improvement. Their longstanding collaboration enabled a smooth transition and continuity of strategic goals.
- Advisory Board Formation: Dr. Rikin convened an LHS Advisory Board of senior Montefiore Einstein health system leaders to identify priority areas for research and implementation. This board provides executive sponsorship and input on initiatives facilitated through ICTR mechanisms (see EQUIP+ and Kwok programs below).
- EQUIP+ Center Partnership: The ICTR partnered with the AHRQ-funded Columbia-Cornell-Einstein EQUIP+ Center to support embedded LHS scientists. As Einstein site PI, Dr. Rikin facilitated informatics and statistical support for the two Einstein EQUIP LHS Scientists through collaboration with ICTR modules. ICTR leaders including Drs. Rikin, Rinke, and Kahn contributed to the EQUIP+ lecture series available to EQUIP LHS Scientists which was also advertised broadly to the IS working group.
- Kwok Pilot Grants Launch: The ICTR launched the Shiu Y. Kwok LHS Pilot Grants program, which are funded through a new philanthropic gift and will support faculty conducting Learning Health Systems (LHS) projects with pilot project funding and intensive mentorship "studios" to drive innovation, implementation, and impact within Montefiore Einstein. In 2025, the ICTR received 16 letters of intent and invited 12 full applications. At least 2 scholars/projects will be supported annually.
- IS Working Group and Grand Rounds Series: The ICTR offered monthly meetings to review and provide feedback for grant applications and quarterly meetings for IS Grand Rounds. Grand rounds speakers in 2025 included Andrew Beck M.D., M.P.H. "Developing and implementing an institutional approach to the pursuit of excellent and equitable pediatric health outcomes," Nathalie Moise, MD, MS "Blueprints for change: Designing Precise, Mechanism-driven implementation strategies."
- PCORI HSII Funding: ICTR leaders received PCORI Health System Implementation Initiative funding for projects on antibiotic prescribing (Dual PI: Rinke, Nori) and hypertension management (Dual PI: Racine, Rikin).
- NYC RING Support: The ICTR supports NYC RING, a practice-based research network with 7 ongoing projects funded by NIH, CDC, and foundations, led by Drs. Andrew Telzak and Jonathan Ross. Current projects include trials on lung cancer screening, lipid-lowering in older adults, diabetes technology use, cancer outreach, penicillin allergy de-labeling, cognitive impairment detection, and asthma treatment (**Table**).

NYC RING Projects 2025			
Study Name	**Principal Investigator(s)**	**Project Type**	**NYC RING Role**
1. Implementation of a Centralized Screening Unit to Increase Lung Cancer Screening and Downstage Tumors in an Urban Minority Population	Dean Hosgood PhD (PI)	Implementation Study	Investigator
2. Pragmatic Evaluation of Events And Benefits of Lipid-lowering in older Adults (PREVENTABLE)	Carlos Rodriguez, MD (Site Co-PI) Andrew Telzak, MD MSc (Site Co-PI)	Pragmatic Clinical Trial (Multisite)	Investigator
3. Enhancing the Community Health Worker (CHW) Model to Promote Diabetes Technology Use in Young Adults from Underrepresented Minority Groups (YA-URMs) with Type 1 Diabetes (T1D) (CATCH - T1D)	Shivani Agarwal, MD (PI)	Randomized Clinical Trial	Investigator
4. NYC Cancer Outreach Network in Neighborhoods for Equity and Community Translation Randomized Controlled Trial (NYC CONNECT)	Bruce Rapkin, PhD (MPI)	Randomized Controlled Trial	Consultation
5. Penicillin Allergy De-labeling Initiative (PADI)	Chris Oh, MD (PI)	Pilot Implementation Study	Investigator
6. 5-Cog Paradigm to Improve Detection of Cognitive Impairment in Primary Care (5-Cog 2.0)	Joe Verghese, MBBS MS (mPI)	Pragmatic Clinical Trial (Multi-site)	Investigator

7. Investigating Dupilumab's Effect in Asthma by genotype (IDEA)	Sunit Jariwala, MD (Site PI)	Phase IV Clinical Trial	Consultation

Challenges Encountered and Plans for Resolution
- Leadership Transition: The transition in leadership could have posed continuity risks, but was mitigated by prior and ongoing collaboration between Drs. Rinke and Rikin and regular onboarding meetings with MPIs.
- Capacity Building Needs: Dr. Rikin conducted a needs assessment of current IS working group participants through interviews, group meetings, and a survey (N=39 respondents). The needs assessment revealed opportunities to enhance available resources and expertise. This survey identified members who are willing to participate as consultants for IS initiatives (N=12), who consider themselves IS investigators (N=31), and who would like to continue participation in the IS working group activities. This feedback will be used to tailor future meeting agendas and resource development.

IS Working Group Needs Assessment: What resources would be helpful for your research?
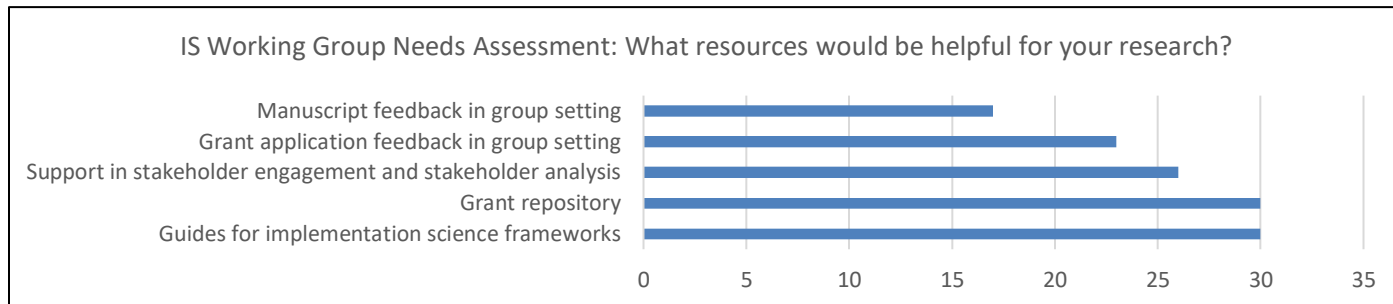
Plans for the Coming Year
- Working Group Agenda Development: The ICTR will continue to hold monthly working group meetings and quarterly grand rounds. The working group meetings will follow a targeted agenda, based on the responses to the needs assessment, to support member needs and research capacity in the coming year.
- Workshops and Training: A workshop titled "How to approach and select Implementation Science designs" is planned for December 4, 2025, indicating a shift toward more structured training opportunities.
- Pilot Grant Expansion: Launching of the Kwok Pilot Grants, which will fund at least 2 scholars/projects annually, will provide sustained investment in early-stage LHS research.
- Enhanced Collaboration: The ICTR's partnerships with EQUIP+, PCORI Health System Implementation Initiative, and NYC RING reflect ongoing efforts to integrate and expand collaborative research infrastructure.

ELEMENT C: TRAINING AND OUTREACH

C1. WORKFORCE DEVELOPMENT FOR CRSP MODULE

Module Goals
1. Expand and enhance CTS educational opportunities to give current and future clinical research professionals the foundational knowledge to engage in high-quality and high-impact research.
2. Develop the translational research workforce by creating new pathway and mentoring programs that will benefit the communities we serve.
3. Support career development and retention of clinical research professionals through communication, mentoring, and leadership skills training.

Highlights, Milestones and Challenges

Over the past year, the Workforce Development (WFD) module has significantly advanced the integration and innovation of training programs that strengthen the clinical and translational research (CTR) workforce. By aligning educational, mentoring, and professional development initiatives across all stages of the translational spectrum – from undergraduate students to faculty – the WFD module has built a cohesive, data-driven framework for cultivating a skilled and broad translational science community. The impact of this work is reflected in the expansion of curricular offerings, strengthened cross-program collaborations, successful acquisition of external funding, and measurable outcomes in career progression and research engagement.

The **Clinical Research Training Program (CRTP)**, a two-year Master's in Clinical Research Methods, remains the cornerstone of the Einstein-Montefiore ICTR's educational mission. With more than 300 alumni and an average of 12 scholars per cohort, CRTP continues to produce highly skilled clinical researchers. Graduates of this program go on to become successful clinical researchers, obtaining grant funding and contributing to the scientific literature. Of note, this past year there have been 30 publications from the scholars in training. Additionally, many of our graduates go on to become Division Heads, Department Chairs, Deans and hold other high-ranking positions, such as Commissioner of the New York State Office of Addiction Services (Chinazo Cunningham, MD MS, CRTP Class of 2008) and Director of Behavioral Health Services and Mental Health, San Francisco Department of Public Health (Hilary Kunins, MD MPH MS, CRTP Class of 2005). This year, the WFD launched a new elective, *Real World Data for Clinical and Translational Research*, developed in collaboration with the Health Informatics Core. This course, led by Dr. Pavel Goriacko, introduces trainees to the practical use of real-world health data, including instruction in SQL, R, and natural language processing for the analysis of structured and unstructured data. The elective's emphasis on Real World Evidence aligns with NIH priorities for data-driven research. Participant evaluations were highly positive, with the majority of students rating the course as a valuable and well-organized learning experience.

The **Translational Science Career Enhancement and Networking Development (TRANSCEND)** Program continues to foster the professional growth of junior faculty pursuing clinical and translational research careers. This past year, the **TRANSCEND** Program was redesigned to more-closely align with K12 Works-in-Progress meetings, enabling cross-cohort engagement and greater interdisciplinary collaboration. New seminars were added on topics such as grant literacy, budgeting, staffing, and resource management, based on participant feedback. Recognizing the relevance of these topics to aspiring career development award applicants, TRANSCEND expanded its reach to include additional junior faculty. Collectively, the program strengthens early-career faculty networks and institutional capacity for research leadership. This responsive and adaptive design has enhanced program relevance and participation while reinforcing the integration of WFD activities with other ICTR programs.

The module also expanded its efforts to broaden the clinical and translational science workforce through innovative partnerships that provide early exposure to research. The **Einstein Discover Research Program**, a collaboration with the Montefiore-Einstein Comprehensive Cancer Center and CUNY Lehman College, continues to allow Lehman students to earn a Master of Science degree by completing one year of coursework at Lehman followed by fifteen months of mentored research in Einstein laboratories. Participants also attend weekly didactic and professional development workshops that strengthen their readiness for research careers. Since inception, six students have graduated and two are currently in training. Among the six graduates, one is currently in medical school, one is Senior Clinical Interviewer at Einstein, one works at Olgam Life Plasma Donation Center and the remaining three have stayed as research technicians in their host labs while they prepare for PhD, MD or MD/PHD programs. The Discover program has successfully transformed a limited Master of Arts pathway into a rigorous research-focused degree, providing a sustainable model for academic partnership and workforce diversification.

Building on the success of the Discover initiative, the WFD team secured **NCATS R25 funding** for the Building Bridges in the **Bronx**: **M**ontefiore **E**instein **E**xplore **T**ranslational Science (**Bronx-MEETS**) Program. Bronx-MEETS offers a ten-week summer curriculum in translational science that integrates undergraduates and master's students into a hands-on research and multilevel mentoring network. The program's design includes a CQI framework that uses feedback from participants and mentors to refine both curriculum content and mentorship models. Together, the Discover and Bronx-MEETS programs now form a cohesive pipeline that connects students from the Bronx community to graduate opportunities in translational research.

Mentorship and communication training remain foundational to the WFD module's approach. Through collaboration with the Center for the Improvement of Mentored Experiences in Research (CIMER), Einstein now has fourteen trained facilitators who deliver the **Einstein Mentor Training** curriculum locally. Over 150 faculty have participated in these workshops, which are now offered quarterly with plans for expansion based on demand. We were successful this year in obtaining a **LifeSci NYC grant**, **S**haping **P**rofessional **A**dvancement through **R**esearch Mentoring and **K**nowledge (**SPARK**), which further extended mentor training to graduate and postdoctoral mentors working directly with undergraduates and master's students. The inaugural training had 12 participants and 100% reported they would recommend the program to others and found the content relevant to their needs across every workshop. Equally important, 100% indicated they were likely to apply what they learned in their mentoring practice. These outcomes highlight that SPARK not only delivers high-quality training but also equips mentors with actionable strategies they are eager to integrate

immediately into their work—evidence of both program effectiveness and strong potential for long-term impact. These initiatives have established a sustainable framework for institutional mentorship excellence, and a manuscript describing the training model and outcomes is in preparation.

Effective **science communication training**, introduced through partnership with the Alda Center for Communicating Science at Stony Brook University, has become a key component of professional development across the ICTR. The initial Creating Connections workshop, offered remotely in 2023, drew 125 participants, 96 percent of whom indicated they would recommend the session to a colleague. Creating Connections continues to be a well-attended program with 110 participants in 2025. Building upon this interest, advanced workshops including The Essentials, Small Group Coaching, and Science Through Narrative were offered in 2025 to 40 participants. Evaluation of these sessions showed significant gains in self-reported knowledge, confidence, and communication skills immediately following participation, with sustained use of these skills at three-month follow-up. These outcomes have been submitted for presentation at Translational Science 2026 and are being prepared for publication.

The **Reach for the First R01** Workshop continues to play a vital role in supporting junior faculty in their transition to independent research careers. Offered twice annually, this structured, mentor-guided series helps promising investigators to refine their NIH R01 applications through a sequence of seven sessions. Since 2021, twenty-eight investigators have completed the program, and ten new applicants were accepted in the most recent cycle. The workshop has proven effective in strengthening proposal quality and building confidence among early-stage investigators, as evidenced by receipt of ten R01's from participants in the earlier workshops, sustained interest and growing departmental participation.

Research Coordinators: In collaboration with the Office of Human Research Affairs (OHRA) and the Office of Clinical Trials (OCT), a standardized clinical research coordinator training program has been developed and adopted across M-E to address the complexities of clinical and translational research. Training consists of in-person workshops and continuing education webinars offered monthly. All webinars are recorded and later made available as self-paced eLearning courses. Webinars are developed in collaboration with ICTR core leads, and research support offices across M-E to enhance coordinator understanding of scientific principles and processes that underlie the research process (e.g. Overview of Study Design, Informatics 101, Sample Processing, Common Audit Findings and How to Avoid Them, and more). The in-person workshop series (4 sessions) are intended to be interactive and use hands-on activities to develop critical thinking skills needed to evaluate research activities in the dynamic healthcare environment. There have been 169 unique learners who have participated in these courses and/or workshops in 2025 which represent ~58% of the coordinator workforce at Montefiore Einstein.

Research Coordinator Forum: A forum for research staff in study/regulatory coordinator roles is hosted in Microsoft Teams and gives members the opportunity to ask questions, share best practice tips, helpful resources and more. This communication channel is also being used to share news about upcoming events, training opportunities, and other important updates.

Human Subjects Research Project Navigation Tool: This was designed to guide research activities throughout the project lifecycle and is organized into five key sections: Education & Training, Planning & Development, Project Setup or Initiation, Project Management, and Close Out. Within each section there are relevant topics, and a summary of the topic's importance, requirements (e.g., federal regulations, institutional policies, etc.), best practice tips, "how to get started", and related tools and resources.

Collectively, these initiatives demonstrate the WFD module's success in integrating programs, fostering innovation, and advancing the institutional mission of developing a broad and well-prepared translational science workforce. Over the past year, the module has achieved key milestones by embedding data science, mentorship, and communication into training programs; creating new pathways for students and faculty alike; and institutionalizing evidence-based practices that enhance research capacity and inclusivity. The WFD module continues to serve as a model for how coordinated, feedback-driven educational infrastructure can advance workforce excellence and sustain the next generation of translational researchers.

C2. COMMUNITY AND STAKEHOLDER ENGAGEMENT RESEARCH MODULE

Module Goals

1. Accelerate CTS research to address the significant burden of conditions that disproportionately affect populations in the Bronx.
2. Promote participation of representative populations in CTR and ensure that community-academic partnerships are fully collaborative.
3. Build capacity for sustainable community and stakeholder engagement in all aspects of CTS research.

<u>Highlights, Milestones and Challenges</u>

1. **Develop a Community Engagement Research Implementation Toolkit to encourage sustained community engagement in clinical and translational research based on established best practices**. The toolkit is approximately 75% complete. We will incorporate feedback and complete the toolkit in the next award period. The toolkit consists of:
   - A community engagement best practices guide with an in-depth compensation guide, developed with institutional representatives in HR and finance, to assist researchers in overcoming barriers and streamlining processes for compensating community members. We collaborated with HR representatives, research stakeholders, and community members to inform the guide.
   - The C4E Connection tool to connect researchers to community- and faith-based organizations based on common interests, goals and resources. In this period, we assisted 11 researchers with links to community organizations, which led directly to 2 grant submissions.
   - The Community Partnership 360 Evaluation, an evidence-based tool to evaluate community experiences collaborating with ICTR researchers. During this award period, we co-designed this tool with our Community Advisory Council, institutional stakeholders, and additional community partners. Using CQI, the 360 evaluation findings will be used to inform priorities for CE tutorials and may inform future efforts to provide individualized coaching support for ICTR researchers.
2. **The continued development of the Community Engagement (CE) Tracker**. The CE Tracker is a dataset of organizations, programs, events, and individual contacts linked to Einstein faculty. In this funding period, we've incorporated >200 pieces of feedback from 36 internal stakeholder groups. The tracker currently has 36 active users and tracks over 150 community and faith-based organizations. In collaboration with the Montefiore Einstein Comprehensive Cancer Center, we are currently developing dashboards for wider implementation and reporting. We are actively learning from and pursuing collaborations with other institutions and organizations creating their own community tracking systems, including Duke and the American Association of Medical Colleges (AAMC). We presented our work on the CE Tracker in October 2025 at the Fall 2025 CTSA Annual Meeting in Washington, DC. Next steps will focus on developing a communication and dissemination strategy to expand use.
3. **CCC's Community Advisory Council (CAC)**. In the last year, the CAC provided recommendations for the NYC RING Study Selection tool, provided feedback on our Community Partnership 360 Evaluation tool, and participated in the co-development of a curriculum for community members engaged in research.
4. **Expanding language translation resources**. In partnership with Montefiore Medical Center, the CCC implemented Proprio, a language translation service that provides both live (phone and video interpretation) and document translation for over 300 languages. Next steps include wider promotion and dissemination of this service to continue efforts in reducing barriers in research recruitment.
5. **Providing access to qualitative data analysis software.** We launched access to Dedoose, a qualitative and mixed-methods analysis online software, to our research community. To date, we have facilitated the qualitative data analysis to 30 users across 10 projects and over 200 transcripts and pieces of media. The service is currently provided free of charge to researchers without funding.
6. **Expanded efforts to promote primary care research infrastructure through the New York City Research and Improvement Networking Group (NYC RING).** NYC RING (described in more detail under Dissemination and Implementation Science) is currently conducting 7 clinical research and implementation science projects and has added 2 additional studies to begin in January 2026. We are planning our annual convocation of practices for Spring 2026.
7. **Developing a new research collaboration with the Montefiore Community Health Worker Institute**. Bolstered by near-universal implementation of social determinants of health (SDOH) screening in clinical settings by the Community Health Worker Institute (led by CCC faculty Dr. Kevin Fiori), the CCC began a collaboration to catalyze new and ongoing SDOH research for new and established researchers. As part of this process, the CCC is taking the lead in working with clinical partners and the BERD and Health

Informatics cores to facilitate protocol development, data extraction, and statistical analysis and interpretation services for SDOH research. We expect this project to fully launch in the next award period.

8. **Ongoing effort to provide CE and qualitative consultations**. The CCC has provided ongoing consultative services consisting of language translation, qualitative and mixed-methods support, grant collaborations and more. Thus far, we have conducted 41 consultations for our research community; these consultations have led to 11 submitted grants.

9. **Qualitative and Mixed Methods Core**. Based on the ICTR's need for greater qualitative expertise, we recruited Dr. Dana Watnick, an experienced NIH-funded qualitative investigator, to be the Director of the new Qualitative and Mixed Methods Core (QMM) in August 2025. The QMM will manage qualitative consultations, trainings, and mentorship requests and maintain close linkage to the CCC.

10. **Successful institutional collaborations to increase community engagement in translational research and increase generalizability of research**.
    - Einstein-Rockefeller-CUNY Center for AIDS Research (P30AI124414, NIAID)
    - Montefiore Einstein Comprehensive Cancer Center
    - National Center for Engagement in Diabetes Equity Research: National CEDER (1U2CDK137135-01, NIDDK)
    - Hispanic Community Health Study – Study of Latinos (HCHS/SOL) 4th contract renewal (N01HC65235, NHLBI)
    - Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR) at Montefiore Einstein (RM1DA055437, NIDA)

Challenges encountered and plans for resolution.

1. <u>Structural changes brought about by changes in leadership and faculty turnover</u>. CCC co-Directors Dr. Earle Chambers and Dr. Carmen Isasi stepped down in April 2025. Dr. Hector Perez was named Director in April 2025 and was joined by Dr. Damara Gutnick as Associate Director in June 2025. The transition has been facilitated by onboarding from Drs. Chambers and Isasi and MPIs Drs. Kahn and Kim.

2. <u>Siloing of community engagement work in the hospital and the medical school</u>. To fulfill our goal of promoting the CE tracker in this award period, we met with stakeholders and obtained feedback about how disconnected some CE work remained. A challenge of broad dissemination of our tracker and our work remains communicating to our stakeholders about the value of connecting CE work to disseminate best practices and lessons learned. In our strategic plan for the next award period, we have developed a communication strategy leveraging Montefiore Einstein Centers such as the Center for AIDS Research and the Comprehensive Cancer Center to promote services and better engage our community of CE researchers. We have also made plans to hold a CE Conference in 2026 to bring together researchers and community members to catalyze new CE research and forge new relationships and connections.

3. <u>Providing necessary support to junior investigators</u>. We found that the need for dedicated mentorship, especially relating to career development awards, is paramount and ensures success of the project and the career development plan. To rectify this, we have identified sustainability as the major priority of our initiatives to support junior investigators. We have recruited further expertise in qualitative research as part of our new QMM and we plan to engage more mid-career faculty as mentors in the CCC so that linking projects to potential mentors is more streamlined.

ELEMENT D: CLINICAL AND TRANSLATIONAL SCIENCE RESOURCES AND PILOTS

D.1 RESOURCES AND SERVICES MODULE

BERD

Module Goals

1. Provide *accessible* and *high-quality expertise* and support in biostatistics, bioinformatics, epidemiology, and research design to maximize the rigor, reproducibility, and impact of CTR, and facilitate research that promotes *health for all.*

2. Develop, implement, and disseminate novel statistical methods and software to advance *translational science*, with emphasis on innovative clinical trial designs, analyses of high dimensional data from new technologies, and causal inference methods for observational studies.

3. Expand biomedical *data science capabilities* to provide seamless support for the extraction, integration, and analysis of large and complex data sets.
4. Provide *educational and training opportunities* in statistics and data science for researchers and clinical research staff of all levels.
5. *Strengthen partnerships* with other regional and national CTSA BERD groups and the CTSA consortium to share resources, to identify opportunities for inter-institutional collaborations, and to disseminate statistical advances to the broader scientific community.

<u>Highlights, Milestones and Challenges</u>

Accessible and high-quality expertise and support (Goal 1): BERD members provide immediate, short, and long-term research support to investigators. We have continued our weekly virtual walk-in statistical consulting clinic via zoom, which is available to all members of the Montefiore Einstein community and consistently well utilized and received by trainees. We have increased our collaborations with clinical departments, including the Department of Obstetrics & Gynecology, and Montefiore's Burke Rehabilitation Hospital. In 2025, our collaborations - which further maximize CTR impact and commitment to rigor and reproducibility - resulted in **93 grant submissions, five successfully funded grants** and **67 peer-reviewed publications**. We have highlighted some notable BERD collaborations that highlight our role in supporting rigorous and high impact clinical and translational research, followed by BERD collaborations that resulted in awarded grants.

<u>Notable collaborative publications in 2025</u>: 1) "Healthy Aging and the Gut Microbiome in People with and Without HIV". *J Infect Dis*. (X. Xue) which examined associations of age with gut microbiome diversity, uniqueness, and genus-level abundance, 2) "Prediction of central line-associated bloodstream infection: focus on time of insertion". *Infect Control Hosp Epidemiol*. (M. Fazzari), which used machine learning approaches in the context of severely imbalanced data to develop a powerful prediction tool for infection. 3) "Enhanced associations between subjective cognitive concerns and blood-based AD biomarkers using a novel EMA approach". *Alzheimers Res Ther.* (C. Wang), which showed that Ecological Momentary Assessment (EMA) offers a promising approach, linking SCC assessed via EMA and traditional measures with blood-based AD biomarkers in a diverse, dementia-free, Bronx NY community-based sample, 4) "Normal bronchial field basal cells show persistent methylome-wide impact of tobacco smoking, including in known cancer genes". *Epigenetics* (K. Ye), which showed that smoking reduced long-term epigenome-wide methylation in bronchial stem cells, and persisted indefinitely beyond smoking cessation, 5) "Gut Microbiome Multi-Omics and Cognitive Function in a Large Latino Cohort". *Alzheimers Dement* (T. Wang), a study within the Study of Latinos - Investigation of Neurocognitive Aging (SOL-INCA) cohort to examine the role of the gut microbiota in cognitive function and assess the accuracy of a Random Forest classifier to distinguish SOL participants with the best vs. the worst cognition, 6) "Impact of an Ophthalmic Knowledge Assessment Program (OKAP) Pre-Test: A Pilot Study at Two Institutions" *Journal of Academic Ophthalmology* (J-Y Moon), which identified each student's specific areas of weakness in ophthalmology and examined whether those weak areas showed a greater improvement on the formal OKAP test to show the usefulness of pre-test.

<u>Grants:</u> BERD collaborations that resulted in grants awarded or receiving fundable scores in 2025 included: 1) *Longitudinal Assessment of Hearing Loss in World Trade Center-Exposed Responders* (NIH NIOSH/CDC, co-I: J. Choi). This project aims to investigate the long-term effects of World Trade Center (WTC) exposures on sensorineural hearing loss (HL) among FDNY rescue and recovery workers, with a focus on inflammation-driven lung function decline resulting from ototoxic exposures. By comparing WTC-exposed workers with an external non-WTC exposed occupational cohort, the study will help distinguish the impact of WTC-specific toxic exposures on hearing from other occupational hazards. Findings will guide interventions to preserve both lung and hearing health in high-risk occupational groups. 2) *Sildenafil to Reduce Vascular Remodeling During Left Ventricular Assist Device Support* (NIH R01, co-I: X. Xue), 3) *Quantifying mid-to-late life physical and sensory functioning in HCHS Sol* (NIH R01, co-I: X. Xue) to define the prevalence of physical and sensory impairments and the associated risks of frailty and disability in middle-aged and older participants of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), and 4) *Dynamic Cognitive Phenotypes for Prediction of Mental Health Outcomes in Serious Mental Illness* (NIH U01, co-I: C Wang) to enhance clinical prediction for individuals with serious mental illness.

Novel methodological development to advance Translational Science (Goal 2):

Translational Science Grants: TS-focused grants awarded or receiving fundable scores in 2025 included: 1) *Pen-and-Paper and Smartphone Self-Reported Cognitive Concerns to Predict Longitudinal Alzheimer's Biomarkers in a Diverse, Non-Demented Older Adult Population* (NIH R03, co-I C. Wang) which aims to evaluate the utility of self-reported subjective cognitive concerns (SCC) as an early screening tool for Alzheimer's Disease (AD) by assessing their relationship with longitudinal AD biomarkers. It will compare traditional pen-and-paper assessments with smartphone-based methods and use machine learning to integrate both approaches for predicting AD plasma biomarkers, which reflect disease risk, and 2) *Dynamic Cognitive Phenotypes for Prediction of Mental Health Outcomes in Serious Mental Illness* (NIH U01, co-I C. Wang) which will enhance clinical prediction for individuals with serious mental illness (SMI), across diagnoses, by incorporation of novel, scalable cognitive measures.

CTSA pilot award update: 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. 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.

Translational Science methods papers published in 2025: BERD-led papers include novel methodological translational science solutions for clinical trials: One such paper, entitled "Two-part model for ventilator-free days in a cluster randomized cross-over clinical trial" (*BMC Medical Research Methodology,* Y. Lo and M. Kim*)* provides a more comprehensive assessment of intervention effects on ventilator-free days in critical care trials. Researchers and clinicians can obtain greater insights with this approach about the direction and magnitude of the intervention effects on mortality, ROSC, and duration of mechanical ventilation. Another published methodologic paper, "Work estimating treatment effects from a randomized controlled trial with mid-trial design changes" (*Clinical Trials,* J. Choi), examined the statistical implications of design changes on treatment effect estimates. Understanding these implications and accounting for them in the analysis of the data are essential for internal validity and reporting of the trial findings.

Expansion of data science (Goals 3 and 4): BERD was highly productive in building Data Science resources in 2025. (1) Montefiore Einstein's **Data Science Institute** (DSI) was launched in July 2025 with several BERD members on the leadership team. As such, the DSI will collaborate closely with BERD to enrich and expand data science collaborations throughout the institution. BERD member Dr. Kim serves as DSI Director, Dr. Fazzari, ICTR BERD Director, is DSI AI/ML program leader, Dr. Xiaonan Xue is DSI Biostatistics program leader, and Dr. Tao Wang is DSI Bioinformatics leader. (2) BERD and the DSI have developed a **Data Science 101 Lunch and Learn series** that was launched in Fall 2025 with more than 100 participants signed up for each session. This weekly series introduces topics in data wrangling, omics, machine learning, EHR data, and biostatistics. (3) In parallel to the DS 101 lecture series, **training opportunities in R coding** are again being provided to faculty, staff, and medical students with three hands-on R workshops in Fall 2025, including a new workshop: ***Machine Learning in R.*** These coding workshops have been highly rated by participants in post-session surveys. (4) **BERD House**, our online biostatistics resource, was redesigned in 2025. Data Science content has continued to be added to BERD House, including new tutorials on support vector machines and cost functions. All training material from our Data Science 101 lecture series will also be added, along with short, introductory training videos for R and RStudio. (5) In collaboration with the ICTR Health Informatics Core, several BERD faculty members will be trained as super-users in **Epic Cosmos** to facilitate researcher access to the EHR data from over 300 million subjects available from this platform. As a result of these efforts, data science capabilities and training opportunities have greatly expanded, allowing researchers to be trained in-house on popular tools, methods, and software as well as reducing barriers to collaborations with data scientists via the Data Science Institute.

CTSA Partnerships (Goal 5): BERD contributes to the national CTSA consortium in many ways. Dr. Mimi Kim is a member of the CTSA Steering Committee. BERD Director, Dr. Melissa Fazzari, continues to serve on the Board of Biostats4you, a website hosted by University of Minnesota which was developed and maintained by members of the Biostatistics, Epidemiology and Research Design Special Interest Group (BERD SIG) of the Association for Clinical and Translational Science (ACTS). Both Drs. Kim and Fazzari participate in the BERD Special Interest Group. Dr. Fazzari is also a voting member of the BIDS enterprise committee.

Challenges encountered and plans for resolution: A key challenge of the BERD core continues to be the strong demand for data science training from our research community. In 2025, we made steady progress in tackling this challenge, with a new R workshop in Machine Learning developed, online tutorials, and a new Data Science 101 lecture series. In addition, the establishment of the new Data Science Institute will bring tremendous synergistic opportunities for growing BERD's capabilities in data science. Our plans for continued resolution of this key training challenge include: 1) integrating more coding, data science, and machine learning content into existing training programs to increase the level of methodological rigor, 2) collaborating with the DSI to develop a Data Science certificate program, 3) continuing to expand and improve our online data science resources such as BERD House, and 4) enhancing collaboration with the Health Informatics Core, which is working closely with BERD and the DSI to develop the DS 101 lecture series and to provide more coordinated methodological support on EHR based observational research. Another challenge for the BERD core is how requests for biostatistics and data science consultations are captured and processed. To serve the research community more effectively, all requests for biostatistics and data science collaborations will now go through a revised centralized ICTR request portal. This new process will allow us to better oversee requests made, facilitate and standardize usage summaries, as well as simplify the request process for investigators. While BERD continues to collaborate closely with the Workforce Development and Health Informatics Modules, more interaction with other ICTR cores is desired. Cross-module collaborations identified during the July 2025 ICTR retreat include: BERD, Informatics and the CCC collaborating on development of novel methods for the incorporation and analysis of social determinants of health in research to advance the ICTR mission of health for all, and BERD members engaging in statistical review of proposals for TS Pilot Projects and K-Awards.

Achievement of Milestones: We achieved our 2025 goals, including the development of a ***Data Science 101 lecture series*** in collaboration with the new Data Science Institute, developing and presenting a webinar focused on ***Study Design***, adding tools and tutorials to ***BERD House***, and strengthening and broadening our expertise in research to overcome barriers to health and translational science.

CLINICAL RESEARCH RESOURCE

Module Goals

1. Provide dedicated, institution-supported space and staff to support clinical and translational research.
2. Enhance regulatory knowledge and support to improve compliance.
3. Provide project-specific support to streamline recruitment, collaboration, ethical considerations, and other aspects of study start up and management.

Highlights, Milestones and Challenges

Clinical Research Center: Studies are conducted in dedicated, institution-supported space, which includes 2 clinical research units (one at Einstein and the other at Montefiore) which serve adult and pediatric patient-oriented research, including first-in-human and early phase NIH and industry-supported clinical and behavioral studies. The CRR supports a diverse research portfolio, including deep phenotyping needed for precision medicine, and numerous observational cohort studies and clinical trials funded by the NIA, NICHD, NIAID, NHLBI, NIDA, NIMH and NIDDK. Many of these studies focus on diseases highly prevalent in the Bronx, including autism, asthma, obesity, diabetes, HIV, neurodevelopmental disorders, opioid use disorder, sickle cell disease, and chronic kidney disease.

Over the past year, 50 research protocols have been supported, with 1,641 visits conducted across our 2 campuses. We have implemented a comprehensive strategy to increase utilization and impact. This includes expanded outreach efforts, increased after-hours and weekend service, and exploring collaborations with other centers at Einstein. Publications resulting from CRC support have addressed highly important areas of medical care including the management of sepsis, the impact of a healthy dietary pattern on age-related cognitive decline, liver transplantation outcomes, and cancer treatment. New technology added to the CRC enables detailed quantitation of body composition via multifrequency bioimpedance analysis, highly relevant for studies of obesity, metabolism, aging, and frailty. In addition, a survey has been conducted among clinical and translational investigators and study teams to understand CRC users' experiences and to identify obstacles

facing investigators. Survey results will inform the development of targeted offerings by the CRC to facilitate research efforts and reduce roadblocks.

Study Coordinator Pool: A pool of highly trained research and nurse study coordinators has been established by the ICTR to assist in the start-up, implementation, and close-out of clinical studies. This cost-effective service is essential for investigators without the resources to hire, train, and manage their own staff. The coordinators, who are registered nurses and non-nurses, provide support to study teams for budget preparation; IRB applications; recruitment; community outreach; project coordination; regulatory documentation; and training in human subjects' protection, cGCP, and biological specimen handling. They also contribute to our standardized coordinator and research nurse training by facilitating workshops and engaging with the peer-to-peer mentoring network. We have experienced consistent interest in this service from across the M-E community and we have redoubled our outreach efforts to ensure all members are aware of this valuable resource. Since its establishment, the coordinator pool has supported 20 principal investigators with activities ranging from protocol development to regulatory support and project management to participant recruitment and study implementation. In addition, staff training has been provided to study teams to enhance regulatory compliance and increase study teams' efficiency. We have also been meeting our goal of supporting the career development of junior investigators: of the 11 studies supported in the past 12 months, the PI has been a junior investigator for 7 of these. This service has supported 14 grant submissions to date, of which 3 have successfully competed for funding. Lastly, outcome surveys have demonstrated outstanding satisfaction with the support provided.

Biomarker and Biorepository Core. The Biomarker and Biorepository Core (BBC) addresses the rapidly changing needs of translational research by implementing novel discoveries in basic sciences and new technology in partnership with the biotech industry into applications of use for clinical and translational investigators. One of the essential components of translational research, patient phenotyping, depends on detailed characterization of biomarkers and tissue specimens. The BBC will advance the biomarker discovery program and develop new biomarker platforms. In addition, the BBC has advanced the BioR program to address precision medicine approaches by expanding and building on testing novel processes and tools to support precision medicine, including a population-based tissue and bio-fluid BioR collection linked to the EHR, and radio-frequency identification (RFID) technology for enhanced efficiency, productivity, sample tracking, integrity and preservation. The Biorepository has started the conversion of processed and current collected legacy samples and continues to be committed to fully converting the current collection of ~550,000 samples to RFID technology for RFID labeling of all sample boxes, retrofitting ~1/3 of legacy sample boxes with RFID labels. We have implemented workflows to accommodate these new RFID tags and tracking abilities to ensure the security of our processed samples. Sample tracking, integrity, and preservation of our samples have increased with this implementation of the tracking tags and new database. After piloting our web client program, we introduced it this year to the research community supported by the BioR. This resource provides investigators with internal and external transparency to see samples that have been processed and put into storage. The web client program also enables investigators to download reports of their samples to share with collaborators and to plan for upcoming sample analyses.

We upgraded our sample tracking database system Freezer Works and incorporated our biomarker database. By consolidating to a single database, we enhanced our efficiency and transparency. This also provides seamless integration for sample tracking from patient entry to sample entry, processing storage for high value annotated samples, and will facilitate linkage of samples to patient records and clinical data. The BBC will thus provide more efficient research support and innovative solutions for the goals of NCATS in accelerating the translational process.

During the past year, we made major progress toward the goal of establishing a set of shared biospecimens that is available for use by all M-E investigators. In collaboration with our Health Informatics Core colleagues, we expanded the linkage of BBC patient samples and data with the EHR, thereby establishing a set of specimens with clinical metadata and linkage with patient outcomes. We have also secured the donation of >9000 sample aliquots to the shared repository.

Recruitment Services. The Hub Liaison Team collectively offers strategies and support to identify, enroll, and retain research participants. Zoe Tsagaris-Dhivakar, CRR Administrative Director, offers recruitment

consultation and planning for clinical research studies and trials. Other services include development of marketing campaigns; participation in local health fairs and community events to encourage research participation; adoption of text messaging and social media to optimize recruitment; and broad access to ResearchMatch, a disease-neutral, web-based national recruitment registry available to all CTSAs to match individuals who wish to participate in clinical research with investigators actively searching for volunteers. An M-E Recruitment Opportunities Newsletter highlights five unique studies every six weeks and is distributed to >1000 individuals through Montefiore's Community Relations listserv and Office of Community Relations e-blast. Study teams are given the opportunity to post study-related content on M-E social media platforms at no cost to expand community outreach. A Research Project Navigation Tool includes internal and external resources for study teams that include recruitment resources, quick guides to local translation and interpretation services, and free self-paced online courses to increase understanding of recruitment as a dynamic process. EHR recruitment support is provided to study teams; as one example, algorithms applied to the EHR Data Warehouse have been successfully used to identify eligible patients for the PCORNet PREVENTABLE statin trial.

Regulatory Knowledge and Support Resource (RKSR)
The RKSR unifies research-related offices at Einstein and Montefiore to enhance regulatory education, compliance and ethics. ICTR staff work closely with the Office of Clinical Trials and the Office of Human Research Administration (OHRA) to assist investigators with research processes. The RKSR provides support services for project management, workflow and standard operating procedure development, quality control and assurance, specialized staff education, and compliance with FDA requirements (IND, IDE, clinicaltrials.gov). The RKSR has delivered monthly continuing education webinars for our research community, which are then archived as self-paced courses in Montefiore's Learning Management System. There are more than 15 such courses currently in the LMS, on topics such as: Reportable Events in Research, Understanding your Protocol-Logistics, Workflows, and Strategies, Fundamentals of Informed Consent, Understanding Monitoring and Auditing, and more.

RKSR has established user-friendly IND and IDE toolkits that include checklists, template documents, and regulation and guidance documents for the M-E community. In collaboration with the OHRA, we have created training seminars for: (1) IND Application Submission, Monitoring, and Reporting Requirements for Investigators, (2) Introduction to Investigational Device Exemptions, (3) IDE: Expanded Access and Humanitarian Use Devices, (4) IDE Special Considerations: Software, Combination Products, General Wellness. These training activities are available for on-demand viewing through our e-Learning platform and links to FDA training videos and resources. To aid investigators in complying with clinicaltrials.gov regulations, an interface was created to link the Protocol Registration and Results System with Velos, our Clinical Trial Management System (CTMS). This integration includes event-based triggers to notify PIs about updates required to maintain regulatory compliance. This effort, along with individualized consultative help, has led to a significant, sustained reduction in clinicaltrials.gov noncompliance across the institutions. For on-demand assistance, we created a quick reference and comprehensive guide to assist study teams.

The Research Project Navigation Tool guides study teams through the entire research lifecycle from education and training through project closeout. To further enhance usability, a new "Essential Documents" toolkit was developed in collaboration with OHRA and M-E Research Compliance Offices which includes a full set (16) of standardized, editable essential documents study teams can leverage and adapt as needed for their studies. For each essential document there is a detailed reference document which includes the purpose of the form, best practice guidance, and links to relevant federal, state and institutional policies.

RKSR continues to support the engagement of our research community with the Trial Innovation Network. This year we have expressed interest in three upcoming trial opportunities and were selected as a participating site for two others (VPS RCT and COMBO AC) which are pending funding. M-E is a participating site of the Optimizing the use of Ketamine to Reduce Chronic Postsurgical Pain (HEAL KALPAS) trial led by Dr. Jing Wang at New York University School of Medicine, which achieved its enrollment target of 750 participants this year.

Challenges encountered and plans for resolution.

Linkage of BBC patient samples and data with the EHR was a major milestone and required developing and validating a matching algorithm for samples lacking a medical record number to establish a direct linkage. We are now working on expanding this linkage from patient level to specimen level to enable accurate phenotyping at time of sample collection. We have developed a user-friendly interface to permit potential users to query the BioR database for sample availability based on clinical criteria and sample characteristics and will complete user testing prior to broad implementation. We anticipate completion of this process, conducted in collaboration with the Health Informatics module, in the upcoming year. In addition, we are continuing to expand the pilot program of prospective sample collection to add to the repository which we initiated in the past year.

D.2 CLINICAL AND TRANSLATIONAL SCIENCE PILOT MODULE

Module Goals
1. Implement and administer the CTS-PM program.
2. Develop and coordinate a CTS educational and mentoring program to stimulate investigators at all levels to lend their expertise to and engage in CTS research.

Highlights, Milestones and Challenges

Aim 1: Implement and administer the CTS Pilot Module program.
Impact: In Year 3, the module put out a request for applications for pilot projects with potential to lead to future breakthrough studies in clinical translational science (TS). Given our prior experience and in an effort to increase the number of applications that address TS, we introduced a requirement for a letter of intent (LOI). The LOIs were reviewed by the Directors of the Pilot Module for their alignment with TS research. We received a total of 23 LOIs, of which 12 aligned with TS and were invited to submit a full application. This two step approach increased the percentage of responsive applications from 87% in Year 2 to 100% in Year 3. Subsequently, we received a total of 11 applications and funded 4 meritorious applications.

This year, we also piloted a new TS scoring system to the application review process, the Translational Science Indicator Tool (TRANSIT). All reviewers were required to score each application on 7 NCATS TS principles (Focus on unmet need, Generalizable solution, Creativity and Innovation, Team Science, Efficiency and speed, Bold and rigorous, Boundry-crossing partnerships). Each TS domain was scored ranging from 1 (does not at all align with TS domain) to 5 (extremely aligned with TS domain). Funding determinations were made by incorporating the TRANSIT scores into the decision.

Innovation: The funded pilot projects were highly innovative and held significant potential for overcoming translational research roadblocks. They included:
(1) *Community-Based Virtual Group Reminiscence Therapy to Improve Loneliness and Apathy in Community-Dwelling Older Adults* (PI: Mirnova Ceide, MD, MS)
(2) *Bridging the Gap: Assessing Digital Health Literacy and Readiness for Behavioral Change in Emergency Department Populations* (PI: Carlo Lutz, MD)
(3) *Predicting population-specific genetic disease risks in biobank-scale data* (PI: Srilakshmi Raj, PhD)
(4) *Finding Neoantigens Using an mRNA Translational-Based Approach* (PI: Kamini Singh, PhD)

Significance: The pilot program advanced translational science by funding 4 pilot projects with potential to advance TS research and positively impact human health. Additionally, we outline below some of the successful outcomes of Montefiore-Einstein CTS Pilot program awardees:

Pilot	PI	Outcomes
Overcoming a Long-Standing Translational Barrier in Stem Cell Research	Gaetano Santulli, MD, PhD (2023)	Publication: Varzideh F, Gambardella J, Kansakar U, Jankauskas S, Santulli G. Molecular Mechanisms Underlying Pluripotency and Self-Renewal of Embryonic Stem Cells. Int J Mol Sci 24, 2023. PMID: 37176093
Cough Capture as a Portal into the Lung	Simon Spivack, MD, MPH (2023)	Grant submitted: "Cough capture development for non-invasive assessment of lung DNA mutation and epimutation" (R61)
A General Cell-Based Approach for Overcoming the Blood-Brain-Barrier to Treat Brain Diseases	Jean Hebert, PhD (2023)	Patent filed: WO2021221879 – Compositions and Methods for using transplanted microglia as a vehicle for widespread delivery of cells and other biologic agents to the brain. Inventors: J. M. Hebert, M. Gronska-Peski and H. Nobuta.

Production of Therapeutic Engineered Red Blood Cells	Eric Bouhassira, PhD (2024)	Publication: Olivier et al. - Stem cell factor and erythropoietin-independent production of cultured reticulocytes. Haematologica. 2024 Nov 1;109(11):3705-3720. PMCID: PMC11532706. Grant submission: Natl Heart, Lung & Blood Inst (NHLBI), R01 HL00221, Bouhassira (PI) "Production of culture red blood cells"
Rapid Antimicrobial susceptibility testing of slow-growing microorganisms using a reporter phage-based system	Phyu Thwe, PhD (2024)	Publication: Rajagopalan et al. 2025. "Luciferase reporter mycobacteriophage (TM4::GeNL) enables rapid assessment of drug susceptibilities and inducible macrolide resistance in Mycobacterium abscessus complex." J Clin Microbiol 63:e00841-25. PMCID: PMC12421814

Aim 2: Coordinate an educational and mentoring program to engage and advise investigators in translational science.

Impact: In Year 3, the module expanded the educational and mentorship program that engaged with potential pilot grant applicants and educated them in the concepts of TS. The program included a compilation of educational materials describing TS and its distinction from translational research that was posted to Einstein's ICTR Pilot Project Program website. The Core also organized a TS Town Hall and TS Seminars where Year 2 (2024) Pilot awardees presented their projects. Additionally, we offered one-to-one consultations for potential applicants that provided advice and clarifications about TS. Judging by the growing number of responsive TS applications, the above mentioned programs enhanced TS knowledge and understanding among the Einstein-Montefiore research and clinical community.

Innovation: These educational and mentorship resources provided the research community with knowledge and understanding of TS, an area of research that was novel for many of them.

Significance: The education and two-step application approach proved very effective, as 100% of submitted applications were aligned with TS goals. Thus, our educational program was successful, and we will continue to build on it in the coming year.

Challenges and plans for resolution

Despite our successes, we continued to <u>encounter members in our community with insufficient understanding and knowledge about TS</u>. This may be due to new learners joining our community. In addition to our expanded educational programs, we plan to introduce the TRANSIT self-assessment tool to assist investigators new to TS. Expanded education plans include:

(1) Introduce an interactive self-assessment and education tool, TRANSIT, to the Einstein-Montefiore research community via the RFA, LOI, and ICTR website. This tool will teach the investigators about TS by allowing them to score their own proposals based on TS domains and providing real-time feedback on whether the project aligns with TS principles.
(2) Organize Translational Science Symposia involving other CTSA hubs to share experiences and discuss strategies to address TS challenges.

D.3 DATA SCIENCE/HEALTH INFORMATICS MODULE

Module Goals
1. Enrich our research data ecosystem through use of non-traditional, multimodal, and heterogeneous datasets, shared community resources, and interoperability of research platforms across the CTR spectrum.
2. Provide democratized, equitable, and accessible informatics and analytics services, with an emphasis on open science, reproducibility, and security.
3. Expand capacity for clinical trial recruitment, to include all populations, and increase engagement of clinicians in research.
4. Develop and offer educational and training opportunities in health informatics and data science.

Highlights, Milestones and Challenges

Health Informatics (HI) is the ICTR core that provides essential informatics and data science resources, services, and training. HI supports clinical and translational research (CTR) by researchers of all levels across

Einstein-Montefiore and supports and collaborates with other ICTR resources. HI is a joint investment of Montefiore and Einstein and accelerates the translation of research findings into practice by integrating research platforms with care delivery systems (EHR/Epic) and engaging clinician investigators in research at the point of care (e.g., controlled or pragmatic trials, comparative effectiveness research, etc.). HI actively participates in national networks such as PCORnet, OHDSI, RECOVER, and All of Us, and contributes to open-source applications that advance open science and network research.

Impact and Significance

Over the past year, HI supported 718 projects, responding to 251 service requests. Eighty-five percent of projects utilized self-service platforms such as Atlas and REDCap, demonstrating HI's ability to scale support for RWE and EHR-based studies. Automated recruitment services matched patients to 36 cancer trials, showcasing innovation in scaling recruitment capacity.

Aim 1: Enhance availability and diversity of research data: HI maintains a comprehensive and dedicated research data warehouse (RDW) that supports both OMOP-Common Data Model (CDM) and PCORnet CDM, with 10 years of EHR data from 2.5 million patients, updated every other day. This repository integrates structured clinical data, 180 million clinical notes, imaging data, and ECG waveforms while incorporating socioeconomic determinants of health and privacy-preserving synthetic datasets. In year 3, we continued enriching the data warehouse by incorporating medical device data and utilizing large language models to map additional test results and medications with missing standardized identifiers.

Aim 2: Democratized and equitable access to informatics and analytics services*:* In year 3 of the award, HI continued to provide and maintain platforms and necessary infrastructure for comprehensive research informatics and data science services, which included:
Access to research ready datasets and real-world evidence: This service was provided through facilitated access to identified, limited deidentified, de-identified, and synthetic datasets.
Self Service Cohort Studies and Analytics: HI continued to enhance the self-service cohort study software capabilities through streamlining the user interface and extending the functionality of the IRB-linked patient-level data retrieval.
Natural language processing: HI provided NLP services through an innovative ElasTex platform that processes all clinical notes for cohort studies, de-identification, and advanced phenotyping, seamlessly integrating with Atlas for comprehensive analyses.
Secured Research Data Capture (REDCap): supported 455 active projects, ensuring secure data capture for institutional and multi-institutional research.
Network Research Collaborations: HI supported and coordinated data submission, networking, and compliance across networks such as PCORnet, INSIGHT, RECOVER, and OHDSI. Dr. David Lounsbury, PhD facilitates coordination and participates in governance.
AI/ML Predictive Modeling and Data Science Services: HI supported data science services through translation of 3 validated AI/ML predictive models (Surgical complications and cancellation, Post-Op Respiratory Failure, Spinal Cord Metastasis and Compression) to practice via Epic and clinical workflow integration. HI refined and maintained privacy preserving Albert LLM Ensemble to support clinical trial matching, clinical note de-identification, comprehensive chart reviews and extraction of surrogate labels and variables for research, clinical decision support, computable phenotyping, and predictive modeling.
Informatics and Data Science Methodological and Grants Support: HI provided free informatics and data science consultations and methodological support, and participated in grant development and submission.

Aim 3. Expand capacity for clinical trial recruitment: In year 3 of the award, HI further enhanced innovative informatics workflows that leveraged ALBERT LLM Ensemble for automated and continuous patient screening, clinical trials matching, low/high touch consenting and recruitment of all populations from the Bronx, Westchester-county, and lower Hudson Valley in CTR. This included matching algorithm refinement and designing a pipeline to incorporate structured EHR data into the model.

Aim 4. Provide educational and training opportunities in health informatics and data science: HI designed the first elective course on Real World Data for Clinical and Translational Research as part of the Clinical Research Training Program (CRTP), which had the highest enrollment of any CRTP elective in the Spring 2025 semester. HI collaborated with Tufts CTSI to develop and disseminate a free online self-training

module on RWE and Cohort-Based Studies (OMOP-CDM), available via the iLEARN platform. HI partnered with BERD and the Data Science Institute on workshops covering data analytics in R and EHR data principles, alongside the IMPACT fellowship program for medical students. Comprehensive online and multimedia training materials for investigators using self-service tools like ATLAS for RWE and EHR-based studies were further refined and expanded to include the biorepository data.

Challenges and plans for resolution
Leadership Transition and Team Restructuring. HI experienced leadership transitions and team restructuring during the reporting period. This transition presented challenges in maintaining continuity across projects, managing institutional expectations, and aligning newly defined roles within the evolving informatics ecosystem of the ICTR. To address these challenges, HI has clarified leadership roles, strengthened communication and coordination across functional areas, and redefined team structures to better align with strategic priorities. The new leadership framework emphasizes collaboration, accountability, and transparency, ensuring that ongoing initiatives continue with renewed focus and momentum.
Awareness and Communication. HI continues to face challenges in raising awareness and maintaining consistent communication about its services, leading to underutilization and missed opportunities for collaboration. The rapid evolution of informatics and data science further underscores the need for regular updates to the research community. To address this, HI will enhance outreach through newsletters, departmental meetings, podcasts, and a redesigned web portal to improve visibility and access to resources.
Talent Management. In the domain of talent management, HI grapples with the increasing complexity of informatics and data science methods, platforms, and skills. Keeping pace with these rapid changes requires continuous learning and adaptation, putting pressure on existing staff to constantly update their knowledge and skillsets. To overcome this, HI will invest in continuous staff training and create opportunities for involvement in research and publications to enhance job satisfaction and professional growth.

E: CTS RESEARCH PROGRAM

Aim 1: Measure knowledge–attitudes–biases–perceptions (KABP) of researcher teams – **completed**. As the quantitative stage of a sequential exploratory mixed-methods study, we conducted a survey to guide Aim 2 dialogues between researchers and people with developmental disabilities (PWDDs). Based on the ADKAR® model of behavior change (Awareness → Desire → Knowledge → Ability → Reinforcement), < 60% of the sample (n = 120) had high/very high awareness of health disparities. We therefore focused Aim 2 qualitative activities on motivating awareness, desire, and knowledge. [*manuscript in progress*]

Aim 2: Co-design training on researcher-level factors contributing to PWDD under-representation in research – **completed**. A PWDD cohort (n = 4) co-designed a dialogue protocol and joined 7 online dialogues (April–August 2025) to (a) share experiences with research and healthcare, (b) reflect on exclusion impacts, and (c) identify actions and messaging for the Aim 3 eLearning module. A medical student and the PWDD cohort conducted thematic analysis of excerpts including "Walking in Their Shoes" (personal narratives to undo assumptions) and "The Cards Are in Your Hands" (researcher agency to shift from gate-keeping to gate-opening). *[manuscript in progress]*. We integrated these insights and Aim 1 findings into the eLearning module. A medical student and the D2/R3 team produced a text + visual blueprint; an instructional designer built two animated versions: (1) REDCap-compliant RCT module and (2) fully accessible public version. To meet budget/timeline, the sample size was revised from 350 to 200, adjusting detectable effect size from 0.3 to 0.4 (80% power, 2-sided).

Aim 3: Conduct randomized controlled trial of eLearning module – **in progress.** The RCT measures changes in researcher perceptions of including PWDDs after exposure to either: (a) Intervention: ~30 min module promoting knowledge of PWDD health disparities and positive attitudes/perceptions toward inclusion, or (b) Control: two ~15-minute modules defining models of disability and reviewing U.S. disability data sources. Participants complete KAP surveys pre/post and 4-week follow-up. Recruitment began; completion expected early 2026.

Collaborations: Occurred with other CTSAs (on proposals), PWDDs, and medical students; and are planned across our CTSA modules.

Impact

- Grant Submissions: LOI to PCORI (Sep 2025) for multi-format training centered on D2/R3 module (with U Rochester CTSA). Proposals for Holistic Disability IAT submitted to ICTR Pilot (Feb 2025) and Centene (May 2025); not funded.
- Manuscripts: Bonuck K, Fishman A. Reducing Translational Science Roadblocks to Disability Research. JCTS 2025; 9(1). Bonuck K et al. Researchers' Roadblocks to Including People with Intellectual and Developmental Disabilities in Research. (in 2nd revision, JCTS)
- Modules: a REDCap compliant module version will be used in the RCT. It includes narration, music and fully-animated visuals. A publicly-available module will include narration, music, limited on-screen visuals, and audio description of key animation, i.e., employs a high level of accessibility.
- Guide: To facilitate the PWDD cohort's participation in coding qualitative data, we produced a guide that uses lay language and visuals to explain the process of assigning codes to textual data.