# University of Rochester Clinical and Translational Science Institute
# KL2 Institutional Career Development Program
# Request for Applications

For Projects with an Earliest Potential Start Date of July 1, 2020

> **Vision**: Scholars of the University of Rochester KL2 Institutional Career Development Program will become national leaders in the next generation of translational scientists, who will have the skills and knowledge to innovate and improve the efficacy and efficiency of translation, from discovery to implementation and dissemination within the Learning Health System and beyond.
>
> **Mission**: The UR KL2 will align with the UR Clinical and Translational Science Institute and CTSA Consortium, and implement a high quality, team-science based research career development program for early career translational scientists.

Note: The University of Rochester (UR) KL2 Institutional Career Development Program (KL2 Scholars Program) is funded by the Clinical and Translational Science Award (CTSA, an NIH-funded grant). The application for renewal of this award was submitted to the NIH in August 2019, with an outcome expected in the spring of 2020.  Applicants should note that funds for this program are predicated upon successful competitive renewal of our CTSA.

## Important Dates

- Friday, October 4, 2019, 5 p.m. Eastern Time - Submit Letter of Intent
- Monday, November 4, 2019, 5 p.m. Eastern Time - Submit application packet
- Friday, February 3, 2020 - Notification of recipient(s)
- July 1, 2020 - The earliest potential start date. As always, awards for this program are contingent upon receipt of funding for the CTSA.

## Program Description

The University of Rochester (UR) KL2 Institutional Career Development Program (KL2 Scholars Program) is a two-year program funded by the [Clinical and Translational Science Award (CTSA) Program](#) from the National Institutes of Health. The KL2 Scholars Program is designed to offer early career postdoctoral scholars advanced training in translational science research aligned with CTSA Program goals of advancing therapeutics (drugs, devices, and preventatives), clinical interventions, and behavioral modifications to improve health. The program offers flexible learning models to engage postdoctoral scholars in team science, individual development plans, advanced research training, and career guidance to those committed to pursuing a career in clinical and translational research.

Trainees will be expected to develop and implement a research experience supervised by a mentor team. The research project should be designed as a pilot project to set the stage for an individual K-award application, or to establish a foundation for a subsequent individual R-award application. The goal of the program is to promote the successful transition of KL2 Scholars to an independent career as a clinical and translational investigator, generally by means of an individual K- or R-award. Scholars are required to commit to devoting 75% effort to the KL2 program (or 50% for candidates who practice in certain procedure-based medical specialties).

The program has devised three training specializations that capitalize on institutional strengths and priorities, including Experimental Therapeutics, Digital Health, and Health Equity-Focused

Dissemination and Implementation. Prospective scholars are encouraged, but are not required, to take advantage of one of the three specializations. If applicants are interested in one of the three training specializations, they are encouraged to contact the Co-Directors of each specialization during the application process via email.

### *Experimental Therapeutics*

Drs. Robert Holloway and Karen Mustian
The UR has unique strengths, infrastructure, and qualifications for programs focused on target identification and development as well as design and oversight of multi-center clinical trials. Training in this specialization pathway should encompass education and experience from different stages of therapeutic development, from discovery to implementation. A sample curriculum may include curriculum will include advanced topics in experimental therapeutics, such as novel study design, virtual research visits, emerging statistical methods, innovations in outcome measurement, novel recruitment approaches, and emerging research ethics topics.

### *Digital Health*

Drs. Scott Steele and Ray Dorsey
The UR is home to a community of clinicians, computer scientists, bioinformaticians, and regulatory science experts who are modernizing methods of measuring and delivering health via digital health tools and data analysis approaches. Training proposed in this specialization pathway may include education in: remote monitoring of individuals medical disorders, treatment adherence, integration of multimodal data (including EHR data), and developing digital measures as novel endpoints.

### *Health Equity-Focused Dissemination and Implementation*

Drs. Kevin Fiscella and Reza Yousefi-Nooraie
Dissemination and Implementation (D&I) is the science and practice of how evidence-based interventions and policies are effectively translated, distributed, and implemented in real world settings. Training in this specialization pathway should include education and experience in research that adapts the core elements of implementation science to promote health equity.

See also:
• [University of Rochester Clinical and Translational Science Institute (UR CTSI)](#)
• [UR CTSI research education programs](#)

# Support Provided

While enrolled in the KL2 Scholars Program, scholars will receive:
- A stipend or salary to help support the proportional effort required to participate in the program. The CTSA Program will provide up to approximately $70,000 per year contingent on available funds. Therefore, the Scholar's home department may be required to supplement support according to institutional guidelines. Salary supplementation may be from extramural sources, except that no federal funds may be used for this purpose. These funds will be audited by the Office of Research Accounting and Costing Standards (ORACS) yearly.
- Typically, $20,000 of non-salary support per year, which can be used for research, tuition, travel expenses, educational materials in support of the scholar's career development plan, or other costs related to the scholar's research project. If you are taking formal coursework, please utilize the UR tuition waiver first, and then apply KL2 funding for the difference.

- Those appointed as postdoctoral clinical or research fellows receive benefits as defined by the University of Rochester School of Medicine and Dentistry's Office of Graduate Medical Education (see their Benefits/Contract for Trainees webpage). Those appointed as faculty receive benefits as defined by the University of Rochester (see the University of Rochester Total Rewards website).

## *Other Details*

KL2 Scholars are expected to attend the annual meeting of the Association for Clinical and Translational Science (ACTS), typically held in the spring in Washington, D.C. Grant funds may be used for this purpose. Candidates selected for the KL2 Scholars Program may be eligible to apply to the NIH Loan Repayment Program.

## *Program Contacts*

For more information about the University of Rochester KL2 Scholars Program in Clinical and Translational research, please contact:

**General inquiries:**
Caroline Callahan
UR CTSI Education Program Manager
585-275-0684
Caroline_Callahan@urmc.rochester.edu

Alfred Vitale, Ph.D.
Director of Research Education, UR CTSI
585-276-4624
Alfred_Vitale@urmc.rochester.edu

**Financial and budgetary inquiries:**
Mary Lyons
UR CTSI Financial Administrator
585-274-0667
Mary_Lyons@URMC.Rochester.edu

**Inquiries regarding degree or certificate programs offered through the Department of Public Health Sciences:**
Edwin van Wijngaarden, Ph.D.
Professor and Associate Chair, Education, Department of Public Health Sciences
585-275-1985
edwin_van_wijngaarden@urmc.rochester.edu
Public Health Sciences Educational Programs Website

**Inquiries regarding other programmatic issues**:
Robert Holloway, MD, MPH
Director, KL2 Scholar Program
Chair of Neurology, and Professor of Neurology and Public Health Sciences
585-273-3079
Robert_Holloway@urmc.rochester.edu
UR CTSI KL2 Career Development Award Website

# Admissions

## *Eligibility*

To be eligible to apply to the KL2 Scholars Program, applicants must define and participate in a translational research project. Translational science aims to understand and refine the process of turning observations in the laboratory, clinic and community into interventions that improve health of individuals and communities.

Note: The CTSA Program is funded by the National Center for Advancing Translational Sciences (NCATS). With the signing of the 21st Century Cures Act (Cures Act) into law in December 2016, the Public Health Service (PHS) Act was amended to allow NCATS to support clinical trial activities through the end of phase II for all diseases or conditions, and through the end of phase III for a rare disease or condition. Please refer to NCATS notice (NOT-TR-18-025) for more information.

## *Qualifications*

Other qualifications for the KL2 Scholars Program include:
- A doctoral-level degree in a health discipline that can be applied to clinical or translational research. These degrees include, but are not limited to MD, DO, DMD, DDS, DPH, PharmD, as well as PhDs in a clinically relevant field, such as biostatistics, epidemiology, behavioral science, and nursing.
- US citizen or permanent resident. Individuals on temporary or student visas are not eligible.
- Must be an early-career postdoctoral scholar committed to advanced training and a career in translational science research aligned with the CTSA Programs goals of advancing therapeutics (drugs, devices, and preventives), clinical interventions, and behavioral modifications to improve health.
- At the time of their appointments, Scholars must not have pending an application for any other PHS mentored career development award (e.g. K07, K08, K22, K23) that duplicates any of the provisions of the K component. Former or current PDs/PIs on any NIH research project grant [this does not include NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants)] or equivalent non-PHS peer reviewed grants that are over $100,000 direct costs per year, or project leaders on sub-projects of Program project (P01) or center grants (P50) are NOT eligible to participate as Scholars. Scholars may have had support on a NRSA grant (F or T) or NIH small grant (R03). Appointed Scholars are encouraged to apply for individual mentored K awards (e.g. K07, K08, K22, K23) and independent awards (R01, R03, R21); if successful, Scholars may be required to reduce effort on the mentored career award to a minimum of six-person months and hold concurrent support from their mentored career award and a competing PHS research grant on which they are the PD/PI or component lead or terminate the KL2 appointment depending on Program requirements (See NIH notice NOT-OD-08-065).
- Commitment to a two-year program. During this time, at least 75 percent of the KL2 Scholar's full-time professional effort must be devoted to the program. The remainder of time may be devoted to developing other clinical or academic pursuits that are consistent with the objectives of developing a career as an independent clinical or translational researcher. Certain clinical specialties may have less than 75 percent effort -- but no less than 50 percent effort -- if sufficiently justified (e.g. surgical specialties requiring 50 percent direct patient care time to keep up surgical skills).

## *Valuing Diversity*

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with their mentor(s) to develop an application for support. Women, individuals from underrepresented racial and ethnic groups, and

individuals with disabilities are encouraged to apply. We encourage applicants to create a diverse mentor team that includes women, individuals from diverse racial and ethnic groups, and/or individuals with disabilities.

The University of Rochester is committed to fostering, cultivating, and preserving a culture of diversity and inclusion. The University believes that a diverse workforce and inclusive workplace culture enhances the performance of our organization and our ability to fulfill our missions. The University is committed to fostering and supporting a culture inclusive of people regardless of their race, ethnicity, national origin, gender, sexual orientation, socio-economic status, marital status, age, physical abilities, political affiliation, religious beliefs or any other non-merit fact, so that everyone feels included, equally valued and supported.

# Application Process

## *Positions*

Two or more positions are available annually and have a start date of June 1, 2020.

## *Timeline*

- Please email Caroline Callahan at Caroline_Callahan@urmc.rochester.edu by **5 p.m. Eastern Time on Friday, October 4, 2019** if you intend to apply**.**
- Submit **application packet** by **5 p.m. Eastern Time on Monday, November 4, 2018.**

## *How to Apply*

**Step 1: Identify a primary mentor and co-mentor(s).** One of the most important steps in applying to the KL2 Scholars Program is to identify a multidisciplinary mentorial team.  Your primary mentor should be located at the University of Rochester.  You and your primary mentor should determine appropriate co-mentor(s) in other disciplines that will bring valuable expertise to your career development and research proposal.  For assistance in identifying a primary mentor and one or more co-mentors, see informational links below.  You may contact the UR CTSI Research Help Desk (ResearchHelp@urmc.rochester.edu) for assistance in identifying potential mentors. See also: Research Departments and Centers at the University of Rochester.

**Step 2: Notify the UR CTSI of your intent to apply by 5pm EST, Friday, October 4, 2019.** The information allows us to better plan the review process and assist potential applicants as necessary. The email should contain two or three sentences describing your areas of interest and the names and specialties of your primary mentor and co-mentor(s).
**Send your email to Caroline Callahan at Caroline_Callahan@urmc.rochester.edu**

**Step 3: Complete the required documentation**. To apply, you will need to submit the following application materials.  Resubmissions should include how you addressed prior reviewer comments in a cover letter. Please follow NIH guidelines for grant style, content, and format contained in the NIH Application Guide.
  1. **Your NIH-format biosketch** (sample and form available online). Do NOT submit a CV. Prepare your personal statement so as to be relevant to your KL2 mentored career development proposal.
  2. **NIH-format biosketches for your mentors**. Mentors should edit the personal statements on their NIH biosketches to describe their specific role in your KL2 program and career development.
  3. **Research Career Development Plan (RCDP)**

a) The candidate and the mentor are jointly responsible for the preparation of the career development plan. See Table 1 for a typical KL2 Scholar 2-year curriculum. (3-page limit, excluding references):

b) A brief summary of your career path to date. This should include a critical self-appraisal of your training needs and description of how the mentor team will meet your needs. Please refer to NCATS Translational Science Education Resources for information regarding translational science skills and the CTSA Program's core and special interest clinical and translational research competencies.

c) Describe a plan: (1) that shows a logical progression from prior research and training experiences to the training and research experiences that will occur during the KL2 award period; (2) that justifies the need for further career development; and (3) that utilizes the relevant research and educational resources of the institution.

d) Descriptions of the training you are seeking and how the training by the Scholars Program will help you achieve these goals. Regarding the proposed training plan:
   i. You should address your commitment to the KL2 foundational curriculum (see Appendix);
   ii. Select additional coursework and programs to best support your individual backgrounds, discipline, and career objectives. Scholars can choose from the UR CTSI's educational programs and coursework that span the translational research spectrum.
   iii. If Scholars are interested in aligning their individualized training curriculum to one of the three training specialization (Experimental Therapeutics, Digital Health, and Health Equity-Focused Dissemination and Implementation), you should contact the Co-Directors for each specialization. See Table 2 for sample coursework and partnerships for each specialization. These are only samples and each training plan should be customized to the career development needs of the applicant.

e) Describe the professional responsibilities/activities including other research projects beyond the minimum required 75% effort commitment to the KL2 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting clinical and translational research.

f) Plans and timing of submission for subsequent funding, including K- or R-series mechanisms, or equivalent, as appropriate to training and research needs. A timeline is often helpful.

4. **Mentored Research Plan.** A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided (4-page limit, excluding references). Organize the research plan as indicated in the Form PHS 398, following instructions for the Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods. The candidate should consult with mentor(s) regarding the development of this section. Studies that involve early stage clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects (see NIH Grants Policy Statement, section 4.1.15.6).

5. **The following 3 letters of recommendation.**
   i. **Letter from proposed primary mentor** detailing his/her support of and commitment to the applicant and the proposed research and training plan. The letter should include the mentor's qualifications; including prior experience in the supervision, training, and successful mentoring of clinical/translational researchers. The letter should also include how often the mentor plans to meet with the candidate, and confirm that adequate space, facilities, and resources will be made available for the successful completion of the research projects. The letter should describe how the proposed research fits into the mentor's research program, including a description of the

specific role of the applicant in the research. The primary mentor letter should not exceed two pages.

ii. **A letter of recommendation from at least one of the proposed co-mentors of the candidate.** The co-mentor must be in a different discipline than the primary mentor. This letter must include the co-mentor's assessment of the candidate's qualifications and potential for future success. The letter should also indicate the co-mentor's qualifications, including experience in providing similar mentorship and research expertise. This letter should not exceed one page.

iii. **A letter of nomination/recommendation from the Chair of the Department or Director of the Center**, including assurances that non-research responsibilities will be restricted to no more than 25% of the trainee's time (or 50% for certain procedure-based specialties such as surgery). The letter should also comment on plans for further career development of the candidate after the period of the Scholar award and should address the candidate's motivation and likelihood to become an independent investigator.

6. A listing of **your and your mentors' current and pending support**, other than this award, using NIH format.

7. A financial analysis, signed by both your Department Chair/Center Director and your department's research administrator, documenting the financial impact of the KL2 award on the Department/Center. The analysis will calculate supplemental funds required of the Department to support the Scholar's salary, if any, based upon current and anticipated applicant salary information for the two years of the award. The applicant must contact Alfred Vitale (alfred_vitale@urmc.rochester.edu), UR CTSI Director of Research Education, who will provide a standard financial analysis template.

**Step 4: You must submit the required materials listed above through our [online application system](#) no later than 5 p.m.** Eastern Time on Monday, November 4, 2019. Supplementary material will not be accepted. You must notify the UR CTSI immediately of any revisions or updates to your current or pending support that occur between submission of your application and the date of official notification of KL2 award status. <u>Failure to notify the UR CTSI of such changes in a timely and accurate fashion may disqualify you from the KL2 program.</u>

# Application Review Process and Criteria

Each application will be reviewed initially for **completeness and eligibility**.

**Step 1:** Applications will be reviewed by the KL2 Recruitment/Selection Committee using a similar format, numerical scoring system (1-9), and template used for NIH Career Development awards. In addition to an overall impact score, reviewers will give a separate score for each of the five following criteria in the determination of scientific and technical merit: 1) Candidate, 2) Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring, 3) Research Plan, 4) Mentor(s), Co-Mentor(s), Consultants, Collaborators, 5) Environment and Institutional Commitment to the Candidate.

Each applicant will receive up to 3 reviews from faculty members at the University of Rochester. Faculty members with a significant conflict of interest will not be allowed to review.

**Step 2:** The KL2 Recruitment/Selection Committee will meet to discuss the written reviews. The Committee may pose additional questions for the applicants; if so, the applicant's will be asked to respond to the reviewer questions in writing.

**Step 3:** The KL2 Recruitment/Selection Committee will present its recommendations to the UR CTSI Executive Team and KL2 Steering Committee for approval.

### *Annual and Final Progress Reports*

An annual progress report is due in March of the first year during the Scholar's term of appointment. Renewal of the award in year 2 is contingent upon presentation of a satisfactory progress report. Additionally, a final research report and a final expenditure report are due within 60 days following the close of the grant term.

### *Publications*

All publications that benefit in whole or in part from support provided by the UR CTSI must do the following:
1. Comply with the NIH Public Access Policy: Assistance with the compliance process is available through the Miner Library.

2. Acknowledge UR CTSI grant funding using this language: "The project described in this publication was supported by the University of Rochester CTSA award number KL2-TR001999 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

### *Clinical Trials*

If the proposed research project involves a clinical trial, the awardee will be required to promptly inform the UR CTSI of all adverse events that are serious, unexpected and related to participation in research. Further guidance is available on the Office for Human Research Protection website. In addition, most clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see the UR CTSI's Regulatory Support pages.

### *Notification of Recipients*

Notification of recipients: Shortly before or on February 7, 2020-
Award start date: June 1, 2020

# Appendix. Elements of the Foundational Curriculum

### *Rigorous Research Training*

*Coursework in Ethics and Professional Integrity (IND506):* This course is required of all clinical and basic science postdoctoral fellows in the School of Medicine and Dentistry. The course features 10 sessions consisting of lecture/case study presentations followed by small group discussions that provide information on the various topics that the National Institutes for Health consider essential for the responsible conduct of research. Specific topics include the ethical issues underlying human experimentation and related conflicts of interest, animal experimentation, the mentor-mentee relationship, scientific misconduct and plagiarism, collaborative and team science, and publication/authorship. The course also provides an introduction to approaches for improving rigor and transparency with the goal of enhancing research reproducibility. This is a non-credit bearing course that cannot be applied to any degree program in the School.

*Good Clinical Practice (GCP) Training*: Scholars engaged in clinical trials will receive GCP training. Scholars will complete an online GCP training program (via the Collaborative Institutional Training Initiative) that has been approved by the UR Human Research Protection Program. NIH requires all funded "investigators and staff who are involved in the conduct, oversight or management of clinical

trials" be trained in Good Clinical Practice. The policy further requires Investigators to take a refresher GCP training course every three years. The course is available through the CITI training platform.

### *Team Science Training*

*Team Science Course (PM 403):* Team Science Course (PM 403): This course introduces Scholars to the concepts, practice, and challenges of team science and collaborative research environments. Scholars will be exposed to both team science initiatives and the science of team science, as presented through practical examples from local research teams and researchers, with a focus on practical implications of a team science approach to biomedical research requiring large-scale data analysis.

### *Grant Preparation Activities*

*Participate and Present at the Research Methods Forum:* Each Scholar will be required to regularly attend, participate in, and present at the bi-monthly UR CTSI Research Methods Forum. The Scholars will present at the Research Methods Forum to obtain feedback on the appropriateness of specific aims (both scope and clarity), strength of preliminary data, and the rigor of research methods. In addition to core Research Methods Forum faculty, additional specific faculty attendees are invited to participate in each session, based on the discipline and content of the presenter's research. Following the presentation, members of the Forum will continue to provide KL2 Scholars with feedback and support by reviewing grant proposals and study protocols in order to improve rigor and transparency of the proposed work.

*Grantsmanship course (PM 438):* The Grantsmanship course will teach Scholars how to identify funding opportunities, prioritize potential grant opportunities, present a research project/program in a grant application, and navigate and complete the application process

### *Other Professional and Leadership Skills*

*KL2 Seminar Series.* This seminar meets approximately 10 times per year and consists of small group sessions in journal club format and case-study presentations that cover professional and leadership skill development. The seminar will focus on the following:

> *Professional and Mentoring Skills*:  The seminar will cover cross-cutting topics, including: "How to Optimize Your KL2 Training," "Managing a Research Team," "Funding Your Career," "Preparing your CV and Biosketch", "Lightning Research Presentation", and "Philanthropy 101". Topics will evolve based on feedback and needs of the Scholars.

> *Leadership Development.* This "Leadership Circle" journal club meets 5 times per year. In each session, faculty, and Scholars discuss one article from Harvard Business Reviews 10 Must Reads: On Leadership (e.g., "What Makes a Leader, What Leaders Really Do?" "Crucibles of Leadership," "Seven Transformations of Leadership"). Discussion will focus on framing each Scholars' own leadership style and challenges in the context of each article.

### *Other KL2 Program Activities*

*UR CTSI-wide Seminar Series.* Scholars will be expected to attend the UR CTSI Monthly Seminar Series, a dynamic program that highlights emerging areas of translational science. The seminars are recorded and made available online with the new option of obtaining Continuing Medical Education (CME) credits. Spring seminar sessions focus on the principles and implementation of translational science competencies in specific research groups.

*Association for Clinical and Translational Science Annual Conference.* Attendance to at least one Annual Conference of the [Association for Clinical and Translational Science](.).

**Table 1. Typical Curriculum for UR KL2 Scholar**

| | Year 1 | | Year 2 | |
| --- | --- | --- | --- | --- |
| | July-December | January-June | July-December | January-June |
| **Application and Orientation*** | Sets the stage for overall program goals, timelines, and expectations | | | |
| **Customized Education Plan** | Chosen from UR's wide range of educational programs and coursework | | | |
| **Mentored Research Project(s)** | Mentored primary and collaborative research projects | | | |
| **Rigor and Team Science Training** | Ethics course and proposed team science experience and training | | | |
| **Program Wide Meetings/Series:** | | | | |
|   KL2 Seminar Series | Monthly meetings covering translational research and career development topics | | | |
|   UR CTSI Seminar and Webinar Series | Monthly seminars focused on emerging areas to strengthen skills and research techniques | | | |
|   Research Methods Forum | Multidisciplinary meeting to present and obtain feedback on grant submissions | | | |
|   Leadership Circle | Journal club reviewing Harvard Business Reviews 10 Must Reads: On Leadership | | | |
| **Other Skill-Building Activities** | As needed for Scholar career development (e.g., process innovation and improvement skills, diversity training, recruitment, regulatory science) | | | |
| **Mentored Grant Writing^** | Prepare and submit grant within 12-18 months | | | |
| **Annual ACTS Meeting** | | x | | x |
| **Monitoring Scholar Progress** | x | x | x | x |

*Orientation occurs April or May prior to the start of Year 1. ^Structured internal grant review and feedback through Research Methods Forum

**Table 2. Sample Coursework and Partnerships with Training Specializations**

| | Experimental Therapeutics | Digital Health | Health Equity-Focus Dissemination and Implementation (DI) |
| --- | --- | --- | --- |
| **Co-Directors** | Robert Holloway and Karen Mustian | Ray Dorsey and Scott Steele | Kevin Fiscella and Reza Yousefi-Nooraie |
| **Sample Coursework** | Experimental Therapeutics (PM488) | Machine Learning (CSC 446) | Intro to HSR and Policy (PM455) |
| | Design of Clinical Trials (BST465) | Artificial Intelligence (CSC 442) | Program Evaluation (PM461) |
| | Recruitment and Retention (PM419) | FDA Reg Process & IP (BME431) | Community-Engagement Studios |
| | Measurement and Evaluation (PM472) | FDA Regulatory & Commercialization Landscape (BME432) | Qualitative Health Care Research (PM458) |
| **External Partnerships** | Trial Innovation Network PhRMA Foundation Praxis Precision Medicine Emerging Research Networks | Critical Path Institute Sage Bionetworks 23andMe | University of Washington DI Research Core Ohio State University Implementation Science Core |