Translational Science Toolkit

Resources to help investigators translate their basic science discoveries from bench to bedside

MICHR MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH
UNIVERSITY OF MICHIGAN

Are you looking to…

Perform research in the early translational realm? Do you want to make a difference to health research at U-M? Are you a young investigator trying to find your way through this maze?

This toolkit is for you.

This manual provides an overview of the necessary knowledge, resources and connections that will guide your exploration of the translational impact of your research findings.

This is not a textbook.

We designed this toolkit to spark action. It is not meant to be comprehensive. Read it long enough to get inspired, then put it down and get to work. Pick it back up again when you need another boost.

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T1 Translational Research

T1 translational research can be divided into the three primary areas of discovery, preclinical, and clinical. There are numerous activities within each area, or in overlapping areas, that are necessary for successful pursuit of T1 research.

Discovery   Pre-Clinical

Technology Development

Animal models of pathophysiology

Lead optimization

High-throughput screening

IP licensing

Drug Metabolism

Pharmacokinetics

Commercialization

Biorepositories

Regulatory

Proof of Concept First in Man

Phase I and II Trials
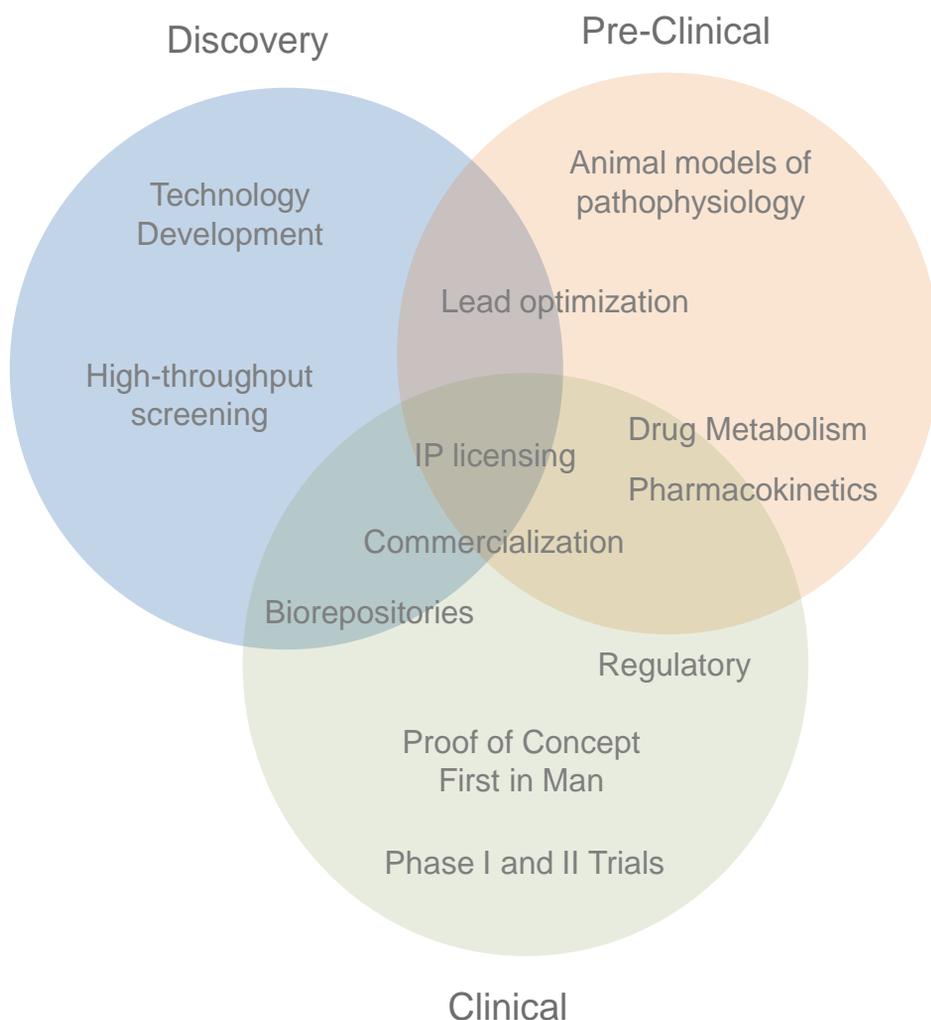
Clinical

Courtesy of the Clinical & Translational Science Awards Program

Early Career Investigators

Early Career Investigators

Are you a junior investigator thinking about a career in early translational research? In addition to understanding a potentially new line of research, it is important to find mentors who can help guide your career development.

MICHR

MICHR Resources

- **MICHR Postdoctoral Translational Scholars Program (PTSP):** PTSP is a multidisciplinary career development award designed to prepare individuals with a PhD in a biomedical science or social science discipline for independent careers in translational research.

- **Introduction to Clinical Health Research for Fellows and Junior Faculty**: This program is designed for fellows and junior faculty interested in developing an academic career focused on health research. The 5-part series is taught by a diverse team of MICHR faculty and staff involved in the full spectrum of research.

- **Translational Research Education Certificate:** The Translational Research Education Certificate (TREC) is designed for doctoral students in basic research programs as a complement to their graduate studies.

Additional Resources

- **Translational Cancer Research Workshop for Basic Scientists**: This workshop is an intensive, week-long introduction to translational cancer research, including cancer medicine, the clinical cancer research environment and collaborative team science, for predoctoral and postdoctoral basic scientists, early-career scientists and senior scientists transitioning to translational research.

- **Introduction to Clinical Research Program:** The curriculum in this University of Cincinnati Children's Hospital course is designed to enhance the participant's knowledge of various aspects of research involving human subjects.

- **NIH New and Early Stage Investigator Policies:** Use these guidelines for establishing new or early stage investigator status on your NIH application.

- **CTSciNet**: CTSciNet, the Clinical and Translational Science Network, is an online community for people interested in or already pursuing careers in clinical and translational research. CTSciNet provides articles and information on navigating a career in clinical and translational research. Investigators can join virtual groups focused on team science, journal clubs, and ethical legal and social issues, and they can access resources from partner organizations.

- **The American Society of Hematology and the European Hematology Association Fellowship**: This year-long training and mentoring experience helps early career investigators build careers in translational research.

Literature: Identifying the Right Mentors

The following articles emphasize the importance of mentoring for scientific career success and provide helpful tips on finding mentors that are right for you.

- [Top Ten Tips to Maximize your Mentoring](#)
- [Mind Matters: Getting Yourself Mentored](#)
- [The Difference Between an Advisor and a Mentor](#)
- [Checklist: The Qualities and Responsibilities of a Good Mentor](#)
- [Reaching Gender Equity in Science: The Importance of Role Models and Mentors](#)

Additional Learning Resources

- [Carving a Career in Translational Research](#)
- [Basic Scientists in the Clinic](#)
- [Perspective: The Successful Physician-Scientist of the 21st Century](#)
- [Podcast: Training Translational Scientists](#)

"In most cases, people need more than one mentor because no one individual is capable of helping the person develop the broad range of skills that are necessary for success."

- Joe Merola, *Mind Matters: Getting Yourself Mentored*

Finding a suitable mentor is a crucial step for early career investigators. It is reasonable to expect your mentor to:

- Help you define and evaluate training goals
- Meet with you one-on-one regularly
- Listen to you and your ideas
- Provide constructive and timely feedback on your ideas
- Support training and professional development opportunities
- Help you to network
- Acknowledge your contributions through authorship

- NIH mentoring guidelines

Identifying Collaborators & Funding Opportunities

Looking for a Collaborator?

How often do you see single author publications? Effective collaboration is essential for a successful scientific career. These tools will help you connect with collaborators at U-M and beyond.

U-M Resources

- **SciVal:** Search U-M resource profiles by concept, author, or full text. Scival also provides a visual analysis of relevant concepts that instantly exposes a researcher's distinctive expertise.

Additional Resources

- **ResearchGate:** This is a global scientific community for presenting yourself and your work and connecting with collaborators.

- **Biomed Experts:** The first literature-based scientific professional network brings the right researchers together and allows them to connect, network, communicate, and collaborate online.

- **Epernicus:** This is a public and free social network for researchers to post profiles, network, and pose questions.

- **DIRECT2Experts:** The DIRECT2Experts network, open to all biomedical institutions, is a pilot project facilitated by the Research Networking Working Group of the NIH-supported Clinical & Translational Science Award (CTSA) Consortium. The goal is to improve biomedical research and leverage our strengths as a community by creating a network that enables easy access to expertise and related resources across institutions, regardless of local platforms and tools, and in collaboration with participating institutions to ensure access to approved and verified data.

> "In the current state of research, there is an increasing need to build bridges between clinical and basic researchers to translate findings from bench to bedside and back again"
>
> - Heidi Kong and Julia Segre, *Bridging the Translational Research Gap*

Team Science Resources

- [National Cancer Institute Team Science Toolkit](): The Team Science Toolkit is a user-generated collection of information and resources that support the practice and study of team science. The Toolkit connects professionals from many disciplines, providing a forum for sharing knowledge and tools to maximize the efficiency and effectiveness of team science initiatives.

- [Northwestern University Clinical and Translational Sciences Institute](): This group offers collaboration enhancement for team-based, cross-disciplinary translational biomedical research. Resources include online learning modules intended to help researchers acquire and apply a basic knowledge of team science. Additional learning modules afford an experiential learning environment where the researcher can adopt different roles and engage virtually in the challenges of team research.

Literature and Web Tutorials

- [Collaboration and Team Science: A Field Guide](): A guide to help researchers navigate the rocky and murky territory associated with building a team on their own or at the request of someone in their organization.

- [The Road We Must Take: Multidisciplinary Team Science](): Translational research is complex and requires a diverse skill set. There is a critical need for understanding how to create and sustain multidisciplinary research teams.

- [Bridging the Translational Gap: A Successful Partnership Involving a Physician and a Basic Scientist](): Although basic and clinical scientists have long collaborated, translational research challenges investigators to move beyond the traditional training of laboratory scientist or clinician. This article discusses such a collaboration, highlighting features specific to interactions as an MD and PhD.

- [Making Team Science Work: Advice from a Team](): Learn how to assemble a team that is prepared to rapidly translate their clinical findings to patients.

- [Collaborative Science Learning Modules](): From Columbia University, these modules highlight the benefits and potential problems that arise in collaborative research.

Funding Opportunities

With the drive towards increasing the speed of translating results from bench to bedside, combined with declining resources, funding agencies are seeking proposals that foster collaboration and the translation of basic discoveries.

MICHR Pilot Grant Program

- [MICHR's Pilot Grant Program](#) seeks proposals from basic, clinical, and social scientists for bench-to-bedside and bedside-to-practice translational research. The Bench to Bedside Translation and Endowment for Basic Sciences (EBS) Partnership Awards aim to foster the translation of innovative discoveries in molecular-, cell- or animal-based models or creation of novel technology platforms that have direct clinical potential of altering our understanding and/or management of human disease. The EBS Partnership Award requires collaboration between a basic scientist from one of the units within EBS and a clinical investigator holding an appointment outside of EBS.

U-M Collaborations

- [MCubed:](#) This is a two-year seed-funding program designed to empower interdisciplinary teams of University of Michigan faculty to pursue new initiatives with major societal impact. The program minimizes the time between idea conception and successful research results by providing immediate startup funds for novel, high-risk and transformative research projects.

U-M Comprehensive Cancer Center

- [Research Grants:](#) Funding is available for investigators performing cancer-related research of for any interesting and innovative collaboration among scientists.
- [Innovation Grants:](#) A principal goal of these awards is to support preliminary collaborative research studies emanating from at least two of our UMCCC Research Programs that would enable and/or enhance new grant application submissions to the National Institutes of Health or other extramural, peer-reviewed funding agencies.

U-M Comprehensive Diabetes Center

- [Diabetes Interdisciplinary Studies Program:](#) The purpose of this award is to promote new interdisciplinary collaboration between at least two U-M faculty members from DISTINCT disciplines to focus their combined research strengths on cutting-edge areas in diabetes research.

Translating Basic Science Findings

- [NIH Bench-to-Bedside Program](): The Bench-to-Bedside Program funds research teams seeking to translate basic scientific findings into therapeutic interventions for patients and to increase understanding of important disease processes.

- [NIDCD Research Grants for Translating Basic Research into Clinical Tools (R01)](): The NIDCD is encouraging applications that translate basic research findings into clinical tools for better human health in the NIDCD mission areas of hearing, balance, smell, taste, voice, speech and language. The intent of this FOA is to provide a new avenue for basic scientists, clinicians and clinical scientists to jointly initiate and conduct translational research projects. Multi-institutional, multi-disciplinary, and academic-industrial collaboration studies are encouraged.

- [Opportunities for Collaborative Research at the NIH Clinical Center (U01)](): The goal of this FOA is to support collaborative translational research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. This opportunity is specifically to promote partnerships between NIH intramural investigators (i.e., those conducting research within the labs and clinics of the NIH) and extramural investigators (i.e., those conducting research in labs outside the NIH).

Tip

Be sure to sign up for U-M Office of Research and Sponsored Projects (ORSP) Email Alerts on the [ORSP website](). You will receive funding opportunities from the DoD, DoE and NASA as well as the latest policies and procedures updates from NIH and ORSP.

Studying Complex Systems & Understanding Human Cognition

- **[James S. McDonnell Foundation Collaborative Activity Awards:](#)** The Foundation offers Collaborative Activity Awards to initiate interdisciplinary discussions on problems or issues, to help launch interdisciplinary research networks, or to fund communities of researchers/practitioners dedicated to developing new methods, tools, and applications of basic research to applied problems.

Tip
Writing collaborative proposals takes considerable time. Give your grant a final and thorough edit to ensure it is cohesive and reads in one voice.

Genetic Factors Influencing Life Span and Health

- **[Notice of Intent to Publish a Funding Opportunity Announcement for Collaborative Research Infrastructure to Develop Research Strategies to Identify Potential Therapeutic Targets Based on Genetic Factors Influencing Human Life Span and Health Span (U24):](#)** The Purpose of this Notice is to indicate the intent to publish a FOA for cooperative agreement applications to support a collaborative research infrastructure that includes a multidisciplinary team of scientists to plan and evaluate translational research strategies to identify potential therapeutic targets based on findings of genetic factors influencing human life span and health span.

International Collaborations

- **[Human Frontier Science Program:](#)** Research grants are provided for teams of scientists from different countries who wish to combine their expertise in innovative approaches to questions that could not be answered by individual laboratories. Emphasis is placed on novel collaborations that bring together scientists, preferably from different disciplines (e.g. from chemistry, physics, computer science, engineering), to focus on problems in the life sciences.

Collaboration in Cancer

- **AACR Team Science Award:** This award has been established by the American Association for Cancer Research and Eli Lilly and Company to acknowledge and catalyze the growing importance of interdisciplinary teams to the understanding of cancer and/or the translation of research discoveries into clinical cancer applications.

Leukemia and Lymphoma

- **Leukemia & Lymphoma Society Specialized Center of Research Program:** The Marshall A. Lichtman Specialized Center of Research (SCOR) program supports interdisciplinary research across at least three independent research projects that are integrated and supported by scientific core laboratories.

Prostate Cancer

- **Prostate Cancer Foundation Challenge Award:** These awards support large-scale research projects from teams of at least three highly experienced investigators capable of providing unique scientific expertise to the solution of a significant problem in prostate cancer research. The team may be assembled from one institution or several institutions from across the globe, and must embed a young investigator as an integral contributor to the team.

Diabetes

- **American Diabetes Association:** Translational Science Awards support research that accelerates the transition of scientific discoveries into clinical applications by efficiently advancing knowledge of efficacy to the next level of clinical application. Translational research supported with these awards will typically involve expertise, collaboration and engagement across disciplines.

Melanoma

- [Melanoma Research Alliance-Hidary Foundation Team Science Award:](#) Characterization of acral melanoma patient samples using cutting-edge approaches; requires teams of two or more scientists.

Travel Awards

- [Burroughs Wellcome Fund Travel Awards:](#) This award supports Ph.D. candidates, postdoctoral fellows, and faculty researchers traveling to laboratories domestically or internationally to acquire new research techniques, facilitate or begin collaborations, or attend courses.

"Running a successful collaboration, especially one with several leaders at multiple sites, means thinking like a CEO: vetting partners, delegating responsibilities and making tough management decisions."

- Chris Tachibana, *Navigating Collaborative Grant Research*

Grant Writing

Given the funding climate, it is important to submit your strongest grant on first submission. Take advantage of excellent U-M resources to receive feedback on federal and non-federal applications.

MICHR Resources

- **Research Development Core (RDC):** RDC offers no-cost one hour consultations designed to strengthen grant proposals. Services may include matching ideas with funding sources, developing research plans and submission strategies, identifying collaborators, and guidance on future career direction. RDC also provides grant editing assistance.

- **K Writing Workshop**: The MICHR Education & Mentoring Group sponsors a K Writing Workshop each year for investigators writing Career Development (K) grants. In this three-part workshop, K writers receive peer critique and feedback from senior faculty experienced in NIH study section thinking.

- **Mock Study Section:** The MICHR Education & Mentoring Group hosts a mock study section, which is an opportunity to learn how NIH grant reviewers, or "study sections," think. As one of nine grant reviewers, you will discuss actual twelve-page K and R grants (already submitted in some version to the NIH). You will learn what happens behind closed doors in a real K or R grant review.

> **Tip**
> Stay informed of the research being funded in your area. NIH RePORTER and Sponsored Awards on the Web (SAW) are excellent resources.

U-M Resources

- **Foundation Funding for Faculty:** This is a collection of resources built for faculty and staff at U-M for securing funding from foundations and other organizations.

- **Marissa Conte, U-M Translational Research Liaison:** Marissa can help investigators identify appropriate funding opportunities for their research interests.

- **MLibrary Grants and Fundraising**: This group provides resources, strategies, and information on grant-seeking, including finding funders, proposal writing, university processes, and related topics.

- [Office of Research Funding Opportunities & Proposal Preparation](): This provides information and tutorials on proposal development and submission, grant writing guides, and additional resources.

    - [Medical School Grant Proposal Sampler:]() This is a repository of sample proposal and proposal sections donated by Medical School faculty members. Its purpose is to offer insight into proposal development, including proposal writing (e.g., organization, detail), responding to reviewers' comments, sample sections, and tables.

    - [NIH Fellowship Proposal Sampler:]() This is a repository of sample proposal and proposal sections donated by U-M graduate students, postdoctoral fellows and faculty members. Its purpose is to offer insight into proposal development.

    - [Resource Profiles](): Boilerplate descriptions of U-M units and resources that can be adapted for grant proposals.

    - [Proposal Preparation Funding Program:]() The goal of the program is to provide funds to support the submission of multi-investigator grants. The funds may be utilized to offset the costs of hiring expert consultants; assembling and hosting brainstorming sessions; paying reviewers; or hiring temporary incremental secretarial, administrative, and/or expert services required to assemble and submit large proposals.

Tip

View the NIH Peer Review Process Revealed video to gain a better understanding of how your grant is evaluated. Also register for the MICHR Mock Study Section. Knowledge of the peer review process is essential to writing a strong application.

NIH Writing and Submission Resources

- [All about grants from NIAID](#)
- [Tips for new grant applications from NIGMS](#)
- [Writing a grant: A technical checklist from NINDS](#)
- [Common mistakes in NIH applications from NINDS](#)
- [10 Steps to a Winning R01 Application](#)
- [The NIH Peer Review Process Revealed (CSR)](#)
- [The grant review process (NCI)](#)
- [NIK K Kiosk](#)
- [Applying electronically](#)
- [SF424 application and electronic submission information](#)

Tips for SBIR/STTR Grants

- [SBIR/STTR policy and grantsmanship information](#)
- [Advice on SBIR/STTR applications from NIAID](#)

Grant Writing Guides

- [Focus on written communication skills](#): Collaborative Learning and Integrated Mentoring in the Biosciences at Northwestern University offers many resources designed to improve writing skills.
- [Proposal Writing for Foundations](#): A web-based course covering the essentials of writing foundation grant applications.

Literature

- [Navigating Collaborative Grant Research](#)

Performing Translational Research

Drug Discovery

Drug discovery and development is a long process from target identification to clinical trials. All points along the pipeline require experts skilled in various disciplines and technologies. These resources aim to help you on your journey to discover new medicines.

Learning Resources

- [Introduction to Drug Discovery Video](#)
- [From "Hit" to Pill Video](#)

U-M Resources

- [Center for the Discovery of New Medicines (CDNM):](#) With a robust community of scientists, extensive research infrastructure and a network of experts in critical legal and business areas, the CDNM coordinates and supports the development of therapeutics from discovery to the market.

- [Center for Chemical Genomics (CCG):](#) The CCG provides expertise and resources for U-M researchers and others to use modern high-throughput screening (HTS) approaches in tackling basic biology or novel drug discovery projects.

- [Vahlteich Medicinal Chemistry Core (VMCC):](#) The VMCC is an on-campus core facility for the design and synthesis of drug-like molecules and diagnostic probes used in biomedical investigations.

- [Pharmacokinetics Core (PK Core):](#) The PK Core supports researchers' efforts in the discovery of new medicines. They provide assistance with obtaining research funding, filing patent applications, and publishing academic research findings for both preclinical and clinical pharmacokinetic applications, including lead compound modeling, dose optimization, and clinical trials.

- [Biomedical Mass Spectroscopy Laboratory:](#) This lab provides state-of-art mass spectroscopy instrumentation and skilled personnel for educational and research efforts. A special focus is the support of studies on metabolism and toxicology, including drug metabolism, formation of reactive intermediates, absorption and distribution of drugs, and measurement of biomarkers.

- [Center for Structural Biology:](#) A comprehensive structural biology resource for researchers at U-M and surrounding areas that houses a high-throughput protein laboratory, protein purification facilities, macromolecular crystallization and crystallography laboratories, and X-ray facilities.

U-M Resources for Drug Discovery

High-Throughput Screening:
Center for Chemical Genomics

Target assay construction and screening

Phase 1: safety

Phase 3: efficacy, safety

Target Identification

Target validation, hits-to-leads medicinal chemistry safety

Phase 2: efficacy, safety

FDA review and approval

Lead Optimization:
Vahlteich Medicinal Chemistry Core

Pharmacokinetics Lab

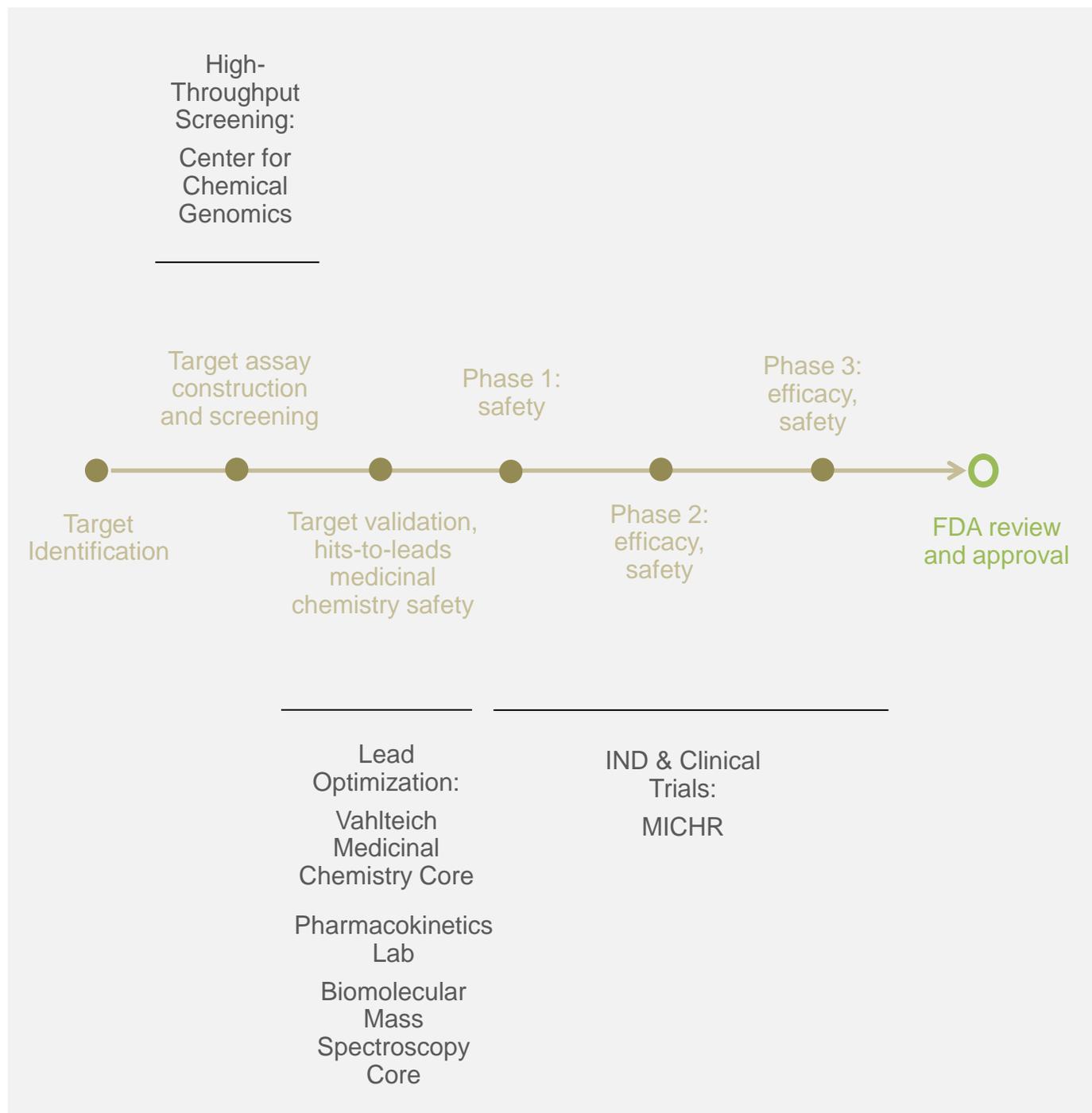Biomolecular Mass Spectroscopy Core

IND & Clinical Trials:
MICHR

Figure adapted from Alan Roses, *Nature Reviews Drug Discovery*, and the U-M Center for the Discovery of New Medicines presentation by Rick Neubig.

Additional Resources

- **[Assay Guidance Manual:](#)** This book provides guidance to investigators who are interested in developing assays useful for evaluating collections of molecules in order to identify probes that modulate the activity of biological targets, pathways, and cellular phenotypes.

- **[National Center for Advancing Translational Sciences (NCATS) Rescuing and Repurposing Drugs](#)**: This initiative focuses on small molecules previously shelved from further development and on identifying new purposes for drugs that are FDA approved to treat one disease or condition.

- **[NCATS Tissue Chip for Drug Screening](#)**: A collaboration among NIH, the Defense Advanced Research Project Agency and the FDA that aims to help scientists more accurately predict therapeutic efficacy of candidate drugs.

- **[NCATS Pharmaceutical Collection (NPC):](#)** The NPC is a comprehensive, publicly accessible collection of approved and investigational molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of disease pathology and intervention.

- **[Academic Drug Discovery Consortium (ADDC):](#)** The goal of the ADDC is to build a collaborative network among the growing number of university-led drug discovery centers and programs. Their website allows scientists to exchange technical expertise on drug discovery and development strategies and form partnerships, and it serves as a repository for drug discovery events, educational material, job postings, and partnership opportunities.

- **[eMolecules:](#)** A search engine for chemical molecules and chemical suppliers.

- **[PubChem:](#)** Provides information on the biological activities of small molecules.

- **[SMARTCyp:](#)** SMARTCyp is a method for prediction of which sites in a molecule that are most liable to metabolism by Cytochrome P450.

- **[Society for Laboratory Automation and Screening:](#)** Provides a wide array of relevant education, information, innovation and access to the world's largest network of professionals focused on leveraging technology for scientific advancement.

Literature

- [Impact of High-Throughput Screening in Biomedical Research](#)
- [How Were New Medicines Discovered?](#)
- [The Influence of Lead Discovery Strategies on the Properties of Drug Candidates](#)
- [Mining for Therapeutic Gold](#)
- [Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings](#)

Funding Opportunities

U-M

- [MICHR Pilot Grant Program Translational Technology Seed Grant](#)
- [Center for the Discovery of New Medicines Funding Opportunities](#)

NIH

- [Development of Assays for High-Throughput Screening for Use in Probe and Pre-therapeutic Discovery (R01)](#)
- [Solicitation of Assays for High Throughput Screening (HTS) to Discover Chemical Probes (R01)](#)
- [Solicitation of Validated Hits for the Discovery of in vivo Chemical Probes (R01)](#)
- [Solicitation of Assays for High Throughput Screening (HTS) to Discover Chemical Probes (R21)](#)
- [High Throughput Screening (HTS) to Discover Chemical Probes (R03)](#)
- [High Throughput Screening (HTS) to Discover Chemical Probes (X01)](#)
- [NCATS New Therapeutic Uses Funding Information](#)

> "Academic drug discovery is taking on a whole new character now, with technology and new partnerships between academia and industry and disease institutes and the government."
>
> - James Inglese, NCATS, *Drug Discovery and Development: A Complex Team Sport*

Protocol Development

Every clinical trial requires a detailed document – a clinical trial protocol – describing how the study will be conducted. It contains much more information than the methods section from your grant and is a critical part of any well-structured study.

A clinical trials protocol is a detailed action plan that outlines how your study will be conducted. The purpose of the protocol is to ensure the safety of your study participants and protect the integrity of the data you collect. Protocols need to be approved by the IRB and may be required to be uploaded to ClinicalTrials.gov.

Effectively written protocols will:
- Provide critical background information about the study
- Specify study objectives, statistical methods and outcomes
- Describe in detail the study design and organization
- Ensure that study procedures are conducted in a consistent manner

A protocol includes detailed information about your objectives, study design, methodology (including inclusion and exclusion criteria), investigational product information, statistical methods, and data safety monitoring plans. Study sponsors and IRBs will have protocol templates that you will need to follow. Check with your department or Clinical Trial Support Unit (CTSU) for the template you should use.

NIH Required Protocol Sections

Title Page (including version and dates, sponsor name, monitor name, IND/IDE and/or IRB approval numbers	Human subjects protection plan
Précis (may include a list of abbreviations)	Privacy and confidentiality plans
Table of contents	Study agents/interventions
Background	Reporting requirements for adverse events
Study Objectives (included primary and secondary objectives)	Data and safety monitoring plan
Study design and methods	Data/record management
Inclusion & Exclusion criteria	Compensation
Clinical and laboratory methods	References
Collection and storage of human specimens or data	Appendices
Statistical analysis plan	

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Learning Resources

Online Training

- ClinicalTrials.gov training:https://medicine.umich.edu/medschool/research/office-research/administration/research-training
- The Study Protocol Parts I and II:https://globalhealthtrainingcentre.tghn.org/study-protocol/
- Fundamentals of Clinical Trials: https://www.edx.org/course/fundamentals-clinical-trials-harvardx-hsph-hms214x

Protocol Templates

- NIH Protocol Template: In 2016 the NIH released a draft protocol template developed in collaboration with the US Food and Drug Administration (FDA), which will apply to NIH-funded Phase II and III clinical trials requiring investigational new drug application (IND) or investigational device exemption (IDE). The template is available in a guided .PDF format that includes instructions as well as blank template.
- National Institute of Dental and Craniofacial Research (NIDCR) Toolkit for Clinical Researchers: This resource contains protocol templates and other documents needed for study start-up.
- National Cancer Institute (NCI) Protocol Templates and Guidelines: NCI maintains an online resource of protocol templates for Phase I and II clinical trials to assist in design and development.
- The National Center for Complimentary and Integrative Health Clinical Research Toolbox: This resource includes templates, sample forms, and information materials to assist clinical investigators in the development and conduct of high-quality clinical research studies.
- Common Protocol Template from TransCelerate Biopharma, INC.: Working with industry stakeholders and regulators, TransCelerate Biopharma has created a model clinical trial protocol template that contains a common structure and model language.

Clinical Trials

No matter the size or complexity, running a clinical trial can be challenging. U-M has resources that can help along the way, including infrastructure for conducting clinical research protocols and programs that assist with participant recruitment.

A **Phase I** trial tests an experimental treatment on a small group of people, to judge its safety and side effects, and to find the correct drug dosage. Sometimes, the study is in healthy people.

A **Phase II** trial uses more people than a Phase I to find out if the experimental treatment is effective and safe.

A **Phase III** trial is usually a large study with many participants. This phase compares the experimental drug or procedure to a placebo or standard treatment to make sure it is safe and works well.

A **Phase IV** trial takes place after the U.S. Food and Drug Administration approves use of a drug. A drug's effectiveness and safety are monitored in large, diverse populations.

- NIH Medline Plus

Learning Resources

Workshops

- [Methods in Clinical Cancer Research Workshop](): An intensive workshop in the essentials of effective clinical trial designs of therapeutic interventions in the treatment of cancer. This workshop is intended for clinical fellow and junior faculty clinical researchers in all oncology subspecialties, including radiation and surgical oncology.

Human Subjects Protection

- [FDA Clinical Trials and Human Subjects Protection](): FDA regulations and guidance documents regarding good clinical practices and human subject protection.
- [Clinical Research and the HIPAA Privacy Rule](): This fact sheet discusses the Privacy Rule and its impact on covered entities that conduct clinical research.

Literature

- [The Clinical Research Team](): Developing and managing a clinical research team is essential to the success of a clinical trial.
- [Clinical Investigator Responsibilities](): When conducting a clinical trial, it is important to meet all research expectations, including Guidelines for Good Clinical Practice.
- [Learning How to Conduct Cancer Clinical Trials](): Information about a training opportunity that focuses on clinical trial design.

MICHR Resources

- **MICHR Clinical Research Unit (MCRU)**: MCRU provides the clinical staff, resources, and infrastructure necessary to conduct human clinical research protocols at the University of Michigan. MCRU hosts investigators funded by federal, state, and local agencies as well as those funded by the private sector. MCRU also serves as an institutional resource for investigators to perform pilot studies that may result in further agency funding.

- **MICHR Clinical & Health Recruitment Program**: The MICHR Recruitment Program provides expertise, tools, and resources to facilitate participant recruitment in clinical and health research studies.

- **UMHealthResearch.org**: UMHealthResearch.org (previously UMClinicalStudies.org) is an innovative tool that connects research study teams to interested study participants. Study teams may query the database to specific inclusion/exclusion criteria based on participants' profile responses. Potential participants may review active study postings to assess their level of interest.

- **MICHR Recruiting Toolkit**: The information and resources provided in this toolkit are designed to help you and your team plan for and execute many of the key communication tactics needed to support your clinical study, specifically volunteer recruitment and publicity of study results.

- **MICHR Biostatistics Group**: This team provides state-of-the-art knowledge, service, education, and methodology in the areas of biostatistics and outcomes measurement.

- **MICHR Clinical Trials Office (MCTO)**: MCTO supports faculty with the pre-award phase of industry-sponsored clinical trials.

- **MICHR Study Coordinator Training**: Tools, resources, education, and networking opportunities are available for study coordinators.

- **MICHR Clinical Research Monitoring**: MICHR's Monitoring program is committed to providing services for all IND/IDE investigator-initiated clinical trials as well as support for industry clinical trials as needed.

U-M Resources

- [U-M Comprehensive Cancer Center Clinical Trials and Research](): Helpful videos provide an introduction to clinical trials and information on participating in clinical trials and the informed consent process.

- [U-M Comprehensive Cancer Center Clinical Trials Office (CTO)](): The CTO serves as the centralized core facility for all clinical research trials conducted by investigators at the University of Michigan Comprehensive Cancer Center (UMCCC).

- [Ravitz Foundation Phase 1/Translational Research Center](): This facility offers a comprehensive array of translational research resources to Cancer Center faculty and investigators at other academic institutions and pharmaceutical and biotechnology companies. The center is open to trials for all types of cancer.

Additional Resources

- [ClinicalTrials.gov](): This is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

- [CenterWatch:]() The CenterWatch mission is to be the leading source of clinical trials information for clinical research professionals and patients.

- [Researchmatch](): Researchmatch is a free and secure registry aimed at both people who are trying to find research studies and researchers who are looking for people to participate in their studies.

"Developing and maintaining an exemplary research team is essential to the success of a quality clinical research program. Functions such as regulatory compliance, protocol maintenance, patient care, tissue acquisition and transmittal, data collection and submission and general administration are among the many tasks on which quality research, protection of human subjects' rights, and advancement of science depend. No single individual could expect to fulfill all of these tasks."

- Allison Baer, *The Clinical Research Team*

Regulatory Support

Investigators need to meet numerous regulatory requirements when initiating a clinical trial. These resources will help you properly adhere to regulatory obligations so you can focus on translating your findings to the clinic.

Learning Resources: IND, IDE and IRB Information

- **Investigational New Drug (IND) Screencasts**: From the Duke Translational Medicine Institute, this is a series of recorded segments on topics relevant to IND Best Practices for Initial Submission and Maintenance.
- **Investigational Device Exemption (IDE) Video**: From the Duke Translational Medicine Institute, this video contains information about best practice for preparation and maintenance of an IDE.
- **FDA IND application**
- **FDA IDE approval process**
- **FAQs about Drug Studies (IND): Children's Hospital Boston-Translational Research Program**
- **FAQs about Medical Device Studies (IDE): Children's Hospital Boston-Translational Research Program**
- **IRB FAQs**: Information sheet providing guidance for IRBs from the FDA.

MICHR Resources

- **MICHR IND/IDE Investigator Assistance Program (MIAP):** The MIAP program was established to provide comprehensive regulatory support, guidance, and education services to faculty investigators involved in FDA-regulated clinical research at U-M. MIAP's primary focus is regulatory assistance to sponsor-investigators of a drugs, biologics, or medical devices.
    - **Responsibilities of IND/IDE Sponsor Investigators**
    - **IND Decision Worksheet**
    - **IDE Decision Worksheet**
- **Navigating the Regulatory Environment at U-M**: A blended learning workshop for faculty and postdoctoral fellows who are new to U-M or new to clinical or translational research at U-M.

U-M Resources

- **Institutional Review Boards of the University of Michigan Medical School (IRBMED)**: IRBMED is charged with protecting the rights and welfare of participants in clinical trials and other human subjects research studies. IRBMED is responsible for monitoring compliance with federal and state laws, university policies, and ethical principles (particularly those articulated in the Belmont Report).

    - **IRBMED Educational Materials**: The University of Michigan's IRBs are committed to providing educational materials online, as well as in the classroom. The presentations provided address topics relating both to ethics in human subjects research and to IRB procedures.
    - **Informed Consent Template**

- **University of Michigan Regulatory Affairs**: The UMMS Office of Regulatory Affairs works to build and maintain a strong foundation of regulatory good-standing upon which the Medical School's missions can flourish. Their mission is to lead or facilitate the prevention or resolution of concerns, disputes, and compliance issues related to laws, regulations, institutional policies, accreditation/certification requirements, and other professionally accepted standards that impact the activities and reputation of the Medical School.

Tip

You may feel intimidated by the thought of meeting with the FDA to discuss the regulatory strategy for your drug or device. These meetings require careful planning and implementation. The MICHR MIAP team has extensive experience guiding meetings with the FDA and assists with all preparation and follow-up.

Clinical Data Management

The data you generate during a clinical trial needs to be reliable and statistically sound. Adhering to quality standards and practices as you collect, clean and manage your data will help ensure confidence in your conclusions.

Learning Resources

- Video Resources on Data Management from the Colorado Clinical & Translational Sciences Institute

    - Managing your research data
    - Why not use excel for data management?
    - Care and feeding of your grant: Part 1
    - Care and feeding of your grant: Part 2

- Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule
- FDA 21 CFR Part 11: FDA guidelines on electronic records and signatures.
- Guidelines for Good Clinical Practice: International Conference on Harmonisation

Tip

Include a clinical data manager on your multidisciplinary clinical trial team. This person will provide expertise in all phases of your trial, including setup, conduct, and closeout.

MICHR Resources

- MICHR Project Database Design and Implementation: Skilled study developers and data management mentors work in partnership with study data managers and other clinical research professionals to design project databases built for efficient collection, management, and analysis of research data.
- MICHR Clinical Research Informatics: This team develops, enhances, and supports multiple clinical research IT applications. They are responsible for several initiatives that have the potential to transform U-M's clinical and translational research mission, including REDCap, OpenClinica Enterprise, UMClinicalStudies.org, TATUM, and the Research Participant Scheduling Portal.
- REDCap training opportunities.

Entrepreneurship & Commercialization

Entrepreneurship & Commercialization

It's never too early to start thinking about the steps involved in translating your research findings to a commercial product. We highlight resources at U-M and in the state of Michigan that can offer you guidance.

Learning Resources
Clinical and Translational Science Institute of Southeast Wisconsin

The path from discovery to commercialization can be long. These training modules provide an introduction to the technology transfer process

- When is something of commercial value?
- How do I document discoveries?
- What is the patenting process?

U-M Resources

- Tech Transfer: The tech transfer team offers a full set of services to ensure effective technology transfer, including disclosure facilitation, patenting and other protections, start-up assistance, licensing, legal support, and decision support.

- Michigan Venture Center: The Venture Center's staff of experienced business formation professionals works with U-M inventors, entrepreneurs, market experts, and investors to create and develop new high growth venture concepts.

- Fast Forward Medical Innovation (FFMI): Part of the U-M Office of Research, FFMI works to accelerate biomedical innovation and commercialization in diagnostics, therapeutics, devices, and healthcare IT. With the ultimate goal of impacting patient health, FFMI supports research at its inception, collaborates with commercial partners via novel methods, and enhances medical education by fostering innovation and entrepreneurship at all levels.

    - FFMI Commercialization Education

U-M Resources

- **College of Engineering Center for Entrepreneurship (CFE):** The CFE offers educational programs focused on entrepreneurship. They help students launch their own ventures through mentorship, micro-grants, networking opportunities, and office space in addition to coordinating entrepreneurial experience trips.
    - **Michigan I-Corps:** Michigan I-Corps, offered by CFE, is a statewide program designed to foster, grow, and nurture a statewide innovation ecosystem. Through partnerships between the National Science Foundation (NSF), Michigan universities, Michigan SmartZones, and venture capital and entrepreneurial communities, Michigan I-Corps has created an opportunity for teams throughout the state to turn technology into commercial opportunities.
    - **TechArb:** A joint program between CFE and Zell Lurie Institute for Entrepreneurial Studies, the TechArb program empowers U-M students to bring their ideas to life and build viable ventures in an intensive hands-on entrepreneurial education experience.

Additional Resources

- **SPARK Business Accelerator:** The mission of the SPARK Business Accelerator program is to create a dynamic environment of entrepreneur-driven innovation within the Ann Arbor region by facilitating the commercialization of technology-based products and services.
- **MichBio:** As the association for Michigan's biosciences community, MichBio promotes cooperation between Michigan's bioscience-related businesses, forges stronger relationships, develops business-to-business opportunities, and serves as a united industry voice to promote a science-friendly environment.
- **Michigan Venture Capital Association (MVCA):** The MVCA consists of firms and professionals dedicated to the development, growth, and sustainability of Michigan's venture capital industry.
- **BBC Entrepreneurial Training and Consulting:** BBC assists clients with technology assessment, commercialization planning, pre- and post-award SBIR/STTR grant assistance, entrepreneurial training, grants/contracts management, and tech-based economic development programs.

Additional Resources

- **Michigan Economic Development Corporation (MEDC):** MEDC is a public-private partnership serving as the state's marketing arm and lead agency for business, talent and jobs, tourism, film and digital incentives, arts and cultural grants, and overall economic growth. MEDC offers a number of business assistance services and capital programs for business attraction and acceleration, economic gardening, entrepreneurship, strategic partnerships, talent enhancement, and urban and community development.

- **Great Lakes Entrepreneur's Quest:** The Great Lakes Entrepreneur's Quest is an engine for the formation of new, high-growth companies in Michigan. The mission of GLEQ, and its business plan competition, is to continually encourage and educate entrepreneurs on the creation, start up, and early growth stages of high-growth businesses within the state of Michigan.

Funding Opportunities

- **U-M MTRAC:** A part of the Medical School's Strategic Research Initiative, U-M MTRAC provides translational research funding and resources to identify, nurture, and "fast forward" projects with a high potential of commercial success.

- **Michigan Initiative for Innovation and Entrepreneurship (MIIE):** The MIIE houses a Technology Commercialization fund that provides gap funding to help launch university spin-off companies and a Talent, Innovation & Entrepreneurship Education Fund that promotes an entrepreneurial risk-taking culture and provides experiential learning opportunities.

- **Michigan Emerging Technology Fund:** Provides commercialization funding to match federal Small Business Innovation Research and Small Business Technology Transfer awards for technology-based Michigan companies.

- **Accelerate Michigan Innovation Competition:** This is an international business competition designed to bring together later stage entrepreneurial companies with local, national, and international investors.

- **NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs:** These programs fund small business early stage R & D. The PI of the SBIR must have greater than 50% employment with the small business.

Additional Research Support

Resource Sharing

The sharing of scientific resources is essential in an environment where investigators are challenged to do more with less. These resources will help you find many tools, from chemical probes to plasmids.

- [Eagle-i](): Free web-based app to discover resources at a growing network of universities. There are currently 26 institutions in the eagle-I network, but anyone, regardless of affiliation, is welcome to search for resources.
- [NCI Clinical Center Collaborations & Assets:]() This site illustrates the special resources at the NIH Clinical Center and provides information about potential opportunities for collaboration.
- [NCATS Pharmaceutical Collection:]() The NCATS Pharmaceutical Collection (NPC), also known as the NIH Chemical Genomics Center (NCGC) Pharmaceutical Collection, is a comprehensive, publicly accessible collection of approved and investigational molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of disease pathology and intervention.
- [Bridging Interventional Development Gaps:]() Led by the NCATS Division of Pre-Clinical Innovation, BrIDGs makes available, on a competitive basis, certain critical resources needed for the development of new therapeutic agents. Successful applicants receive access to NIH contractors who conduct preclinical studies at no cost to the investigator. In general, synthesis, formulation, pharmacokinetic, and toxicology services in support of investigator-held investigational new drug (IND) applications to the FDA are available.
- [NIH Molecular Libraries:]() The Molecular Libraries Screening Centers Network (MLSCN) is a national high-throughput biological screening resource that was launched on June 15, 2005. The goals of the MLSCN are to expand the availability and use of chemical probes to explore the function of genes, cells, and pathways in health and disease and to provide annotated information on the biological activities of compounds contained in the central [Molecular Libraries Small Molecule Repository]() in a public database ([PubChem]()).
- [Addgene](): A non-profit plasmid repository dedicated to helping scientists around the world share high-quality plasmids.
- [CTSA Tool Shop Webinars](): This webinar series focuses on a single tool each session, highlighting its features and benefits and how it can be transported and installed at another site.

U-M Core Services

It is impossible to be an expert in everything. U-M has numerous core services that provide the equipment and the know how for achieving your scientific goals.

U-M Core Services

- [Core Facilities:](#) The U-M Office of Research provides a comprehensive table of the U-M cores available to investigators.

> **Tip**
>
> The MICHR Pilot Grant Program has a Translational Technology Seed Grant that provides vouchers for core service support. Visit the [MICHR Pilot Grant Program](#) website for eligibility information.

U-M Seminars

Attending seminars is a great way to network and stay apprised of the latest research. Although not a comprehensive list, we highlight several standing U-M clinical research seminars.

U-M Clinical Seminars

- [Frontiers in Cardiovascular Medicine](#)

- [Department of Internal Medicine Medical Grand Rounds](#)

- [Department of Psychiatry Grand Rounds](#)

- [OBGYN Grand Rounds](#)

- [Department of Radiology Grand Rounds](#)

- [Pediatrics & Communicable Diseases Grand Rounds](#)

- [Comprehensive Cancer Center Grand Rounds](#)

- [Kellogg Eye Center Grand Rounds](#)

Attending seminars may not always be a priority, but their benefits can be far-ranging and include:

- Guidance for solving your own scientific challenges
- Learning about new techniques and procedures
- Opportunities for networking
- Exposure for you and your research
- Improving communication skills through asking questions and participating in discussions

- NIH Office of Intramural Training and Education

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While MICHR takes full responsibility for any shortcomings with the toolkit, we cannot take responsibility for any of its successes. Those successes are yours.

This is a working prototype.
To give feedback for the next edition of this toolkit and to let us know what you found useful, please email michr-rdc@umich.edu.

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