

# TRANSLATIONAL RESEARCH Town Hall

Friday, November 11, 8-9 a.m.  
Ford Auditorium, University Hospital

A light breakfast will be provided at 7:30 a.m.

Discuss the state of translational  
research and learn about the many  
services and resources available to  
research teams across U-M

**George A. Mashour, MD, PhD**



RSVP: <http://umhealth.me/trtownhall>

Executive Director, Translational Research (U-M Office of Research)  
Executive Director, Michigan Institute for Clinical & Health Research (MICHHR)  
Associate Dean for Clinical & Translational Research (Medical School)  
Bert N. La Du Professor & Associate Chair of Anesthesiology Research

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RESEARCH

Town Hall

# Welcome

George A. Mashour, MD, PhD

Executive Director, Michigan Institute for Clinical & Health Research

Executive Director, Translational Research (Office of Research)

Associate Dean for Clinical & Translational Research (Medical School)

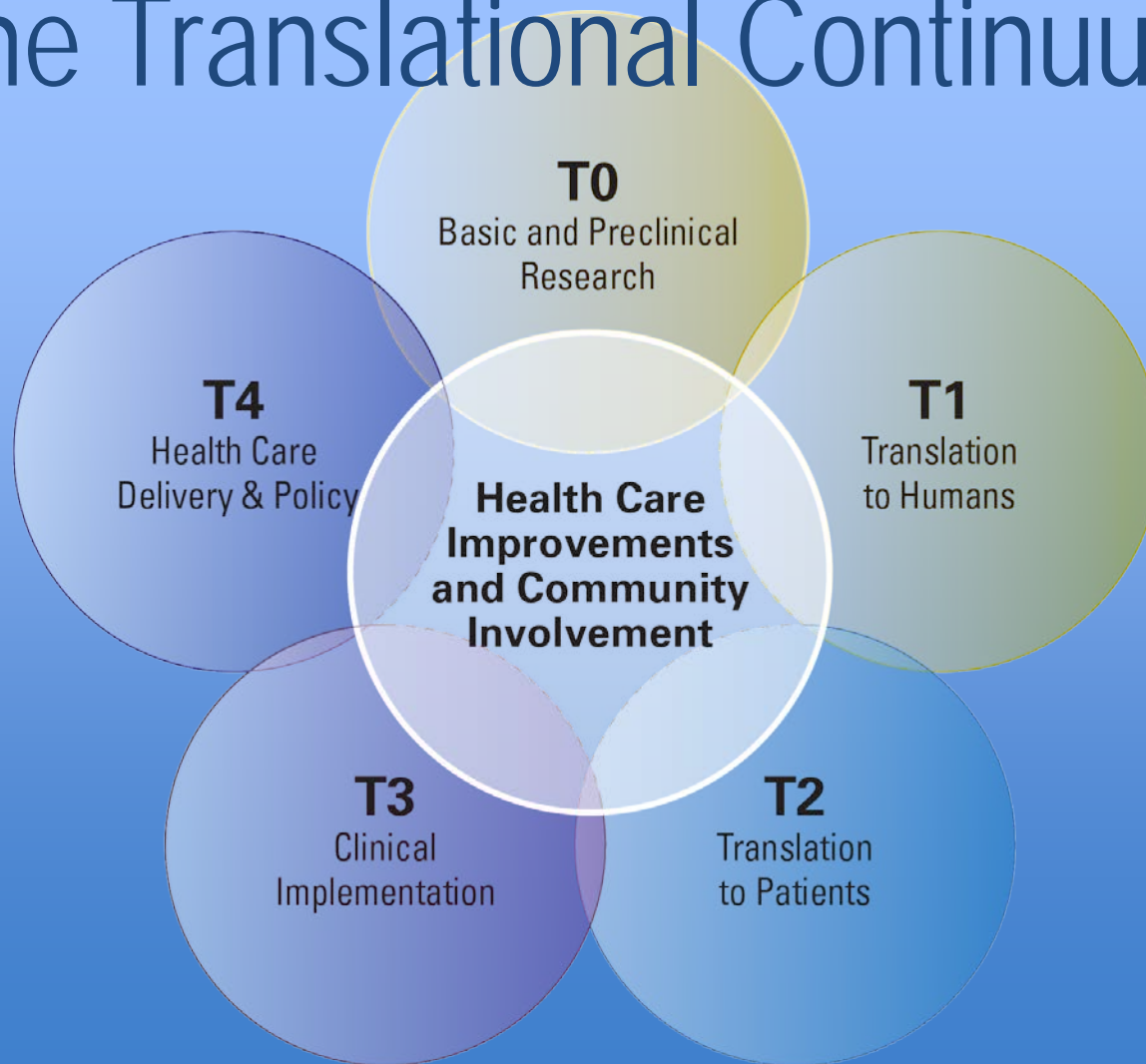
Bert N. La Du Professor & Associate Chair of Anesthesiology Research



# Outline

- The translational research continuum
- Moving through the continuum at U-M
- Support across the continuum
- Discussion

# The Translational Continuum



# The Translational Continuum



**T0**

- Basic Science Departments
- Life Sciences Institute
- Center for the Discovery of New Medicines
- Engineering

**T1**

Clinical Research  
Network

**T2**

**T3**

- Institute for Healthcare Policy & Innovation
- Institute for Social Research
- School of Public Policy

**T4**

Community & Industry Partners



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# Town Hall

**M** | LIFE SCIENCES INSTITUTE



**M** UNIVERSITY OF MICHIGAN

# Current Faculty Landscape

23

## TENURED / TENURE-TRACK FACULTY

11

Research Professors

8

Research Associate Professors

3

Research Assistant Professors

1

Professor Emerita

10

American Association for the Advancement of Science Fellows

5

U-M Medical School Distinguished Faculty Lectureship in Biomedical Research Awardees

5

National Academy of Medicine

4

Pew Biomedical Scholars

3

Howard Hughes Medical Institute Investigators

3

National Academy of Sciences

# Overview

## 22 Faculty Labs

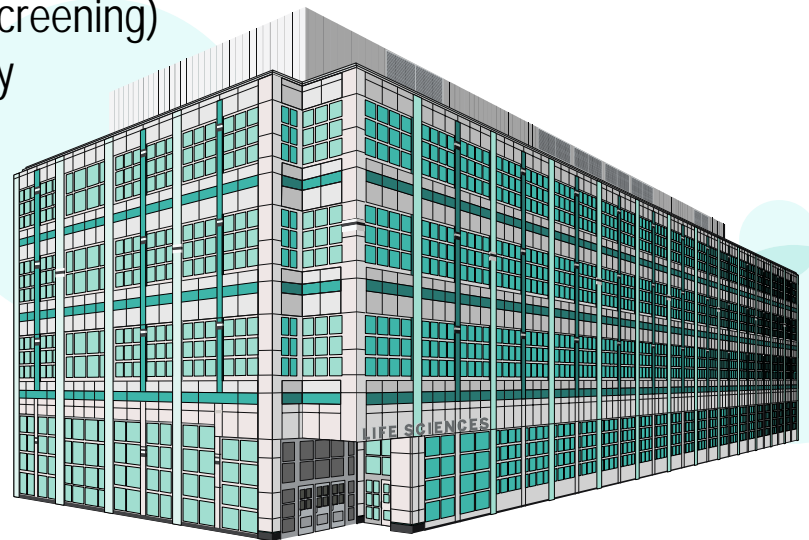
- Faculty hold joint appointments at Medical School, LSA, and Pharmacy

## Two core facilities available to U-M PIs

- Center for Chemical Genomics (high-throughput screening)
- Center for Structural Biology (X-ray crystallography & protein production)

## Administrative home to:

- Program for Chemical Biology (PhD / MS)
- Center for the Discovery of New Medicines (grants and mentoring for drug discovery projects)





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OFFICE OF RESEARCH

UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

# Overall Objective of Transformation

- Elevate quality of clinical trials across UMHS
  - ↑ Impact
  - ↑ Efficiency
  - ↓ Cost & liability
- Facilitate new collaborations across specialties



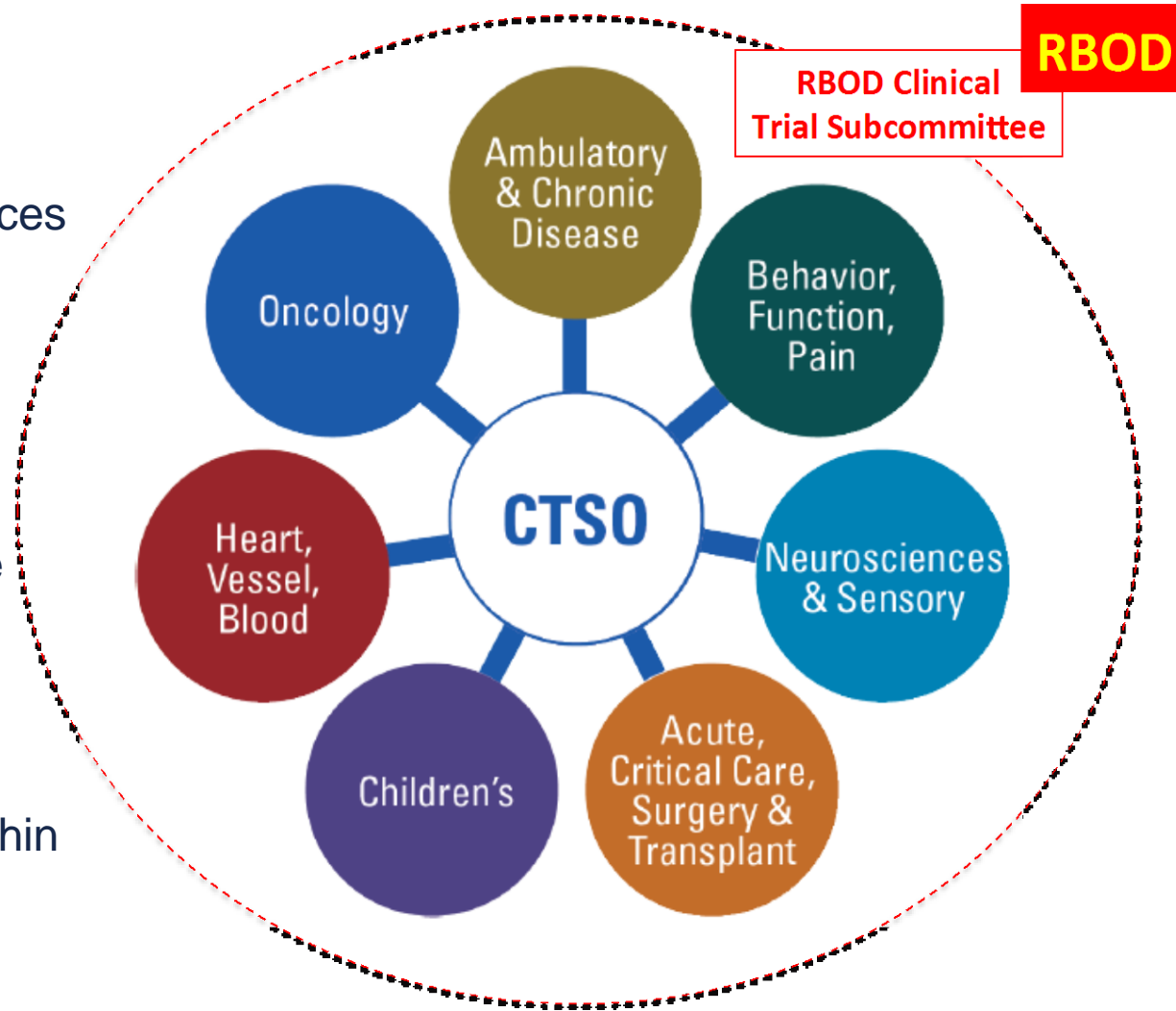
# UMHS Enterprise Goal & Strategies

Create the new knowledge needed to improve clinical care, value, and health outcomes by successfully executing a diverse portfolio of high-quality clinical trials

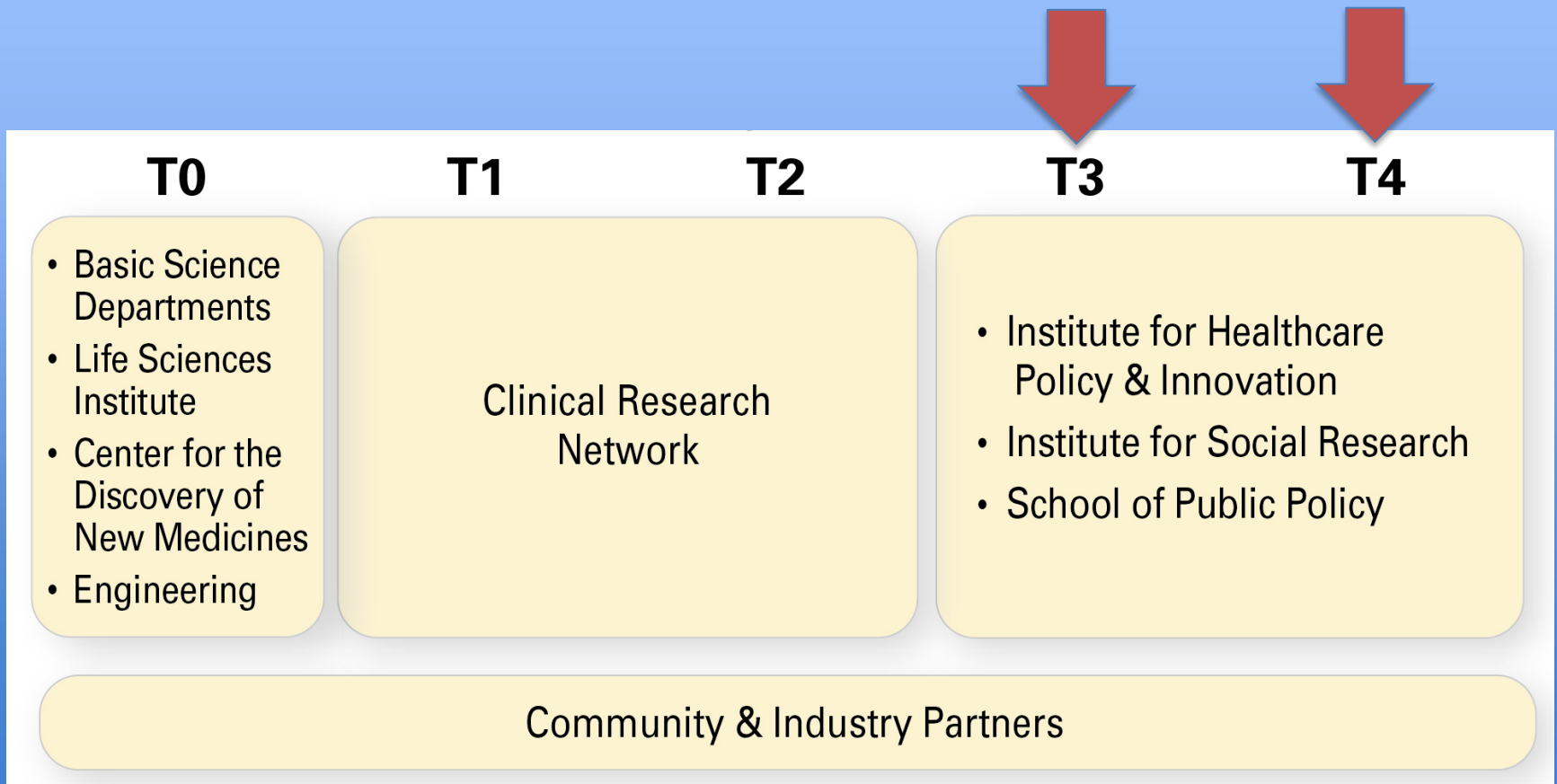
- Strategy 1:** Foster an UMHS culture that values, rewards, and supports clinical trial activities
- Strategy 2:** Develop a coordinated, sustainable infrastructure that supports operational excellence throughout the life cycle of clinical trials
- Strategy 3:** Develop a highly trained, innovative, motivated, and skilled workforce, including those who initiate and those who conduct clinical trials
- Strategy 4:** Translate U-M discoveries into clinical trials
- Strategy 5:** Fully integrate the clinical trials enterprise and the clinical care delivery system
- Strategy 6:** Demonstrate the value of clinical trials to patients, families & society

# Clinical Trial Infrastructure

- Clinical Trials Support Units (CTSUs) are regional, trans-departmental clinical trial offices
- Science determines which CTSU faculty use
- CTSUs may vary in size, structure, and scope
- Common, standardized base services provided
- Transparent performance metrics
- All clinical trials will occur within the system by January 2018



# The Translational Continuum





# Institute for Healthcare Policy & Innovation



# Mission and Priority Themes

Improving quality, safety, equity, affordability



Promote greater value in healthcare



Improve health of communities



Evaluate impact of healthcare reform

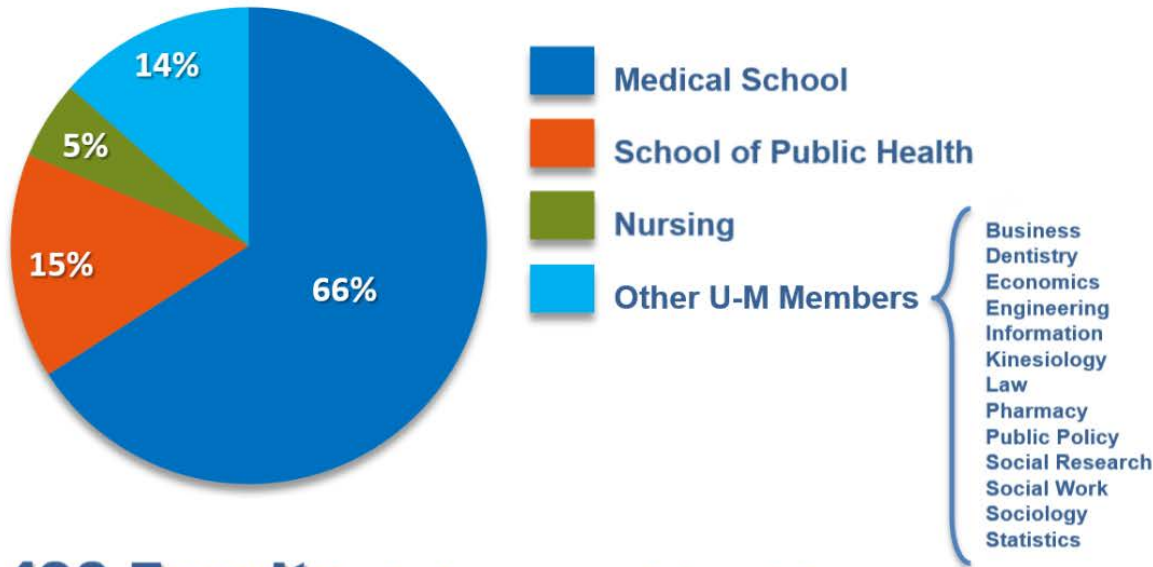


Innovate in healthcare delivery



# MEMBERSHIP

## *A Coalition of the Willing*



Health services & health care policy researchers evaluating how health care works & how it can be improved, & advising policy makers to inform change.

**Active research award portfolio of over \$700M, \$144M spend in FY16**

**490 Faculty** w/primary appointments in:

- 13 U-M Ann Arbor Schools & Colleges
- 2 U-M Ann Arbor Institutes (ISR & IRWG)
- 2 U-M Flint & Dearborn Schools & Colleges



# Research Centers & Programs

## CanSORT

Cancer Surveillance  
& Outcomes  
Research Team

## CHCR

Center for Health  
Communications  
Research

## V-BID

Center for  
Value-Based  
Insurance  
Design

## IHPI CSP

IHPI Clinician  
Scholars  
Program

## MPOG

Multicenter  
Perioperative  
Outcomes Group

## CMCD

Center for  
Managing  
Chronic Disease

## CBSSM

Center for Bioethics and  
Social Sciences  
in Medicine

## CHEPS

Center for Healthcare  
Engineering and  
Patient Safety

## CHEAR

Child Health  
Evaluation and  
Research Unit

## Injury Center

## PSEP

Patient Safety  
Enhancement  
Program

## MHSOT

Mental Health  
Services, Translation,  
and Outcomes  
Program

## CODA

Center for  
Clinical Outcomes  
Development  
& Application

## CHOP

Center for  
Healthcare Outcomes &  
Policy

## DOW UHSR

Dow Division for  
Urologic Health  
Services Research

## KECC

Kidney Epidemiology  
and Cost Center

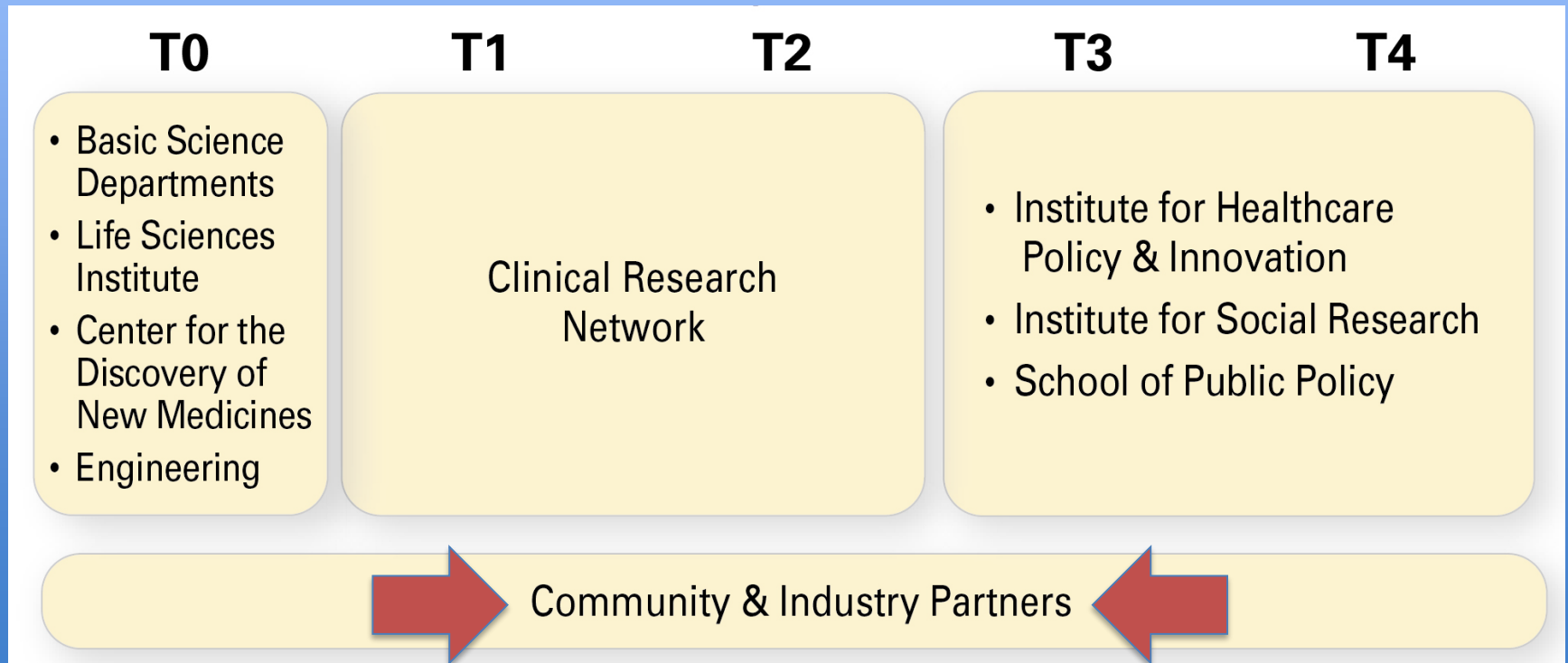
## PWHER

Program on  
Women's Healthcare  
Effectiveness  
Research

## VA CCMR

VA Center  
for Clinical  
Management  
Research

# The Translational Continuum





*Funding  
and  
Mentors*



Create the  
**INNOVATION  
NAVIGATOR**

*Create a Culture of  
Commercialization and  
Entrepreneurship*



Building Novel  
**EXTERNAL  
PARTNERSHIPS**

*Industry  
Partnership  
and  
Collaboration*



Commercialization  
**EDUCATION**



# FFMI Program Mission



*Helping the U-M  
Biomedical  
Research  
Community  
Accelerate  
Ideas to Impact*





## **Funding & Mentorship**

- Idea Consultation
- MTRAC State-Wide Hub
  - Mi-Kickstart (early)
  - Mi-MTRAC (mid-stage)
- Targeted
  - GI, TBI, Therapeutic, Sleep, partnered with departments, centers
- Monroe-Brown Seed Fund (for U-M start-ups)



## **Business Development**

- Industry partners
- Relationship management
- Creative contracts
- Hosting visits



## **Educating Future Innovators**

- Faculty, post-docs, graduate & med students
- Early Tech Development Course
- PACE: Program Accelerating Commercialization Education
- Innovation & Entrepreneurial Path of Excellence
- Scale up nationally through CTSA network

# Key Product Verticals

Guided by Faculty Champions and Innovation Chiefs from each Med School department, center, and institute

## THERAPEUTICS



Mike Holinstat, PhD  
Pharmacology,  
Cardiovascular Medicine

## DEVICES



Dan Orringer, MD  
Neurosurgery

## DIAGNOSTICS



Tim Cornell, MD  
Pediatric Critical Care

## HEALTH IT/ DIGITAL MEDICINE



Sinan Baran, MD  
Psychiatry



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# UMOR and Innovation

University of Michigan Office of Research



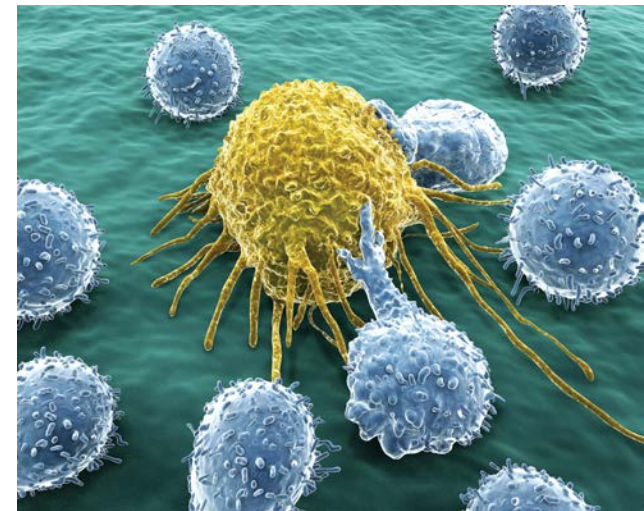
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UNIVERSITY OF MICHIGAN



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# U-M Office of Research (UMOR)

- Foster New Research
- Build Partnerships
- Negotiate Research Contracts
- Oversee Ethics and Compliance
- Set Research Policy
- Manage Tech Transfer
- Advocate for Research





# Business Engagement Center

- Coordinates with outreach across all three campuses
- 1,200 on-going relationships
- 1,255 meetings with industry





# Tech Transfer

- 428 invention disclosures
- 135 patents issued
- 173 licenses
- \$23 million revenues
- 12 start-ups
- Average of 1 startup/month for last ten years



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# Town Hall



MICHR

MICHIGAN INSTITUTE FOR  
CLINICAL & HEALTH RESEARCH  
UNIVERSITY OF MICHIGAN



UNIVERSITY OF MICHIGAN





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- The Michigan Institute for Clinical & Health Research (MICHR) is here to enable & enhance clinical & translational research at the University of Michigan
- We do this by being a catalytic partner that educates, funds, connects & supports research teams here and beyond





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*Accelerating Discoveries Toward Better Health*

**CTSA** Clinical & Translational  
Science Awards

**M** | MICHR

CELEBRATING 10 YEARS

- MICHR was created in 2006, awarded a \$55M CTSA grant from the NIH in 2007, and renewed in 2012
- Part of a consortium of 62 CTSA institutions *working together to accelerate discoveries toward better health*



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# 170

- Unique U-M departments/divisions MICHR serves across campus, representing support provided to 20 different schools, colleges, and institutes





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# 900

- Average number of investigators MICHHR serves each year

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educate • **fund** • connect • **support**

**consultation** • education & mentoring

**funding & grant support** • engaging

communities • participant recruitment •

**study preparation** • **clinical research**

**services** • **regulatory support** •

**informatics** • **research management**





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# Educate

- Education & Mentoring
  - Degree/Certificate Programs
  - Mentored Research Programs
  - Education & Training Initiatives

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH

## Education & Mentoring

**MICHR'S EDUCATION TEAM PROVIDES ENGAGING AND EFFECTIVE EDUCATION, CAREER DEVELOPMENT, & MENTORING PROGRAMS.**

**Degree/Certificate Education Programs**

- One-year master's degree in clinical research (MSCR) for students in professional degree programs
- Nine credit hour Translational Research Education Certificate (TREC) for PhD students in basic sciences

**Mentored Research Programs**

- Postdoctoral Translational Science Program (PTSP) for PhDs in basic sciences
- MICHR K Career Development Award for clinicians
- Practice-Oriented Research Training (PORT) program for allied health professionals wishing to acquire research skills
- Summer Immersion Program with a focus in either health disparities or clinical research

**Education and Training Initiatives**

- Study coordinators
- Workshops





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# 1,200

- Annual attendees at MICHR education & mentoring workshops, webinars, and seminars



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# 97%

- Graduates who remain in clinical and translational research after completing the MICHR KL2 program



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# Fund

- Research Development Core
  - Expert consultation
  - Grant editing assistance

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## Research Development Core (RDC)

THE RESEARCH DEVELOPMENT CORE (RDC) PROVIDES FREE IN-PERSON CONSULTATIONS WITH FACULTY AND GRANT EDITING ASSISTANCE TO STRENGTHEN RESEARCH IDEAS AND GRANT PROPOSALS

- RDC provides expert feedback on specific aims, study design, and biostatistics
- RDC matches your research ideas with funding sources and helps you connect with potential collaborators, mentors, and resources
- RDC advises on future research and career directions
- RDC grant editing helps you polish your proposal before submission

Contact RDC at michigan.edu to schedule a consultation or grant review.

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# 934

- Research development consultations and grant editing services provided to investigators since 2007



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# Fund

- Pilot Grant Program
  - Funds translational research to promote development of novel solutions that improve patient and community health outcomes

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH  
**Pilot Grants**

MICHR'S PILOT GRANT PROGRAM PROVIDES FUNDING FOR CLINICAL AND TRANSLATIONAL RESEARCH TO PROMOTE THE DEVELOPMENT OF NOVEL SOLUTIONS THAT WILL ULTIMATELY IMPROVE PATIENT AND COMMUNITY HEALTH OUTCOMES.

- Faculty from all schools and colleges are eligible to submit applications for novel research that spans the translational spectrum from discovery to practice to policy.
- Several funding mechanisms offered, from \$5,000 seed grants to larger two-year awards.
- Two funding cycles per year for most opportunities.
- To date, MICHR has awarded more than \$19M in pilot grants, which has led to over \$204M in extramural funding.

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# \$21M

- Amount MICHR has awarded in pilot grants to U-M investigators, resulting in more than **\$217M** in extramural funding



# What is MCubed?

Rapid distribution of seed funding to self-organized, multi-unit faculty/student teams to initiate innovative projects

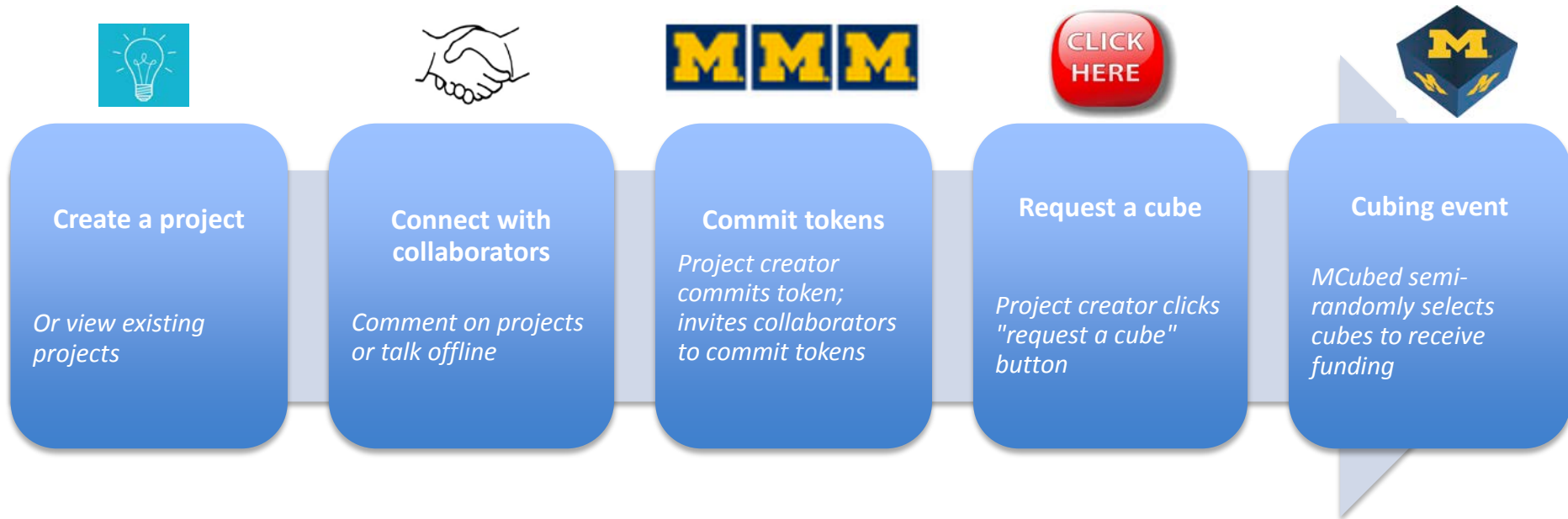


# Mcubed

- 459 new projects funded
- 1,300 faculty from all schools
- 75% first-time collaborations
- \$60 million in new external grants
- Student involvement is key



# How to form a cube





# M | A. ALFRED TAUBMAN MEDICAL RESEARCH INSTITUTE



Founded in 2007 to provide U-M clinician-scientists with unrestricted funds for translational research

## Nearly 40 faculty have received one of the following grants:

- Taubman Scholar (senior professors): \$150K/yr. for three yrs.
- Emerging Scholar (assistant professors): \$200K over 5 yrs., funded by individual donors

## Scholar accomplishments:

- 14 Startups
- 106 Patents
- 309 Grants
- Numerous collaborations nationally and internationally
- 72 Clinical Trials
- 1,800+ Publications (2012-16)

Annual \$100K Taubman Prize recognizes clinician-scientists outside U-M

# Shift to Team Science

New emphasis on large-scale, multi-disciplinary, multi-investigator projects

- Phase 1 Innovation Grants: \$200K
- Phase 2 Multi-Year Grants: Up to \$5M over 5 yrs.
- Initial projects to be led by Taubman Scholar
- Desired outcome: Change in medical practice
- Teams must include investigators from at least two departments
- Co-investigators can be PhDs
- Teams should include early-career clinician-scientists







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# Connect

- Community Engagement
  - Developing community-university partnerships
  - Creating research training opportunities for communities

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH

## Community Engagement



COMMUNITY ENGAGEMENT (CE) AIMS TO MEET THE NEEDS OF THE UNIVERSITY OF MICHIGAN AND OUR COMMUNITY PARTNERS. CE IS A COMMUNITY ENGAGEMENT PROGRAM WITH THE FOLLOWING GOALS:

- Develop long-standing, collaborative, and equitable community-university research partnerships with community-based organizations and practice-based research networks
- Create and test new innovative methods for Community engagement and practice-based research
- Enhance infrastructure and tools to support community-university research partnerships
- Create educational and training opportunities that promote bi-directional knowledge flow
- Provide regional and national leadership to help ensure bi-directional community-university research partnerships
- Address community research priorities and perform clinical, translation, and effectiveness research

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# 75

- Training events for 1,500 participants on community-engaged research have been held by MICHR in the past five years



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# Connect

- Study Participant Recruitment
  - UMHealthResearch.org website
  - >100,000 people clicked, “I am interested” in health research
  - >100,000 secure messages sent within the site
  - >2,300 studies posted since 2007





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# 26,000

- Volunteers registered to participate in studies in [UMHealthResearch.org](https://UMHealthResearch.org)





“

*It's not that often in life that you can impact someone's life for the better. Maybe this is how I can make a difference.*

**WHAT'S YOUR REASON FOR PARTICIPATING IN HEALTH RESEARCH?**

Find a study by topic or condition

Search

[More search options](#)

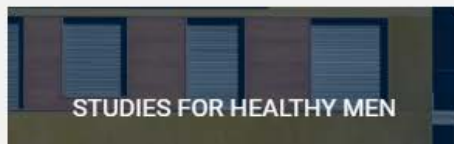
**26,279**

**VICTORS** are already making a difference in health research

[Sign up](#)

for yourself or a loved one to get personalized study recommendations. [Tell me more](#)

### Highlighted searches





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# Support

- Michigan Clinical Research Unit (MCRU)
  - Facilities in CVC, Domino's Farms
  - Medical assistants, dietitians, lab personnel
  - Specimen collection, processing, and shipping
  - MCRU2U mobile team

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH  
**MCRU**

THE MICHIGAN CLINICAL RESEARCH UNIT (MCRU) IS HERE TO SUPPORT HUMAN CLINICAL RESEARCH PROTOCOLS WITH SERVICES INCLUDING:

- Extended stay and outpatient facility in the CVC
- Outpatient facility at Domino's Farms
- Research nurses, medical assistants, dietitians, and lab personnel
- A mobile clinical research team including a community-based research team, to support selected protocol-specific services
- In collaboration with the Michigan Nutrition Obesity Research Center (MNORC), a bionutrition core providing nutrition services for research protocols
- A specimen collection, processing, and shipping core laboratory with a computerized specimen management and tracking system
- A scheduling portal that allows online scheduling requests

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# Support

## ■ MCRU

- Reorganized due to NIH funding reductions
- Partnering with Taubman Ambulatory Care Infusion Unit
- Changes will strengthen MCRU's ability to provide sustainable services onsite and across all locations
- Lower chargeback rates

MCRU will continue to provide ancillary research support, including:

- Research Phlebotomy
- MCRU2U
- MCRU Core Lab
- Central Line Access (Port, PICC)
- Point of Research Testing (Blood Glucose, Urine Pregnancy, Urine)
- Vital Signs / Height & Weight
- EKG
- Oral Glucose Tolerance Test (OGTT)
- Sigmoidoscopy
- Six Minute Walk Test
- Clinical Phenotyping





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# Support

<i>Rate per Hour</i>	<i>Current Rate</i>	<i>New Rate</i>
<b>MA/LPN service</b>	\$125	\$60
<b>MA/LPN + Lab Service</b>	\$125	\$75
<b>Lab Service</b>	\$60	\$30
<b>MCRU2U</b>	\$185	\$90
<b>Space Only</b>	\$9	\$9
<b>Administrative Fee</b>	\$2,500	<b>\$ 0 (Waived)</b>



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# 380,000

- Specimens processed by MICHR's clinical research unit since 2009, from 65,000 participant visits



- Offers increased technical & regulatory expertise to PIs
- Provides consistent, standardized processes driven by quality control
- Links clinical data to specimens for increased scientific value
- Speeds the pace of research through greater access to biomaterials
- Supports precision medicine







## Storage and Management

- Framework for patient consent, sample tracking & governance support
- Infrastructure for kit production, secure storage, automated processing, and logistics

- Accredited by the College of American Pathologists for quality
- Linkage to patient medical record via Research Data Warehouse

## Access

- Availability across multiple research areas
- GWAS data from Illumina HumanCoreExome array
- Multiple sample types (e.g. DNA, serum, plasma, urine)



# CBR By the Numbers

**310,000  
Stored**

**102,000  
Plasma**

**97,000  
Urine &  
derivatives**

**44,000  
DNA**

**34,000  
Serum**

**32,000  
Whole  
Blood**

**1,600  
Frozen  
Tissue**

**37,000  
Genotyped**

*and counting...*



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# Support

- IND/IDE Investigator Assistance Program (MIAP)
  - Consultation on Investigational New Drug (IND) and Investigational Device Exemption (IDE)
  - Preparation and submission to FDA



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# 90%

- Percentage of U-M's IND, IDE, and expanded access requests to the FDA that MICHR's investigator assistance program supports



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# Support

- Clinical Research Management
  - Database Development
  - Study Monitoring
  - Data Management
  - Study Management
  - Resource

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH  
**Clinical Research Management**

**THE CLINICAL RESEARCH MANAGEMENT (CRM) PROGRAM PROVIDES SERVICES AND MENTORING SUPPORT FOR INVESTIGATOR-INITIATED FEDERALLY AND PRIVATELY FUNDED SINGLE- AND MULTI-CENTER TRIALS**

- **Database Development:** Database creation and ongoing support for efficient data collection and extraction for analysis.
- **Study Monitoring:** Full services to support protocol and regulatory adherence.
- **Data Management:** Mentoring services include Case Report Form (CRF) design strategies and techniques for improving data quality.
- **Study Management:** Mentoring services from protocol implementation through study completion.
- **Resource Center:** Tools and resources available for guidance.

Consistent and practical means of conducting research will lead to higher quality and reliable clinical data, reduced resource time, and savings. A MICHR CRM consultant is available to discuss specific study needs.

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# Support

- **Biostatistics**
  - Expert advice on:
    - Research design
    - Grant development
    - Protocol development
    - Randomization
    - Statistical analysis & data

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**Biostatistics**

THE MICHR BIostatistics GROUP CONSULTS AND COLLABORATES WITH RESEARCHERS TO PROVIDE EXPERTISE IN A VARIETY OF AREAS:

- Research design
- Grant development
- Protocol development
- Randomization scheme development and implementation
- Statistical analysis and data summarization
- Case report form and database review planning and execution
- Data quality assessment
- Study conduct assessment
- Manuscript development and review

Our level of involvement in each study team starts early in the

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# Support

## ■ Clinical Research Informatics

- Informatics software and services, including:
  - REDCap
  - OpenClinica
  - TATUM
  - Research Participant Scheduling Portal
  - UMHealthResearch.org

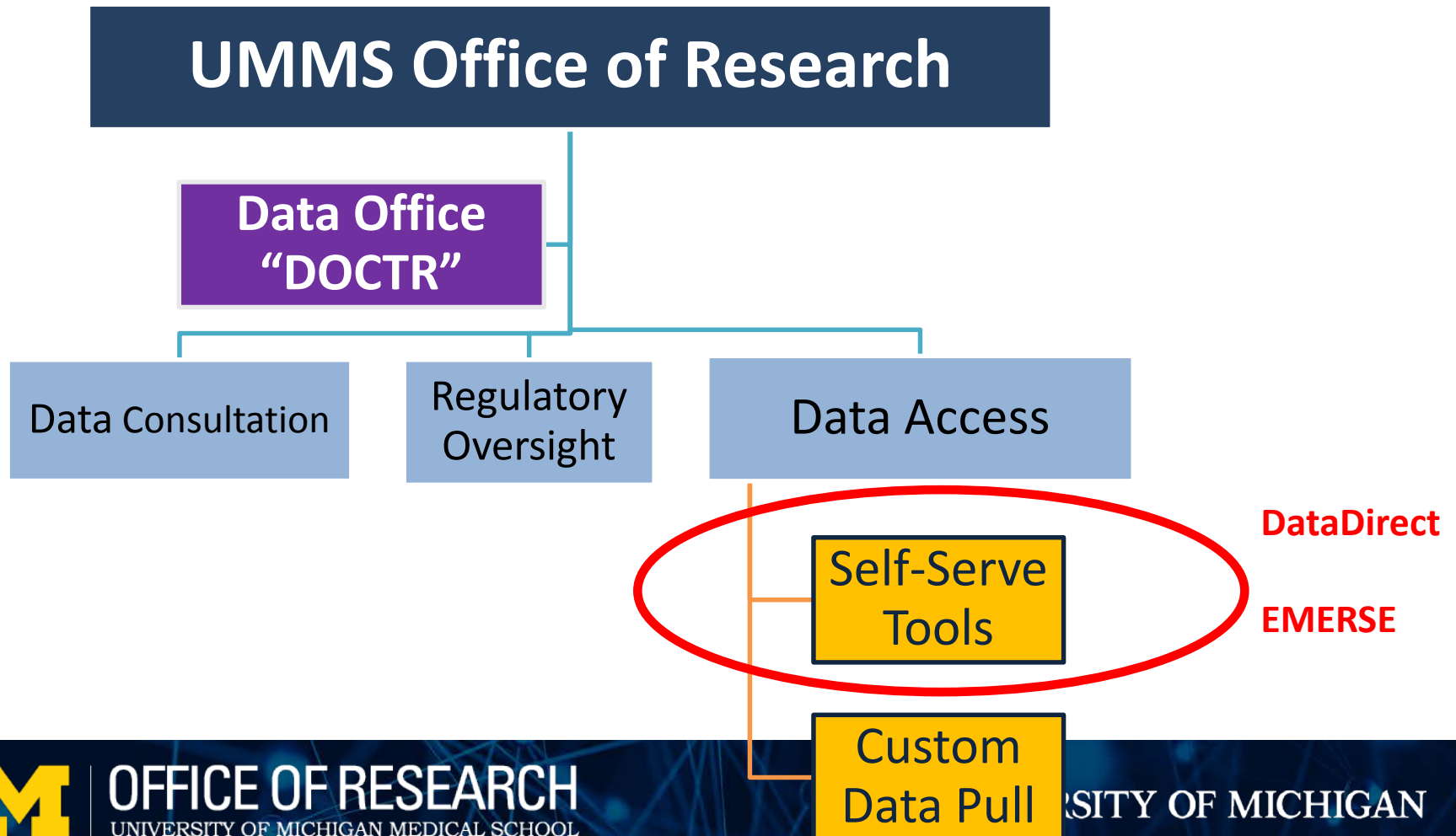
MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH  
**Clinical Research Informatics**

THE CLINICAL RESEARCH INFORMATICS TEAM PROVIDES CUTTING-EDGE INFORMATICS SOFTWARE AND SERVICES, INCLUDING:

- REDCap, a secure, web-based application that provides electronic data capture for clinical research studies.
- OpenClinica Enterprise V-OC, which provides web-based data capture and clinical data management, and is validated and compliant with regulatory requirements and standards.
- OpenClinica Enterprise Mi-OC which is the same software as OpenClinica Enterprise V-OC, but allows study teams to build and manage their own clinical research study databases.
- TATUM, an interactive web-based system that manages randomized study participant treatment assignments.
- Research Participant Scheduling Portal, which allows investigators to submit scheduling requests online.
- UMClinicalStudies.org, which helps match people interested in participating in clinical research with investigators and study teams in need of participants.

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# Data Office for Clinical and Translational Research



# DataDirect

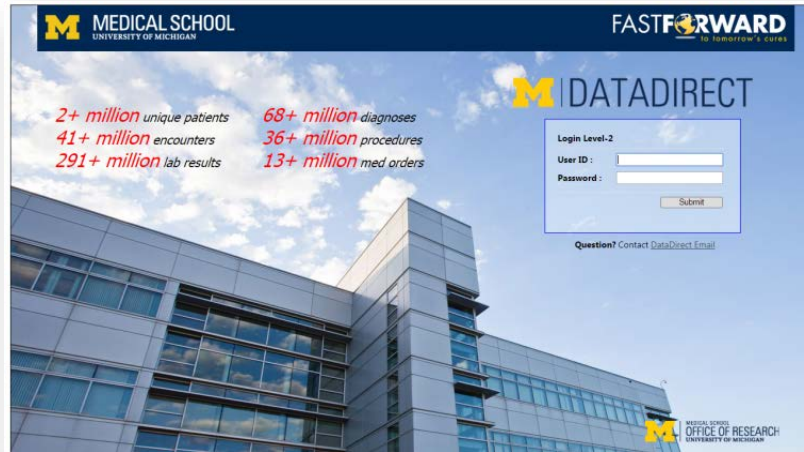
*Self-serve access to clinical data for research*

## **Key Features:**

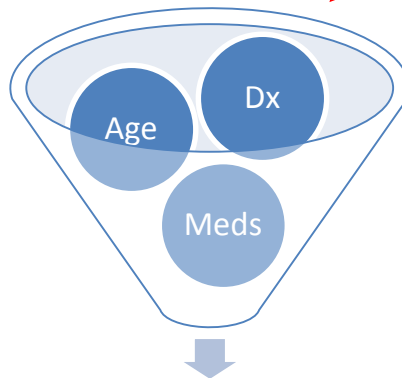
- 3.9 million unique patients to search
- Clinical data from 2004
- Two levels of access
  - Cohort/Aggregate counts
  - Patient-level data for download
- 650+ users



## Self-serve access to clinical data for research



Cohort Discovery  
(no IRB)



Aggregate Count

Patient-Level Data  
for Download  
(with IRB)

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	142232	TURKEY Sliced 3 Oz	Ben E Keith 4 - FROZEN FOOD	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
2	642371	DRESSING CAESAR CREAMY	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
3	779243	MAARGARINE LIQUID OLEO	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
4	815306	LID PLAS SOUFFLE CLEAR	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
5	860095	LID PLAS LBS. SLOTTED	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
6	860095	CUP TOAST BRDZ 2418	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
7	774704	PARMESA	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	1.00 \$	3.75	0.00 \$	-	0.00 \$	-
8	664005	Mustard Prepared	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	1.00 \$	3.75	0.00 \$	-	0.00 \$	-
9	750100	CHEESE PARMESAN SHRED	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	1.00 \$	13.27
10	200025	EGG FRESH SHELL MED USDA AA	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	1.00 \$	13.89	0.00 \$	-	0.00 \$	-	0.00 \$	-
11	66034	VINEGAR APPS COOR 400GRAIN	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	1.00 \$	13.77	0.00 \$	-	0.00 \$	-
12	28078	LINE 12CT	Ben E Keith 1 - PRODUCE	12	0	0.00 \$	-	2.00 \$	8.89	0.00 \$	-	0.00 \$	-	0.00 \$	-
13	620547	TOMATO DICED W/GREEN CHILES	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	1.00 \$	18.88	0.00 \$	-	0.00 \$	-	0.00 \$	-
14	286500	Ice Cream Vanilla 1/2 Gal	Ben E Keith 4 - DAIRY	3647	0	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-	0.00 \$	-
15	650474	KETCHUP FANCY 33% SOLIDS	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	1.00 \$	20.69	0.00 \$	-	0.00 \$	-	0.00 \$	-
16	140095	MUSHROOM WHITE SMALL BUTTON	Ben E Keith 1 - PRODUCE	0	0	0.00 \$	-	1.00 \$	20.98	0.00 \$	-	0.00 \$	-	0.00 \$	-
17	771311	CRUITION SEASONED-HOMESTYLE	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	1.00 \$	23.30	0.00 \$	-	0.00 \$	-
18	640489	SALCE LOUISIANA RED HOT	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	1.00 \$	11.24	0.00 \$	-	1.00 \$	11.24	0.00 \$	-
19	150015	Onion Green InShell W/Root	Ben E Keith 1 - PRODUCE	3200	0	0.00 \$	-	1.00 \$	8.29	1.00 \$	8.29	0.00 \$	-	0.00 \$	-
20	780099	SUGAR BROWN LIGHT PN BAGS	Ben E Keith 4 - GROCERY	0	0	0.00 \$	-	0.00 \$	-	1.00 \$	27.69	0.00 \$	-	0.00 \$	-
21	155010	Onion Yellow Jumbo	Ben E Keith 1 - PRODUCE	8800	0	0.00 \$	-	0.00 \$	-	1.00 \$	13.98	0.00 \$	-	0.00 \$	-



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# Support

- MICHR Clinical Trials Office (MCTO)
  - Supporting start-up of industry-initiated clinical trials

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH  
**Clinical Trials Office**

THE MICHR CLINICAL TRIALS OFFICE (MCTO)  
IS HERE TO SUPPORT THE START-UP OF  
INDUSTRY-INITIATED CLINICAL TRIALS:

- Submit Unfunded Agreements (UFA) and Clinical Trial Routing Forms (CTRF)
- Develop feasibility budget and negotiate with sponsor
- Generate billing calendar in Michigan Budget Enrollment Calendar Tool (MBECT) for Calendar Review and Analysis Office (CRAO) approval
- Draft and negotiate consent language between IRB and sponsor
- Submit initial IRB application and follow progress through to final approval
- Facilitate approval of Clinical Trial Agreement (CTA) between departments, school, ORSP, and sponsor

MICHIGAN



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# MARCH Consortium

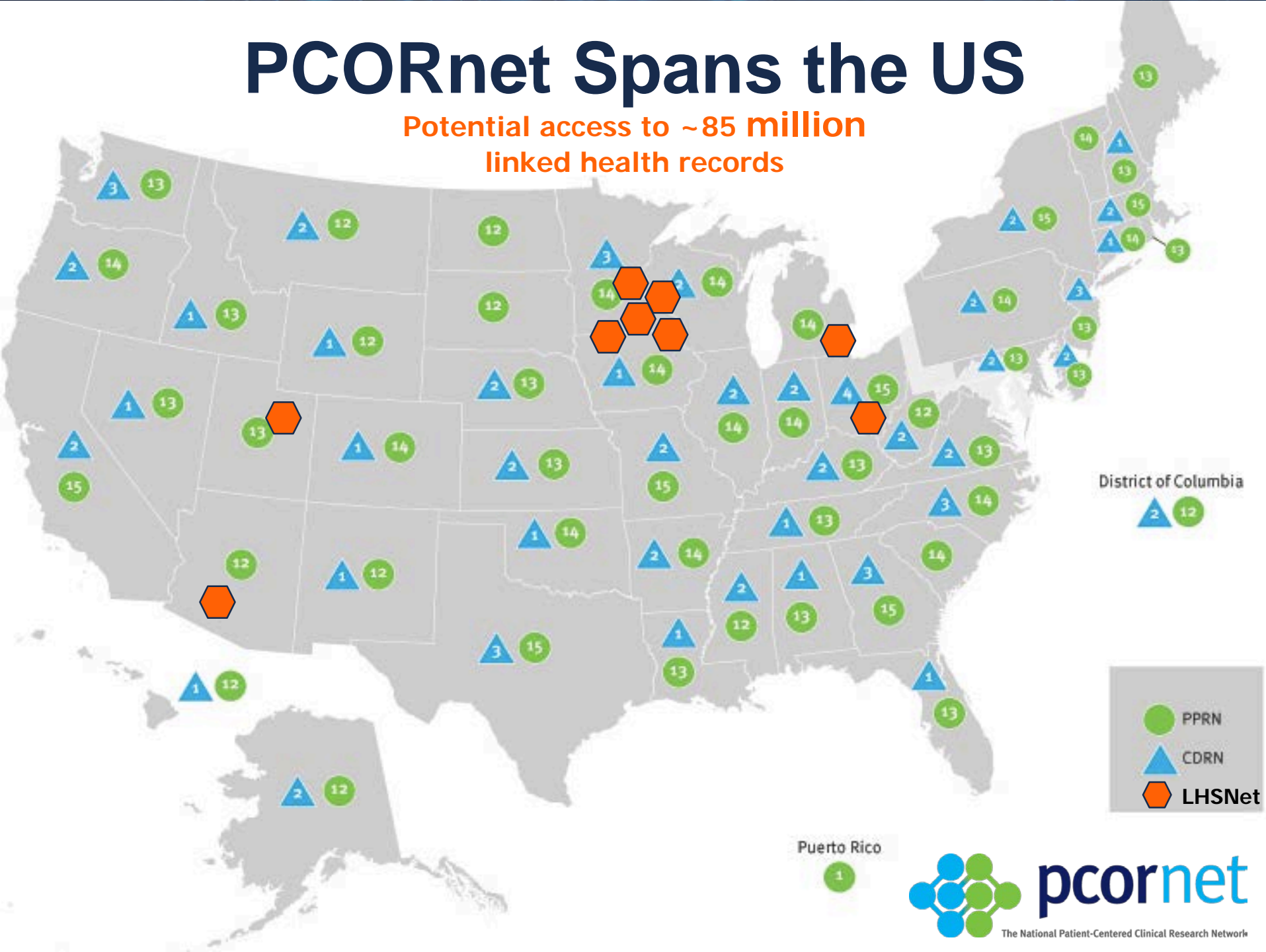
- Midwest Area Research Consortium for Health
  - Infrastructure for investigators/ external sponsors who want to conduct multisite clinical research
  - Members: U-M, Indiana University, Mayo Clinic, Medical University of Wisconsin, Ohio State University, University of Minnesota, University of Wisconsin-Madison





# PCORnet Spans the US

Potential access to ~85 million  
linked health records



District of Columbia

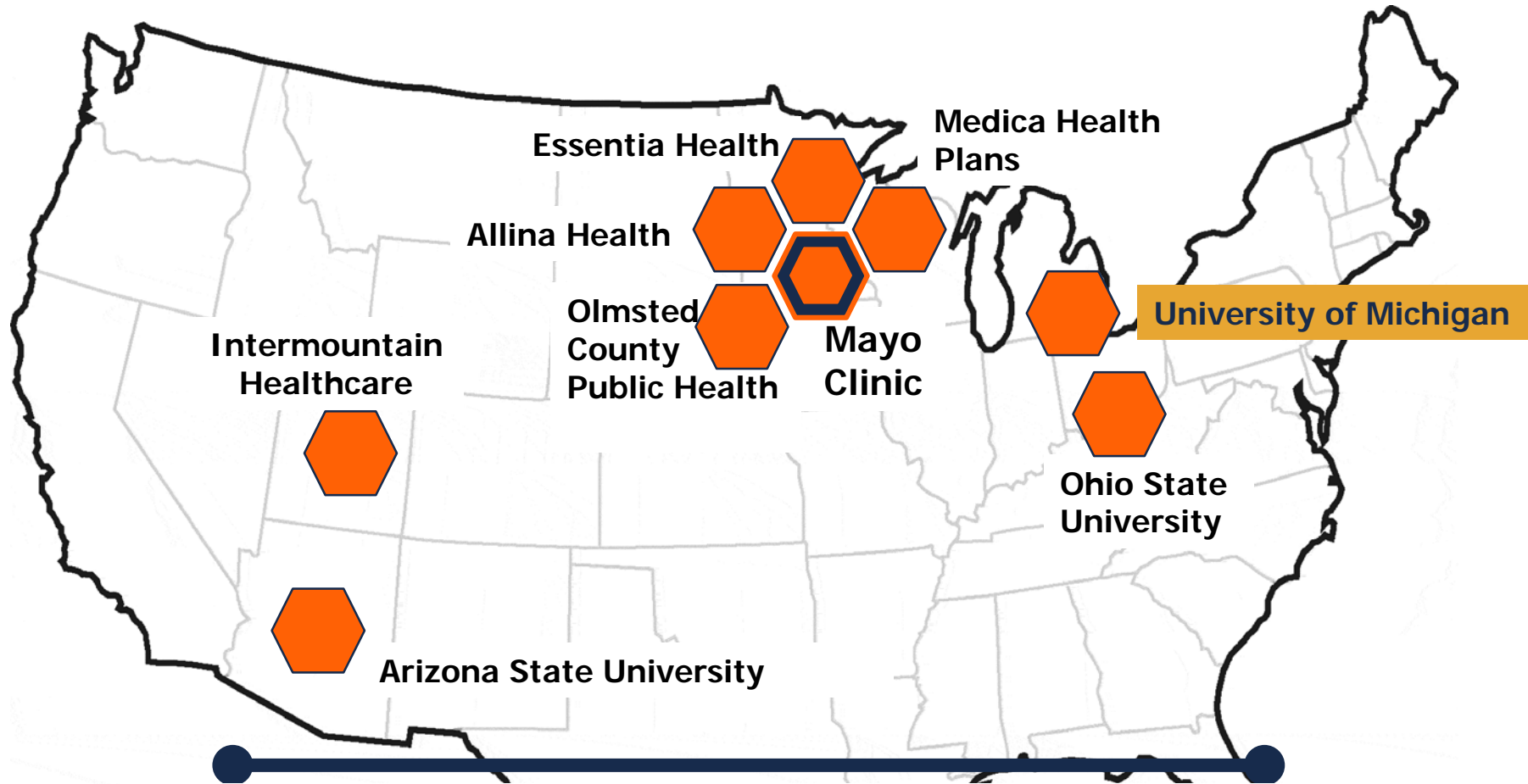


- PPRN
- CDRN
- LHSNet

Puerto Rico



# LHSNet CDRN



Potential access to ~ 9.5 million linked health records



UM-LHSNet Team: PI: Chuck Friedman; Co-Is: Marcy Harris; Molly White; Deb Gipson; Patient Advocates: Georgiann Ziegler; Cathy Hanson; Jim Pantelas; and Anita Johnson



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Unique U-M departments  
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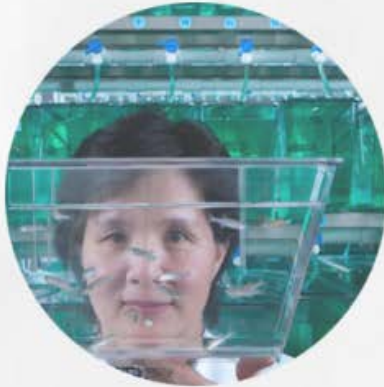


- Biostatistics
- Clinical Research Unit
- Consultation
- Education & Training
- Engaging Communities
- Grant Writing Support
- MICHR Funding
- Participant Recruitment
- Regulatory Support
- Research Management

or search for services 

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Basic Scientists



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Investigators



Investigators



Study Teams



Community Partners



Research Participants



# DISCUSSION

*What questions  
do you have?*



# TRANSLATIONAL RESEARCH Town Hall

Friday, November 11, 8-9 a.m.  
Ford Auditorium, University Hospital

A light breakfast will be provided at 7:30 a.m.

Discuss the state of translational  
research and learn about the many  
services and resources available to  
research teams across U-M

**George A. Mashour, MD, PhD**



RSVP: <http://umhealth.me/trtownhall>

Executive Director, Translational Research (U-M Office of Research)  
Executive Director, Michigan Institute for Clinical & Health Research (MICHHR)  
Associate Dean for Clinical & Translational Research (Medical School)  
Bert N. La Du Professor & Associate Chair of Anesthesiology Research