1. Statistical Highlights
2. Michigan Medicine Overview
2. Certifications
3. Computer & Internet
4. Budgets & Contracts
5. Budgets & Payment
5. Contracts
6. Department-Specific
6. Facilities
6. Radiology and Other Testing
7. Laboratory
7. Pharmacy
8. IRB/Regulatory
9. Participant Population
10. Study Teams
10. General
ALL SPONSORED PROJECTS
Fiscal Year 2016

2,817 NUMBER OF ACTIVE AWARDS

66,620 TOTAL CASES
including discharges and observation

1,043 Average Number of Operating Beds

4.9 Average Length of Stay in Days

$442.8M EXPENDITURES

$511M AWARDS

626,429 Diagnostic Imaging Procedures

2,320,254 Outpatient Clinic Visits, Treatments, Procedures

5,850,622 Pathology/Laboratory Medical Procedures

1,639 ACTIVE Clinical Trials

342 NEW Clinical Trials

>2.3k FACULTY FTEs
3,261 Headcount

>20.3k TOTAL EMPLOYEES
Full Time

FY2016
MARKET SHARE
$287.7M Awards
2.53%
In fiscal year 2016, our sponsored research reached $511 million. Michigan Medicine is committed to improving clinical care, value, and health outcomes by successfully executing a diverse portfolio of high-quality clinical trials. To that end, Michigan Medicine recently created a new organizational structure to better support the conduct of clinical trials, including a central Clinical Trials Support Office (CTSO) with seven affiliated Clinical Trial Support Units (CTSUs) that provide robust infrastructure, training, and oversight for studies performed at U-M. The seven Clinical Trial Support Units are business units that partner with investigators and their teams to ensure the timely and efficient activation and execution of clinical trials.

Michigan Medicine Overview

In fiscal year 2016, our sponsored research reached $511 million. Michigan Medicine is committed to improving clinical care, value, and health outcomes by successfully executing a diverse portfolio of high-quality clinical trials. To that end, Michigan Medicine recently created a new organizational structure to better support the conduct of clinical trials, including a central Clinical Trials Support Office (CTSO) with seven affiliated Clinical Trial Support Units (CTSUs) that provide robust infrastructure, training, and oversight for studies performed at U-M. The seven Clinical Trial Support Units are business units that partner with investigators and their teams to ensure the timely and efficient activation and execution of clinical trials.

a. The **Acute, Critical Care, Surgery & Transplant CTSU** provides infrastructure to study time-sensitive, unscheduled clinical interventions in the emergency medical services system, emergency department, critical care unit, transplant, or studies conducted in an acute hospital setting.

b. The **Heart, Vessel, Blood CTSU** enhances performance of cardiovascular, coagulation, and nonmalignant hematologic clinical trials across the lifespan of acute and chronic disease.

c. The **Children's Clinical Trials Support Unit (CCTSU)** specializes in clinical trials for pediatric subjects. The unique needs of children and their families are the focus of this CTSU. The CCTSU provides enhanced support to a variety of pediatric clinical trials, including but not limited to pediatric disciplines such as hematology/oncology, intensive care, nephrology, neurology, and endocrinology.

d. The **Oncology Clinical Trial Support Unit** serves as the centralized core facility of all oncology clinical research trials conducted by investigators at the University of Michigan Comprehensive Cancer Center and the Michigan Medicine community.

e. The **Neurosciences and Sensory CTSU** is a multidisciplinary, multi-departmental CTSU that aims to provide a full range of services for investigators with clinical trials related to the skin or nervous system. The CTSU is open to any faculty within the departments of Neurology, Neurosurgery and Dermatology, along with participants outside these departments who find a natural fit with the CTSU theme.

f. The **Behavior, Function, and Pain CTSU** represents investigators who conduct trials that involve behavioral interventions or behavioral or biomedical trials intended to impact the following types of outcomes: health behaviors (physical activity, self-management), psychological states (e.g. mood, anxiety), maladaptive behaviors (e.g. substance use, eating disorders), physical function (e.g. recovery from stroke, rehabilitation therapies), psychosocial function, or pain.

g. The **Ambulatory Chronic Disease CTSU** is the home for all chronic, non-ICU diseases in the non-ICU adult population (excluding cancer and cardiovascular disease). These diseases constitute the majority of clinical trials in the ambulatory Internal Medicine divisions and Department of Ophthalmology & Visual Sciences. Divisions involved include rheumatology, endocrinology, pulmonary medicine, geriatrics, nephrology, and gastroenterology, along with the Department of Ophthalmology, which account for a large number of the ambulatory trials within Michigan Medicine.

The CTSUs are trans-departmental and are thematically aligned based on research foci. These local units provide comprehensive support to study teams, offering high-quality and efficient service in support of a mix of clinical trials. The CTSUs provide a professional environment of expert personnel accessible to all investigators, especially early-career faculty. The central CTSO provides enterprise-wide standards, policies, and a common infrastructure that is utilized by the units and study teams.
Computer & Internet

How is access to the study data controlled? External users are required to use their unique credentials, and when working remotely, access the network through the secure Virtual Private Network (VPN).

How do Clinical Research Associates (CRA/Monitors) access secure study data? Unique user IDs are used to access the Electronic Medical Record (EMR) with an appropriate role assigned. This allows view access to a limited number of records for a limited time period.

Can the Clinical Research Associate (CRA/Monitor) connect to the internet while on-site? Yes, the Clinical Research Associates (CRA/Monitor) are permitted access to the internet through the wireless networks.

Can the Clinical Research Associate (CRA/Monitor) access the Electronic Medical Record (EMR) to verify that source data is accurate? Yes, the Clinical Research Associates (CRA/Monitor) will be able to access the EMR through our Michigan Medicine provider portal.

Are all research personnel who are supporting the study trained on the proper handling of sensitive data? Yes, formal awareness training is required for all employees, contractors, sponsors, and other parties. There are documented disciplinary policies for violations of privacy or security of protected health information (PHI) or other sensitive data.

Are all accesses to ePHI, including view-only, logged? Yes, including who performed the access, what was accessed, and when the access occurred.

Are there CD-ROM drives available? Information on CD-ROM access can be provided by the CTSU. Only FIPS 140-2 Michigan Medicine-approved removable media can be used. Michigan Medicine recommends that shared files are authorized through the use of MiShare. MiShare is a secure collaborative file transfer system that provides a method approved by the Michigan Medicine Compliance Office for Michigan Medicine personnel, non-Michigan Medicine business partners, patients, and researchers to securely transfer files, including files that contain electronic Protected Health Information (ePHI), protected research data, or other sensitive information. Files are encrypted while being uploaded or downloaded and are encrypted while they are on the MiShare server.

Has the information system for the study undergone a security assessment and received authorization to operate from an appropriate authority? Yes, it is the policy of Michigan Medicine to ensure the confidentiality, integrity, and protections of all sensitive data, including ePHI. Security assessments are conducted by the office of the Chief Security Officer and research systems containing ePHI are required to have IRB approval, a risk assessment, and authorization to operate.

Do you have an EMR (Electronic Medical Record) available? Yes, we operate our Epic EMR system in line with federal, state, and local regulations, including application of the NIST 800-53 family of controls. Epic is considered 21 CFR Part 11 compliant for electronic records and signatures.

Is the information system used by the study built upon a secure baseline configuration? Yes, underlying information systems supporting clinical trials management have change control processes to document, test, and approve changes.

Are changes to the information system(s) tracked? Yes, underlying information systems supporting clinical trials management have change control processes to document testing and approve changes.

Are study users required to have secure accounts that are managed by a central authority? Yes, in order to use information systems, users are required to have a unique ID managed by an Identity and Access Management team.

How is the information system maintained? Systems are regularly maintained along their lifecycle from design, implementation, and operation to retirement.
The University of Michigan Office of Research and Sponsored Projects (ORSP) enables and safeguards the conduct of research and other sponsored activity for U-M. The ORSP primarily handles pre-award activities such as contract negotiations and sponsor payment information as part of the U-M Office of Research. A second unit, the Office of Sponsored Programs, primarily handles financial post-award activities and is part of U-M Business & Finance. The CTSUs closely partner with the ORSP and Sponsored Programs on pre- and post-award activities.

Do you require that the contract and budget are finalized before submitting to the IRB for initial approval? or vice versa? No, the budget, contract, and IRB can be developed and approved in parallel. Once the budget is finalized, it will route to ORSP and once the budget and contract are finalized it will then be processed for signatures. U-M is unable to sign electronically at this time, but we do accept, and prefer, PDF-scanned signatures. The turnaround time for final signature (after principal investigator signature) is typically less than three business days; however, the sponsor requirement of originals will likely prolong the signature process.
Budgets and Payment Information:

To ensure proper processing of your payment, regardless of the payment method please notify the University of Michigan that a payment has been sent by sending an email to electronicpmts@umich.edu.

**Payment via check or money order by courier, FedEx, UPS or Express Mail**

MAKE CHECK REMITTANCES PAYABLE TO:
The Regents of the University of Michigan
Box 223131
Pittsburgh PA 15251-2131
United States

*Please include Michigan Medicine Reference ID (e.g. 1X-PAF0XXXXX or University of Michigan invoice number).*

**Payment via EFT/ACH:**

Payable to: The Regents of the University of Michigan
Account number: 5401125777
ABA/Routing number: 071000039
Bank name: Bank of America, 2600 W. Big Beaver Road, Troy, MI 48084

**Payment information: Wire/routing number:**

Payable to: The Regents of the University of Michigan
Account number: 5401125777
ABA/Routing number: 026009593 (from inside USA)
Swift Code: BOFAUS3N (from outside USA)
Bank name: Bank of America, 2600 W. Big Beaver Road, Troy, MI 48084

**Payment information:**

Tax ID Number 38-6006309

**Who is responsible for budget negotiations?**
The Clinical Trials Support Units (CTSUs) are responsible for developing a study budget and working collaboratively with the principal investigator and their academic department to negotiate a final budget with the sponsor. The CTSUs will submit the final budget to the University of Michigan Office of Research and Sponsored Projects to include in the study agreement along with negotiated payment terms.

**Can budget negotiations begin with a draft protocol?**
The Clinical Trials Support Units will assist U-M investigators in estimating the cost of conducting a trial at Michigan Medicine based on a draft protocol. However, to avoid significant re-work and inefficiencies, the sponsor is expected to provide a near-final draft, if the final draft is not yet available. Costs are subject to change based on the final protocol.

**What is your overhead (indirect) rate for industry sponsored clinical trials?** 29%

**Contact Information for budgets:**
Each CTSU or program can provide the budget specialist information upon request, or for general inquiries, please contact the [Clinical Trials Support Office](#).

**Contracts:**

**Address where grants and contracts may be sent:**
Contracts are handled by the Office of Research and Sponsored Projects. Contact for a contract specialist will be provided upon request.
Wolverine Tower, First Floor
3003 South State St.
Ann Arbor, MI 48109-1274

**Do you have a separate department(s) responsible for contracts?** Yes, the [Office of Sponsored Projects (ORSP)](#)

**Will the institution accept a unilateral confidentiality disclosure agreement (CDA)?** Yes, the CTSUs will assist with routing all draft CDAs to the Office of Research and Sponsored Projects for review and execution. CDAs are executed typically within two weeks.

**What is the average time for negotiation of clinical research contract at your site?** Negotiation of Clinical Trial Agreements varies, and can range from a few weeks to two months. University of Michigan supports and encourages the use of the [Accelerated Clinical Trials Agreement (ACTA)](#) to speed the pace of trial activation.

**Who is responsible for budget negotiations?**
Each CTSU or department administrator will provide the contract specialist information as needed upon request.

**What documents are required upon execution of the CDA?** Michigan Medicine requires the following documents:
- Protocol
- Contract
- Draft Budget
- Informed Consent
- Investigator brochure
- Subject material requiring IRB approval
Department Specific

Is there prior site experience with use of an Electronic Data Collection (EDC) system? Yes, Michigan Medicine has four internal EDCs that are utilized by study teams. These include REDCap (Research Electronic Data Capture), OpenClinica Mi-OC, OpenClinica V-OC, and Velos eResearch. Details on these systems can be obtained here. Michigan Medicine study teams also have experience with numerous sponsor-specific EDC systems. Each CTSU can provide the list of EDC systems upon request.

Contact information for a new study:
Each CTSU can assist you with identifying a potential U-M investigator and navigating the U-M system. The contact information for each CTSU is provided below. For assistance determining the appropriate CTSU for your study, contact the central Clinical Trial Support Office.

- Acute, Critical Care, Surgery & Transplant CTSU
  AcuteCriticalCareSurgeryTransplant@umich.edu
  Phone: 1.734.936.5956

- Children’s CTSU
  Childrens@umich.edu
  Phone: 1.734.998.9979

- Heart, Vessel, Blood CTSU
  HeartVesselBlood@umich.edu
  Phone: 1.734.998.9976

- Oncology CTSU
  Oncology@umich.edu
  Phone: 1.734.936.7506

- Ambulatory & Chronic Disease CTSU
  AmbulatoryChronicDisease@umich.edu
  Phone: 1.734.998.6059

- Behavior, Function & Pain CTSU
  BehaviorFunctionPain@umich.edu
  Phone: 1.734.998.9976

- Neuroscience & Sensory CTSU
  NeurosciencesandSensory@umich.edu
  Phone: 1.734.936.1788

Contact Information for Potential PI: Each CTSU will provide the potential PI information, as needed.

Contact Information Potential Study Coordinator: Each CTSU will provide the study coordinator information, as needed.

Are all staff English speaking (including PI and at least one study coordinator)? Yes

How many studies do coordinators work on at a time? The number of studies each coordinator works on depends on the requirements and complexity of the studies.

Facilities

What kind of setting is your site? Our site is an academic medical center.

Review of beds and care centers etc. Michigan Medicine provides two dedicated locations for the conduct of clinical research: Michigan Clinical Research Unit (MCRU) and Ravitz Cancer Center Research Unit (CCRU). Both facilities provide research-supported treatment beds, chairs, and trained research staff to ensure high-quality research-focused care. Clinical trials are also conducted in other adult or pediatric inpatient and outpatient facilities throughout Michigan Medicine.

Radiology and Other Testing

Do you have a radiology facility at or near your site? Yes.

Does your site have the capability to access imaging data (i.e. digital CT/MRI images) for a computer that has internet access? Yes.

Is your site able to obtain multiple ECG assessments using equipment provided to you and transmitting the results electronically to a central ECG service provider? Yes.
Laboratory

Are there onsite laboratory facilities?
Yes. Multiple clinical laboratories are available. The Cancer Center, Michigan Clinical Research Unit (MCRU), and other independent program laboratories are available for research specimen processing, storage, and shipping. The Medical School Central Biorepository, a College of American Pathologists (CAP) accredited state-of-the-art facility, is also available for specimen storage, processing, and distribution services.

Are your lab personnel HAZMAT or International Air Transportation Association (IATA) certified (equivalent certification is acceptable)? Yes.

College of American Pathologist (CAP): Yes. A list of CAP accreditations can be obtained at Mlabs.

Clinical Laboratory Improvement Amendment (CLIA): Yes, all Michigan Medicine Clinical Laboratories are CLIA certified. Clinical research laboratories do not require CLIA certification. A list of CLIA certifications can be obtained at Mlabs.

Are there qualified staff members to draw blood and prepare multiple samples for shipping? Tumor tissue? Frozen samples? Yes.

Are local normal laboratory ranges available from the university? Yes, the Local Normal Ranges (LNRs) can be found here.

Is a -70°C/-20°C specimen storage freezer available? Yes, through the Michigan Clinical Research Unit, Cancer Center, other independent program laboratories, and the Medical School Central Biorepository there are appropriate specimen storage freezers that are temperature alarmed and monitored.

Pharmacy

Does your site have a dedicated pharmacy and pharmacists to handle, store and dispense investigational drugs? Yes. U-M has an investigational pharmacy with a dedicated research pharmacist utilized for drug preparation. Administration of the study drug is performed by appropriately trained and credentialed personnel at the unit and/or study team level.

Contact Information Pharmacy:
Michigan Medicine Research Pharmacy
UH B2D301, Box 5008
1500 East Medical Center Drive
Ann Arbor, MI 48109-5008
Phone: 734.936.9699 (Desk)
Phone: 734.936.7469 (Research Pharmacy)
Fax: 734.647.9302
Questions can be directed to: Pharm-IDS-RPh@med.umich.edu

Are there onsite investigational pharmacies with locked storage? Yes, the dedicated investigational pharmacy has limited access to pharmacy personnel only.

Is the drug storage facility temperature-controlled? Yes, the environment is monitored using an automated electronic system, Temp Track.

Is your pharmacy or site staff willing to collect batch numbers of drug? Yes, for investigational drugs that the Research Pharmacy manages.

Does someone from your pharmacy attend the Site Initiation Visit (SIV)? Yes.

Does someone from your pharmacy attend the pre-site qualification visit? Yes.

Does your pharmacy have additional information to provide upon request? Yes.

Certifications

- College of American Pathologist (CAP)
- Clinical Laboratory Improvement Act/Amendment (CLIA)
- American Nurses Credentialing Center (Magnet)
- FWA – 00004969
- Laboratory International Air Transport Association for Hazardous Materials (HAZMAT & IATA)
IRB/Regulatory

Contact Information:
IRBMed
Plymouth Road, Bldg 520, Room 3214
Ann Arbor, MI 48109-2800
(734) 763-4768
irbmed@umich.edu

Does your site follow ICH and GCP guidelines? 
Yes. Studies are conducted per sponsor requirements.

Can regulatory documents be collected simultaneously with the contract/budget and IRB review/approval process? 
Yes.

Is the use of a central IRB permitted? 
Yes. U-M currently has master agreements with several central IRBs.

How often does the local IRB meet? 
Weekly.

Certification, AAHRPP: 
Yes. U-M was reaccredited with Full Accreditation in 2016 for five years. U-M has held Full Accreditation since 2008.

Certification, FWA: 
FWA 00004969

What is the submission time prior to an IRB meeting? 
There is no deadline for IRB submission because IRBMED meets weekly and submissions are assigned to the earliest possible review board agenda.

What is the turnaround time for written approval documentation from the IRB? 
Turnaround time from the placement of the submission on an IRB board meeting agenda is 2-4 weeks.

Is there a need to have informed consent documents translated into other languages? 
If a need exists, access to the interpreter services is available upon request and appointment.

Do you agree to have monitoring visits, possible sponsor audits, and possible IEC/IRB and regulatory inspections conducted during the course of the clinical trials? 
Yes.

Are there any other committees that need to approve the protocol? 
Yes, all new clinical trials in a CTSU will initially go through a feasibility review or a Cancer Center Protocol Review Committee (PRC) review. The reviews are conducted in partnership between the PI and CTSU.

For regulatory review, the protocol is submitted through an electronic application to the IRB. The study will proceed to the applicable ancillary committees. U-M has several ancillary review committees, including: Clinical Research Calendar Review and Analysis Office, Conflict of Interest, Research Pharmacy, Radioactive Drug Research Committee, Subcommittee on Human Use of Radioisotopes, and Tissue Procurement Core.

Studies are reviewed only by those review units that are applicable and our electronic regulatory review system utilizes a concurrent ancillary review process. After ancillary committee review and approval the study proceeds on for final IRB review.

What is the submission time prior to a meeting for these other approval committees? 
Upon submission of the IRB application, U-M’s electronic management system sends the IRB application to all applicable ancillary committees simultaneously based on information provided in the application. The IRB approval will occur in parallel with the other committees.

How often do these other approval committees meet? 
Meetings occur to meet the demands of the submitted studies.

What is the turnaround time for written approval documentation for these other approval committees? 
The average approval time for each committee is shown in the table below. The review process is conducted concurrently.

<table>
<thead>
<tr>
<th>Ancillary Review Committee</th>
<th>Average Turnaround (calendar days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calendar Review &amp; Analysis Office</td>
<td>7.8</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>16.3</td>
</tr>
<tr>
<td>Investigational Drug Services Pharmacy</td>
<td>6.7</td>
</tr>
<tr>
<td>Radioactive Drug Research Committee</td>
<td>2.0</td>
</tr>
<tr>
<td>Subcommittee on Human Use of Radioisotopes</td>
<td>0.5</td>
</tr>
<tr>
<td>Tissue Procurement Core</td>
<td>1.1</td>
</tr>
</tbody>
</table>
**Participant Population**

**How do you identify patients for participation in research studies?** DataDirect: The Medical School Office of Research has developed a self-serve tool, Data-Direct, for CTSUs and study teams to use to facilitate cohort discovery. DataDirect enables access to robust, up-to-date data on more than 2 million unique patients from across the health system to inform study design and determine availability of eligible patients for study recruitment.

**UMHealthResearch.org** is a participant registry that enables the public to view active clinical research studies at U-M, be potentially matched to a study based on information they input, indicate their interest in participation, and communicate with study team members—all within this secure application. More than 27,000 volunteers are already registered.

**MiChart:** The Best Practice Alerts (BPAs) can be developed in our EMR as recruitment or screening tools using potential participant identifiers associated with study eligibility, diagnosis codes, problem lists, appointment dates, attending physicians, and other variables.

**EMERSE:** The Electronic Medical Records Search Engine (EMERSE) works with free text clinical documents with the EMR to support rapid data retrieval.

**How do you support participant recruitment?** Recruitment plans are customized to meet the needs of the study. The study team works with the investigators to identify targeted referring physicians and patient populations through printed materials (fliers, banners, mailers, outcome brochures, newsletters, email), along with daily screening in the patient care areas of Michigan Medicine, satellite clinics, and community events.

Opportunities for study-specific communication include Grand Rounds presentations, tumor boards, support groups (locally and nationally), health fairs, and expos. Social media (Facebook, Twitter, and Pinterest) has become another area for study-specific communication.

**What are the demographic statistics about the geographic area and others who come to the institution?** Geographic distribution: In-state 62%, out-of-state: 38%. Race: 76% Caucasian, 10% Black/African.

**Do you have patients whose first language is not English?** Yes; however, 97% of patients speak English as their first language. A small percentage speak Spanish, Japanese, Chinese, or Arabic. Interpreter services are available upon request.
Study Teams

Tell us about your clinical trial center and office. More information related to the Clinical Trials Support Office (CTSO) and the seven affiliated Clinical Trials Support Units (CTSUs) is available at: CTSOgroup@umich.edu.

Is additional investigator background available on request? Yes, more information can be obtained once an investigator has been identified, including the investigator’s CV and the population that the investigator has access to.

Do you have the personnel to meet the study requirements? U-M is well positioned with highly trained study personnel, including principal investigators, co-investigators, radiologists, pathologists, pharmacists, biostaticians, project managers, study coordinators, research nurses, research treatment nurses, LPNs, medical assistants specialists, research assistants, multisite coordinators, laboratory technicians, database developers, data managers, regulatory coordinators, study monitors, and recruitment consultants. Each department or program personnel may vary slightly.

Are investigator profiles available? Yes, more information can be obtained once an investigator has been identified. This information will be provided by the CTSU.

How many studies do coordinators work on at a time? The number of studies each coordinator works on depends on the requirements and complexity of the studies. Each CTSU works closely together to provide coverage to deliver shared study support.

Do you use long-term off-site storage? Yes.

General

Is the institution part of a Site Managed Organization (SMO)? No.

Is clinical research conducted on adult and pediatric populations? Both.

Cancer Care Centers: University of Michigan's Comprehensive Cancer Center – All cancers represented

Magnet Certification: Yes.

Other Institutional Certifications: An extensive list of accreditations/certifications is available at the provided link.

Phases of studies conducted at the institution? Phase I thru Phase IV and post marketing approval.

Specialty and Treatment Centers: Michigan Medicine has several specialty and treatment centers, including: Comprehensive Cancer Center, Rehabilitation Center, Kellogg Eye Center, Frankel Cardiovascular Center, and Geriatrics and Rehabilitation Centers. A complete list is available at: http://www.uofmhealth.org/our-locations/specialty-care-centers.

NIH Clinical and Translational Science Award (CTSA): Yes. U-M’s CTSA is housed in the Michigan Institute for Clinical & Health Research (MICHR).