The Center which is housed in the McGuire Translational Research Facility was established in 2005. Initial efforts were focused on continuation of epilepsy research. In 2007, a formal name was selected, Center for Orphan Drug Research (CODR), and a mission statement was adopted:

The mission of the Center for Orphan Drug Research (CODR) is to improve the care of individuals who have rare diseases through research on new drug therapies; education of health professionals and health profession students; and contributions to the discussion and formulation of public policy relating to rare diseases and orphan drugs. The focus of CODR research is rare pediatric neurological disorders.

In the ensuing 10 years, the Center has added research staff; grown our research portfolio; entered into a wide range of interdisciplinary, inter-collegiate collaborations; expanded membership; attracted graduate, professional, and undergraduate students; added a post-doctoral fellowship; and developed and maintained an active outreach/advocacy program.

The following is a summary of the Center’s accomplishments over the last 2 years. Full details about our activities are found in the attached appendices.
Research

The Center has enjoyed substantial growth over the last 2 years as we have expanded our portfolio in all three focus areas: epilepsy and seizure disorders, spasticity, and neurodegenerative disorders. The impending receipt of a NOGA* for an R01 (Coles, PI) supporting a 5 year study of the pharmacokinetics and pharmacodynamics of the 3 drugs used in the Established Status Epilepticus Treatment Trial will further add to our research program. The Center continued expanding its collaborations within and outside the University.

26 proposals were submitted to various sponsors
1 orphan designation was approved, 1 is pending
18 proposals were ultimately funded for a total of $1,981,532.00 from various sponsors
3 patents were approved
3 INDs were approved
23 articles were authored and published in various publications

Orphan destinations: IV TPM and IV Baclofen (pending)
Approved patents: Development of water-soluble benzodiazepines activated by enzymes for use as intranasal seizure rescue, IV carbamazepine, and IV topiramate

* This award was received by the Center on 8/4/2017.
Education

The Center makes a substantial commitment to all levels of University education. The Center has attracted a number of outstanding trainees who participate in our various research projects. Many of these students have received support from Clinical and Translational Science Institute (CTSI) and Undergraduate Research Opportunities Program (UROP). Several have gone on to pharmacy school.

- 20+ Lectures & Seminars
- 2 Postdoctoral Fellows
- 3 Pharmacy Students
- 5 Graduate Students
- 7 Directed Studies Students
- 6 Undergraduate Students (this year two undergraduate students have been admitted to our PharmD program)
Outreach/Advocacy

Rare Disease Day: The Center annually co-sponsors Rare Disease Day. The most recent event occurred on 2/24/2017 in the McNamara Alumni Center. The event attracted 150 attendees, 16 Patient Advocacy Groups, and 30 research posters. The keynote speaker was Steve Groft, PharmD, Senior Advisor to the Director, National Center for Advancing Translational Sciences, NIH.

The Center participates in multiple other advocacy activities throughout the year including Feed My Starving Children, Rotary Club lecture, University of Minnesota’s Graduate School Research Showcase, the Epilepsy Foundation’s Walk for Epilepsy, and the Anita Kaufmann Foundation’s Walk for Epilepsy and Guinness World Record Largest Epilepsy Training Session.
Honors & Awards

The students of the Center have received a number of honors and awards over the past 2 years:

**Bridget Curtin, BS**
- Accepted into the University of Minnesota College of Pharmacy PharmD program
- 2016 CTSI Pathways to Research Program scholar
- 2017 CTSI Pathways to Research Program scholar
- 2016 CTSI Pathways to Research Program best poster travel award
- 2016 Undergraduate Research Opportunity Program award

**Ghada Elnashar, BS**
- 2015 Melendy Fellowship

**David Kraus, BS**
- 2016 UMN Department of Chemistry Senior Award

**Patricia Maglalang, BS**
- Accepted into the University of Minnesota College of Pharmacy PharmD program
- 2015 CTSI Summer Research Scholar
- 2015 Center for Health Equity Research Scholar
- 2nd Place Best Student Poster Award Winner, Institute for Engineering and Medicine Annual Conference
- 2016 UMN Department of Chemistry Senior Award

**Abhishek Sathe, PhD student**
- 2016 James C. Cloyd Neuropharmacology Research Fellowship

**Natalie Schmitz, PharmD, MPA, PhD student**
- 2017 Zaske Fellowship
- 2016 James C. Cloyd Neuropharmacology Fellowship
- 2015 CTSI Advanced Research Scholar

**Irene Vuu, PharmD, PhD student**
- 2017-2018 American Epilepsy Society Pre-Doctoral Fellowship
- 2017-2018 American Foundation of Pharmaceutical Education Pre-Doctoral Fellowship
- 2016 American Epilepsy Society Fellows Program
- 2016 American Neurological Association Translational and Clinical Research Course for Clinician-Scientists

**Kwangchae Yoon, PharmD, Fellow**
- 2016-2017 Genzyme LDN Fellowship
The faculty and staff of the Center have received a number of honors and awards over the past 2 years:

**James Cloyd III, PharmD**
- 2015 Rho Chi Lecture Award, Rho Chi Society
- 2015 Sumner J. Yaffe Lifetime Achievement Award in Pediatric Pharmacology and Therapeutics, Pharmacy Pediatric Advocacy Group
- 8th Annual Denis J. Crankshaw BioPharm Lectureship, McMaster University, Hamilton, Ontario
- Invited Lectureship: 60th Annual Julius Koch Lecture, School of Pharmacy, University of Pittsburgh
- Outstanding Advising and Mentoring Award, awarded by the UMN Graduate and Professional Student Association
- 2016 UMN CTSI Mentor of the Year

**Lisa Coles, MS, PhD**
- 2015 Anti-epileptic Drug Development Fellowship
- 2016 Junior Mentor of the Year

**Reena Kartha, MS, PhD**
- 2016-17 Rare Disease Clinical Research Network Clinical Research Certificate Program Scholar
- 2016-17 Lysosomal Disease Network Clinical Fellowship

**Usha Mishra, MS**
- 2017 Elected to Board of Directors for Minnesota Mass Spectrometry Society

**Marcia Terluk, PhD**
- 2017 Certified Phlebotomist
Financial Overview
7/1/16-6/30/17

Revenue Sources for Fiscal Year 2017

- Grants & Contracts: 65%
- Gifts & Endowed Chair Income: 23%
- External Sales & Service: 9%
- University of Minnesota: 3%

Expenses for Fiscal Year 2017

- Salaries & Benefits: 50%
- Lab Operations: 47%
- Travel: 2%
- General Operations: 1%
NEW HIRES/APPOINTMENTS:
Jim White, MD (Minnesota Epilepsy Group) and Sam Roiko, PhD (Gillette Specialty Healthcare) were welcomed as new CODR members.

Marcia Terluk, PhD joined the Center as a Research Scientist.

CURRENT ROSTER

MEMBERS
Dick Brundage, PharmD
Linda Krach, MD
Marie Kuker, RPh
Jim White, MD
Sam Roiko, PhD

ASSOCIATE DIRECTOR OF PHARMACOMETRICS
Lisa Coles, MS, PhD

LABORATORY SCIENTIST
Usha Mishra, MS

ADMINISTRATIVE ASSOCIATE
Lori Endsley, BA

ASSOCIATE DIRECTOR OF TRANSLATIONAL PHARMACOLOGY
Reena Kartha, MS, PhD

DIRECTOR
James Cloyd, PharmD

ASSOCIATE DIRECTOR OF CLINICAL STUDIES
Robert Kriel, MD

FELLOWS/GRAD STUDENTS/RESIDENTS
Natalie Schnitz, PharmD, MPh, PhD student
Irene Vu, PharmD, PhD student
Abhishek Sathe, PharmD, PhD student
Kwangchae Yoon, PharmD, Fellow

SUMMER RESEARCH ASSISTANTS
Patricia Maglalang, BS
Bridget Curtin, BS

RESEARCH SCIENTIST
Marcia Terluk, PhD

PROFESSIONAL/UNDERGRADUATE STUDENTS
Kathleen Sullivan, PharmD
Abigail Travis, CSE
Ann Petersen, PharmD
Karna Terpstra, Visiting Student

HIGH SCHOOL STUDENT VOLUNTEERS
Abigail Li
Tariq Qassam
Appendices

- 2015-2017 Submitted proposals
- 2015-2017 Peer-reviewed publications
- 2015-2017 Presentations
- 2015-2017 Research projects
- 2015-2017 Education
- 2015-2017 Additional activities and accomplishments
- FY17 Financial Overview