MARIA C. MANCINI, MHP, RAC
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PROFESSIONAL EMPLOYMENT

Catabasis Pharmaceuticals **2012-present**

Vice President, Clinical Operations, 2017-present

- Responsible for defining and executing robust Clinical Development Plans to achieve the desired target product profile, for the assigned product from preclinical stage onwards.
- Guide group with creative but realistic approaches to drug development across therapeutic areas.
- Serve as a clinical lead at health authority interactions, advocacy meetings, and investigator meetings.
- Participate in authorship, review, and refinement of all outward facing company communications relating to clinical programs.
- Provide strategic consultation and guidance to the organization on decisions that have significant clinical components and implications
- Ensure organizational growth plans for the department such that the shape and structure meet the company's needs.

Senior Director, Clinical Operations, 2014-present

- Provide strategic planning expertise for compounds entering the clinical development phase.
- Responsible for final review with respect to all controlled documents including protocols, IBs, informed consent forms and clinical study reports
- Mentor and develop department to successfully advance to higher levels of responsibility

Director, Clinical Operations, 2012-2014

- Leads weekly meetings with senior management to discuss clinical development activities and milestones.
- Assists in the development of the clinical study protocol and executes all clinical development plans created by the Chief Medical Officer and senior management team.

Genzyme, a Sanofi Company **2005-2012**

Associate Director, Clinical Research, Genzyme, a Sanofi Company, 2012 – present

- Provide strategic planning expertise and a leadership to manage global operations for key sNDA trial including development of project timeline, study budget, resourcing, global site feasibility and selection, vendor selection and management and project deliverables.

Manager, Clinical Research, Genzyme Corporation, 2010 – 2012

- Manage Phase 3 clinical program. Shortened timeline to first Site Initiation Visit, first patient screened, and first patient treated.
- Lead cross-functional team across global operational aspects, including data collection, packaging and release of investigational product, regulatory submissions, data analysis and medical writing.

Principal Clinical Research Associate, Genzyme Corporation, 2008-2010

- Manage Phase 3 clinical program and identified novel approach to track study metrics including country submission and approval timelines and enrollment modeling.
- Developed and executed new paradigm for regional Investigator meetings.
- Identified as key contributor on collaboration team, recipient of Vice President's Award.

Senior Clinical Research Associate, Genzyme Corporation, 2005-2008

- Managed global CRO for Phase 2 and 3 trials in infectious disease.
- Presented at Investigator Meetings
- Provided oversight and mentoring to colleagues.

Senior Clinical Research Associate, Smith & Nephew Endoscopy 2003-2005

- Provided oversight of study start-up activities including SIVs and execution of site contracts.
- Conducted domestic and international monitoring for medical device trials.
- Developed key documents including the ICF template, clinical trial protocol and investigator brochure.
- Provided supervision / mentoring to junior CRA staff.

Program Manager, Northeastern University, School of Pharmacy, 2000-2003

- Developed and executed medical education activities to support the continuing professional education program for the School of Pharmacy.
- Developed continuing education programs that were in strategic alignment with alumni needs and developed program content and executed programs in compliance with the regulations.

Clinical Research Associate, Harvard Clinical Research Institute, 1998-2000

- Assumed primary oversight for the data collection and monitoring of medical device trials.
- Presented at Investigator Meetings.

TEACHING EXPERIENCE

Adjunct Professor, Massachusetts College of Pharmacy and Health Sciences 2013-present

- Teach graduate level on-ground & online bioscience global regulatory affairs and clinical research courses including a global regulatory affairs course and a course on conducting clinical research studies.

Adjunct Faculty, Regulatory Affairs, Northeastern University, Boston, MA 2007-present

- Teach graduate level on-ground & online bioscience global regulatory affairs courses including global clinical trial management and the co-creation of a course on Orphan drug development.

EDUCATION

RAC	Regulatory Affairs Certification, December 2008 Regulatory Affairs Professional Society
MHP	Health Policy, June 1999 Northeastern University, Boston Massachusetts
BS	Health Science, May 1995 Merrimack College, North Andover Massachusetts

REVIEWER

- New edition of *Pharmacy Practice and the Law* for Jones & Bartlett Publishers, 2009
- New edition of *Basic Physical Pharmacy* for Jones & Bartlett Publishers, 2009
- American Psychological Association Conference, 2000 *"Enhancing Outcomes in Women's Health: Translating Psychosocial and Behavioral Research into Primary Care, Community Interventions and Health Policy."*

ABSTRACTS and PRESENTATIONS

Global Phase 3 PolarisDMD Trial for Edasalonexent, an Oral NF- κB Inhibitor in Boys with DMD. J Donovan, R Finkel, K Vandenborne, L Sweeney, E Finanger, G Tennekoon, P Shieh, R Willcocks, G Walters, S Forbes, W Triplett, S Yum, M Mancini, J MacDougall, A Fretzen, P Bista, A Nichols. Presented at the 12th Annual Neuromuscular Translational Medicine Conference | April 4-5, 2019, Newcastle, UK

MoveDMD®: Positive Effects of Edasalonexent, an NF-κB Inhibitor, in 4 to 7-Year Old Patients with Duchenne Muscular Dystrophy in Phase 2 Study with an Open-Label Extension Richard Finkel, MD, Krista Vandenborne, PT, PhD, Lee Sweeney, PhD, Erika Finanger, MD , Gihan Tennekoon, MBBS, MRCS, LCRP, Perry Shieh, MD, PhD, Rebecca Willcocks, PhD, Sean C. Forbes PhD, William T. Triplett, BSc, Sabrina Yum, MD, Maria Mancini, MHP, Angelika Fretzen PhD, Joanne Donovan, MD, PhD. Presented at the 22nd International Congress of the World Muscle Society | October 3-7, 2017 | St. Malo, France

Preclinical development and clinical translation of edasalonexent (CAT-1004), a small molecule using SMART Linker℠ technology as a potential disease modifying therapy for the treatment of Duchenne muscular dystrophy. Hanlan Liu, Joanne Donovan, Maria Mancini, Mike Zimmer, Rafif Dagher, Dominic Picarella, Amal Ting, Diana Lee, Derek Wachtel, Feng Liu, Pradeep Bista, Sachin Chandran, Ron Shmueli, Angelika Fretzen, and Andrew Nichols. Presented at the 4th Ottawa International Conference on Neuromuscular Disease and Biology | September 7-9, 2017 | Ottawa, Ontario

Utilization of Corticosteroids in DuchenneConnect Registry Participants. Leslie Cowen, Maria Mancini, MHP, Ann Lucas, MS, CGC, Ann Martin, MS, CGC, Jenifer Lavigne, MSHP, Joanne M. Donovan, MD, PhD. Presented at Parent Project Muscular Dystrophy (PPMD) Connect Conference | June 29-July 2, 2017 | Chicago, Illinois

MoveDMD: Phase 1/2 Trial of Edasalonexent, an NF-κB Inhibitor, in 4 to 7-Year Old Patients with Duchenne Muscular Dystrophy Richard Finkel, MD; Krista Vandenborne, PT, PhD., H Lee Sweeney, PhD. Erika Finanger, MD, Gihan Tennekoon, MBBS, MRCS, LCRP Perry Shieh, MD, PhD, Sabrina Yum, MD4, Maria Mancini, MHP, Pradeep Bista, PhD, Andrew Nichols, PhD, Joanne Donovan, MD, PhD at Muscular Dystrophy Association, March 2017

CAT-1004, an Oral Agent Targeting NF-kB: MoveDMD Trial Results in Duchenne Muscular Dystrophy (DMD) Finanger, Erika, Oregon Health Sciences University, Portland, OR Donovan, Joanne, Catabasis Pharmaceuticals, Cambridge, MA Vandenborne, Krista, U Florida, Gainesville, FL Sweeney, H Lee , U Florida, Gainesville, FL Tennekoon, Gihan, Children's Hospital of Philadelphia, Philadelphia, PA Yum, Sabrina, Children's Hospital of Philadelphia, Philadelphia, PA Mancini, Maria , Catabasis Pharmaceuticals, Cambridge, MA Danis, Jeff , Catabasis Pharmaceuticals, Cambridge, MA Finkel, Richard, Nemours Children's Hospital, Orlando, FL. Presented at World Muscle Society, October 2016.

Phase 1 Single and Multiple Ascending Dose Study of CAT-2003, a Novel Activator of Lipoprotein Lipase, Demonstrates Reductions in Postprandial Triglycerides JM Donovan, R Dunbar, L Biernat, D Logue, M Mancini, M Curtis, M Jirousek. American College of Cardiology Conference, March 2014.

Drug Development and Clinical Trials. Chinese-American BioMedical Association, October 2011, October 2012.

Food Regulation and Drug Regulation: Resemblances and Difference. Chinese-American BioMedical Association, October 2009, August 2010

Investigator Training: Making the Investigator Meeting Work for You. Barnett International, Cambridge Healthtech Institute's Clinical Training Forum, October 2009

Clinical Trials Overview. Boston College, Carroll School of Management, February 2009, February 2010

Prevalence of epidemic REA types of *Clostridium difficile* from a recent European clinical treatment trial. Anaerobe Society of the Americas 2008

Involving Students in Pharmacy Course Revision. International Federation of Pharmacy, Annual Meeting, France, 2002. Barr J, Sargent E, Elliott A, Chiano L, Duprey A, Li L, Trundy B, Mancini M, Schumacher G

PUBLICATIONS

Cowen L., Mancini M., Martin A., Lucas A., Donovan J. Variability and trends in corticosteroid use by male United States participants with Duchenne muscular dystrophy in the Duchenne Registry, BMC Neurology (2019) 19:84 https://doi.org/10.1186/s12883-019-1304-8

Phase 1 Study of Edasalonexent (CAT-1004), an Oral NF-κB Inhibitor, in Pediatric Patients with Duchenne Muscular Dystrophy. Finanger E, Vandenborne K, Finkel R, Lee Sweeney, Tennekoon G, Yum S, Mancini M, Bista P, Nichols A, Liu H, Fretzen A, Donovan JM. J Neuromuscul Dis. 2019;6(1):43-54. doi: 10.3233/JND-180341.

Cheknis AK, Sambol SP, Davidson DM, Nagaro KJ, Mancini MC, Hidalgo-Arroyo GA, Brazier JS, Johnson S, DN Gerding. Distribution of *Clostridium difficile* Strains from a North American, European and Australian Trial of Treatment for *C. difficile* Infections: 2005-2007. Anaerobe 2009 Dec; 15(6):230-3.