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Welcome to the newly rechristened FTD Research Roundtable. Formerly known as the FTD Treatment Study Group (FTSG), the Research Roundtable convenes representatives from industry, academia, government, and independent organizations in a collaborative, precompetitive environment. We have much to accomplish over the next several days, and look forward to spending productive time together discussing the present and future of FTD drug development and clinical trials.

Our strong hope is that, sooner rather than later, clinical trials will begin to bear fruit in the form of viable FTD treatments. But you don’t have to take our word for it. Earlier this year, speaking at the AFTD Education Conference, world-renowned FTD expert Dr. Bruce Miller said that “over the next decade, I believe we will see effective therapies for the different forms of FTD.” Everyone gathered here in Arlington has the knowledge, the creativity, and the passion to make Dr. Miller’s vision a reality.

Here, we will work together on ensuring that FTD clinical trials are as effective as possible. Given that FTD is a rare disease, and clinical-trial recruitment remains a challenge, this year’s Research Roundtable will focus on improving clinical trial efficiency and power. How can we work around the inherent limitations of FTD clinical trials to maximize their impact? We have planned an agenda designed to help answer this very question.

Much has changed in the FTD landscape since we last convened this meeting in 2021, and not just its name. Bruce Willis’s diagnosis, and his family’s brave, generous choice to share it with the public, has attracted greater attention to FTD than ever before, giving our mission a newfound sense of urgency. While challenges remain, we know that we have assembled the right people in this room to solve them. On behalf of AFTD, thank you for your participation in the FTD Research Roundtable, and for your ongoing work to hasten a future free of FTD.

Susan L-J Dickinson, MSGC  
AFTD Chief Executive Officer

Kimberly Pang Torres  
AFTD Board Chair
Special Thanks to our 2023 Leadership Committee

Adam Boxer, MD, PhD  
UCSF  
Co-Chair

Michael Gold, MS, MD  
Neumora Therapeutics  
Co-Chair

Howard Feldman, MD  
UCSD

Serena Hung, MD  
Arkuda Therapeutics

Penny Dacks, PhD  
AFTD

Michelle Campbell, PhD  
Food and Drug Administration (FDA)

Rodney Pearlman, PhD  
The Bluefield Project to Cure FTD
Special Thanks to our 2023 Research Roundtable Members
SEPTEMBER 6, 2023

7:30 a.m. - 8:30 a.m. ET
Breakfast

8:30 a.m. - 8:45 a.m. ET
Event Welcome
FDA Office of Neuroscience: Teresa Buracchio
European Medicines Agency: Steffen Thirstrup
Co-Chairs: Adam Boxer (UCSF) & Michael Gold (Neumora Therapeutics)

8:45 a.m. - 10:00 a.m. ET
SESSION 1: Defining the Landscape
Chair: Gary Romano (Alector)
• 8:45 a.m. - 8:50 a.m. ET
  Session Orientation
  Speaker: Session Chair
• 8:50 a.m. - 9:05 a.m. ET
  Defining FTD in the Context of a Clinical Trial
  Speaker: Adam Boxer (UCSF)
• 9:05 a.m. - 9:20 a.m. ET
  Current Realities for FTD Clinical Trial Design
  Speaker: David Irwin (University of Pennsylvania)
• 9:20 a.m. - 9:35 a.m. ET
  Success in Rare Disease Drug Development – Friedrich’s Ataxia
  Speaker: Jennifer Farmer (Friedreich’s Ataxia Research Alliance)
• 9:35 a.m. - 10:00 a.m. ET
  Q&A

10:05 a.m. - 10:20 a.m. ET
Coffee Break
10:20 a.m. - 12:30 p.m. ET
SESSION 2: Biomarkers for FTD clinical trials
   Chair: Jeffrey Sevigny (Prevail Therapeutics/Eli Lilly)
   • 10:20 a.m. - 10:25 a.m. ET
     Session Orientation
     Speaker: Session Chair
   • 10:25 a.m. - 10:45 a.m. ET
     Neurofilament Light Biomarkers
     Speaker: Michael Benatar (University of Miami)
   • 10:45 a.m. - 11:20 a.m. ET
     Progranulin and Lysosomal Biomarkers
     Speaker: Gil Di Paolo (Denali Therapeutics)
   • 11:20 a.m. - 11:40 a.m. ET
     Imaging Biomarkers - Volumetric MRI, FDG-PET
     Speaker: Howie Rosen (UCSF)
   • 11:40 a.m. - 12:30 p.m. ET
     Panel discussion

12:30 p.m. - 1:30 p.m. ET
Lunch

1:30 p.m. - 1:50 p.m. ET
REGULATORY SCIENCES - Resources for Rare Neurodegenerative Diseases
   Speaker: Collin Hovinga (Critical Path Institute: Rare and Orphan Disease Programs)

1:55 p.m. - 4:30 p.m. ET
SESSION 3: Outcome Assessments – Clinical and Surrogate
   Chair: Serena Hung (Arkuda Therapeutics)
   • 1:55 p.m. - 2:10 p.m. ET
     Session Orientation
     Speaker: Session Chair
   • 2:10 p.m. - 2:30 p.m. ET
     Clinical Endpoints
     Speaker: Carmela Tartaglia (University of Toronto, University Health Network)
FTD Research Roundtable
2023 Agenda (continued)

• 2:30 p.m. - 3:00 p.m. ET
  Surrogate and Response Biomarkers – The Path Forward
  • 2:30 p.m. - 2:40 p.m. ET
    Surrogate Biomarkers – Learning from Tofersen
    Speaker: Toby Ferguson (Biogen)
  • 2:40 p.m. - 2:50 p.m. ET
    Establishing Biological Surrogates for FTD
    Speaker: Ben Shykind (Prevail Therapeutics/Eli Lilly)
  • 2:50 p.m. - 3:00 p.m. ET
    Q&A

• 3:05 p.m. - 3:20 p.m. ET
  Coffee Break

• 3:20 p.m. - 3:35 p.m. ET
  Novel Methodologies to Build Confidence with Restricted Sample Sizes
  Speaker: Suzanne Hendrix (Pentara Corporation)

• 3:35 p.m. - 3:50 p.m. ET
  Digital Assessments
  Speaker: Adam Vogel (Redenlab, University of Melbourne)

• 3:50 p.m. - 4:35 p.m. ET
  Panel Discussion

4:40 p.m. - 4:55 p.m. ET
Closing Reflections
  Speaker: Arthur Simen (Takeda Pharmaceuticals) and Richard Tsai (Denali Therapeutics)

5:00 p.m. - 7:00 p.m. ET
Reception
SEPTEMBER 7, 2023

7:30 a.m. - 8:30 a.m. ET  
Breakfast

8:30 a.m. - 8:45 a.m. ET  
Opening remarks  
    Speaker: Mark Forman (Passage Bio)

8:45 a.m. - 9:15 a.m. ET  
HOT TOPICS SESSION: Precompetitive Strategies to Increase Participant Numbers

9:20 a.m. - 12:30 p.m. ET  
SESSION 4: Disease Progression Modeling & Statistical Designs  
    Chair: Michael Gold (Neumora Therapeutics)
    • 9:20 a.m. - 9:25 a.m. ET  
        Session Orientation  
        Speaker: Session Chair
    • 9:25 a.m. - 10:30 a.m. ET  
        Disease Progression Models and Clinical Trial Simulation Tools
            • 9:25 a.m. - 9:35 a.m. ET  
                Disease Progression Modeling with FPI  
                Speaker: Adam Staffaroni (UCSF)
            • 9:35 a.m. - 9:45 a.m. ET  
                Lessons Learned from Use of Disease Progression Modeling for Tofersen  
                Speaker: Toby Ferguson (Biogen)
            • 9:45 a.m. - 9:55 a.m. ET  
                Bayesian Disease progression Modeling for Rare Disease  
                Speaker: Melanie Quintana (Berry Consultants)
FTD Research Roundtable
2023 Agenda (continued)

- 9:55 a.m. - 10:05 a.m. ET
  Synthetic Controls – Building Upon Historical Controls
  Speaker: Charles Fisher (Unlearn.AI)
- 10:05 a.m. - 10:30 a.m. ET
  Q&A
- 10:35 a.m. - 10:50 a.m. ET
  Coffee Break
- 10:55 a.m. - 12:30 p.m. ET
  Historical Controls: Applicability and Availability for FTD
  - 10:55 a.m. - 11:15 a.m. ET
    Natural History Studies as Historical Controls
    Speaker: Jennifer Farmer (Friedreich’s Ataxia Research Alliance)
  - 11:15 a.m. - 11:35 a.m. ET
    Mapping FTD Data by Source and Regulatory Framework
    Lightning Round Speakers:
    - ALLFTD - Hilary Heuer (UCSF)
    - GENFI - Jonathan Rohrer (UCL) (prerecorded)
    - FPI - Adam Boxer (UCSF)
    - Industry Placebo-arm Data – Bruce Morimoto (Alto Neuroscience)
  - 11:35 a.m. - 12:30 p.m. ET
    Panel Discussion
    - FARA: Jennifer Farmer
    - Lightning Round Speakers
    - FDA: Teresa Buracchio and Michelle Campbell
    - EMA: Steffen Thirstrup

12:30 p.m. - 1:30 p.m. ET
Lunch

1:30 p.m. - 3:30 p.m. ET
SESSION 5: Brainstorming Tools to Achieve Success in FTD Clinical Trials
  Moderator: Penny Dacks (AFTD)
  Discussants: Michelle Campbell (FDA), Teresa Buracchio (FDA), Adam Boxer (UCSF), Michael Gold (Neumora Therapeutics), Howard Feldman (UCSD), Serena Hung (Arkuda Therapeutics), Rodney Pearlman (The Bluefield Project to Cure FTD), Steffen Thirstrup (EMA)

3:30 p.m. ET
Adjourn
MEET THE SPEAKERS

Michael Benatar, MD, PhD | University of Miami

Michael Benatar, MBChB, MS, DPhil, is a professor of neurology; the Walter Bradley Chair in ALS Research; Executive Director of the ALS Center; Chief of Neuromuscular Division; and Vice Chair for Clinical & Translational Research in the Department of Neurology at the University of Miami. Dr. Benatar obtained his medical degree at the University of Cape Town in South Africa, and his doctorate in neuroscience while a Rhodes Scholar at the University of Oxford. After completing residency and fellowship training at Harvard, he obtained formal training in research methodology through a Master’s in the Science of Clinical Research degree while a faculty member at Emory. He runs an active clinical/translational research program focused on biomarker and therapy development for ALS. He leads the Pre-Symptomatic Familial ALS (Pre-fALS) study, which he initiated in 2007, and the CReATE Consortium, a ~35-center network focused on therapy development for ALS and related disorders. Dr. Benatar is known internationally for his pioneering work in defining the field of pre-symptomatic ALS, including discovery of the first biomarker of pre-symptomatic disease that has been critical to the design and initiation of the first pre-symptomatic ALS trial. He has also been a thought-leader in challenging existing paradigms for pre-clinical therapeutic studies; shaping how we conceptualize and use biomarkers for therapy development; and championing the use of enrichment strategies in ALS trial design.

Adam L. Boxer, MD, PhD | UCSF

Adam L. Boxer, MD, PhD is the Endowed Professor in Memory and Aging in the Department of Neurology at the University of California, San Francisco (UCSF). He received his MD and PhD from the New York University Medical Center Medical Scientist Training Program, completed a Neurology Residency at Stanford and a Neurobehavior Fellowship at UCSF. Dr. Boxer directs the Neurosciences Clinical Research Unit and the Alzheimer’s Disease and Frontotemporal Degeneration (FTD) Clinical Trials Program at the UCSF Memory and Aging Center. Dr. Boxer has been a pioneer in developing new treatments and biomarkers for frontotemporal lobar degeneration. He is co-Principal Investigator of the
ARTFL/LEFFTDS Longitudinal Frontotemporal Lobar Degeneration (ALLFTD) project, a 27 site research network focused on preparing for FTLD clinical trials, and the FTD Prevention Initiative (FPI), a global collaboration focused on preparing for prevention trials in autosomal dominant FTLD. He is PI of the Neurofilament Surveillance Project (NSP), a privately funded study that is developing blood biomarkers for use in FTLD clinical trials. He also leads the Four Repeat Tauopathy Neuroimaging Initiative (4RTNI), a NIH-funded, multicenter, longitudinal tau PET and biomarker study focused on PSP and CBD. He has been the PI for a variety of multicenter, randomized, placebo controlled clinical trials in neurodegenerative diseases, including memantine for FTLD, davunetide for PSP, TPI-287 for primary and secondary tauopathies, a Phase 1b trial of gosuranemab for PSP, and salsalate for Alzheimer’s Disease and PSP. He is the lead PI of the planned NIH Alzheimer’s Clinical Trial Consortium’s (ACTC) Tau Platform clinical trial. He has co-chaired the National Alzheimer’s Project Act (NAPA) FTLD Research Committee for the past four years. He also co-chairs the FTLD Research Roundtable and the PSP Research Roundtable, academic-industry collaborative groups working to speed the development of new therapies for FTLD, CBD and PSP.

Teresa Buracchio, MD

Teresa Buracchio, MD, is Acting Director of the Office of Neuroscience in the Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA). She oversees the review of new drug programs for a variety of neurologic and psychiatric diseases, including Alzheimer’s disease, Parkinson’s disease, ALS, neuromuscular diseases, neurogenetic disorders, major depressive disorder, and schizophrenia. Dr. Buracchio joined FDA in 2013, where she has worked as a clinical reviewer and team leader for several disease areas, including Alzheimer’s disease and dementia, epilepsy, and neuromuscular and neurogenetic diseases. Prior to joining FDA, Dr. Buracchio worked at AbbVie as an Associate Medical Director for Neuroscience Clinical Development. Dr. Buracchio received her medical degree from Rush Medical College and completed a neurology residency at Rush University Medical Center in Chicago, Illinois. Dr. Buracchio completed fellowship training in geriatric neurology at Oregon Health & Science University and Portland Veterans Affairs Medical Center in Portland, Oregon.

Michelle Campbell, PhD

Dr. Michelle Campbell is the Associate Director for Stakeholder Engagement and Clinical Outcomes in the Office of Neuroscience, Office of New Drugs (OND) in FDA’s Center for Drug Evaluation and Research. Dr. Campbell joined the FDA in 2014 and previously was a reviewer on the Clinical Outcome Assessments (COA) Staff and Scientific Coordinator of the COA Qualification Program in OND. Dr. Campbell’s focus is in patient-focused drug development and the use of patient experience data in the regulatory setting. Prior to joining FDA, Dr. Campbell spent more than 10 years conducting research in the academic-clinical setting, including five years in a neurology and developmental medicine department. Dr. Campbell earned her BA in Biology from the College of Notre Dame, her MS in Health Science from Towson University, and her PhD in Pharmaceutical Health Services Research from the University of Maryland School of Pharmacy.
Gilbert Di Paolo, PhD | Denali Therapeutics

Gil Di Paolo received a Ph.D. in Biology from the University of Lausanne in 1998, studying the role of microtubule regulators, stathmin and SCG10/Stathmin-2, in neuronal differentiation and survival in the lab of Dr. Gabriele Grenningloh at the Glaxo Institute for Molecular Medicine in Geneva. Gil subsequently conducted his postdoctoral studies at Yale University in the lab of Dr. Pietro De Camilli, where he discovered novel roles for phosphoinositide signaling in regulation of clathrin-mediated endocytosis and synaptic vesicle trafficking at mammalian synapses.

In 2005, he obtained a Faculty appointment at Columbia University Medical Center and at the Taub Institute for Research on Alzheimer’s Disease and The Aging Brain, where he revealed a role for phosphoinositide and phospholipase signaling in the synaptotoxic actions of Ab and autophagy. He then moved to Denali Therapeutics Inc. in 2016 to pursue his translational research on the role of lipid and immunometabolism dysregulation as well as endolysosomal dysfunction in neurodegenerative disorders. His team discovered a role of TREM2 and APOE in cholesterol metabolism and inflammation. They co-developed a brain-penetrant agonist clinical candidate antibody to TREM2 (DNL919) to enhance microglial functions in AD, identified novel lysosomal functions for progranulin and co-developed a brain penetrant progranulin biotherapeutic (DNL593) for GRN-associated frontotemporal dementia, both of which are currently in clinical development.

Shana Dodge, PhD | AFTD

Shana joined AFTD in May 2021 as Director of Research Engagement. A licensed clinical psychologist, she holds a Ph.D. in Clinical Psychology from the University of Hawaii, an MA in Psychology from the New School, and a BA in Psychology from George Washington University. Shana works to ensure clinical researchers and regulatory bodies understand the needs, priorities, and values of people directly impacted by FTD, and that people with FTD and their loved ones are able to make informed decisions about research participation. Shana has research and clinical experience in cognitive therapy and remediation, early detection of psychiatric conditions, and serious mental illness. Previously, she worked for SAIC, a contractor for the Department of Defense, supporting program evaluation and change management of military health programs.

Jennifer Farmer, MS | Friedreich's Ataxia Research Alliance (FARA)

Jennifer Farmer is the Chief Executive Officer of the Friedreich’s Ataxia Research Alliance. Jennifer has a Master’s degree in Genetic Counseling and prior to joining FARA she worked at the University of Pennsylvania and Children’s Hospital of Philadelphia. As a genetic counselor, Jennifer developed a special interest in neurogenetic conditions and then went on to establish and coordinate clinical and research programs for individuals and families diagnosed with Friedreich Ataxia (FA) and other neurodegenerative diseases. Having established relationships with the families who founded FARA and sharing in their vision to treat and cure FA she joined the organization full time in 2006.
Jennifer has led FARA’s efforts to establish clinical research infrastructure and clinical trial readiness, grown the research grant program from funding <1M annually to >9M annually, led efforts to engage biopharma industry in FA drug discovery and development, and ensured highly efficient and transparent organizational growth and development. In her current role at FARA as CEO, she helps to carry out the strategic mission of the organization through leading FARA’s research and partnership initiatives.

Howard Feldman, MD | UCSD

Dr. Howard Feldman is a neurologist with special expertise in the care and research of cognitive disorders associated with aging and neurodegenerative dementias. His research focuses on the epidemiology, natural history, and experimental therapeutics of these conditions within an approach that includes longitudinal observational cohort studies in clinical and population samples, disease modeling, clinical pathological correlative studies, and trials across the spectrum of preclinical to most severe dementia stages.

His research contributions in the field of frontotemporal dementia (FTD) include the elucidation of both the progranulin and C9ORF72 mutations as the cause of some forms of familial autosomal dominant disease. He also contributed, through familial and neuropathological studies, to the discovery of TDP43 as being the constituent protein of intranuclear and cytoplasmic inclusions within these forms of FTD.

Currently, he serves as Professor in the Department of Neurosciences and Dean of Alzheimer’s and Neurodegenerative Research at UC San Diego where he also directs the Alzheimer’s Disease Cooperative Study (ADCS). The ADCS coordinating center and national network has completed the largest number of Alzheimer Disease clinical trials over the three decades since its inception. Since arriving at UCSD in 2016, he has led the successful development and completion of eight multicenter, randomized clinical trials with the ADCS.

Toby Ferguson, MD, PhD | Biogen

Toby is a neuromuscular neurologist and neuroscientist who joined Biogen in 2013. His professional experience has focused on developing treatments for neuromuscular disease, with a focus on ALS and SMA as well as a more recent focus on movement disorders. He is currently the Head of the Neuromuscular and Movement Disorders Development Unit at Biogen. He plays a key role in developing clinical trials across his therapeutic areas and in driving clinical and preclinical strategy within neurodegenerative disease more broadly. His group also works closely with the preclinical scientific and biomarker teams as well as with external collaborators to identify novel disease targets and to develop the needed tools for efficient clinical development.

At Biogen, he has advanced multiple programs into the clinic for ALS, SMA, Myotonic Dystrophy, and Parkinson’s disease. He has also helped to successfully develop Qalsody (tofersen) an ASO indicated for the treatment SOD1 ALS. He is dedicated to the successful development of meaningful therapeutics for neurologic disease and strongly believes that collaboration across industry, academia, and advocacy organizations is crucial to developing meaningful therapies.
Prior to Biogen, Toby had a clinical neuromuscular neurology practice and a lab focused on peripheral axon injury and regeneration at Shriners Research Center and Temple University in Philadelphia. Toby trained in neurology and neuromuscular neurology at the University of Pennsylvania. He obtained an MD and PhD (Neuroscience) at the University of Florida.

**Charles Fisher, PhD | Unlearn.AI**

Dr. Charles Fisher is CEO of Unlearn.AI, a role he’s held since co-founding the company in 2017 with the aim of advancing artificial intelligence to eliminate trial and error in medicine. During that time, Unlearn has raised $85M in venture capital, grown to almost 50 full-time employees (and still growing), and pioneered applications of AI in clinical research through pharma partnerships, regulatory qualifications, and peer-reviewed publications. Prior to Unlearn, Dr. Fisher was a theoretical physicist and software engineer working at the intersection of machine learning and biology. His research has spanned areas of biology from predicting clinical outcomes to modeling the motion of atoms in proteins and RNA to understanding the organization of large ecosystems. Dr. Fisher’s machine learning research has primarily focused on deep learning, probabilistic generative models, and Bayesian inference.

In industry, he worked as a machine learning engineer at virtual reality startup Leap Motion. As a computational biologist at Pfizer, he developed machine learning-based approaches to the analysis of large-scale ‘omics data. As an academic researcher, Dr. Fisher was a Phillippe Meyere Fellow in theoretical physics at École Normale Supérieure in Paris, France, and a postdoctoral scientist in theoretical biophysics at Boston University. He holds a Ph.D. in biophysics from Harvard University and a B.S. in biophysics from the University of Michigan.

**Mark Forman, MD, PhD | Passage Bio**

Mark Forman, M.D., Ph.D. has served as Chief Medical Officer at Passage Bio since July 2021. Dr. Forman is a neuropathologist and neuroscientist with deep expertise in development of drugs for neurological and psychiatric disorders. From January 2021 to July 2021, Dr. Forman led the Alzheimer’s Drug Discovery Foundation (ADDF) Scientific Affairs team that oversees their drug discovery and drug development portfolio. Prior to joining the ADDF, Dr. Forman was Vice President at Acadia Pharmaceuticals from March 2019 to January 2021, where he was Head of Translational Medicine, responsible for preclinical and early clinical development and contributed to the development of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis and trofinetide for Rett syndrome. Dr. Forman also spent 12 years at Merck where he was Executive Director and Neuroscience Lead in Translational Medicine, responsible for the neuroscience portfolio in early clinical development including contributions to the development of more than 20 novel therapeutics and multiple New Drug Applications. Prior to joining Merck, Dr. Forman was an Assistant Professor of Pathology at the University of Pennsylvania where his research focused on the pathogenesis of neurodegenerative disease, including Alzheimer’s disease, Parkinson’s disease and Frontotemporal Dementia. Dr. Forman received his Ph.D. at Rockefeller University, M.D. at Duke University and a B.S. at Yale University.
Suzanne Hendrix graduated from Boston University with a Ph.D. in mathematics. Dr. Hendrix has worked as a clinical trials statistician, and has now accumulated over 30 years of experience with time spent at CROs and pharmaceutical companies, including projects across many disease areas. Since becoming CEO of Pentara in 2008, Dr. Hendrix has maintained a central focus on analysis of clinical trials for degenerative diseases, especially Alzheimer’s disease (AD). Suzanne has first authored or co-authored over 150 peer-reviewed publications related to both clinical trial results and statistical approaches for clinical trials, many of which include significant contributions to statistical methodology for Alzheimer’s disease. Dr. Hendrix also played an important role in the development of ADCOMS, an AD

Prior to joining AbbVie, Dr. Gold spent several years in large pharmaceutical companies (BMS, J&J and GSK) in roles of increasing responsibility as well as in senior leadership roles in several biotech companies (CMO of Allon Therapeutics and Accera Inc.), in a specialty pharmaceutical company (UCB) and a short stint in a CRO (PPD). Dr. Gold has worked across all stages of CNS drug development, on small molecules, biologicals, drug-device combinations and diagnostics. Dr. Gold and his teams have worked on compounds for AD, PD, Stroke, RLS, migraine, epilepsy, MS, chronic somatic and neuropathic pain resulting in a number of successful approvals in the US, EU and Japan. Dr. Gold earned his BS (Chemistry, cum laude), MS (Mathematics and Computer Science) and MD degrees at the University of Miami, completed his Neurology training at the Albert Einstein College of Medicine in New York and then completed a fellowship in Behavioral Neurology at the University of Florida College of Medicine. After completing his training, Dr. Gold was appointed as an Assistant Professor in the Department of Neurology at the University of South Florida (Tampa) where he provided care for patients, trained medical students, residents and fellows. During his tenure at USF, Dr. Gold was appointed as the Medical Director for USF’s Memory Disorder Clinic, where patients from a large catchment area with a broad range of cognitive impairments were evaluated, treated and offered participation in clinical trials.

Over the last 20 years, Dr. Gold has been involved in many clinical trials for neurodegenerative disorders from the investigator, sponsor and CRO perspectives and has continuously pushed for the adoption of innovative designs in clinical trials. Dr. Gold has served on a number of Scientific Advisory Boards for biotech companies, serves as a grant reviewer for several philanthropic organizations and serves as an editor and reviewer for several peer-reviewed medical journals and has been invited to present at several international scientific conferences. Dr. Gold is an author of approximately 50 peer-reviewed publications.

Michael Gold, MS, MD | Neumora Therapeutics

Dr. Michael Gold joined Neumora on January 17, 2023, to serve as Chief Medical Officer. Dr. Gold is responsible for leading the clinical organization and accountable for advancing Neumora’s pipeline through the clinic. Prior to joining Neumora, Dr. Gold was Vice President, Therapeutic Head CNS Development at AbbVie, where he has spent the past 6 years leading a team of approximately 40 physicians and scientists focused on AbbVie’s CNS pipeline from first-in-man studies through life cycle management for a broad range of neurological and psychiatric indications.
Serena Hung M.D. is the Chief Medical Officer at Arkuda Therapeutics, a biotechnology company that focuses on lysosomal dysfunction in neurodegenerative diseases. She joined Arkuda in April 2020. She is a board-certified neurologist with subspecialty training in movement disorders. She has approximately 20 years of clinical research experience both in industry and academia, including leadership roles in Phase I through Phase III development with successful INDs, BLA/NDAs. She has experience in multiple therapeutic areas in CNS and rare diseases including Parkinson’s disease and composite score to measure cognitive function in individuals with mild cognitive impairment due to AD. Overall, Suzanne’s main goal for Pentara is to “give studies and clients the best chance of success for effective treatments” by implementing better standards and methods for statistical analysis and study design that guarantee accurate results with clinical data.

**Hilary Heuer, PhD | UCSF**

Dr. Hilary Heuer, a researcher at the University of California, San Francisco, serves as co-Program Manager for the ARTFL-LEFFTDS Longitudinal Frontotemporal Lobar Degeneration (ALLFTD) study, which evaluates both familial and sporadic FTLD patients at 28 sites across the US and Canada. She has been an active leader in observational research in FTLD and related disorders for over a decade after transitioning from a career in systems neurophysiology, where she specialized in oculomotor control, visual perception, and sensorimotor integration. She has served as a member of the Executive Committee of the global FTD Prevention Initiative (FPI) to harmonize research in genetic FTLD internationally since its inception in 2018.

**Collin Hovinga, PharmD, MS, FCCP | Critical Path Institute**

Collin Hovinga, PharmD, MS, FCCP, serves as Vice President of the Rare and Orphan Disease Programs at the Critical Path Institute overseeing C-Path’s Rare Disease Cures Accelerator-Data and Analytics Platform and the Critical Path for Rare Neurodegenerative Diseases public-private partnership. Dr. Hovinga completed his Bachelor of Science Degree in Biology and Doctor of Pharmacy degrees from Creighton University in Omaha, Nebraska. After which he pursued a Residency and Fellowship in Pediatric Pharmacotherapy with emphasis in Pediatric Neuroscience at the University of Tennessee, Memphis, LeBonheur Children’s Medical Center. He has a Masters of Epidemiology from the University of Tennessee Health Science Center. Dr. Hovinga has been active in studying factors that influence the efficacy and safety of medications in children and in rare/orphan diseases. Dr. Hovinga is recognized as an expert in neuropharmacology and has served as an advisor to NIH/NINDS and FDA SGE (CNS/PNS and DSRM).

**Serena Hung, MD | Arkuda Therapeutics**

Serena Hung M.D. is the Chief Medical Officer at Arkuda Therapeutics, a biotechnology company that focuses on lysosomal dysfunction in neurodegenerative diseases. She joined Arkuda in April 2020. She is a board-certified neurologist with subspecialty training in movement disorders. She has approximately 20 years of clinical research experience both in industry and academia, including leadership roles in Phase I through Phase III development with successful INDs, BLA/NDAs. She has experience in multiple therapeutic areas in CNS and rare diseases including Parkinson’s disease and...
other movement disorders, Huntington's disease, dementia, ALS, ataxia, and multiple sclerosis. Previously she worked at Wave Life Sciences and Biogen, where she assumed roles of increasing scope and responsibility. She holds a medical degree from Wake Forest University School of Medicine, and a B.S.E. in chemical engineering at the University of Michigan.

She is a Board Director at the National Ataxia Foundation.

**David Irwin, MD | The University of Pennsylvania**

Dr. David Irwin is the co-director of the Penn Frontotemporal Degeneration Center and PI of the Penn Digital Neuropathology Lab at the University of Pennsylvania Perelman School of medicine. He has dual training in cognitive neurology and neuropathology and his lab focuses on integrating human brain histopathology with image analysis methods to integrate fine-grained measures of postmortem neuropathology with antemortem biomarker data, with the overall goal of identifying therapeutic targets and markers of disease progression that can serve as endpoints in treatment trials for FTD, LBD, AD and related neurodegenerative disorders.

**Bruce Morimoto, PhD | Alto Neuroscience**

Dr Morimoto has over 25 years of industry experience leading project teams in the development of innovative medicines for neurodegenerative diseases including Parkinson's, Alzheimer's, ALS and frontotemporal dementias. Previously, Bruce held leadership roles at Alkahest, Celerion, Cerecin and Allon Therapeutics, and works closely with the Michael J Fox Foundation, chairing one of their scientific review panels. He is an advisor to several biotech companies. Bruce started his career on the faculty in the Chemistry Department at Purdue University. Bruce earned his doctorate in biochemistry from UCLA and completed a postdoctoral fellowship at the University of California Berkeley.

**Rodney Pearlman, PhD | The Bluefield Project to Cure FTD**

Rodney Pearlman is President of The Bluefield Project to Cure Frontotemporal Dementia. Bluefield is a non-profit medical research foundation based in San Francisco that manages a consortium of 21 researchers focused on developing treatments for FTD.

Previously he was President and CEO of Nuon Therapeutics, a company developing drugs for treating diseases of the immune system and inflammation.

Prior to joining Nuon, Rodney was a co-founder, President and CEO of Saegis Pharmaceuticals until its acquisition by H. Lundbeck A/S in January 2007. Saegis developed drugs for treating Alzheimer's Disease (AD), mild cognitive impairment and schizophrenia.
He was formerly Senior Vice President of Research and Development at Valentis, a gene therapy company that utilized non-viral vectors to administer gene therapeutics in a variety of applications including cystic fibrosis, cancer and DNA vaccines.

Before joining Valentis, he was Director of Pharmaceutical Research and Development at Genentech, where he and his group developed novel formulations, processes and delivery systems for recombinant human proteins. He also was the Project team Leader for Nutropin® human growth hormone through its NDA approval.

Prior to that, he taught at the University of Texas in Austin and was previously a Senior Scientist with Eli Lilly and Company. Rodney received his Ph.D. in pharmaceutical chemistry from the University of Kansas with Prof. Takeru Higuchi on the delivery of drugs to the brain. He received his B. Pharm. from the Victorian College of Pharmacy, Monash University, Melbourne, Australia.

Melanie Quintana is a Director of Consulting and Senior Statistical Scientist at Berry Consultants where she is an expert in utilizing Bayesian statistics to design innovative clinical trials and answer complex clinical questions across a wide range of therapeutic areas.

Her work includes numerous examples in designing platform trials and clinical trials in rare and progressive disease with a focus on developing models of disease progression to design better and more powerful clinical trials.

She earned her Ph.D. in Statistics from Duke University and went on to pursue a Postdoc in Biostatistics at The University of Southern California where she developed and implemented strategies to assess genetic risk factors for various complex disease. This work led to a passion for consulting and collaborating with clinical experts to find analytical solutions to hard medical problems, which has only expanded since joining Berry Consultants in 2013.

Jonathan Rohrer is a Professor of Neurology at the Dementia Research Centre in the Queen Square UCL Institute of Neurology as well as a Consultant Neurologist at the National Hospital for Neurology and Neurosurgery. He is also a Clinical Co-Investigator at the UK Dementia Research Institute. His team are focused on developing novel clinical, cognitive, digital, imaging and fluid biomarkers of frontotemporal dementia (FTD). He runs the Genetic FTD Initiative, GENFI, an international multicentre cohort study of presymptomatic genetic FTD as well as co-leading the international FTD Prevention Initiative (FPI) which brings together cohorts from around the world. He is also the incoming chair of the Alzheimer’s Association Professional Interest Area in FTD.
Dr. Rosen is a behavioral neurologist and holds the Dorothy Kirsten French Foundation Endowed Professorship for Parkinsonian and Other Neurodegenerative Disorders. He received his medical degree from Boston University School of Medicine, trained in internal medicine at the Albert Einstein College of Medicine in New York, and subsequently completed a neurology residency at UCSF. After residency, Dr. Rosen pursued fellowship training in brain imaging at the Washington University School of Medicine, and then returned to UCSF to join the team at the Memory and Aging Center (MAC) in 1999.

Dr. Rosen's primary research interest is in the effects that atypical neurodegenerative diseases, in particular frontotemporal dementia, have on the brain, especially the emotional systems. His current projects use psychophysiology and imaging to examine how these diseases affect self-awareness and to determine how imaging and other biological markers can be used to track and to anticipate how these diseases affect the brain over time. He is also the director of education and outreach for the education core at UCSF's Alzheimer's Disease Research Center.

As part of the Memory and Aging Center, the Global Brain Health Institute and the UCSF Department of Neurology, he participates in the training of medical students, residents and fellows, and he participates in the evaluation of new patients in the MAC clinic as well as the continued management of care for individuals in the continuity clinic.
Ben Shykind, PhD | Prevail Therapeutics/Eli Lilly

Ben Shykind is a molecular biologist and neuroscientist, who received his Ph.D. from M.I.T. where he studied gene regulation before going on to do post-doctoral training in neuroscience at Columbia University. After a short stint in academia running a lab studying the development and diversification of neurons in the mammalian nervous system, he joined industry and was immediately drawn to the possibility of using gene therapy to treat neurodegenerative disease. Ben ran preclinical programs for ALS and Parkinson's before joining Prevail Therapeutics (a wholly-owned subsidiary of Eli Lilly and Company), where he is currently the Associate VP of Preclinical Research and Development.

Adam Staffaroni, PhD | UCSF

Dr. Staffaroni is an assistant professor at the UCSF Memory and Aging Center. The focus of his research is to improve early detection, prognosis, and monitoring in neurodegenerative diseases, particularly frontotemporal dementia. He is a co-investigator in the ALLFTD consortium and has led several efforts to develop reliable, valid, and scalable remote data collection methods to help surmount barriers to FTLD clinical trials and augment sensitivity to the earliest clinical manifestations of FTLD pathology. He is also Co-PI of the FTD Prevention Initiative’s data infrastructure project and has led the harmonization of data across international familial FTD consortia to enable disease progression modeling, endpoint selection, and clinical trial simulations.
Carmela Tartaglia, MD, FRCPC | University of Toronto

Dr. Tartaglia is a clinician-scientist at the University Health Network Memory clinic and the Centre for Research in Neurodegenerative Diseases, University of Toronto. She received her medical degree from McGill University, completed her residency at the University of Western Ontario and did three years of clinical/research fellowship in Cognitive/Behavioral neurology at the University of California, San Francisco Memory and Aging Center. She maintains a cognitive/behavioral clinic where she sees patients with neurodegenerative diseases with a focus on Frontotemporal lobar degeneration-related syndromes. As well, she is interested in the delayed effects of concussions and sees patients with persisting symptoms of concussion and those with multiple concussions who are at risk of developing a neurodegenerative disease. She holds the Marion and Gerald Soloway Chair in Brain Injury and Concussion Research. She uses a multi-modal approach to better understand the neural substrate of brain-behavior changes seen in neurodegeneration and discover biomarkers for early detection with the ultimate goal of bringing precision medicine and targeted, early treatments to her patients.

Steffen Thirstrup, MD, PhD | European Medicines Agency (EMA)

Steffen Thirstrup is a medical doctor and board-certified specialist in clinical pharmacology and therapeutics. He holds a PhD in pharmacology and has a long background in clinical internal medicine with special emphasis on adult respiratory medicine. Additionally, Dr. Thirstrup was appointed adjunct professor in pharmacotherapy at the Faculty of Health Sciences, University of Copenhagen, in 2012.

From 2004-09 Steffen Thirstrup worked at Danish Medicines Agency first as the Danish member of CHMP at the European Medicines Agency (EMA) for five years including 10 months as joint CHMP- and CAT member, followed by a short period as head of Danish Institute for Rational Pharmacotherapy dealing with HTA and best practice guidelines for primary care. In 2011 Prof. Thirstrup rejoined the licensing division at the Danish Medicines Agency acting as Head of Division for Medicines Assessment and Clinical Trials. During this period Prof Thirstrup co-chaired the European Commission’s working group on market access for biosimilars medicinal products and acted as key scientific contact for the managing entity of the IMI beneficiaries for the PROTECT collaboration (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium).

In March 2013, Prof Thirstrup joined the pharmaceutical consultancy company NDA Group AB as a full time medical advisor on NDA’s regulatory advisory board. In April 2014 Prof Thirstrup was appointed as director for the Regulatory Advisory Board at NDA Regulatory Services Ltd. Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands.

Prof Thirstrup is author of more than 30 scientific papers, guidelines and text-book chapters as well as co-editor of 5th edition of Basal og Klinisk Farmakologi (Medical school pharmacology textbook in Danish).

Prof Thirstrup shares his life between Amsterdam and with his family in a small community (Værlose) just outside Copenhagen, Denmark.
Richard Tsai, MD, MBA  |  Denali Therapeutics

Richard Tsai MD, MBA is a Senior Medical Director in Early Clinical Development at Denali Therapeutics. In this role he partners with preclinical teams, including translational and development sciences, to design and conduct first-in-human, biomarker, experimental medicine and other early studies in healthy subjects and patients. He is the project lead for Denali’s frontotemporal dementia program and has served on committee for the National Institute of Health Alzheimer’s Disease-Related Dementias 2022 Summit.

Previously, Richard was an Assistant Professor of Neurology and Associate Director of Alzheimer’s Disease and Frontotemporal Dementia Clinical Trials Program at the Memory and Aging Center, University of California, San Francisco. He had a research interest in imaging biomarkers and therapeutic development in neurodegeneration under the mentorship of Drs. Adam Boxer and Gil Rabinovici.

Richard received an undergraduate degree in biochemistry at the University of California, Berkeley, and a joint MD/MBA degree at Drexel University. He completed his neurology residency at Albert Einstein College of Medicine in New York, serving as chief resident in his last year. He then completed a fellowship in behavioral neurology at the University of California, San Francisco.

Adam Vogel, PhD  |  Redenlab Inc./The University of Melbourne

Adam Vogel PhD is an Australian Research Council Fellow and Full Professor in School of Health Sciences at The University of Melbourne. He is a global leader in the assessment and treatment of speech and swallowing deficits resulting from neurodegenerative disease. Adam completed his clinical training in psychology and speech pathology at The University of Queensland and research training (PhD) in behavioural neuroscience at The University of Melbourne, Australia. He spent 3 years working clinically at Great Ormond Street Hospital, London before undertaking post-doctoral training the University of Tübingen, Germany.

Alongside his research and clinical load, Adam is Chief Science Officer of Redenlab, a global tech bio company working in the pharmaceutical industry. Since founding in 2017, Redenlab have serviced more than 50 clinical studies through the deployment of meaningful and objective speech and language clinical endpoints for measuring treatment efficacy and disease state. Redenlab work across 25 countries and >250 sites, in indications spanning neurology, gastroenterology and respiratory conditions.
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Frontotemporal degeneration (FTD) is the most common dementia for people under 60, affecting more than 60,000 Americans. That number is very likely an undercount, as this disease is frequently misdiagnosed. FTD is characterized by progressive, irreversible changes to personality, language, behavior, and/or movement. Today, FTD is incurable and there are no approved therapies to slow or alter the course of this disease.

For more than 20 years, The Association for Frontotemporal Degeneration (AFTD) has worked with a dedicated community of volunteers and donors to uplift the voices of families affected, and empower all who face this disease. The leading nonprofit focused on FTD, our mission is to improve the quality of life of people affected by FTD, and drive research to a cure. AFTD advances collaborative research; supports all directly impacted by FTD; raises awareness and educates healthcare professionals; and advocates for appropriate, affordable services.

Thank you for your support.

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