JUNE 2019 VOLUME III



# Message from our CEO

MIGANUSH STEPANIANS, PH.D.

As we reach the halfway point of the year 2019, I am pleased to report to you that our team has grown to approximately 90 employees and our list of clients stands at about 120 large and small biotechnology and pharmaceutical companies who look to us for nimble, creative and high-quality services. Our data management and clinical departments have grown significantly and we have added to our team 5 new data managers and several regional CRAs. I am also happy to report management level additions to these departments including managers, senior managers, and associate directors of clinical operations, drug safety, database programming, and data management. Our statistical and programming team also has grown; we have added several senior level biostatisticians and statistical programmers. In the past 6 months our team has initiated 3 full service studies including full clinical operations support, locked 7 databases, delivered expert statistical services for more than 30 studies and 2 NDAs, and provided medical writing services for several CSRs, IBs, manuscripts, and scientific journal publications.

I am thrilled to report that, in the past 6 months, an additional NDA on which we have collaborated was approved by the FDA. I am proud that we were a part of Sage's Zulresso™ NDA team that brought this important therapy to market, promising to help millions of woman suffering from postpartum depression. We are honored that PROMETRIKA was entrusted with this critical project. Finally, I am excited about all the new technologies that we have now incorporated in our service offerings including advanced data analytics, eTMF, CTMS, TSDV, imaging data repositories, and many more.

Kind regards,



## PROMETRIKA Published

Congratulations to PROMETRIKA's Miganush Stepanians, PhD and Nicole LaVallee, PhD, coauthors of a publication in the American Journal of Medical Genetics. "Maladaptive Behaviors in Individuals with Angelman Syndrome" reports the results of a study of over 300 individuals with AS and how the characteristic behaviors of this genetic disease affect the individuals and their families. Characteristics such as irritability, hyperactivity, and aggression were examined. How these maladaptive behaviors affected parental stress and family quality of life were also measured.

### INNOVATIVE CLINICAL PROGRAM DEVELOPMENT STRATEGIES IN RARE DISEASES

Our Spring 2019 Roundtable in Cambridge, MA brought together a dynamic group of industry leaders to spotlight various challenges and innovations in rare disease clinical program development. Thanks to the breadth of experience of the attendees, we were able to do a deep dive into issues such as the differences in



opinion between regulatory bodies about the acceptability of novel biomarkers in rare disease, the role of patient engagement during clinical program development, and the pitfalls of an accelerated approval pathway. We look forward to hosting our next roundtable event in the fall, which will focus on Oncology Clinical Program Development, and hope you will join us.

JUNE 2019 VOLUME III

### **Celebrating New Partnerships**

PROMETRIKA is proud to announce that we will be managing full trial services to a local biotechnology company on their Phase I dose-escalation study in subjects with advanced solid tumors. PROMETRIKA will provide clinical operations, data management, biostatistics, and medical writing expertise. Our sponsor is an immuno-oncology company with a comprehensive and cutting edge pipeline designed to deliver innovative therapies to patients with cancer. The investigational therapy is expected to selectively deplete immunosuppressive T regulatory cells from the tumor microenvironment.

Emmaus Life Sciences, Inc. has chosen PROMETRIKA to provide full-service trial support for their Phase I study of pharmaceutical grade L-glutamine oral powder in patients with diverticulosis. PROMETRIKA's clinical operations, pharmacovigilance, data management, biostatistics, and medical writing experts will manage the trial. Emmaus Life Sciences, Inc. is a biopharmaceutical company engaged in the discovery, development and commercialization of innovative treatments and therapies primarily for rare and orphan diseases.

# MOVING TOWARDS AN INTEGRATED DATA PLATFORM

PROMETRIKA is growing our strategy for creating an integrated data platform, and we are excited to introduce a number of new additions to our portfolio of clinical trial technologies. As a Medidata CRO Partner, we added the Edge eTMF, Edge Targeted SDV, and Rave Imaging modules to our library of clinical operations and data management products this year. These new tools reinforce our company's commitment providing cutting centralized and risk-based solutions for monitoring strategies for our clients.

### ::: medidata

### Real-Time Data Analytics & Visualization

We are proud to announce that we have partnered with **Comprehend** to bring our clients a solution for real-time data analytics and data visualization. This new platform will enhance PROMETRIKA's data aggregation and reporting offerings by producing on-demand dynamic line listings and graphical patient profiles across different data sources within a single study, or even across different studies within a program. Our clients will be able to explore their own data with visibility into multiple different data sets in a single view, and run descriptive analytics customized for their centralized monitoring strategy.



#### PROMETRIKA Congratulates Dr. Soudeh Ansari

PROMETRIKA announces that Soudeh Ansari, Biostatistician, has completed her PhD in Biostatistics at Boston University. Dr. Ansari began her work here at PROMETRIKA as an intern, eight years ago, while she pursued her degree. Over the ensuing years, she has distinguished herself with her fine analytical skills in our sponsors' projects. Dr. Ansari's research, entitled 'T



herself with her fine analytical skills in our sponsors' projects. Dr. Ansari's research, entitled 'The Causal Effect of Dynamic Fertility Treatment Strategies on the Probability of Pregnancy: A Novel Application of Marginal Structural Models (MSMs),' will be presented this October at the annual congress of the American Society for Reproductive Medicine, to be held in Philadelphia. Sincere congratulations from the whole PROMETRIKA team!