PROMETRIKA
A FULL-SERVICE CRO
NEWSLETTER

# Message from our CEO

*MIGANUSH STEPANIANS, PH.D.*

Welcome to PROMETRIKA's 2019 year-end newsletter! This year has arguably been our most successful and productive since our founding in 2003. We expanded our client base to 125 companies. Our amazing team has contributed to the success of 40 clinical trials and 2 NDAs. We have initiated several full-service trials, moved to production 7 databases and locked another 7. Our statisticians and programmers have analyzed the data for 29 studies, and our writers have completed 12 documents in a variety of indication areas. Our clinical and biometrics teams have grown significantly, with added management-level personnel. Our leadership team was enhanced with the addition of **Barry Mirrer** (former Global Head of Quality Management for the Late Phase division of IQVIA) as our new Head of Quality Assurance. We advanced our mission of adding more technological tools to our clinical trials management offering with our recent accreditation for Medidata's Targeted Source Data Verification module.

We are always expanding our skillset to ensure we are current with the latest methods and thinking of regulatory bodies. In turn, we contribute to our professional communities by sharing our expertise. Our team members have led several roundtables and made presentations attended by many in our vibrant Cambridge biotechnology community. Additionally, our organization has increased its charitable efforts; the PROMETRIKA employer matching program has been successfully leveraged by our team to raise more than $20,000 for various causes including suicide prevention, pancreatic cancer research, funding a bone marrow donor registry, fighting MS and kidney disease, and tutoring economically disadvantaged youth.

On behalf of the entire PROMETRIKA Team, I send you all my best wishes for a successful 2020. May the new year bring advancements and greater successes in development of new medicines to help improve the lives of patients and their families.

Kind regards,

## Real-World Evidence Forum

On December 4th, members of Cambridge's dynamic clinical development community attended an exciting and informative forum sponsored by MassBio titled:

***Closing the Real-World Evidence Gap: Pragmatic Clinical Trials & Observational Studies***


The distinguished speakers included **Dr. Robert Califf**, Former FDA Commissioner and currently Head of Medical Strategy and Policy for Verily Life Sciences and Google Health divisions, **Dr. Rebecca Miksad**, Sr. Medical Director, Flatiron, and **Dr. Jane Liang White**, Sr. Director in Biostatistics, Pfizer. The discussion, moderated by Dr. Miganush Stepanians, explored the use of real-world evidence to support regulatory decision making, the present and future role of pragmatic trials, and use of real-world data as a synthetic control arm in trials.

## CLINICAL PROGRAM DEVELOPMENT STRATEGIES IN IMMUNO-ONCOLOGY

On October 29, PROMETRIKA hosted a roundtable for our colleagues researching immunologic treatments for cancer. **Dr. Joanna Horobin**, Former CMO at Idera Pharmaceuticals, opened with a history of recent oncology advancements and described the need for more efficient study designs for genomically-targeted agents. Dr. Horobin explained that traditional dose escalation trials do not provide insight into the safety and effectiveness of dose levels of immuno-oncology treatments. Effects may develop over years after treatment.

**Aileen Ryan**, Head of Regulatory Affairs and Compliance at LICR, discussed the regulatory landscape. Ms. Ryan indicated that the FDA and other regulators have been very interested in innovative designs and analyses for these new treatments. Biostatisticians who can provide strong mathematical arguments for new analytic designs are the strongest ally of Sponsors in this research area. Participants agreed that opposition to change and novelty often comes from those with financial responsibilities within companies. Assessment of risk can be difficult when methods are groundbreaking.

# Fireside Chat "Through the Eyes of the Innovators"

Last July, PROMETRIKA welcomed **Dr. Steven Burke** and **Dr. Thomas Neenan** of AbFero Pharmaceuticals, and **Dr. Philip Jones** of MD Anderson Cancer Center's Institute of Applied Cancer Science to a Fireside Chat moderated by Heather Paden, PROMETRIKA's Head of Clinical Operations, during our annual Client Appreciation Event. The spotlight panel about building clinical development programs from the ground up for diseases with unmet medical need was an amazing opportunity for the biotech community to hear what it takes to start new research institutions and build partnerships with other biopharmaceutical companies in this competitive environment. We wish to thank our speakers and guests for their attendance and their enthusiastic participation in this event.

## RISK-BASED MONITORING FORUM


In October, our Senior Manager of Clinical Trial Management, Chelsey Ryan, moderated a panel at MassBio's Cambridge headquarters about *Lessons Learned from Implementing Risk Based Monitoring (RBM).*

CRO and Sponsor thought leaders were featured as speakers on the panel, providing insights from varying perspectives. The panel explored the pros and cons of RBM, impact on clinical development costs and timelines, and how a Sponsor can select the right CRO partner to achieve success while implementing RBM.

The panel provided insights on their experiences using tools such as the Risk Assessment and Categorization Tool (RACT) developed by TransCelerate, developing a Risk Management Plan, introducing key performance indicators (KPIs) and key risk indicators (KRIs), and the monitoring of indicators manually or by utilizing specialty quality/risk management software, to plan, track and execute RBM.

The panel ended with a question to each panelist regarding takeaway recommendations that audience members could immediately implement at their own companies or institutions. The key recommendations included performing a risk assessment as early in the project lifecycle as possible, ideally during protocol development, and, if nothing else, maintaining a risk register and log throughout the project.

## ASA-FDA Workshop

In September, Neil Wohlford and Patricia Feeney each hosted a roundtable lunch at the ASA-FDA Biopharmaceutical Workshop in Washington, D.C. to discuss the logistical challenges involved in analyses and reporting. The roundtable format allowed for an interactive exploration of these issues with statisticians from industry and the FDA.

Neil's roundtable discussed strategies for maintaining the blind when analyzing randomized open-label studies. They explored approaches to the planning and implementation of data summarization and access while the trial is ongoing to limit or prevent the introduction of detection bias.

Patty's group discussed approaches for presenting study results prior to database lock to diverse stakeholders. The attendees discussed the use of standardized transformed datasets (CDISC model) versus raw study data, handling dirty data, and general methods to provide decision-makers confidence in the results from the interim output.


As thought leaders in the industry, we at PROMETRIKA embrace opportunities to share our knowledge of methods and strategies with the wider community.

## Happy Retirement, Judy Harris!

In September, PROMETRIKA celebrated the esteemed career of Judy Harris, Head of Project Management, at a party honoring her retirement, at Benedetto Restaurant in Cambridge. Judy was one of PROMETRIKA's founding members in 2003. Judy's leadership roles in project management, compliance, medical writing, and clinical development spanned 30 years. Her dedication and hard work in these areas have been key to PROMETRIKA's growth and success. All of Judy's colleagues will miss her camaraderie and support, and wish her great success in life's next adventures.