PROMETRIKA A FULL-SERVICE CRO

NEWSLETTER

Message from the CEO

Miganush Stepanians, Ph.D.

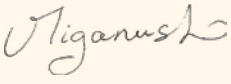
Welcome to PROMETRIKA's 2024 year-end newsletter!

This has been a very busy and successful year for the PROMETRIKA Team. We have started partnerships with 19 new sponsor companies, expanding our client base to 205, and welcomed 13 new employees to our company! This year, we collaborated with 66 sponsors in support of their Phase 1 to 4 clinical trials. Our Clinical Operations and Pharmacovigilance team worked on 12 clinical trials with small and mid-sized innovative sponsor partners. Our Data Managers and Database Programmers built 6 new databases, worked on 24 ongoing clinical trials, and locked the databases of 6 studies. Our Biostatistics and Statistical Programming team has designed and/or analyzed data from 102 studies. Medical Writing supported 13 sponsors with numerous documents, including clinical trial protocols and study reports. In 2024, we helped our sponsors with submission of 4 IND/CTAs and 3 NDA/BLA/MAA, and celebrated the marketing approval of 1 product.

In 2024, we expanded our usage of innovative clinical trial technologies to further automate our processes around the conduct of clinical trials, both in collaboration with our longtime technology partner, Medidata, and by leveraging our internal robust programming resources. We also continued to expand our global clinical trial offering through collaborations with our colleagues at the Association of International CROs (AICROS). PROMETRIKA continued its tradition of contributing to our professional communities. We presented and participated in panels in several statistical, data management/data science, and medical writing conferences. Our team of industry thought leaders continued to expand and enhance our comprehensive training programs for our interns and entry-level staff. Our subject matter experts participated in industry standards development bodies.

Consistent with our commitment to patients and the broader community, PROMETRIKA made charitable contributions of more than $30,000 to non-profit organizations fighting devastating diseases, organizations providing opportunities for the next generation, and relief to those affected by this year's natural disasters.

On behalf of our entire team, I send you my best wishes for a successful new year. May 2025 bring advancements and greater successes in the development of new treatments to help improve the lives of patients and their families.



Case Study: Strategies for Success in Complex Trials with Medidata

Sponsors and their CRO partners must strategically plan complex study designs and operations to maximize trial outcomes. PROMETRIKA partnered with Medidata to seamlessly integrate EDC and RTSM for a sponsor studying a phenylketonuria treatment. EDC data and information on study logistics and patient recruitment and retention were available in real time. We hope you'll read our case study, illustrating the challenges and the joint PROMETRIKA/Medidata solutions that led to successful completion of this study.

White Paper: A Small CRO's Approach to Global Clinical Trial Execution

PROMETRIKA offers planning and conduct of full-service global clinical trials through a team of seasoned industry experts and a vast global site network. We are happy to announce that we will be publishing a white paper exploring the advantages of partnering with a small global CRO for a global trial. We will highlight how streamlined communications, specialized expertise, quality relationships, advanced technology and processes, and agile workstreams offered by small CROs are ideal for Sponsors looking to successfully execute a complex and geographically diverse trial.

PROMETRIKA CEO as Keynote Speaker at 7th Annual NERDS Workshop 2024

Miganush Stepanians, PhD, was the keynote discussant at the New England Rare Disease Statistic (NERDS) Workshop. Dr. Stepanians commented on the keynote presentations of John Scott, PhD, FDA and Kelley Kidwell, PhD, University of Michigan. The keynote presentations focused on the statistical design and analysis challenges of rare disease trials and different methodologies used to address those challenges using both Bayesian and frequentist frameworks. An overview of FDA programs that promote innovation in design and analysis of rare disease trials was also presented. Slides from the discussion are available here.

PROMETRIKA Biostatistician Proposes New Scoring Method for Composite Endpoints

In clinical trials, patient-reported outcomes (PROs) are widely used to measure patient quality of life, and are included as composite endpoints in many oncology trials. In a generalized pairwise comparison (GPC), it is challenging to establish a clear ranking order for PRO scales. This summer, at the Joint Statistical Meetings (JSM), Peiwen Yu, Biostatistician III, presented a semi-prioritized GPC method that avoids the need for a strict order of PRO scales while preserving the importance of the primary endpoint.

PROMETRIKA Discusses AI at SCDM 2024

Kathy Zheng, MPH, Director of Project Management and Clinical Innovations, spoke at this year's SCDM 2024 Annual Conference in Boston, MA about Using AI in Clinical Operations, Data Management and Science: A Practical Blueprint for Streamlined Clinical Trials. Her discussion focused on the practicality of implementing AI with CROs' Sponsor partners and how PROMETRIKA works with our Sponsors to help develop a practical strategy for addressing common roadblocks.

PROMETRIKA Hosts Roundtable at 2024 Medical Writing & Communications Conference

At the American Medical Writers Association (AMWA) 2024 annual meeting, Andrew Park, PharmD, Sr Medical Writer, presented a roundtable to discuss the best practices for QC'ing a protocol during the development stage. Andrew shared his experiences relating to the most common sources of internal protocol inconsistencies, the QC steps that can identify problems, and the approaches to avoid inconsistencies during protocol writing.

PROMETRIKA with a Purpose: Supporting Hurricane Helene Disaster Relief Efforts

All of PROMETRIKA supported team members who live in North Carolina and who volunteered to log phone requests for help and load small planes with hurricane relief supplies. Thanks to the generosity of PROMETRIKA employees and our corporate matching program, PROMETRIKA donated $3,710 to the Ashville Family Church and Operation Airdrop.

Pan-Mass Challenge:

PAN-MASS CHALLENGE

This summer, PROMETRIKA employees donated to the Pan-Mass Challenge (PMC), a two-day bicycle ride across Massachusetts in support of the Dana-Farber Cancer Institute. For the past 44 years the PMC has raised more money for cancer research than any other national event. Through employee donations and company matching, PROMETRIKA raised $3,790! We're proud of all our employees' commitments to helping patients.

Employee Spotlight: Dennishia Bell

Beacon Academy offers a 10-year program catalyzed by a transformational gap year between 8th and 9th grade, designed to prepare highly motivated learners from historically under-resourced and /or underrepresented communities to succeed in competitive high schools, colleges, and careers. Beacon Academy's mission is to continue to advance education equity and make a long-term commitment and investment in its students because they believe education is a crucial vehicle for achieving this goal. Dennishia Bell, Human Resources and Recruiting Generalist, recently participated in Beacon Academy's Explore Beacon event as a panel speaker, sharing her experience as a founding class member of 2006. Dennishia enjoys volunteering as a Beacon Academy Ambassador, supporting the needs of students and alumni while advocating for resources and career networking opportunities, especially during Beacon Academy's milestone 20th anniversary year.

Congratulations

Travere Therapeutics has received full FDA approval for FILSPARI® to slow the decline of kidney function in adults with primary IgA nephropathy (IgAN), a rare kidney disease. FILSPARI® is the first and only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney.

Cogent Biosciences has completed enrollment and interim futility analysis in its phase 3 PEAK study evaluating bezuclastinib in combination with sunitinib for the treatment of patients with gastrointestinal stromal tumors (GIST).

Aptevo Therapeutics has partnered with PROMETRIKA to conduct its frontline, open-label, dose-finding, AML study of its potential new treatment in combination with venetoclax and azacitidine (ven/aza).

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