PROMETRIKA A FULL-SERVICE CRO NEWSLETTER

Message from the CEO

Miganush Stepanians, PhD

The first half of 2026 has been a busy, productive, and very successful time for our entire team!

In the first half of 2026, the PROMETRIKA team celebrated a major regulatory success with one of our longstanding sponsor partners: the FDA approval of the first and only treatment for a devasting rare disease! Our team also collaborated with several sponsor partners on successful database lock and key result readouts for their critical phase 3 trials. These milestones represent great successes for our sponsors and, more importantly, bring hope to patients suffering from serious and life-threatening diseases.

We have had several occasions to accompany our sponsor partners in their meetings with regulatory bodies to advance their drug development programs by leveraging innovative regulatory pathways and clinical trial designs. We have started collaborations with several new innovative and dynamic biotechnology companies that welcome us as a full-service extension of their teams. Some of these new collaborations have started with PROMETRIKA's expert Regulatory and Medical Writing teams working with our sponsors in the preparation of pre-IND and IND submissions to the FDA and authoring regulatory meeting briefing books.

We continue to expand our team and have welcomed several new team members, including a highly experienced leader in information technology and cyber security. Indeed, rapidly advancing technological tools, including AI, are a large focus of our leadership team. Our goal is to ensure that the right pieces of technology are implemented strategically in the service of enhanced efficiency and quality of our service provision model, while prioritizing data integrity and information security.

In our continuing efforts to advance the careers of future industry leaders, our team of SMEs and industry thought leaders have further developed and enhanced our comprehensive training programs for our interns and entry-level staff.

We look forward with hope and great enthusiasm to the second half of 2026!

Medidata Interim Lock Tool

PROMETRIKA is excited to expand our suite of clinical trial technologies and Data Management workflows with the addition of Medidata Interim Lock. This innovative solution helps automate and streamline the locking of data on an ongoing basis, enabling faster interim analyses and database locks while reducing manual effort and operational burden. By supporting continuous data cleaning, the tool enhances efficiency, accelerates study readouts, and promotes faster decision-making with early access to high quality data.

Medidata NEXT 2026

Chelsey Ryan, MSHS, PMP, PROMETRIKA's Director of Clinical Operations and Pharmacovigilance, joined a panel of distinguished speakers at Medidata NEXT NYC to discuss "Modernizing Patient Payments and Travel Management," demonstrating how unified payment workflows, automated reimbursements, and simplified travel management reduce site burden, eliminate delays, and create a more supportive environment for patients and caregivers.

PROMETRIKA Joins Panel at SCOPE 2026

Chelsey Ryan, MSHS, PMP, joined the Beyond the Budget Line panel with Medidata at SCOPE 2026. She shared insights on navigating complex budgeting, forecasting, and financial strategy in clinical operations from a CRO perspective, and what it really takes to go beyond the budget line.

Rethinking Global Clinical Trials for Biotechs

How Regional Expertise Can Accelerate Global Clinical Trial Execution

In a global drug development landscape, many biotechs face significant challenges: varying regulatory regimes, local site infrastructure, supply chain logistics, language barriers, and consistency of data integrity across regions. PROMETRIKA hosted a webinar diving into how a region-specialized, global partnership of CROs can help you overcome these complexities – without sacrificing quality or control. The webinar provided insight into the following solutions:

- How a centralized CRO can serve as the project lead, collaborating with local partners to deliver regional expertise.
- How this model can offer our Sponsors a high-touch solution for ensuring quality across regions and offer seamless oversight.
- How this model offers a leaner, more flexible approach to running global clinical trials.

In case you missed it, watch the webinar here.

PROMETRIKA with a Purpose

Volunteering for Our Communities

MGH Ketamine Clinic for Depression

Navigating appropriate treatments can be overwhelming for patients struggling with dependency. At the Massachusetts General Hospital Ketamine Clinic for Depression, volunteers escort patients through the treatment visit, providing assurance to patients and allowing the healthcare team to focus on deeper treatment interactions. Cara Jackson, Clinical Trial Associate III at PROMETRIKA, provides her support for the program as part of our PROMETRIKA with a Purpose volunteer initiative.

MCPHS Institutional Animal Care and Use Committee

At the Massachusetts College of Pharmacy and Health Sciences, the Institutional Animal Care and Use Committee (IACUC) plays a critical role in ensuring the humane and ethical treatment of animals involved in research. While PROMETRIKA's work is focused on protecting human safety in clinical research, animal welfare is also deserving of careful oversight and accountability. Edita Mirković, Senior Project Manager at PROMETRIKA, serves on the committee as a Community Member, providing an outside, community perspective on ethical and responsible animal research practices and accountability.

Employee Spotlight

Mark Dunning, CISSP, CISA

PROMETRIKA is excited to welcome Mark Dunning, Head of Technology, Executive Advisor of IT & Security Strategy. Mark brings over 25 years of strategic IT and cybersecurity leadership driving enterprise-wide transformation, risk reduction, and cost optimization. In his most recent prior position, Mark provided client services as Chief Information Security Officer and consulted as a Cyber Security Advisor.

Mark's extensive experience includes the full range of Information Technology functions. He has applied his deep knowledge of system standards and available technologies to developing risk strategies for AI threats and creating information security programs for government and private enterprise clients. He has created a global IT function from several regional and local operations, with a single business strategy, budget, and set of standards.

Congratulations

Seaport Therapeutics reported that GlyphAgo™ (glyphed agomelatine) for generalized anxiety disorder (GAD) achieved therapeutic levels of agomelatine at substantially lower doses that reduced liver exposure in healthy volunteers.

At the ASH conference, **Kelonia Therapeutics** presented early positive results for its in vivo CAR-T product, KLN-1010, in four patients with relapsed or refractory multiple myeloma. At the recent ASCO meeting, Kelonia reported that patients assessed at 6 months post-treatment and one patient assessed after 10 months remained cancer-free.

Novo Nordisk announced the topline results from HIBISCUS, a pivotal phase 3 trial of once-daily oral etavopivat in adults and adolescents with sickle cell disease (SCD). The results showed that etavopivat successfully met both co-primary endpoints, demonstrating superior reduction in vaso-occlusive crises (VOCs) and superior improvement in haemoglobin (Hb) response compared to placebo.

Travere Therapeutics announced full FDA approval of FILSPARI™ (sparsentan) to reduce proteinuria in patients aged 8 years and older with the rare kidney disease, focal segmental glomerulosclerosis (FSGS).

Intellia Therapeutics reported positive results for single-dose lonvoguran ziclumeran (lonvo-z) in hereditary angioedema (HAE), an in vivo CRISPR gene editing candidate intended to lower kallikrein and bradykinin levels that lead to recurrent and potentially life-threatening angioedema attacks.

Cogent Biosciences had their NDA accepted by the FDA with Priority Review for bezuclastinib in combination with sunitinib for patients with gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib.