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PROMETRIKA A FULL-SERVICE CRO

NEWSLETTER

Message from the CEO

Miganush Stepanians, PhD

Welcome to PROMETRIKA's 2025 mid-year Newsletter!

The first half of 2025 has been productive and very successful for our teams and our sponsor partners!

Along with our sponsors, we have celebrated NDA and marketing authorization approvals for dossiers submitted last year. We had several successful meetings with regulators, in which we gained agreements on product development programs and study protocols that PROMETRIKA has helped design. Our Regulatory, Medical Writing, and Biostatistics teams collaborated with sponsors in the preparation of pre-IND and IND submissions to the FDA.

Since the beginning of the year, we have started collaborations with innovative and dynamic sponsor companies and continue to collaborate with our current sponsors. PROMETRIKA enters these relationships as the extension of the sponsor's team; in many cases, providing full-service collaboration including protocol development, clinical operations, data management, statistical analysis, writing of the CSR, drug safety, and independent data monitoring committee services.

At recent industry conferences, PROMETRIKA's team members and leaders have shared their expertise and innovations with the professional community by making presentations and participating in industry leadership panels. To assist sponsors planning global clinical trials, we have published a White Paper on a small CRO approach to addressing the many facets of these trials.

In collaboration with our technology partner, Medidata Solutions, the PROMETRIKA team is piloting the usage of smart analytics tools that harness the power of AI to tackle the challenges inherent in today's complex studies.

And we are excited to continue to expand our team! So far in 2025, we have welcomed 11 new team members and 3 new interns. Our team of industry SMEs 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 2025!

PROMETRIKA at Fenway Park

PROMETRIKA hit a home run with our event at Fenway Park! Against the backdrop of Boston's iconic ballpark, our colleagues and Sponsors met for an evening filled with camaraderie and conversation. All who attended made this event one of the year's highlights.

Learn about FDA and EMA Expedited Development Pathways

Interested in learning about the expedited development pathways offered by the FDA and EMA? PROMETRIKA recently produced a short video that might be helpful. Aileen Ryan, PROMETRIKA's Senior Regulatory Affairs Advisor, covers key aspects of the FDA's Fast Track, Breakthrough Therapy, and Accelerated Approval and the EMA's PRIME and Conditional Marketing Authorisation pathways.

Aileen walks through:

- The main differences between the various FDA and EMA pathways
- Eligibility criteria for these programs
- How to assess which pathway is right for you

Click here to watch the video: FDA and EMA Expedited Development Pathways

PROMETRIKA Explores Data Standardization in Academic Research using REDCap at 2025 CDISC + TMF Europe Interchange

At 2025 CDISC + TMF Europe Interchange, Susan Mutter, Director of Statistical Programming, delivered a session entitled, "Mapping REDCap Data into SDTM: A Case Study of Healthy Volunteer Research Data." Research Electronic Data Capture (REDCap) is a free, user-friendly web-based interface designed specifically for use by academic and public health non-profit institutions. The REDCap consortium consists of thousands of institutions and millions of users and studies, representing the potential for a huge pool of data that could be tapped to support clinical trials. Susan shared the lessons learned by PROMETRIKA's Statistical Programming team from mapping REDCap data to SDTM, and recommended strategies for improving data standardization in academic research.

PROMETRIKA Presents at PharmaSUG US Conference

Speeding SAE Reconciliation with SAS

Patrick Dowe, Statistical Programmer III, and Gina Hird, Sr. Statistical Programmer, discussed, "Automating Recurring Data Reconciliation for SAEs Using SAS" at PharmaSUG 2025. The program developed by Patrick and Gina, in collaboration with Valerie Jurasek, Senior Safety Specialist, performs a series of cascading matches by key variables to reconcile pharmacovigilance data (in this case in Excel format) with the SAS dataset from the clinical database. The differences between data points are highlighted for follow-up. Thereafter, the program uses a second series of cascading matches by key variables to compare the latest run to the prior run. Prior discrepancies that have been resolved are identified and new changes and discrepancies are highlighted. These methods significantly reduce the Data Managers' time spent on reconciliation; improve data integrity and consistency; and preserve comment history.

Streamlining Retrieval and Customization of SAS Programming

Ning Ning, Statistical Programmer, presented, "Optimizing SAS Programming Pipelines: %Unpack and %SearchReplace Macros for Version Control and Customization," co-written with Assir Abushouk, Manager, Statistical Programming, at PharmaSUG 2025. %Unpack enables quick access to the latest versions of SAS macros, programming shells, and directory structures. %SearchReplace automates searching for and replacing specific strings in SAS programs to customize them to user needs. These macros automate repetitive tasks such as retrieval of current template folders and files; project-related changes; and streamlining SAS programming workflows. Ultimately, this integrated solution enhances regulatory compliance and pipeline efficiency.

Supporting Walk MS Boston 2025

PROMETRIKA team members joined hundreds in Boston for the annual Walk MS event. Through employee donations and a generous company match, PROMETRIKA raised $18,600, the seventh largest donation in Massachusetts. This is the 11th year that PROMETRIKA has participated in this event to support the National MS Society, the largest private funder of MS research in the world.

Employee Spotlight: Benjamin King, Associate Director, Medical Writing

PROMETRIKA has welcomed Benjamin King, PhD, to the position of Associate Director, Medical Writing. In his new role, Dr. King will be responsible for Medical Writing leadership and management, and closely collaborating with other departments in the development of regulatory submission documents.

Dr. King most recently served as Director of Medical Writing at Immunovant, Inc. Prior to that, Dr. King held positions as Manager and Associate Director of Medical Writing and Clinical Submissions Planning at GlaxoSmithKline, Inc.

After receiving his PhD in Biomedical Science, Dr. King began his career as a clinical research associate, going on to positions as a clinical research scientist, associate director of clinical development, and senior medical writer at several sponsor companies.

Dr. King's vast regulatory writing experience and leadership skills are a valuable addition to PROMETRIKA's writing team.

Congratulations

Travere Therapeutics, Inc. and CSL Vifor have announced that the European Commission and the United Kingdom's MHRA have converted the FILSPARIÆ (sparsentan) conditional marketing approvals to standard marketing authorizations for the treatment of adults with immunoglobulin A nephropathy (IgAN), a rare progressive kidney disease. FILSPARI significantly decreased chronic disease progression over two years versus an active comparator.

Travere Therapeutics, Inc. has submitted a supplemental NDA (sNDA) to the US FDA for FILSPARIÆ (sparsentan) for the treatment of focal segmental glomerulosclerosis (FSGS), a rare proteinuric kidney disorder.

GRIN Therapeutics, Inc./Neurvati Neurosciences Co. has announced orphan drug designations from the EMA and FDA, and a breakthrough drug designation from the FDA, for its investigational drug radiprodil. Radiprodil will be studied for the treatment of GRIN-related neurodevelopment disorder (GRIN-NDD), a family of rare pediatric disorders caused by mutations in GRIN genes. The company is preparing to initiate a pivotal clinical trial examining radiprodil's effects on seizures associated with GRIN-NDD.

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