A Vision for *Therapeutic Innovation & Regulatory Science*

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We are living in a period of astonishing medical and scientific advances. Our global pharmaceutical pipeline is increasingly complex, full of innovative treatments with novel mechanisms of action that offer the potential to transform how patients live with chronic diseases, and even offering cures for debilitating genetic disorders. At the same time, we are also seeing significant advances in regulatory science tools and best practices across the globe. In the United States, strong bipartisan support for initiatives like the 21st Century Cures Act and the Food and Drug Administration (FDA) Reauthorization Act of 2017 enable and support a modern US FDA. Similarly, regulatory authorities across the globe are moving to become more innovative, nimble, and responsive to developing technologies. In this heady time as medicine advances and the scientific and regulatory approaches innovate and evolve, critically important questions arise about how best to enable better patient access and ensure affordability without dampening innovation.

DIA and TIRS are uniquely poised to address these vital questions and many more. TIRS strives to advance medical product discovery, development, regulation, and use through the publication of peer-reviewed original and review articles, commentaries, and letters to the editor across the spectrum of converting biomedical science into practical solutions to advance human health globally. To realize this mission, the journal must be the home for rigorous research and expert commentary on science and scientific methods to advance the development and use of medical products and the home for the needed evidence to advance new policy as well as evaluate the impact of existing policy to advance and improve health.

As the new Editor-in-Chief of TIRS, I encourage you to continue to submit your research and thought leadership in these areas as well as related high-priority areas, globally, including:

Incentives for new innovation in neglected diseases and areas of high unmet need. One critical example is multidrug-resistant infections and antimicrobial resistance (AMR). Challenging market dynamics have led to a weak pipeline of targeted therapies as most companies have exited the antimicrobial market. Since reimbursement systems reward revenue to companies based on volume of drug used, many experts across the globe have called for new ways to reward companies

for successfully marketing a new high-priority antibiotic that delinks revenue from sales volume. We need to hear from the DIA community about how to quantify the societal value of having effective antibiotics, how to design the most appropriate push-and-pull financial incentives for investment, how new payment models should be designed, and how to ensure global coordination and access.

Expanding development and use of real world evidence (RWE) to support regulatory decisions and coverage and payment. We clearly need examples of designs that produce high-quality, acceptable evidence. Specifically, how do we ensure that the real-world data are fit-for-purpose? How can we ensure that observational designs and randomized designs are developing rigorous and substantial RWE? How do we improve RWE transparency so that regulators can trust the evidence? I look to you to grapple with these difficult global questions.

Supporting access for high-cost drugs and devices. We must consider how best to ensure that patients can access promising medical products at an affordable price and at an appropriate level of societal investment. In consideration globally is the role of value-based payment approaches for medical products in addressing high prices, bringing better value and access to patients and the health care system through risk-sharing, and support of improved data collection. TIRS is a great venue for analyses of potential impact of these ideas and suggestions on how these approaches and other payment reforms can lead to better outcomes and information for patients.

Last year, TIRS was accepted for inclusion in MEDLINE and is now indexed in PubMed. Along with increased high-quality submissions from around the globe, we are seeing increased readership and interest. I am truly looking forward to working with you, our readers and authors, the TIRS Associate Editors and Editorial Advisory Board, and DIA leadership and staff, to ensure continued momentum and the upward trajectory of this promising journal.

Gregory Daniel, PhD, MPH, RPh
Editor-in-Chief,

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