A Milestone: *Therapeutic Innovation & Regulatory Science* Has Been Accepted for Inclusion in MEDLINE

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At the end of March, the United States National Library of Medicine (Department of Health and Human Services, National Institutes of Health) accepted *TIRS* for inclusion in MEDLINE. MEDLINE citations are searchable in PubMed, thus making the abstracts of our authors' papers readily accessible to patients, payers, regulators, clinicians, academic/industry researchers, and all other stakeholders across the global health care product development continuum.

This is a true milestone in the evolution of the journal's contributions to thought leadership in the domains of therapeutic innovation and regulatory science, contributions whose quality continues to grow ever higher and whose influence on health care product development and therapeutic use continues to increase. I offer sincere thanks to all authors who submit their work to the journal, reviewers who donate precious time to enable the peer review system to work effectively, members of the journal's Editorial Board, our Associate Editors, and our Senior Managing Editor, Ranjini Prithviraj, PhD, PMP.

Biological, clinical, statistical, and manufacturing sciences have long been central components of new health care product development and hence therapeutic innovation. Regulatory science has now been firmly added to that list. On October 6, 2010, in Washington, DC, then US Food and Drug Administration (FDA) Commissioner Dr Margaret Hamburg announced the release of a White Paper titled "Advancing Regulatory Science for Public Health: A Framework for FDA's Regulatory Science Initiative." She noted that regulatory science refers to "the science and tools needed to assess and evaluate a product's safety, efficacy, quality, and performance. Regulatory science involves the development of new methods, standards, and models we can use to speed the development, review, approval, and ongoing oversight of medical products."¹ In August 2011, the agency released its document titled "Advancing Regulatory Science at FDA: A Strategic Plan."² The plan identified eight priority areas of regulatory science where new or enhanced engagement in regulatory science research was considered essential to the continued success of FDA's public health and regulatory mission: a ninth strategic priority was added in 2013. The priorities are as follows:

1. Modernize toxicology to enhance product safety.
2. Stimulate innovation in clinical evaluations and personalized medicine to improve product development and patient outcomes.

3. Support new approaches to improve product manufacturing and quality.
4. Ensure FDA readiness to evaluate innovative emerging technologies.
5. Harness diverse data through information sciences to improve health outcomes.
6. Implement a new prevention-focused food safety system to protect public health.
7. Facilitate development of medical countermeasures to protect against threats to US and global health and security.
8. Strengthen social and behavioral science to help consumers and professionals make informed decisions about regulated products.
9. Strengthen the global product safety net.

I should note that the US FDA is not the only regulatory agency advancing regulatory science. It is also very important at the European Medicines Agency,³ the Japan Pharmaceuticals and Medical Devices Agency,⁴ and other regulatory agencies around the world.

It is also important to note that, in addition to regulatory agencies, other stakeholders play major roles in advancing regulatory science. Academic medical centers have considerable scientific expertise, and interaction between regulators and academicians can help shape "the regulatory science agenda."⁵ The same applies to experts from industry. As a result of the contributions and collaborations of experts from this triumvirate of stakeholders, consortia are playing a particularly significant role in the advancement of regulatory science. Since its launch in Europe in 2008, the Innovative Medicines Initiative "has catalyzed the formation of many consortia to address challenges in drug development and regulation."⁶ Consortia are also important to the FDA's involvement in the advancement of regulatory science: since their Critical Path Initiative was launched in 2004, FDA's Center for Drug Evaluation and Research has participated in more than 20 science-driven consortia to improve the science of drug development and regulation.⁷ Additional references addressing regulatory science are provided.⁸⁻¹²

While the value of "pure play" journals (journals focusing exclusively on one discipline, such as statistics or clinical pharmacology) is unquestioned, journals that encourage the submission of manuscripts describing multidisciplinary collaborations and translational science approaches are of increasing importance: as a journal embracing such work,

TIRS's acceptance for inclusion in MEDLINE is a timely occurrence. All of us involved with the production of the journal look forward to continuing to serve our readers.

J. Rick Turner, PhD, DSc, FASH, FACC, FESC, FCP
Editor-in-Chief

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