TRANSLATIONAL AND REGULATORY SCIENCES

Instructions for Authors

ABOUT THE JOURNAL

Aim

The aim of this international open access journal, Translational and Regulatory Sciences (TRS), is to create a new platform for launching new ideas, by not only industry and regulatory authorities but also members of the academe who want to contribute to better use of their research activities within the medical realm. Thereby, the journal aims to render a significant impact on the abilities of those communities to bring new medicines and medical devices to patients in need. An expected effect of TRS is that experts from the industry, academe, and government will harmonize their efforts on equal footing and will promote academic progress and dissemination regarding the regulatory science of pharmaceuticals, medical devices, and related aspects using this journal.

Scope

Categories

- Translational Science
- Regulatory Science

Including but not limited to:

- Analytical Chemistry
- Assay Development for Screening
- Automation of screening (high throughput screening)
- Clinical Research Efficiency
- Collaboration and Partnerships
- Compound/Library Management
- Data Transparency and Sharing
- De-risking Therapeutics Development
- Early-Stage Drug Repurposing
- Flexible Study Designs
- Groundbreaking Efforts to Transform the Way Drugs and Medical Devices are Developed, Evaluated, and Manufactured
- Informatics
- involvement and Ethical Aspects
- Late-Stage Drug Repurposing
- New Animal Models of Human Diseases
- New Approaches to Assess the Safety, Efficacy, Quality, and Performance of Medical Products
- New Biomarkers and Clinical Application
- New Concepts of Benefit/Risk Assessment, Submission, and Approval Strategies, Patient's Involvement and Ethical Aspects
- New Human Health and Ecological Risk Assessment Procedures and Post-marketing Evaluation Method and Processes for Drugs and Medical Devices
- New Methods/Approaches to Improve Patient Recruitment and Retention in Clinical Research Studies
- New Methods/Approaches to Reduce Research Costs and Complexity
- New Predictive Methods/Models for Efficacy Evaluation
- New Predictive Methods/Models for Toxicity Evaluation
- New Standards and Approaches to Facilitate Sound and Transparent Regulatory Decision-making Regarding Drugs and Medical Devices
- New Standards, Concepts, Proposals, and/or Regulations for Gene Therapy, Cell Therapy, and Regenerative Medicine
- Patient and Contact Registries
- Probe Development and Lead Optimization
- Translational Clinical Sciences from Animals to Humans
- Target Identification and Validation

Sub-categories

One of the following sub-categories should be noted as the field of the paper:

Biochemistry, Organic Chemistry, Natural Product Chemistry, Herbal Medicine, Metabolism, Neuroscience, Immunology/Allergy, Experimental Animal, Cell Signaling, Stem Cell/iPS, Oncology, Genome/Epigenome, Drug Delivery System, Drug Metabolomics, Toxicology, Evaluation Study, Public Health, Risk Assessment Study, and Epidemiology

Frequency of publication

TRS is issued quarterly, and the inaugural issue of TRS will be published in August 2019.

Ethical Treatment of Subjects

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Article Structure

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State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

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The following are examples of References:

1. Beiser, J. A., Gustin, K. M., Pearce, M. B., Maines, T. R., Zeng, H., Pappas, C., Sun, X. S., Camey P. J., Villanueva, J. M., Stevens, J., Katz, J. M. and Tumpey, T. M. 2013. Pathogenesis and transmission of avian influenza A (H7N9) virus in ferrets and mice. Nature 501: 556–559.
2. Hamm, L. L., Alpern, R. J. and Preisig, P. A. 2013. Cellular mechanisms of renal tubular acidification. pp. 1917–1978. In: Seidin and Giebisch's The Kidney, 5th ed. (Alperm, R. J., Caplan, M. J. and Moe, O. W. eds.), Elsevier, Amsterdam.
3. Sasaki, H., Sasaki, N., Nishino, T., Nagasaki, K., Kitamura, H., Torigoe, D. and Agui, T. 2014. Quantitative trait loci for resistance to the congenital

nephropathy in tensin 2-deficient mice. PLOS ONE 9: e99602.
4. Wild, D. G. 2013. The Immunoassay Handbook, 4th ed., Elsevier Science & Technology, Oxford.

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