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Call for papers

Translational and Regulatory Sciences

Catalyst Unit

https://cutrs.jp/

About the new international journal

Translational and Regulatory Sciences (TRS)

With the cooperation of the Japan Agency for Medical Research and Development (AMED), The University of Tokyo, the Graduate School of Agriculture and Life Sciences, and the National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN), etc., we have now established an e-Journal named **Translational and Regulatory Sciences (TRS)**. The Pharmaceuticals and Medical Devices Agency (PMDA), the National Institute of Health Sciences (NIHS), and Japan Pharmaceutical Manufacturers Association (JPMA) will also support TRS.

TRS is an international peer-reviewed e-Journal with an entirely new concept of handling Translational Sciences and Regulatory Sciences. **Translational Sciences (TS)** is different from Translational Research (TR). TS is a division of Biomedical Sciences designed to maintain the efficiency and speed of TR. It is our hope that TS will pioneer medical research that supports and leads to further developments in TR.

In recent years, medications have diversified from small-molecule drugs to include medium-molecule drugs, nucleic acid drugs, and even antibody drugs. In addition, tools such as medical devices and cell therapies including iPS and stem cells are also becoming increasingly diverse. Evaluating the safety, accuracy, and efficiency of research in the field of **Regulatory Sciences (RS)** is highly important. For the purpose, open discussion and fusion within the field of drug discovery research is essential. TRS is a journal with the objective to provide "**the place for the forum**". In addition, we hope that the articles published in TRS will operate as a strict evaluator of the efficacy and safety of new drugs coming into the market in and around the country.

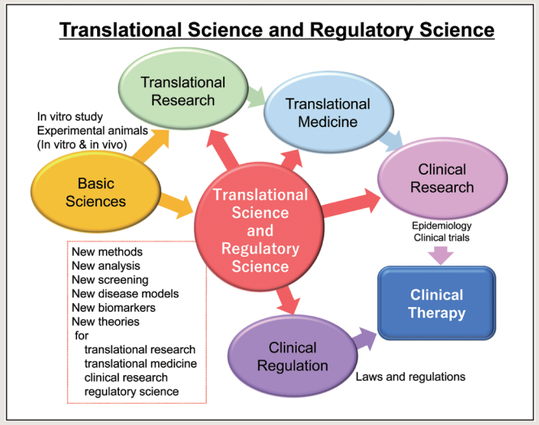
TRS is not an international agency magazine of a certain academic society. As previously mentioned, academic institutions, national research institutes, and private companies will continue to support and expand TRS, which in turn will lead to the establishment of academic societies throughout Japan, allowing it to lead the field in the near future.

We are waiting for numerous original papers, columns, and review posts.

From the Editorial Board

1. Purpose of TRS

Translational science is a field of biomedical sciences. Translational science is different from translational research and translational medicine. Translational research is wide and encompasses everything between non-clinical and developmental research, and aims to establish the results obtained in basic research in the academe as new medical technology/medicine that can be used clinically. In translational medicine, research results obtained in translational research are applied in clinical trials and lead to the actual clinical setting. Meanwhile, translational science is the underlying research of translational research, and it refers to basic research that has the potential to advance to translational research in the future and that contributes to the development of regulatory science.



Regulatory science in the development of medicine indicates the basic and applied sciences that refer to the establishment of test studies to ensure the quality, safety, and effectiveness of pharmaceuticals and medical devices, and to establish evaluations, prediction, and judgment. Regulatory science is a scientific field that is also required for the inspection, safety evaluation, manufacturing control, and quality control of pharmaceuticals and medical devices, as well as for inspection and internal audit, such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP).

Translational science and regulatory science have quickly evolved over the last decade, and are both interdisciplinary and multidisciplinary, depending upon a large number of basic and applied scientific disciplines. Translational science and regulatory science are mutually involved in a complex manner. Therefore, both have to progress scientifically with respect to each other.

Translational and Regulatory Sciences (TRS) creates a new platform for launching new ideas, not only for industry and regulatory authorities but also by members of the academe who want to contribute to the better use of their research activities within medical aspects. Thus, TRS significantly impacts the abilities of these communities to bring new medicines and medical devices to patients in need.

The expected effect of TRS is that industry, academic, and government experts 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.

2. Spectrum of TRS

a) Original article (Full paper, Short communication)

The journal adopts a peer-review system and aims for publishing high-quality research.

The translational and regulatory science (TRS) spectrum represents each stage of research along the path from the biological basis of health and disease to interventions, including core technologies and clinical innovation. Through these stages, innovative methods and approaches that improve and accelerate the development of new pharmaceuticals and medical devices for translational and regulatory sciences are created and tested. TRS also accepts papers on toxicity evaluation and basic data necessary for new drug applications.

b) Review

Post type: adopts a peer-review system

Request type: by the planning and recommendation of the editorial committee

c) News

Introduces highly promising and epoch-making practical cases and new drugs

Introduces new regulations

Introduces new facilities for drug discovery of the world

d) Platform

The journal invites opinion from both the translational science and regulatory science sides regarding problems and direction in current and future drug discovery research worldwide.

3. Scope of TRS

Translational Sciences Section

- Establishment of new technology for drug discovery and drug toxicity evaluation: assay system(including high throughput screening (HTS), antibody, cell line, diagnostic marker, drug delivery system, target identification and validation, de-risking therapeutic development, cell therapy, regenerative medicine, gene therapy, and so on
- Establishment of new animal models of human diseases
- Identification of new target molecules and/or signaling in human diseases
- Translational clinical sciences in experimental small animals, from dogs and monkeys to humans
- New technology, method, and/or theory for analytical chemistry, early- or late-stage drug repurposing, compound library management, collaboration and partnerships, data transparency and sharing, patient and contact registries

Regulatory Sciences Section

- Evaluation of efficacy of new drugs before approval
- Evaluation of toxicity of new target molecules
- Proof of safety of new target compounds, antibodies, drug delivery systems
- New method to identify toxicity using new technology
- New concepts in benefit/risk assessment, submission and approval strategies, patient involvement, and ethical aspects
- 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

Aspiring to be a Navigator of Innovative Drug Discovery Development

Three years have passed since the Japan Agency for Medical Research and Development (AMED) was established. The name and roles of AMED are becoming familiar among people who engage in medical research in academia and industry, but are still not well-recognized among patients and the general public. Prof. Makoto Suematsu, President of AMED, often encourages AMED staff with the message that the mission of AMED is to deliver the results of medical innovation to patients and their families in the earliest way. He demonstrates pride in our work, which encompasses more than just funding, and is determined to meet the expectation of patients who are awaiting the new medical therapies that follow from medical research in timely manner. His words essentially represent the mission to be fulfilled and the determination shared by all AMED staff.

AMED offers various programs to support drug development. Among them, the Drug Discovery Support Network, has unique qualities, as experienced AMED Science Coordinators, as an advisor, accompany researchers and collaborate to translate the results of research into clinical application. In the early phase of drug development, academic researchers and research projects need a wide range of support. More specifically, from a drug development perspective, advice on many aspects is provided, including what type of studies should be conducted, the provision of technology and archives of public research organizations and those from the private sector, and the collection and validation of necessary data by using the data from prospective seeds from academic researchers, and consideration of the strategic plan of intellectual property management and industry-university collaborations. Throughout the course of our support, there are situations in which we have to be daring and suggest ideas outside of the researchers' comfort zone. Such suggestions are based on our mission to "deliver the results of the scientific research to patients and their families in the earliest way" with limited resources. In this situation, we try to explain reasons for our judgement and carefully suggest possible alternatives personalized to each researcher. I believe that discussions like that are very important for innovative drug discovery and development (iD3).

It takes a decade and the collective enthusiasm and expertise of many people to market a single new drug. We wish to navigate prospective seeds to patients in the best way to avoid deadlocks during this process. As navigators who "envision and go forward with researchers", iD3 coordinators and all AMED staff members will continue to contribute to innovative drug discovery and development through this Drug Discovery Support Network project.

Noriatsu Kono

Managing Director,
Department of Innovative Drug Discovery and Development, Japan Agency for Medical Research and Development

Mission of AMED iD3 Catalyst Unit

1. About the Catalyst Unit

The Catalyst Unit is one of the "Drug Discovery & Development" program units created by the Department of Innovative Drug Discovery and Development (iD3) of the Japan Agency for Medical Research and Development (AMED). AMED iD3 has constructed eight units in the Infrastructure Program for Drug Discovery Seeds Development to create a bridge between valuable resources in private sector and academic research organizations (ARO) to further drug development research. The goals of the program are strengthening support network and driving force for innovative drug discovery and development. The Catalyst Unit is responsible for public relations activities, such as sharing information among the eight AMED iD3 Units, and providing a place for transmitting information, presenting problems, and creating discussion for stakeholders in academia, industry, and regulatory agencies.

2. The world situation surrounding drug development

To enhance development of drugs, medical devices, and regenerative medical products, various scientific technologies are necessary. Recently, regulations of review medical products have changed significantly in order to accommodate new types of medicines, including antibody drugs, nucleic acid drugs, and accelerated implementation of iPS cells. Under these circumstances, further advancement of **"Translational Science"** is essential for the development of research in medical areas. Here, the term translational science subsumes the exploratory technology that bridges basic research into practical use of drugs, medical devices, and regenerative medical products, and scientific technology that evaluate efficacy and toxicity. In other words, it is of great importance to proactively identify biomedical science research conducted by academia that may lead to translational research and translational medicine. In addition, promotion of **"Regulatory Science"** is also mandatory to optimize the advancement of science and technology in accordance with regulations. Therefore, in Japan, cooperation with Ministry of Health, Labour and Welfare (MHLW), Pharmaceuticals and Medical Devices agency (PMDA), pharmaceutical companies, and medical engineering companies are critical. In addition, it is necessary to create a place where members of the global community of researchers into translational science and regulatory science can share their research results and inspire each other. The National Institutes of Health (NIH) and National Center for Advancing Translational Sciences (NCATS) in the US and the Innovative Medicines Initiatives (IMI) in Europe work on large national projects similar to AMED in Japan; therefore, harmonization with such overseas organizations is also necessary.

3. Aim and activities of the Catalyst Unit

The Catalyst Unit is operated by the Department of Veterinary Pharmacology, of the Graduate School of Agricultural and Life Sciences, University of Tokyo. The mission of the unit is to be an information hub to disseminate outcomes of research into translational science and regulatory science by projects granted by AMED, as well as research outcomes from overseas organizations by means of the international e-journal **"Translational and Regulatory Sciences"**, which will be released in 2019. TRS is a peer reviewed international journal but not journal for one academic society. Therefore, all researchers working in not only the academia but also pharmaceutical companies, medical equipment manufactures and National Research Institutes are required to back up the TRS with full strength.

At the same time, the Catalyst Unit would also like to collaborate with organizations in academia, industry, and regulators by hosting international symposia and public relations activities through this website. I appreciate your understanding and cooperation for our activities.

Masatoshi Hori, Ph.D., D.V.M.

Head of Catalyst Unit
Professor of Laboratory of Veterinary Pharmacology
Graduate School of Agriculture and Life Sciences, The University of Tokyo

TRANSLATIONAL AND REGULATORY SCIENCES

Instructions for Authors (Brief version)

Please visit our website https://cutrs.jp for whole instructions

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, 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

Submission of a manuscript implies that the authors warrant compliance with institutional policies governing the ethical treatment of human subjects and animals, and are ready to share the original approval documents if so requested.

Human and animal rights

If the work involves the use of human subjects, the authors should ensure that the work has been carried out in accordance with the International Code of Medical Ethics of the World Medical Association, Inc. (Declaration of Helsinki) for experiments involving humans and Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.
All animal experiments should comply with the Law (or guidelines) for the Humane Treatment and Management of Animals as well as Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain. Such studies should be carried out in accordance with the official guidelines for experimental animal treatment and reporting, as current in the countries where the reporting manuscript originated. Examples of these guidelines are the Guidelines for Proper Conduct of Animal Experiments stipulated by the Science Council of Japan, Animals (Scientific Procedures) Act 1986 and associated guidelines in the U.K., European Communities Council Directive of 24 November 1986 (86/609/EEC), and National Institutes of Health Guide for the Care and Use of Laboratory Animals (NIH Publications No. 8023, revised 1978). The authors should conform to the internationally accepted "3R" (Replacement, Reduction, and Refinement) principle in accordance with the Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities compiled by the related ministries, and should clearly indicate in the manuscript that such guidelines have been followed.

Types of Manuscript

Original articles (Full papers, Short communication), Letters, News, Platform, and Review articles that are principally related to translational and regulatory sciences and are unpublished and not being considered for publication elsewhere can be accepted. Submitted manuscripts not rejected at the first screening will undergo a peer-review process that occasionally could require substantial revision and may last several months, depending on the timeliness of author response. All manuscripts must be written in good English (American or British usage is accepted, but not a mixture of these). Manuscripts are selected for publication according to an editorial assessment of their suitability and reports from referees. Papers are rejected if the ethical treatment of subjects has not been appropriate.

Submission Declaration, Verification, and Fee

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. Written authorization by personal sources may be required at the editor's discretion.
The submission charge and publication fee are free as a temporary arrangement.

Submission

All manuscripts must be submitted through e-mail: submission@cutrs.jp

Peer review

All contributions will be initially assessed by the editor for suitability for the journal. Papers deemed suitable are then typically sent to a minimum of two independent expert reviewers to assess the scientific quality of the paper. The editor is responsible for the final decision regarding acceptance or rejection of articles. The editor's decision is final.

Article Structure

Introduction

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

Material and methods

Provide sufficient details to allow the work to be reproduced by an independent researcher. Methods that are already published should be summarized, with the reference indicated. If quoting directly from a previously published method, use quotation marks and also cite the source. Any modifications to existing methods should also be described.

Theory/calculation

A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

Results

Results should be clear and concise.

Discussion

This section should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A. 1), Eq. (A. 2), etc.; in a subsequent appendix, Eq. (B. 1) and so on. Similarly, for tables and figures: Table A. 1; Fig. A. 1, etc.

Abstract

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results, and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Non-standard or uncommon abbreviations should be avoided, but if essential, they must be defined at their first mention in the abstract itself. The abstract should be fewer than 250 words.

Highlight

Highlight is mandatory for this journal. It consists of the significance and core findings of the manuscript (maximum 150 words.) the highlight provides readers with an at-a-glance overview of the main findings of your manuscript and lets them quickly identify what they want to read.

Keywords

Provide up to five keywords.

Abbreviations

Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in footnotes. Ensure consistency in abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance, or proofreading the article).

Role of the funding source

You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:
Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].
It is not necessary to include detailed descriptions of the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding. If no funding has been provided for the research, please include the following sentence: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Figure captions

Ensure that each illustration has a caption. A caption should comprise a brief title (not on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

Tables

Please submit tables as editable text and not as images. Each term or phrase should begin with a capital letter. Tables can be placed either next to the relevant text in the article or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Reference to footnotes should be designated by symbols in the order a), b), c). Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

Abbreviations, Units, and Nomenclature

Scientific terms for animals, plants, and microorganisms must be italicized. Abbreviations should be written in parentheses after spelling out the term in full at the first appearance in the manuscript. Arabic numerals should be used for quantities. Units and abbreviations should conform to the following examples: M, mM, μM, N, %, m, cm, mm, μm, nm, pm, cm^2, l, ml, kg, g, mg, μg, ng, pg, hr, min, sec, msec, rpm, Hz, Bq, mBq, μBq, kBq, cpm, dpm, ppm, °C, J, KJ, lux, CPE, LD. Nomenclature used in the manuscript should be appropriately given in accordance with the rules and guidelines of international nomenclature. Nomenclature used for chemical compounds shall be in accordance with the nomenclature rules formulated by International Union of Pure and Applied Chemistry (IUPAC). Alternatively, naming may conform to the nomenclature in the index of Chemical Abstracts or the Ring index. The scientific name of animals used in animal experimentations should be given.

References

References should be cited in the text as numbers in square brackets in the order of appearance (e.g., [1, 3–5, 7]). References should be listed in the reference list by these numbers. Only articles that have been published or are in press should be included in the references. Unpublished results or personal communications should be cited as such in the text.

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.
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4. Wild, D. G. 2013. The Immunoassay Handbook, 4th ed., Elsevier Science & Technology, Oxford.

Editorial board