

EDITORIAL

Advancing Clinical and Translational Science

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The vision for the 2015–2020 American Society for Clinical Pharmacology and Therapeutics (ASCPT) strategic plan is that ASCPT's influence and leadership make it the authority on the science and practice of translational medicine, building on a foundation of clinical pharmacology and therapeutics (<http://www.ascpt.org/About-ASCPT/ASCPT-Strategic-Plan>). The vision for *Clinical and Translational Science (CTS)* is well-suited for ASCPT.¹ Our vision is to become the beacon and organizing principle for the field of translational medicine, as well as to provide a vehicle for ASCPT member publications. The ASCPT definition of translational medicine¹ serves as a framework for the CTS strategy. In brief, "From ASCPT's perspective, translational medicine is a multi-faceted discipline with a focus on translational therapeutics. In a broad sense, translational medicine bridges across the discovery, development, regulation, and utilization spectrum. For clinical pharmacology, the focus of translational research is on the discovery, development, regulation and use of pharmacologic agents to improve clinical outcome, and inform optimal use of therapeutics in patients."

With this translational medicine definition in mind, CTS has concluded its first year of publication as an official journal of ASCPT with many accomplishments. By the numbers, CTS published six issues in 2016, which included two editorials, two commentaries, five reviews, 28 original research articles, two tutorials, and one phase forward article. In addition, the CTS blog, *Translational Bytes*, posted 20 blog entries, most related to content published in CTS. By all measures, these numbers constitute a successful first year.

One particular accomplishment is the beginning of a series of tutorial publications.² CTS tutorials are meant to address the general increasing concern over the lack of reproducibility of biomedical research results as well as an overall paucity of education and training on translational medicine topics. The tutorials are dedicated to relevant topics in the broad field of clinical pharmacology and translational medicine according to the scope of CTS. Tutorials provide best practices, education, training, and perspective, with an emphasis on practical advice. The debut tutorial by Arwood *et al.*³ outlined a practical framework for implementing pharmacogenetic testing in the clinic, which should prove useful as precision medicine and pharmacogenetic testing increasingly penetrate general clinical care. Tutorials will become a regular feature in CTS and we welcome your suggestions and contributions.

In 2016 we also introduced two new, impactful members to the editorial team. Our Chief Science Advisor is

Christopher P. Austin, MD, Director, National Center for Advancing Translational Sciences (NCATS). The Chief Science Advisor is charged with at-large identification and pursuit of scientific breaking trends in translational medicine. Our Chief Patient Advisor is Sharon F. Terry, President and CEO of Genetic Alliance, a large network engaging individuals, families, and communities to transform health. Genetic Alliance works to provide programs, products, and tools for ordinary people to take charge of their health. Given the increased engagement of patients in scientific research,⁴ the Chief Patient Advisor leads at-large identification and pursuit of patient engagement trends and their relevance to translational medicine.

Open access has been a foundational guiding principle for CTS, and is a tremendous advantage in today's rapidly evolving field of translational medicine. All manuscripts selected for acceptance in CTS are published open access and are immediately made freely available. CTS employs gold open access, meaning that the article is universally and permanently outside access control, and costs of publication are typically paid by the author's institution, funding agency, or grant. Publication fees are comparable between page and color charges in subscription journals and open access journals, such as CTS. Further information on available open access license agreements can be found in the CTS Guide to Authors (available at www.cts-journal.com). Because all content is made freely available immediately upon publication, CTS enables the fastest, widest possible audience, together with the highest standards for rigorous, rapid scientific peer review.

As CTS enters its second year, we have refined the aims and scope of the journal to better serve the field of translational medicine. CTS highlights original translational medicine research that helps bridge laboratory discoveries with the diagnosis and treatment of human disease. Translational medicine is a multifaceted discipline with a focus on translational therapeutics. In a broad sense, translational medicine bridges across the discovery, development, regulation, and utilization spectrum. Research may appear as Full Articles, Brief Reports, Commentaries, Phase Forwards (clinical trials), Reviews, Tutorials, or Brief Reports. CTS also includes invited didactic content that covers the connections between clinical pharmacology and translational medicine. These additional features provide context for research articles and facilitate understanding for a wide array of individuals interested in clinical and translational science. CTS welcomes high-quality, scientifically sound, original articles

Table 1 Example topics of interest for *Clinical and Translational Science*

Translational medicine, including studies focused on interrogation/evaluation of mechanism-of-action, human physiology, and interruption of disease pathophysiology
Hypothesis generating nonclinical and clinical studies, including small clinical trials
Clinical pharmacology studies with a focus on translational research in discovery, development, regulation, and use of pharmacologic agents to improve clinical outcome, and inform optimal use of therapeutics in patients
Evaluation of various biomarkers as well as assessing the linkage between biomarker response and clinical endpoints in patients, including studies that identify or support biomarkers that can be used at any stage of drug development
Studies of response to a therapeutic intervention in a particular disease that may translate to a response in another disease, as well as translation of safety signals across species and/or patient populations
The science and practice of translational medicine, including topics such as models of human disease and their therapeutic implications as well as practical aspects like improvements to study design or conduct and translational medicine methods
Studies that guide phase II dose selection
Studies that demonstrate effective translation between basic and clinical science
Precision medicine
Genomic medicine, including pharmacogenomics, next-generation sequencing, pharmacometabolomics, and functional genomics
Electronic and mobile health applications as well as wearables
Regulatory and public health policy implications of translational studies
Quantitative and systems pharmacology, PK/PD model-based and mechanistic understanding of disease biology and pharmacology, as these relate to translational medicine

focused on clinical pharmacology and translational science, including animal, *in vitro*, *in silico*, and clinical studies supporting the breadth of drug discovery, development, regulation, and clinical use of both traditional drugs and innovative modalities. Example topics of interest have also been expanded and refined since last year, and are displayed in **Table 1**. The topics of interest now extend from the fundamentals of translational medicine, including studies focused on interrogation/evaluation of mechanism-of-action, human physiology, and interruption of disease pathophysiology, to some of the newest innovations including electronic and mobile health applications as well as wearables.⁵ The topics of interest are an excellent indicator of the scope of *CTS*, but the best gauge of the journal is a review of the table of contents over the last year.

In addition to the refined scope of *CTS*, several new features have been added. Brief Reports are intended as short and complete reports of novel research findings of high importance to the field. Reports of preliminary experiments are unacceptable. Brief Reports should be especially significant and timely and reach a clear conclusion. For more details on Brief Reports, see the *CTS* Guide to Authors. Themed Virtual Issues enhance access to our diverse range of content by putting all of our original research articles, reviews, tutorials, and commentaries into focused collections that match the field's interests. *CTS*'s themed virtual issues will be tied to the many dimensions of translational medicine. In January 2017, we began by highlighting three areas that are at the heart of translational science: Biomarkers, Early Clinical Trials, and Oncology. Please view our inaugural issues (www.cts-journal.com), and submit your manuscripts to have your work featured. Also in January 2017, the inaugural *CTS* webinar, "Driving Patient-Centered Translational Medicine," was broadcast (<https://www.youtube.com/watch?v=ZdgBSb7m7Dw&feature=youtu.be>). Patient engagement is more that recruitment and retention. In order to create a more efficient system, patients and study par-

ticipants should be involved throughout the process. This webinar focused on patient-centered issues, including institutional review boards, compassionate use / early access programs, and patient involvement in therapeutic discovery and development.

Clinical and translational science holds the promise to put the patient at the top, the beginning, middle, and end of research. Translational medicine is evolving to become a paradigm of bedside-to-bench-to-bedside research, which will in turn drive a new era of medicine and therapeutics. Our vision for *CTS* is to become the beacon and organizing principle for the field of translational medicine, as well as a widely recognized platform for the rapid, broad, and open dissemination of high-quality translational science research leading to the optimal advancement of medicine. *CTS* is open for business and encourages submissions according to the new scope and topics of interest (**Table 1**) across the translational sciences spectrum from discovery, development, regulation to clinical use of therapeutics.

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1. Wagner, J.A. & Kroetz, D.L. Transforming translation: Impact of clinical and translational science. *Clin. Transl. Sci.* **9**, 3–5 (2016).
2. Kroetz, D.L. Best practices for clinical and translational research and implementation. *Clin. Transl. Sci.* **9**, 231–232 (2016).

3. Arwood, M.J., Chumnumwat, S., Cavallari, L.H., Nutescu, E.A. & Duarte, J.D. Implementing pharmacogenomics at your institution: Establishment and overcoming implementation challenges. *Clin. Transl. Sci.* **9**, 233–245 (2016).
4. Terry, S.F. The study is open: Participants are now recruiting investigators. *Sci. Transl. Med.* **9**, pii: eaaf1001 (2017 Jan 4). doi: 10.1126/scitranslmed.aaf1001. PMID: 28053150.
5. Kumari, P., Mathew, L. & Syal, P. Increasing trend of wearables and multimodal interface for human activity monitoring: A review. *Biosens Bioelectron.* **90**, 298–307 (2017).

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