CLINICAL INVESTIGATION

FOREWORD
Clin. Invest. (2011) 1(1), 1–2

Welcome to *Clinical Investigation*

E Michael Lewiecki, Senior Editor

"... it is essential that stakeholders in many disciplines have an easily accessible platform for rapid and effective communication."

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The clinical development of a new therapeutic agent is a long and complex process that begins with the translation of basic science and preclinical data to potential applications in humans, followed by the design and conduct of clinical trials, the evaluation and publication of results, and continuing through the regulatory approval process and postmarketing surveillance. Those who are involved at any level of drug development are familiar with the immense opportunities and the many challenges of such an undertaking. The total cost of bringing a new drug to market can be as high as US$1.3 billion, with much of this incurred during clinical evaluation; only one of every 10,000 potential medicines survives the development and approval process. To optimize the probability of success in this increasingly globalized endeavor, it is essential that stakeholders in many disciplines have an easily accessible platform for rapid and effective communication. This is an introduction to the first issue of a journal intended fill this need.

It is my great pleasure to welcome you to *Clinical Investigation*. This is an international forum for communicating and evaluating the vast amount of information associated with the clinical development of new therapeutic agents. Journal coverage will include all areas of therapy with drugs ranging from conventional small molecules to biotech-derived compounds such as vaccines, monoclonal antibodies, recombinant proteins, antisense, cell and gene therapies. We publish original research, review articles, perspectives, commentaries, debates of controversial issues and more. In order to assure high-quality content, manuscripts submitted to *Clinical Investigation* are rigorously vetted through a systematic peer-review process. The intended audience for *Clinical Investigation* includes clinical investigators, clinicians, healthcare policy makers, drug formulary managers, healthcare statisticians, healthcare economists, regulatory affairs personnel and others involved in the design and conduct of clinical trials.

Specific types of manuscripts that will be considered for publication are overviews of the clinical progress of new drugs, drug classes and therapeutic areas; reports of Phase I to IV clinical trials; healthcare outcomes and pharmacoeconomics; clinical trial design and methodology; commentary on trials in progress; practical aspects of clinical research; drug safety issues and adverse event monitoring; the use of biomarkers in clinical trials; regulatory issues; and clinical trial data management and analysis. If you have clinical research information that you would like to share with colleagues worldwide, consider submitting your manuscript to *Clinical Investigation*. If you wish to stay informed on new developments in clinical research, become a regular reader.

The globalization of clinical trials is addressed in this inaugural issue through viewpoints on developing an international network for clinical research with community-acquired pneumonia [1]. Novel new and emerging oral anticoagulants for prevention of stroke in patients with atrial fibrillation are reviewed by Weitz and Eikelboom [2]. Perspectives on new drug development are addressed in the pitfalls and progress of early-phase oncology clinical trial design [3] and the potential impact of neoadjuvant trials on clinical practice [4]. Clinical trial outcomes include data on pazopanib for renal cell carcinoma [5], and lacosamide for partial-onset seizures [6]

ISSN 2041-6792 10.4155/CLI.10.13

as well as SGLT2 inhibitors in the treatment of Type 2 diabetes [7] and new therapies for hypertensive patients with osteoarthritis [8].

I hope that the authors and readers of *Clinical Investigation* benefit from participation with this exciting new journal. In the interest of continuing quality improvement, please provide your feedback on how we are doing and how we could do it better. I look forward to receiving your comments.

Financial & competing interests disclosure

The author has received grant/research support from Amgen, Merck, Eli Lilly, Novartis, Warner Chilcott, and Genentech. He has served as a consultant, advisory board member, speakers' bureau participant, or given presentations at sponsored speaking events for Amgen, Eli Lilly, Novartis, and Genentech. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

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