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# Introduction: Global Clinical Trials

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Welcome to the inaugural issue of *RF Quarterly* featuring original, thematically developed content by regulatory experts addressing key areas and emerging issues in the global regulatory landscape. *RF Quarterly* is a member-exclusive addition to the regular monthly *Regulatory Focus* feature articles and replaces the former quarterly article series. The theme for this issue is Global Clinical Trials.

Clinical trials are an essential component of pharmaceutical research and development. In recent years, clinical trials have become more global, and while they offer many advantages for patients and sponsors, the logistics and complexities of operating in a number of countries are challenging. In this issue, regulatory experts examine clinical development planning, the regulations and guidelines governing local and multiregional clinical trials, good clinical practice and compliance, and clinical trial applications. A cluster of articles also addresses the importance of innovation and adaptability in initiating and maintaining clinical trials. In addition to providing valuable context, the articles also have a strong "how-to" subtext, providing tools and resources for readers to draw on in daily, real-world regulatory practice. And as is often the case in regulatory practice, almost all the articles carry a cautionary message about staying up to date with the dynamic clinical and regulatory landscape.

I thank the authors for their generosity in sharing their knowledge and expertise with their regulatory colleagues.

## Strategizing, planning, and compliance

Establishing an effective strategy for the clinical development of a new product requires striking a balance between research, strategic planning, and critical thinking. Clinical development is extremely costly, so the resulting plan should chart the quickest, most efficient pathway to successful global registration for the product, write **William Sietsema** and **Eric Brass** in Strategies for clinical development planning (p. 5). A key first step is to develop a vision for the product. The authors suggest starting with the target product profile and a supporting indication statement and then, using the reverse-engineering approach, refine the trial design and stages, define the patient population and measurable endpoints, and establish the statistical analysis plan. Most important, they caution, is to speak to regulators early and often to make sure regulatory needs and changes are addressed and factored in continuously.

Planning and conducting a clinical trial, whether in single or multiple regions, requires in-depth knowledge of international good clinical practice (GCP) and regional and national legislation, regulations, and guidances, write **Anu Gaur, Bettina**

**Merz-Nideroest,** and **Andrea Zobel**. In Clinical trials, good clinical practice, regulations, and compliance (p. 15), the authors provide an overview of the international and national guidelines for clinical trials and outline the principles of the International Council on Harmonisation (ICH) GCP Guideline and regulatory compliance. In addition, Gaur and colleagues provide invaluable resources for readers, including a user-friendly, in-depth glossary of commonly used definitions and terms relating to clinical trials, documentation, and quality and compliance. These authors echo Sietsema and Brass in advising continuous monitoring of the global and local regulatory landscapes and speedy adaptation to any regulatory changes along the trajectory of the trial.

Global, multiregional clinical trials have become more prevalent in recent years, offering a range of advantages, such as improved access to treatment-naïve participants, a better opportunity for demonstrating the true impact of an investigational drug, and reducing trial costs in developing countries. Planning these trials has become more exacting and essential for successful trial initiation, management, and maintenance. In Planning for a clinical trial application (p. 33), **Sharry Arora** notes that the key considerations in designing a global clinical trial are selecting the most appropriate trial sites with a representative patient population, choosing to work with the right partners, and staying stay up-to-date with the changing regulatory and clinical landscape. She offers hands-on guidance on site selection; assembling a global dossier; product supply, labeling, and storge; document translations; amendments and updates; financial disclosures; and investigation records.

## Keeping up with change

Since 2017, Health Canada has introduced a plans to modernize its clinical trial regulations to be more flexible and adaptive to change and innovations, such as artificial intelligence, advanced cell therapies, and 3D-printed bioproducts. In Modernizing clinical trial regulations in Canada (p. 40), **Tanya Ramsamy** provides an overview of these efforts to date and examines how clinical trials in several health care product lines can be modernized. Ramsamy looks at how lessons learned from the COVID-19 pandemic experience can help set up a more flexible regulatory framework better aligned with international standards and practices. She concludes that closer alignment with international, risk-based approaches and enabling novel clinical trial design will increase treatment options and product access for Canadians.

Canada is an attractive destination for conducting clinical trials, in part because of its shorter approval timelines and more universal submission requirements. In The Canadian application process and alternate pathway for COVID-19–related trials (p. 45), **Mukesh Kumar** and **Melanie Oakley** describe the clinical trial application process for biologics (schedule D) and pharmaceuticals (schedule F) and provide an overview of guidance on the regulatory obligations for clinical trials in humans under Part C, Division 5 of Canada's Food and Drug Regulations. The authors also share useful information on clinical trial submission requirements, folder structure and transmission of data, the review and screening processes, communication with the relevant directorates and offices; and post-authorization requirements.

China-based clinical trials for medical device and in vitro diagnostic device products are an increasingly viable option for non-Chinese companies of all sizes, writes **Hamish King** in Initiating clinical trials in China: What foreign medtech companies need to do (p. 55). King discusses China's regulatory framework and recent regulatory developments to align with international standards and outlines what foreign companies should consider before initiating a clinical trial in China.

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## Upcoming issues

This year, *RF Quarterly* will address:

- Artificial Intelligence in Regulatory Affairs (June)
- Quality and Compliance in Regulatory Affairs (September)
- RAPS 2021 Convergence (December)

To contribute to the June issue of *RF Quarterly* or any upcoming issue, email rmatthews@raps.org.

For more information, see Guidelines for Authors and the 2021 Editorial Calendar.

## About the author

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