When planning for the May issue of *Regulatory Rapporteur* commenced in late 2012 with its theme as clinical trials, we had aspirations of attracting expert articles focused on the emerging Clinical Trials Regulation in Europe. But as we began approaching authors from the European Commission, national agencies and industry, it became clear that there were concerns about covering this topic at such an early stage in the process, given the Regulation’s expected evolution to 2015. There will, of course, be a lot to say and to learn relating to the new legislation, and coverage will appear in many formats as and when developments occur.

In the meantime, we have turned our attention to other important areas in the clinical trials sector. This includes a perspective on clinical trials in the Asia-Pacific region, from colleagues at PRA (UK) Ltd, which profiles the increased trending for studies in this region – of particular importance when we take into consideration the potential greater challenges in Europe until application of the new Regulation. Coupled with these challenges, the downturns in patient recruitment in the EU, economic factors and the emergence of new markets all point towards clinical studies in Asia-Pacific becoming an increasingly attractive proposition. However, significant issues present themselves here, including the diversity of regulatory processes and requirements for clinical trials across countries.

It is useful to note that while currently less than 18% of global clinical studies are conducted in Asia-Pacific, the region actually comprises around 40% of the global population, thus representing a significant market for drug development and its output. Some insights with respect to operational conduct of clinical trials in China, South Korea, Australia and New Zealand are summarised, with a view to encouraging regulatory professionals to consider these territories within their global clinical strategy.

With the advent of more global studies, we have a thought-provoking article and very salient reminder of the need for clear thinking in trial design; our Daiichi-Sankyo authors discuss data integrity and the impartial evidence regulators require, highlighting the three key factors of “appropriate” evidence, “adequate” evidence and “reliable” evidence. The longstanding and renowned “Bradford Hill” criterion – linking causation between a clinical intervention and a meaningful outcome – is highlighted as a timely reminder. The article builds from ICH E8 and E9 guidance on main considerations for clinical trials, around the choice of endpoints, control groups, statistical hypotheses, trial conduct and finally assessment of results to give the most reliable conclusions that can be drawn, presenting a useful and practical guide through these facets. The authors advocate that good adherence to such guidance should lead to label claims and marketing assertions based on robust, defendable and enduring evidence.

Finally on the theme of clinical trials, we are grateful to Lindsey Toon at TSGE LLP for a conference report on the topic of genetically modified organisms in the animal heath setting, which details the preparation and submission of applications for deliberate release of veterinary vaccines for the purpose of clinical trials.

This edition is complemented by an article on the switching of medicinal products from prescription-only to over-the-counter (“POM to P” switches), from Amy Whyte and Kim Wharton at Regulis Consulting, which gives in-depth coverage of process for such change in six EU countries. In addition, colleagues at GFA UK have provided a report for us on the recent 2013 DIA EuroMeeting, focusing on sessions of particular interest to regulatory professionals, including how European regulatory systems could adapt to better support innovation.