Although the new EU clinical trials regulation is not due to come into effect until late 2018, now is the time to get to grips with its implications, writes *Dr Martine Dehlinger-Kremer*

In perfect harmony

The recently-issued European Union Clinical Trials Regulation has two main goals – to harmonise procedures for conducting clinical trials across the EU and simplify the submission of an application dossier through a clinical trial database and single EU portal.

The European Parliament and Council hope that this new regulation will make the EU more attractive for clinical trial research, increase the number of clinical trials conducted here, maintain high standards of patient safety and boost transparency.

Although the regulation was originally due to come into effect in 2016, the launch has been postponed to October 2018, with a three-year transition period. In the first year, clinical trial applications may be made either under the new regulation – through the single EU portal and clinical trial database – or under the former Directive 2001/20/EC, although any trial still ongoing after the three years will then be governed by the new regulation.

Guidelines for enacting the regulation are being prepared, with member states assigned to lead the work in specific areas. For example, the UK will lead the development of guidelines (and a template) for the layperson clinical study summary, although different timelines apply to paediatric and phase I trials. The UK and Germany are co-leading the development of guidance on investigational medicinal product/auxiliary product guidelines and risk proportionality.

Testing, testing

In the UK, a pilot phase for the new clinical trials regulation is proposed for early 2017, with the Medicines and Healthcare products Regulatory Agency (MHRA) currently determining how this will work given that there are 60 ethics committees in the UK. The Health Research Authority (HRA), devolved administrations (DA) and MHRA are collaborating to develop a solution.

To implement the regulation, the UK will need to develop national IT solutions, including a new MHRA database, a system to facilitate MHRA and HRA collaboration, and an interface with the EMA portal. A series of workshops is currently being planned for process development and mapping.

In addition, each country will need to develop and implement a number of legislative items, most importantly establishing a system to enable ethics committees to comply with the regulation. The choice is to use existing ethics committees or to set up new ones to share understanding of the regulation and support best practice. A local appeal mechanism >>

>> will also be needed for when a clinical trial application is refused. Also, in terms of the legal representative, the regulation provides an option for a legally designated representative or a contact person involved in the trial, so countries will need to make a selection.

Several legal components are still under consideration, including legislation covering incapacitated subjects, minors, interviews prior to informed consent, investigators, auxiliary medicinal products, authorisation of manufacturing and import, fees, IMPs free-of-charge, inspections, sanctions and penalties. Some areas can be dealt with administratively while others will need new legal text.

Next steps

Here in the UK, the next steps in the process are the drafting of legal text before a public consultation in the second quarter of 2017. This will be followed by redrafting, internal approvals and Parliamentary approvals before the final legislation is laid before Parliament in the third quarter of 2017.

The MHRA will use a range of media and meetings to ensure high levels of awareness and preparation within the UK research community, engaging industry (including SMEs), academia and healthcare organisations on what the regulation will mean for them. The EU will offer a network training centre for assessors from all 28 member states and the UK has a coordination centre to provide Competent Authorities training and to prepare assessors to workshare.

In conclusion, the new EU clinical trials regulation has the potential to greatly improve the EU as a place to conduct clinical trials through an attractive and streamlined regulatory environment. The route to implementation is now much clearer with identified work-streams at EU and national level. However, the UK and all other countries still have work to do to successfully prepare for and implement the new requirements.

Dr Martine Dehlinger-Kremer is global vice-president, medical and regulatory affairs, at SynteractHCR Deutschland

HOW WILL THE NEW EU CLINICAL TRIALS REGULATION AFFECT RESEARCH COMPANIES?

- By allowing better planning of clinical trial authorisations (CTA) and approval, the regulation will help improve planning of the start of a study, a great advantage over the current situation
- The regulation will create greater centralisation of CTAs, although local knowledge will still be important as local specificities must still be complied with
- With short timelines for responses to questions, under the new regulation companies/CROs will need to plan well and have adequate resources available for when the responses are due
- Pharma companies and CROs can improve their preparedness for the new regulation by participating in the pilot phase initiated by each Member State.

Staying power

While opinion polls are evenly split in the 'Brexit' referendum, the life sciences industry seems firmly in the Remain camp – and for good reason, writes *Ana Nicholls*

From the public pronouncements, it appears that the UK pharma and life sciences industry is single-mindedly opposed to the idea of the UK leaving the EU. In February, senior managers of 50 leading life sciences companies, including AstraZeneca and GlaxoSmithKline, wrote to the *Financial Times* to state the case against a 'Brexit', while in early March academics, researchers and entrepreneurs from the Cambridge biotech cluster added their voices to the Remain campaign.

This is understandable, if only on the level of practicality. Firstly, the European Medicines Agency is based in London and would have to move out (Sweden fancies its chances). Secondly, the UK leads many of the EU's debates on healthcare, partly because of the influence of the National Institute for Health and Care Excellence (NICE) and York University. Thirdly, although the pharma industry is not generally reliant on immigrant labour, the free movement of labour has seen Frenchman Pascal Soriot, head of AstraZeneca, among the many EU citizens to move here.

Perhaps more importantly, the pharma industry has a unique perspective on a key argument in favour of Brexit – that it would free up businesses from EU regulation. The pharma industry is used to regulation, indeed it wouldn't function without it. Intellectual property rights, quality standards, clinical trial rules and strict criteria for product approval underpin the industry's ability to make money from its products and invest in new ones. Given that, it is far more