Get ready for the impact of Brexit on clinical trials

The UK's decision to leave the EU could have far-reaching consequences for the way pharmaceutical research is governed. **CSM** will be on hand to help overcome the uncertainty of changing regulations.

Europe – especially the 28 member nations of the EU – is an important nexus in the clinical trials ecosystem. Trials can be authorised and overseen through this single centralised authority that represents a pool of 500 million potential patients.

Many pharmaceutical companies running clinical trials in Europe work with contract research organisations (CROs) and contract manufacturing organisations (CMOs) based in the UK.

March deadline

On 30 March 2019, EU laws will cease to apply to the UK, and UK-based CMOs and CROs will no longer legally be part of the EU. The UK will become a 'third country'. This will have a dramatic effect on the European portion of the global ecosystem of testing or distributing investigational medicinal products (IMPs).

Developments derailed

Brexit could lead to a disruption of the supply chain of clinical trials. The results could completely derail the development of a new drug, with significant negative financial and economic consequences.

Qualified persons

Many companies outsource services around the manufacturing, packaging and labelling of their drug product to third-party vendors and rely on external consultants for certification.

The most important of these external roles is the qualified person (QP) who, in accordance with EU regulations, certifies every batch of a medicinal product before it can be released for use. About 25% of QPs in the EU are UK-based. In the future, they will not be allowed to release drug products for the EU. Some experts are projecting an overall shortage of QPs in the EU, but whether or not that shortage develops, demand will increase for the services of the remaining EU-based QPs.

Companies currently working with UK-based QPs should, therefore, now start looking elsewhere in the EU to ensure a seamless transition for their clinical trials in post-Brexit Europe.

The supply chain

Changing QPs may impact the existing qualified and audited supply chain, for ongoing and planned clinical studies. If a firm needs to switch QPs mid-trial, it may be necessary for the new QP to requalify the entire supply chain, with significant financial and efficiency costs.

Movement of drugs

Another change post-Brexit will be the movement of drugs between the UK and EU. Currently, they can be moved and distributed without import or export duties.

After 2019, drug products manufactured in the UK will be subject to a value-added tax (VAT) if shipped into the EU. Thus, drug products currently stored in the UK should be transferred to an EU country now to avoid the future import VAT on existing inventories.

Now is the time to act

For all of these reasons, pharma and biotech companies should now be planning for all trials; those already under way, those that begin prior to 30 March 2019, and those that will commence after that date.

CSM is well positioned to serve post-Brexit needs, no matter what the final post-Brexit regulations will be. Its EU GMP facilities in Brussels and Frankfurt are staffed with certified QPs who can support drug product EU release and batch certification. Both facilities have decades of experience, and outstanding quality and regulatory track records.

Miminise risk

The Brexit clock is ticking. CSM is prepared to handle drug products for new clinical trials without any risk of disruption at any time during the study. ■

Further information
CSM
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