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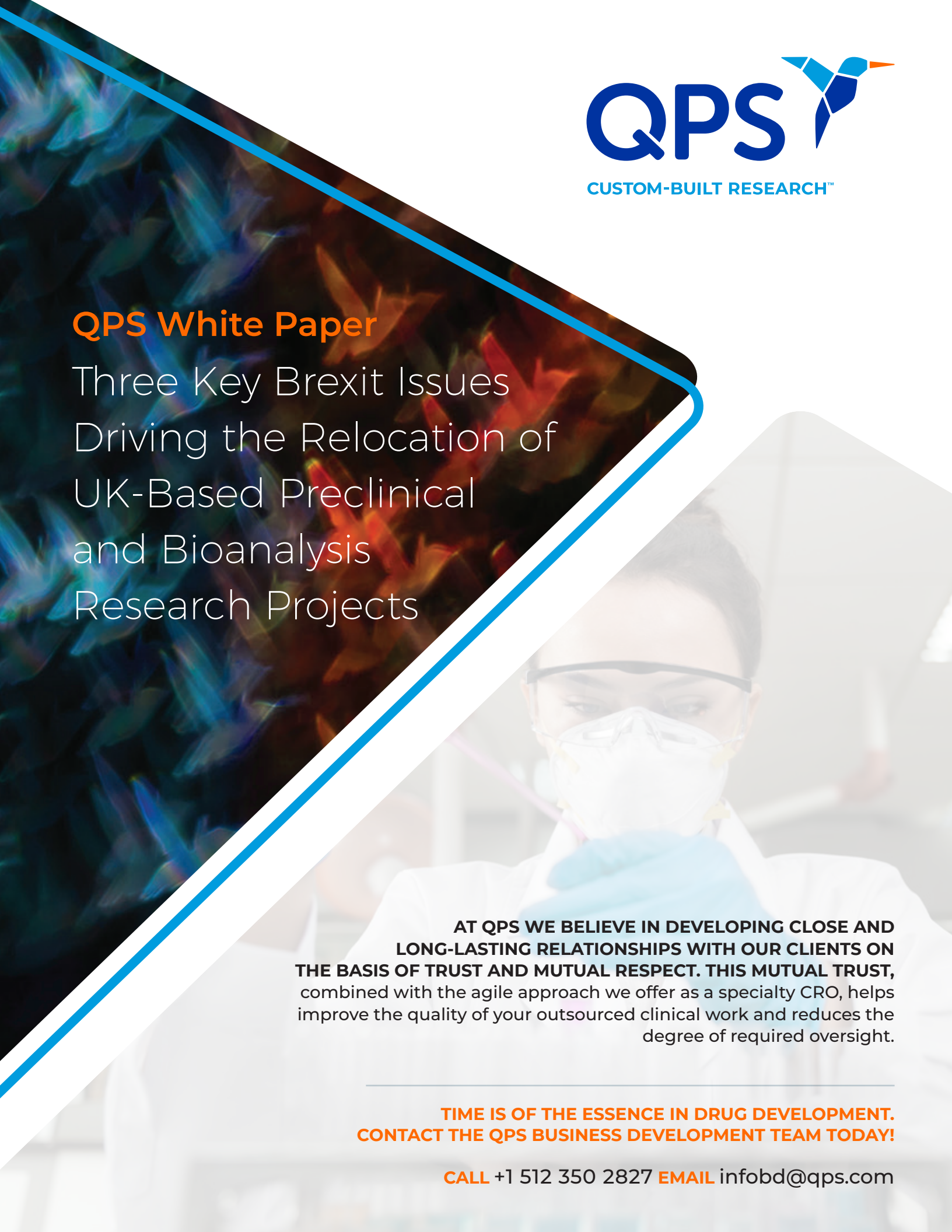
QPS White Paper

Three Key Brexit Issues Driving the Relocation of UK-Based Preclinical and Bioanalysis Research Projects



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Biosimilars And Gene Therapy Treatments Are Poised For Growth. Will The UK Miss Out?

On the heels of recent FDA approvals of gene therapies in the US market, more pharmaceutical and biotech companies around the globe are actively investing in research for developing cell and gene therapy candidates focused on treating, and possibly curing, the neediest of more than 1.5 billon individuals who have mutations linked to genetic diseases.

Meanwhile, patents for a number of blockbuster bio-pharmaceuticals have either expired or are on the verge of expiration, according to Allied Market Research. This trend is driving rapid growth in the biosimilars industry, with a focus on the European market.

These key areas of growth for the industry are being impacted by Brexit in a big way.

Here are three Brexit issues that will likely result in biosimilar, as well as gene and cell therapy research, moving out of the UK into continental Europe and the US:

1. Loss Of Research And Development Funding

Research projects related to the development of biosimilars and gene therapy have been priorities for the European Union's Horizon 2020 project.
Additional funding is likely with Horizon Europe, which currently has €8.2 billion earmarked for health research.

However, Britain's departure from the EU puts UK-based preclinical research projects that are required to prove safety, efficacy and translatability of biosimilars and gene therapy at risk of losing Horizon Europe funding.

2. Departure Of Highly Skilled Personnel

Money is important, but highly-skilled scientific roles are just as essential. With research and development funds leaving the UK, pharmaceutical and biotech companies, scientists, personnel and research projects will follow. In fact, it's already happening. According to the European Pharmaceutical Review, life science companies in the UK are now struggling to fill senior positions with non-UK candidates falling from around 40 percent to just 15 percent of applicants, on average. As skilled scientists and life science workers move away from the UK to follow jobs and projects to EU member countries and the US, the UK risks losing its foothold in research and development, particularly in the areas of gene therapy and biosimilars.

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3. Disruption Of The Supply Chain

Brexit's disruption of the supply chain and logistics will make access to the most common preclinical and bioanalytical research materials problematic, endangering the continuation of testing facilities located in the UK. For example, supply chain issues related to importing non-human primates (NHPs) into the UK will be a problem for UK-based preclinical and bioanalysis research projects, particularly in the areas of gene therapy and biosimilars. This research requires a steady supply of NHPs because they are similar to humans in terms of physiological functions and drug metabolism, which is important for assessing the safety and efficacy of these advanced therapeutics. In preclinical research, most facilities do not breed their own animals but rather import them from the EU or Asia. With Brexit and the unclear path of import/export licenses, acquiring adequate colonies of NHPs will likely be an issue.

Without a steady supply of research animals, it will be difficult, if not impossible, to carry out pharmacology, DMPK and toxicology studies for biosimilars, as well as gene and cell therapy research projects, in the UK. The net result is the UK may no longer be a country where bioanalytical innovation is feasible.

With the uncertainty surrounding Brexit and the challenges associated with relocating research projects, don't underestimate the importance of asking the right questions during the CRO selection process. It's one of the most important decisions you'll make as you figure out how to succeed in the post-Brexit environment.

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Preclinical And Bioanalysis Research Relocation Will Require New CRO Partners

10 Questions To Ask During The CRO Selection Process

As research and development moves out of the UK into other EU countries and the US, biotech and pharmaceutical companies will be on the hunt for new research partners. When looking to relocate UK-based preclinical and bioanalysis research projects, here are 10 key questions to ask CRO candidates:

1. How agile is the CRO? Can the CRO get your research project up and running quickly, without losing momentum?
2. Is the CRO consultative in nature?
3. Does the CRO have ready access to NHPs and other research animals through its research network?
4. Does the CRO have all the necessary technology platforms?
5. Does the CRO specialize in the required research area, such as gene and cell therapy or biosimilars?
6. Can the CRO customize research projects to fit your specific requirements?
7. Does the CRO have a history of delivering against promised timelines?
8. All CROs employ scientists. However, does the CRO you're considering have the right scientists assigned to your project? Are the scientists trained and highly-skilled in the specific research area?
9. Have you toured the labs and met with the scientists tasked with your research?
10. Is your primary contact a scientist who is doing the work?

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