Maintaining GDPR Compliance upon Brexit

It would be an understatement to say that the timing and terms of the UK's withdrawal from the European Union is uncertain and that this is creating challenges for the pharmaceutical manufacturers. Of particular concern in our industry is the impact that Brexit will have on a sponsors' ability to comply with the General Data Protection Regulation (GDPR) with respect to trials running in either the UK or the EU.

Against this backdrop, endpoint has been staying abreast of the situation, making contingency plans, and completing preparatory steps so that the work we perform on a sponsors' behalf will continue without interruption or complication, no matter how the withdrawal unfolds. Below, we highlight both what we are doing in preparation and offer recommendations to sponsors on steps they should be taking in advance of 31 October 2019 so that they remain in compliance with GDPR.

Brexit Options

The UK will have to leave the EU by 23:00 on 31 October 2019. The terms of the deal are being negotiated and may, or may not, be concluded by that date. So, one of three things will happen:

- The UK could be granted an extension on this deadline to finalize the terms of the trading relationship between the parties. As two extensions have already been granted on prior deadlines, there appears little appetite in the EU for another delay.
- The UK could leave the EU on the planned date, having worked out all of the terms and conditions, ensuring a transition that is as smooth as possible.
- The UK could leave the EU on the planned date without a deal, meaning that all ties are severed, without agreed-upon terms for the ongoing relationship. This is the so-called "no-deal" possibility.

The Implications for GDPR Compliance

The GDPR was enacted 25 May 2018, to govern the processing of personal data of EU citizens. The regulation is far-reaching in that it applies to organizations no matter where in the world they're located. The consequences for non-compliance are serious, with fines of up to €20M, or 4 percent annual turnover, whichever is higher.

Once Brexit takes place, the GDPR will no longer be the law of the land in the UK. However, according to the UK Information Commissioners Office, the UK government intends to adopt a UK-specific version.[1] Note that the European Commission can deem a country's data protection laws adequate, provided that it meets certain standards. Such a designation would enable EU members states to transfer personal data to that country as if it were a member state. If the UK indeed adopts the GDPR into its own laws, this should, in theory, satisfy the Commission's criteria.[2]

However, with the details of these legislative changes up in the air, appropriate provisions must be made so that data transmissions of patient data between the EU, the US, and the UK (as occur routinely during clinical trials conducted in the UK and supported by endpoint) are safeguarded in compliance with GDPR. The use of "standard contractual clauses" will satisfy the need for appropriate safeguards for restricted transfers to and from the UK. The Commission has approved four sets of such clauses, which must be agreed to by the data exporter and the data importer. Template contracts are available through your endpoint sales representative.

[1] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/international-transfers#dp-clauses

[2] https://www.passwordprotectedlaw.com/2018/11/implications-of-brexit-on-gdpr/

endpoint's Preparations

More than a year ago, we began analyzing the business risks associated with Brexit. Having established an action plan, we've been busy since then putting all of the pieces in place so that we will be ready in any event.

We've amended our privacy policy by adding in specific language around the UK and have gotten approval from the US Federal Trade Commission (FTC) on its use. We have also designated a representative in Belgium in the event of any unresolved issues about our data protection practices. We are also proactively contacting customers to amend Data Protection agreements to include transfers to the UK.

"endpoint customers should know that preparing for ongoing compliance with the GDPR is something that we have taken very seriously," said Elana Rose, endpoint's Senior Director, Global Business Development. "Our approach has been to cover all the bases in the event of each possible Brexit scenario so that our customers need not worry and can stay focused on bringing life-saving drugs to market."

Recommendations for Trials in Progress

In terms of GDPR compliance, there are two main activities that sponsors should be undertaking now so that everything is in place by the date of Brexit, leaving no possible period of noncompliance. These are:

- Update contracts with investigator sites that are currently running studies to include provisions in the "standard contractual clauses" mentioned above. Getting freshly signed contracts back from all sites by 31 October may be a time-consuming process and may require both legal expertise and a determined clinical operations staff.

- Update notice and consent forms for patients, indicating that patients' data may leave the EU and go to the UK (via the US). Enrolled patients should be asked to sign revised forms, and all as-yet-to-be enrolled patients should be given the new form.

Regardless of how and when Brexit transpires, we've taken the necessary steps to protect patient data flowing through endpoint. We invite our customers to contact us with questions and concerns and will help in any way that we can, although of course, we cannot offer legal or regulatory advice. Our goal is to ensure business continuity and unbroken GDPR compliance with your clinical trials.

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