Legal Impact Assessment of Brexit:

Part B

Privacy Law in Clinical Trials and Data Exchange

21 June 2018

SFL Regulatory Affairs & Scientific Communication GmbH

Margarethenstrasse 47, CH-4053 Basel, Switzerland, Tel: +41 61 361 9443, office@sfl-services.com, www.sfl-services.com

Table of Contents

List of Abbreviations

CCI	Commercially Confidential Information
CTR	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158/1
Data concerning health	Personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status, as per the definition provided by Article 4(15) GDPR
ECJ	Court of Justice of the European Union
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
FTA	Free Trade Agreement
GDPR	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data [2016] OJ L119/1
ICF	Informed Consent Form
ICESCR	International Covenant on Economic, Social and Cultural Rights
MA	Marketing Authorization issued in accordance with Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Medicinal Products Regulation No 726/2004) [2004] OJ L136/1
MAA	Marketing Authorization Application
MRLR	Medical Research Law & Policy report, Bloomberg Law, The Bureau of National Affairs, Inc. (800-372-1033)
Special categories of data	Genetic data[1], biometric data[2] and data concerning health as defined above
UN	United Nations
WMA	World Medical Association
WTO	World Trade Organization

[1] "Genetic data" means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as per the definition in the GDPR, under Article 4(13), which for the first time provides for a legal definition of this notion.

[2] "Biometric data" means personal data resulting from specific technical processing relating to the physical, physiological or behavioral characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data, as per the definition in the GDPR, under Article 4(14).

Introduction

Among the vast number of factors that will influence the impact and outcome of Brexit are the European Union legislations on clinical trials and data protection and the extent of alignment or divergence between a post-Brexit UK and the EU-27. These are two critical key legislations for the entire healthcare sector as well as for patients' access to medicines and to all kind of healthcare services that involve the exchange of data beyond the current UK borders with the other EU member states (on the continent and in Ireland).

The actual arrangements for Brexit will be set out in a Withdrawal Agreement[3] that has to be achieved within the two-year period that started upon the UK triggering the Article 50 process of the Treaty on European Union (TEU)[4] on 29 March 2017. The said document encompasses "[t]*he Article 50 negotiation process and principles for the United Kingdom's departure from the European Union*".[5] At the time of writing this article certain progress has been made towards such an agreement, but there were still substantial uncertainties about the final Withdrawal Agreement and even more about the UK's plans for its future relationship with the EU. Legally, the Withdrawal Agreement will take the shape of a treaty between the UK and the EU, which will contain the framework of the EU-UK future relationship.

Whatever the framework for the EU-UK future relationship, "*the United Kingdom will become a third country*."[6] Under the EU General Data Protection Regulation (GDPR)[7], this activates the application of the rules for transfer of personal data to third countries.[8]

The 'hard' Brexit scenario is best pictured by a Letter of 62 UK Conservative MPs sent to UK Prime-minister Theresa May on 16 February 2018.[9] It means leaving the EU Customs Union and the Single Market, in order to be able to conclude free trade agreements (FTAs) with other countries. The 'hard' Brexit scenario favors applying WTO rules between the withdrawal date and the moment FTAs would be secured with different countries, However, applying WTO rules is not automatic and transitional procedures will be necessary, after first reaching consensus between WTO members. A more recent letter of 60 MPs focuses on advocating for rejection of any participation in the EU Customs Union and the Single Market.[10] The UK must first become a third country to the EU in order to conclude

[3] Commission (EU) Draft Withdrawal Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement) [2018] https://ec.europa.eu/commission/publications/draft-withdrawal-agreement-withdrawal-united-kingdom-great-britain-and-northern-ireland-european-union-and-european-atomic-energy-community_en, accessed 9 May 2018.

[4] Maastricht Treaty, 1992, published in consolidated version in the EU OJ C202/13 of 7 June 2016.

[5] Commission (EU) https://ec.europa.eu/commission/brexit-negotiations_en, accessed 9 May 2018.

[6] Parliament (EU) 'Motion for a Resolution on the framework of the future EU-UK Relationship B8xxxx/2018' (Parliament (EU) Motion B8xxxx/2018), let. G, p. 3.

[7] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) [2016] OJ L119/1.

[8] GDPR Chapter V.

[9] A. Asthana, https://www.theguardian.com/politics/2018/feb/20/tory-mps-sign-letter-to-theresa-may-outlining-hard-brexit-goals and https://www.scribd.com/document/371977491/Letter-from-European-Research-Group-to-PM-May#from_embed, accessed 9 May 2018.

[10] J. Elgot, https://www.theguardian.com/politics/2018/may/02/pro-brexit-mps-urge-pm-to-drop-deeply-unsatisfactory-customs-model, accessed 9 May 2018.

separate FTAs. However, any FTA is very unlikely to resemble membership-level rights to the EU for the UK or ensure its participation to the EU Single Market or even parts thereof.[11]

However, despite the many shades of Brexit (from hard to soft or even BINO[12], from immediate to open-end transition) and the posturing of the negotiators on both sides, it is considered very likely that the post- Brexit UK will have at least some sort of aligned legislation and policies with the EU in the fields of public health and data protection and privacy, considering the importance of the sector not only for the economy, but also for the healthcare of the entire population. In this context, one should consider the announcement of the European Parliament, that has to ratify any Withdrawal Agreement, briefly saying that it will only endorse a framework for the future EU-UK relationship if it ensures a level-playing field in public health and data protection (among other fields)[13]. More extensively, such a level-playing field amounts to "*the United Kingdom's continued adherence to the standards provided by international obligations and the Union's legislation and policies*."[14]

This article aims to provide a brief summary of currently relevant legislation on dealing with personal data throughout the life cycle of clinical trials, followed by a discussion on how different levels of divergence between legislation in post-Brexit UK and EU-27 can impact this field. The discussion is anchored around several core activities in clinical trials, including: collection of clinical data from trial subjects (triggering the relevance of discussing matters such as Informed Consent Forms, rights of the trial subjects and lawfulness of processing), disclosure of information (at different stages in the process of approval of medicines and subsequent potential EU-UK cooperation for purposes of clinical trials unified database[15]), and transfers of data outside the EU (from the EU or to the EU), be it at company level or in the context of obtaining EU approval of new medicines.

While this article does not aim at evaluating the level of regulatory alignment currently explored for the UK in relation to the EU, as this may significantly change, its goal is to explore the impact of different levels of divergence in the most relevant areas of health and privacy law.

The following Part B addresses questions related to "*Privacy Law in Clinical Trials Data Exchange*". Part A of our larger contribution addresses questions of "*Disclosure of Clinical Trials Data*". For ease of reading, Part A is shared with you in a separate file.

[11] Council (EU) (Art. 50) Guidelines for Brexit negotiations, EUCO XT 20004/17, Chapter IV, p. 8, para. 20 [2017] http://www.consilium.europa.eu/en/press/press-releases/2017/04/29/euco-brexit-guidelines/, accessed 9 May 2018. [12] Brexit in Name Only.
[13] Parliament (EU) Motion B8xxxx/2018, n° 4, p. 4.
[14] Ibid.
[15] The 'EU database', as defined by Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (CTR) [2014] OJ L 158/1, Article 81.

Part B. Privacy Law in Clinical Trials Data Exchange

Section 1. Status quo: Health data in the context of EU privacy law

The GDPR is in the process of being implemented in the UK through the Data Protection Bill. This makes most provisions of the GDPR relevant for the UK.

Several challenges have been raised in the pharma field by the upcoming GDPR and CTR. Among these challenges, are the legal basis for processing the clinical research subjects' personal data; the transfers of data outside the EU; and new activities related to data protection, like the appointment of an EU representative for data protection purposes.

Under the GDPR, consent must be express, informed, unambiguous and freely given.[50] It should also be given per purpose of processing.[51]

Traditionally, the consent to process personal data is gathered through the same ICFs that collect consent for participating in the clinical trial itself. Under the GDPR, it may not be possible to collect a valid consent in contexts where the consent is a *sine qua non* condition for the performance of an activity. In such a case, it would be an implicit consent. Whereas, one of the conditions of collected consent is that it must be express and freely given. In situations where consent is intrinsically linked to the performance of an activity, it is difficult to argue consent was freely given. Also, gathering consent for processing personal data for scientific research purposes may prove difficult because it may not be possible to clearly identify the exact purpose of processing from the outset of collecting the data. Thus, two alternatives are possible: either conceiving a particular dimension of consent in scientific research settings or use another legal basis for processing.

Recital 161 GDPR draws the inevitable and close connection between the CTR and the GDPR. It provides that *"*[f]*or the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of the* [CTR] *should apply."*

Under the GDPR's Article 9(1), it is prohibited to process special categories of personal data, as defined above. Exceptionally, processing can be made either on the basis of the data subject's consent (as provided for in Article 9(2)(a)) or on the basis of the other legal grounds in Article 9(2)(b)-(j).

Consent in clinical trials

The CTR has a great impact on the GDPR and determines a particular read of the latter. Therefore, "consenting" under the GDPR is different in a clinical trial setting. While the rule is that consent should be given per purpose of processing, Recital 33 GDPR acknowledges that *"data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research."* The Recital further provides that it should be ensured that consent can be given only to certain research areas or to parts of research projects.

Are the GDPR conditions for consent fulfilled if the data processor intends to switch to another legal

[50] GDPR, Article 4(11).
[51] GDPR, Article 9(2)(a).

basis for processing, in case the data subject withdraws consent?[52] In a clarifying attempt, the GDPR provides that "*consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment*".[53] In the scenario that the data controller or the data processor use scientific research purposes as the legal basis for processing after withdrawal of consent, then withdrawing consent did not effectively produce the effect intended by the data subject. In other words, giving or withdrawing consent did not reflect a "genuine choice" of the data subject eventually. This raises serious doubts on whether consent was freely given in the first place, in the light of Recital 42 quoted above. Asking for a person's consent in a situation where processing could anyway be based on another legal ground, "*could be considered as misleading or inherently unfair*".[54]

However, the situation is not the same if, in the course of the processing activities, there is a change in circumstances which subsequently justifies further processing for different reasons, i.e. on a new legal basis.

In any event, the UK data protection agency – the Information Commissioner's Office ("ICO") issued guidance on consent which suggests that consent and another legal basis may be used simultaneously as the basis for lawful processing.[55] This practice may be adopted in other EU member states too.

From a practical perspective, the ICF may specify that in case of withdrawal of consent, "*processing of the subject's data may continue as needed to preserve the integrity of the research under the scientific research basis for processing*".[56]

Legal basis for processing other than consent

When read in its entirety, the GDPR displays consent as a very complex tool. It may thus be necessary to look for other grounds for processing, like:

(i) protecting the vital interests of the data subject or of another natural person, whereby 'vital interests' could mean a "life or death" situation[57]
(ii) reasons of public interest in the area of public health, e.g. to take measures for the quality and safety of health care and of medicinal products[58]
(iii) scientific research purposes[59], archiving or statistical purposes[60]

[52] Barnes M and others, '*Reconciling Personal Data Consent Practices in Clinical Trials with the EU General Data Protection Regulation*' [2017] 16 MRLR 18, 09/20/2017, p. 3.
[53] GDPR, Recital 42. Furthermore, WP29 explains in their Guidelines on consent that "*consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences (e.g. substantial extra costs) if he/she does not consent. Consent will not be free in cases where there is any element of compulsion, pressure or inability to exercise free will*" (17/EN/WP259, p. 8).
[54] WP29, 'Opinion 15/2001 on the definition of consent' [2011] 01197/11/EN WP187, p. 13. The remark is still valid, even if provided under the past legislation because the consent's characteristic in cause.
[55] ICO, Consultation on GDPR Consent Guidance, started 2 March 2017 and ended 31 March 2017.
[56] Barnes (n 52), p. 4.
[57] GDPR, Article 9(2)(c).
[58] GDPR, Article 9(2)(i). A situation which is considered to be in the legitimate interest of the controller/processor.
[59] "scientific research purposes" should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research, etc. (GDPR, Recital 159)
[60] GDPR, Article 9 (2)(j). A situation which is considered to be in the legitimate interest of the controller/processor.

Processing for scientific research purposes, as provided for in Article 9(2)(j) of the GDPR, may be possible only under certain conditions further provided by member states. It is yet unclear, but one such condition may be the pre-existence of consent to the processing, consent which, for various reasons, is not valid anymore, but, the particular context of the processing requires further use of the data. For instance, one can imagine the situation whereby a trial subject gives its consent to the processing of his medical data at the beginning of the clinical trial, but later withdraws it. In this case, the withdrawal of consent cannot be without limitations, because it would affect the efficacy of the trial data collected and its further use. In this case, continuous use of the data may potentially be done on the basis of this letter 'j'.

In any event, processing under Article 9(2)(j) must be accompanied by appropriate safeguards, as provided in Article 89 of the GDPR. If safeguards are in place, then member state law may provide for derogations in the field of data subjects rights. In particular, the rights of access, to rectification, to restriction of processing, or to object can be restricted if "*such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfillment of those purposes.*"[61] The provisions in the national law must also ensure that the derogations are "*proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject*."[62]

The right to be forgotten has a limited enforcement in scientific pursuits. Nonetheless, it cannot be waived in the ICF.

Some[63] asked whether it is necessary to first have a legislation interpreting Article 89(1) – i.e. what is the 'public interest' hereunder and what are the 'appropriate safeguards' – before being able to rely on the 'public interest' ground in Article 9(2)(j). This interpretation is likely a matter left to the member states to decide.

Transfers of data outside the EU

Transfers of personal data to third countries from the EU are possible based on one of the means laid down in Chapter V GDPR and as acknowledged by the Commission in its Notice to Stakeholders[64]. There are four ways to accomplish it:

- pursuant to an adequacy decision
- subject to appropriate safeguards, being:
    - standard data protection clauses (SDPCs)
    - binding corporate rules (BCRs)

[59] The "scientific research purposes" should be interpreted in a broad manner, including for example technological development and demonstration, fundamental research, applied research and privately funded research, studies conducted in the public interest in the area of public health. (GDPR, Recital 159)
[60] GDPR, Article 9 (2)(j). This is also a situation which is considered to be in the legitimate interest of the data controller / data processor.
[61] GDPR, Article 89(2). [62] GDPR, Article 9(2)(j). [63] Barnes (n 52), p. 2.
[64] Commission (EU), 'Notice to Stakeholders, Withdrawal of the United Kingdom from the Union and EU rules in the field of data protection' 9 January 2018.

- approved Codes of Conduct
- approved certification mechanisms.

- under specific derogations[65]
- in a special case for non-repetitive transfers[66]

BCRs are meant to approve transfers within a group of companies, outside and inside EEA. These "appropriate safeguards" ensure lawful transfers either (a) within a group of companies which are placed outside EEA or in a country which is not on the EU adequacy list or (b) outside and inside EEA, as well as to countries on the EU adequacy list.

The transfers based on SDPCs and BCRs are not subject to approval on a case by case basis by a supervisory authority. The reason is that SDPCs are issued by the competent authorities themselves and BCRs must be approved by the competent authorities prior to being used. If, among the possible safeguards, SPDCs are used, it is essential not to amend or change them in any way, and instead leave them exactly as issued by the EU Commission.

The Codes of Conduct and the certification mechanisms are new tools for transfers to third countries, "*entailing binding commitments by the controllers and the processors receiving the data in the third country.*"[67]

The special case for non-repetitive transfers

It may be used if several conditions are complied with: (i) the transfer is not repetitive, (ii) it concerns a limited number of data subjects[68], (iii) it is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject and (iv) after assessing all the circumstances, the controller has provided suitable safeguards with regard to the protection of personal data.[69]

With reference to the third condition, Recital 113 GDPR points out that "*for scientific or historical research purposes or statistical purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration*." Then, Recital 159 underlines the relevance of the Union's objective to achieve a European Research Area.[70] It can thus be inferred that the legitimate interests of scientific advancements should not be understated vis-a-vis private interests.

The controller should inform the supervisory authority and the data subject about the transfer, as well as about the compelling legitimate interests pursued.[71]

[65] GDPR Article 49(1).
[66] Ibid.
[67] Commission (EU) (n 64).
[68] However, what a «limited» number of data subject means is not clearly defined, neither in the body of the GDPR, nor in its recitals.
[69] GDPR Article 49(1).
[70] As further provided in the EC Treaty (Treaty of Rome, as amended), Article 179(1).
[71] GDPR Recital 113.

The EU representative for data protection

When it is necessary to appoint an EU representative, sponsors are often tempted to appoint their EU Clinical Research Organization (CRO) as their EU representative. This is of course possible, but then the CRO might prefer, for organizational purposes, to act as EU representative only for the clinical trials it conducts itself. But can a sponsor have a representative only for one clinical trial? Rather not. According to Article 27 GDPR, the EU representative is appointed for *all* the processing activities in the EU.[72] Such role can be taken up by a legal or a natural person established in a member state.[73] The member state in which the representative is established is not irrelevant as it must be in a member state where the data subjects are.[74] As the appointment of the representative is for the EU and the representative must ensure timely communication with the competent supervisory authorities, translation services may facilitate the communication with the competent supervisory authorities where the representative is not multilingual.

Section 2. Brexit impact: Privacy law in the UK

The section addresses the GDPR impact in the UK depending on whether the UK closely aligns with the EU or whether it rather distances itself.

The areas left unharmonized by the GDPR leave room for maneuver for the EU member states. The GDPR contains around fifty situations where member states can pass laws, because of the distinct national criminal laws. These are called member states flex provisions. Recitals will thus be used by national courts to interpret the GDPR. How might the UK use this?

Supporters of a 'hard' Brexit plead for full regulatory autonomy of the UK, which will create just the necessary context to diverge from the GDPR significantly, not only in the 50 or so member states flex provisions in the GDPR. But a high degree of divergence would hinder potential data transfers between the EU and the UK.

A 'soft' Brexit scenario would amount to a high degree of alignment of UK law to EU law. It would be achieved if the GDPR is closely implemented in UK law.

The interaction of the GDPR with health law impacts the post-Brexit UK in the sense that transfers of data will be possible in the regulated ways presented in Section 1 above. After Brexit, the biggest unknown factor comes from the upcoming CTR, and not from the GDPR. While the GDPR is already being implemented into UK law, the CTR only becomes applicable in the EU after the withdrawal date[75].In this context, assuming that trial data might need to be communicated to EU partners or to EU authorities when, for example, seeking medicines approval, then transfers of personal data, *in casu* health data, will also need to respect the high requirements of EU law, i.e. the GDPR.

[72] Once appointed, the EU representative of a sponsor automatically fulfills this function for all the clinical trials undertaken by the sponsor in the EU, and not only for the clinical trials conducted by the CRO in question.
[73] GDPR Article 4(17),
[74] GDPR Article 27(3).
[75] 30 March 2019.

'EU retained law'

The current proposal of the UK Government is to leave aside the Charter of Fundamental Rights[76] from the "EU retained law" after Brexit.[77] This fact raises concerns in terms of showing regulatory equivalence with the EU standards, which is absolutely necessary for continuous cooperation between the EU and the UK after Brexit. Moreover, adopting a selective (also referred to as "cherry-picking") system in defining the "EU retained law" creates further inconsistency and confusion: the ECJ often refers to Articles 7 and 8 (right to privacy and right to data protection) of the Charter in taking its decisions interpreting EU data protection law. While the EU makes it clear in its withdrawal negotiations that the ECJ remains central and also the highest judicial authority in matters of interpretation and application of EU law, it would be difficult, if not impossible, to leave aside legal instruments which are essential to the ECJ activity. Instead of the references to the Charter of Fundamental Rights, "*underlying rights and principles will be carried forward and will be substitute reference points in pre-Brexit case-law referring to the Charter*".[78]

Data and information received by the UK from EU-27 member states before the withdrawal date shall continue to be protected in accordance with the provisions in Union law restricting the use or access to such data and information applicable on the withdrawal date.[79] In this category fall also the rules concerning regulatory data protection of pre-clinical, clinical, and toxicological (human health and environment) studies as well as other data submitted in accordance with applicable Union law.[80]

Adequacy decision for data protection purposes by the EU – how likely?

The EU officially declared it is prepared to support a smooth and timely mechanism for data transfers with the UK after Brexit: "[i]*n the light of the importance of data flows in several components of the future relationship, […] personal data, protection should be governed by Union rules on adequacy with a view to ensuring a level of protection essentially equivalent to that of the Union.*"[81]

At the time of writing this paper, the UK Government has also announced in an official position paper[82] that "*the UK's domestic data protection rules will be aligned with the EU data protection framework*" on the withdrawal date. The Data Protection Bill 2017-19 is the developing means to bring the GDPR into UK law before the Brexit.

This is important in order to infer the extension to which the EU will have the ground prepared for issuing an adequacy decision for the UK for GDPR purposes. In fact, the above-mentioned position

[76] Charter of Fundamental Rights of the European Union (the Charter) [2000] OJ C364/1.
[77] Considering the definition of "Union law" in Withdrawal Agreement, Article 2(b)(i).
[78] House of Commons, Briefing Paper n° 7838, 10 October 2017, p. 4.
[79] Withdrawal Agreement, Articles 67, 69.
[80] Commission (EU) Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU, 'Position paper on the Use of Data and Protection of Information Obtained or Processed before the withdrawal date' [2017], p. 4.
[81] Council (EU), (Art. 50) Draft Guidelines EUCO XT 20001/18, 23 March 2018, p. 6, para. 14.
[82] UK Government 'The exchange and protection of personal data. A future partnership paper', 24 August 2017, n° 2 https://www.gov.uk/government/publications/the-exchange-and-protection-of-personal-data-a-future-partnership-paper accessed 9 May 2018.

paper confirms the UK's intention to submit to the negotiating table "*a model for exchanging and protecting personal data, which could build on the existing adequacy model*"[83].

However, the decisions on equivalence are "*always of unilateral nature*"[84] so that the decision fully rests with the EU. From the EU side, the Parliament underlined that an adequacy decision would be "*the preferred and securest option*"[85].

The most optimistic scenario is that the European Commission issues an adequacy decision with regard to the UK. However, upon interpellation by the House of Lords Select Committee, a UK academic and lawyer on data protection points out that adequacy decisions are issued by the European Commission with respect to third countries.[86] Only after becoming a third country, would the legislative process for issuing the adequacy decision begin at the EU. Any legislative process is more formal and virtually lengthier than negotiations that might lead to an expedite and informal decision. But when it comes to an adequacy decision, the ability to make a choice between these two is not really the reality. An adequacy decision in itself needs to follow an orderly legislative process.

With the UK Data Protection Bill yet to be passed as an Act of Parliament, maybe the UK delivers just what is needed in order to obtain the adequacy decision. But, if the adequacy decision will depend upon a lengthy legislative process, then the UK companies will need to familiarize themselves with the other ways of transferring data from the EU to third countries, e.g. BCRs, SDPCs etc.

In consultations undertaken recently by the British-Swiss Chamber of Commerce, stakeholders underlined that the business world should start preparing for Brexit assuming a worst-case scenario. That is, the event that no adequacy decisions exist.[87]

The recent US Cloud Act

One factor that could influence the adequacy decision are the recent developments in the US with respect to privacy law. They are also relevant in the context of the GDPR application. A bill on data protection has just been annexed to the US Budget for approval – the US Cloud Act. Thus, the bill did not pass through Parliament and not even the US President can veto it without hampering the entire US budget for next year.

The US Cloud Act is at the other extreme of the GDPR. It enables transmission of personal data from one company to another, without the prior consent of the data subject. An opposition can be filed by the company asked to do this, if two conditions are fulfilled: (i) the personal data belongs to a foreign citizen (i.e. not US citizen, US resident or US registered company) and (ii) the disclosure would break the law of the country where the data is stored.

In this sense, if the UK decides to align its legislation to the US Cloud Act, it can potentially impact an

[83] Idem. n° 4.
[84] Parliament (EU) Motion B8xxxx/2018, n° 17, p. 7.
[85] Idem. n° 29, p. 8.
[86] UK House of Commons, Briefing paper n° 7838, 10 October 2017, p. 11.
[87] British-Swiss Chamber of Commerce,' Brexit White Paper' [2018], p. 9.

adequacy decision of the EU Commission with respect to the UK.

However, the bill is drafted in such a way that exceptions can only be made under very narrow conditions. The US Cloud Act also pushes for quick negotiations by the US President to conclude bilateral agreements with third countries that would overrule the 'jus loci' principle (these bilateral agreements should disregard the legal principle providing that the applicable law is that of the country where data is stored). Priority in the negotiations have the UK and Australia. Assuming that the UK concludes such an agreement with the US, what are the chances that it is still granted an adequacy decision by the EU?

Probably very little. An approach close to the US Cloud Act means insignificant data protection under EU standards.

Confidentiality measures and secondary uses of personal data

One determinant of being granted an adequacy decision is the way a country deals with personal data. Apart from the use by governmental agencies, patients' personal and medical data issued from clinical trials might also be used for research (studying efficacy of medicines and equipment, monitoring adverse drug reactions), or for building databases (e.g. disease registers). Secondary uses of personal data, such as analysis, audit and research claim particular attention to "*the publication or otherwise disclosure*"[88] of such data. Here, special conditions need to be complied with and strictly regulated under the GDPR and the post-Brexit UK might not be able to avoid these requirements. If "further processing" of the data is allowed in the interest of scientific research, it should not be paving the way for collecting data for purposes unknown to the data subject.

Then, records in clinical trials are relevant because they generate questions like: how long does data need to be kept before and after the approval of the medicine? In what format? Pseudonymized? Provided that under the GDPR, pseudonymized data is now considered personal data which falls under the data protection requirements, a new question arises in connection with ongoing clinical trials: to what extent is the GDPR a game-changer?

In terms of confidentiality requirements, pseudonymization is about balancing the aim to protect personal data with the need to efficiently use the data obtained from clinical trials. On the one hand, unnecessary information about a trial subject, like its name, should not be shared with all the persons involved in conducting the clinical trial, e.g. the sponsor, who only needs aggregate reports. On the other hand, the treating physician needs to be able to link the reporting of an adverse event to one or the other among its patients. It is also necessary to monitor the effects of the medicine even after approval of the medicine.

Consequently, pseudonymized data can be used in virtually all kinds of clinical trials. Thus, the GDPR will find its applicability because of the processing of pseudonymized data.

This is all the more so in developing gene targeted therapies. When working with genetic data, the activity will always fall under the scope of the GDPR, because anonymization is never an option.

[88] GDPR, Recital 159.

Genetic data can always be used to re-identify the individual it belongs to, because the genetic code is unique to each and every person.

Conclusion

The UK publicly declared in various instances that they are positive about leaving the EU, but also very keen in aligning with the EU legislation in order to maintain close cooperation with the EU. Also, more than 60 conservative MPs publicly communicated their position that the UK should significantly distance from the EU. On the EU side, it was made clear that a non-member cannot have the same EU privileges while not assuming corresponding obligations.

On paper, the situation is far from being clear. Certain progress has been recorded in drafting the Withdrawal Agreement, but the areas which should settle clear rules or answers are to date left open.

With respect to data protection, the same level of protection is allegedly sought after in the UK. Hence, a decision from the EU – unilaterally taken – would include the UK on the list of countries ensuring an adequate level of protection to personal data, thus paving the way for smooth data flows between the EU and the countries on the adequacy list. However, there is still plenty of time to see whether the US Cloud Act will influence the UK's data protection policy. If this is the case, the pursuit of an adequacy decision from the EU Commission is seriously hampered.