# Legal Impact Assessment of Brexit

# Part A

# Disclosure of Clinical Trials Data

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# List of Abbreviations

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| 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

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[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.

and the Single Market.[10] The UK must first become a third country to the EU in order to conclude 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 A addresses questions of "*Disclosure of Clinical Trials Data*". Part B of our larger contribution addresses questions related to "*Privacy Law in Clinical Trials Data Exchange*". For ease of reading, Part B is shared with you in a separate file.

[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.
[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 A. Disclosure of Clinical Trials Data

## Section 1. Status quo: The public interest in the EU, at the crossroads of confidentiality and disclosure

This section focuses on health-related data whether from clinical trials or other processes requiring the exchange of data between centers or service providers. It will briefly address why there is public interest in accessing clinical trials data, and how public interest indirectly stems from EU citizens' right to health. One of the dimensions of the right to health is the right to information (access to data concerning health).

Disclosure of clinical trials data to regulatory agencies is a requisite in the process of approving the marketing of pharmaceutical products, in order to prove safety and efficacy of medicines. In the context of the WTO's legal framework for the protection of intellectual property rights, test data is protected against further public disclosure, unless a superseding public interest sustains disclosure and such disclosure is accompanied by measures against unfair commercial use (e.g. exclusivity period).[16] Thus, disclosure is closely linked to the concept of 'public interest'. 'Public interest' is a fluctuating concept depending on the society that defines it. Recent jurisprudence and literature considers it more and more to be in the public interest to disclose trials data on a large scale. Here, 'public interest' is read broadly, as being directly determined by people's need to have access to clinical trials data, "*as a crucial component of credible, accountable, and public safety-oriented research.*"[17] In other words, access to health data is a determinant of the right to health.[18]

The right to health is stipulated in Article 12 of the UN International Covenant on Economic, Social and Cultural Rights (ICESCR), which reads that *"states parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."*

Discerning the right to access clinical trials data from the right to health is marked by several milestones, including the:

- UN ICESCR
- UNESCO Universal Declaration on the Human Genome and Human Rights
- WMA Declaration of Helsinki
- WHO Forum further defining WHO's roles and responsibilities

The UN ICESCR in its Article 15 provides that *"states parties to the present Covenant recognize the right of everyone to […] enjoy the benefits of scientific progress and its applications."* A step mentioned in Article 15 for the *"full realization of this right"* includes *"the diffusion of science".*

[16] World Trade Organization, Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Article 39(3).
[17] Trudo Lemmens, Candice Telfer, 'Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency', American Journal of Law & Medicine, 38 (2012): 63-112, p. 99.
[18] WHO (Bamako Global Ministerial Forum on Research for Health), 'WHO's Role and Responsibilities in Health Research [2009], in particular n° 4, p. 4.

A further legal milestone in achieving disclosure of health data is the UNESCO Universal Declaration on the Human Genome and Human Rights providing that *"benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all"* (Article 12).

The right to information is a dimension of the right to health ever since the World Medical Association proclaimed the Declaration of Helsinki in 2008. It stated for the first time that *"every research study involving human subjects must be registered in a publicly accessible database"* (Article 35); also, that "*researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports*" (Article 36).

The same year, the Global Ministerial Forum on Research for Health, organized by the WHO in partnership with other UN bodies, encouraged governments to *"develop, set and enforce standards, regulations, and best practices for fair, accountable, and transparent research processes, including those related to… the registration and results reporting of clinical trials, and open and equitable access to research data."*[19]

At EU level, the transition from confidentiality with respect to company-issued health data to disclosure of such data on the basis of the public interest in this access has involved several stages. Some key developments include:

- Regulation (EC) 1049/2001 on public access to documents[20]
- Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency
- EMA Policy 0043[21]
- Annulment by the ECJ of interim injunctions sought by two companies to prevent EMA from disclosing trials reports
- Clinical Trials Regulation (CTR)
- EMA Policy 0070[22]
- ECJ landmark rulings on commercially confidential information

Firstly, the tone was set with the adoption of the EU law on public access to documents, i.e. Regulation 1049/2001. But only in 2010, was a first step effectively taken in this direction. In its Decision closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency (EMA)[23], the European Ombudsman advised in the sense that a competitor had the right to access clinical study reports submitted to EMA in the approval procedure for a medicine. The immediate

[19] Ibid.
[20] Regulation (EC) of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43.
[21] European Medicines Agency, 'Policy on access to documents (related to medicinal products for human and veterinary use)' (Policy 0043), effective 1 December 2010, EMA/110196/2006.
[22] European Medicines Agency, 'Policy on publication of clinical data for medicinal products for human use' (Policy 0070) effective 1 January 2015, EMA/240810/2013.
[23] https://www.ombudsman.europa.eu/cases/decision.faces/en/5459/html.bookmark#top, accessed 9 May 2018.

outcome was EMA adopting its Policy 0043 to implement Regulation 1049/201. Policy 0043 recalls that, in principle, EU documents are accessible to the public, with the observance of some exceptions, as outlined in Regulation 1049/2011.

Secondly, in 2013, the ECJ annulled the interim injunctions sought by two companies (*AbbVie* and *Intermune*) to prevent EMA from disclosing trials reports.[24]

Thirdly, the CTR adopted in 2014 and expected to apply as from end 2019[25], enhances the trend towards disclosure of clinical trials data. The CTR in Article 37 explicitly provides for disclosure of clinical study reports trial data subject to a mandatory reporting system "*within 30 days after the day the marketing authorization has been granted, the procedure for granting the marketing authorization has been completed, or the applicant for marketing authorization has withdrawn the application*."[26] However, exemptions are also provided in the CTR for the purpose of e.g. protecting personal data (in accordance with Regulation EC 45/2001) or CCI.[27]

Fourthly, in 2015, the EMA Policy 0070 entered into force, making a further step towards disclosure of clinical data and introducing transparency requirements. Policy 0070 introduces a proactive publication mechanism relating to clinical data, "*composed of clinical reports and individual patient data*".[28] Under Policy 0070, commercially confidential information (CCI) is defined as "*any information contained in the clinical reports submitted to the Agency by the applicant/Marketing Authorization Holder* [MAH] *that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH.*"[29]

Fifthly, in 2018, the ECJ ruled, in three landmark decisions,[30] in favor of disclosing information comprised in: toxicology study reports, orphan similarity reports, superiority reports, clinical study reports, as well as in documents prepared by the EMA in the context of an MAA. The core of the ECJ's reasoning resided in the fact that companies failed to give any concrete evidence of how the release of the contested documents would undermine their commercial interests. The grounds were several: (i) upon redaction, the documents did not contain CCI;[31] (ii) there can be no CCI in question

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[24] Case C-390/13 P(R) *EMA v InterMune UK Ltd and Others* ECLI:EU:C:2013:795, Case C-389/13 P(R) *EMA v AbbVie*, Inc., Ltd ECLI:EU:C:2013:794.
[25] The date of application of the CTR depends on the EU database achieving full functionality. See Articles 96(1) and 99 CTR.
[26] CTR, Article 37(4) para. 4.
[27] CTR, Article 81(4)(a)-(d).
[28] EMA Policy 0070, 2 'Scope', p. 2.
[29] European Medicines Agency, 'EMA Policy on Publication of Clinical Data for Medicinal Products for Human Use' [2014], EMA/240810/2013, p. 3.
[30] Case T-235/15 *Pari Pharma v EMA* ECLI:EU:T:2018:65, Case T-718/15, *PTC Therapeutics International v EMA* ECLI:EU:T:2018 :66, Case T-729/15, *MSD Animal Health Innovation and Intervet international* ECLI:EU:T:2018:67.
[31] EMA presented 3 categories of CCI: (i) intellectual property; (ii) trade secrets and (iii) commercial confidences (i.e. "*every piece of information which does not have a commercial value as such but its disclosure might provoke damage to the party, e.g. structures and development plans of company, marketing strategies, etc.*") The Ombudsman argued that none of the categories were identifiable in the clinical study reports, because:
(i) products are patented before MAA submission and, upon redaction, do not include their composition
(ii) clinical study reports do not contain information on drug formulae, manufacturing or control processes.

if the EMA publishes, in the context of an MAA procedure, the outcome of its assessments of the data submitted to it, as well as its scientific assessments of the approved medicine; (iii) the MAA contains documents requested by EMA and do not reflect the company's particular business strategy. Importantly, the ECJ makes it clear that there is no general presumption of confidentiality, even after considering the TRIPS Agreement. Thus, the EMA can always make a balancing exercise between protecting CCI and the need to inform the public about a medicinal product's test.[32]

These rulings thus also amount to determining what is CCI and what is not, alongside previous EU documents. Thus, these ECJ decisions increase legal certainty and enhance foreseeability for businesses. Generally, detailed manufacturing information is CCI.[33] Development information concerning the active substance, formulation and manufacturing and test procedures and validation are accepted as CCI.[34] In addition, the names of manufacturers or suppliers of the active substance or the excipients are also accepted as CCI, unless disclosure is necessary for public health reasons (e.g. for some biological products).[35]

## Section 2. Brexit impact: UK interaction with the EU legal framework for clinical trials

This section will evaluate (i) the consequences for all involved stakeholders if the UK will depart from the community acquis, i.e. current community legal standard, on clinical trials, and (ii) to what extent different models of Brexit can attenuate or aggravate such consequences. Main questions of concern are: to what extent can the UK participate in the EU regulatory schemes? Will the EU's position of not permitting the UK access to the EU database after Brexit become a reality?

### *Overarching implications of Brexit*

The impact of a 'hard' Brexit is mostly a reason of concern for companies active in highly regulated fields, like pharmaceuticals.[36] A 'hard' Brexit would mean issuing regulations in the UK different from the existing EU ones. For EU-based or overseas pharmaceutical companies, this would mean investing time and financial resources in achieving compliance with UK requirements coming on top of those they have to comply with for access to the large EU market. For UK companies, this scenario would amount to a potential business isolation for a certain period of time, until either

[32] It must be underlined that the balancing exercise is not made between the pharmaceutical companies' interests and the general public interest of having access to trial data. One must not confuse the public interest with access to trial data. Broad access to trial data might not be in the public interest when such access hinders pharma companies' opportunities to develop innovative medicines and treatments. Free access to achievements which are the result of significant efforts will cut the motivation to achieve further improvements. It is (mainly) in the public interest to have in place a mechanism that favors competition and thus the conduct of business. If the market is regulated by free competition, as opposed to strict regulations heading towards an 'open' market, then the race to better products will lead to improvement and will regulate the prices. A free market regulates itself.

[33] HMA/EMA Working Group on Transparency 'Guidance document on the identification of commercially confidential information and personal data within the structure of the MA application – release of information after the granting of a marketing authorization', [2012], p. 4, para. 3.1.

[34] Idem., para. 3.1.1.

[35] Ibid.

[36] British-Swiss Chamber of Commerce, Brexit White Paper [2018], p. 6.

alignment is ensured or until just enough FTAs are concluded with as many countries as possible. In other words, if the UK significantly changes the regulatory landscape in a 'hard' Brexit scenario, it engages itself in a race of convincing business partners to invest stand-alone resources in order to transform the UK into a field of investments in its own right, separate from the EU. A regulatory disruption is currently expected, due to the current lack of detail in the Withdrawal Agreement.

### *The EU database*

Different models of Brexit determine variations in the extent to which clinical trials data can be disclosed and the means to do it.

The current version of the Withdrawal Agreement provides for UK alignment with Union law, including case law handed down both before and after the end of the transition period.[37]

In search for legal stability, ministers are expected by the UK Parliament to accept the substance of an amendment, which would keep the CTR– which is not yet applicable – in UK law. In particular, an amendment was proposed by the House of Lords to the EU Withdrawal Bill to ensure incorporation of the CTR into UK law, but upon reassurances from the Government, the amendment was apparently withdrawn.[38] So the UK Government may be preparing a close alignment of its domestic law to the CTR.

The current version of the Withdrawal Agreement states that a non-EU member cannot, with some exceptions, have access to network and information systems and databases.[39] In other words, be it a 'hard' or a 'soft' Brexit scenario, access is likely to not be granted to non-EU members, neither to agencies (e.g. EMA), nor to EU tools and databases (e.g. the EU database for clinical trials).

With or without access to the EU database gathering clinical trials data, the UK is anyway a WTO member, thus party to the TRIPS Agreement. From the analysis under Section 1 further above, it follows that the UK is anyway under an obligation increasingly substantiated (by jurisprudence and governmental guidelines and directives) to disclose clinical trials data with the aim to ensure the right to health for its citizens.

When recording clinical trials information in the new EU database, the CTR provides that "[n]*o personal data of data subjects participating in a clinical trial should be recorded*" (Recital 67).

The EU database cannot be implemented and used without due regard to all EU laws. Thus, the interaction of the EU database with the GDPR and all its future amendments is far reaching and the implications are various. Here, only a few of them are presented and further information is provided under Part B of this paper.

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[37] Withdrawal Agreement, Article 4(4), (5).

[38] H. Stewart, https://www.theguardian.com/politics/2018/apr/18/ministers-to-announce-brexit-climbdown-as-they-face-lords-defeat, accessed 9 May 2018.

[39] *"At the end of the transition period, the United Kingdom shall cease to be entitled to access any network, any information system, and any database established on the basis of Union law. The United Kingdom shall take appropriate measures to ensure that it does not access a network, information system, or database which it is no longer entitled to access."* (Withdrawal Agreement, Article 7). Derogations are provided pursuant to Article 46 and Annex [y+4]. The latter is yet to be defined by a list of databases to which the UK will have access.

In terms of records keeping, GDPR requirements are very likely to be valid in any Brexit scenario: 'hard', 'soft' or BINO. If, amongst the sponsor, the clinical research organization, or the various participants in the clinical trial, only one category falls under the scope of the GDPR, then data protection measures imposed by the EU will become a necessity, not an option. It is thus apparent that, when conducting clinical trials, either by EU-based companies or with EU-based citizens, then the GDPR requirements will need to be complied with and duly documented.

Besides, it is also very likely that the EMA, as an EU body, which needs to abide by EU rules and regulations, requires that GDPR standards are respected in order to issue authorizations for the placing on the market of medicinal products. The reason is that, when taking a decision, the EMA relies, for instance, on clinical study reports that are drawn in accordance with strict requirements, which altogether reflect the EU acquis.

## *Protection of disclosed clinical trial data*

Another aspect to explore further is the protection of intellectual property rights and how to enforce them. Are there Brexit implications in this field?

Currently, in the EU, upon disclosure, clinical trial data is protected against "unfair commercial use", on a first level, by the TRIPS Agreement (Article 39(1)), and, on a second level, by EU documents. It is protected by EU documents, such as Policy 0070, in the sense that it defines which kind of clinical trial data can be considered CCI and which not. Relying on this definition, the ECJ may later make a binding decision, as it did in the three landmark rulings presented above. By these means, the ECJ determines the IP protection granted to clinical trial data.

Recent developments in the EU jurisprudence[40] set the grounds for new interpretation of the extension of protection granted by the TRIPS Agreement, in the sense that its provisions may be read in light of the EU public interest in approaching transparency and confidentiality. The EU's current perspective is twofold. On the one hand, clinical study reports *"are protected by copyright or other intellectual property rights […] and can be considered commercially valuable"*[41]. In other words, not all clinical trial data publicly disclosed can be further used by those who have access to it, because, being considered commercially valuable, it may be protected by copyright and other IP rights. On the other hand, the ECJ (bindingly) stated that "*no direct effect may be given to the provision of* [the TRIPS Agreement]"[42], because the TRIPS Agreement needs implementing laws/regulations.

Pursuant to the Withdrawal Agreement, *"*[t]*he provisions of this Agreement referring to Union law or concepts and provisions thereof shall in their implementation and application be interpreted in conformity with the relevant case law of the Court of Justice of the European Union handed down before the end of the transition period."*[43]

[40] Case T-729/15 *MSD Animal Health Innovation and Intervet international vs. EMA* [2016] ECLI:EU:T:2018:67, 48.
[41] EMA Policy 0070, Annex 1 'Terms of Use for general information purposes' para. 2.
[42] Idem 40, para. 47-50.
[43] Withdrawal Agreement, Article 4(4).

Under these circumstances, upon implementing the TRIPS Agreement into UK law, the EU's view is to be adopted. This view is that even though undisclosed data must be protected against unfair commercial use, a national body cannot prevent such use, upon disclosure, because it lacks the means to do it.

It is thus apparent from the above-cited provision in the draft Withdrawal Agreement that the UK will adopt the same position.

Moreover, in a 'soft' Brexit scenario or, even more so, in case of BINO, the recent EU developments remain fully relevant, because 'soft' Brexit means closer alignment to the EU.

## *Recent developments*

A 2017 EU Commission communication ("stakeholder dialogue") follows up on the 2012 policy package containing measures to improve access to scientific information in Europe. This stakeholder dialogue proved "*strong support for non-regulatory measures to maximize and organize access to and reuse of data in business-to-business contexts.*"[44] This communication makes recommendations which amount (i) to the reusability of public sector data and (ii) to establishing open science objectives. On the one hand, it is recommended that "*a revised law on Public Sector Information […] facilitate the reusability of open research data resulting from public funding and oblige Member States to develop open access policies*."[45] On the other hand, open science policies are recommended for implementation, commensurate with open science objectives, research data and data management and the creation of a European Open Science Cloud. The Commission also highlights the importance of incentives and rewards in "*the era of networked research*".[46]

This points towards creating more and more transparency in various areas of activity, health and care systems included. The potential impact is both on the regulatory incentives landscape, as it is on intellectual property rights. Eventually, such a trend calls for new business structures, especially in the pharmaceutical field.

## *Marketing Authorizations*

One of the major and immediate implications of Brexit is that for medicinal products centrally authorized by the EMA the MAs granted to UK-based companies will need to be transferred to companies in EU member states, as the MAH "*must be established in the Community*".[47] This is an

[44] Commission (EU), 'Data in the EU: Commission steps up efforts to increase availability and boost healthcare data sharing' Press release of 24 April 2018 http://europa.eu/rapid/press-release_IP-18-3364_en.htm, accessed 9 May 2018.
[45] Ibid.
[46] Ibid.
[47] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1, Article 2(2) and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, Article 8(2).

implication of any Brexit scenario, be it 'hard', 'soft' or BINO as on the withdrawal date, the UK will no longer be "in the Community". Arrangements for such transfers are already made under the Withdrawal Agreement.[48]

The only other option to escape the need to transfer existing MAs from the UK to an EU jurisdiction, would be if the UK would become part of the EEA. But, is this a real option? In order to join the EEA, the UK must first become a third country in relation to the EU. Only afterwards can the long procedure of admission to the EEA begin.

A significant impact will also be registered in connection to "*the certification and manufacturing of manufacturing plants or quality releases in individual countries*".[49] The UK may try to borrow the Swiss example of concluding Mutual Recognition Agreements with the EU. But one should be mindful of how long of a process that was for Switzerland, being extended over years of negotiations. In addition, another big and widely underestimated difference between Switzerland and the UK is that Swiss negotiations and contracts were conducted in a mindset of approaching the EU while the UK negotiations are done in the mindset of primarily separating each other and trying to find a solution for a workable access afterwards.

# 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.

Regarding clinical trials data, most likely the UK will keep the EU acquis, as it is upon the withdrawal date. This means defining CCI in the light of the ECJ's jurisprudence and considering the EU rules and regulations (e.g. EMA policies) which precede 30 March 2019. It also means maintaining the EU level of protection of clinical trials data, both from a regulatory and an intellectual property point of view. After the withdrawal date, the UK would be free, from a legal point of view, to create variations in these standards. However, business partnerships are often a more stringent determinant to such potential variations in approaching protection of clinical trials data.