22 January 2019

Science and Technology Committee
House of Commons
London
SW1A 0AA

RE: ACRO Comment on:
House of Commons Science and Technology Committee
Brexit, Science and Innovation: Preparations for 'No-Deal' inquiry

Dear Committee members,

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. In 2018, ACRO member companies managed or otherwise supported a majority of all biopharmaceutical-sponsored clinical investigations worldwide. With more than 130,000 employees engaged in research activities in 114 countries, including more than 13,000 in the United Kingdom, the member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.
ACRO welcomes this opportunity to provide comment to the Science and Technology Committee. ACRO will refrain from repeating the comments submitted in its October 2018 response to the House of Commons' Health and Social Care Committee Inquiry on the Impact of a No Deal Brexit on Health and Social Care. Instead, ACRO offers new comments on three key topics relevant to the current inquiry: (1) access to animals, (2) Preparations of the Department of Health and Social care (DHSC) and Medicines and Healthcare Products Regulatory Agency (MHRA) relative to clinical trials, and (3) issues related to data protection and data transfers.

Section I. Access to Animals

Access to live animals and to biological samples taken from animals is critical to biomedical research in the UK and absolutely required to meet legal obligations for testing medicines with animals prior to first-in-human trials. Two serious obstacles exist in a no deal scenario:

Airline embargos:
Concern:
Ongoing embargoes by British Airways and other carriers mean that research animals cannot be transported by air directly to the UK. While a long-standing and serious problem, the risks to UK based biomedical research are significantly higher in a no deal scenario due to uncertainties about air transport authorisations, the functioning of customs and other controls, and likely delays as animals transit through the EU27 in route to the UK.

Recommendation:
ACRO suggests that the government engage directly with UK carriers to eliminate the existing embargoes for legally compulsory biomedical research regardless of the Brexit result.

CITES permitting:
Concern:
A pilot project conducted by Covance (an ACRO member company) and deemed a success by APHA paves the way for simplified CITES permitting for the export of biological samples for biomedical research. The first phase of the pilot is scheduled to be concluded by end January 2019, at which time the simplified procedure will be available for the biomedical community. A second phase, which will explore use of the system for purposes of imports of biological samples for biomedical research (permits for imports are not required by CITES but are obligated by EU law which imposes stricter domestic measures) and other facilitations that save resources and time for both the authorities and the regulated community is likely to be implemented shortly. Some of the same facilitations, such as use of off the shelf software to enable online applications for CITES permits, might also be useful for permitting for the movement of live animals. Any such advances established before the end of March 2019 will be tremendously useful should a no deal scenario result.

Recommendation:
ACRO suggests that the government support immediate exploration of facilitating options for CITES permitting including off the shelf electronic permitting systems.

Section II. Preparations of the Department of Health and Social Care (DHSC) and Medicines and Healthcare Products Regulatory Agency (MHRA) relative to clinical trials

ACRO has divided its comments on this topic into two key sections:

- Informing the Committee of concerns with DHSC operational readiness guidance
- Informing the Committee of concerns with current MHRA guidance and the proposed statutory instrument on medicinal products and clinical trials.

DHSC EU Exit Operational Readiness Guidance
Concern
DHSC published EU Exit Operational Readiness Guidance on 21 December 2018. It includes a section on Clinical Trials and Clinical Investigations that states "The Department continues to engage with the life sciences industry regarding contract research and clinical trials of IMPs and medical devices. The Department is working closely with the NHS and is undertaking a comprehensive assessment of the potential impact of 'no deal' exit on clinical trials and investigations, to gain a greater understanding of those which might be affected by supply issues. This includes examining supply chains for IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables, used in clinical trials and investigations, which originate from, or travel through, the EU and EEA. This assessment aims to conclude in January 2019 and, if necessary, further guidance will be issued thereafter. All organisations participating in and/or recruiting patients to clinical trials or clinical investigations in the UK should contact their relevant trial sponsors for confirmation of plans for supply chains for IMPs and medical devices as soon as possible. The Department has communicated with Sponsors of trials to emphasise their responsibility for

ensuring the continuity of IMP supplies for their trials. The Government will monitor for any clinical trials or clinical investigations impacted due to disruptions to clinical trial supplies. Organisations should therefore continue to participate in and/or recruit patients to clinical trials and clinical investigations from 29 March 2019, unless they receive information to the contrary from a trial sponsor, organisation managing the trial or investigation, or from formal communications."

ACRO member companies are working with DHSC on the current review, but are concerned that any resulting guidance will come too close to the anticipated exit date for adequate implementation. As noted in ACRO's October 2018 response to the House of Commons' Health and Social Care Committee Inquiry on the Impact of a No Deal Brexit on Health and Social Care, supply chains for investigational medicinal products (IMPs) and other materials used in or arising from clinical trials, which cannot be stockpiled in the way that is ongoing for marketed medicinal products, are a major concern for ACRO members. To date, other than placing responsibility on clinical trial sponsors to ensure the continuity of clinical trial supplies, there has been no guidance or support from government to facilitate this.

Recommendation

ACRO suggests that practical DHSC guidance to ensure continuity of supply of clinical trial supplies is published no later than end-January 2019 and that DHSC puts arrangements in place to support clinical trial sponsors and CROs in maintaining continuity of supply.

MHRA Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal

Concern

ACRO welcomes the guidance on regulation of medicinal products and clinical trials in the event of a no-deal exit from the EU provided by DHSC in August 2018 and by MHRA on 3 January 2019, the latter representing the arrangements to be included in the proposed statutory instrument to be laid before Parliament. However, additional details are needed to ensure that clinical trials and the marketing of medicines can continue in the UK without interruption. Examples (not exhaustive, but indicative of the scale of the problem faced by the pharmaceutical industry in the UK) include the need for detailed specifications for the formatting, presentation and validation of regulatory application dossiers and pharmacovigilance monitoring reports (especially electronic submissions, where revisions to existing processes may need a lead time of 6 months or more), details of baseline data required to continue regulatory maintenance of medicinal products, the need for a full standalone UK paediatric investigation plan for any product intended to be marketed in the UK, how ongoing variations within the EU mutual recognition/decentralized regulatory procedures will be managed in standalone UK applications, the applicability of the EU Sunset clause in the UK and how this will be managed, etc.

Specifically in relation to the management of clinical trials, ACRO notes that the supply chain for IMPs is very complex with many integral parts and processes and, while the MHRA position of accepting EU/EEA Qualified Person certification of IMP with no need for re-certification in the UK is welcomed, the planned addition of an assurance system that must be overseen by a Qualified Person for IMPs coming from countries on the approved country list to confirm that these IMPs have been QP-certified in the EU or EEA is unnecessary and simply adds another burden and layer of complexity to what is already a very multifaceted process, and would disadvantage the UK in relation to other countries competing for the placement of clinical trials.

Recommendation

ACRO suggests that the forthcoming statutory instrument on regulation of medicinal products and clinical trials should be scrutinized rigorously to ensure that no unnecessary additional burdens are placed on marketing authorization holders and clinical trial sponsors in the UK, including the planned addition of an assurance system that must be overseen by a Qualified Person for IMPs coming from countries on the approved country list to confirm that these IMPs have been QP-certified in the EU or EEA. Additionally, ACRO suggests that the MHRA should, as soon as possible, issue detailed guidance on post-exit UK regulatory requirements and procedures, taking due account of practical lead times for the implementation of new requirements and also avoiding any unnecessary additional burdens.

Section III. Data Protection and Data Transfer Issues

ACRO has divided its comments on this topic into three key sections:

- Informing the Committee that ACRO members are prepared to follow the guidelines published by the UK Department for Digital, Culture Media & Sport ('DCMS') on 13 December 2018
- Informing the Committee that ACRO member companies are prepared to follow the December 2018 communication from the International Trade Administration's Privacy Shield Team
- A Request from ACRO

1--DCMS December 2018 Guidelines

ACRO member companies are prepared to follow the guidelines published by the UK Department for Digital, Culture Media & Sport ('DCMS') on 13 December 2018 (https://www.gov.uk/government/publications/data-protection-law-eu-exit/amendments-to-uk-data-protection-law-in-the-event-the-uk-leaves-the-eu-without-a-deal-on-29-march-2019):

*Transfers of personal data from the EEA **into the UK**:*

- *DCMS acknowledges that the free flow of data into the UK would cease in the event of a No Deal Brexit. Therefore, the guidance refers to the mechanisms that might be available under other jurisdictions' laws to legitimise any such data flows.*

  In terms of transfers of data from the EEA to a third country that are not deemed adequate (such as the UK after Brexit in the absence of a deal), the menu of different options available is set out in Article 46 of the GDPR such as executing EU Standard Contractual Clauses.

*Transfers of personal data **from the UK**:*

- *The UK will transitionally recognise all EEA states, EU and EEA institutions, and Gibraltar as providing an adequate level of protection for personal data.*

  This means that personal data can continue to flow freely from the UK to these destinations following the UK's exit from the EU.

- *The UK intends to preserve the effect of all existing adequacy decisions in respect of a country or territory outside of the EU made by the European Commission before the Brexit date.*

  This means that the following jurisdictions will continue to be regarded as safe recipients of data: Andorra, Argentina, Canada (for commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Jersey, New Zealand, Switzerland and Uruguay. It is also possible that Japan may be added to this list in early 2019.

- *In line with the above, the EU-U.S. Privacy Shield will also be recognised as providing an adequate level of protection for transfers of personal data from the UK to Privacy Shield certified companies in the USA without the immediate need of a separate agreement between the UK and U.S. governments.*
- *Data transfer agreements incorporating the Standard Contractual Clauses issued by the European Commission will continue to be regarded as a valid mechanism for international data transfers from the UK.*
- *All existing authorisations of Binding Corporate Rules made by the UK Information Commissioner will continue to be recognised under domestic law for transfers of data from the UK.*

2--International Trade Administration's Privacy Shield Team Communication

ACRO member companies are prepared to follow the December 2018 communication from the International Trade Administration's Privacy Shield Team. On 20 December 2018 the International Trade Administration's Privacy Shield Team published the following Privacy Shield guidelines for US companies certified compliance to the US Privacy Shield framework:

> *The International Trade Administration's Privacy Shield Team would like to make you aware of new guidance explaining how a Privacy Shield participant may rely on the EU-U.S. Privacy Shield Framework to receive personal data from the United Kingdom in light of the UK's planned withdrawal from the EU. The guidance is available on the Privacy Shield website (https://www.privacyshield.gov/article?id=Privacy-Shield-and-the-UK-FAQs) and is included below for your convenience.*
>
> ***Can a Privacy Shield participant rely on the EU-U.S. Privacy Shield Framework to receive personal data from the United Kingdom in light of the UK's planned withdrawal from the EU?***
>
> *The United Kingdom (UK) has notified the European Union (EU) of its intention to withdraw from the European Union on March 29, 2019. In order to receive personal data from the UK in reliance on the EU-U.S. Privacy Shield Framework ("Privacy Shield" or "the Framework"), Privacy Shield participants must update their Privacy Shield commitments by the Applicable Date, as explained below, depending on how the UK and the EU implement the withdrawal.*

Scenario (1) "Transition Period":

The UK and EU have preliminarily agreed that from March 30, 2019 until December 31, 2020, a Transition Period will take place during which EU law, including EU data protection law, will continue to apply to and in the UK. During the Transition Period, the European Commission's decision on the adequacy of the protection provided by Privacy Shield will continue to apply to transfers of personal data from the UK to Privacy Shield participants. During the Transition Period, the United States will consider a Privacy Shield participant's commitments to comply with the Framework to include personal data received from the UK in reliance on Privacy Shield with no additional action on the part of a participant required.

Privacy Shield participants seeking to receive personal data from the UK in reliance on the Privacy Shield after the end of the Transition Period must take the steps below by the Applicable Date of December 31, 2020. The Department of Commerce encourages Privacy Shield participants to use the Transition Period as an opportunity to update their privacy policies.

Scenario (2) "No Transition Period":

In the event that the UK and the EU do not finalize an agreement on the Transition Period, Privacy Shield participants receiving personal data from the UK in reliance on the Privacy Shield must take the steps below by the Applicable Date of March 29, 2019.

Updates by the Applicable Date:

To receive personal data from the UK in reliance on Privacy Shield in the case of no Transition Period, or after the Transition Period, a Privacy Shield participant will be required to adhere to the following:

***1. First, a Privacy Shield organization must update its public commitment to comply with the Privacy Shield to include the UK**. Public commitments must state specifically that the commitment extends to personal data received from the UK in reliance on Privacy Shield. If an organization plans to receive Human Resources (HR) data from the UK in reliance on Privacy Shield, it must also update its HR privacy policy. Model language for these updates is provided below:*

(INSERT your organization name) complies with the (INSERT EU-U.S. Privacy Shield Framework [and the Swiss-U.S. Privacy Shield Framework(s)]) (Privacy Shield) as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the (INSERT European Union and the United Kingdom and/or Switzerland, as applicable) to the United States in reliance on Privacy Shield. (INSERT your organization name) has certified to the Department of Commerce that it adheres to the Privacy Shield Principles with respect to such information. If there is any conflict between the terms in this privacy policy and the Privacy Shield Principles, the Privacy Shield Principles shall govern. To learn more about the Privacy Shield program, and to view our certification, please visit *https://www.privacyshield.gov/*.

> ***2. Second, organizations must maintain a current Privacy Shield certification****, recertifying annually as required by the Framework.*
>
> *An organization that does not modify its commitment as directed above will not be able to rely on the Privacy Shield Framework to receive personal data from the United Kingdom after the Applicable Date (either March 29, 2019 if there is no Transition Period or December 31, 2020, at the end of the Transition Period).*
>
> *After the Applicable Date, an organization that has publicly committed to comply with Privacy Shield with regard to personal data received from the UK and that has committed to cooperate and comply with the EU Data Protection Authority panel under the Framework will be understood to have committed to cooperate and comply with the UK Information Commissioner's Office (ICO) with regard to personal data received from the UK in reliance on Privacy Shield.*

3--Request from ACRO

ACRO members would appreciate it if they could also rely on the Privacy Shield Framework to transfer key-coded study data from the UK to the USA. Unfortunately, this is currently not possible because the US Department of Commerce (DoC) does not consider the transfer of key-coded study data to the United States as the transfer of personal data:

> *Supplemental Principle referring to key-coded study data in the final Annex III Supplemental Principles (page 66 - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D1250&from=EN):*
> *14. Pharmaceutical and Medical Products*
> *g. Key-coded Data*
> *i. Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he or she can identify the research subject under special circumstances (e.g., if follow-up medical attention is required). A transfer from the EU to the United States of data coded in this way would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles.*

And the EU data protection authorities therefore clarified in their "Opinion 01/2016 on the EU – U.S. Privacy Shield draft adequacy decision" of April 13, 2016 (https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2016/wp238_en.pdf), that this Supplemental Principles prevent a transfer of key-coded study subject data from the EU to the USA under the Shield Framework:

> *2.2.8 Pharmaceutical and medical products*
> *Scope*
> *The Privacy Shield considers that transfers of key-coded data from the European Union to the U.S. in the context of Pharmaceutical and Medical products do not constitute transfers that would be subject to the Privacy Shield (Annex II, III.14.g.). However, the transfer of key-coded data enjoys protection under European data protection law. This means that in practice the Privacy Shield cannot cover such transfers. The WP29 calls on the EU Commission to explicitly provide that the draft adequacy decision will not cover the transfer of key-coded data for pharmaceutical or medical reasons and as a consequence, such transfers must be covered by other safeguards, such as EU Standard Contractual*

Clauses or Binding Corporate Rules (BCRs). The WP29 suggests this could be clarified in the final adequacy decision.

As additional background, in the past the UK data protection authority ICO also shared the view of the US DoC because the anonymization code of practice clarified (https://ico.org.uk/media/1061/anonymisation-code.pdf) on page 66:

> *Case study 1: limited access to pharmaceutical data*
> *In a clinical study, only key-coded data is reported by clinical investigators (healthcare professionals) to the pharmaceutical companies sponsoring the research. No personal data is disclosed. The decryption keys are held at study sites by the clinical investigators, who are prohibited under obligations of good clinical practice and professional confidentiality from revealing research subject identities. The sponsors of the research may share the key-coded data with affiliates overseas, scientific collaborators, and health regulatory authorities around the world. In all cases, however, recipients of the data are bound by obligations of confidentiality and restrictions on re-use and re-identification, whether imposed by contract or required by law. Given these safeguards, the risk of re-identification of the key-coded data disclosed by a pharmaceutical sponsor to a third party under such obligations is extremely low.*

It would be helpful if the UK government joined the current understanding of the US DoC that after Brexit the transfer of key-coded study data from the EEA to the US will not be classified any longer as transfer of personal data.

This approach could:

- simplify the transfer of key-coded study subject data from the UK to the USA (because no additional data protection compliance related legal measures must be implemented to justify such transfer)
- potentially also simplify their further use in Big Data analysis projects
- therefore make the UK a Life Sciences data analysis champion

Thank you for the opportunity to provide feedback on this inquiry on the meaning of a No Deal Brexit for the science and innovation community. Please contact ACRO if we can answer any questions or provide additional details.

Respectfully submitted,

Karen A. Noonan

Karen A. Noonan
Vice President, Global Regulatory Policy, ACRO
knoonan@acrohealth.org
+1 202 464 9340