

## Response ID ANON-8JP8-J2S4-D

Submitted to **MHRA EU Exit no-deal contingency legislation for the regulation of medicines and medical devices**

Submitted on 2018-11-01 12:47:29

### Introduction

### Basic information

#### 1 What is your name?

**Name:**

Association of Clinical Research Organizations (ACRO) -- submitted by Karen Noonan, VP of Global Regulatory Policy

#### 2 What is your email address?

**Email:**

knoonan@acrohealth.org

#### 3 Are you happy for MHRA to use your email address to contact you to clarify points in your response if necessary?

Yes

#### 4 What is your organisation? If you represent a business, please indicate if you are a small or micro business (1-9 or 10-49 employees)

**Organisation:**

Association of Clinical Research Organizations (ACRO)

### How to complete this consultation

#### Medicines - Changes M1-M9

#### 5 Do you want to complete the Medicines section of the consultation?

No

#### Clinical Trials - Changes CT1 - CT3

#### 22 Do you want to complete the Clinical Trials section of the consultation?

Yes

#### Change CT1: Legal presence – clinical trials

#### 23 Do you agree with the approach proposed, for a sponsor or legal representative to be established in the UK or a designated country?

Yes

**Please explain your answer:**

#### 24 Do you agree with the additional requirement on the sponsor to ensure that, where both the sponsor and legal representative are not UK-based, a CI is continuously available to assist with the actioning of any relevant licensing authority or sponsor required changes to the conduct of the trial?

No

**Please explain your answer:**

ACRO strongly disagrees. While a chief investigator (CI) holds primary responsibility in UK law for the conduct of a trial, it is quite possible that a CRO may be contracted by the sponsor to undertake interaction with the MHRA on behalf of the sponsor or legal representative. ACRO believes a CRO should be able to act as a "point of contact for the licensing authority". To ensure the safety of trial participants and effective communication to ensure that prompt action can be taken by the sponsor, we recommend that the national point of contact should be established by the clinical trial authorisation applicant/holder. The "contact point" approach is basically how MHRA interpreted the legal representative requirement prior to the Clinical Trial Regulation and the ACRO member companies frequently provided this contact point. However, ACRO requests assurance that the proposed contact point is exactly that and, by virtue of acting as a contact point, the organisation doing so will not assume any of the liabilities of the sponsor or legal representative with respect to the clinical trial.

## Change CT2: Transparency

25 Do you agree with this approach?

Yes

Please explain your answer:

ACRO agrees with the proposed transparency requirements as set out in the indicative draft text and recognises that this may not be representative of the final legal provisions. Consequently, ACRO recommends that, to ensure there is no detrimental effect on clinical research in the UK following the UK's exit from the EU, the transparency provisions should not exceed those of current EU law.

## Change CT3: Use of designated country lists, including for legal presence and importation of investigational medicinal products (IMPs)

26 Do you agree with the proposed designated country lists?

Yes

Please explain your answer:

## Impact Assessment - Clinical Trials

27 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer:

ACRO does not have these data.

28 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Clinical Trials Impact Assessment, please give your views below

Please explain your answer:

ACRO does not have these data.

29 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

Please upload here :

No file was uploaded

## Medical Devices - Change D1

30 Do you want to complete the Medical Devices section of the consultation?

No

## Fees - Changes F1-F2

35 Do you want to complete the Fees section of the consultation?

No

## NIBSC - Change N1

41 Do you want to complete the NIBSC (biological medicines) section of the consultation?

No

## Impact Assessment - Further Comments

47 If you have any further comments about the content and analysis in the Impact Assessment, please provide them below.

Please give your views:

## Public Sector Equality Duties

48 Do you foresee any impacts (positive or negative) of these proposals on groups with protected characteristics for the purposes of the Equality Act 2010 or on other groups of people who suffer health inequalities? If so, do you have any suggestions for mitigating negative

**impacts?**

Not Answered

**Please explain your answer:**

**Any further questions or comments on this consultation?**

**49 Please give any comments or questions below**

**Please explain your views:**

The Association of Clinical Research Organizations (ACRO) thanks the MHRA for the opportunity to provide comment on this consultation. Please do not hesitate to contact ACRO if we can provide additional information or answer any questions at all.

Respectfully submitted,

Karen Noonan  
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