Annex B – Summary of consultation questions and how to respond

How to respond

The Government invites responses on the specific questions raised. The questions can be found through the consultation document and are also listed in full in below. This consultation is intended to provide members of the public with information about the proposed changes and an opportunity to comment. This consultation is being made available in England, Wales, Northern Ireland and Scotland and the proposed changes to the legislation would apply throughout the United Kingdom.

This consultation will close on 17 March 2022, at 23:00.

Please respond using our online consultation survey.

When responding please say if you are a business, individual or representative body. In the case of representative bodies, please provide information on the number and nature of individuals or firms you represent.

Summary of questions

Background questions

Which best applies to you:

- ☐ I am responding as an individual
- ☐ I am responding on behalf of an organisation

Where do you live?

- ☐ England
- ☐ Northern Ireland
- ☐ Scotland
- ☐ Wales
- ☐ Other – please specify

If you are responding on behalf of an organisation, please tell us the geographical area(s) your organisation covers

- ☐ United Kingdom
- ☐ Great Britain
- ☐ England
- ☐ Northern Ireland
- ☐ Scotland
- ☐ Wales

☐ Other – please specify

Name of organisation
Main activities of your organisation

Are you

☐ a patient / carer
☐ a healthcare professional / trial investigator
Working in:
☐ Pharma
☐ Biotech
☐ Contract Research Organisation
☐ academia /non-commercial
☐ a trial funder
☐ charity
☐ Other – please specify

Please describe your previous experience(s) with Clinical Trials (if applicable)

Consultation questions

1. Do you agree that the legislation should include a requirement for the involvement of people with relevant lived experience in the design, management, conduct and dissemination of a trial?

2. Do you agree that the legislation should include a requirement to register a trial?

3. Do you agree that the legislation should include a requirement to publish a summary of results within 12 months of the end of the trial unless a deferral has been agreed?

4. Do you agree that the legislation should include a requirement to share trial findings with participants? (or explain why this is not appropriate)

5. Do you support a combined MHRA and ethics review, with an initial decision given on the application (i.e. approval or a request for further information) within a maximum timeline of 30 days from validation?

6. Do you support a sponsor-driven timeline to respond to any requests for further information (nominally 60 days but with flexible extension)?

7. Do you support a combined MHRA and ethics final decision on a trial of a maximum of 10 days, following receipt of any Requests for Further Information (RFI)

responses? The overall time for a final decision would be sponsor driven, depending on their need to take an extended time to respond to an RFI.

8. Do you support the ability for the regulators to extend the timeframe for medicinal products or trials where the risks involved may be greater so that independent expert advice can be sought?

9. Do you consider it appropriate that a clinical trial approval should lapse after a specified time limit if no participants have been recruited?

10. Do you agree that the detail currently outlined in schedule 3 would be better in the form of guidance rather than legislation?

11. Do you consider that a trial sponsor having sight of Requests for Further Information (RFI) when they are ready, rather than issued when the final part of the assessment is complete would be advantageous?

12. Do you consider that the ability to receive an RFI during the review of a substantial amendment would be beneficial?

13. Do you agree that we introduce the concept of a notification scheme into legislation?

14. Do you consider that the proposed provisions for clinical trial approvals strike the right balance of streamlined, proportionate approval with robust regulatory and ethical oversight?

15. Do you have any views about the membership or constitution of Research Ethics Committees?

16. Should we introduce legislative requirements to support diversity in clinical trial populations?

17. Do you agree that legislation should enable flexibility on consent provisions where the trial is considered to have lower risk?

18. Do you agree that it would be appropriate for cluster trials comparing existing treatments to use a simplified means of seeking agreement from participants?

19. Do you agree to remove the requirement for individual SUSARs to be reported to all investigators? They will still be informed via Investigator's Brochure updates.

20. Do you agree with removing the requirement to report SUSARs and annual safety reports to RECs? Noting that MHRA will still receive these and liaise with the REC as necessary.

21. Do you agree that, where justified and approved by the regulatory authority, SUSARs can be reported in an aggregate manner?

22. Do you agree with the proposal to remove the requirement to include listings of serious adverse events and serious adverse reactions in annual safety reports and instead include an appropriate discussion of signals/risks associated with the use of the medicinal product as well as proposed mitigation actions?

23. Do you agree with the proposal to extend the written notification for Urgent Safety Measures from no later than 3 days from when the measure was taken, to no later than 7 days?

24. Do you agree that the proposed safety reporting requirements will reduce burden on researchers but maintain necessary levels of safety oversight?

25. We are proposing changing the current legislation to incorporate more elements on risk proportionality. Our desire is that this will facilitate a culture of trial conduct that is proportionate and 'fit for purpose' for both researchers and regulators. Do you agree with this approach?

26. Do you agree that service providers of electronic systems that may impact on participant safety or reliability of results should also be required to follow the principles of GCP?

27. Do you agree that the current GCP principles require updating to incorporate risk proportionality?

28. What GCP principles do you consider are important to include or remove and why?

29. Do you agree that regulators should be permitted to take into account information on serious and ongoing non-compliance that would impact participant safety they hold when considering an application for a new study?

30. Do you agree it would be appropriate to enable regulatory action to be taken against specific part of a trial rather than the trial as a whole?

31. Do you agree that we should introduce the term 'non-investigational medicinal product' into legislation to provide assurance on the quality and safety of these products?

32. Do you agree that where a medicine is labelled according to its marketing authorisation (and is used in its approved packaging) that specific clinical trial labelling may not be required?

33. Do you agree that it is appropriate for radio pharmaceuticals used in a trial to be able to be exempted from the need to hold a Manufacturers Authorisation for IMPs?

34. Do you have any comments or concerns with the proposed updates to the definitions outlined?

36. Which healthcare professionals do you consider should be able to act as an Investigator in a trial?

37. Do you consider that the legislation should state that any appropriately trained and qualified member of the investigator's team can seek consent?

38. Do you agree that the proposed changes introduce improvements to streamline processes and to remove unnecessary burdens to trial sponsors?

39. Are there other aspects of the Clinical Trials legislation that you believe have not been considered but need to be? For example, is there something you think should be addressed now or should be considered for future legislative changes?

Impact Assessment

40. Are there potential costs or financial implications of the proposals outlined that you think we need to especially consider? Can you provide any evidence or comment that would help us develop the cost benefit analysis on the proposed changes?

Equality and Rural Screening

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, which places a statutory duty on public authorities, to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016 which requires public authorities to have due regard to rural needs.

41. We do not consider that our proposals risk impacting people differently with reference to their protected characteristics or where they live in NI. We welcome any further views on this point.

42. Do you think the proposals could impact people differently with reference to their [or could impact either positively or adversely on any of the] protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998? If so, please provide details.

43. Do you have any evidence that we should consider in the development of an equality assessment?

Confidentiality of Information

Information published in response to this consultation, including personal information may be published or disclosed in accordance with the access to information regimes.

These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), UK General Data Protection Regulation (UK GDPR) and the Environmental Information Regulations 2004.

If you want the information that you provide to be treated as confidential it would be helpful if you could explain to us why you regard the information you have provided as confidential. Any information not published, including personal information, may still be subject to disclosure in accordance with the Freedom of Information Act. If we receive a request for disclosure of such unpublished information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. We will not take a standard confidentiality statement included in an email message as a specific request for non-disclosure.

The MHRA will process your personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be published in a summary of responses to this consultation.