

NHS European Office

EU consultation on draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT-3'):

A development in response to 2009/10 public consultation on the EU Directive 2001/20, the Clinical Trials Directive

The European Commission published the [results of its public consultation](#) on the functioning of EU Directive 2001/20, the Clinical Trials Directive (CTD)¹, in March 2010. The NHS European Office (NHS EO) responded to this consultation, and continues to engage with the legislative process in regards to this Directive.

As a result of this feedback, the Commission has drafted [new guidance](#) to clarify the rules on safety reporting in clinical trials. It is hoped that the new guidance will offer a short-term solution to this specific area of concern, whilst work continues in parallel to review the CTD legislation.

The draft guidance is a revision of the existing guidance of the European Commission on adverse reaction reporting, including suspected unexpected serious adverse reactions (SUSAR) reporting.

We hope that colleagues from NHS organisations involved in clinical trials will review this draft guidance and respond to us to let us know if they feel it improves/clarifies the rules for safety reporting. We have also been invited to comment on more structural issues regarding safety-reporting which could be considered through the revision of the CTD.

The deadline for consultation responses is 10 September 2010. The NHS European Office will be coordinating a response on behalf of the NHS and would welcome contributions to this by **31 August 2010**.

Please email this completed form with your views to Sally.Elkes@nhsconfed.org or complete the questionnaire on-line at: http://www.nhsconfed.org/NationalAndInternational/NHSEuropeanOffice/OurWork/Pages/Clinical_trials_directive.aspx

¹ The Clinical Trials Directive was implemented in the UK in 2004 through Regulations 2004. It is widely accepted that the Directive has improved the safety and ethical soundness of clinical trials in the EU, in addition to improving cooperation between regulatory authorities in the EU countries. However, a number of issues have also emerged which have contributed to making the EU a much less attractive location to carry out clinical trials. This has, in turn, restricted innovation and reduced the competitiveness of clinical research in the EU with knock-on effects for patients' access to new medicines and treatments.

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The Future of the Clinical Trials Directive (CTD)

The European Commission is completing an impact assessment report on the CTD which will be published in the course of 2010/11.

This impact assessment will consider various options for improving the functioning of the CTD and, if appropriate, will make legislative proposals to go to the European Parliament and Council to debate through the co-decision process.

The NHS European Office will continue to monitor progress in this area and will work with NHS partners to influence legislative developments.

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A development in response to 2009/10 public consultation on the EU Directive 2001/20, the Clinical Trials Directive

The European Commission has launched a public consultation seeking views on new draft guidance on adverse reaction reporting, including suspected unexpected serious adverse reactions (SUSAR) reporting.

The NHS European Office will be coordinating a response on behalf of the NHS and this questionnaire has been prepared to help facilitate responses, in particular, from stakeholders with limited time.

The draft revised guidance can be viewed via our website:

This questionnaire has 3 parts and a total of 8 questions. It should take about 20 minutes to complete. The deadline for responding is **31 August 2010**.

Part 1: About you and your organisation

Q1. Are you responding on your own behalf, or on behalf of an organisation?

- Individual response
- NHS trust or foundation trust
- academic institution
- other NHS organisation
- other

If you answered 'Other NHS organisation' or 'Other', please specify

Q2. How much experience do you/your organisation have of participating in clinical trials?

- Lots – we participate in several each year as a sponsor
- Lots – we participate in several each year but not as a sponsor
- Some – we have participated in less than 5 trials in the last year
- Little or none

Q3. Can we contact you for more information about your answers?

- Yes
- No

If yes, please give name and contact details of the best person to get in touch with.

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Part 2: Key issues aiming to be addressed in this revised guidance

Q4. Does this revised guidance improve/clarify the rules for safety reporting in clinical trials? If not, can you suggest improvements?

- Yes
- To some extent
- Not possible to say
- No

Possible improvements

Q5. Does the guidance clarify the procedures of reporting SUSARs? If not, can you suggest improvements?

- Yes
- To some extent
- Not possible to say
- No

Possible improvements

Q6. Will the guidance reduce the scope for variations in interpretation of the Directive? If not, can you suggest improvements?

- Yes
- To some extent
- Not possible to say
- No

Possible improvements

Q7. Do you think the new guidance clarifies the definition of SUSARs adequately in order to enable more accurate reporting? If not, can you suggest improvements?

- Yes
- To some extent
- Not possible to say
- No

Possible improvements

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Part 3: Other issues

Q8. Are there more structural issues regarding safety-reporting which could be considered through the revision of the CTD?

Other issues

Thank you very much for completing this survey.

If you would like any more information on the issues discussed here, please contact Sally.Elkes@nhsconfed.org

12 July 2010