

Summary of the responses to the public consultation on the Commission Implementing Act on Detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors, pursuant to Article 78(7) of Regulation (EU) No 536/2014

1. General remarks

Currently, the inspection procedures and qualification and training requirements for inspectors are covered by Chapters 5 and 6 of Commission Directive 2005/28/EC. This Directive was adopted on a basis of Article 1(3), Article 13(1) and Article 15(5) of Directive 2001/20/EC.

Regulation (EU) No 536/2014, which will repeal Directive 2001/20/EC, provides in Article 78(7) a legal basis for the Commission to adopt an Implementing Act on detailed arrangements for clinical trials inspections procedures, including the qualifications and training requirements for inspectors.

With a view to prepare the Implementing Act the Commission services launched a public consultation to seek the views of stakeholders on the detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors. The public consultation closed on 24 November 2015.

This document presents a factual summary of the responses to the public consultation. It does not present the views of the European Commission.

2. Contributors to the public consultation

The Commission received 5 responses to the public consultation. None of the responses claimed confidentiality, therefore all of them will be published.

Contributors can be classified as:

Sector	Contributors
Public authorities	1
Industry stakeholders	4
Professional organisations	0
Academia	0

3. Outcome of the public consultation

Two of 5 contributions received were general. One expressed an overall support. Both of them declared interest in the final outcome.

The remaining contributions concerned:

- the requirement of practical experience prior to the appointment of an inspector;
- competences required from the GCP inspectors with regard to risk assessment;
- guarantee of impartiality of GCP inspectors with regard to the previous employer;

- specifying the requirement of the Member State to provide sufficient resources;
- GCP inspections in third countries;
- Participation in the GCP inspection in an EU Member State of inspectors from another Member State;
- proposal for a formal review of inspection findings with critical findings;