

APRIL 23-27
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GCP Compliance at Clinical Sites Regulatory Differences

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The European Union: 493 million people – 27 countries



Regulatory Environment



Comprises a range of legal and other texts

- EU Council Regulations
 - EU Directives
 - EU Guidelines and Guidance
- (authored by the Commission, the EMEA or the MRFG) } x 27

-
- National legislation
 - National guidance



EU Clinical Trials Directive

Declaration of Helsinki

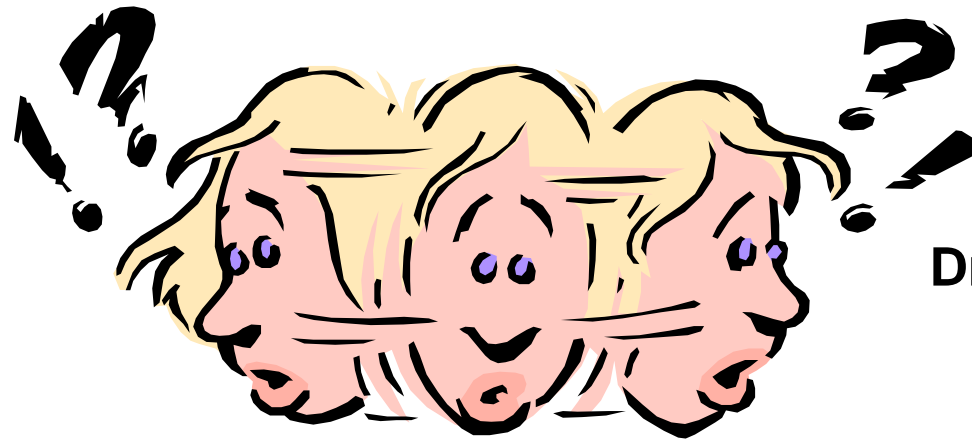
GCP Directive

GMP for IMPs

ICH E 6 (GCP)

Drug Importation

Data Protection



SUSAR and CIOMS

Audits & Inspections

Pediatric Directive



European Commission Enterprise and Industry Pharmaceuticals

European Commission > Enterprise and Industry > Sectors > ... > Eudralex > Vol 10: Clinical Trials

Enterprise and Industry

Policy highlights

Industry sectors

Pharmaceuticals

Reference documents

- EU Legislation - Eudralex
 - Vol 1: Legislation Human
 - Vol 2: Notice to Applicants Human
 - Vol 3: Guidelines Human
 - Vol 4: GMP Human & Veterinary
 - Vol 5: Legislation Veterinary
 - Vol 6: Notice to Applicants Veterinary
 - Vol 8: MRL Veterinary
 - Vol 9: Pharmacovigilance Human & Veterinary
 - Vol 10: Clinical Trials
 - EudraLex on CD Version 21 - September 2009
 - Vol 7: Medicinal Products Veterinary
- Community Register
- Pharmaceutical Committee
- Case Law

EudraLex - Volume 10 Clinical trials guidelines

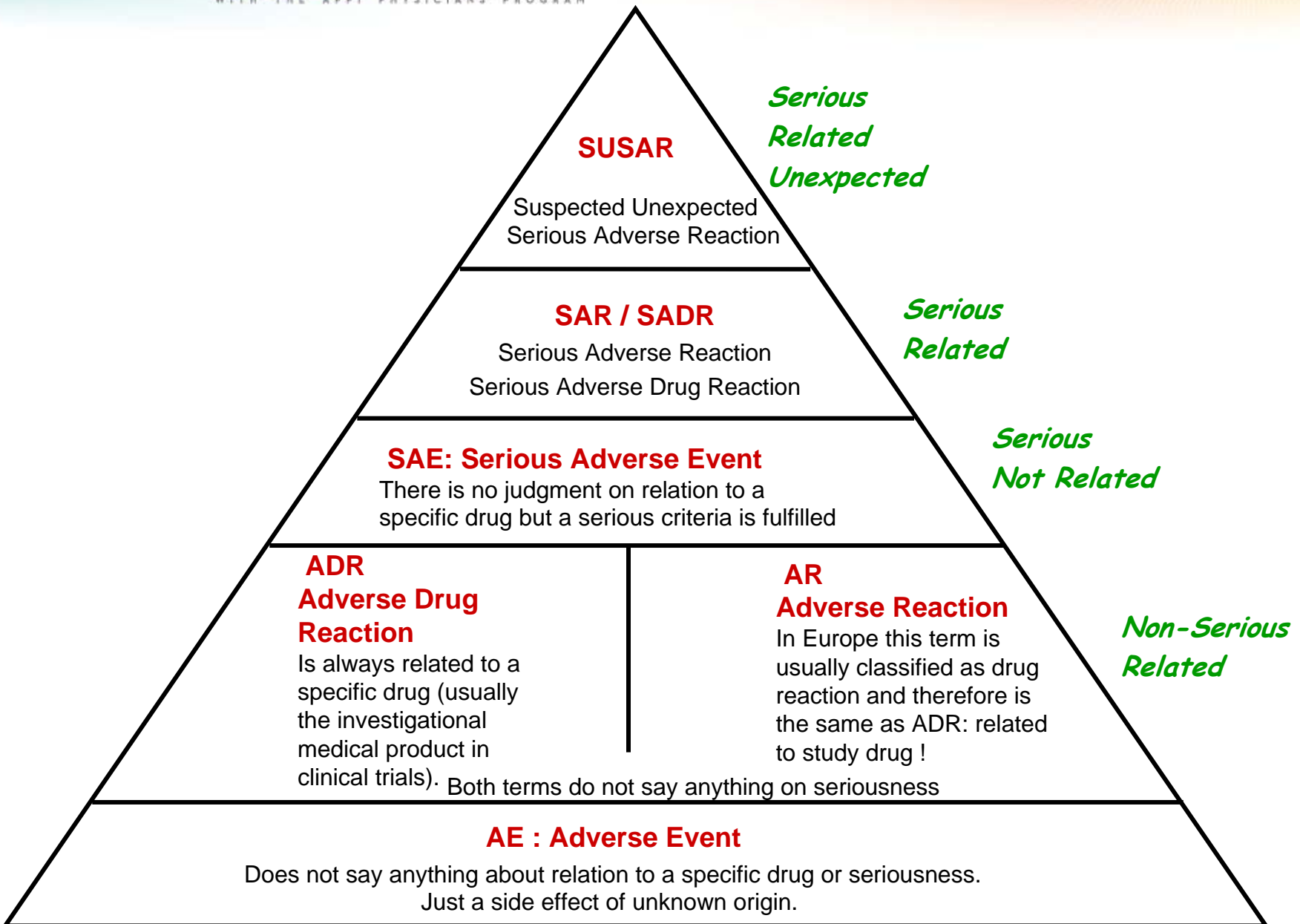
On this page:

- [Chapter I: Application and Application Form](#)
- [Chapter II: Monitoring and Pharmacovigilance](#)
- [Chapter III: Quality of the Investigational Medicinal Product](#)
- [Chapter IV: Inspections](#)
- [Chapter V: Additional Information](#)
- [Chapter VI: Legislation](#)

Volume 10 of the publications "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.

Chapter I: Application and Application Form

- [General information](#) [375 KB] (July 2006)
 - [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial](#) [334 KB] (revision 2 of October 2005)
 - [Annex 1: "Clinical trial application form"](#) [226 KB] (revision 2 of October 2005)
 - [Annex 2: "Substantial Amendment Form"](#) [136 KB] (revision 2 of October 2005)
 - [Annex 3: "Declaration of the end of the trial"](#) [104 KB] (revision 2 of October 2005)
 - [Annex 1 revised](#) [86 KB] (revision 4 of December 2009)
- Please note:** Recent changes in the regulatory framework for pharmaceuticals and clinical trials in the EU (mainly consequences of the paediatrics legislation and the legislation on advanced therapies) have required changes to the clinical trials application form. This is the revised version of the clinical trials application form. It will become applicable in the course of the first half of 2010, and is published in advance to allow stakeholders time for preparation. A precise date for applicability is going to be published on this website.



European Studies / US IND

- European Ethic Committees are unlikely to fulfill 21 CFR 56.107
 - Discuss situation with FDA and request waiver for IEC that operate in accordance with GCP (ICH E6)
- It is not necessary to conduct multinational studies (or parts of it) under IND, they can be conducted in compliance with 21 CFR 312.120
- Applications based on those studies must meet criteria listed in 21 CFR 314.106
- <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm>

Monitoring

- Reporting of protocol deviations
 - Monitoring time, amount & complexity
 - Influence on site performance
 - Patient recruitments & retention strategies
 - Query Management
 - Drug Accountability
 - GCP Sec. 5.18 (verify vs. do)
-

Audits & Inspections

- Audits by companies / Inspections by authorities
- No publication of findings in Europe
- Different inspection expertise per Member State

EudraLex - Volume 10 Clinical trials guidelines

Chapter IV: Inspections

- [Guidance for the preparation of GCP inspections](#) [46 KB] (June 2008)
- [Recommendation on inspection procedures for the verification of good clinical practice compliance](#) [170 KB] (July 2006)
- [Guidance for the conduct of GCP inspections](#) [26 KB] (June 2008)
- [Annex I to Guidance for the conduct of GCP inspections - investigator site](#) [45 KB] (June 2008)
- [Annex II to Guidance for the conduct of GCP inspection - clinical laboratories](#) [38 KB] (June 2008)
- [Annex III to Guidance for the conduct of GCP inspections - computer systems](#) [13 KB] (June 2008)
- [Annex IV to Guidance for the conduct of GCP inspections - Sponsor and CRO](#) [42 KB] (June 2008)
- [Annex V to Guidance for the conduct of GCP inspections - Phase I Units](#) [34 KB] (November 2008)
- [Annex VII to Guidance for the conduct of GCP inspections - Bioanalytical part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials](#) [38 KB] (November 2008)
- [Guidance for coordination of GCP inspections and co-operation between GCP inspectors, the reference and concerned Member States and CMD\(h\) in the context of the evaluation of the GCP compliance of marketing authorization applications for mutual recognition and decentralized procedures](#) [66 KB] (June 2009)
- [Guidance for exchange of GCP Inspection Reports according to Article 15\(2\) of Directive 2001/20/EC](#) [27 KB] (revision 1 - May 2009)
- [Guidance for the communication on GCP inspections and findings](#) [23 KB] (June 2008)
- [Procedure for standardisation of GCP inspection entries in EudraCT](#) [32 KB] (November 2008)
- [Guidance for the preparation of Good Clinical Practice inspection reports](#) [30 KB] (June 2008)
- [Recommendations on the qualifications of inspectors verifying compliance in clinical trials with the provisions of Good Clinical Practice](#) [125 KB] (July 2006)

BUT we are united in diversity 😊

- Communication preferences
- Language & Vocabulary
- Cultural differences
- Time zones
- Currency
- Travel capabilities
- Information technology
- Legislation and best practice
- Medical state of the art
- Ethics review
- Clinical Trial Approval
- Drug import and shipping
- Monitoring style
- Data formats
- Safety reporting
- Audits & Inspections
- Different expectation on Quality

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Thank you !

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