

European Regulatory Perspectives on Quality Clinical Trials



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Ethics Committees

- Request for EC opinion process is different to US
- EC opinion process varies between EU countries
- EC composition is different to US
(non-compliant to FDA 21 CFR 56)
- List of voting members
- GCP often not seen as standard for vote
- Approval, but no continuous supervision on site performance and compliance
- No review of protocol deviations / violations
- EC reviews qualification of investigators and sites



European Studies / US IND

- European ECs are unlikely to fulfill 21 CFR 56.107
 - discuss situation with FDA
 - request waiver
- It is not necessary to conduct multinational studies (or parts of it) under IND
 - 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>



FDA1572: Views by EU Inspectorates

- Some EU inspectors say that it is illegal for investigators to sign the FDA1572 in Europe
 - Possible conflicts with national laws
 - The German GCP inspectorate stated that German investigators who signed a FDA1572 form will get an inspection finding
 - Norwegian Medicines Agency informed that FDA1572 are not to be used in clinical trials in Norway
 - The British GCP inspectors take the view that investigators can sign them if they wish to, if it does not lead to non-compliance



Financial Disclosure

- Collecting financial information fall under EU data protection legislation and require written consent (sensitive personal data)
- The form FDA3455 is not widely used in EU
- EU investigators have to declare potential financial conflicts (see Directive 2001/20/EC)
- Details on investigator payments are part of the submission for CTA and EC review
- Various EU sponsors plan to disclose their investigator payments via their web pages



Safety Reporting

- SUSAR concept
- Medical assessment
 - Seriousness (severity grade 3 ≠ serious)
 - Expectedness / Listedness (Reference Documentation !!!)
 - Causality
- A_nnual S_aafety R_eport / D_evelopment S_aafety U_pdate R_eport
- CIOMS form vs. MedWatch form
- Electronic reporting to authorities and EMA
- European Qualified Person for Pharmacovigilance



Further considerations

- 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



Thank you !

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