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Summary on EMA Guidance for Publication and Access to Clinical-Trial Data

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German CDISC User Group Meeting

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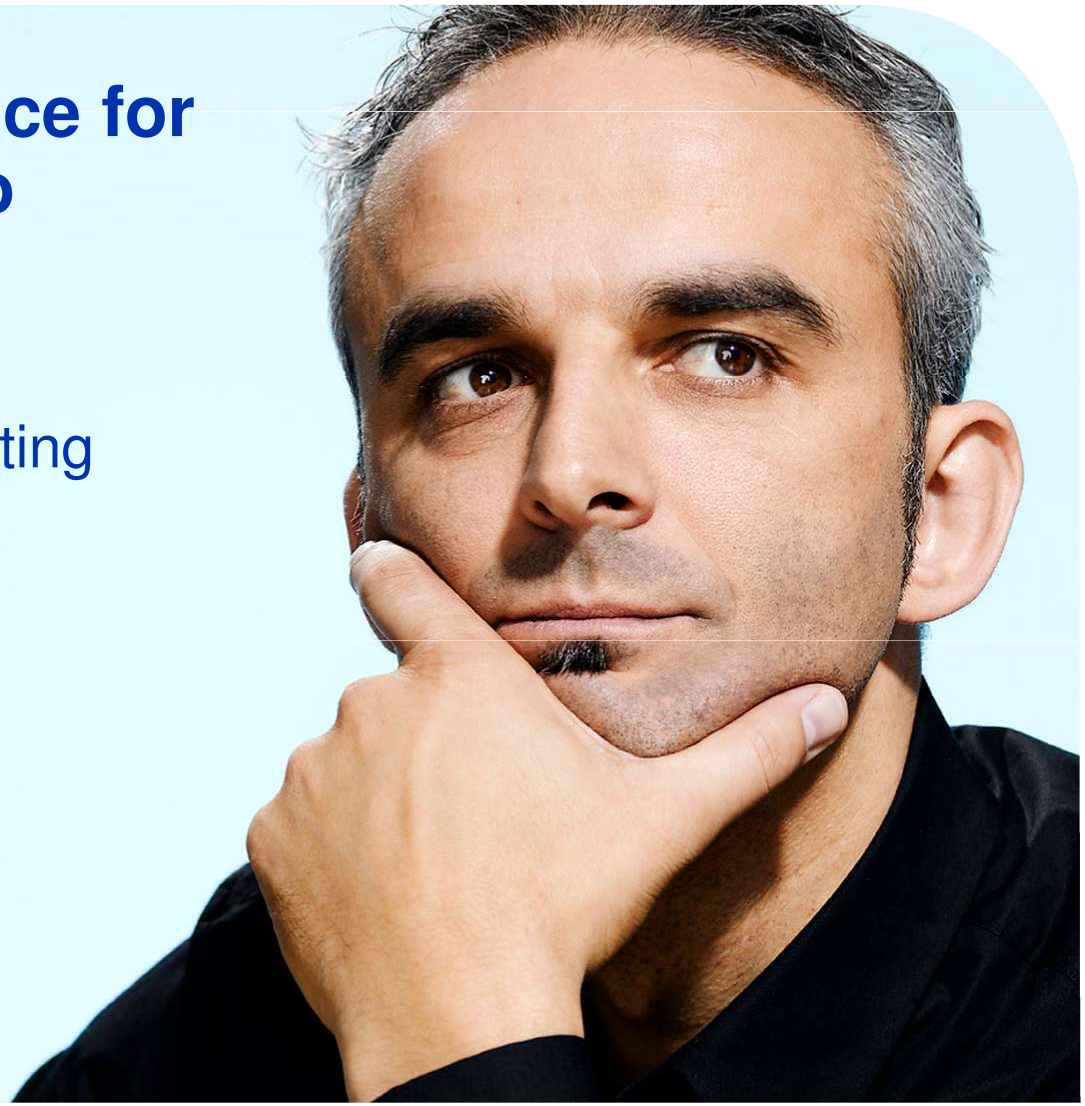

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Agenda

1 EMA Guidance for Publication and Access to Clinical-Trial Data

2 Clinical Data Transparency – Status Summary

3 Transparency @Merck KGaA

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1 **EMA Guidance for Publication and Access to Clinical-Trial Data**

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EMA Guidance for Publication and Access to Clinical-Trial Data

Transparency Policy on EMA Homepage (LinkTo)

- Draft EMA Policy 70 (LinkTo)
  Guidance for Publication and Access to Clinical-Trial Data
  - Draft published 26-June-2013 with 3 months review period
  - More than 1.000 comments received until end of September
  - Timeline for publication of final policy (Oct. 2013) postponed
  - European Medicines Agency's Management Board Meeting 11-12-Dec-2013
    - Implementation and Timeline for final policy to be discussed on Board Meeting in March 2014

Draft EMA Guidance for Publication and Access to Clinical-Trial Data

Key messages…

- Protect and foster public health
- Enable public scrutiny and secondary analysis of Clinical Trials
- Protect personal data (PPD)
- Respect the boundaries of patients' informed consent
- Protect commercially confidential information (CCI)
- Ensure future investment in bio-pharmaceutical R&D

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Clinical Data Transparency – Status Summary

Collaboration Initiatives between Pharma stakeholders...

- EFPIA & PhRMA
  - Principles for Responsible Clinical Trial Data Sharing
- Association of the British Pharmaceutical Industry (ABPI)
  - Clinical trial disclosure toolkit (Aug 2013)
- TransCelerate (launched in September 2012)
  - Clinical Data Transparency initiative, e.g., developing redaction standards for CSRs

Clinical Data Transparency – Status Summary

CBI Conference News

Main issues/concerns (cross companies) collected on CBI conference on Clinical Trial Disclosure and Transparency, Philadelphia, US, 30-31Jan14

- Protecting the personal data (PPD) and confidentiality of research participants (patients, study personnel), anonymization of patient-level data (PLD), respect for the boundaries of patients' Informed Consent Form (ICF)
  - HIPAA standard: well-defined and accepted, but lose information (reproducibility)
  - Many companies avoid stringent data redaction but rely on a system based on trust
- Protection of commercially confidential information (CCI) and Intellectual Property (IP) of study sponsors
- Protection of regulatory decision-making process (most sensitive prior to approvals in US, EU, etc.)
- Ensuring future investment in bio-pharmaceutical research and development
- Unclear workload expectations

Clinical Data Transparency – Status Summary

Implementation Examples

- Jan-2014 GSK launched new multi-sponsor platform for public requests www.clinicalstudydatarequest.com.
  - Boehringer Ingelheim, GSK, Roche, Sanofi and ViiV Healthcare committed to use this site
  - GSK is driving the development of a multi-sponsor access system (idea-point, SAS), hoping other industry and academic study sponsors will join and that an independent body will come on board to administer the initiative and manage the independent review of research proposals.
  - Has setup call center to support requestors

- Pfizer plans to provide access to patient level clinical trial data to qualified researchers
- In General, companies do not yet have a lot of requests if at all. All of them are unclear about how many requests might come and the expected costs and efforts for the requests handling

Clinical Data Transparency – Status Summary

CBI Conference News

Summarized **recommendations** from presenters…

- Prepare studies (data and documents) to address requests
- Revisit standards and templates for Clinical Study Reports (CSRs)
- Write ICH E3 (Structure and Content of CSR) Synopses to be “transparency ready”
- Separate personal data from other information
- Prepare for results disclosure in EudraCT V9

Clinical Data Transparency – Status Summary

CBI Conference News

Other topics discussed…

- CSR redaction
  - take care to redact also file/document path references in TLFs section, as this might be a source for cyber attacks
  - make sure a document is created containing documentation about which parts have been removed, and which have been redacted, and reasons why
- Rare disease trials
  - access usually denied
- Data and documents discussed to be required
  - requestors must understand the Protocol, SAP, CTR, as well as dictionaries, therefore it's recommended to redact and provide all necessary documents, as well as raw data (in SDTM), analysis data (in ADaM), and all related (but redacted) documents (aCRF(blankcrf.pdf), define.xml/pdf, Reviewer's Guide, ...)
- cross sponsor analysis is a hot topic, and followed/initiated/supported by most of big pharma - GSK is currently in a process of setting this up (idea-point, SAS)

Clinical Data Transparency – Status Summary

CBI Conference News

Other topics discussed…

- disclosure of patient level data (PLD) are often based on unknown content of signed ICFs

- Redaction issues
  - some companies are doing spot checks of TLFs and statistical results based on redacted PLD compared to original TLFs and statistical results to get a handle on the 'to be expected' differences between when redact data are re-analyzed by requesters

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Transparency @Merck KGaA

Merck Serono´s Data Sharing Policy, effective since 01-Jan-2014

- Request Review
  - All requests are reviewed by the *appropriate* internal committee at Merck Serono. If a request is denied, it will be escalated for a second review by the Merck Serono scientific review board (external Scientists/Healthcare Professionals, at least one employee from Merck which is SME in the respective therapeutic area).
- Information shared
  - Protocols
  - Anonymized PLD and Study Level Data
  - Redacted CSRs
  - Only data of trials are shared which are part of an approval of new product or approval of a new indication for an approved product in both, EU and US after 01. January 2014

Transparency @Merck KGaA

Merck Serono´s Data Sharing Policy, effective since 01-Jan-2014

- Requirements for data sharing
  - Legitimating of request and requestor (reviewed by committee/board)
  - Signed Data Sharing Agreement (DSA) in place
  - Merck Serono is owner of the data and results and is not restricted by property rights to share the information requested

- Access to shared data
  - Depends on nature of request and data to be shared. No obligation to provide software for data access and analysis.

- How to apply a Request
  - Please refer to our Merck Serono *Responsible Data Sharing* Internet site (LinkTo)

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Thank You!

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Links

- EMA Transparency Policy Homepage

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000187.jsp&mid=WC0b01ac0580556179

- Guidance for Publication and Access to Clinical-Trial Data

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp

- Merck Serono *Responsible Data Sharing* Internet site

http://www.merckserono.com/en/research_development/clinical_trials/clinical_trials_transparency/responsible_data_sharing/responsible_data_sharing.html