“EMA policy on publication of Clinical Data”

Two main objectives

In the interest of public health:

- To enable public scrutiny - To establish trust and confidence in the system
- To enable application of new knowledge in future research

Policy development

2007	• Nordic Cochrane center requested EMA for clinical report
2010	• EMA policy on access to document: Reactive and proactive disclosure
2012	• EMA Workshop with all stakeholders: *" The process on publication of clinical trial data is irreversible"*
2013	• EMA draft policy (Publication and access to clinical-trial data) June 2013
2014	• EMA policy on publication of clinical data for medicinal products for human use - 02 October 2014

Beginning of the story

- **Request**, from a Danish research and information centre, **for access to trial protocols and clinical study reports** for two anti-obesity drugs
- **Objective:** to conduct an independent analysis
- Firstly, **refusal of the EMA** arguing that it undermines the drug producers' commercial interests
- **EU ("Ombudsman")** called on EMA to disclose the documents or provide a convincing explanation
- Finally, **EMA granted access** to the requested documents

www.ombudsman.europa.eu/en/cases/summary.faces/en/5646/html.bookmark

EMA policy on access-to-documents

- Two-fold approach:
  - Proactive approach:

    Release of documents (EPARs(1), PIP(2), …)
  - Reactive approach:

    Release of documents (including clinical trial reports) submitted as part of application for Marketing Authorisation (MA) on request

    Once the completion of the decision making process for MA

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/11/WC500099472.pdf

(1) European Public Assessment Report
(2) Paediatric Investigation Plan

A long process for consultation

- First outline of the agency to move towards « public disclosure of raw trial data » - Article in PLoS Medicine, April 2012.
- Public workshop, November 2012, on clinical-trial data and transparency involving a broad range of institutions, groups and individuals
- Set up of five advisory groups (protecting patient confidentiality, clinical data formats, rules of engagement, good analysis practice and legal aspects) involving more than 200 people from all stakeholder groups
- Final advice of the advisory groups provided to EMA in April 2013

http://www.plosmedicine.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.1001202&representation=PDF
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/07/event_detail_000656.jsp&mid=WC0b01ac058004d5c3
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000368.jsp&mid=WC0b01ac058067d984

EMA draft policy

- Level of proactive publication according 3 categories of Clinical trial data:
  - Category 1: documents containing CCI(1) information - Not available
  - Category 2: documents without PPD(2) concern – Open access
  - Category 3: documents with PPD(2) concern – Controlled access
- 3 month public consultation: 1138 comments from 169 stakeholders
- Main concerns related to:
  - Protection from unfair commercial use (concept of CCI(1))
  - Protecting patient confidentiality
  - The concept of "raw data"
- In parallel, initiatives from pharmaceutical companies to provide on request view-on-screen access to Clinical Trial database (ex: GSK, Roche, …)
- Final round of targeted consultation in May 2014: Concept of view-on-screen access criticised by academia, research bodies, consumer organisation, EU institutions…..
- In June 2014, EMA Management Board agreed to remove the on-screen-only restriction and to adopt a more "user-friendly" approach allowing the user to download the information

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/09/WC500174226.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/10/WC500174377.pdf

(1) Commercially Confidential Information
(2) Protection of Personal Data

EMA policy adopted

- Scope: ***Clinical data*** defined as ***clinical reports*** (i.e. clinical overview, clinical summaries and Clinical Study Reports (CSRs)) and ***Individual Patient Data*** (IPD), submitted under centralised procedure
- Two sets of Term of Use (ToU):
  - ***Clinical reports*** available for general information purposes ***on-screen*** for any user with a simple registration process (ID/password)
  - ***Downloadable clinical reports*** available for academic and non commercial research purposes to identified users (i.e. name, date of birth, e-mail, address in EU, passport n°, …)
- Common elements to both ToU:
  - Not seek to re-identify the Trial subjects
  - No unfair commercial use
  - Watermark applied to the published information
  - No EMA responsibility for monitoring compliance with the ToU
- Some limited information in the clinical report may be considered as CCI
  - Redaction principle established, but a justification from the applicant is needed,
  - Final decision taken by EMA

EMA policy adopted

- Stepwise implementation
  - ***1rst phase:*** Publication of clinical reports only
  - ***2nd phase:*** Review of various aspects in relation to IPD
- Effective dates
  - ***01/01/2015*** for any new Marketing Authorisation Application (MAA) phase
  - ***01/07/2015*** for extensions of indications
  - ***TBD*** for other post-authorisation procedures
- Next step:
  - Protection of patient's identity being of crucial importance, to discuss with stakeholders to agree on the optimal approach avoiding (re)-identification of patients
  - Public consultation on various aspects in relation to IPD to provide clarification
  - Revision of the policy in June 2016 at the latest

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf