EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proactive publication of clinical trial data

Feedback from the EMA workshop

Francesco Pignatti, MD

PCWP-HCPWG Joint meeting 27-28 Feb 2013

Open Clinical Trial Data for All? A View from Regulators

- Clinical trial data should not be considered commercial confidential information
- Publication of full sets of raw data runs the risk of breaches of patient confidentiality
- Analysis by independent groups is not always equivalent to it being free of conflicts of interest and of high quality
- Need to develop:
  - standards for the protection of personal data;
  - standards for meta-analyses and other types of confirmatory study;
  - rules of engagement for sharing raw data from clinical trials.

Eichler H-G, *et al.* (2012) Open Clinical Trial Data for All? A View from Regulators. PLoS Med 9(4): e1001202.

Why Open Clinical Trial Data for All?

- Build trust and confidence in the system
- Ethical responsibility to the patients enrolled in clinical trials
- Public health benefit: independent (re)analysis of data broadens knowledge base
- Scientific progress: sharing of complex data can open new horizons

G. Rasi. Workshop on access to clinical trial data 22 November 2012

Workshop on clinical-trial data and transparency (22/11/2012)

- "We are not here to decide if we publish clinical-trial data, but how" (G. Rasi)

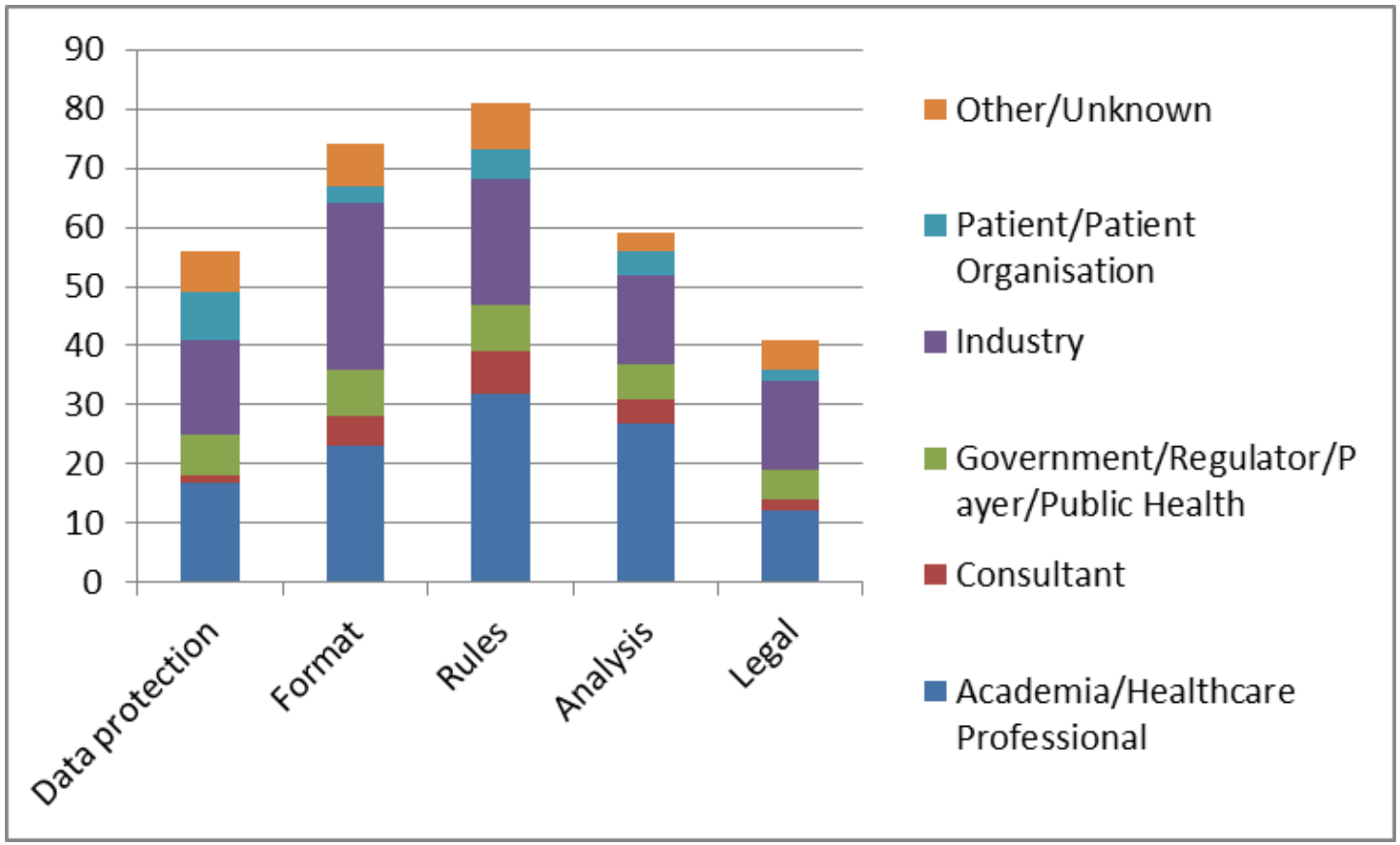
Selected speakers	Affiliation
Guido Rasi	EMA
François Houÿez	EURORDIS
Mark Walport (moderator)	Wellcome Trust
Susan Forda; Neil Weir	EFPIA
Ben Goldacre	Author and journalist
Virginia Barbour	PLoS Medicine
Peter Gøtzsche	Cochrane Collaboration

Next Steps

Advisory Groups to propose policies for adoption by the EMA:

1. Protecting Patient Confidentiality
2. Clinical Trials Data Formats
3. Rules of engagement
4. Good Analysis Practice
5. Legal aspects

External nominations to the advisory Groups



http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/01/WC500137363.pdf

1 - Protecting patient confidentiality

How to ensure that patient and other personal information will be adequately protected?

- Clinical trial personnel not confidential;
- A combination of indirect identifiers pose a risk of revealing subjects' identity;
- Options
  - Widely publish de-identified (transformed) data but loose information?
  - Restricted access with confidentiality arrangement, keep original (key-coded) data?
  - Both of the above?

2 - Clinical Trial Data Formats

How to ensure that clear data format for sharing and analysis?

- Do we need standard formats?
- Should standard formats be mandatory for all?
  - One or several formats allowed?
  - Agreed formats already available? CDISC?
- International harmonisation across regulatory agencies

3 - Rules of engagement

What conditions when an external party wishes to download clinical trial data?

- Should the requesters:
  - Identify themselves (two-way transparency)?
  - Agree to respect personal data protection?
  - Agree to refrain from commercial uses?
  - Agree to adhere to acceptable quality standards?

4 – Promoting Good Analysis Practice

Place restrictions on exploratory analyses to ensure quality?

- Use of guidelines and 'quality assurance' checklists for retrospective analyses?
- Require a formally signed off protocol and an audit trial for any subsequent amendments?
- Data recipients to provide open access to computer codes and interim datasets to facilitate later evaluation of the results?

5 – Legal aspects

Any legal aspects other than personal data protection?

- Circumstances under which data can be claimed to be commercially confidential?
- Copyright issues?
- Availability of legal remedies against the disclosure of data?

Time line

• Five advisory groups were established	**January 2013**
• 2-3 Meetings to take place	**January to April 2013**
• Final advice from each group by	**30 April 2013**
• Draft EMA policy	**30 June 2013**
• End of consultation phase	**30 September 2013**
• Publication of final EMA policy	**30 November 2013**
• Coming into force	**01 January 2014**

References

Doshi, P., T. Jefferson, et al. (2012). "The imperative to share clinical study reports: recommendations from the Tamiflu experience." PLoS Med **9**(4): e1001201.

Eichler, H. G., E. Abadie, et al. (2012). "Open clinical trial data for all? A view from regulators." PLoS Med **9**(4): e1001202.

Workshop on clinical-trial data and transparency (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/07/event_detail_000656.jsp&mid=WC0b01ac058004d5c3)

Twitter hashtag #ctdata

http://www.youtube.com/watch?v=upinaTryTho&feature=share&list=PL7K5dNgKnawYrjJQQSTTr2rdy3SlmxCdZ