Open Clinical Trial Data for All? The Paradox of Transparency

Alasdair Breckenridge

- Should the public have access to data on which regulatory decisions are taken?
- Advantages and disadvantages of increased transparency
- Distinction between transparency and communication
- Will increased transparency lead to increased trust in regulators and industry?

Transparency Policy at the EMA

OBJECTIVES

- To apply a more proactive approach towards transparency
- To further strengthen interaction with EMA stakeholders
- To promote closer collaboration with the regulatory authorities of EU member states

EMA Working Groups doing further work

- Protecting patient confidentiality
- Clinical trial data formats
- Rules of engagement
- Good analysis practice
- Legal aspects

Is the EMA moving too quickly?

- Independent evaluations of past transparency schemes
- Workshops on science based communication
- “Communicating Risks and Benefits”. Barusch Fishhoff

European regulatory information already available to the public

- EU Clinical Trials Register
- European Product Assessment Reports (EPARs)
- Minutes of EMA meetings
- Eudravigilance database
- Product label (SPC and PIL)

European regulatory information proposed to be available in Europe

- Web portals
- Public hearings at PRAC
- Periodic Safety Update Reports(PSURs)
- All clinical trial data

Challenge to EMA

- Since November 2010, EMA has released 1.9 m pages of information on products in response to FoI requests In 2013
- Abbvie and InterMune appealed to General Court of EU to prevent EMA releasing clinical data on their biopharmaceutical products, Humira and Esbriet
- Court sustained the appeal in May 2013

The case of oseltamivir (Tamiflu)

- 1999 Granted marketing authorisation
- 2005 Roche meta analysis of effects on influenza complications
- 2009 Cochrane Collaboration asks Roche for clinical study reports
- Involvement of BMJ and Lancet

Meta analyses

- Important source of synthesised evidence of interventions
- Selective inclusion and exclusion of data

- Should the public have access to data on which regulatory decisions are taken?
- Advantages and disadvantages of increased transparency
- Distinction between transparency and communication
- Will increased transparency lead to increased trust in regulators and industry?

Why should clinical trial data be open to all?

- Patients have ethical right to have access to the data
- Benefits of independent re –analysis of clinical trial data
- Allow predictive models for patient drug selection

Why should clinical trial data not be open to all?

- Commercial confidentiality
- Patient confidentiality
- Re –analysis and conflicts of interest
- Independent re-analysis and quality

The way forward?

- Agreement on timing of release of information
- Agreement on nature of information to be released
- Standards of protection of personalised data
- Standards for meta analyses
- Rules of engagement for observational studies

Ethical Standards in Health and Life Science

- Accessible and timely register of clinical trial plans
- Timely availability of results
- Failed applications

- Should the public have access to data on which regulatory decisions are taken?
- Advantages and disadvantages of increased transparency
- Distinction between transparency and communication
- Will increased transparency lead to increased trust in regulators and industry?

Transparency and Communication (1)

- Literacy and numeracy of the public
- Medicine labels, SPCs and PILs
- Road testing of information

Transparency and Communication (2)

- Obesity and BMI
- Calculation of dosages
- Low health literacy and standard of health
- Involvement in shared decision making
- Adherence
- Benefit risk

Transparency and Communication (3)

Lessons of sound risk communication

- Avoid premature reassurances and promises of 100% safety
- Narratives of benefit and risk

- Should the public have access to data on which regulatory decisions are taken?
- Advantages and disadvantages of increased transparency
- Distinction between transparency and communication
- Will increased transparency lead to increased trust in regulators and industry?

Transparency and Trust

- Increased transparency does not lead to increased trust
- Trust depends on perceptions of honesty and competence
- Transparency may expose inherent inefficiencies in a system

Conclusions

- Patients and the public should have access to clinical trial data
- Many advantages to transparency of clinical trial data, few disadvantages
- How information is provided is of critical importance
- Increased transparency does not necessarily lead to increased trust