EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Opening clinical trial data: the EMA experience

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1995 2015 EMA

An agency of the European Union

The basis of medicines ("drugs") regulation

Marketing authorisation requires demonstration of:

- Quality, Safety, Efficacy ("QSE")

Companies seeking marketing authorisation submit "dossier":

- Pharmaceutical module
- Non-clinical part
- Clinical module

Mostly reports of (randomised) clinical trials in patients. Arguably the most important part of the dossier

The challenges for EMA

- Strong political push to share data of clinical trials that support marketing authorisations
- Need to find the best possible balance between different stakeholders' competing interests, →
- Long process of consultation to find such balance →
- Agreement on policy on 'Publication and access to clinical-trial data'

Date of coming into effect of policy

1/1/2015	Any new Marketing Authorisation Applications […], submitted after this date
1/7/2015	Extension of indication applications and line extension applications for existing products, submitted after this date

First phase: Clinical study reports

Second phase: Individual patient data (IPD) sharing modalities to be discussed

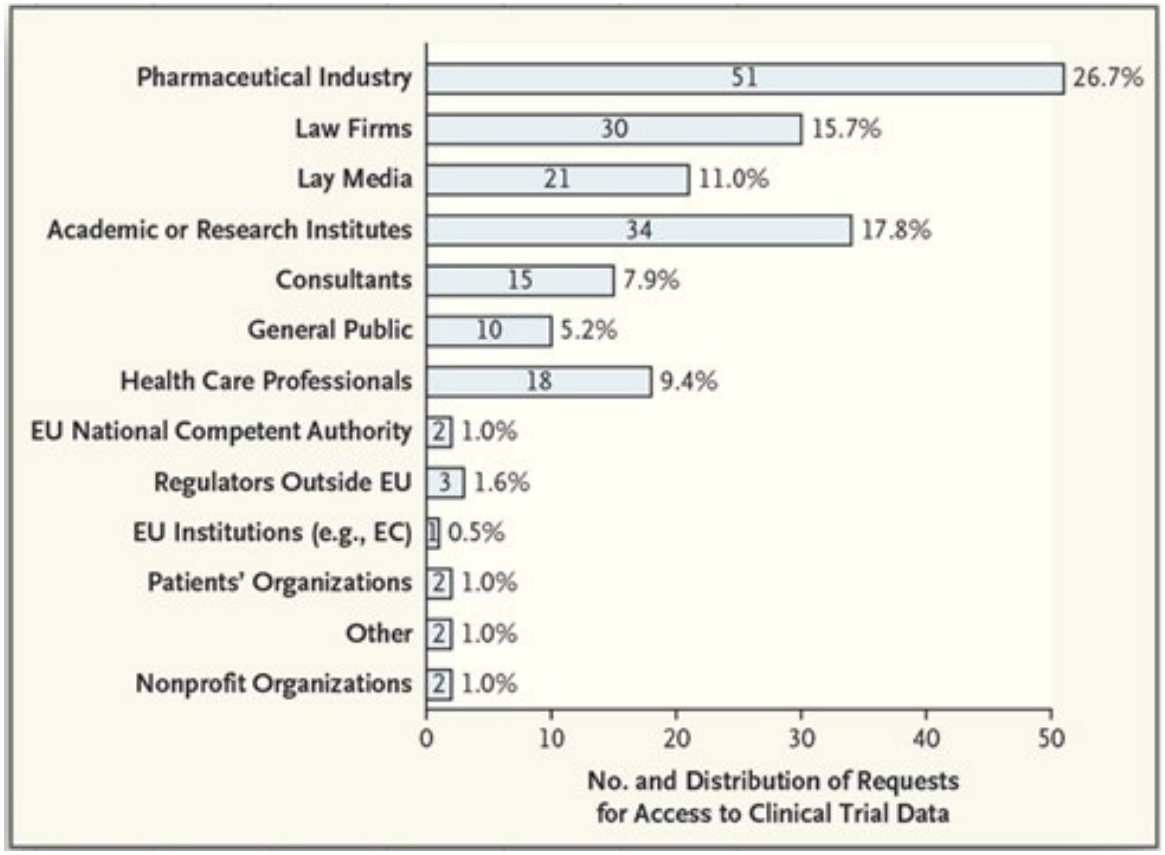
Not in scope: Legacy data (submitted before 01/01/2015) [or non-centrally authorised products].

Terms of use governing access / use of clinical study reports

Need to allow access to clinical data and discourage unfair commercial use, prevent re-identification of patients

- Redaction consultation procedure with sponsor company → ensure appropriate level of redaction of commercial confidential information
- Clinical reports, available on-screen only, for any user, limited registration process
- Clinical reports, downloadable for academic and non-commercial research purposes; requires identity of the user
- Terms of use governing the access to and use of clinical reports

Who seeks to obtain clinical trial data? The EMA experience (2010 – 2013)



Bonini S et al. N Engl J Med 2014;371:2452-2455

Hypothesis: Access to clinical trials data will benefit the industry

- Improvements in the design and analysis of subsequent trials
- Comprehensive, quality-controlled databases that may inform future projects and research questions
- Explore heterogeneity of treatment effects
- Comparative-effectiveness information
- Avoid repetition of clinical trials

HG Eichler, *et al.*, N Engl J Med 2013; 369:1577-1579

Experience: Data Sharing, Year 1 (GSK), Requests for clinical trials data (n).

- Studies of risk factors or biomarkers (6)
- Methodological studies (5)
- Studies comparing treatment regimens (3)
- Studies aimed at optimizing treatments (3)
- Patient-stratification efforts (3)

Strom BL et al. N Engl J Med 2014;371:2052-2054

Conclusion: What have we achieved so far?

- Stimulated pharma companies to become pro-active in sharing data.
- Moved the debate from 'all clinical trial data are commercial confidential' to 'what in a clinical trial report can be commercial confidential'?
- Moved the debate from "lack of trust" to a constructive use supporting future drug development.

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Thank you for your attention

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