



Briefing paper; April 2013

Clinical trials Regulation: Choose transparency!

Debunking secrecy myths which hinder transparency

Myth number 1: Clinical trial data are “commercially confidential”

- The Helsinki Declaration requires authors to make the results of their research on human subjects publicly available. In fact, clinical trials data are scientific data and represent a public good.
- Clinical trial results belong first and foremost to the volunteers who put themselves at risk of unexpected adverse drug reactions in the hope that their contribution will benefit the advancement of science, and ultimately to society at large.
- By claiming ownership of clinical trial results, pharmaceutical companies are arguing for the right to keep secret information that could save lives and also advance biomedical research (e.g. making available data of earlier trials could avoid the repetition of similar trials, reducing both private and public expenditure).
- The European Ombudsman has ruled that clinical study reports (CSRs) contain no “commercially confidential” information.

Myth number 2: The disclosure of clinical trials data puts patients’ confidentiality at risk

- Clinical trial investigators are responsible for the protection of patients’ personal data. According to good clinical practice, codes are used to protect patients’ identity,.
- A recent study published in *BMJ open* has shown that clinical study reports contain solely anonymised individual data.
- Proportionality in ethics has to be taken into account. Even if some researchers, digging into the details of the clinical data, might in an exceptional case be able to identify a single patient (rare diseases), for what purpose would the researcher use that information? This “unlikely to happen” risk needs to be evaluated against the current situation, where millions of otherwise avoidable adverse drug reactions are taking place mainly the pharmaceutical industry routinely hides drug-induced harm.
- Which would volunteers who participate in clinical trials favour: that their contribution will allow early detection of a safety signal, so preventing others from experiencing the same adverse effects? Or to see their data withheld to benefit the private financial interests of a pharmaceutical company or the career of unscrupulous academic researchers?

Myth number 3: Clinical trial data disclosure puts an added burden on academics or non-commercial researchers

- Science has to be reproducible and researchers are already ethically obliged to write a report. In the duty to report outcomes of clinical trials to their participants and to the public, the requirements from the industry and from academic researchers should be same: their responsibilities are the same.
- Academics need not write a study report that conforms to the ICH criteria, but need to write one that reflects what was planned in the protocol, what actually happened and what the trial achieved in terms of benefits and harms.
- Data can be converted and exported to different formats to be analysed, so clinical data from academic trials can be simply released as raw data, so enabling independent researchers to explore their findings and the public to be informed.
- Establishing a full dataset does not represent an added burden for academics or non-commercial researchers. Given the numerous well-documented examples of bias and concealment of data in trial reports, major medical journals have opted to require researchers to upload files containing the full dataset of individual anonymised patients data on the publisher’s website.

Myth number 4: Clinical trial data disclosure will be misinterpreted and that will scare the public

- Claims that the disclosure of clinical trial data would risk misinterpretation of data and to the dissemination of skewed information that would scare the public reflect outdated paternalism.
- Again, proportionality in ethics has to be taken into account. There is overwhelming evidence of drug-induced harm being routinely hidden by pharmaceutical companies in detriment of public health while there is no example of misinterpretation of data and misuse from the last 2.5 years during which the European Medicines Agency has released clinical data to researchers on request.
- There is no evidence of data manipulation from data sharing/open data.