

PP25 Data Transparency

“Moving from Bad Pharma to Good Science?”

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Evolving landscape

The case for increased transparency is overwhelming:

- Regulatory agencies, BMJ, Cochrane Collaboration and the [Alltrials](#) campaign
- Secrecy considered increasingly unacceptable in today's society



Industry Concerns:

- Protecting patient confidentiality
- Preserving regulatory integrity (protecting intellectual property)
- Maintaining incentives for investment in clinical research

Industry Benefits:

- Opportunities for pharma to rebuild reputation in media and society
- Avoid accusations of publication bias
- It's the right thing to do!

Researcher Experience

- Conduct meta-analyses & systematic reviews
- Request & access data
- Different request models: [CSDR.com](#), [YODA](#), [Duke](#), individual pharma websites
- Obligations on both data providers & receivers



Principles for Responsible Clinical Trial Data Sharing
Our Commitment to Patients and Researchers



1) Enhanced Data Sharing with Researchers

Patient-level trial data, study-level data, full CSRs (clinical study reports) and protocols for medicines approved in US & EU from 1 Jan 2014 will be shared with qualified scientific and medical researchers upon request & subject to “terms necessary to protect patient privacy & confidential commercial information”.

2) Enhanced Public Access to Clinical Study Information

Researchers granted access to data will be expected to publish their findings.

[Link to Principles](#)

3) Shared Results with Patients Who Participate in Clinical Trials

Companies will work with regulators on establishing a mechanism to provide “factual summaries” of clinical-trial results to patients who take part in trials.

4) Certifying Procedures for Sharing Clinical Trial Information

Synopses of CSRs submitted to FDA, EMA or EU national authorities will be made publicly available once a new medicine /indication approved.

5) Reaffirming Commitments to Publish Clinical Trial Results

Companies will publish clinical-trial results regardless of study outcomes. At a minimum, results from all Phase III studies and clinical-trial results “of significant medical importance” should be filed for publication.

What does Data Transparency mean for Doctors and Patients?



- Higher quality, well designed clinical trials bringing better medicines to patients more quickly
- More informed prescribing
- Research into disease mechanisms
- Increased longer term monitoring of safety and efficacy

Considerations for Programmers

- Receiving & approving requests
- Operational considerations (QC steps, standard macros and approaches, SAS data access systems)
- Resource requirements, skillsets needed
- A broadening role for the Programmer
- Share experiences at PhUSE (A Day in the Life of a “Data Sharing Specialist”)
- Cross-pharma collaborations

Protecting Patient Confidentiality

- De-identification / anonymisation requirements to consider
- Methodologies & process
- Data utility & risk assessment
- Industry standardisation (PhUSE, EFSPi-PSI, TransCelerate)



Regulatory

- Recent [EMA policy announcement](#) on publication of clinical reports (currently only documents). **Future:** EMA plans to make individual patient data available
- Other policies point to increased transparency (e.g. new Clinical Trial Regulation April 2014 ensures all new studies are publicly registered and results published in publicly accessible register)



Looking to the future

Programmers role in providing data and documentation likely to become increasingly important as pharmaceutical industry incorporates transparency activities into standard process of clinical trial reporting