Data Transparency
EFSPi Stats leader conference 2013

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Some caveats...

- This is a rapidly moving area:
  - Details of the Roche policy are still being finalized
  - This presentation reflects current thinking
  - All opinions are the presenter’s own and should not be considered to be the Roche position

- Will not go into too many details as Roche has recently to a large extent aligned with GSK...
Tamiflu – focal point for Data Transparency

BMJ open trial data campaign

• Launched in October 2012
• Details all correspondence on Tamiflu between Roche & other organisations i.e. WHO, EMA, CDC
• [http://www.bmj.com/open-data](http://www.bmj.com/open-data)

Ben Goldacre – Bad Pharma book

• Released in September 2012
• Mentions Tamiflu numerous times within book, alongside Roche practices
Key Principles of Data Transparency

Respect for Patients
- Who have participated in our trials and have been prescribed our products.
- Generation of data is for the overall benefit of patients. Scientific use should be maximized.
- All reasonable steps taken to ensure confidentiality of individual patients.
- Informed consent is central to any policy.

Product Availability
- Product availability is dependent on approval by regulatory authorities.
- Policy therefore places review by regulators as a prerequisite.

Innovation & Sci. Progress
- No restrictions on our ability to commercialize our products or to protect our products by intellectual property rights.
- Data transparency as far as possible with respect to our contractual obligations to third parties.
Data Transparency covers a number of aspects

1. Disclosure of clinical study reports (CSRs) and summary reports such as periodic safety reports after review by regulatory authorities.

2. Posting of Roche-sponsored trial information and tabular study results on the US National Institutes of Health’s ClinicalTrials.gov and RocheTrials.com

3. Publication in peer-reviewed publications

4. Access to analyzable datasets from clinical trials used for registrational purpose

5. Confidentiality and Informed consent as a pre-requisite
Roche strategy

- Roche supports providing access to anonymized patient-level, analyzable data sets when:
  - Prior condition of a meritorious study proposal
  - A signed agreement is in place
  - After regulatory review

- The signed agreement will include the Requestor’s agreement to share results of the research analyses with Roche and, if relevant, with regulatory authorities prior to any publication.

- Independent Review Panel (IRP), comprised of independent global experts external to Roche, will assess the scientific merit and value of all research proposals. The IRP will consider, whether the research question is clearly defined and whether there is a well documented and rigorous statistical analysis plan.

- The IRP will be the final decision maker on the availability of data.

- Data will be made available via SAnS
Data Transparency will change our industry
Access to patient level data

**Opportunities**
- Increase scientific community’s understanding of successful and failed MOAs
  - Provide directions for drug discovery and development
  - More efficient use of patients in future clinical trials
- More collaboration between research groups and companies
- “Across drug class” analyses
  - Meta analyses
  - Safety profiles
  - Identify responders and non-responders
- Improve public perception

**Challenges**
- Users misunderstanding the data and/or analyses
  - Erroneous conclusions
  - Time lost re-analysing and correcting external requesters work
  - Health scares
- Resource implications of generating anonymized datasets and supporting external requesters using our data
- Risk for patient confidentiality
- Mature products
  - Locating data
  - Informed consent
Data Transparency isn’t new …
the public sector are leading the way
Final thought:

Data access will need statisticians to convert gigabytes of patient level data into meaningful and robust messages

“I keep saying that the sexy job in the next 10 years will be statisticians, and I’m not kidding.”

Hal Varian, chief economist at Google (2009)

Not sure however if we statisticians will all like this!
Doing now what patients need next