A perspective on sharing of patient-level data
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Some caveats…

• This is a rapidly moving area:
  – Roche ‘Global Policy on Sharing of Clinical Trials Data’ published to company website
  – Details of how to practically implement the policy with respect to sharing of PLD are still being finalized
  – This presentation reflects current thinking
  – All personal opinions are the presenter’s own and should not be considered to be the Roche position
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

Ben Goldacre – Bad Pharma book

• Released in September 2012
• Mentions Tamiflu numerous times within book, alongside Roche practices
What Issues were Considered in the Development of the Roche Data Sharing Policy?

Roche intends to be an Industry Leader on the issue of Data Sharing with a policy that meets or exceeds the industry standard.
# Core Principles embedded in Data Sharing Policy

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<th>Guiding Principle</th>
<th>Data that patients have helped to generate should be used for overall benefit of patients like themselves</th>
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| Respect for Patients | Confidentiality of individual patient data in compliance with GCP principles  
Informed consent by patients for release of anonymized clinical trial data |
| Role of Regulatory Authorities | Regulatory authorities have pivotal role in making risk-benefit decisions that determine access to our products  
Review by regulators as prerequisite to release of information |
| Innovation & Sci. Progress | Protection of our intellectual property rights  
Preservation of our ability to develop and commercialize our products. |

Roche
Key Elements of the Policy

Disclosure of redacted CSRs and summary reports (e.g., PSURs)  
Posting of ClinicalTrials.gov and RocheTrials.com

Confidentiality and Informed consent

Review by Regulatory Authorities

Timely publication in peer-reviewed journals

Access to patient-level analyzable datasets
Key features of the PLD Sharing Policy

- Requires meritorious research proposal and signed data sharing agreement from requestor
- Independent Review Panel (IRP) approval step
- Patient confidentiality and anonymisation
- Secure access to datasets and documentation
- Studies in scope:
  - Roche sponsored CTs intended for registration purposes (approved and terminated)
  - Adequately powered testable efficacy hypothesis
  - CTs with FPE ≥1\textsuperscript{st} Jan 1999
  - To be made available after regulatory approval
Implications: Broader data sharing will change our industry and the clinical research landscape

**Opportunities**

- Increase scientific community’s understanding of successful and failed medicines and related data
  - Provide directions for drug discovery and development
  - More efficient and effective future clinical trials
  - Analyses across treatments to inform safety and efficacy
- More collaboration between research groups and companies
- Promote Public Trust

**Challenges**

- Users misunderstanding the data and/or analyses
  - Erroneous conclusions
  - Time lost re-analysing and correcting external requesters work
  - Health scares
- Resource implications of redacting CSRs, generating anonymized datasets, and supporting external requesters
- Mature products
  - Locating data
  - Informed consent
Final thought:

Data access will need statisticians and programmers 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)
Doing now what patients need next