

A perspective on sharing of patient-level data

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Some caveats...

- This is a rapidly moving area:
 - Roche policy on wider data-sharing recently published to company website
 - Details of how to practically implement the policy with respect to patient-level data 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

Tamiflu – catalyst / poster child for Data Sharing

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
- Key note speaker PhUSE conference Brussels



Key Principles of Data Sharing

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.
- All reasonable steps to ensure confidentiality of individual patients
- Informed consent is central to any policy

Product Avail- ability

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

Innovatio n & 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 Sharing 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

Data Sharing 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
 - 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
- Mature products
 - Locating data
 - Informed consent

Data Sharing isn't new ...

the public sector are leading the way (example from UK)

The screenshot displays the DATA.GOV.UK website interface. At the top, there's a green header with the HM Government logo and a 'Log in or sign up' link. Below the header, a navigation bar includes links for Home, Data, Participate, Data requests, Apps, Location, Linked Data, Library, and About. A secondary navigation bar lists Search, Map Search, Publishers, Tags, Public Roles & Salaries, Spend Browser, Spend Reports, and Site Usage.

The main content area is divided into several sections:

- Search Datasets:** Shows 9398 datasets with a search bar and a 'Search' button.
- Tags:** Displays various tags like 'child spend-transactions', 'transparency', 'Environment', 'education', 'Health disclosure', 'care', 'Spending Data', 'children', 'health-well-being-and-care', 'communities', 'health-and-social-care', 'nhs', 'school', 'finance', 'population', 'NERC_DDC', 'local-government', and 'health'. A 'View all tags' button is present.
- Publishers:** Lists various government departments and their dataset counts, such as 'Office for National Statistics (822)', 'Department for Communities and Local Government (772)', 'NHS Information Centre for Health and Social Care (629)', 'British Geological Survey (374)', 'Department for Environment, Food and Rural Affairs (336)', 'Welsh Government (273)', 'Centre for Ecology & Hydrology (272)', 'Department of Health (242)', 'Home Office (238)', and 'Department for Children, Schools and Families (227)'. A 'View all publishers' button is included.
- UK Location:** Describes the UK Location Programme, which has introduced over 1000 location data records into data.gov.uk. It mentions that users can use 'Map Based Search' to find datasets covering a particular location. A 'Conduct map based search' button is provided.
- Featured dataset:** Highlights the 'Organogram and staff pay data for' (partially visible).
- Data Requests:** Provides information on making data requests and their progress, with a 'Request new data' button.

Final thought:

Data access will need statisticians and programmer to convert gigabytes of patient level data into a 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***