Data sharing 3 years on – from baby to toddler…
DH12 PhUSE October 2016
Katherine Tucker
Senior Manager, Patient-level Data Sharing
A few caveats…

• All opinions are the presenter’s own and should not necessarily be considered to be the Roche position.

• Brand and product names are trademarks of their respective companies.

• No babies or toddlers were harmed in the making of this slideset.
Data sharing 3 years on – from baby to toddler…

- PhUSE 2013
- What has changed since in data sharing?
- Reflect on opportunities and challenges
- Future
- Conclusions
Data sharing 3 years on – from baby to toddler…

Data sharing in 2013?
Data sharing 3 years on – from baby to toddler…

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Data sharing in 2013?
Data sharing 3 years on – from baby to toddler…

… and in 2016?
Data sharing 3 years on – from baby to toddler…

… or ?
A perspective data transparency – the journey so far and where’s next?
PhuSE October 2013

Katherine Macey - Senior Manager, Statistical Programming and Analysis
A perspective data transparency – the journey so far and where’s next?
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Implications: Broader data sharing will change our industry and the clinical research landscape

**Opportunities**
- Increase scientific community’s understanding of successful / failed medicines & 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/correcting external requesters work
  - Health scares
- Resource implications of redacting CSRs, generating anonymized datasets, supporting requesters
- Mature products
  - Locating data
  - Informed consent
What has changed since in data sharing?

- PLD request sites
- Regulators & Registries
- Industry initiatives
- Other initiatives
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**ClinicalTrials.gov**
A service of the U.S. National Institutes of Health

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**European Medicines Agency policy on publication of clinical data for medicinal products for human use**

2 October 2014
EMA/240810/2013

POLICY/0070
Status: Adopted
Effective date: 1 January 2015
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Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors
US National Academies: Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk

Clinical Trial Life Cycle: When To Share Data

CLINICAL TRIAL MILESTONE

1. TRIAL DESIGN & REGISTRATION
2. PARTICIPANT ENROLLMENT
3. STUDY COMPLETION OR TERMINATION
4. PUBLICATION
5. REGULATORY APPLICATION?

WHEN TO SHARE

- At trial registration
- 12 months after study completion
- 6 months after publication*
- 18 months after study completion
- 18 months after product abandonment OR 30 days after regulatory approval**

WHAT TO SHARE

- DATA SHARING PLAN
- SUMMARY-LEVEL RESULTS
- POST-PUBLICATION DATA PACKAGE
- FULL DATA PACKAGE
- POST-REGULATORY DATA PACKAGE

KEY:

- METADATA
- INDIVIDUAL PARTICIPANT DATA
- SUMMARY DATA

* No later than 6 months after publication applies to all studies, whether intended or not intended to support regulatory applications and regardless of publication timing relative to study completion, though publication is most likely to occur after study completion.

** Sharing the post-regulatory data package should occur 30 days after approval or 18 months after study completion, whichever is later; 18 months after abandonment of the product or indication. This applies to all studies intended and to support regulatory applications, even if abandonment occurs prior to actual regulatory application.
Vivli Vision

**INTAKE**
- Anonymize Data: privacy
- Define standards
- Harmonize data sharing policies

**OUTPUT**
- Administer researcher requests
- Centralized review process
- Robust search engine

**CENTRALIZED PLATFORM**
Enables access to data & combined data sets – interfaces with existing & partner programs

**SPONSOR DATA SETS**
**CONTRIBUTORS**
**PARTNER DATA SETS**

**REQUESTORS**
PhUSE 2013
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Future

• Data Sharing = business as usual?
  – Integrating data transparency activities into processes, including risk assessments
  – Holistic data transparency thinking across the study lifecycle

Protocol/results ↔ Results to patients ↔ Publications ↔ PLD access
Future (ctd.)

• Data availability
  – Data discoverability, curation, data standards
  – Continued ↑ of availability of data types (genomic/genetic, RWD, CT etc.)
  – Availability and access of all CT and other data across all types of sponsors (pharma, charities, academia etc.)

• Realising potential of ↑ data transparency (internal and external)

• ↑ collaboration
Conclusions

• Data sharing is now the norm - the world has not ended!
• We are still learning - collaboration has been key
• Patient privacy considerations more crucial than ever as data access becomes more open
• Not just a pharma issue
• Integrated ‘data access thinking’, data curation and discoverability is a must
• Too early to see outcomes of new research in terms of scientific understanding
Questions?
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Doing now what patients need next