

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...



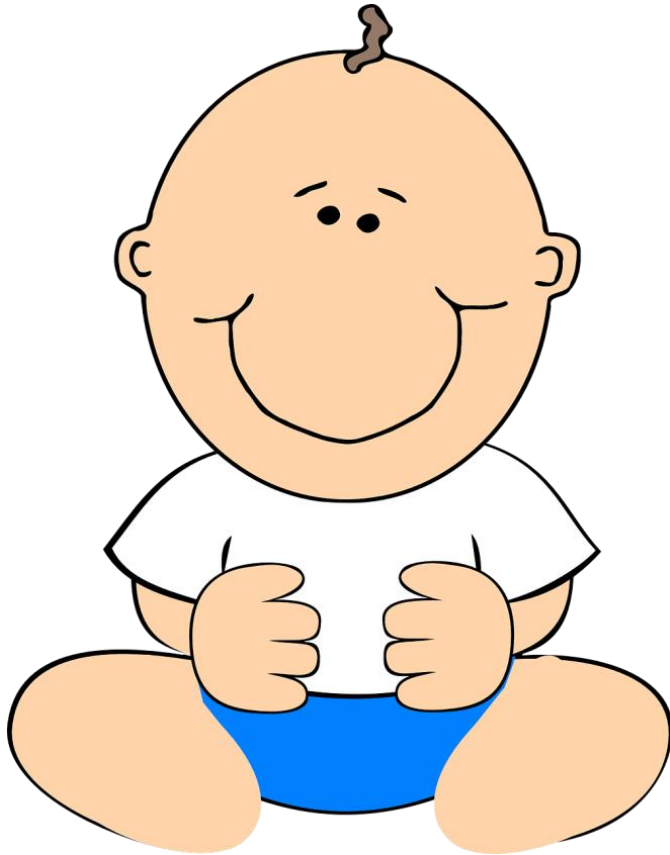
**Data sharing
in 2013?**

Data sharing 3 years on – from baby to toddler...



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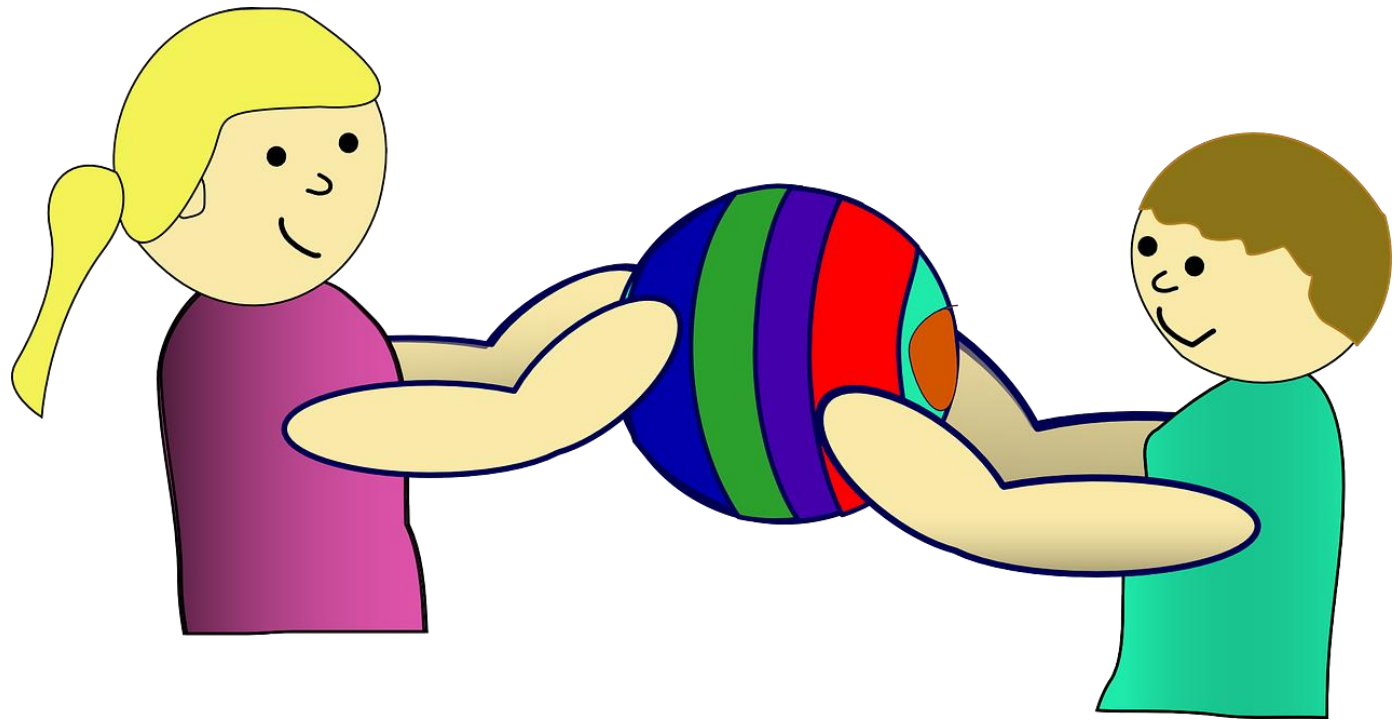
Data sharing 3 years on – from baby to toddler...

... 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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A screenshot of the YODA Project website. The top section has a green background with the text "the YODA PROJECT" in white, followed by the tagline "Forging a unified scientific community". There are two blue buttons labeled "ABOUT" and "REQUEST". Below this is a white section with the heading "Johnson & Johnson" in blue. Underneath is the subheading "Partnership with Johnson & Johnson Family of Companies" in blue. The main body of text describes the partnership: "As of October 2014, the Yale University Open Data Access (YODA) Project is enabling scientists across the world to gain access to the company's clinical trial data assets. The goal is to balance data availability with an intention to promote strong scientific research and serve the public good. This effort will accelerate the movement of the clinical research enterprise toward more cooperative learning and sharing."

What has changed since in data sharing?

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ClinicalTrials.gov

A service of the U.S. National Institutes of Health

2 October 2014
EMA/240810/2013

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

POLICY/0070
Status: Adopted
Effective date: 1 January 2015

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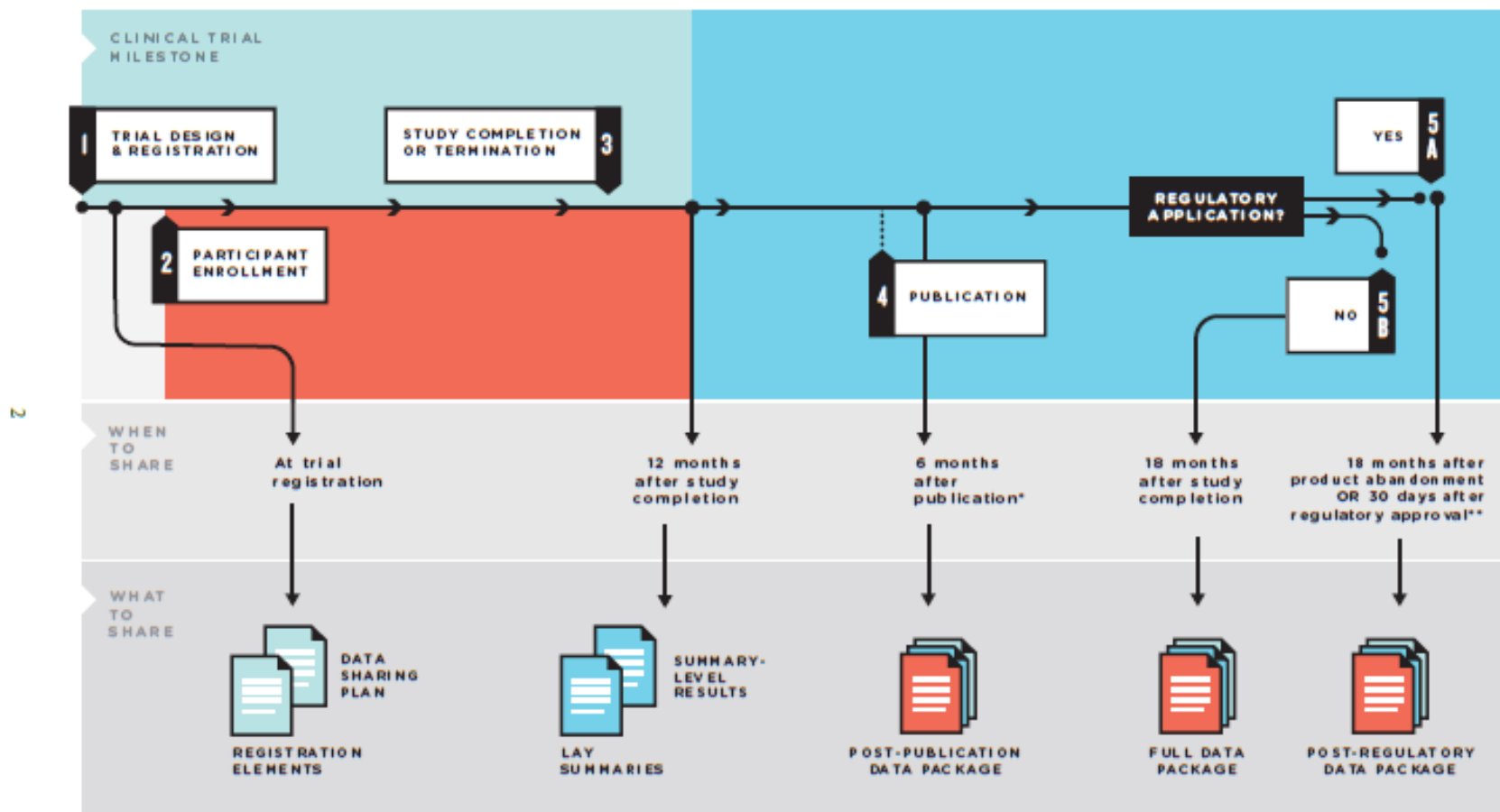
Annals of Internal Medicine

EDITORIAL

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

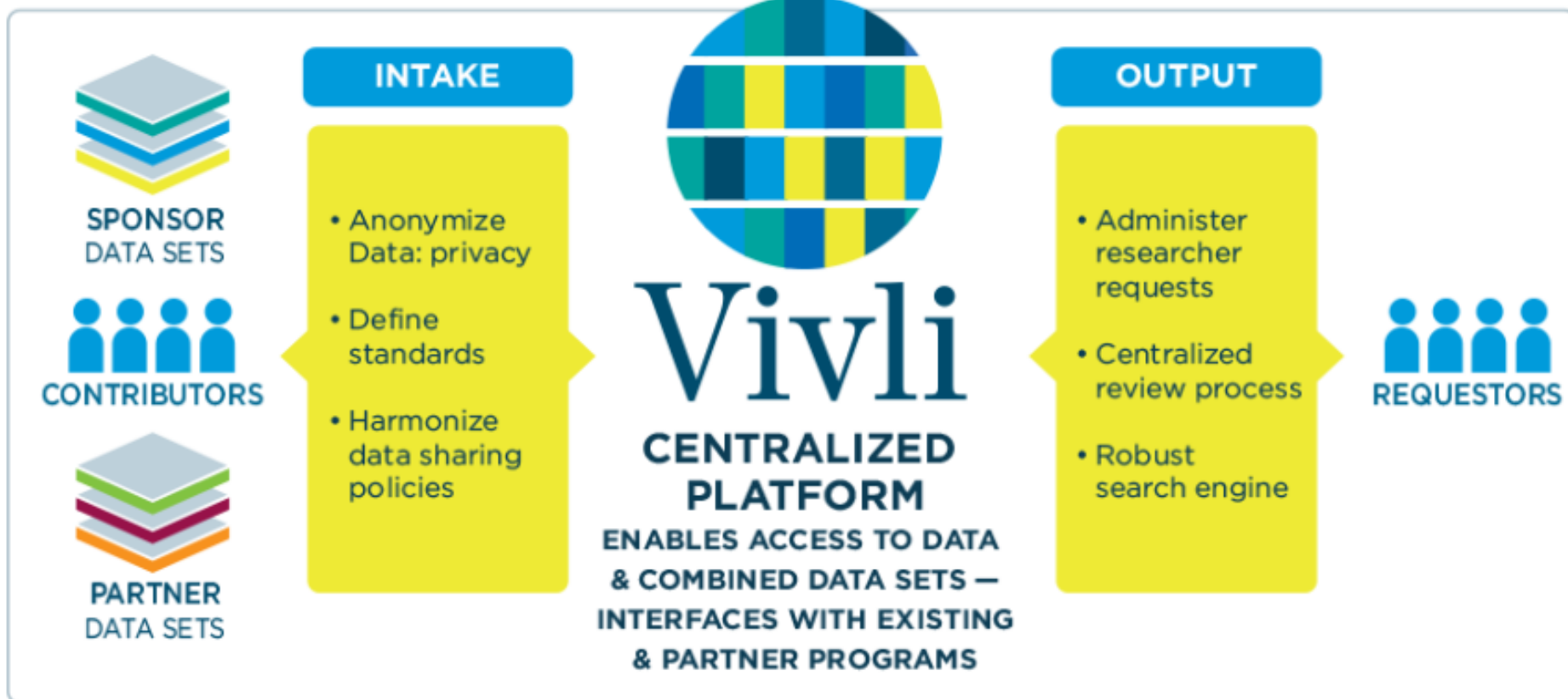
Clinical Trial Life Cycle: When To Share Data



* 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



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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 in registries ↔ *Results to patients /lay summaries* ↔ *Publications* ↔ *PLD access*

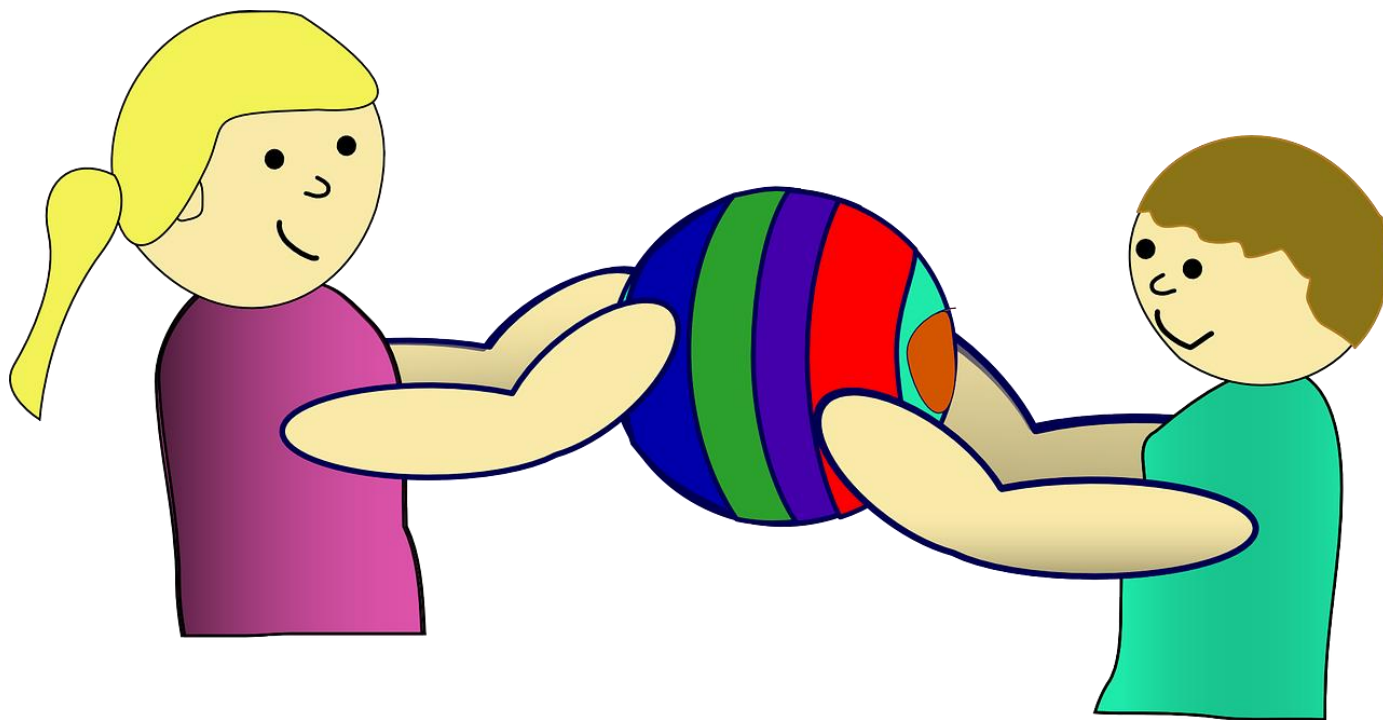
Future (ctd.)

- 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?



Contact details

- Katherine Tucker
- Roche Products Limited, Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW, United Kingdom
- Email: katherine.tucker@roche.com

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- <http://mrctcenter.org/projects/vivli/>
- <http://www.nationalacademies.org/hmd/Reports/2015/Sharing-Clinical-Trial-Data.aspx>
- <http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf>

Doing now what patients need next