



DS13 - Patient Level Data Sharing in pharmaceutical companies

Sophie Buyle, 10 October 2017



Context



Process



Future requirements



How to facilitate the process?



Conclusion



Q&A





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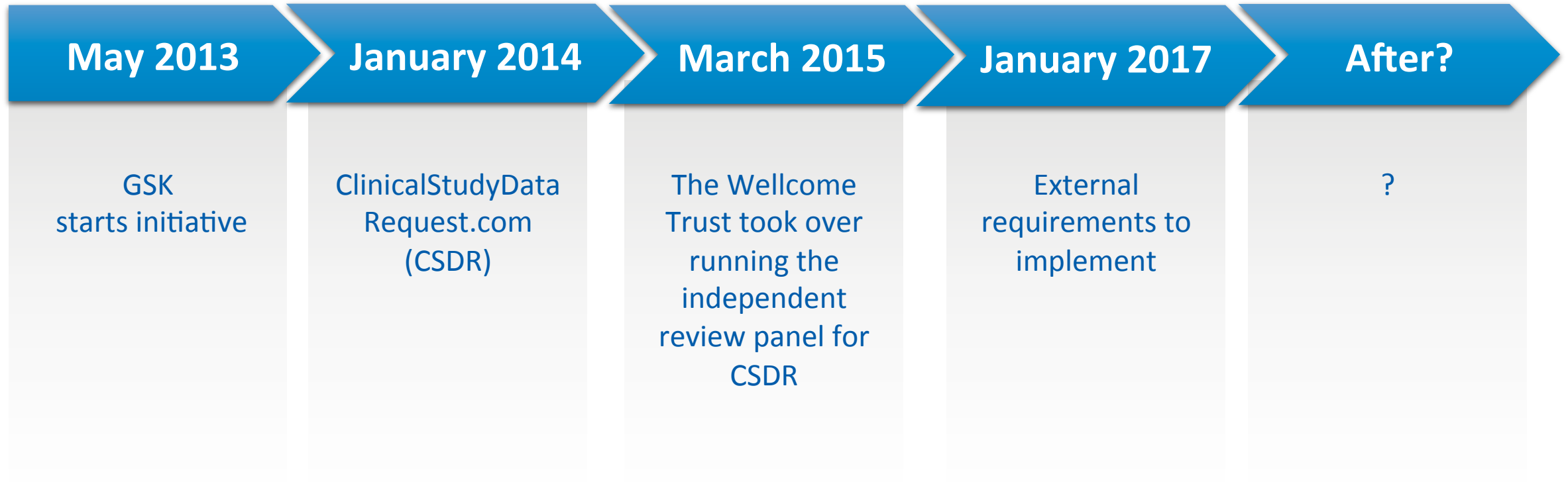


Conclusion



Q&A

Time line



Different systems

CSDR (clinical study data request)	PDS (project data sphere)
Listed studies on a website open to request	Request via website
Gatekeeper model	Sharing platform
2 panels review (independent and internal)	Authorised user approval



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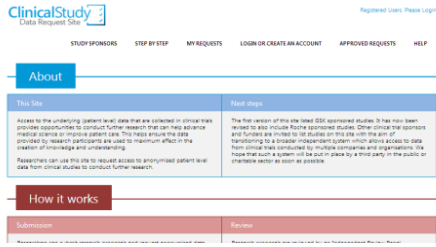
Conclusion



Q&A



How it works for the researcher?



Multi-sponsor request site

Select studies that are needed for the research

Submit a research proposal

Independent review panel

Review of proposal by independent review panel

Agree: when approved, a data sharing agreement is signed

Secure access system

Access data in secure access system

Raw dataset, Analysis-ready dataset , Protocols with any amendments, Annotated case report form, Reporting and analysis plan, Dataset specification, Redacted Clinical Study Report including modular appendices (*potentially identifiable information, including patient level data and patient narratives are redacted*)

Register research, conduct and publish

Current requirements

	Interventional human subject research		Non-interventional studies and studies using data or biological samples from previous studies	
	Studies that evaluate products	Studies that do not evaluate products	Studies that evaluate products	Studies that do not evaluate products
Full Protocol	At the time of results summary posting ^a			-
Statistical Analysis Plan	At the time of results summary posting ^a			-
Regulatory package	Within 60 days of decision for marketing authorisation ^b			
Clinical study report (CSR)	Defined by each company at the moment			
Patient Level Data Sharing (PLDS)				

^aFDA Final Rule, 18 Jan 2017

^bEMA POL070, 1st Jan 2015

Redaction

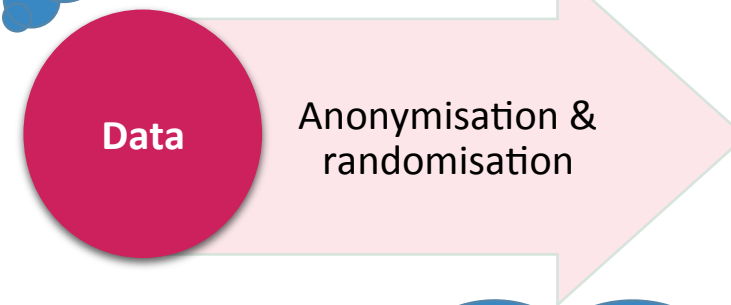


Examples:

PPD: investigator CV, subject ID...

CCI: doses/composition of products...

Removal of PPD/CCI involves redacting (masking from view with a blue/black bar) specific content and removing certain sections of the CSR with an explanation of what has been removed and why



CCI: Commercially Confidential Information
PPD: Patient Personal Data

Anonymisation of data

- *Standards defined*
- *Data have to be de-identified so that Patient Personal Data (PPD) has been removed*
- *Anonymised datasets to be stored in a central holding repository*



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Companies

Follow requirements but can go beyond with internal guidances to proactively prepare for next steps

Journals

Some journals to require authors to agree to share the data underlying the studies they publish

EMA

2019, **clinical trials conducted in the EU** and paediatric trials conducted outside the EU that are part of paediatric investigation plans: All clinical trial-related information generated during the life cycle of a clinical trial to be made available on future EU portal.

Within 30 days of decision on Marketing authorisation for clinical trials included in a marketing authorisation application in EU (EU CTR, Q4 2018)

NIH

FDA Final Rule, 18 Jan 2017
Expand of scope



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Facilitators

- *Standardised templates and databases will allow external researchers to compare results/conclusions from different trials*
- *Facilitate process to ensure data sharing to a maximum extend*
- *Exchange with other companies should empower the process*



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Conclusion

- *Initiative is an expanding one and new requirements will keep on coming*
- *Sharing patient level data has the potential to increase public understanding and interest*
- *Pharmaceutical companies adapting to external requirements*
- *External environment is encouraging multiple models to co-exist*



Questions...



ROI²
return on investment
through
return on information

 **Business & Decision**
Life **Sciences**