Setting up the Pharma System: operational aspects of sharing patient information and data sharing

PhuSE SDE, 15 July 2014

Kelly Mewes

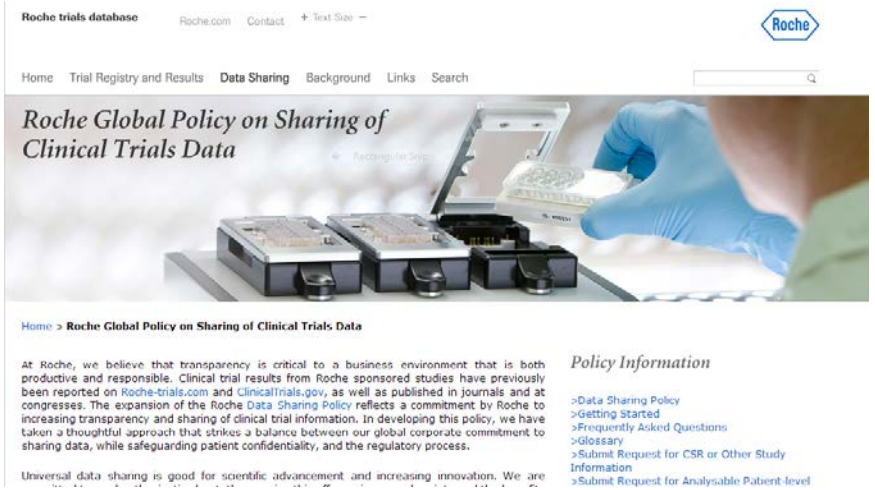
Data Sharing Specialist

Agenda

1. Introduction: Roche policy, timeline, objectives of data sharing
2. Cross pharma collaboration: multi sponsor request website (Ideapoint) and data access system (SAS)
3. Different approaches, Roche strategy: in-scope criteria, reactive to proactive, data de-identification
4. Post go-live: resources, requests received, lessons learned
5. The future: future for CSDR.com, new paradigms and what does it mean for you?

1. Timeline …

- **Roche Data Sharing policy published June 2013** (http://roche-trials.com/dataSharingPolicy.action)

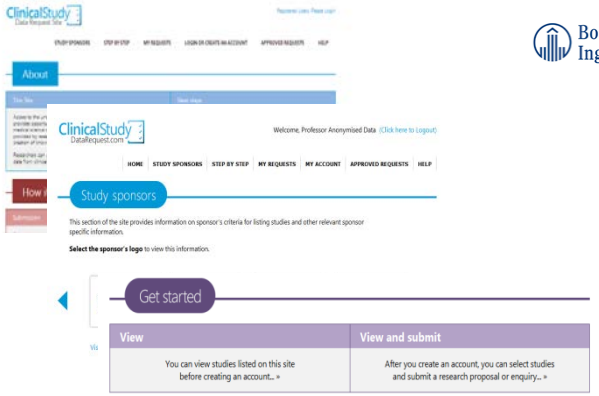


- **Co-operation with GSK** even before Roche policy was published; vision and approach very similar to GSK‘s policy (pub. Q1/2013)

- Roche and GSK in **agreement on technical solution approach**
  - Request/request management tool (clinicalstudydatarequest.com – ideaPoint)
  - Analysis environment (SAS)

1. Timeline …

- **July – December 2013: GSK, Roche & ideaPoint work on www.clinicalstudydatarequest.com**
  - GSK‘s tool transformed into a general web-site, de-personalised
  - Intention: create a tool which has the potential to be a standard for all sponsors
  - Over time, others joined:
    - ViiV Healthcare
    - Boehringer-Ingelheim
    - Sanofi



- **Go-live: 02 January 2014**
- **Two more companies joined 01 May 2014:**
- **Multiple pharma work together with SAS on “multi-sponsor research environment” (MSE)**

1. Objectives of patient level data sharing

- Maximise the value of clinical trial data to benefit scientific research, increase medical understanding and get the right treatments to the right patients
- Responsibility of all sponsors of clinical trials (industry, academia, charities)
- Multi-sponsor solutions will facilitate such research
  - Easier access to data
  - Combine/compare data across sponsors
  - More cost efficient
  - Tiered pricing

2. ClinicalStudyDataRequest.com website (CSDR.com) – go-live 2nd Jan 2014

ClinicalStudy DataRequest.com

Registered Users, Please Login

HOME | STUDY SPONSORS | STEP BY STEP | MY REQUESTS | LOGIN OR CREATE AN ACCOUNT | APPROVED REQUESTS | HELP

About

This site

Access to the underlying (patient level) data that are collected in clinical trials provides opportunities to conduct further research that can help advance medical science or improve patient care. This helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding.

Researchers can use this site to request access to anonymised patient level data and supporting documents from clinical studies to conduct further research.

Next steps

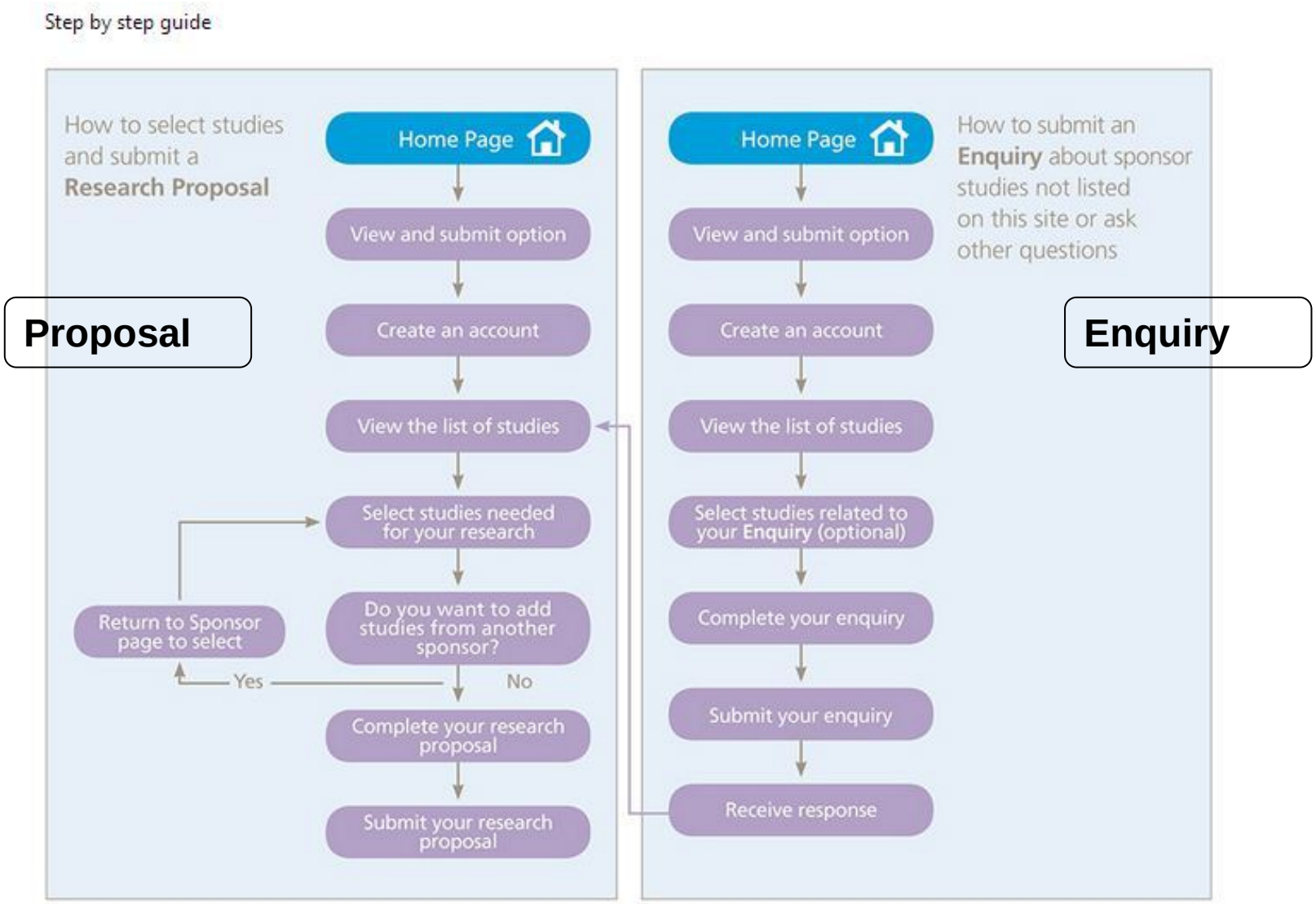
Study sponsors who have committed to use this site are **Bayer, Boehringer Ingelheim, GSK, Novartis, Roche, Sanofi** and **ViiV Healthcare**.

Other clinical trial sponsors and funders are invited to join with the aim of transitioning to a fully independent system which allows access to data from clinical trials conducted by multiple companies and organisations. It is hoped that such a system will be put in place as soon as possible.

If you are a study sponsor interested in listing studies on this site, contact information is provided here.

How it works

2. How the site works

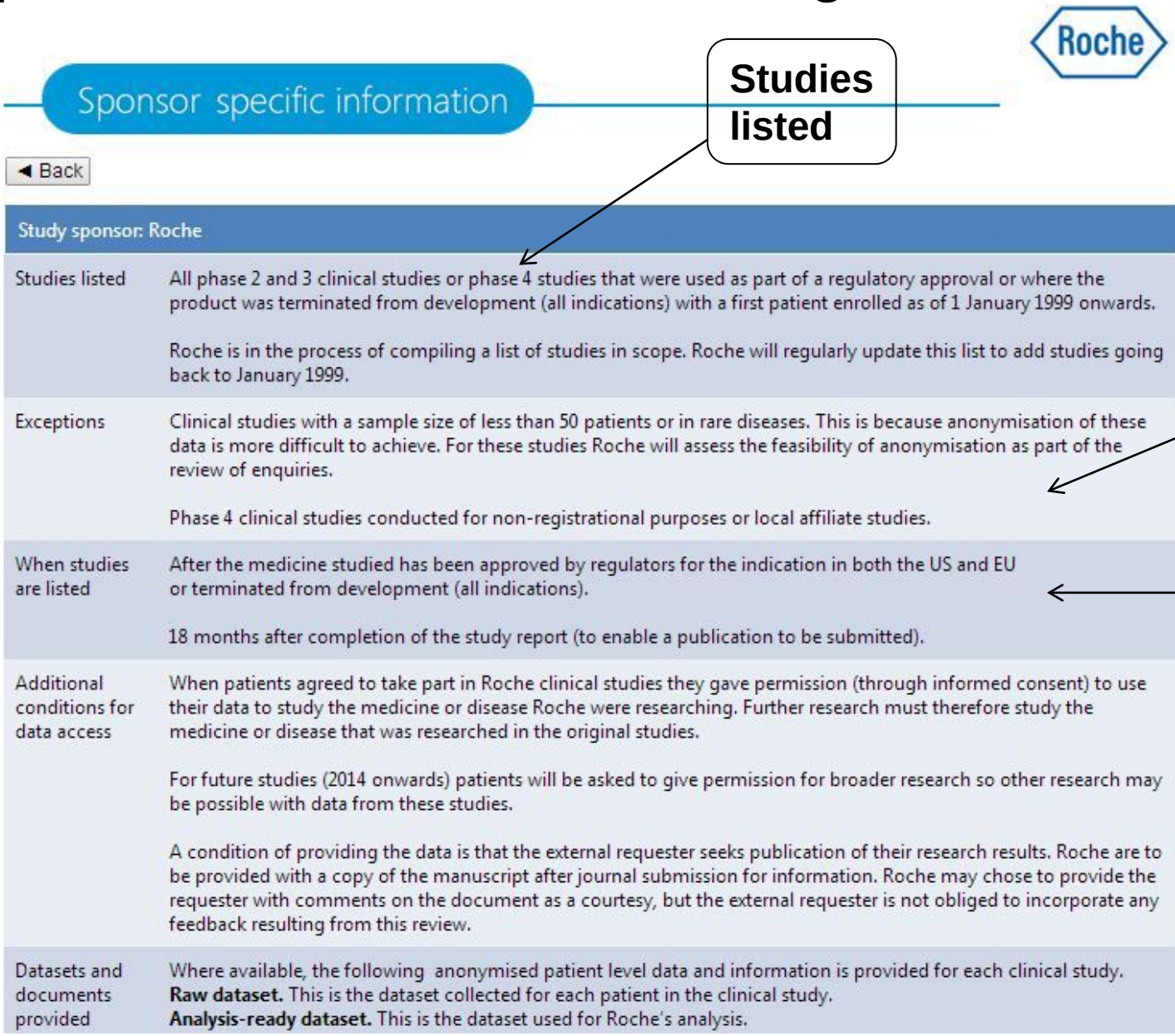


2. Patient Level Datasets access : Key concepts

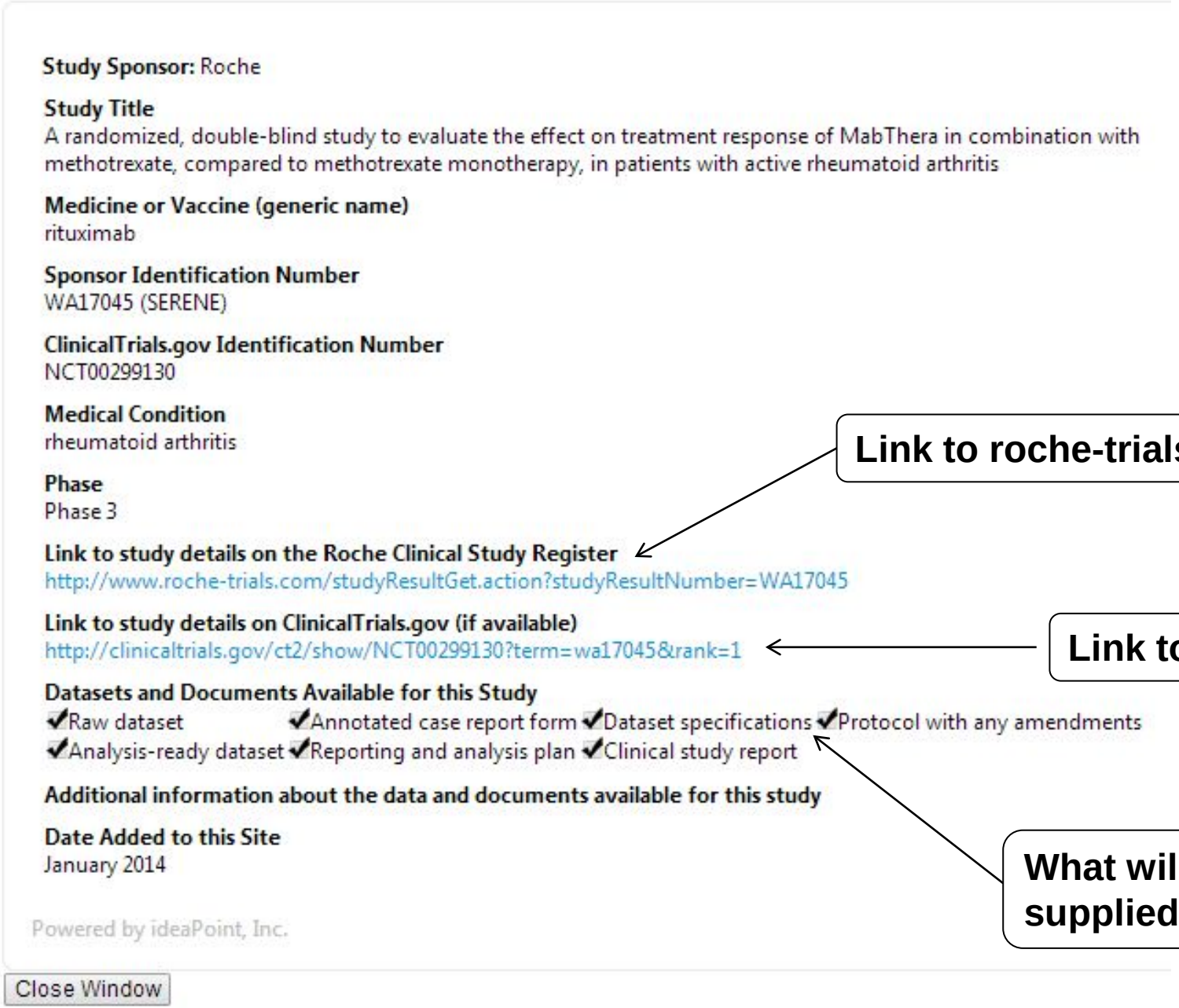
Controlled access – learned intermediary model

- **Research proposal** written (analysis objectives, statistical analysis plan, researcher affiliations and conflicts of interest (if any), team includes a qualified statistician)
- Access approval by in **Independent Review Panel** (not Roche employees)
- Patient identifiers (direct and indirect) removed from datasets
- Researchers sign a **Data Sharing Agreement**
- Data (and associated documentation) shared via a **secure website** (safe haven for the data) – hosted by SAS and based on SAS DD
- Research published – copy to sponsor for information

2. Sponsors list criteria for sharing



2. Studies listed on the website are in scope for s



Study Sponsor: Roche

Study Title
A randomized, double-blind study to evaluate the effect on treatment response of MabThera in combination with methotrexate, compared to methotrexate monotherapy, in patients with active rheumatoid arthritis

Medicine or Vaccine (generic name)
rituximab

Sponsor Identification Number
WA17045 (SERENE)

ClinicalTrials.gov Identification Number
NCT00299130

Medical Condition
rheumatoid arthritis

Phase
Phase 3

Link to study details on the Roche Clinical Study Register
http://www.roche-trials.com/studyResultGet.action?studyResultNumber=WA17045

Link to study details on ClinicalTrials.gov (if available)
http://clinicaltrials.gov/ct2/show/NCT00299130?term=wa17045&rank=1

Datasets and Documents Available for this Study
✔Raw dataset ✔Annotated case report form ✔Dataset specifications ✔Protocol with any amendments
✔Analysis-ready dataset ✔Reporting and analysis plan ✔Clinical study report

Additional information about the data and documents available for this study

Date Added to this Site
January 2014

Powered by ideaPoint, Inc.

Close Window

Link to roche-trials.com

Link to CT.gov

What will be supplied

2. Metrics will be published

Approved requests

When this site is updated a summary of the number of research proposals and enquiries that have been submitted is provided here. The information below is for the period from May 2013 to 30 November 2013.

For research proposals that have been approved and where signed Data Sharing Agreements have been received, the name and affiliation of the lead researcher, the title of the research, the requested studies, the lay summary, the funding source and any potential conflicts of interest that were provided in the research proposal are also provided. The publication citation and statistical analysis plan is also included after the research has been published.

Approved research proposals with signed Data Sharing Agreements »

Research proposals requesting access to patient level data (number of proposals)

Submitted	Being checked for compliance with requirements	Under review by the IRP	Rejected by the IRP	Advised to re-submit by the IRP	Approved by the IRP with conditions	Approved by the IRP	With signed DSAs	With publication citations
16	4	0	0	0	2	10	6	0

IRP: Independent Review Panel DSA: Data Sharing Agreement

Enquiries requesting access to data from studies not listed on this site (number of studies)

Study sponsor	Number of studies	Undergoing feasibility assessments	Studies with a positive response (access to data1 can be provided2)	Studies with a negative response (access to data1 cannot be provided)
GSK	803	37	40	3

Enquiries - Reasons why access cannot be provided

Reason	Number of studies
Medicine not approved or terminated	2

2. SAS CTDT portal (MSE)

- Based on SAS DD
- ‘Locked’ box approach
- Sponsors load data and documents into the system
- Researchers access data/docs securely
- SAS, R-studio and Open Office tools available
- Controls on exports / downloads
- MSE: enables researchers to access data from more than one sponsor in a single research area. Sponsors cannot access others data

3. Different approaches to patient level data sharing

- CSDR.com website contains a variety of approaches from sponsors
  - Retrospective studies
  - Prospective only
  - Which phases?
  - Registrational versus commercial trials
- Janssen and YODA (Yale)
- Individual company solutions

3. Roche in-scope criteria

Criteria for studies in scope:

- Roche sponsored CTs intended for registration purposes (approved and terminated)
- Adequately powered testable efficacy hypothesis
- CTs with FPE ≥1st Jan 1999
- To be made available after regulatory approval (US & EU)

3. Roche approach to studies on offer

- At go-live, 65 (66) studies listed as available on website
  - Mainly studies with previous E-sub and approval in both EU and US
  - For all studies, they are deemed in-scope and have located data
  - De-identify/anonymise data once requested
  - Plans to systematically expand list of studies in 2014
- Studies not listed can be requested by researchers via an ‘enquiry’
- Evolution to proactive mode:
  - increased focus on availability of data after submission and approval
  - write docs assuming they will be shared
  - CDISC models will allow for automation of de-identification steps, driven by specs

3. Roche approach – patient data de-identification and anonymisation

- Removing PII (personally identifiable information):
  - Remove original patient id, centre number and replace with new random id/centre
  - Remove verbatim text, comments
  - Remove all dates and replace with day, replace DOB with age
- Destroying the link (code key) between provided dataset and original dataset:
  - Some Data Protection Authorities in Europe suggest data only considered anonymised if personal information is removed/redacted and subject code number cannot be linked to a research participant.
  - Therefore, research participants' patient id is anonymised by destroying code key used to generate the new code number from the original (i.e. destroying the link between the two code numbers)

4. Resources

- 2013: 18 staff (7 FTEs) divided across 5 key activities
- 2014: Patient Level Data Sharing Team ('PLDST')
  - Data Sharing Co-ordinators (Stats/Prog 1.5 FTE), DS Specialists (Prog 2 FTE), in-house contract programmers (1 FTE)
  - Project mngt and tech support (0.45 FTE)

- Chose to resource using in-house staff initially
  - Experts on GNE/Roche data structures
  - Responsible for all dataset anonymization activities in Roche
  - Job rotations (12 months)

4. Roche Data Sharing Requests Jan – April 2014

CSRs

Requested Total	Under internal discussion	Rejected	Fulfilled/ in fulfillment process
13	0	6*	7

*3 protocol identifier not given, 2 CSRs not yet signed off, 1 LPLV planned for April 2017

PLD

			Research proposals			
Received Total	Enquiries	Research proposals*	Rejected before IRP review**	Under internal discussion	Under review by IRP	IRP approved
9	3	6	3	1	0	2

Notes:

* Research proposals: 3 Roche Only, 3 Multi-sponsor

** Rejected before IRP review: 2 due to request for documents only, 1 due to request for images and did not want data alone

4. Lessons Learned and Key Messages

+ Roche policy as guidance with very clear deadline
+ Main leads were 100% on data sharing activities
+ Cross-pharma collaboration
- Rest of 2013 team were small %'s
- Creation of trials list was much more difficult than envisioned
- Data sharing agreements logistics, detailed processes de-prioritised

Key messages:

– **Sharing and collaboration** is key (yes, even wi
your competitors)!!!

– We're all still **learning**!! ("Don't let the perfect be the enemy of the good!")

– There is **not one right answer** as to how to plan and resource

5. Future evolution of the CSDR.com website

Short term

- Steering Committee oversees any changes to process and web pages
- Continue to invite other clinical trial data holders to join

Medium term

- IRP being organised and managed by a 3rd part

Long term

- Website and all systems run by an independent non-profit group

5. What data sharing will mean to statisticians and programmers

- For studies which statisticians and programmers work on now….
  - the audience for CSRs and datasets will chang

- For development projects you will work on in the future…
  - you will be able to use information from many more sources
- End-game for studies and data is no longer regulatory submission
- Tomorrow's Data Leaders will be:
  - those who know where the **relevant data are located**, how to **access** it, how to **aggregate** it, how to **analyze** it for meaning and how to **effectively communicate**

5. What skills are needed to work in data sharing ?

- Experienced in liaising with other functions and navigating the Pharma organisation and its processes.
- Knowledge of clinical trials, patient level datasets, study documentation and regulatory knowledge.
- Good communication skills as you are the front facing person of the organisation for researchers requesting data, IRP members, vendors, other companies and study groups.
- Good investigative skills, be able to make decisions and be proactive.
- Ability to analyse current state, work up solutions to improve processes and working practices, make recommendations and implement as the roles and working practices are still developing as data sharing evolves ….

5. The role of a data sharing specialist at Roche

- Responding to proposals and enquiries, through from initial request received to close out in the system, use of tracking system.
- Liaising with other functions and departments within Roche.
- Data and documentation accessibility and anonymisation.
- Management of the SAS CTDT-MSE.
- Providing advice and dataset anonymization support for project teams that instigate data sharing with external groups outside of the website.
- Participation in cross company forums and initiatives.
- Maintenance and updates to study inventory.

Want to find out more?

- Roche-trials.com
- ClinicalStudyDataRequest.com
- GSK article on data sharing

  http://www.nejm.org/doi/full/10.1056/NEJMsr1302541
- Roche TOPRA article

  http://www.topra.org/sites/default/files/regrapart/1/5660/2014-4-regulatory-rapporteur-focus-transparency-clinical-trial-data.pdf
- EFSPI/PSI Special Interest Group
- Transcelerate group on patient de-identification coming soon
- SAS CTDT Linked in area

  http://www.linkedin.com/groups/Clinical-Trial-Data-Transparency-Roundtable-7410543/about

Questions?

Doing now what patients need next