Overview of Data Sharing Initiatives in Industry and Current Experiences

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Overview

- Data Sharing Landscape
  - Why it's important
  - Clinical Documentation (CSRs, PBRERs etc.)
  - Patient Level Data
    - Common concepts/frameworks
    - What are pharma companies doing?
    - SAS Clinical Trial Data Transparency Tool (CTDT)
- Roche Data Sharing experiences to date

Data Sharing Landscape

- The lifecycle of clinical data is changing ....
  - What your companies will be sharing
  - What you can access from other Data Holders
- Many signed up to the EFPIA/Pharma principles, but each company has their own approach

Data Sharing : Clinical Documentation

Who is sharing what?

”

Data Sharing : Clinical Documentation

And when?

Historic

2014 onwards

Not sure:

Amgen

Janssen

Takeda

AstraZeneca

PLD access : Common model +/- variations

- **Research proposal** written (analysis objectives, statistical analysis plan, researcher affiliations and conflicts of interest (if any), team includes a qualified statistician, CVs)
- Access approval by a **Review Panel**
- Patient identifiers (direct and indirect) removed from datasets
- Researchers sign a **Data Sharing Agreement** (legal agreement)
- Data (and associated documentation) shared
  - via a **secure website** (safe haven for the data)
  - directly
- Research published – copy to sponsor for information

Different approaches to sharing patient level data ....

- Cross-company collaboration
  - Bayer, BI, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB, ViiV
  - Advantages:
    - Easier for researchers to access to data from multiple sources
    - More cost efficient
    - Tiered pricing
- Collaboration with academic group
  - J&J (Janssen) and Yale (YODA), BMS and Duke
- "Home grown" solutions
  - Online applications: Pfizer's INSPIIRE portal
  - Email directly: AstraZeneca, Amgen, Merck, Shire, Novo Nordisk

Patient Level Datasets available from ?

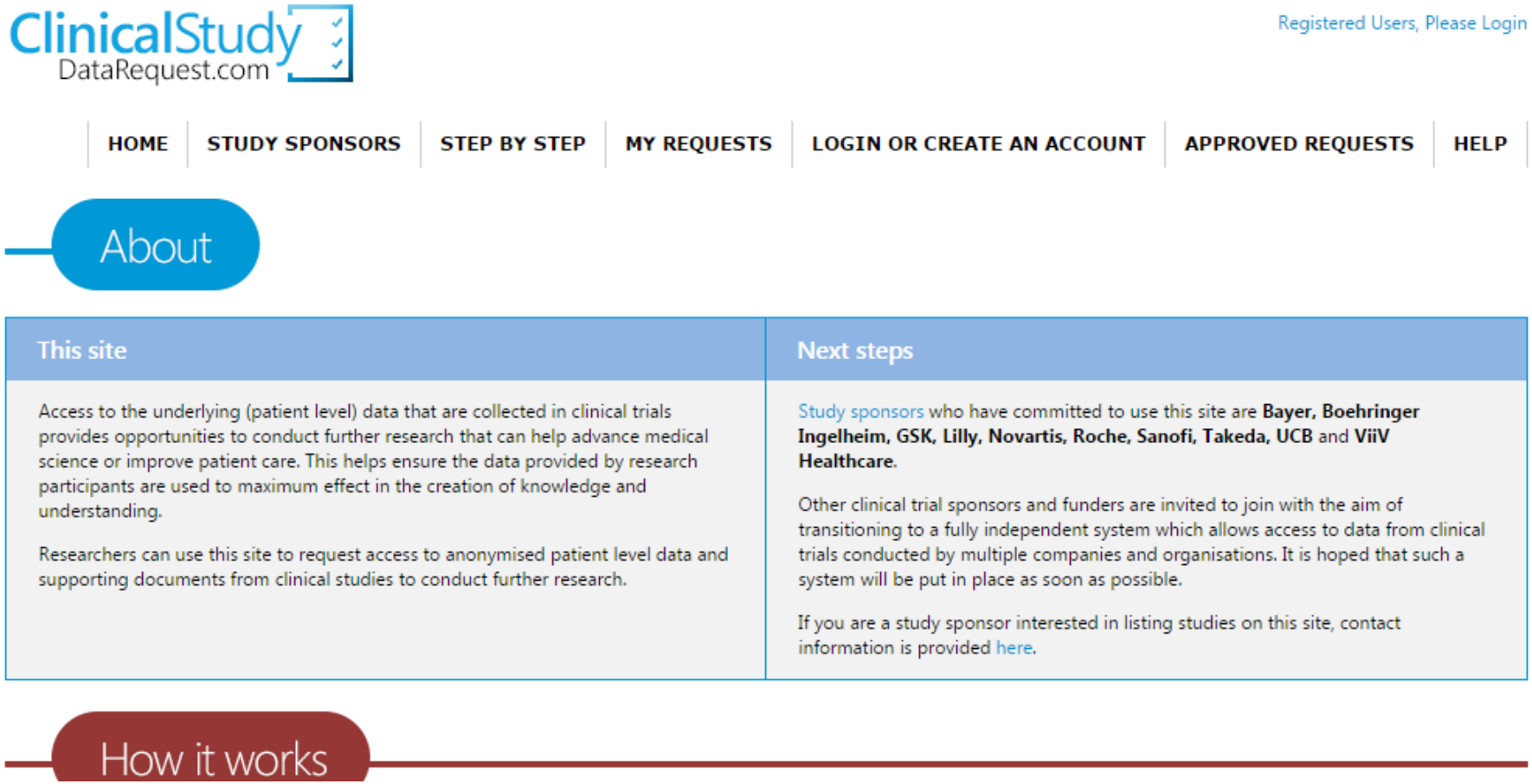
- Which types of studies?
  - Phase 1
  - Phase 2 and 3 (“registrational”)
  - Phase 4, local affiliate studies
- When available? Approval in US and EU and
  - after primary publication accepted
  - >18m after sign-off of CSR (Merck, Roche)
- Prospective (Jan 2014 onwards) only
- Retrospective studies and terminated programs
  - BI, Janssen, GSK, Lilly, Merck, Novo Nordisk, Pfizer, Roche, ViiV

ClinicalStudy DataRequest.com

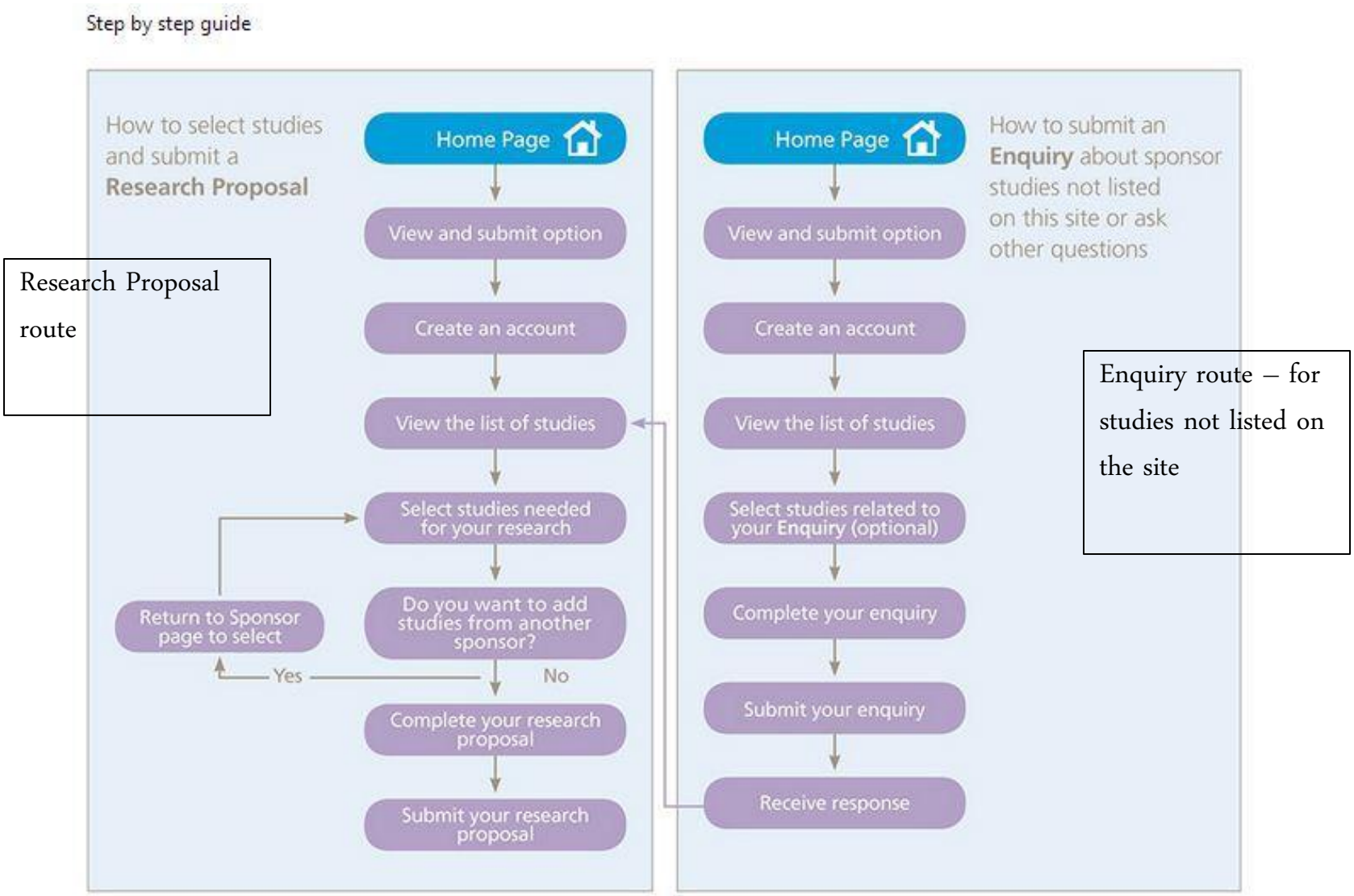
Roche

- Expansion of model and system developed by GSK with ideaPoint
- Website designed to be transparent regarding the patient level data request process
- Facilitates cross-company analyses (one Research Proposal, one Data Sharing Agreement, data accessed from one system)
- Behind website (POMS)
  - Tracks a research proposal from “initial submission” through to “citation received”
  - All correspondence held with the proposal
  - Metrics can be easily produced
  - IRP reviews documents and approves within the system
  - Cross-company data requests visible to all sponsors involved

ClinicalStudyDataRequest.com website (CSDR.com)



How the site works



Research Proposal route

Enquiry route – for studies not listed on the site

Sponsors list criteria for sharing

Sponsor specific information

◄ Back

Study sponsor: Roche	
Studies listed	All phase 2 and 3 clinical studies or phase 4 studies that were used as part of a regulatory approval or where the product was terminated from development (all indications) with a first patient enrolled as of 1 January 1999 onwards. Roche is in the process of compiling a list of studies in scope. Roche will regularly update this list to add studies going back to January 1999.
Exceptions	Clinical studies with a sample size of less than 50 patients or in rare diseases. This is because anonymisation of these data is more difficult to achieve. For these studies Roche will assess the feasibility of anonymisation as part of the review of enquiries. Phase 4 clinical studies conducted for non-registrational purposes or local affiliate studies.
When studies are listed	After the medicine studied has been approved by regulators for the indication in both the US and EU or terminated from development (all indications). 18 months after completion of the study report (to enable a publication to be submitted).
Additional conditions for data access	When patients agreed to take part in Roche clinical studies they gave permission (through informed consent) to use their data to study the medicine or disease Roche were researching. Further research must therefore study the medicine or disease that was researched in the original studies. For future studies (2014 onwards) patients will be asked to give permission for broader research so other research may be possible with data from these studies. A condition of providing the data is that the external requester seeks publication of their research results. Roche are to be provided with a copy of the manuscript after journal submission for information. Roche may chose to provide the requester with comments on the document as a courtesy, but the external requester is not obliged to incorporate any feedback resulting from this review.
Datasets and documents provided	Where available, the following anonymised patient level data and information is provided for each clinical study. **Raw dataset.** This is the dataset collected for each patient in the clinical study. **Analysis-ready dataset.** This is the dataset used for Roche's analysis.

Studies listed on the website are in scope for sharing

Study Sponsor: Roche

Study Title
A randomized, open-label phase III Intergroup study: Effect of adding Bevacizumab to cross over fluoropyrimidine based chemotherapy in patients with mCRC and disease progression under first-line standard CTx/Bevacizumab combination

Medicine or Vaccine (generic name)
bevacizumab

Sponsor Identification Number
ML18147

ClinicalTrials.gov Identification Number
NCT00700102

Medical Condition
malignant neoplasm of colon; malignant neoplasm of rectum

Phase
Phase 3

Link to study details on the Roche Clinical Study Register
http://www.roche-trials.com/studyResultGet.action?studyResultNumber=ML18147

Link to study details on ClinicalTrials.gov (if available)
http://clinicaltrials.gov/ct2/show/NCT00700102

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.

Metrics are published

ClinicalStudy DataRequest.com

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Approved requests

A summary of the number of research proposals and enquiries that have been submitted for the period **7 May 2013** to **31 May 2014** is provided here.

The table below provides metrics for different parts of the process following submission of a research proposal (Requirements check, Independent Review Panel (IRP) review, Data Sharing Agreement, Data preparation and conduct of the research project). The "In process" rows provide the number of research proposals in this part of the process on 31 May 2014. The other rows for each part of the process provide the total number of research proposals that have achieved that outcome from 7 May 2013 to 31 May 2014.

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

Number of Research Proposals submitted		58
Requirements check	In process	4
	Withdrawn by the requestor	2
	Did not meet requirements (further details)	7
	Met requirements	45
IRP review	In process	6

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 party

Long term

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

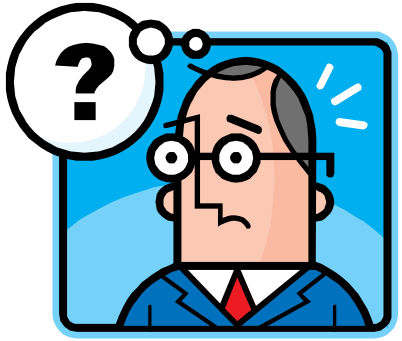
SAS Clinical Trial Data Transparency (CTDT) Tool

- Single sponsor instance
- Multi-sponsor instance
- Tiered pricing structure available
- MSE Governance Board
  - Charter in development “voice of the customer”
  - BI, Bayer, GSK, J&J, Lilly, Merck, Novartis, Pfizer, Roche, Sanofi, Takeda, ViiV
- Researcher has private space (SAS, R and open office) to perform analyses
- Researcher can import files, limitations on what they can export

The biggest challenge?

Identifying the studies “in scope”

- Whose study is it?
- Who is the data holder?
- Can we share it?



  - Co-developed products, co-licenced products
  - Studies run with co-operative groups
  - Executive Committees with publication oversight
  - How does a researcher know who the data holder is?

Clinical Documentation Request: Metrics

- Roche Requests for redacted documents
  - Jan to August 2014
  - Via the Website: 25 requests, 13 accepted
  - Via EMA: 15 (PSURs, RMPs, meeting minutes, selected tables)

Patient Level Data Sharing: Metrics

- How many requests?
  - 58 research proposals
    - 45 met requirements
    - 36 approved by IRP
    - 23 have signed Data Sharing Agreement
    - 13 access to data
- Who's requesting datasets?
  - Academic groups
  - UK, USA, Europe

ClinicalStudy DataRequest.com

May 2013 to May 2014

Patient Level Data Sharing: Metrics

- Re-analysis versus secondary research?

  Based on 23 proposals with a signed DSA

Re-analysis	1
New analyses*	22

*understanding risk factors, comparing treatments, optimising treatments, sub-groups, informing future study design

Data Sharing Landscape

- The lifecycle of clinical data is changing ....
  - What your companies will be sharing
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Statisticians are in a unique position to both inform and help shape this new landscape

Doing now what patients need next