CLINICAL TRIAL DATA TRANSPARENCY

- CURRENT PROGRESS AND MOVING TOWARDS ONE MULTI-SPONSOR ENVIRONMENT

PHUSE SDE LONDON, 22 MAY 2014

AGENDA

Content

- Review timeline of major CTDT news and developments
- Different clinical trial data sharing models in the industry
  - Single-sponsor and multi-sponsor solutions
  - SAS involvement
- Five steps to success with CTDT
- Q&A

REVIEW TIMELINE

REGULATORY TIMELINE

EUROPEAN MEDICINES AGENCY (EMA)

22 Nov 2012
EMA CTDT workshop

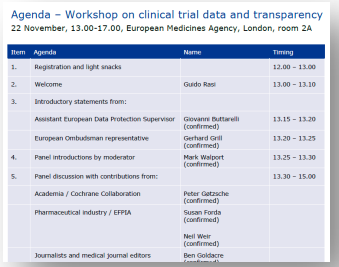
24 Jun 2013
DraftPolicy 70

1 Oct 2013
Public Consultation closed

13 Nov 2013
Progress Update

17 Dec 2013
Notive of delay

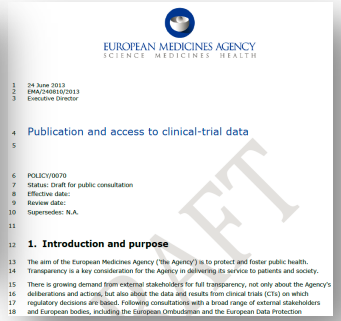
June 2014
Management Board Meeting



Agenda – Workshop on clinical trial data and transparency

22 November, 13.00-17.00, European Medicines Agency, London, room 2A

Item	Agenda	Name	Timing
1.	Registration and light snacks		12.00 – 13.00
2.	Welcome	Guido Rasi	13.00 – 13.10
3.	Introductory statements from:		
	Assistant European Data Protection Supervisor	Giovanni Buttarelli (confirmed)	13.15 – 13.20
	European Ombudsman representative	Gerhard Grill (confirmed)	13.20 – 13.25
4.	Panel introductions by moderator	Mark Walport (confirmed)	13.25 – 13.30
5.	Panel discussion with contributions from:		13.30 – 15.00
	Academia / Cochrane Collaboration	Peter Gøtzsche (confirmed)	
	Pharmaceutical industry / EFPIA	Susan Forda (confirmed) Neil Weir (confirmed)	
	Journalists and medical journal editors	Ben Goldacre (confirmed)	



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2013
EMA/240810/2013
Executive Director

Publication and access to clinical-trial data

POLICY/0070
Status: Draft for public consultation
Effective date:
Review date:
Supersedes: N.A.

1. Introduction and purpose

The aim of the European Medicines Agency ('the Agency') is to protect and foster public health. Transparency is a key consideration for the Agency in delivering its service to patients and society.

There is growing demand from external stakeholders for full transparency, not only about the Agency's deliberations and actions, but also about the data and results from clinical trials (CTs) on which regulatory decisions are based. Following consultations with a broad range of external stakeholders and European bodies, including the European Ombudsman and the European Data Protection

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Text size: A A

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European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

Press release

13/11/2013

European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

In-depth analysis of more than 1000 stakeholders' comments received on draft policy currently underway

The European Medicines Agency is currently reviewing and analysing more than 1,000 comments received during the public consultation on its draft policy on publication and access to clinical-trial data, which ran from June to end of September 2013.

The public consultation on the policy has generated input from an unprecedented range of stakeholders. Patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies and a range of others sent their comments to the Agency. Many of the contributors provided detailed in-depth comments, some of them substantial, some of them technical, including suggestions relating to methodological and technical aspects of the implementation of the policy.

The Agency is grateful for this exceptional contribution from its stakeholders. As part of its collaborative approach to developing a methodology for the release of clinical-trial data with its stakeholders, the Agency is currently devoting attention to all comments received and reaffirms its commitment to transparency and the principles of publication

CLINICAL TRIAL DATA TRANSPARENCY

INDUSTRY POSITIONING

PhRMA
RESEARCH • PROGRESS • HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

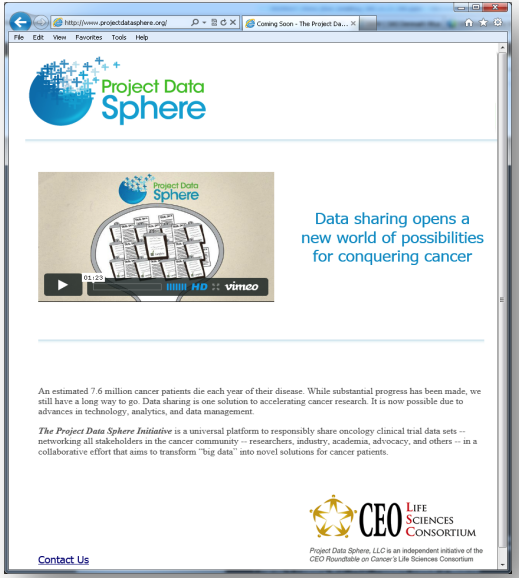
- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

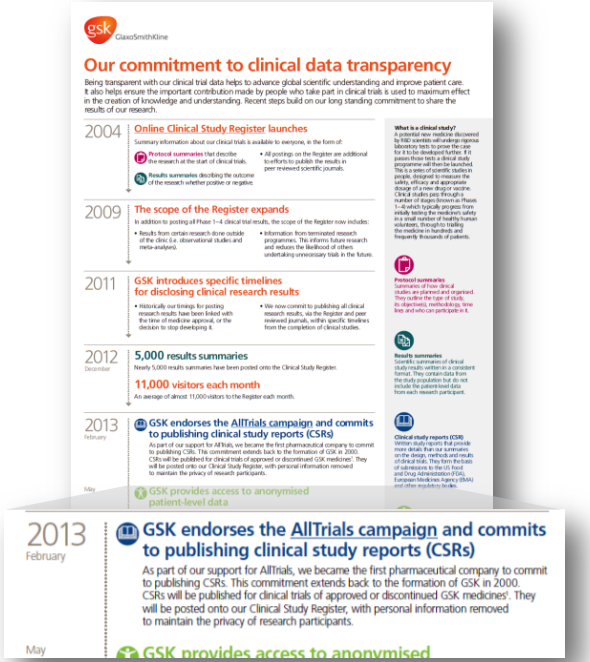
http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf

1. Enhancing Data Sharing with Researchers
2. Enhancing Public Access to Clinical Study Information
3. Sharing Results with Patients Who Participate in Clinical Trials
4. Certifying Procedures for Sharing Clinical Trial Information
5. Reaffirming Commitments to Publish Clinical Trial Results

CLINICAL TRIAL DATA TRANSPARENCY

THE JOURNEY UNTIL NOW





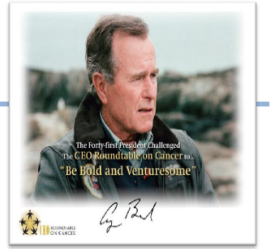
- Conducted multiple webinars and conferences
- 7 major pharmas acquired SAS Transparency solution
- Ongoing roundtable discussions
- Collaborating with McKinsey

Industry is moving towards a multi-sponsor solution on a shared, clinical trial data transparency environment

2012 | 2012 / 1H-2013 | Last 6 months

DATA SHARING | PROJECT DATA SPHERE

CEO Roundtable on Cancer



- "Life Sciences Consortium" working team
- Address issues in cancer research
- Accomplish together what no single company might consider alone

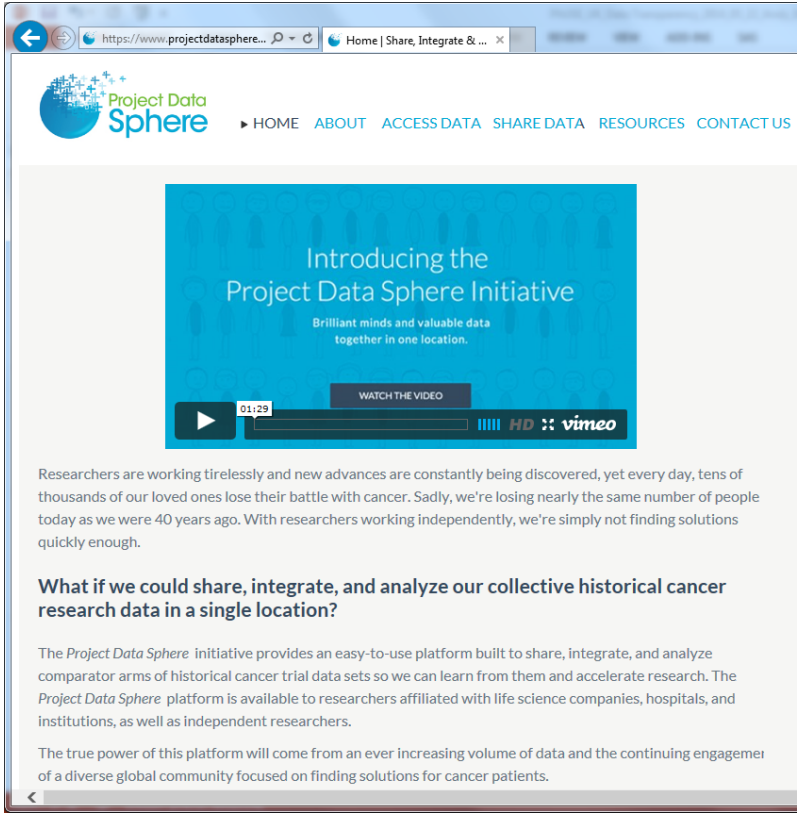
COVANCE · MD Anderson Cancer Center · PPD · Astellas · Duke Medicine · Takeda Millennium · Quintiles · AstraZeneca · GSK · Moffitt Cancer Center · Sanofi · Pfizer · Johnson & Johnson · Novartis · SAS · Lilly

Engages 3rd parties as "Safe Harbors"

National Cancer Institute · Institute of Medicine · FDA

an LSC initiative www.ceo-lsc.org

PROJECT DataSphere



https://www.projectdatasphere.org/projectdatasphere/html/home

CLINICAL TRIAL DATA TRANSPARENCY

INDRUSTRY LEADERS

http://www.forbes.com/sites/matthewherper/2012/10/11/with-transparency-pledge-glaxo-makes-promises-no-other-drug-company-has/

CLINICAL TRIAL DATA TRANSPARENCY

INDRUSTRY LEADERS

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR

NEWS TOPICS ANALYSIS FEATU

Topics: R&D

Roche follows GSK in move to unlock its data vault on drugs

February 26, 2013 | By John Carroll

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99

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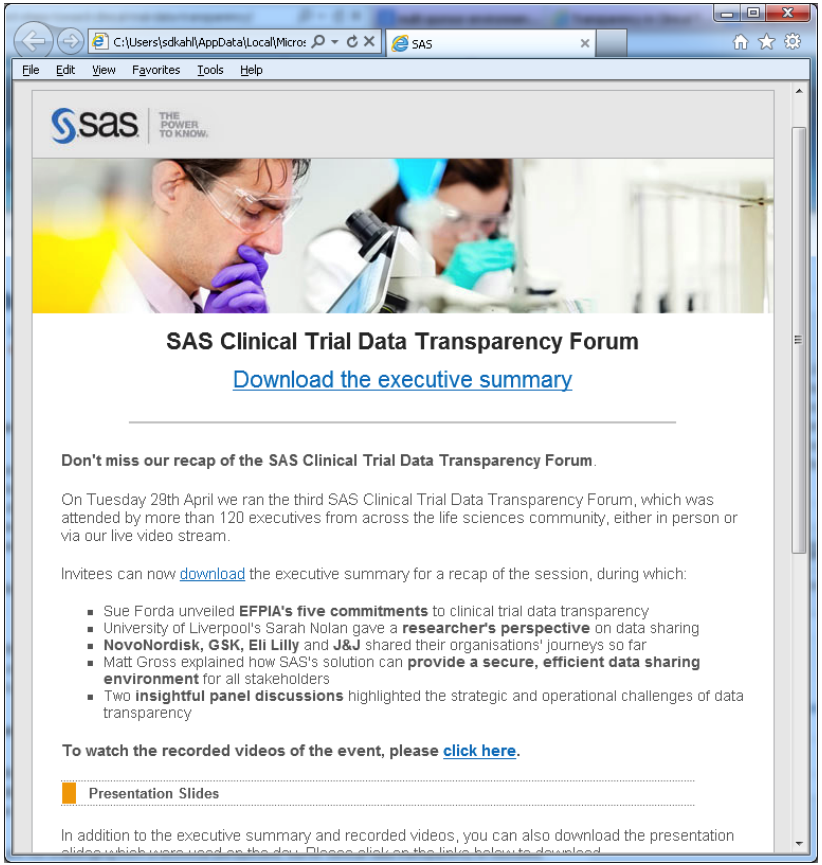
GlaxoSmithKline encountered some stiff industry headwinds when it pledged to open up its data vault to outside investigators. But as of today it has a high-profile convert on its side. The biopharma giant Roche ($RHHBY) has agreed to follow in GSK's ($GSK) footsteps, saying that it will work with an independent group which will be charged with sorting out and approving requests for access to anonymized clinical trial data for all approved products. If regulators can't provide the data, says Roche, then the company will make it available.

http://www.fiercebiotech.com/story/roche-follows-gsk-move-unlock-its-data-vault-drugs/2013-02-26

CLINICAL TRIAL DATA TRANSPARENCY

SAS SPONSORED FORUMS



http://www.sas.com/offices/europe/uk/downloads/clinicaltrialdata-exec-summary.pdf

DISCUSSION TOPICS

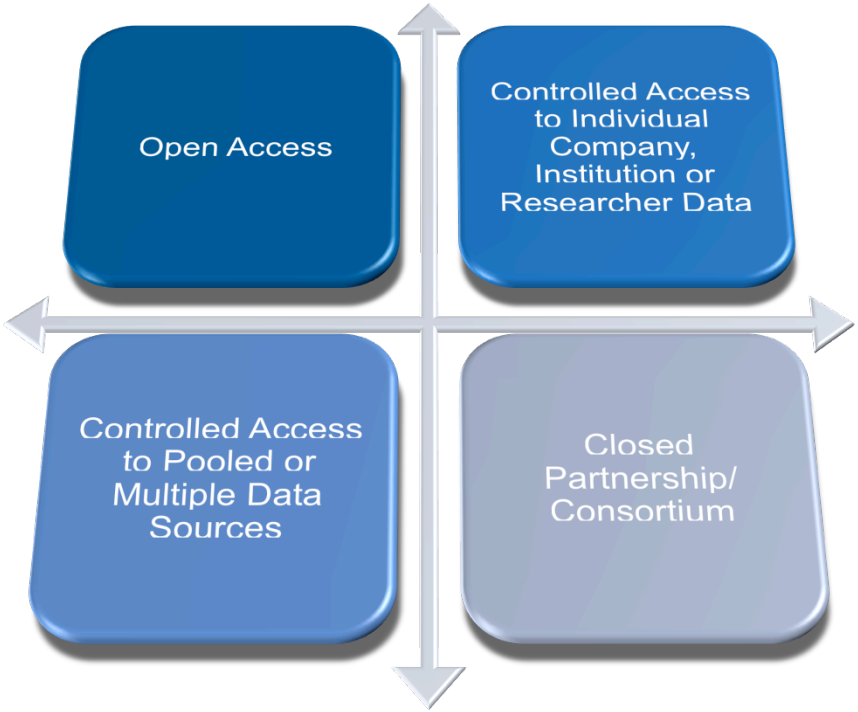
WIDE RANGE OF DISCUSSION TOPICS?

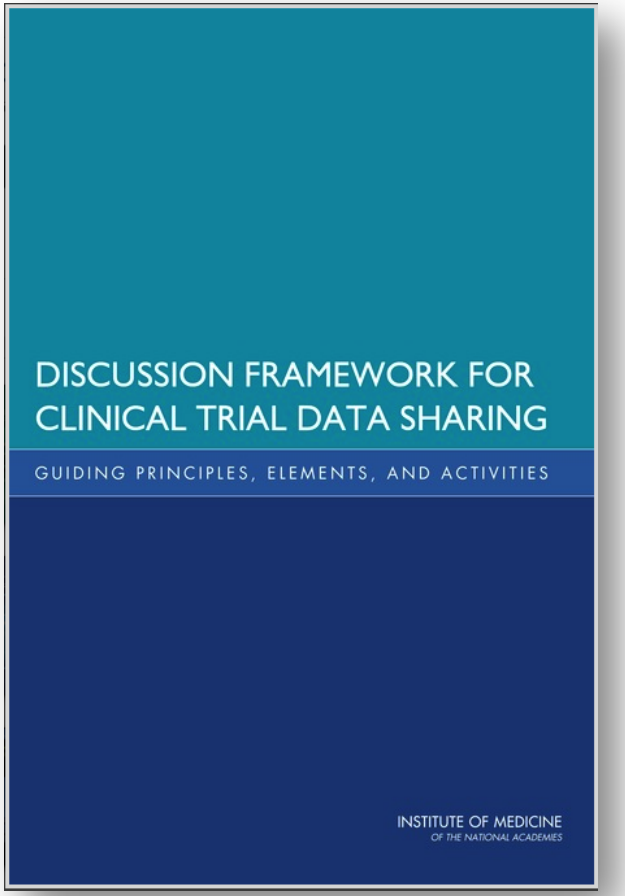
- De-identification
- Approval Criteria
- Informed Consent
- Independent Review Panel (IRP)
- Commercially Confidential Information (CCI)
- Data Standards
- Publication of Results
- Analysis
- Environment for Data Access
- Future

CLINICAL TRIAL DATA SHARING MODELS

CLINICAL TRIAL DATA TRANSPARENCY

DATA SHARING MODELS





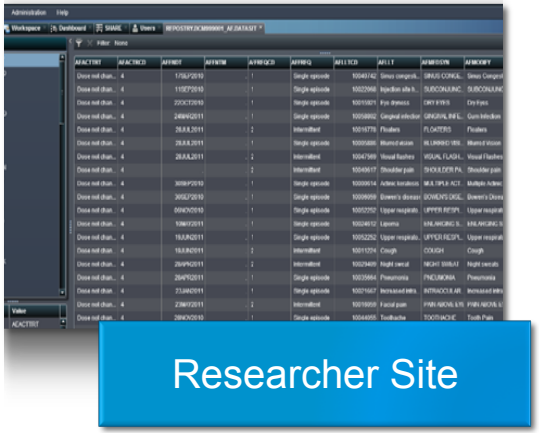
Source:
http://www.iom.edu/Reports/2014/Discussion-Framework-for-Clinical-Trial-Data-Sharing.aspx

CLINICAL TRIAL DATA TRANSPARENCY

THREE MAIN COMPONENTS

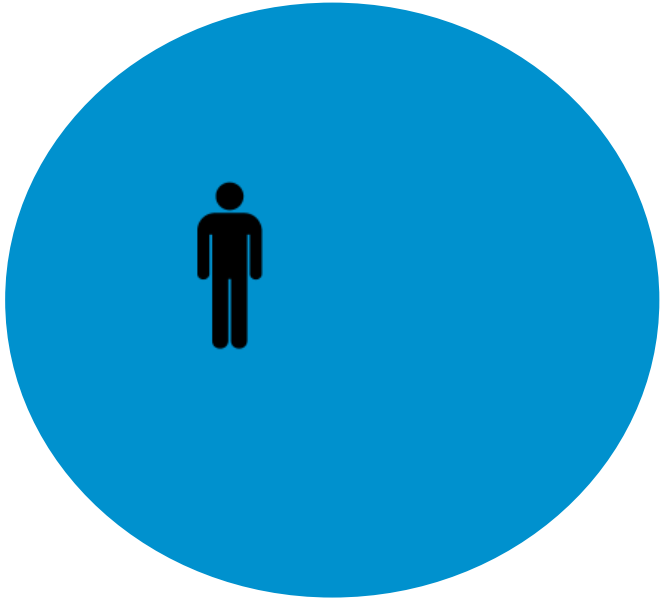
Public Access Site

Independent Review Panel



Researcher Site

SINGLE OR MULTI-SPONSOR DATA ENVIRONMENT



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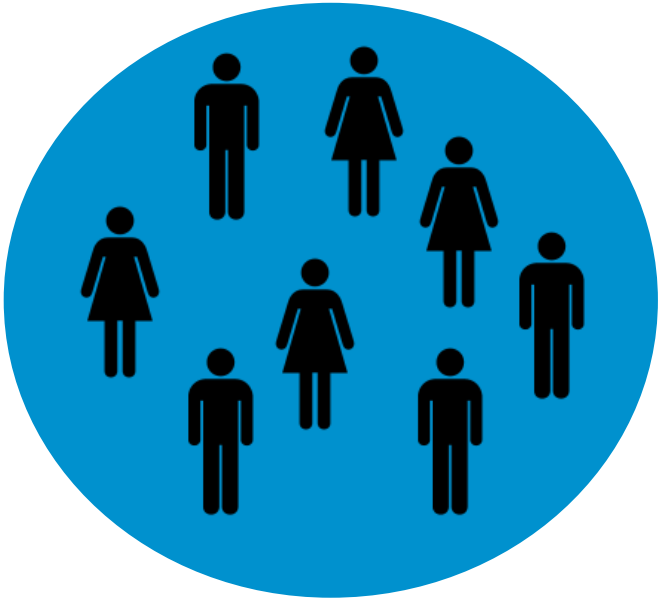
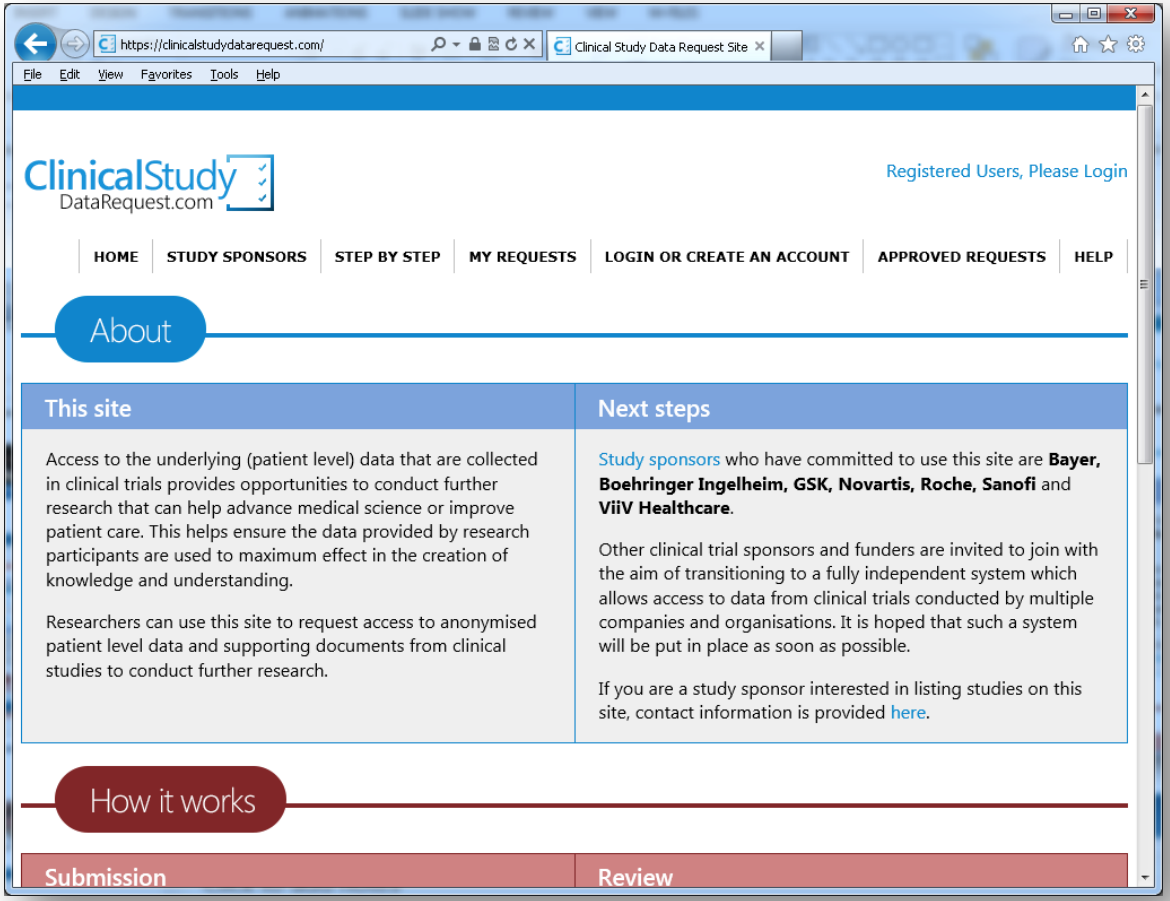


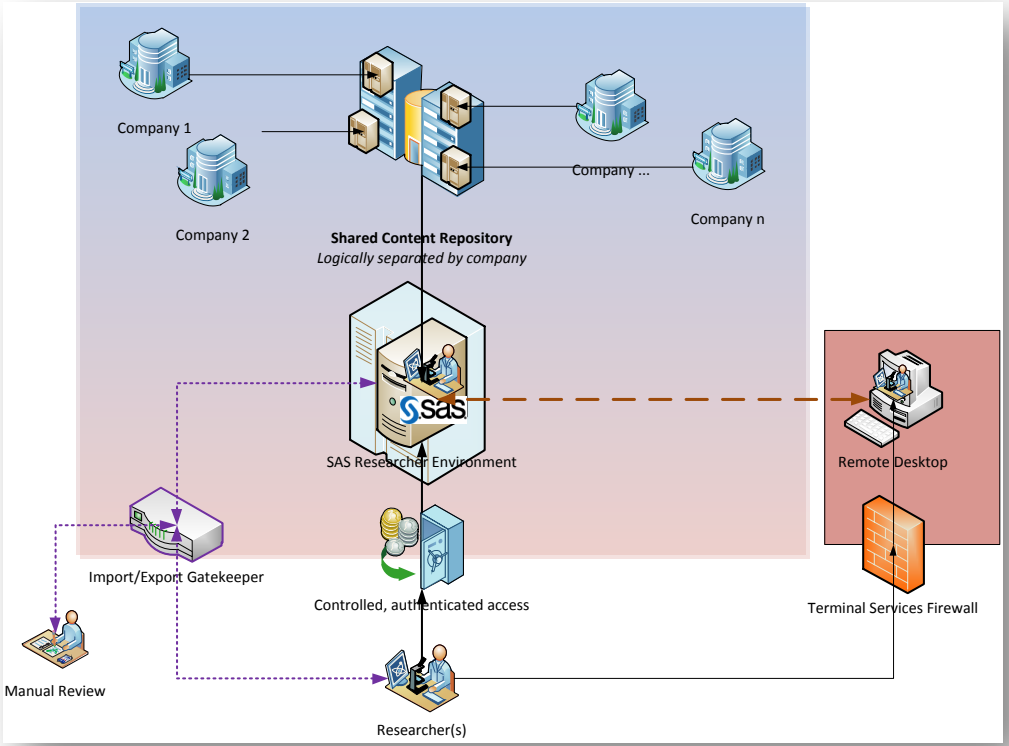
MULTI-SPONSOR DATA REQUEST SITE

- Bayer
- Boehringer Ingelheim
- GSK
- Novartis
- Sanofi
- ViiV Healthcare



https://clinicalstudydatarequest.com/

MULTI-SPONSOR ENVIRONMENT



- Shared environment
- Logically segregated sponsor data
- Researcher access to multiple sponsors' information
- Research Project-based model
- Supports requests for multiple sponsors' data
- Distributed costs for hosting, hardware, administration and support
- Supports low-entry cost for non-profits

SAS CLINICAL TRIAL DATA TRANSPARENCY

SPONSOR PERSPECTIVE

- Storage for Clinical Trial Data
- Granular permissions for controlled access
- Researcher setup and User Management
- Researcher Group setup
- Support for Third-Party Apps
- Import / Export Controlled Information Process
- User Education
- User Technical Support for Lead Researchers
- Hosting , Maintenance and Administration
- Monitoring of researcher activities (if desired) and Reports

SAS CLINICAL TRIAL DATA TRANSPARENCY

RESEARCHER PERSPECTIVE

- Web-access anywhere to research environment
- Research Project Environment
  - Organization and storage of files
  - Read-only access to approved sponsor's data
  - Import and export process to request information into and out of system
- Analysis environment(s)
  - SAS, "R"
- Additional Third-Party Apps
  - OpenOffice, R Studio, Adobe Acrobat Reader
- Support
  - User Guides, videos and access to technical support
  - Supporting documentation and support from sponsor

ENVIRONMENT PERSPECTIVE

- Always available except for scheduled downtimes
- Backups of system
- Updates to environment
- Updates to solution
- 24x7 access to technical support for Researchers
- Scalable Platform
  - Storage, Researcher Projects, Analysis Environment
- Support/Project Management for Customers

SAS CLINICAL TRIAL DATA TRANSPARENCY

Dashboard and Reports

SPONSOR MANAGEMENT AND ADMINISTRATION

By User:

Last Updated: 17-APR-14 12:58:46 EDT

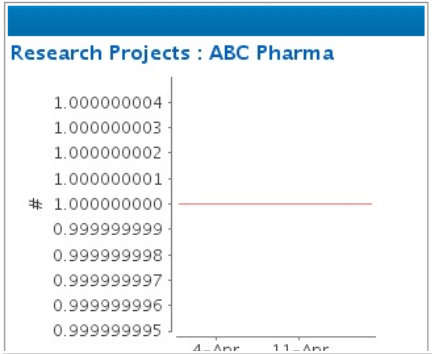
User	User ID	Role	Organization	Size	Involved Companies
Researcher, Lead [LRES]	ctdt_leadresearcher	Lead Researcher	State U	54.307365 MB	• ACME • ABC Pharma

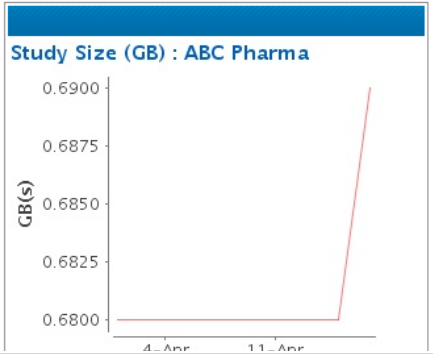
By Company:

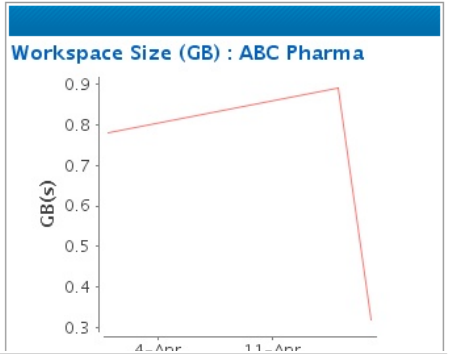
Last Updated: 17-APR-14 12:58:46 EDT

Company	Type	Status	Size
ABC Pharma	Large	Active	63.976562 MB

Company: ABC Pharma ▼ Start Date: 02-MAR-2014 End Date: 01-MAY-2014 View



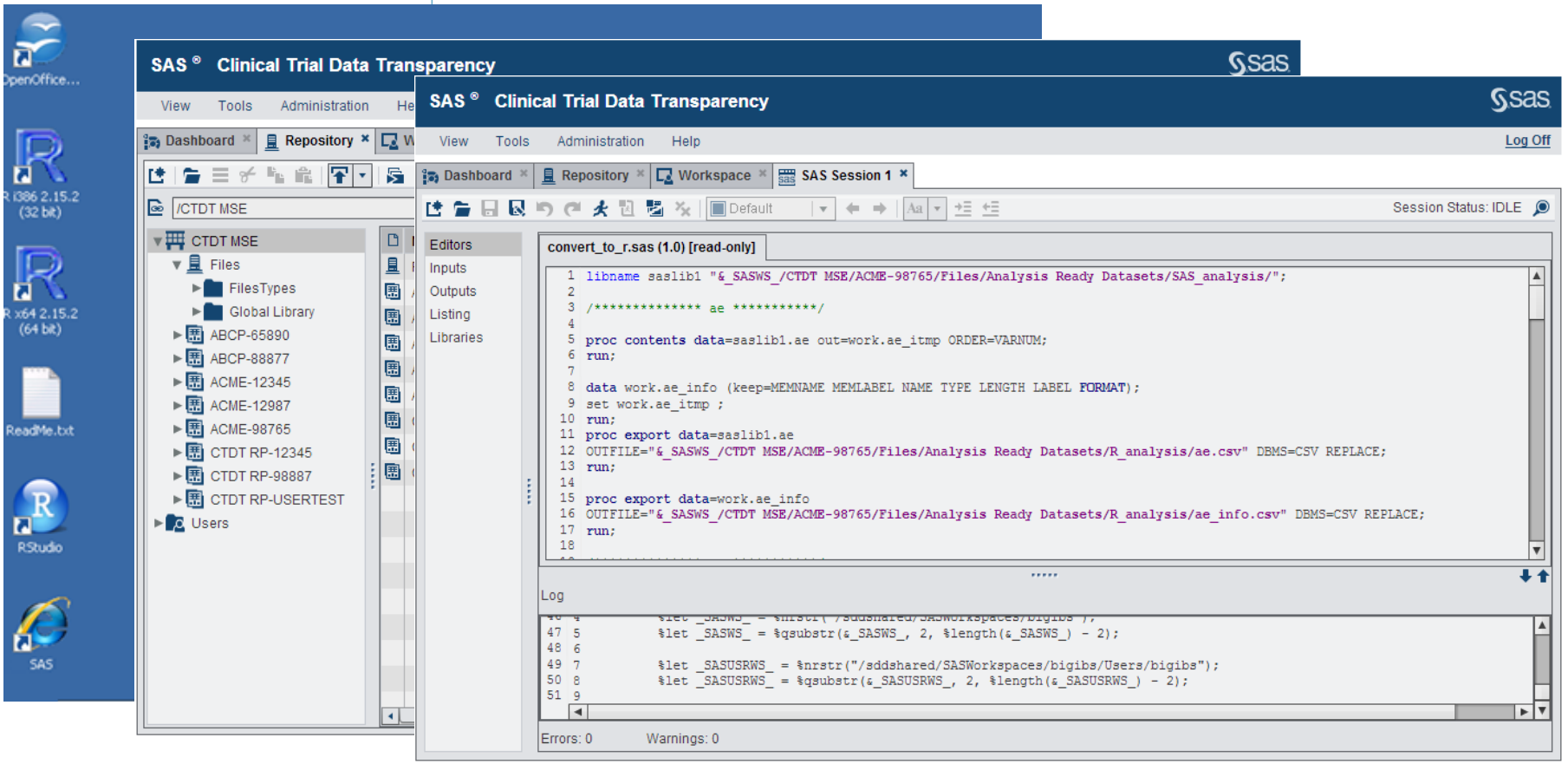




User Access Summary: 4 record(s)

Last Name	First Name	User ID	Role	Status (Request)	Status (Portal)	Status (Repo)	Company	Groups	Studies	Related Companies	History
Admin	ABC Pharma	ctdt_abcadmin	ABC Pharma Admin	Account Created	✓	✓	ABC Pharma	• CTDT ABC Pharma Admin	• ABCP-65890 • ABCP-88877	• ABC Pharma	ⓘ
Barnes	Karen	barnesk	Lead Researcher	Account Created	✓	✓	Pharma Research	• CTDT RP-USERTEST - Full	• ABCP-65890 • ACME-12345 • ACME-12987 • CTDT RP-USERTEST	• ABC Pharma • ACME	ⓘ
Researcher	General	ctdt_researcher	Researcher	Account Created	✓	✓	State U	• CTDT RP-12345 - Full	• ABCP-65890 • ACME-12345 • ACME-12987 • CTDT RP-12345	• ABC Pharma • ACME	ⓘ
Researcher	Lead	ctdt_leadresearcher	Lead Researcher	Account Created	✓	✓	State U	• CTDT RP-12345 - Full	• ABCP-65890 • ACME-12345 • ACME-12987 • CTDT RP-12345	• ABC Pharma • ACME	ⓘ

ACCESS | RESEARCHER VIEW – REMOTE DESKTOP



5 STEPS TO SUCCESS

CLINICAL TRIAL DATA TRANSPARENCY

5 STEPS TO SUCCESS

- Decide to participate
- Making the data decisions
- Implement a governance process
- Deploy a secure data repository with built-in analytics
- Inform the research community and public

Source:
http://blogs.sas.com/content/hls/?s=5+steps+to+success+transparency

AGENDA

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  - Single-sponsor and multi-sponsor solutions
  - SAS involvement
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Thank you!

sas | THE POWER TO KNOW.