

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 CTD
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	Giovanna Buttarelli (confirmed)	13.15 – 13.20
	European Ombudsman representative	Gerdard 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 Gatzsche (confirmed)	
	Pharmaceutical industry / EFPIA	Susan Fonda (confirmed)	
	Journalists and medical journal editors	Neil West (confirmed) Ben Goldacre	



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 24 June 2013
2 EMA/CHMP/SCD/13
3 Executive Director

4 **Publication and access to clinical-trial data**

5

6 POLICY/0070
7 Status: Draft for public consultation
8 Effective date:
9 Review date:
10 Supersedes: N.A.
11

12 **1. Introduction and purpose**

13 The aim of the European Medicines Agency (‘the Agency’) is to protect and foster public health.
14 Transparency is a key consideration for the Agency in delivering its service to patients and society.
15 There is growing demand from (external) stakeholders for full transparency, not only about the Agency’s
16 deliberations and actions, but also about the data and results from clinical trials (CTs) on which
17 regulatory decisions are based. Following consultations with a broad range of external stakeholders
18 and European bodies, including the European Ombudsman and the European Data Protection



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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



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

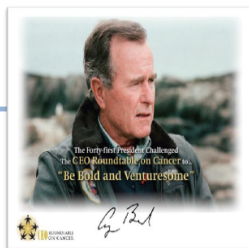
2012 / 1H-2013

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



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

Introducing the Project Data Sphere Initiative

Brilliant minds and valuable data together in one location.

WATCH THE VIDEO

01:29

HD vimeo

Researchers are working tirelessly and new advances are constantly being discovered, yet every day, tens of thousands of our loved ones lose their battle with cancer. Sadly, we're losing nearly the same number of people today as we were 40 years ago. With researchers working independently, we're simply not finding solutions quickly enough.

What if we could share, integrate, and analyze our collective historical cancer research data in a single location?

The Project Data Sphere initiative provides an easy-to-use platform built to share, integrate, and analyze comparator arms of historical cancer trial data sets so we can learn from them and accelerate research. The Project Data Sphere platform is available to researchers affiliated with life science companies, hospitals, and institutions, as well as independent researchers.

The true power of this platform will come from an ever increasing volume of data and the continuing engagement of a diverse global community focused on finding solutions for cancer patients.

The screenshot shows a web browser displaying a Forbes article. The browser's address bar shows the URL: <http://www.forbes.com/sites/matthewherper/2012/10/11/with-transp...>. The Forbes logo is at the top left, with navigation links for 'New Posts', 'Most Popular', 'Lists', and 'Video'. The article is dated 10/11/2012 at 12:05AM and has 6,893 views. The title is 'With Transparency Pledge, Glaxo Makes Promises No Other Drug Company Has'. Below the title, it says '3 comments, 2 called-out' and provides links to 'Comment Now' and 'Follow Comments'. The main text begins with 'In an unprecedented move that could signal dramatic changes in the drug industry, GlaxoSmithKline is promising to make detailed data from its clinical trials available to independent researchers so that scientists can draw their own conclusions about the safety and effectiveness of its new drugs.' To the right of the text is a photo of Andrew Witty, GlaxoSmithKline Chief Executive, wearing a medal. Below the photo is a caption: 'LONDON, UNITED KINGDOM - MAY 15: GlaxoSmithKline Chief Executive Andrew Witty (Image credit: Getty Images via @daylife)'. On the right side of the article, there are social media sharing buttons for Facebook (185 shares), Twitter (299 tweets), LinkedIn (152 shares), and Reddit (0 shares). At the bottom right, there are buttons for Google+ (9 shares) and a 'g+1' button. A 'Cookies on Forbes' link is visible on the left side of the article content.

Forbes New Posts +3 posts this hour Most Popular 5 LinkedIn Strategies Lists The Most Powerful People: Hillary C Video

BUSINESS | 10/11/2012 @ 12:05AM | 6,893 views

With Transparency Pledge, Glaxo Makes Promises No Other Drug Company Has

3 comments, 2 called-out + Comment Now + Follow Comments

In an unprecedented move that could signal dramatic changes in the drug industry, [GlaxoSmithKline](#) is promising to make detailed data from its clinical trials available to independent researchers so that scientists can draw their own conclusions about the safety and effectiveness of its new drugs.

The change, which has yet to be implemented, is being announced at a speech in London at the Wellcome Trust, where Glaxo chief executive Andrew Witty is also detailing how the British drug giant has made its chemical libraries available to researchers working on drugs

LONDON, UNITED KINGDOM - MAY 15: GlaxoSmithKline Chief Executive Andrew Witty (Image credit: Getty Images via @daylife)

185 f Share 299 Tweet 152 in Share 0 reddit 9 g+1

Cookies on Forbes

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

Topics: R&D

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

February 26, 2013 | By John Carroll

SHARE



Email

99

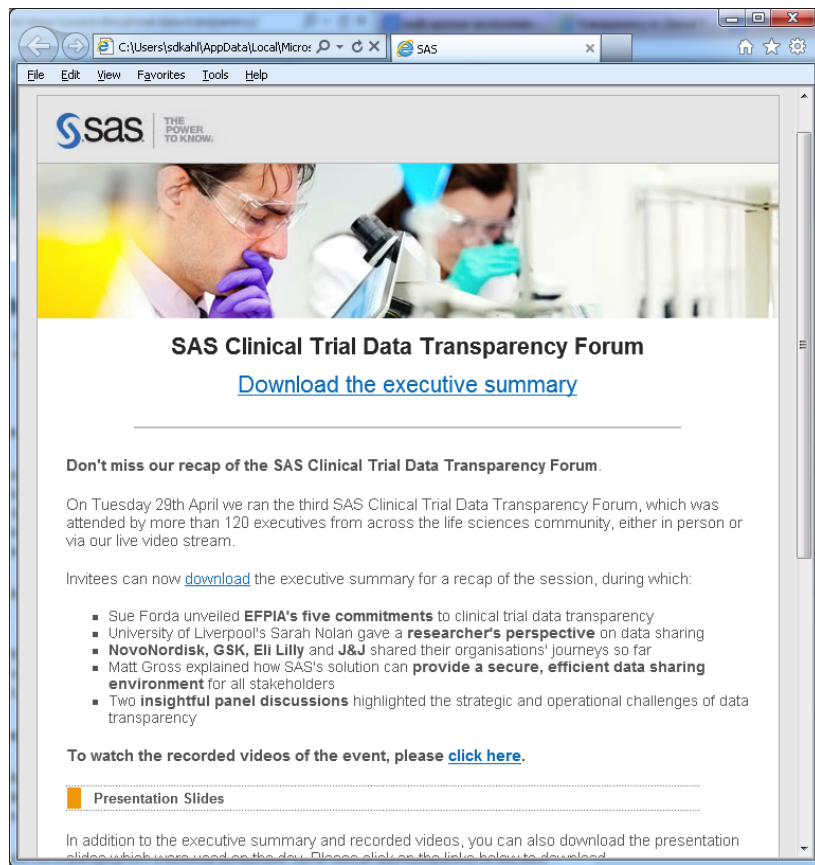


Tweet

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.

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?

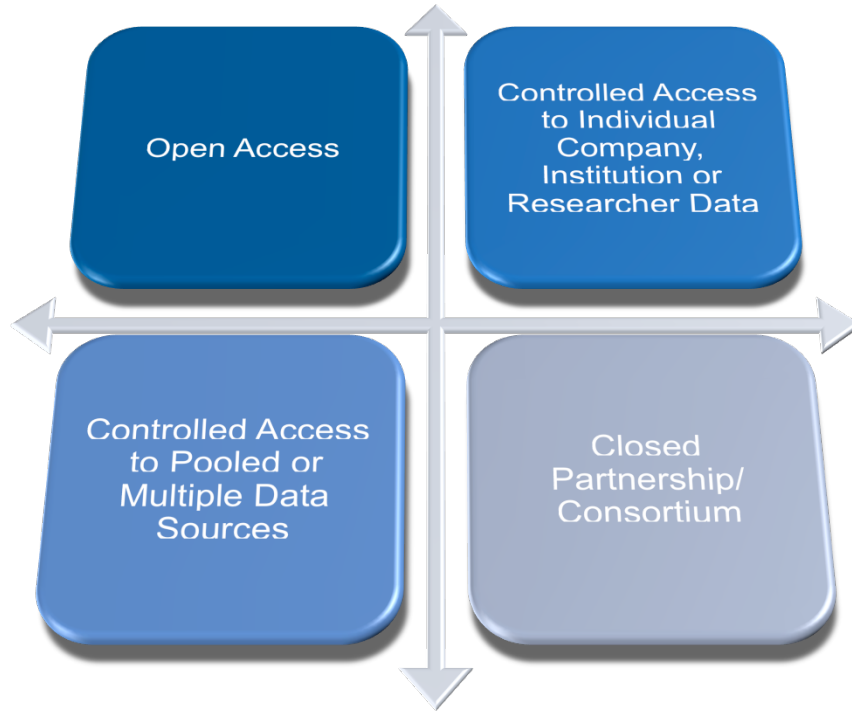
- De-identification
- Approval Criteria
- Informed Consent
- Independent Review Panel (IRP)
- Commercially Confidential Information (CCI)
- Data Standards
- Publication of Results
- Analysis
- Environment for Data Access
- Future

CLINICAL TRIAL DATA SHARING MODELS



CLINICAL TRIAL DATA TRANSPARENCY

DATA SHARING MODELS



DISCUSSION FRAMEWORK FOR CLINICAL TRIAL DATA SHARING

GUIDING PRINCIPLES, ELEMENTS, AND ACTIVITIES

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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

CLINICAL TRIAL DATA TRANSPARENCY

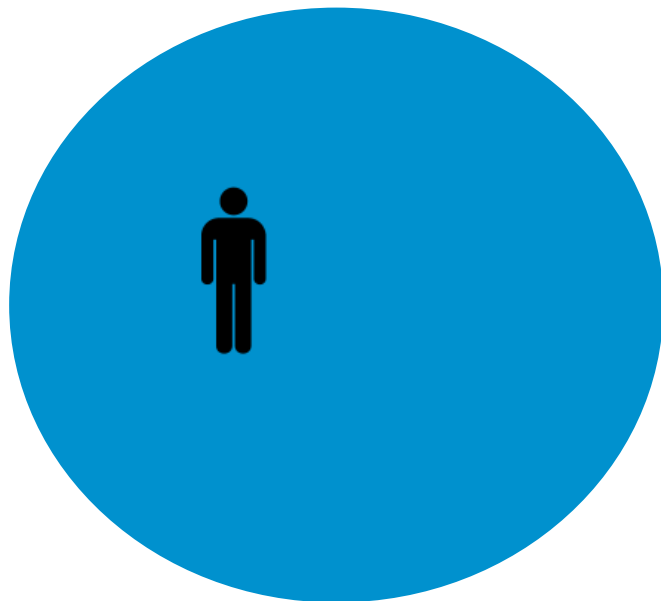
THREE MAIN COMPONENTS



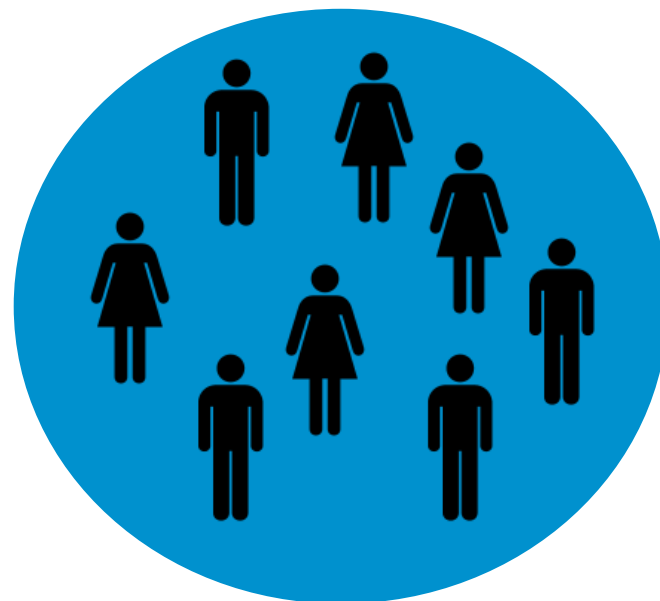
Public Access Site




Researcher Site

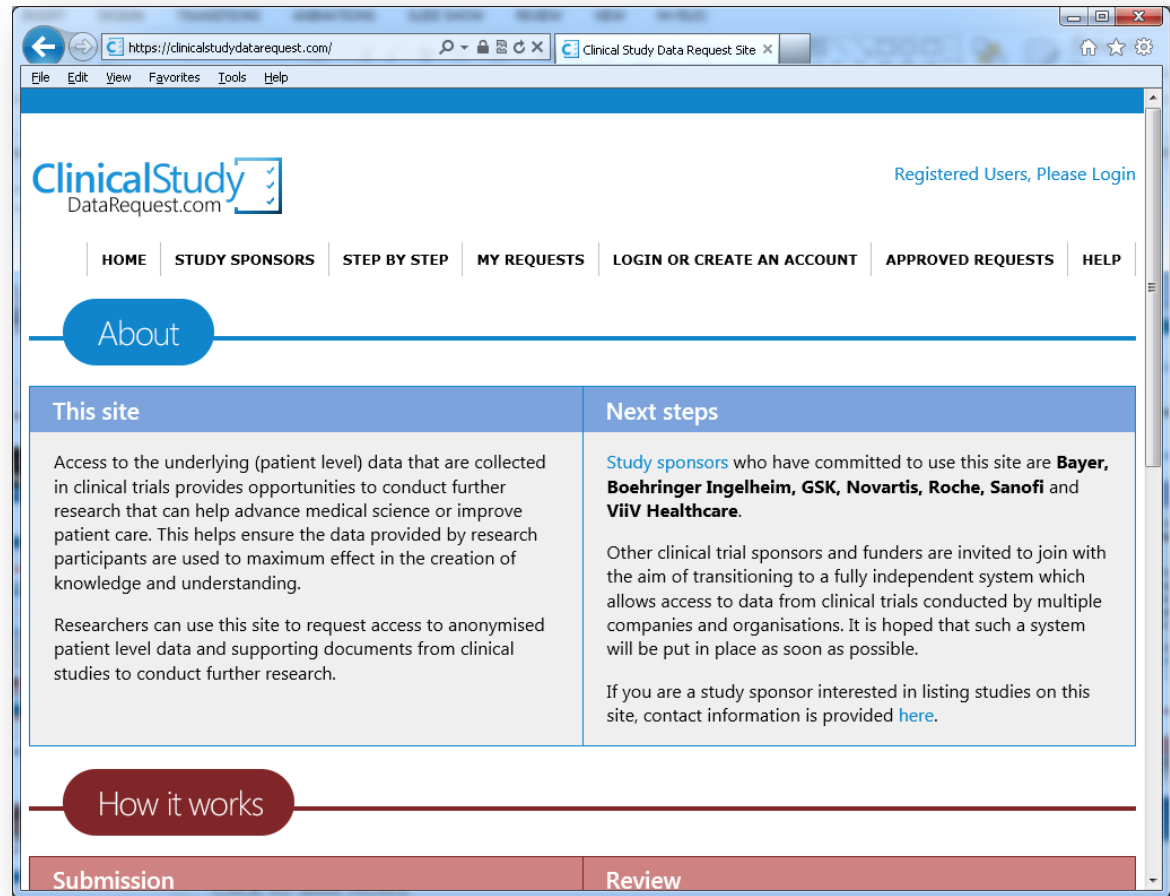


Vs



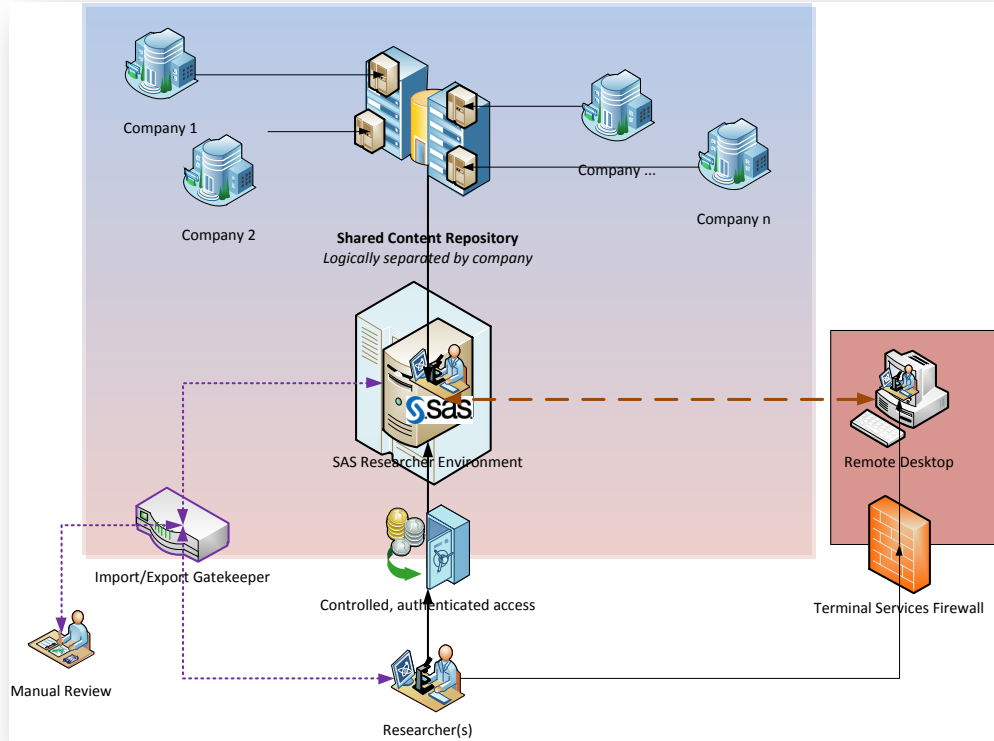
MULTI-SPONSOR DATA REQUEST SITE

- 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

- 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

- 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

- 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

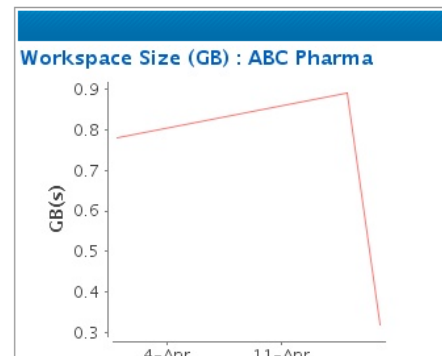
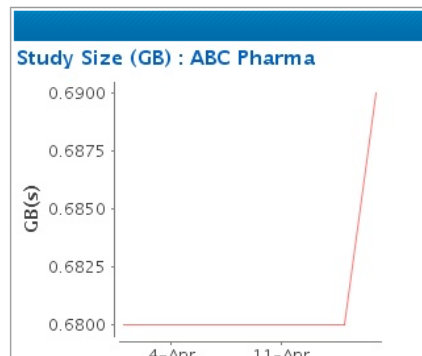
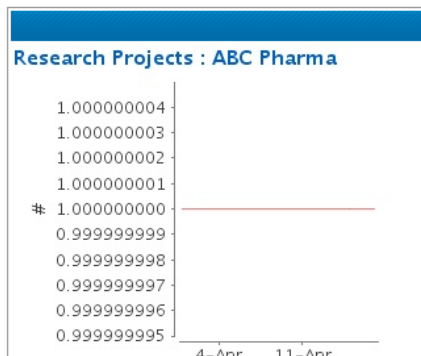
SAS CLINICAL TRIAL DATA TRANSPARENCY

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

By Company:			
Last Updated: 17-APR-14 12:58:46 EDT			
Company	Type	Status	Size
ABC Pharma	Large	Active	63.976562 MB



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_abcdadmin	ABC Pharma Admin	Account Created	✓	✓	ABC Pharma	• CTD T ABC Pharma Admin	• ABCP-85890 • ABCP-88877	• ABC Pharma	
Barnes	Karen	barnesk	Lead Researcher	Account Created	✓	✓	Pharma Research	• CTD T RP-USERTEST - Full	• ABCP-85890 • ACME-12345 • ACME-12987 • CTD T RP-USERTEST	• ABC Pharma • ACME	
Researcher General		ctdt_researcher	Researcher	Account Created	✓	✓	State U	• CTD T RP-12345 - Full	• ABCP-85890 • ACME-12345 • ACME-12987 • CTD T RP-12345	• ABC Pharma • ACME	
Researcher Lead		ctdt_leadresearcher	Lead Researcher	Account Created	✓	✓	State U	• CTD T RP-12345 - Full	• ABCP-85890 • ACME-12345 • ACME-12987 • CTD T RP-12345	• ABC Pharma • ACME	

ACCESS RESEARCHER VIEW – REMOTE DESKTOP

The screenshot displays a remote desktop session of the SAS Clinical Trial Data Transparency application. The interface is divided into several sections:

- Top Bar:** Features the SAS logo and the text "SAS Clinical Trial Data Transparency".
- Menu Bar:** Includes "View", "Tools", "Administration", and "Help".
- Toolbar:** Contains icons for file operations and session management.
- Sidebar:** Displays a file tree for the "CTDT MSE" repository, including folders like "FilesTypes", "Global Library", and "Files".
- Main Editor:** Shows the SAS code for the "convert_to_r.sas (1.0) [read-only]" script. The code includes:

```
1 libname saslib1 "&_SASWS_/CTDT MSE/ACME-98765/Files/Analysis Ready Datasets/SAS_analysis/";
2
3 /***** ae *****/
4
5 proc contents data=saslib1.ae out=work.ae_itmp ORDER=VARNUM;
6 run;
7
8 data work.ae_info (keep=MEMNAME MEMLABEL NAME TYPE LENGTH LABEL FORMAT);
9 set work.ae_itmp ;
10 run;
11 proc export data=saslib1.ae
12 OUTFILE="&_SASWS_/CTDT MSE/ACME-98765/Files/Analysis Ready Datasets/R_analysis/ae.csv" DBMS=CSV REPLACE;
13 run;
14
15 proc export data=work.ae_info
16 OUTFILE="&_SASWS_/CTDT MSE/ACME-98765/Files/Analysis Ready Datasets/R_analysis/ae_info.csv" DBMS=CSV REPLACE;
17 run;
18
```
- Log Window:** Displays the execution log, showing the path to the SAS workspace and the successful completion of the export process.

```
47 5 $let _SASWS_ = %qsubstr(&_SASWS_, 2, %length(&_SASWS_) - 2);
48 6
49 7 $let _SASUSRWS_ = %nrstr("/sddshared/SASWorkspaces/bigibs/Users/bigibs");
50 8 $let _SASUSRWS_ = %qsubstr(&_SASUSRWS_, 2, %length(&_SASUSRWS_) - 2);
51 9
```
- Status Bar:** Indicates "Errors: 0" and "Warnings: 0".

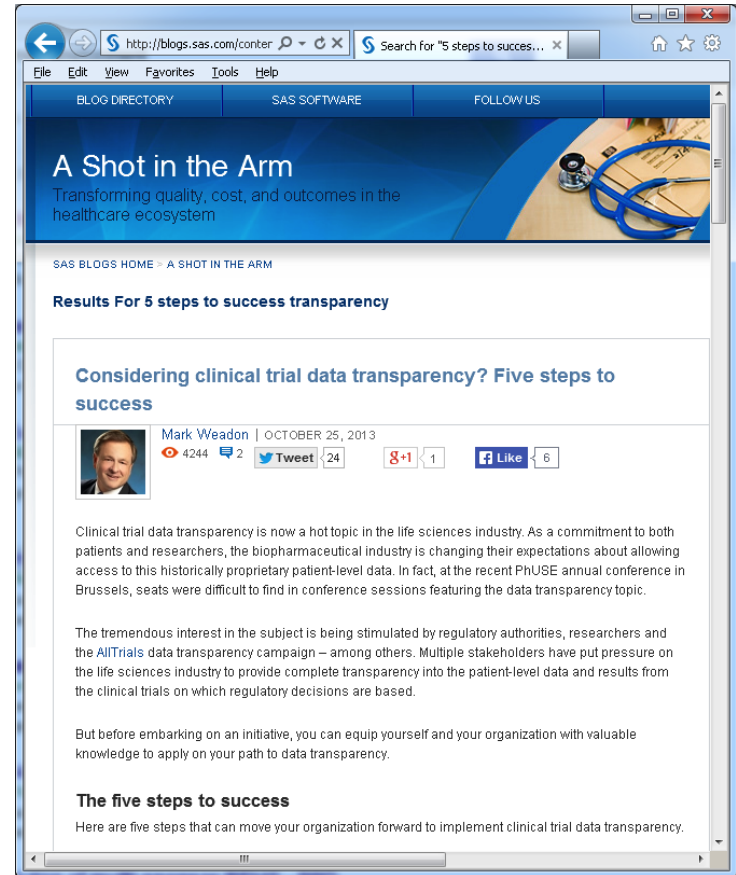
5 STEPS TO SUCCESS



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>

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Thank you!