

IT ENVIRONMENTS FOR CTDS



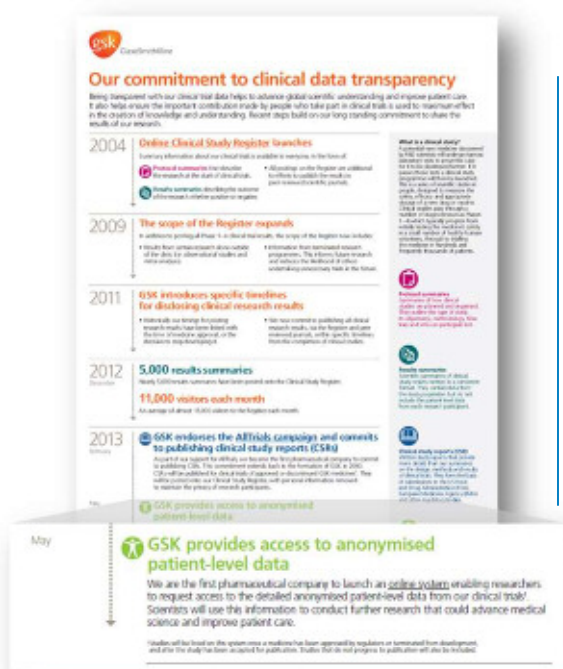
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SAS Institute Japan
June 30, 2015

CTDT* ADOPTION AND USAGE



* Clinical Trial Data Transparency

CTDT CTDT USAGE AND TRENDS



Early 2013

Late 2013

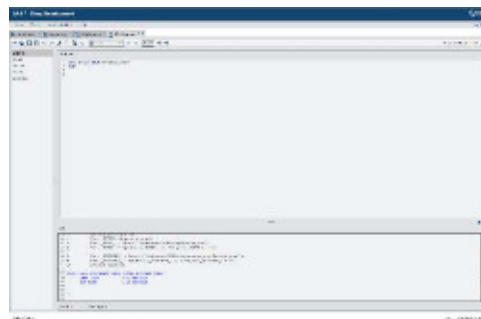
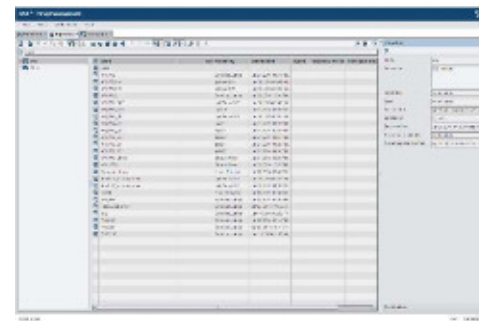
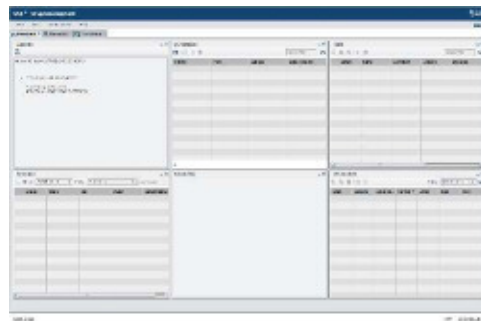
2014

Sponsors participating

1

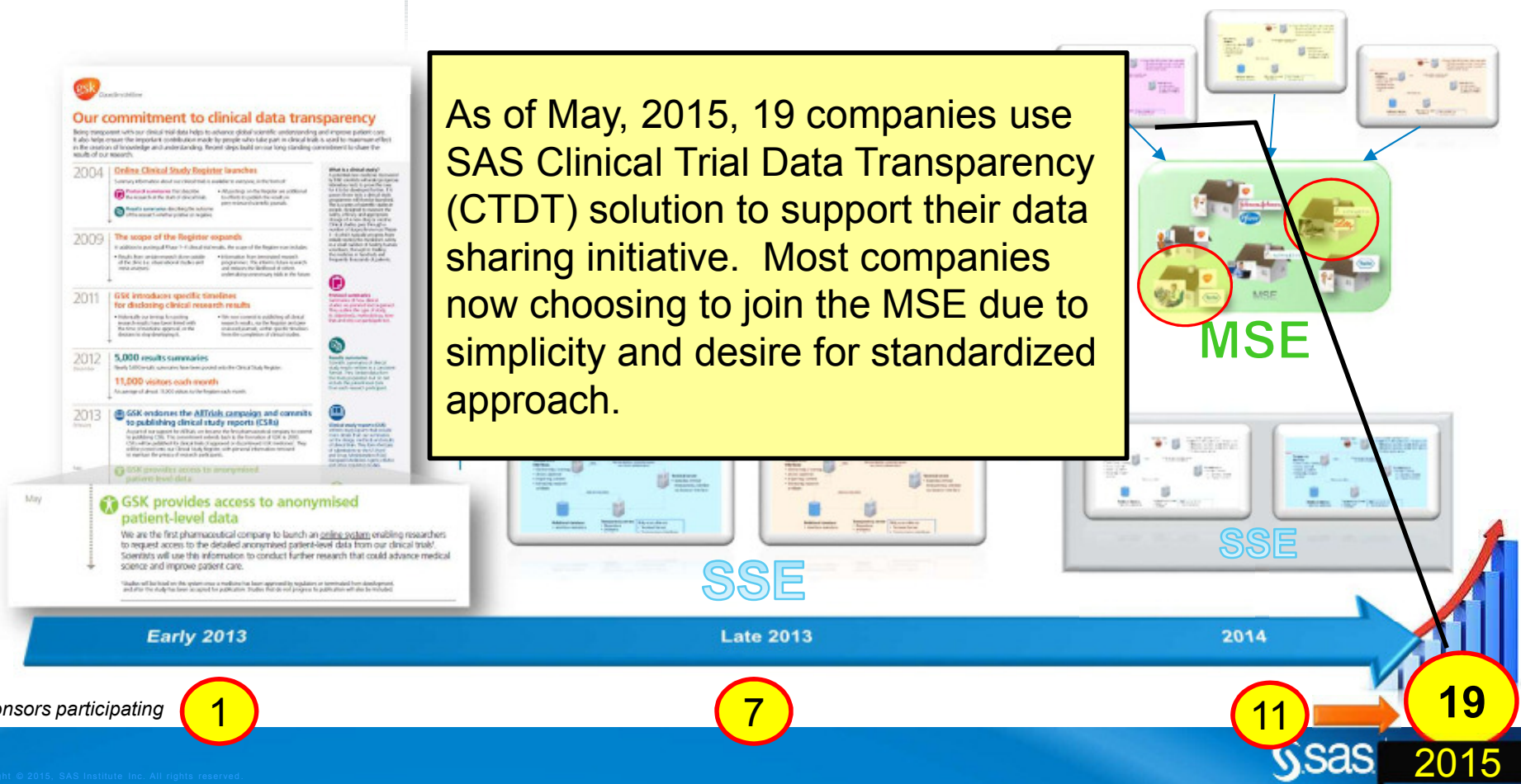
CTDT OVERVIEW OF SAS DRUG DEVELOPMENT (SDD)

SDD is Part 11-compliant web-based CDR (clinical data repository) & SCE (statistical computing environment) for clinical development. CTDT was developed based on SDD.



- Dashboard / Repository / Workspace
- Versioning / E-signature / Check-in/Check-out / Groups / Permissions / Privileges / Audit trail
- SAS Program Development / Execution
- Hosted Environment

CTDT CTDI USAGE AND TRENDS



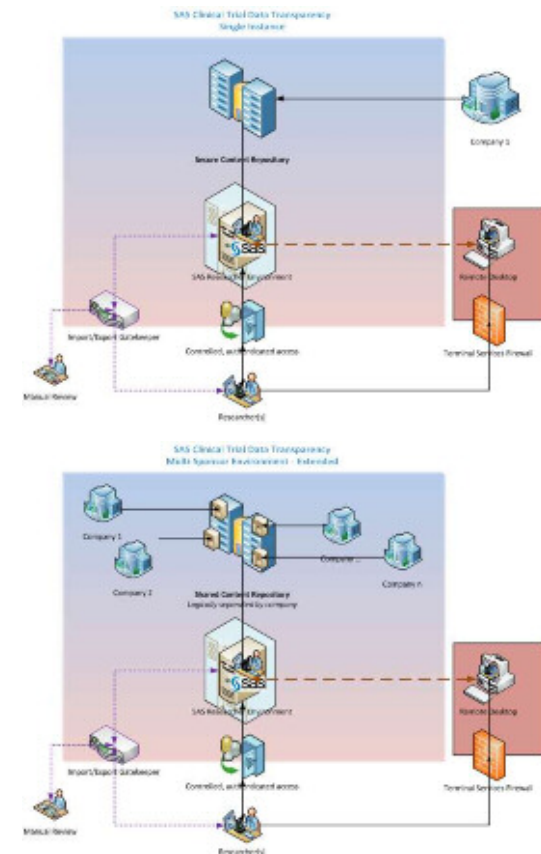
CTDT SINGLE SPONSOR VS. MULTI-SPONSOR ENVIRONMENT

SINGLE SPONSOR ENVIRONMENT (SSE)

- Individual company owns the instance
- Physically separated hardware and data storage

MULTI-SPONSOR ENVIRONMENT (MSE)

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



CTDT SOLUTION OVERVIEW

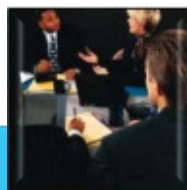


CTDT SOLUTION'S COMPONENTS



Public access site

- Researcher request process
- New data inquiries



Independent Review Panel and Process

- Panel
- Notification



The Researcher Access Solution

- Secure storage and access of data
- A collaborative, analytic environment
- Easily accessible from anywhere with all tools included



Multi-Sponsor Environment

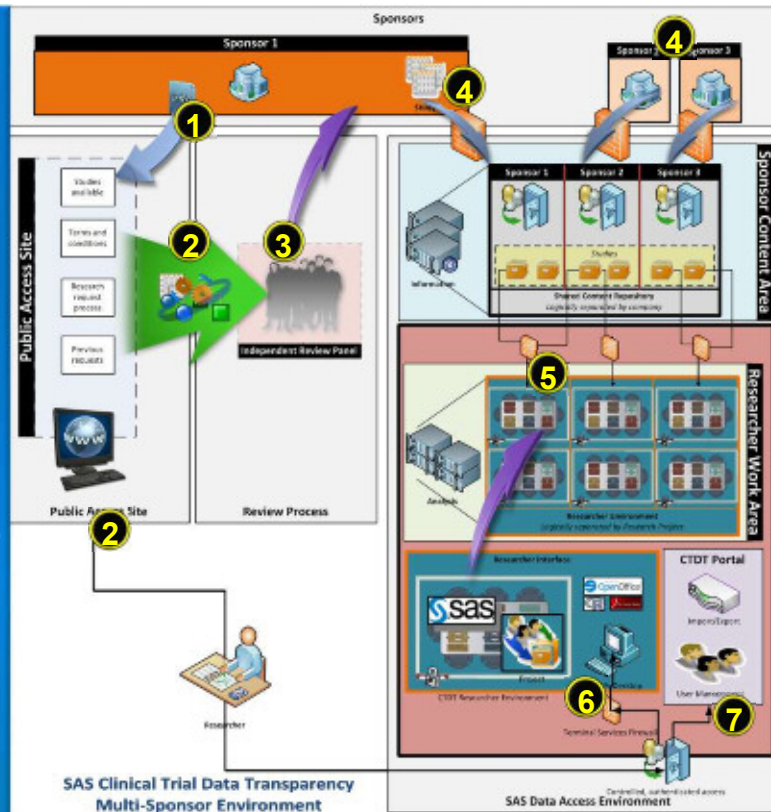
- Playing nicely with your peers

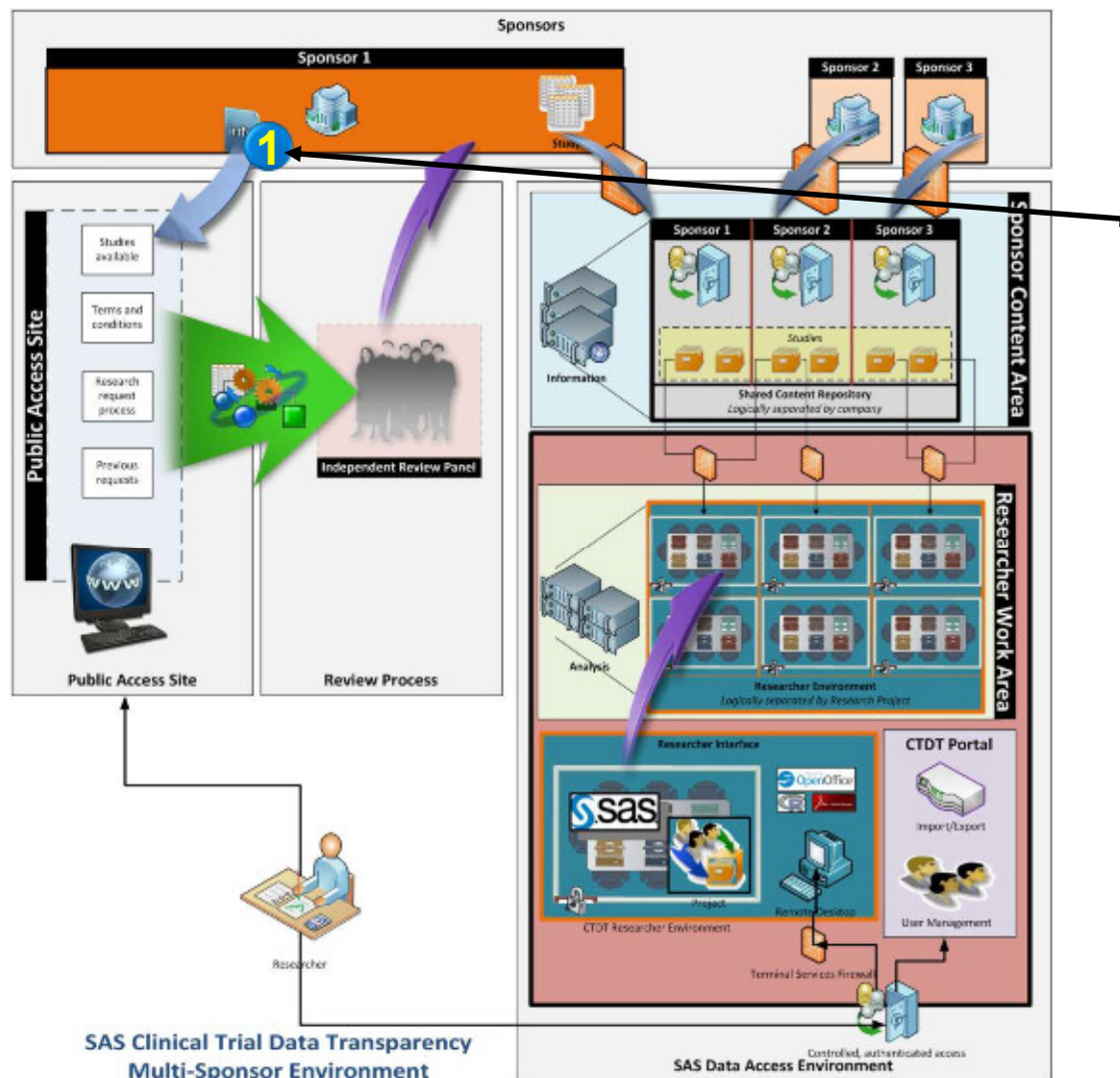
CTDT HIGH LEVEL OVERVIEW AND FLOW

Flow

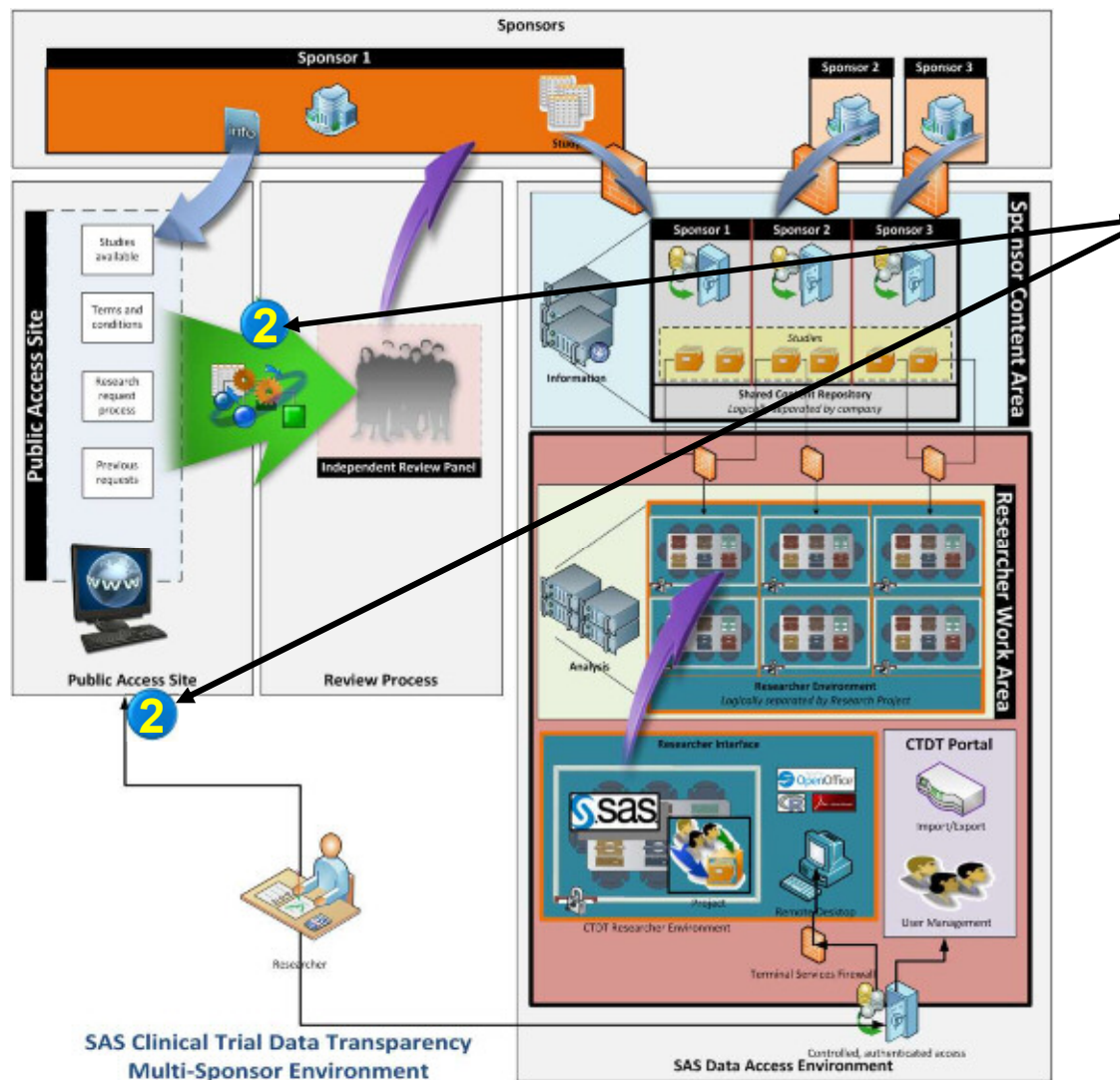
1. List of available studies
2. Researcher request
3. IRP Review
4. Notification to Sponsor(s)
5. Research environment set up
6. Researcher access and analyses
7. Administrative requests

High Level Overview

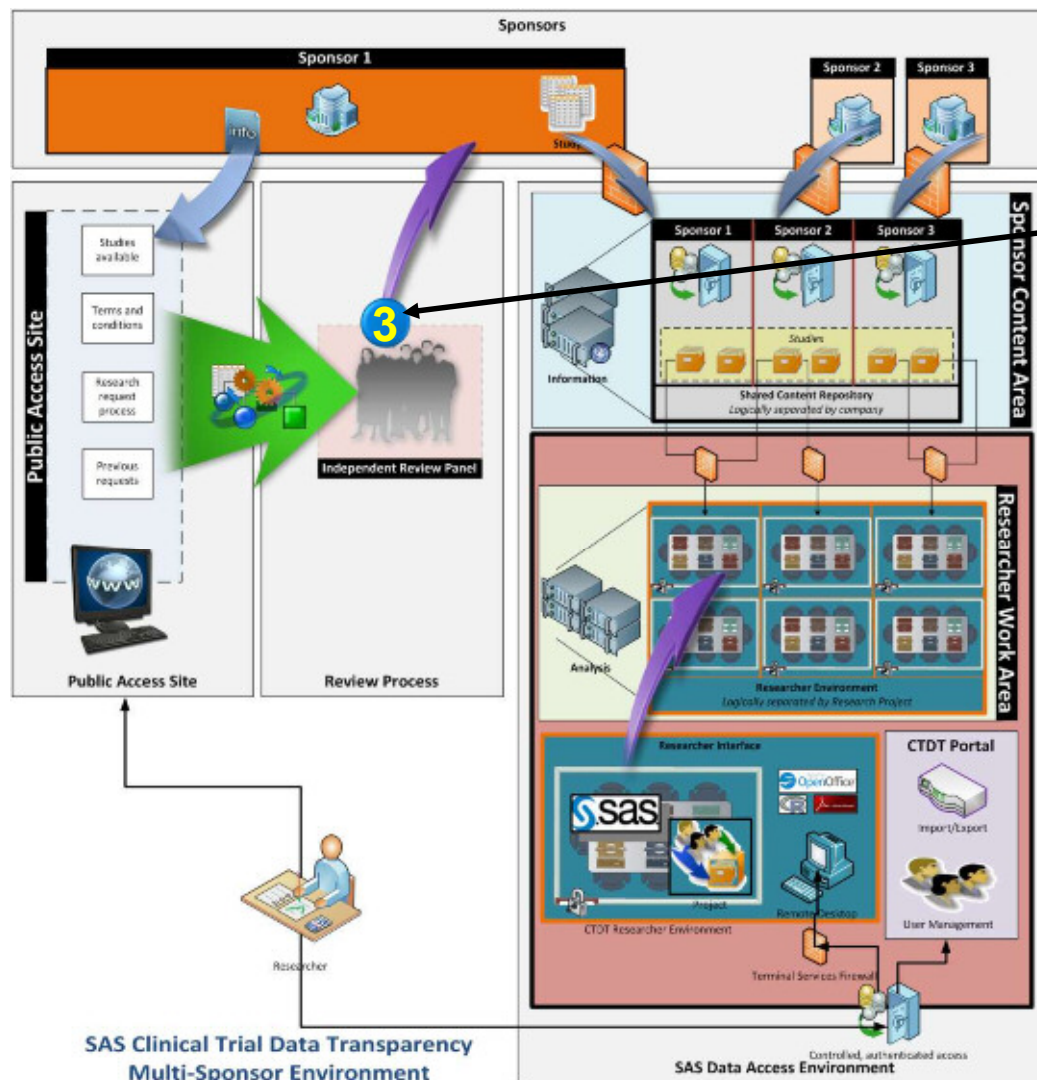




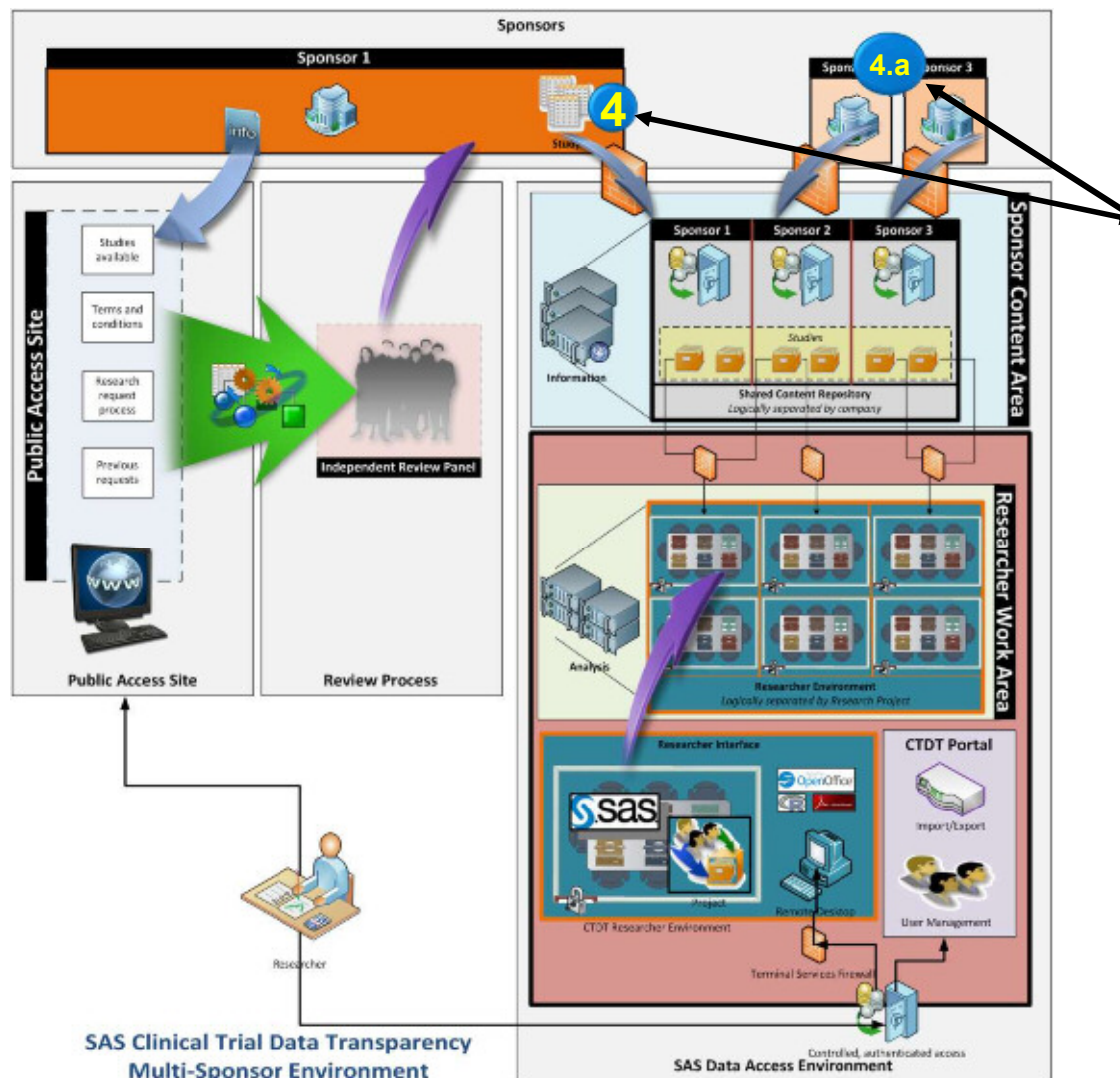
1. Sponsors list on public access site the list of studies available. They also list how to request access to the information, the terms and conditions to use their information as well as what other research requests have been made.



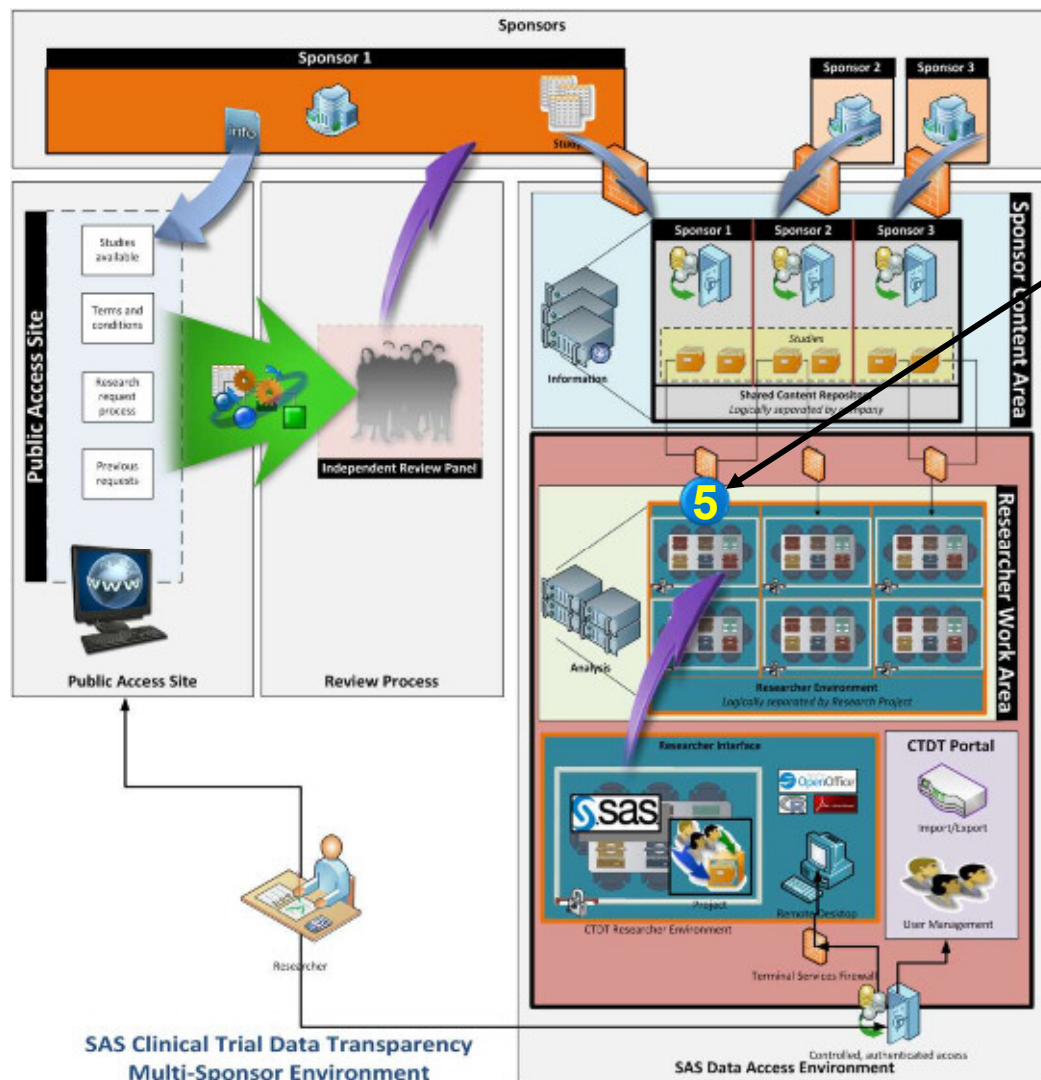
2. Researcher accesses the Public Access site, fills out appropriate request form and submits.



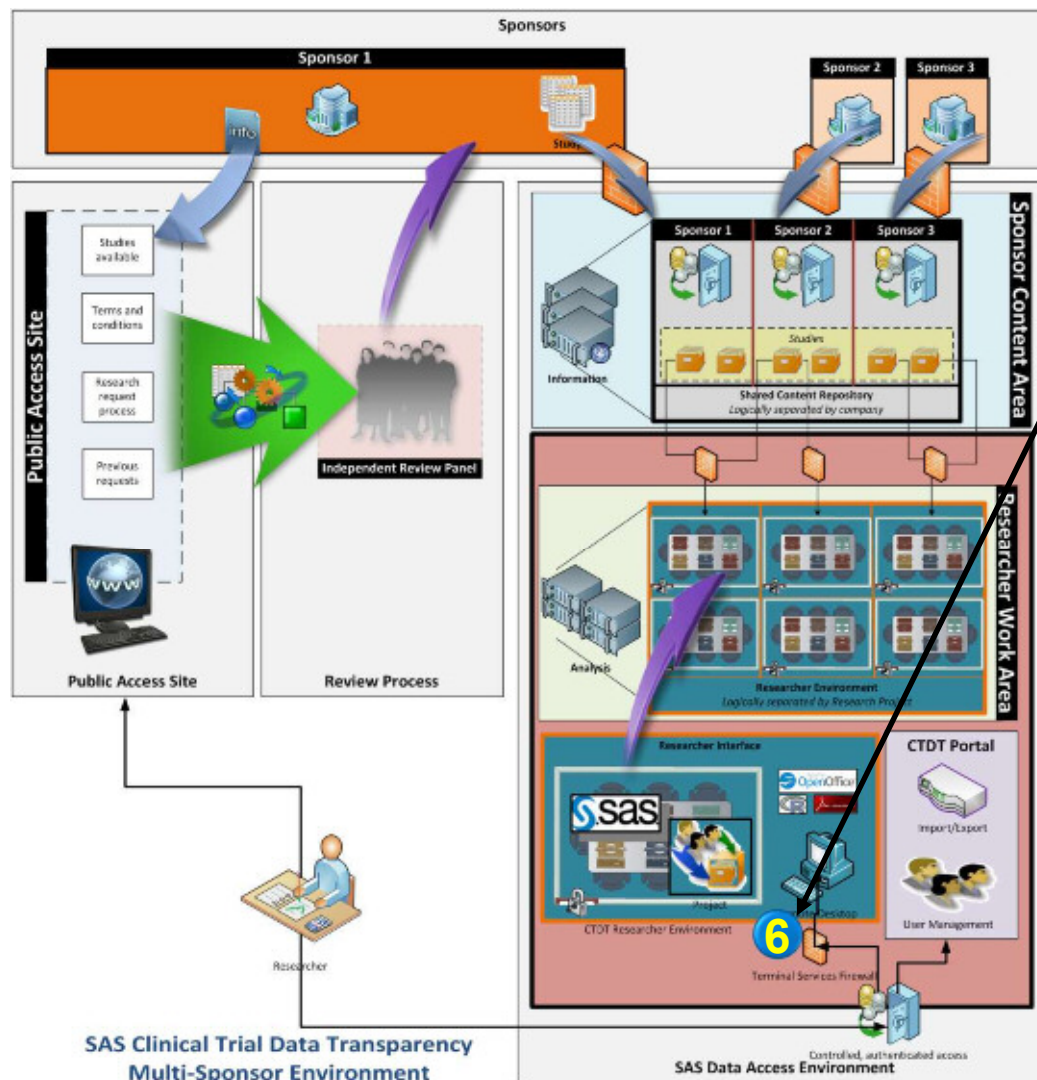
3. Sponsor's review panel reviews request. If approved according to Sponsor's criteria, Sponsor is notified. If rejected, Researcher is notified with reason and given opportunity to request again if appropriate.



4. Sponsor gets information from studies requested and prepares data for sharing (standardize and de-identified). Information is loaded into Sponsor's secure information area in CTD environment.
 - a. If multiple Sponsors' data is requested, other Sponsors load their information into their separate content area.



5. Private research project area is set up for researchers with read-only access to the information from all of the Sponsors contributing data to the analysis.

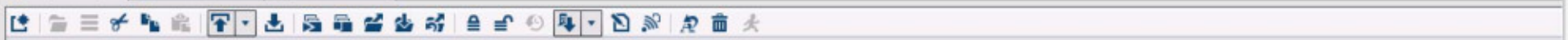


6. Researcher(s) log in to their private research area with their unique ID and password. They access a remote environment where they have secure access to the information as well as a variety of analytical tools and supporting tools in order to do all analyses within environment.

SAS® Clinical Trial Data Transparency

[View](#)
[Tools](#)
[Administration](#)
[Help](#)

Repository x Workspace x Dashboard x



[/CTDT/ACME-12987/Files/Analysis Ready Datasets](#)

[illegible]

Dashboard x Repository x Workspace x SAS Session 1: myprogram.sas x

Default

Session Status: IDLE

Editors

Inputs

Outputs

Listing

Libraries

myprogram.sas*

```
1 libname testlib "&_SASWS_/CTDT/ACME-12987/Files/Analysis Ready Datasets/SAS_analysis";
```

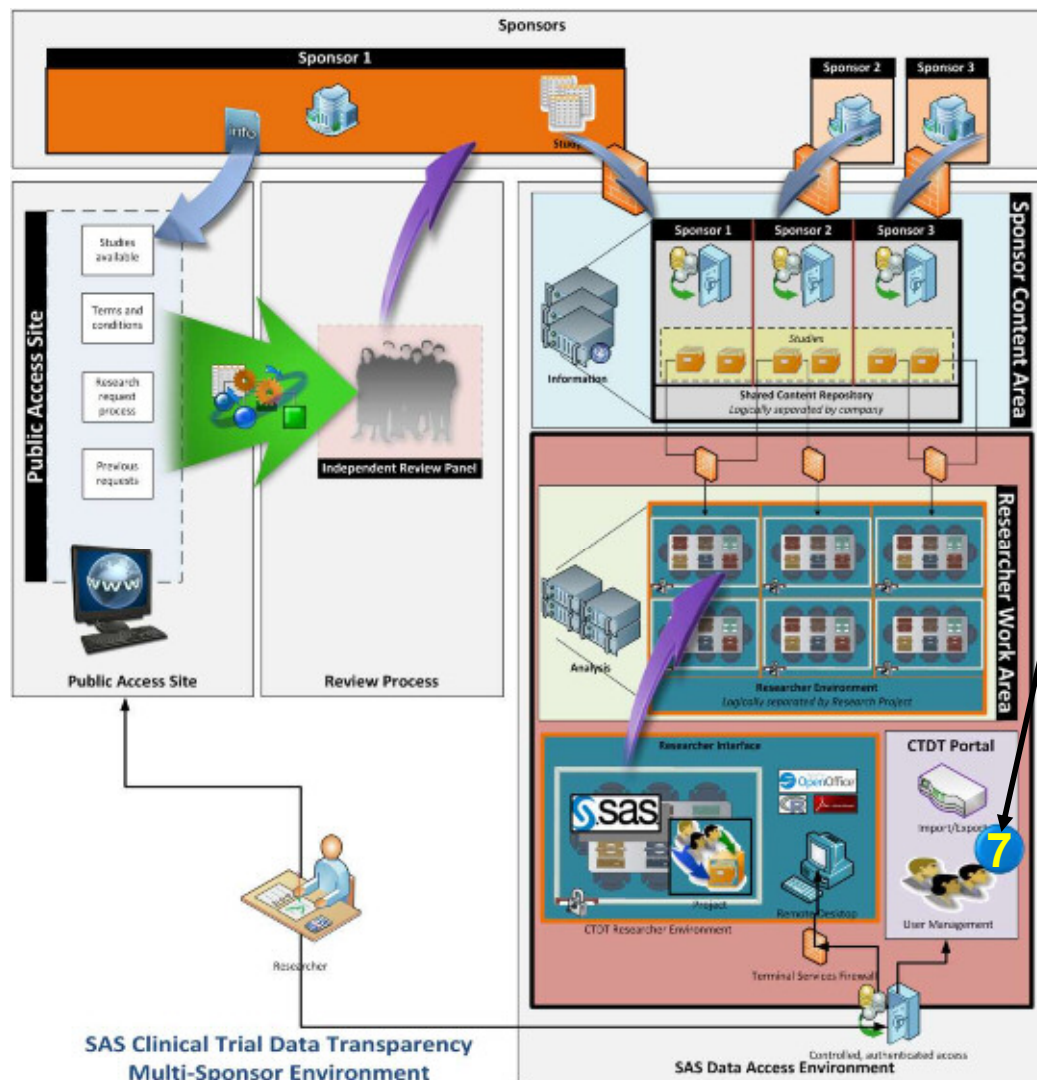
Log

```
100 35      ;*:*:*/*/*);run;quit;
101 36      proc scaproc; write; run;
102
103 NOTE: PROCEDURE SCAPROC used (Total process time):
104      real time          0.02 seconds
105      cpu time           0.00 seconds
106
107
108 37      options nonotes;
109 38
110
111 /*****
112  * Submission End: myprogram.sas*
113  * May 20 2014, 17:49:44 GMT
114  *****/
115
```

Errors: 0

Warnings: 0

[Action Status](#) User: [Test Researcher](#)



7. Researcher accesses CTDT Portal directly over web to request information to be uploaded or downloaded from CTDT environment. Also able to manage their accounts if necessary. Sponsors may access Sponsor-specific reports from the Portal.

IMPORT AND EXPORT PROCESS



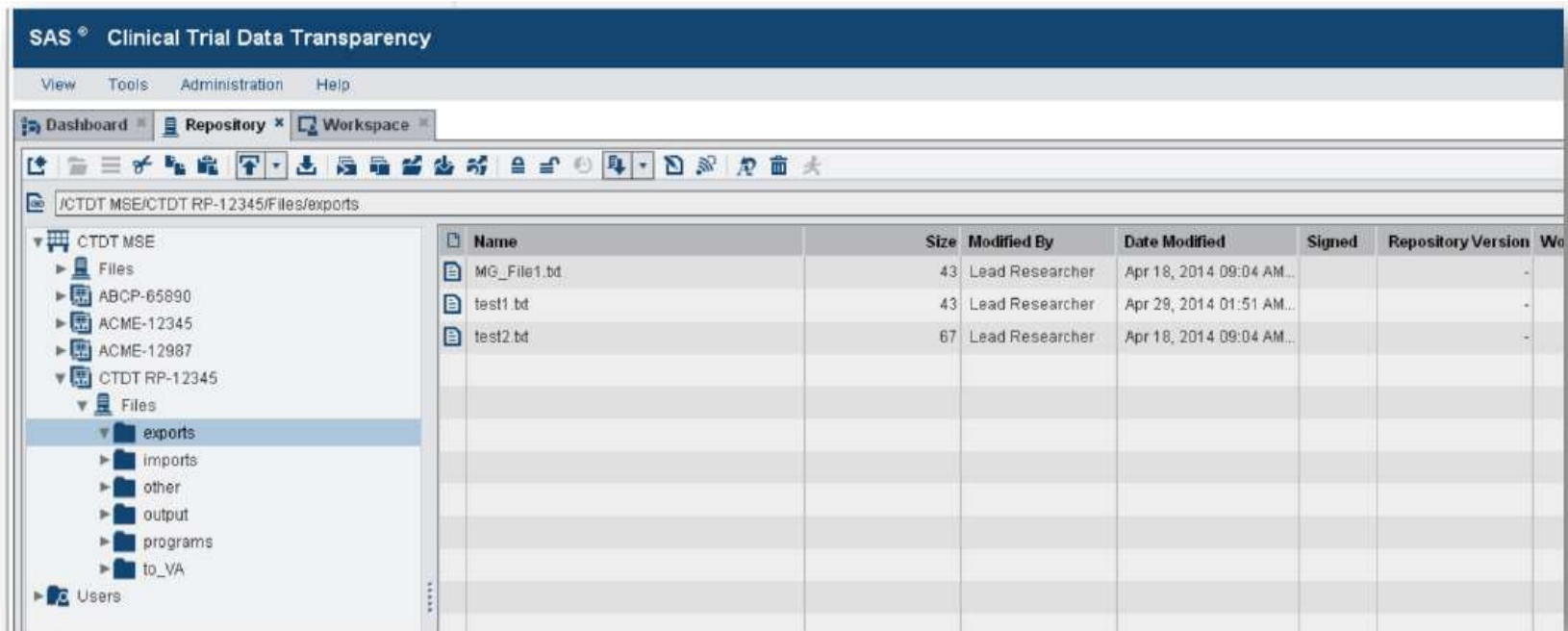
IMPORT AND EXPORT PROCESS

IMPORT AND EXPORT PROCESS

- Similar process for both
- Export Use Case
 - Researcher identifies what needs to be exported
 - Submits request
 - Request reviewed
 - If approved, sent to researcher

IMPORT AND EXPORT PROCESS

IMPORT AND EXPORT PROCESS



Researcher moves items into Exports folder

IMPORT AND EXPORT PROCESS

IMPORT AND EXPORT PROCESS

The image displays three overlapping screenshots of the Clinical Trial Data Transparency Portal interface.

Leftmost screenshot: Shows the login page. The header includes the SAS logo and the tagline "THE POWER TO KNOW." Below the header, there is a "Login" button and a "User ID" field containing "ctdt_leadresearcher". A "Password" field with masked characters is also present, followed by another "Login" button. At the bottom, there are links for "SAS.com" and "Support".

Middle screenshot: Shows the portal after login. The header now includes the user name "User: Lead Researcher" and links for "Help" and "Logout". The main navigation bar has "Home" and "CTDT Options". Below this, the "Section: CTDT Home" is selected, and a sidebar menu lists "Options" with sub-items: "Exports: List", "Exports: Add Request", "Imports: List", and "Imports: Add Request".

Rightmost screenshot: Shows the "Add Export Request" form. The header includes the user name "User: Lead Researcher" and links for "Help" and "Logout". The main navigation bar has "Home" and "CTDT Options". Below this, the "Section: CTDT Home" is selected, and a sidebar menu lists "Options" with sub-items: "Exports: List", "Exports: Add Request", "Imports: List", and "Imports: Add Request". The form itself has a title "Add Export Request" and a subtitle "Update of settings for the export occurs after add of the request." It contains fields for "User" (Lead Researcher), "Select Source Location for Export" (CTDT MSE/CTDT RP-12345/Files/Exports), "Option" (Full - Latest File), and a "Summary / Details" section with the text "Export of my current work". An "Add" button is at the bottom right.

Researcher logs into Export Request utility

Researcher fills out Export request

IMPORT AND EXPORT PROCESS

IMPORT AND EXPORT PROCESS

The screenshot displays the SAS CTD1 Options web interface. At the top, there's a navigation bar with 'Home' and 'CTD1 Options'. A green status message 'Request Added' is visible in the top right. The breadcrumb trail shows 'Section: CTD1 Home | Exports | Imports'. The main content area is divided into two panels. The left panel, titled 'Export Request', contains fields for ID (11), User (Researcher, Lead [LRES]), Summary / Details (Export of my current work), Option (Full - Latest File), Status (Approved to Start), Deleted? (checkbox), Revision (3), Last Modified By (Researcher, Lead [LRES]), Last Modified Date (29-APR-14 02:14:03 EDT), and a Comments section. The right panel, titled 'Export Paths', has an 'Update / Add' link and a list containing 'INCLUDE: /CTD1 MSECCTD1 RP-12345/Files/exports'. Below this is a 'Generated Exports' table with columns 'File', 'Date', and 'Comments', currently showing 'None'. An 'Update' button is at the bottom of the left panel.

File	Date	Comments
None		

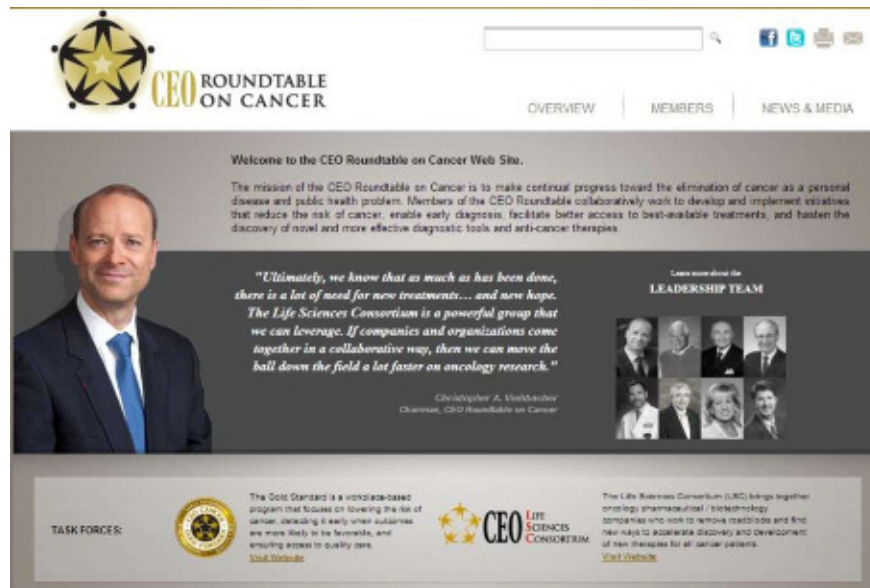
- System creates ticket and associates zip file of all information from export folder
- System automatically runs export rules
- If criteria triggered for manual review, ticket routed to appropriate reviewer(s) for the Sponsor
- When approved, zip file is sent to configured location

COMPARISON WITH OTHERS



COMPARISON WITH OTHERS

CEO ROUNDTABLE ON CANCER: PROJECT DATA SPHERE



- Under the leadership of founder and CEO, **Jim Goodnight**, SAS was among the first companies in the nation to achieve CEO Cancer Gold Standard™ accreditation
- As a charter member of the CEO Roundtable on Cancer, Dr. Goodnight has long recognized that employers have a unique opportunity to positively impact the health and well-being of employees and their families
- As part of his sponsorship of the CEO Roundtable on Cancer SAS is supporting Project Data Sphere by providing access to key technology to support the advancement of cancer research.

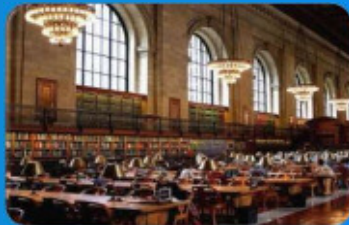
COMPARISON WITH OTHERS

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Office

- Secure environment
- Authenticate access
- Trust those inside with information
- Provide tools for work and collaboration
- Easy partner access



Library

- Unknown users
- Accessible information
- Need to register to check-out information
- Can do work there or take home
- Some work tools provided if needed



Castle

- Information secured inside
- Guards at gate
- All work done inside castle walls

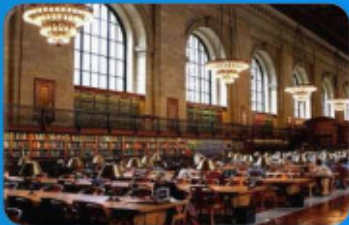
COMPARISON WITH OTHERS

COMPARISON WITH OTHERS



SAS Drug Development (Life Science Analytics Framework)

- Enables industry compliance
- Secure, easy to access environment
- Collaborative work environment
- Integrated SAS development and execution environment



Project Data Sphere

- Consortium approach to sharing lower-risk data
- Easy to access
- SAS Tools available
- Information can be exported to local environment



Clinical Trial Data Transparency

- Controlled access to information
- Gatekeeper approach to information in and out of environment
- Integrated SAS development and execution environment
- Third-party tools supported
- Enables researcher access across multiple sponsors' data

SUMMARY



CTDT SUMMARY

CTDS can safeguard the privacy of patients through using CTDT solution as well as de-identification and adequate research proposal and researcher selection process by IRP;

- ✓ Securely hosted system
- ✓ One-Time Password
- ✓ Secure content repository with Permissions / Privileges controls
- ✓ Secure access through remote desktop
- ✓ Controlled download and upload of data

