

Integrating a sponsor CTMS with data from a CRO

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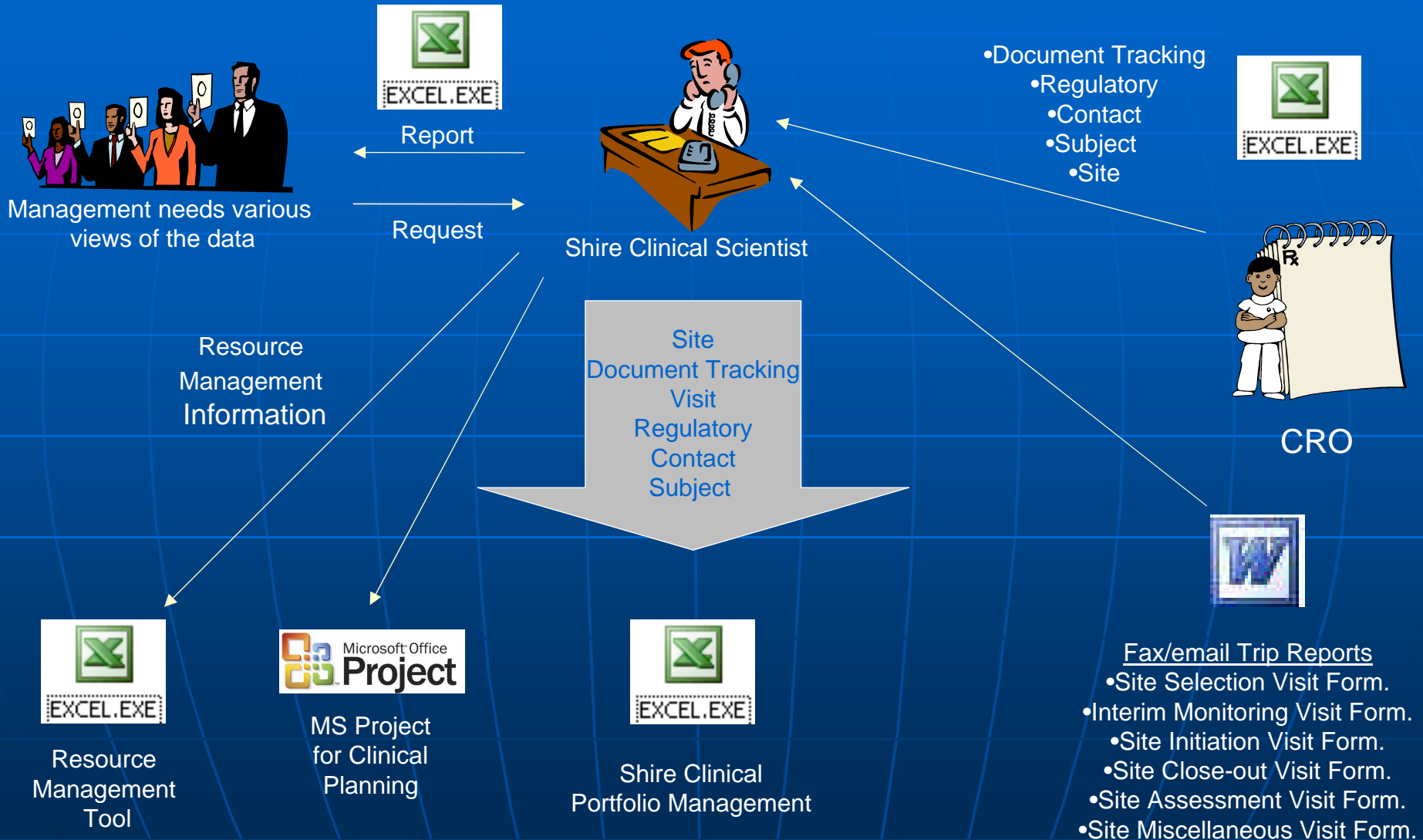
What is the Shire CTMS?

- n Shire outsources a majority of their Clinical Trials to CROs.
 - Need a view of the day-to-day information about our trials.

- n Clinical Trials Management System: creates a single view for all Shire employees of our clinical portfolio.
 - Data: Creates a single repository that contains a complete clinical trial portfolio.
 - Import: Enables study teams to easily enter their data into the system.
 - Reports: Provides access to the information through robust reporting capabilities.

- n Study teams no longer need to maintain additional Excel spreadsheets or Access databases with trial information.

Where we came from.....



Where we are now.....



CRO creates data feeds directly into the Shire CTMS



Resource Management Tool



Shire Clinical Scientist



Management needs various views of the data

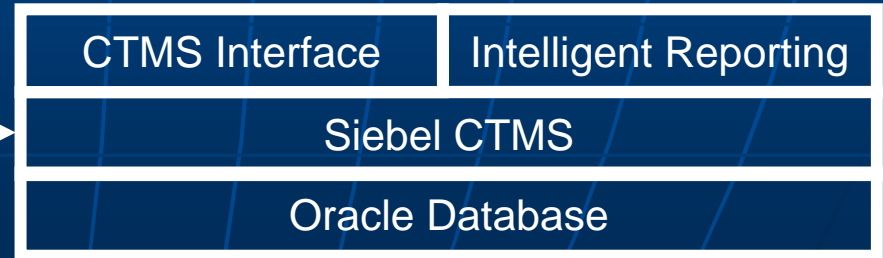
- Site
- Document Tracking
- Visit
- Regulatory
- Contact
- Subject



Adobe Forms

- Monitor fills out trip reports
- They are automatically uploaded to Shire CTMS

Secure Internet Site



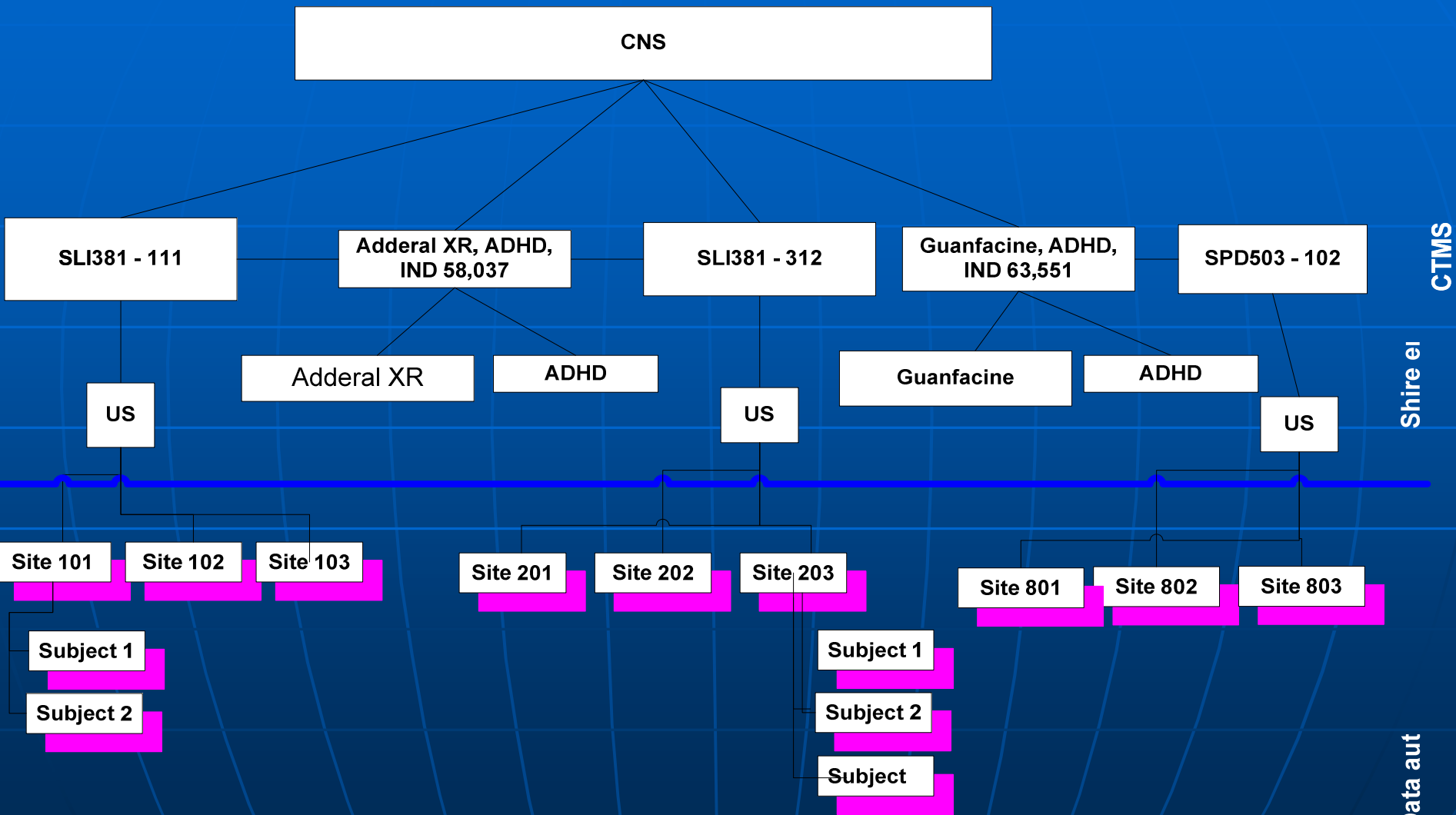
CTMS History

- n Live and in production since May-2006
 - Base Siebel CTMS (Version 7.8.2)
 - Siebel Business Analytics

- n Fully Validated environment
 - Followed all relevant IS SOPs (Shire Project Quality Model)
 - CTMS has 3 environments
 1. Development
 2. Test
 3. Production

- n Users were heavily involved in the project
 - Created and approved requirements
 - Assisted with testing and system acceptance
 - Conduct on-going training (1 on 1 and group sessions)

High-level View of CTMS Data



CTMS

Shire e

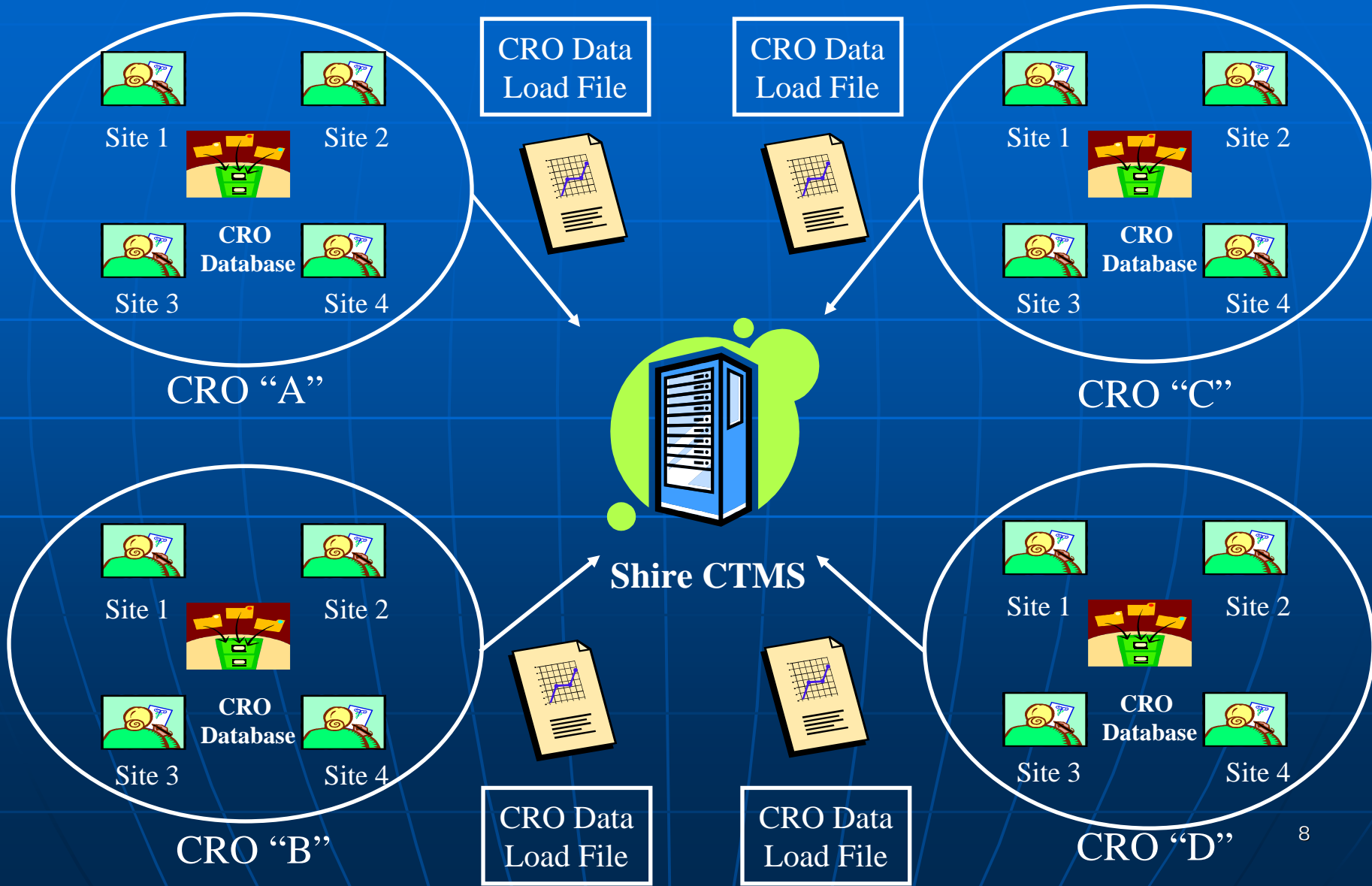
CRO Data aut

CTMS Current State

- n Create an interface for data exchange with our CROs
 - Develop generic data file formats that CROs would send to Shire (daily, weekly or monthly depending on the the study)

- n Manage Trip Reports created by CROs
 - Upgraded the Shire Trip Report templates (Word to PDF Forms)
 - Provided a utility to allow Shire and CROs to collaborate on Trip Reports
 - CTMS links to the final version of the Trip Report (extract some data)

Solution: Central CTMS



CRO Data Interface

- n Information is passed to Shire through a secure portal
 - Typically transferred once a week (can vary on trial)
- n There are 6 types of Data Files
 - 1.Site
 - 2.Document Tracking
 - 3.Visit
 - 4.Subject
 - 5.Regional Ethics and Regulatory
 - 6.Study Contact
- n Each row of data contains the following identification (header info):

Protocol#	PI Last Name
Site#	PI Street Address
Site Integration ID	PI City
PI Integration ID	PI State or Province
PI First Name	PI Country
	PI Postal Code

Trip Report Interface

- n PDF Forms were used to create a standard interface.
 - CROs only need Adobe Reader to edit forms.
 - CROs use the Shire Secured Gateway to exchange forms.
- n Six types of trip report templates were created.
 1. Site Selection Visit Form.
 2. Interim Monitoring Visit Form.
 3. Site Initiation Visit Form.
 4. Site Close-out Visit Form.
 5. Site Assessment Visit Form.
 6. Site Miscellaneous Visit Form.
- n Trip Report is matched within the CTMS.
 - PI Name and Address, Protocol # and Visit Start Date and Visit Type.

Sample Trip Report

Shire
INVESTIGATOR SITE SELECTION REPORT

Protocol No: Site No: NA Visit Start Date:
 Visit End Date:

Investigator Name: First: <input type="text"/> Last: <input type="text"/>	Monitor Name: Title: <input type="text"/> First: <input type="text"/> Last: <input type="text"/>
Investigator / Institution Address Address1: <input type="text"/> Address2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Postal: <input type="text"/> Tel: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>	Monitor Company Name Address: Address1: <input type="text"/> Address2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Postal: <input type="text"/> Tel: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>
Study Coordinator Address (if different from above): N/A <input type="checkbox"/> Address1: <input type="text"/> Address2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Postal: <input type="text"/> Tel: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>	Pharmacy Address (if different than Investigator address): N/A <input type="checkbox"/> Address1: <input type="text"/> Address2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Postal: <input type="text"/> Tel: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>
Local Laboratory Address (if different than Investigator address): <input type="text"/>	Other (e.g., satellite site, radiology department [if different than Investigator address]): <input type="text"/> Address1: <input type="text"/> Address2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Postal: <input type="text"/> Tel: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>

DRAFT

SPD476-404 About Affi 100

Menu | New | Delete | Query

Site #: 100 Protocol #: SPD476-404 Account: Aurora Sinai Medic Withholding Amount:
 PI First Name: Aboud PI Last Name: Affi Region: USA Withholding %:
 Versions: RBEC Approval Date: 11-May-2007 Currency Code: Exchange Date:
 Contract Amount: No Subject Info: Site Initiated: Site Terminated:

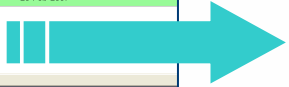
More Info | Activities | Attachments | Site Monitor | Contacts | Document Tracking | Site Visits | Ethics Committee | Subjects

Site Visits Detail | Site Visit Issues | Site Visit Issues By Visit Type | Site Visit Report By Visit Type

Visit Name	Visit Type	Received Date	Comments	Active Monitor	Visit Monitor	Visit Status	Visit Start	Visit Completed	Initial Report Com Assigned To
PSV	Site Selection Visit	25-Jul-2007		David Uhir	Katie Frank	Completed	22-Feb-2007	22-Feb-2007	23-Feb-2007

Posted Visit Attachments | Menu | Delete | Query | New File

Attachment Name	Type	Size	Modified	Auto Update	Comments
Aff_100_PSV_Final_ZF_xdp		5,812	25-Jul-2007 09:52:1	<input checked="" type="checkbox"/>	



Success Factors for CRO Integration

1. Over-communicate.

- Prepare User Guide for CRO partners to reference
- Agree to and sign data mapping specification
- Provide data file examples for the CRO to model from
- Mutually agree to timelines

2. Limited scope of the initial release.

- Focused on 6 basic transactions.
- Make it easy for any CRO regardless of technical capabilities and resources.
- **DO NOT IMPACT THE STUDY!**

Integration Plan

Initial Planning 10 days

- n Identify CRO single point of contact
- n Initial walk thru and presentation of Data Mapping with CRO,
- n Create and explain CRO Data Mapping Specification template
- n Data Mapping analysis , 5 days, SHIRE, CRO
- n Data Mapping Gap Analysis and drop down mediations
- n Estimates of time and effort to close Gaps

CRO Development 10 days

- n CRO prepares test files
- n CRO delivers test files

Shire Development 10 days

- n Document & Communicate Protocols that are participating
- n Document & Communicate - CRO specific Ids
- n Create CRO data folders in development
- n Create CRO SharePoint on test Website

Setup CRO for Data feed - Development environment

- n Setup CRO folder for EIMScheduler
- n Setup CRO Oracle control files
- n Add EIMScheduler job for the CRO
- n Test CRO Database changes in Development Environment

Integration Plan (cont.)

Load test files into development, 3 days

- n Review, analyze, and give feedback on initial loading of test data files
- n Requested changes are documented and communicated
- n Data Mapping specification is approved by both parties

Shire Testing Environment Preparation , 3 days

- n Create CRO data folders in Test environment
- n Setup CRO for Data feed in Test environment
- n Setup CRO folder for EIMScheduler
- n Setup CRO Oracle control files
- n Add EIMScheduler job for the CRO
- n Test CRO Database changes in Test environment

Systems Test, 7 days

- n Deliver a month worth of CRO data for system testing
- n Systems testing of the test files
- n Post testing Review

Integration Plan (cont.)

Production Roll Out, 3 days

- n Preparation for production deployment
 - n Create CRO data folders in production
 - n Create Sharepoint sub website in production for CRO
 - n Setup CRO for Data feed - Production environment
 - n Copy CRO folder for EIMScheduler from test environment
 - n Copy CRO Oracle control files from Test environment
 - n Schedule EIMScheduler job for the CRO
 - n Delivery of final files to be loaded into production
 - n Review CRO Production Data files
 - n Go Live
- Post Deployment review and support

CTMS Transfer Phases

- n Preparation & Development
 - Communication is critical to establish expectations and determines success of transfer implementation.
- n Implementation
 - Educate study teams to perform tasks
- n Maintenance
 - Ensure quality and documentation evolution

Preparation & Development

- n Analyze transfer specifications to establish expectations
 - Provide single point of contact.
 - Discuss how information is maintained in CRO CTMS.
 - Evaluate data transfer from external vendors to integrate data for providing consolidated data sets.
 - Assess how often data is updated to ensure sponsor reporting needs are met.
 - Content of transfer files through GAP analysis.
 - Method used to submit files to Sponsor.
 - Maintenance plan to support process after implementation.

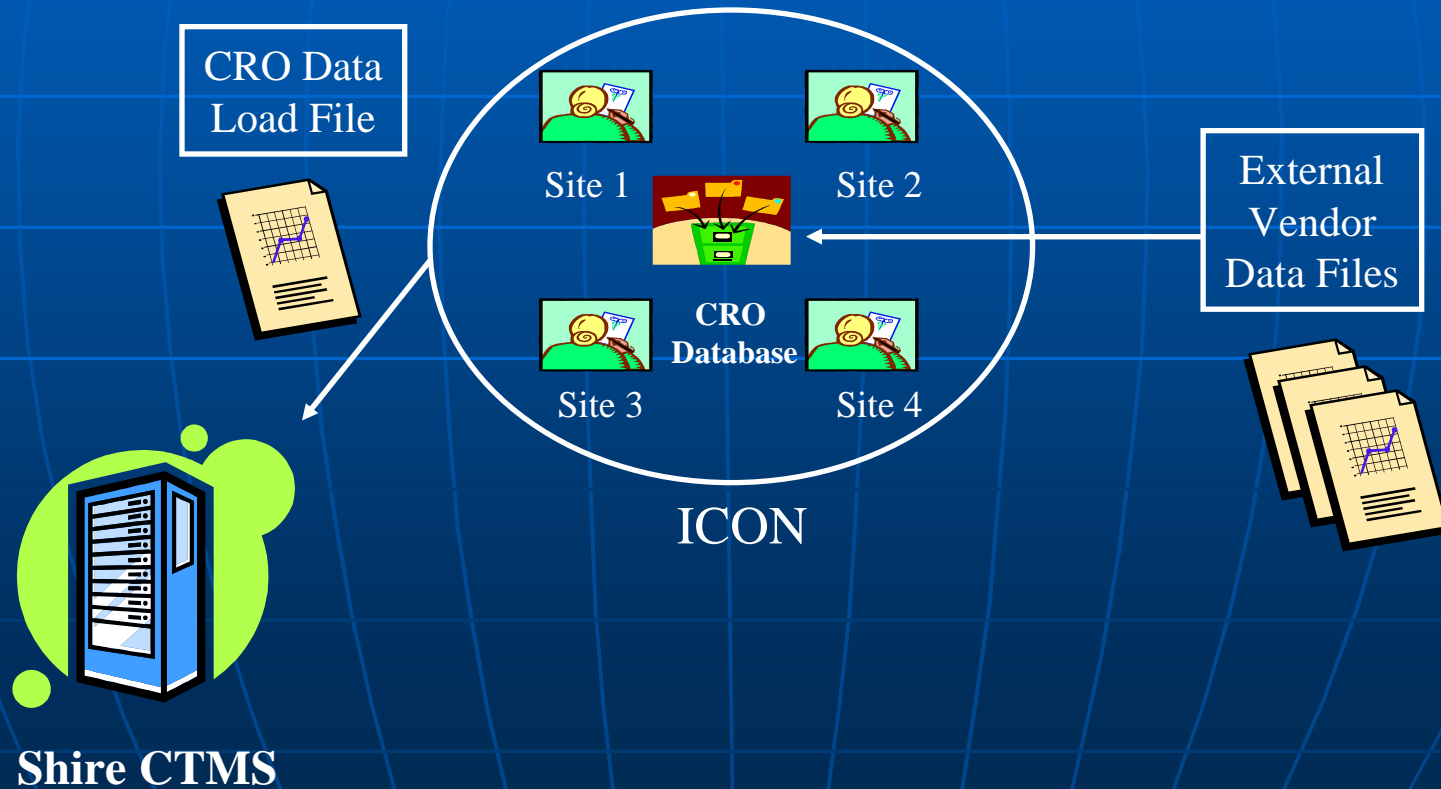
- n Conduct development and create documentation
 - Maintain global focus on reusability for future opportunities.
 - Create extract specifications and transfer utility.
 - Standardize configuration guidelines for future studies.
 - Create process documentation and study team training materials.

ICON: CRO Perspective

Centralize Vendor Information

Consolidating External Vendor Data

- n Minimize feeds to sponsor by working with external vendors for EDC, IVR, etc.



ICON: CRO Perspective

Implementation Phase

- n Establish forum with study teams
 - Facilitates communication with study teams
 - Communicate support plan and contact for study teams

- n Educate Study teams
 - Communicate expectations of study team.
 - Review transfer process and transfer frequency.
 - Review how information will be maintained.
 - Review integration of other vendor information.

- n Support
 - Offer central support contact for study teams.
 - Work closely with study team through initial transfers.
 - Establish integration from external vendors.

ICON: CRO Perspective

Maintenance Phase

- n Communicate updates for both parties
 - Ensure compatibility as CTMS versions evolve.
 - Obtain feedback from Sponsor to evolve guidelines and maintain data integrity.

- n Evolve process documentation
 - Analyze feedback from previous transfers for opportunities to streamline documentation and data entry guidelines
 - n Obtain feedback from study teams.
 - n Monitor data transfer logs.

- n Monitor CTMS transfer process
 - Communicate support plan and contact for study teams
 - Work closely with new study teams through initial transfers.
 - Analyze process for additional efficiencies.

ICON: CRO Perspective

Summary Statements

- n CTMS Transfer offers the most efficient way to get information to Sponsor study team.
 - Minimizes reporting needs
 - n Sponsor CTMS provides reporting capabilities for Sponsor study team.
 - n Reduces study team resource time required to deliver customized reports.
 - n Internal reporting standardized.
- n Increasing trend for CTMS Transfer functionality.

Questions?

Thank You!