

AUTOMATED SDTM CREATION AND DISCREPANCY DETECTION JOBS: THE NUMBERS TELL THE TALE

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PhUSE Conference 2014

12-15 Oct 2014

WHEN YOU NEED TO BE SURE



- Setting the scene
 - SGS' Conversion Center
 - SDTM data sources
 - Timing for CDMS data refresh
- SGS' Conversion Center
 - Glossary
 - Technologies used
 - What is it?
 - Code snippets
 - Performance tuning

SETTING THE SCENE: SGS' CONVERSION CENTER

REQUEST

DOWN
LOAD

INSTALL

CONVERT

META
DATA

REPORTS

PAGES 2
LOCK

A2O

SAS

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TRIAL

- A central tool to manage the end-to-end flow of refreshing the Data Management study databases
 - REQUEST: sends an automatic data request via:
 - Web browser, on a variety of vendor specific platforms
 - SAS Connect
 to obtain a new extract of the data
(unless scheduled transfer is available)
 - DOWNLOAD: downloads new data extract from:
 - Web browser, on a variety of vendor specific platforms
 - SAS Connect
 - sFTP server

SETTING THE SCENE: SGS' CONVERSION CENTER

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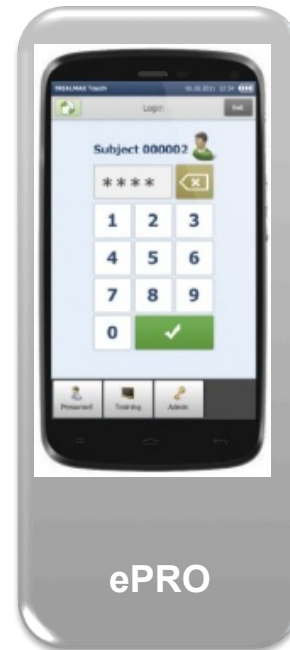
A2O

SAS

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TRIAL

- INSTALL: loads new data extract (Oracle dmp, CSV, SAS, excel, etc.) into the Data Management database
- CONVERT: converts all current study data into SDTM format
- METADATA: generates new metadata files for the SDTM data
- REPORTS: generates reports for external distribution
- PAGES2LOCK: generates overview of eCRF pages that meet locking criteria
- A2O: refreshes output of checks and listings
- SAS: creates SAS datasets from the SDTM data
- CLINTRIAL: starts the synchronisation of the SDTM database to Clintrial

SETTING THE SCENE: SDTM DATA SOURCES



SETTING THE SCENE: TIMING FOR CDMS DATA REFRESH

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■ Refreshing

- the SDTM database
- the output of checks and listings

impacts the work of Data Management (DM), so

- the best time is overnight, when DM staff is not at work
- but also DM Programmers are not around

meaning that the entire end-to-end flow should run unattended

■ Windows Powershell

- Microsoft's **task automation** and configuration management framework
- Consists of a command-line shell and associated scripting language built on **.NET Framework**
- Administrative tasks are generally performed by cmdlets (pronounced command-lets), which are specialized .NET classes implementing a particular operation
- Sets of cmdlets may be combined into **scripts**, executables (which are standalone applications).

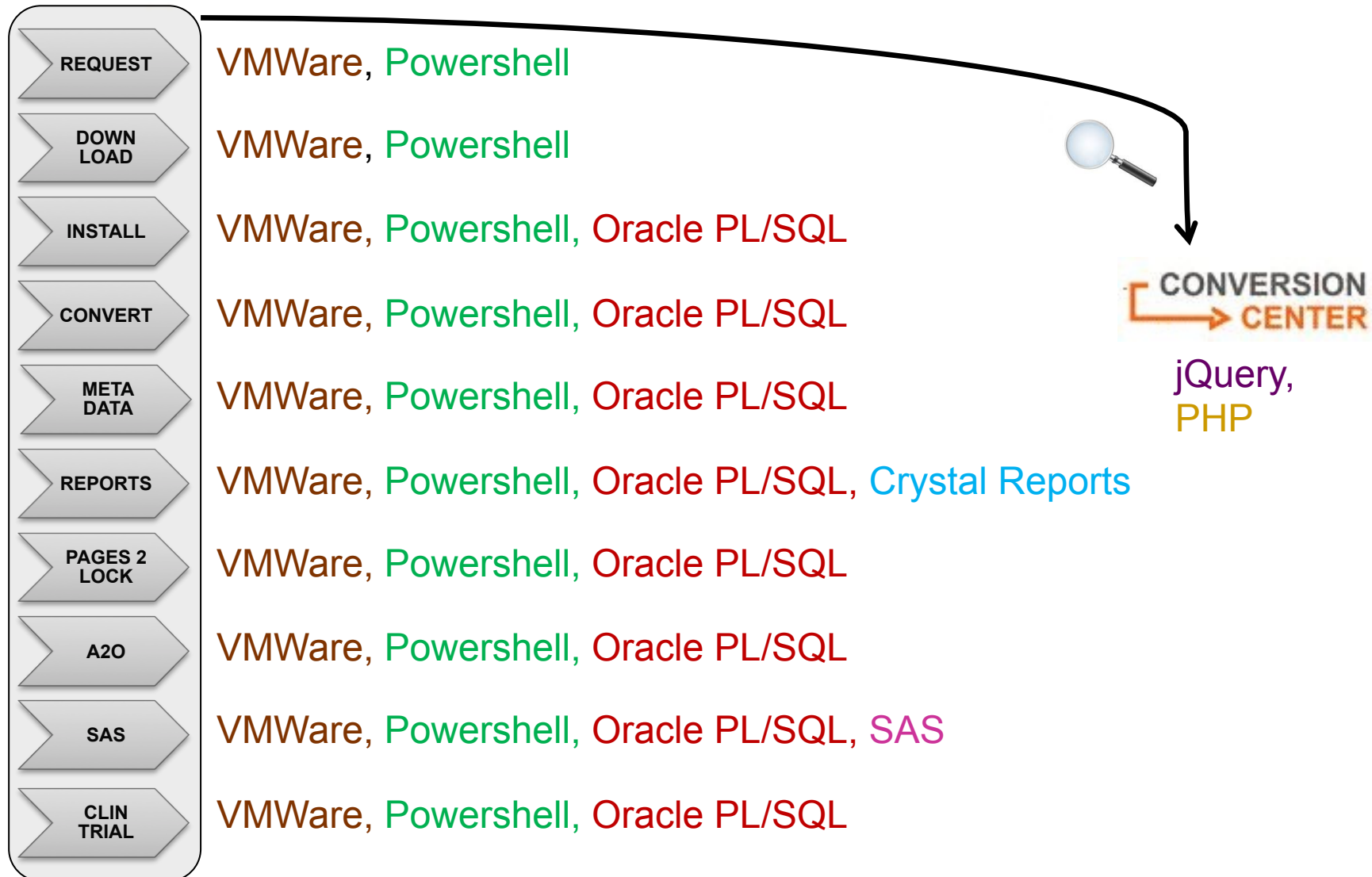
■ jQuery

- cross-platform **JavaScript library** designed to simplify the client-side scripting of **HTML**
- free, **open source software**, licensed under the MIT License
- jQuery's syntax is designed to make it easier to navigate a document, select DOM elements, create animations, handle events, and develop **Ajax applications**.

■ VMWare

- provides cloud and **virtualization software** and services

SGS' CONVERSION CENTER TECHNOLOGIES USED





SGS' CONVERSION CENTER WHAT IS IT?

- All end-to-end study process information one-click-away in a single overview

CONVERSION CENTER

NEW

MONDAY 25-AUG-2014
Hi Joris (EDCDS)

OVERVIEW

STATISTICS

NOTIFICATIONS

VERSIONS

SETUP

FAQ

Refresh

EDC CONVERSION OVERVIEW DMPROD

DMPROD | DMTEST | DMDEV Show all trials: ☐FILTER: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☒ RED ☐ X SEARCH:



SGS' CONVERSION CENTER WHAT IS IT?

History information

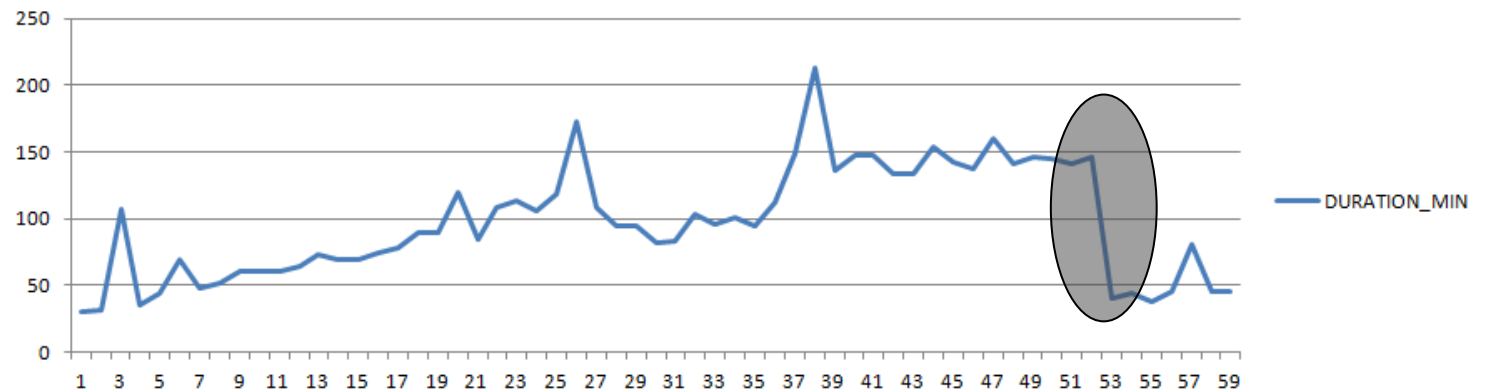
7		SDS	1090992	INFORM46	FINAL_FINISHED	SVRO	Y												
+ History Alerts Info Scripts Detail Progress Issues/Errors Mapping DataSyncs PackageSyncs DBMF Tabcompare Activities Schedule Sas Parameters Metadata Checks Load																			
CONVERSION HISTORY FOR								_SDS										Compare	
CONVID	START_DATE	DAY	DUR	A2O_SYNC	PACK	DUMPFIL	COMM	ERROR	FLOW	STATUS	INSERTS	UPDATES	REPO	ERR	AH	IN	SEL		
90144	24-AUG-14	SUN	05:18	25-AUG-14 04:44	V4_9_MCD	20140824				FINAL_FINISHED	339750	1068575	V3_RRAD	0	N	N	☐		
90096	23-AUG-14	SAT	05:27		V4_9_MCD		1			FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐		
90052	22-AUG-14	FRI	06:44		V4_12_MCD		2			FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐		
89703	17-AUG-14	SUN	05:38	18-AUG-14 05:04	V4_9_MCD	20140817				FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐		
89298	10-AUG-14	SUN	05:27	11-AUG-14 04:53	V4_9_MCD	20140810				FINAL_FINISHED	339766	1068658	V3_RRAD	0	N	N	☐		
88922	03-AUG-14	SUN	05:16	04-AUG-14 04:42	V4_9_MCD	20140803				FINAL_FINISHED	339765	1068654	V3_RRAD	0	N	N	☐		

Error information

7		SDS	1090992	INFORM46	FINAL_FINISHED	SVRO	Y										
+ History Alerts Info Scripts Detail Progress Issues/Errors Mapping DataSyncs PackageSyncs DBMF Tabcompare Activities Schedule Sas Parameters Metadata Checks Load																	
CONVERSION HISTORY FOR SDS																	
								Compare									
CONVID	START_DATE	DAY	DUR	A2O_SYNC	PACK	DUMPFIL	COMM	ERROR	FLOW	STATUS	INSERTS	UPDATES	REPO	ERR	AH	IN	SEL
90144	24-AUG-14	SUN	05:18	25-AUG-14 04:44	V4_9_MCD	20140824				FINAL_FINISHED	339750	1068575	V3_RRAD	0	N	N	☐
90096	23-AUG-14	SAT	05:27		V4_9_MCD		1			FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐
90052	22-AUG-14	FRI	06:44		V4_12_MCD			- Dumpfile date of 20140817 is not today nor yesterday		FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐
89703	17-AUG-14	SUN	05:38	18-AUG-14 05:04	V4_9_MCD	20140817				FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐
89298	10-AUG-14	SUN	05:27	11-AUG-14 04:53	V4_9_MCD	20140810				FINAL_FINISHED	339766	1068658	V3_RRAD	0	N	N	☐
88922	03-AUG-14	SUN	05:16	04-AUG-14 04:42	V4_9_MCD	20140803				FINAL_FINISHED	339765	1068654	V3_RRAD	0	N	N	☐

SGS' CONVERSION CENTER WHAT IS IT?

- Performance statistics, for detecting problems and possible improvements



Performance tuning

```

Sasondemand.ps1
39 $ie = new-object -com "InternetExplorer.Application"
40
41
42 $studyProj = $studyProj.substring(1)
43
44 if($studyProj.Contains("/"))
45 {
46     $studyProj = $studyProj.substring(0,$studyProj.LastIndexOf("/"))
47 }
48
49
50 $studyProj = $studyProj.Trim()
51 Write-Host $studyProj
52 $ie.navigate("about:blank")
53 $ie.visible = $true
54 [System.Threading.Thread]::Sleep(2000)
55
56 $url = "https://sgs.mdsol.com/"
57 $ie.Navigate2($url)
58 Start-Sleep -Seconds 2
59 While ($ie.ReadyState -ne 4)
60 {
61     Start-Sleep -Seconds 2
62 }
63
64
65 $ie.document.getElementById("UserLoginBox").value = $user
66 Start-Sleep -milliseconds 500
67 $ie.document.getElementById("UserPasswordBox").value = $pass
68 Start-Sleep -milliseconds 500
69 $ie.document.getElementById("LoginButton").Click()
70
71 # assume on SOD request page.
72 Start-Sleep -Seconds 2
73 While ($ie.ReadyState -ne 4)
74 {
75     Start-Sleep -Seconds 2
76 }
    
```

Windows PowerShell length: 4869 lines: 224

Automatic 'On demand' request of Rave SAS datasets

- Via "InternetExplorer.Application" object
- Setting the URL
- Adding username and password



```
$(document).ready(function() {
    getInfoTrials('<?php echo $vInstance; ?>');
    getSelections();
    convspecMode();
    checkRemote();
    createColumnFilter();

    $(function() {
        $(".sgstooltip").tipTip({maxWidth:"600px"});
        $(".flow").tipTip({edgeOffset: 20});
        $(".colorfilter").tipTip({edgeOffset: 20});
    });
});
```

- Customized SGS tooltip enablement to allow for a web 2.0 experience

SDS

1090992

INF ORM46

FINAL_FINISHED

SVRO

Y

+ History

Alerts

Info

Scripts

Detail

Progress

Issues/Errors

Mapping

DataSyncs

PackageSyncs

DBMF

Tabcompare

Activities

Schedule

Sas

Parameters

Metadata Checks

Load

CONVERSION HISTORY FOR

_SDS

Compare

CONVID	START_DATE	DAY	DUR	A2O_SYNC	PACK	DUMPFIL	COMM	ERROR	FLOW	STATUS	INSERTS	UPDATES	REPO	ERR	AH	IN	SEL
90144	24-AUG-14	SUN	05:18	25-AUG-14 04:44	V4_9_MCD	20140824				FINAL_FINISHED	339750	1068575	V3_RRAD	0	N	N	☐
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90052	22-AUG-14	FRI	06:44		V4_12_MCD		2			FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐
89703	17-AUG-14	SUN	05:38	18-AUG-14 05:04	V4_9_MCD	20140817				FINAL_FINISHED	339768	1068664	V3_RRAD	0	N	N	☐
89298	10-AUG-14	SUN	05:27	11-AUG-14 04:53	V4_9_MCD	20140810				FINAL_FINISHED	339766	1068658	V3_RRAD	0	N	N	☐
88922	03-AUG-14	SUN	05:16	04-AUG-14 04:42	V4_9_MCD	20140803				FINAL_FINISHED	339765	1068654	V3_RRAD	0	N	N	☐

DOWNLOAD

start date: 2014-08-24 23:30

end date: 2014-08-24 23:56

duration: 00:26:54

status: FINISHED

error:

[Compare](#)

DOWNLOAD
 start date: 2014-08-24 23:30
 end date: 2014-08-24 23:56
 duration: 00:26:54
 status: FINISHED
 error:



SGS' CONVERSION CENTER PERFORMANCE TUNING

- Processing time for small phase I trials ⇔ large phase III trials
 - From minutes to hours
 - When to start tuning efforts?

```
CONVERSION
start_date: 2014-08-26 05:07
end_date: 2014-08-26 05:12
duration: 00:05:15
status: FINISHED
error:
```

Phase I

```
CONVERSION
start_date: 2014-08-26 03:48
end_date: 2014-08-26 05:25
duration: 01:36:08
status: FINISHED
error:
```

Phase IIB

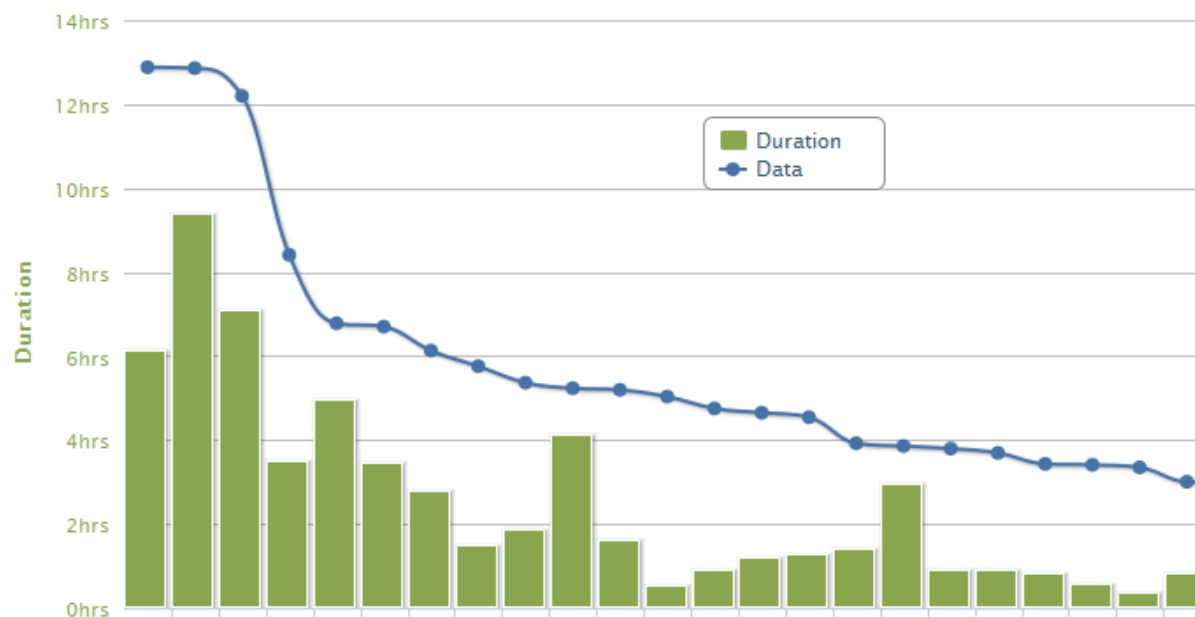
```
CONVERSION
start_date: 2014-08-25 00:58
end_date: 2014-08-25 04:29
duration: 03:31:13
status: FINISHED
error:
```

Phase III



SGS' CONVERSION CENTER PERFORMANCE TUNING

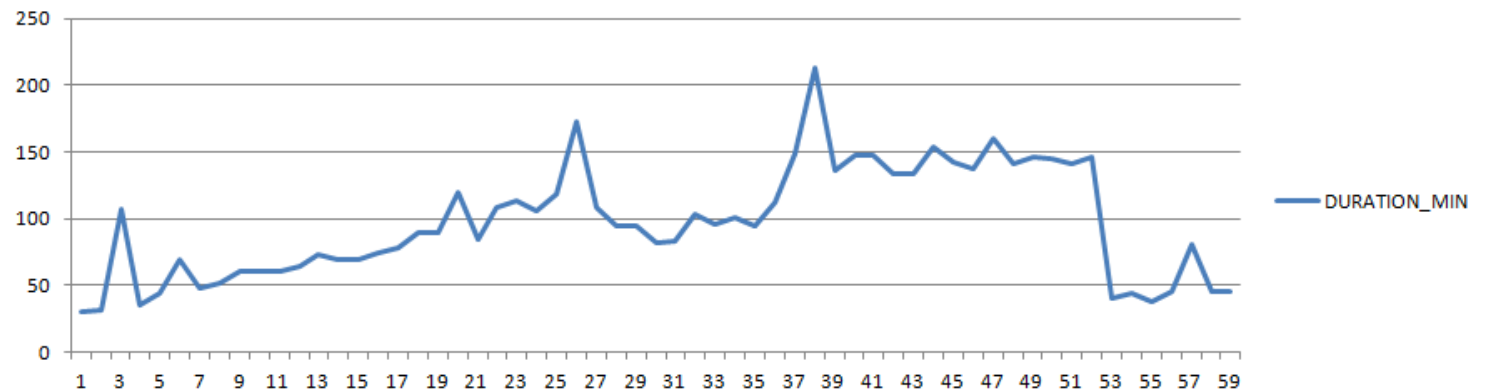
■ Based on overall **cross-study** comparison





SGS' CONVERSION CENTER PERFORMANCE TUNING

- Based on overall timing evolution on **study** level





- “Expected Time of Arrival”

1555

■ Allowing for targeted performance tuning

➤ Data download

```
DOWNLOAD
start_date: 2014-04-06 23:30
end_date: 2014-04-07 00:27
duration: 00:57:45
status: FINISHED
error:
```

```
DOWNLOAD
start_date: 2014-04-15 23:30
end_date: 2014-04-15 23:56
duration: 00:26:46
status: FINISHED
error:
```

➤ SDTM conversion

```
CONVERSION
start_date: 2014-04-07 01:40
end_date: 2014-04-07 06:08
duration: 04:28:08
status: FINISHED
error:
```

```
CONVERSION
start_date: 2014-04-25 12:25
end_date: 2014-04-25 16:03
duration: 03:37:27
status: FINISHED
error:
```

■ Data Management centers

- face wide variety of
 - source data
 - data provider platforms
- process small phase I to large phase III trials
- require minimal impact of data refresh for DM staff

■ IT solutions can be put in place to run a sequence of DM actions unattended overnight

- allowing for DM Programmers to
 - Track unexpected errors
 - Tune the process performance
 - Manage all trials with minimal oversight effort

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LOCK

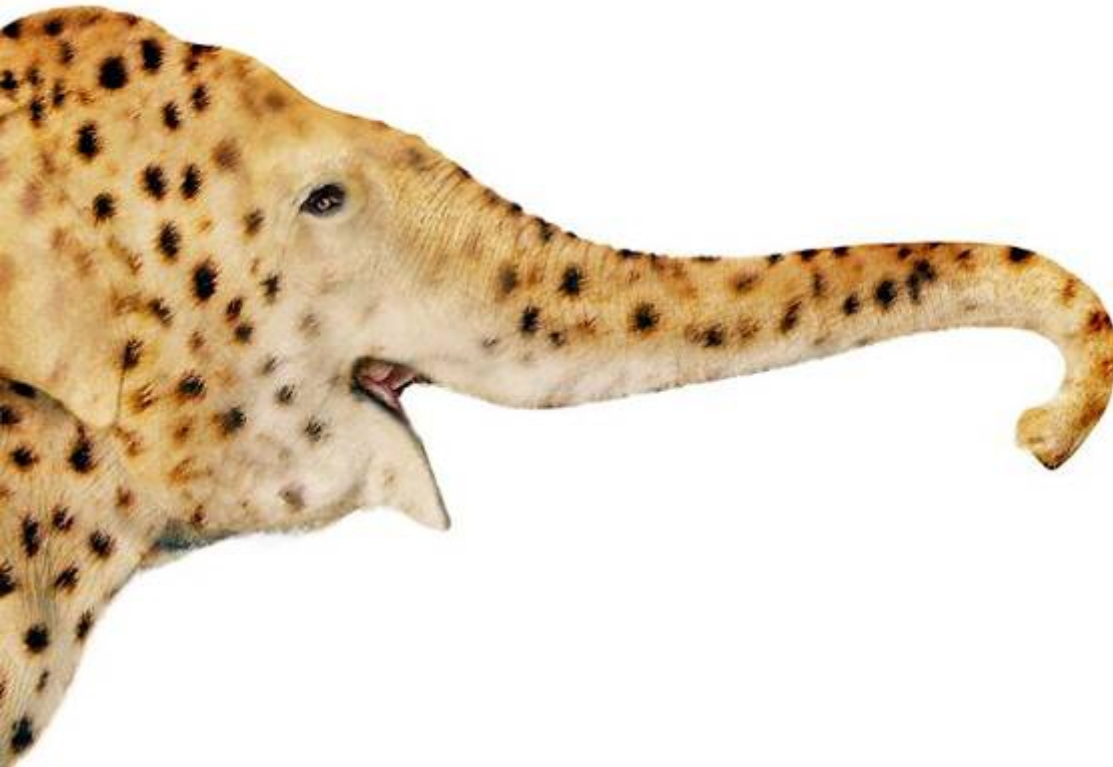
A20

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THANK YOU FOR YOUR ATTENTION



WHERE MEETS EXPERIENCE SPEED

CONTACT US

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