

Trials and Tribulations of Automated SDTM Delivery

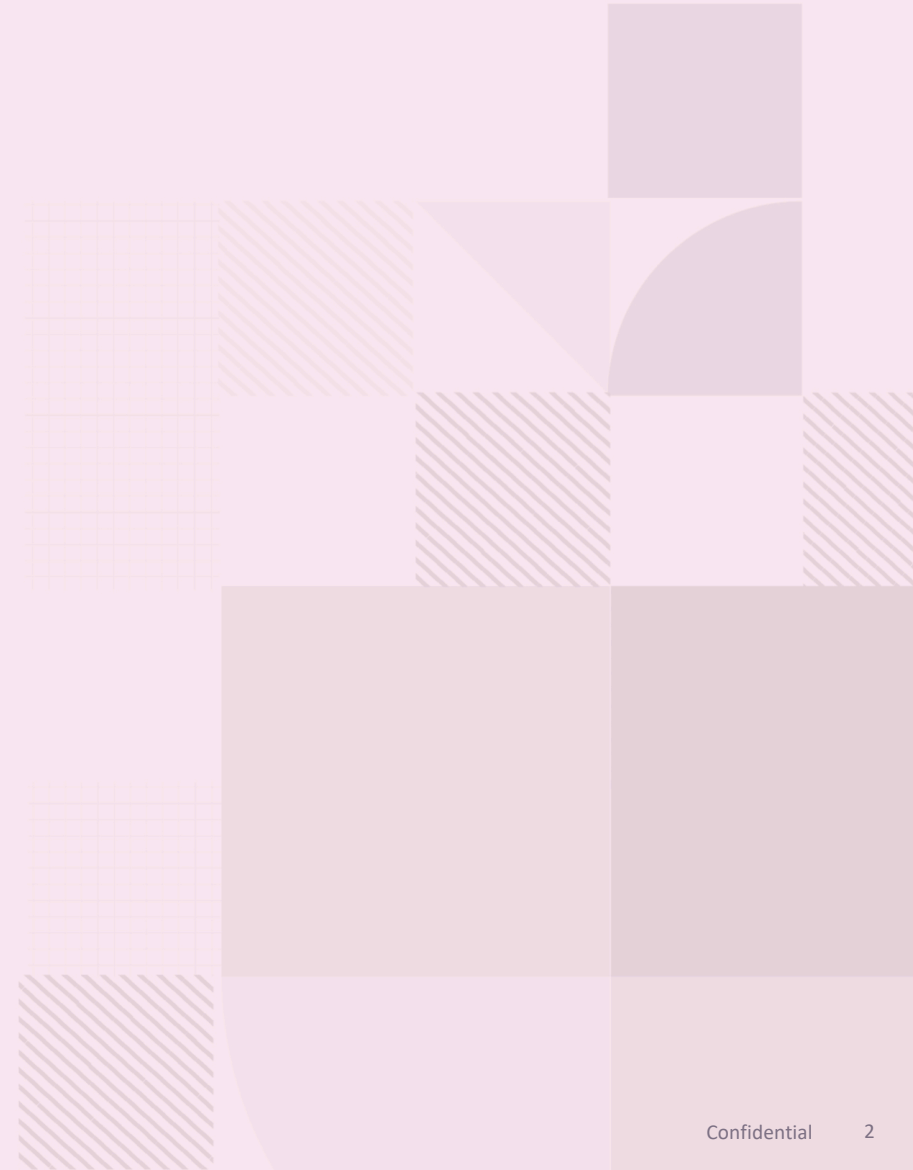
Edward Jones

Nov 2019





“In The Beginning There Was Man...”





“In The Beginning There Was Man...”





Presentation Title: Trials and Tribulations of Automated SDTM Delivery





Submission Data Standards – 1997-1999





SDTM v3.0 – 2003

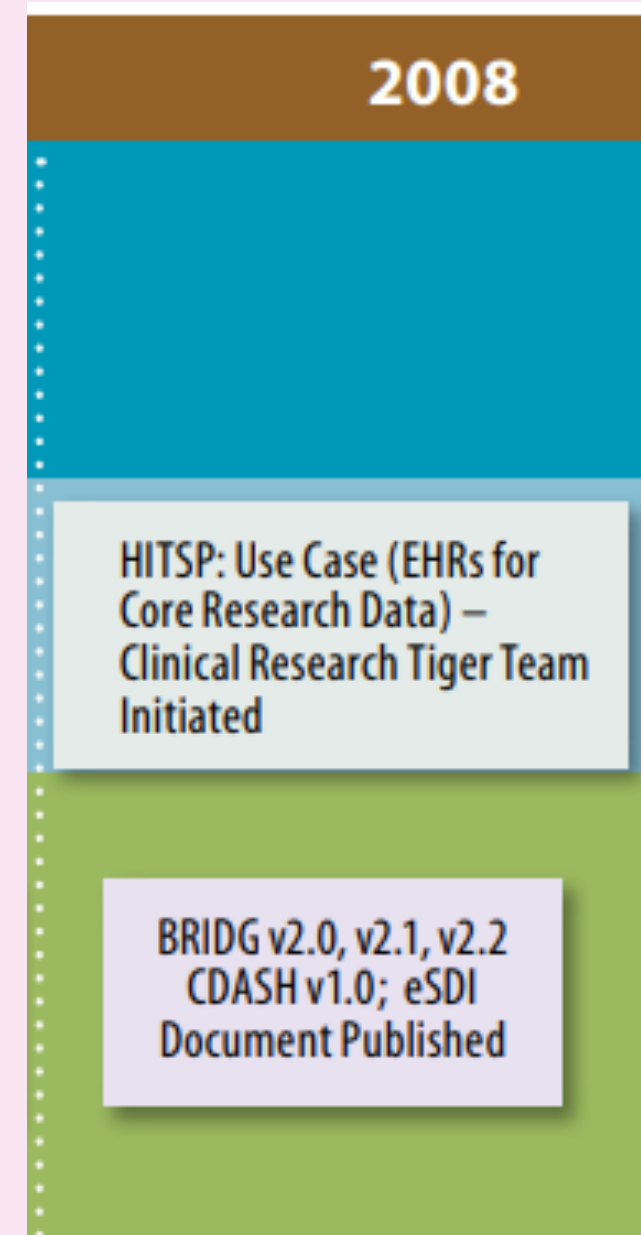


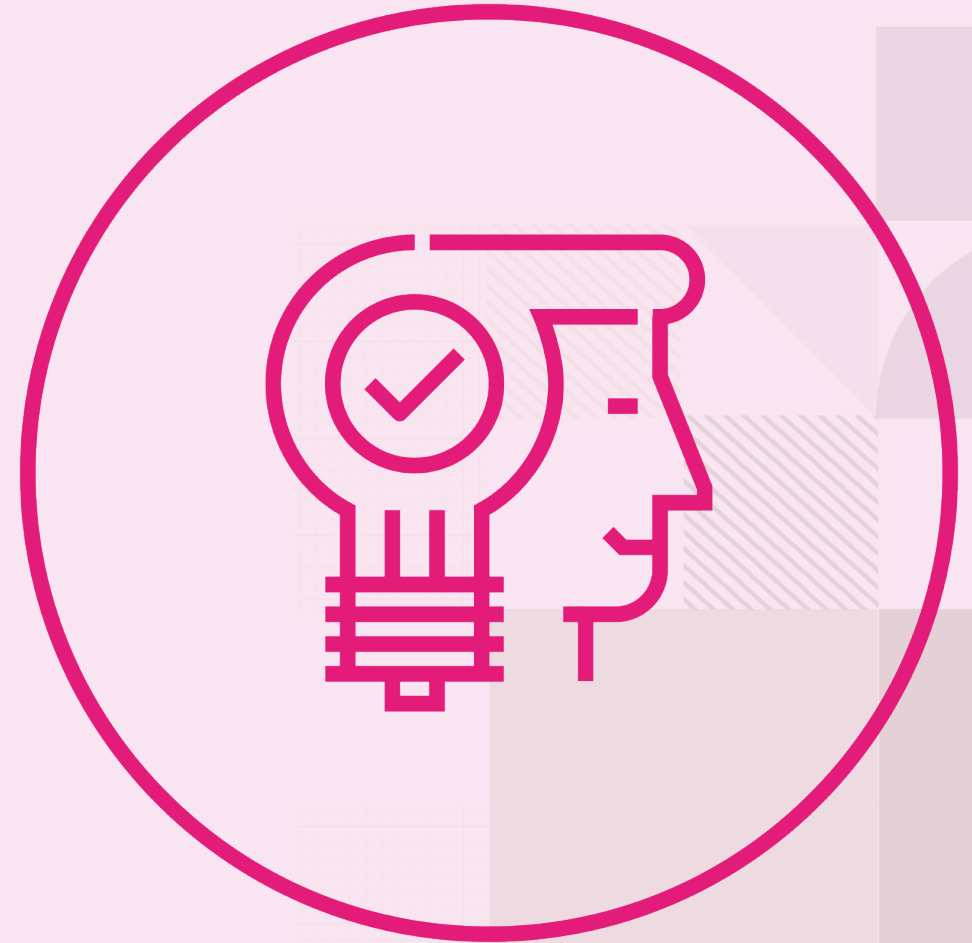


Presentation Title: Trials and Tribulations of Automated SDTM Delivery

CDASH v1.0 – 2008

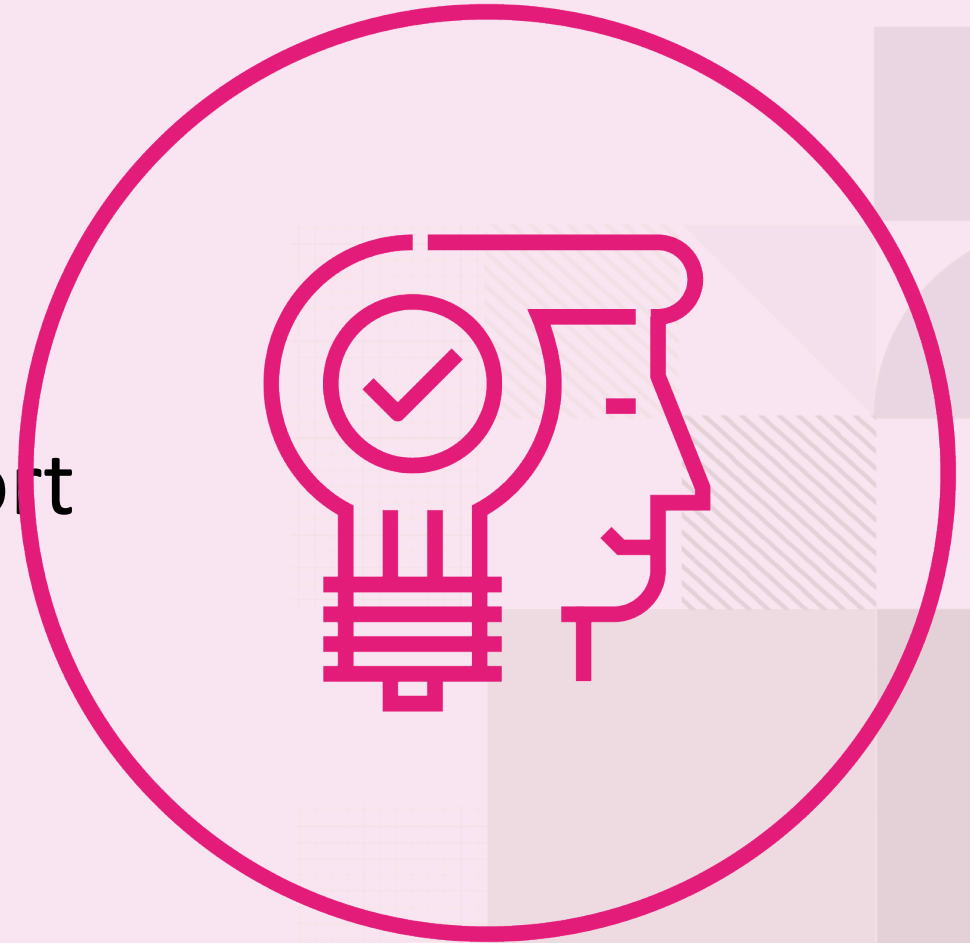
https://www.cdisc.org/system/files/all/CDISC-4-Pager_pages_web.pdf







Use SDTM-like datasets to support operational review activities





Regular SDTM Deliveries Begin

```
/*Name of zip file to be created with the .zip extension inside of quotes.*/
/*Please do not edit or replace the macro &today.*/
%let zipfile=PRA_IM025-006_RACLP88-99123_SDTM_&today..zip;

/*What tables you want to place into the zip file inside of the quotes.*/
%let what1=\\11File\XYZ\RACLP88-99123\EXACT\Blinded\Primary\Study Data\SDTM Datasets\XPT

/*Location of the annotated pdf file.*/
%let what2=\\11File\XYZ\RACLP88-99123\Unrestricted\Reporting\Docs\Tabulation\SDTM_Specs\

/*sFTP Folder location to upload the file.*/
%let FTPFolder = /DMND0009089/DMND0009089.1943/inbound;

/*The below data step constructs the command line to be submitted on the SAS GRID. */
/*
                                DO NOT CHANGE THE BELOW LINES.                                */

***----- ;
*** Convert SAS datasets from EXACT to XPT files;
%let XPTPath = &FileLoc\XPT;

options dlcreatedir;
libname source "&FileLoc";
libname xptlib "&XPTPath";

proc contents data=source._all_ noprint out=dsets(keep=memname);
run;

proc sort data=dsets;
    by memname;
run;

data null ;
```



LIFE WAS GOOD





Humans Aren't Good At Spotting Rare Issues In Automated Processes





**HUMANS AREN'T GOOD AT SPOTTING RARE
ISSUES IN AUTOMATED PROCESSES**

Scripted Process Proves Problematic

- “NTSB: Autopilot flaw, driver inattention caused Tesla crash”: Lethbridge News Now; Sept 4th 2019





HUMANS AREN'T GOOD AT SPOTTING RARE ISSUES IN
AUTOMATED PROCESSES

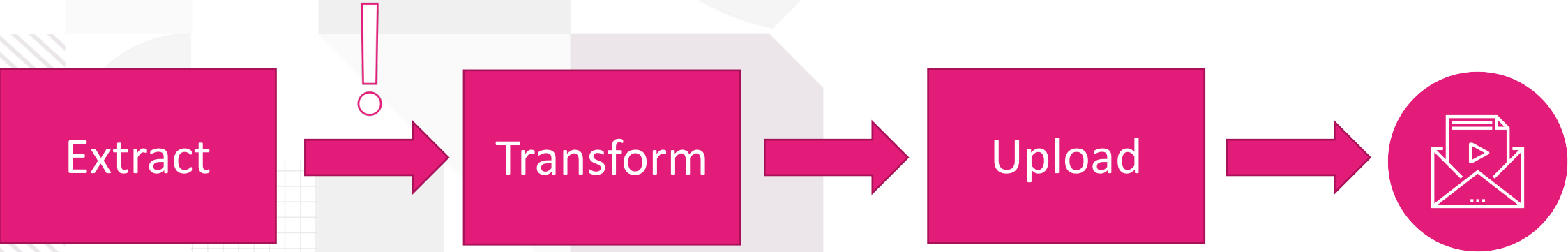
Scripted Process Proves Problematic

▼ Last Month		
SCRIPTEDSERVICE@PRAHS.COM		29/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		28/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		27/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		26/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		25/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		24/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		23/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		22/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		21/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		20/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		19/09/2019
RACLP1-CP123 Delivery		
SCRIPTEDSERVICE@PRAHS.COM		18/09/2019
RACLP1-CP123 Delivery		



NO DEPENDENCY MANAGEMENT

Scripted Process Proves Problematic





Evolve To Enterprise Scheduler





WHAT?

Evolve To Enterprise Scheduler

- enterprise scheduler
- batch manager or batch scheduling
- workload automation
- middleware



WHAT?

Evolve To Enterprise Scheduler





WHY?

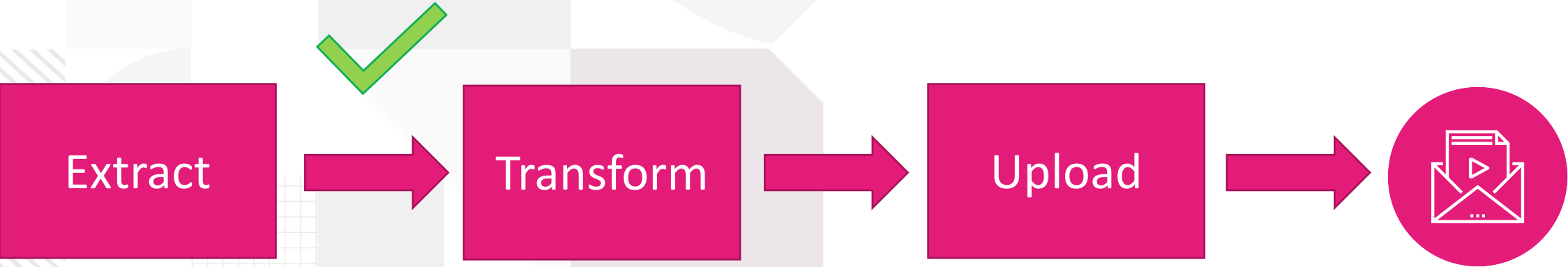
Evolve To Enterprise Scheduler

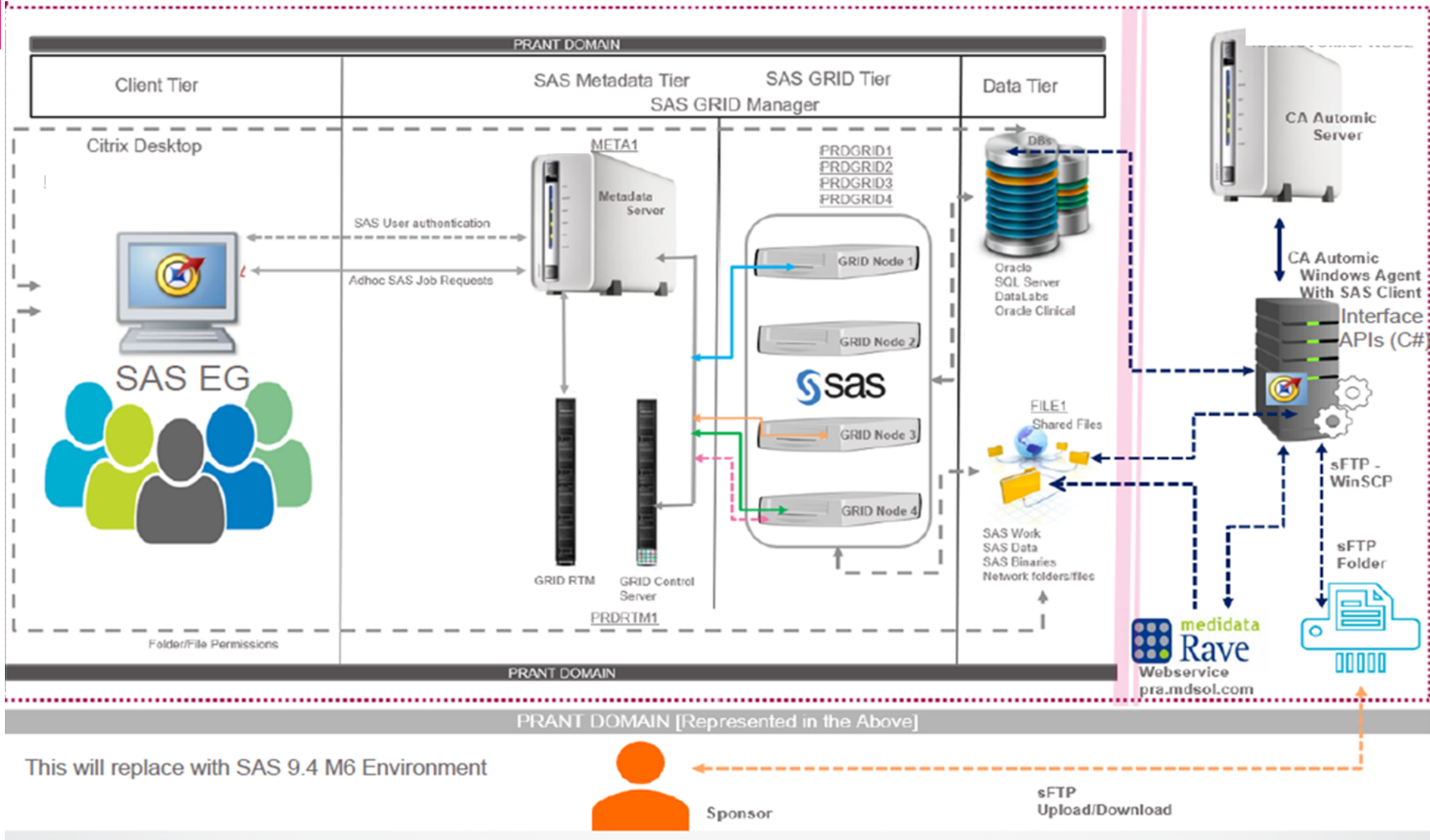
- Sequence scheduled processes that may have dependencies across multiple systems
 - Databases
 - Files servers
 - Web services
 - Applications
- Can be event driven
- Built in (configurable) re-try functionality
- Allows the Programming department to avoid dealing with day-to-day automation / scheduling issues.



DEPENDENCIES MANAGED

Evolve To Enterprise Scheduler





Confidential



Evolve To Enterprise Scheduler

- Use a consolidated success/Failure e-mail
- Attach relevant log files

This message was sent with High importance.

0192765286.ACT.txt .txt File	0192765286.POCO.txt .txt File	0192765286.POST.txt .txt File	0192765286.REP.txt .txt File
0192765286.REV0.txt .txt File	0192765286.REV1.txt .txt File	0192765286.REV2.txt .txt File	

CLIENT_QUEUE (NONPROD) - CA Automic - Automated Email Notification

The delivery for <Project ID #####> has failed

- Step 1: Extraction from Medidata - Success
- Step 2: Extraction Job - RaveCSV_to_SAS - Success
- Step 3: Extraction Job - make files - Success
- Step 4: sFTP Upload - Failed

Note: This email was automatically generated based on the job definition. Please do not reply.



Other Things You Can Do That'll Help

- Create your SDTM datasets early – Use protocol compliant dummy data
- Decide how to control quality of regular deliveries, and to what extent
- Establish SLAs



Takeaway Message





Takeaway Message

Use and Enterprise Scheduler.

- It'll make your life easier
- You've almost certainly got one available to you already

