

INCORPORATING PINNACLE21[®] WITH LSAF[®]

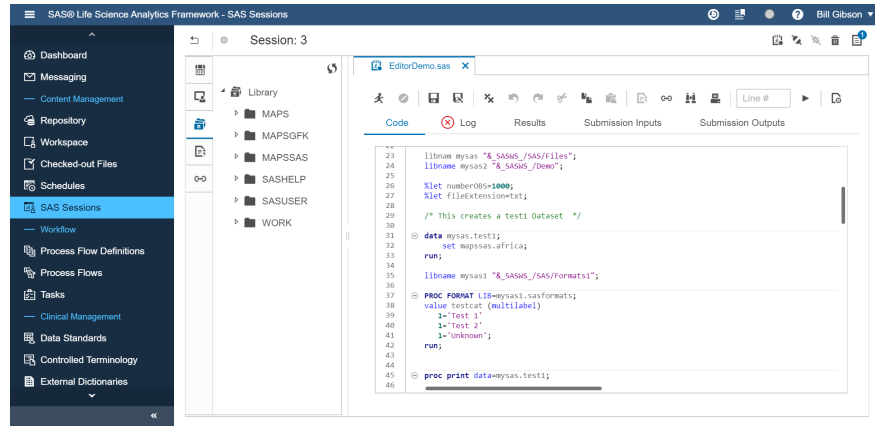
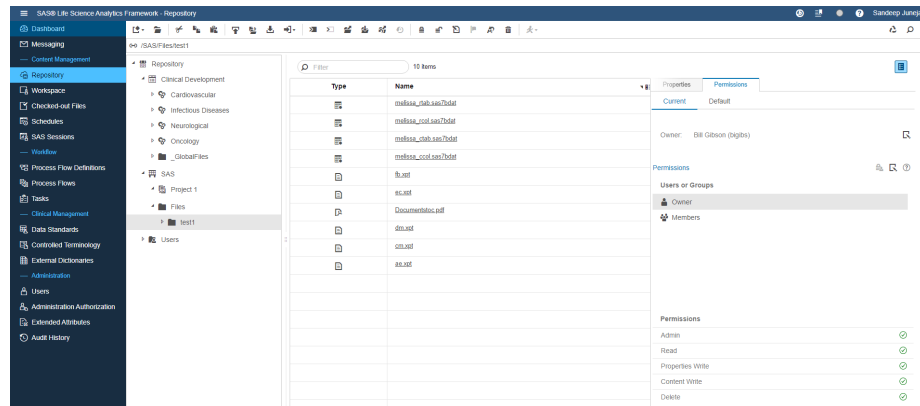
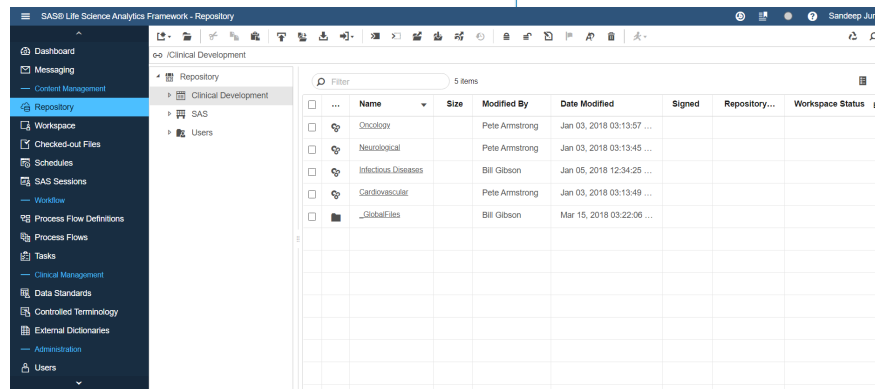


SONALI GARG, ALEXION PHARMACEUTICALS
ALEKSEY VINOKUROV, PINNACLE 21
SANDEEP JUNEJA, SAS

AGENDA

- Introduction
 - LSAF
 - Pinnacle 21
- Problem Definition & Solution
- Benefits

INTRODUCTION LIFE SCIENCE ANALYTICS FRAMEWORK (LSAF)



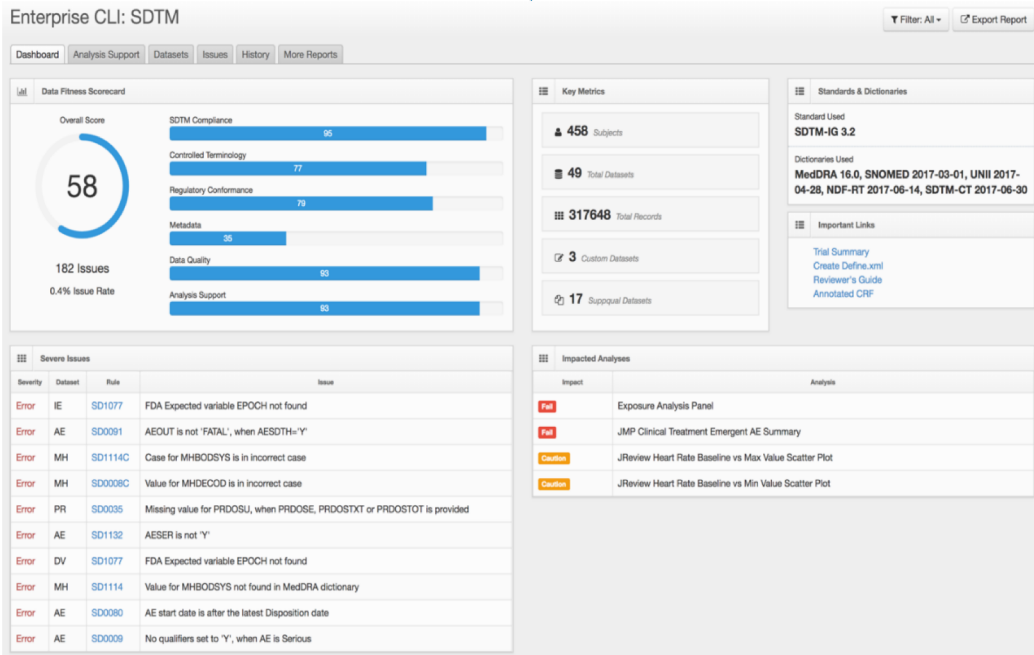
- Web Based Environment
- Dashboard / Repository / Workspace
- Versioning / E-signature / Check-in/ Check-out / Permissions / Privileges / Audit trail
- SAS Programming Environment
- Hosted Environment

INTRODUCTION | PINNACLE 21 CLI TOOL

- Command Line Interface, SAS Program with X Command or *javaobj*
- Establishing documented evidence which provides an assurance that a specific process will consistently produce result with predetermined specification and quality attributes.
- Achieve high level of process automation. CLI will prep and automatically push data or send requests to P21 Enterprise Server to pull data from LSAF system.
- Enable high level result evaluation and process flow automation. CLI produces return codes that correspond to validation severity levels.
- Transparent process execution and error reporting. Comprehensive set of error codes to aid process development and debugging.
- Tight integration with LSAF environment. CLI results are checked into repository.
- Configurable connectivity options and full utilization of P21 Enterprise security model.

INTRODUCTION PINNACLE21 ENTERPRISE

Enterprise CLI: SDTM

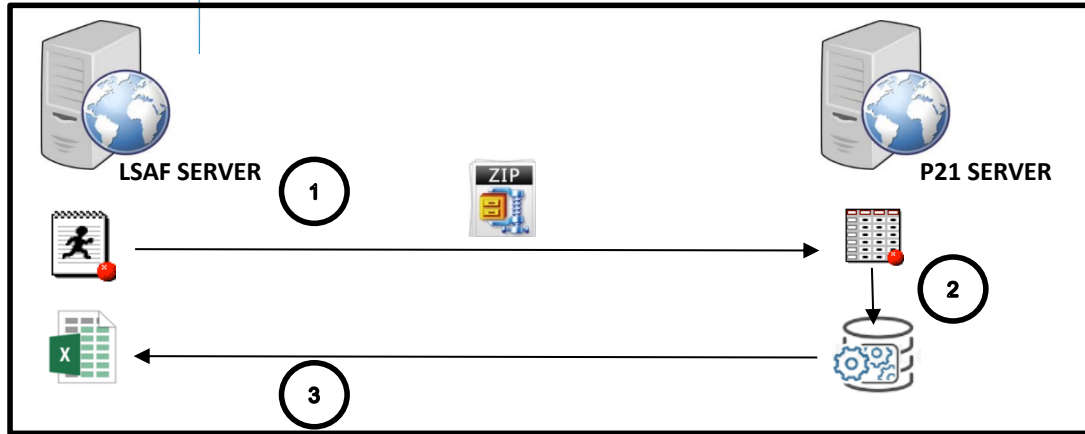


- Enterprise level reporting and issue analysis.
- Complete issue details capture
- Enterprise managed rules and standards.
- Other Enterprise features ...

PROBLEM DEFINITION

- LSAF is hosted environment at SAS
- Pinnacle Enterprise is hosted environment at Pinnacle
- **How to use single credentials for end user?**
- **How to run Enterprise checks and maintain full data traceability?**
- **How to run Enterprise checks and maintain validation parameters traceability?**
- **How to run Enterprise checks and maintain validation report history?**
- **How to run Enterprise checks and automate process flow and result analysis?**
- **PMDA and FDA checks are run in 1 step.**

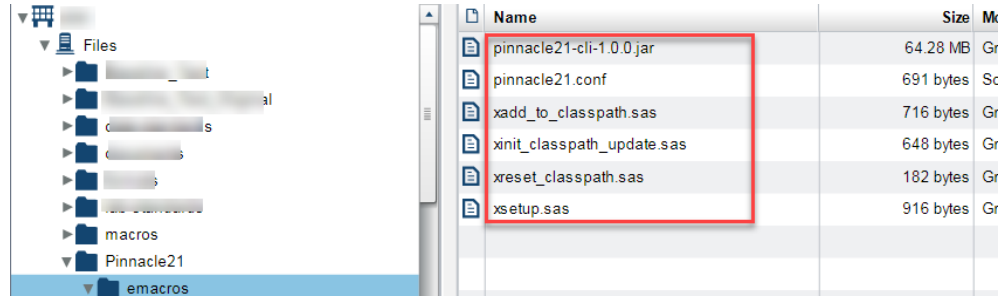
SOLUTION PROCESS FLOW



1. SAS Program/ SAS Job is executed within LSAF controlled Environment which authenticates and connect to Pinnacle 21 Server. Data is securely transferred in compressed format to P21 Server.
2. Data is extracted on P21 server and checks are executed.
3. Final Excel report generated via execution checks is transferred back to LSAF environment.

SOLUTION PINNACLE SAS MACROS FOR LSAF

- Macros & config file to be saved in the global area so as to be accessible to all projects



SOLUTION PINNACLE21 CLIENT FILES

- p21-client-1.0.7.jar - Java application
- pinnacle21.conf

```
web.host="[https://[p21 server].pinnacle21.net]"
api.key=[API access key provided by the P21 Enterprise Server Admin. P21 Enterprise Server will be
configured with an API key]
group=[user group. Typically, P21 Server will be configured with default user group called
enterprise_cli]
# To enable HTTPS connectivity between LSAF and P21 Server
# the following configuration is needed:
  default.http.proxy.host="[proxy server URL]"
  default.http.proxy.port=[port number]
```

SOLUTION SAS CODE

```
data _null_;
  dcl javaobj jCmd("net/pinnacle21/oce/utils/ProcessUtils"); class ProcessUtils;
  length exitCode 8.;
  array s{&i.} $200 (&cmd.); String[] s
  jCmd.callStaticVoidMethod("startFromCommandLine",s); public static void startFromCommandLine(String[] s)
  jCmd.callStaticIntMethod("exit", exitCode);
  put exitCode=;
run;

%init_classpath_update;
%add_to_classpath(&macloc./&version..jar);
%pinnacle21(version=&version..jar,
  Params=%nrbquote(
    --project=Project name,
    --study=Study,
    --standard=sdtm,
    --standard.version=3.2,
    --meddra.version=19.0,
    --cdisc.ct.sdtm=2017-03-31,
    --source.sdtm="lsaf:///&study_path",
    --report=&report_path./&report_name..xlsx,
    --report.cutoff=10),
  report_path=&report_path.,
  debug=N);
%reset_classpath;
```

- **Documentation Reference:**
 - How to Automate Validation with Pinnacle 21 Command Line Interface and SAS
 - Pinnacle21 Parameter Reference - <https://www.pinnacle21.com/documentation>
 - SAS JavaObj - <http://support.sas.com/rnd/base/datastep/dot/javaobj.html>
 - Dynamically setting Classpath - <http://support.sas.com/kb/38/518.html>

SOLUTION HOW TO CALL THE MACRO

Call the macro from study, specifying the versions of standard, controlled terms and various dictionaries

```
run_p21ent_sdtm.sas [read-only] x  Untitled.sas* x
1
2 %let study_path = %str(...../Files/sdtm-v3.2/compliance);
3 %let report_path = %str(&_SASWS_/...../Files/utilities/development/output);
4 %let report_name = S_P21E;
5 %let version = %str(pinnacle21-cli-1.0.0);
6 %put &report_name;
7 *| Validate datasets;
8 %gp21ent(version=&version..jar,
9         Params=%nrquote(
10             --project=.....,
11             --study=.....,
12             --standard=sdtm,
13             --standard.version=3.2,
14             --meddra.version=19.0,
15             --cdisc.ct.sdtm=2017-03-31,
16             --snomed.version=2016-09-01,
17             --unii.version=2016-09-06,
18             --report.cutoff=20,
19             --ndf-rt.version=2016-10-03,
20             --group=enterprise_cli,
21             --source.sdtm="lsaf:///&study_path",
22             --report=&report_path/&report_name..xlsx),
23         report_path=&report_path/&report_name..xlsx,
24         debug=Y);
```

SOLUTION OUTPUT

- Output pushed back from Pinnacle21 to LSAF repository, accessible to project team only
- PMDA and FDA checks are run in 1 step.

/Files/utilities/development/output							
Name	Size	Modified By	Date Modified	Signed	Repository Version	Wc	
S_P21E.xlsx	106.04 KB		N ...		1.0		

Pinnacle 21 Enterprise Validation Report							
Generated: 2017-11-08T18:07:39							
Standard: ADaM-IG 1.0							
CDISC CT Version: 2017-09-29 (SDTM), 2017-09-29 (ADaM)							
MedDRA Version: 19.0							
Software Version: 3.2.2							

BENEFITS DATA TRACEABILITY AND ACCESSIBILITY

- Since multiple team members work on different studies, instead of everyone downloading data manually on local machines, this method allows to run validation directly from within LSAF hence protecting data and preventing multiple local copies of data on different PCs
- This mechanism allows to run validation without losing data traceability as the data is transmitted securely and tracked across systems
- Saves admin work of creating more than one set of credentials for all users
- Result Reports are stored securely and accessible to study team members only within LSAF environment

BENEFITS

Question	Solution
How to use single credentials for end user?	Running through LSAF, saves the hassle of creating a separate credentials for P21 url
How to run Enterprise checks and maintain full data traceability?	Since data is being directly pulled off of LSAF, there is no manual download and upload of data as needed otherwise, thus maintaining the full data traceability.

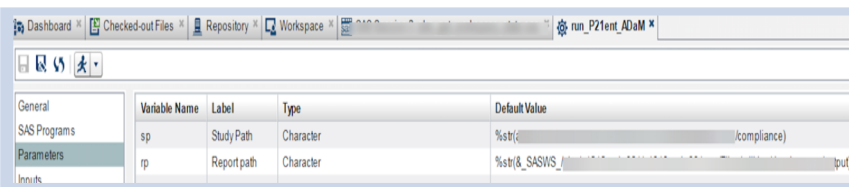
BENEFITS

Question

How to run Enterprise checks and maintain validation parameters traceability?

How to run Enterprise checks and maintain validation report history?

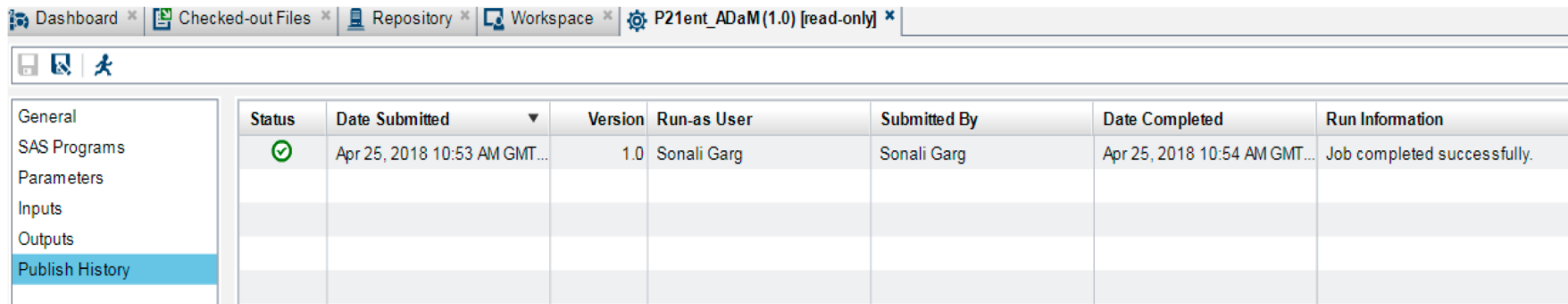
Solution



The screenshot shows the SAS Enterprise Guide interface with the 'Parameters' tab selected. The table below lists the parameters for the validation run.

General	Variable Name	Label	Type	Default Value
SAS Programs	sp	Study Path	Character	%str(...../compliance)
Parameters	rp	Report path	Character	%str(&_SASVIS_...../put)
Inputs				

Since LSAF has a built in version control system, it maintains a report history for each validation run.



The screenshot shows the SAS Enterprise Guide interface with the 'Publish History' tab selected. The table below lists the history of validation runs.

General	Status	Date Submitted	Version	Run-as User	Submitted By	Date Completed	Run Information
SAS Programs	✓	Apr 25, 2018 10:53 AM GMT...	1.0	Sonali Garg	Sonali Garg	Apr 25, 2018 10:54 AM GMT...	Job completed successfully.
Parameters							
Inputs							
Outputs							
Publish History							

BENEFITS

Question

PMDA and FDA checks are run in 1 step.

Define.xml

Solution

Pinnacle 21 Enterprise Validation Report

Issue Summary						
Dataset	Rule ID	Publisher ID	Message	FDA	PMDA	Found
ADAE	SD0059	FDAC034	Define.xml/dataset variable type mismatch	Error	Warning	2
ADCM	AD0047		Required variable is not present	Error	Error	2

Define file can be created using the validation ran from within LSAF
Only define creators need to have login credentials to Pinnacle 21 url

SDTM-IG 3.2

- + Annotated Case Report Form
- + Study Data Reviewer's Guid
- + Tabulation Datasets
 - Trial Arms (TA)
 - Trial Elements (TE)
 - Trial Inclusion/Exclusion C
 - Trial Summary (TS)
 - Trial Visits (TV)
 - Demographics (DM)
 - Subject Elements (SE)
 - Subject Visits (SV)
 - Concomitant Medications (CM)
 - Exposure (EX)
 - Procedures (PR)
 - Adverse Events (AE)
 - Disposition (DS)
 - Protocol Deviations (DV)
 - Medical History (MH)
 - ECG Test Results (EG)
 - Findings About Events or I
 - Inclusion/Exclusion Criteri
 - Immunogenicity Specimen
 - Laboratory Test Results (L
 - Pharmacokinetics Concent

Tabulation Datasets for Study

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned element per arm	Tabulation	STUDYID, DOMAIN, ARMCD, TAETORD,	ta.xml	
TE	Trial Elements	TRIAL DESIGN	One record per planned element	Tabulation	STUDYID, DOMAIN,	te.xml	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, DOMAIN,	ti.xml	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, DOMAIN,	ts.xml	
TV	Trial Visits	TRIAL DESIGN	One record per planned visit per arm	Tabulation	STUDYID, DOMAIN,	tv.xml	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xml	
SE	Subject Elements	SPECIAL PURPOSE	One record per actual element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC,	se.xml	
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, SVGRPID, VISITNUM,	sv.xml	
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dose interval occurrence	Tabulation	STUDYID, USUBJID, CMGRPID, CMSTDTC, CMENDTC, CMTRT,	cm.xml	

Date of document generation: 2018-03-12T17:19:06Z
Stylesheet version: 2013-04-24

THANK YOU



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