INCORPORATING PINNACLE21 ® WITH LSAF ®

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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.
PINNACLE21 ENTERPRISE

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

```plaintext
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]
```
```sas
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);  
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  
  • Dynamically setting Classpath - http://support.sas.com/kb/38/518.html
```
Call the macro from study, specifying the versions of standard, controlled terms and various dictionaries

```
%let study_path = %str(\&/\&SASWS/_\&/\&study_path\&/\&SDTM\&/compliance);
%let report_path = %str(\&/\&SASWS/\&/\&report_name\&/\&SDTM\&/development/output);
%let report_name = &report_name;
%let version = %str(pinnacle21-cli-1.0.0);
%put &report_name;
%validate datasets;
%gp21ent(version=%version..jar,
    Param="\n        --project=xxxx xxx xxx,
        --study=xxxx xxx xxx,
        --standard=sdtm,
        --standard.version=3.2,
        --meddra.version=19.0,
        --odisc.ct.sdmt=2017-03-31,
        --anmed.version=2016-09-01,
        --unii.version=2016-09-06,
        --report.cutoff=20,
        --nif-rt.version=2016-10-03,
        --group=enterprise_cli,
        --source.sdmt=\&study_path",
    --report=&report_path/&report_name..xls),
report_path=&report_path/&report_name..xls,
    debug=Y);
```
• Output pushed back from Pinnacle21 to LSAF repository, accessible to project team only
• PMDA and FDA checks are run in 1 step.
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
<table>
<thead>
<tr>
<th>Question</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>How to use single credentials for end user?</td>
<td>Running through LSAF, saves the hassle of creating a separate credentials for P21 url</td>
</tr>
<tr>
<td>How to run Enterprise checks and maintain full data traceability?</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Question</strong></td>
<td><strong>Solution</strong></td>
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<tr>
<td>How to run Enterprise checks and maintain validation parameters traceability?</td>
<td>Since LSAF has a built in version control system, it maintains a report history for each validation run.</td>
</tr>
</tbody>
</table>
**Question**

PMDA and FDA checks are run in 1 step.

**Solution**

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