

A NOVEL APPROACH TO BIOSTATISTICAL PROGRAMMING ENVIRONMENT

Jeff Cao, PhD
CEO, Viitai
02/27/2020

AGENDA

- Roles Involved In Biostatistical Programming
 - Issues/challenges
 - Proposed Solution
-

ROLES INVOLVED IN BIOSTATISTICAL PROGRAMMING

- Lead Programmer
 - Source Programmer
 - Validation Programmer
 - Biostatistician
 - Data manager
 - Application Administrator
 - Biometrics Management
 - Project Team
-

ISSUES/CHALLENGES

- TOC
 - Milestone Folder Structure
 - Program Header & Template
 - Team Communication
 - Security/Permission Management
 - Compliance & FDA Audit
 - Team/Project Management
 - Interface
 - TLF Review Workflow
 - Document Management
 - Data & Data Transfer
-

ISSUES/CHALLENGES

- **TOC**
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- **Not allow simultaneous access**
- **Lack of audit trail**

Output File Name	QC Dataset Name	Number	Title
t-disp.rtf	t-disp.sas7bdat	14.1.1	Subjct Disposition \ All Enrolle...
t-demo.rtf	t-demo.sas7bdat	14.1.2.1.1	Demographics and Baseline Ch...

Footnotes	Artificial Program	Source Program	Output Type
The percentage is based on N.	t-disp.sas	t-disp.sas	Table
SOC is defined as any of the followi... Growth is measured by recumbent l...	t-demo.sas	t-demo.sas	Table

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Inconsistent
- Not aligned with standard
- Too complicated
- Lack of metadata

▼ 1st Interim Analysis

Programs
Data
Output
Validation
Utilities
Stats
m5
Documents
Transfer
Data Management

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- **Program Header & Template**
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Manual





```
/*sch*****  
* Company Name       : Happy Therapeutics  
* CODE NAME          : t-demo.sas  
* PROJECT NAME       : HT002-201  
* DESCRIPTION         : Demographics and Baseline Character  
* SPECIFICATIONS     : E:\BPSApp\bps\Workspace\HT002\201\  
* VALIDATION DETAILS : null  
* MACRO USE           :  
* SOFTWARE/VERSION#  : 9.4  
* DATA INPUT         : E:\BPSApp\bps\Workspace\HT002\201\  
* OUTPUT              : E:\BPSApp\bps\Workspace\HT002\201\  
* SPECIAL INSTRUCTIONS:  
* VERSION             :  
*  
* DOCUMENTATION AND REVISION HISTORY SECTION (required):  
* -----  
* DATE      AUTHOR      DESCRIPTION  
* -----  
*  
*  
**eoh*****  
  
options mprint symbolgen;  
proc sql noprint;  
  select xpath into :lastopen  
  from dictionary.extfiles  
  where fileref like "#LN%"  
  having fileref = max(fileref)  
  ;  
quit;  
  
%let file=&lastopen;  
%let folder=Programs;
```

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- **Team Communication**
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- No notification on status changes
- Using Excel tracking issues
- Using email communicate progress and resolution
- Time-consuming issue log reporting

Listing	l-TCL23.sas	In Development
SDTM	aaa.sas	Ready For Validation
SDTM	bbb.sas	Validation Completed
Table	t-conmed.sas	In Production
Table	t-demo.sas	In Validation

 Issues		0
 Export Issue Log To Excel		2
 View Review Comments		0

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- **Security/Permission Management**
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Users can see content they are not supposed to see
- Access change has to log a ticket with IT, which is time consuming
- Difficulty in creating a report showing all the permission change history to satisfy FDA's requests

Folder Name		User ID	User Name	RW	RO
Programs	<input type="checkbox"/>	Administr...	Administrators	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Data	<input type="checkbox"/>	BPSQAAd...	BPSQAAdmin	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Documents	<input type="checkbox"/>	jcao	jcao	<input checked="" type="checkbox"/>	<input type="checkbox"/>
m5	<input type="checkbox"/>	jwood	jwood	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Output	<input type="checkbox"/>	test1	test1	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Stats	<input type="checkbox"/>	Test2	Test2	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Utilities	<input type="checkbox"/>	wtownes	wtownes	<input checked="" type="checkbox"/>	<input type="checkbox"/>

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- **Compliance & FDA Audit**
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- **Version Control**
 - Commercial version control software is an overkill (big overhead with little benefit)
- **Audit Trail**
 - No audit trail
- **Dependency Binding**
 - No dependency binding record

 View Versions

View Batch Run Binding History

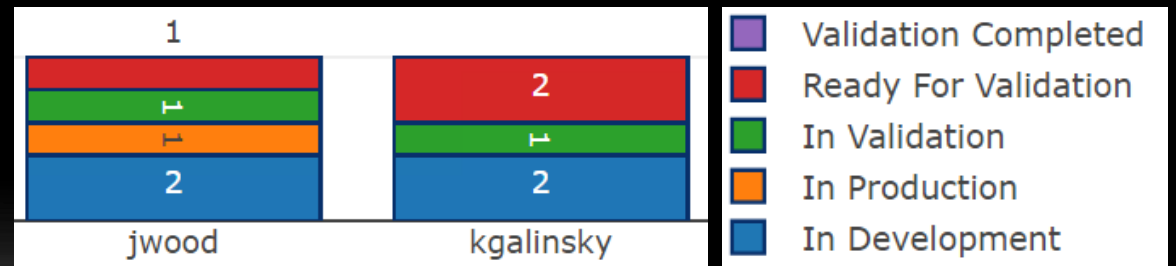
View Audit Trail

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- **Team/Project Management**
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Use Excel
- Require offline efforts

Due Date	Priority	Programmer	Validator	Validation Type	Lead Programmer
2020-02-04	1	jmao	kgalinsky	Level 2	test1
2020-01-27	2	wtownes	test1	Level 2	jcao
2020-02-04	1	wtownes	jmao	Level 2	jcao
2020-02-26	2	jwood	kgalinsky	Level 2	wtownes



ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- **Interface**
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Require switching interfaces to complete a task
- Statistical programmers, biostatisticians, data managers, and management work on different applications/interfaces
- Validation programmers need to visit multiple places to get job done

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- **TLF Review Workflow**
- Document Management
- Data & Data Transfer

- Use offline review
- Lack of necessary security in communicating the TLF files
- No real-time review status or comments available to programmers



Notification

To Jeff Cao

Please follow this link to view and comment on the tables, listings, and figures by 02/1

<https://clientqa-bps.viitai.com/main?key=SFQwMDI6MjAxOjFzdCBJbnRlcmltIEFuYWx5>

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- Data & Data Transfer

- Study level documents vs milestone level documents
- Document version management

ISSUES/CHALLENGES

- TOC
- Milestone Folder Structure
- Program Header & Template
- Team Communication
- Security/Permission Management
- Compliance & FDA Audit
- Team/Project Management
- Interface
- TLF Review Workflow
- Document Management
- **Data & Data Transfer**

- **Organization of historic data transfer from different sources**
- **Versions of data**
- **Archiving**

Data Type	Data File Name	Last Modified...	Modification Time	Data Origin	Validated?
ADaM	adtteos.sas7bdat	jcao	2014-05-07T12:06:26		
ADaM	adttepfs.sas7bdat	jcao	2014-05-07T12:06:28		

▼ Data
ADaM
SDTM
Submission
Dataset
Raw
Other

PROPOSED SOLUTION: A BIOSTATISTICAL PROGRAMMING ENVIRONMENT; SIMPLE, EFFICIENT, AND COMPLIANT

- Everyone working on the same simple & efficient interface
 - Standard and consistent folder structure
 - TOC in database with automatic SAS program shell generation & header population
 - Notification on program status changes
 - One-stop source programming and one-stop validation
 - Audit trail & versioning, no more wet signature or tracking sheet
 - Permission management without IT
 - Streamlined TLF review
 - In-app instant messaging
 - Secure and accurate combined, bookmarked PDF generation, no more 3rd party tool is needed. 100% bookmark accuracy
 - Real-time online team resource management and program status across milestones
 - Audit ready anytime
-

Questions?

Contact: Jeff Cao jcao@viitai.com
6000 Shoreline Court, Suite 201
South San Francisco CA 94080
