An Automatic QC Status Tracking and Management System

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ABSTRACT

Tracking the developing, QC status and comments for hundreds of programs in multiple projects is a challenge work, with the programs and their outputs are frequently changed by multiple programmers every day during the project life cycle; Record and review the status manually are boring, labor intensive, and difficult to assure the accuracy and timeliness; how to improve the project progress communication efficiency is also a big topic.

Based on these needs, we developed a tracking system using VBA and PHP. It stores the tracking data in an independent database, and can be reviewed and modified through Microsoft Excel and html. The tracking database can be also used for other analysis or summary for management purpose. Use this system, we can achieve the following goals: (1) Automatically track status and latest modified time of the programs, corresponding outputs and comparison status (pass/fail) timely without any manually inputting; (2) Detect time logic error between among programs, outputs and QC status timely; (3) Manage the centralized pool of TFL titles, footnotes, populations and input data sets. Additionally, any changes of them can be saved and reminded for the rerun automatically; (4) Through a hyperlink icon at the tool bar area, a web-based issues log tracking tool can be accessed for tracking the comments and its status, programmers can add, modify and close the comments for each programs, or review the summary of all comments for the project; (5) The project manage team can easily find out the up-to-date progress of each project via the web-based project progress interface with visual progress bar and see the details of the progress for each program.

INTRODUCTION

In pharmaceutical industry, the most common task for SAS programmers is to create SAS programs that produce SDTM (Study Data Tabulation Model), ADaM (Analysis Data Model) and TFLs (tables, figures, listings) for FDA submission. In addition to source output from source programmer, QC output from QC programmer is needed to ensure independent double programming and achieve QC/QA endpoints. These programs and outputs are frequently updated due to new raw data transferred, updated macros or programs released, or new requests received from sponsors. Under these circumstances, recording and summarizing the completion and comparison status of programs and outputs after each update are becoming more and more challenging during project management.

To avoid wasted effort and facilitate efficient communication within and across projects, we developed this system to automatically track the status of programs and outputs, and reduce manual works as many as possible. This system comprises three key components, which are shown below at Figure 1.
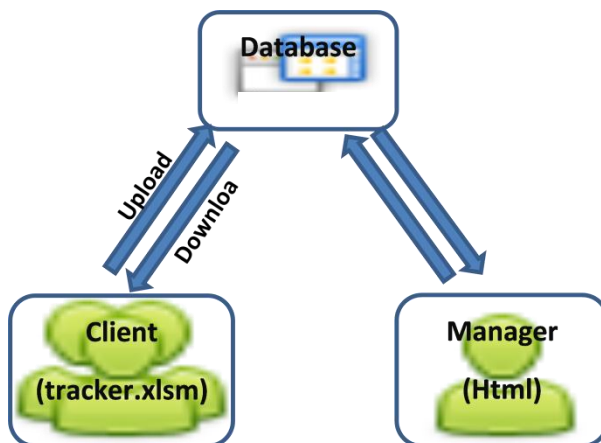

Figure 1.Workflow of QC Status Tracking and Management System

Based on one of the most popular office tools - Microsoft Excel, the client interface provides convenient input and real-time summary within project, making this system user friendly; in addition to client interface, the HTML-based

manager interface provides trail-leaving input and visual status summary within or across projects, making this system highly efficient; by help of integrated background database collecting all projects data, this system achieves fast upload/download and one-click update, and is centrally controllable.

CLIENT INTERFACE

The client interface is able to automatically track status and latest modified time of the programs, corresponding outputs and comparison status (pass/fail) timely without any manually inputting; detect time logic error between among programs, outputs and QC status timely; and manage the centralized pool of TFL titles, footnotes, populations and input data sets.

BASIC CONFIGURATION

Only basic configuration regarding project information and access control is required before the system start to work. For system setup, only sponsor name, project name, study name, study type and parent study path are needed. And access to this system is strictly controlled, no user is allowed except project members authorized with access levels below at Table 1.

Access Level	Access to Project Setup and Authority Control	Access to Dataset/TFLs Modification
1	Read-Write	Read-Write
2	Read-Only	Read-Write
3	Read-Only	Read-Only

Table 1.Summary of different authority levels

Access to data set/TFLs modification means adding, removing and modifying pre-specified data set or TFL items, including corresponding category (SDTM/ADaM/TFL), derivation order, data set name or TFL output name, data set label or TFL title/footnote/population/input data, etc.

All members have the access to check the status of QC process, including program completion status, output completion status, comparison status between source and QC output, leader review status, and statistician review status.

DATASET AND TFL STATUS TRACKING

During status tracking and management, users with different access levels have different responsibilities, separated at different columns by different colors. Each user is able to easily recognize his/her responsibility. Table 2 below shows how we distinguish different roles.

	To be completed by lead programmer
	Automatically completed by status track
	To be completed by lead programmer
	To be completed by statistician

Table 2.Summary of Colors for Different Roles

After data set and TFL items are specified at grey columns by lead programmer, the blue columns will be automatically filled after one-click status track. Project members can easily recognize the programs created or not, date/time of latest programs, outputs created or not, and date/time of latest outputs. If programs or outputs are not yet created, "0" will be noted provided with no system date/time.

Category	Derive Order	Dataset Name	Dataset Label	Source Program Name	Source Program Date	Source Output Name	Source Output Date	QC Program Name	QC Program Date	QC Output Name	QC Output Date
SDTM	1	DM	Demographics	dm.sas	2016-07-12 11:02:12	dm.sas7bdat	2016-07-12 13:08:22	dm.sas	2016-06-10 21:45:50	dm.sas7bdat	2016-07-12 13:02:50
SDTM	2	DS	Disposition	ds.sas	2016-07-13 11:29:30	ds.sas7bdat	2016-07-13 11:44:35	ds.sas	2016-07-13 14:28:24	ds.sas7bdat	2016-07-13 14:28:30
SDTM	5	AE	Adverse Events	ae.sas	2016-06-03 19:46:43	ae.sas7bdat	2016-07-12 13:32:50	ae.sas	2016-05-09 16:27:18	ae.sas7bdat	2016-07-12 14:44:01
SDTM	5	CM	Concomitant Medications	cm.sas	2016-06-03 13:17:23	cm.sas7bdat	2016-07-12 13:54:10	cm.sas	2016-06-04 12:35:13	cm.sas7bdat	2016-07-12 14:47:27
ADaM	1	ADSL	Subject Level Analysis	adsl.sas	2016-06-14 13:24:57	adsl.sas7bdat	2016-06-14 13:54:34	adsl.sas	2016-06-03 17:25:19	adsl.sas7bdat	2016-06-03 17:26:38
ADaM	2	ADAE	Adverse Event Analysis	adae.sas	2016-06-14 13:32:10	adae.sas7bdat	2016-06-14 13:54:35	adae.sas	2016-06-03 17:30:06	adae.sas7bdat	2016-06-03 17:30:13
ADaM	3	ADCM	Concomitant Medication Analysis	adcm.sas	2016-06-14 13:54:36	0		adcm.sas	2016-06-03 17:38:01	adcm.sas7bdat	2016-06-03 17:38:14
ADaM	4	ADVS	Vital signs Analysis	advs.sas	2016-06-14 13:25:56	advs.sas7bdat	2016-06-14 13:54:38	advs.sas	2016-06-03 17:41:35	advs.sas7bdat	2016-06-03 17:41:43
ADaM	5	ADLB	Laboratory Analysis	adlb.sas	2016-06-14 13:54:45	adlb.sas7bdat	2016-06-14 13:22:48	adlb.sas	2016-06-04 17:43:41	adlb.sas7bdat	2016-06-03 17:43:27
ADaM	8	ADEG	ECG Analysis	adeg.sas	2016-06-14 13:12:05	adeg.sas7bdat	2016-06-14 13:54:53	adeg.sas	2016-06-03 17:48:06	adeg.sas7bdat	2016-06-07 14:59:20
ADaM	9	ADPD	PD Analysis	adpd.sas	2016-07-01 16:00:13	adpd.sas7bdat	2016-07-01 16:01:22	0		0	

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Category	Active	Output Type	File Type	Key	Original Output Name	Output Number	Source Program Name	Source Program Date	Source Output Name	Source Output Date	QC Program Name	QC Program Date	QC Output Name	QC Output Date
TFL	Y	T	RTF	T2015110916590547	t-1-1	1.1	t-1-1.sas	2016-06-14 13:29:50	t-1-1.rtf	2016-06-14 14:00:59	t-1-1.sas	2016-06-12 17:14:07	t-1-1.sas7bdat	2016-06-12 17:40:05
TFL	Y	T	RTF	T2015110916590549	t-1-2	1.2	t-1-2.sas	2016-06-14 13:30:31	t-1-2.rtf	2016-06-14 14:01:13	t-1-2.sas	2016-06-12 17:14:31	t-1-2.sas7bdat	2016-06-12 17:40:16
TFL	Y	T	RTF	T2015110916590559	t-1-3	1.3	t-1-3.sas	2016-06-14 13:37:22	t-1-3.rtf	2016-06-14 14:53:32	t-1-3.sas	2016-06-12 17:15:31	t-1-3.sas7bdat	2016-06-12 17:41:41
TFL	Y	T	RTF	T2015110916590570	t-1-4	1.4	t-1-4.sas	2016-06-14 13:40:05	t-1-4.rtf	2016-06-14 15:23:42	t-1-4.sas	2016-06-12 17:22:31	t-1-4.sas7bdat	2016-06-13 07:46:24
TFL	Y	L	RTF	L2015110516435117	l-2-1	2.1	l-2-1.sas	2016-06-12 11:00:08	l-2-1.rtf	2016-06-15 21:13:08	l-2-1.sas	2016-06-12 17:02:19	l-2-1.sas7bdat	2016-06-15 19:24:53
TFL	Y	L	RTF	L2015110516435110	l-2-2	2.2	l-2-2.sas	2016-06-12 11:03:57	l-2-2.rtf	2016-06-15 21:53:51	l-2-2.sas	2016-06-12 17:03:01	l-2-2.sas7bdat	2016-06-15 19:25:07
TFL	Y	L	RTF	L2015110516435117	l-2-3	2.3	l-2-3.sas	2016-06-12 11:03:58	l-2-3.rtf	2016-06-12 11:19:13	l-2-3.sas	2016-06-12 17:36:55	l-2-3.sas7bdat	2016-06-12 19:07:52
TFL	Y	L	RTF	L2015110516435123	l-2-4	2.4	l-2-4.sas	2016-06-14 10:12:41	l-2-4.rtf	2016-06-12 10:17:24	l-2-4.sas	2016-06-12 17:06:17	l-2-4.sas7bdat	2016-06-12 19:11:55
TFL	Y	F	PDF	F2015110916590591	f-3-1	3.1	f-3-1.sas	2016-06-12 10:58:09	f-3-1.rtf	2016-06-13 15:30:44	f-3-1.sas	2016-06-12 15:18:01	f-3-1.sas7bdat	2016-06-13 13:11:19
TFL	Y	F	PDF	F20151109165905106	f-3-2	3.2	f-3-2.sas	2016-06-15 20:12:06	f-3-2.rtf	2016-06-15 21:19:25	f-3-2.sas	2016-06-12 15:17:05	f-3-2.sas7bdat	2016-06-14 16:54:27

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Project members can also easily recognize the completion status, comparison status (between source and QC output), lead programmer review status (manually confirmed at green columns), and statistician review status (manually confirmed at dark blue columns).

Category	Derive Order	Dataset Name	Source Program Status	QC Program Status	Compare Status	Compare Date	Review Status - Leader	Review Date - Leader	Issue ID - Leader	Review Status - Statistician	Review Date - Statistician	Issue ID - Statistician
SDTM	1	DM	Ready for Compare	Ready for Compare	Pass	2016-07-12 13:08:32	Ready for Review			Ready for Review		
SDTM	2	DS	Ready for Compare	Ready for Compare	Pass	2016-07-13 14:28:57	Ready for Review			Ready for Review		
SDTM	5	AE	Ready for Compare	Ready for Compare	Pass	2016-07-12 14:46:29	Ready for Review			Ready for Review		
SDTM	5	CM	Ready for Compare	Ready for Compare	Pass	2016-07-12 14:48:19	Ready for Review			Ready for Review		
ADaM	1	ADSL	Ready for Compare	Ready for Compare	Pass	2016-06-14 14:03:37	Ready for Review			Ready for Review		
ADaM	2	ADAE	Ready for Compare	Ready for Compare	Comparing	2016-06-14 14:02:21	Ready for Review			Ready for Review		
ADaM	3	ADCM	Programing	Ready for Compare	Not Ready for Compare		Not Ready for Review			Not Ready for Review		
ADaM	4	ADVS	Ready for Compare	Ready for Compare	Ready for Compare		Not Ready for Review			Not Ready for Review		
ADaM	5	ADLB	Re-Run Needed	Re-Run Needed	Not Ready for Compare		Not Ready for Review			Not Ready for Review		
ADaM	8	ADEG	Ready for Compare	Ready for Compare	Re-Compare Needed	2016-06-06 14:02:43	Not Ready for Review			Not Ready for Review		
ADaM	9	ADPD	Ready for Compare	Not Start	Not Ready for Compare		Not Ready for Review			Not Ready for Review		

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Category	Active	Output Type	File Type	Key	Original Output Name	Output Number	Source Program Status	QC Program Status	Compare Status	Compare Date	Review Status - Leader	Review Date - Leader	Issue ID - Leader	Review Status - Statistician	Review Date - Statistician	Issue ID - Statistician
TFL	Y	T	RTF	T2015110916590547	t-1-1	1.1	Ready for Compare	Ready for Compare	Pass	2016-06-14 16:25:41	Re-Review Needed	2016-01-15 14:05:32	1	Pass	2016-06-16 09:19:11	
TFL	Y	T	RTF	T2015110916590549	t-1-2	1.2	Ready for Compare	Ready for Compare	Pass	2016-06-14 16:25:42	Re-Review Needed	2016-01-15 14:05:23	3	Pass	2016-06-16 09:19:18	
TFL	Y	T	RTF	T2015110916590559	t-1-3	1.3	Ready for Compare	Ready for Compare	Pass	2016-06-14 16:25:48	Re-Review Needed	2016-01-15 13:39:41	4, 5, 6	Pass	2016-06-16 09:20:03	
TFL	Y	T	RTF	T2015110916590570	t-1-4	1.4	Ready for Compare	Ready for Compare	Pass	2016-06-14 16:25:53	Re-Review Needed	2016-01-15 11:42:45	7, 8	Pass	2016-06-16 09:20:52	
TFL	Y	L	RTF	L20151051643517	l-2-1	2.1	Ready for Compare	Ready for Compare	Pass	2016-06-30 14:47:08	Re-Review Needed	2015-11-09 10:53:54	11, 20	Pass	2016-06-16 09:22:24	
TFL	Y	L	RTF	L2015110516435110	l-2-2	2.2	Ready for Compare	Ready for Compare	Pass	2016-06-15 22:22:09	Re-Review Needed	2015-11-09 10:54:32	12	Pass	2016-06-16 09:22:38	
TFL	Y	L	RTF	L2015110516435117	l-2-3	2.3	Ready for Compare	Ready for Compare	Pass	2016-06-13 16:52:23	Re-Review Needed	2015-11-09 11:42:36	13	Pass	2016-06-16 09:23:03	
TFL	Y	L	RTF	L2015110516435123	l-2-4	2.4	Ready for Compare	Ready for Compare	Pass	2016-06-14 10:21:35	Re-Review Needed	2015-11-09 17:12:30	15, 16, 17	Pass	2016-06-16 09:23:41	
TFL	Y	F	PDF	F2015110916590591	f-3-1	3.1	Ready for Compare	Ready for Compare	Pass	2016-07-01 14:19:34	Re-Review Needed	2016-01-15 15:49:45	18	Pass	2016-06-16 09:26:41	
TFL	Y	F	PDF	F20151109165905106	f-3-2	3.2	Ready for Compare	Ready for Compare	Pass	2016-06-15 21:20:45	Re-Review Needed	2016-01-15 15:45:57	22	Pass	2016-06-16 09:28:53	

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Table 3 below clarifies the status at different columns involved.

Column Name	Auto or Manually Input	Possible Value	Instruction
Source/QC Program Status	Auto	Not Start	Program name noted as "0"; SAS program is not yet created
	Auto	Programing	Output name noted as "0"; SAS program is created, but corresponding output is not yet created
	Auto	Re-Run Needed	Date/time of output is earlier than date/time of SAS program; reminding for program re-run
	Auto	Ready for Compare	Corresponding output is successfully created
Compare Status	Auto	Not Ready for Compare	Either source or QC output is not successfully created; comparison is pending
	Auto	Ready for Compare	Both source and QC output are successfully created; reminding for comparison
	Auto	Re-Compare Needed	Date/time of comparison result is earlier than date/time of source or QC output; reminding for re-comparison
	Auto	Comparing	Comparison result is not exactly equal; need to solve the differences when possible, or explain the proper reason not equal
	Auto	Pass	Both source and QC output are successfully created, and comparison result is exactly equal
Review Status - Leader/ Statistician	Auto	Not Ready for Review	Compare status is not passed; manual review is pending
	Auto	Ready for Review	Compare status is passed; reminding for manual review
	Manually	Fail	Fail for manual review; reminding for solving the comments at issue log
	Manually	Pass	Corresponding output pass the manual review
	Auto	Re-Review Needed	Date/time of manual review is earlier than date/time of source output; reminding for re-review

Table 3.Summary of program status, QC status and review status

To further understand how the status is automatically created as passed or not, please refer to Figure 2 below.
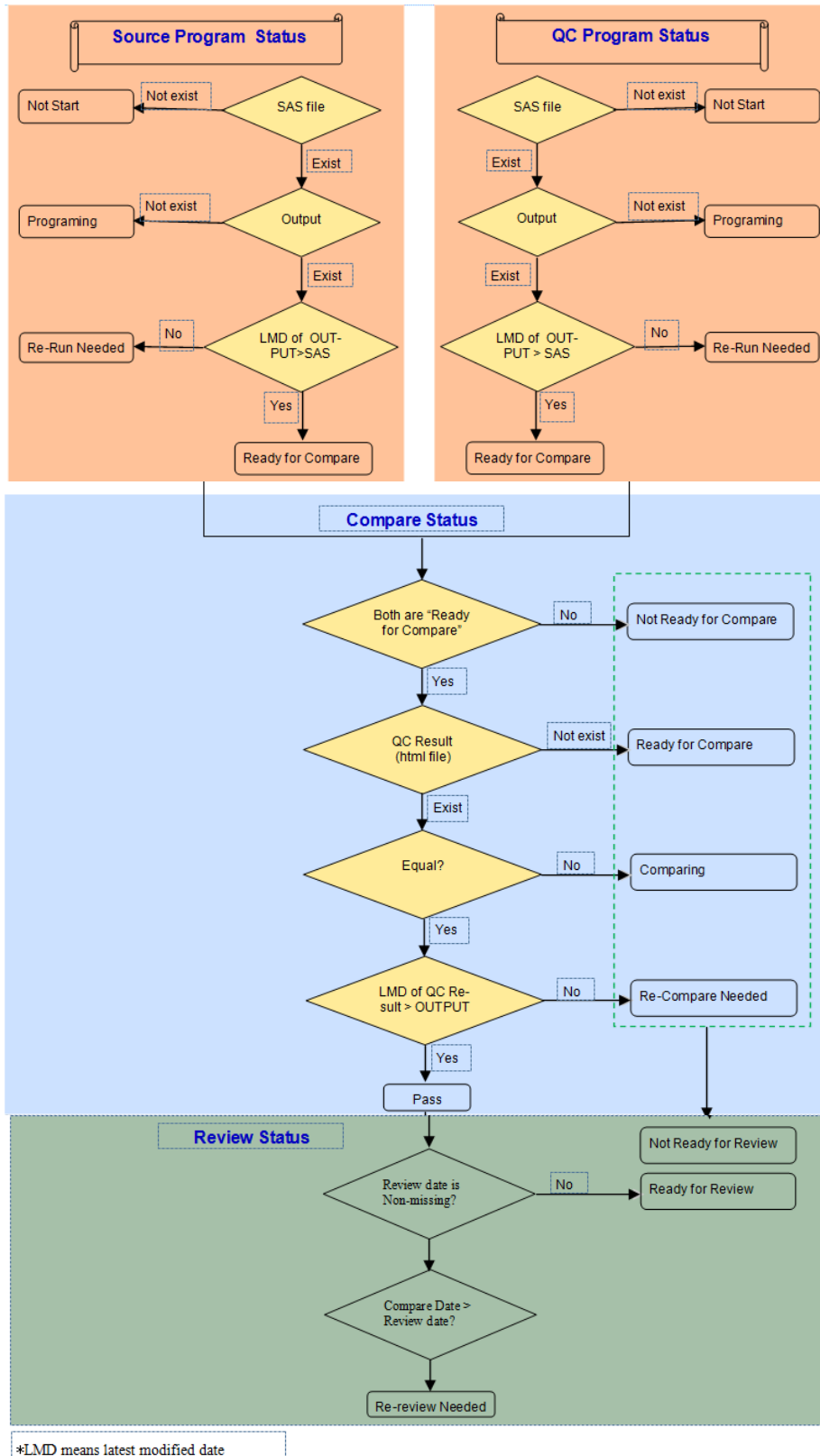
Figure 2.Flowchart of How QC Status Is Automatically Determined

Every time one-click status track is performed, real-time status summary will be automatically updated and clearly displayed. Project members are given the chances to pay more attention to what is to be done next without wasting time and efforts figuring out what has been changed or not.

Besides columns defined at table 3, additional ones from this system provide further functions. One example is column Mockup Code that allows project members to link between TFL outputs and company TFL mockup library. Another example is column Validation Level that allows project validation to be categorized into level 1, 2 and 3, representing different validation priorities including manual review, independent double programming, and third part statistical review respectively.

CENTRALIZED POOL OF TFL INFORMATION

Another outstanding advantage of the client interface at this system is being able to centrally collect and manage the TFL information needed for subsequent programming. Corresponding TFL titles, footnotes, population and input data sets used are input and cautiously reviewed by lead programmer. Then they will be pooled as SAS macro for subsequent TFL generation, facilitating efficient one-way information flow.

When each one of these four columns is modified, modification date/time will be immediately extracted and reflected at column Latest Modify Date. Project members will receive pop-up window reminding for SAS macro re-creation, and will not be able to continue status tracking until re-creation is performed. After SAS macro is re-created, both of source and QC program status will be updated as "Re-Run Needed", reminding for TFL re-run after information update.

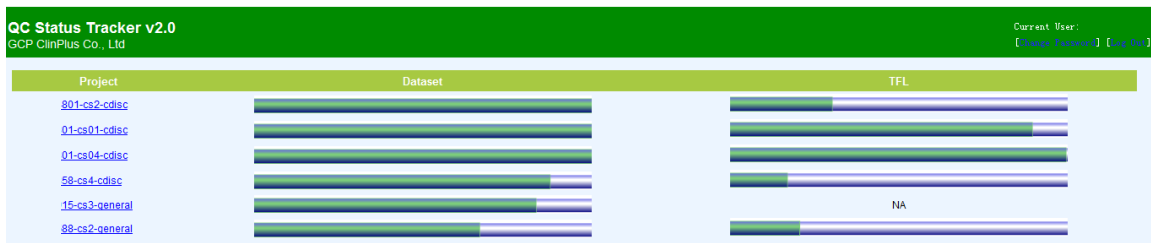| Category	Active	Output Type	File Type	Key	Original Output Name	Output Number	Title	Footnote	Population	Input Datasets	Mockup Code	Latest Modify Date
TFL	Y	T	RTF	T2015110916590547	t-1-1	1.1	Title 1.1	Footnote 1.1	Safety Set	ADaM.ADSL		2016-08-7 20:36:42
TFL	Y	T	RTF	T2015110916590549	t-1-2	1.2	Title 1.2	Footnote 1.2	Safety Set	ADaM.ADCM		2016-08-7 20:36:45
TFL	Y	T	RTF	T2015110916590559	t-1-3	1.3	Title 1.3	Footnote 1.3	Safety Set	ADaM.ADAE		2016-08-7 20:36:45
TFL	Y	T	RTF	T2015110916590570	t-1-4	1.4	Title 1.4	Footnote 1.4	Safety Set	ADaM.ADLB		2016-08-7 20:36:45
TFL	Y	L	RTF	L2015110516643517	l-2-1	2.1	Title 2.1	Footnote 2.1	All Subjects	ADaM.ADSL		2016-08-7 20:36:45
TFL	Y	L	RTF	L2015110516435110	l-2-2	2.2	Title 2.2	Footnote 2.2	All Subjects	SDTM.CM		2016-08-7 20:37:02
TFL	Y	L	RTF	L2015110516435117	l-2-3	2.3	Title 2.3	Footnote 2.3	All Subjects	SDTM.AE		2016-08-7 20:37:07
TFL	Y	L	RTF	L2015110516435123	l-2-4	2.4	Title 2.4	Footnote 2.4	All Subjects	SDTM.LB		2016-08-7 20:36:45
TFL	Y	F	PDF	F2015110916590591	f-3-1	3.1	Title 3.1	Footnote 3.1	Safety Set	ADaM.ADLB		2016-08-7 20:36:45
TFL	Y	F	PDF	F20151109165905106	f-3-2	3.2	Title 3.2	Footnote 3.2	Safety Set	ADaM.ADLB		2016-08-7 20:36:45

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MANAGER INTERFACE

For project managers, how to balance the triangle of tasks, resources and timelines seems an eternal topic. They might still overestimate or underestimate the situations after extra efforts are made for project evaluations. To help balance the project and personnel arrangement, we developed HTML manager interface where all project data are integrated into one database and based on that project evaluation can be more accurate, reliable and efficient.

In addition to covering all functions from client interface, the manager interface allows project manager to easily find out the up-to-date progress within or across projects provided with visual progress bar, and see the details of how each program and output progresses. Also it is able to track the comments status where project members can add, reply and close the comments for each program and output, or review the overall summary of all comments.

OVERALL SUMMARY OF PROJECT PROGRESS

At the home page of manager interface, all authorized projects of the users are listed and briefly summarized with visual progress bar, showing the up-to-date progress status of each project. One can get an overall impression at first sight about the data set and TFL completion status. By clicking each project name, one can enter into corresponding data set or TFL pages of corresponding project.

QC Status Tracker v2.0 GCP ClinPlus Co., Ltd		Current User: [ ] [Log In]
Project	**Dataset**	**TFL**
801-cs2-cdisc		
01-cs01-cdisc		
01-cs04-cdisc		
58-cs4-cdisc		
15-cs3-general		NA
88-cs2-general		

At the individual project page below, one can easily get the real-time detailed summary of how many outputs are

successfully created, compared and reviewed shown by progress bars and actual percentage numbers. This can significantly provide more accurate, reliable, efficient and real-time reference data for the project evaluation; project managers and other members are able to pay more attention to quality issues of the production.
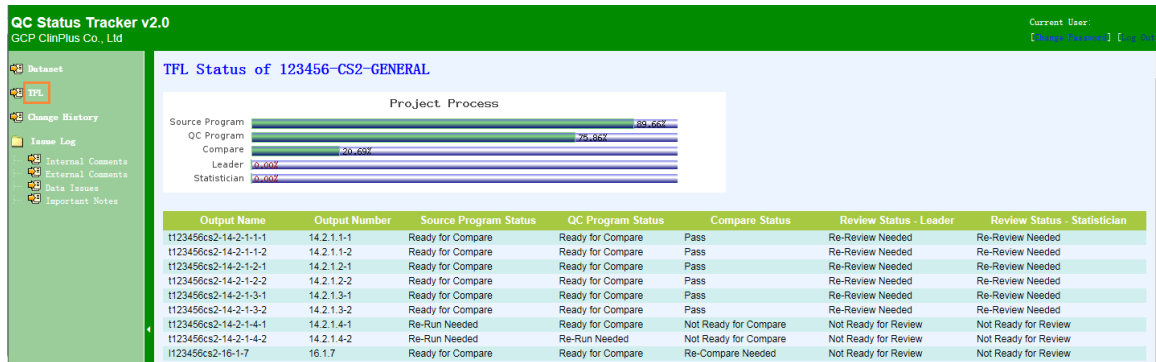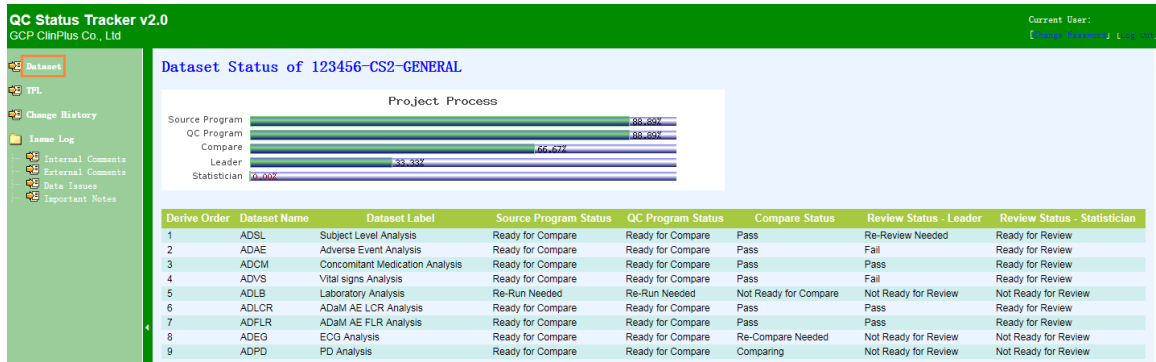
ISSUE LOG

One of the most outstanding demands during project management is to facilitate internal and external communication efficiently and explicitly, which can be face to face or by media tools like phones, emails, etc. Project manager need to collect instructions from sponsor and give feedback to project members, which could awfully cause extra workloads sometimes. To avoid massive and inefficient communication and keep track of all findings from internal and external reviewers, we developed issue log function as a real-time platform where everyone is able to work on the same page.

Issues can be generally separated into four categories: Internal Comments, External Comments, Source Data Issues, and other Important Notes. Based on these categories, issue log at this system is also separated into four areas. They all share the same structure at the interface.

Figure 3 below shows the overall flow chart of issue log, including original comments recorded, replies populated, and confirmation.
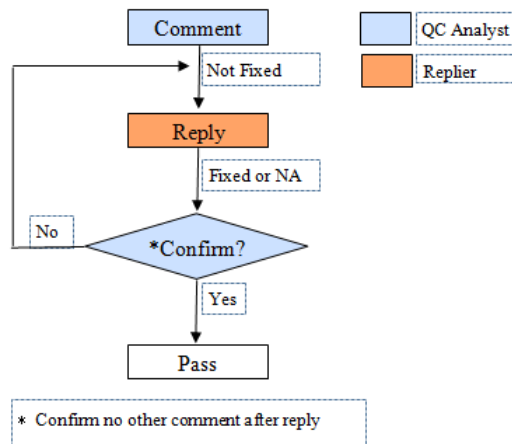
Figure 3.Flow Chart of Issue Log

When QC programmers or manual reviewers have findings for individual or overall outputs, they record the original comments. Corresponding sequence ID, name of recorder, date/time of record, and original status "Not Fixed" are automatically created. Then repliers fix the described issues and close the comments as "Fixed"; or take no action and close the comments as "NA" with reasons. After replies, original recorders confirm if the comments are fixed or closed reasonably; and provide new findings if they disagree with the replies. All added comments and replies can be seen immediately by webpage refresh.

Overall summary of pending and closed comments within project will be displayed.

CONCLUSION

With this system, QC status tracking and project management are simplified but significantly improved in various aspects Including efficiency and quality. Except functions already introduced, one of the further benefits of this system is to promote modularized validation (manual review, independent double programming, and third part statistical review) with different validation methods applied for outputs from different hierarchies. Those critical outputs with the most priorities are able to be created and validated first.

Beyond benefits to the ongoing projects, the integrated database and centralized management pool at this system provide macroscopic basis when quantifying workloads, resources, and their interaction, which can significantly avoid high workload and overlapped timeline schedule, thus improve current and future project arrangement.

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