



AD05

Programming Development and Validation Tracking Application “iTrack”

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PhUSE EU connect - Frankfurt 2018

AD05: Programming Development and Validation Tracking Application “iTrack”



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Director of Statistical Programming at ICON plc.

Why did we develop iTrack at ICON?

iTrack is an Oracle APEX Database that tracks the programming and statistical workflow

Legacy Workflow

- Multiple legacy spread sheets Programming Tracker
- Validation Comments Log
- Programming Lead Review Comments log
- Statistical Review Tracker
- Statistical Review Comments Log
- Peer Review Form

Current Workflow

- Data within our workflow is now centralised
- We have increased documentation compliance
- We have seen reduction in documentation and filing burdens on teams and leads
- We have better work forecasts, progress reports and metrics

Programmers Home Screen

⚙️ PDVD

👤 Roles

📄 Reports

📋 Access Log

Study List

Study Number

1234/5678

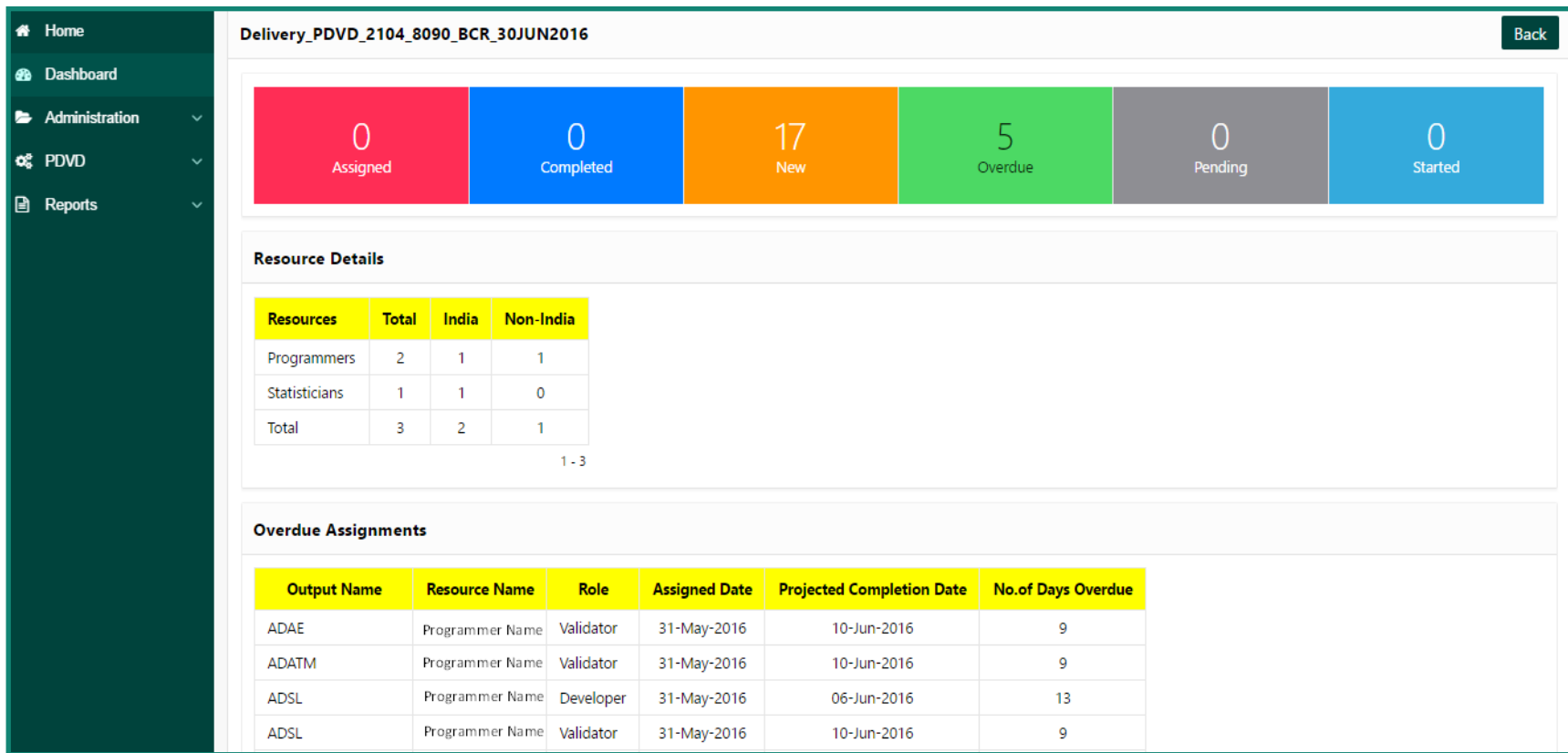
1 - 1

Rows 10

Actions

Delivery PDVD Name	Program Name	Output Name	Title	Item Type	Type of Work	Projected Completion Date	Assigned Date
Delivery_PDVD_1234/5678_RMP_Dry Run_31DEC2016	de_sum.tot	Table 14.1.2.1	Demographic Characteristics	Table	Development	09-Dec-2016	08-Dec-2016
Delivery_PDVD_1234/5678_BDR_Draft_31DEC2016	Table 14.3.1.7.11.1	Table 14.3.1.7.11.1	Summary of Target Medical Events (TME) by Maximum CTCAE Grade (All Causalities)	Table	Development	09-Dec-2016	08-Dec-2016
Delivery_PDVD_1234/5678_BDR_Draft_31DEC2016	aectc1s11_de.tot	Table 14.3.1.2.11.2	Decreasing Order of Frequency Treatment-Emergent Adverse Events by MedDRA Preferred Term and Maximum CTCAE Grade (Treatment Related)	Table	Development	09-Dec-2016	08-Dec-2016
Delivery_PDVD_1234/5678_BDR_Draft_31DEC2016	aectc1s11_de.tot	Table 14.3.1.2.11.1	Decreasing Order of Frequency Treatment-Emergent Adverse Events by MedDRA Preferred Term and Maximum CTCAE Grade (All Causalities)	Table	Development	09-Dec-2016	08-Dec-2016

Lead and Managers Dashboard



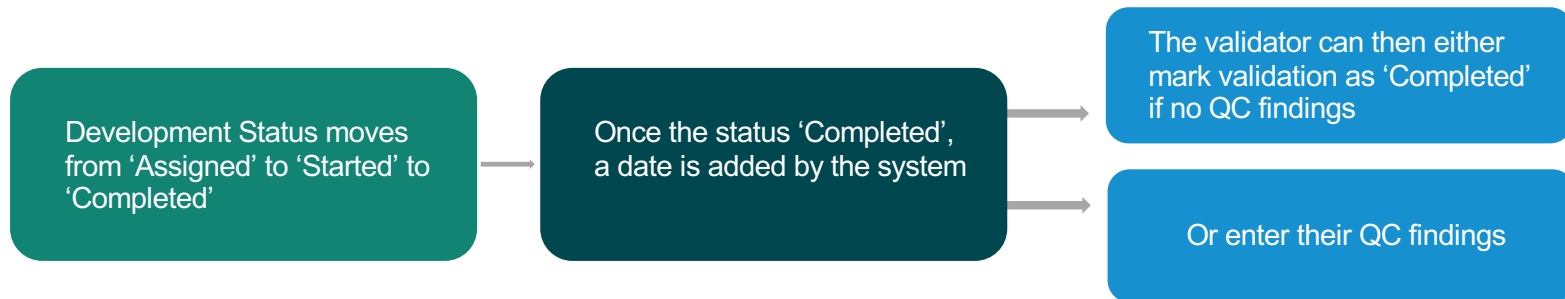
Planning Programming Tasks

☐	Item / Identifier	Program Name	Output Name	Validation Program Name	Title	Theme	Item Type	Unique Replicate Indicator	Replicate Of	Rerun	Validation Type
☐	D011	d1_adae	ADAE	v_d1_adae	Adverse Events Analysis Data	Safety	Dataset	Unique		No v	A
☐	D003	d1_adcm	ADCM	v_d1_adcm	Concomitant Medication Analysis Data	Safety	Dataset	Unique		No v	A

Study Number	Item / Identifier	Program Name	Unique/Replicate	Developer	Production Projected Completion Date	Production Status	Production Actual Completion Date	Validator	Validation Projected Completion Date	Validation Status	Validation Actual Completion Date
1234/5678	D001	ADAE.sas	Unique	Programmer Name	03-Oct-2017	Assigned		Programmer Name	03-Oct-2017	Assigned	
1234/5678	D002	ADCM.sas	Unique	Programmer Name	03-Oct-2017	Assigned		Programmer Name	03-Oct-2017	Assigned	
1234/5678	D003	ADDA.sas	Unique	Programmer Name	03-Oct-2017	Assigned		Programmer Name	03-Oct-2017	Assigned	

Status of Tasks

Study Number	Item / Identifier	Program Name	Developer	Production Projected Completion Date	Production Status	Production Actual Completion Date	Validator	Validation Projected Completion Date	Validation Status	Validation Actual Completion Date
1234/5678	D001	ADAE.sas	Programmer Name	13-Sep-2017	Completed	11-Sep-2017	Programmer Name	13-Sep-2017	Completed	11-Sep-2017
1234/5678	D002	ADCM.sas	Programmer Name	13-Sep-2017	Completed	11-Sep-2017	Programmer Name	13-Sep-2017	Completed	11-Sep-2017
1234/5678	D003	ADDA.sas	Programmer Name	13-Sep-2017	Completed	11-Sep-2017	Programmer Name	13-Sep-2017	Completed	11-Sep-2017



Adding QC comments

Delivery Item - Status

Title

Subject Disposition by Treatment Sequence

Process

Validation

Status

Pending

Reason

Provided Comments

Comments

Cancel

Add Validation Comment

Add Review Comment

Save

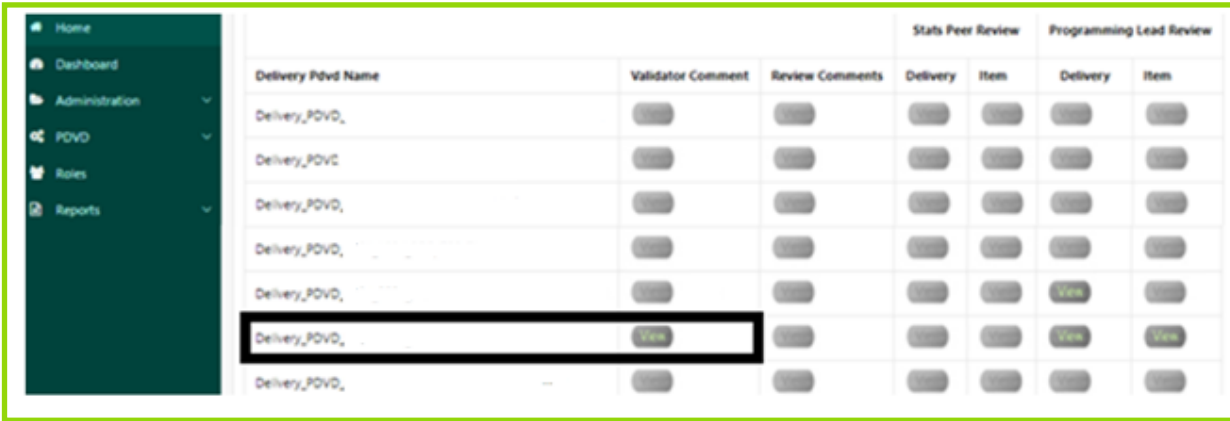
☒	☐	Validator Comment	Parent Comment	Error Type	Error Category	Developer Response	Developer Comments	Finding Status	Add Attachment
☒	☐	Need more clarity		Cosmetic updates	Programming		-	New	

1 rows selected

Total 1

Cancel Save

Viewing and Addressing Comments

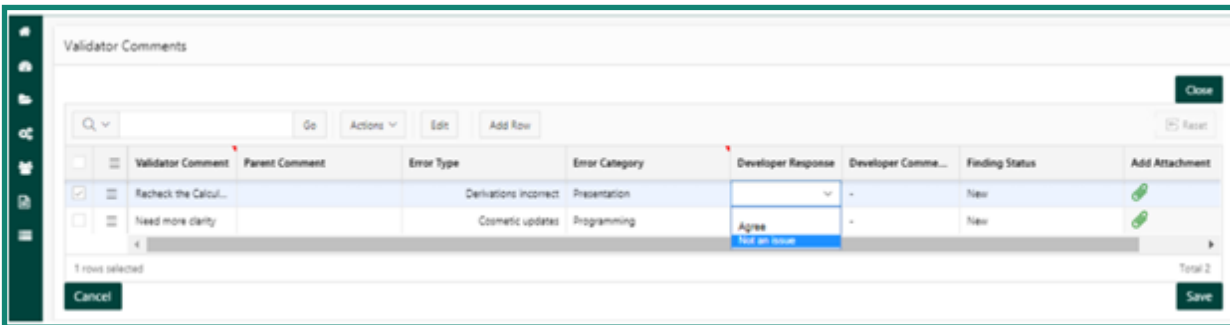


Delivery POVD Name	Validator Comment	Review Comments	Stats Peer Review		Programming Lead Review	
			Delivery	Item	Delivery	Item
Delivery_POVD_1						
Delivery_POVD_2						
Delivery_POVD_3						
Delivery_POVD_4						
Delivery_POVD_5						
Delivery_POVD_6						
Delivery_POVD_7						
Delivery_POVD_8						
Delivery_POVD_9						
Delivery_POVD_10						
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Delivery_POVD_99						
Delivery_POVD_100						

Once validation comments have been entered the development programmer is notified through their dashboard

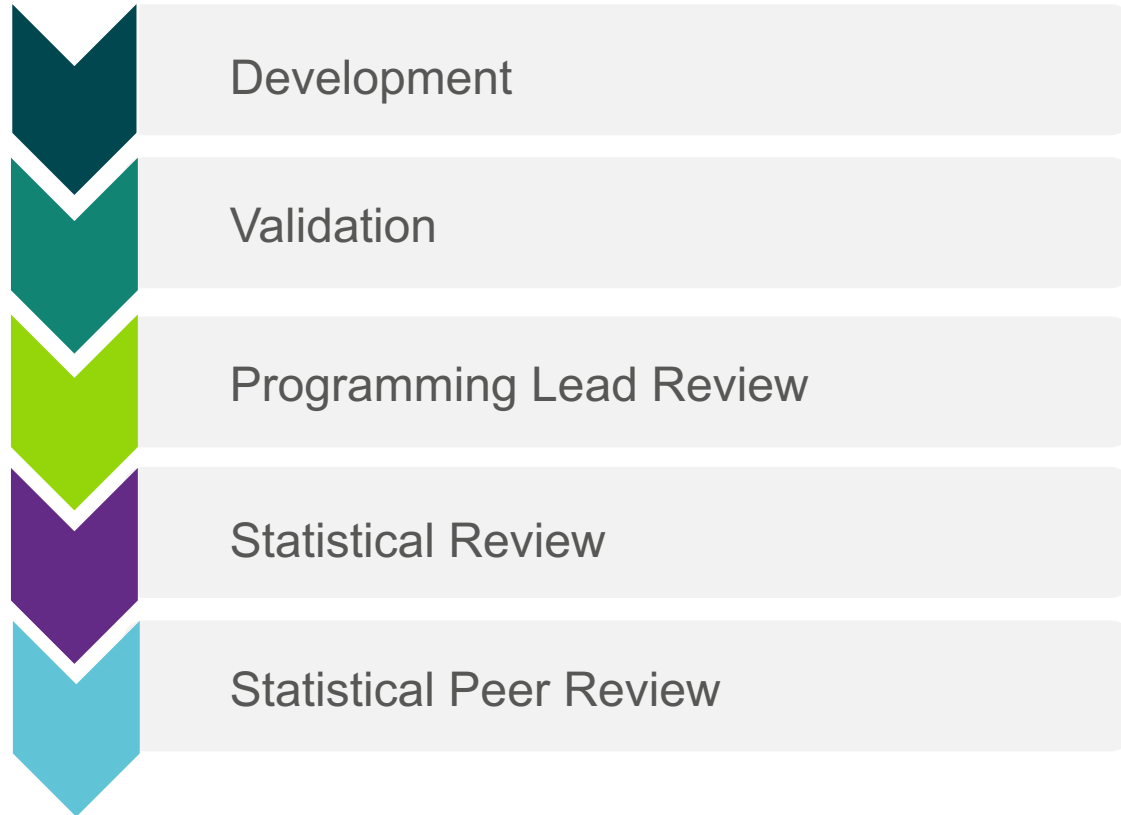
They accept the comment, status is automatically set to 'Pending', and the date set to 'null'

Or they reject the comment entering the reason



Validator Comment	Parent Comment	Error Type	Error Category	Developer Response	Developer Comment	Finding Status	Add Attachment
Recheck the Calcul...		Derivations incorrect	Presentation		-	New	
Need more clarity		Cosmetic updates	Programming	Agree	-	New	

Similar Workflow



Each step is either tracked as complete or reviewer comments are added.

If comments are accepted, there is a step back in the process

Process Compliance & Controls

- The tool has built in controls to assist with process compliance, for example
 - Delivery date should always greater than or equal to the system date.
 - Developer and Validator cannot be same for a single task
 - Production completion date cannot be after Validation completion date.
 - Back dating is not permitted
 - There cannot be any missing values in mandatory fields defined in ICON SOP/WPs.
 - Pre-populated drop down lists to ensure consistency in completion
 - Access controls to the study information.
 - Dates are the current system date, no manual entry permitted
 - Users have write access only to the tasks that have been assigned to them.
 - And so on...

Evidence of QC and Filing

- Per ICON SOPs, the delivery sheet serves as evidence that the QC process has occurred and had been completed as expected – who completed what task & when

The screenshot displays a software interface with a confirmation dialog box in the foreground. The dialog box, titled "Confirmation", asks "Do you want to archive this Delivery-POVD now?" and has "Yes" and "No" buttons. In the background, there is a table with columns: "Item / Ident...", "Program Name", "Output name", "Validation", "Validation Actual Compl...", "Valid status com...", and "General comments". A single row is visible with the value "0001" in the first column, "ADSL" in the second, "ADSL" in the third, and "17-Oct-2017" in the fifth. Below the table, there are several action buttons: "Allocate Resources", "Update Projected Completion Date", "Rework", "Bulk Update", "Lead Comments", "Delete", "Archive Delivery POVD" (highlighted in red), "Delete Delivery POVD", and "Save".

- The delivery sheet can be downloaded once all fields have been entered and all tasks are completed for a delivery
- The system creates a signature form, with the delivery sheet appended
- The study lead electronically signs the form and files in the study TMF

Reporting - Planning and Quality Metrics



Planning Reports

- Overdue Assignments
- Assignment Summaries
- Workload Forecast Reports
- Delivery & Output Summaries



Quality Reports

- Re-work Cycle Reports
- First Time Right Reports
- Findings Summaries
- Quality metrics

**The Report Hierarchy is Department, Sponsor, Study, Programmer
(availability dependent on role)**

Sample of reports

Quality - Department level

Department		Dataset	Tables	Listings	Figures	Others	Total
OverAll	Total	2/992 (.2%)	3/3252 (.09%)	0/1161 (0%)	1/679 (.11%)	0/165 (0%)	6 / 6469 (.09%)
	Programming	2	2	0	1	0	5
	Presentation	1					

Quality - Sponsor Level

Sponsor Name		Dataset	Tables	Listings	Figures	Others	Total
	Total	2/21 (9.52%)	3/105 (2.86%)	0/40 (0%)	1/3 (33.33%)	0/0 (0%)	6 / 169 (3.55%)
	Programming	2	2	0	1	0	5
	Presentation	1	1				

Quality - Study level

Study No		Dataset	Tables	Listings	Figures	Others	Total
/0001	Total	0/0 (0%)	1/3 (33.33%)	0/2 (0%)	1/2 (50%)	0/0 (0%)	2 / 7 (.29%)
	Programming	0	1	0	1	0	2
	Presentation	0	0	0	0	0	0
/0004	Total	2/13 (15.38%)	2/101 (1.98%)	0/38 (0%)	0/0 (0%)	0/0 (0%)	4 / 152 (.03%)
	Programming	2	1	0	0	0	3
	Presentation	1	1	0	0	0	2

Path to Roll Out

Communication

- Business Case
- Vendor Selection
- Project Charter
- Requirement Specifications
- Development
- Validation
- Testing
- Pilot
- Training
- Roll-out

- iTrack was rolled out in 2 Phases over 2 years
- Phase I included programming development, validation and lead review tracking, with associated reports and metrics
- Phase II included statistical review, additional reports and other enhancements

What have we experienced?



Data within our workflow is now centralised



Increased documentation compliance



Reduction in documentation and filing burdens on teams and leads



Better work forecasts, progress reports and metrics



Regular communication, repeat training and maintenance support is vital



Recognition and planning for the learning curve for staff also important

Summary & Closing Remarks

Phase III – What's next?

- We are considering extending the iTrack database to include our programming and statistics resourcing tool, costing tool and revenue reporting
- We have established a connection between iTrack and our SAS programming environment, so we plan to build tools that cross check the tracking data against the data on our computing environment (e.g. date tasks are indicated in iTrack as complete versus the dates the outputs were generated)
- Establish a link between the database and our e-signature tool

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Thank You

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