

# PhUSE 2017

## Paper PP11

# Programming Development and Validation Tracking Application

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## ABSTRACT

Just like other companies, ICON has been tracking programming work flows and quality review findings within a series of Microsoft Excel (XLS) files. In 2016, ICON rolled out a Programming Development and Validation Tracking Application (“PDVD”) to replace these XLS files. This paper/poster is an introduction to the application, including the user interface, and reporting functionality available within the application. It will also discuss ICONs approach and experience with vendor selection, designing, developing, testing, piloting and rollout of the application, along with our 2017 plans to include further quality tracking and reporting functionality.

## INTRODUCTION

This paper is an introduction to the ICON Programming Development and Validation Tracking Application (“PDVD”), an APEX Oracle application. The paper will provide an overview of the user interface, planning and tracking functionality, along with the current reports available. It will also discuss ICONs approach and experience with vendor selection, designing, developing, testing, piloting and rollout of the application, along with our 2017 plans to include further quality tracking and reporting functionality.

## USER INTERFACE

### HOME SCREEN:

This is the home screen that an individual programmer will see. The home screen indicates the counts of Completed/Pending/Overdue tasks. The Study List will display the List of Studies assigned to the logged in Programmer. They can also view tasks that are assigned to them, but not yet completed.

The screenshot shows the PDVD application interface. On the left is a dark green sidebar with navigation options: PDVD, Roles, Reports, and Access Log. The main content area is titled 'Study List' and features a search box for 'Study Number' with the value '1234/5678' and a '1 - 1' indicator. Below the search box is a table with columns: Delivery PDVD Name, Program Name, Output Name, Title, Item Type, Type of Work, Projected Completion Date, and Assigned Date. The table contains four rows of data.

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

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## DASHBOARD:

The dashboard is displayed for management, and leads. It provides the status of each study delivery PDVD with respect to status count, resource details, overdue assignment and completion status.

Home
Delivery\_PDVD\_2104\_8090\_BCR\_30JUN2016
Back

0  
Assigned

0  
Completed

17  
New

5  
Overdue

0  
Pending

0  
Started

**Resource Details**

Resources	Total	India	Non-India
Programmers	2	1	1
Statisticians	1	1	0
<b>Total</b>	<b>3</b>	<b>2</b>	<b>1</b>

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**Overdue Assignments**

Output Name	Resource Name	Role	Assigned Date	Projected Completion Date	No.of Days Overdue
ADAE	Programmer Name	Validator	31-May-2016	10-Jun-2016	9
ADATM	Programmer Name	Validator	31-May-2016	10-Jun-2016	9
ADSL	Programmer Name	Developer	31-May-2016	06-Jun-2016	13
ADSL	Programmer Name	Validator	31-May-2016	10-Jun-2016	9

## PLANNING AND TRACKING

### PLANNING THE DELIVERY

#### STUDY DELIVERY PLAN

This screen shows the list of all the planned deliveries for the logged in user along with other details such as sponsor identifiers, delivery dates, team list etc.

Delivery PDVD Name	Study Number	Sponsor Name	SAS Version	Operating System	Delivery Date	Unblinded Flag	Study Type	Team
Delivery_PDVD_1234/5678_BDR_Dry_Run_30JUN2017	1234/5678	Sponsor Name	9.3	Windows 2003	30-Jun-2017	Yes	-	
Delivery_PDVD_5678/1234_CSR_Dry_Run_20JUL2017	5678/1234	Sponsor Name	9.4	Windows 2003	20-Jul-2017	Yes	-	

### PLANNING TASKS

The Lead programmer assigns various attributes to each Output which helps in setting up the criteria for any filter options. ICON filter options would include safety/efficacy designation, output type (Dataset/Tables/Listing/Graphs), unique and replicate designation etc.

<input type="checkbox"/>	Item / Identifier	Program Name	Output Name	Validation Program Name	Title	Theme	Item Type	Unique Replicate Indicator	Replicate Of	Rerun	Validation Type
<input type="checkbox"/>	D011	d1_adae	ADAE	v_d1_adae	Adverse Events Analysis Data	Safety	Dataset	Unique		No <input type="text" value=""/>	A
<input type="checkbox"/>	D003	d1_adcm	ADCM	v_d1_adcm	Concomitant Medication Analysis Data	Safety	Dataset	Unique		No <input type="text" value=""/>	A

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The Lead programmer assigns tasks to developer and validator along with projected completion dates which makes it easier for the programmers to plan and prioritise their work.

Delivery PDVD											
<input type="text" value="Q"/> <input type="button" value="Go"/> <input type="button" value="Actions"/>											
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	

### COMPLETING TASKS

Programmers update the production and validation status, along with completion dates.

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

### TRACKING

#### EVIDENCE OF QUALITY CONTROL

This application has lot of advantages over excel as it centralizing the data, and most of the functionalities in the tool are automated. Also there are various edit checks implemented which result in high quality of the tracking data.

Some of the edit checks within the tool are:

1. Delivery date should always greater than or equal to the system date.
2. Developer and Validator cannot be same for a single task.
3. Production completion date cannot be after Validation completion date.
4. There is no possibility of entering back date, so the system has to be current and up to date.
5. There cannot be any missing values in mandatory fields. The delivery PDVD cannot be saved with missing values.
6. The only section which has to be manually entered is the comment field. The rest of the fields have prepopulated drop down lists.
7. A team will be allocated and assigned in the PDVD and only those people can view and access the study information / PDVD.
8. Once the status is changed to 'Completed', the completion date will be defaulted to the current system date.
9. Some functionality is only visible to Leads. For example, only the study lead can create a new delivery PDVD for that study, the lead can only assign resources, change the delivery date, delete the PDVD, close /reopen the PDVD and so on.
10. Users have write access only to the tasks that have been assigned to them.

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## REPORTING

Numerous reports can be generated using this tool. These reports are created just by a click of a button. All reports can also be downloaded in XLS format and can be shared if required. Below is a summary of the different types of reports available within the tool:

### OVERDUE ASSIGNMENT REPORT

This report provides a summary of the tasks that are overdue. This report is available to managers, leads and the individual programmers, from their home screen.

Item / Identifier	Program Name	Output Name	Title	Theme	Item Type	Production Programmer	Production Projected Completion Date	Production Status	Production Actual Completion Date
D001	d0_adsl	ADSL	Subject Level Analysis Data	Safety	Dataset	Programmers Name	31-Jul-2017		

### DELIVERY PDVD SUMMARY REPORT

This report tracks the progress of the delivery by displaying the status of each task in the delivery wrt count and percentage.

ItemType	Total	Unique	Replicate	Development					Validation				
				New	Assigned	Started	Pending	Completed	New	Assigned	Started	Pending	Completed
Dataset	15	15	0	15 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Table	83	68	15	44 (53%)	11 (13%)	0 (0%)	1 (1%)	27 (33%)	44 (53%)	24 (29%)	0 (0%)	3 (4%)	12 (14%)
Figure	0	0	0	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Listing	21	16	5	0 (0%)	0 (0%)	0 (0%)	1 (5%)	20 (95%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	20 (95%)
Other	0	0	0	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

### REWORK SUMMARY REPORT

This report has the data for the number of times a program was reworked/updated.

Study Number	Delivery PDVD Name	Item Count	Rework Count	Rework Percentage
1234/5678	Delivery_PDVD_1234/5678_CSR_Dry_Run_14JUL2017	8	2	25
5678/1234	Delivery_PDVD_5678/1234_Advisory_Committee_Final_03APR2017	31	3	9.68

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## RESOURCE PRODUCTIVITY REPORT

This report is used to measure the productivity of our team members, and summarizes the completed work per programmer

Name	Datasets			Tables				Listings				Figures			
	Unique	Rerun	Rework	Unique	Replicate	Rerun	Rework	Unique	Replicate	Rerun	Rework	Unique	Replicate	Rerun	Rework
Programmers Name	13	265	0	46	112	436	16	50	0	172	0	5	2	34	0
Programmers Name	55	31	33	29	57	49	130	1	0	16	1	5	0	6	0

A similar report is also available to indicate future assignments per programmer

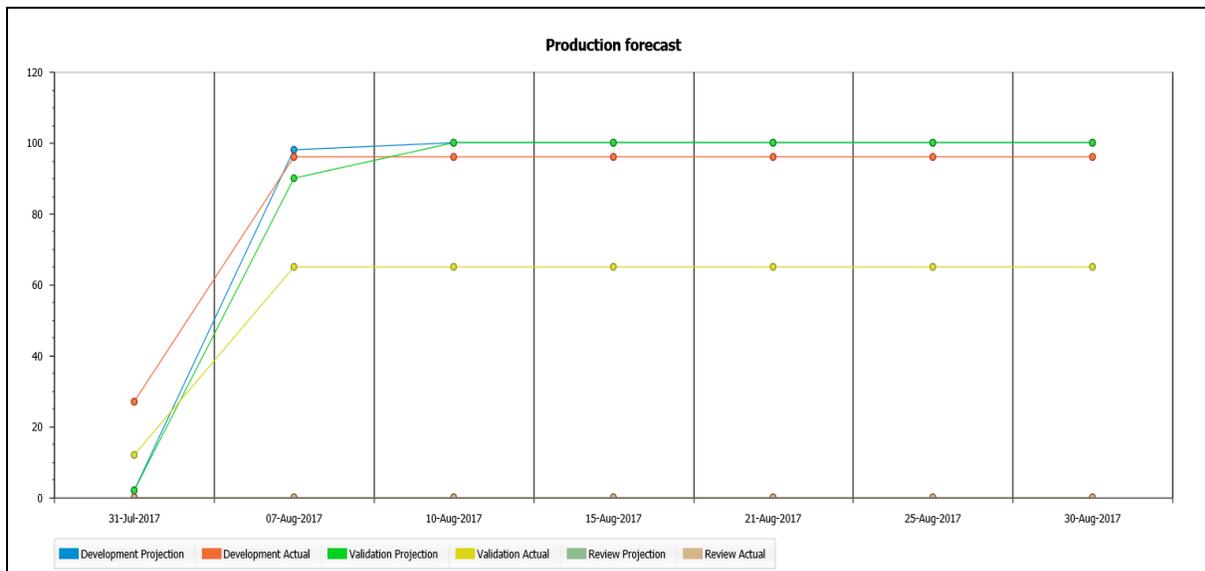
## DATASETS, TABLES, LISTING AND FIGURES SUMMARY

This report provides the summary of completed units of the task per study for a given period.

Study Number	Sponsor Name	Datasets		Tables				Listings			
		Developed	Validated	Unique Developed	Unique Validated	Replicate Developed	Replicate Validated	Unique Developed	Unique Validated	Replicate Developed	Replicate Validated
1234/5678	Sponsor Name	0	0	0	0	0	0	0	0	0	0
5678/1234	Sponsor Name	51	51	55	55	21	21	20	20	3	3

## PRODUCTION FORECAST REPORT

This is a graphical representation of projected work versus actual completed work. This is useful representation of work that may be off track.



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## VENDOR SELECTION

ICON has a well-defined vendor management process, which was followed to choose a vendor to build this application. An important initial discussion before a vendor is selected is around the risk impact assessment (RIA) of the proposed system and the degree of validation required. The next is identifying a capable vendor with the desired level of experience and processes, which also met the relevant documentation standards. Our vendor selection involved liaison between IT, procurement and business operations to define the selection criteria and to ensure that the vendor met the needs of all areas to deliver the project on time, to budget and with the desired quality.

## PATH TO SUCCESSFUL ROLLOUT

### DESIGNING

As this tool was the first of its kind for ICON, the designing took lot of time and effort, approximately 3 months. A document was created defining the purpose and functionality of each field, what it should look like, list of values etc. This document was discussed with vendor regarding feasibility.

### DEVELOPING

Development of the tool took almost 3 months.

### TESTING

User Acceptance Testing was done to test the user interface and functionalities of the tool. 2 rounds of UAT was required to confirm that all bugs were fixed.

### PILOTING

We launched the tool with 4 pilot studies. Pilots were done to check the robustness of tool across different studies.

Our major lessons learnt from pilot studies were:

1. There was lot of difference between the test data and actual study data, so the quality of test data should as close actual study data as possible.
2. While designing the tool, consultation was done with the vendor and ICON operational management, however ideas and suggestions from end users should have also been considered.

### ROLL-OUT

Prior to the department roll-out, communication was shared on a frequent basis regarding the roll-out plans for the application. Mandatory department level training was also delivered prior to roll-out. Training was also a prerequisite to gaining access to the application. Roll out of the tool came with some resistance which is very common for anything new. There was a steeper learning curve for end users when compared to the excel sheets. We also recognized that there were different and unique study scenarios beyond what was identified in the UAT and pilot phase.

Within 2 months of roll-out all critical issues were addressed.

We also continue to do repeat training and knowledge share sessions with our teams. Overtime, our teams have become familiar with the application and its advantages.

### MAINTENANCE

ICON established a PDVD SME team responsible for answering questions and maintaining the application (coordinating bug fixes, adding /removing users etc.). This SME team also received user enhancement requests, and has consolidated these requests for inclusion into the next phase of the tool. Some example of the enhancement requests include:

1. Selection criteria by "sponsor".
2. Hiding column in delivery PDVD to allow for ease of review.
3. Server date that accommodate different time zones.

## NEXT PHASE

"ITrack" is the name of our PDVD phase III!

Along with existing functionality and enhancements requests, we are also integrating the ICON Validation, Stats Review, Lead review, Peer review and Sponsor review tracking sheets.

- The reports which can be extracted from this tool are:

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- Quality reports by study
- Quality reports by programmer
- Quality reports by issue type
- Quality reports by review cycles

### CONCLUSION

Our quality control and tracking process has become more complaint due to the standardization and controls within the application. Our study tracking data is now centralized and gives us the ability to track and report easily. The success of the tool has led to the next version which is an extension of the existing functionality to integrate other documents that are also part of the ICON processes.

### CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

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