SQA Metric Items From FPA Spreadsheet - July $2018\,$

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Abstract

Evaulation of various potential matrics, performance indicators from the Excel workbook that Software Quality Assurance collected called First Pass Acceptance. This will only be run for the month of January 2018. 1

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	Started	3	5		e Metrics Document Approval Rate	25 25
	by Type	4		5.2	First Pass Acceptance .	25

¹Date Ran: Wednesday 1st August, 2018 at 10:43

1 Introduction

The data is processed using R², Version 3.5.1 named "Feather Spray". The only extension (package or library) utilized is lubridate (version 1.7.4) to provide key functionality in the processing of dates.

The data is read into R from a comma seperated value (csv) file which is derived (saved) from the spreadsheet without modification. Additional values are computed as needed.

This report is prepared in the R environment using a collection of packages know as Sweave that included knitr which in turn feeds the package into LATEX 2_{ε} a typeseting program to produce a PDF file. LATEX 2_{ε} in implented in MiTeX. LATEX 2_{ε} is utilizing the following packages to control style and formating:

- datetime and
- multitoc

This will only show a point in time summary and no trends.

2 Data and Calculations

2.1 Data

A seperate data dictionary will be prepared to for both the source data and computed values stored in R.

2.2 Calculations

All calculations presented here have not been implemented in R as formulas.

3 Work Yet to be Completed

3.1 Formula

Some calculations would be better implemented as formulas. The calculations need to be evulated and the formulas developed where needed.

3.2 Trending

Eventually the "System" will be updated to select the data on a for a calander month. After processing the resulots will be stored in a seperate file. This will allow for longer term trending of this data.

3.2.1 Graphs

When "trending" is implented graphs of the trends will also be added.

 $^{^2}$ RStudio is utilized as an IDE

4 Quanity Metrics

4.1 Application supported

This is a list of all application support this period.

Note: Alphabatize the list

- [1] "Pulse"
- [2] "WWLIMS"
- [3] "PEAR"
- [4] "ADD Shop Floor Paper (SFP) Report System"
- [5] "eNovator"
- [6] "DARA Filler DHM and RU"
- [7] "EP Evaluator"
- [8] "Groninger"
- [9] "Alinity S Non-LIMS spreadsheets"
- [10] "DFCS"
- [11] "TrendReader"
- [12] "GS Reports"
- [13] "AP 24 CIP"
- [14] "RSLMS"

4.2 Number of Projects

The total number of projects worked on in this period. This may differ from the application list because some applications may have more than one project in the periond.

[1] 22

4.3 Number of Reviews

This is the number of items reviewed, a document will be counted more than once if it is reviewed more than once.

[1] 138

4.4 Number of Items Reviewed

This is the number of unique items reviewed, each item is only counted once regardless of how many times it is reviewed.

Note: This is reporting low due to certian items having no way to descrimate between such as multiple executions of the same test script or results from an IIVP run on different computers within the same project.

[1] 110

4.5 Number of Projects Started

The point at which a project is started is when version 1 of the *Software Change Request* is approved.

Note: This now counts ML type projects (Metrics Library and GS Reports) using the Project Plan as the point that a project starts.

[1] 7

4.6 Projects Completed

The point at which a project is considered completed is when version 1 of the *System Certification Summary* is approved.

Note: now counts GS (Global Service) Reports Move to Production as the end of project.

[1] 5

4.7 Number Of Deliverables by Type

This is unique for each deliverable. It only counts each document once so a deliverable that is disapproved and then approved is only counted once.

Cancellation	CII
1	4
Decommissioning Report Design Docum	mentation
0	0
Design Verification	ERES
6	0
FRS	IDP
2	1
IIVP IIVP	P results
10	14
IIVP Results	ISSD
1	3
Maintenance Plan Move to Pr	roduction
1	2
Other Proj	ject Plan
0	2
Release Notes Risk As	ssessment
4	0
Software Change Request Software Compliance As	ssessment
8	3
System Certification Summary Test	Protocol
5	11
Test Protocol Results Trac	ceability
26	2

URS				URS/FRS
2				0
User Acceptance Protocol	User	Acceptance	${\tt Protocol}$	results
0				0
Validation Plan				
2				

4.8 Number of Deliverable by Application

This is the number of unique deliverables that each application submitted. Itonly counts each document once, regardless of the status.

```
Abbott Transfusion Medicine
ADD Shop Floor Paper (SFP) Report System
                                      AFMS
                                         0
         Alinity S Non-LIMS spreadsheets
                 Alinity Source Verifier
                                         0
                                       AMM
                                         0
                                AP 24 CIP
                               Apollo/PHM
                      Assay File Database
           BioCommand Batch Control Plus
                                  {\tt CMSnext}
                                         0
                                   CMSNext
                                         0
                  DARA Filler DHM and RU
                                         9
                                  DaVinci
                                         0
                                     DFCS
                                        11
                                       DPW
                                         0
                                     EDMS
                                         0
```

```
eNovator
        EP Evaluator
            GDSN/GS1
           Groninger
          GS Reports
           ideaPoint
                IRIS
Knowledge Management
     Metrics Library
          Navigator
             PCN/SCN
                   0
                PEAR
            Power BI
     Print on Demand
               Pulse
                  22
                QIMS
     Reliasoft Xfmea
               RSLMS
                   4
                 SAS
                   0
        TestComplete
                TODS
         TrendReader
              WWLIMS
                  23
```

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A A-FP D 29 88 21

4.10 Table of Deliverables by Application

	Cancellation	CII
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	1	0
Apollo/PHM	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	0	1
QIMS	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0

TODS	0	0
TrendReader	0	0
WWLIMS	0	3

Decommissioning Report Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System 0 AFMS 0 Alinity S Non-LIMS spreadsheets 0 Alinity Source Verifier 0 AMM 0 AP 24 CIP 0 Apollo/PHM 0 Assay File Database 0 BioCommand Batch Control Plus 0 ${\tt CMSnext}$ 0 CMSNext 0 DARA Filler DHM and RU 0 0 DaVinci **DFCS** 0 DPW 0 **EDMS** 0 eNovator 0 EP Evaluator 0 GDSN/GS1 0 Groninger 0 **GS** Reports 0 ideaPoint 0 IRIS 0 Knowledge Management 0 Metrics Library 0 Navigator 0 PCN/SCN 0 PEAR 0 Power BI 0 Print on Demand 0 Pulse 0 QIMS 0 Reliasoft Xfmea 0 RSLMS 0 SAS 0 ${\tt TestComplete}$ 0 TODS 0 TrendReader 0 WWLIMS 0

	Design	Documentation	1		
Abbott Transfusion Medicine	Design	O O			
ADD Shop Floor Paper (SFP) Report System		0			
AFMS		0			
		0			
Alinity S Non-LIMS spreadsheets		0			
Alinity Source Verifier					
AMM		0			
AP 24 CIP		0			
Apollo/PHM					
Assay File Database		0			
BioCommand Batch Control Plus		0			
CMSnext		0			
CMSNext		0			
DARA Filler DHM and RU		0			
DaVinci		0			
DFCS		0			
DPW		0			
EDMS		0			
eNovator		0			
EP Evaluator		0			
GDSN/GS1		0			
Groninger		0			
GS Reports		0			
ideaPoint		0)		
IRIS		0)		
Knowledge Management		0)		
Metrics Library		0)		
Navigator		0)		
PCN/SCN		0)		
PEAR		0)		
Power BI		0)		
Print on Demand		0)		
Pulse		0)		
QIMS		0)		
Reliasoft Xfmea		0)		
RSLMS		0)		
SAS		0)		
TestComplete		0)		
TODS		0)		
TrendReader		0)		
WWLIMS		0)		
	Design	Verification	ERES	FRS	IDP
Abbott Transfusion Medicine		0	0	0	0
ADD Shop Floor Paper (SFP) Report System		0	0	0	0
AFMS		0	0	0	0

Alinity S Non-LIMS spreadsheets				0	0	0	0
Alinity Source Verifier				0	0	0	0
AMM				0	0	0	0
AP 24 CIP				0	0	0	0
Apollo/PHM				0	0	0	0
Assay File Database				0	0	0	0
BioCommand Batch Control Plus				0	0	0	0
CMSnext				0	0	0	0
CMSNext				0	0	0	0
DARA Filler DHM and RU				0	0	0	0
DaVinci				0	0	0	0
DFCS				1	0	1	1
DPW				0	0	0	0
EDMS				0	0	0	0
eNovator				0	0	0	0
EP Evaluator				0	0	0	0
GDSN/GS1				0	0	0	0
				0		0	0
Groninger					0		
GS Reports				0	0	0	0
ideaPoint				0	0	0	0
IRIS				0	0	0	0
Knowledge Management				0	0	0	0
Metrics Library				0	0	0	0
Navigator				0	0	0	0
PCN/SCN				0	0	0	0
PEAR				0	0	0	0
Power BI				0	0	0	0
Print on Demand				0	0	0	0
Pulse				2	0	1	0
QIMS				0	0	0	0
Reliasoft Xfmea				0	0	0	0
RSLMS				1	0	0	0
SAS				0	0	0	0
TestComplete				0	0	0	0
TODS				0	0	0	0
TrendReader				0	0	0	0
WWLIMS				2	0	0	0
		IIVP	results	IIVP	Res		
Abbott Transfusion Medicine	0		0			0	-
ADD Shop Floor Paper (SFP) Report System			1			0	
AFMS	0		0			0	
Alinity S Non-LIMS spreadsheets	0		0			0	
Alinity Source Verifier	0		0			0	
AMM	0		0			0	
AP 24 CIP	0		0			0	0

Apollo/PHM	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CMSnext	0	0	0	0
CMSNext	0	0	0	0
DARA Filler DHM and RU	0	3	0	1
DaVinci	0	0	0	0
DFCS	0	0	0	0
DPW	0	0	0	0
EDMS	0	0	0	0
eNovator	1	0	0	1
EP Evaluator	1	0	0	0
GDSN/GS1	0	0	0	0
Groninger	0	0	1	1
GS Reports	0	0	0	0
ideaPoint	0	0	0	0
IRIS	0	0	0	0
Knowledge Management	0	0	0	0
Metrics Library	0	0	0	0
Navigator	0	0	0	0
PCN/SCN	0	0	0	0
PEAR	0	0	0	0
Power BI	0	0	0	0
Print on Demand	0	0	0	0
Pulse	1	2	0	0
QIMS	0	0	0	0
Reliasoft Xfmea	0	0	0	0
RSLMS	0	0	0	0
SAS	0	0	0	0
TestComplete	0	0	0	0
TODS	0	0	0	0
TrendReader	0	2	0	0
WWLIMS	7	6	0	0
		D1 W		
	Maintenance		to Production	
Abbott Transfusion Medicine		0		0
ADD Shop Floor Paper (SFP) Report System		0		0
AFMS		0		0
Alinity S Non-LIMS spreadsheets		0		0
Alinity Source Verifier		0		0
AMM		0		0
AP 24 CIP		0		0
Apollo/PHM		0		0
Assay File Database		0		0
BioCommand Batch Control Plus		0		0

 ${\tt CMSnext}$

CMSNext DARA Filler DHM and RU DaVinci DFCS				
DaVinci DFCS		0		0
DFCS		0		0
		0		0
P. P. C.		0		0
DPW		0		0
EDMS		0		0
eNovator		1		0
EP Evaluator		0		0
GDSN/GS1		0		0
Groninger		0		0
GS Reports		0		2
ideaPoint				
		0		0
IRIS		0		0
Knowledge Management		0		0
Metrics Library		0		0
Navigator		0		0
PCN/SCN		0		0
PEAR		0		0
Power BI		0		0
Print on Demand		0		0
Pulse		0		0
QIMS		0		0
Reliasoft Xfmea		0		0
RSLMS		0		0
SAS		0		0
TestComplete		0		0
TODS		0		0
TrendReader		0		0
		0		
WWLIMS				0
WWLIMS				0
	er Project	Plan Release	e Notes	0
	er Project O	Plan Release		0
Oth Abbott Transfusion Medicine	0	0	0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System	-		0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS	0 0 0	0 0 0	0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets	0 0 0	0 0 0	0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier	0 0 0 0	0 0 0 0	0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM	0 0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSNext	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSNext DARA Filler DHM and RU	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0	0
Oth Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM AP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSNext	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0

DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	1
EP Evaluator	0	0	0
GDSN/GS1	0	0	0
Groninger	0	0	1
GS Reports	0	2	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	0	0
Navigator	0	0	0
PCN/SCN	0	0	0
PEAR	0	0	0
Power BI	0	0	0
Print on Demand	0	0	0
Pulse	0	0	0
QIMS	0	0	0
Reliasoft Xfmea	0	0	0
RSLMS	0	0	0
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	0	0	0
WWLIMS	0	0	0

Risk Assessment

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0

GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

Software Change Request

```
Abbott Transfusion Medicine
                                                                       0
ADD Shop Floor Paper (SFP) Report System
                                                                       0
                                                                       0
Alinity S Non-LIMS spreadsheets
Alinity Source Verifier
                                                                       0
\mathsf{MMA}
                                                                       0
AP 24 CIP
                                                                       0
Apollo/PHM
                                                                       0
Assay File Database
                                                                       0
BioCommand Batch Control Plus
                                                                       0
{\tt CMSnext}
                                                                       0
{\tt CMSNext}
                                                                       0
{\tt DARA} Filler DHM and RU
                                                                       0
                                                                       0
DaVinci
DFCS
                                                                       1
DPW
                                                                       0
                                                                       0
EDMS
                                                                       0
eNovator
EP Evaluator
                                                                       1
GDSN/GS1
                                                                       0
Groninger
                                                                       0
GS Reports
                                                                       0
{\tt ideaPoint}
                                                                       0
```

IRIS			0
Knowledge Management			0
Metrics Library			0
Navigator			0
PCN/SCN			0
PEAR			1
Power BI			0
Print on Demand			0
Pulse			1
QIMS			0
Reliasoft Xfmea			0
RSLMS			2
SAS			0
TestComplete			0
TODS			0
TrendReader			0
WWLIMS			2
9	Software	${\tt Compliance}$	Asse
Abbott Transfusion Medicine			

essment

Abbott Iransiusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0

PCN/SCN				0
PEAR				1
Power BI				0
Print on Demand				0
Pulse				1
QIMS				0
Reliasoft Xfmea				0
RSLMS				1
SAS				0
TestComplete				0
TODS				0
TrendReader				0
WWLIMS				0
	System	Certification		
Abbott Transfusion Medicine			0	
ADD Shop Floor Paper (SFP) Report System			0	
AFMS			0	
Alinity S Non-LIMS spreadsheets			0	
Alinity Source Verifier			0	
AMM			0	
AP 24 CIP			0	
Apollo/PHM			0	
Assay File Database			0	
BioCommand Batch Control Plus			0	
CMSnext			0	
CMSNext			0	
DARA Filler DHM and RU			1	
DaVinci			0	
DFCS			1	
DPW			0	
EDMS a Navasta as			0	
eNovator EP Evaluator			0	
GDSN/GS1			0	
Groninger			1	
GS Reports			0	
ideaPoint			0	
IRIS			0	
Knowledge Management			0	
Metrics Library			0	
Navigator			0	
PCN/SCN			0	
PEAR			0	
Power BI			0	
Print on Demand			0	

Pulse	1
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	1
	Pulse QIMS Reliasoft Xfmea RSLMS SAS TestComplete TODS TrendReader WWLIMS

Test Protocol Test Protocol Results Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier MMAAP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext ${\tt CMSNext}$ DARA Filler DHM and RU DaVinci **DFCS** DPW **EDMS** eNovatorEP Evaluator GDSN/GS1 Groninger **GS** Reports ideaPointIRIS Knowledge Management Metrics Library Navigator PCN/SCN PEAR Power BI Print on Demand Pulse QIMS Reliasoft Xfmea RSLMS

SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	4
WWLIMS	1	0

	Traceability	URS	URS/FRS
Abbott Transfusion Medicine	Ö	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0
AFMS	0	0	0
Alinity S Non-LIMS spreadsheets	0	0	0
Alinity Source Verifier	0	0	0
AMM	0	0	0
AP 24 CIP	0	0	0
Apollo/PHM	0	0	0
Assay File Database	0	0	0
BioCommand Batch Control Plus	0	0	0
CMSnext	0	0	0
CMSNext	0	0	0
DARA Filler DHM and RU	1	0	0
DaVinci	0	0	0
DFCS	1	1	0
DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	0
EP Evaluator	0	1	0
GDSN/GS1	0	0	0
Groninger	0	0	0
GS Reports	0	0	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	0	0
Navigator	0	0	0
PCN/SCN	0	0	0
PEAR	0	0	0
Power BI	0	0	0
Print on Demand	0	0	0
Pulse	0	0	0
QIMS	0	0	0
Reliasoft Xfmea	0	0	0
RSLMS	0	0	0
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	0	0	0

WWLIMS 0 0 0 User Acceptance Protocol Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System 0 AFMS 0 Alinity S Non-LIMS spreadsheets 0 Alinity Source Verifier 0 AMM 0 AP 24 CIP 0 Apollo/PHM 0 Assay File Database 0 BioCommand Batch Control Plus 0 ${\tt CMSnext}$ 0 CMSNext 0 DARA Filler DHM and RU 0 DaVinci 0 **DFCS** 0 DPW 0 **EDMS** 0 eNovator 0 EP Evaluator 0 GDSN/GS1 0 Groninger 0 0 GS Reports ideaPoint0 IRIS 0 Knowledge Management 0 Metrics Library 0 Navigator 0 PCN/SCN 0 PEAR 0 Power BI 0 Print on Demand 0 Pulse 0 0 QIMS Reliasoft Xfmea 0 RSLMS 0 SAS 0 ${\tt TestComplete}$ 0 TODS 0 TrendReader 0

User Acceptance Protocol results

Abbott Transfusion Medicine

WWLIMS

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

Validation Plan Abbott Transfusion Medicine 0 ADD Shop Floor Paper (SFP) Report System 0 AFMS 0 Alinity S Non-LIMS spreadsheets 0 Alinity Source Verifier 0

AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	1

4.11 Table of Rejection Reasons

Incorrect scope	Inaccurate information
0	13
Insufficient traceability	Insufficient testing
0	0
Not compliant with procedure	N/A
2	0
Not following document version control	Not following configuration management
0	0

Not using template	Other
1	3
Requirement deficiency	

4.12 Defects Verses Application

Groninger

Pulse

RSLMS

WWLIMS

4.12 Defects Verses	Application	
	Inaccurate information Incorre	ct scope
DARA Filler DHM and RU	1	0
DFCS	2	0
eNovator	2	0
EP Evaluator	1	0
Groninger	1	0
Pulse	3	0
RSLMS	2	0
WWLIMS	1	0
	Insufficient testing Insuffici	ent traceability N/A
DARA Filler DHM and RU	0	0 0
DFCS	0	0 0
eNovator	0	0 0
EP Evaluator	0	0 0
Groninger	0	0 0
Pulse	0	0 0
RSLMS	0	0 0
WWLIMS	0	0 0
	Not compliant with procedure	
DARA Filler DHM and RU	0	
DFCS	0	
eNovator	1	
EP Evaluator	0	
Groninger	0	
Pulse	1	
RSLMS	0	
WWLIMS	0	
	Not following configuration ma	nagement
DARA Filler DHM and RU		0
DFCS		0
eNovator		0
EP Evaluator		0
a ·		^

0

0

0

0

	Not	following	document	version	control
DARA Filler DHM and RU					0
DFCS					0
eNovator					0
EP Evaluator					0
Groninger					0
Pulse					0
RSLMS					0
WWLIMS					0

	Not using	template	Other	Requirement	deficiency
DARA Filler DHM and RU		0	0		0
DFCS		1	0		0
eNovator		0	0		0
EP Evaluator		0	2		0
Groninger		0	0		0
Pulse		0	0		0
RSLMS		0	0		0
WWLIMS		0	1		0

4.13 Defects Verses Deliverable

> table(as.character(subset(FPA, subset = (status == "D"))\$deliverable),
+ subset(FPA, subset = (status == "D"))\$reason)

Inaccurate	information	Incorrect	scope
	2		0
	1		0
	1		0
	0		0
	0		0
	2		0
	1		0
	3		0
	1		0
	2		0
	0		0
	Inaccurate	2 1 1 0 0 2 1 3	1 3 1

	Insufficient testing	Insufficient	traceability
Design Verification	0		0
IDP	0		0
IIVP results	0		0
ISSD	0		0
Maintenance Plan	0		0
Software Change Request	0		0

Software Compliance Assessment			0	
System Certification Summary			0	
Test Protocol			0	
Test Protocol Results			0	
URS			0	
	N/A	Not compl:	iant with p	orocedure
Design Verification	0			1
IDP	0			0
IIVP results	0			0
ISSD	0			0
Maintenance Plan	0			1
Software Change Request	0			0
Software Compliance Assessment	0			0
System Certification Summary	0			0
Test Protocol	0			0
Test Protocol Results	0			0
URS	0			0
	Not	following	configurat	tion management
Design Verification				0
IDP				0
IIVP results				0
ISSD				0
Maintenance Plan				0
Software Change Request				0
Software Compliance Assessment				0
System Certification Summary				0
Test Protocol				0
Test Protocol Results				0
URS				0
	Not	following	document v	version control
Design Verification				0
IDP				0
IIVP results				0
ISSD				0
Maintenance Plan				0
Software Change Request				0
Software Compliance Assessment				0
System Certification Summary				0
Test Protocol				0
Test Protocol Results				0
URS				0

Not using template Other

Design Verification	1	0
IDP	0	0
IIVP results	0	0
ISSD	0	0
Maintenance Plan	0	0
Software Change Request	0	1
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	0
URS	0	2

Requirement deficiency

<u> </u>	,
Design Verification	0
IDP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
URS	0

4.14 Rejection Reason by Deliverable

Design Verification	IDP
4	1
IIVP results	ISSD
1	2
Maintenance Plan	Software Change Request
1	3
Software Compliance Assessment	System Certification Summary
1	3
Test Protocol	Test Protocol Results
1	2
URS	
2	

4.15 Number of Rejections by Project

eNovator	DFCS	DARA Filler DHM and RU
4	3	1
Pulse	Groninger	EP Evaluator
4	2	3

RSLMS WWLIMS 2 2

5 Rate Metrics

5.1 Document Approval Rate

This is portion of documents that are approved upon review.

It is computed by counting the number of approvals devided that by the total number of reviews.

[1] 0.8478261

5.2 First Pass Acceptance

this is the portion of documents that are approved on the first review conducted by SQA.

It is computed by counting the number of first pass approvals devided by the number of reviews.

[1] 0.6376812