# SQA Metric Items From FPA Spreadsheet - June 2018

### Nick Lauerman

#### Abstract

Evaulation of various potential matrics, performance indicators from the Excel workbook that Software Quality Assurance collected called First Pass Acceptance. This is for the month of June 2018.  $^{\rm 1}$ 

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<sup>&</sup>lt;sup>1</sup>Date Ran: Monday 2<sup>nd</sup> July, 2018 at 09:22

#### 1 Introduction

The data is processed using R<sup>2</sup>, Version 3.5.0 named "Joy in Playing". 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  $2_{\varepsilon}$  a typeseting program to produce a PDF file. LATEX  $2_{\varepsilon}$  in implented in MiTeX. LATEX  $2_{\varepsilon}$  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.

 $<sup>^2\</sup>mathrm{RStudio}$  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] "GS Reports"
- [2] "DARA Filler DHM and RU"
- [3] "CMSNext"
- [4] "EP Evaluator"
- [5] "TrendReader"
- [6] "CMSnext"
- [7] "GDSN/GS1"
- [8] "Alinity S Non-LIMS spreadsheets"
- [9] "WWLIMS"
- [10] "DFCS"
- [11] "IRIS"
- [12] "Pulse"
- [13] "Knowledge Management"
- [14] "ADD Shop Floor Paper (SFP) Report System"
- [15] "eNovator"

### 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] 28

### 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] 176

### 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] 134

### 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] 8

#### 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] 7

### 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
2	10
Decommissioning Report	Design Documentation
0	0
Design Verification	ERES
4	1
FRS	IDP
1	5
IIVP	IIVP results
10	21
ISSD	Maintenance Plan
2	2
Move to Production	Other
4	1
Project Plan	Release Notes
6	0
Risk Assessment	Software Change Request
1	8
Software Compliance Assessment	System Certification Summary
1	5
Test Protocol	Test Protocol Results
17	14
Traceability	URS
9	3

URS/FRS	User Acceptance Protocol
0	1
User Acceptance Protocol results	Validation Plan
4	2

### 4.8 Number of Deliverable by Application

This is the number of unique deliverables that each application submitted. It only 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
                                      AMM
                                        0
                               Apollo/PHM
                      Assay File Database
           BioCommand Batch Control Plus
                                  {\tt CMSnext}
                                        1
                                  CMSNext
                  DARA Filler DHM and RU
                                         7
                                  DaVinci
                                         0
                                     DFCS
                                        9
                                      DPW
                                         0
                                     EDMS
                                        0
                                 eNovator
                                         1
                             EP Evaluator
                                         1
```

```
GDSN/GS1
           Groninger
          GS Reports
           ideaPoint
                   0
                IRIS
Knowledge Management
     Metrics Library
           Navigator
             PCN/SCN
                   0
                PEAR
            Power BI
     Print on Demand
               Pulse
                   7
                QIMS
     Reliasoft Xfmea
                   0
                 SAS
                   0
        TestComplete
                   0
                TODS
                   0
         TrendReader
                  13
              WWLIMS
                  36
```

### 4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A A-FP D 33 100 43

# 4.10 Table of Deliverables by Application

Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS O Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM O Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSnext CMSnext I DARA Filler DHM and RU DaVinci DFCS DPW O EDMS eNovator EP Evaluator GDSN/GS1 Groninger GS Reports ideaPoint IRIS Knowledge Management Metrics Library Navigator PCN/SCN PCN/		Cancellation	CII
AFMS 0 0 0 Alinity S Non-LIMS spreadsheets 0 0 0 Alinity Source Verifier 0 0 0 AMM 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 1 3 3 DARA Filler DHM and RU 0 2 DaVinci 0 0 0 DFCS 0 0 0 DFW 0 0 0 EDMS 0 0 0 EDMS 0 0 0 EDMS 0 0 0 EONOVATOR 0 0 0 EF Evaluator 0 0 0 GDSN/GS1 0 0 0 Groninger 0 0 0 GS Reports 0 0 0 GG Reports 0 0 0 IRIS 0 0 0 IRIS 0 0 0 Knowledge Management 0 0 0 Metrics Library 0 0 0 Metrics Library 0 0 0 PCN/SCN 0 0 0 PEAR 0 0 0 PCN/SCN 0 0 0 PCN/SCN 0 0 0 PCN/SCN 0 0 0 PEAR 0 0 0 PCN/SCN 0 0 0	Abbott Transfusion Medicine	0	0
Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM Apollo/PHM Apollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSnext CMSnext DARA Filler DHM and RU DaVinci DFCS DPW DEDMS ON EDMS ON ENOvator EP Evaluator GDSN/GS1 Groninger GS Reports ideaPoint IRIS Non-Budge Management Metrics Library Navigator PCN/SCN PEAR Power BI Print on Demand Pulse QIMS Reliasoft Xfmea SAS TestComplete TODS TrendReader  O	ADD Shop Floor Paper (SFP) Report System	0	0
Alinity Source Verifier  AMM  Apollo/PHM  Assay File Database  BioCommand Batch Control Plus  CMSnext  CMSnext  DARA Filler DHM and RU  DaVinci  DFCS  DPW  DPW  DO  EDMS  eNovator  EP Evaluator  GDSN/GS1  Groninger  GS Reports  ideaPoint  IRIS  Knowledge Management  Metrics Library  Navigator  PCN/SCN  PEAR  POWER BI  Print on Demand  Pulse  QIMS  Reliasoft Xfmea  SAS  TestComplete  TODS  To O  O O  O O  O O  O O  O O  Assay File Database  O O  O O  O O  O O  O O  O O  O O  O	AFMS	0	0
AMM	Alinity S Non-LIMS spreadsheets	0	0
Apollo/PHM 0 0 0 Assay File Database 0 0 0 BioCommand Batch Control Plus 0 0 CMSnext 0 0 0 CMSNext 1 3 DARA Filler DHM and RU 0 2 Davinci 0 0 0 DFCS 0 0 0 DPW 0 0 0 EDMS 0 0 0 EDMS 0 0 0 EDMS 0 0 0 EODS/GS1 0 0 0 GTOSINGER 0 0 0 GTOSINGER 0 0 0 GROSINGER 0 0 0 GROSINGER 0 0 0 GROSINGER 0 0 0 IRIS 0 0 0 Knowledge Management 0 0 0 Knowledge Management 0 0 0 Metrics Library 0 0 0 Metrics Library 0 0 0 PCN/SCN 0 0 0 PCN/SCN 0 0 0 PCN/SCN 0 0 0 PCN/SCN 0 0 0 PTINT 0 DEMAND 0 0 PTINT 0 0 0 PTINT	Alinity Source Verifier	0	0
Assay File Database BioCommand Batch Control Plus CMSnext 0 0 0 CMSNext 1 3 DARA Filler DHM and RU 0 2 DaVinci 0 0 DFCS 0 0 DPW 0 0 EDMS 0 0 EDMS 0 0 ENovator EP Evaluator GGDSN/GS1 0 0 Groninger 0 0 0 GS Reports 0 0 0 IRIS Knowledge Management Metrics Library Navigator PCN/SCN PEAR Power BI Print on Demand Pulse QIMS Reliasoft Xfmea SAS TestComplete TODS TrendReader 1 1 1	AMM	0	0
BioCommand Batch Control Plus       0       0         CMSnext       0       0         CMSNext       1       3         DARA Filler DHM and RU       0       2         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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0	Apollo/PHM	0	0
CMSNext       1       3         DARA Filler DHM and RU       0       2         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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         ToDS       0       0	Assay File Database	0	0
CMSNext       1       3         DARA Filler DHM and RU       0       2         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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         ToDS       0       0	BioCommand Batch Control Plus	0	0
DARA Filler DHM and RU       0       2         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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TondReader       1       1	CMSnext	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TondReader       1       1	CMSNext	1	3
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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TrendReader       1       1	DARA Filler DHM and RU	0	2
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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TrendReader       1       1	DaVinci	0	0
EDMS 0 0 0 eNovator 0 0 0 EP Evaluator 0 0 0 GDSN/GS1 0 0 0 GDSN/GS1 0 0 0 Groninger 0 0 0 ideaPoint 0 0 0 ideaPoint 0 0 0 IRIS 0 0 0 Knowledge Management 0 0 0 Metrics Library 0 0 0 Metrics Library 0 0 0 PCN/SCN 0 0 0 PEAR 0 0 0 PEAR 0 0 0 Pint on Demand 0 0 0 Print on Demand 0 0 0 Print on Demand 0 0 0 Reliasoft Xfmea 0 0 0 TestComplete 0 0 0 TrendReader 1 1 1	DFCS	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         Tods       0       0         TrendReader       1       1	DPW	0	0
EP Evaluator  GDSN/GS1  Groninger  GS Reports  ideaPoint  IRIS  Knowledge Management  Metrics Library  Navigator  PCN/SCN  PEAR  Power BI  Print on Demand  Pulse  QIMS  Reliasoft Xfmea  SAS  TestComplete  TODS  TrendReader  O 0  O 0  O 0  O 0  O 0  CO	EDMS	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         Tods       0       0         TrendReader       1       1	eNovator	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         ToDS       0       0         TrendReader       1       1	EP Evaluator	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         ToDS       0       0         TrendReader       1       1	GDSN/GS1	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       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	Groninger	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         SAS       0       0         TestComplete       0       0         ToDS       0       0         TrendReader       1       1	GS Reports	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         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	ideaPoint	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         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	IRIS	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         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	Knowledge Management	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         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	Metrics Library	0	0
PEAR       0       0         Power BI       0       0         Print on Demand       0       0         Pulse       0       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	Navigator	0	0
Power BI       0       0         Print on Demand       0       0         Pulse       0       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	PCN/SCN	0	0
Print on Demand       0       0         Pulse       0       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	PEAR	0	0
Pulse       0       0         QIMS       0       0         Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1	Power BI	0	0
QIMS 0 0 Reliasoft Xfmea 0 0 SAS 0 0 TestComplete 0 0 TODS 0 0 TrendReader 1 1	Print on Demand	0	0
Reliasoft Xfmea       0       0         SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1		0	0
SAS       0       0         TestComplete       0       0         TODS       0       0         TrendReader       1       1			
TestComplete         0         0           TODS         0         0           TrendReader         1         1		-	-
TODS         0         0           TrendReader         1         1			
TrendReader 1 1	<del>-</del>		
			-
WWLIMS 0 4			
	WWLIMS	0	4

### Decommissioning Report

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0

Alinity 5 Non-Limb spreadsheets			U
Alinity Source Verifier			0
AMM			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
SAS			0
TestComplete			0
TODS			0
TrendReader			0
WWLIMS			0
	Design	Documentation	
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	
Apollo/PHM		0	
Assay File Database		0	
BioCommand Batch Control Plus		0	
		v	

Alinity S Non-LIMS spreadsheets

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

0

0

0 0 0 0 0

0 0

0

0

DaVinci

DFCS

DPW

EDMS	0	0	0	0
eNovator	0	0	0	1
EP Evaluator	0	1	0	0
GDSN/GS1	0	0	1	0
Groninger	0	0	0	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	0	0	0	0
QIMS	0	0	0	0
Reliasoft Xfmea	0	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	1

#### IIVP IIVP results ISSD Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System Alinity S Non-LIMS spreadsheets Alinity Source Verifier AMM Apollo/PHM Assay File Database BioCommand Batch Control Plus ${\tt CMSnext}$ CMSNext DARA Filler DHM and RU DaVinci **DFCS** DPW **EDMS** eNovator EP Evaluator GDSN/GS1 Groninger GS Reports

ideaPoint	0	0	0
IRIS	2	0	0
Knowledge Management	0	0	1
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
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	1	3	0
WWLIMS	3	11	0

#### Maintenance Plan Move to Production Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier MMAApollo/PHM Assay File Database BioCommand Batch Control Plus CMSnext CMSNext DARA Filler DHM and RU DaVinci DFCS DPW **EDMS** eNovator EP Evaluator GDSN/GS1 Groninger GS Reports ideaPointIRIS Knowledge Management Metrics Library Navigator PCN/SCN

PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	0	0
QIMS	0	0
Reliasoft Xfmea	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	1	0
WWLIMS	0	0

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

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 Alinity Source Verifier	0
AMM	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 CS Paparta	0
GS Reports 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
SAS	0
TestComplete	0
TODS	0
TrendReader	1
WWLIMS	0

	Software	Change	Request
Abbott Transfusion Medicine		O	0
ADD Shop Floor Paper (SFP) Report System			0
AFMS			0
Alinity S Non-LIMS spreadsheets			1
Alinity Source Verifier			0
AMM			0
Apollo/PHM			0
Assay File Database			0
BioCommand Batch Control Plus			0
CMSnext			0
CMSNext			1
DARA Filler DHM and RU			0
DaVinci			0
DFCS			2
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			1
QIMS			0
Reliasoft Xfmea			0
SAS			0
TestComplete			0
TODS			0
TrendReader			2
WWLIMS			1
	Software	Complia	ance Assessment
Abbott Transfusion Medicine	SOLOWALE	Jompile	O
ADD Shop Floor Paper (SFP) Report System			0
AFMS			0
Alinity S Non-LIMS spreadsheets			0
Alinity Source Verifier			0
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1

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	1
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	1

	Test	Protocol	Test	Protocol	Results
Abbott Transfusion Medicine		0			0
ADD Shop Floor Paper (SFP) Report System		0			0
AFMS		0			0
Alinity S Non-LIMS spreadsheets		1			0
Alinity Source Verifier		0			0
AMM		0			0
Apollo/PHM		0			0
Assay File Database		0			0
BioCommand Batch Control Plus		0			0
CMSnext		0			0
CMSNext		10			9
DARA Filler DHM and RU		0			0
DaVinci		0			0
DFCS		0			0
DPW		0			0
EDMS		0			0
eNovator		0			0

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2	0
0	0
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0	0
0	0
2	0
2	5
	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

#### Traceability URS URS/FRS Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System Alinity S Non-LIMS spreadsheets Alinity Source Verifier $\mathsf{MMA}$ Apollo/PHM Assay File Database BioCommand Batch Control Plus ${\tt CMSnext}$ CMSNext DARA Filler DHM and RU DaVinci DFCS DPW **EDMS** ${\tt eNovator}$ EP Evaluator GDSN/GS1 Groninger **GS** Reports ideaPointIRIS

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
Print on Demand		0	0	0
Pulse		4	0	0
QIMS		0		0
Reliasoft Xfmea		0	0	0
SAS		0		0
TestComplete		0		0
TODS		0		0
TrendReader		0		0
WWLIMS		2	1	0
		_	_	
	User	Acceptanc	e Pi	rotocol
Abbott Transfusion Medicine		1		0
ADD Shop Floor Paper (SFP) Report System				0
AFMS				0
Alinity S Non-LIMS spreadsheets				0
Alinity Source Verifier				0
AMM				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
LOMET DI				U

			•	
Print on Demand			0	
Pulse			0	
QIMS			0	
Reliasoft Xfmea			0	
SAS			0	
TestComplete			0	
TODS			0	
TrendReader			0	
WWLIMS			0	
	Haan	Accomtonce	Dmo+0001	magu]+a
Abbott Transfusion Medicine	user	Acceptance	PIOCOCOI	results 0
ADD Shop Floor Paper (SFP) Report System				0
AFMS				0
Alinity S Non-LIMS spreadsheets				0
Alinity Source Verifier				0
AMM				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				3
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

0

SAS

TestComplete

TODS	0
TrendReader	0
WWLIMS	1

	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
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		1
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
SAS		0
TestComplete		0
TODS		0
TrendReader		0
WWLIMS		1

# 4.11 Table of Rejection Reasons

Inaccurate information	Incorrect scope
21	0
Insufficient testing	Insufficient traceability
1	4
N/A	Not compliant with procedure
2	8
Not following configuration management	Not following document version control
0	1
Not using template	Other
2	3
Requirement deficiency	
0	

# 4.12 Defects Verses Application

	Inaccurate	information	Incorrect	scope
Alinity S Non-LIMS spreadsheets		0		0
CMSnext		1		0
CMSNext		9		0
DFCS		1		0
eNovator		0		0
GDSN/GS1		2		0
Knowledge Management		0		0
Pulse		3		0
TrendReader		1		0
WWLIMS		4		0

		Insufficient	testing
Alinity S Non-LIMS s	spreadsheets		0
CMSnext			0
CMSNext			1
DFCS			0
eNovator			0
GDSN/GS1			0
Knowledge Management	t		0
Pulse			0
TrendReader			0
WWLIMS			0

	Insufficient	traceability	N/A
Alinity S Non-LIMS spreadsheets		1	0
CMSnext		0	0
CMSNext		3	2
DFCS		0	0

eNovator GDSN/GS1 Knowledge Management Pulse TrendReader WWLIMS	0 0 0 0 0 0 0 0 0 0
Alinity S Non-LIMS spreadsheets CMSnext CMSNext DFCS eNovator GDSN/GS1 Knowledge Management Pulse TrendReader WWLIMS	Not compliant with procedure  1 0 5 0 1 1 1 0 0 0 0 0 1 1 0 0 0 0
Alinity S Non-LIMS spreadsheets CMSnext CMSNext DFCS eNovator GDSN/GS1 Knowledge Management Pulse TrendReader WWLIMS	Not following configuration management  0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Alinity S Non-LIMS spreadsheets CMSnext CMSNext DFCS eNovator GDSN/GS1 Knowledge Management Pulse TrendReader WWLIMS	Not following document version control  0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Alinity S Non-LIMS spreadsheets	Not using template Other  0 1 0 0

CMSNext		0	2
DFCS		0	0
eNovator		0	0
GDSN/GS1		0	0
Knowledge Management		0	0
Pulse		0	0
TrendReader		2	0
WWLIMS		0	0
	Requirement	deficiency	
Alinity S Non-LIMS spreadsheets		0	
CMSnext		0	
		•	

Alinity S	Non-LIMS spreadsheets	0
${\tt CMSnext}$		0
CMSNext		0
DFCS		0
eNovator		0
GDSN/GS1		0
Knowledge	Management	0
Pulse		0

### 4.13 Defects Verses Deliverable

 ${\tt TrendReader}$ 

WWLIMS

CII

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

	${\tt Inaccurate}$	${\tt information}$	${\tt Incorrect}$	scope
CII		0		0
Design Verification		0		0
IDP		1		0
IIVP results		1		0
ISSD		0		0
Maintenance Plan		0		0
Other		0		0
Project Plan		1		0
Software Change Request		5		0
Software Compliance Assessment		1		0
System Certification Summary		5		0
Test Protocol		3		0
Test Protocol Results		1		0
Traceability		0		0
URS		0		0
Validation Plan		3		0

Insufficient testing Insufficient traceability  $0 \hspace{0.25cm} 0$ 

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Design Verification IDP IIVP results ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment					0 0 0 0 0 0			
System Certification Summary					0			
Test Protocol					1			
Test Protocol Results					0			
Traceability					0			
URS					0			
Validation Plan					0			
	N/A	Not	compli	iant	with	procedi	ıre	
CII	0	.,,,	compan	Luiro	W _ 011	proces	0	
Design Verification	0						2	
IDP	0						1	
IIVP results	0						0	
ISSD	0						0	
Maintenance Plan	0						1	
Other	0						1	
Project Plan	0						0	
Software Change Request	1						0	
Software Compliance Assessment	0						0	
System Certification Summary	1						1	
Test Protocol	0						0	
Test Protocol Results	0						0	
Traceability	0						1	
URS	0						1	
Validation Plan	0						0	
	Not	fol	lowing	conf	igura	ation ma	anageme	ent
CII								0
Design Verification								0
IDP								0
IIVP results								0
TOOD								^

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ISSD

Other

Maintenance Plan

Software Change Request

Software Compliance Assessment

System Certification Summary

Project Plan

Test Protocol Test Protocol Results Traceability URS Validation Plan					0 0 0 0
CII	Not	following	document	version	control 0
Design Verification					0
IDP					1
IIVP results					0
ISSD					0
Maintenance Plan					0
Other					0
Project Plan					0
Software Change Request					0
Software Compliance Assessment					0
System Certification Summary Test Protocol					0
Test Protocol Results					0
Traceability					0
URS					0
Validation Plan					0
	Not	using temp	plate Oth	ner	
CII			1	0	
Design Verification			0	0	
IDP			^	0	
			0		
IIVP results			0	0	
ISSD			0	0 1	
ISSD Maintenance Plan			0 0 1	0 1 0	
ISSD Maintenance Plan Other			0 0 1 0	0 1 0 0	
ISSD Maintenance Plan Other Project Plan			0 0 1 0	0 1 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request			0 0 1 0 0	0 1 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment			0 0 1 0 0 0	0 1 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary			0 0 1 0 0	0 1 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol			0 0 1 0 0 0 0	0 1 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results			0 0 1 0 0 0 0	0 1 0 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol			0 0 1 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results Traceability			0 0 1 0 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results Traceability URS			0 0 1 0 0 0 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0 2 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results Traceability URS Validation Plan		uirement de	0 0 1 0 0 0 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results Traceability URS Validation Plan		uirement de	0 0 1 0 0 0 0 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
ISSD Maintenance Plan Other Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Test Protocol Results Traceability URS Validation Plan		uirement de	0 0 1 0 0 0 0 0 0 0 0	0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	

IIVP results	0
ISSD	0
Maintenance Plan	0
Other	0
Project Plan	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
Validation Plan	0

### 4.14 Rejection Reason by Deliverable

Design Verification	CII	
2	1	
IIVP results	IDP	
1	3	
Maintenance Plan	ISSD	
2	1	
Project Plan	Other	
1	1	
Software Compliance Assessment	Request	Software Change
1	7	
Test Protocol	Summary	System Certification
8	7	
Traceability	Results	Test Protocol
3	1	
Validation Plan	URS	
3	1	

### 4.15 Number of Rejections by Project

CMSnext	Alinity S Non-LIMS spreadsheets
1	3
DFCS	CMSNext
1	22
GDSN/GS1	eNovator
3	1
Pulse	Knowledge Management
3	1
WWLIMS	TrendReader
4	4

### 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] 0.7556818

### 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] 0.5681818