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19

Hybrid Agile Delivery Methodology – How Pfizer Meets Quality Document Compliance in a Highly Regulated Environment

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Pfizer

Agenda

- 1 QDoC Overview
- 2 Overview of QDoC Modules
- 3 Benefits
- 4 DMS Process Flow
- 5 QDoC Innovations
- 6 QC Metrics
- 7 Demonstration
- 7 Future QDoc Enhancements
- 8 Questions

Submission Quality at Pfizer



Our purpose is grounded in our commitment to fund programs that provide public benefit, advance medical care and improve patient outcomes. Our belief is that all people deserve to live healthy lives. This drives our desire to provide access to medicines that are safe, effective, and affordable.

Document Quality and Compliance

- Performs Quality Control activities for all submissions to regulatory agencies (e.g. FDA)
- Reviews more than 1500 submission documents per year
- Provides detailed metrics for process quality improvement

QDoC Overview

QDoC is a global business platform management tool used across quality organizations. It addresses the overall quality process for the following groups:



Safety & Regulatory Quality (SRQ)

- Quality Reporting and Analytics - Individual Case Safety Report (ICSR) Quality
- Document Quality and Compliance



Vaccines Quality Control and Medical Writing Quality Team



Medical Quality Assurance (MQA) and Global Clinical Submission Quality (GCSQ)

- Reports for Submission Quality Planning
- Identification of Submissions for Audit

Overview of QDoC Modules

QDoC has two modules:



Document Management System

The Document Review Management System (DMS) supports quality review of regulatory submission documents.



Case Management System

The Case Management System (CMS) supports quality review of Individual Case Safety Reports (ICSRs) from Pfizer's safety database.

Benefits



Compliance - Timely support of audit and inspection request for evidence of QC

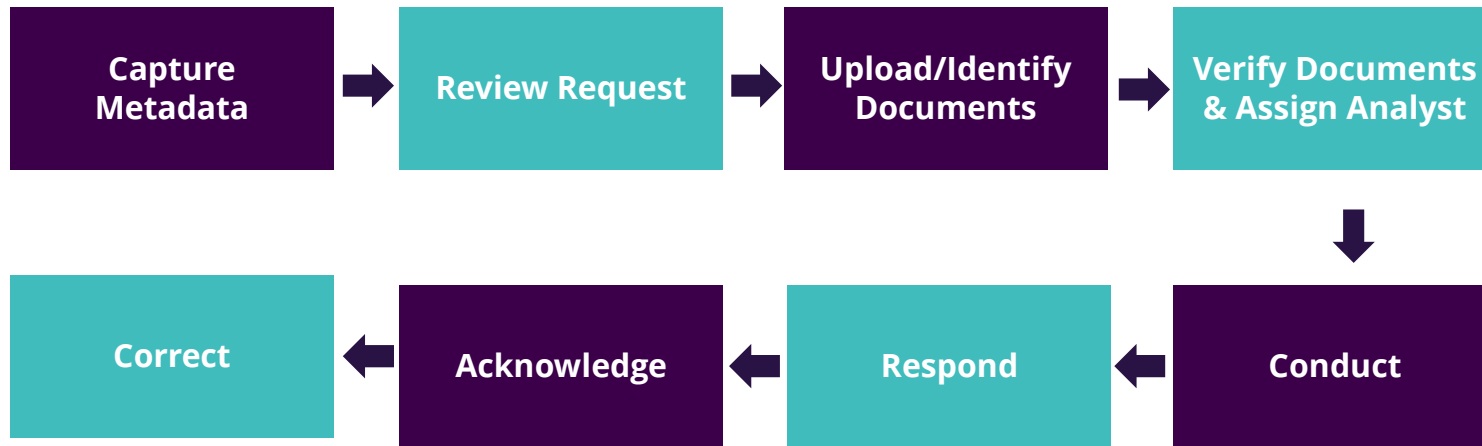
Productivity - Quality metrics reporting will be reduced from 3 weeks to 1-2 days; integrated tracking of workload/resource allocation worldwide

Function-agnostic - Supportive of business reorganizations, 2-way communication with QC target users

Technical - Flexibility to support business process changes over time; Easily extended for use by other QC groups

DMS Process Flow

The quality review of the regulatory submission documents is performed in eight stages.



Document Authors, Document Coordinators, Quality Analysts, and Business Admin perform various activities in each stage.

QDoC Innovations

General Purpose Document QC

- QC Observation Categories configurable
- Supports multiple QC groups and documents
- Supports review of MS Word, Excel, PDF, and Powerpoint

Documentum Integration

- Documents for QC identified in Documentum
- QDoC uploads document directly from Documentum to PleaseReview



PleaseReview Integration

- Integrates with PleaseReview to automate creation of reviews
- Automates extraction of QC Observations and Responses
- Automates creation of QC Report

ANSI/ASQ Z1.4 Sampling

- ANSI/ASQ sampling methodology implemented in Pega
- Automated switching logic for sampling methodology

PleaseReview



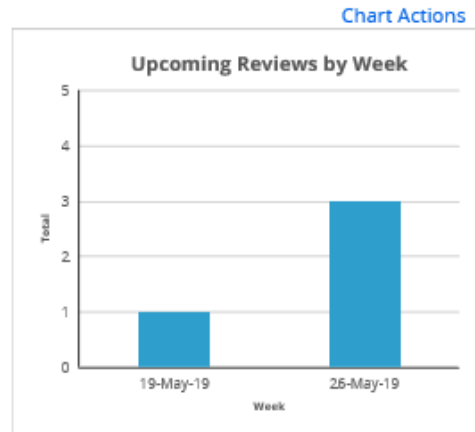
Ideagen PleaseReview is a leading in-document document review, co-authoring and redaction software application that provides:

- MS Word track changes-like interface for review and observations on Word, Excel, PowerPoint, and PDF documents.
- Ability to schedule, assign, and conduct document reviews.
- Record and store details of the review including observations, comments, and responses.

<https://www.ideagen.com/products/pleasereview>

Available QC Metrics

- Efficiency Metrics
 - Reviews Completed by Analyst
 - Pages Reviewed per Hour by Analyst
 - Observation Accuracy
- Document Quality Metrics
 - Observation Rate (per page) by Author
 - Observation Rate by Category
- Trending Metrics
 - Observation Category



DEMONSTRATION

Slides 12 to 23 are backup slides instead of live demo in case of issues

QDoC Landing Page - Dashboards

DOCUMENT REVIEW MANAGEMENT SYSTEM
Support

- + New
- Dashboard
- My Work
- My Cases
- Pulse
- My Teams
- Reports
- Administration
- Tags
- Schedule
- Search
- Recents
- Following

Summary for Document Review Management System

Reviews Completed

Month	Count
Apr-2019	45
May-2019	2

Upcoming Reviews by Week

Week	Total
19-May-19	1
25-May-19	1

Case stages for Document Review

Capture Metadata (1555)	Review Request (120)	Upload Documents (1486)	Verify Documents... (1726)	Conduct (1174)	Respond (1136)
Capture Metadata	Review Request	Upload Documents	Verify Documents and Assign Analysts	Conduct	Respond
			Agent Process	Agent Process	Agent Process

Hanson, Jeffrey 8 OPEN 7 OVERDUE

Due In	Document Review ID	Document Type	Product	Lead Author	Number of Pages in Document	Status	Due Date
-11mo	DR-225	Development Safety Update Report (DSUR)	[REDACTED]	Fan, Zhaowei	3	Pending-Conduct	08-Jun-2018 11:25:43 AM EDT
-10mo	DR-297	Development Safety Update Report (DSUR)	[REDACTED]	Singhal, Shrey	11	Pending-Conduct	15-Jun-2018 10:57:21 AM EDT

Create New Document Review Request

Capture Metadata

Requester Name*
Hanson, Jeffrey

DOCUMENT INFORMATION

Functional Line* SSRM	Document Type* PADER/PAER (Annual)	Quality Group* SRQ DQC
Product (Generic Name)* minerals, vitamins	Therapeutic Area Unknown	Product Type Dietary Supplement
Business Unit/Research Unit* PEH	Complexity Medium	Expected Date Sent to QC* 29-May-2019
Review Document Name* PegaWorld 2019	Estimated number of pages in entire document* 22.00	Number of Pages to be Reviewed* 22.00
Total Number of Tables and Figures* 5	Number of Immutable Tables 5	Time Allotted for QC Review* Enter number of days

Market/Territory*
United States

Activity Tracker code

Protocol Number

Submission ID

Re-Review
No

Reason for Re-Review

MOA Audit Required? *
No

Rationale For No Audit*
Derived

Additional Comments/safety Topics

Remaining: 1000 characters

Cancel Save Submit

Case details

Last updated by
Hanson, Jeffrey (1m ago)

Created by
Hanson, Jeffrey (1m ago)

Open assignments

Capture Metadata (Capture Metadata)
(Current)
Hanson, Jeffrey

Participants

Hanson, Jeffrey
LeadAuthor

Manage

QDoC Schedule View

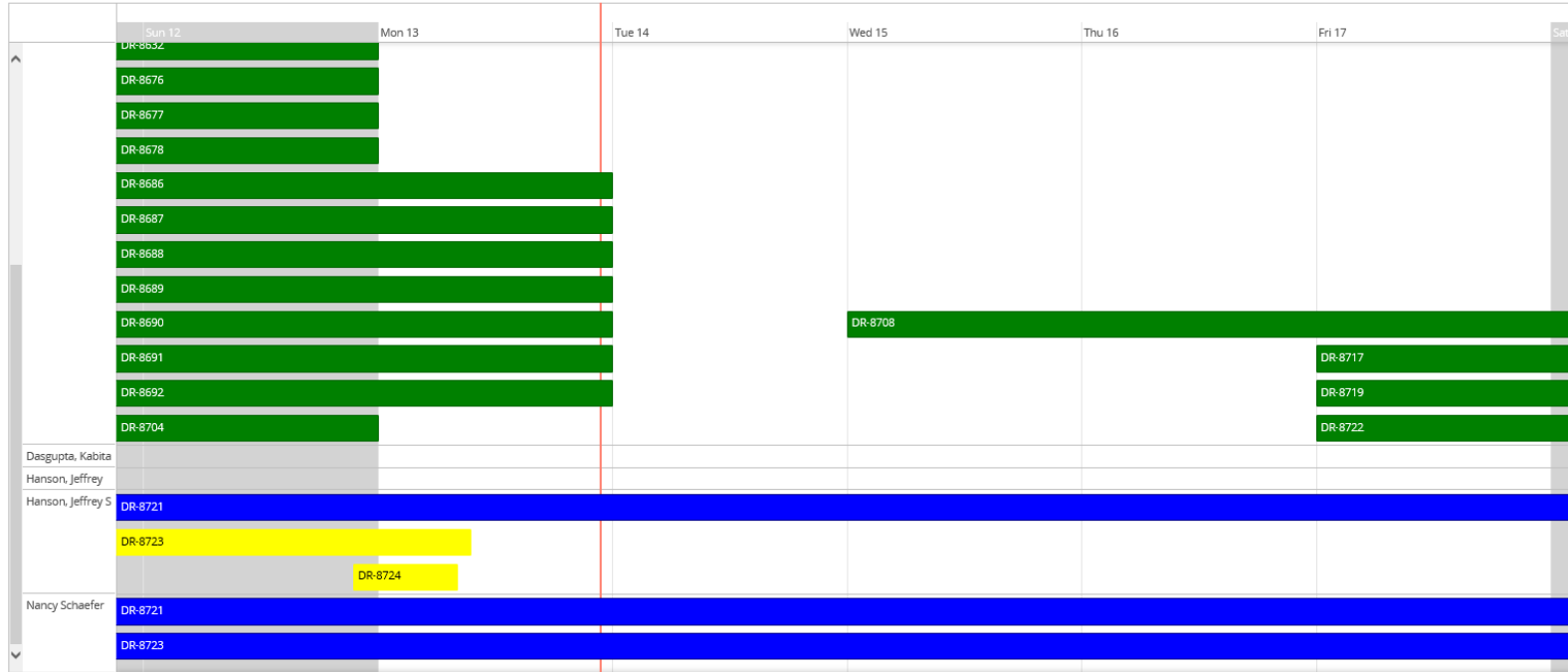
Analyst's Schedule ■ Out of office ■ Unavailable (Busy) ■ Unassigned ■ Conduct Completed ■ Upcoming/Ongoing

Quality Group

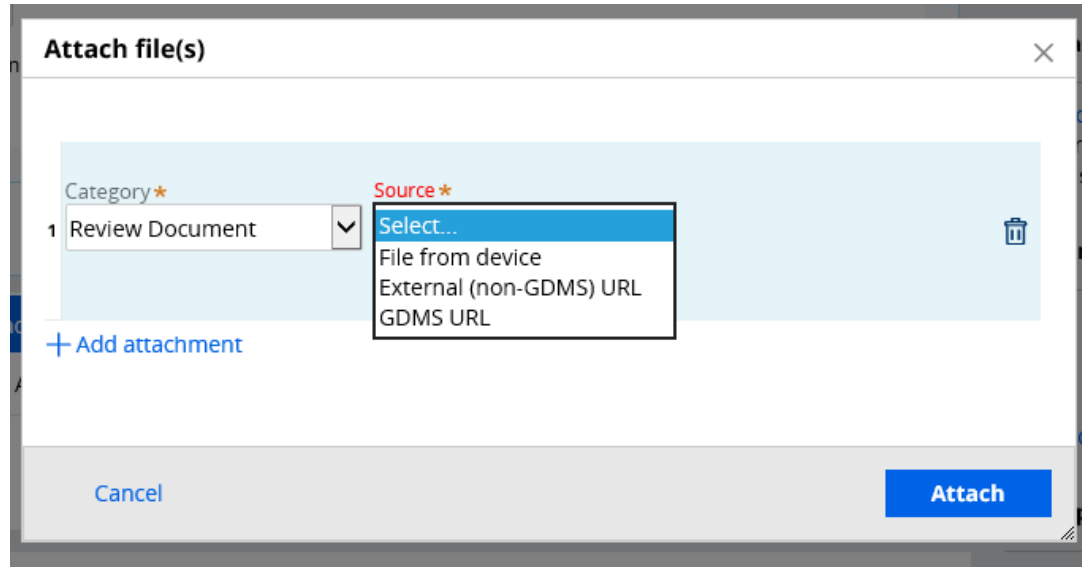
All

Users

Dasgupta, Kabita x Hanson, Jeffrey x Hanson, Jeffrey S x Nancy Schaefer x



QDoC – Upload Documents



QDoC – PleaseReview Integration

Verify Documents And Assign Analyst

Verify documents, assign Analysts and click Submit to begin document review

Issues with Review?
Press ↓ to see available values

[Cancel](#) [Save](#) [Submit](#)

Capture M... > Review Req... > Upload Do... > **Verify Docu...** > Conduct > Respond > Acknowledge

[Information](#) [Comments and Responses](#) [Audit](#)

Requester Name
Hanson, Jeffrey

DOCUMENT INFORMATION

Functional Line SSRM	Document Type PADER/PAER (Annual)	Quality Group SRQ DQC
Product (Generic Name) minerals, vitamins	Therapeutic Area Unknown	Product Type Dietary Supplement
Business Unit/Research Unit PEH	Complexity Medium	Expected Date Sent to QC 29-May-2019
Review Document Name PegaWorld 2019	Estimated number of pages in entire document 22.00	Number of Pages to be Reviewed 22.00
Total Number of Tables and Figures 5	Number of Immutable Tables 5	Time Allotted for QC Review 5
Market/Territory United States	Activity Tracker Code —	
Protocol Number —	Submission ID —	

Case details

Last updated by
Hanson, Jeffrey (1m ago)

Created by
Hanson, Jeffrey (31m ago)

Open assignments

Verify Documents and Assign Analyst (Verify Documents and Assign Analyst) (Current) SRQ DQC

Attachments (3)

Document(s) Uploaded: DR-...
DR-8725 | Correspondence | Agent(System-Queue-Notification.pzProcessNotification)

Pega-Business-Process-Man...
DR-8725 | AnnotatedCopy | Hanson, Jeffrey

Pega-Business-Process-Man...
DR-8725 | ReviewDocument | Hanson, Jeffrey

+ Attach new

Participants

Hanson, Jeffrey
Requester

Hanson, Jeffrey
Primary Analyst

SS Singhal, Shrey
LeadAuthor

QDoC – PleaseReview Integration

Document Review (DR-8725) PENDING-AGENT PROCESSING

Assignments View all

Task	Assigned to	
— Agent Process (Verify Documents and Assign Analyst)	ConnectPleaseReview	Begin

QDoC – PleaseReview Integration

Conduct

DUE IN 6 DAYS FROM NOW HJ

Review URL: <http://pleasereviewst.pfizer.com/Main/Default.aspx?action=loaddocument&reviewid=7392>

Is Review Complete and have you referenced QC Checklist? ⓘ ★ Yes

Number of Pages Reviewed ★ Time Spent in Review (Hrs) ★

Issues with Review (Added by Coordinator) Issues with Review?

Scope of Review ★ Review Comments

Remaining: 548 characters Remaining: 1000 characters

Case details


Last updated by
Agent(PFE-QA-DMS-Work-DocumentReview.ProcessToPleaseReview)
(9m ago)

Created by
Hanson, Jeffrey (47m ago)

Open assignments

- Conduct ⓘ (Current)
Hanson, Jeffrey
- Wait (Conduct) ⓘ
ResumeConduct

Attachments (5)

-  [Document Quality Reviewer...](#)
DR-8725 | Correspondence | Agent(System-Queue-Notification.p2ProcessNotification)

Please Review Interface - Comment

The screenshot displays a web editor interface with a dark top bar containing 'View', 'Search', 'Annotate', and 'Redact' options. Below this is a toolbar with various editing tools. The main content area shows a document titled 'Pega Business Process Management' with the subtitle 'Build for Change®'. The document is divided into sections: 'AT A GLANCE', 'The Market Leader in BPM', and a quote from Mhoyse Samatya, President of Commercial Business Insurance at Farmers Insurance. A comment box is open on the right side of the document, containing the text 'Spell Out as Business Process Management' and a dropdown menu set to 'Editorial (Format, Grammar, Spelling)'. The comment box has 'Apply' and 'Cancel' buttons. At the bottom of the editor, there is a zoom control set to 100%.

View Search Annotate Redact

Pega Business Process Management

Build for Change®

AT A GLANCE

KEY CHALLENGE: Improve efficiency, visibility, and agility of critical business processes. Build flexible and easy-to-use business solutions that help your business innovate and differentiate in a fast-changing market.

THE SOLUTION: Pega BPM helps you simplify and automate your operations so that you can reduce costs and improve business agility. Pega's unique Build For Change® technology delivers repeatable solutions that can be efficiently reused and tailored to meet the requirements of diverse customers, product lines, channels, and geographies.

The Market Leader in BPM

Pega leads with the industry's most comprehensive and unified platform to build intelligent business process management (BPM) solutions, including dynamic case management, business rules, mobile application development, reporting, security, integration and predictive and adaptive analytics.

Pega BPM helps large organizations bring products to market faster; make, market and sell more profitably, and deliver superior customer engagement.

Pega's unique Build for Change technology completely eliminates the hard-coded programming that makes traditional business applications hard to build and hard to adapt to diverse product lines, channels, geographies and regulations. As a result, customers report 30 percent faster time-to-market using Pega over competing solutions.

"We went from having people in a room thinking about what is possible, to having something on the street for the agents to use in five months. That's lightning speed."

Mhoyse Samatya
President
Commercial Business
Insurance

FARMERS
INSURANCE

"We were able to capture a major share of the prescription drug plan market and grow our

Solutions
Procedures Dynamic Case Management

Spell Out as Business Process Management

Editorial (Format, Grammar, Spelling) Apply Cancel

I 100%

PleaseReview Interface – Proposed Change

Pega Business Process Management


Build for Change®


AT A GLANCE

KEY CHALLENGE: Improve efficiency, visibility, and agility of critical business processes. Build flexible and easy-to-use business solutions that help your business innovate and differentiate in a fast-changing market.

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 **Mhayse Samatya**
President
Commercial Business
Insurance


Solutions

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C **Hanson, Jeffrey S** 13 May 2019 11:23 PM #1
Category: Editorial (Format, Grammar, Spelling)

Spell Out as Business Process Management

P **Hanson, Jeffrey S** 13 May 2019 11:23 PM #2
Category: Discrepancy with Source/Textual/Other

45 percent

Use updated stats

PleaseReview Interface - Respond

Pega Business Process

Build for Change®

AT A GLANCE

KEY CHALLENGE: Improve efficiency, visibility, and agility of critical business processes. Build flexible and easy-to-use business solutions that help your business innovate and differentiate in a fast-changing market.

THE SOLUTION: Pega BPM helps you simplify and automate your operations so that you can reduce costs and improve business agility. Pega's unique Build For Change® technology delivers repeatable solutions that can be efficiently reused and tailored to meet the requirements of diverse customers, product lines, channels, and geographies.

"We went from having people in a room thinking about what is possible, to having something on the street for the agents to use in five months. That's lightning speed."

Mihaya Samaha
President
Commercial Business
Insurance

"We were able to capture a major share of the prescription drug plan market and grow our business from zero to more than \$1 billion in less than a year."

Andy Anderson
Vice President
Pharmacy Services

Reason For Accepting #2

Accept as suggested

Editorial (Format, Grammar, Spelling) - Apply Cancel

predictive and adaptive analytics.

Pega BPM helps large organizations bring products to market faster, make, market and sell more profitably, and deliver superior customer engagement.

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PegaRULES Process Commander®
On Cloud • On Premises

C **Gontarz, Joan E** 14 May 2019 8:31 AM #2
Category: Editorial (Format, Grammar, Spelling)

Suggest spelling out first use of abbreviation. Accept

C **Gontarz, Joan E** 14 May 2019 8:33 AM #3
Category: Internal Document

Inconsistency/Textual/Benefit-Risk or Statistical Information

Consider adding additional benefits here.

C **Gontarz, Joan E** 14 May 2019 8:31 AM #1
Category: Discrepancy with Source/Textual/Benefit-Risk or Statistical Information

Per source should reflect 50 percent.

PleaseReview Interface – Import Observations

Document Review (DR-8726) PENDING-ACKNOWLEDGE

Information Review Details Comments and Responses Audit

Paragraph #
PO;Y000220.03;X000120.07;L0;C253;N0000005
Original Text
BPM

Reviewer		Author	
Reviewer Name	Gontarz, Joan E	Author Name	Hanson, Jeffrey S
Comment Entered Date/Time	14-May-2019 08:31:59 AM EDT	Response Date/Time	14-May-2019 11:16:42 AM EDT
Comment Type	Comment	Status	Accepted
Comment Category	Editorial (Format, Grammar, Spelling)	Standard Response	Accept as suggested
1		Response	---
2			
3			
Comment	Suggest spelling out first use of abbreviation.		

Paragraph #
PO;Y000222.45;X000270.00;L0;C1011;N0000088
Original Text
faster; make, market and sell more profitably; and deliver superior customer engagement

Reviewer		Author	
Reviewer Name	Gontarz, Joan E	Author Name	Hanson, Jeffrey S
Comment Entered Date/Time	14-May-2019 08:33:39 AM EDT	Response Date/Time	14-May-2019 11:17:07 AM EDT
Comment Type	Comment	Status	Accepted
Comment Category	Internal Document Inconsistency	Standard Response	Accept with modification
1		Response	Added benefits in table below.
2			
3			
Comment	Consider adding additional benefits here.		

Sample Metrics Report

Filtered by: **Review Completion Date = Previous month** and **Any Functional Line** and **Any Document Type** and **Quality Group = SRQ DQC**

[Collapse all group headings](#)

Functional Line	Document Type	Total Documents	Re-Review/Related Review	Total Unique Docs	Total Number of Pages Reviewed	Accepted (excluding Editorial and Source not Provided)	Not Accepted (excluding Editorial and Source not Provided)	Total (excluding Editorial and Source not Provided)	Total Hours	Accepted (Editorial)	Not Accepted (Editorial)	Total Editorial	Accepted (Source not Provided)	Not Accepted (Source not Provided)	Total Source not Provided
∨ALL		45	4	41	179	17	9	26	182	8	8	16	9	8	17
∨Epidemiology		6	0	6	57	2	1	3	62	1	2	3	3	0	3
	3/4 Month Safe...	4	0	4	48	2	1	3	38	0	1	1	2	0	2
	Clinical Overvie...	1	0	1	5	0	0	0	20	1	1	2	0	0	0
	PADER (Annual)	1	0	1	4	0	0	0	4	0	0	0	1	0	1
∨PSSR		24	4	20	46	14	8	22	36	7	5	12	6	8	14
	3/4 Month Safe...	4	0	4	8	3	3	6	2	2	2	4	2	2	4
	Bridging Docu...	8	3	5	10	4	3	7	5.5	4	1	5	2	2	4
	Briefing Docum...	7	1	6	10	6	0	6	8	0	1	1	2	1	3
	Clinical Overvie...	2	0	2	12	1	1	2	13	1	0	1	0	1	1
	PADER (Annual)	2	0	2	4	0	1	1	5	0	1	1	0	1	1
	PADER/PAER (A...	1	0	1	2	0	0	0	2.5	0	0	0	0	1	1
∨SSRM		15	0	15	76	1	0	1	84	0	1	1	0	0	0
	Briefing Docum...	1	0	1	1	1	0	1	1	0	1	1	0	0	0
	Clinical Overvie...	12	0	12	65	0	0	0	61	0	0	0	0	0	0
	Clinical Study R...	2	0	2	10	0	0	0	22	0	0	0	0	0	0

Future QDoC Enhancements

- Integration with Pega-Based application for regulatory document triggering and authoring (COMPASS)
- AI-Based automated Quality Control:
 - Automated QC Checks of tabular data in documents against sources
 - Automated QC Checks of textual narratives against source data
 - Automated creation of textual narratives using source data
- Further integration with document repository (Documentum)
- Integration with Pfizer's Quality Management System (QMS)



Why choose Pega?



Flexibility and ability to address change



Life Sciences Framework - Provides built-in, robust audit trail



Past implementation success at Pfizer



Integration Capabilities



Hybrid Agile approach to development

- Allows for adjustment through development process
- Reduces development time



Process-centric approach to implementation

Questions





PEGA[®]

Build for Change[®]