



Transitioning Project Requirements: Worth The Risk

George Edwards
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MERCK

Presenter: George Edwards

Background

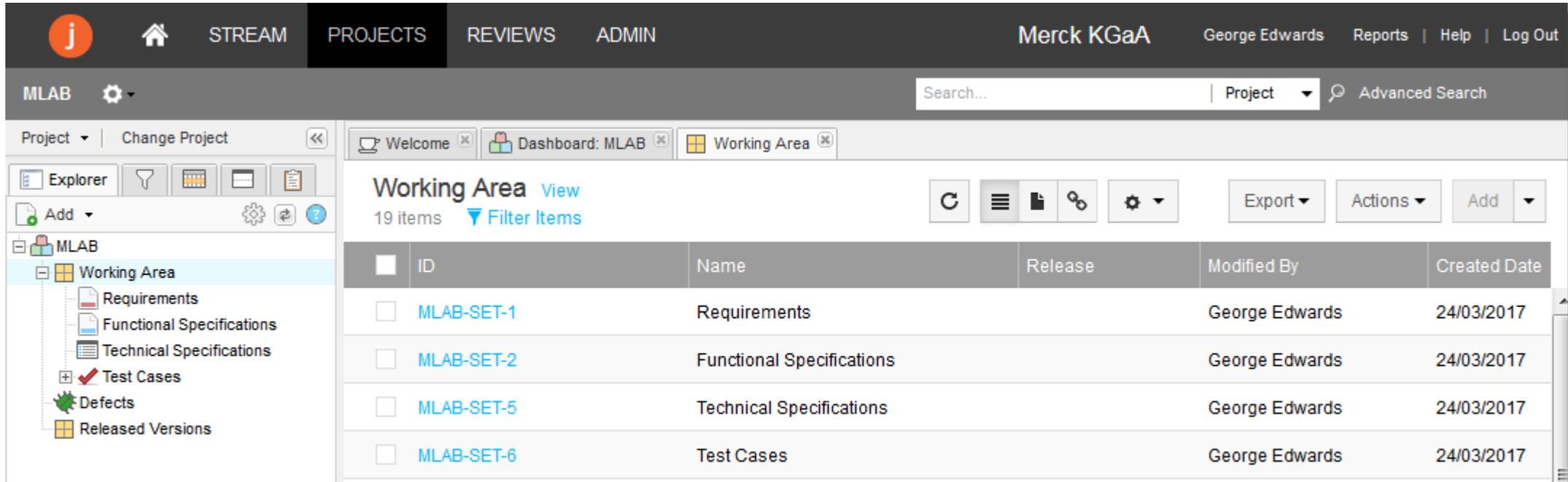
- Five years at Merck KGaA\Millipore (Boston)
- Manager, Agile Practices Team in Merck's Business Technology Department
- Certified Scrum Master
- SME for Jama and JIRA

Prior Experience

- Software Quality Assurance Manager
- Worked at Lotus/IBM, Intranets.com, MathWorks



Jama – A brief introduction



The screenshot displays the Jama software interface. At the top, there is a navigation bar with tabs for STREAM, PROJECTS (selected), REVIEWS, and ADMIN. The user is identified as George Edwards, and the company is Merck KGaA. Below the navigation bar, there is a search bar and a dropdown menu for 'Project'. The main workspace is titled 'Working Area' and contains a table with 19 items. The table has columns for ID, Name, Release, Modified By, and Created Date. The items listed are:

ID	Name	Release	Modified By	Created Date
MLAB-SET-1	Requirements		George Edwards	24/03/2017
MLAB-SET-2	Functional Specifications		George Edwards	24/03/2017
MLAB-SET-5	Technical Specifications		George Edwards	24/03/2017
MLAB-SET-6	Test Cases		George Edwards	24/03/2017

Product development application | Web-based and local installation supported |

Users have project-specific permissions |

Teams like the great features without sacrificing usability

They also like breaking away from paper-based project management

Project Explorer | Review Center | Test Center

Merck KGaA: What we do



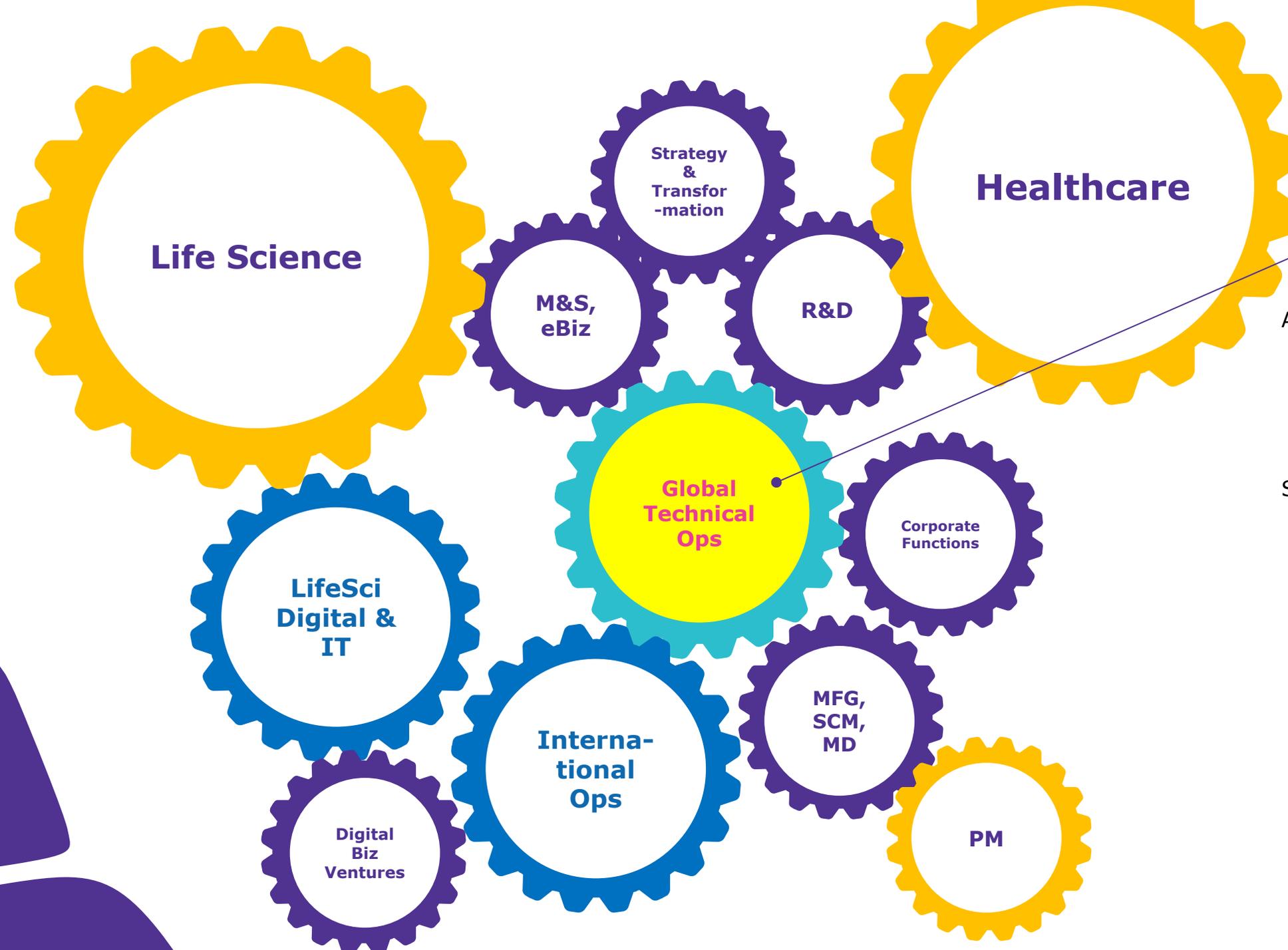
Prescription medicines to treat, for example, cancer, multiple sclerosis and infertility, **over-the-counter pharmaceuticals** for everyday health protection or to provide fast relief of colds and pain, as well as innovations in the areas of **allergies** and **biosimilars**.



Innovative **tools** and **laboratory supplies** for the life science industry that make **research** and **biotech** production easier, faster and more successful.



A wide range of specialty chemicals, such as **liquid crystals** for displays, **effect pigments** for coatings and cosmetics, or **high-tech materials** for the electronics industry.



Agile Practices

- 1 Identify Products that are ripe candidates for Agile & Scrum and foster them
- 2 Support teams with their critical success factors:
 - Product Ownership
 - Training
 - Coaching & Support
 - Impediment removal
- 3 Engage clear, vocal sponsorship for the Agile initiative

The Struggle to Manage Project Data

Teams are switching away from Word and Excel / paper-based processes

- Traceability – “How do I know there are tests for all requirements?”
- Transparency – “How are others to make sense of this folder of files?”
- Collaboration – “Who’s got the current version of the spec?”
- Issue tracking – “Did everyone report issues that they found?”
- Version control – “This doesn’t seem right. Did someone change this?”



For Merck BT & Biz: Many Projects Turning to **Jama**

Jama's growing popularity due to...

- Robust functionality
- Teams like its ease of use
- Adaptable to globally distributed team

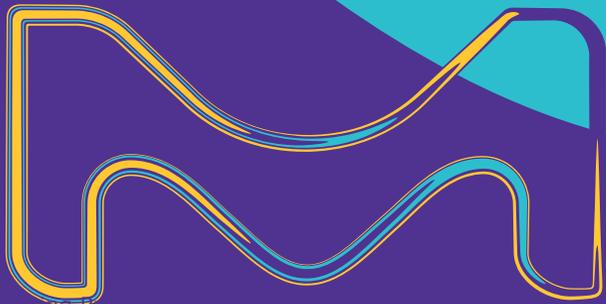
The question they commonly ask: **Can our *active* project team switch to Jama?**

- Adopting a new tool introduces risks
- Nobody wants to disrupt a functioning team

For Merck BT, the answer is often "Yes"



Keys to a successful
transition



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Plan for success: Move slow to go fast

People like that Jama is easy to use, but success comes with good planning:

- **Provide Training** to ensure team members use Jama correctly
- **Re-use existing documentation** by importing into Jama
- **Understand key Jama functionalities** that will help your project
- Be clear on your **project team's workflows**
- **Evaluate project reporting and documentation**
- **Consider your schedule**

Offer Jama Training to your Team

- **Training options:**

- Internal experts
- Jama Customer Success Rep
- Jama videos on YouTube
- Jama eLearning & Help

- **Hands-on training** is recommended

- PM's report that trained teams become productive quickly

- One tip: Start with a small group. Make sure they use Jama correctly.

- *Important: Adhere to Jama Best Practices*

"...people that we thought were early adopters were using the tool the wrong way and discrediting it (e.g. exporting the item to send an email for review them instead of using the Review tool)."

Re-use Existing Documentation

"No need to retype anything"

- Import Requirements, Specs, Test Cases from Word and Excel
- Avoid down time typically associated with switching systems
- Consistent formatting and structured information make importing easy
 - **Important:** Evaluate doc structure to see if it is import-ready

"Creating test scripts in Excel and importing them was easy"

Description	Details	Necess	Backlog
1.1.1 Sub process "Data Posting" - Process ID: 1	The Process covers the creation, review and		
System shall have the ability to track the trial registration process and subsequent updates to the record posted		MAND	DP-001
System shall have the ability to track the results posting process		MAND	DP-002
System shall accommodate current and future global study registration and results posting requirements.		MAND	DP-003
System shall incorporate local and regional		MAND	DP-004

Excel data imported into Jama.
The yellow row tells Jama to create a folder.



Explorer

Add

- Working Area
 - Requirements
 - 1 Table of Tables
 - 2 Introduction
 - 3 Definitions/Abbreviations
 - 4 Overview
 - 5 Range of Users / User Groups
 - 6 Requirements Definition
 - 1.1.1 Sub process "Data Posting" - Process ID: 1
 - System shall have the ability to track the trial registration process
 - System shall have the ability to track the results posting process
 - System shall accommodate current and future global study registration and results posting requirements.
 - System shall incorporate local and regional
 - System shall contain
 - System shall have t
 - System shall contain

System shall have the ability to track the trial registration process

CTD-REQ-524 · Requirement

Working Area » Req

Trans

Unique ID: CTD-REQ-524

Name: System shall have the ability to track the trial registration process and subsequent updates to the record posted.

Assigned: -

Priority: Unassigned

Rating: MAND

Description: -

Release: -

Centralize the Project IP in Jama's Project Explorer

The screenshot displays the Jama Project Explorer interface. The top navigation bar includes 'STREAM', 'PROJECTS', and 'REVIEWS'. The main content area is divided into two sections. The left section shows a project tree for 'COSMOS' with various sub-items like 'Project Overview for Reviewers' and 'Approved Cosmos URS'. The right section displays project details for 'System of record for global pricing and market access - V4' (Project ID: COS-REQC-2645). A yellow callout box highlights 'Export when needed' in the top right of this section. Another yellow callout box highlights 'Capture templates based on Merck standards' over the project details. A third yellow callout box highlights 'Sort and Filter based on your project role' over a table of project items. A fourth yellow callout box highlights 'One single source of truth shared with whole team' in the bottom left corner.

Export when needed

Capture templates based on Merck standards

Sort and Filter based on your project role

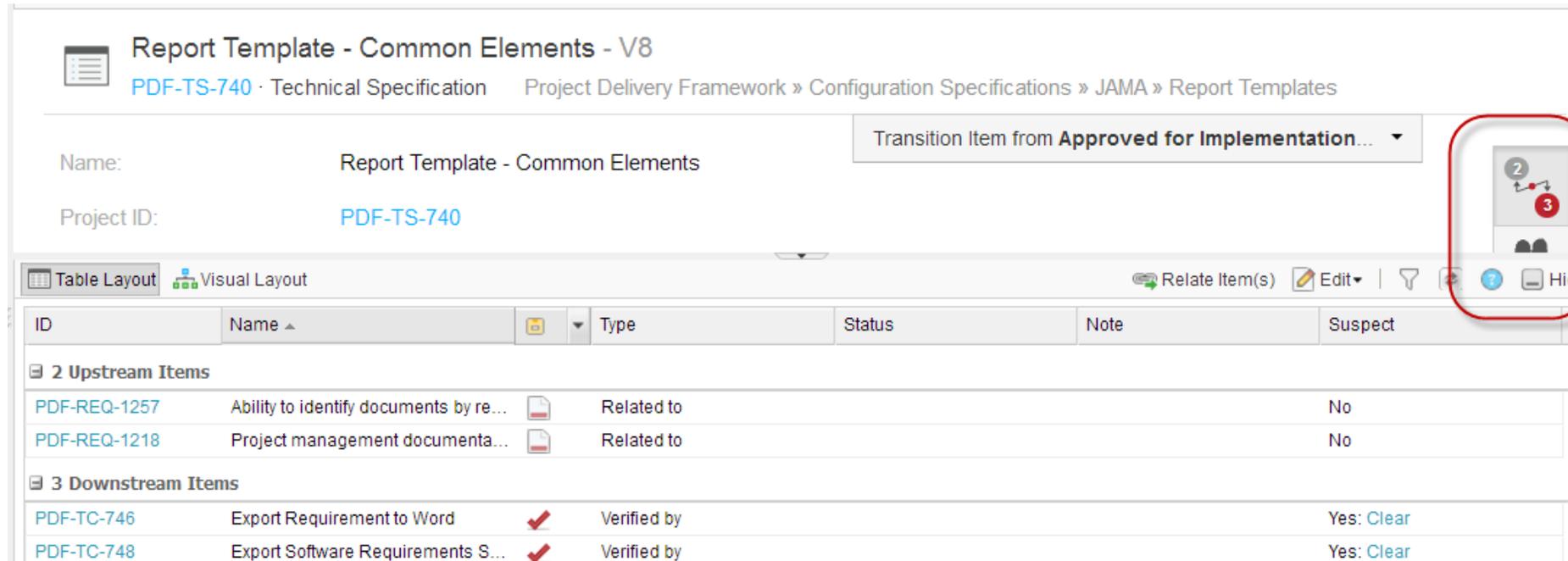
One single source of truth shared with whole team

Project ID	Name	Assigned	Modified Date
PDF-TS-716	JAMA Naming conventions	-	17/12/2015
PDF-FLD-40		-	28/12/2015
PDF-TXT-163		-	07/01/2016
PDF-TS-761	Global Permissions	-	21/01/2016
PDF-TS-750	Organization User Groups	-	19/01/2016
PDF-TS-757	Project User Groups	-	20/01/2016
PDF-TS-758	Users Management - Basic Routines	-	18/01/2016
PDF-TS-762	User Management - Special Users	-	11/01/2016
PDF-FLD-395	Editor Templates	-	01/12/2015
PDF-TXT-154	Editor Templates Rules	-	05/01/2016
PDF-TS-717	Editor Template - User Story	-	

Track Traceability of all Requirements

- Alternative to huge unwieldy spreadsheets
- “Coverage Explorer” identifies gaps in traceability coverage
- Relationship Rules flag items with missing relationships
- **Important:** Set clear expectations about who creates/checks relationships. Otherwise, there’s the risk that they won’t get done.

“Traceability was almost impossible in Word/Excel yet it is mandatory to cover regulatory requests.”



The screenshot shows a software interface for managing requirements. At the top, it displays the title "Report Template - Common Elements - V8" and a breadcrumb trail: "PDF-TS-740 · Technical Specification » Project Delivery Framework » Configuration Specifications » JAMA » Report Templates". Below this, there are fields for "Name: Report Template - Common Elements" and "Project ID: PDF-TS-740". A dropdown menu is set to "Transition Item from Approved for Implementation...". A red circle highlights a small icon in the top right corner of the interface, which appears to be a notification or status indicator showing a flow diagram with nodes 2 and 3.

ID	Name	Type	Status	Note	Suspect
2 Upstream Items					
PDF-REQ-1257	Ability to identify documents by re...	Related to			No
PDF-REQ-1218	Project management documenta...	Related to			No
3 Downstream Items					
PDF-TC-746	Export Requirement to Word	Verified by			Yes: Clear
PDF-TC-748	Export Software Requirements S...	Verified by			Yes: Clear

Improve Team Collaboration with the Review Center

Important - Figure this out early. Your team will love it.

Track and facilitate complex review cycles.
Capture all feedback.

The screenshot displays the Jira Review Center interface. At the top, there is a navigation bar with 'STREAM', 'PROJECTS', and 'REVIEWS' tabs. The 'REVIEWS' tab is active, showing 'My Reviews (Showing 11 of 38)' and 'All Public Reviews'. A yellow callout box highlights the text: 'Track and facilitate complex review cycles. Capture all feedback.'

The main dashboard shows a grid of review items, each with a title, version, and status. For example, 'Project Delivery Framework Sprint 2 - Users and Groups V9' is in a 'Requested New Revision' state, while 'Project Delivery Framework Technical Specification: JIRA Workflow Schemes V5' is 'Approved'.

The detailed view of a review cycle for 'Technical Specification: JIRA Workflow Schemes - V5' is shown below. It includes a progress bar (100%), a list of filters (e.g., '1 item I've approved'), and a table of workflow configurations:

Project type	Default Issue Workflow
Regulated	MERCK Regulated Issue V
Regulated	MERCK Regulated Defect
Non-Regulated	MERCK Non-regulated Iss

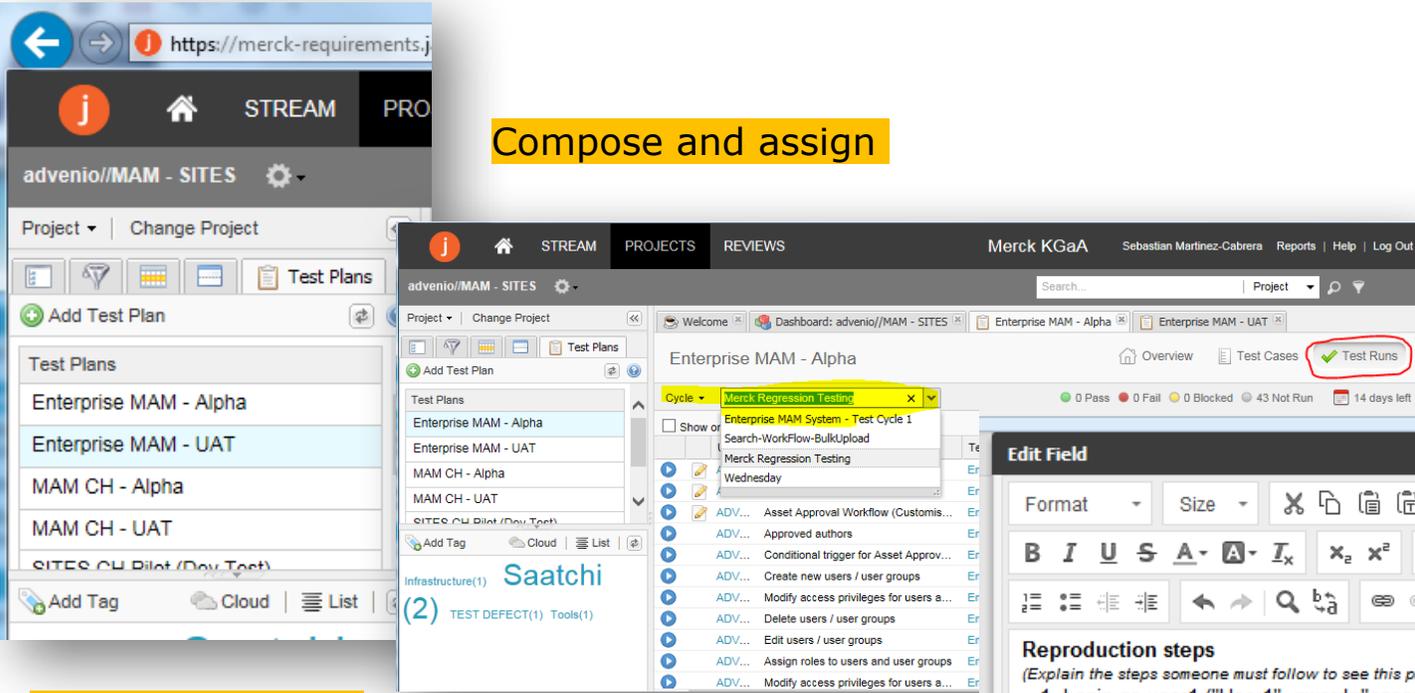
Below the table, it states: 'Following workflow schemes will be configured: Project type Default Workflow Scheme'.

The detailed view also shows a review item '1.5.2 Framework supports requirements authoring and management' with a progress bar (18%) and a list of user requirements. A feedback dialog box is open, asking 'Do we need to specify the format?' with a 'Submit Feedback' button.

At the bottom right, there is a summary of the review status: 'Approved 1' and 'Needs More Work 0'.

Managing Testing Efforts in the Test Center

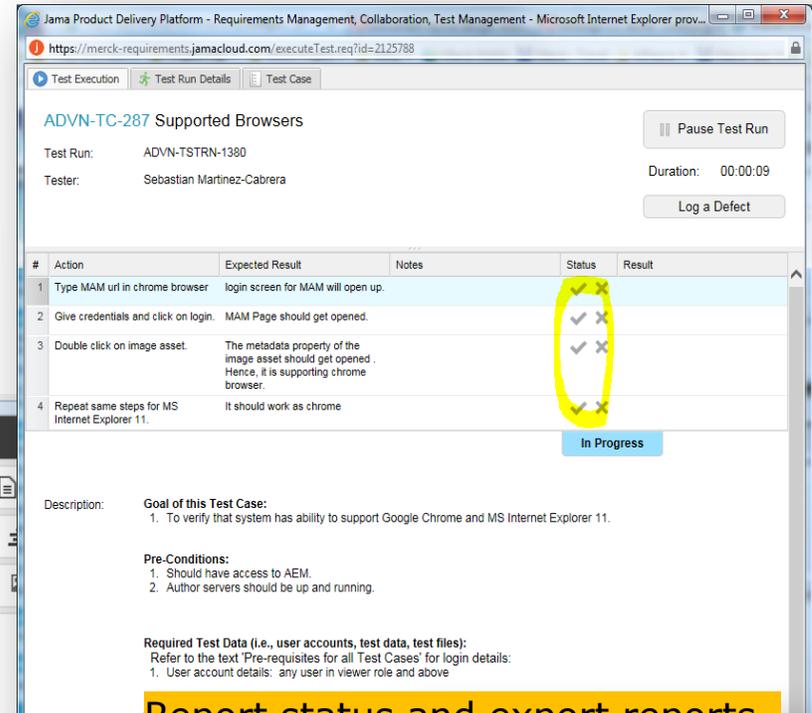
Compose and assign



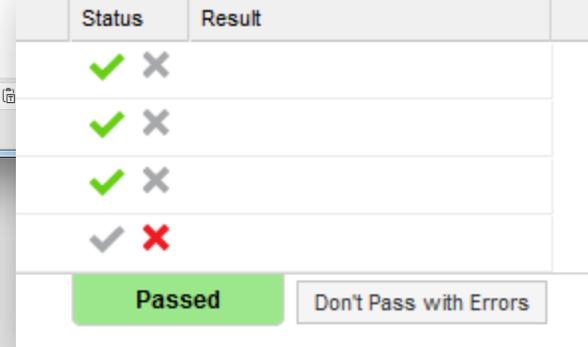
Plan and organize

Important: Jama supports a well-planned test effort. Think through test structure, assignments, and reporting.

Track execution progress and pass/fail



Report status and export reports



Log defects – Can xfer to applications like JIRA

Clarify Project Workflows

- Are project workflows & roles as clear as they should be?
 - SDLC methodology: Waterfall or Agile?
 - Review process: Process and roles
 - Feedback: Agree on how feedback to be collected and responded to
 - Completion: Make sure everyone understands how to get to “DONE”
- Use other applications to manage Stories, Defects, or Final Approval?
 - Decide when information should transfer to the other application
 - Defect workflow: Make sure team understands how issues life cycle

Evaluate Jama Reporting & Export functionality

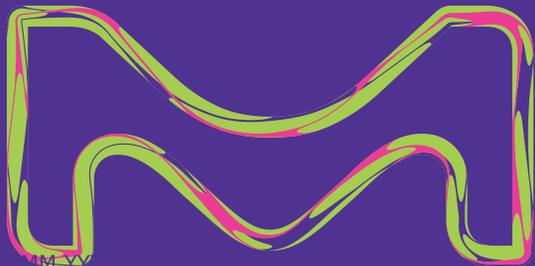
- Reports – written in BIRT/Velocity
- Exports – Word templates, allow teams to some flexibility in structuring/formatting the data
- Many teams find these easy to use and adequate for generating documentation
- **Important:** Determine early if your PMO/Compliance groups approve Jama's project documentation
 - If no, assess your options:
 - Do you have internal resources who can create new Reports or Word templates?
 - Contact Jama Software or a Jama Consultant who can offer professional services assistance

Is there time?

Evaluate what you want to accomplish with the amount of time you have

- Expect at least 3 weeks for
 - Project and user account creation
 - Importing and cleaning up project data
 - Getting team buy-in, providing training, and letting people get familiar with the app
- That being said, some teams tactically use Jama for managing user acceptance testing
 - These teams have been know to cut it close schedule-wise but many teams have benefitted from the structured testing environment

In Summary



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Jama's Features Make Transitioning Worth the Effort

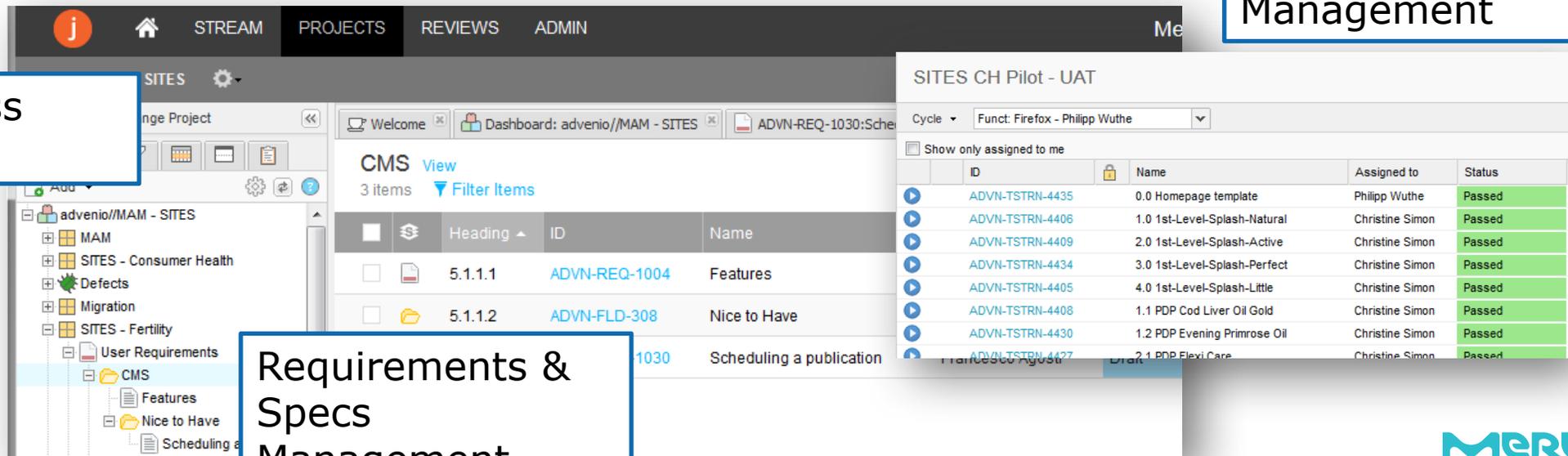
- By keeping IP in one secure, organized, highly usable and version-controlled location
- By re-using existing project information
- By leveraging the Review Center for quicker & more productive review cycles
- By demonstrating traceability; knowing that everything planned is tested
- By managing Testing end-to-end

8+ years used at Merck

Agile process support

Test Management

Requirements & Specs Management



To get there, think it through

- **Provide Training**
- **Re-use documentation**
- **Understand key Jama functionalities**
- **ID project team's workflows**
- **Evaluate reporting and compliance needs**
- **Consider your schedule**

Good transition planning = Happy Merck Project Managers

"Since transitioning to Jama we have been able to **work on reviews, testing, defect management and traceability all at the same time.**

"**JAMA** has become **the hub of activity** on the project and **our central collaboration resource.**

"We simply would not be able to do the advanced testing we are leveraging for the project without it."

"Switching to Jama was an easy decision for our project as it represented best-practices in the industry, which we recognized would benefit all parties that we support at Merck.

"After utilizing Jama for the past year, we can comfortably attest to the many benefits we experienced."

"We had a project with a large number of testers, a huge number of Test Cases, and only 3 days for on-site UAT.

"We were able to get our UAT done as planned, and I don't think it would have been possible without the Jama.

"**Using it, we were able to give testers guidance that was clear and easy to follow, track all incidents and integrate our efforts with the vendor.**"

UAT: Traditional PM vs. Jama (& JIRA) Project Management

Traditional Project Management	JAMA/JIRA Project Management
Upfront investment to create scripts using WORD is moderate	Upfront investment to setup JAMA/JIRA required, consider right way of setting up instance otherwise risk of rework
Effort required to train testers on UAT process	Effort required to train testers on UAT process
<p><i>„Due to efficiency gains using JAMA/JIRA during UAT, we could wrap up UAT phase very quickly. This allowed us to consider releasing our application a few days earlier than planned!</i></p> <p>Strong recommendation to use JAMA/JIRA for non-GxP projects!</p>	
Project manager can see issues straight away and follow-up & resolve	Project manager can see issues straight away and follow-up & resolve
Aggregate test summary manually & labour intensive using Excel or other tools	Easy, built in reporting gives ad-hoc status & overview of testing phase. Report engine produces summary out of test cases (Generate ~350 pages test report in 10 seconds)
Printed 2.000+ pages testing documentation	0 pages (saved more than 1/40 part of a tree)
Same effort for enhancement releases ☹️	Same efficiency for enhancement releases 😊



Notes

Transitioning project information, such as requirements, tests and defects, to a project development application can seem daunting. Especially when the project teams are accustomed to using Word and Excel. How can it be done without causing widespread disruption? Why take on that risk?

Within the large Business Technology (BT) department of Merck KGaA, Darmstadt, Germany, Jama Software has made the risk worth taking. Adoption rates within BT for in-stream projects have grown steadily as word spread about improvements to collaboration, transparency, and reporting.

The purpose of this talk is to illustrate the approach for transitioning project requirements and other information into Jama Software. This includes transition planning, importing the data, clarifying workflows, and identifying key functionalities to take advantage of - particularly in regards to establishing traceability.