A young child is smiling and holding a glowing light stick at a night festival. The background is filled with colorful bokeh lights in shades of blue, green, and yellow. The child is wearing a light-colored t-shirt with a graphic design.

Risk Based Test Strategy

Implementation within PH MR R&D

Paul Derckx

Philips HealthTech – MR R&D

October 6th, 2015

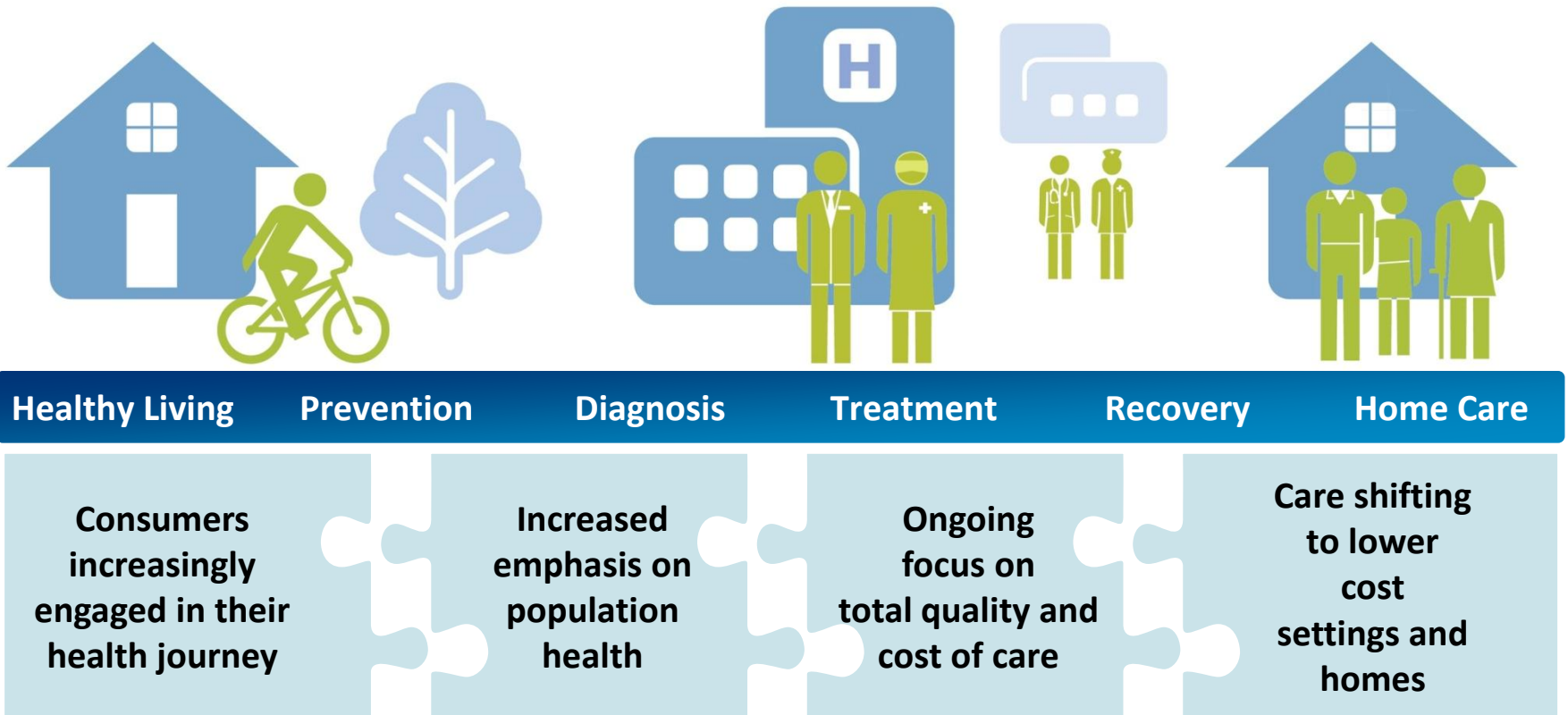
PHILIPS

Content of the presentation

- Introduction Philips HealthTech – Diagnostic Imaging – MRI
- Development characteristics
- Risk based test approach
- Summary

Philips HealthTech

Convergence between Healthcare and Consumer markets



Philips HealthTech – Imaging Modalities

Examples

CT



PET/CT



MRI



Interventional x-ray



Diagnostic x-ray



UltraSound



Philips HealthTech - MR Product Family

Ingenia



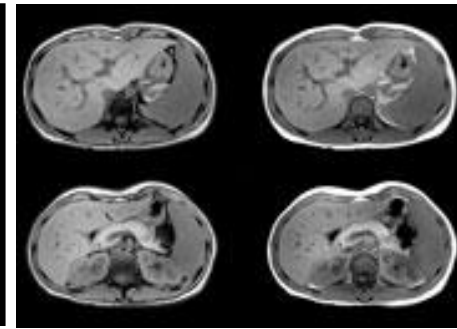
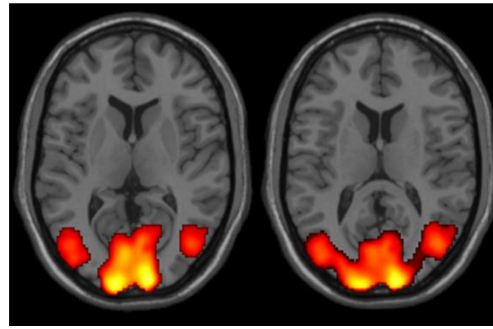
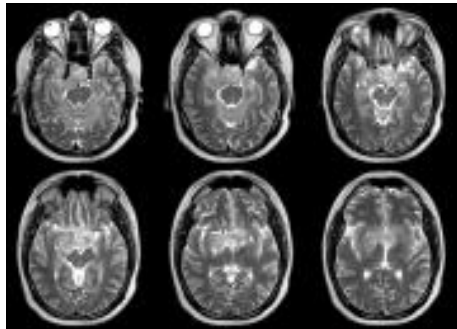
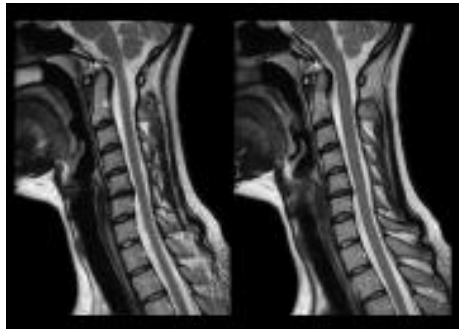
Ingenia CX



Achieva



Multiva



Business importance of testing for MR

Always remember there is a patient connected to everything we do, and that patient, their clinicians, and their family are counting on us.



Content of the presentation

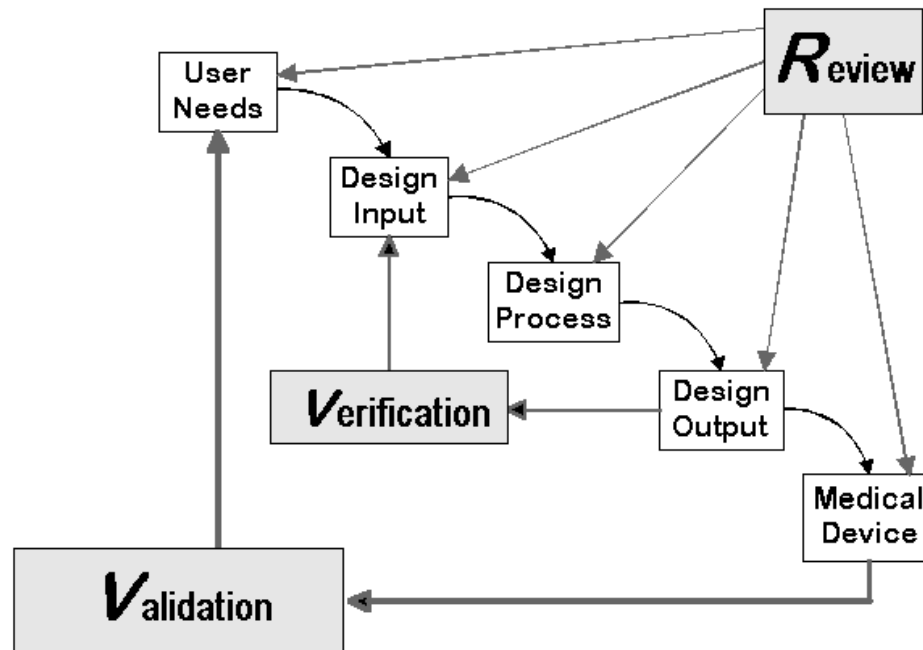
- Introduction Philips HealthTech – Diagnostic Imaging – MRI
- Development characteristics
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Development Characteristics

Regulatory Requirements

FDA 21 CFR 820.30 - Design Controls:

Each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met



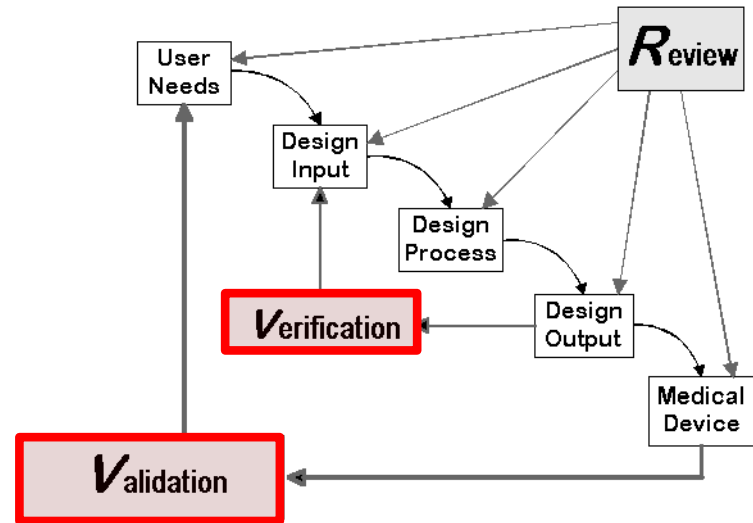
Development Characteristics

Regulations – Design Controls

FDA 21 CFR 820.30(f) - Design Verification

Each manufacturer shall establish and maintain procedures for verifying the device design.

- Design verification shall confirm that the design output meets the design input requirements
- The result of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the design history file



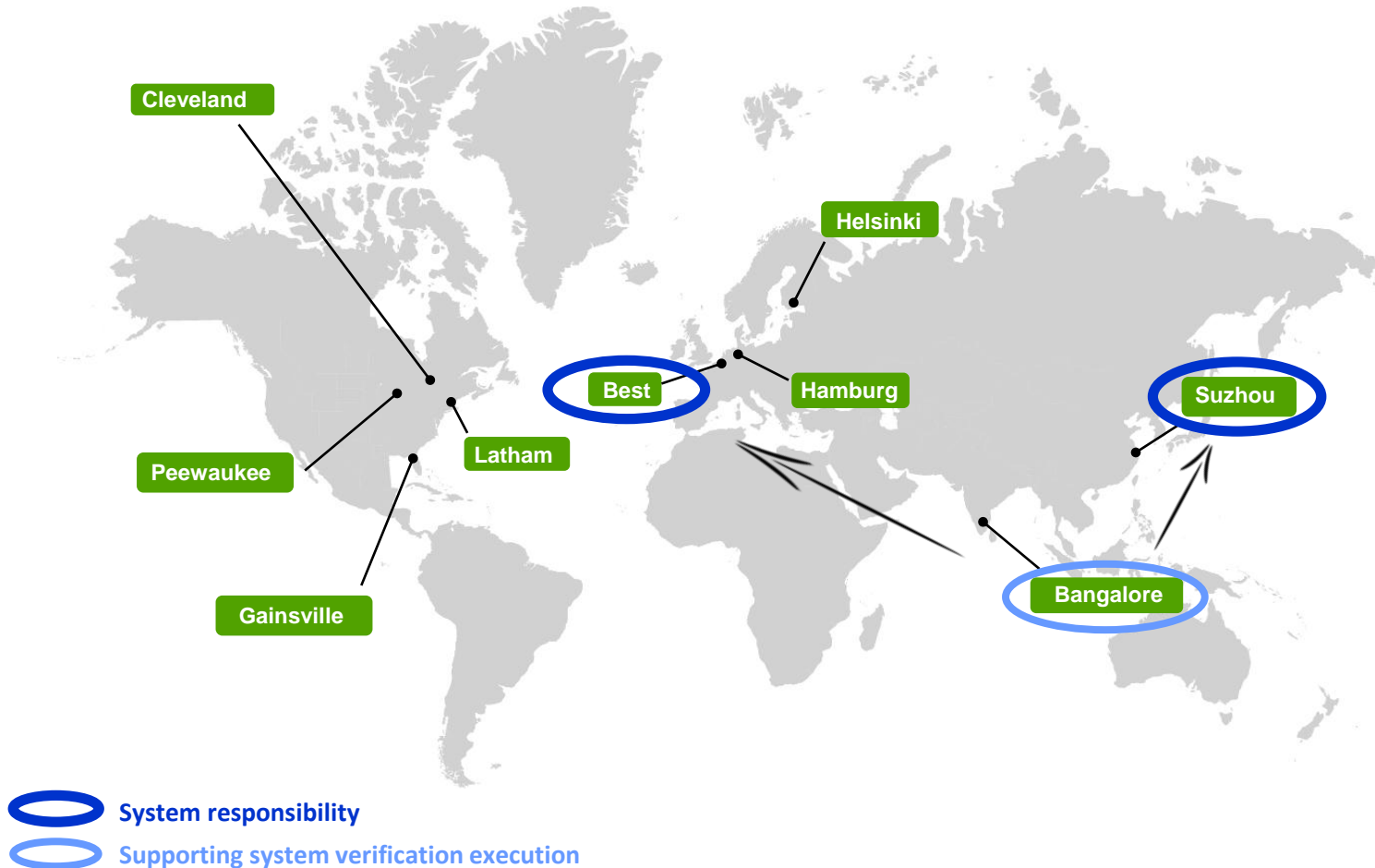
FDA 21 CFR 820.30(g) - Design Validation

Each manufacturer shall establish and maintain procedures for validating the device design.

- Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents
- Design validation shall ensure that devices confirm to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions
- Design validation shall include software validation and risk analysis, where appropriate
- The result of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the design history file

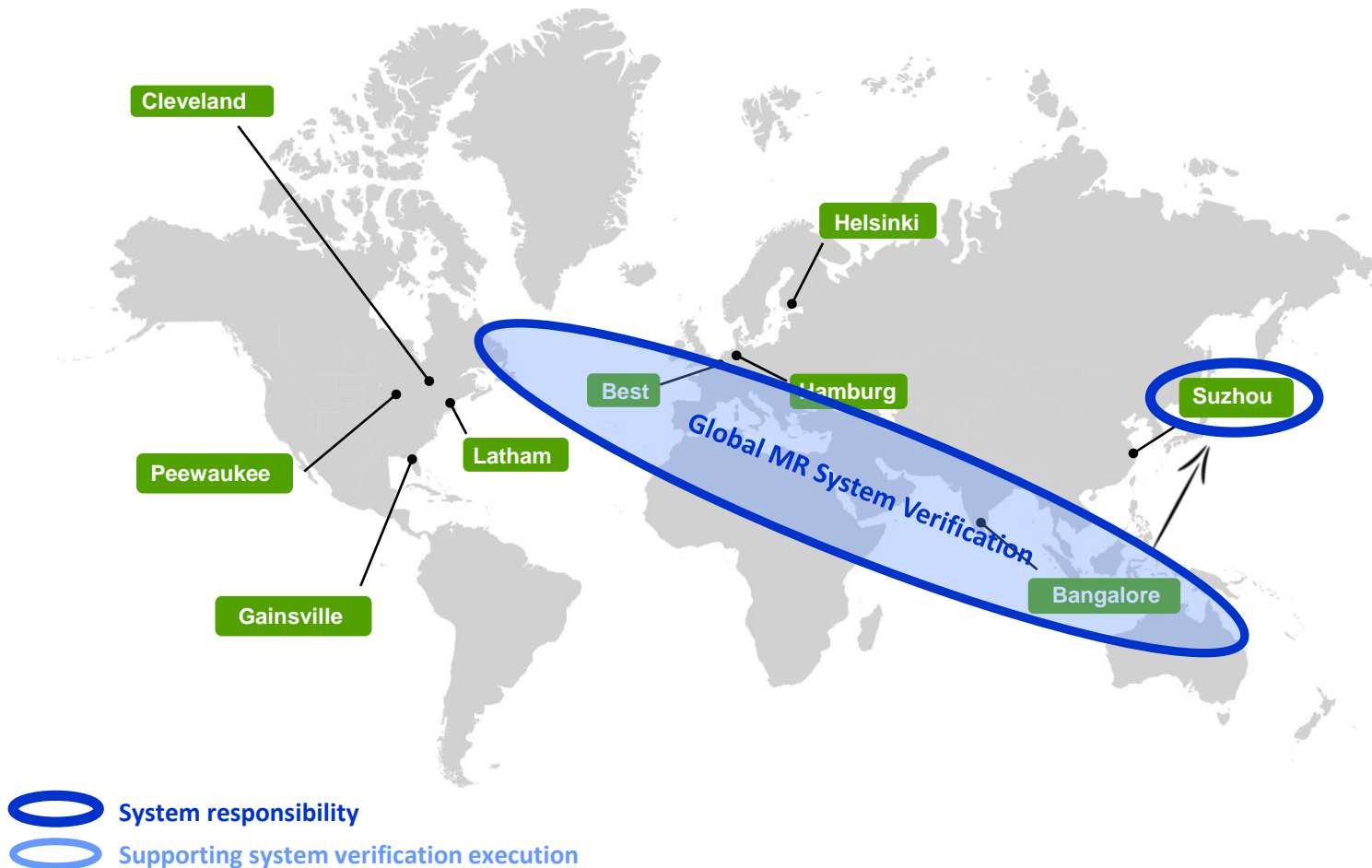
Development Characteristics

Global MR R&D Footprint



Development Characteristics

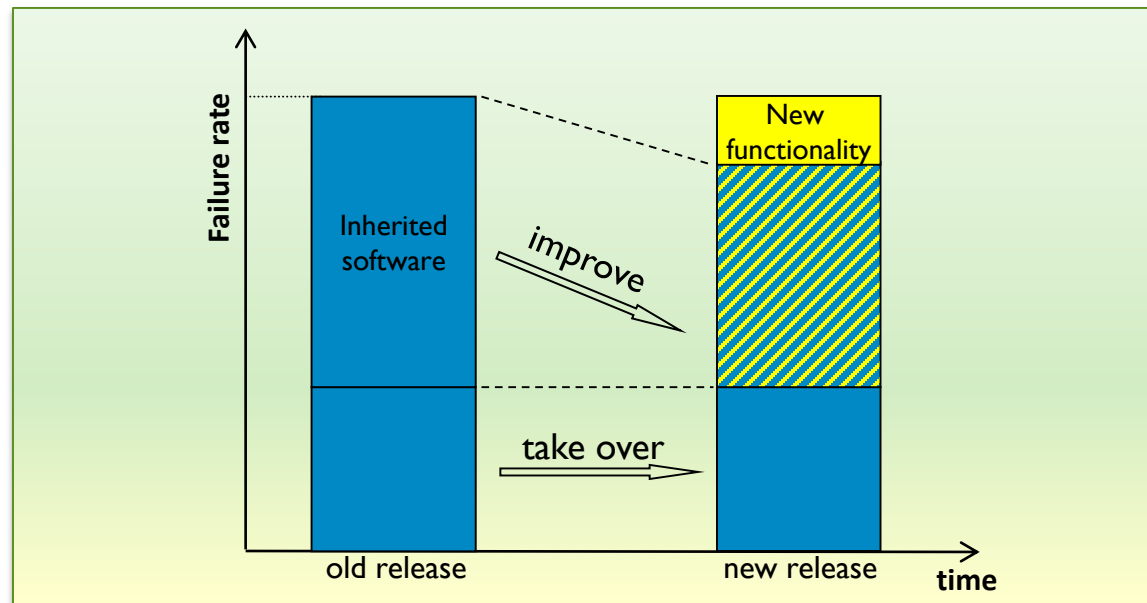
Global MR R&D Footprint



Development Characteristics

Evolutionary Development

- Projects inherit most of the software/hardware from previous projects
- New functionality introduces risk of new defects, so when doing nothing reliability may decrease
- Test strategy must also be focused on improving overall quality/reliability or at least keep quality/reliability the same, therefore the "old" functionality needs to be improved, either by:
 - explicit actions
 - implicitly going through additional test and defect removal cycle(s)



Development Characteristics

And more ...

- Testing performed at defined levels (component/unit, subsystem, system)
- Incremental development cycles within programs
- Programs running in parallel
- Safety & Norm compliance
- External/internal suppliers
- Installed Base support
- Resource availability
- Lean
- ...

Risk Based Test approach

Regulatory requirements ...

- Design Verification activities shall provide objective evidence that the Design Output meets the Design Input requirements -> **100% requirements coverage!!**
 - Evolutionary development -> When re-using verification evidence from previous release the **rationale(s)** shall be documented
 - Activities shall be explicit and thorough in their execution and **appropriate verification techniques shall be selected and applied**
 - Tools, test equipment and scripts used with verification must be **validated for their intended use**
 - Verification activities can include tests, inspections, analyses, measurements or demonstrations
 - Complex designs may require more and different types of verification activities than simple designs
- *Any approach selected by the firm, as long as it establishes conformance of the output to the input, is an acceptable means of verifying the design with respect to that requirement*

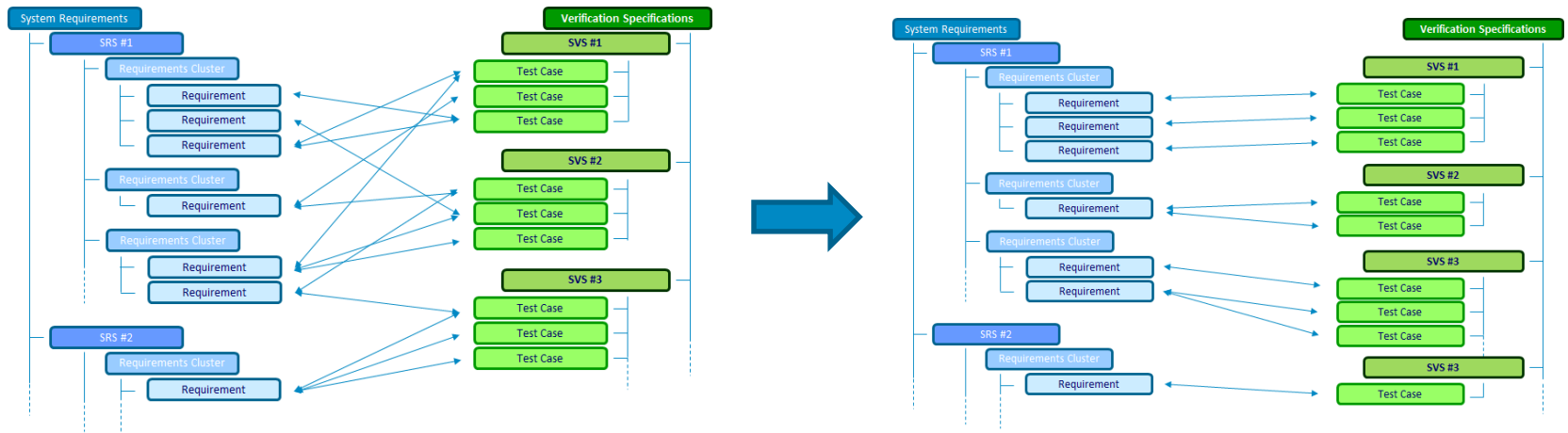
Content of the presentation

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Risk Based Test Approach

Traceability Implementation

- Requirements structure drives the structure of verification specifications



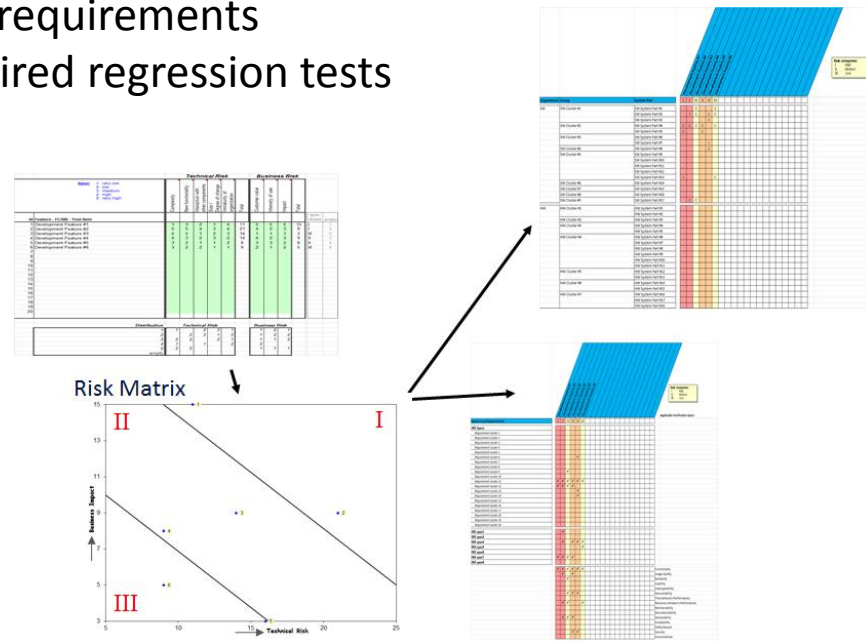
- Dedicated tests showing 100% traceability to requirements to prove we have built the system right and Workflow tests not linked to requirements to prove we built the right system
- Responsibilities for verification specifications allocated at different sites
- Global HP ALM implementation to manage requirements and tests

Risk Based Test Approach

Impact Analysis

Four steps

- Assess risks involved with changing/implementing new features
- Assess the impact of changes to the design
- Assess the impact of changes to the requirements
- Definition of required tests and required regression tests



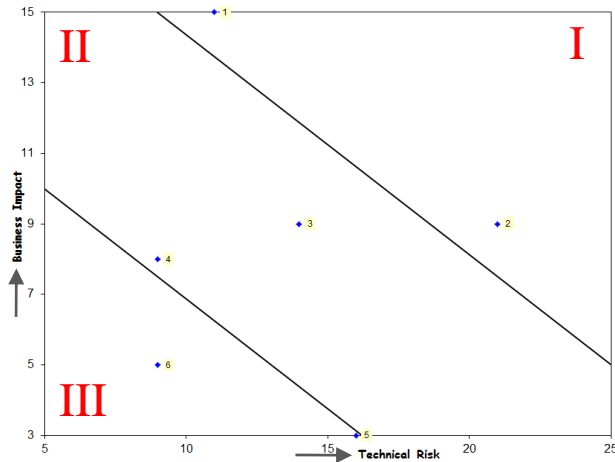
Risk Based Test Approach Implementation

ID	Feature - FCMB - Test Item	Technical Risk					Business Risk			Total	Risk Category
		Complexity	New functionality	Integration with other components	Scope of changes	Intensity of integration	Customer value	Intensity of use	Impact		
1	Development Feature #1	1	2	2	1	4	5	5	15	I	
2	Development Feature #2	4	4	3	3	4	4	4	21	II	
3	Development Feature #3	2	2	3	3	3	3	3	18	II	
4	Development Feature #4	2	1	3	2	2	2	2	14	III	
5	Development Feature #5	2	1	1	1	1	1	1	9	III	
6	Development Feature #6	1	1	1	1	1	1	1	6	III	

System Group	System Part	Risk Category			
		I	II	III	IV
SW Cluster #1	SW System Part #1	C	C	C	
	SW System Part #2	A	C	C	
	SW System Part #3	C	C	C	
	SW System Part #4	C	C	C	
	SW System Part #5				
SW Cluster #2	SW System Part #6				
	SW System Part #7				
	SW System Part #8				
	SW System Part #9				
	SW System Part #10				
SW Cluster #3	SW System Part #11				
	SW System Part #12				
	SW System Part #13				
	SW System Part #14				
	SW System Part #15				
SW Cluster #4	SW System Part #16				
	SW System Part #17				
	SW System Part #18				
	SW System Part #19				
	SW System Part #20				
SW Cluster #5	SW System Part #21				
	SW System Part #22				
	SW System Part #23				
	SW System Part #24				
	SW System Part #25				
SW Cluster #6	SW System Part #26				
	SW System Part #27				
	SW System Part #28				
	SW System Part #29				
	SW System Part #30				
SW Cluster #7	SW System Part #31				
	SW System Part #32				
	SW System Part #33				
	SW System Part #34				
	SW System Part #35				
SW Cluster #8	SW System Part #36				
	SW System Part #37				
	SW System Part #38				
	SW System Part #39				
	SW System Part #40				

Input for SubSystem Test and System Integration

Risk Matrix



Subsystem Verification & System Integration

	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> Risk categories: I High II Medium III Low </div> </div>												
System Part	i	II	III	II	III	I	III	II	i	III	II	II	III
	Feature #1	Feature #2	Feature #3	Feature #4	Feature #5	Feature #6	Feature #7	Feature #8	Feature #9	Feature #10	Feature #11	Feature #12	Feature #13
Subsystem #1	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #2	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #3	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #4	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #5	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #6	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #7	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #8	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #9	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #10	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #11	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #12	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #13	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #14	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #15	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #16	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #17	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #18	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #19	III	III	III	III	III	III	III	III	III	III	III	III	III
Subsystem #20	III	III	III	III	III	III	III	III	III	III	III	III	III

Subsystem Verification & System Integration

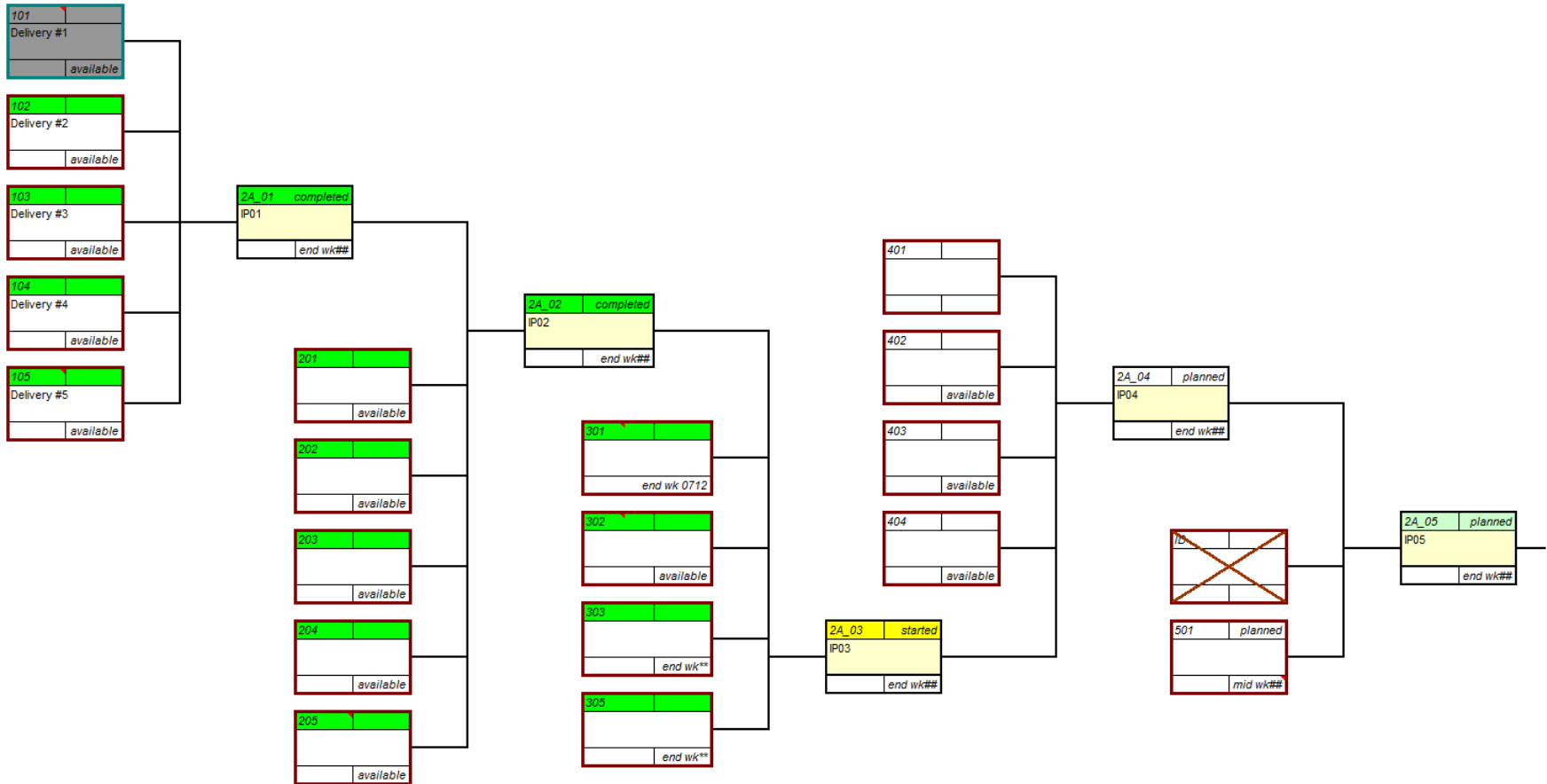
	Feature #1	Feature #2	Feature #3	Feature #4	Feature #5	Feature #6	Feature #7	Feature #8	Feature #9	Feature #10	Feature #11	Feature #12	Feature #13
Full subsystem verification	i	II	III	II	III	I	III	II	i	III	II	II	III
Subsystem #1	C			I	C	C						C	C
Subsystem #2	C		C	I	C	C	I					C	C
Subsystem #3						C	C						
Subsystem #4	C			I	C	C		I	C				C
Subsystem #5						I							
Subsystem #6													
Subsystem #7				I		C					C		
Subsystem #8							C						C
Subsystem #9			C	C	C	C					C		
Subsystem #10		C				C				C	C		
Partial subsystem verification	C					C							
Subsystem #12	C	C	C	C	C	C		C			C	C	
Subsystem #13		C		C									
Subsystem #14	C							I		C			C
No subsystem verification													
Subsystem #16	I				C	C		I					C
Subsystem #17													
Subsystem #18	C												
Subsystem #19	C												
Subsystem #20													

Risk categories:
 I High
 II Medium
 III Low

Legenda:
 C Change in System Part is required to implement the feature
 I Possible impact/interaction on the System

Planned system Integration

Subsystem Verification & System Integration

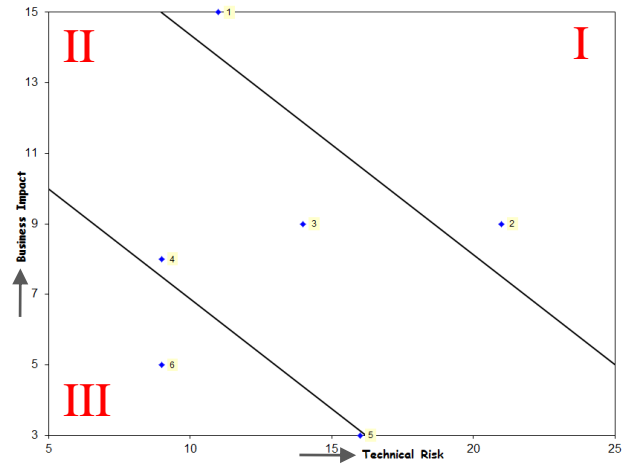


Risk Based Test Approach Implementation

ID	Feature / CAB - Test Item	Technical Risk					Business Risk					Total	Risk Category
		Complexity	New functionality	Integration with other components	Changes of design	Frequency of integration	Customer value	Intensity of use	Impact	Total			
1	Development Feature #1	1	2	3	4	5	1	2	3	4	5	15	I
2	Development Feature #2	2	4	3	3	4	2	4	4	4	4	21	II
3	Development Feature #3	3	2	2	3	3	3	3	3	3	3	9	III
4	Development Feature #4	2	1	1	1	1	1	1	1	1	1	3	III
5	Development Feature #5	3	3	3	3	3	3	3	3	3	3	9	III
6	Development Feature #6	1	2	2	2	2	1	2	2	2	2	11	III

Department Group	System Part	I	II	III
SW	SW Cluster #1	C	C	C
	SW Cluster #2	A	C	C
	SW Cluster #3	C	C	C
	SW Cluster #4	C	C	C
	SW Cluster #5	I		
	SW Cluster #6	C		
	SW Cluster #7	I		
	SW Cluster #8	C		
	SW Cluster #9	C		
	SW Cluster #10	C		
HW	HW Cluster #1	C	C	C
	HW Cluster #2	C	C	C
	HW Cluster #3	C	C	C
	HW Cluster #4	C	C	C
	HW Cluster #5	C	C	C
	HW Cluster #6	C	C	C
	HW Cluster #7	C	C	C
	HW Cluster #8	C	C	C
	HW Cluster #9	C	C	C
	HW Cluster #10	C	C	C
	HW Cluster #11	C	C	C
	HW Cluster #12	C	C	C
	HW Cluster #13	C	C	C
	HW Cluster #14	C	C	C
	HW Cluster #15	C	C	C
	HW Cluster #16	C	C	C
	HW Cluster #17	C	C	C

Risk Matrix



System Part	I	II	III	IV
System Part #1	✓	✓	✓	✓
System Part #2	✓	✓	✓	✓
System Part #3	✓	✓	✓	✓
System Part #4	✓	✓	✓	✓
System Part #5	✓	✓	✓	✓
System Part #6	✓	✓	✓	✓
System Part #7	✓	✓	✓	✓
System Part #8	✓	✓	✓	✓
System Part #9	✓	✓	✓	✓
System Part #10	✓	✓	✓	✓
System Part #11	✓	✓	✓	✓
System Part #12	✓	✓	✓	✓
System Part #13	✓	✓	✓	✓
System Part #14	✓	✓	✓	✓
System Part #15	✓	✓	✓	✓
System Part #16	✓	✓	✓	✓
System Part #17	✓	✓	✓	✓
System Part #18	✓	✓	✓	✓
System Part #19	✓	✓	✓	✓
System Part #20	✓	✓	✓	✓

Input for Design Verification and Design Validation

System Verification

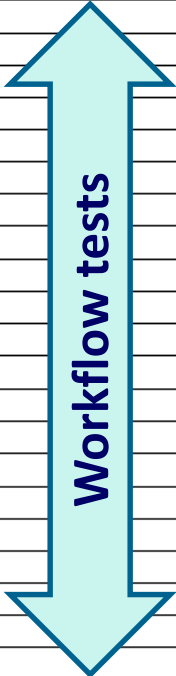
	Feature #1	Feature #2	Feature #3	Feature #4	Feature #5	Feature #6	Feature #7	Feature #8	Feature #9	Feature #10	Feature #11	Feature #12	Feature #13	
System Level Requirements	i	II	III	II	III	I	III	II	i	III	II	II	III	
SRS #1														
Requirements cluster #1														
Requirements cluster #2														
Requirements cluster #3														
Requirements cluster #4														
Requirements cluster #5														
Requirements cluster #6														
SRS #2														
Requirements cluster #1														
Requirements cluster #2														
Requirements cluster #3														
SRS #3														
Requirements cluster #1														
Requirements cluster #2														
SRS #4														
Requirements cluster #1														
Requirements cluster #2														
Requirements cluster #3														
Requirements cluster #4														
Requirements cluster #5														
Requirements cluster #6														

Risk categories:
 I High
 II Medium
 III Low

System Verification

	Feature #1	Feature #2	Feature #3	Feature #4	Feature #5	Feature #6	Feature #7	Feature #8	Feature #9	Feature #10	Feature #11	Feature #12	Feature #13
System Level Requirements	i	II	III	II	III	I	III	II	i	III	II	II	III
SRS #1 No system verification								✓					
Requirements cluster #2								✓					
Requirements cluster #3													
Requirements cluster #4								✓					
Requirements cluster #5			✓		✓			✓					
Requirements cluster #6					✓			✓					
SRS #2 Partial system verification		✓						✓					
Requirements cluster #2		✓						✓					
Requirements cluster #3								✓					
SRS #3					✓	✓		✓	✓			✓	
Requirements cluster #1					✓	✓		✓	✓			✓	
Requirements cluster #2	✓				✓			✓				✓	
SRS #4 Full system verification		✓	✓		✓	✓	✓	✓		✓		✓	
Requirements cluster #1		✓	✓		✓	✓	✓	✓		✓		✓	
Requirements cluster #2		✓	✓		✓	✓	✓	✓		✓		✓	
Requirements cluster #3					✓	✓	✓	✓		✓		✓	
Requirements cluster #4	✓	✓	✓		✓	✓	✓	✓		✓		✓	✓
Requirements cluster #5					✓			✓					
Requirements cluster #6					✓	✓		✓					

Risk categories:
 I High
 II Medium
 III Low



SRS #1
No system verification

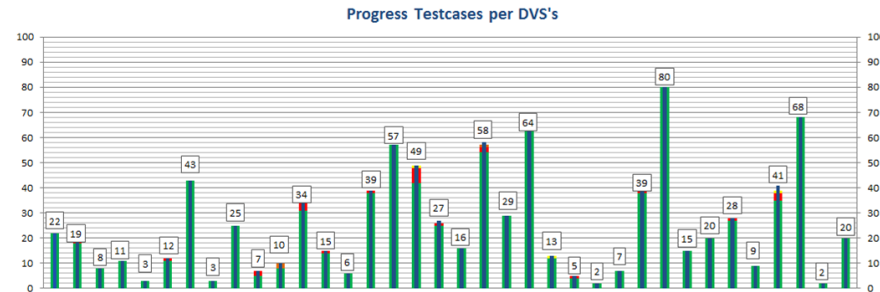
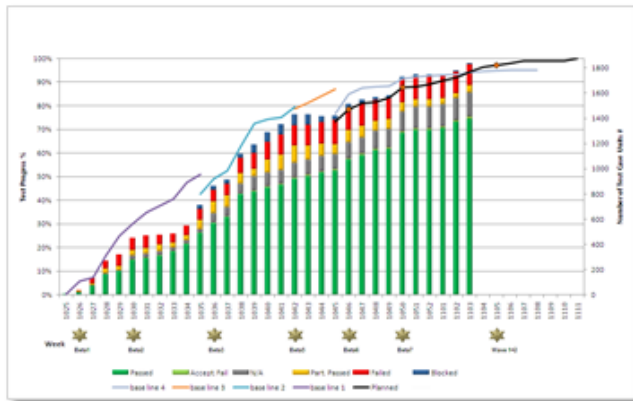
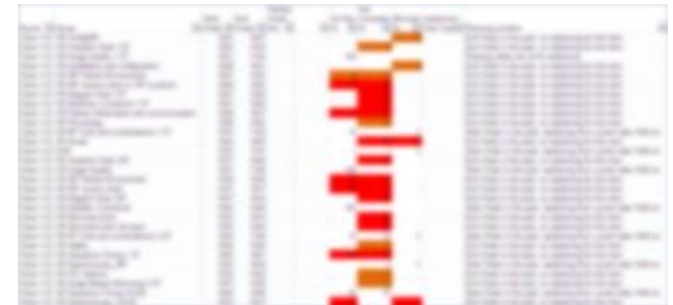
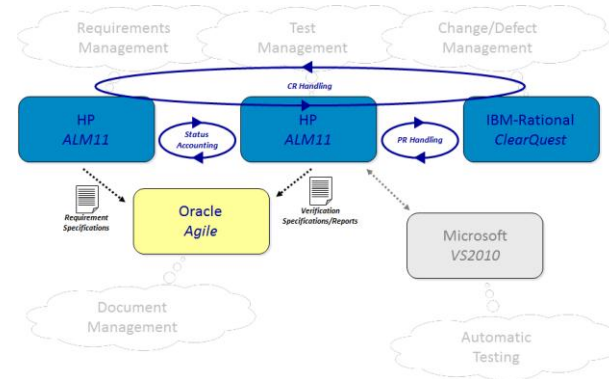
SRS #2
Partial system verification

SRS #4
Full system verification

Risk Based Test Approach

Test Execution

- Test execution distributed at different sites
- Execution on baselined test configurations
- Continuously assess impact of changes to the baseline on the test plans and where needed adapt the test plan(s)
- HP ALM implementation to manage test execution / scripting for test planning and monitoring progress
- Automated testing where applicable



Content of the presentation

- Introduction Philips HealthTech – Diagnostic Imaging – MRI
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Summary

- Need for Speed?
Yes, but not at the cost of quality and compliance!
- Regulatory requirements impact verification and validation activities
- Risk based test approach
 - SW/HW architecture drives subsystem verification and system integration activities
 - Requirements structure drives system verification and validation activities
 - Documented rationales to justify reuse of verification evidence of previous program
 - Execute tests globally on baselined configurations
 - Impact analysis of changes continues throughout test execution



Questions



