

SM04

An Automated Compliance in Project is possible!

PHUSE EU Connect 2023

November 7th, 2023

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MSD
INVENTING FOR LIFE

Agenda

1. Compliance
2. The Tool: program0status
 - a. Flow
 - b. Working steps
 - c. Examples
3. Benefits and Conclusion



Compliance

What is “Compliance”?

“Compliance” refers to the act of **adhering** to **laws**, **regulations**, **rules**, **standards**, and **guidelines** set forth by external entities or internal policies within an organization.

Compliance to internal standard operational procedures guarantees **efficiency**, **trust**, **quality**, **reproducibility**, **consistency**, **time savings**, among others.



To be or not to be... compliant?



Safe and regulated environment

High-Quality

Robustness

Streamlined approval process

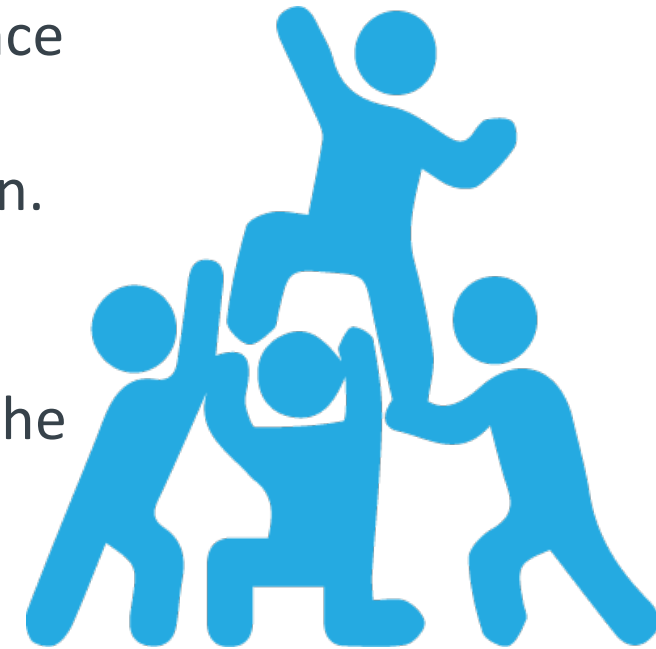
Reliability & Trust

Company's Reputation

Who is responsible?

- ★ The **project leaders** may be seen as “the” responsible for reaching full compliance.
- ★ All the **teammates** are also expected to ensure a constant compliance during the project life.
 - To avoid rework, delay, lack of quality, loss of trust and reputation.
- ★ Great **leaders** make great teammates!
Leaders (managers and mentors) are also responsible for teaching the teammates to become compliant.

We are **all** accountable!



The tool: program0status

The I-O process flow

Development area



Project Tracker



Validation area



Report Review



**Compliance
Confirmed!**

1. The call program

```
%include "\\phuse0compliance0path\program0status.sas" /LRECL=2000;  
  
%program0status(protpath          =    &phuse0compliance0path,  
                  input_tracker   =    tracker.xlsx,  
                  output_path      =    &phuse0compliance0path,  
                  rename_outf      =    status.xml,  
                  debug             =    N) ;
```

2. The Report – Summary Tab

	A	B	C	D	E
1	Summary		Details		
2	# programs	Status	# programs	Problem Details	Comments
3	27	Programs ok	.		
4	0	Programs with some issues			

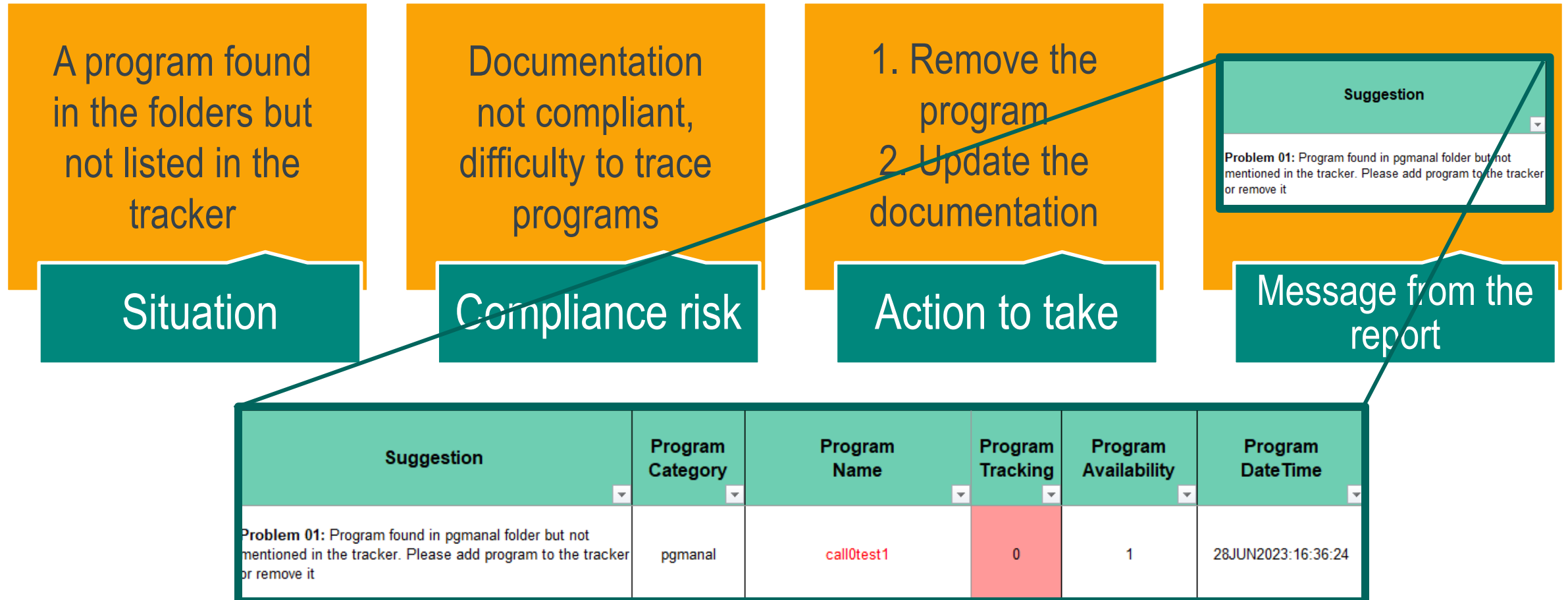
2. The Report – Summary Tab

	A	B	C	D	E
1	Summary		Details		
2	# programs	Status	# programs	Problem Details	Comments
3	27	Programs ok	.		
4	87	Programs with some issues	3	Problem 01	
5	.		4	Problem 02	
6	.		2	Problem 03	
7	.		1	Problem 04	
8	.		4	Problem 05	
19	.		6	Problem 16	
20	.		2	Problem 17	
21	.		2	Problem 18	
22	.		5	Problem 19	
23	.		3	Problem 20	
24	.		2	Problem 21	
25	.		3	Problem 22	
26	.		5	Problem 23	
27	.		12	Problem 24	
28	.		1	Problem 97	
29	.		8	Problem 98	

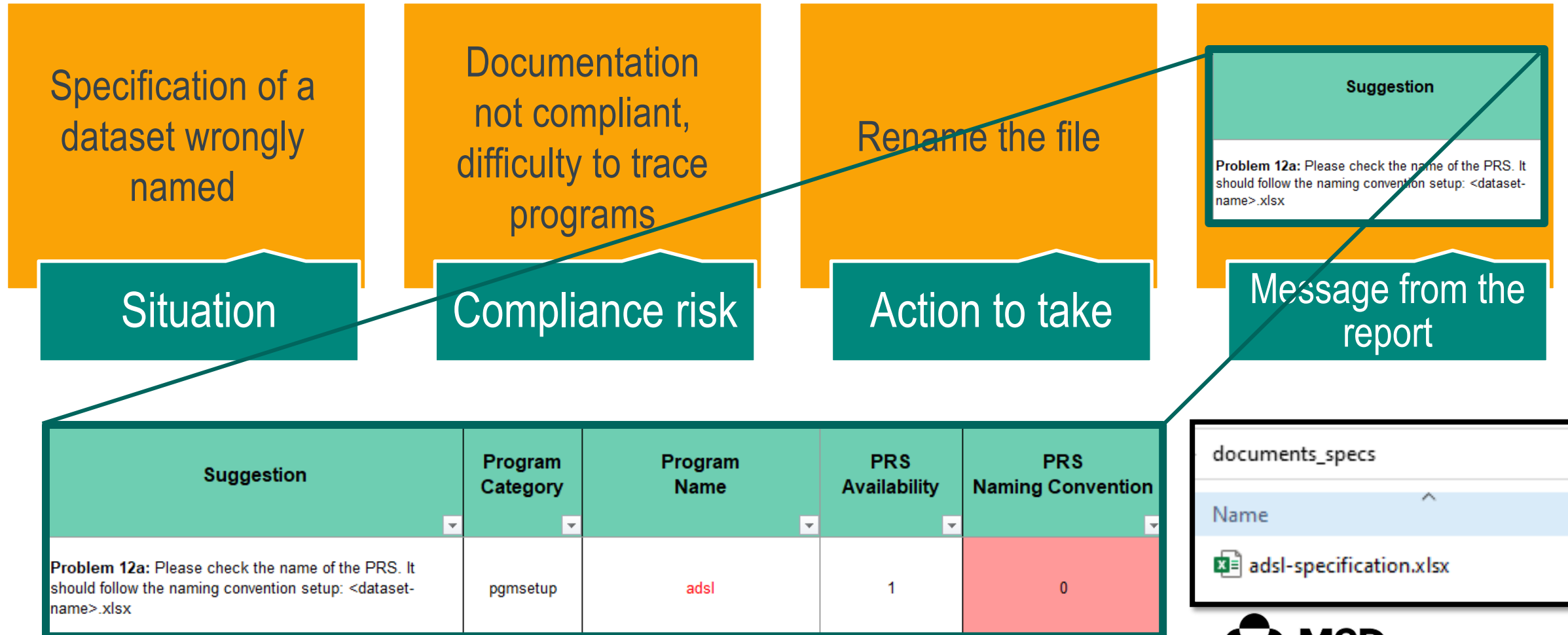
2. The Report – Details Tab

Summary	Identifiers		Program						Program Request Specification			Exceptions	Developer Testing			Validation								Approval
Suggestion	Program Category	Program Name	Program Tracking	Program Availability	Program DateTime	Description	Header Date vs Timestamp	Log ok	PRS Availability	PRS Naming Convention	PRS Date Before Validation	Exceptions Issue	Developer Tester	DevTest In Tracker	DevTest Availability	DevTest Pgm Date	DevTest Log Date	DevTest Header Date vs Timestamp	Latest Version Validated	DevTest Done After Dvlp	Input Data	Output Data	Program Approved	
Problem 02: Program mentioned in the tracker but not found in any folder. Please create it or remove it from the tracker		macrotest07	1	0		Program only in tracker	0	0			1		name1	1	1	01MAR2022:18:00:34	01MAR2022:18:20:35	0	1	0	1	1	1	
Problem 02: Program mentioned in the tracker but not found in any folder. Please create it or remove it from the tracker		setuptest07	1	0		Program only in tracker	0	0			1		name1	1	1	01MAR2022:18:12:11	01MAR2022:18:20:35	0	1	0	1	1	1	
Problem 02: Program mentioned in the tracker but not found in any folder. Please create it or remove it from the tracker		startup-hta-unix-remote	1	0		startup	0	N/A	N/A	N/A	N/A		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Problem 03: Program found in validation folder but not mentioned in the tracker and not found in any folder. Please delete validation of the program		macrotest20	0	0			0	0			1			0	1	01MAR2022:18:08:15	01MAR2022:18:20:35	0	1	0	1	1		
Problem 03: Program found in validation folder but not mentioned in the tracker and not found in any folder. Please delete validation of the program		setuptest20	0	0			0	0			1			0	1	01MAR2022:18:17:31	01MAR2022:18:20:35	0	1	0	1	1		
Problem 04: Program mentioned in the 'exception' tab of the programming tracker but not in the 'Plan and track' tab. If an exception is entered, an entry in the 'Plan and track' tab expected. Please check		only_in_exception_tab	0	0			0	0			0	Missing Exceptions from Plan & Track Sheet: dv12		0	0					0	0	0		
Problem 05: Description of the program is missing in the programming tracker. Please add a description	pgmanal	calltest08	1	1	02MAR2022:17:27:13		1	1	See A&R Grid	N/A	N/A		name1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	

Case 1: The right file at the right place



Case 2: Naming Convention



Case 3: Timestamps

Validation not rerun after latest updates to a program

Situation

Possible issues in the outputs

Compliance risk

Rerun validation

Action to take

Suggestion

Problem 20: The validation of this program has run before the tested program date, or the log of the validation is older than the devtest program. Please rerun validation

Message from the tool

Suggestion

Program Category

Program Name

Program Date Time

DevTest Pgm Date

DevTest Log Date

Problem 20: The validation of this program has run before the tested program date, or the log of the validation is older than the devtest program. Please rerun validation

protocol-macros

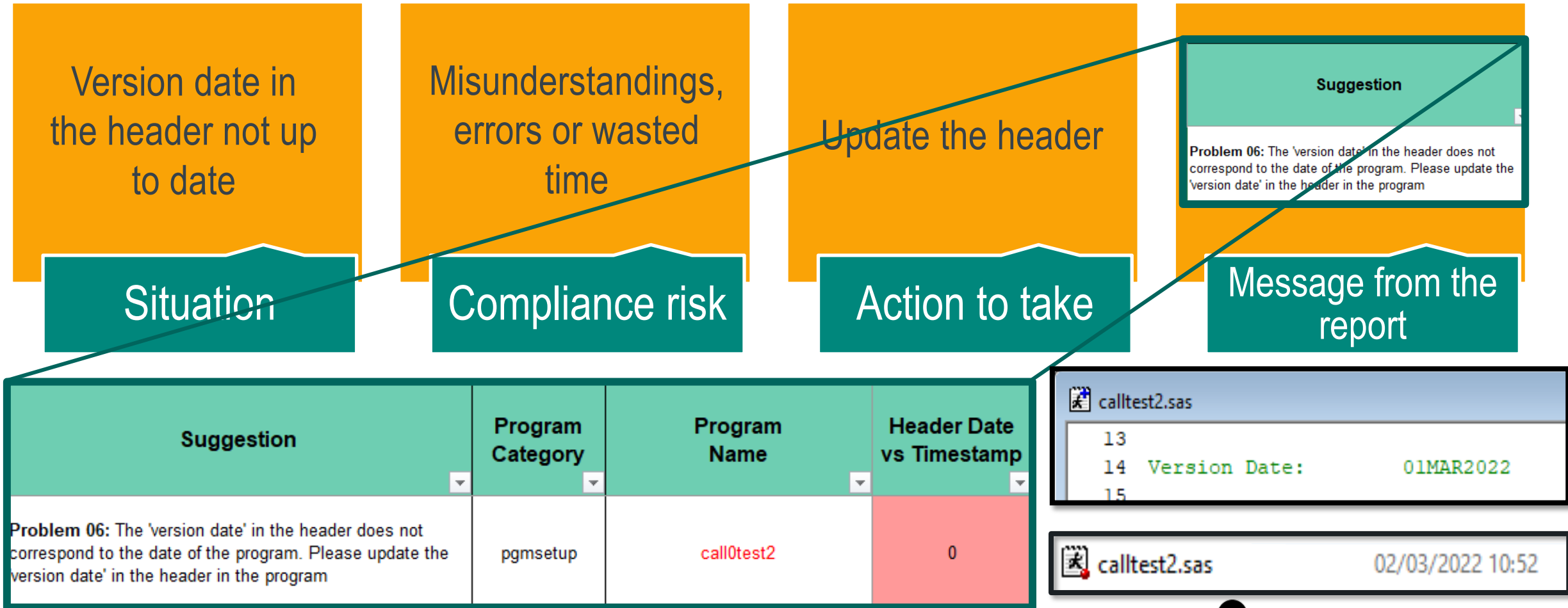
macrotest12

01MAR2022 18:51:00

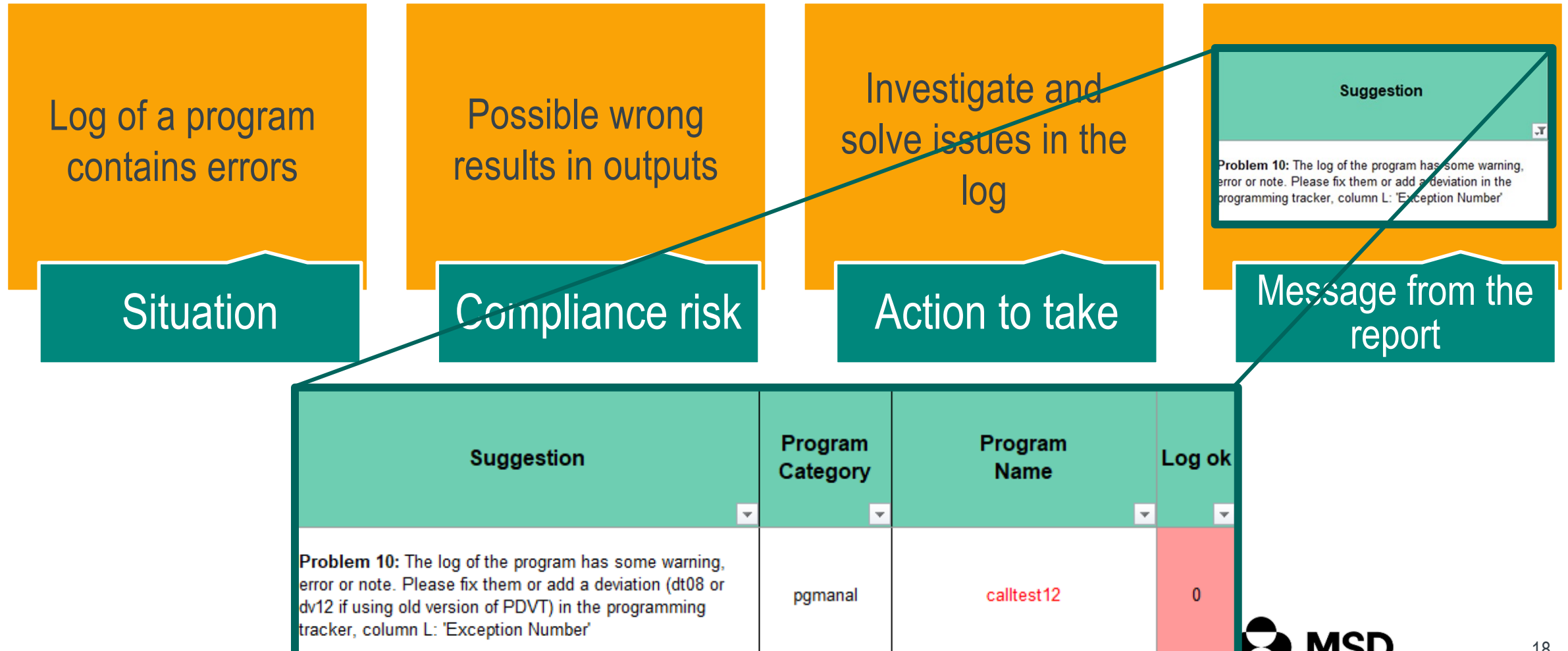
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01MAR2022:18:20:35

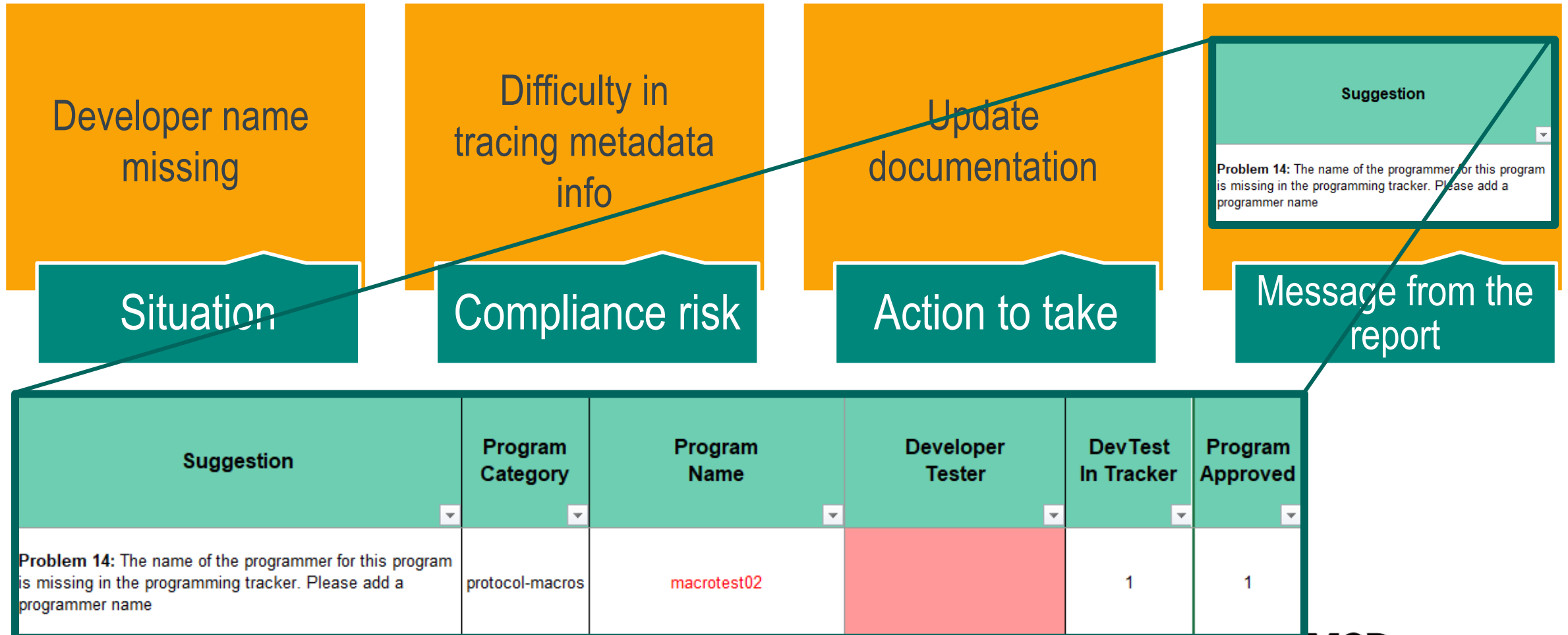
Case 4: Program Header Info



Case 5: Clean Log



Case 6: Tracker Information



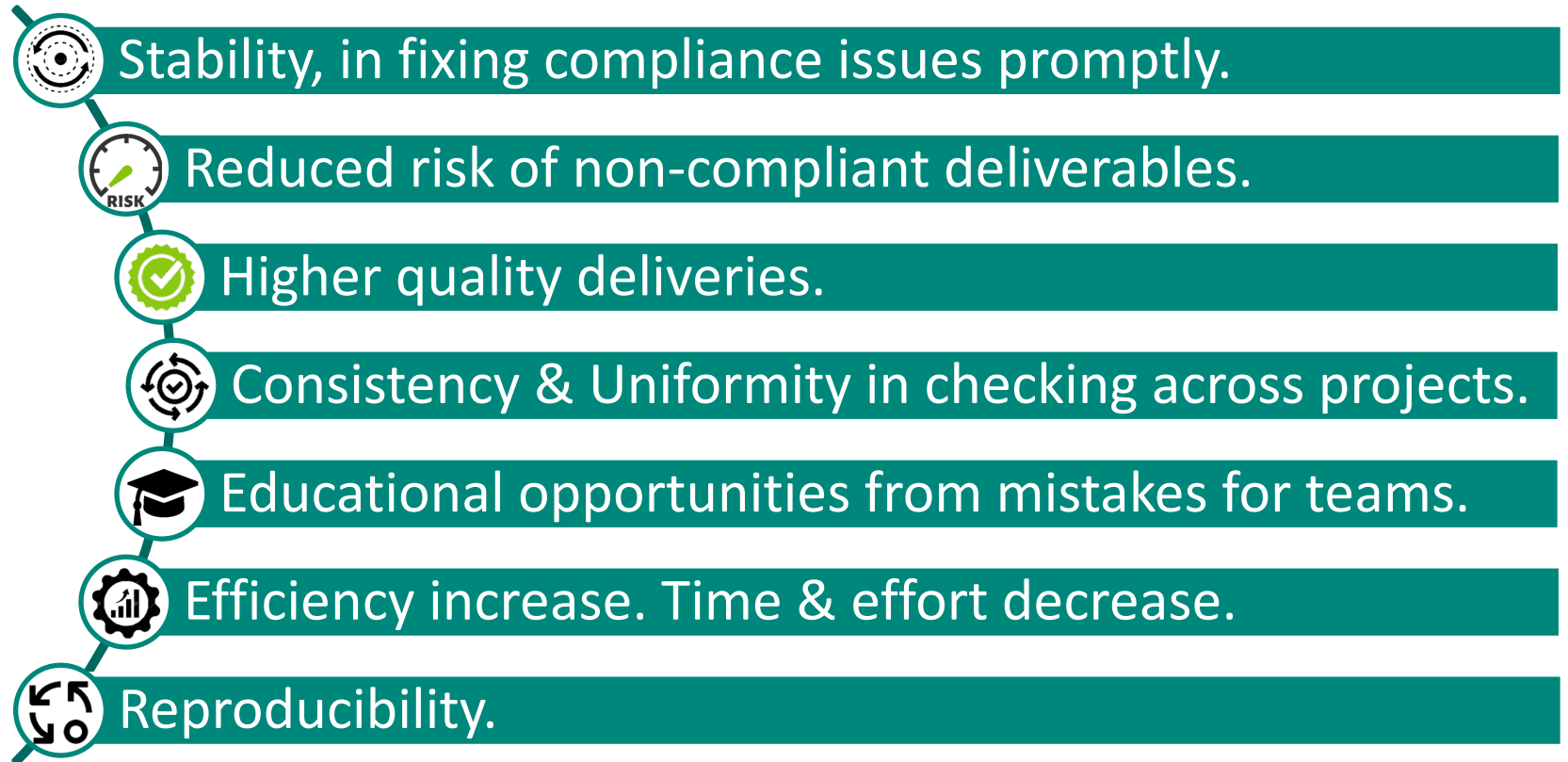
Benefits

Benefits

Standardized Structure



Processes & Conventions



Lessons Learnt

Rank the reported issues

Efficient communication between SOP and developers' teams

Be open to feedback from users

THANK YOU



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