

QC Job Aid: Quality checks made easy

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Statistical Programming

4th September, 2023

Agenda

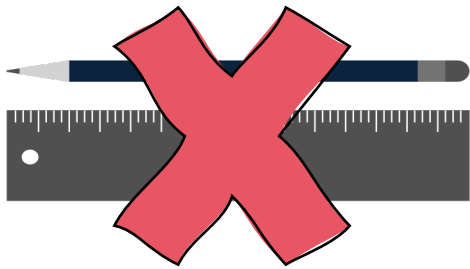
- 1 Define inefficiencies
- 2 Our goal
- 3 Solution – stage 1: Checklist
- 4 Solution – stage 2: QC Job Aid Tool
- 5 How can we automate the checks?
- 6 Examples, highlights and limitations
- 7 Lessons learnt
- 8 Conclusions

Pain points – define inefficiencies



Quality

Review time



Standards

Communication time





Our goal

How can we improve quality by design of outputs before initializing the review?

Solution – stage 1: Checklist



Solution – stage 1: Checklist

Still time consuming as the checks were executed manually

Can we automate those checks?

Yes!

Consistency vs. CSR	NA	SP+ST	If a table presents the same endpoint/analysis/population as CSR, check that the numbers are matching with the CSR outputs. If a table presents a new endpoint/analysis/population, check if the numbers are as expected and not contradicting with similar CSR outputs.
Consistency vs. ATSC	NA	SP	AMNOG only - If the table is a standard AMNOG table, check that it's aligned with ATSC (Title, headers, columns, footnotes, methods...)
title vs. AAR grid	Y	SP	Check that the title is the same as defined in the AAR Grid (population subtitle included)
title - type	NA	SP	Check that no typo exists in the title from the AAR Grid
title - double blanks	Y	SP	Check that no double blank exists in the title in output
title vs. table contents	NA	ST	Check that no inconsistency exists between the title and the table's content (main title, population title, etc.)
title - case	Y	ST	Check that the case of (all) the title(s) is consistent through the project and follows WMA standards (see References tab for info about WMA)
title - split	NA	SP	Ensure that long titles are split correctly to ensure a good understanding and easy reading
title - symbols	NA	SP	Check that all the special characters (if any) are correctly displayed with appropriate spaces/superscript (e.g.: & xxx; & xxx; mm', etc.)
footnote - consistent	Y	ST	Ensure that the population title is consistent through the project (abbreviation in the footnotes)?
footnote - orphan	Y	SP	Ensure that no orphan footnotes (bottom/symbols footnotes with no matching letter in the body) exists
footnote - aligned	Y	SP	Check that all the footnotes are aligned (start from the same position) and have appropriate line break if needed
footnote - cutoff	Y	SP	Ensure that we have a footnote for the database cutoff date?
footnote - pop	Y	SP	AMNOG only - Ensure that we have a footnote for the population description?
footnote - symbols	NA	SP	Ensure that all the special characters (if any) are correctly displayed with appropriate spaces/superscript (e.g.: & xxx; & xxx; mm', etc.)
footnote -	Y	SP	AMNOG only - If applicable, ensure that all the abbreviations used in the table (in headers or body) are listed and detailed in the alphabetical
footnote - data source	Y	SP	Ensure that no data source footnotes is expected in the tables created in the HTA environment (outside the table).
footnote - dot	Y	SP	AMNOG only - ensure that no final dot is displayed at the end of any footnotes row.
footnote - typogr	NA	SP	Check that no typo or extra space exists in the footnotes
footnote - content	NA	ST	Check that the footnotes (method used, population, definitions of endpoints or calculations, etc.) and aligned with the SAP
footnote -	Y	SP	Check if abbreviations are used in the footnotes (can be excluded if MECON)
footnote -	Y	SP	Check that the abbreviations are used in the footnotes (can be excluded if MECON)
footnote - extra space	Y	SP	Check if there is no extra space in the footnotes
footnote - double	Y	SP	Check that no extra space exists in the footnotes
headers - PRS/ATSC	NA	SP	Ensure that the headers match with the PRS mock-up or ATSC standards for AMNOG?
headers - Treatment labels		SP	Ensure that the treatment group labels are correct (vs. AAR grid)
headers - Treatment labels		ST	Ensure that the treatment group labels are consistent through the project
headers - big N	NA	SP+ST	Check that the big N's are displayed and correct (if applicable) based on the selected population. Please use the Pop_counts spreadsheet (see references)
headers - split	NA	SP	Check that the split are correctly handled
headers - alignment	NA	SP	AMNOG - Check that the headers are correctly aligned (horizontally centered and bottom aligned)
headers - N vs. NM	NA	SP+ST	Check that the big N's match with number in risk (NM) on the table matching the NM plot
headers - superscripts	Y	SP	Check that the superscripts (AMNOG: letters in alphabetical order) are correctly placed; all superscripts are detailed in a corresponding footnote.
headers - N	NA	SP+ST	Check that the big N's match across the tables with the same population/sub-population (including CSS tables), taking into account the missing/observable categories
column1 - truncation	NA	SP	Check that no truncated values are displayed
column1 - width	NA	SP	Check that the column width is high enough. If space available, please increase the width to avoid splits.
column1 - superscript	Y	SP	Check that all superscripts are detailed in footnotes.
column1 - categories labels		SP	Check that all the categories or sub-groups are included/displayed based on the specs in the global tabcheet of AAR Grid or in the PRS mock-up respecting the defined order.
column1 - categories order		ST	Check that the categories/subgroups order and text in the AAR Grid is matching with the SAP
column1 - units	Y	SP	Check that the same of variables that represent some measurements are accompanied by measurement units (e.g. age (years), height (cm) or weight (kg)).

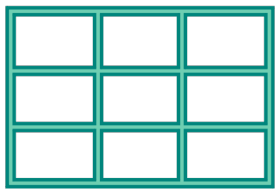
Solution – stage 2: QC Job Aid Tool



How can we automate the checks? Input

What are the tool's **inputs** to use?

Outputs:
Datasets/RTFs



Specification of
outputs



Standards as metadata
(eg. dictionary)



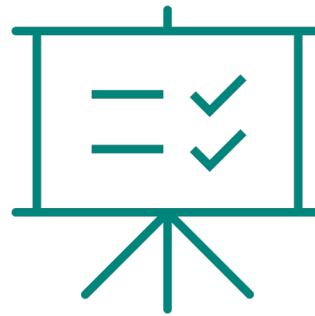
How can we automate the checks? Output

How would the tool's **output** look like?

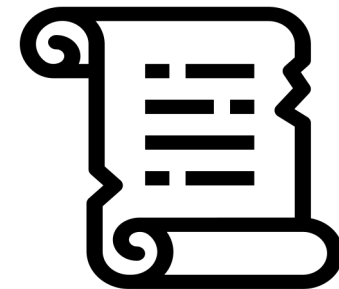
Clear and short
messages



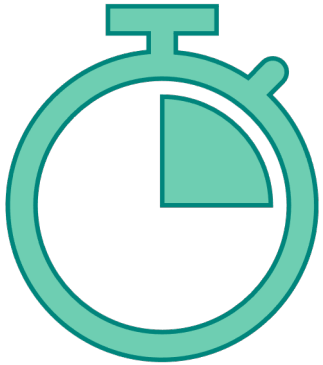
Actionable
items



Maintain same
QC report



How can we automate the checks? Program



Efficiency



Modularity



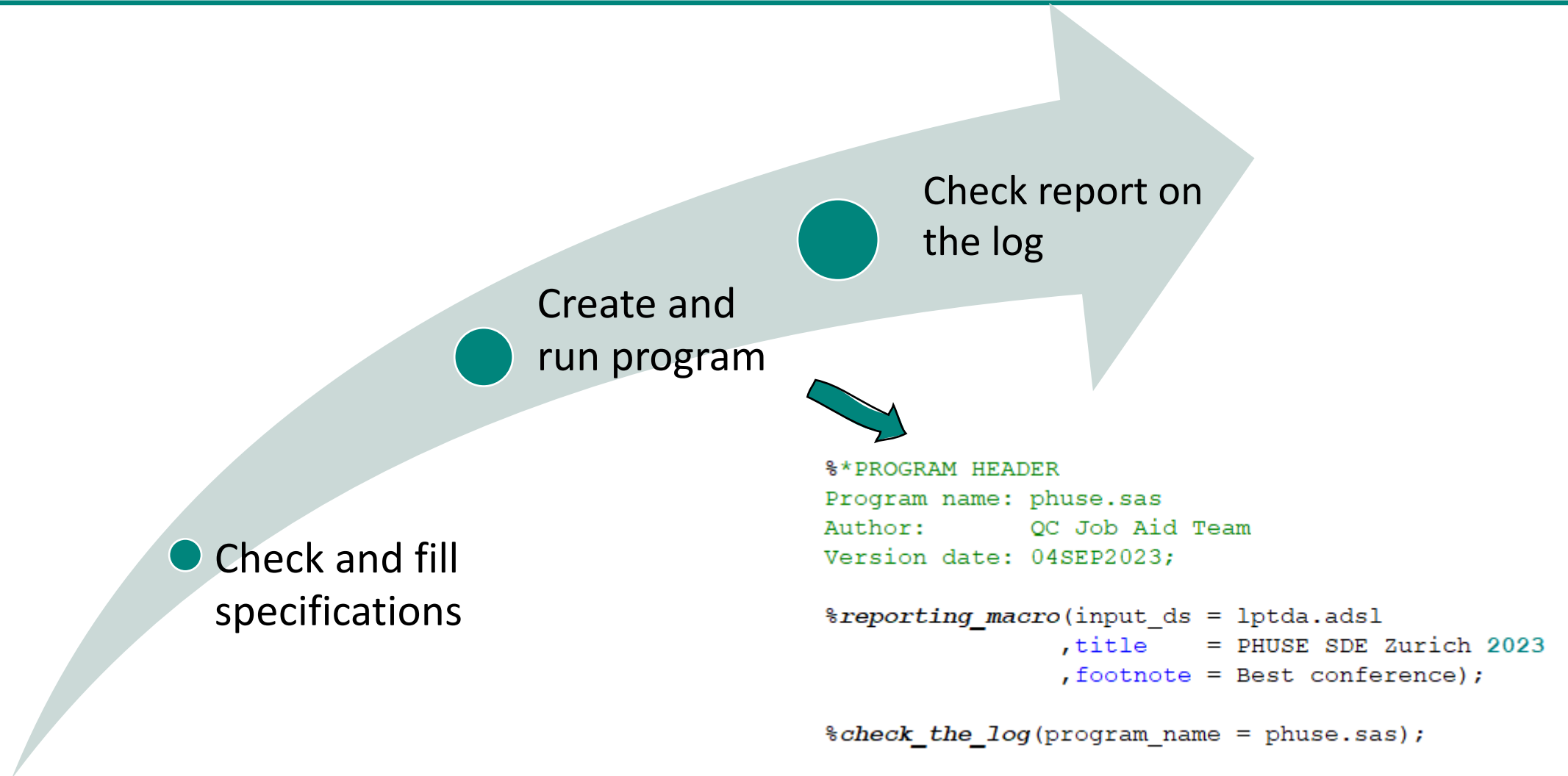
Robustness

```
%* (...) Import what is needed;
```

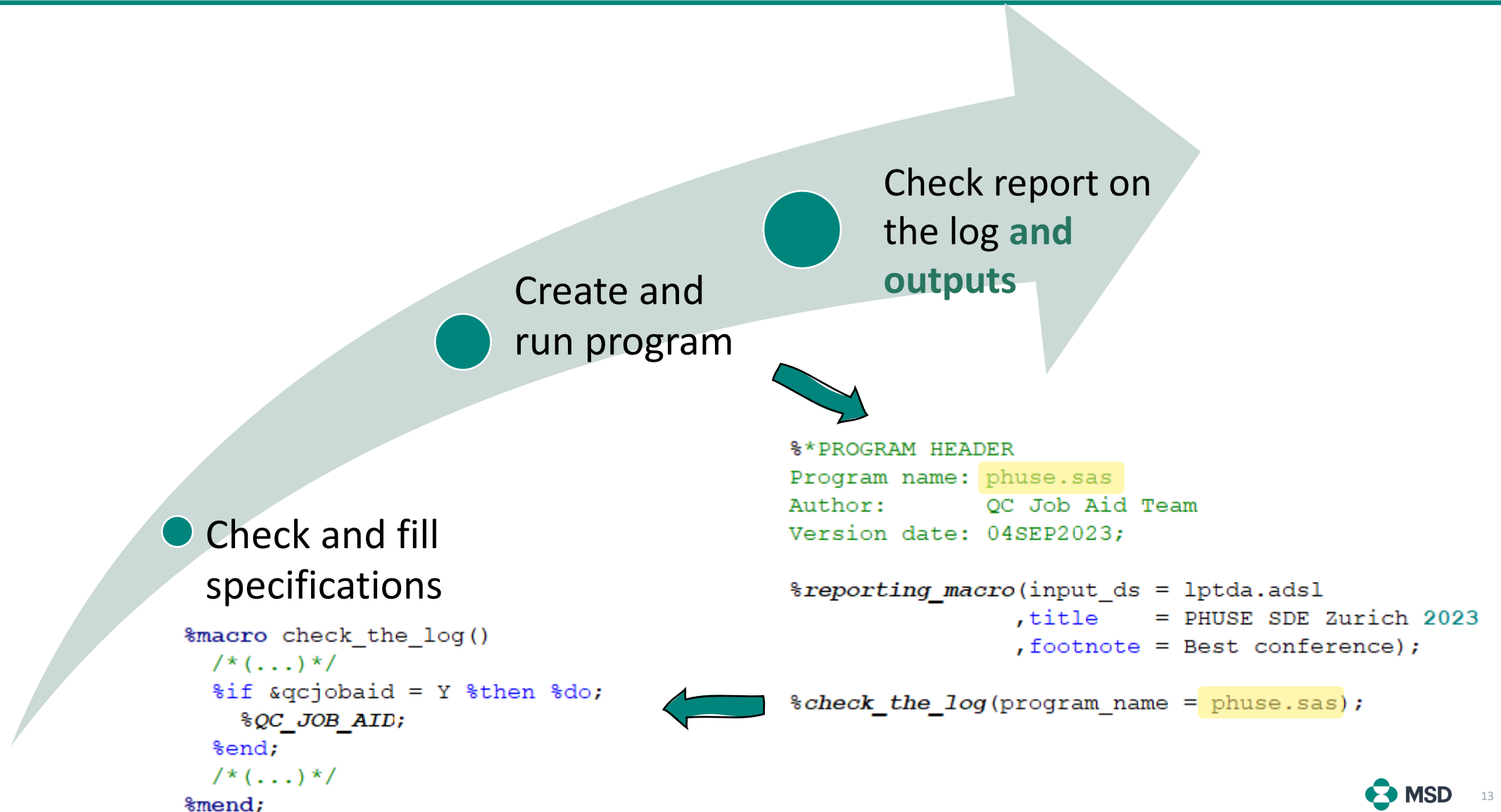
```
%check_on_footnotes  
%check_on_titles  
%check_on_headers
```

```
%* (...) Gather all the findings  
and create report;
```

Statistical programmer legacy life



Statistical programmer ~~legacy~~ new life



Output: HTML QC report

[Report Summary on the log files created by call0hta0baselinechar](#)

Summary of Issues found in the log files in

Filepath				
Log File Name	Error	Warning	Other	User
call0hta0baselinechar.log	1	0	0	0

Detailed issues list within the log files in

Filepath			
Log File Name	Line Number	MSGTYPE	Log Message
call0hta0baselinechar.log	8	Error	ERROR: This is False

[Report Summary of QC Job Aid checks on the outputs created by call0hta0baselinechar](#)

Summary of Issues found in the outputs in

Filepath		
Output	Warning	Note
c0bschar	5	-

List of suggested actions to take on the outputs in

Filepath		
Output	Category	Problem
c0bschar	Warning	The main population subtitle of the output does not match the A&R Grid. Please update the subtitle.
	Warning	The superscript c is found in the body or head of the table and is not explained in the footnotes. Please check if a

section
on the log

additional section
on the output

summary



details



Real life examples: title

Summary of Patient Characteristics
(Intention-to-Treat Population)

	Study: DUMMY_DATA	
	Treatment 1 N=90	Treatment 2 N=92
Gender, n (%)		
Male	45 (50.0)	44 (47.8)
Female	45 (50.0)	48 (52.2)
Age (Years)		
Mean (SD)	78.6 (8.3)	70.1 (7.9)
Median (Q1; Q3)	76.5 (70.0; 84.0)	73.0 (87.5; 89.0)
Min; Max	44.0; 90.0	53.0; 91.0
Age Group , n (%)		
<65	10 (11.1)	12 (13.0)
>80	30 (33.3)	19 (20.7)
65-80	50 (55.5)	55 (59.8)
Discontinuation of Therapy, n (%)		
Yes	80 (88.9)	62 (67.4)
No	10 (11.1)	30 (32.6)
a: In AR Grid this footnote is not defined with a letter and a colon. The 'a:' has been added in call program b: In AR Grid this footnote is defined with the letter 'b' and a colon at the beginnig. FYI: better use single quotation marks than double quotation marks when defining footnotes in AR Grid c: This output is considered because in the filepath there is no word 'test1' nor 'test2'. This means population footnotes are not expected (but permissibile) and abbreviation footnote is not expected either. If you want to have abbreviaiton explanation in the footnote, you need to specify them as any other footnote. All footnotes must not with a dot. Ooooooooooops. Number of participants: all-participants-as-treated population		

Output	Category	Problem
c0bschar	Warning	The title of the output does not match the specification. Please update the title.
	Warning	The main population subtitle of the output does not match the specification. Please update the subtitle.
	Warning	The superscripts b,c are found in the footnotes of the table and are not found in the table. Please check if the footnotes should be removed, or if the superscripts should be added to the table.
	Warning	Footnotes are not aligned. Please align them so they all begin at the same position.
	Warning	The footnotes contain double blanks. Please remove them.
	Warning	No cutoff footnote found. Please add a cutoff footnote.

TLF Title	Request number	Footnotes	Output Filename	Reporting macro Name	Call program	Population
TITLES	REQNUM	FOOTNOTES	OUTPFILE	MACRO	CALLPGM	POPDESC
Baseline Characteristics	c0bschar	&footer_demo1 &footer_demo2 &footer_demo3	c0bschar	hta0baselinechar	call0hta0baselinechar	APAT

Note: the data used in this example are dummy data

Real life examples: subtitle

Summary of Patient Characteristics
(Intention-to-Treat Population)

	Study: DUMMY_DATA	
	Treatment 1 N=90	Treatment 2 N=92
Gender, n (%)		
Male	45 (50.0)	44 (47.8)
Female	45 (50.0)	48 (52.2)
Age (Years)		
Mean (SD)	78.6 (8.3)	70.1 (7.9)
Median (Q1; Q3)	76.5 (70.0; 84.0)	73.0 (87.5; 89.0)
Min; Max	44.0; 90.0	53.0; 91.0
Age Group , n (%)		
<65	10 (11.1)	12 (13.0)
>80	30 (33.3)	19 (20.7)
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Discontinuation of Therapy, n (%)		
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TLF Title	Request number	Footnotes	Output Filename	Reporting macro Name	Call program	Population
TITLES	REQNUM	FOOTNOTES	OUTPFILE	MACRO	CALLPGM	POPDESC
Baseline Characteristics	c0bschar	&footer_demo1 &footer_demo2 &footer_demo3	c0bschar	hta0baselinechar	call0hta0baselinechar	APAT

APAT

(All-Participants-as-Treated
Population)

Note: the data used in this example are dummy data

Real life examples: superscripts

Summary of Patient Characteristics
(Intention-to-Treat Population)

	Study: DUMMY_DATA	
	Treatment 1	Treatment 2
	N ^a =90	N ^a =92
Gender, n (%)		
Male	45 (50.0)	44 (47.8)
Female	45 (50.0)	48 (52.2)
Age (Years)		
Mean (SD)	78.6 (8.3)	70.1 (7.9)
Median (Q1; Q3)	76.5 (70.0; 84.0)	73.0 (81.5; 89.0)
Min; Max	44.0; 90.0	53.0; 91.0
Age Group, n (%)		
<65	10 (11.1)	12 (13.0)
>80	30 (33.3)	19 (20.7)
65-80	50 (55.5)	55 (59.8)
Discontinuation of Therapy, n (%)		
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	Warning	Footnotes are not aligned. Please align them so they all begin at the same position.
	Warning	The footnotes contain double blanks. Please remove them.
	Warning	No cutoff footnote found. Please add a cutoff footnote.

N^a=84

N^a=84

Note: the data used in this example are dummy data

Real life examples: footnotes

Summary of Patient Characteristics
(Intention-to-Treat Population)

	Study: DUMMY_DATA	
	Treatment 1 N=90	Treatment 2 N=92
Gender, n (%)		
Male	45 (50.0)	44 (47.8)
Female	45 (50.0)	48 (52.2)
Age (Years)		
Mean (SD)	78.6 (8.3)	70.1 (7.9)
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Min; Max	44.0; 90.0	53.0; 91.0
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Output	Category	Problem
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	Warning	The footnotes contain double blanks. Please remove them.
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• a: In
pro
• b: In
sing
• • c • T

Note: the data used in this example are dummy data

Highlights of automated checks

Checks on Datasets

1:1 match between PARAM/PARAMCD/PARAMN

Check if AVAL and CNSR values are as expected

And many
more...

Checks on TLF

Footnotes and all titles matching the specs, no double blanks, consistent casing, order as per standards

Footnotes (not) ending with full dot, aligned

Abbreviations: all explained in the footnotes without orphans, right order, consistent definitions

Superscripts: 1-1 match between output and footnotes

If number of all categories sums up to 100% in the treatment group

Limitations – on the road of full automation

Some checks cannot be automated yet

time tmie

Typos in text

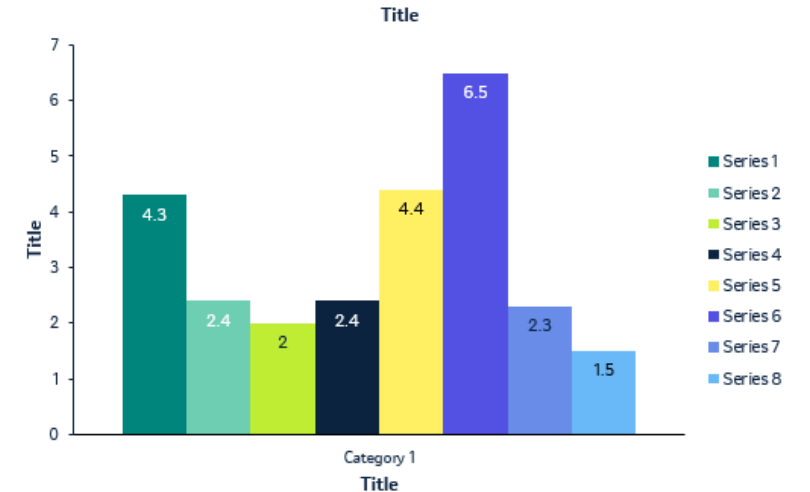
Kaplan – Meier plot of Overall

Survival

Kaplan – Meier plot of

Overall Survival

Wrapping text at
the best spot



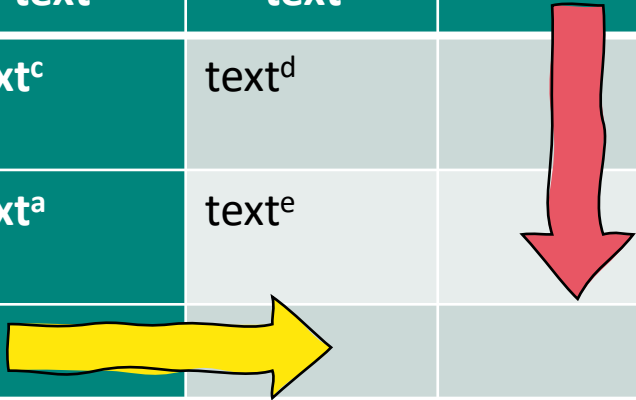
Content of .png (plots,
eg. axis labels)

Limitations – on the road of full automation

Some checks can only offer suggestions

Order of the
superscripts

text ^a	text ^b	
text ^c	text ^d	
text ^a	text ^e	



~70% of the checks from the
checklist were automated

Lessons learnt

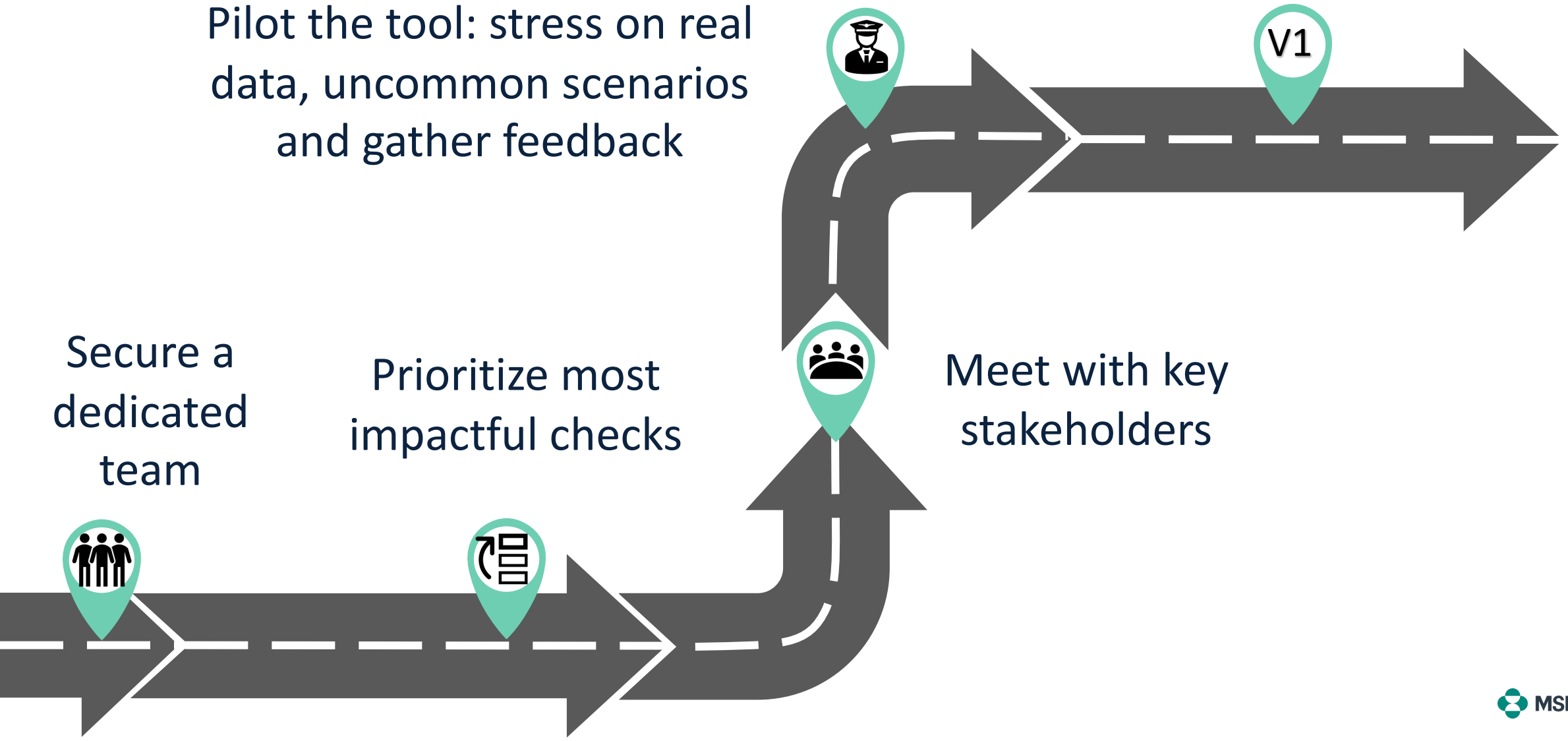
Release sooner and do not expect to have a first-time perfect tool

Pilot the tool: stress on real data, uncommon scenarios and gather feedback

Secure a dedicated team

Prioritize most impactful checks

Meet with key stakeholders

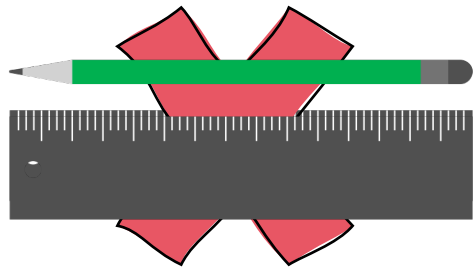


Conclusion



Quality

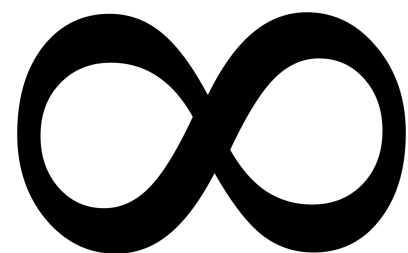
Review time



Standards

Communication time





Thank You!

MSD

E-mail: michal.lewandowski1@msd.com, elisa.natale@msd.com

Address: The Circle 66, 8058 Zürich, Switzerland

Back-up slides

Examples of automated checks

Checks on Datasets:

1-1 match between PARAM/PARAMCD/PARAMN

Check general values of AVAL and CNSR when present

Checks on TLF:

Name of output matching with the specs

Correct population and subpopulation used and mentioned in subtitles and footnotes

Use of special symbols (e.g. $\leq/\geq$) instead of $<=/>=$

Latest version of macros being used [I would not include this as very company-specific]

Examples of automated checks

Checks on titles/footnotes:

Footnotes (not) ending with full dot, aligned, presented only in the last page and not in every page

Footnotes and title with no double blanks

Footnotes and title matching with specs

If DCO footnote is present when mandatory, with correct value and format

Abbreviations: if all explained in the footnotes, in the right alphabetical order, with consistent definitions

Superscripts: if 1-1 match between output and footnotes

Casing of titles consistent across outputs

Order of titles and footnotes as per standards

And many more...