

How to clean up dirty data in Patient reported outcomes?

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Nele, living with lupus



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- Introduction
- Regulatory Aspects / Guidelines / Rules
- Approach
- Process Description
- Summary and Conclusions

Introduction

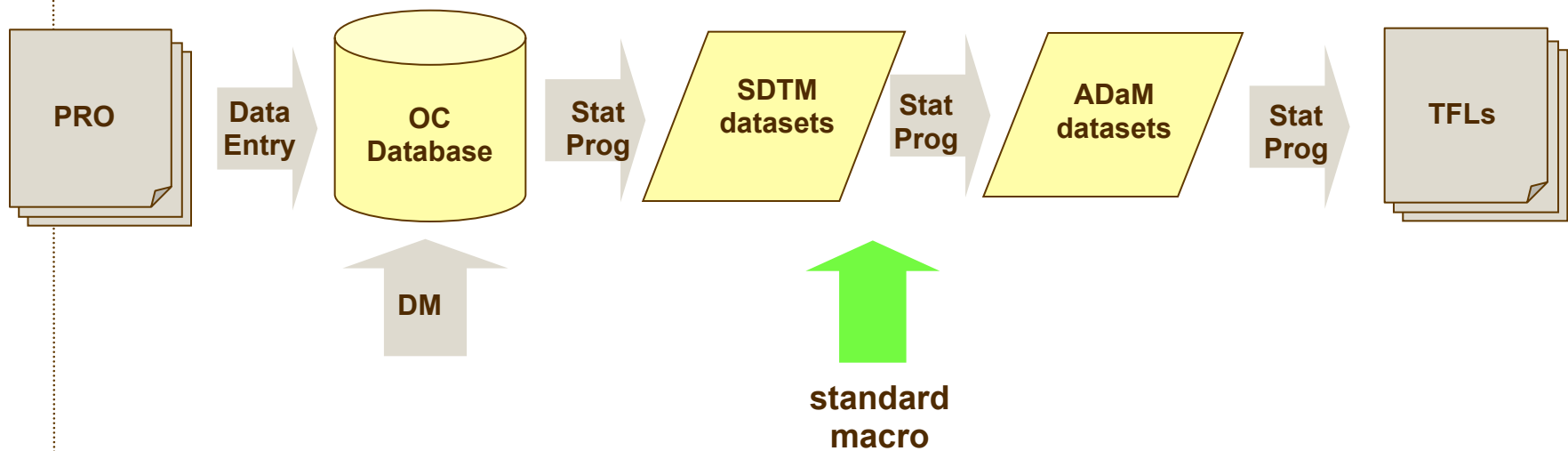
- Patient Reported Outcomes
- Unclean Data
- Traceability
- Keep valuable information

Guidelines and Rules

- FDA Guidance for Industry – Patient-Reported Outcome Measures
- Counting Rules set up by Health Outcomes department
- No on-site transcription of ambiguous data
- track and report original answers of the subject

Approach

5



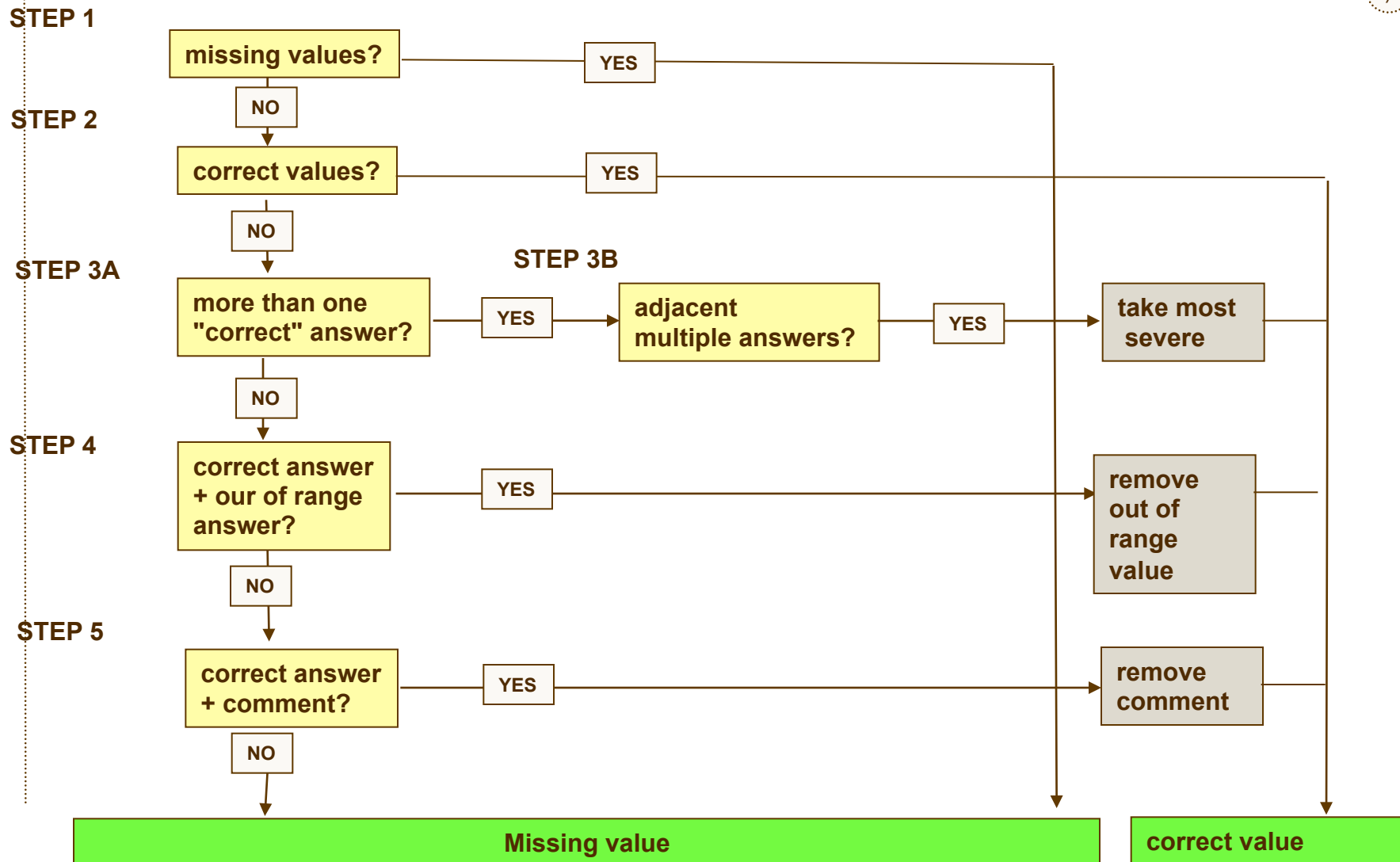
Approach

6

- Development of a validated Standard macro
- can be used similar to CALL routine
- number of paramters <6
 - Identification, invar, outvar, values, most severe value, tracking variable
- User friendliness

Process description - overview

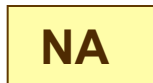
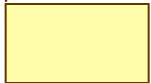
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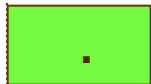
Process description – step 1

8

Missing value or missing code?



IF YES → missing value



IF NO → GO TO STEP 2

Process description – step 2

9

Correct value?

"2"

"3"

"1"

"4"

IF YES → take this value

2

3

1

4

IF NO → GO TO STEP 3A

Process description – step 3A

10

multiple answer, all answers inside the range, no more than maximum?

"2/3"

"3/5"

"1/2"

"1/4"

IF YES → GO TO STEP 3B

IF NO → GO TO STEP 4

Process description – step 3B

All values adjacent ?

"2/3"

"3/5"

"1/2"

"1/4"

IF YES → take the most severe value

2

1

IF NO → missing value

.

.

Process description – step 4

Correct value plus out of range answer?

"2/6"

"5/7"

"0/1"

"5/6"

IF YES → remove the out of range value

2

5

1

5

IF NO → GO TO STEP 5

Process description – step 5

13

Correct value plus comment?

"2?"

"5++"

"+/-1"

"3/4/5"

IF YES → remove the comment

2

5

1

IF NO → missing value

.

Caveats

- ⤵ All decisions have to be carefully tracked and checked
- ⤵ especially step 5 handles cases that aren't as closely defined than the others
- ⤵ unexpected cases

- What about e PROs?
- need to be validated
- technical equipment necessary
- probably the solution for the future

Conclusions

- Compliance with FDA Guidance
- use of validated standard macro saves programming time
- the CALL routine approach still provides a considerable amount of control over the process
- Necessity of close quality checks