

Laboratory Result conversion – and the Rounding Problem

17th German CDISC User Group Meeting 24-Sep-2013
Joachim Blume



PAREXEL[®]
Right where you need us[™]

Laboratory Result conversion – and the Rounding Problem

After conversion to standard units laboratory data shows more decimals than the original values.

Other data after conversion or calculation e.g.:

- **Weight and Height after conversion from US to SI units.**
- **Calculation of BMI.**

When should we round?

3 Options for Rounding

- **Rounding in SDTM data**
- **Rounding in ADaM data**
- **Rounding in TFL programs**

Laboratory Result conversion – and the Rounding Problem

Rounding in SDTM data

- + Consistent rounding from SDTM data to TFL**
- + SDTM data is more readable**
- Not possible to use different rounding in ADaM data or TFL**
- Not possible to use original values in analysis.**
- SDTM data has to be revised if rounding precision needs changes**
- Rounding precision has to be defined early in the study process**

Laboratory Result conversion – and the Rounding Problem

Rounding in ADaM data

- + Rounding precision can be changed during creation of ADaM and after SDTM finalization.**
- + Rounding is consistent within ADaM and TFL**
- Analysis on SDTM and ADaM may give different results**

Laboratory Result conversion – and the Rounding Problem

Rounding in TFL Programs

- + Possible to change rounding during TLF programming**
- + Precision could be changed without changes in SDTM and ADaM**
- + Possible to run analysis on not rounded data**
- Inconsistencies of rounding in tables, tests and listings possible**
- Inconsistencies in grouping, flagging of normal/abnormal or CTCAE grading possible**

Laboratory Result conversion – and the Rounding Problem

Inconsistencies

Normal ranges or NCI-CTCAE grades

CTCAE Hemoglobin: <4.9 – 4.0 mmol/L Grade 3; <4.0 mmol/L Grade 4

Original g/dL	Converted mmol/L	CTCAE Grading	Rounded mmol/L	CTCAE Grading
6.3	3.9098...	Grade 4	3.9	Grade 4
6.4	3.9719...	Grade 4	4.0	Grade 3
6.5	4.0340...	Grade 3	4.0	Grade 3

Statistical Test

Not rounded:

p-value = 0.0243 → Significant

Rounded:

p-value = 0.0251 → Not significant

Laboratory Result conversion – and the Rounding Problem

Discussion:

- Do you know guidelines for rounding?
- How do you handle rounding?

Laboratory Result conversion – and the Rounding Problem

Thank You

Laboratory Result conversion – and the Rounding Problem

Repeated rounding:

2.3448 \longrightarrow 2.34

2.3448 \rightarrow 2.345 \rightarrow **2.35**