



Author Guideline for Reporting Data Analysis and Statistical Methods in Pharmacology Reports

Dorothee Tamarelle

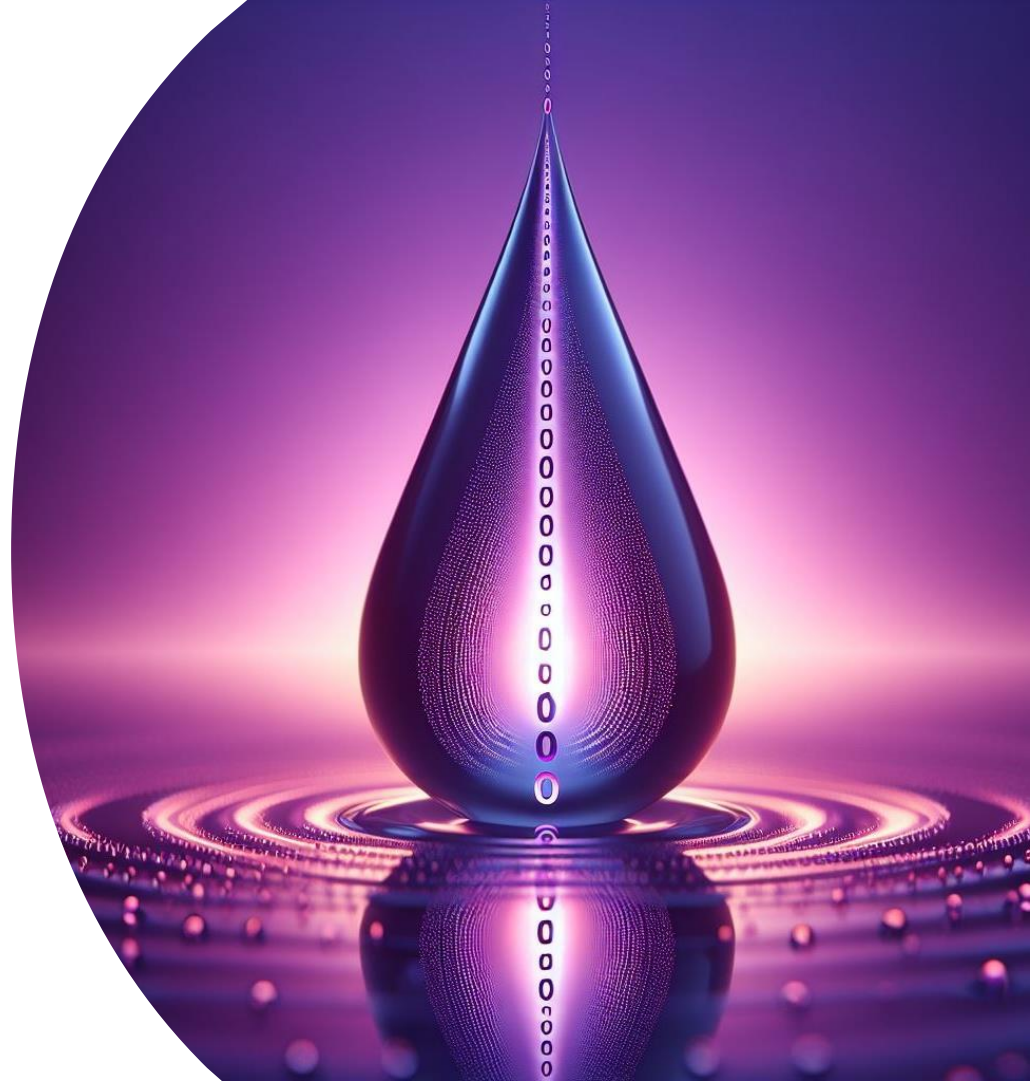
Non-Clinical Efficacy and Safety Biostatistics
Sanofi

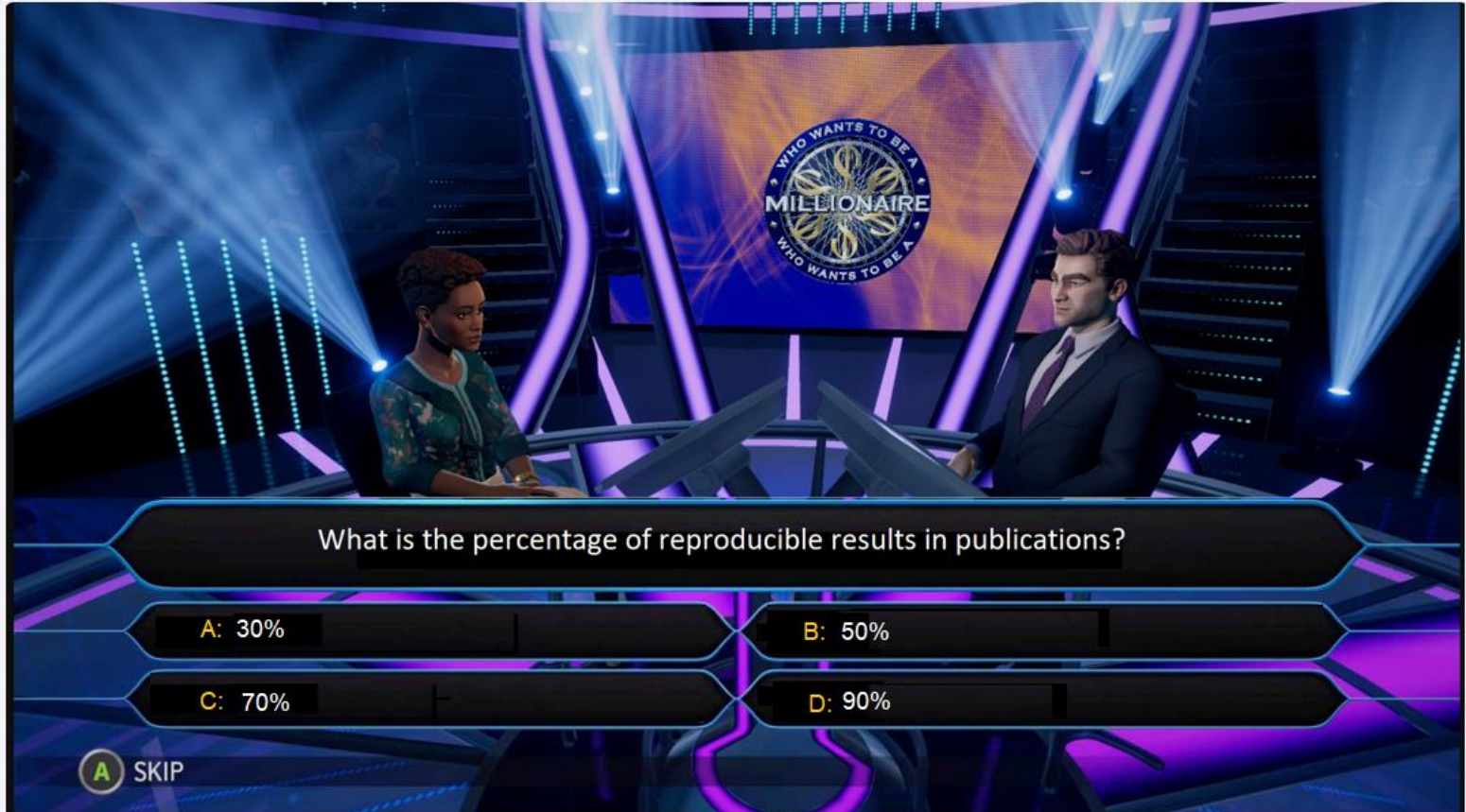


NCS

Non-Clinical
Statistics
Conference

Wiesbaden, DE / 25-27 September, 2024





What is the percentage of reproducible results in publications?

A: 30%

B: 50%

C: 70%

D: 90%

A SKIP



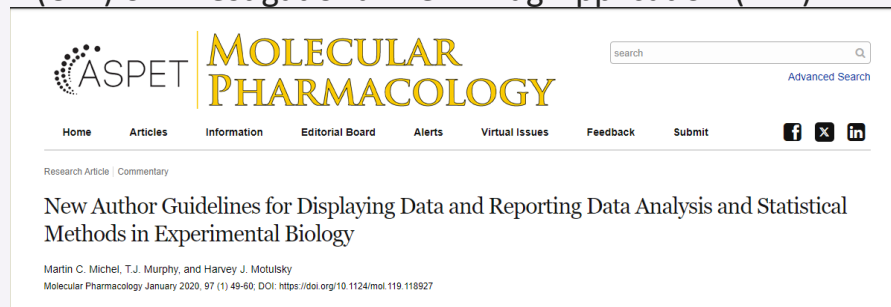
Context

Failures of reproducibility cannot be traced to a single cause, but one of the most significant is:

A lack of access to methodological details, raw data, and research materials.

For publications but also in the context of submission, it is important to ensure that the information is clear, exhaustive and succinct.

Based on existing published recommendations for reporting data analysis and statistical methods in experimental biology publications, a guidance has been released to assist authors and to facilitate the improved reporting in vivo and in vitro research results for Clinical Trial Authorisation (CTA) or Investigational New Drug Application (IND).



The Guidance

Table of contents	Tabulated summary	Study design	Data exclusion	Statistical methods	Presenting results	Tables & figures	Presentation of numbers	Individual data	References
Table of contents	Tabulated summary	Study design	Data exclusion	Statistical methods	Presenting results	Tables and Figures	Presentation of numbers	Individual data	References

QU-OPE-0540099 _ Version V1.0

For any question related to statistical analysis, interpretation and presentation of results, please do not hesitate to contact your non-clinical statistical support team.

QU-OPE-0540099 _ Version V1.0

Job Aid for Author for Reporting Data Analysis and Statistical Methods in SPRs

Author: Luc Esserméant

from QU-OPE-0532104

Authors should critically evaluate how the data are presented in the SPR to ensure that the information that is needed to support a certain conclusion is presented **as clearly and succinctly as possible**. Tables, figures and individual data should be generated with an equal amount of care and attention to detail; specific guidelines for their preparation are given below.

In this document, main recommendations come mainly from the ARRIVE guideline (1) and Mitchell, Murphy and Mubajeky (2).

References

1. Percie du Sert N, Hurst V, Ahluwalia A, Alam S, Avey MT, Baker M, Browne WJ, Clark A, Cuthill IC, Dirnagl U, Emerson M, Garner P, Holgate ST, Howells DW, Karp NA, Lazic SE, Lidster K, MacCallum CJ, Macleod M, Pearl EJ, Petersen O, Rawle F, Reynolds P, Rooney K, Sena ES, Silberberg SD, Steckler T and Wurbel H (2020). The ARRIVE guidelines 2.0: updated guidelines for reporting animal research. *PLoS Biol.* [doi: 10.1371/journal.pbio.3000410](https://doi.org/10.1371/journal.pbio.3000410)
2. Martin C. Michel, T.J. Murphy and Harvey J. Motulsky (2020). [Reporting Data Analysis and Statistical Methods](#), *Molecular Pharmacology*, 97 (1) 49-60; [DOI: https://doi.org/10.1124/mol.119.118927](https://doi.org/10.1124/mol.119.118927)

•
Thank you
•