The PREPARE and ARRIVE guidelines and EDA tool for planning and reporting animal experiments

Guideline No. 3

The Animal Welfare Body at Karolinska Institutet

Dnr 1-649/2024

Gäller fr.o.m. 2024-06-27

Karolinska Institutet

The PREPARE and ARRIVE guidelines and EDA tool for planning and reporting animal experiments

Innehåll

Diarienummer	Dnr föreg. version:	Beslutsdatum:	Giltighetstid:
Dnr 1-649/2024	1-1077/2017	Beslutsdatum	Tills vidare från beslutsdatum.

Beslut:	Dokumenttyp:
2024-06-27	Riktlinje från Djurskyddsorganet
Handläggs av avdelning/enhet: Djurskyddsorganet vid KI	Beredning med: Elisabet Andersson (NACWO), Velmurugesan Arulampalam (expert advisor), djurskyddsorgan

Revidering med avseende på:
Förtydligande av titel, länkar, dokumentutformning, text samt bilder

Introduction

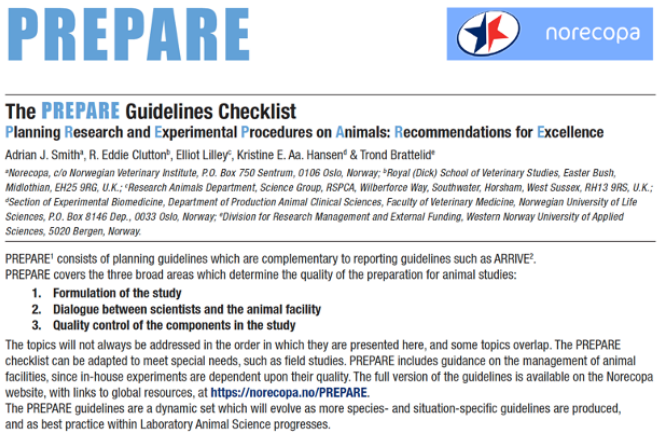
The reproducibility crisis, especially for experiments carried out in research animals requires that everybody involved implements measures to ensure highest standards for planning of animal experiments, when conducting animal experiments and when analysing the data that originates from animal experiments. Therefore, the Animal welfare body at Karolinska Institutet (KI) strongly recommends that the guidelines ARRIVE and PREPARE from NORECOPA and NC3R respectively, are used for experimental planning and reporting of data where research animals have been used. The Animal welfare body also recommends that the EDA tool (Experimental Design Assistant) from NC3R is used as assistant for experimental design of studies using research animals.

The three tools can be used separately but preferably together.

The PREPARE Guideline

"PREPARE" stands for Planning Research and Experimental Procedure on Animals: Recommendation for Excellence

The PREPARE guideline facilitates experimental planning with focus on both creating significant and reproducible scientific data and at the same time implementing the 3Rs – to Reduce the number of research animals, to Replace research animals where scientifically possible, and to Refine animal experiments.



PREPARE

norecopa

The PREPARE Guidelines Checklist

Planning Research and Experimental Procedures on Animals: Recommendations for Excellence

Adrian J. Smith[a], R. Eddie Clutton[b], Elliot Lilley[c], Kristine E. Aa. Hansen[d] & Trond Brattelid[a]

[a]Norecopa, c/o Norwegian Veterinary Institute, P.O. Box 750 Sentrum, 0106 Oslo, Norway; [b]Royal (Dick) School of Veterinary Studies, Easter Bush, Midlothian, EH25 9RG, U.K.; [c]Research Animals Department, Science Group, RSPCA, Wilberforce Way, Southwater, Horsham, West Sussex, RH13 9RS, U.K.; [d]Section of Experimental Biomedicine, Department of Production Animal Clinical Sciences, Faculty of Veterinary Medicine, Norwegian University of Life Sciences, P.O. Box 8146 Dep., 0033 Oslo, Norway; [e]Division for Research Management and External Funding, Western Norway University of Applied Sciences, 5020 Bergen, Norway.

PREPARE[1] consists of planning guidelines which are complementary to reporting guidelines such as ARRIVE[2].
PREPARE covers the three broad areas which determine the quality of the preparation for animal studies:

1. **Formulation of the study**
2. **Dialogue between scientists and the animal facility**
3. **Quality control of the components in the study**

The topics will not always be addressed in the order in which they are presented here, and some topics overlap. The PREPARE checklist can be adapted to meet special needs, such as field studies. PREPARE includes guidance on the management of animal facilities, since in-house experiments are dependent upon their quality. The full version of the guidelines is available on the Norecopa website, with links to global resources, at **https://norecopa.no/PREPARE**.
The PREPARE guidelines are a dynamic set which will evolve as more species- and situation-specific guidelines are produced, and as best practice within Laboratory Animal Science progresses.

The PREPARE guideline was developed by Norecopa together with a group of experts from Norway and UK.
Importantly, the PREPARE guideline covers many factors that can dramatically influence the validity and outcome of an animal study but are not always included in the scientific reports.

The PREPARE guideline focuses on three broad areas:

- Formulation of the study.
- Dialogue between the scientists and the animal facility.
- Quality controls of the components in the study.

The PREPARE guideline includes a two-page checklist summarising the 15 topics covered by the guideline. More information about each topic can be found on the PREPARE webpage here.

The PREPARE guideline has been translated in many languages, is continuously updated, and can be adapted to different species and animal models.
The latest version of the PREPARE guideline you can find here.

The PREPARE guideline for planning animal experiments is a complement to the guideline for reporting animal experiments – the ARRIVE guideline. Both types of guidelines should be used to ensure that animal experiments are performed to the highest standards, with flawless reproducibility and adhering to the 3R principles.

The ARRIVE Guideline

"ARRIVE" stands for *A*nimal *R*esearch: *R*eporting of *I*n *V*ivo *E*xperiments

The ARRIVE guideline were developed in consultation with the scientific community as a part of an NC3R´s initiative to improve the standard of reporting research using laboratory animals, and was originally published in PLoS Biology.

The ARRIVE guideline focuses on the following areas:

- Advice on planning animal experiments Including experimental design, strategies for minimising experimental bias, calculation of a suitable sample size, and statistical analysis.
- Documentation of information during an animal experiment that will be required when preparing a manuscript.
- Relevant information which must be included in a manuscript to ensure proper reporting of experimental design and data acquired.
- When reviewing a manuscript to ensure that all relevant information is available to evaluate the research.

ARRIVE guideline is organised into two prioritised sets:

- "ARRIVE Essential 10" which are the basic minimum that must be included in any manuscript where animals are used.
- A recommended set that complements the "ARRIVE Essential 10" for more detailed reporting.

In addition to ARRIVE, there may be journal or research area specific guidelines for reporting in vivo data that can aid identifying important specific information to collect.

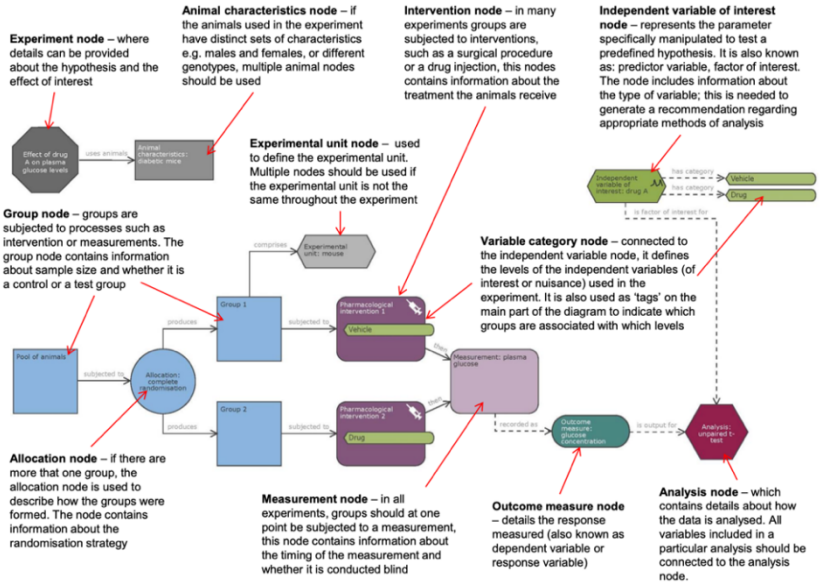
For example: Reporting Standards for Preclinical Studies of Stroke: https://www.ahajournals.org/doi/10.1161/strokeaha.116.013643

The EDA tool

"EDA" stands for *E*xperimental *D*esign *A*ssistant

The EDA tool was developed by NC3R together with experts in *in vivo* research, statisticians and software designers.

The EDA tool is a free online application for experimental planning designed for scientists performing animal research. The EDA tool complements PREPARE and ARRIVE guidelines.



The EDA tool focuses on the following areas:

- Provide advice and feedback on experimental design of animal experiments.
- Recommends statistical analysis methods.
- Provides support for randomisation and blinding.
- Provides support for sample size calculations.

The EDA tool can be found here.

References

1. Kilkenny C. et. al. (2010) Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. PLoS Biol 8(6): e1000412. https://doi.org/10.1371/journal.pbio.1000412
2. Percie du Sert N. et. al. (2017) The Experimental Design Assistant. *Nature Methods* Epub Sept 29, 2017. doi:10.1038/nmeth.4462 (Full paper via ReadCube)
3. Percie du Sert N. et. al. (2017) The Experimental Design Assistant. *PLoS Biology* 15:e2003779. doi:10.1371/journal.pbio.2003779
4. Pierce du Sert, N. et. al. (2020) Reporting animal research: Explanation and elaboration for the ARRIVE guidelines 2.0 PLoS Biol. 18(7): e3000411. https://doi.org/10.1371/journal.pbio.3000411.
5. *Smith, AJ, et. al. (2018) PREPARE: Guidelines for planning animal research and testing. Laboratory Animals, 52(2): 135-141. DOI: 10.1177/0023677217724823*