Reduction og replacement: Hva skjer innen alternativer til dyreforsøk?

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norecopa.no/KPM

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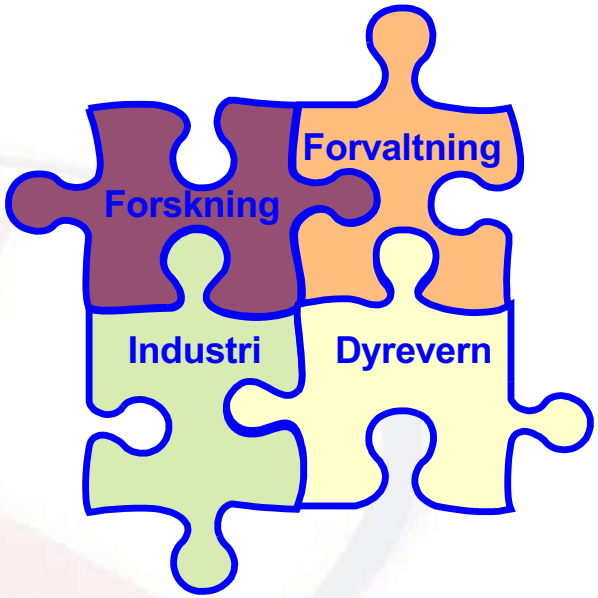
https://frame.beaconforms.com/form/5dea91b6

Program:
https://frame.org.uk/app/uploads/2023/10/3Rs-and-Ethics-by-Design-Training-Programme-DRAFT-Online-V2.pdf

European Consensus-Platform for Alternatives

ecopa.eu

- Etablert i 2000
- Anerkjenner nasjonale konsensusplattformer med 4 interesseparter i sitt styre:



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7-8 detaljerte nyhetsbrev i året

Norecopa: PREPARE for better Science

norecopa.no / Meetings / Meetings Calendar

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Webinar and Meetings calendar

- Gentle Mouse Handling workshop, Zurich, 20 October 2023
- 74th AALAS National Meeting, Salt Lake City, 22-26 October 2023
- ASCCT 12th Annual Meeting - Spotlight on NAMs: Elevating New Approaches in Risk Assessment, Silver Spring, 23-25 October 2023
- Behavioral testing: a good practice guide, webinar, 25 October 2023
- To care for those who care - what does that need?, webinar (Sonja Rumpel), registration, 26 October 2023
- Cooperative care training in laboratory animals, webinar (Mirjam Roth), registration, 26 October 2023
- Altertox and CEHTRA: Integrating NAMS into Next Generation Risk Assessment, Brussels, 26-27 October 2023
- AI Use for Regulatory Application: using machine learning to reduce animal use in toxicology, webinar, 27 October 2023
- Selection and Use of Personal Protective Equipment (PPE), ABSA webinar, 27 October 2023
- Leveraging Knowledge of Research Animal Behavior to Enhance Welfare, webinar (Kathryn Bayne), 27 October 2023
- The Animal Free Research UK Animal Free Antibody Database, webinar (Stephanie Modi), 30 October 2023
- 30th RSPCA/UFAW/IAT Rodent Welfare Group Meeting, London, 31 October 2023
- Applying the 3Rs to urinalysis assessments in toxicity studies: refining procedures and adopting a case-by-case approach, London, 31 October 2023

November 2023

- Puzzles for mice - investigating intelligence and improving well-being, webinar (Katharina Hohlbaum), registration, 2 November 2023
- Different strategies on the way to in-vitro bone modelling, webinar (Moritz Pfeiffenberger), registration, 2 November 2023
- Danish 3R-Center's Annual Symposium, Copenhagen, 6-7 November 2023
- Fin3R Annual Symposium: Improving the quality and translatability of biomedical research through the 3R principle, Helsinki/online, 6-7 November 2023
- GA Rodent Colony Management, London, 6-7 November 2023
- CBMAlt 2023, Rio de Janeiro, 6-9 November 2023
- International Forum on Cell Manufacturing & Engineering, Berlin, 7-8 November 2023
- Launch of the Norwegian Forum for Animal Law, Oslo, 8 November 2023
- Improving Openness in Animal Research in Denmark, Copenhagen, 8 November 2023
- The COLAAB: The Author Guide for Addressing Animal Methods Bias in Publishing, webinar, 8 November 2023
- The new OECD (Q)SAR Assessment Framework: guidance for assessing (Q)SAR models and predictions, webinar, 9 November 2023
- Veterinary Skills Net - simulation-based education in Berlin, webinar (Samira Schlesninger), registration, 9 November 2023
- Assessment and refinement of the wellbeing of mice during metabolic cage housing, webinar (Philipp Villiger), registration, 9 November 2023
- Altertox and EPITHELIX: Lung *in vitro* models, Geneva, 9-10 November 2023
- Systematic review and meta-analysis of animal studies, workshop, 10 November 2023
- Designing a good score sheet for animal welfare assessment, webinar (Philippe Bugnon), 10 November 2023
- 18th Transgenic Technology Meeting, Houston, 12-15 November 2023
- Practical course in zebrafish husbandry and procedures, Stockholm, 13-15 November 2023
- EPAA annual conference, Brussels, 15 November 2023
- Biomimetic robots - a new way to fulfil the 3Rs requirements, webinar (David Bierbach), registration, 16 November 2023
- Brain organoids to model human brain diseases, webinar (Agnieszka Rybak-Wolf), registration, 16 November 2023
- RSPCA Focus on Severe Suffering: Humane Endpoints in Regulatory Toxicology, Surrey, 16 November 2023
- Importance of systematic assessment of scientific validity in *in vivo* study design, webinar, 16 November 2023
- Networking meeting for Nordic zebrafish managers, Stockholm/online, 16-17 November 2023
- Practical approaches and challenges for microbiological monitoring of rodents and zebrafish, Milan, 16-17 November 2023
- Mice learning in social interaction and consequences for welfare and data quality, webinar (Benjamin Lang), 17 November 2023
- Online media training for veterinarians, EARA webinar, 20 November 2023
- 6th Annual SAAE-India Conference: Alternatives to Higher Animals in Biological Research, Aligarh/online, 20-21 November 2023
- Oxford / Berlin Autumn School on Open and Responsible Research, Oxford, 20-24 November 2023
- LASA Annual Meeting, 21-23 November 2023
- QASH2 *(Quantitative Atlantic Salmon Health assessment)*: Towards an international standard for health of salmon, program to be announced, Bergen, 22 November 2023
- EALAS-2023 (European Academy of Laboratory Animal Surgery), congress and wetlabs, Rome, 22-24 November 2023
- Forsøksdyrkomitéens seminar med dyrevelferdsenhetene, Oslo, 23 November 2023
- Göttingen Minipigs Academy: Christmas seminar, Copenhagen, 23 November 2023
- Gastrointestinal assembloids, webinar (Michael Sigal), registration, 23 November 2023
- New approaches to tackle inflammatory and genetic diseases of human epithelia, webinar (Sarah Hedtrich), registration, 23 November 2023
- Pain Recognition and Analgesia in Zebrafish, webinar (Lynne Sneddon), 27 November 2023
- Rodent Surgery Course (3 or 5 days), Almere, 27 November - 1 December 2023
- Assessment, Prevention and Alleviation of Pain in Laboratory Animals workshop, online, 27-30 November 2023
- SGV Annual Meeting, Zurich, 28-29 November 2023
- Lab Animal Publication School, online course, 28-30 November 2023
- CLAST course on Researching data and using information, start 30 November 2023
- Brain organoids for the discovery of novel mechanisms and targets in stroke and neurodegeneration, webinar (Philipp Mergenthaler), registration, 30 November 2023
- 6R: Robustness, Registration and Reporting aspects in 3R *in vitro* research, webinar (Maren Hülsemann), registration, 30 November 2023

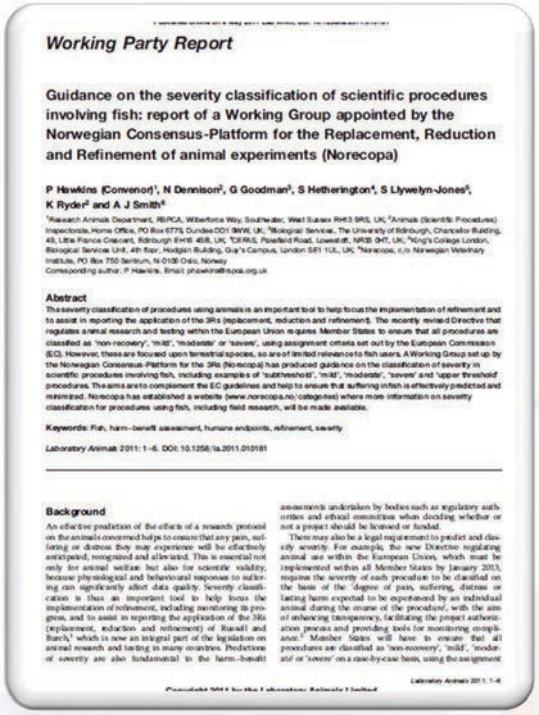
Samling av innspilte webinarer, sortert etter emnene i PREPARE

1. Literature searches
2. Legal issues
3. Ethical issues, harm-benefit assessment and humane endpoints
4. Experimental design and statistical analysis
5. Objectives and timescale, funding and division of labour
6. Facility evaluation
7. Education and training
8. Health risks, waste disposal and decontamination
9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
    - *Terrestrial animals*
    - *Aquatic animals*
13. Experimental procedures
    - *Terrestrial animals*
    - *Aquatic animals*
    - *Anaesthesia and analgesia*
14. Humane killing, release, reuse or rehoming
15. Necropsy

https://norecopa.no/meetings/recorded-webinars/webinars-prepare

3R-Guide (over 400 retningslinjer for dyreforsøk)

norecopa.no/3r-guide



Working Party Report

Guidance on the severity classification of scientific procedures involving fish: report of a Working Group appointed by the Norwegian Consensus-Platform for the Replacement, Reduction and Refinement of animal experiments (Norecopa)

P Hawkins (Convenor)[1], N Dennison[2], G Goodman[3], S Hetherington[4], S Llywelyn-Jones[5], K Ryder[2] and A J Smith[6]

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Abstract

The severity classification of procedures using animals is an important tool to help focus the implementation of refinement and to assist in reporting the application of the 3Rs (replacement, reduction and refinement). The recently revised Directive that regulates animal research and testing within the European Union requires Member States to ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe', using assignment criteria set out by the European Commission (EC). However, these are focused upon terrestrial species, so are of limited relevance to fish users. A Working Group set up by the Norwegian Consensus-Platform for the 3Rs (Norecopa) has produced guidance on the classification of severity in scientific procedures involving fish, including examples of 'subthreshold', 'mild', 'moderate', 'severe' and 'upper threshold' procedures. The aim is to complement the EC guidelines and help to ensure that suffering in fish is effectively predicted and minimized. Norecopa has established a website (www.norecopa.no/categorise) where more information on severity classification for procedures using fish, including field research, will be made available.

Keywords: Fish, harm–benefit assessment, humane endpoints, refinement, severity

Laboratory Animals 2011; 1–6. DOI: 10.1258/la.2011.010181

Background

An effective prediction of the effects of a research protocol on the animals concerned helps to ensure that any pain, suffering or distress they may experience will be effectively anticipated, recognized and alleviated. This is essential not only for animal welfare but also for scientific validity, because physiological and behavioural responses to suffering can significantly affect data quality. Severity classification is thus an important tool to help focus the implementation of refinement, including monitoring its progress, and to assist in reporting the application of the 3Rs (replacement, reduction and refinement) of Russell and Burch,[1] which is now an integral part of the legislation on animal research and testing in many countries. Predictions of severity are also fundamental to the harm–benefit assessments undertaken by bodies such as regulatory authorities and ethical committees when deciding whether or not a project should be licensed or funded.

There may also be a legal requirement to predict and classify severity. For example, the new Directive regulating animal use within the European Union, which must be implemented within all Member States by January 2013, requires the severity of each procedure to be classified on the basis of the 'degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure', with the aim of enhancing transparency, facilitating the project authorization process and providing tools for monitoring compliance.[2] Member States will have to ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe' on a case-by-case basis, using the assignment

AVMA Guidelines for the Euthanasia of Animals: 2020 Edition*

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*The AVMA Panel on Euthanasia develops the content of the guidelines, with support from its working groups. The panel is required to do a comprehensive review and update of the report at least every 10 years, although more frequent major revisions are possible based on substantive information gleaned from new research and experience with practical implementation. To ensure the guidelines remain as up-to-date as possible, interim revisions (reaffirmed, substantive updates, but of a less extensive nature than a major revision) are also recommended

A Gold Standard Publication Checklist to Improve the Quality of Animal Studies, to Fully Integrate the Three Rs, and to Make Systematic Reviews More Feasible

Carlijn R. Hooijmans, Marlies Leenaars and Merel Ritskes-Hoitinga

Radboud University Nijmegen Medical Centre, Central Animal Laboratory and 3R Research Centre, Nijmegen, The Netherlands

Summary — Systematic reviews are generally regarded by professionals in the field of evidence-based medicine as the highest level of medical evidence, and they are already standard practice for clinical studies. However, they are not yet widely used nor undertaken in the field of animal experimentation, even though there is a lot to be gained from the process. Therefore, a gold standard publication checklist (GSPC) for animal studies is presented in this paper. The items on the checklist have been selected on the basis of a literature analysis and the resulting scientific evidence that these factors are decisive in determining the outcome of animal studies. In order to make future systematic reviews and meta-analyses of animal studies possible, to allow others to replicate and build on work previously published, diminish the number of animals needed in animal experimentation (reduction), improve animal welfare (refinement) and, above all, improve the quality of scientific papers on animal experimentation, this publication checklist needs to be used and followed. We have discussed and optimised this GSPC through feedback from interviews with experts in the field of animal experimentation. From these interviews, it became clear that scientists will adopt this GSPC when journals demand it. The GSPC was compared with the current instructions for authors from nine different journals, selected on the basis that they featured a high number of publications on animal studies. In general, the journals' demands for the description of the animal studies are so limited that it is not possible to repeat the studies, let alone carry out a systematic review. By using the GSPC for animal studies, the quality of scientific papers will be improved. The use of the GSPC and the concomitant improvement in the quality of scientific papers will also contribute to decreased variation and increased standardisation and, as a consequence, a reduction in the numbers of animals used and a more reliable outcome of animal studies. It is of major importance that journal editors become convinced of and adopt these recommendations, because only then will scientists follow these guidelines to the full extent.

Key words: *animal experimentation, meta-analysis, publication checklist, scientific quality, systematic review*

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Introduction

A systematic review (SR) is a literature review focused on a single question which tries to identify, appraise, select and synthesise all available high-quality research evidence relevant to that question (1). SRs are generally regarded by evidence-based medicine professionals as the highest level of medical evidence, and they are already standard practice in clinical studies. However, SRs are not yet widely used nor undertaken in the animal experimentation field, although there would be a lot to be gained from the process. A systematic approach to incorporate all available relevant literature into the design of an animal experiment is a prerequisite for research which is of high scientific quality. Good science, from a scientific as well as an animal welfare point of view, is the basis of the book, *The Principles of Humane Experimental Technique*, by Russell and Burch (2). In this book, they recommend that the Three Rs principles (*Refinement, Reduction* and *Replacement*) should be applied whenever possible in animal studies. Besides producing high-quality research, SRs of animal experiments will result in direct implementation of the Three Rs. SRs may provide the proper argumentation to decide which animal model will give the best answer to the (clinical) research question (3, 4) and to detect whether there are gaps in scientific knowledge that require new animal experiments (*replacement and refinement*). This will also aid in preventing unnecessary duplication of animal experiments (*reduction*), and thus discourage unnecessary animal use and time loss. A SR of animal studies will also lead to a better interpretation of the already existing scientific results from animal experiments, through which a better

Tim Allen, USDA

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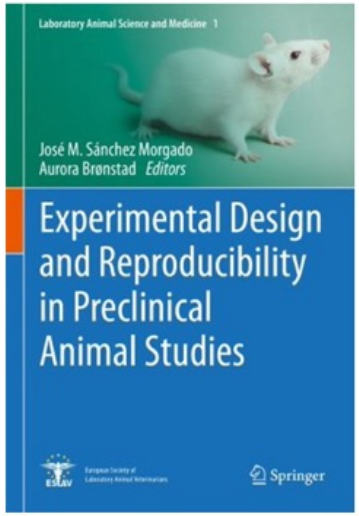
Experimental Design and Reproducibility in Preclinical Animal Studies

By José M. Sánchez Morgado & Aurora Brønstad (Eds.)

Record number: 8619d

This book provides grounds on how to plan and conduct animal experiments that can be reproduced by others. It touches on factors that may impact the reproducibility of animal studies including: the animal genetic background, the animal microbial flora, environmental and physiological variables affecting the animal, animal welfare, statistics and experimental design, systematic reviews of animal studies, and the publishing process.

The book addresses advanced undergraduates, graduate students and all scientists working with animals.



norecopa.no/textbase/experimental-design-and-reproducibility-in-preclinical-animal-studies

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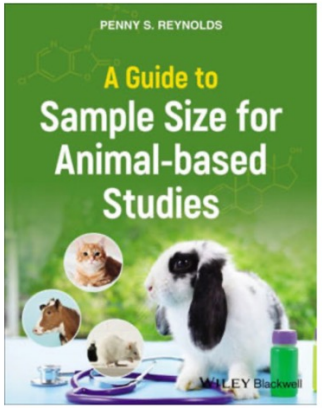
A Guide to Sample Size for Animal-based Studies

By Penny S. Reynolds

Record number: 9c417



Animal-based research poses a unique set of experimental design challenges. The most important of these are the 3Rs - Replacement, Reduction and Refinement - the principles comprising the ethical framework for humane animal-based studies. However, many researchers have difficulty navigating the design trade-offs necessary to simultaneously minimise animal use, and produce scientific information that is both rigorous and reliable.

A Guide to Sample Size for Animal-based Studies meets this need with a thorough, accessible reference work to the subject. This book provides a straightforward systematic approach to "rightsizing" animal-based experiments, with sample size estimates based on the fundamentals of statistical thinking: structured research questions, variation control and appropriate design of experiments. The result is a much-needed guide to planning animal-based experiments to ensure scientifically valid and reliable results.

Webinar: https://www.youtube.com/watch?v=fFHC9glL8hc

norecopa.no/education-training/films-and-slide-shows

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Rat i.p. injection (method 2)
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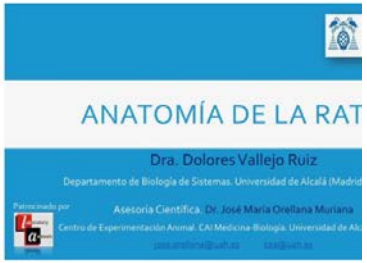

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Databases & Guidelines

- 3R Guide: a global overview of **databases, guidelines, information centres, journals, email lists, regulations and policies** which may be of use when planning experiments which might include animals. A quick overview of all the guidelines can be accessed here. Norecopa has written several of these, including the PREPARE guidelines for planning animal research and testing.
- NORINA: a global overview of audiovisual aids and other items which may be used as **alternatives or supplements to animals in education and training** at all levels from junior school to University, including dissection alternatives and surgical simulators.
- TextBase: a global overview of **textbooks and other literature within laboratory animal science** and related topics.
- Classic AVs: a subset of NORINA covering **audiovisual aids that are based on older technology**.

These databases are updated regularly. Please give us feedback if you discover errors or omissions.

The Norecopa website also includes five other collections:

- NAL: a collection of literature references relating to the 3Rs from the US National Agricultural Library
- European Commission datasets:
  - 3Rs Knowledge Sources: over 800 resources collected by the Commission in 2016
  - 3Rs Education and Training Resources, over 560 items collected in 2018
  - Non-animal models for respiratory tract diseases, over 280 models identified in a literature review of over 21,000 papers, published in 2020
  - Non-animal models for cardiovascular diseases, citing over 400 models, identified in a literature review of over 14,000 papers, published in 2022

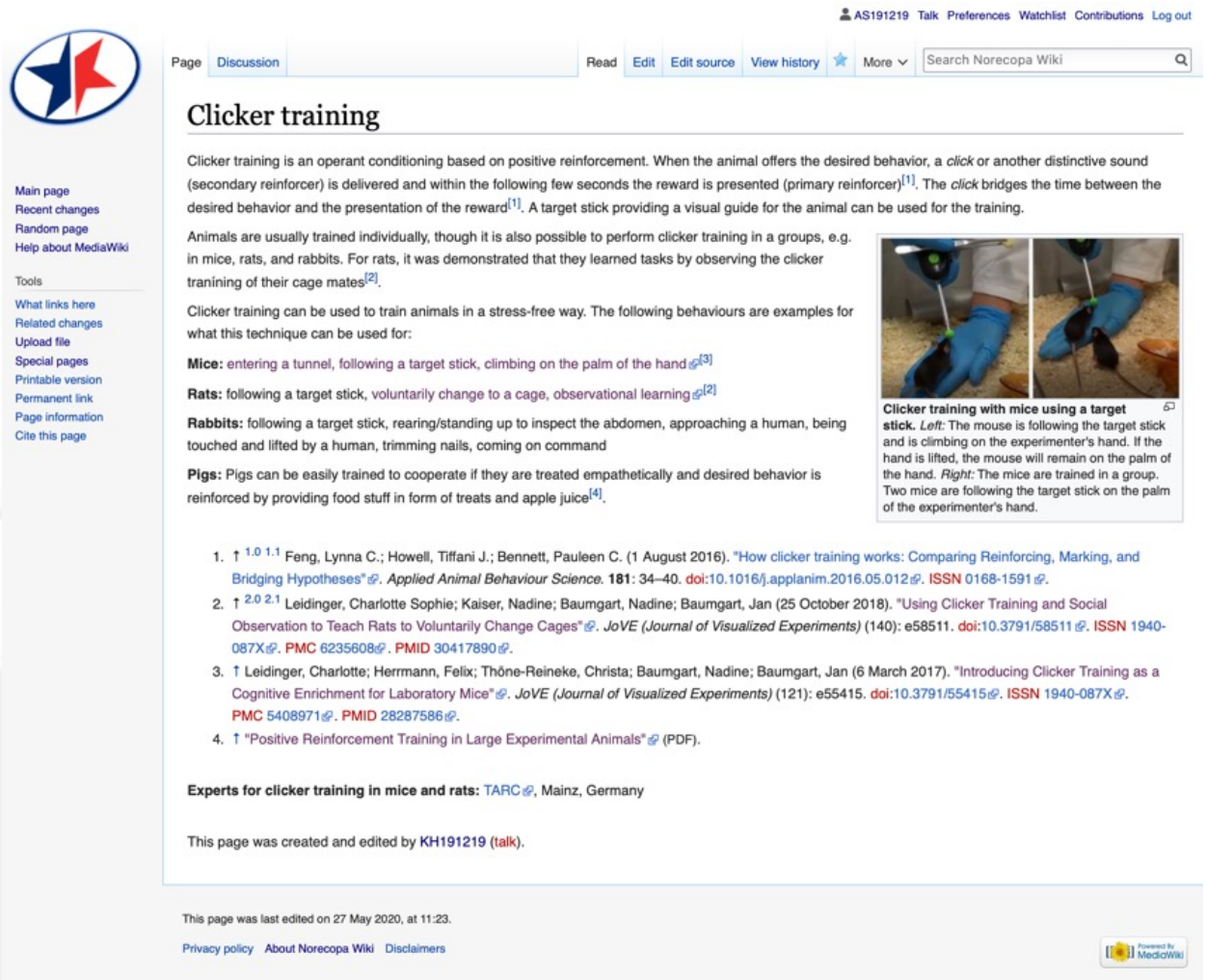
The EU Commission has now published 30 datasets of this type.

Here is an alphabetical global list of all the databases cited on the Norecopa website.

norecopa.no/databases-guidelines

lenker til over 70 eksterne databaser

Refinement Wiki: wiki.norecopa.no



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Clicker training

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Clicker training is an operant conditioning based on positive reinforcement. When the animal offers the desired behavior, a *click* or another distinctive sound (secondary reinforcer) is delivered and within the following few seconds the reward is presented (primary reinforcer)[1]. The *click* bridges the time between the desired behavior and the presentation of the reward[1]. A target stick providing a visual guide for the animal can be used for the training.

Animals are usually trained individually, though it is also possible to perform clicker training in a groups, e.g. in mice, rats, and rabbits. For rats, it was demonstrated that they learned tasks by observing the clicker tranining of their cage mates[2].

Clicker training can be used to train animals in a stress-free way. The following behaviours are examples for what this technique can be used for:

Mice: entering a tunnel, following a target stick, climbing on the palm of the hand[3]

Rats: following a target stick, voluntarily change to a cage, observational learning[2]

Rabbits: following a target stick, rearing/standing up to inspect the abdomen, approaching a human, being touched and lifted by a human, trimming nails, coming on command

Pigs: Pigs can be easily trained to cooperate if they are treated empathetically and desired behavior is reinforced by providing food stuff in form of treats and apple juice[4].

Clicker training with mice using a target stick. *Left:* The mouse is following the target stick and is climbing on the experimenter's hand. If the hand is lifted, the mouse will remain on the palm of the hand. *Right:* The mice are trained in a group. Two mice are following the target stick on the palm of the experimenter's hand.

1. ↑ 1.0 1.1 Feng, Lynna C.; Howell, Tiffani J.; Bennett, Pauleen C. (1 August 2016). "How clicker training works: Comparing Reinforcing, Marking, and Bridging Hypotheses". *Applied Animal Behaviour Science*. **181**: 34–40. doi:10.1016/j.applanim.2016.05.012. ISSN 0168-1591.
2. ↑ 2.0 2.1 Leidinger, Charlotte Sophie; Kaiser, Nadine; Baumgart, Nadine; Baumgart, Jan (25 October 2018). "Using Clicker Training and Social Observation to Teach Rats to Voluntarily Change Cages". *JoVE (Journal of Visualized Experiments)* (140): e58511. doi:10.3791/58511. ISSN 1940-087X. PMC 6235608. PMID 30417890.
3. ↑ Leidinger, Charlotte; Herrmann, Felix; Thöne-Reineke, Christa; Baumgart, Nadine; Baumgart, Jan (6 March 2017). "Introducing Clicker Training as a Cognitive Enrichment for Laboratory Mice". *JoVE (Journal of Visualized Experiments)* (121): e55415. doi:10.3791/55415. ISSN 1940-087X. PMC 5408971. PMID 28287586.
4. ↑ "Positive Reinforcement Training in Large Experimental Animals" (PDF).

Experts for clicker training in mice and rats: TARC, Mainz, Germany

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This page was last edited on 27 May 2020, at 11:23.

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- Acclimatisation
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- Alphaxalone
- Anaesthesia in neonates
- Analgesia
- Asepsis
- Blood sampling of hamsters
- Blood sampling of pigs
- Blood sampling of rainbow trout
- Breeding strategies for mice
- Clicker training
- Contingency plans
- Decapitation
- Detecting early onset of clinical signs in the mouse model of Covid-19
- Detection of pain and distress in mice
- EMLA cream
- Embryo transfer
- Experimental Autoimmune Encephalomyeltis (EAE)
- Facial expression analysis
- Food crunchers
- General discusson on use of analgesics
- Genotyping mice
- Habituation training
- High-fat diets
- Hot Bead Sterilisers
- Housing nude mice
- Housing research fish
- Humane endpoints
- Hydrodynamic gene delivery
- Intra-ocular injections
- Intranasal administration
- Intraperitoneal injection
- Intraperitoneal pentobarbitone
- Ketamine and alpha-2 agonist combinations
- Long-term anaesthesia in rodents
- Lumpfish
- Main Page
- Marble Burying Test
- Metabolic cages
- Minipumps
- Montanide adjuvant
- Mouse Grimace Scale
- Mouse handling
- Nest building material
- Oestrus suppression in ferrets
- Pneumocystis murina
- Recapping needles
- Rotarod Test
- Screening cell lines
- Sedation of cattle
- Splenectomy
- Sterilisation of instruments
- TTEAM and TTouch
- Tail vein injection
- Tramadol
- Transport stress
- Tumour cell implant into mammary fat pad
- Ulcerative Dermatitis in Mice
- Water quality
- Xenopus laevis
- Zebrafish swabbing

Culture of Care

The International Culture of Care Network

norecopa.no/coc

En synlig satsing gjennom hele institusjonen på å øke:

- dyrevelferd
- den vitenskapelige kvaliteten
- trivselen hos personalet
- åpenhet til alle interessepartene, inkl. samfunnet

Culture of Care – ærlige og respekltfulle diskusjoner mellom forskere og personalet

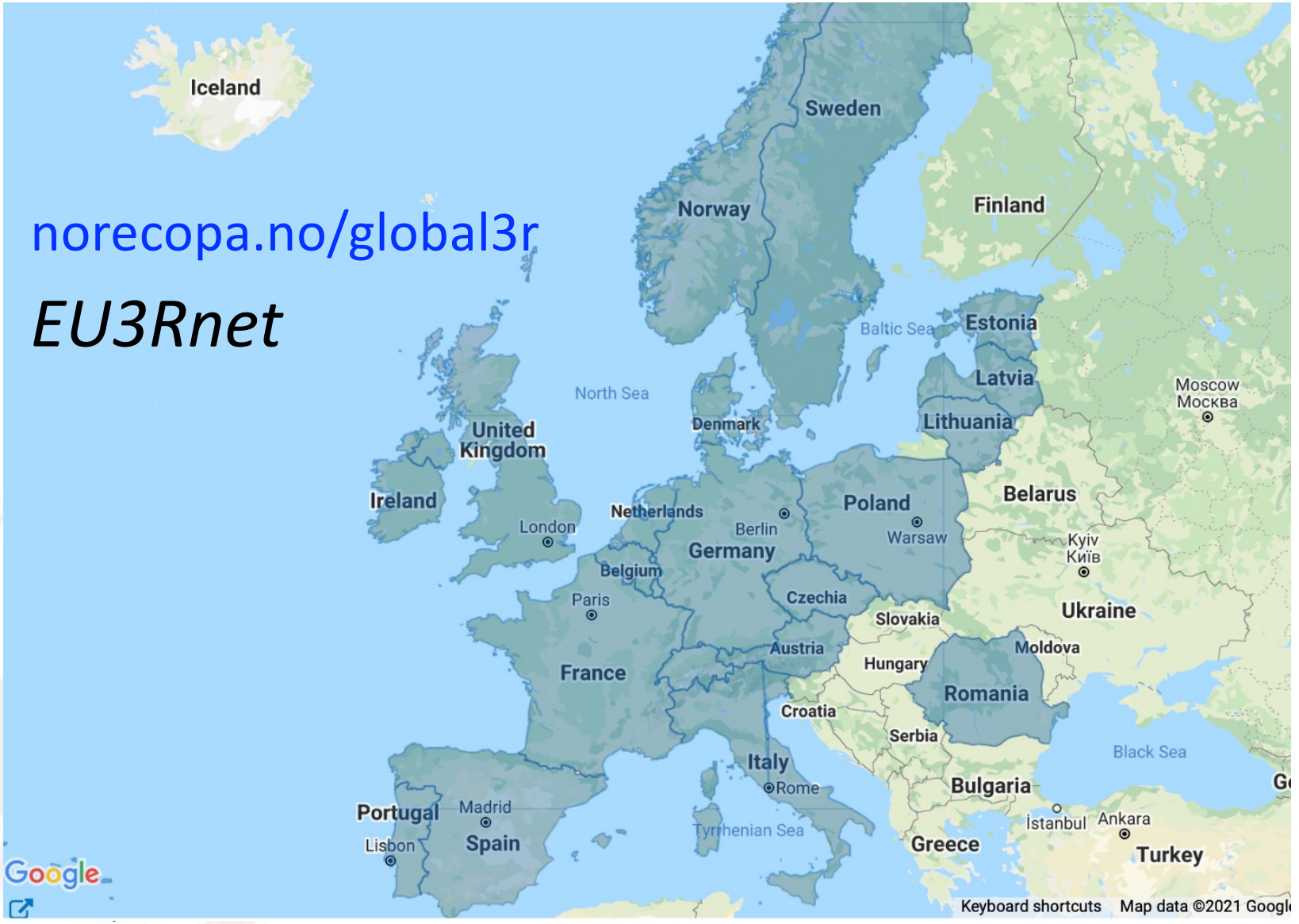
"fordi vi har alltid gjort det slik"

"så ofte som nødvendig"

"det finnes ikke alternativer"

Nært relatert til dette er **Culture of Challenge** (Louhimies, 2015)**:**

Let etter det som er akseptabelt, ikke det som er akseptert


norecopa.no/global3r
EU3Rnet
Iceland
Sweden
Norway
Finland
Baltic Sea
Estonia
Latvia
Lithuania
Moscow
Москва
North Sea
Denmark
United Kingdom
Ireland
London
Netherlands
Berlin
Poland
Warsaw
Belarus
Germany
Kyiv
Київ
Belgium
Paris
Czechia
Slovakia
Ukraine
Austria
Moldova
Hungary
France
Romania
Croatia
Serbia
Black Sea
Italy
Rome
Bulgaria
Portugal
Madrid
Lisbon
Spain
Tyrrhenian Sea
İstanbul
Ankara
Greece
Turkey
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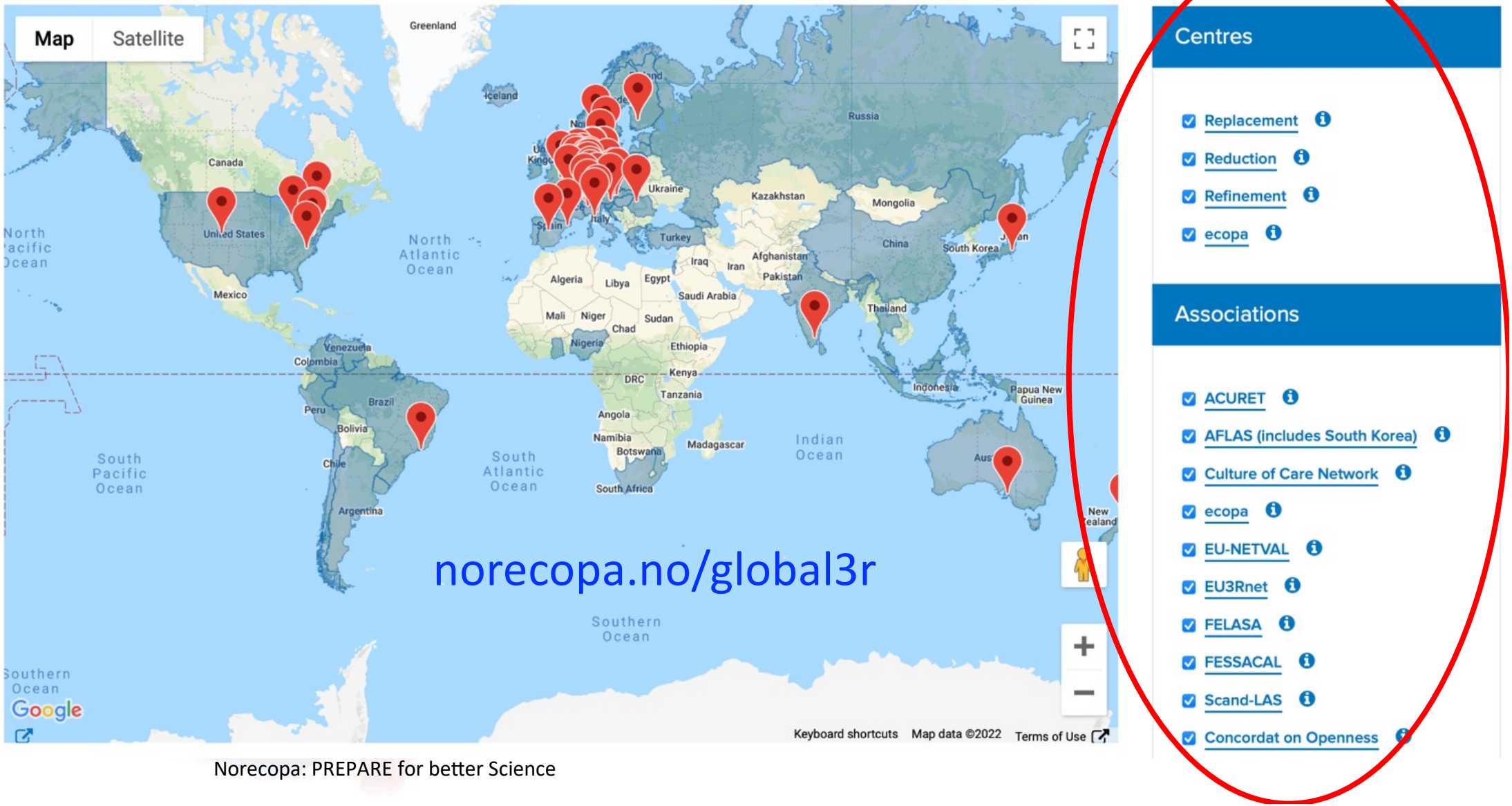
Map data ©2021 Google



Centres

- Replacement
- Reduction
- Refinement
- ecopa

Associations

- ACURET
- AFLAS (includes South Korea)
- Culture of Care Network
- ecopa
- EU-NETVAL
- EU3Rnet
- FELASA
- FESSACAL
- Scand-LAS
- Concordat on Openness

Norecopa: PREPARE for better Science

Reduction og replacement: Hva skjer innen alternativer til dyreforsøk?

adrian.smith@norecopa.no

@adrian_3r

norecopa.no/KPM

Norecopa: PREPARE for better Science

"...better science?"

- gyldige data (en ekte behandlingseffekt)
- reproduserbare og overførbare studier
- den best mulige dyrevelferden
- en omsorgskultur ved institusjonen – alle er hørt
- kommunisering av beste praksis, innad og utad
- HMS (både for personalet og andre dyr på avdelingen)

colourbox.com

Norecopa: PREPARE for better Science

https://norecopa.no/prepare-care-share-flag

Direkte / indirekte påkjenninger

(direct and contingent suffering)

Russell & Burch påpekte disse

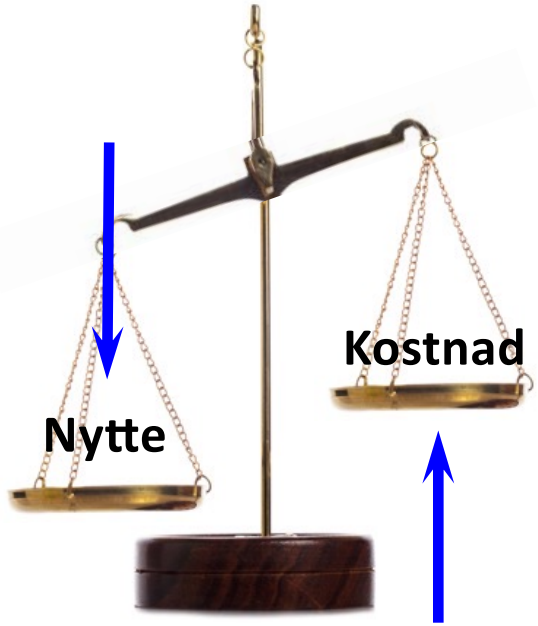
- **direkte**: smerte eller lidelse forårsaket av prosedyren (selv om den er utført på beste måte)

- **indirekte**: bivirkningene av en prosedyre som ikke er nødvendig for dens suksess
  f.eks. dårlig oppstalling, stell, håndtering eller smertestillelse

colourbox.com

Smerte og lidelse oppleves på individnivå

Mer enn 3R (som dreier seg mest om å redusere lidelse)



De 3 S-ene - sunn fornuft og kritisk antromopomorfisme

- *Good Science*
- *Good Sense*
- *Good Sensibilities*

De 3 V-ene – øke gyldigheten av data fra et forsøk:

- *Construct Validity (kan studieobjektet svare på spørsmålet?*
- *Internal Validity (er studiet blitt designet riktig?)*
- *External Validity (er resultatene overførbare til målgruppen, f.eks. mennesker?)*

norecopa.no/3R
norecopa.no/3S
norecopa.no/3V

40 slides om 3R (powerpoint/pdf)

ccac.ca

The 3Rs of Russell and Burch:

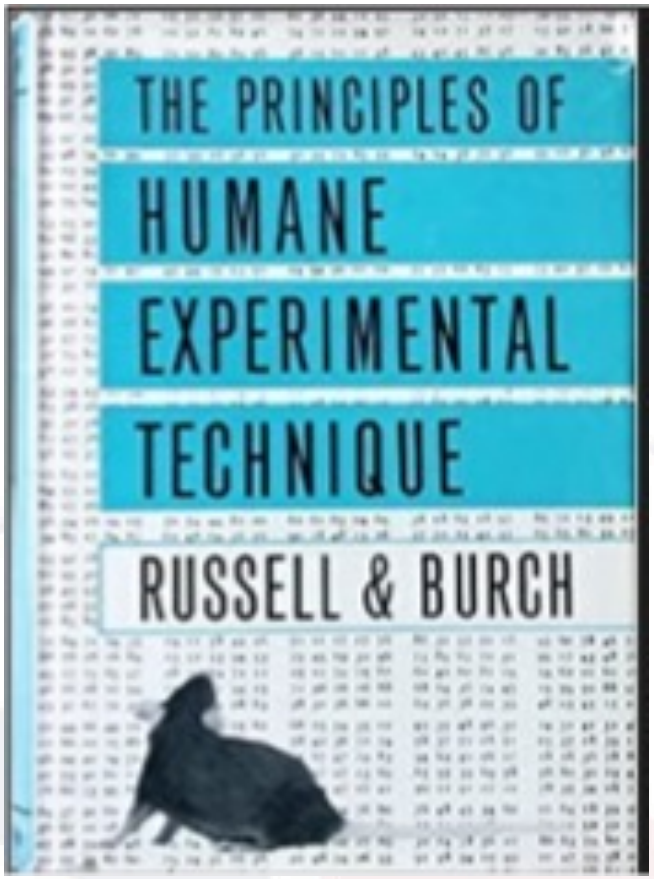
Replacement, Reduction & Refinement

Tilgjengelig fra norecopa.no/3Rs

På engelsk, spansk og fransk (og snart tysk)

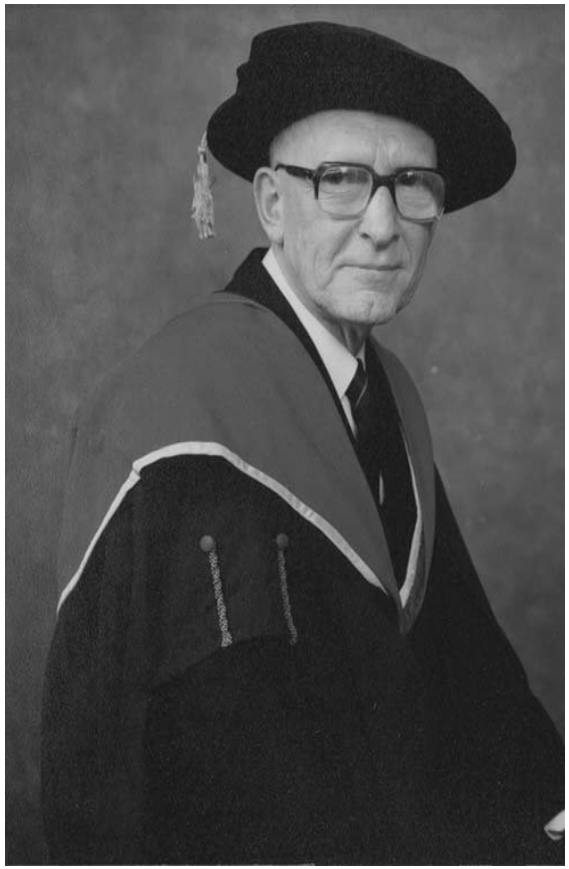
Norecopa: PREPARE for better Science

William (Bill) Russell and Rex Burch, 1959:



W.M.S. Russell (1925 - 2006)

en.wikipedia.org/wiki/W._M._S._Russell



R.L. Burch (1926 - 1996)

fra Stephens (2009)

De opprinnelige definisjonene fra Russell & Burch:

- **Replacement**: *en vitenskapelig metode som benytter ikke-bevisst materiale som kan erstatte bevisste levende virveldyr*
- **Reduction**: *metoder for å minimere antallet dyr som trengs for å få en viss mengde informasjon av en viss kvalitet*
- **Refinement**: *metoder som fører til en nedgang i hyppigheten eller alvorsgr*aden av *inhumane prosedyrer hos dyrene som fortsatt må brukes.*

	Basic	Updated
Replacement	Avoiding or replacing the use of animals in areas where they otherwise would have been used.	Bruke robuste verktøy basert på den nyeste teknologien for å erstatte dyr
Reduction	Minimising the number of animals used consistent with scientific aims.	Robuste og reproduserbare dyreforsøk med korrekt design og dataanalyse, som virkelig øker vår kunnskap
Refinement	Minimising the pain, suffering, distress or lasting harm that research animals might experience.	Bruk av den nyeste teknologien for å forstå hvordan dyrenes velferd påvirker utfallet av dyreforsøk

Norecopa: PREPARE for better Science

nc3rs.org.uk/who-we-are/3rs

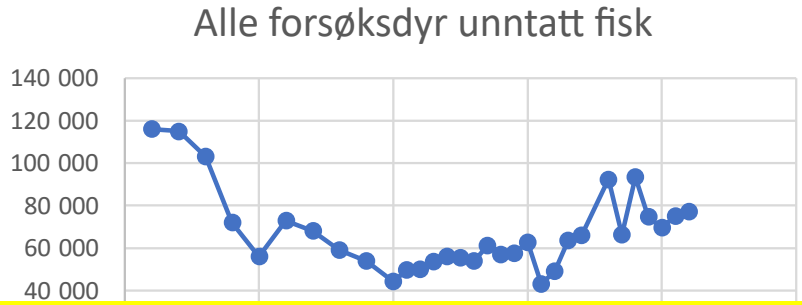
Moderne definisjoner av 3R ofte fremhever velferdsgevinster og økt kunnskap i tillegg til reduksjonen i dyreplageri

Det britiske 3R-senteret: en 18-minutters video

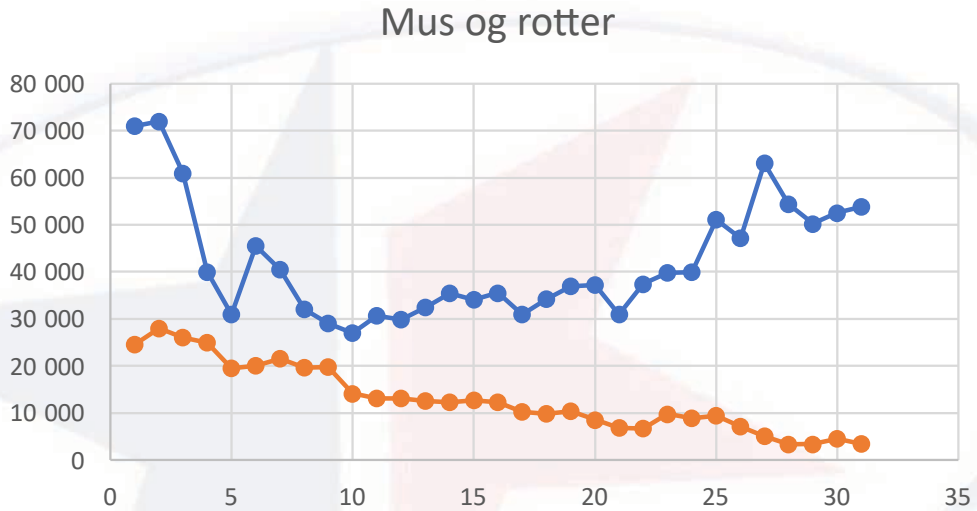
vimeo.com/289645718

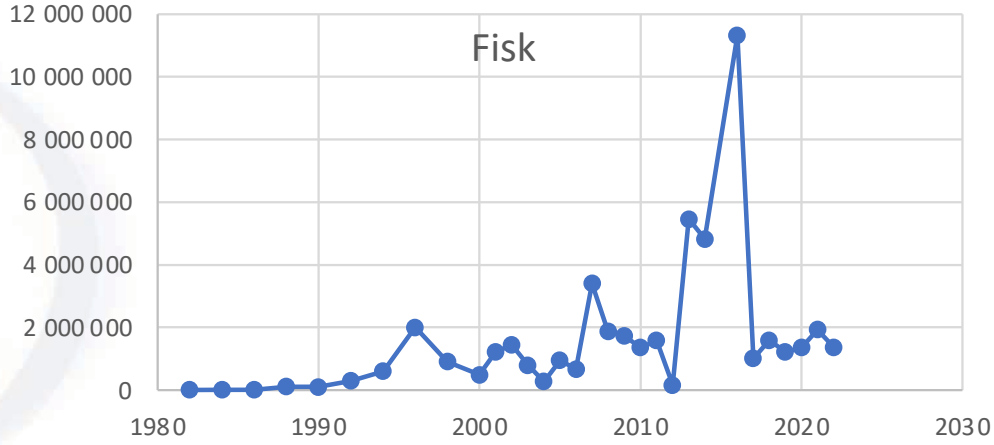
nc3rs.org.uk/who-we-are/3rs

Reduksjon - Reduction



Aktivitetsnivået innen forskning påvirker selvsagt antallet dyr (f.eks. produksjon av genmodifiserte dyr), men reduksjonen på 80- og 90-tallet skyldes kanskje økt 3R-fokus?

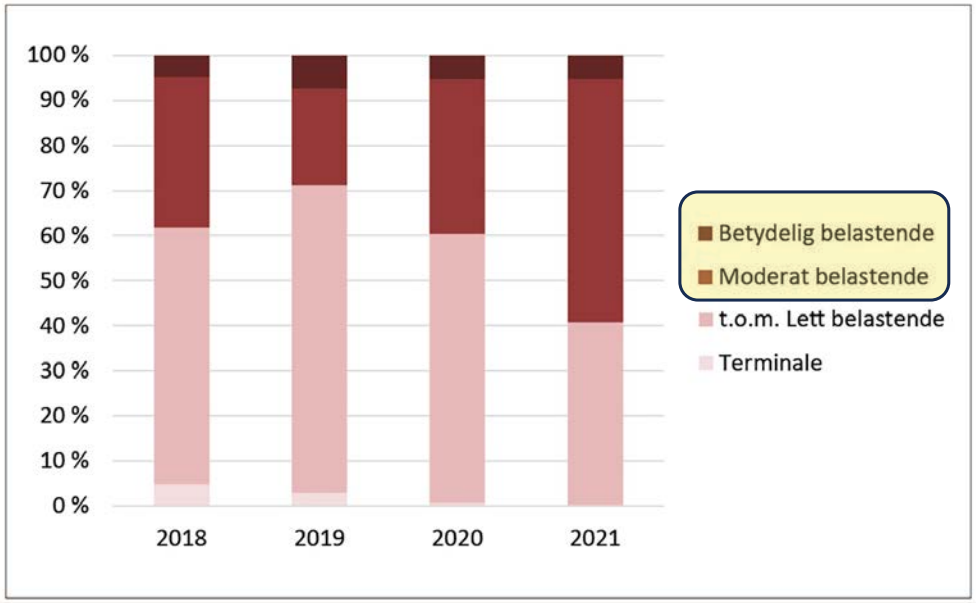




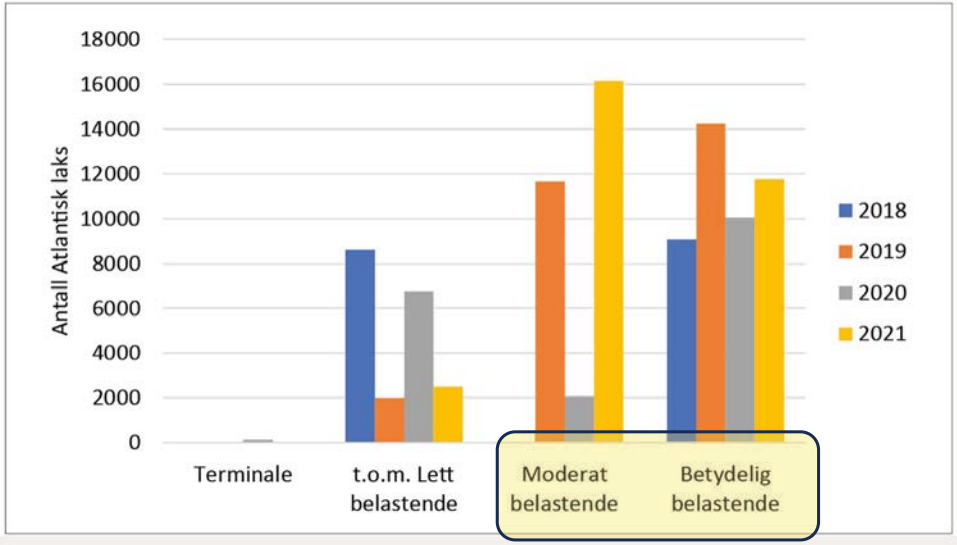
Norecopa: PREPARE for better Science

https://norecopa.no/statistics

Antallet belastende forsøk må reduseres



Figur 4 : Prosent anvendelse etter belastningskategori (alle dyrearter).



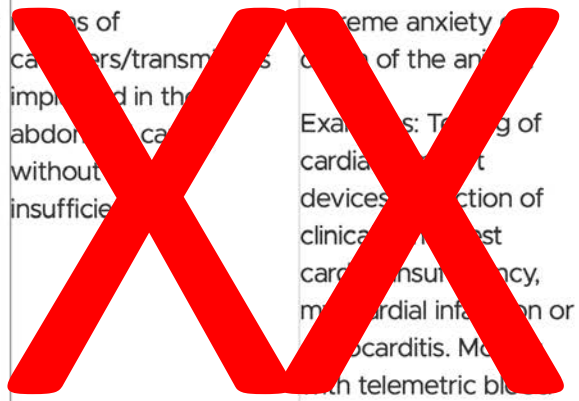
Figur 6: Antallet Atlantisk laks brukt innenfor regulatoriske arbeid og kvalitetskontroll, sortert etter belastningskategori.

https://norecopa.no/statistics

Belastningsgrader ved dyreforsøk

Mild (nålestikk e.l.)
Moderat
Betydelig
Under terskelen

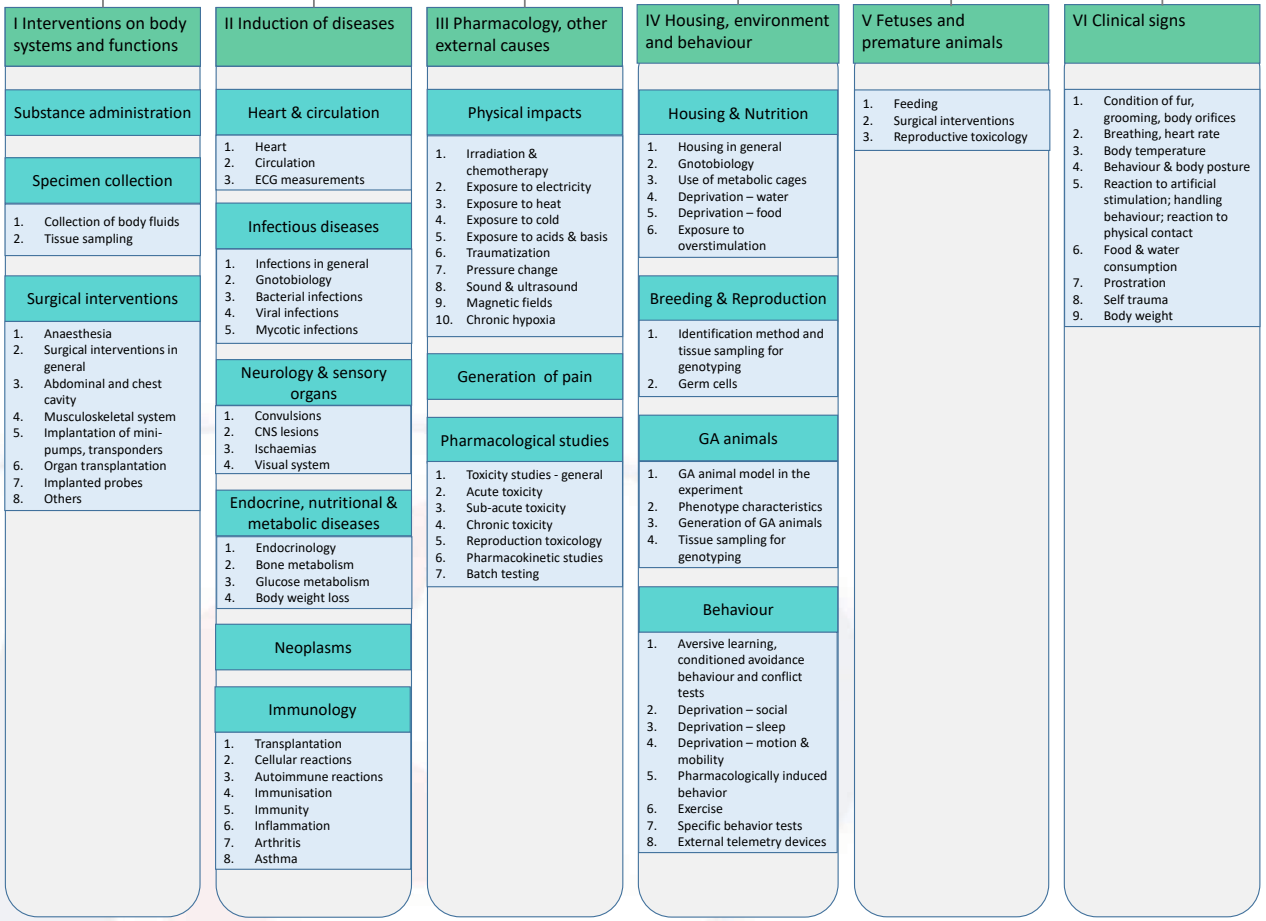
Hjerte	Non-harmful / below threshold / severity degree 0	Mild / severity degree 1	Moderate / severity degree 2	Severe / severity degree 3
Federal Food Safety and Veterinary Office FSVO (2018)	Examples: Monitoring ECG by non-invasive methods, leading to no or minimal impairment in habituated animals.	.Examples: Models with ECG recordings in the conscious dog after administration of test substances in non-toxic doses. Preterminal infarction models in the anaesthetised animal and euthanasia while under anaesthesia. Reperfusion models in the anaesthetised animal and euthanasia while under anaesthesia.	Examples: Models with telemetric heart-rate measurements in the conscious animal by [illegible]	Models resulting in clinical insufficiency or interventions that may cause severe pain, [illegible] pressure measurements in the conscious animal by means of catheters/transmitters implanted in the abdominal cavity. Models with experimentally induced hypertension in the animal.



Norecopa: PREPARE for better Science

https://norecopa.no/severity

COMPILATION OF SEVERITY CLASSIFICATIONS ACROSS EUROPE



Norecopa: PREPARE for better Science

https://norecopa.no/severity

En mulig vei frem:

Eliminere de betydelig belastende forsøk, og så de moderat belastende

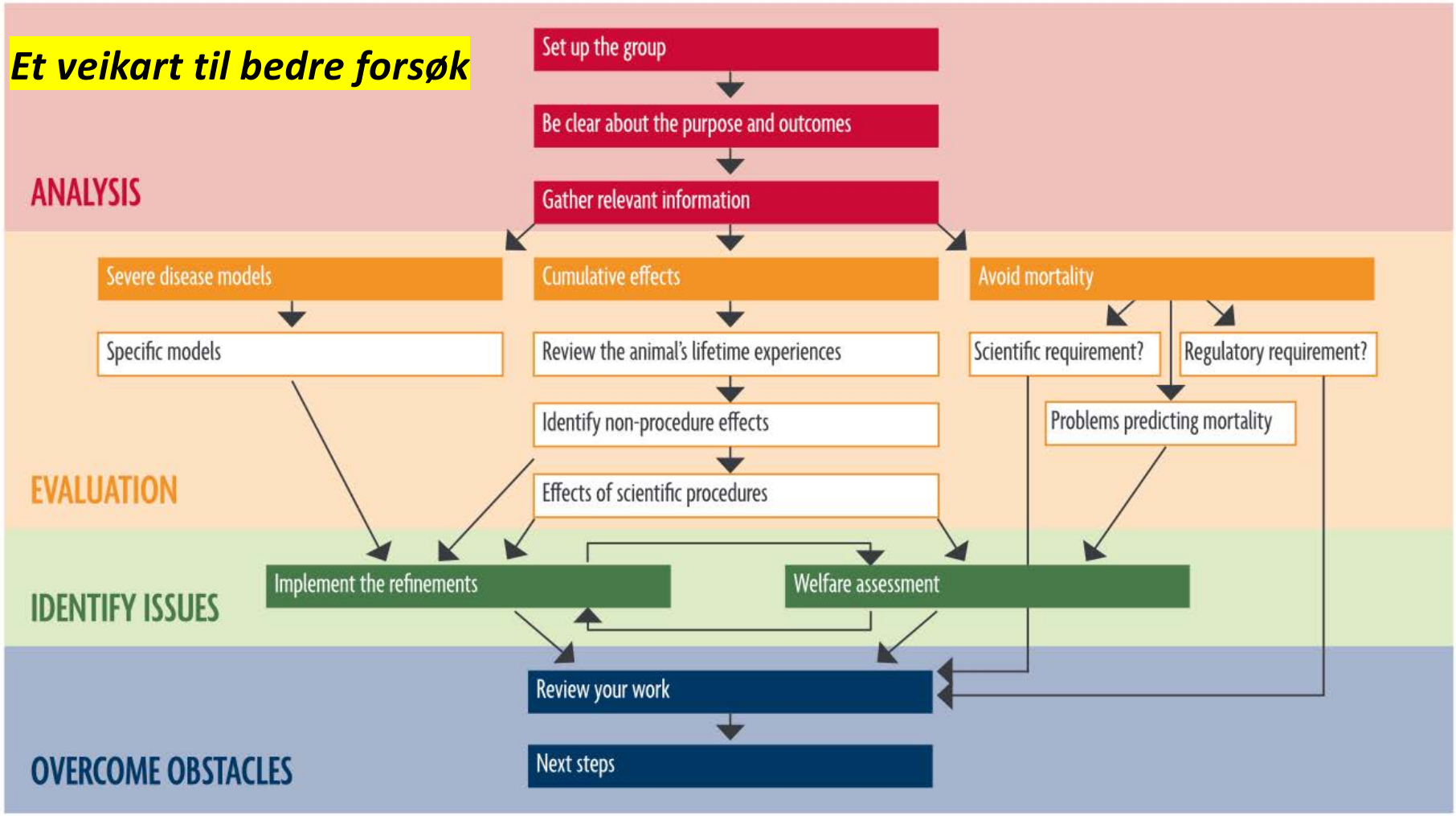
Da er vi på omtrent det samme nivået som hold av hund og katt!

Noen setter seg mål, f.eks. *Focus on Severe Suffering*, RSPCA, Storbritannia

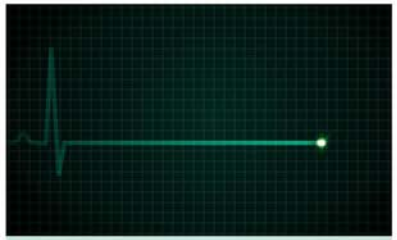
https://focusonseveresuffering.co.uk

Norecopa: PREPARE for better Science

Et veikart til bedre forsøk



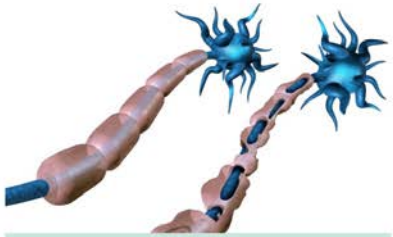
https://focusonseveresuffering.co.uk/roadmap



Avoiding mortality

Hawkins et al. (2019)

Avoiding mortality in animal research and testing.
ISBN: 978-0-901098-17-7A



Experimental Autoimmune Encephalomyelitis (EAE)

Wolfensohn et al. (2013)

Reducing suffering in experimental autoimmune encephalomyelitis (EAE).
Journal of Pharmacological & Toxicological Methods 67, 169-176

Rheumatoid arthritis

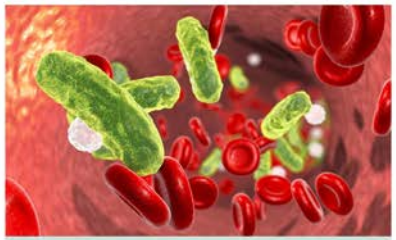
Hawkins et al. (2015)

Applying refinement to the use of mice and rats in rheumatoid arthritis research.
Inflammopharmacology 23, 131-150

Seizures, convulsions and epilepsy

Wolfensohn et al. (2013)

Reducing suffering in animal models and procedures involving seizures, convulsions and epilepsy.
Journal of Pharmacological & Toxicological Methods 67, 9-15



Sepsis

Lilley et al. (2015)

Refinement of animal models of sepsis and septic shock.
Shock 43, 304-316

Spinal cord injury

Lilley et al. (2020)

Refining rodent models of spinal cord injury.
Experimental Neurology 328, 113273

Hva kunne Norge oppnå ved etableringen av et 3R-senter?

Et notat fra Norecopa på oppdrag fra Nærings- og fiskeridepartementet, hvor det ønskes spesielt fokus på samfunnsøkonomiske fordeler.

https://norecopa.no/3rsenter

https://crueltyfreeeurope.org/sites/default/files/Cruelty%20Free%20Europe%20Reducing%20and%20replacing%20animal%20experiments%20Europe%20needs%20an%20action%20plan%20%281%29.pdf

What are some examples of why animals would be bred and then not used?

- **Genetically altered animals**
  Animals that do not meet the genotype of a given genetically modified strain that is required, for instance in Covid-19 research, and cannot be included in a study. There is currently no technology available to ensure that all animals bred will possess the desired genetics required – those bred can sometimes actually be 'genetically normal'.

- **Inconsistent and unpredictable demands**
  Research programmes are considered in advance and require authorisation through licenses or ethical permits. Individual studies are also planned in advance. At this stage the process of breeding the required animals begins. However, as research progresses the results may indicate the hypotheses being investigated are not valid (hence the research stops), or the results may lead to different theories that require additional investigation. This can lead inadvertently to a considerable surplus of animals being bred because the breeding programmes cannot effectively be switched on and off.

- **Sex bias**
  The requirement of researchers for an unequal number of male and female animals, leading to a surplus of one sex. This may be driven by the research area e.g: basic research first evaluated in one sex, only followed by confirmation in the other sex if there are good results.

- **User demand**
  Trying to meet research needs by breeding animals to requirements over a wide range of ages. Sometitmes animal studies will require the use of animals of differing age ranges depending on the research area, body organ, and/or the hypothesis being researched.

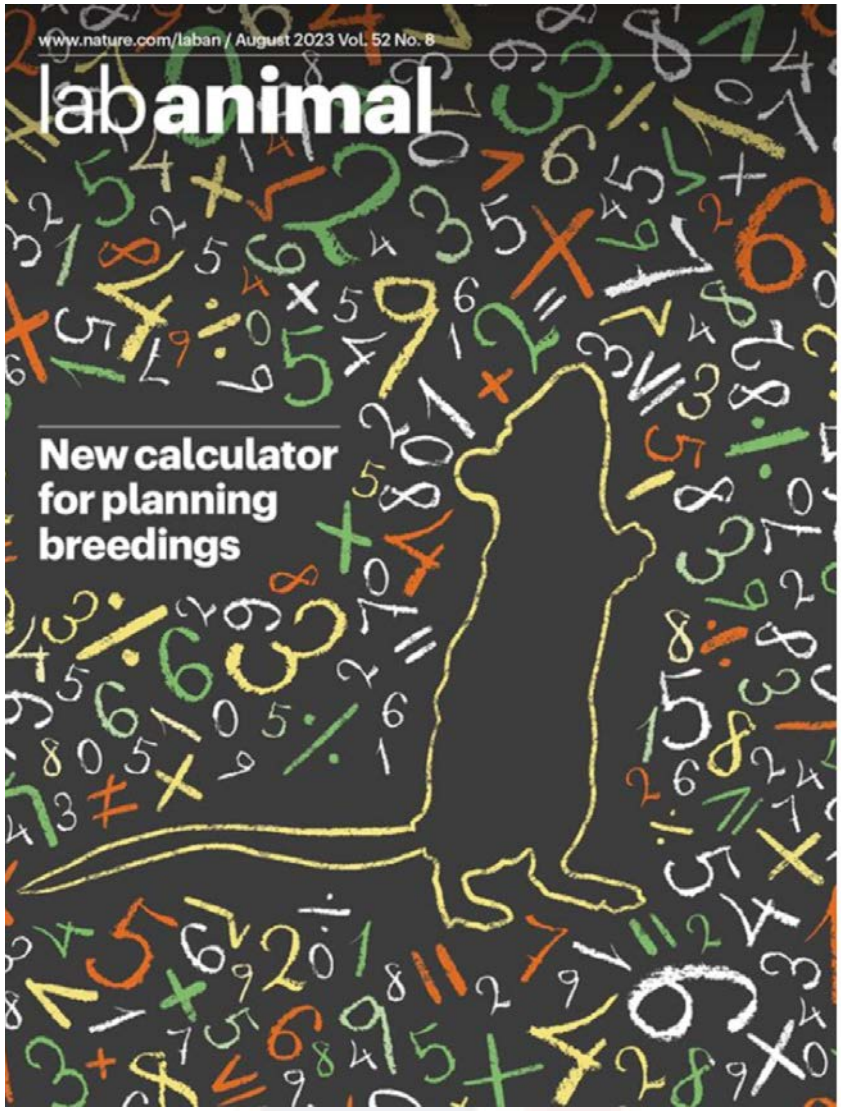
- **The number bred**
  This may be over and above the numbers needed for the research programme - litter sizes and individual mortality rates can be unpredictable (for instance, litter sizes for mice being abnormally large, or if more individuals survived than usual), which can result in more animals being bred than are required.

- **Animals used for the collection of tissues**

- **Breeding animals**
  Animals used for the purpose of breeding alone are likely to undergo no procedures themselves. Animals are also used to sustain inbred colonies.

- **'Sentinel animals'**
  Animals from a batch bred which are used for health screening of the other animals in the laboratory.

https://www.eara.eu/why-animals-are-bred-but-not-used-in-research



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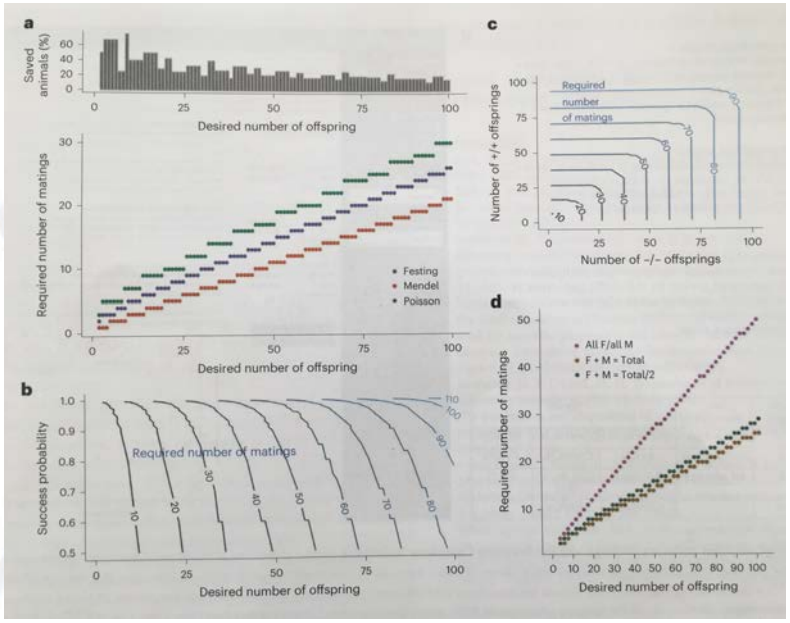
Article | Open access | Published: 24 July 2023

Group size planning for breedings of gene-modified mice and other organisms following Mendelian inheritance

Vladislava Milchevskaya, Philippe Bugnon, Emiel B. J. ten Buren, Dominique Vanhecke, Frank Brand, Achim Tresch & Thorsten Buch



https://www.nature.com/articles/s41684-023-01213-1

I dag!

10:05-10:45 am (CET)

Ginger tool for sample design in animal experiments

Univ. Prof. Dr. Georg Heinze

Medical University of Vienna

10:50-11:30 am (CET)

Breeding Calculator

Prof. Dr. Thorsten Buch

University of Zurich

https://norecopa.no/meetings/recorded-webinars

https://www.reprefred.eu/uploads/pics/Einladung%20Reduction.pdf

Deling av dyrematerialе er en måte å iverksette Reduction

Sharing animal tissue

Collaboration with other internal or external laboratories should be considered, to reduce the number of animals needed. Here are some resources:

- AniMatch
- Anishare (open source web-based software) - see also abstract S2E1.1 from FELASA 2022
- The Otlet database (biological research samples)
- The SEARCH Framework (Morrissey *et al.*, 2017)
- Shared Ageing Research Models (ShARM)
- NERD (Neuro Ecological Research Denmark) - no longer available
- ATEX (animal and tissue exchange platform at Utrecht University)
- The Munich MIDY Pig Biobank
- SEARCHBreast (breast cancer models) (blog)
- MiTO (Models in Translational Oncology)
- BrainBits® (rat and mouse tissue and cells)
- The EUPRIM-Net Project biobanks (non-human primate tissue, serum and blood; gene bank)
- BPRC (Biomedical Primate Research Centre) Biobank of non-human primate tissue
- University of California San Francisco (UCSF) Tissue Sharing Program
- Examples of University protocols: Minnesota; USF; Indiana; Wayne State

Guidance on sharing

- Recommendations from an expert working group on the sharing and archiving of material from genetically altered mice
- Importing genetically altered animals: ensuring quality (Birling *et al.*, 2021)

Part of the planning process should be to evaluate whether human tissue can be used instead of animal material.

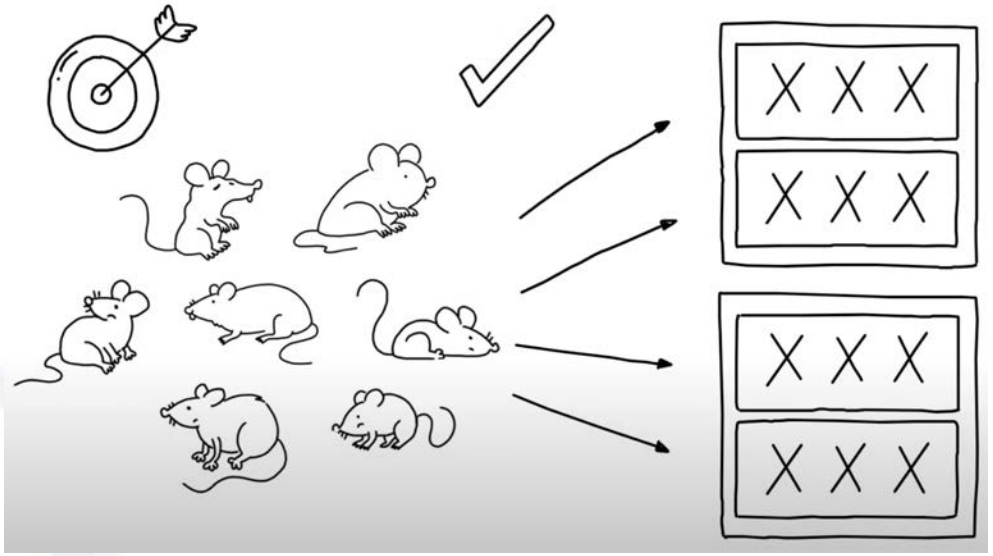
På arbeidsplassen
Nasjonalt
Internasjonalt

https://norecopa.no/prepare/10-experimental-animals/10a/general-principles

Reduction betyr ikke at man må bare bruke ett kjønn eller standardiserte (innavlede) dyr.

Med riktig design og statistisk analyse kan begge kjønn og utavlede dyr inkluderes i det samme forsøk
- uten økning i antallet dyr og med større relevans for forsøket (**økt *External Validity***)

Biological Variation and Reproducibility



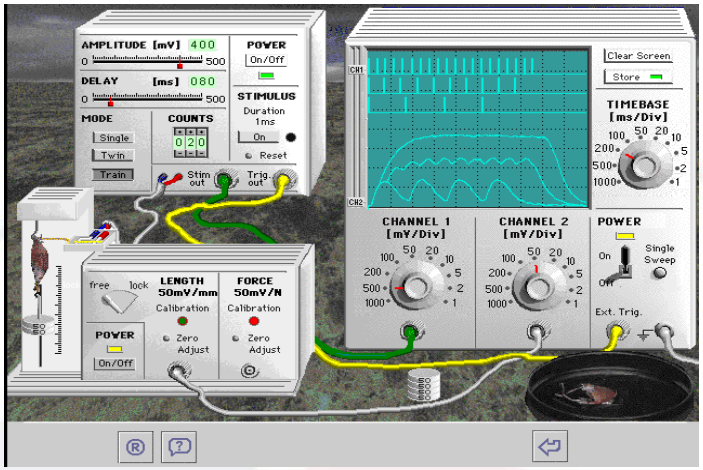
https://www.youtube.com/watch?v=-tiZeQQDpJg
https://eda.nc3rs.org.uk/experimental-design-animal-characteristics#sex

Gjelder også andre store populasjoner, f.eks. sebrafisk og husdyrflokker

norecopa.no/Difford

Erstatning - Replacement

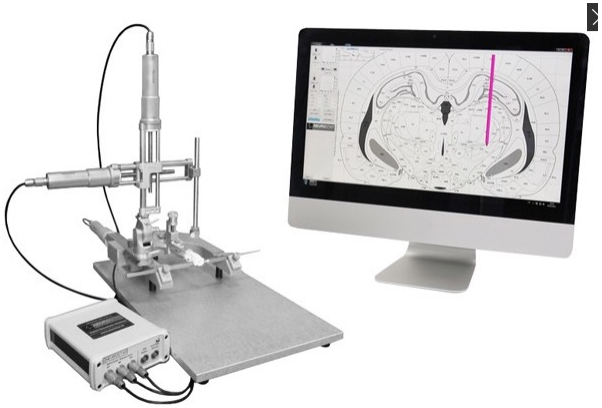
Full/absolute replacement



virtual-physiology.com

En datasimulering av det klassiske nerve-muskelpreparat fra frosk

Partial/relative replacement



agnthos.se/569-stereotaxic-frames

Akuttforsøk/terminale forsøk: studier på totalt anesteserte dyr som ikke våkner fra anestesien

Eksempler

Partielle / Relative

- dyr som pr. i dag ikke regnes som bevisste*
  f.eks. bananfluer, rundormer, og veldig tidlige utviklingsstadier av bevisste arter
- prosedyrer på dyr som er totalanestestert før prosedyren starter, og som avlives før anestesien opphører (= non-recovery, terminal, akuttforsøk)
- celler og vev fra dyr
- tilovers forsøksdyr, kliniske veterinærpasienter og slaktehusmateriale
- observasjon av dyr under kortvarig fangenskap eller i deres naturlige omgivelser

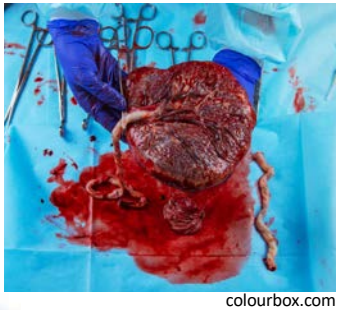
**ikke alle dyr som regnes som bevisste dekkes av all lovgivning f.eks. blekksprut og tifotkreps*

Fulle / Absolutte

- datasimuleringer
- filmer, video, virtual reality
- modeller, dukker, simulatorer
- QSAR *(Quantitative Analysis of Structure/Activity Relationships)*
- menneskeceller og vev
- Organs-on-a-chip og organoider fra menneskevev
- High Throughput Screening (HTS)
- biokjemiske og immunologiske metoder (RIA, ELISA)
- hybrid DNA teknikk
- innsamling av miljø-DNA fra dyr (f.eks. hår, avføring, urin, fotavtrykk)
- genetisk modifiserte mikroorganismer
- planter
- frivillige mennesker
- Synthesis of Evidence fra tidligere publiserte studier etter Systematic Review
- erstatning av en studentklasse med en teoretisk sesjon

NAMs og NATs

NAMs: New Approach Methodologies (ikke *Non-Animal Methods!*)
Unngåelse (d.v.s metoder som ikke direkte erstatter dyreforsøk)
f.eks. "Read-Across"
forsøk på morkake


colourbox.com

NATs: Non-Animal Technologies
Alternativer til dyreforsøk
f.eks. organoider
organs-on-chips
forsøk på bananfluer

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Structure	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx
Property 1	● ⇨ ○		● ⇨ ○	
Property 2	● ⇨ ○		○ ⇦ ●	
Property 3	○ ⇦ ●		● ⇨ ○	
Activity 1	● ⇨ ○		● ⇨ ○	
Activity 2	● ⇨ ○		○ ⇦ ●	
Activity 3	○ ⇦ ●		● ⇨ ○	

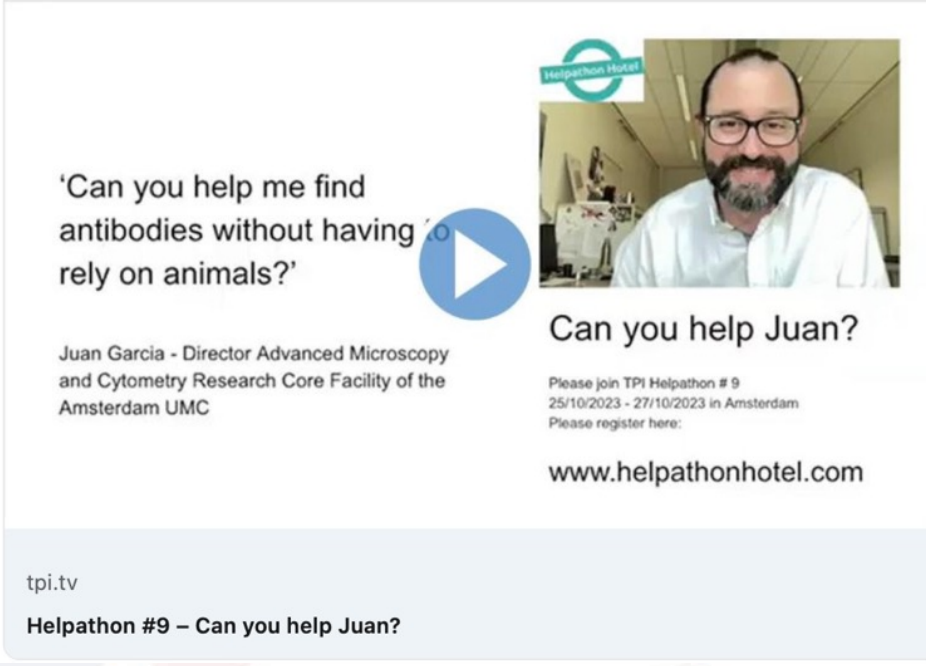
● Existing data point ○ Missing data point

NB. De som arbeider med disse teknikkene er ikke klare engang at de arbeider med noe som kan erstatte dyreforsøk. Det er derfor viktig at vi bygger broer mellom forsøksdyrmiljøet og NAMs/NATs-miljøene !

https://www.oecd.org/chemicalsafety/risk-assessment/groupingofchemicalschemicalcategoriesandread-across.htm
https://nc3rs.org.uk/sites/default/files/documents/NonAnimalTechCO082_RYE_4_nrfinal2.pdf

Transitie Proefdiervrije Innovatie
917 followers
1mo •

Do you use antibodies in your in vitro research? Are you open to animal-free innovations? Is your company developing animal-free antibodies? Are you keen on side-by-side comparisons between conventional antibodies and non-animal antibodies? Or are you simply willing to contribute to the transition to animal-free innovations with an out-of-the-box view? On 25-27 October, you can join the next Helpathon. Watch the video with the central question on **#TPItv**. You can register here to join: **https://lnkd.in/eRFNVsrg**
https://tpi.tv/watch/126

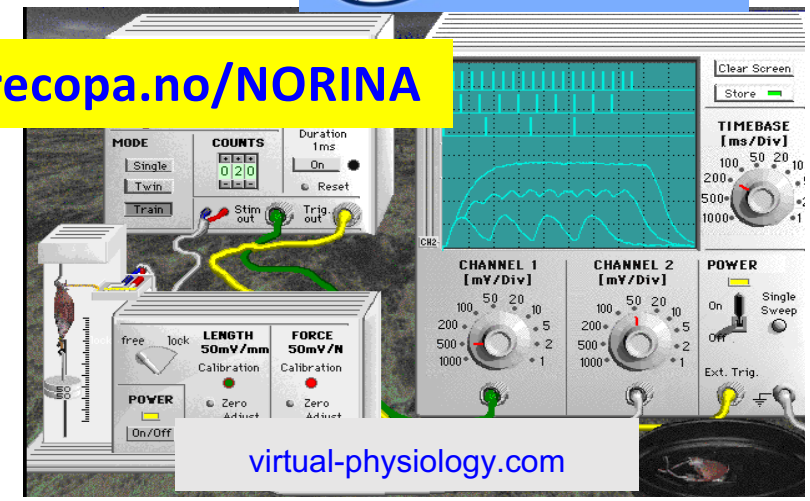


tpi.tv
Helpathon #9 – Can you help Juan?

Replacement innen opplæring og trening – den enkleste del-R?

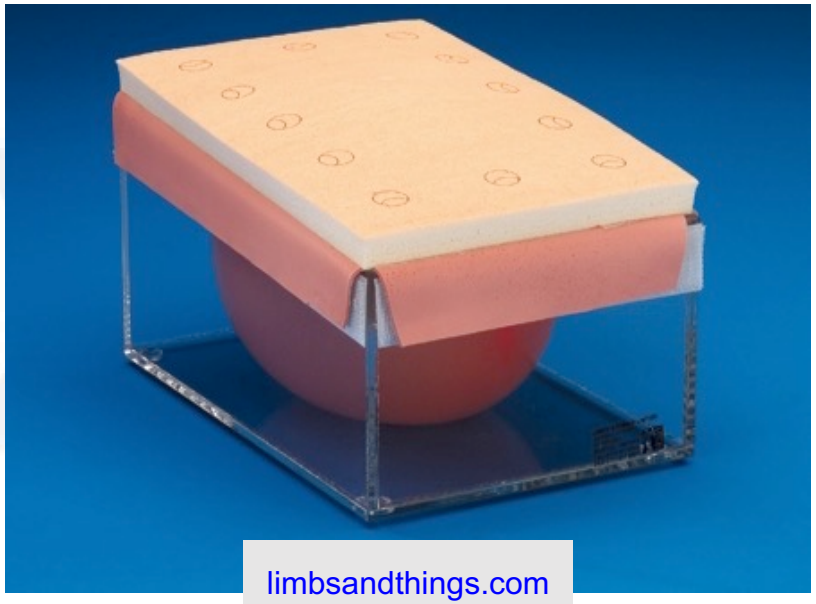
norecopa

NORINA databasen: norecopa.no/NORINA



virtual-physiology.com

rescuecritters.com

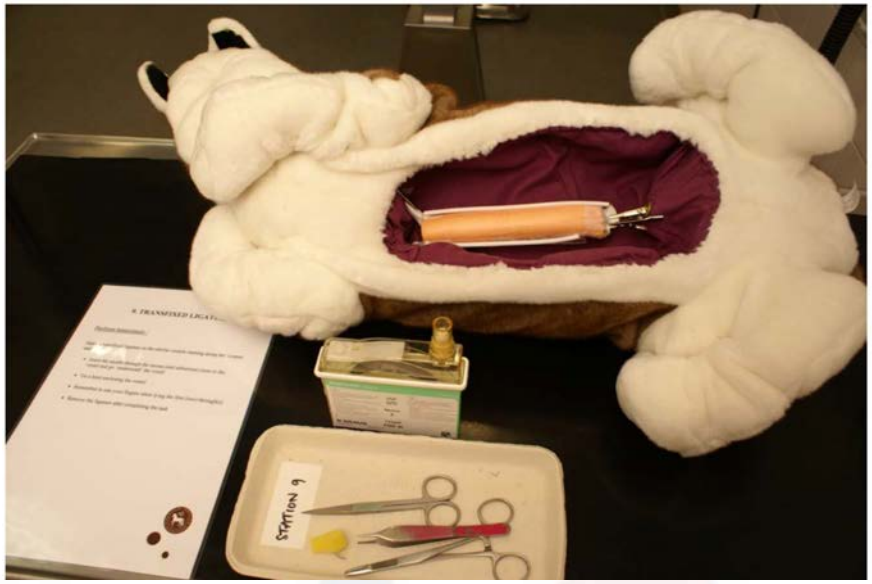


limbsandthings.com

norecopa.no/homemade

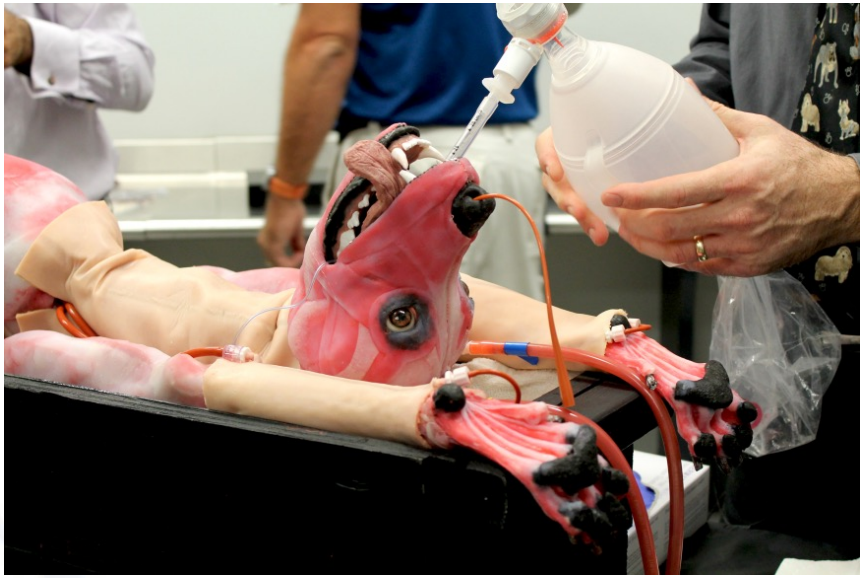
Rikke Langebæk, København

Fidelity and Discrimination



Rikke Langebæk, University of Copenhagen

Low Fidelity, High Discrimination



https://syndaver.com

High Fidelity, Low Discrimination

norecopa

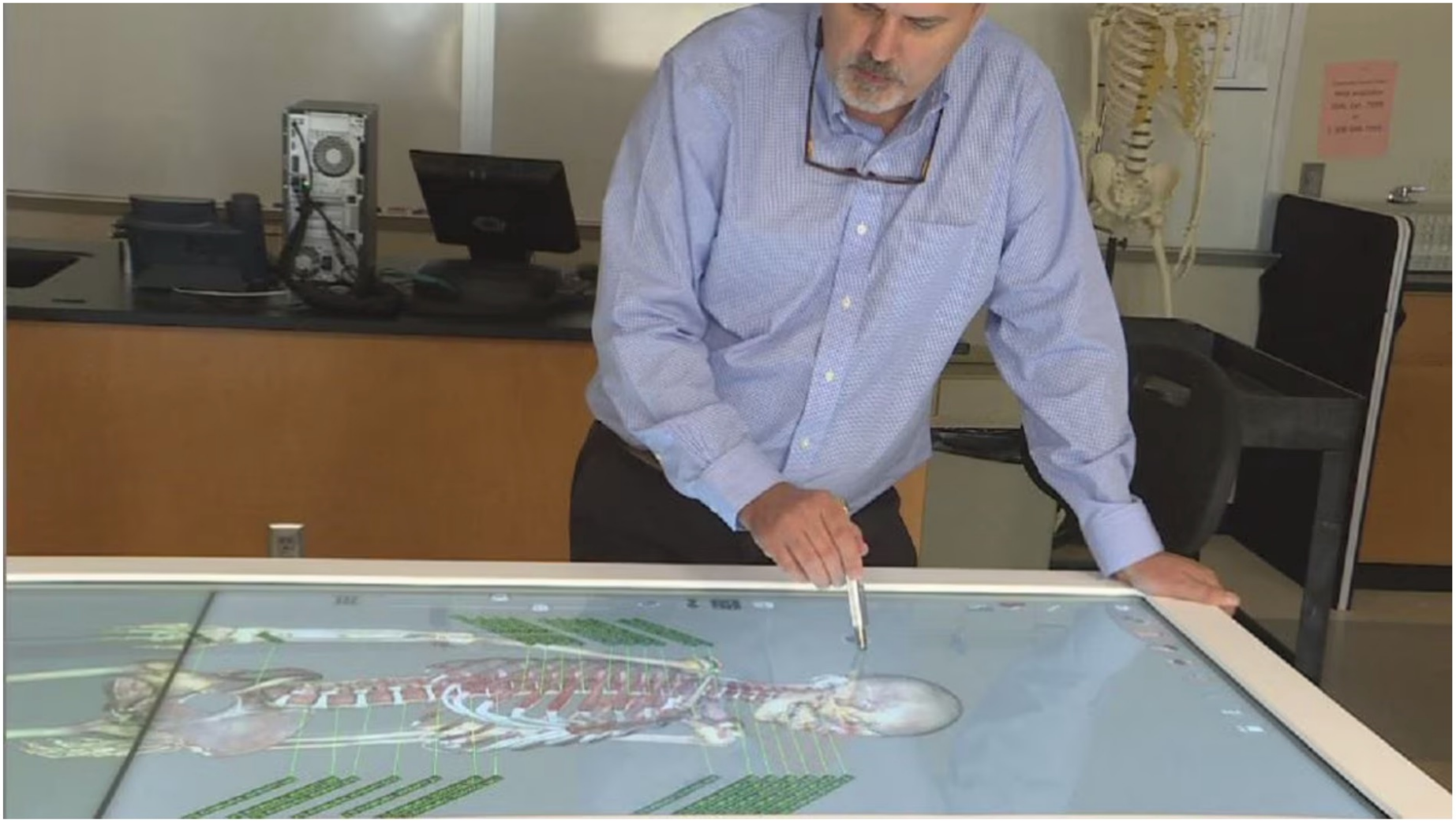
3d4medical.com/student

Augmented reality

Norecopa: PREPARE for better Science

Virtual Anatomy | Healthcare Simulation | HealthySimulation.com

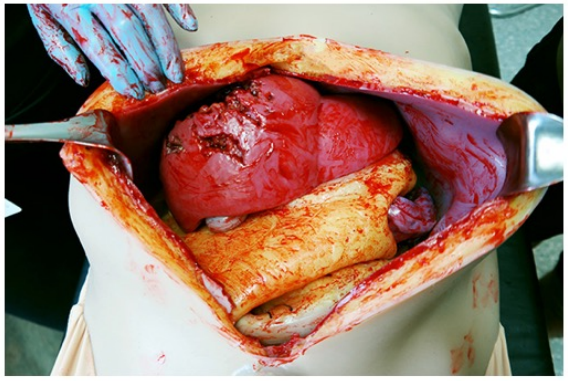
Besøk



Central Community College - Grand Island instructors introduces Anatomage Table to their biology students. (Hailey Mach, KSNB)

https://www.ksnblocal4.com/2021/09/28/central-community-college-adds-anatomage-table-biology-classroom

Skuespillere som bærer utstyr som simulerer organer og skader



https://www.strategic-operations.com

’We may need the animals, as it were, on the night;
but the machines will do very well at rehearsals’

Europarådets konvensjon (ETS123), 1986:

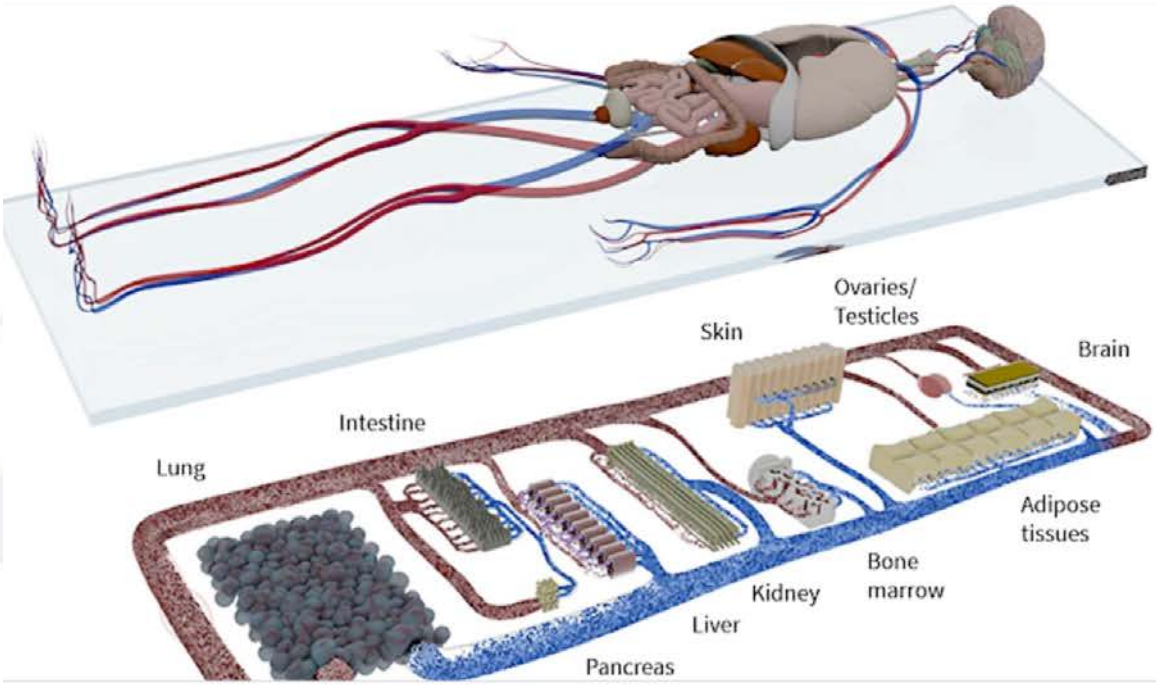
Artikkel 25, pkt 3:

Slike forsøk som er nevnt i 1. ledd i denne artikkel skal begrenses til det absolutt nødvendige for det aktuelle undervisnings- eller treningsformål og skal bare tillates dersom formålet ikke kan oppnås like effektivt med audiovisuelle hjelpemidler eller andre passende metoder.

En god rettesnor for forskning også!

Sentrale utfordringer

Validering av nye metoder
Regulatorisk aksept
“Oversell” – hos begge parter?



Aug 25

Expert Panel Discussion on the Future of Science in the EU & Beyond

by Landestierschutzbeauftragte von Berlin, SenJustVA

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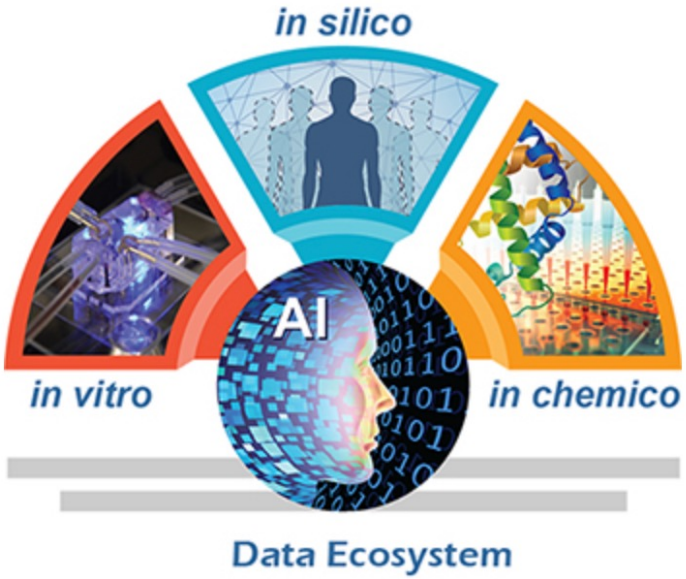
NIH Listening Sessions on “Complement Animal Research in Experimentation (Complement-ARIE)”

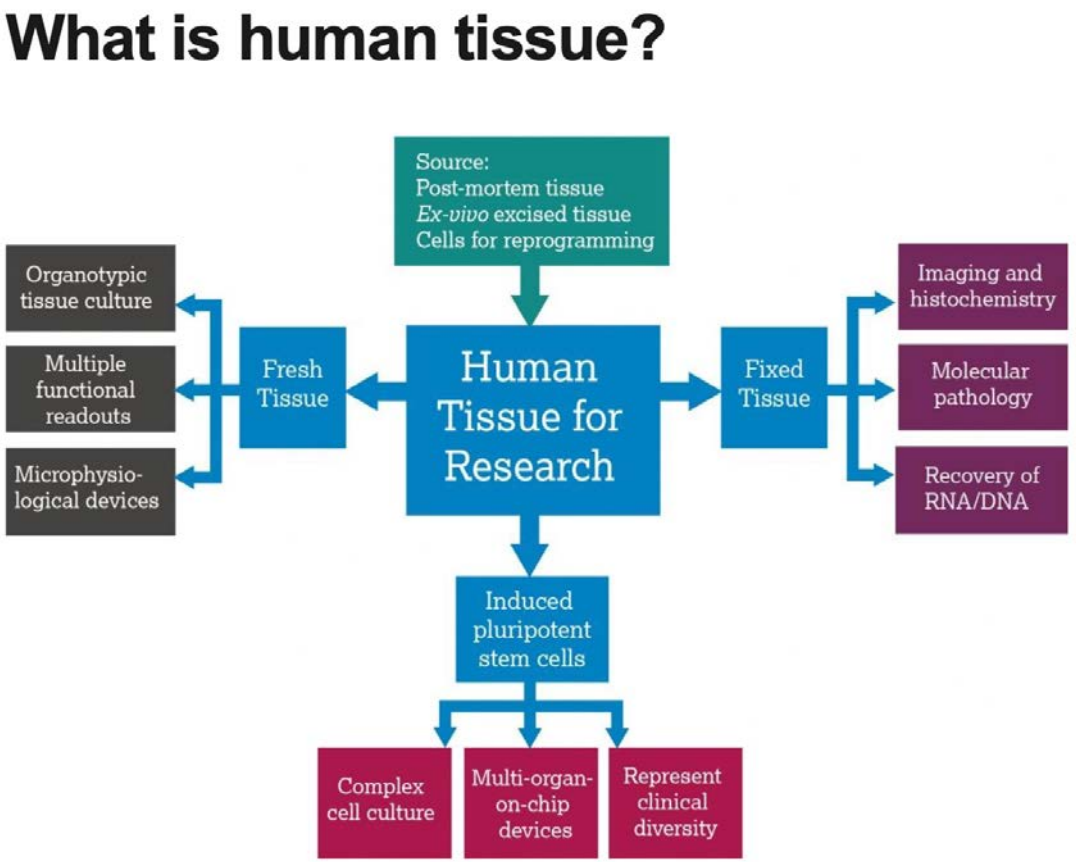
Monday October 2 – Industry and Academic Partners
Monday, October 16 – Non-governmental Organization Representatives
Monday, October 30 – U.S. Government and International Partners

The NIH is gathering input to inform a potential Common Fund research program called “Complement Animal Research in Experimentation (Complement-ARIE)” aimed at development, standardization, validation, and use of **new approach methodologies (NAMs)**. These NAMs are intended to more accurately model human biology, and will complement, or in some cases replace, traditional animal models, transforming the way we do basic, translational, and clinical sciences.



https://www.niehs.nih.gov/news/events/complement-arie

Biobanker av menneskevev



https://www.nc3rs.org.uk/3rs-resources/increasing-human-tissue-use

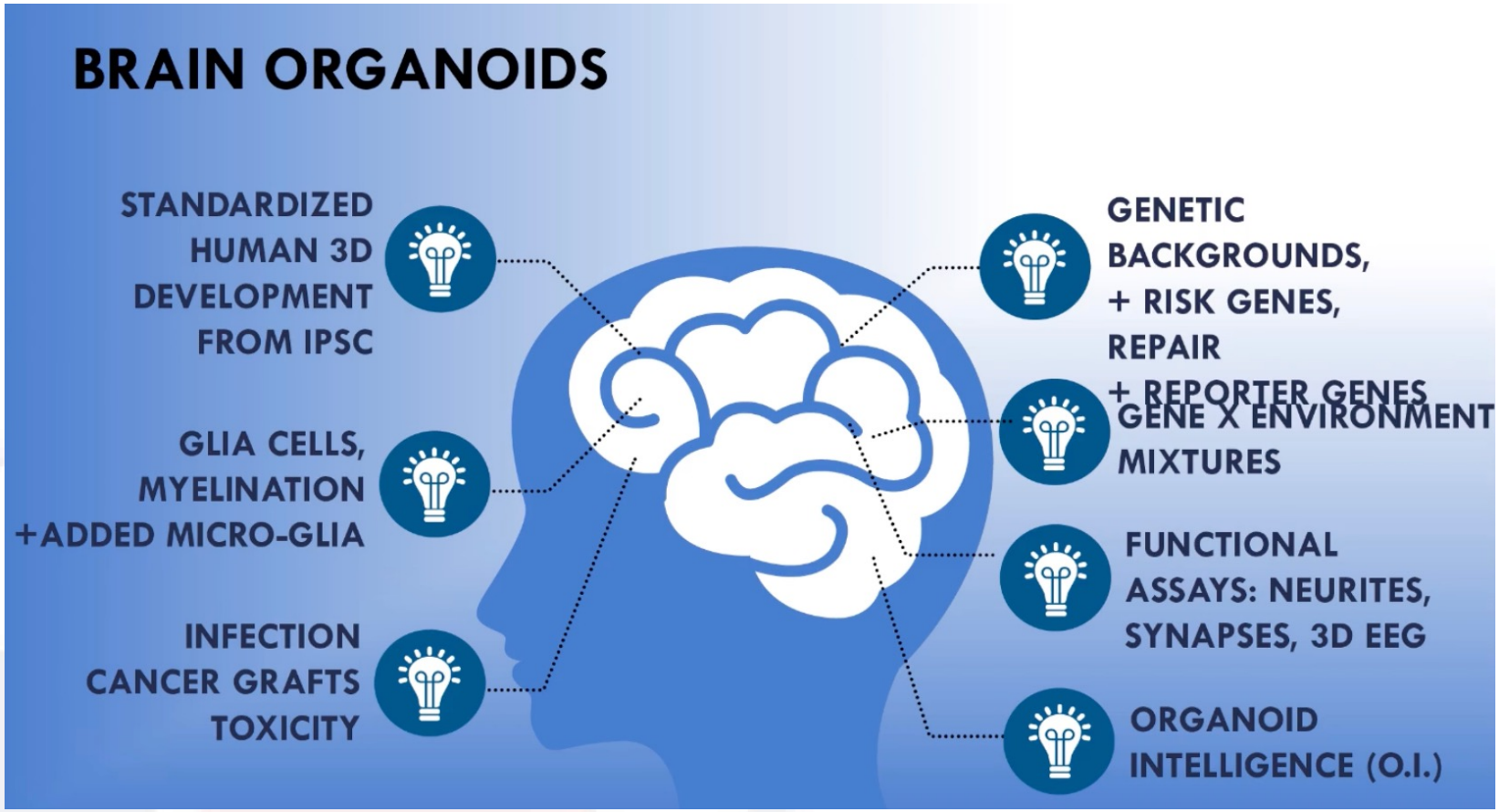
The difficulty lies not in the new ideas,

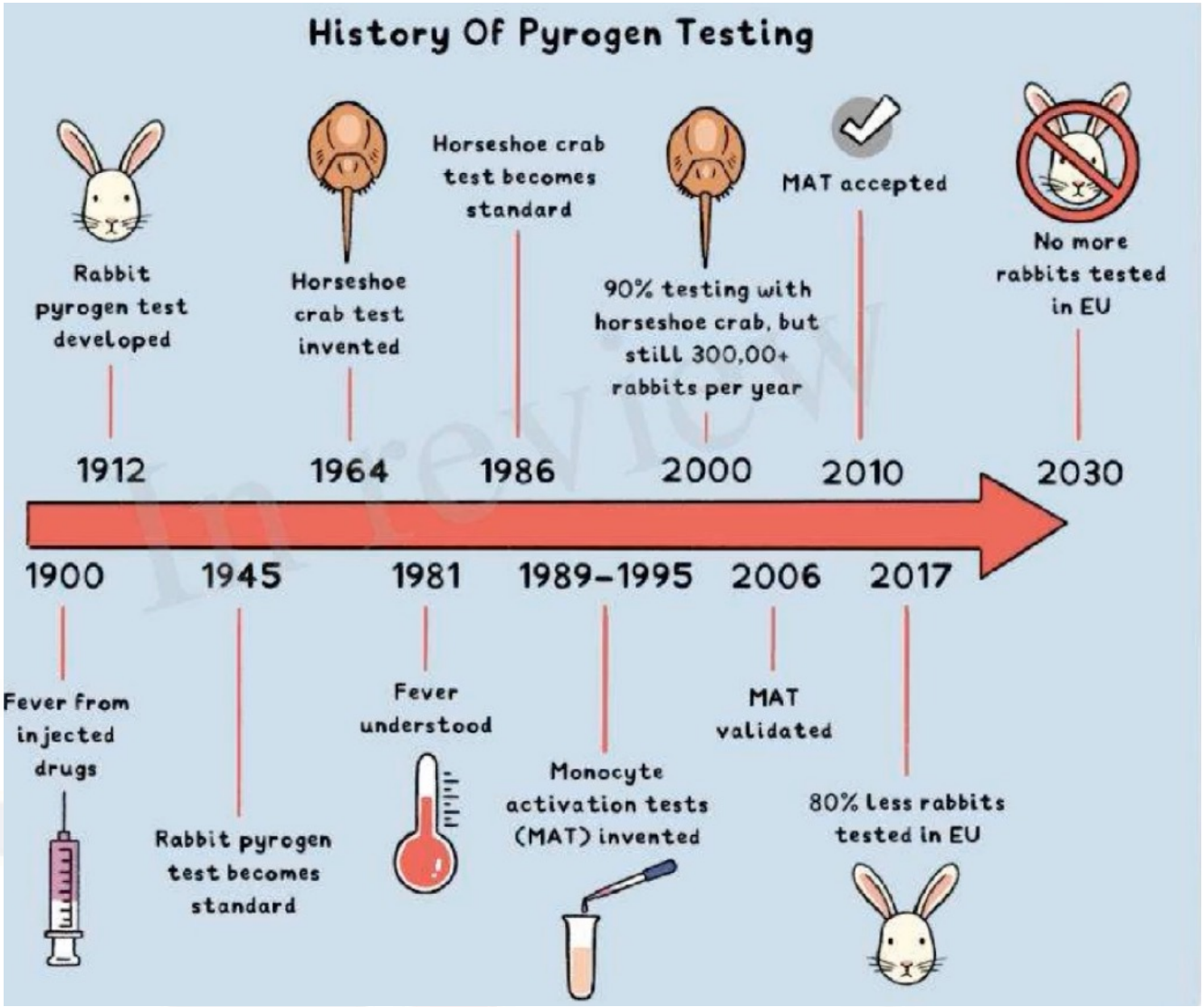
but in escaping from the old ones.

John Maynard Keynes

(1883 - 1946)

https://webinars.elsevier.com/elsevier/Successful-Alternatives-to-Animal-Testing


BRAIN ORGANOIDS
STANDARDIZED HUMAN 3D DEVELOPMENT FROM IPSC
GLIA CELLS, MYELINATION +ADDED MICRO-GLIA
INFECTION CANCER GRAFTS TOXICITY
GENETIC BACKGROUNDS, + RISK GENES, REPAIR
+ REPORTER GENES
GENE X ENVIRONMENT MIXTURES
FUNCTIONAL ASSAYS: NEURITES, SYNAPSES, 3D EEG
ORGANOID INTELLIGENCE (O.I.)



https://webinars.elsevier.com/elsevier/Successful-Alternatives-to-Animal-Testing

The difficulty lies not in the new ideas,

but in escaping from the old ones.

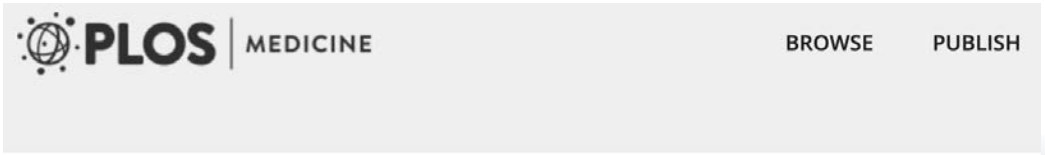
Guidance Document on Good Cell and Tissue Culture Practice 2.0 (GCCP 2.0)

ALTEX 2022, 39:30-70

NATURE | NEWS

Swiss survey highlights potential flaws in animal studies

Poor experimental design and statistical analysis could contribute to widespread problems in reproducing preclinical animal experiments.



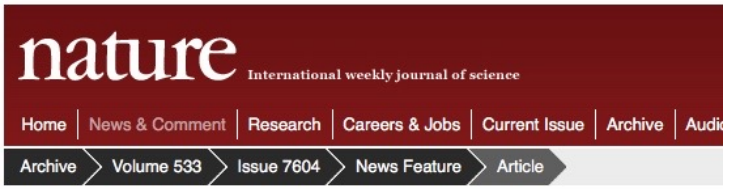
OPEN ACCESS

ESSAY

Why Most Published Research Findings Are False

John P. A. Ioannidis

Published: August 30, 2005 • https://doi.org/10.1371/journal.pmed.0020124



NATURE | NEWS FEATURE

1,500 scientists lift the lid on reproducibility

Survey sheds light on the 'crisis' rocking research.

Monya Baker

25 May 2016 | Corrected: 28 July 2016

More than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments. Those are some of the telling figures that emerged from *Nature*'s survey of 1,576 researchers who took a brief online questionnaire on reproducibility in research.

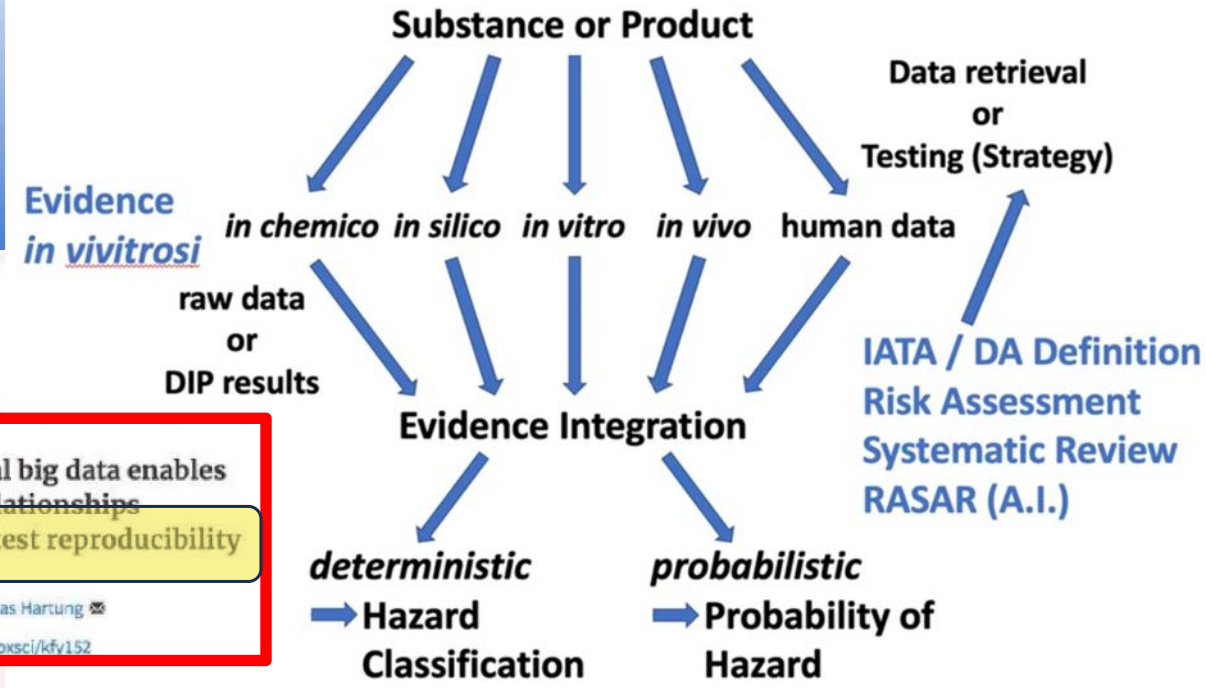
THE LANCET

In vivitrosi

Replacement of animal testing by integrated approaches to testing and assessment (IATA): a call for in vivitrosi

Francesca Caloni[1] · Isabella De Angelis[2] · Thomas Hartung[3,4] Arch Toxicol 2022

Aka Integrated Testing Strategies, IATA, Defined Approaches…



ACCEPTED MANUSCRIPT

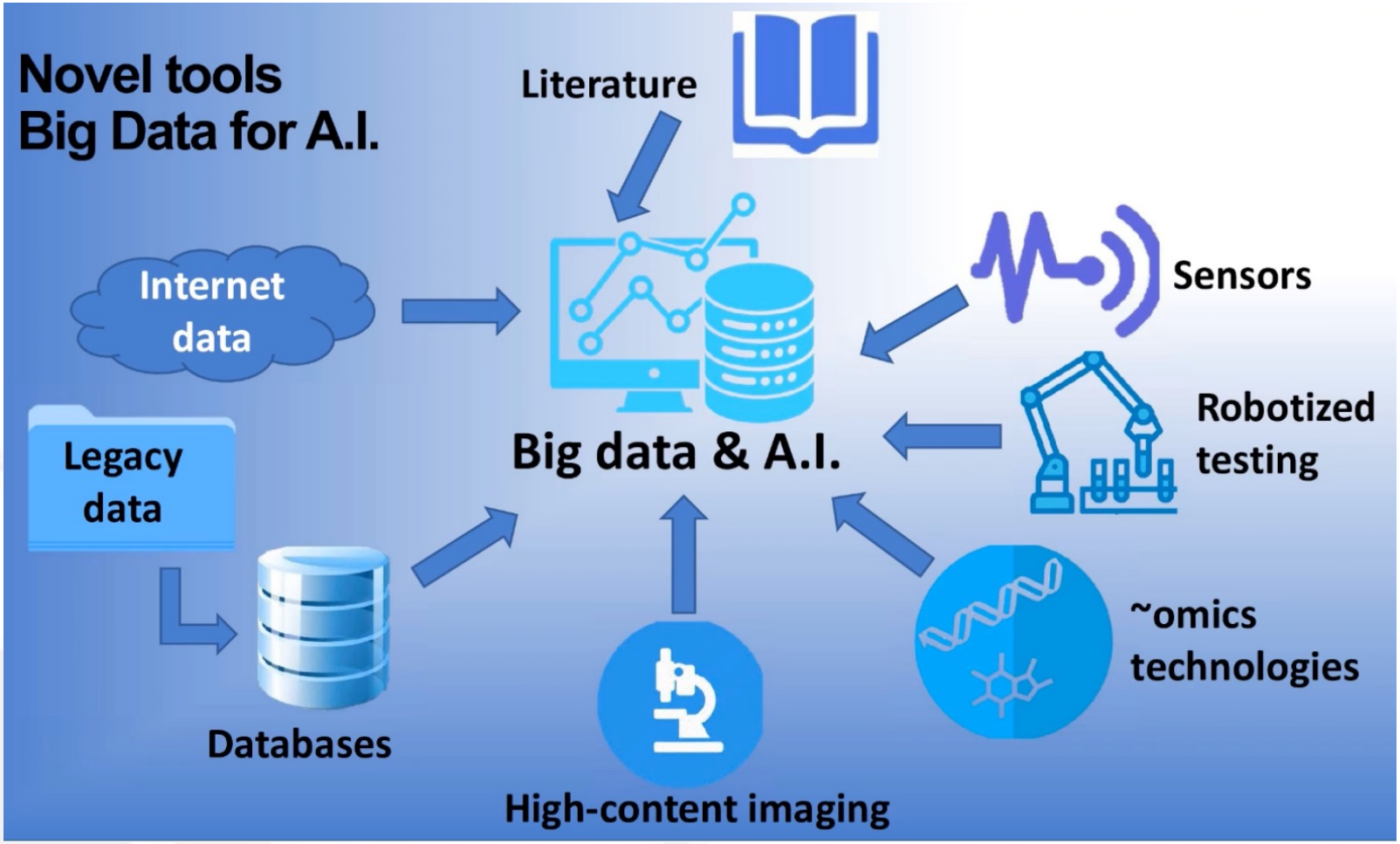
Machine learning of toxicological big data enables read-across structure activity relationships (RASAR) outperforming animal test reproducibility

Thomas Luechtefeld, Dan Marsh, Craig Rowlands, Thomas Hartung

Toxicological Sciences, kfv152, https://doi.org/10.1093/toxsci/kfv152

https://link.springer.com/article/10.1007/s00204-022-03299-x

https://webinars.elsevier.com/elsevier/Successful-Alternatives-to-Animal-Testing



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https://webinars.elsevier.com/elsevier/Successful-Alternatives-to-Animal-Testing

Text analysis...could be exploited to deal with the skyrocketing body of evidence. Integrating this into a "publomics" approach would not only help to tackle the data deluge but also enable evidence-based planning before conducting animal research.

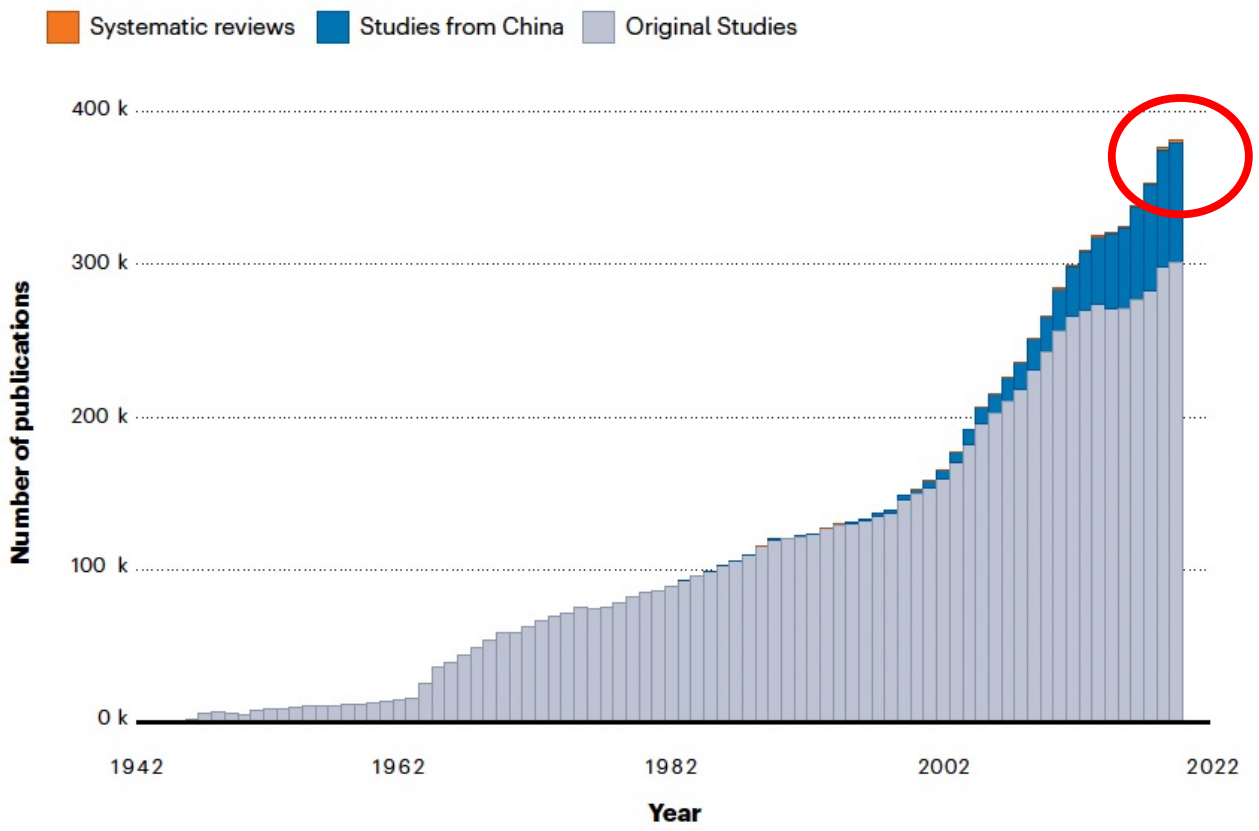
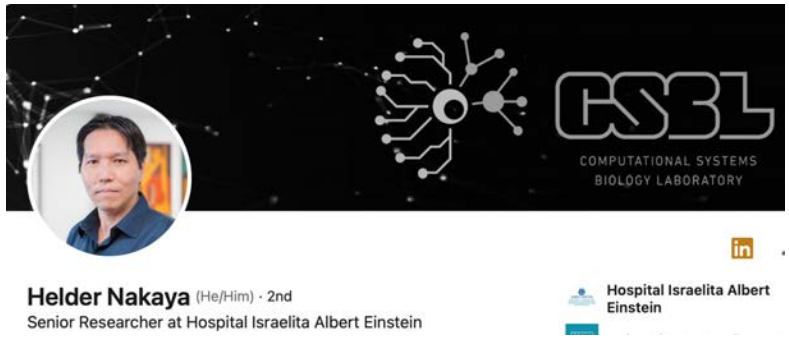


Fig. 1 | The number of newly released publications in animal research is skyrocketing. Today, more than eight million publications referring to animal studies are referenced in PubMed alone (grey), and numbers are likely to increase further with countries such as China (blue) playing an increasingly important role on the global scientific stage. Systematic reviews only make up a small fraction of animal studies (red). Filters and keywords used can be consulted in the supplementary data.

Ineichen, Rosso & Macleod (2023)
https://www.nature.com/articles/s41684-023-01256-4

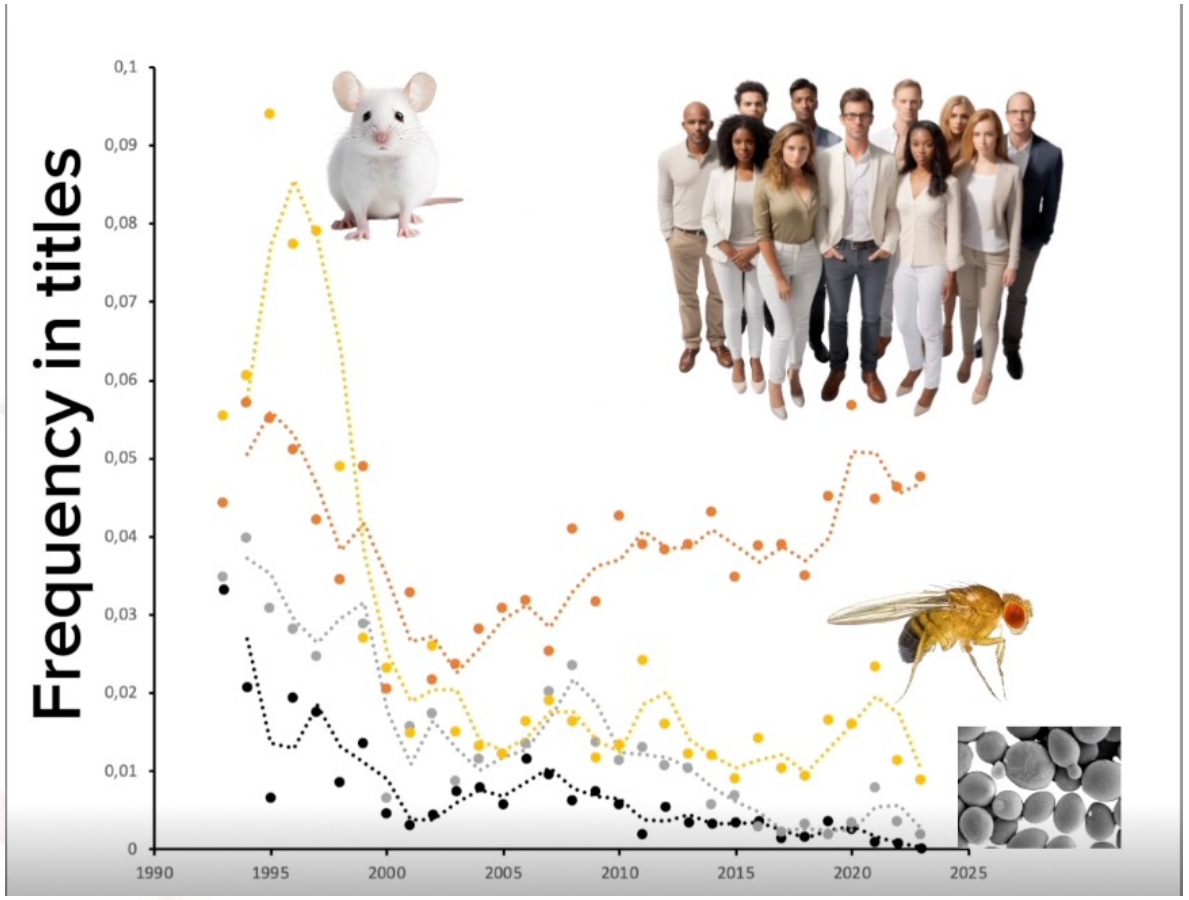


https://www.linkedin.com/in/helder-nakaya-2b249367

norecopa

Analyse av 31.000 artikler, kommentarer og brev publisert i *Nature*

Mer fokus nå på mennesker enn på modellorganismer



Norecopa: PREPARE for better Science

3R Online-Seminar „Alternatives to animal use in research and education – Refine, Reduce & Replace“

Winter semester 23/24

17. november	Brain organoids to model human brain diseases	Agnieszka Rybak-Wolf, PhD

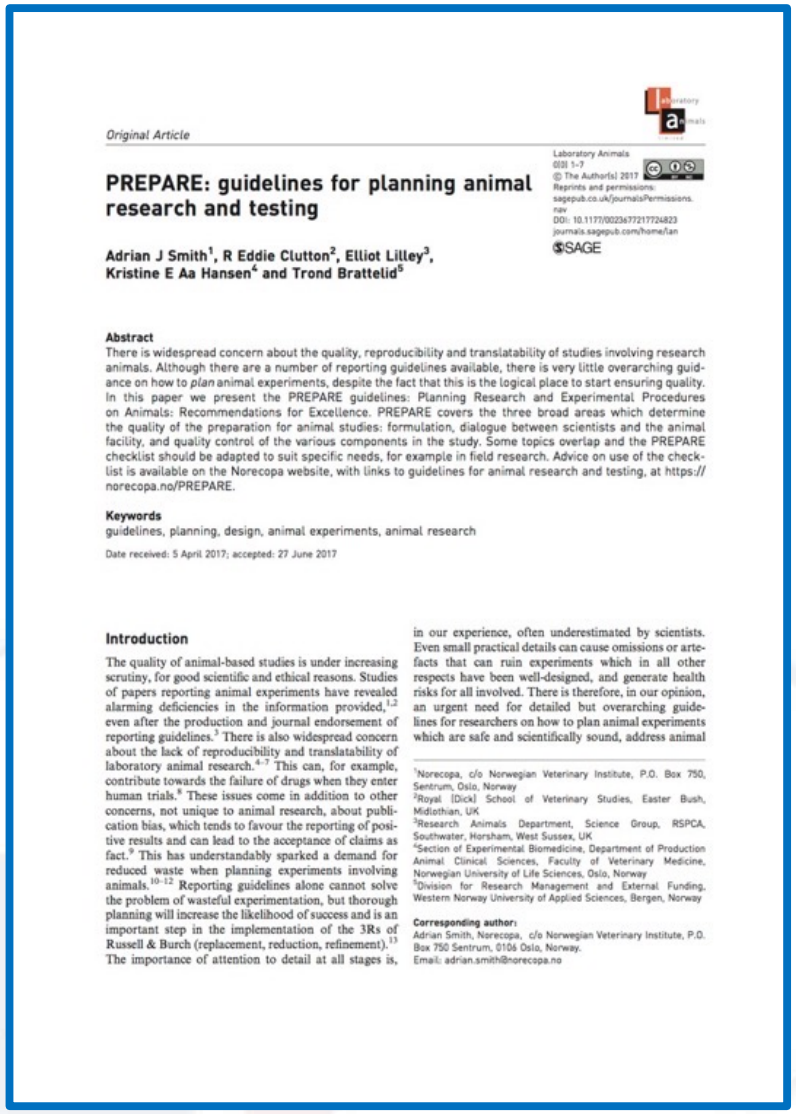
https://norecopa.no/meetings/webinars-and-meetings-calendar

Stien til *better science*

reddit.com

Norecopa: PREPARE for better Science

norecopa.no/PREPARE *og*
ivd-utrecht.nl/en/news/better-animal-research-through-open-science-1



Original Article

PREPARE: guidelines for planning animal research and testing

Adrian J Smith[1], R Eddie Clutton[2], Elliot Lilley[3], Kristine E Aa Hansen[4] and Trond Brattelid[5]

Laboratory Animals
0(0) 1–7

DOI: 10.1177/0023677217724823
journals.sagepub.com/home/lan
SAGE

Abstract

There is widespread concern about the quality, reproducibility and translatability of studies involving research animals. Although there are a number of reporting guidelines available, there is very little overarching guidance on how to *plan* animal experiments, despite the fact that this is the logical place to start ensuring quality. In this paper we present the PREPARE guidelines: Planning Research and Experimental Procedures on Animals: Recommendations for Excellence. PREPARE covers the three broad areas which determine the quality of the preparation for animal studies: formulation, dialogue between scientists and the animal facility, and quality control of the various components in the study. Some topics overlap and the PREPARE checklist should be adapted to suit specific needs, for example in field research. Advice on use of the checklist is available on the Norecopa website, with links to guidelines for animal research and testing, at https://norecopa.no/PREPARE.

Keywords

guidelines, planning, design, animal experiments, animal research

Date received: 5 April 2017; accepted: 27 June 2017

Introduction

The quality of animal-based studies is under increasing scrutiny, for good scientific and ethical reasons. Studies of papers reporting animal experiments have revealed alarming deficiencies in the information provided,[1,2] even after the production and journal endorsement of reporting guidelines.[3] There is also widespread concern about the lack of reproducibility and translatability of laboratory animal research.[4–7] This can, for example, contribute towards the failure of drugs when they enter human trials.[8] These issues come in addition to other concerns, not unique to animal research, about publication bias, which tends to favour the reporting of positive results and can lead to the acceptance of claims as fact.[9] This has understandably sparked a demand for reduced waste when planning experiments involving animals.[10–12] Reporting guidelines alone cannot solve the problem of wasteful experimentation, but thorough planning will increase the likelihood of success and is an important step in the implementation of the 3Rs of Russell & Burch (replacement, reduction, refinement).[13] The importance of attention to detail at all stages is, in our experience, often underestimated by scientists. Even small practical details can cause omissions or artefacts that can ruin experiments which in all other respects have been well-designed, and generate health risks for all involved. There is therefore, in our opinion, an urgent need for detailed but overarching guidelines for researchers on how to plan animal experiments which are safe and scientifically sound, address animal

[1]Norecopa, c/o Norwegian Veterinary Institute, P.O. Box 750, Sentrum, Oslo, Norway
[2]Royal [Dick] School of Veterinary Studies, Easter Bush, Midlothian, UK
[3]Research Animals Department, Science Group, RSPCA, Southwater, Horsham, West Sussex, UK
[4]Section of Experimental Biomedicine, Department of Production Animal Clinical Sciences, Faculty of Veterinary Medicine, Norwegian University of Life Sciences, Oslo, Norway
[5]Division for Research Management and External Funding, Western Norway University of Applied Sciences, Bergen, Norway

Corresponding author:
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Email: adrian.smith@norecopa.no

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Pre-publisert under Open Access 3. august 2017, sponset av Universities Federation for Animal Welfare (UFAW), UK

https://doi.org/10.1177/0023677217724823

Over 30,000 treff / nedlastninger

norecopa.no/PREPARE/prepare-checklist

PREPARE

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[e]

[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, P.O. Box 8146 Dep., 0033 Oslo, Norway; [e]Division for Research Management, Sciences, 5020 Bergen, Norway.

PREPARE[1] består av retningslinjer for planlegging av dyreforsøk. Di
som f.eks. ARRIVE[2]. PREPARE dekker de tre store områdene som b

1. **Designet av studiet**
2. **Dialogen mellom forskerne og dyreavdelingen**
3. **Kvalitetskontroll av de ulike komponentene i studiet**

I praksis vil ikke temaene alltid behandles i den rekkefølgen som e
PREPARE-sjekklisten kan endres for å ivareta spesielle behov, f.eks
dyreavdelinger, fordi laboratorieforsøk er helt avhengige av deres k
Norecopas nettsider, med lenker til globale ressurser, på **https://n**
PREPARE-retningslinjene er et dynamisk sett som vil videreutvikles
produseres, og etterhvert som "best praksis" innenfor forsøksdyrmiljøet forbedres.

Tema	Anbefaling
(A) Designet av studiet	
1. Litteratursøk	☐ Formulere en klar hypotese, med primære og sekundære mål. ☐ Vurdere å foreta en systematisk undersøkelse av litteraturen (Systematic Review). ☐ Bestemme hvilke databaser og informasjonsspesialister som skal brukes, og konstruere søkebegrep. ☐ Vurdere relevansen av dyrearten som skal brukes, dens biologi og egnethet til å svare på de eksperimentelle spørsmålene med minst mulig lidelse, og artens velferdsbehov. ☐ Evaluere prosjektets reproduserbarhet og overførbarhet.
2. Juridiske spørsmål	☐ Vurdere hvordan forsøket er påvirket av relevant lovgivning for dyreforsøk og andre aktuelle områder som f.eks. dyretransport og helse, miljø og sikkerhet. ☐ Finne relevante veiledningsdokumenter (f.eks. EUs retningslinjer for prosjektevaluering).
3. Etiske spørsmål, kostnad-nytteanalyse og humane endepunkter	☐ Skrive et sammendrag av prosjektet på legmannsspråk. ☐ I dialog med etiske komitéer, vurdere om uttalelser om denne typen forsøk er allerede blitt produsert. ☐ Adressere "de 3 R-ene" (Replacement, Reduction, Refinement) og "de 3 S-ene" (Good Science, Good Sense, Good Sensibilities). ☐ Vurdere forhåndsregistrering av forsøket og publisering av negative resultater. ☐ Foreta en kostnad-nytteanalyse ("Harm-Benefit Assessment") og diskutere eventuelle lidelser som kan oppstå under forsøket. ☐ Diskutere læringsmålene dersom dyrene skal brukes i undervisnings- eller treningsøyemed. ☐ Klassifisere prosjektet etter belastningsgraden. ☐ Definere objektive, lett målbare og utvetydige humane endepunkter. ☐ Diskutere behovet (hvis det er noe) for å bruke død som endepunktet for forsøket.
4. Eksperimentelt design og statistisk analyse	☐ Vurdere pilotforsøk og diskutere statistisk styrke og signifikansnivåer. ☐ Definere den eksperimentelle enheten og bestemme antallet forsøksdyr. ☐ Bestemme metodene for randomisering, forhindre observasjonsskjevheter, og bestemme inklusjons- og eksklusjonskriterier.

+ 2 online versjoner
35 språk

Tema	Anbefaling
(B) Dialogen mellom forskerne og dyreavdelingen	
5. Mål og tidshorisont, finansiering og arbeidsfordeling	☐ Arrangere møter med alle relevante personell når tidlige planer for prosjektet foreligger. ☐ Lag en omtrentlig tidsramme for prosjektet, som viser behovene for assistanse med forberedelser, dyrestell, prosedyrer og avfallshåndtering/dekontaminasjon. ☐ Diskutere og legge frem alle forventede og potensielle kostnader. ☐ Lage en detaljert plan for fordelingen av både arbeidsoppgavene og utgiftene, på alle stadiene i forsøket.
	☐ iltetene, for å evaluere bygningsmassen, standarden på utstyret og ☐ perioder med ekstra risiko.
	☐ sen hos personalet og evaluere behovet for videreutdanning og
	☐ foreta en risikoevaluering som omfatter alle personene og dyrene ☐ kte, av studiet. ☐ ere, spesifikke retningslinjer for alle stadiene av prosjektet. ☐ kontaminere og avhende alt utstyret som skal brukes i studiet.
(C) Kvalitetskontroll av de ulike komponentene i studiet	
9. Testsubstanser og -prosedyrer	☐ Oppgi så mye informasjon som mulig om testsubstansene. ☐ Evaluere gjennomførbarheten og validiteten av testprosedyrene, og de praktiske ferdighetene som er nødvendige for å gjennomføre dem.
10. Forsøksdyr	☐ Bestemme egenskapene til dyrene som er essensielle for studiet og som må rapporteres. ☐ Unngå produksjon av overskuddsdyr.
11. Karantene og helsemonitorering	☐ Diskutere dyrenes sannsynlige helsestatus, og eventuelle behov for transport, karantene og isolasjon, samt helsemonitorering og konsekvensene for personalet.
12. Oppstalling og stell	☐ Ta hensyn til dyrenes spesifikke instinkter og behov, i samråd med eksperter. ☐ Diskutere akklimatisering, optimale oppstallingsforhold og prosedyrer, miljøfaktorer og eventuelle begrensninger på disse (f.eks. fasting eller oppstalling i enebur).
13. Eksperimentelle prosedyrer	☐ Utvikle optimale metoder for fangst, immobilisering, merking og frisetting eller omplassering. ☐ Utvikle optimale metoder for å gi dyrene behandling, samt for prøvetaking, sedasjon og anestesi, kirurgi og andre inngrep.
14. Human avliving, frisettelse eller omplassering	☐ Konsultere relevant lovgivning og retningslinjer i god tid før studiet. ☐ Definere de primære metodene for avliving, samt metoder som kan brukes i en nødssituasjon. ☐ Evaluere kompetansen til personene som må foreta disse handlingene.
15. Obduksjon	☐ Lage en systematisk plan for alle stadiene i obduksjonen, inkl. hvor den skal foregå, og identifikasjon av alle dyrene og prøvene som tas.

Referanser

1. Smith AJ, Clutton RE, Lilley E, Hansen KEA & Brattelid T. PREPARE:Guidelines for Planning Animal Research and Testing. *Laboratory Animals*, 2017, DOI: 10.1177/0023677217724823.
2. Kilkenny C, Browne WJ, Cuthill IC *et al.* Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. *PloS Biology*, 2010; DOI: 10.1371/journal.pbio.1000412.

Mer informasjon
https://norecopa.no/PREPARE / *post@norecopa.no* / @norecopa

Norecopa: PREPARE for better Science

PREPARE:

Planning **R**esearch and **E**xperimental **P**rocedures on **A**nimals: **R**ecommendations for **E**xcellence

PREPARE dekker 15 hovedemner:

Designet av studiet

1. Litteratursøk
2. Juridiske spørsmål
3. Etiske spørsmål, kostnad-nytteanalyse og humane endepunkter
4. Eksperimentelt design og statistisk analyse

Dialogen mellom forskerne og dyreavdelingen

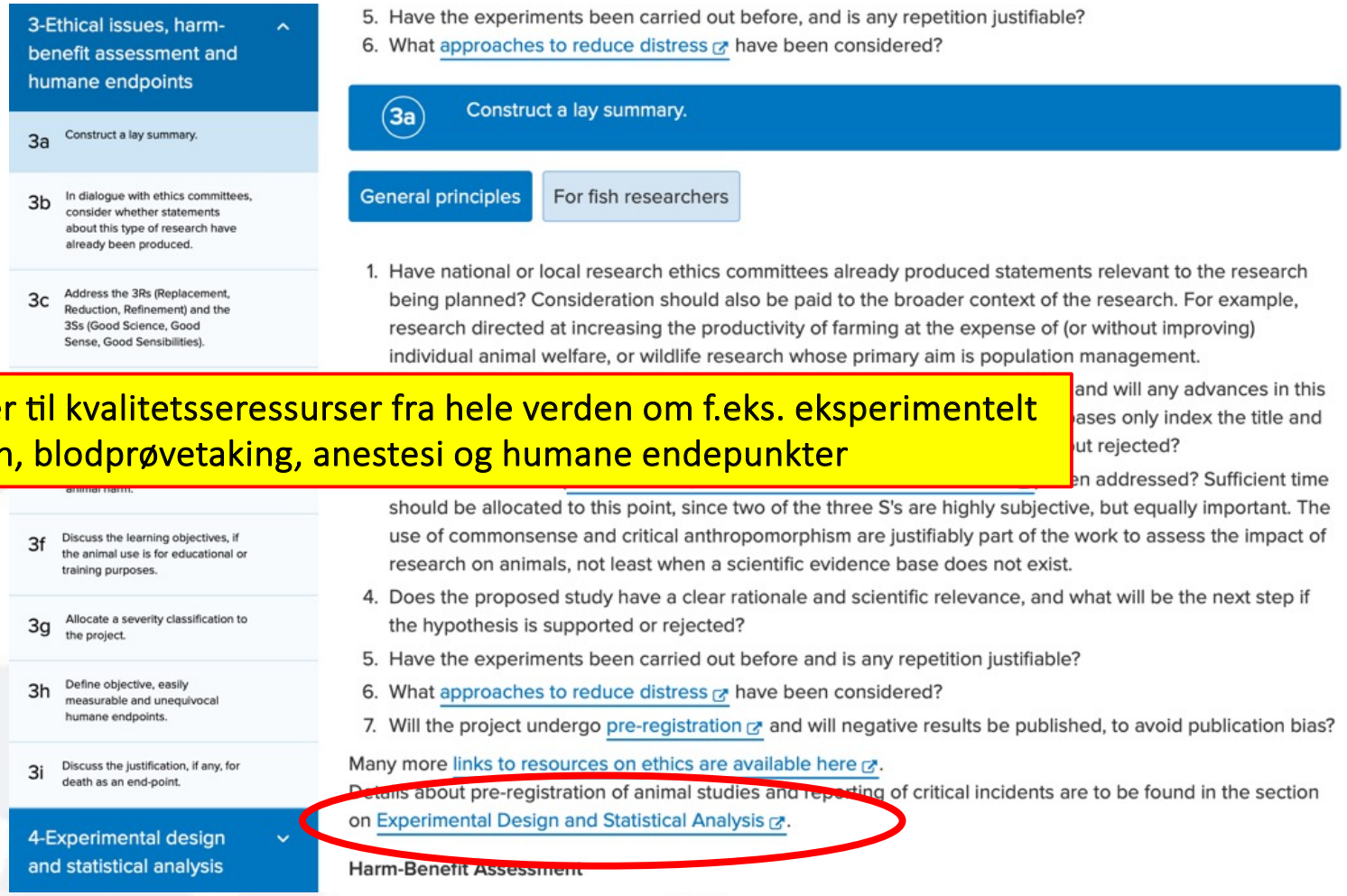
5. Mål og tidshorisont, finansiering og arbeidsfordeling
6. Evaluering av dyreavdelingen
7. Utdanning og trening
8. Helsefarer, avfallshåndtering og dekontaminasjon

Kvalitetskontroll av de ulike komponentene i studiet

9. Testsubstanser og -prosedyrer
10. Forsøksdyr
11. Karantene og helsemonitorering
12. Oppstalling og stell
13. Eksperimentelle prosedyrer
14. Human avliving, frisettelse eller omplassering
15. Obduksjon

Emnene i rosa mangler ofte i retningslinjer for **rapportering** av dyreforsøk

norecopa.no/PREPARE



Lenker til kvalitetsseressurser fra hele verden om f.eks. eksperimentelt design, blodprøvetaking, anestesi og humane endepunkter

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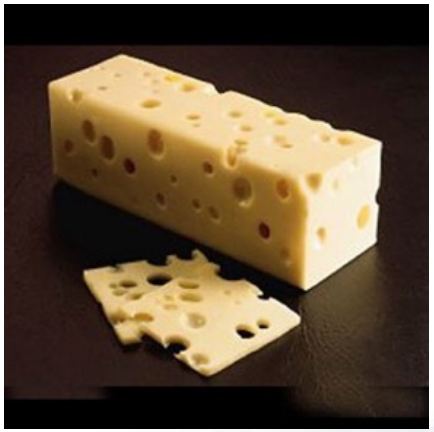
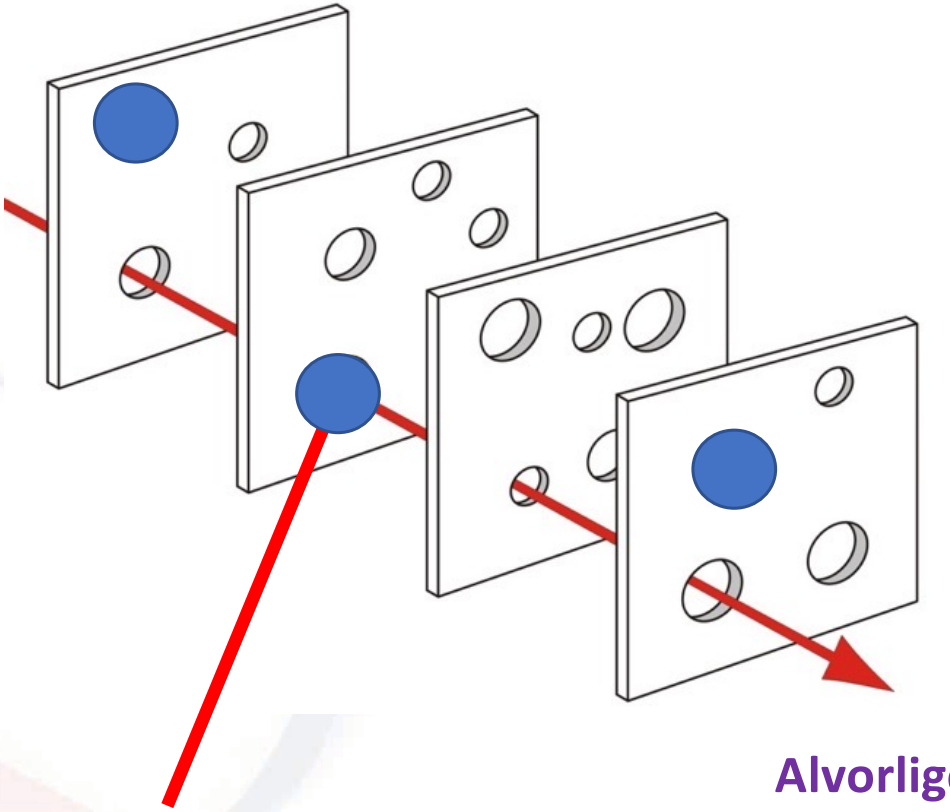
“Threat and Error Management”



eaugallecheese.com/Swiss-Cheese



Svakheter / farer

Alvorlige feil

wikipedia.org/wiki/Swiss_cheese_model

Contingency and redundancy

Det som kan gå galt, vil gå galt... (Murphys lov)

...når det passer dårligst *(Sods lov)*

photo: NVH

Dagbladet.no Publisert fredag 23.04.2010 kl. 18:26

Solveig (38) forsket på kreft, ble selv uhelbredelig syk

Slår alarm om arbeidsforholdene på Radiumhospitalet. Sykehuset innrømmer rutinesvikt.


ASLE HANSEN
ash@dagbladet.no


DIANA BADI
dba@dagbladet.no

HELSEFARLIG ARBEIDSMILJØ: Solveig Garman-Vik (38) har fått diagnosen akutt myelogen leukemi (AML) etter å ha jobbet med kreftforskning på Radiumhospitalet i elleve år. Her får hun en klem av sykepleier Elisabeth A. Saghaug før hun går hjem for helgen. Få med hvor fantastiske alle her på Lovisenberg er mot meg, sier Solveig. Foto: LARS EIVIND BONES/DAGBLADET

https://www.dagbladet.no/nyheter/solveig-38-forsket-pa-kreft-ble-selv-uhelbredelig-syk/65076395

Verdien av retrospektive vurderingar

https://cdfn.se/utvarderingar

https://ui.ungpd.com/Issues/f33401a1-d29c-473d-bebb-9b0fb2b54214

Verdien av retrospektive vurderingar

3R

Djuren har fått adekvat smärtlindring när så krävdes och ensamhållningen minimerades.

FL anger att djur med en skadlig fenotyp bör vägas en ggr/vecka med avbrytande av försöket om en total viktminskning överskrider 15% av högsta vikt eller om en viktminskning av minst 10% ses mellan två mättillfällen.

Övriga kommentarer

Bättre kunskap om avbrytningspunkter för vissa musstammar har erhållits. Vissa försök kommer framgent att kunna göras in vitro enligt FL. Detta kommer minska djuranvändningen.

Etablerad rapportstandard

PREPARE planering	ARRIVE publikation	Annan	Nej
	X		

https://cdfn.se/utvarderingar

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https://ui.ungpd.com/Issues/f33401a1-d29c-473d-bebb-9b0fb2b54214

Et FRAME webinar - anbefales

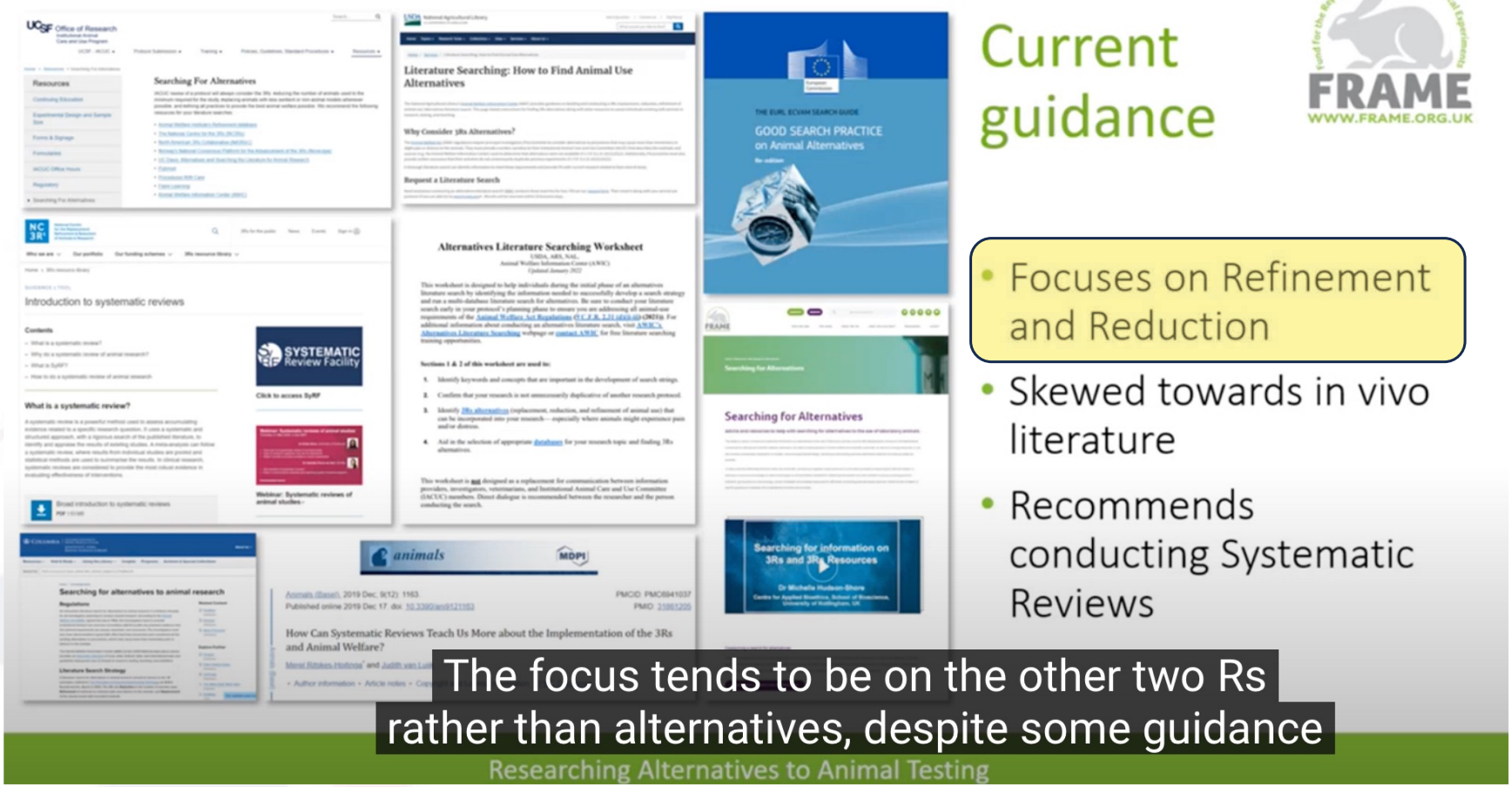
Why is Replacement so poorly addressed?

- Perception that it is the 'trickiest' of the 3Rs
- Lack of knowledge of where to look and how to look
- No labelling: authors and databases rarely use 'alternatives', NATs, NAMs terminology in tags, titles, abstracts or keywords in papers
- Lack of confidence in addressing it
  - Subject-specific
  - Cross-disciplinary solutions
  - Novel tech - adopting new methodology is not straightforward
- Inappropriate guidance is limited and misdirecting
- Focus is on methodology rather than thinking about the goal of the research

We're consistently hear that the R of Replacement is the trickiest of the 3.

Researching Alternatives to Animal Testing

https://www.youtube.com/watch?v=8j3mBb7QEEs



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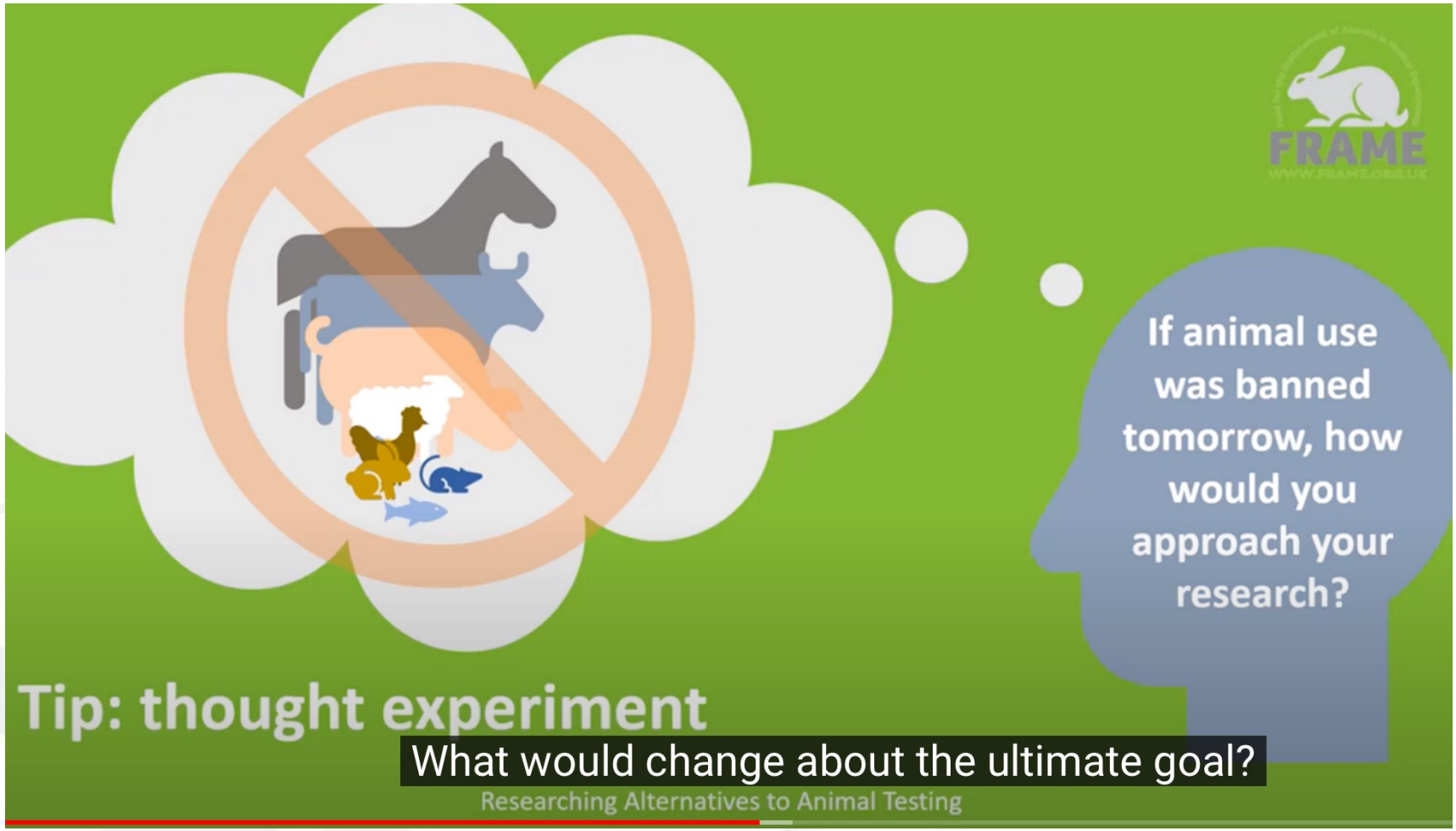
https://www.youtube.com/watch?v=8j3mBb7QEEs



https://www.youtube.com/watch?v=8j3mBb7QEEs

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7. Know how to assess what's out there

FRAME
WWW.FRAME.ORG.UK

- Do retrieved articles cover what you really need?
- Can retrieved protocols replace part of your work?
- Can you adapt or optimise protocols to make them more applicable?
- Remember that 1:1 replacement is rare
- Could a combination of approaches collectively answer the same question?

Researching Alternatives to Animal Testing

https://www.youtube.com/watch?v=8j3mBb7QEEs

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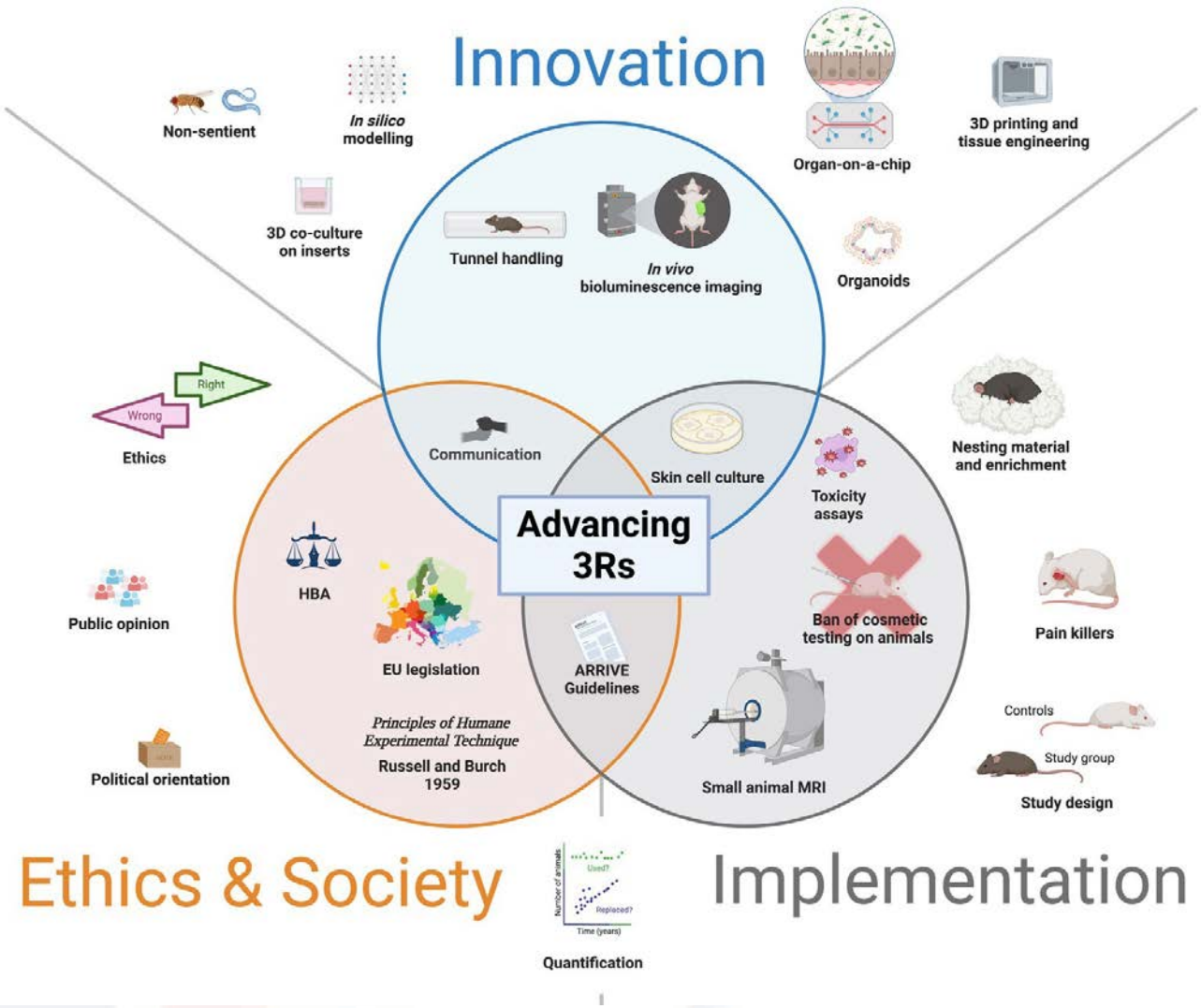
All 'models' have limitations

					2D cell culture	3D cell culture	Human organoids	Organ-on-a-chip
Recapitulation of developmental biology	Y	Y	Y	Y	N	N	N/Y	N/Y
Duration of experiments	Y	Y	Y	Y	Y	Y	Y	Y
Genetic manipulation	Y	Y	Y	Y	Y	Y	Y	Y
Genome-wide screening	Y/N	Y/N	Y/N	Y/N	Y	Y	Y	Y
Physiological complexity	Y	Y	Y	Y	N	N	Y/N	Y/N
Relative cost	N	N	Y	Y	Y	Y	Y	Y
Recapitulation of human biology	N/Y	N/Y	N/Y	N/Y	Y	Y	Y	Y
High throughput screening	N	N	Y	Y	Y	Y	Y	N
Vascularisation	Y	Y	N	N	N	Y/N	Y	Y/N
Ethical concerns	Y	Y	Y/N	Y/N	N	N	Y/N	N

Adapted from: Kim, J., Koo, BK. & Knoblich, J.A. Human organoids: model systems for human biology and medicine. *Nat Rev Mol Cell Biol* **21**, 571–584 (2020). https://doi.org/10.1038/s41580-020-0259-3, and Sokolowska P, Zuchowska A, Brzozka Z. Why Can Organoids Improve Current Organ-on-Chip Platforms? *Organoids*. 2022; 1(1):69-84. https://doi.org/10.3390/organoids1010007

https://www.youtube.com/watch?v=8j3mBb7QEEs



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Grimm *et al*. (2023)
https://www.frontiersin.org/articles/10.3389/fvets.2023.1185706/full


Sustainable
future


History

Engelskspråklige nyhetsbrev

norecopa.no/news/newsletters

7-8 ganger i året

Norecopas 3R-pris
kr. 30.000 + diplom

nr. 4-2023 var den 115. !

- Norecopa's Annual Meeting and 3R Prize
- Updates about Norecopa
- Nordic Zebrafish Network and course
- News of PREPARE
- News of other 3R Centres and activities
- Harmonisation of education and training
- New forum for behavioural research
- New textbook on anaesthesia
- Fish research
- Glimpses from research
- Food for thought
- For Norwegian readers
- From the media
- Webinars and Meetings Calendar
- Have your colleagues subscribed?

Front Pharmacol. 2023; 14: 1225806.
Published online 2023 Jul 19. doi: 10.3389/fphar.2023.1225806

PMCID: PMC10395092
PMID: 37538182

Editorial: Advances in alternative methods in preclinical pharmacology and toxicology

Andresa Heemann Betti, [1] John Gerry Kenna, [2] Terry R. Van Vleet, [3] Palanisamy Aruselvan, [4] and Liz Girardi Müller [5,*]

Review article

New approach methodologies in human regulatory toxicology – Not if, but how and when!

Sebastian Schmeisser [a1], Andrea Miccoli [ab1], Martin von Bergen [cde], Elisabet Berggren [f], Albert Braeuning [a], Wibke Busch [c], Christian Desaintes [g], Anne Gourmelon [h], Roland Grafström [i], Joshua Harrill [j], Thomas Hartung [k], Matthias Herzler [a], George E.N. Kass [l], Nicole Kleinstreuer [m], Marcel Leist [n], Mirjam Luijten [o], Philip Marx-Stoelting [a], Oliver Poetz [pq], Bennard van Ravenzwaay [r], Rob Roggeband [s]...Tewes Tralau [a]

Open Access Review

Whole Liver Derived Acellular Extracellular Matrix for Bioengineering of Liver Constructs: An Updated Review

by Tanveer Ahmed Mir [1,*], Alaa Alzhrani [1,2,3], Makoto Nakamura [4], Shintaroh Iwanaga [4], Shadil Ibrahim Wani [4], Abdullah Altuhami [1], Shadab Kazmi [1,5], Kenchi Arai [6], Talal Shamma [1], Dalia A. Obeid [1], Abdullah M. Assiri [1,3] and Dieter C. Broering [1,3]

Where Have All the Rodents Gone? The Effects of Attrition in Experimental Research on Cancer and Stroke

Constance Holman, Sophie K. Piper, Ulrike Grittner, Andreas Antonios Diamantaras, Jonathan Kimmelman, Bob Siegerink, Ulrich Dirnagl

Given small sample sizes, loss of animals in preclinical experiments can dramatically alter results. However, effects of attrition on distortion of results are unknown. We used a simulation study to analyze the effects of random and biased attrition. As expected, random loss of samples decreased statistical power, but biased removal, including that of outliers, dramatically increased probability of false positive results. Next, we performed a meta-analysis of animal reporting and attrition in stroke and cancer. Most papers did not adequately report attrition, and extrapolating from the results of the simulation data, we suggest that their effect sizes were likely overestimated.

https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002331

Vi utvikler teknologier som kan redusere dyreforsøk i medisinsk forskning

SINTEF-forskerne Linda Sønstevold (t.h.) og Elizaveta Vereshchagina har nylig tatt i bruk et helt spesielt plastmateriale i såkalte mikrofluidbrikker med gode resultater. Teknologien kan blant annet gjøre dyreforsøk unødvendig. Foto: William Husby Hoven

https://www.sintef.no/siste-nytt/2023/vi-utvikler-teknologier-som-kan-redusere-dyreforsok-i-medisinsk-forskning

Noen konklusjoner / påstander

- Forvaltningen vil sjelden være eksperten på alle 3R-mulighetene innenfor fagfeltene som søker om tillatelse til å drive dyreforsøk. I beste fall kan man håpe på at de har litt kunnskap om eksperimentelt design.

- Mye av ansvaret for reduksjon og erstatning må derfor ligge på søkeren, som pr. definisjon skal ha en god oversikt over sitt fagfelt.

- Ifølge regelverket skal det bare søkes om tillatelse til å drive dyreforsøk når det ikke finnes alternativer. Det kan være vanskelig for en forsker å innrømme at de har tatt feil.

- Både de som utvikler potensielle alternativer og de som driver dyreforsøk har en tendens til å «overselge» sine metoder.

- Det er ikke alltid nødvendig å bruke hele dyret hvis det er kun én metabolsk prosess som er av interesse. Det åpner for forsøk på celler, vev og organoider – t.o.m. mennesker.

- Hvis vi egentlig er interessert i å lære mer om prosesser hos mennesker, er ikke det bedre å bruke vev fra mennesker enn å «humanisere» (genmodifisere) dyr?

Takk til Norecopas sponsorer:

- Næringskomitéen, Stortinget
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- Laboratory Animals Ltd.
- Arkitekt Finn Rahns legat
- Nordisk Samfunn Mot Smertevoldende Dyreforsøk
- Dyrebeskyttelsen Norge
- Dyrevernalliansen
- Novo Nordisk
- Sanofi
- Scanbur
- Scottish Accreditation Board
- Stiansen Stiftelsen
- Universities Federation for Animal Welfare (UFAW)
- US Department of Agriculture (USDA)

Grafikk: colourbox.com

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norecopa.no/KPM

nederst på nettsidene

Nyhetsbrevene