Cruelty Free EUROPE

Reporting the predicted harms of animal experiments in the Non-Technical Summaries

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Our 2015 Review of the NTS

2015
Availability:
<50% MS were publishing
7 MS were >18 months behind
Accessibility:
• Grouped
• PDFs
• 27 websites
• Not searchable
Quality:
• Variable at best
• Adverse effects only partially reported

Taylor, K, Rego, L and Weber T. (2018) Recommendations to Improve the EU Non- Technical Summaries of Animal Experiments. ALTEX 35, 193-210.

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Cruelty Free EUROPE

We are a Brussels based network of animal protection groups working to bring animal testing to an end across Europe

We work directly with regulatory bodies (ECHA, EMA) to encourage the use of alternatives and reduction of animal testing

We provide scientific input into EU bodies (EURL ECVAM, NCP, CARACAL), working groups and consultations to ensure animals are taken seriously

We work with members of the European Parliament to ensure animals remain on the political agenda

Netherlands, Croatia, Bosnia and Herzegovina, Ireland, Serbia, Belgium, Finland, France, Portugal, Denmark, Norway, Poland, Spain, Czech Republic, Malta, Italy, United Kingdom, Slovakia

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What changed?

✓ Regulation (EU) 2019/1010 on the alignment of reporting obligations:
- *Centralised database*

✓ Implementing Decision (EU) 2020/569 of 16 April 2020:
- *Common (improved) template*

✓ ALURES database published July 2021

✓ NTS guidance updated Nov 2021

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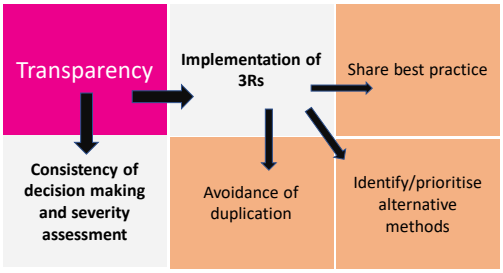
Importance of the Non-Technical Summaries (NTS)



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2013

In the context of what is being done to the animals, what are the **expected adverse effects** on the animals, the likely/expected level of **severity** and the **fate** of the animals?

2020

Elements in Predicted harms section	Completed?
In **what procedures** will the animals typically be used (for example, injections, surgical procedures)?	yes/partial/no
…Indicate the number [**frequency**]	yes/partial/no
…and **duration** of these procedures.	yes/partial/no
What are the expected impacts/**adverse effects** on the animals, for example pain, weight loss, inactivity/reduced mobility, stress, abnormal behaviour, and the duration of those effects?	yes/partial/no
What are the **expected severities** and the numbers of animals in each severity category?	yes/partial/no
What will happen to the animals kept alive at the end of the procedure? [**fate**]	yes/partial/no

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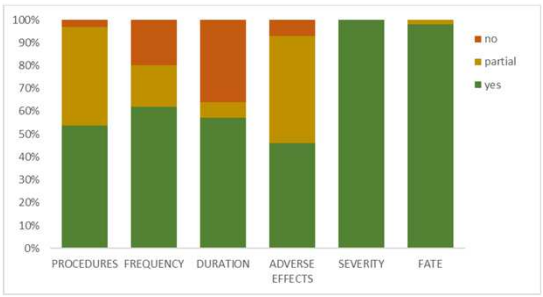
2022 Review of NTS

300 NTS from 2021/22 from the top five animal using Member States:

Germany	France	Spain	Italy	Belgium
N=100	N=50	N=50	N=50	N=50



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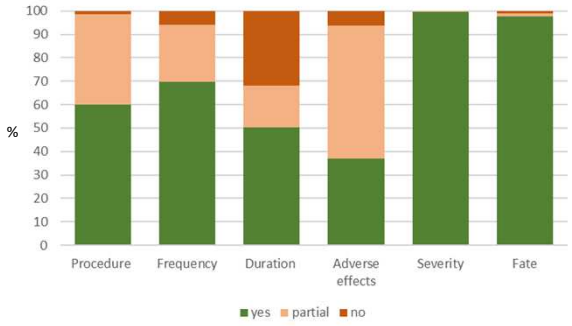
More detailed review of Belgian NTS

300 NTS from 2022:



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Issues with procedural information

- Too vague
  - E.g. 'treated with', 'administered', 'receive', 'induced'
- Too technical
  - E.g. percutaneous instrumentation, cecal ligation and puncture, laparotomy
  - E.g. detail on surgical procedures
  - E.g. use of abbreviations e.g. IV, SC, IP, CT, CLP
- Missing aspects
  - E.g. what is being injected, route of administration, details of behaviour tests
  - E.g. duration of the experiment
- Would it help to have common terminology?

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Issues with adverse effect information

- Talking in terms of *severity level* ascribed to the project, i.e. mild, moderate,
- Forgetting the impact of *what* they are administering to the animal
- Ignoring the impact of any genetic modification
- Struggling to use terms other than pain, weight loss, suffering, stress
- Using humane endpoints instead of actual effects
- Description at odds with severity level
- Missing 'the duration of these effects'

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Unnecessary information

- *All operations will be carried out by trained personnel, so that they will always cause a minimum duration of inconvenience*
- *General health will be monitored daily/ the animals will be closely monitored*
- *The expected negative effects in this study will be reduced to a minimum*
- *The time required for handling the animals is kept to a minimum and all measures are taken to limit stress*
- *When the mice show signs of severe pain or other unnecessary suffering, they will be euthanized*
- *The animals will be euthanized at the end of the trial*

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Issues with keywords

- Not bad!
  - General research area, e.g. immunology and organ/disease of interest, e.g. cancer
- Too technical/specific
  - e.g. MRI - useful?
- Too general!
  - E.g. preclinical, therapy, mouse model
- Repeating words in the title
- Using different terms to say same thing
  - E.g. Cancer research, lung cancer, therapy, cancer cells, tumor model
- Consistency would be useful
  - Disease - in lay person terms, e.g. 'cancer' instead of tumor or oncology
  - Animal model type- e.g. EAE, CLP, GM model

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Recommendations

Users should be encouraged to read the updated NTS guidance document - it does address most of these issues

Competent authorities should be checking the NTS

Competent authorities could consider assisting in the development of agreed wording for:
- keywords
- common procedures
- adverse effects of standard procedures

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