

NC3Rs stakeholder survey: facilitating the development and uptake of new approach methodologies in safety assessment

Overview

The UK National Centre for the Replacement, Refinement and Reduction of Animals in Research (**NC3Rs** <<http://www.nc3rs.org.uk>>) is seeking to identify and prioritise activities to take forward over the next three to five years to support the scientific community in the use of new approach methodologies for safety assessment. This scoping survey is being conducted to gather information from across the community (method developers, conducting laboratories, industry data submitters, data assessors at regulatory agencies, consultants and other relevant stakeholders) on their specific key needs and gaps related to the use of new approach methodologies, and to gather ideas for future activities or initiatives the NC3Rs could initiate to address areas of unmet need in this area.

The NC3Rs recently convened an expert cross-sector advisory group (the **Regulatory Sciences Forum** <<https://nc3rs.org.uk/regulatory-sciences-forum>> core group) to provide strategic steer to the NC3Rs on priority areas in regulatory safety assessment and to support the prioritisation and establishment of future NC3Rs workstreams. This group comprises experts and scientists representing UK regulatory/government agencies, contract research organisations, industry, as well as independent experts. The information from this survey will be used to support this group in prioritising the potential projects and workstreams, and will result in establishing a three-to-five-year workplan in this area. **This is your opportunity to contribute to shaping the NC3Rs' plans for the coming years.**

Further information on completing the survey and its data management can be seen below, please take a moment to read this.

[Start the survey](#) <consultation/>

A link to start the survey can also be found at the bottom of this page.

Further information on completing the survey

Thank you for considering participating in this survey! Before you decide whether to take part, it is important for you to understand why the survey is being done and what it would involve. Please take time to read the following information carefully and discuss with others if you wish. Please contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part and remember that your participation is voluntary. If you decide to take part, we ask you to confirm your consent at the beginning of the survey, prior to beginning the survey.

The survey can be completed in either a personal capacity or on behalf of your organisation. It comprises four components covering:

1. The participant demographic.
2. Current experience regarding new approach methodologies.
3. Suggestions for potential NC3Rs projects and/or initiatives that would be useful in addressing specific challenge areas/key needs.
4. Other information and optional contact details for follow-up.

Multiple ideas can be submitted for Part Three, if desired. The full set of questions in this survey can be viewed [here](#) <<http://link>> . The survey can be completed anonymously. All questions/responses, apart from providing consent to participate, are optional and we appreciate consideration of all questions or a part of the survey, as appropriate. The amount of time taken to complete the survey will be dependent on how much of the survey is completed and whether multiple ideas are submitted in Part Three. It is anticipated that each part will take no longer than ten minutes to complete

Although this survey primarily focuses on new approach methodologies, any information related to wider 3Rs opportunities (e.g. initiatives to support reduction/refinement approaches) can be provided in question 17.

The survey can be saved at any point and returned to.

If you are happy to be contacted for further information in relation to your responses, please provide your email address in Part Four of the survey. Providing this information is optional. Contact details may be used for follow-up by the NC3Rs within six months of the survey closing. This will initially be via email to clarify or gather further information related to your survey response where greater detail would be beneficial to the analysis, and/or to enquire as to whether you would be interested in participating in next steps of the projects that are planned by the NC3Rs as a result of this activity. Not all participants who provide an email address will be contacted, this will be on a case-by case basis. If you provide your optional contact details, you are free to withdraw your responses without giving a reason, up to the point of data collation.

Data Management: The NC3Rs has a strong track record in large data sharing projects. Any identifying data provided in this survey will be treated in strict confidence and only used for the context of this survey. The survey data will be stored on our password-protected server. Data will be blinded prior to its collation and subsequent discussion within the Regulatory Sciences core group (see below). Your identifying information (email address), where provided, will also be kept confidential and will not be used for any purpose except in the context of the survey by NC3Rs staff in the case of follow-up (further information on potential follow-up is provided above). The data management plan for this survey is available on request (please email natalie.burden@nc3rs.org.uk). Participants should not compromise themselves by breaching any non-disclosure agreements (NDAs), company policy or confidentiality requirements, in completing the survey. There is no financial incentive to take part in this survey.

What will happen to the results of the survey? When the survey has been completed, we will analyse the data we have collected and discuss potential recommendations for NC3Rs activities/initiatives within the Regulatory Sciences core group. The anonymised findings may be published (e.g. on the NC3Rs website) and will be presented at scientific meetings or webinars. It will be used by the NC3Rs for future project planning.

What are the possible risks of taking part? There are no anticipated risks to you in taking part in the survey. To mitigate the potential for a risk of a breach of any identifying data that has been provided (i.e. optional email contact details):

- Data will be managed and only analysed by NC3Rs staff.
- NC3Rs staff will ensure all data including any identifying information is stored securely, with access limited to NC3Rs staff, and deleted as soon as it is no longer needed for the purpose of survey follow-up as described above, and the appropriate UKRI corporate policies and standards are applied.
- NC3Rs staff will also adhere and comply with UK legislation, General Data Protection Regulation and Data Protection Act 2018.
- Data will be securely stored using UKRI platforms supported by its Digital, Data and Technology team during the project's lifetime and its data retention period. After exporting the data from Citizen Space, the data will be retained for up to one year.

- Data collected through Citizen Space will be exported onto secure servers provided by UKRI. All responses and any other supporting data will be deleted from Citizen Space within three months of the survey closing.

What are the possible benefits of taking part? There are no direct benefits to you taking part; however, providing the requested information allows a unique opportunity for you/your organisation to contribute to shaping the NC3Rs' plans over the next three to five years to support the wider use of new approach methodologies.

Can I withdraw my data after I have participated in the survey? This will be possible if you provided your email address (which is optional), as long as the request is received before we begin collation of the dataset (anticipated to be immediately after closure of the survey). After this time, we will be unable to withdraw your data.

Who is organising and funding the research? This study is organised and funded by the NC3Rs. More information about the organisation can be found on our website www.nc3rs.org.uk.

Who has reviewed the survey? The survey was developed and reviewed by the Regulatory Sciences Forum core group, consisting of experts and scientists representing UK regulatory/government agencies, contract research organisations, industry, and independent experts.

Ethics approval: Ethics approval has been given by the Social Science Research Ethical Review Board at the Royal Veterinary College, London UK (URN SR2025-00490304).

Mandatory consent to participate

Please read the following statements. If you agree with these and wish to take part in the survey, please select "I understand the above points and consent to take part" at the bottom.

- I confirm that I have fully read and understood all the information in the **Further information on survey completion** section on the previous page and that I have had the opportunity to ask questions.
- If I asked a question I was given a satisfactory answer.
- I understand and acknowledge that this investigation is designed to promote scientific knowledge.
- I understand that my responses collected during the survey may be looked at by individuals from the NC3Rs.
- I understand that the anonymous survey data collected may be used in future research projects but that the conditions on this form under which I have provided the data will still apply.

1 Do you consent to take part in this survey?

(Required)

Please select only one item

- Yes
- No

Part One: Participant demographic

2 Are you completing this survey on behalf of yourself, your organisation, or a specific department within your organisation?

3 Where are you located?

Please select only one item

- UK
- Continental Europe
- North America
- South America
- Asia
- Africa
- Oceania/Australasia

4 Do you work internationally/does your work have application outside of your primary location?

Please select only one item

- No
- Yes - please provide further information below

5 What is your career stage?

Please select only one item

- Early career
- Mid-career
- Established

6 What is your/your organisation's primary area of interest?

Please select only one item

- Protection of human health
- Protection of wildlife/environmental safety
- Both/other - please provide further information below

7 What size is your organisation?

Please select only one item

- Small - <100 employees
- Medium - 100-999 large employees
- Large - >1000 employees

8 How would you describe your organisation? Select all that apply.

Please select all that apply

- Developer of methods to inform assessment of human health or environmental safety (please provide further information below on type of methods/aspects of biology covered)
- Organisation conducting tests to provide safety assessment data to industry registrants (please provide further information below on which assays)
- In-house laboratory within industry product developer/manufacturer (please provide further information below on which assays)
- Industry product developer/manufacturer/submitter of data to regulatory agencies (please provide information below on the industry sector)
- Data assessor/reviewer at a government/regulatory agency (please provide further information on which substance or product type you assess/regulations you implement)
- Consultancy (please provide information below on the industry sectors covered/specific expertise offered)
- Other (e.g. research funder, not-for-profit organisation) – please provide further information below

Part Two: Your current experience regarding new approach methodologies

Definition of new approach methodologies/NAMs

In the context of this survey, new approach methodologies refer specifically to **full and partial replacement** <<https://nc3rs.org.uk/who-we-are/3rs#replacement>> approaches for assessing chemical or drug toxicity. That is, any *in silico*, *in chemico* and *in vitro* technology, methodology, approach, or combination thereof that can be used to provide information on chemical or pharmaceutical hazard and risk ("safety") assessment that avoids the use of intact animals.

9 In what context are new approach methodologies of interest to you/your organisation?

10 For you/your organisation what are the main drivers for your activities in new approach methodologies? Select all that apply.

Please select all that apply

- New business opportunities (e.g. supporting economic growth)
- Potential for increased efficiency in product development process
- More human/species-relevant safety assessment
- Ethical reasons
- The scientific challenge
- Regulatory need
- There are none
- Other - please specify below

11 What resources do you have to support your organisation's new approach methodologies activities? Select all that apply.

Please select all that apply

- Staff
- Research/other funding
- Other - please specify below
- None

12 What resources are currently lacking to support your organisation's new approach methodologies activities? Select all that apply.

Please select all that apply

- Staff
- Research/other funding
- Other - please specify below
- None

- 13** Please share any information on case studies, success stories or positive experiences you have had with new approach methodologies, describing the outcomes and key factors that contributed to the success.

- 14** What specific challenges (at an individual or organisational level) have you have faced regarding new approach methodologies?

Part Three: Suggestions for potential NC3Rs projects/initiatives that would be useful to you in addressing specific challenge areas/key needs

For each of these questions, more than one project or initiative can be suggested. **You can save and return to these questions at any time.**

For all of these questions:

- Please outline the problem to be addressed, how this relates to specific challenges or barriers you have encountered, and the key objective of the proposed project or initiative.
- Please specify whether this relates to implementation/acceptance of new approach methodologies for regulatory purposes, either for UK-specific needs or if applicable to other/multiple regions. If relevant, please describe specific changes or improvements in regulatory guidance and/or within specific with regulatory regimes that would facilitate the implementation of new approach methodologies.
- Please specify which industry sectors this work would apply to, or if it would be relevant across sectors.
- Please specify the **potential 3Rs impact**.
- Please describe any ongoing initiatives you are aware of that are linked/relevant to the suggested project or initiative.
- Where applicable for potential data sharing initiatives, please describe, with specific information: what types of data you would be willing/able to share and any conditions for sharing; what would encourage greater data sharing; and what platforms or infrastructure you currently use for data sharing, and if there any improvements or new features you would like to see in these platforms.

For questions 15 and 17, for each idea suggested, please choose the most relevant category/categories from this list and provide the requested information as far as possible:

- Activity/event that facilitates cross-sector discussion and knowledge exchange.
- Potential collaboration opportunities or partnerships that support implementation of new approach methodologies.
- Training/learning and development programme.
- Establishment of platform/infrastructure for dissemination, information or data sharing.
- Sharing of existing data to enable development of scientific evidence bases that inform recommendations for best practice/enable identification of knowledge gaps.
- Other (please do not include research and development here).

Note regarding question 17 (reduction and refinement opportunities)

Please see the [NC3Rs definitions of the 3Rs](https://nc3rs.org.uk/who-we-are/3rs) <<https://nc3rs.org.uk/who-we-are/3rs>> prior to completing question 17.

- 15** Please describe ideas for specific projects or initiatives that, if taken forward, would be most useful to you or your organisation in addressing challenges you are facing related to new approach methodologies. Note: research and development needs are not in the scope of this question but are covered by the next question.

- 16** Focusing on your technical and scientific area of expertise, please outline any specific R&D needs or opportunities that would support the use of new approach methodologies if they were addressed. These can include key knowledge gaps, technology and innovation opportunities and fundamental research needs that could be addressed through basic or innovation-focused funding.

- 17** Beyond new approach methodologies, in terms of wider 3Rs opportunities (including those related to reduction and refinement of animal use; see note above) please describe any ideas for specific projects or initiatives that would be most useful to you or your organisation.

Part Four: Other information and optional contact details for follow-up

- 18** Please provide any further information, ideas or comments not captured above. This can include information on other potential initiatives or feedback on ongoing NC3Rs initiatives.

19 Are you willing to be contacted for further follow-up related to your answers? If yes, please provide a contact email address. (Note: these contact details may be used for the NC3Rs within six months of the survey closing date, initially via email to clarify or gather further information related to your survey response where greater detail would be beneficial to the analysis, or to enquire as to whether you would be interested in participating in next steps of the projects that are planned by the NC3Rs as a result of this activity).

20 Are you a member of the NC3Rs NAMs Network?

Please select only one item

Yes

No - more information and sign up can be found here: www.nc3rs.org.uk/3rs-resource-library/nams-network