

NAMWISE

Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators

Deliverable 18 (D2.6) Mapping of training and educational resources

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Executive Summary

This deliverable provides a detailed mapping and analysis of educational and training resources related to New Approach Methodologies (NAMs) across the European Union. NAMs include non-animal scientific methods such as *in vitro* systems, *in silico* models, organ-on-chip technologies, and omics-based approaches, which are increasingly critical for developing regulatory toxicology and safety assessments in line with Directive 2010/63/EU and ongoing EC roadmap towards phasing out animal testing.

Using a combination of structured web searches, partner input, and a categorization system developed via Excel-based mapping, over one hundred training initiatives were identified and classified by method, target audience, and training format. The analysis revealed that while a growing ecosystem of resources exists, the overall landscape remains fragmented, under-coordinated, and poorly standardized, especially in terms of regulatory applicability, cross-border accessibility, and harmonized academic curricula.

The discussion is structured around six major stakeholder groups: academic institutions and researchers, students, NAM-developing and NAM-implementing CROs, industry and consultants, and regulatory authorities. Each group faces specific challenges and gaps in training provision. For example, universities lack integrated NAMs curricula, early-career researchers report insufficient exposure to animal-free science, and regulators call for more case-based, decision-relevant education.

Multiple initiatives, such as the COST Action IMPROVE, PARC, EPAA, and student-led platforms like TPI Young and ASPIS Academy, offer promising examples of targeted, innovative training schemes. However, access to NAMs training remains uneven, and many resources are not yet centralized or accredited. Platforms such as PARC repository, TOXlearn4EU or RE-Place illustrate potential blueprints for future EU-wide training hubs.

The report concludes by recommending a harmonized, modular, and stakeholder-specific approach to NAMs training, anchored in cross-sector collaboration and policy support. This mapping provides a foundational resource for NAMWISE and the European Commission to define strategic actions and investments needed to accelerate the mainstream adoption of animal-free testing strategies across Europe.



Glossary

3R	Replacement, Reduction and Refinement of animal procedures
3RsWP	3Rs Working Party
ADME	Absorption Distribution Metabolism and Excretion
AFARA	Animal-Free Assays for endocrine disruption – from science to Regulatory Acceptance
AFSA	Animal-Free Safety Assessment
AI	Artificial Intelligence
ALI	Air-Liquide Interface
ALTEX	Alternatives to Animal Experimentation
AMAP™	Alternative Methods Advancement Project™
AOP	Adverse Outcome Pathways
APCRA	Accelerating the Pace of Chemical Risk Assessment
ASCCT	American Society for Cellular and Computational Toxicology
	Animal-free Safety assessment of chemicals: Project cluster for Implementation of
ASPIS	novel Strategies
ATLA	Alternatives to Laboratory Animals
BCF	Bioconcentration Factor
BMD	Benchmark Dose
BMFTR	German Federal Ministry of Research, Technology and Space
BPR	Biocidal Products Regulation
DB-ALM	Database Service on Alternative Methods to Animal Experimentation
CAAT	Center for Alternatives to Animal Testing
CEO	Chief Executive Officer
CFPD	Computational Particle Fluid Dynamics (model)
CHIASMA	Accessible Innovative Methods for the Safety & Sustainability Assessment of Chemicals & Materials
CIVMs	Complex In Vitro Models
CLP	Classification Labelling and packaging
CRL	Charles River Laboratories
CRO	Contract Research Organisation
CVMP	Committee for Veterinary Medicinal Products
DA	Defined Approach (framework integrating multiple NAMs for regulatory decision-making)
DL	Deep Learning
DNT	Developmental Neurotoxicity
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DPRA	Direct Peptide Reactivity Assay
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
ECOPA	European Consensus Platform on Alternatives
EFSA	European Food Safety Authority
ELIXIR	the European life-sciences infrastructure for biological information
EMA	European Medicine Agency
EMBL	European Molecular Biology Laboratory
EPA	U.S. Environmental Protection Agency
EPAA	European Partnership for Alternative Approaches to Animal Testing
ERA	European Research Area
ERASMUS+	European Union program for education, training, youth and sport
ESTIV	European Society of Toxicology <i>In Vitro</i>
ETPLAS	Education and Training Platform for Laboratory Animal Science
EU	European Union
EU-NETVAL	European Union Network of Laboratories for the Validation of Alternative Methods
EURION	European cluster to improve identification of endocrine disruptors
EURL ECVAM	European Union Reference Laboratory for alternatives to animal testing/European Centre for the Validation of Alternative Methods
EUROTOX	Federation of European toxicologists and European societies of toxicology
EUROOC	Organ-on-a-chip technology in Europe
EUROOCS	European Organ-on-Chip Society
EUSAAT	European Society for Alternatives to Animal Testing
FC3R	French Centre for the Replacement, Reduction and Refinement of animal testing
GHS	Globally Harmonized System
GIVIMP	Good <i>In Vitro</i> Method Practices
IATA	Integrated Approaches to Testing and Assessment
ICCS	International Collaboration on Cosmetics Safety
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ILMERAC	International Life Sciences Institute's Multi-Regional Assessment Center
IMPROVE	3Rs concepts to improve the quality of biomedical science
INERIS	Institut National de l'Environnement Industriel et des Risques



InterNICHE	International Network for Humane Education – promoting alternatives to animal use in education
IVIVE	In Vitro–In Vivo Extrapolation
KE	Key Event (in AOP context)
KEMI	The Swedish Chemicals Agency
LLNA	Local Lymph Node Assay
ML	Machine Learning
MICOFOOD	Mycotoxins and Toxigenic Fungi and their Decontamination Processes (Training school in toxicology organized under the TOXlearn4EU Erasmus+ initiative)
MOOCs	Multi-organ-on-chip systems
NAM	New Approach Methodologies or Non-Animal Methods
NAMWISE	New Approach Methodologies Within Integrated Safety and Efficacy evaluation of chemicals and pharmaceuticals
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NGRA	Next Generation Risk Assessment
NGO	Non-Governmental Organisation
NORECOPA	Norway's 3R centre and National Consensus Platform
OECD	Organisation for Economic Co-operation and Development
ONTOX	Ontology-driven and artificial intelligence-based repeated dose toxicity testing of chemicals for next generation risk assessment
ООС	Organ-On-a-Chip
PARC	Partnership for the Assessment of Risks from Chemicals
PARERE	Preliminary Assessment of Regulatory Relevance (EURL-ECVAM network of regulators)
PB(P)K	Physiologically Based (Pharmaco)Kinetic
PCRM/Nura	Physicians Committee for Responsible Medicine / NURA – provider of free NAM-focused toxicology training
PEPPER	Public-private platform for the pre-validation of testing methods on endocrine disruptors
PETA	People for the Ethical Treatment of Animals
PET	Postgraduate Education in Toxicology
PINK	Pathways towards the Integration of Next generation Knowledge
POD	Point of Departure
PrecisionTox	Toward Precision Toxicology: New Approach Methodologies for Chemical Safety
QSAR	Quantitative Structure–Activity Relationship – computational method used in in silico toxicology
RAB	Regulatory Advisory Board



REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
RE-Place	Belgian national platform for sharing knowledge and training resources on NAMs
RhE	Reconstructed human Epidermis
Risk-Hunt3R	RISK assessment of chemicals integrating HUman centric Next generation Testing strategies promoting the 3Rs
RIVM	National Institute for Public Health and the Environment (Neetherlands)
sc	Steering Committee
sccs	Scientific Committee on Consumer Safety
SETAC	Society of Environmental Toxicology and Chemistry
SOP	Standard Operating Procedure
SOT	Society of Toxicology
TG	Test Guideline
TPI	Transition Programme for Innovation without Animals
TOX-OER	Toxicology Open Educational Resources
TSAR	Tracking System for Alternative methods towards Regulatory acceptance
US-EPA	Environmental Protection Agency (USA)
ValNAM	Validating and implementing New Approach Methodologies in a regulatory context
VHP4SAFETY	Virtual Human Platform for Safety Assessment
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WPx	Work Package X



1 Introduction

1.1 NAMWISE project summary

The vision of the NAMWISE project is to provide a supporting framework to pave a scientifically substantiated way towards a paradigm-shift in (eco)toxicology that will not rely on *in vivo* data. To fulfil its vision, the project will leverage the acquired knowledge on New Approach Methodologies (NAMs) and then gather new input from all stakeholders to refine, improve and optimize their use in regulatory contexts for chemicals and pharmaceuticals. The project will merge under its umbrella inputs from a multi-disciplinary consortium comprising academia, NAM-developers, NAM users (CROs), regulators while reaching out towards societal expectations. The workplan of NAMWISE is organized along farreaching objectives driven by the interest for all the stakeholders:

- To sustain and amplify the momentum built by similar initiatives by combining expertise on *in silico* tools, *in vitro* assays and a widespread network with external projects,
- To provide a pragmatic approach based on case studies for hazard/risk assessment and drug
 efficacy that will guide the project in implementing NAMs strategies. These procedures will be
 submitted to a peer-review to ensure that what the NAM community receives is of a high
 standard,
- To deliver an analysis of requirements in terms of standardization/validation of NAMs that benefits from the input of the PEPPER platform on pre-validation, a unique French initiative on NAMs based on public and private funding,
- To foster fruitful interactions between stakeholders catalyzed by several actions, including a series of workshops and training initiatives targeted on the needs of CROs identified during the project,
- To propose a way forward for solving NAMs' shortcomings and enhancing their drivers.

The work packages of the project are the following:

- 1. Project management and synergies with other initiatives,
- 2. Mapping of the existing NAMs knowledge and frameworks,
- 3. Assessment of the regulatory implementation of NAMs: obstacles and opportunities
- 4. Case studies for the effective use of NAMs for the assessment of chemicals and pharmaceuticals,
- 5. Analysis of the requirements for the validation and standardization of NAMs,
- 6. Communication, dissemination and capacity building.



1.2 Deliverable introduction

This deliverable (D2.6) is part of Work Package 2 of the NAMWISE project, which aims to provide a comprehensive mapping and critical analysis of training and educational resources available across the European Union that are relevant to NAMs. These methodologies, ranging from *in vitro* and *in silico* tools to omics and organ-on-chip, represent a fundamental shift away from traditional *in vivo* testing for chemical and pharmaceutical safety assessments.

The purpose of this deliverable is not only to create an inventory of existing NAM-related trainings but also to evaluate their accessibility, quality, target audience, and relevance to different stakeholder groups: academia, Contract Research Organizations (CROs), industry consultants, and regulatory authorities. In doing so, this deliverable supports the broader ambition of NAMWISE to foster a harmonized and structured educational hub for transition towards animal-free science across the EU.

This report outlines the methodology used to gather and analyze training resources, presents the resulting categorization, and highlights current strengths and gaps in the training landscape. It concludes with practical recommendations for improving the coherence, visibility, and impact of NAMs-related education and training in Europe.

2 Methodology

2.1 Methodology principle and introduction to actions undertaken

Task 2.5 of the NAMWISE project aimed to map existing educational and training resources related to New Approach Methodologies (NAMs) within the European Union.

The main objective was to compile, categorize, and analyze available training opportunities that contribute to capacity building in NAMs, for both academic and professional audiences.

To achieve this, a set of coordinated actions were undertaken since the beginning of the project, including:

- Identification of publicly available training resources;
- Development of a centralized data collection excel sheet;
- Consultation with NAMWISE partners for additional inputs;
- Organization of coordination meetings to refine categories and ensure data consistency.

The research was conducted using a mixed-method approach combining desk research, partner input, and expert validation. The process followed these main steps:

a. Data Collection

Structured online searches across European education platforms, research networks, EU project portals, and institutional websites were conducted. NAMWISE members were asked to provide training which they were aware of. Emphasis was placed on resources openly accessible and relevant to NAMs.

In parallel, a standardized Excel sheet was created to facilitate harmonized data collection.

b. Data Entry, curation and categorization

Entries were systematically added to the Excel sheet. Duplicate entries, outdated links, or low-relevance training were excluded. Some entries were enriched with missing information, when available after checking link contents.

Each training was also categorized based on its primary NAMs category, specifically those related to Replacement (e.g., *in silico* approaches, omics technologies..). Trainings addressing Refinement or Reduction were excluded from the scope. In NAMWISE's context, NAMs are understood as innovative methodologies or tools aimed at replacing the use of animals in scientific and regulatory testing. This categorization enabled a comparative analysis of training offers across different scientific disciplines and target audiences.



Monthly coordination meetings were held within the Task 2.5 members and with other NAMWISE partners to:

- Align on methodology and definitions (e.g. what constitutes a "training resource")
- Share awareness between task members linked to already existing European projects linked to NAMs training.
- Review preliminary data entries in the Excel file
- Ensure cross-task synergies

These meetings contributed to a shared understanding of the project's objectives and quality assurance for data collection.

2.2 Details and chronology of actions

2.2.1 Initial data gathering

Extensive desktop research was conducted using keywords related to NAMs training (e.g. "training for new approach methodologies," "in vitro training," "training for alternative methods to animal testing" in combination with subject areas like "toxicology", "pharmacology", and "chemical risk assessment").

Research was performed using websites of Contract Research Organisations (CROs), regulatory agencies, and academic institutions, such as University course catalogues and open education platforms.

To complement the public search, data were also collected from NAMWISE consortium members via e-mail requests and discussions during the kick-off workshop. Task leaders and partners were asked to contribute by communicating their known training resources from their own networks or previous project experience.

This collaborative approach maximized the diversity and relevance of the database and contributed to a more comprehensive mapping.

Data preliminary gathered consisted in the following:

2.2.1.1 JRC 2017 Table:

AIT (AUSTRIAN INSTITUTE OF TECHNOLOGY GMBH) provided an inventory of NAMs training compiled during the 2015-2017 period and has not been updated since 2017. The compilation of this table had been led by JRC. Most of the information compiled in the table is related to academic training (i.e. from universities and research institutes).

2.2.1.2 FC3R Table:

FC3R through INSERM (INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE), provided a table listing various training courses. A person supervises the weekly update of this catalog. FC3R, being the French representative of 3R network, most of the information gathered in the table is related to academic trainings delivered in France.



2.2.1.3 Altertox table:

Altertox provided the list of training courses they managed between 2016 and 2023. These training courses are also listed on their website.

2.2.1.4 Other publicly available information

This table contains a first list of EU-funded projects and initiatives, as well as a list of training mostly related to NAMs applications and methods for regulatory purposes in Chemical domain.

2.2.2 Refinement of data entries

The absence of expected/on-going update of the JRC table has been confirmed by Professor Maurice Whelan of the JRC (communication by e-mail with CEHTRA). The huge number of provided links was decreased by checking and then disregarding links that were not valid anymore.

Coordinators of potential EU projects firstly identified as of potential interest (namely Risk Hunt3r, Chiasma, Pink) were also contacted. This ensured the inclusion, if any, of domain-specific and emerging/on-going training activities that were not readily visible through public search for this project.

Discussions with identified key partners were organized to gather their view on NAMs training and European landscape associated to this topic:

- Winfried Neuhaus (AIT AUSTRIAN INSTITUTE OF TECHNOLOGY GMBH; member of 3R network)
- Aleksandra Cavoski and Laura Holden (THE UNIVERSITY OF BIRMINGHAM)
- Doris-Lou Demy and Athanassia Sotiropoulos (INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE; member of 3R network)
- Sebastian Hoffman (Institute of Evidence-Based Toxicology)
- Matthieu Duchemin (DM Conseil and lecturer at master degree level in Université Paris Cité)
- Thomas Loret and Laure Geoffroy (INSTITUT NATIONAL DE L'ENVIRONNEMENT INDUSTRIEL ET DES RISQUES INERIS)
- François Douillard and François Busquet (ALTERTOX)

As part of these informal calls, the content of information and details were discussed with those partners who had provided some listed training, checking with them, as far as possible, if their information should be considered relevant. Especially, discussions with Winfried Neuhaus, Doris-Lou Demy and Athanassia Sotiropoulos, as part of project IMPROVE, brought some insights regarding the work done in the context of this "Cost Action" project.

In parallel, a questionnaire was sent to the 3 CRO companies, partners within NAMWISE, to enquire:

- whether they were trainee, or trainer of NAMs or both,
- what kind of NAMs they were dealing with,
- what were the drivers (if developer and/or implementer), when deciding to assist to a training session,
- what support they used to provide their training...



The questionnaire and answers filled in by 2 CRO partners are compiled in Annex 1 of the document. Although this questionnaire was sent as a test for a potential extend of the survey to other CROs, limited information has been found appropriate and used in this report.

From the above data primarily collected, an Artificial Intelligence tool (Biolevate, 2024) was used to include description of the content of each training and to discriminate between the two main categories of audience, namely "Students" and/or "Professionals". This complementary information and additional categorization have been checked manually.

Additionally, it was identified that there were very limited training offers explicitly linked to certain NAM categories such as organ-on-chip (OOC), organoids, and omics. To address this gap, a complementary keyword-based search was conducted using terms such as "training on organ-on-a-chip," "training on organoid," and "training in omics toxicology." The review was further extended with newly available or updated information identified during the work period, including secondary sources retrieved from websites of initiatives, training platforms, scientific literature, and review reports.

Importantly, artificial intelligence tools (Biolevate, 2024) were not used to support the analysis of these additional datasets. This decision was made to ensure a manual review and extraction of only the most relevant information, and to avoid misclassification or oversight that could result from automated processing.

Some links have also been disregarded, because they were clearly out of scope, such as the ones not related to NAMs in toxicology for replacement of animal testing, as well as those associated to reduction (i.e. fake animals) or drug synthesis.

Nevertheless, despite these actions, some limits remained for performing the analysis based on currently available training resources on NAMs in the EU.

2.2.3 Analysis of the data

2.2.3.1 Limits identified:

Two main categories of limits (analysis settings and information source) have been elicited:

a. Analysis settings:

- Broad definition of NAMs (methods, endpoints, regulatory domain of application, non-animal methods, new approach methodologies...),
- Methods and regulatory applications under constant development and with different maturation levels.
- Broad and borderless landscape of NAMs and training:
 - Audience (academic, regulatory authorities, agencies, consulting companies, Contract Research Organizations, universities ...),



- Purpose (scientific principle, regulatory applications, methods development, implementation, handling...),
- Category of a NAM and regulatory domain,
- Format and duration of the training courses (webinar, workshop, congress, master class, lecture at the university, train the trainers...; generic training on (eco)toxicology methods/approach but without being dedicated mainly to NAMs),
- Terminology for describing a training format (https://event-help.stanford.edu/event-publishing/classification-categories-and-terms), trainee status and a type of NAMs.
- Geography: although mapping is limited across the European Union, a vast majority of NAMs training is provided on-line or through distance learning, so that they can be accessed world widely.

b. <u>Information source:</u>

- Awareness:
 - Diffusion channels (Internet page, LinkedIn, communications from email, congress meetings...) and referencing.
 - Diversity of consulted organizations according to their domains of expertise, geography, landscape...,
- Content available through the link:
 - Description of the content of the training was very poor, or, at least, very often not sufficient information reported for deriving the covered categories within the landscape of NAMs and training; absence of description of composition of panel, speakers, during events; only agenda of a symposium, on-line training restricted to members-only ...,
 - Links giving access to other links, or referenced several times because reported individually and indirectly as part of a web platform; various information that could be about NAM but not only training, ...
- Temporality, i.e. period of work for this report from January 2025 to June 2025:
 - Relevance of "old" information, such as past events but that may be recurrent,
 - Existing information gathered that is regularly updated, such as website links not anymore active, so it is not possible to check the listed information provided,
 - Information under development not yet published, new information...

2.2.3.2 Categorization of the NAMs training:

The very first aim was to categorize the European resources for NAMs training associated to replacement of animal testing for chemical risk assessment, according to audience profile and



associated timing objective (long-term versus short-term), content category and whether they were past, on-going or planned for the next future.

Pending on the content presented through the links, NAMs training were listed in the Excel table according to this initial category of NAMs:

- *in vitro* cellular model: a method that takes place outside the human organism or a living system. The study or experiment is carried out in an artificial medium or in an experimental environment. For example, for *in vitro* cell culture, or laboratory methods that enable the growth of eukaryotic or prokaryotic cells in physiological conditions. (National Research Council. 2007).
- **organoid**: a miniaturized and simplified version of an organ, produced *in vitro* in three dimensions that mimics the key functional, structural, and biological complexity of that organ. It is derived from one or a few cells from a tissue, embryonic stem cells, or induced pluripotent stem cells, which can self-organize in three-dimensional culture owing to their self-renewal and differentiation capacities (Ramirez *et al.* 2023).
- **organ on chip**: a multi-channel 3-D microfluidic cell culture, integrated circuit (chip) that simulates the activities, mechanics and physiological response of an entire organ or an organ system (Zhang *et al.* 2018), (Bhatia *et al.* 2014).
- **omics**: refers to the collective characterization and quantification of entire sets of biological molecules and the investigation of how they translate into the structure, function, and dynamics of an organism or group of organisms. Omics are various disciplines in biology whose names end in the suffix -omics, such as genomics, proteomics, metabolomics, metagenomics, phenomics and transcriptomics (Yamada *et al.* 2021), (Subedi *et al.* 2022).
- *in silico*: refers to the use of computer-based models and simulations to predict the biological or toxicological effects of substances, using chemical structure, biological data, or mechanistic knowledge. These methods are entirely non-experimental and rely on algorithms, databases, and mathematical modelling. Common *in silico* tools include: QSARs (Quantitative Structure—Activity Relationships), PB(P)K (Physiologically Based (Pharmaco)Kinetic) Models, Read-across approaches, Molecular docking/simulation (Duan *et al.* 2023)
- artificial intelligence: (AI) in the context of NAMs typically refers to the use of machine learning (ML), deep learning (DL), and related algorithms to process, analyze, and predict complex biological or chemical data. AI learns from large datasets—often generated through high-throughput screening, omics, or imaging—to forecast toxicity, efficacy, or other biological endpoints (Lin *et al.* 2022)
- **imaging**: refers to the use of advanced visualization technologies (e.g., microscopy, fluorescence imaging, high-content screening, 3D imaging) to observe biological and chemical processes without the use of animal models. This includes the ability to monitor cell behavior, molecular pathways, organoid responses, and tissue dynamics in real-time and in high resolution (Guo *et al.* 2019)

Two other categories were also firstly set-up to arrange the information when content described could not fit within the categories above-mentioned:

- replacement (alternatives): This category was applied to trainings identified that were initially developed for traditional toxicology approaches involving firstly animal use, but also potentially NAMs.
- others



Because of all the limits listed and especially the absence of clear delimitation within the different categories of NAMs and the scarce information gathered on NAMs training, no precise figures nor ratios within the landscape were derived for comparing each potential category of NAMs training with each other. Also, the categories used for presenting the NAMs training in this document have been amended, when compared to the initial categories as presented above.

Finally, the high amount of information collected has been used for presenting:

- How to find information on regulatory landscape of NAMs, such as initiatives, platforms, and events?
- What kind of training is proposed for getting an holistic view on the approach on how NAMs can be used, and for major categories of NAMs, and according to your audience status?
- What are the individual gaps per audience and general ones, and some options that may help to fill these gaps?

3 Data collection outcomes

3.1 Gaining access to NAMs within EU

An organization which provides trainings can use different ways for diffusing their training material. This can be through webinar, presentation during workshop, on-boarding training, hands-on, case-studies, summer school, masterclass, Master's degree at the University, Post-graduate course ... The training can be free of charge or after paying a fee or with access limited to members only ... For raising awareness, organizations can communicate through dedicated page(s) within their website, e-mailing and newsletter, professional network, social media such as LinkedIn, ...

As an example, Aquatox-Solutions GmbH, who provides NAMs training on the methods developed in their CRO, mentioned in their answer to our questionnaire (see Annex 1)., that their "training is free via publicly available webinars (Youtube) and talks at conferences (e.g., SETAC and World Congress on 3Rs) and workshops (e.g., NC3Rs workshop on animal alternatives)".

When filling the questionnaire as trainee, both CROs who answered the questionnaire CRL (Charles River Laboratories and Aquatox-Solutions GmbH) mentioned that in order to stay up to date with developments in NAMs, they attend to webinars or conferences, and participate to projects/collaborations, such a VHP4Safety, RiskHunt3R, Afara.

Consequently, this section will refer to platforms, projects or initiatives containing information dedicated to NAMs, including training and education, and some selected events with stakeholders from various sectors organizing the awareness to NAMs. Journals where access to resources dedicated to NAMs are also described.

3.1.1 Projects, initiatives and platforms associated with NAMs trainings:

In the landscape of NAMs training, various projects are dedicated to raising awareness of NAMs. These projects or initiatives can deal with training exclusively or only as part of them. They may include an individual or very few links to training course(s), only events or include large set of training courses through repository lists:

3.1.1.1 Platforms, projects or initiatives including links to NAMs trainings and/or events:

PARC (Partnership for the Assessment of Risks from Chemicals)

PARC is a major European initiative co-funded by the EU's Horizon Europe programme and national partners. PARC aims to advance chemical risk assessment by promoting innovation, collaboration, and the transition to Next Generation Risk Assessment (NGRA) approaches that reduce or eliminate the need for animal testing. Available at: https://www.eu-parc.eu

PARC provides freely a curated repository of NAMs educational resources, accessible via a public platform https://www.eu-parc.eu/news/building-capacities/parcs-repository-learning-and-educational-materials-now-available



TPI (Transition Programme Innovation without animals)

The TPI—led by Utrecht University in partnership with PETA UK and Dutch stakeholders—has launched a Global Education Hub to promote knowledge-sharing and co-creation of resources on animal-free research methods. It includes working groups spanning 18 countries, targeting educators, students, NGOs, and industry. This structured network can create a modular, multi-stakeholder training pipeline, incorporating younger generations and academic institutions. Available at: https://www.animalfreeinnovationtpi.nl

RE-Place

Belgium's national freely available repository lists webinars, lectures, courses, and a database of NAM expertise, explicitly curated for educational and training purposes. It also issues calls for submissions on "Education in laboratory animal science and the 3Rs." RE-Place exemplifies a national-level knowledge hub that could scale to the EU level, centralizing resource visibility and accessibility. Available at: https://www.re-place.be/news/available-educational-and-training-resources-nams

Altertox

On this platform, Altertox list events that they have organized. But it does not give access to the content provided during these events, such as hands-on courses and online training on organ-on chip, in vitro methods, in silico tools, and regulatory frameworks. It is one of the few structured commercial training providers for practical NAMs implementation. Available at: https://academy.altertox.be/services/trainings/

EURL/ECVAM (European Union Reference Laboratory / European Centre for the Validation of Alternative Methods)

Provides free regulatory-aligned NAMs education content and guidance trough Training materials, webinars, Good *In Vitro* Method Practices (GIVIMP), test method protocols, validation documentation for free. Available at: <a href="https://joint-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-reference-laboratories/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam en

InterNICHE (International Network for Humane Education)

InterNICHE is a free, open and diverse network of students, teachers, and animal advocates. It focuses on replacing animals with alternative methods in the teaching of biological, medical, and veterinary sciences and offers a multilingual "Alternatives Database" with teaching tools, case studies, and software aids—supporting educators in implementing non-animal methods. Available at: https://www.interniche.org/fr

PCRM (Physicians Committee for Responsible Medicine)/Nura



NURA offers free educational training in toxicology focused on NAMs that reduce or replace animal testing. The program provides online webinars, on-demand training, and showcases innovative nonanimal methods for regulatory applications. Available at: https://www.pcrm.org/ethical-science/animal-testing-and-alternatives/nura

Pan-European NAMS Platform

NAMs registry and collaborative network (under development). The access is expected to be free; currently focused on stakeholder registration and content aggregation. It contains aggregate NAM tools, provider profiles, and educational materials. Available at: https://airtable.com/app0nDVXhwd3NMGLB/shrSIEWuNPoqBZ76L/tbl9SBetC6PxIHxZa/viwEZOW4aLVd6m8oj

EPAA (European Partnership for Alternative Approaches to animal testing)

EPAA is a public-private partnership between the European Commission and industry that aims to replace, reduce, and refine animal testing by promoting innovative non-animal testing methods (New Approach Methodologies) and supporting their regulatory acceptance in line with the 3R principle. It freely provides sector-specific training materials, regulatory alignment resources, and stakeholder network tools. EPAA's framework exemplifies how public-private collaboration supports industry-targeted training—a format that can be expanded across CROs, SMEs, and regulators. Available at: https://single-market-economy.ec.europa.eu/sectors/chemicals/european-partnership-alternative-approaches-animal-testing/activities-and-events_en

ICCS (International Collaboration on Cosmetics Safety)

ICCS offers a range of educational and training opportunities, including in-person hands-on courses, lectures, panel discussions, webinars, and consultations, covering topics relevant across sectors and including non-animal methods. Available at: https://www.iccs-cosmetics.org/education

AFSA (Animal Free Safety Assessment)

Is a collaborative network developing NAM-based risk assessment strategies likely free; specific programs and resources not clearly advertised yet. The content consists in webinars, case studies, and mapping of NAMs methods—based on project outputs. Available at: https://www.afsacollaboration.org/

PETA (People for the Ethical Treatment of Animals) Science Consortium International e.V.

The International division of PETA collaborates on scientific NAM projects. It is a mixed, open purchase or grant-based access to workshops, reports, e-learning formats and webinars. Available at: https://www.thepsci.eu/early-career-scientists/



ESTIV (European Society of Toxicology In Vitro)

A scientific society dedicated to advancing *in vitro* toxicology science. The ESTIV training course focuses on *in vitro* toxicity methods, particularly in response to European legislative changes that emphasize mechanistically-based decision-making. Member-only access to some content. Available at: https://www.estiv.org/projects-activities/training-course/about-the-course/

PET (Postgraduate Education in Toxicology)

PET (Postgraduate Education in Toxicology) is a well-established Dutch program offering a wide range of advanced toxicology courses for professionals, including several modules on New Approach Methodologies (NAMs). Relevant courses include: New Approach Methodologies for Toxicology; Physiologically Based Kinetic (PBK) Modelling; Read-Across and Chemical Grouping for Regulatory Use; Toxicogenomics and Omics in Risk Assessment. Courses are delivered by academic and regulatory experts and combine lectures, practical sessions, and case studies aligned with current EU legislation (e.g. REACH, CLP, EFSA guidance). The access is not free. Available at: https://toxcourses.nl/courses-list/

ELIXIR - the European Life-sciences infrastructure for biological information

A European bioinformatics infrastructure—supports NAM development through free data and tool sharing. It offers tutorials, webinars, and workflows in computational biology, omics integration, and data reuse. Available at: https://elixir-europe.org/services/tag/training

ECHA (European Chemicals Agency)

Offers free comprehensive guidance documents, regulatory case studies, webinars, and e-learning modules related to EU chemical legislation (REACH, CLP, BPR) and NAMs application in hazard and risk assessment. A list of webinars and events is available at: https://echa.europa.eu/events

EFSA (European Food Safety Authority)

Publishes scientific opinions, guidance documents, updates on methodologies, including *in vitro*-based developmental neurotoxicity (DNT) testing batteries. Provides webinars and case examples. Available at: https://www.efsa.europa.eu

ONTOX – ontology-driven and artificial intelligence-based repeated dose toxicity testing of chemicals for next-generation risk assessment

ONTOX is a Horizon 2020-funded project (2021–2026) under the ASPIS cluster (shared with PrecisionTox and RISK-HUNT3R). Its core aim is to create next-generation risk assessment frameworks using ontology-based data integration, AI modelling, AOP integration and *in vitro/in silico* workflows. ONTOX also develops and shares resources on human-relevant, non-animal NAMs for repeated dose



toxicity. It provides free access to scientific publications, training webinars, and early-career training activities through the ASPIS Academy.

ONTOX also aims to build generic, reusable NAMs to predict systemic toxicity induced by repeated exposures. The focus is on three critical organs—liver, kidney, and developing brain—with two NAMs being developed for each (e.g., for steatosis and cholestasis in the liver). The website is available at: https://ontox-project.eu

EURION Cluster - European cluster to improve identification of endocrine disruptors

Provides publicly accessible resources such as webinars, workshops, case studies, and reports focused on nanomaterials, *in silico* and *in vitro* strategies used within chemical safety assessments. Available at: https://eurion-cluster.eu

EUROTOX - federation of European toxicologists and European societies of toxicology

EUROTOX offers an education program promoting toxicology training at all levels, including recognized certificated courses for professional registration and continuing development. Only meetings and webinars are free. Available at: https://www.eurotox.com/education-program/

EUROoCS (European Organ-on-Chip Society)

EUROoCS is a European scientific society that aims to promote the development and implementation of organ-on-chip technologies for scientific, industrial, and regulatory applications. It brings together academia, industry, and regulators to support networking, knowledge sharing, and standardisation in the OoC field. The society emerged as a direct continuation of the Horizon 2020 EUROoC project (MSCA-ITN, Grant No. 812954). The access to the platform is free for public information but a membership is required for some benefits. EUROoCS plays a pivotal role in advancing advanced *in vitro* models—particularly OoC systems—that are central to the future of NAMs. As an active community hub, it helps shape educational content, coordinate training workshops, and explore standardization pathways for next-generation NAMs. Although it does not yet host structured training offers, its growing influence and technical focus make it a strategic platform for cross-sector education and early-career engagement. Available at: https://euroocs.eu

US-EPA (Environmental Protection Agency (USA))

To implement the Work Plan's objective of "Engage and Communicate with Stakeholders," EPA developed and implemented a NAMs training program in 2021-2023. This program provides users courses and workshop with the appropriate level of oversight to enable them to use EPA NAMs tools and approaches in their own work. Available at: https://www.epa.gov/chemical-research/new-approach-methods-nams-training



3.1.1.2 European projects or initiatives dedicated to NAMs education of students and/or early-career scientists:

ASPIS Academy

Focusing on capacity building for early-career scientists working with NAMs. It provides free training and networking opportunities via registration on the ASPIS website, Webinars, workshops, PhD-level trainings, and summer schools addressing NAMs technologies, risk assessment, and systems toxicology. Available at: https://aspis-cluster.eu/aspis-academy/

PARC Junior

A sub-initiative within the PARC programme aimed at training and mentoring early-career scientists in regulatory science and NAMs. The activities are coordinated through the PARC consortium and can be summer schools, workshops, mentoring sessions on risk assessment, hazard evaluation, and integrated approaches. No dedicated webpage available on the PARC website.

TPI Young

An initiative under the Dutch-led TPI programme engaging early-career researchers in the transition to non-animal methods. The participation to networking events, guest lectures, career guidance, and educational talks are various activities of the program. Available at: https://youngtpi.com

EUROTOX Faculty

The EUROTOX Faculty is to promote education and training of toxicologists. It was created to help foster this mission by bringing together experts in toxicology who are willing to offer their expertise to help train the next generation of toxicologists. Faculty members provide a source of volunteer expertise that will be available to help teach EUROTOX courses as and when they are needed across Europe. Available at: https://www.eurotox.com/faculty/

ERASMUS +

The EU's education funding programme supports higher education mobility, cooperation partnerships, and curriculum innovation—including projects related to NAMs (e.g., TOXlearn4EU, TOX-OER,). It provides a mechanism and funding channel for curriculum development and cross-border training initiatives.

It provides training modules, joint degrees, exchange opportunities, and open educational resources developed through funded projects. Training catalogue available at: https://drive.google.com/file/d/1yz2xGtgU5L16jxIe-v8B gYfR9O9KsEF/view



ToxLearn4EU

This Erasmus+ funded initiative is transforming toxicology education via open-access interactive free e-learning and problem-based methodologies, recorded lectures, and training schools such as MICOFOOD in Valencia. Its final conference in January 2025 gathered participants from across Europe. Freely available at: https://toxlearn4eu.eu/

TOX-OER

Supported by Erasmus+, this Massive Open Online Course platform offers seven free structured modules in toxicology using open educational resources, interactive design, and credit designation across universities in seven European countries. Available at: toxoer.com

EUROoC - Interdisciplinary training network for advancing Organ-on-a-chip technology in Europe)

A completed European research and training project funded under Horizon 2020 through the Marie Skłodowska-Curie Innovative Training Network (ITN). EUROOC (CORDIS Project ID 812954 – 2019–2023) aimed to train a new generation of researchers in organ-on-chip (OoC) technologies, bringing together academic institutions, industry partners, and regulators. It provided PhD-level training through 15 Early-Stage Researchers (ESRs), focusing on development, validation, and regulatory acceptance of OoC models. A platform, the European Organ-on-Chip Society (EUROOCS; see chapter 3.1.1.1 of this document), has emerged from this project. Available at: https://cordis.europa.eu/project/id/812954

Within Europe, some initiatives or programs have worked, as part of their missions and objectives, on definition of training needs on NAMs and building capacities:

3.1.1.3 European projects or initiatives on definition of needs and building capacities related to NAMs training:

ERA (European Research Area) action on NAMs

The aim of ERA action on NAMs is to coordinate and streamline Member States' and other stakeholders' actions on NAMs. This project focusses on biomedical research and regulatory testing of medicinal products and medical devices. It should increase the knowledge of education and training on biomedical research and regulatory testing of medicinal products and medical devices —aligning closely with the NAMWISE goals of harmonisation and shareability. Available at: https://european-research-area.ec.europa.eu

CPBT - Centre for animal-free Biomedical Translation

Centre established in University Medical Center of Utrecht for the development and dissemination of animal-free biomedical innovations and expertise. The centre will implement the developed methods,



tools and expertise together with researchers and companies, and will offer education, training, advice, and support to enhance the acceptance and use of animal-free biomedical innovations.

Available at: https://www.umcutrecht.nl/en/over-ons/nieuws/algemeen/government-invests-in-animal-free-innovations

PARERE; EURL-ECVAM network

This network of national regulators provides upstream regulatory assessment on the relevance of NAMs submitted to EURL-ECVAM. Meetings include updates on the 3Rs and regulatory acceptance. PARERE's regulatory input highlights the need to embed similar regulatory-relevance training for competent authorities and risk assessors. Available at: <a href="https://joint-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-reference-laboratories/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/alternative-methods-toxicity-testing/advisory-and-consultation-bodies/parere-eurl-ecvam-network en

PrecisionTox

PrecisionTox employs a multi-disciplinary approach combining genomics, metabolomics, toxicology, and Al-driven analysis across various model organisms (e.g., zebrafish, flies, nematodes). Its aim is to identify evolutionarily conserved toxicity pathways, contributing to a broader understanding of toxic effects. It has worked on solutions to existing roadblocks (including training) for usage of NAMs in regulation. Available at: https://precisiontox.org

RIVM (National Institute for Public Health and the Environment – Netherlands)

RIVM has issued two reports "The Landscape NAMs", one for chemicals (issued on 05-06-2024) and one for pharmaceuticals (issued on 25-03-2024). These reports provide an overview of which steps (including training) can be taken to implement NAMs in regulatory frameworks. Gaining insight into these steps is essential to facilitate the implementation of NAMs Available at: https://www.rivm.nl/en/alternatives-to-animal-testing/landscape-nams

PARC

PARC aims to provide its partners and stakeholders the opportunity to build and strengthen their skills and research capacities, and thereby contribute to their preparedness to address current and new challenges in the field of chemical risk assessment.

Available at: https://www.eu-parc.eu/sites/default/files/2023-11/PARC%20training%20needs%20survey_short%20report_12.09.2022.pdf

EUROoCS

Educational activities and coordination of training needs are part of their ongoing initiatives.



Within 3R network, some common initiatives or individually by members have been set up for education on NAMs of students and/or early-career scientists. They are concerned with 3R, so that training courses for the replacement of animal procedures are included.

3.1.1.4 European projects or initiatives on NAMs training within 3Rs network:

Cost Action IMPROVE (CA21139 – 3Rs concepts to improve the quality of biomedical science)

Cos Action IMPROVE is mapping 3Rs education across Europe, spanning from secondary school to professional training. It brings together a pan-European network of 3Rs (Replacement, Reduction, Refinement) centres, researchers, educators, and stakeholders with the goal of harmonising and elevating the quality of biomedical research through enhanced 3Rs implementation. They might make the link between NAMWISE and academic institutions in the 3R network. Available at: https://cost-improve.eu; https://www.cost.eu/actions/CA21139/

ETPLAS (Education and Training Platform for Laboratory Animal Science)

ETPLAS hosts an EU-wide course directory covering modules such as "Searching for existing non-animal alternatives" and "Developing *in vitro* methods," along with legal, ethical, and project design training. It was initially focused on lab animal training, but now actively promotes integration of NAMs and 3Rs with free course. The access to the content is freely available at: https://etplas.eu/en

3RsWP (3Rs Working Party)

The EMA 3RsWP is a joint working party of the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Veterinary Medicinal Products (CVMP). It advises these committees on all matters concerning the use of animals in the regulatory testing of medicines, with particular focus on the application of the so-called 3Rs principles - replace, reduce and refine. Available at: https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/3rs-working-party

ECOPA (European Consensus Platform on Alternatives)

The free content available is annual conferences, workshops, consensus statements, and guidance reports on NAMs and the 3Rs, bringing together academics, regulators, and NGOs. Available at: https://ecopa.eu/events/

NORECOPA - Norway's National Consensus Platform for the advancement of "the 3 Rs"



Norwegian advisory organisation promoting 3Rs alternatives and high animal welfare standards. Freely available resources such as: shares guidelines, educational materials, and methodology advice for 3Rs implementation. Available at: https://norecopa.no/education-training/courses/

FC3R (French Centre for the 3R)

FC3R training catalog offering various modules on animal experimentation, the 3Rs (Replacement, Reduction, Refinement) and alternative methods (NAMs), including regulatory courses, webinars and documentary resources. Available at: https://www.fc3r.com/formations/

NC3R (National Centre for the Replacement, Refinement & Reduction of animals in research, UK)

The NC3Rs offers free training sessions on the 3Rs (Replacement, Reduction, Refinement) in animal research, covering topics such as research ethics, experimental design, animal welfare, and practical implementation of NC3Rs resources. Training is delivered across the UK and sometimes internationally. Available at: https://nc3rs.org.uk/3rs-training

CRO developers and implementers collaborate in European projects to develop their skills in NAMs. The ones presented below are those mentioned by CRL when filling in the questionnaire (see details in Annex 1)

3.1.1.5 Selected projects on NAMs in Europe including collaboration with CROs:

PEPPER - public-private platform for the pre-validation of testing methods on endocrine disruptors

PEPPER is a French public—private pre-validation platform for endocrine disruptor testing. The access is free and this platform coordinates pre-validation of in vitro NAMs for endocrine disruption via ring trials and SOP development, it also issues annual "call for methods" to support candidate assays and collaborates on OECD submission. Available at: https://ed-pepper.eu

EU-NETVAL - European Union network of laboratories for the validation of alternative methods

A network of 37 specialized laboratories coordinated by EURL-ECVAM, established under Directive 2010/63/EU to conduct multi-laboratory validation studies of *in vitro* NAMs. The access is free but the selection is based on eligibility; results, SOPs, and reports available via EURL-ECVAM's TSAR (Tracking System for Alternative methods towards Regulatory acceptance) and DB-ALM (Database Service on Alternative Methods to Animal Experimentation). This Network aims to validates candidate *in vitro* NAMs (e.g., thyroid hormone disruption assays, genotoxicity tests, organ-on-chip) via cross-lab ring trials; publishes SOPs, scientific advice, and peer reviews. Available at: <a href="https://joint-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-



<u>reference-laboratories/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/alternative-methods-toxicity-testing/european-union-network-laboratories-validation-alternative-methods-en-</u>

AFARA (Animal-Free Assays for endocrine disruption – from science to Regulatory Acceptance)

The Dutch AFARA (Animal-Free Assays for endocrine disruption – from science to Regulatory Acceptance) project studies the process of acceptance and implementation of animal-free models in the human risk assessment of Endocrine Disrupting Chemicals (EDCs). Available at: https://www.rivm.nl/en/international-projects/afara

RISK-HUNT3R (RISK assessment of chemicals integrating Human centric Next generation Testing strategies promoting the 3Rs)

RISK-HUNT3R develops integrated approaches that combine *in vitro* hazard data, toxicokinetics/toxicodynamics, and human exposure scenarios to enable risk assessment grounded in NAMs. Although the project's deliverables have not yet been made public, a number of publications—some overlapping with ONTOX—have been identified and compiled. It also includes webinars, workshop outputs focus on NGRA. Website available at: https://www.risk-hunt3r.eu

ValNAM (Validating and implementing New Approach Methodologies in a regulatory context)

A joint initiative by BMFTR (German Federal Ministry of Research, Technology and Space) and ZonMw (The Dutch organisation for knowledge and innovation in health, healthcare and well-being) funding call (closing in May 2025) to support validation and regulatory implementation of existing animal-free NAMs toward OECD guidelines or pharmaceutical efficacy testing. The submission is open and participating consortia (EU partners) receive grants. It Funds multi-institutional projects aiming to raise methods toward regulatory readiness; includes supporting webinars and proposal guidance materials. Available at: https://www.valnam.eu/

VHP4SAFETY (Virtual Human Platform for SAFETY assessment)

VHP4Safety project aims to build a platform to protect human health and revolutionize the safety assessment of chemicals and pharmaceuticals by transitioning from animal-based to human-based approaches. By developing in silico tools and in vitro models, it provides a platform for precision safety testing that aims to eliminate the need for laboratory animals. VHP4Safety helps risk assessors evaluate the safety of chemicals for human use, focusing on vulnerable groups like infants, the elderly, and individuals with health conditions. Available at: https://platform.vhp4safety.nl/



3.1.2 Events for European and member states regulatory framework of NAMs

Irrespectively of the audience status, i.e. NAM method user, such as regulator, consultant, industrial, NAM method developer, NAM method implementer, or even as student, considering its status of next-generation risk assessor, stakeholders need to be informed about acceptance of NAMs. Regulatory acceptance of NAMs is an iterative process that is constantly moving.

There are multiple kinds of formats and events, which allow maintained awareness regarding development and regulatory acceptance of NAMs. This can be collective initiatives and participatory. This can be done through lecture, as part of the training program within a master-class event, Master degree cursus at the university..., A very common way is to participate to an event (workshop, symposium, congress, meeting...) dedicated to this topic. Below in this section some events are presented, having been selected to illustrate the variety of the NAMs regulatory landscape and of the stakeholders involved.

3.1.2.1 Event focusing on progress of EC roadmaps:

On 16-17 June 2025, the 3rd workshop on Roadmap towards phasing out animal testing for chemical safety assessments, organized by the European Commission (EC), in collaboration with ECHA, was held in Helsinki (European Commission, 2025). The purpose was to present recommendations and milestone proposals of the roadmap for stakeholder consultation. The audience was very broad, composed of European institution representatives and Member States regulators, industrials, consultants, as well as representatives of Animal Welfare Organizations, CROs and universities.

As part of the discussions, the 15 regulations that are to be considered within the scope of the Roadmap, were mentioned:

- Chemicals registered under the REACH Regulation (ECHA)
- Biocides (ECHA)
- Pesticides (EFSA)
- Food improvement agents (food additives, food enzymes and food flavourings) (EFSA)
- Chemicals used in food contact materials (EFSA)
- Feed additives (EFSA)
- Human medicinal products (EMA)
- Veterinary medicinal products and MRLs for active substances in veterinary medicinal products for food-producing animals (EMA)
- Medical devices
- Chemicals used in materials/products in contact with drinking water (ECHA)
- Chemicals covered by the occupational safety directives CAD and CMRD (ECHA)
- Chemicals used in human nutrition (EFSA)
- Detergents
- Classification, labelling and packaging of chemicals (ECHA)
- Water and Waste legislation (identification of priority substances)



Among these safety assessments, agencies and regulations, the ones related to cosmetic products are not listed. Indeed, the testing ban on finished cosmetic products has been applied since 11 September 2004 and the testing ban on ingredients or combination of ingredients has been applied since 11 March 2009.

3.1.2.2 Event focusing on regulator needs:

During the Nordic NAM Training and Networking event lasting 2 days European and Nordic regulators were brought together to build capacity in assessing and interpreting NAM data. Day 1 provided European regulators with the latest updates on NAMs within different regulatory frameworks.

Presentations began with a keynote speech on the EU Commission's roadmap for phasing out animal testing in chemical safety assessments. Experts from European Chemical Agency (ECHA), European Food Safety Authority (EFSA), Scientific Committee on Consumer Safety (SCCS) and other key organizatons (namely OECD, Swedish Chemicals Agency (Keml), DG JRC, US-EPA) highlighted their ongoing NAM-related initiatives. Participants gained insights into global efforts, such as the ongoing work at the GHS on non-animal methods in health hazard classification, and updates from the OECD on NAMs in Test Guidelines. The day also covered practical experiences of performing risk assessments with NAMs and a forward-looking session on the future regulatory framework for chemicals in the EU, titled "Chemicals 2.0." Together, these presentations provided participants with essential knowledge and context for the role of NAMs in Europe's evolving regulatory landscape.

Full report associated to this event is available on-line (Nordic Council of Ministers, 2022)

Although the event featured a large panel of speakers, neither the EMA nor any organization directly associated with pharmaceuticals or medical devices was represented. It is worth noting that no event could be identified that focused on the regulatory acceptance of NAMs and included representatives from both pharmaceutical/medical authorities and other regulatory bodies simultaneously—although such an event may have taken place. In any case, this topic is actively discussed within the community. A major European initiative has recently been launched (see "ERA action on NAM" in section 3.1.1.3 of this report). Furthermore, the pharmaceutical industry's development of an actionable roadmap based on a 'three-basket approach' for phasing out animal testing is seen as a valuable contribution to advancing a non-animal testing regulatory framework (European Commission, 2024).

3.1.2.3 Event involving on the pharmaceutical or medical devices community:

A series of five workshops on integrating NAMs into regulatory nonclinical pharmaceutical safety assessment was conducted with 13 international experts, including regulators, preclinical scientists, and NAM developers. The objective was to identify feasible NAMs and explore their application in specific safety assessment contexts.

During these sessions, participants developed four conceptual 'maps' illustrating how NAMs can be applied to assess the safety of the liver, respiratory, cardiovascular, and central nervous systems. Each



map outlines the relevant endpoints measured, the tools used (e.g., cell types, assays, platforms), and highlights existing gaps where further development and validation of NAMs are still needed.

Additionally, concise lists summarizing the advantages of NAMs, barriers to their adoption, and factors likely to promote their uptake derived from these workshops are available online (Turner et al., 2023).

3.1.2.4 Events organised by animal welfare NGOs:

Two expert panel discussions on non-animal NAMs in the context of regulatory safety assessments were convened as webinars (Courtot et al., 2025). These events were initiated and hosted by the scientific committee Pro Anima, with the participation of internationally recognized experts in the field. The discussions provided a comprehensive examination of the evolving global landscape concerning the regulatory acceptance and harmonisation of NAMs. Key themes included the scientific and regulatory challenges associated with NAMs, the importance of multi-stakeholder engagement, validation and standardisation hurdles, and international initiatives aimed at facilitating their broader and more effective integration into regulatory decision-making processes. The panels also addressed the transformative potential of emerging technologies—particularly Al—in advancing NAMs, and highlighted illustrative case studies, ongoing initiatives, and both the opportunities and limitations currently facing the field.

In conclusion, while each regulatory domain maintains specific requirements regarding data generation and the degree of NAMs acceptance for chemical safety assessments, there is a growing convergence around shared methodological frameworks and categories. This alignment supports the overarching objective of progressively phasing out animal testing in chemical safety evaluations across Europe.

During this transitional phase, several targeted initiatives and events have emerged, focusing specifically on the application of NAMs to newly prioritized toxicological endpoints from a European regulatory perspective.

3.1.2.5 Events focusing on NAMS and some emerging toxicological issues:

For endocrine properties and NAMs, some meetings/symposiums/workshops of particular interest were identified. These events were intended for the Professionals working in the field of regulatory affairs, registration, risk assessment, toxicology, ecotoxicology. The discussions were dealing with regulatory requirements and NAMs methods, methodologies presentations from experts from industry and/or authorities in charge of assessment for endocrine disruptions.

ChemAcademy organizes in September 2025 "11th International Conference Endocrine Disruptors" (END-2025). Akademie Fresenius organizes "A Practical Guide to the ECHA/EFSA Endocrine Disruptors Guidance: Biocides, REACH and PPPs" in July 2025 (programm 01tbH0000071z2DQAQ 00PbH00000KhL2ZUAV.pdf). The same organization organized in February 2023 "Assessment of Thyroid Disrupting Chemicals".

Focusing on validating of NAMs methods, PEPPER (public-private platform for the pre-validation of testing methods on endocrine disruptors) has organized a one-day symposium in December 2024



"ENDOCRINE DISRUPTORS accelerating methods validation to improve our protection" (Programme PEPPER-symposium-0612 EN.pdf).

One key event occurred in March 2022 that was organized by EFSA (European Food Safety Authority) on NAMS and developmental Neurotoxicity. This 2-day event is named "European stakeholders' workshop on new approach methodologies (NAMs) for developmental neurotoxicity (DNT) and their use in the regulatory risk assessment of chemicals". All the presentations are available at https://www.efsa.europa.eu/en/events/european-stakeholders-workshop-new-approach-methodologies-nams-developmental-neurotoxicity.

The ESTIV 2026 Congress is the flagship scientific meeting of the European Society for Toxicology *In Vitro* (ESTIV), to be held in Ljubljana, Slovenia. This biennial congress brings together leading researchers, industry experts, regulators, and early-career scientists focused on advancing *in vitro* and *in silico* toxicology, with strong emphasis on NAMs. The congress will cover cutting-edge topics such as organ-on-chip, omics technologies, computational toxicology, regulatory science, and translational applications. ESTIV 2026 aims to foster cross-sector dialogue, highlight educational initiatives, and promote scientific innovation that supports the replacement of animal testing in toxicology and biomedical sciences. It also serves as a platform for early-career development through poster sessions, awards, and dedicated networking activities. The event website is available at: https://www.estiv.org/congress2026/.

Another event of interest is the EUSAAT Congress. It's the annual scientific meeting of the European Society for Alternatives to Animal Testing (EUSAAT), serving as one of the most prominent European platforms dedicated to the 3Rs. The congress brings together researchers, educators, industry representatives, regulators, and advocacy groups to present and discuss advancements in NAMs, including *in vitro*, *in silico*, organ-on-chip, imaging, and Al-driven tools. Special focus is also placed on regulatory acceptance, NAMs education, and the ethical dimensions of animal-free science. The event features keynote lectures, scientific sessions, training workshops, and student awards. The next edition of the congress will be held in 2027, continuing its mission to foster dialogue, knowledge exchange, and cross-sector collaboration for the advancement of humane science. The link to the last event held in 2024 is available at: https://eusaat.eu/eusaat-congress/24th-edition/congress-2024/.

Some journals provide access to resources dedicated to NAMs.

3.1.2.6 Scientific journal

NAM Journal (open access)

NAM Journal embraces these recent advancements by serving as a hub for dissemination and worldwide exchange of information regarding state-of-the-art NAM developments. *NAM Journal* welcomes original research papers, review papers, opinion papers and meeting reports dealing



with NAM production and their use in human toxicology, ecotoxicology, chemical risk assessment and biomedical research, amongst other fields. While focus is put on full replacement of animal

ALTEX – Alternatives to Animal Experimentation

ALTEX is a peer-reviewed, open-access journal published by the Swiss Society ALTEX Edition. It is the official journal of the European Society for Alternatives to Animal Testing (EUSAAT), the American Society for Cellular and Computational Toxicology (ASCCT), and the Center for Alternatives to Animal Testing (CAAT). The journal focuses on the development, validation, and application of alternatives to animal experimentation, with a strong emphasis on NAMs. It publishes original research, reviews, and policy articles on *in vitro*, *in silico*, organ-on-chip, omics, and Al-based methods. All issues and articles are freely available at: https://www.altex.org

ATLA - Alternatives to Laboratory Animals

ATLA is a peer-reviewed journal published by FRAME (Fund for the Replacement of Animals in Medical Experiments). It has a long-standing role in promoting the 3Rs (Replacement, Reduction, Refinement) and now increasingly covers New Approach Methodologies. The content can be articles on method development, validation, and regulatory acceptance of NAMs, case studies, commentaries, and educational discussions related to animal-free science. The access to some content is freely available at: https://journals.sagepub.com/home/atl while other articles require a subscription or purchase.

Toxicology in Vitro

It's a peer-reviewed scientific journal published by Elsevier and serves as the official journal of the European Society for Toxicology in Vitro (ESTIV). It focuses on the development, validation, and application of *in vitro* models relevant to toxicology, pharmacology, and biomedical sciences. The journal publishes original research, reviews, and methodological studies that support the replacement, reduction, and refinement of animal use. Special attention is given to NAMs, including advanced cell-based assays, organoids, high-throughput screening, and integrated testing strategies. Toxicology *in Vitro* is a key platform for researchers and regulators advancing human-relevant safety testing. Articles are available at: https://www.sciencedirect.com/journal/toxicology-in-vitro

Computational Toxicology

It's a peer-reviewed, open-access journal published by Elsevier that focuses on the use of computational and data-driven approaches in toxicology. It covers a broad range of topics relevant to NAMs, including *in silico* modeling, machine learning, Al-based predictions, systems biology, QSARs, PBK modeling, and data integration frameworks. The journal supports the development and regulatory application of computational tools that contribute to reducing or replacing animal testing. It provides a platform for interdisciplinary research aimed at enhancing the scientific basis and reliability of predictive toxicology. All articles are freely available at: https://www.sciencedirect.com/journal/computational-toxicology

• State-of-the-Art of New Approach Methodologies in Next-Generation Risk



Assessment

It's a special issue published by *Computational Toxicology* (Elsevier). It compiles peer-reviewed articles that showcase cutting-edge research in the field of NAMs, with a focus on their integration NGRA frameworks. The issue highlights advancements in *in vitro*, *in silico*, omics, and Al-driven approaches, including case studies and methodological developments aimed at replacing or reducing animal testing. It provides insights into regulatory applicability, mechanistic toxicology, and data integration strategies. This special issue serves as a key reference for scientists, regulators, and policymakers interested in the future of human-relevant safety assessment. All contributions are freely available at: https://www.sciencedirect.com/special-issue/322807/state-of-the-art-of-new-approach-methodologies-in-next-generation-risk-assessment

3.2 European training offer on NAMs presented according to NAMs approaches and methodologies:

NAMs, being an umbrella term, covers a multitude of new concepts or approaches in chemical safety assessment. PBPK modeling is a mathematical modeling technique for predicting absorption, distribution, metabolism and excretion (ADME). *In vitro* to *in vivo* extrapolation (IVIVE), AOP (Adverse Outcome Pathway), IATA (Integrated Approach to Testing and Assessment), are also relevant terms for description of approaches in the context of NAMS. In this document the focus was decided to be only global generic term "NGRA" for covering new concepts or approaches around chemical safety assessment.

From a NAM's perspective for replacement of animal testing, grouping concerns both read-across approach and use of QSARs (Quantitative structure—activity relationships). This approach can also be named "in silico" approach (as an analogy to the in vitro and in vivo approach). Artificial Intelligence (AI) methods and tools, including omics data integration platforms could also have been considered. But for commodity reasons, the focus will be only on QSARs for illustrating NAMs methodologies related to grouping approach in this report.

Omics and then organoids, organs-on-chips (OoCS) will also be presented these later can also be called Multi-organ-on-chip systems (MOOCs).

Finally, some trainings that are proposed for other NAMs will also be described in this section.

The NAM definition used for this project NAMWISE is the following: NAM is an approach that does not rely on live non-human vertebrate animals including independently feeding larval forms; and foetal forms of mammals as from the last third of their normal development, and live cephalopods (as defined by the directive 2010/63/EU).



3.2.1 NGRA (Next Generation Risk Assessment):

NGRA is an exposure-led and hypothesis-driven risk assessment approach that includes one or more NAMs. This framework involves a tiered approach that uses relevant data to comprehensively assess safety risks of chemicals and/or their similar compounds.

Although this NAMs approach is relevant for all regulatory domains, this section presents key initiatives and training programs coming from the cosmetic community. Indeed, this is the domain where this type of approach is the most advertised, proposing various training programs, which put forward the term NGRA. Additionally, as it is seen as a promising framework for the safety evaluation of cosmetic ingredients, it is already taken into consideration in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation (European Commission, 2023).

The International Collaboration on Cosmetics Safety (ICCS) is composed of individual companies, federations from the cosmetic sector, organizations for defending animal free-cruelty and testing institutes.

You can have access through their platform (available at: https://www.iccs-cosmetics.org/education) dedicated to educational training and resources to various materials, not only workshops announcements but also a free on-line video presenting the NGRA Case Study on Benzophenone. They give also access to Web pages for on-line registration to the webinars series they organize. They cover topics ranging from NGRA, PBPK modeling, validation, (Q)SARs.

Their platform also provides links to external trainings such as the Master Class in Animal-Free Safety Assessment (AFSA) of Cosmetics and Chemical Ingredients.

The AFSA Master Class is a free, online, self-paced course designed to build capacity and confidence in animal-free safety assessment of cosmetics and chemical ingredients. It covers the full risk assessment process using next-generation, non-animal approaches, and is aimed at regulators, manufacturers, and other stakeholders seeking to implement and accept animal-free methods in regulatory safety decisions available at: https://www.afsacollaboration.org/masterclass/)

This free course is focused on safety assessment of cosmetics and cosmetic ingredients without new animal data. The 10-part course:

- Covers all aspects of the process for internal and regulatory safety assessments.
- Covers the spectrum of available risk assessment tools as well as some tools.
- Builds understanding about the information generated from the tools and how to use this information.
- Regulators, manufacturers, ingredient suppliers, CROs and NGOs are the target audience.

Among other programs of interest mentioning NGRA, a master class has been organized by ALTERTOX in collaboration with CEHTRA (2 days-course), with an audience coming exclusively from Industry available at: https://academy.altertox.be/services/trainings/.

From academic programs related to NGRA training, the « DU (Diplôme Universitaire) Évaluateur de la sécurité toxicologique pour les produits chimiques et cosmétiques Université Paris Cité » can be cited (available at: https://odf.u-paris.fr/fr/offre-de-formation/diplome-d-universite-du-diu-1/sciences-technologies-sante-STS/du-evaluateur-de-la-securite-toxicologique-pour-les-produits-chimiques-et-cosmetiques-FU54_131.html?search-keywords=toxicologique).

The French "DU" (university diploma, also called institutional diploma), does not fit into the traditional scheme of university diplomas, as not subject to accreditation by the Ministry of Higher Education. As



a theoretical teaching has a minimum duration of 70 hours per year and can be provided over one or two years. Although DU courses can be followed by a student, the audience in generally Post-Graduate.

3.2.2 QSARs:

QSAR models are models linking a property or effect, such as boiling point or toxicity, to parameters associated with chemical structure, such as certain molecular descriptors. They can be used to assess chemical substances within the so-called *in silico* approach. Models are issued from datasets.

Many tools and developer companies exist, service providers for using of QSARs in the context of a regulatory dossier, regulatory acceptance pending on applicability domains of the models for deriving (eco)toxicity properties that may be covered or not from the datasets (ToxCast and Tox21 are two of the major ones) used to derive algorithms ...

In brief, most of the service providers of QSARs training do not provide so many information on their website and provide their training with charges. In the vast majority, the information describing the content of their training courses is not much developed. The following service providers for training on QSARs were found, but it is likely that there should be others:

OASIS, KREATIS, SIMPLY PREDICT (CEHTRA solution), QSARLab, TOXNAVIGATION

ECHA also provides regularly some trainings through on-line webinars. Very often, the training for QSARs is related to (Q)SAR Assessment Framework and how to report QSAR results in the context of a regulatory dossier the On-line. But, you can find also on Youtube a video which gives an overview of the QSAR Toolbox available at https://www.youtube.com/watch?v=4mlNzYUvnf0.

VEGAHUB is a repository of freely available, downloadable tools based on computational toxicology methodologies.)

An ebook on how to use the VEGA tools published within the PARC project (https://www.vegahub.eu/the-new-ebook-with-a-complete-guide-about-vegahub-is-available/). With this e-book you will learn about the state of the QSAR art. This book is composed of three parts:

- 1) The first addresses the scientific aspect of modelling.
- 2) and 3) some practical cases are examined.

In the context of this report, discussions with Matthieu Duchemin (Lecturer at University Paris-La Sorbonne in regulatory ecotoxicology in the "Master Ecophysiologie Ecotoxicologie" and formerly regulatory ecotoxicologist within industrial company for more than 10 years) were taken into account. He mentioned that, because of the current absence of regulatory acceptance of any other NAMs for assessing the ecotoxicological properties of chemicals, grouping was the only NAMs approach discussed during his lectures. But, because only to be used in a weight-of-evidence approach, QSARs



presentation was not so much developed. On the same ground, he also pointed out that QSARs might be costly for the companies, as this often necessitates external advice by an expert in the field.

A course for students fully dedicated to grouping approach and QSARs was identified (https://www.vegahub.eu/course-advanced-school-in-benefits-and-risks-in-life-sciences/):

The course, at the IRCCS - Istituto di Ricerche Farmacologiche Mario Negri, aimed at training researchers in the field of computational toxicology. It involved integration of the students own theoretical preparation with practical experience that the student had acquired at the Institute in the development and use of *in silico* models and, in general, non-testing methods. The course was run at the Institute in Milan and lasted three years. At the end of the course, students who have passed a final exam were issued an "Attestation of Attendance".

3.2.3 Omics:

"Omics" was one of the initial categories used for listing the NAMs trainings. Therefore, its definition is already presented in section 2.2.3.2 of this document.

One well known NAM omics is GARD™, that measures changes in gene expression of 200 genes relevant to the skin sensitization adverse outcome pathways (AOP).

The GARD test methods (OECD Guideline 442E) make use of a machine learning algorithm (Support Vector Machine) to process genomic data to identify chemicals that can induce skin allergies (GARDskin) and to distinguish between strong and weak sensitisers (GARDpotency), as described by the GHS for the CLP. (European Commission, 2021)

When you look for training on omics, you can find various trainings such as, for example:

A semester-long 'do-it-yourself' (DIY) transcriptomics course that teaches basic principles of bioinformatics, covering best practices for the analysis of high-throughput sequencing data from gene expression (RNA-seq) studies (https://diytranscriptomics.com/).

A virtual training course entitled "Cell Biology and Omics for Educators", intended for secondary school science teachers. This professional development course provides an overview of the development of the field of cell biology, insights into the latest advances made possible with omics techniques, and inspiration for teaching the topic in the classroom. It lasts 10 hours. (https://www.embl.org/ells/training/cell-biology-and-omics-for-educators/)

This latest course is organized by EMBL (European Molecular Biology Laboratory)'s Science Education in partnership with Merck. It is hosted on ELIXIR's platform.

There are many applications and constant progress of omics in toxicology domains, such as *in vitro* battery testing to assess developmental neurotoxicity (DNT). Two trainings, judged very interesting because related to ecotoxicology and repeated toxicity for which currently there is no alternative *in vitro* methods to animal testing were selected.

EuroMarine is a member-based, interdisciplinary, collaborative network of European marine organizations and research institutes. They have organized a workshop session called "MOST:



Application of omics in marine ecotoxicology" (https://euromarinenetwork.eu/activities/most-application-of-omics-in-marine-ecotoxicology/). The purpose of this 2-day on-line meeting was to assess the state-of-art and potential for implementation of omics technologies in marine ecotoxicological research, and developing tools and standards to match researchers' and regulatory needs.

The main expected deliverables were the following:

- Benchmarking knowledge and tools,
- Description of best practices for data standardization,
- Bringing together and training a network of marine ecotoxicologists.

It was proposed to the following audience: MSc, PhD, Early Career Researchers (priority registration) and researchers, mainly for the fields of toxicology, comparative physiology and functional genomics with priority given to EuroMarine members.

ONTOX, member of the ASPIS cluster, is dedicated to developing generic, reusable NAMs to predict systemic toxicity caused by repeated exposure to chemicals. The project focuses on three vital organs: the liver, kidney, and developing brain, with two toxicity endpoints studied per organ (e.g., steatosis and cholestasis for the liver).

A major innovation of ONTOX lies in its integration of omics data including transcriptomics, proteomics, and metabolomics into its predictive frameworks. These omics datasets are used to identify biomarkers of effect, improve mechanistic understanding, and refine AOPs. The incorporation of omics is essential for building human-relevant, mechanistically informed models that can support regulatory safety assessments.

To promote transparency and knowledge sharing, ONTOX regularly organizes webinars, participates in international conferences, and provides access to recorded presentations through a dedicated "Meet Us" section on its website: https://ontox-project.eu/meet-us/. These activities help disseminate the project's findings and support education on omics-based NAMs among both researchers and regulators.

3.2.4 Organoids and Organs-on-a-chip:

"Organoids" and "Organs-on-a-chip" were among the initial categories used for listing the NAMs trainings, therefore their definitions are already presented in section 2.2.3.2 of this document.

Two cases of such method uses are reported as having been accepted in regulatory contexts for chemical safety assessment:

- Organoid/organ-on chip: 3-D reconstructed lung model MucilAir™ tissues, that has been accepted by the Scientific Committee on Consumer Safety (SCCS) as relevant method for assessing the local lung effect of the substance Acetylated Vetiver Oil, cf 'The findings of an *in vitro* study using Mucilair™ also support this conclusion' (European Commission, 2024, October 25)
- One of the most significant advances in the application of in vitro tissue-based methods for inhaled safety assessment is the regulatory decision to use an in vitro 3D lung model in combination with estimates of respiratory tissue exposures to assess



the hazard from an inhaled pesticide—chlorothalonil. Specifically, the US EPA accepted a NAM combining CFPD-based IVIVE modeling, real-world particle exposure characterizations, and benchmark dose (BMD) modeling of a contact cytotoxicity point of departure (POD) observed in human respiratory epithelial cell cultures exposed at the air—liquid interface (ALI). This NAM was accepted in lieu of additional rodent 90-day repeat dose inhalation toxicity testing, normally required for product reregistration. This process was recently published as a case study by the OECD. (Wallace *et al.*, 2025).

Such as for omics, there are a lot of applications for organoids and organs on-chip: a major application neurosciences for brain organoids with a high-level neuroscience training hub in Europe, called CAJAL (in honor of Santiago Ramon y Cajal, neuroscientist who received a Nobel Prize in 1906), can be cited.

Such as for omics also, one of the topics which is taught in this area concerns RNA sequencing, as illustrated in the content of the 3-week course that they have organized in Bordeaux School of Neuroscience (https://cajal-training.org/on-site/brain-organoids/).

A master course of 2 days is organized in Utrecht, with the following content:

- Tutorials
- Hands-on lab sessions
- Expert views
- Commercial hands-on sessions
- Develop an organ on a chip system for an application of your choice

This master-class is organized by AZAR INNOVATION (https://azar-innovations.com/organ-on-a-chip-masterclass-lectures-and-hands-on-lab-trainings/), who organize regularly this kind of masterclass, as well as custom-designed workshops to clients.

Another company, STEMCELL TECHNOLOGIES, organizes this kind of trainings on demand related to the organoids they produce (https://www.stemcell.com/technical-resources/area-of-interest/organoid-research/intestinal-organoids/training.html).

NETRI, specialized in the chips, provide organ-on-chip kits and provide trainings on site and on-line designed to help users understand and master the fundamentals of microfluidics — a key technology in organ-on-chip systems. It also includes dedicated modules on electrophysiology and NETRI's proprietary software, such as NeuroFluidics Sensory Neurons MEA (Multi-Electrode Array) (https://www.shop.netri.com/products/online-trainings-pack).

The European Organ-on-Chip Society (EUROoCS) Is an independent, not-for-profit organization established to encourage and develop Organ-on-Chip research. EUROoCS members contribute widely to workshops, summer schools and seminars in the field of organs-on-chips. In addition, many EUROoCS members also participate in teaching on the graduate and post-graduate level at their academic institutions.

EUROOCS is organizing the EUROOCS Academy yearly as part of the MPS (Microphysiological Systems) World Summit in Brussels.



The EUROOCS Academy is a collection of lectures on various disciplines of Microphysiological Systems and Organ-on-Chips. This event, organized by EUROOCS, is exclusively for EUROOCS members (https://euroocs.eu/euroocs-academy/).

3.2.5 Others:

NAMs area is very broad. It can cover non-animal stand-alone methods, or combination of various *in silico* and *in vitro* methods. It can also refer to mechanistic information, such as metabolic and adverse outcome pathways. Methods measuring toxicity on feeding larval forms; and foetal forms of mammals as from the last third of their normal development, and live cephalopods (as defined by the directive 2010/63/EU) can also be considered as NAMs.

CROs members of NAMWISE (namely WATCHFROG, Aquatox Solutions Gmbh and CRL), develop and/or implement any kind of NAMs and propose as well training on their methodology: this can be on site, distance learning, also accessible on-line...

Public private partnership between EC and industry can also offer similar training. As a concrete example of training within this section, EPAA provides a link through its website to their video tutorial which describes a cell-based *in vitro* method for assessing phototoxicity - the potential for chemicals to cause damage after being exposed to light (https://www.youtube.com/watch?v=0fwN5ssEUo8)

3.3 European training offer on NAMs presented according to audience:

3.3.1 Academics and CROs NAMs developers

There is a huge amount of training in the academic landscape which is deemed to cover at least partially the NAM area.

For example, at University College Dublin, the UCD MSc program covers current regulatory landscapes and toxicological techniques, offers full-time and part-time study options, and enables eligibility for professional accreditation as a European Registered Toxicologist. It is delivered by academic and industry experts and includes opportunities for internships and networking (https://sisweb.ucd.ie/usis/!W HU MENU.P PUBLISH?p tag=PROG&MAJR=F167).

More than 50 years after the 3Rs definition and despite the continuous implementation of regulatory measures, animals continue to be widely used in basic research. Their use comprises not only *in vivo* experiments with animal models (https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/animal-model), but also the production of a variety of supplements and products of animal origin for cell and tissue culture, cell-based assays, and therapeutics.

Training from companies intended for laboratory personnel are available (https://www.stemcell.com/forms/hematopoietic-on-demand-training.html).

Also, various links from training in animal sciences were gathered (such as for example, LAST Ireland, (https://www.last-ireland.ie/last-new/home-2/). These types of training courses may be relevant to the topic, as they are likely to include content on NAMs approaches and methods within the broader framework of the 3Rs—particularly replacement. However, it cannot be guaranteed that every individual course listed specifically addresses NAMs-related topics.



IMPROVE is currently (July 2025) working on deriving a training inventory from their 3R network and for each European country.

Utrecht University has demonstrated leadership in integrating NAMs into both academic and continuing education. They offer NAMWISE concrete examples of structured, interdisciplinary training models that combine foundational science, applied skills, and regulatory relevance—key elements needed to scale NAMs education across Europe.

3.3.1.1 Students

Utrecht University provides a rich ecosystem of advanced academic Masters programs that align with the development and implementation of NAMs (https://www.uu.nl/en/education/programmes). Two of its flagship Masters programs—Cancer, Stem Cells and Developmental Biology (https://www.uu.nl/en/masters/cancer-stem-cells-and-developmental-biology) and Environmental Biology (https://www.uu.nl/en/masters/environmental-biology) —integrate NAMs-relevant content through modules in omics technologies, human organoid models, advanced imaging, ecotoxicology, and systems biology. These programs emphasize human-relevant and environmentally sustainable alternatives to animal testing, preparing students for both academic research and regulatory careers.

3.3.1.2 Post-graduate

Beyond academic degrees, Utrecht University is closely linked to the PET (Postgraduate Education in Toxicology) course series, notably the "New Approach Methodologies for Toxicology" course hosted via (https://toxcourses.nl/courses/new-approach-methodologies-for-toxicology/). This paid professional training offers a week-long, certificate-awarding curriculum focused on modern toxicology practices, including *in vitro* models, *in silico* tools, PBK modelling, read-across, and exposure assessment.

3.3.1.3 NAMs developers

At ETPLAS, (https://etplas.eu/en/eu-modulescourses) you can find two training modules that can be accessed for free, but you need first to register:

Module EU52 ("Searching for (existing) non-animal alternatives) introduces the main elements needed to search for and identify (existing) non-animal methods and approaches. The module includes an introduction to the Three Rs, with emphasis on Replacement, and then splits into three parts focusing on each necessary step of the search process: 1) developing research questions, 2) designing a search strategy and searching appropriate sources, and 3) documenting the searches and their results. The module discusses and is applicable to several contexts such as research, regulatory testing and education and training.

Module EU-60 ("Developing *in vitro* methods and approaches for scientific and regulatory use") provides guidance to *in vitro* test method developers and others interested in ensuring the quality of new methods or approaches and in improving the efficiency with which these are developed, tested, optimized and approved by regulatory bodies. The module consists of 4 parts: 1) Context and needs for reliable and relevant *in vitro* methods; 2) Method development and implementation based



on Good *In Vitro* Method Practices (GIVIMP), 3) Demonstrating the scientific validity of a new method or approach and 4) Knowledge assessment.

In France, e-thiX education is a training organization specializing in the ethical use of animals for scientific purposes and their alternative methods. Within their catalog (https://www.e-thix.eu/nosformations/?taxonomy=category&term=distanciel), they have 2 courses of particular interest, both being half-a-day distance learning (in French):

- « Remplacement : introduction aux méthodes alternatives (non animales) », meaning: "Replacement: Introduction to alternative (non-animal) methods",
- « Remplacement : rechercher une méthode alternative (non animale) », meaning "Replacement: look for an alternative (non-animal) method"

3.3.2 <u>Non-academic: CROs implementers, representatives of Animal Welfares</u> <u>Organizations, industrials and consultants, regulators:</u>

All these actors can be part of European projects and discussions within events on this topic. They are also the ones who often organize these events, on their own, or through their sector association, and often in collaboration with organisms in charge of organizing events.

CROs implementers, firstly, but also industrials and consultants can be contacted by developers of assays who want to sell their assays and results functionalities. Based on the pitches of these oftensmall companies (less than 50 employees) they can stay up to date with new developments.

3.3.2.1 CRO developers

CRL (Charles River Laboratory) also indicated by filling our questionnaire form that, in addition to the above, they also participated "in ring-trials e.g. via Pepper, EU/Netval, ValNam". For NAMs follow-up and implementation, they are organising themselves through a Global "Alternative Methods Advancement Project™ (AMAP™) team (https://www.criver.com/about-us/abou

3.3.2.2 Consultants

CEHTRA, like other European consultants, closely monitors NAMs progress for regulatory acceptance in the context of dossiers, through participating regularly to events dedicated to NAMs, but also more advanced NAMs training programs.

In 2025:

- The collaborator in charge of QSARs team (https://www.simplypredict.ai/) has participated to the SOT event in Orlando, Florida (https://www.toxicology.org/events/am/AM2025/index.asp);
- The collaborator in charge of the cosmetic team is participating to AFSA master class (https://www.afsacollaboration.org/masterclass/);



- A toxicologist will participate to the PET (Postgraduate Education in Toxicology) "New Approach Methodologies for Toxicology" course (https://toxcourses.nl/courses/new-approach-methodologies-for-toxicology/).

3.3.2.3 Regulators

During the 2nd day of Nordic NAM Training and Networking workshop (Nordic Council of Ministers, 2022) Nordic regulators participated to interactive, hands-on training. Two parallel training sessions for human health and environmental assessments occurred to focus on topics directly relevant to specialized regulatory responsibilities.

a Human health training session

The human health training session concentrated on skin sensitization endpoint. Expert Laura Rossi from ECHA acted as the trainer and gave first an introductory presentation on the developments in the *in vitro/in chemico* methods for skin sensitization including the key events (KE) in question for the respective method. These included methods for peptide binding as the KE (DPRA, kDPRA), inflammatory responses in keratinocytes (KeratinoSens, LuSens, EpiSensA), or activation of dendritic cells (h-CLAT, U-SENS, GARD, IL-8 Luc). For each method, acceptance criteria, limitations, and prediction models were described. It was also pointed out that not all are stand-alone methods. An overview and background of defined approaches (DA) were also given, and of those DAs that have been approved for skin sensitisation (2 out of 3, integrated testing strategy (ITS) 1 and ITS 2), including their application rules and predictive capacity.

Hands-on exercises followed with case studies using anonymised real-world REACH registration data to evaluate whether conclusions of the results could be agreed, whether based on *in vitro* data performance of an *in vivo* LLNA test was justified, or whether it was possible to conclude on skin sensitisation potential based on the data provided.

b Environmental training session:

The environmental session of the training focused on *in vitro* bioaccumulation assessment and the prediction of bioconcentration factors (BCF) using *in vitro-in vivo* extrapolation (IVIVE) and regression models. Expert Heike Laue from Givaudan acted as the trainer.

The session began with a lecture on the importance of biotransformation rate determination and an overview of the OECD TG 319 A/B methods. A hands-on exercise followed, where participants worked with *in vitro* data to calculate biotransformation rates. The regulatory section introduced IVIVE and regression models for BCF prediction, demonstrating their regulatory applications. In the final hands-on training session, participants used case studies with real data (biotransformation rates, log Kow) to practice BCF predictions using spreadsheets with different models. The training concluded with a checklist-based evaluation of OECD TG 319 A/B data quality, enabling participants to assess real data from ECHA registration dossiers.



4 Discussion and areas for improvement

4.1 NAMs Trainee roles and training needs

The mapping of NAM-related educational and professional training resources across Europe reveals a growing but fragmented ecosystem. Indeed, each actor involved for animal phasing out is not the same and resulting training needs are therefore different. Additionally, for a same status of audience, your role can be different according to the size of your structure and how it is organised. Finally, the needs of training will not be the same according to your educational feedback and whether you have already followed post-graduate courses on NAMs topics.

Nevertheless, this presented as a rough outline:

Academic institutions are foundational to the success of NAMs. They educate future scientists and drive innovation, yet most European universities have not structurally embedded NAMs into their life sciences curricula. Traditional animal-based methods remain dominant, while NAMs are often taught as optional modules or niche postgraduate specialisations.

As mentioned by CROs, when answering to our questionnaire (see details in annex 1), the main driver for developing and implementing the NAMs is the client request. This is also the case for consultants. Clients are industrials, e.g. those who must comply with regulations and associated chemical risk assessments. Therefore, the key driver for NAMs training for this category of audience is the regulatory acceptance. Regulators, those in charge of evaluation of the dossiers have the same key driver.

Finally, for those people working in laboratories developing NAMs, and those regulators in charge of validation of these NAMs, you need to be able to implement and assess all the criteria associated to methods validation.

Some documents further develop the presentation of the needs for training:

- PARC first training needs survey -2023 short report https://www.eu-parc.eu/sites/default/files/2023-11/PARC%20training%20needs%20survey_short%20report_12.09.2022.pdf): needs are listed as topics, the first ones being "risk assessment Fundamental and Approaches", "Fair Data", "Databases", and "New approaches Methodologies" is listed in 4th position. The survey was completed by 81 institutions from 25 different countries.
- Report issued from the "Nordic Workshop on New Approach Methodologies (NAMs) for Grouping and Read-Across under REACH and CLP November 9th – 11th 2021" (Nordic Council of Ministers, 2022): general needs are listed, but also most advanced regarding specific NAMs, including Omics, AOPs, interpolation between animal and humans or specific needs for Nordic regulators...
- The expert workshop in Zurich, as reported by Deckha et al. (2025), which explores how universities can actively lead the transition away from animal-based research by accelerating the development, adoption, and normalization of New Approach Methodologies (NAMs). The context is Swiss universities, but the lessons apply broadly across the EU and Global North as participants from Netherlands, Germany, Denmark, UK and Canada were present.



4.1.1 Recommendations from past events

In the report issued from the (Nordic Council of Ministers, 2022), the key recommendations were the following:

1. Improve availability of practical training

- A Hands-on skills development (e.g. using *in vitro* or *in silico* tools) is essential for both academic and regulatory professionals.
- Calls for experimental workshops, case-based learning, and access to state-of-the-art lab tools.
- Training should be directly aligned with real-world regulatory applications, enhancing relevance and impact.

2. Integrate NAMs into curricula

- Universities are encouraged to embed NAMs systematically into Bachelor's and Masters level programs—especially in biology, toxicology, pharmacology, and biomedical sciences.
- Emphasis on making NAMs not just optional modules but core elements of scientific education.

3. Promote cross-border cooperation

- Nordic countries can benefit from joint training initiatives, exchange programs, and recognition of NAMs-related credentials across borders.
- Recommendation to pool resources (e.g., shared databases, common e-learning modules) to avoid duplication and enhance quality.

4. Develop a structured training pathway

• The event stressed the need for clear progression routes for NAMs education: from introductory awareness to advanced regulatory applications.

Proposed model:

- Introductory courses: awareness of NAMs and ethical context
- Intermediate level: practical techniques (e.g. organ-on-chip, omics)
- Advanced level: regulatory decision-making, risk assessment frameworks

5. Bridge the academia-regulator gap

- Need training that is co-developed or endorsed by regulatory bodies, ensuring it meets practical and compliance needs.
- Encourages dialogue between scientists and policymakers through joint workshops and ongoing networks.
- Take advantage of the EU interagency cooperation program as well as the one substance one assessment EU law to harmonise NAM training for regulators.

6. Create a shared training resource platform

Proposal for a Nordic (or EU-level) digital platform to collect and share:

- Training offers
- Recorded lectures and webinars
- Tools, guidelines, and best practices



Could be linked to broader European efforts (e.g. RE-Place, PARC, ASPIS cluster)

In the expert workshop in Zurich, as reported by Deckha *et al.* (2025), recommendations were approximately the same so that the recommendations from the Workshop in 2021, can be a good overview of this topic.

4.1.2 Key NAMs mapping initiatives

As elicited in this report there are a multitude of European initiatives that have been developed and on-going regarding the development of NAMs for regulatory purposes and the offer of events, training courses proposed in this area is highly broad.

Nevertheless, two key initiatives for covering both academic and non-academic audiences are presented:

Initiatives such as the IMPROVE COST Action (CA21139) are mapping 3Rs education across Europe, spanning from secondary school to professional training. It brings together a pan-European network of 3Rs (Replacement, Reduction, Refinement) centers, researchers, educators, and stakeholders with the goal of harmonizing and elevating the quality of preclinical research through enhanced 3Rs implementation.

The COST Action IMPROVE is structured in four working groups whose topics are heavily interlinked to each other, thus, achievements for single topics will be applicable for the other topics and the 4th is on education: it aims to establish and optimize connections of educational 3Rs related activities within Europe and share experiences, methodologies and best practices through a mapping of 3Rs related training education resources. It typically provides webinars and organizes hybrid training schools on 3D cellular models, dissemination tools and how to educate 3Rs. Trainings are available at: https://www.i3s.up.pt/training-detail.php?v=375

While broader than NAMs alone, IMPROVE's Education Working Group provides valuable insight into shared challenges, curriculum gaps, and training opportunities. The initiative's cross-country, multistakeholder approach offers a useful model from which to build an EU training benchmark.

The PARC Learning Materials Repository is a curated, open-access platform designed to support education and training in chemical risk assessment and NAMs. It is available at: https://www.eu-parc.eu/learning-materials

The Repository contains materials provided by PARC partners as from external contributors. The Repository is searchable and filterable by topic, audience level, and format etc. It is regularly updated with new content from PARC partners and external contributors.

The table below is providing the list of available filters for searching educational and training materials and the number of materials made available:

Domain of interest	Scope	Target Stakeholder	
Policy and regulation:	Advanced	Academia	
7	(nano)materials:	(PhD and MSc student, professor,	
	9	researcher):	



		47	
Exposure assessment:	Biotechnology:	Consultants:	
8	1	28	
Hazard and risk:	Chemical mixtures:	Education (schools and undergraduates):	
23	2	17	
FAIR data and data	Chemicals:	Industry:	
management:	19	30	
3			
Safe and Sustainable by	Pesticides:	NGOs:	
Design:	1	27	
24			
Statistics:		Regulator, policy maker, risk assessor:	
1		41	

The repository may be searched by type of material, level of expertise or reading time; the table below is providing the list of available filters for searching educational and training materials and the number of materials made available:

Type of Material	Level of Expertise	Reading time
Course:	Beginner:	Less than 1 h:
3	39	21
E-learning tool:	Intermediate:	1-4 h:
3	20	27
Presentation / slides:	Advanced:	1 day:
2	1	5
Reading materials:		More than 1 day:
10		5
Video:		
5		
Webinar recording:		
35		

Several filters may be selected simultaneously; however, the repository cannot be searched by free word.

Below is an example of presentation of material:





While the materials are listed on the PARC website, they are not managed by PARC, therefore any prospective trainee must directly contact the course organisers.

The information on available training is regularly updated. Any interest to share additional training course can be expressed by completing an online form (https://survey-insa.min-saude.pt/redcap/surveys/?s=JWW7F8W4DJ).

4.2 Further insights for improving the dissemination of NAMs training in Europe:

"NAMs, which is largely considered to be a generational issue whereby younger toxicologists have a better understanding of NAMs, unlike longer established staff. This also applies to industry, as there are different levels of knowledge and application of NAMs here. Additionally, there is a need to improve the public knowledge of NAMs, which requires working with NGOs as well" (PrecisionTox, 2024).

Following extensive review of the existing training offer in Europe and gathering information from events, discussions with various stakeholders involved in NAMs and trainings, including academics, those who have a better understanding of NAMs should be better qualified as "younger scientists" rather than "younger toxicologists". Indeed, for example, in Utrecht University, which is a leading organization for teaching omics, there is no mention of "toxicology" in the title and program presentation of their 2 flagship Master's programs Cancer, Stem Cells and Developmental Biology (https://www.uu.nl/en/masters/cancer-stem-cells-and-developmental-biology) and Environmental Biology (https://www.uu.nl/en/masters/environmental-biology).

Also, it has been told that NAMs were not so much developed in MSc related to regulatory toxicology cursus in France. The expert workshop in Zurich, as reported by Deckha *et al.* (2025), highlights student-driven frustration due to outdated curricula and the lack of meaningful exposure to NAMs in scientific education. Students and early-career researchers advocated for a rethinking of how universities conceptualize and teach human-relevant science, ethics, and systematic review methodologies.

We would then recommend filling the gap between regulatory toxicology based on animal methods and the MSc or equivalent program fully dedicated to specific methods, such as QSARs, omics or organoids. Indeed, and as already recommended by others, embedding NAMs systematically into Bachelor's and Masters level programs, is needed but may be also putting forward 'life science' in the title of training course, and not only 'toxicology', or 'regulatory'.

For "longer established staff", e.g. those working since decades for chemical safety assessment, NAMs is often perceived as difficult to access, because of the terminology and the level of complexity needed to develop a method, when compared to the animal methods for which they are more familiar with. For a part, and not only because of the current low regulatory acceptance of NAMs, NAMs trainings are presented in too much detail and it may contribute to reluctance of the audience to go deeper in the process.

As a proposed action, it may be appropriate to prepare training formats for a first introduction i.e. 101 courses to the NAMs landscape. This could include answers to this kind of naïve questions:



"NAMs stands for new method or new approach or non animal?

What is a stand-alone method for NAMs?

Does grouping approach consist in only read-across strategy and/or QSARs tools?

What is the role of genomics in toxicology?

What are omics, organoids, organ-on-chip technologies?

..."



5 **Conclusion**

The current landscape of education and training related to NAMs within the European Union reflects notable progress, yet remains fragmented and inconsistently developed across target audiences. This deliverable has identified that, although a wide array of resources exists, they often lack harmonisation, broad accessibility, and alignment with the practical needs of diverse professional and academic stakeholders. Nevertheless, the proliferation of initiatives—such as IMPROVE, PARC, RE-Place, TPI, EPAA, and student-led efforts like the ASPIS Academy and Young TPI—demonstrates both a growing demand and momentum for systemic transformation.

A key finding from this mapping exercise is the necessity for NAMs training to be diversified and modular. Each stakeholder group—academic institutions, students, CROs, industry consultants, and regulatory authorities—possesses distinct needs, prior knowledge, and institutional constraints. Consequently, a uniform, "one-size-fits-all" training model is inadequate. Instead, training must be tailored, modular, and adaptable to both foundational and advanced levels of expertise.

Academic institutions, in particular, must play a leading role in this transformation by embedding NAMs into the core curricula of life sciences and regulatory toxicology programmes. As underscored by initiatives such as IMPROVE, PARC, and the workshop reported by Deckha *et al.* (2025), this shift requires moving beyond elective modules toward fully integrated programmes that address both the ethical imperatives and scientific underpinnings of NAMs. The need for harmonised and updated curricula was consistently emphasised across events and initiatives, particularly by students and early-career researchers.

CROs engaged in the development or application of NAMs face specific challenges related to regulatory expectations, validation standards, and practical implementation. Feedback from NAMWISE partners, including AQUATOX and Charles River, highlights the demand for clearer regulatory guidance and targeted training on method application—especially for NAMs still under development. These findings underscore the value of flexible, co-designed modules and hands-on training that reflect real-world testing scenarios.

For industry professionals and consultants, continuing professional development remains the primary avenue for acquiring NAMs-related knowledge. Professional training programmes, such as the PET series, should increasingly incorporate up-to-date NAMs content. Platforms like RE-Place, ETPLAS, and PARC's repository can support this evolution, provided they are effectively promoted and aligned with user needs.

Regulatory authorities, while increasingly aware of NAMs, require structured, case-based training frameworks that bridge the gap between scientific innovation and regulatory practice. As demonstrated in the Nordic workshops, effective training for regulators should combine theoretical instruction with simulated dossier evaluations to build confidence in the use of NAM-derived evidence.

Crucially, this deliverable shows the importance of interdisciplinary collaboration and stakeholder-driven approaches. EU initiatives such as ASPIS, TPI, and the EPAA illustrate how partnerships between academia, industry, and policymakers can foster capacity-building and drive systemic change.

However, to achieve these objectives, it is essential that all stakeholders—including students enrolled in regulatory affairs programmes—develop a foundational understanding of NAMs from the outset.



Before delving into the technical details of specific methods and approaches, learners must first be trained in the basic principles of what NAMs are and their intended applications.

By capitalising on existing momentum and fostering coordination across ongoing initiatives, the European Union is well-positioned to establish a cohesive, forward-looking education and training ecosystem—thereby reinforcing its leadership in non-animal, human-relevant safety science.



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<u>Annexes</u>

1. Annexe 1, NAMWISE 2.5 CROs questionnaire_answered_CRL_AQUA:

CRO questionnaire: In blue CRL and in red AQUATOX

Dear,

I am contacting you as part of the European NAMWISE project coordinated by INERIS (see attached file for project summary) on new methodological approaches (NAM) in (eco)toxicology.

One of the tasks of this project is to map existing training and education resources on NAMs. The NAM definition for this project is the following: NAM is an approach that does not rely on live non-human vertebrate animals including independently feeding larval forms; and foetal forms of mammals as from the last third of their normal development, and live cephalopods (as defined by the directive 2010/63/EU).

The various categories of NAMs covered within NAMWISE are: *In vitro* Cellular model, Organ-on-chips, *in silico*, Artificial Intelligence, Omics, Imaging, Defines approaches, AOP, IATA...

Is it possible for you to answer the following questions?

As a trainee of NAMs

NAMs development tracking and decision for implementation What is the driver for implementing NAMs in your lab or institution (e.g., regulatory needs, client requests, internal innovation, ethical reasons)?

Client requests, internal innovation, and ethical reasons.

The request from the market is the main driver for implementation of new NAMs Regulatory needs. Requests from the market go often parallel with regulatory needs Moreover, we are a lab that wants to innovate and therefore we participate in several ringtrials each year. This is also a way for us to get trained for new NAMs.

How does your organization stay up to date with developments in NAMs (e.g., networks, literature, courses, partnerships)?

Development of NAMs in house, conference participation (e.g., SETAC and World Congress on 3Rs), actively participating in collaboration projects relating NAMS, literature.

Participation in ring-trials e.g. via Pepper, EU/Netval, ValNam
We have an innovation team that implements assays that have a guideline or draft guideline. We also implement assays based on specific client requests.
Participation in projects/collaborations: VHP4Safety, RiskHunt3R, Afara Webinars

We are regularly contacted by developers of assays who wants to sell their assays. Based on the pitches of these small companies we stay up to date with new



developments.

Who in your organization is responsible for surveying of NAMs developments and implementation (e.g., job role or team)?

No specific person is assigned to this task in our small organisation, but our R&D scientists stay informed via the methods described above.

Local in the Netherlands: Innovation team + scientist in general Global we have the AMAP team (https://www.criver.com/about-us/about-us-overview/alternative-methods-advancement-project?region=3696). The innovation team in the Netherlands participates in this global project.

People and objective of the NAMs training

Which categories of staff have received training on NAMs?

All categories. Our team members either perform NAMs for clients (study directors and technicians), research and develop NAMs (scientists and research assistants) and disseminate NAMs to the wider audience (scientists and management).

Study directors and Technicians, QA personnel also get a training. Moreover there is specific higher laboratory education in the Netherlands. So almost all students have some experience with cell culture and NAMs.

What types of training formats have been followed (masterclass, intervention during events/congress, summer school, webinars, workshop.)

Congress participation, internal trainings, webinars, workshops.

Internal training of new technicians and Study directors by experienced personnel. Webinars, Collaborations, attending local or international meetings

What was the goal of this training?

Conducting reliable NAM based experiments as a CRO.

Technicians: mainly hands-on training; Study directors: Training at the lab and theoretical training

Format of the NAMs training

When implementing a new NAM, what kind of support or training is used? e.g., direct collaboration with NAM developer, training from ECVAM partner lab, internal train-the-trainer approach?

In our case as developers of NAMs, we provide internal training as well as train external users.

Dependent on the type of assay. Often we have contact with the developer or supplier of the test system. We start in the innovation team and then transfer the assay to operations.



Does the training include practical experimentation and method implementation (technical training / hands on training on a specific method for example PBPK Modeling, Aerosol Inhalation Toxicology, *In Silico* Models, Liver & Skin & Gastrointestinal Regulatory Model...)?

Practical training and desk training supervised by in company experts on in vitro cell culture based NAMs.

Sometimes the training is practical but more often we get the detailed SOPs and then implement the assays ourselves...

Does the training cover the integration of NAMs results for risk assessment, such as regulatory requirements?

Not applicable at the moment, but we hope in the future the NAMs we provide will be used for regulatory purposes.

Yes, sometimes this part is covered in workshops.

As a service provider of NAMs training:

Do you provide NAMs training?

No we do not offer NAMs training. Our business model is performing testing services for the chemical and pharmaceutical industry.

What we do of course is internal training for new employees. These employees are trained by other experienced employees. Moreover, for completely new assays, these are mostly implemented in the innovation team and then transferred to operations. This includes internal training.

What courses are provided by your organization (title of the NAMs course, audience: regulators, industrial/consultant, academics, publicly available link if any)?

OECD TG249, https://aquatox-solutions.ch/en/digital-media/

Do you have a catalog or customized training sessions, according to the audience?

For each of them please specify the category (e.g., *In vitro* Cellular model, Organ-on-chips, *in silico*, Artificial Intelligence, Omics, Imaging, Defined approaches, AOP, IATA) Please further specify the method domain (PBPK Modeling, Aerosol Inhalation Toxicology, Liver & Skin & Gastrointestinal Regulatory Model...)?

In vitro Cellular model.

Do your NAM courses include practical experimentation and methods implementation? No.

Do your NAM courses cover the interpretation of NAMs results for risk assessment, such as regulatory requirements?



No, not applicable as currently OECD TG249 is not a regulatory requirement.

If you have experience with training of 3Rs (Reduction, Replacement, Refinement), how did you adapt your program/training session for taking into consideration specifically the NAMs?

Sorry, this question is not clear to us. Perhaps needs to be reworded?

What is the price of your training sessions? Do they vary only according to the duration, or can they vary according to the content, level of expertise etc.?

Training is free via publicly available webinars (Youtube) and talks at conferences (e.g., SETAC and World Congress on 3Rs) and workshops (e.g., NC3Rs workshop on animal alternatives).

How do you evaluate the success of your NAMs training (e.g., exams, feedback forms, follow-up surveys, certification)?

NA

Approximately how many participants have you trained in NAMs-related content over the past three years?

Hard to say as the webinars are free to view. The Youtube video view counts are 325, 253 and 421 for the three videos, totaling to approximately 1000 views. Live audiences are difficult to estimate.

If your trainings are recognized or accredited by official bodies, can you specify which ones? Otherwise leave blank.

We would like to thank you in advance for your contribution, which will enable the project to provide an overview of NAM pedagogy and a better understanding of which pedagogical tools support new generations of (eco)toxicologists on our continent.

Do not hesitate to come back to us for more information or if you have any questions.

Best regards,

