



Practical Methods
TRAINING IN NEW APPROACHES FOR RIGHT NOW

Gaining Confidence in NAMs with Education and Outreach

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Institute for In Vitro Sciences
Advancing Science & Animal Welfare Together

What is Education and Outreach?

- Lectures, workshops
- Hands-on exercises
- Demonstrations
- Targeted or general

- Comments to agencies
- Client/agency consultations
- Journal articles
- Society activities
- OECD projects and activities
- Expert groups

Training

Outreach

Education

Validation

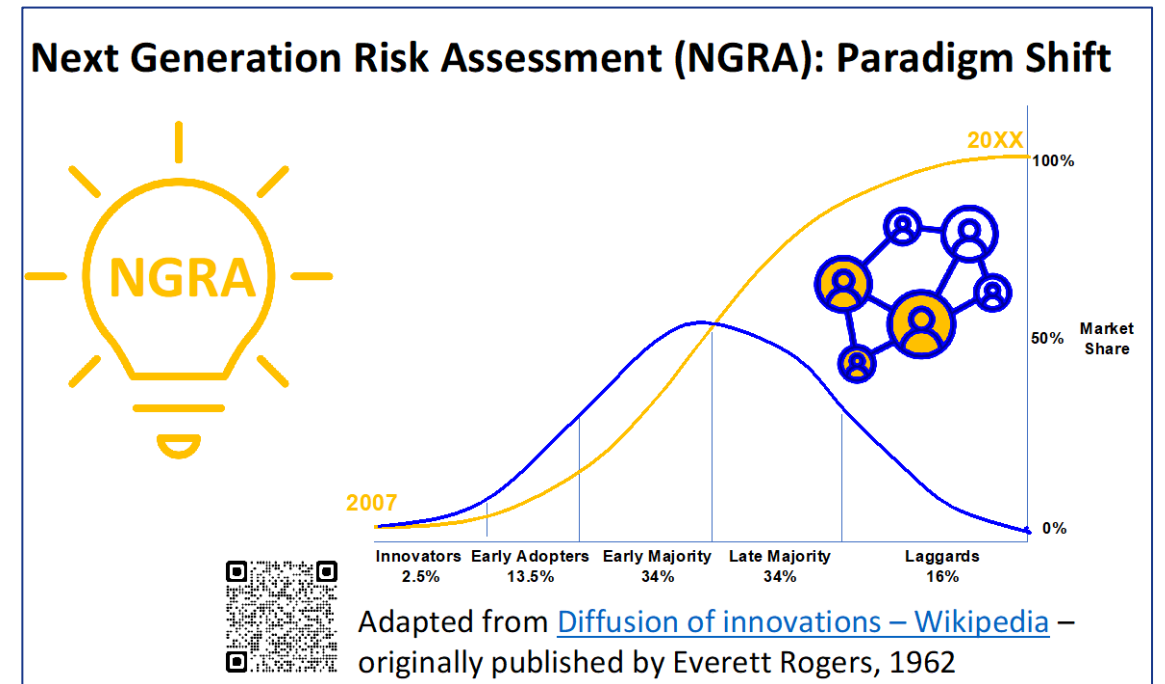
- Webinars
- One on one / small group discussions
- Workshops
- Presentations

- Method assessment
- Protocol development
- Harmonization
- Shipping studies
- OECD guideline work
- Equipment evaluation
- Stakeholder collaborations

Science
Education &
Outreach

Education Is Needed to Facilitate Acceptance and Use of New Methods

- Addresses barriers to acceptance: comfort, experience, familiarity
- Shows how new methods can be applied
- Addresses variable education and career pathways
- Increases likelihood of method conduct and acceptance
- Ensures trusted science




Priorities for Education and Training

- Data analysis and Weight of Evidence
 - Multiple in vitro methods
 - Choosing information sources
 - NGRA framework
- Challenges in the lab, data quality
- Good practices
- Train the trainer
- International outreach and capacity building
- Hands-on / experiential activities for computational tools
- Training in “gaining confidence” principles for test method developers

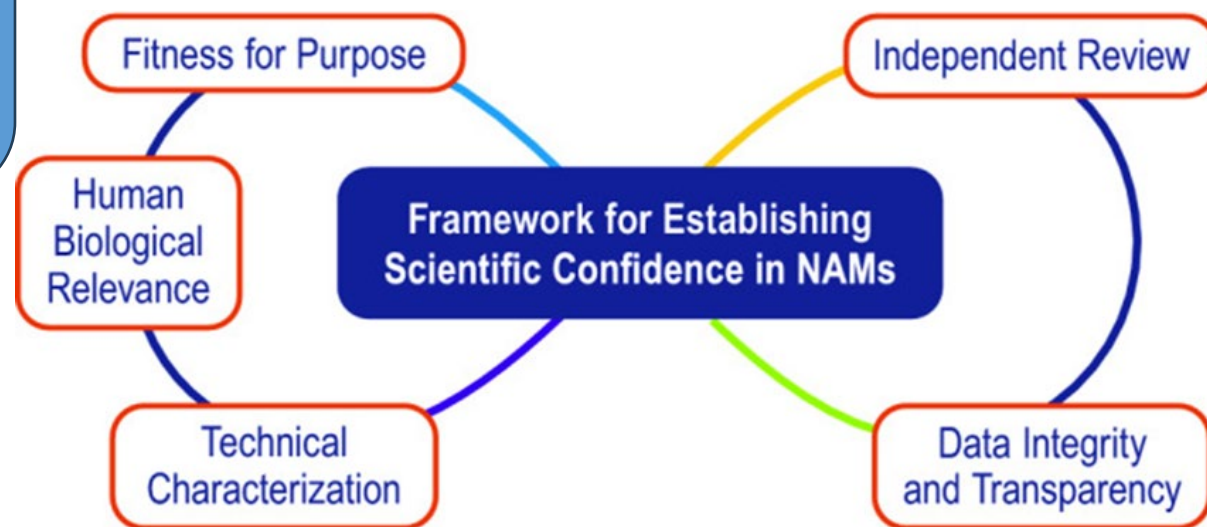


Gaining Confidence in NAMs

A framework for establishing scientific confidence in new approach methodologies

[Anna J. van der Zalm](#) , [João Barroso](#), [Patience Browne](#), [Warren Casey](#), [John Gordon](#), [Tala R. Henry](#), [Nicole C. Kleinstreuer](#), [Anna B. Lowit](#), [Monique Perron](#) & [Amy J. Clippinger](#)

[Archives of Toxicology](#) **96**, 2865–2879 (2022) | [Cite this article](#)



- How will the NAM be used?
- Does the information provided meet regulatory needs?
- Which regulatory statutes are data intended to comply with?

What level of peer review is needed?

- Publications
- Validation bodies or govt. committees
- OECD
- Independent committee

- Are the data that the NAM provide relevant to the species of interest?
- Can concordance with the responses of the species of interest be shown?
- Is the test system physiologically or mechanistically aligned with what is known about the biology of the species of interest?

- Evaluate
 - Protocol and equipment
 - Reproducibility, Transferability
 - Limitations
 - Reference chemicals and controls
 - Accuracy

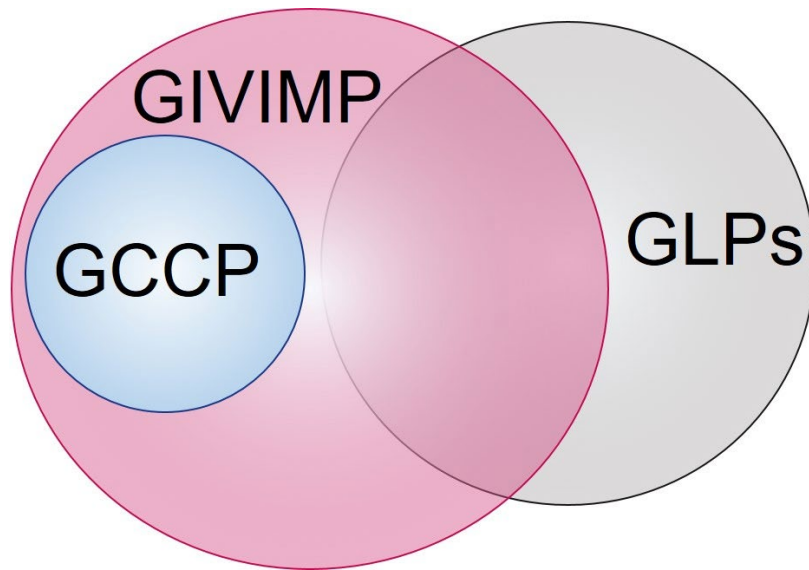
- Were GIVIMP principles followed?
- What information is provided?
- How were uncertainties and challenges addressed?

Best Practices for In Vitro Testing

ETPLAS Training Platform Module

EU-60: Developing in vitro methods and approaches for scientific and regulatory use

<https://learn.etplas.eu/courses/eu-60/>



Ulrey et al 2021. How a GIVIMP Certification Program Can Increase Confidence in In Vitro Methods. ALTEX 38(2), 316-318. doi:10.14573/altex.2102261



Upcoming Trainings

IIVS ToxTracker genetic toxicity assay: Focused lecture/discussion and hands-on training over 1.5 days

- August 15-16, 2024 in Gaithersburg
- Register: <https://bit.ly/ToxTracker>

NICEATM ICE Hands-on Training

- Tomorrow afternoon! See Nicole to register.

Practical Methods Laboratory Training

- September 23-26, 2024
- Observe multiple assays in the lab and participate in discussions with study directors and biologists



Key Training Resources

- IIVS Practical Methods Hands-on and more: <https://www.iivs.org>
- PCRM NURA: <https://www.pcrm.org/nura>
- ASCCT: <https://www.ascctox.org/webinars>
- AFSA Master Class: <https://www.afsacollaboration.org/masterclass/>
- PETA Science Consortium International webinars: <https://www.thepsci.eu>
- EPA NAMs Training Site: <https://www.epa.gov/chemical-research/new-approach-methods-nams-training>

