How Following GIVIMP Aligns Your Work with the Framework

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A Framework for Establishing Scientific Confidence in New Approach Methodologies

- Built on information compiled over several years, published in many places
- Original focus on pesticide and industrial chemicals but these concepts can easily be applied more broadly

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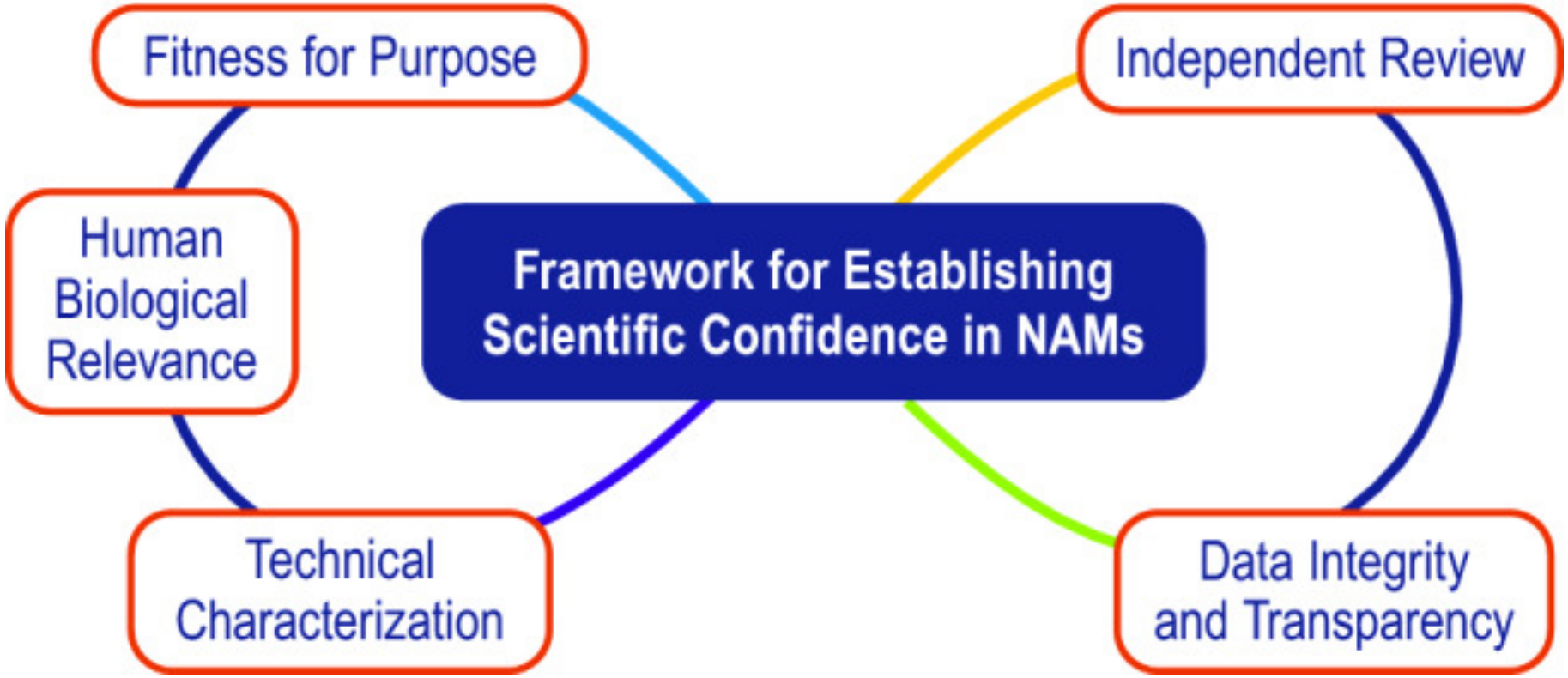
A framework for establishing scientific confidence in new approach methodologies

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

Five Elements of the Framework



Arch Toxicol. 2022; 96(11): 2865–2879.

Good In Vitro Method Practices (GIVIMP)

1) A detailed update on good practices for state-of-the-art *in vitro* methods applied to regulatory human safety assessment of a variety of compounds

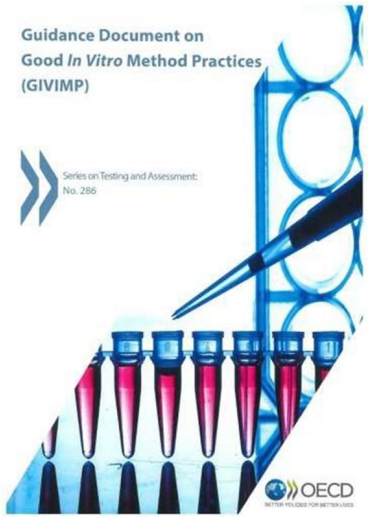
2) Guidance to users and implementers of *in vitro* methods to help to ensure that methods are well-designed, robust, well-defined and well-described

3) Description of the key aspects that may impact the reliability and relevance of *in vitro* data

4) Description of the importance of reporting criteria, including establishing acceptance criteria and performance standards from *in vitro* data sets

Available on OECD e-Library
https://doi.org/10.1787/20777876

Also available on the
OECD Series for Testing and Assessment No. 286



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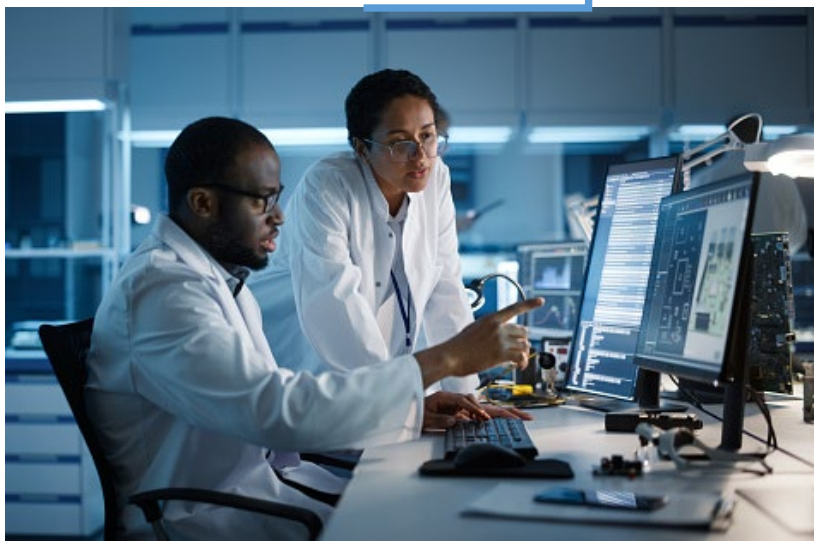
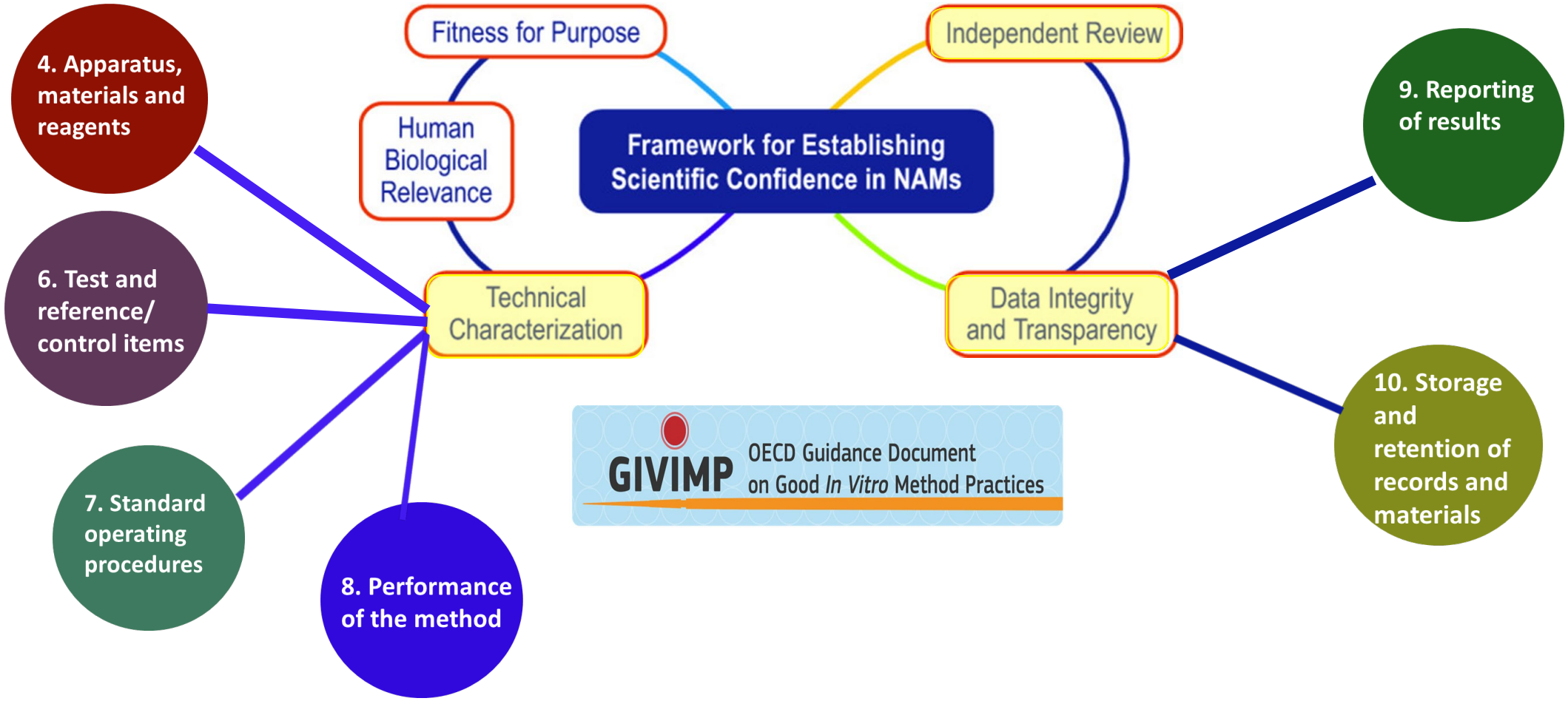
Confidence



Where GIVIMP Overlaps with the Framework



Technical Characterization

Point from the Framework Document	GIVIMP Section
Assess and Describe the Method	7.1 In vitro method standard operating procedures development 8.2 Experimental design
Transferability	8.4 Proficiency chemicals
Applicability Domain	6.2 Applicability and limitations of the method
Reference Chemicals	6.1 Reference and control items
Controls	6.1 Reference and control items
Limits of Detection and Quantification	4.1 Apparatus 8.3.1 Detection limits and cut-off values 8.3.2. Linearity and dynamic range
Accuracy	8.3.3. Accuracy and precision

Technical Characterization

"*Evaluate* the protocol, the equipment used, and any computational models being used for endpoint prediction…"

- GIVIMP includes guidance that can be referenced for many types of methods

Bench Marks!

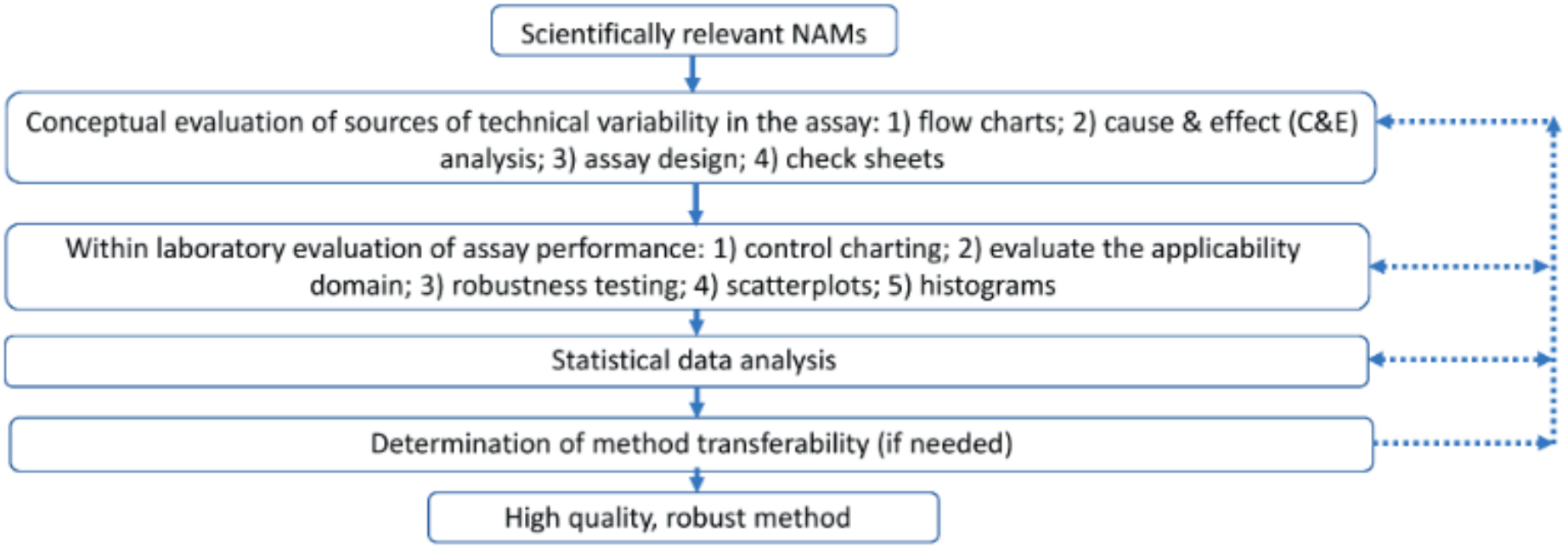
Technical Framework for Enabling High Quality Measurements in New Approach Methodologies (NAMs)

Elijah J. Petersen[1], John T. Elliott[1], John Gordon[2], Nicole C. Kleinstreuer[3], Emily Reinke[4], Matthias Roesslein[5] and Blaza Toman[1]

[1]National Institute of Standards and Technology (NIST), Gaithersburg, MD, USA; [2]US Consumer Product Safety Commission, Rockville, MD, USA; [3]National Institute of Environmental Health Sciences, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, Research Triangle Park, NC, USA; [4]U.S. Army Public Health Center, Aberdeen Proving Ground, MD, USA; [5]Empa, Swiss Federal Laboratories for Material Testing and Research, Particles-Biology Interactions Laboratory, St. Gallen, Switzerland

Technical Characterization

Approach for method optimization



Petersen EJ, Elliott JT, Gordon J, Kleinstreuer NC, Reinke E, Roesslein M, Toman B. Technical framework for enabling high-quality measurements in new approach methodologies (NAMs). ALTEX. 2022 Jul 15. doi: 10.14573/altex.2205081. Epub ahead of print. PMID: 35867862.

Applicability and Limitations

- GIVIMP calls for transparent discussion and reporting of the applicability domain and limitations of the method.

- This allows for the assessment of the same method in many different contexts
  - Regulatory frameworks
  - Chemistries of test items

Reproducibility and Transferability

Reproducibility – the measurement of how closely results of a particular method agree when repeated using the same protocol and substance

Following GIVIMP recommendations leads to the development of well defined methods, which are more reproducible and easier to transfer to new laboratories.

Data Integrity and Transparency

Demonstrate the integrity and credibility of data – from raw data to final report

Table 10.1. **Terms associated with ALCOA**

	Criteria	Description / Explanation	Comments
A	Attributable	Who performed an action and when? If a record is changed, who did it and why? Link to the source data.	**Who did it? Source data**
L	Legible	Data must be recorded permanently in a durable medium and be readable.	**Can you read it? Permanently recorded**
C	Contemporaneous	The data should be recorded at the time the work is performed and date / time stamps should follow in order.	**Was it done in "real time"?**
O	Original	Is the information the original record or a certified true copy?	**Is it original or true copy?**
A	Accurate	No errors or editing performed without documented amendments.	**Is it accurate?**

OECD (2018), *Guidance Document on Good In Vitro Method Practices (GIVIMP)*, OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris, https://doi.org/10.1787/9789264304796-en.

Independent Review

- Demonstrate data integrity prior to the independent/peer review process

- In addition to the scientific review, independent evaluation of the process used for data acquisition, transfer, and processing.

Summary

The quality of data cannot be improved once collected, but data integrity can be lost without proper governance and management practices.

GIVIMP has best practices for you to follow in the lab for new method design, execution, and reporting.

Laboratory behaviors that follow GIVIMP allow for you to meet the points raised in the Framework for Establishing Scientific Confidence in NAMs.

Thank You

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Download GIVIMP here