

# NANORIGO

<b>DELIVERABLE No.</b>	<b>D1.6</b>
<b>DELIVERABLE TITLE</b>	Verification of mutually accepted tools to ensure availability of high quality data
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## Executive Summary

The primary objective of D1.6 was to assess the viewpoints of different stakeholders (spanning from scientists and regulators to members of non-governmental organizations [NGOs]) on the issue of data quality assessment and its role within regulatory risk assessment and decision making. This has been accomplished through interview-style questionnaires which also partly aim to verify/gather viewpoints on the use of tools (i.e., data quality assessment methods) for the mutual acceptance of data that have not otherwise been strictly produced under MAD conditions (otherwise referred to as 'mutually accepted tools').

The **mutual acceptance of data (MAD)** system was developed by the Organization for Economic Co-operation and Development (OECD) to harmonize national approaches to chemical testing and regulation to reduce conflicting and duplicative requirements and decrease barriers to trade. Study/data adherence to MAD requirements encompasses the following:

1. The study was conducted according to OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP);
2. The study was conducted in a test facility which was inspected by a national GLP compliance monitoring program (CMP), and
3. The national GLP CMP successfully passed evaluation by the OECD (OECD, 2019).

In trying to both expand the pool of available data for regulatory risk assessment and decision making beyond strictly MAD-compliant studies and better incorporate all stakeholder interests into the future NANORIGO NRGF and NRGF, the main goal of D1.6 was to gather and assess the viewpoints of different stakeholders (e.g., [industry] scientists, regulators, and members of NGOs) on data quality and its role within regulatory governance. To that end, two separate but related questionnaires: one for respondents from science-based sectors and another for respondents from social science-based sectors, were administered either by phone or over video conferencing software to relevant experts within these fields.

Based on the responses to the questionnaire gathered, several main points/conclusions could be made:

- The use of data quality assessment methods is not very widespread.
- Data that can be considered as being of 'high' or 'acceptable' quality is heavily dictated by 'fitness-for-purpose.'
- The concept of 'good quality' is so dependent on the purpose for which data is produced that the whole concept of using comprehensive, discipline-specific data quality assessment tools/schemes and their construction may need to be reconsidered.

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- Of relevance to the future NANORIGO NRGC and NRGF, there is a widespread understanding of the need for and importance of including all stakeholder perspectives.

On the basis of these conclusions, some recommendations were suggested:

- More emphasis should be put on data producers to supply experimental metadata.
- Informative tools are needed to increase Data Readiness Levels (DRLs).
- Greater guidance and support are needed for dealing with outdated, unreliable, and incomplete data.
- The implementation of a formalized/standardized method for taking low quality data into account during regulatory risk assessment and decision-making.

## **References**

OECD. (2019). *Mutual Acceptance of Data (MAD)*—OECD.  
<https://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm>

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