# From Principles to Reality. FAIR Implementation in the Nanosafety Community

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## Abstract

Nanoscience as a key enabling technology will be fundamental to address several of the current global challenges. Developing safe and sustainable solutions requires high quality data and appropriate analysis approaches. Therefore, implementation of the Findability, Accessibility, Interoperability and Reusability (FAIR) principles within the nanosafety community is key to achieve this and the main goal of the AdvancedNano GO FAIR Implementation Network. Here we highlight the activities of the network to support the nanosafety community in achieving this goal under the overarching aim of maximizing both safe and sustainable application of nano- and advanced materials.

## A FAIR Implementation Network for nanosafety data

Nanoscience has a key role in the achievement of the ambitious green and sustainable policy goals, in the EU and globally. The possibility to produce tailor-made nanomaterials (NMs) with exceptional characteristics provides significant contributions to societally relevant innovations. Today, NMs already have a broad range of applications in green technology, food safety, medicine, cosmetics, agriculture, etc. Progress in the field, towards increasingly advanced materials (AdMa, as described recently[1]), depends on analysis and modelling of large experimental and/or computational (simulated) datasets allowing for the prediction of NMs' functionalities, behaviours and effects in complex environments[2]. Prediction of the NMs' potential for release from products, fate (in humans and the environment) and hazard will support innovation by facilitating safety and sustainability assessment, in line with the recently proposed Safe and Sustainable by Design (SSbD) framework[3,4] (see also details in[5]). For SSbD approaches, comprehensive evaluations of data originating from the wide-ranging field of nanosafety research is essential. The need for data sharing in a harmonised and quality-controlled way has been identified as a prerequisite to optimise the efficiency of the innovation process and is under continuous refinement[6-10]. While facilitating gathering of nanosafety data, the data-sharing field remains far from functionally perfected for efficient reuse of the massive amounts of data produced over the past decades[11,12]. Available data is scattered over different databases/sources and represented with different standards (or without standards) hampering both its reuse and large-scale machine-driven analyses[10,13]. Moreover, many of the data providers are not fully aware of the need and the possibilities to enable data for reuse.

The AdvancedNano GO FAIR Implementation Network[i] (IN) was created to implement the FAIR (Findable, Accessible, Interoperable and Reusable) principles[14] within nanosafety data management, thereby maximising the value of scientific data generated within the domain. The

AdvancedNano IN is rooted in the GO FAIR initiative[ii] which offers an open and inclusive FAIR data ecosystem for individuals, institutions and organisations working together through Implementation Networks in otherwise different and complementary domains. The overarching aim of the AdvancedNano IN is to promote data-driven innovation in nanoscience. This aim should be coupled to ensuring protection of human health and the environment via machine-driven reuse of existing safety data in support of overcoming the 21st century toxicology-derived challenge "too many chemicals [and materials], too little data"[15]. Collaborative actions are needed for making nanosafety data machine-actionable, and thus, the network aims to identify key partners for data governance, to engage relevant stakeholder groups, and to provide cross-domain solutions for implementing the FAIR principles among the diverse nanosafety research fields. In parallel with the establishment of the AdvancedNano IN, a manifesto was published to describe the concerted action needed to implement the above task[16]. Here we build further on the implementation principles and objectives presented in the AdvancedNano IN manifesto. While we acknowledge that the efforts towards FAIRification of data relate to a wide number of important aspects and challenges as described in the original paper and by others[6,14], the focus in this Comment lies on outlining the role and action plan of the network, as well as to provide an overview of the impact expected from this initiative.

## Challenges for FAIR implementation and the role of the AdvancedNano IN

Despite the advances made within nanosafety data management during the past years, several challenges for the implementation of the FAIR principles have recently been identified and described both within and beyond the nanoscience community[2,10,17]. They can be summarised as (a) a lack of awareness, (b) a lack of harmonisation, (c) a lack of tools for FAIRification, and (d) an overarching lack of infrastructures to support an adequate addressing of the former challenges. Additionally, a lack of incentives and funding for data FAIRfication is recurrently reported by data producers and has been identified as a further challenge. Thus, the role of the AdvancedNano IN is to provide support towards overcoming these challenges as follows:

People: The AdvancedNano IN aims to raise awareness, propose incentives and support education of researchers, regulators and industry, and to provide guiding principles to bring about cultural change and allow for the development of data standards and governance strategies within nanoscience. The AdvancedNano IN manifesto[16] provides an overview of 10 initial implementation principles outlining the requirements for creating a FAIR culture within the field. The principles, which cover aspects such as (i) data owners' control over their data, (ii) reusability of both data and code (FAIR models/tools), (iii) machine-readability, (iv) data

standards, (v) governance, and (vi) promotion of the solutions developed, align tightly with the guiding principles recently proposed by the European Commission in their data governance and data policies strategy[18]. Further aspects to be considered within the AdvancedNano IN include: (vii) sustainability of the solutions, (viii) measurability of the progress of FAIRification, (ix) embedded solutions supporting data governance that minimizes any additional administrative burden, and (x) a "comply-or-explain" principle entailing a recommendation that FAIR principles should be implemented as far (and as soon) as possible, or else a justification for why this had not been done should be provided. Thus, the role of the AdvancedNano IN is to offer FAIR guidance specific to the nanosafety domain, building on the solutions already in place or in development as outlined briefly below. The AdvancedNano IN will take an active role to establish a set of domain-specific implementation principles and involve, participate, engage and collaborate with all stakeholders identified to date, including data generators, database developers, data(base) users in different environments, including industry, academia, and regulatory instances. The AdvancedNano IN is committed to engage publishers and journal editors, as well as funding and governance agencies to increase awareness of the advantages of the FAIRification process for data reuse.

Harmonisation: In order to harmonise FAIRification endeavours and allow for interoperability, the use of standards is necessary throughout the lifecycle of data reuse. The role of the AdvancedNano IN is to facilitate high-level international initiatives for metadata capture (reporting standards), terminology (ontology standards), representation (identifier standards), data retrieval (application programming interface (API) standards), format standards (file type and structure) and modelling (software and model reporting standards). The AdvancedNano IN aims to engage with a wide range of key organisations and initiatives relating to nanoscience and beyond, including the Organization for Economic Cooperation and Development Working Party for Manufactured Nanomaterials (OECD WPMN[iii]), the US-EU Communities of Research on NMs Environmental Health and Safety (nanoEHS[iv]), the EU Nanosafety Cluster[v], the EU Observatory for Nanomaterials (EUON[vi]), the European Life Science Infrastructure ELIXIR[vii], the NanoFabNet Hub[viii], and other European projects funded under the Horizon Europe framework[ix], including large ones, such as the recently initiated Partnership for the Assessment of Risks from Chemicals (PARC[x]) involving nearly 200 partners from 28 different countries, the International Network Initiative on Safe and Sustainable nanotechnology (INISS-nano[xi]), the International ecosystem for accelerating the transition to Safe-and-Sustainable-by-design materials, products and processes (IRISS[xii]) project, and the WorldFAIR project[xiii] which specifically addresses NMs as one of its domains for FAIRification.

Tools: The AdvancedNano IN will support the development of tools for FAIRification of nanosafety data, including data handling strategies, approaches for implementation of training/education, FAIR assessment tools, data models and repositories, electronic laboratory notebooks, data reporting/capture templates, ontology/semantic mapping, generation of machine-ready datasets, metadata generators, and more. Examples of tools currently in development and supported by this action include databases providing searchable interfaces[10,19,20], systems and data access architectures to support optimal data management across multiple data sources and the entire life cycle of NMs[6], strategies for generating global unique identifiers and machine-readable structural representation approaches for NMs (e.g. the InChI for nano)[21,22], and data-driven approaches and methodologies for safe (and sustainable) by design (SSbD) approaches[3,23,24].

Infrastructure: The AdvancedNano IN provides a basis for the continued development of digital infrastructures for the implementation of the FAIR principles within the nanosafety field. This effort also includes engagement exercises with other GO FAIR Foundation initiatives to implement suitable standards and tools, including for example the GO FAIR Chemistry[xiv] Implementation Network. The AdvancedNano IN will collect and adopt other project experiences and principles to continuously monitor, refine and improve the development of a FAIR data-driven nanosafety infrastructure.

## The AdvancedNano IN Action Plan

The AdvancedNano IN action plan builds on the data governance and policy strategies outlined by the European Commission[18]. The AdvancedNano IN will primarily support three main action categories as depicted in Figure 1; **1) Definition and set-up**, where domain-specific descriptions of FAIR implementation principles are developed under the aim of creating general and specific *FAIR Implementation Profiles (FIPs)*, which technically specify FAIRification of data and software fit for the nanosafety community and its down-stream research and innovation fields. This first action category also covers endeavours to install monitoring strategies to measure the progress of FAIRification within the field and its continuous refinement ultimately leading to improvement; **2) Implementation**, where new solutions, methods and tools are employed and endorsed as *FAIR Enabling Resources (FERs)* within and beyond the nanosafety community *e.g.,* through development of case studies for monitoring-, refinement- and improvement-solutions. This second action category also involves identification of gaps to category 1-related solutions; and finally, **3) Roll-out and operation**, where principles, solutions and tools are embedded in practice through several widespread communication, training and education initiatives. In parallel, the third action

category includes iterative monitoring, refinement and improvement work for generating feedback to action categories 1 and 2.

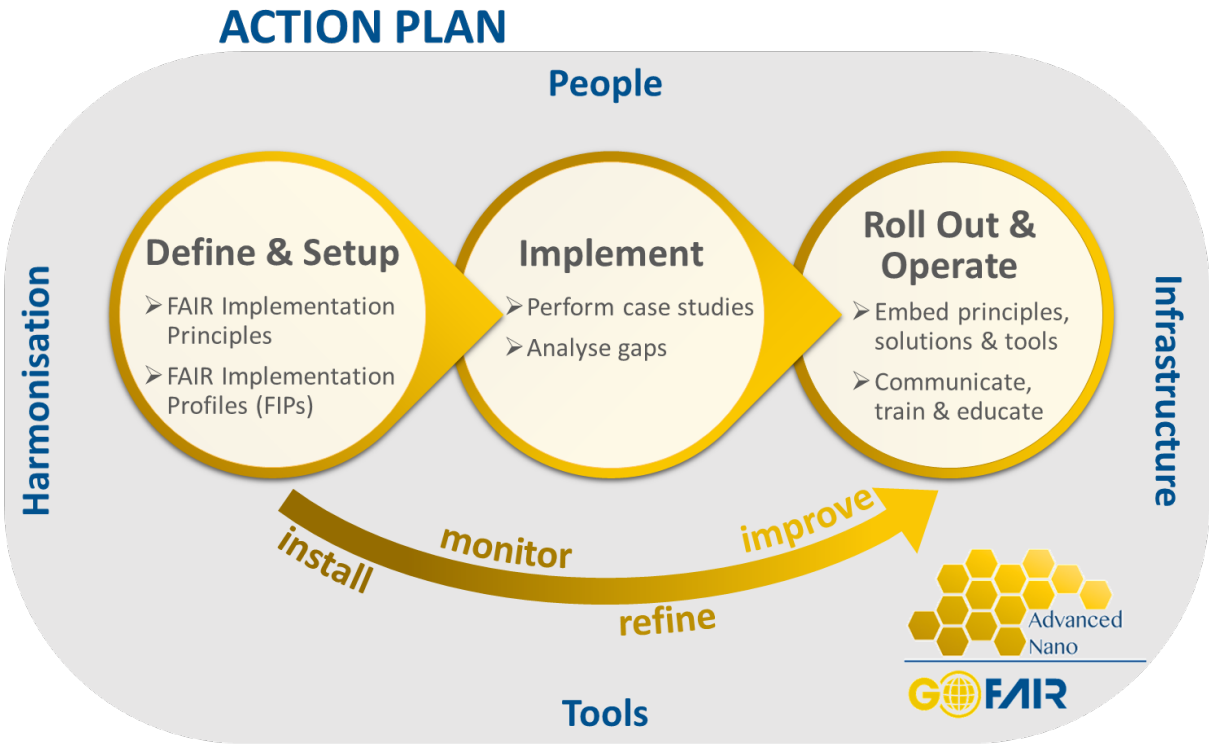


**Figure 1.** The AdvancedNano IN action plan foresees three main action categories at the center of the identified FAIRification challenges, *i.e.* people's awareness, harmonisation, tools, and infrastructure, and involves monitoring strategies enabling refinement and further improvement of the FAIRification process.

All three categories of action involve activities relating to the previously outlined support to people, harmonisation, tools development and infrastructure establishment. An example is support for data providers, including development and dissemination of tutorials with practical examples (*e.g.,* data search and download; data upload *via* templates), and implementation of (meta)data standards at the stage of data production, which is crucial and couples to identifying obstacles to FAIRification solutions. In relation to these aspects, the education of for example so-called data stewards (i.e. experts in data-handling) are considered for supporting implementation of the FAIR principles and the use of available tools for FAIRifying data[6,18]. The AdvancedNano IN will support existing solutions helping to drive improved embedding of these tools into nanosafety research data workflows as part of standard practice. Another important activity in support of data producers includes reaching out to scientific journals[25] to implement guiding principles and harmonize FAIRification requirements across the field beyond just

indexing of publications. Such activities have proven highly central within other fields of data-rich research, such as omics and bioinformatics[26-28].

Other types of activities in support of data science/use, as well as other related INs, include wide dissemination activities, liaising with relevant projects and initiatives, and organising webinars, workshops and training schools. For example, as part of its mission, the GO FAIR Initiative hosts collaborative workshops among stakeholders of INs. Furthermore, the AdvancedNano IN aims to disseminate through yearly events such as the NanoSafety Cluster's activities[xv], the Nanosafety Training School[xvi], and other nano-events and –conferences. Moreover, educational resources, available for uptake in academic curricula with focus on materials and toxicology education, will be considered. Examples include dissemination of "open educational resources" such as the ELIXIR FAIR Cook Book[xvii] and the NanoCommons User Guidance Handbook[xviii].

## Impact of the AdvancedNano IN

The AdvancedNano IN will raise awareness of the value of reusable NMs (safety) data, highlighting the far-reaching impact within the nanosafety community and beyond, including support for the much-needed transparency of safety information within the responsible and sustainable development of green nanotechnology. Overall, the AdvancedNano IN aims to drive the necessary cultural change and to bridge the gap between available tools/infrastructures and stakeholders to embed FAIR workflows into everyday research practice in the nanosafety community.

The network is expected to have broad impact on the shift towards machine-driven reuse of nanosafety data in line with the recently coined complementary and forward-looking interpretation of the FAIR acronym; "*Findable and AI-Ready*" data[2], where the "AI" is a reference to artificial intelligence and the use of machine learning approaches. The advantages of data reuse will be manifested in the AdvancedNano IN through directed case studies to predict the potential hazards of NMs with specific characteristics framed within clear applicability domains.

The activities of the AdvancedNano IN are expected to contribute to novel risk assessment approaches involving New Approach Methodologies (NAMs)[24], Integrated Approaches for Testing and Assessment (IATAs)[29], and being better aligned with innovation processes (SSbD approach[4]). Data reuse is essential for the development and application of relevant NAMs and IATAs in order to minimise uncertainties[29]. In addition, SSbD strongly benefits from data reuse

at early stages of innovation where costly toxicity testing is rarely possible and initial data-driven modelling and screening of hazard-alerts becomes crucial[24,30]. Furthermore, SSbD aims for fully transparent processes along the whole life cycle of the assessed materials (NMs or AdMa) and thus requires implementation of FAIR criteria.

Through collaboration with other key initiatives, as outlined throughout the text, the AdvancedNano IN will aim to raise awareness of the need of funding to become self-sustained and to support the action plan of the EU CSS[31] (*e.g.* the “One substance, one assessment” approach especially regarding the common open data platform that should facilitate the sharing, access and re-use of information), paving the way for the "zero pollution" ambition announced in the European Green Deal[32]. Notably, the interaction with the PARC initiative is of particular relevance because the data libraries therein are built on the results of the review ‘Feasibility Study on a Common Open Platform on Chemical Safety Data’[33].

Overall, the AdvancedNano IN aligns with the data governance policies outlined by the European Commission[18] and contributes to boosting the impact of the nanosafety community by clearly defining roles and responsibilities, and by introducing FAIR implementation principles and practices relevant for the domain. The network is committed to transforming the nanosafety field into a data-driven field of research enabled by an effective data ecosystem ultimately supporting improved transparency and efficiency of regulatory risk assessment of NMs, AdMa and products containing these.

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