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From principles to reality. FAIR implementation in the nanosafety community

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ABSTRACT

Developing safe and sustainable nanomaterials-based solutions to current global challenges including clean energy, sustainable food production and water security requires access to high quality data and appropriate analysis and modelling approaches. Achieving these challenges requires increased re-use of research data to accelerate progress and support development of new materials that are safe and sustainable for energy capture and storage, nano-agriculture and environmental remediation. The principles of Findability, Accessibility, Interoperability and Reusability (FAIR) provide a roadmap to enhanced data sharing and re-use, but require consensus within the nanosafety community on metadata, ontologies and persistent identifiers (among other things) and guidance to support implementation and achieve machine-readability. Here, we highlight the main focus of the AdvancedNano GO FAIR Implementation Network in supporting the nanosafety community with implementation of FAIR to maximize data-driven safe and sustainable application of nano- and advanced materials.

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A FAIR implementation network for nanosafety data

Nanoscience has a key role in the achievement of green and sustainable policy goals, in the EU and globally [1–3]. The possibility of producing tailor-made nanomaterials (NMs) with exceptional characteristics promises significant contributions to societally relevant innovations. Today, NMs already have a broad range of applications in green technology, food safety, medicine, cosmetics, agriculture, *etc.* [1–3]. Progress in the field, towards increasingly advanced materials (AdMa, as described recently [3-5]), depends on the analysis and modelling of large experimental and/or computational (simulated) datasets which predict the NMs' functionalities, behaviors and effects in complex environments [6]. Prediction of the potential release of NMs from products, their 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 [7,8] (see also details in [4,9]). In SSbD approaches, comprehensive evaluations of data originating from the wide-ranging field of nanosafety research is essential. The need for data sharing in a harmonized and quality-controlled way has been identified as a prerequisite to optimize the efficiency of the innovation process and is under continuous refinement [10–14]. While facilitating the gathering of nanosafety data, the data-sharing field remains far from perfected for efficient reuse of the massive amounts of data produced over the past decades [15,16]. Available data is scattered over different databases/sources and structured using different standards (or without standards) hampering both its reuse and large-scale machine-driven analyses [14,17]. Moreover, many data providers are not fully aware of the need and the possibilities to enable data for reuse.

Data reuse is stimulated by application of the FAIR (Findable, Accessible, Interoperable and Reusable) principles [18]. These principles are generic by character and aimed to be applicable to largely any type of data for the overarching purpose of enabling both humans and machines to reuse data in efficient manners. How to apply these broad principles to data generated within a specific scientific area (*e.g.,* what metadata are relevant for nanosafety data?) is up to the respective scientific community and requires extensive communication and collaboration in order to effectively implement the principles. The GO FAIR initiative[1] provides support to scientific communities and offers an open and inclusive FAIR data ecosystem for individuals, institutions and organizations to work together within implementation networks [19,20]. For this purpose, *i.e.* the management of nanosafety data, the AdvancedNano GO FAIR Implementation Network[2] (IN) was created. 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-enabled reuse of existing safety data in support of overcoming the 21st century toxicology-derived challenge "too many chemicals [and materials], too little data" [21,22]. Collaborative actions are needed for structuring nanosafety data in such a way that machines can work with them (*i.e.* 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 [23]. 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 [10,18], the focus in this Opinion lies in outlining the role and action plan of the network, as well as providing 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 over 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 [6,14,24]. They can be summarized as lack of (a) awareness, (b) harmonization, (c) tools for FAIRification, and (d) overarching infrastructures to support the addressing of these challenges adequately. Additionally, a lack of incentives and funding for data FAIRification 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. In addition, it aims at providing guiding principles to bring about cultural change and allow for the development of data standards and governance strategies within nanoscience. The AdvancedNano IN manifesto [23] provides an overview of 10 initial implementation principles for creating a FAIR culture within the field. These 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 developed solutions, align tightly with the guiding principles recently proposed by the European Commission in their data governance and data policies strategy [25]. 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 minimize 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 provide a justification for why this had not been done. 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 in establishing a set of domain-specific implementation principles and engage and collaborate with all stakeholders identified to date, including data generators, database developers, data(base) users in different environments, such as industry, academia, and regulatory bodies. 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.

Harmonization

In order to harmonize FAIRification endeavors 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 international initiatives for metadata capture (*e.g.* reporting standards, so that data providers report the data in harmonized manners), terminology (*e.g.* ontology standards to make sure interpretation of (meta)data is unambiguous), representation (*e.g.* identifier standards to ensure unambiguous identification of materials), data retrieval (*e.g.* application programming interface (API) standards to allow for interoperability), format standards (*e.g.* file types

[1] www.go-fair.org
[2] www.go-fair.org/implementation-networks/overview/advancednano/

Table 1
Key organizations and initiatives engaged by AdvancedNano IN and its outreach.

Organization or Initiative	Acronyms	Extent of outreach
Organization for Economic Cooperation and Development Working Party for Manufactured Nanomaterials	OECD WPMN[a]	OECD member states[b]
US-EU Communities of Research on NMs Environmental Health and Safety	US-EU CoRs nanoEHS[c]	Europe, US
Partnership for the Assessment of Risks from Chemicals	PARC[d]	Europe (200 partners in 28 countries, national agencies and research organizations, ECHA, EFSA, EEA)
International Network Initiative on Safe and Sustainable nanotechnology	INISS-nano[e]	Europe, Asia
The WorldFAIR Project	WorldFAIR[f]	Europe, Kenya, Australia, Latin America
EU Nanosafety Cluster	EU Nanosafety Cluster[g]	Europe
EU Observatory for Nanomaterials	EUON[h]	Europe
European Life Science Infrastructure – Toxicology Community[22]	ELIXIR[i]	Europe
International Hub for sustainable High-Tech Innovation	NanoFabNet Hub[j]	Europe, (*i.e.* EEA), UK, US, Japan
European projects	Horizon Europe framework[k]	Europe (incl. Associated Countries, UK, EEA) and third countries[l]
International ecosystem for accelerating the transition to Safe-and-Sustainable-by-design materials, products and processes	IRISS[m]	Europe
International Network For Researching, Advancing, and Assessing Materials for Environmental Sustainability	INFRAMES[n]	US, Europe, West Africa
IUPAC Working group on Extension of InChI to Nanomaterials	IUPAC[o]	Europe, US (plus experts from Brazil, Mexico, Australia, China, Japan, South Korea, South Africa and more)
European Materials Modelling Council and European Materials Characterization Council	EMMC[p] and EMCC[q]	Europe
Advanced Materials 2030 Initiative	AMI2030[r]	Europe

[a] www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm
[b] https://www.oecd.org/about/members-and-partners/
[c] www.niehs.nih.gov/research/supported/exposure/nanohealth/index.cfm
[d] https://www.eu-parc.eu
[e] zenodo.org/record/5004929
[f] worldfair-project.eu
[g] www.nanosafetycluster.eu
[h] euon.echa.europa.eu
[i] https://elixir-europe.org/communities/toxicology
[j] www.nanofabnet.net
[k] research-and-innovation.ec.europa.eu
[l] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021–2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf
[m] www.ivl.se/english/ivl/press/press-releases/2022–06–28-major-eu-initiative-launched-to-accelerate-the-transition-to-safe-and-sustainable-materials-products-and-processes.html
[n] https://inframes.pratt.duke.edu/
[o] https://iupac.org/project/2022–001–2–800/
[p] https://emmc.eu/
[q] http://characterisation.eu/
[r] https://www.ami2030.eu/

and structure) and modelling (including software and model reporting standards). The AdvancedNano IN aims to engage with a wide range of key organizations and initiatives relating to nanoscience and beyond (see Table 1).

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 [14,26,27], systems and data access architectures to support optimal data management across multiple data sources and the entire life cycle of NMs, strategies for generating global unique identifiers and machine-readable structural representation approaches for NMs (*e.g.* the InChI for nano) [28–30], and data-driven approaches and methodologies for SSbD approaches [31,32].

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[3] 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 [25]. The AdvancedNano IN will primarily support three main action categories as depicted in Fig. 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 specify data and software technically fit for the nanosafety community and its down-stream research and innovation fields. This first action category also covers endeavors to install monitoring strategies to measure the progress of FAIRification within the field and its continuous refinement; **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 the development of

[3] www.go-fair.org/implementation-networks/overview/implementation-networks-archive/chemistryin/

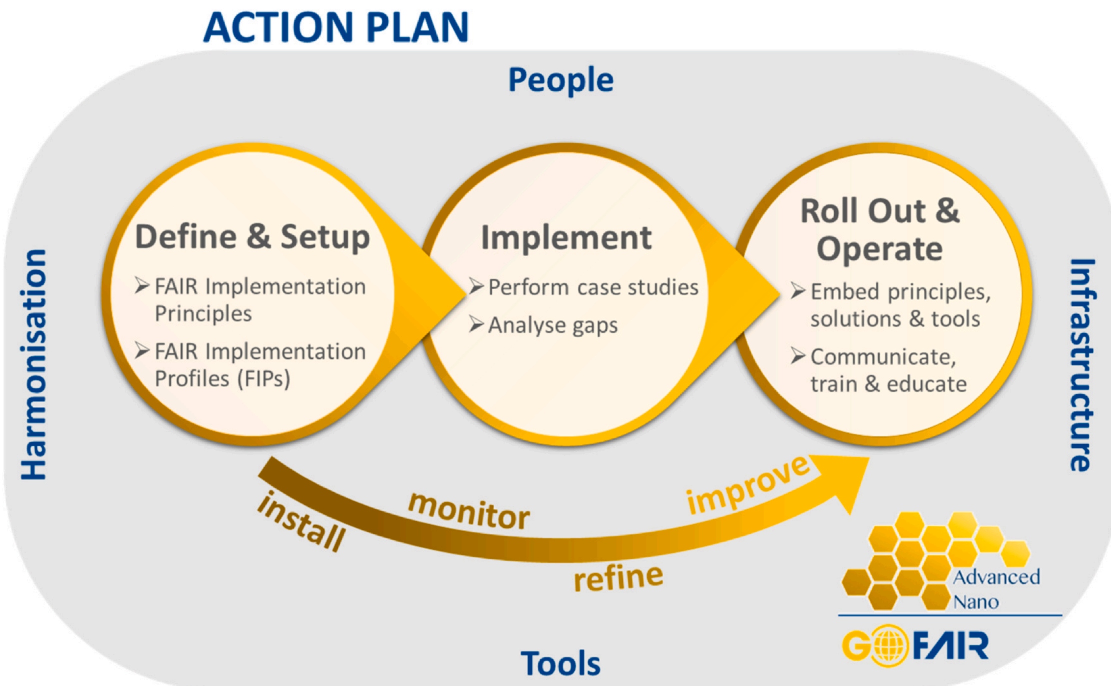

Fig. 1. The AdvancedNano IN action plan foresees three main action categories at the center of the identified FAIRification challenges, *i.e.* people's awareness, harmonization, tools, and infrastructure, and involves monitoring strategies enabling refinement and further improvement of the FAIRification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

case studies for monitoring-, refinement- and improvement-solutions. This second action category also involves identification of gaps in 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.

All three categories of action relate to activities relating to the previously outlined support to people, harmonization, tools development and infrastructure establishment. An example is support for data providers, including the 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 individuals, such as data stewards who specialize in data management, is seen as a means to support the implementation of FAIR principles and the utilization of existing tools for making data FAIR [10,25]. The AdvancedNano IN will support improved use of existing solutions for FAIR implementation within nanosafety research data workflows as a part of standard practice in the field. Another important activity in support of data producers includes reaching out to scientific journals to implement guiding principles and harmonize FAIRification requirements across the field beyond just indexing of publications. Such activities have proven central to other fields of data-rich research, such as omics and bioinformatics [33–36].

Other types of activities in support of data science/use, as well as other related INs, include dissemination activities, liaising with relevant projects and initiatives, and organizing 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 organize or contribute to yearly events such as the NanoSafety Cluster's activities,[4] the Nanosafety Training School,[5] and other nano-events and –conferences. Moreover, educational resources focused on materials and toxicology can be made available for use in academic curricula. Examples include dissemination of "open educational resources" such as the ELIXIR FAIR Cookbook [37] and the NanoCommons User Guidance Handbook.[6]

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, and advocating much-needed transparency of safety information. Overall, the AdvancedNano IN aims to drive the necessary cultural change and 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 a 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 [6], where AI refers to artificial intelligence. The advantages of data reuse will be demonstrated in the AdvancedNano IN through directed case studies to predict the potential hazards of NMs with specific characteristics in specific application areas.

The activities of the AdvancedNano IN are expected to contribute to novel risk assessment approaches involving New Approach Methodologies (NAMs) [32] and Integrated Approaches for Testing and Assessment (IATAs) [38], while being better aligned with innovation processes such as SSbD [8]. Data reuse is essential for the identification of data gaps [18] and for the development and application of relevant NAMs and IATAs in order to minimize uncertainties [38]. In addition, SSbD strongly benefits from data

[4] www.nanocommons.eu/nano-week-and-nanocommons-final-conference/nanoweek-2022-cyprus/

[5] www.nanosafetycluster.eu/nanosafety-training-school-from-basic-science-to-risk-governance/

[6] nanocommons.github.io/user-handbook/

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 [32,39]. Furthermore, SSbD aims for fully transparent processes throughout the whole life cycle of the assessed materials (NMs or AdMa) and thus requires implementation of FAIR criteria. While FAIR does not directly address data quality, rich metadata accompanying datasets can include detailed description of the quality assurance/quality control procedures.

Through collaboration with other key initiatives, as outlined throughout the text, the AdvancedNano IN will aim to raise awareness of the need for funding to become self-sustained and support the action plan of the EU CSS [40] (*e.g.* the “One substance, one assessment” approach especially regarding the common open data platform that aims to facilitate access to, sharing, and re-use of information), paving the way for the "zero pollution" ambition announced in the European Green Deal [41]. Notably, interaction with the PARC initiative [42] is of particular relevance because its data libraries are built on the results of the review ‘Feasibility Study on a Common Open Platform on Chemical Safety Data’ [43].

Overall, the AdvancedNano IN aligns with the data governance policies outlined by the European Commission [25] and aims to boost the impact of the nanosafety community by clearly defining roles and responsibilities, and introducing FAIR implementation principles and practices. The network is committed to transforming nanosafety into a data-driven field of research enabled by an effective data ecosystem supporting improved transparency and efficiency in regulatory risk assessments of NMs, AdMa and their associated products.

CRediT authorship contribution statement

Verónica I. Dumit: Conceptualization, Investigation, Writing-Original draft preparation, Writing- Reviewing and Editing. Ammar Ammar: Writing- Reviewing and Editing. Martine I. Bakker: Resources, Supervision, Conceptualization, Writing- Reviewing and Editing. Miguel A. Bañares: Reviewing and Editing. Cecilia Bossa: Resources, Writing- Reviewing and Editing. Anna Costa: Writing- Reviewing and Editing. Hilary Cowie: Writing- Reviewing and Editing. Damjana Drobne: Resources, Conceptualization, Writing- Reviewing and Editing. Thomas E. Exner: Resources, Supervision, Conceptualization, Writing- Reviewing and Editing. Lucian Farcal: Resources, Writing- Reviewing and Editing. Steffi Friedrichs: Supervision, Writing- Reviewing and Editing.Irini Furxhi: Writing- Reviewing and Editing. Roland Grafström: Supervision, Writing- Reviewing and Editing. Andrea Haase: Supervision, Writing- Reviewing and Editing. Martin Himly: Visualization, Writing- Reviewing and Editing. Nina Jeliazkova: Investigation, Writing- Reviewing and Editing. Iseult Lynch: Resources, Supervision, Writing- Reviewing and Editing. Dieter Maier: Reviewing. Cornelle W. Noorlander: Resources, Writing-Reviewing and Editing. Hyun Kil Shin: Reviewing. Galo J. A. A. Soler-Illia: Reviewing. Blanca Suarez-Merino: Writing- Reviewing and Editing. Egon Willighagen: Resources, Conceptualization, Supervision, Writing- Reviewing and Editing. Penny Nymark: Investigation, Conceptualization, Writing- Original draft preparation, Writing- Reviewing and Editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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