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Introduction

This Milestone outlines a prototype implementation of support tools to allow FAIR data generation throughout all stages of the data production and management workflow using the FAIR maturity indicators as guiding principles.

The Research Data Alliance Foundation (RDA) has published a Recommendation on the RDA FAIR Data Maturity Model[1]. This recommendation includes a set of maturity indicators and evaluation levels for assessment of FAIRness in research data, assessed against each of the FAIR principles[2]. Based on the RDA report, the FAIR data maturity indicators include:

Findability:

- F1: Metadata are assigned globally unique and persistent identifiers (essential).
- F1: Data are assigned globally unique and persistent identifiers (essential).
- F2: Rich metadata are provided to allow discovery (essential).
- F3: Metadata includes the identifier for the data (essential).
- F4: Metadata are offered in such a way that it can be harvested and indexed (essential).

Accessibility:

- A1: Metadata contains information to enable the user to get access to the data (important).
- A1: Metadata can be accessed manually (i.e., with human intervention) (essential).
- A1: Data can be accessed manually (i.e., with human intervention) (essential).
- A1: Metadata identifier resolves to a metadata record (essential).
- A1: Data identifier resolves to a digital object (essential).
- A1: Metadata is accessed through standardised protocol (essential).
- A1: Data is accessible through standardised protocol (essential).
- A1: Data can be accessed automatically (i.e., by a computer program) (important) (essential).

[1] RDA FAIR Data Maturity Model Working Group, B., FAIR Data Maturity Model: specification and guidelines. Res. Data Alliance, 2020. 10.

[2] Wilkinson et al. 2016. 2016. The FAIR Guiding Principles for scientific data management and stewardship. Sci. Data 3, 160018. https://doi.org/10.1038/sdata.2016.18

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- A1.1: Metadata is accessible through a free access protocol (essential).
- A1.1: Data is accessible through a free access protocol (important).
- A1.2: Data is accessible through an access protocol that supports authentication and authorisation (useful).
- A2: Metadata is guaranteed to remain available after data is no longer available (essential).

Interoperability:

- I1: Metadata uses knowledge representation expressed in standardised format (important).
- I1: Data uses knowledge representation expressed in standardised format (important).
- I1: Metadata uses machine-understandable knowledge representation (important).
- I1: Data uses machine-understandable knowledge representation (important).
- I2: Metadata uses FAIR-compliant vocabularies (important).
- I2: Data uses FAIR-compliant vocabularies (useful).
- I3: Metadata includes references to other metadata (important).
- I3: Data includes references to other data (useful).
- I3: Metadata includes references to other data (useful).
- I3: Data includes qualified references to other data (useful).
- I3: Metadata includes qualified references to other metadata (important).
- I3: Metadata include qualified references to other data (useful).

Reusability:

- R1: Plurality of accurate and relevant attributes are provided to allow reuse (essential).
- R1.1: Metadata includes information about the licence under which the data can be reused (essential).
- R1.1: Metadata refers to a standard reuse licence (important).
- R1.1: Metadata refers to a machine-understandable reuse licence (important).

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- R1.2: Metadata includes provenance information according to community-specific standards (important).
- R1.2: Metadata includes provenance information according to a cross-community language (useful).
- R1.3: Metadata complies with a community standard (essential).
- R1.3: Data complies with a community standard (essential).
- R1.3: Metadata is expressed in compliance with a machine-understandable community standard (essential).
- R1.3: Data is expressed in compliance with a machine-understandable community standard (important).

While all are relevant, different priorities have been set for each of the indicators, i.e., essential, important, and useful. Categorisation for each can be seen in parentheses next to the respective maturity indicator. We note that there is still some discussion of these and the essential / important / useful categorisation is somewhat contested, although it can be useful to help prioritisation of effort within a specific domain. The full implementation of these maturity indicators and respective tools is a stepwise process considering the complexity of data and metadata generation during the entire data lifecycle (see Figure 1). Table 1 presents a status summary across the FAIR sub-principles, and then some more detailed description of progress and the nano-specific implementation or prototype development is presented below.

Table 1. Overview of tools implemented or in prototype implementation for nano-domain data and metadata FAIRification.

Tool	FAIR Data Principles addressed		Status
DOIs	F1	(Meta)data are assigned a globally unique and persistent identifier	Implemented
UUIDs	F1	(Meta)data are assigned a globally unique and persistent identifier	Implemented
ORCID	F1	(Meta)data are assigned a globally unique and persistent identifier	Implemented
ROR	F1	(Meta)data are assigned a globally unique and persistent identifier	Prototype
ERMs	F1	(Meta)data are assigned a globally unique and persistent identifier	Implemented
NInChI	F1	(Meta)data are assigned a globally unique and persistent identifier	Prototype

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NIKC Templates	F2	Data are described with rich metadata	Implemented
ELNs	F2	Data are described with rich metadata	Prototype
Peer-reviewed publications	F3	Metadata clearly and explicitly include the identifier of the data they describe	Implemented
Zenodo	F3	Metadata clearly and explicitly include the identifier of the data they describe	Implemented
ELNs	F3	Metadata clearly and explicitly include the identifier of the data they describe	Prototype
Peer-reviewed publications	F4	(Meta)data are registered or indexed in a searchable resource	Implemented
Zenodo	F4	(Meta)data are registered or indexed in a searchable resource	Implemented
Google data search	F4	(Meta)data are registered or indexed in a searchable resource	Implemented
APIs	A1	(Meta)data are retrievable by their identifier using a standardised communications protocol	Implemented
Peer-reviewed publications	A2	Metadata are accessible, even when the data are no longer available	Implemented
Zenodo	A2	Metadata are accessible, even when the data are no longer available	Implemented
eNanoMapper ontology	I1	(Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation	Implemented
	I2	(Meta)data use vocabularies that follow FAIR principles	Implemented
NPO ontology	I1	(Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation	Implemented
	I2	(Meta)data use vocabularies that follow FAIR principles	Implemented
Peer-reviewed publications	I3	(meta)data include qualified references to other (meta)data	Implemented
NICK template	I3	(meta)data include qualified references to other (meta)data	Implemented
ELN	I3	(meta)data include qualified references to other (meta)data	Implemented
NIKC templates	R1	(Meta)data are richly described with a plurality of accurate and relevant attributes	Implemented
QMRF templates	R1	(Meta)data are richly described with a plurality of accurate and relevant attributes	Implemented
FIPs	R1	(Meta)data are richly described with a plurality of accurate and relevant attributes	Prototype

The nanomaterials safety community is in the process of implementing solutions to pave the way for data and metadata FAIRification. Currently, we are in the stage of prototype implementation and testing, gathering feedback from the wider community to optimise the guidelines and practices for

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adoption. This Milestone presents the tools implemented so far, and their usage in everyday scientific practice by the nanomaterials safety community.

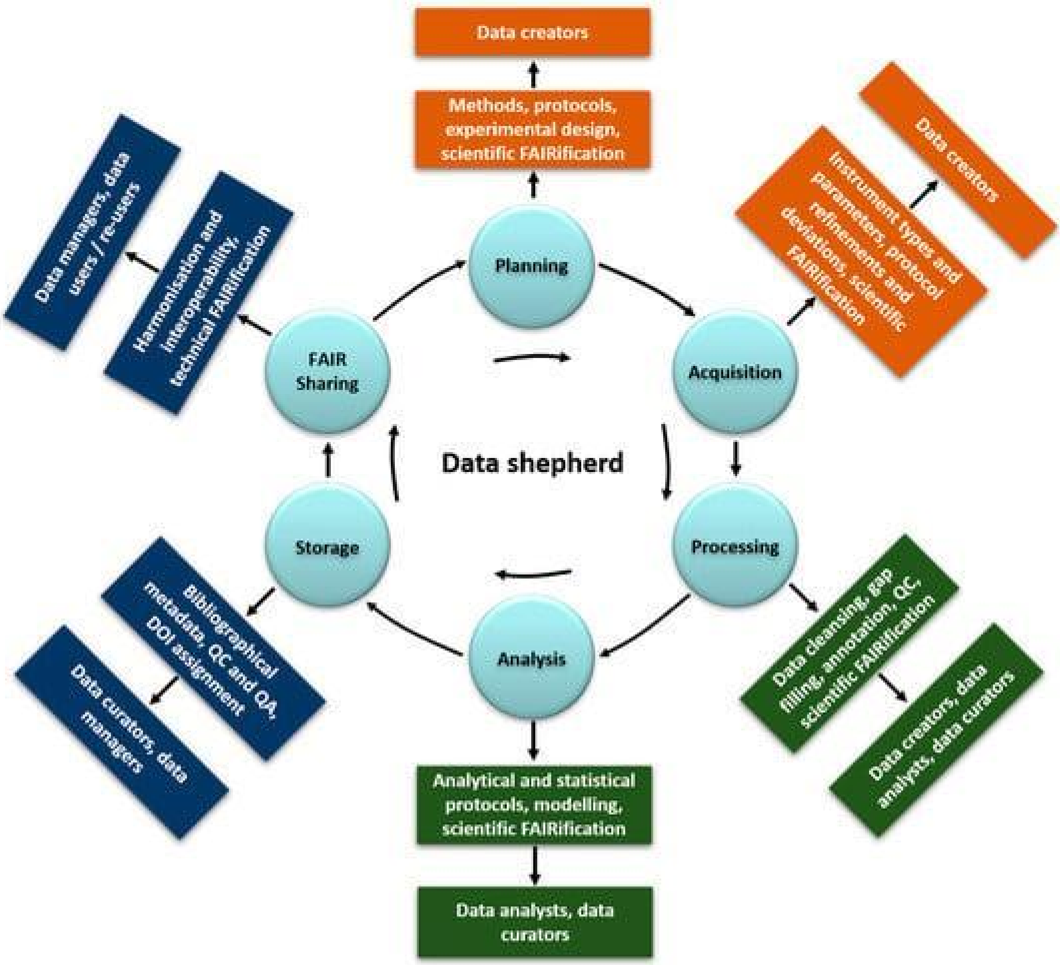

Figure 1. The data lifecycle, the metadata requirements at each stage, and the roles responsible for collecting and reporting the metadata at each step. Key: technical metadata = green, descriptive metadata = orange, bibliographical metadata = navy blue.

Implementation of FAIRification tools

The implementation of FAIRification tools covering the entirety of the data lifecycle is an evolving and stepwise process. This process is based on technological advances and tool development, coupled with changing the mindset of scientists to embrace the need for and benefit of good data management and data management as an intrinsic aspect of data generation. Furthermore, it is based on the identification and reuse of tools already established in the wider and nano scientific

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community to facilitate acceptance and reduce the workload and costs required to develop new. This should lead to community acceptance and adoption of the various tools able to support FAIR data management. The current ('As Is'), as well as some of the planned to be adopted ('To Be'), tools adopted by the nanomaterials safety community have been reported in the respective FAIR Implementation Profile (FIP) as described in detail in WorldFAIR Deliverable Report D4.1: "Nanomaterials domain-specific FAIRification mapping" and briefly presented in WorldFAIR Deliverable Report D2.1: "FAIR Implementation Profiles (FIPs) in WorldFAIR: What Have We Learnt?".

So far, in terms of findability, the most adopted globally unique, persistent, and resolvable identifier adopted by the nanomaterials safety community is the Digital Object Identifier (DOI). DOIs are used for both data and metadata. This implementation has been demonstrated for peer-reviewed scientific publications containing both data and metadata, where the datasets are made available through (for example) Zenodo, and the accompanying publication mentions that the underpinning datasets are available via Zenodo with the corresponding Zenodo DOI provided in the publication, Google Data Search[3], and for experimental protocols through protocols.io[4]. Besides these, there are ongoing community efforts for creating and using such unique identifiers via nano-related repositories such as the NanoCommons Knowledge Base[5], the NanoSolveIT Knowledge Portal[6], and the eNanoMapper Database[7]. In terms of materials and to ensure scientific provenance, the European Registry of Materials (ERM) has been established where specific nanomaterials are assigned unique identifiers[8], which have been and are being used by various EU-funded projects, e.g., NanoFASE[9], NanoCommons[10], NanoSolveIT[11], ASINA[12], RiskGONE[13], and CompSafeNano[14].

Work is ongoing in WorldFAIR to bring the proposed extension of the IUPAC International Identifier for Chemicals (InChI) for nanomaterials (NanoInChI[15]) towards a standard, which will be an essential step forward for the nanomaterials field. An existing demonstrator for NanoInChI generation[16] is being updated according to the revised specifications, based on extensive discussions with a set of international collaborators facilitated via IUPAC (Project No. 2022-001-2-800)[17], CODATA (Task Group

[3] https://datasetsearch.research.google.com/search?src=0&query=nanosafety&docid=L2cvMTF2MHgydnY0Yw%3D%3D
[4] https://www.protocols.io/view/gold-nanoparticle-synthesis-ewov14zokvr2/v1
[5] https://ssl.biomax.de/nanocommons/cgi/login_bioxm_portal.cgi
[6] https://ssl.biomax.de/nanosolveit/cgi/login_bioxm_portal.cgi
[7] https://www.enanomapper.net/data
[8] https://github.com/NanoCommons/identifiers
[9] http://nanofase.eu/
[10] https://www.nanocommons.eu/
[11] https://nanosolveit.eu/
[12] https://www.asina-project.eu/
[13] https://riskgone.eu/
[14] http://compsafenano.eu/
[15] https://www.mdpi.com/2079-4991/10/12/2493
[16] http://www.enaloscloud.novamechanics.com/nanocommons/NInChI/
[17] https://iupac.org/

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on Extension of InChI for Nanomaterials)[18] and VAMAS TWA 34 (new project 17 - proposal for NInChI)[19]. InChI and InChIKey identifiers are widely used in data FAIRificiation workflows: via KNIME nodes, for instance, which are being used to produce theInChI and InChIKey from the respective substance structures. Similarly, KNIME nodes will be created and implemented for NanoInChI, as discussed in WorldFAIR Deliverable D4.1: Nanomaterials domain-specific FAIRification mapping.

Other unique identifiers used in nanomaterials safety data and metadata include the Open Researcher and Contribution ID (ORCID), the Universally Unique Identifier (UUID), and the Research Organisation Registry (ROR). The ORCID is a FAIR Enabling Resource (FER)[20] that allows provenance linking of scientific outputs to data owners and contributors. ORCIDs have been established as identifiers for individual researchers in scientific publications, where the authors' ORCIDs are linked, and open repositories, e.g., Zenodo where the authors' ORCIDs are provided through the authors list. Work is underway to enable ORCIDs to also capture researchers contributions to ontology terms/classes also to encourage further engagement.

UUIDs are being used in specific nanosafety related databases like eNanoMapper[21] and were adopted by projects using that database e.g., NANoREG[22] and Nanoreg2[23]. RORs[24] are used to identify research organisations contributing to science and act as part of the metadata provenance. Furthermore, for the machine actionability of the actual datasets, there have been several examples of transformations of datasets, including their metadata, from Excel files into RDF format and subsequent publishing in Zenodo (see for example [25] which is the Zenodo record of the RDF form of the dataset).

To capture data and metadata, nanomaterials-specific templates have been designed to capture all information required to increase FAIRness. A characteristic example is the Nanomaterials Informatics Knowledge Commons[26] (NIKC) template, which has been designed to capture relevant information linking multiple types of metadata (bibliographical, technical, scientific, data ownership, licence) along with the data (**Figure 2**). The NIKC template includes different tabs for capturing information on specific publications and their unique identifiers, the people and organisations involved in the data production (including data owners and licences), the protocols and instruments used for transparency and interoperability, as well as a dictionary where ontological or structured dictionary terms can be included for semantic annotations. These templates can be uploaded to specific repositories, such as the purpose-built NanoCommons Knowledge Base[27], and can be

[18] https://codata.org/initiatives/task-groups/extension-of-inchi-for-nanomaterials/
[19] http://www.vamas.org/twa34/index.html
[20] https://doi.org/10.5281/zenodo.7378109
[21] https://data.enanomapper.net/substance?type=&search
[22] https://nanoreg.eu/
[23] https://www.rivm.nl/en/international-projects/nanoregii
[24] https://ror.org/
[25] https://zenodo.org/records/7602354
[26] https://ceint.duke.edu/research/nikc
[27] https://ssl.biomax.de/nanocommons/cgi/login_bioxm_portal.cgi

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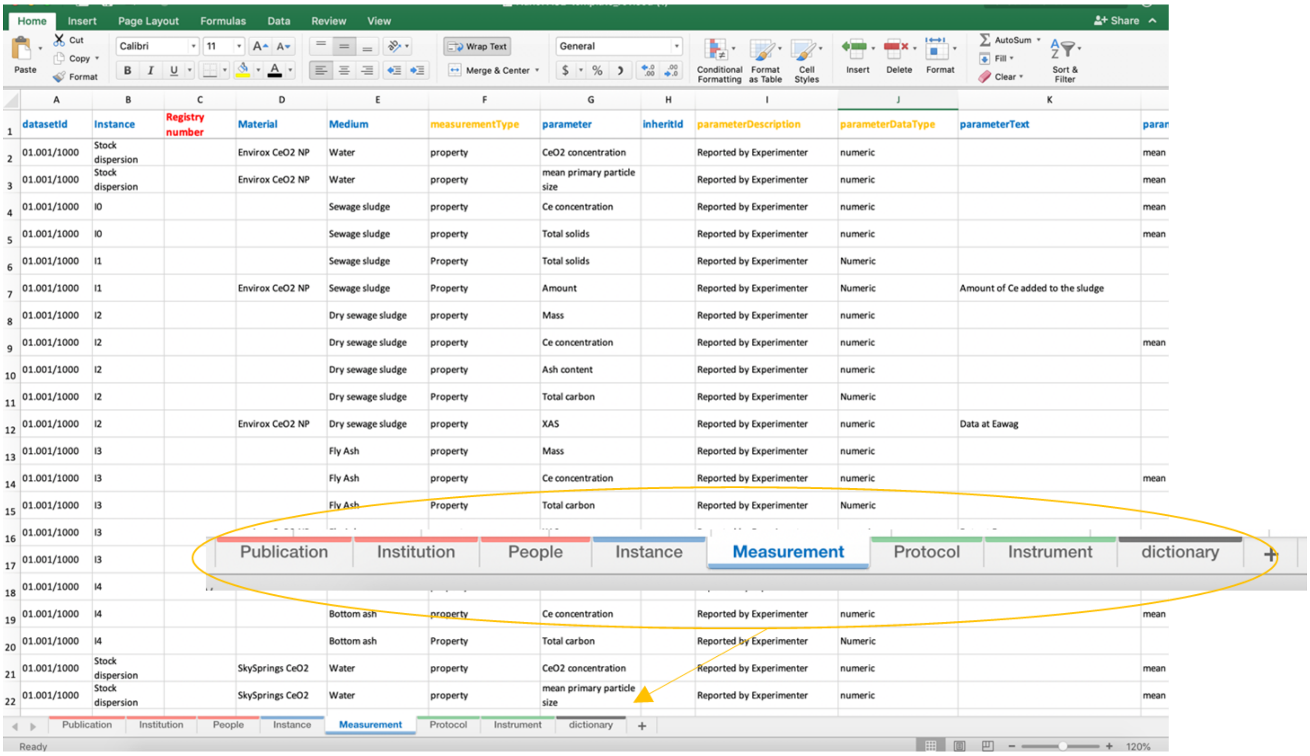
automatically parsed and the data and metadata be made available for search, download, direct upload into modelling tools and more. Full details of the tools for annotating and uploading datasets into the NanoCommons KnowledgeBase, the application programme interface for integration with other data sources and the KNIME nodes for integration of datasets into various modelling tools, and the automated assessment of dataset completeness are also presented in Maier et al.[28].



	datasetId	Instance	Registry number	Material	Medium	measurementType	parameter	inheritId	parameterDescription	parameterDataType	parameterText	paran
2	01.001/1000	Stock dispersion		Envirox CeO2 NP	Water	property	CeO2 concentration		Reported by Experimenter	numeric		mean
3	01.001/1000	Stock dispersion		Envirox CeO2 NP	Water	property	mean primary particle size		Reported by Experimenter	numeric		mean
4	01.001/1000	I0			Sewage sludge	property	Ce concentration		Reported by Experimenter	numeric		mean
5	01.001/1000	I0			Sewage sludge	property	Total solids		Reported by Experimenter	numeric		mean
6	01.001/1000	I1			Sewage sludge	Property	Total solids		Reported by Experimenter	Numeric		
7	01.001/1000	I1		Envirox CeO2 NP	Sewage sludge	Property	Amount		Reported by Experimenter	Numeric	Amount of Ce added to the sludge	
8	01.001/1000	I2			Dry sewage sludge	property	Mass		Reported by Experimenter	numeric		
9	01.001/1000	I2			Dry sewage sludge	property	Ce concentration		Reported by Experimenter	numeric		mean
10	01.001/1000	I2			Dry sewage sludge	property	Ash content		Reported by Experimenter	numeric		
11	01.001/1000	I2			Dry sewage sludge	Property	Total carbon		Reported by Experimenter	Numeric		
12	01.001/1000	I2		Envirox CeO2 NP	Dry sewage sludge	property	XAS		Reported by Experimenter	numeric	Data at Eawag	
13	01.001/1000	I3			Fly Ash	property	Mass		Reported by Experimenter	numeric		
14	01.001/1000	I3			Fly Ash	property	Ce concentration		Reported by Experimenter	numeric		mean
15	01.001/1000	I3			Fly Ash	Property	Total carbon		Reported by Experimenter	Numeric		
16	01.001/1000	I3										
17	01.001/1000	I3										
18	01.001/1000	I4										
19	01.001/1000	I4			Bottom ash	property	Ce concentration		Reported by Experimenter	numeric		mean
20	01.001/1000	I4			Bottom ash	Property	Total carbon		Reported by Experimenter	Numeric		
21	01.001/1000	Stock dispersion		SkySprings CeO2	Water	property	CeO2 concentration		Reported by Experimenter	numeric		mean
22	01.001/1000	Stock dispersion		SkySprings CeO2	Water	property	mean primary particle size		Reported by Experimenter	numeric		mean

Figure 2. Overview of the NIKC template.

For data and metadata digitisation, Electronic Laboratory Notebooks (ELNs) are being implemented. ELNs are being used to catalogue experimental workflows, and digitise the data and technical metadata as they are being produced. Among the metadata produced and stored are provenance metadata, e.g., when the data and metadata were produced, and who produced them, as well as metadata linking the data to specific materials via their ERM identifiers. Other functionalities include adding keywords and importing protocols from repositories such as protocols.io with their respective DOIs. An example implementation is the SciNote open source code ELN, which has been implemented in the DIAGONAL project[29] (**Figure 3**).

[28] https://doi.org/10.3389/fphy.2023.1271842
[29] https://cordis.europa.eu/project/id/953152

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ELNs offer the ability to capture and digitise data and metadata during the entire data lifecycle, as they offer the ability to create stepwise workflows starting from design of experiments to dataset finalisation and extraction in different formats.

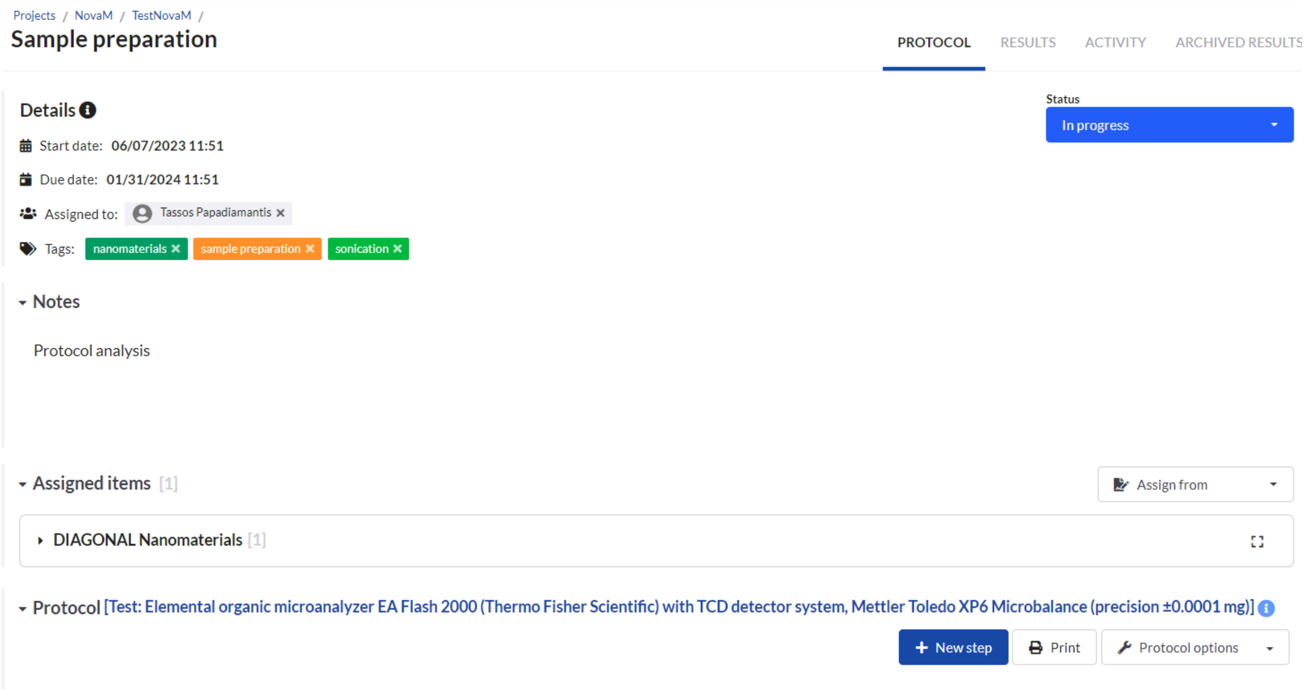

Figure 3. ELN environment for data and metadata digitisation.

Nanomaterials and nanosafety specific ontologies have also been developed, including the Nanoparticle Ontology[30] (NPO) which represents the basic knowledge of physical, chemical and functional characteristics of nanotechnology as used in cancer diagnosis and therapy, and the eNanoMapper Ontology[31] that is application ontology targeting the full domain of nanomaterial safety assessment, and intentionally re-uses classes from several other ontologies including the NPO, CHEMINF[32] which is a chemical information ontology (cheminf) that describes information entities about chemical entities, ChEBI[33] the dictionary of molecular entities focused on 'small' chemical compounds, and ENVO[34] which describes environmental entities of all kinds, from microscopic to intergalactic scales. The ENM ontology is really a community effort, and its ongoing

[30] https://bioportal.bioontology.org/ontologies/NPO
[31] http://www.ebi.ac.uk/ols4/ontologies/enm
[32] http://www.ebi.ac.uk/ols4/ontologies/cheminf
[33] https://www.ebi.ac.uk/chebi/
[34] https://sites.google.com/site/environmentontology/

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maintenance and extension has been passed from EU-funded nanosafety project to project, initially developed in eNanoMapper, then further extended in NanoCommons[9], then NanoSolveIT[10] and now in the SbD4Nano[35] project. A process for consensus building of ontology terms was implemented, whereby terms are defined initially, then refined and voted on prior to inclusion in the ontology.

Conclusions

In summary, a range of different tools have been or are being implemented (prototypes) and used to FAIRify nanomaterials safety-related data (see Table 1 for current status of implementation or prototype status across the full set of FAIR principles). While in the implementation phase, the tools cover the entirety of the data lifecycle. These include the assignment of unique identifiers, dedicated data templates to capture all types of metadata including annotation with ontologies, ELNs for capturing and digitising data and metadata, and dedicated repositories that can take these templates, parse them and automatically annotate them. Integration of these workflows as KNIME nodes is underway.

The current milestone reflects the current status of prototype implementation of tools to support nanosafety data FAIRification, reflecting the initial focus on those principles identified as essential by the RDA, and on those that were not already reported in D4.1 or in recent publications from WorldFAIR's predecessor project for nanosafety data, NanoCommons[36]. These tools demonstrate the stepwise integration of interoperability standards and guidelines for increasing FAIRness in the interlinked scientific disciplines (chemical toxicity, nanomaterials toxicity and characterisation, risk assessment, advanced materials, environmental science).

Furthermore, through the respective publications and wider usage they promote the further adoption of the FAIR principles by the international nanomaterials safety community and encourage greater alignment with neighbouring disciplines and communities. This is achieved by introducing and extending human- and machine-readable nanomaterials data provenance trails that can be easily implemented using the distributed FAIRification approach. These implementations will also set the foundations for the upcoming WorldFAIR WP04 deliverable on Nanomaterials Human/machine-readable provenance and persistence policies (WorldFAIR Deliverable report D4.3 due at Month 24), as well as setting the baseline for FAIRification of nanoinformatics tools and models recommendations (WorldFAIR Deliverable Report D4.2, due Month 21).

One example indicated in Table 1 for FAIRification of models is the QMRF (QSAR Model Report Form), which is intended for summarising and reporting key metadata on quantitative structure activity relationship (QSAR) models, including the results of any validation studies, in a highly structured and thus machine-actionable manner. These prototype tools improve the metrics for FAIR nanosafety datasets and are able to increase their interoperability leading to larger datasets that can be used for developing more robust and validated nanomaterials property and toxicity

[35] https://www.sbd4nano.eu/
[36] https://www.nanocommons.eu/

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prediction models. The provided dataset provenance will also increase the models' FAIRness, as well as enhancing regulatory trust in such models by reducing their perceived "black-box" nature. Through the provided provenance, the use of repositories dedicated to model development providing ready-for-modelling datasets, e.g., NanoPharos[37], and by applying UUIDs it will be possible to provide models with a high degree of FAIRness. The models' metadata will be published containing the unique identifiers of the datasets used and the model itself, as per the F3 principle, i.e., 'metadata clearly and explicitly include the identifier of the data they describe'. In this case, the model is treated as a form of "data" outcome. When implemented these will allow the development of guidelines to further improve the interoperability of nanoinformatics models.

[37] https://db.nanopharos.eu/Queries/Datasets.zul?datasetID=1

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Web resources

http://compsafenano.eu/

http://nanofase.eu/

http://www.enaloscloud.novamechanics.com/nanocommons/NInChI/

http://www.vamas.org/twa34/index.html

https://codata.org/initiatives/task-groups/extension-of-inchi-for-nanomaterials/

https://cordis.europa.eu/project/id/953152

https://data.enanomapper.net/substance?type=&search

https://datasetsearch.research.google.com/search?src=0&query=nanosafety&docid=L2cvMTF2MHg ydnY0Yw%3D%3D

https://db.nanopharos.eu/Queries/Datasets.zul?datasetID=1

https://doi.org/10.3389/fphy.2023.1271842

https://doi.org/10.5281/zenodo.7378109

https://github.com/NanoCommons/identifiers

https://iupac.org/

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https://nanoreg.eu/

https://nanosolveit.eu/

https://riskgone.eu/

https://ror.org/

https://ssl.biomax.de/nanocommons/cgi/login_bioxm_portal.cgi

https://ssl.biomax.de/nanosolveit/cgi/login_bioxm_portal.cgi

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