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## 1. Target audience

This is a high-level project plan and has as target audience:

- the program board of the NFU program Data4lifesciences
- the operational board which consists of the Data4lifesciences work package leaders and UMC Data4lifesciences representatives
- members/participants/collaborators and working groups of Data4lifesciences work package1 (“Collection and harmonization of guidelines for data stewardship”).
- People with interest in Data4lifesciences work package1 (“Collection and harmonization of guidelines for data stewardship”).

## 2. Introduction

A data stewardship policy supported by all UMCs is an important prerequisite for the sharing and reuse of research data. This forms the basis for the implementation of the Data4lifesciences infrastructure at the University Medical Centers (UMCs). The programme line (WP1) entitled “Collection and harmonization of guidelines for data stewardship” therefore developed an online handbook, [HANDS](#) (Handbook for Adequate Natural Data Stewardship), to promote good data stewardship. It was published online on November 4<sup>th</sup> 2015. This handbook with pointers to local and national expertise provides guidelines for researchers at all stages of research. It addresses subjects as protection of privacy, involvement of patients, ethics, the reliability and provenance of data, monitoring quality, legislation and regulations. HANDS is managed as a living set of guidelines: researchers, developers of IT infrastructure, policy makers, and other experts are invited to suggest improvements to the HANDS pages on the website.

### 2.1. Original aims stated

In August 2013 the NFU committee Research Data Infrastructure has advised the deans of the UMCs to develop a data stewardship policy document, that can serve as a starting point for policy at both national and institutional level. It would describe the quality assurance of research data and offer a framework for, and a coordinated approach to, implementation in the UMCs. It would give the researcher guidelines on how to handle research data, for instance regarding privacy. The policy document forms the implementation framework for the UMCs. The chairmanship of the working group providing the content was held by dean prof. dr. Jaap Verweij of Erasmus MC. The content would be supplied by representatives of NFU and other stakeholders.

Assumptions & conditions:

1. Responsibility for the data remains at the institutes; after all, the Boards of Directors are responsible.
2. The data stewardship policy document can be regarded as an extension of the advice ‘Kwaliteitsborging mensgebonden onderzoek 2.0’ (2012).
3. Close interactions with ZonMw, ‘Platform Klinisch Onderzoek’, and other parties, who are active in this area are necessary.

### 2.2. Current situation

#### Consultation round

In October 2015 a consultation round has been held on the pre-final version of HANDS 1.0.

The document was sent to:

1. All deans of 8 UMCs with the request to at least have it be reviewed by:
  - Security officer
  - Privacy officer (data protection officer)
  - Research Policy Advisors
  - A number of researchers
  - A number of IT-specialists
2. Organizations:
  - Centrale Commissie Mensgebonden Onderzoek (CCMO),
  - Center for Translational Molecular Medicine (CTMM/TraIT),
  - Dutch Techcentre for Life Sciences (DTL/ELIXIR),
  - Nederlands Normalisatie Instituut (NEN),
  - Nictiz,
  - Nederlandse Patiënten Consumenten Federatie (NCPF),
  - Parelsnoer Instituut (PSI),
  - Samenwerkende Gezondheidsfondsen (SGF),
  - Vereniging van Universiteiten (VSNU),
  - 3TU Datacentrum (3TU/SURF),
  - NWO,
  - BBRMI,
  - Data4lifesciences Programme committee and operational board

This resulted in 22 reactions with 35 comments on the content, 15 comments on the layout/appearance, and 8 additional remarks. All comments that could be processed in time before the release were processed into the final version. Others were ‘parked’ until HANDS was to be updated.

#### Comments by readers

Readers of HANDS could comment and ask additional questions through the website. These questions can be added to the frequently asked questions.

### Open Science

The Netherlands is playing a leading role in the Open Science movement: sharing and re-use of data. The thought being, that results from publicly funded research needs to be made freely available worldwide. Besides sharing and re-using data, Open Science also focuses on Open Access publishing, which is universal free access to scientific publications. On April 4<sup>th</sup> and 5<sup>th</sup> 2016 the international conference '[Call for Action on Open Science](#)' took place in Amsterdam.

### FAIR Guiding Principles

In March 2016 the [FAIR guiding principles](#) for scientific data management and stewardship were published in Nature Scientific Data.

### New laws and regulations

After publication of HANDS, the [EU General Data Protection Regulation \(GDPR\)](#) was published. Also, since January 1<sup>st</sup>, 2016 the [Meldplicht Datalekken](#) has come into action. Both have consequences for the data stewardship policy.

### Developments in other organizations

Other organizations (among which, very importantly, funding organizations) are also working on this subject and have made considerable strides in the past 1,5 years.

For instance:

- VSNU has started the "[Landelijk Coördinatiepunt Research Data Management \(LCDRM\)](#)"
- ZonMw has made data management plans a mandatory part of their funding applications and is working towards good data management and FAIR data in their program '[Toegang tot data](#)'.
- NWO also requires [data management plans](#) in line with the Open Science movement.
- Horizon2020 requires data management plans and has developed [Guidelines on FAIR Data Management](#) (vs. 3.0, 26 July 2016).
- COREON/Federa published the document "[Vermenigvuldigen door Delen. Data delen in gezondheidsonderzoek: van ambitie naar praktijk](#)", which describes the current view of researchers on sharing of data, and gives a number of recommendations. Scientific organizations are advised to:
  - [Draft policy on data stewardship](#)
    - Draft data stewardship policy on an organizational level and monitor the effectuation.
    - Combine data stewardship policy with guidelines for Scientific Integrity
  - [Develop a good infrastructure for data sharing](#)
    - Join NFU programme Data4lifesciences for access to experts
    - Develop IT infrastructure for storing data and making data available on organizational level.
  - [Offer support to researchers in the organization](#)
    - Create central support for knowledge on data stewardship within organizations
    - Ensure departments and researchers can easily access this knowledge support
    - Offer training/education to researchers/students
- [Dutch Techcentre for Life sciences \(DTL\)](#) is a key enabler to achieve international-grade data stewardship for research data and information to be published in a 'FAIR' manner. They offer courses, trainings and workshops at the intersection of life sciences and high-end technologies.
- [Openaccess.nl](#) is offering an overview of organizations that offer services regarding research data and publications.
- A [Data Stewardship Wizard](#) has been developed by ELIXIR and DTL, which may be useful in Data4lifesciences.

### All universities have formulated Research Data Management Policies

The universities have taken a harmonized approach into the local implementation of data management policies. These policies are now implemented by faculties.

Universiteit van Amsterdam  
Vrije Universiteit Amsterdam  
Rijksuniversiteit Groningen  
Universiteit Utrecht

[Research Data Management](#)  
[Research Data Management & Datamanagement voor onderzoekers](#)  
[Human Subject Research Dataservice](#) & [Research Data Office](#)  
[Research Data Management](#)

[Universiteit Leiden](#)  
[Universiteit Maastricht](#)  
[Universiteit Nijmegen](#)  
[Erasmus Universiteit Rotterdam](#)

[Wat is datamanagement?](#)  
[Research Data Management](#)  
[Research Data Management](#)  
[Data Management Plan](#)

**UMCs have made individual policies to deal with funders’ expectations**

Some UMCs actively work with universities to formulate their policy, others have formulated a policy according to European guidelines, while others have developed their own specific data management policies. Data stewardship is not (yet) a commonly known or used term.

The practical approach of UMCs to needs regarding data management is diverse. Some leave it up to researchers to meet the data management requirements, others offer a number of UMC-approved practical solutions, and others offer a package of solutions (e.g. Toolbox (UMCG), Digital Research Environment (DRE; Radboudumc) to their researchers.

Institute	Research Code (incl. data management)	Data management policy	Data management plan template	DMP course
AMC	<a href="#">Research Code: data management</a>	<i>SOP Research Data management policy</i>	<i>DMP template</i>	
VUmc	<a href="#">Research Code: data management</a>			
UMCG	<a href="#">Research Code UMCG</a>	<a href="#">Procedures concerning clinical research at the UMCG (Research Toolbox) &amp; video</a>	<a href="#">RDM Template &amp; RDM plan</a>	<a href="#">Make a Research Data Management Plan (english)</a>
UMCU	<a href="#">Good Scientists make Good Science</a>	<a href="#">Datamanagement van mensgebonden onderzoek</a>	<i>-DMP template gereed in dec '17-</i>	<a href="#">Datamanagement (klinisch onderzoek)</a>
LUMC	<a href="#">Good Research Practice &amp; Integrity</a>			<a href="#">Advanced Data Management onderwijs</a>
MUMC	<a href="#">Research code Maastricht UMC+</a>			<a href="#">CTCM dienst Data Management incl. video</a>
Radboudumc		<a href="#">Datamanagement according to the "Normenkader"</a>	<a href="#">Datamanagement Documents and Templates</a>	<a href="#">Data stewardship Technology Center &amp; Datamanagement</a>
Erasmus MC	<a href="#">Research Code</a>			

**Data4lifescience Programme lines are in development**

In 2017 a number of tangible deliverables are expected from the other programme lines of Data4lifesciences. These are expected to offer harmonized practical solutions to UMCs, regarding IT processes and architecture, access to data and sample collections, a digital research environment, reuse of clinical data for research, procedures and technologies for privacy and security, computing capacity and access to experts, training and support.

**Health-RI**

The Health Research Infrastructure for personalized medicine & health research is listed on the ‘KNAW-Agenda *Grootschalige onderzoeksfaciliteiten*’:

In 2025, we envisage a globally unique research infrastructure in the Netherlands that will both drive and support cross-disciplinary research into personalized medicine & health and optimize personalized healthcare. Data4lifesciences is part of the collaboration that is working towards realization of this vision.

**Meanwhile researchers are still looking for clear rules**

Ever more researchers are advocates of a better storage and exchange of research data, so that these data are findable and reusable for future researchers. Yet there are still practical obstacles. This is described in [Mediator in June 2016](#).

A frustrating [cartoon](#) describing the current hassle when trying to obtain data was published this year.

### 3. Deliverables plan

#### 3.1. Overall aim of the Data4lifesciences program – True North

The overall aim or True North of the Data4lifesciences program, as defined by André Dekker, WP5 lead, but modified for WP1, is:

- What* all clinical, biosamples, imaging and experimental data, including metadata (e.g. context, definitions of data) of all patients and/or study-participants should be made available
- Who* by every UMC of the Netherlands
- Why* for every valid research question
- When* now and forevermore
- Where* in a scalable, secure, and distributed environment
- How* as findable, accessible, interoperable and re-usable (FAIR) data, with full protection of privacy of patients, with full control by the owner (e.g. UMC; taking into consideration the “privacy” of researchers and research consortia to develop products as result of their research) and without disturbing/impacting clinical care

#### 3.2. Specific aims and deliverables for WP1

There is still a major discrepancy between the data stewardship policy described in HANDS, the local implementation in UMCs and the actual experience for researchers. Although data management has become a well-known term, data stewardship is not generally used. In 2017 efforts have to be made to close the gaps. For this reason it is crucial that each UMC identifies a local ambassador for data stewardship, who is also part of the WP1/HANDS group.

#### **Proposed approach**

##### **Implementation**

In the second half of 2016 interviews have been held at UMCs to learn about the implementation of data stewardship policies. Policy, organization, procedures, experts and tools were discussed. In the first months of 2017, these interviews will be finalized and a report will be written and shared within the Data4lifesciences project teams and the UMCs. A meeting will be organized with the different UMCs and the relevant Data4lifesciences project members to discuss the implementation process: success stories, best practices, practical tools from UMCs will be shared and discussed between UMCs in an informal manner. Information from these interviews and meetings will be used to improve the next version of HANDS.

##### **HANDS pilot with a research project**

As a pilot for the practical usability of HANDS, a collaboration with an active multicenter research project will be set up. The lessons learned from this pilot will be used to refine and improve HANDS.

##### **HANDS 2.0**

The group of experts, that has collaborated to develop the first version of HANDS has come together on January 19<sup>th</sup> 2017 to discuss the update of HANDS. HANDS will be adapted based on:

- the comments that have been received
- the new laws and regulations
- practical implementation in UMCs (in collaboration with WP6)
- experts in UMCs (in collaboration with WP9)
- the current situation (e.g. developments in other organizations, new documentation)

Specific aims and associated activities/deliverables of Work package 1 contributing to the True North are:

Number	Activity/Deliverable	Approach
1	UMC data-stewardship implementation report	Site visits UMCs
2	UMC data stewardship meeting	Organize a meeting to <ul style="list-style-type: none"> <li>- Share best practices</li> <li>- Share D4LS solutions</li> <li>- Share ideas</li> </ul>
3	Initiate pilot research project with HANDS	- Select a multi-center research project that uses HANDS for data stewardship and comments
4	HANDS 2.0	Update with input from:

Number	Activity/Deliverable	Approach
		-expert group -WP6 & WP9 -UMCs -pilot research project

## 4. Time schedule

This paragraph gives an overview of the long, mid-term and short term timelines of which the deliverables as presented in paragraph two (with more detailed timelines) are part of.

### 4.1. Long term (2020+)

In the long term, to get to the program's True North, a large scale facility for (bio)medical (translational) research data in the Netherlands is needed. This is currently further developed under the name Health-RI (also part of the [\*KNAW-Agenda "Grootschalige Onderzoeksfaciliteiten"\*](#)).

### 4.2. Medium term (2017-2020)

- Cooperate intensively with policymakers, data-managers and researchers at UMCs to make good data stewardship reality:
  - HANDS is known in the UMCs
  - HANDS is used as a knowledge source by research supporting staff as well as researchers
  - HANDS offers easy routes to correct expert help and tools at specific UMCs
- Cooperate actively with VSNU and universities to improve common knowledge and practices.
- Cooperate actively with other research infrastructure-related projects to ensure shared goals, policies and practices, such as with BBMRI-NL2.0, Parelsnoer (PSI), COREON/Federa, DTL, DANS, SURF, and other relevant initiatives.
- Cooperate actively with patient organizations to ensure closer collaboration between researchers and patients in research.
- Cooperate actively with funding organizations, such as ZonMw and NWO, to ensure harmonization of data stewardship policies.

### 4.3. Short term (2017)

- Ensure that HANDS 2.0 is truly an informative, yet useful and practical source for researchers.
- Make a true connection with UMCs and further develop the data stewardship policy (HANDS) and local, practical implementation.
- Demonstrate the practical usability of HANDS in a pilot in collaboration with a starting research project.
- Organize UMC data stewardship meetings



## 5. Organization plan

### 5.1. HANDS 2.0 expert committee

Name	Home Institute/Project	Project Role
Jan Hazelzet	Erasmus MC Rotterdam	Expert/Chairman
Jan-Willem Boiten	Lygature/D4LS programme manager	Expert
Morris Swertz	UMCG/BBMRI-NL	Expert
Evert-Ben van Veen	COREON/Federa	Expert
Cor Oosterwijk	VSOP	Expert
Rob Hoof	DTL/WP9 D4LS	Expert
Margreet Bloemers	ZonMw	Expert
Peter Doorn	DANS	Expert
Arnoud van der Maas	Radboudumc	Expert
Jan-Jurjen Uitterdijk	UMCG	Expert
Ingeborg Verheul	SURFsara/VSNU	Expert
Paula Jansen	UMCU	Chief editor

### 5.2. UMC contact persons (interviews)

UMC	Contact person	
AMC	Hans vd Berg	
	Rudy Scholte	
	Jessika van Kammen	
Erasmus MC	Bert van Ooijen	
	Hanneke den Breeijen	
	Jan Hazelzet	
	Jonas Rubrech	
	Erik Flikkenschild	
LUMC	Petra van Overveld	
	Louise Veltrop	
	Szymon Kielbassa	
	Ineke vd Veen	
	Karin vd Hoorn	
	Nienke vd Werf	
	Mark Thompson	
	Peter Bram 't Hoen	
	MUMC	Pascal Suppers
		Mirjam Prevoo
Christianne Aussems		
J Pisters		
Radboudumc	Tom Delnoy	
	Arnoud vd Maas	
	Ariaan Siezen	
UMCG	Jan-Jurjen Uitterdijk	
	Salome Scholtens	
UMCU	Harry Pijl	
	Martine Ros	
	Els Dees	
VUmc	Ronald van Schijndel	
	Michel Paardekoper	
	Janine Stolwijk	
	Wim Kraan	
	Fons Ullings	

## 6. Communication plan

Information on the progress and results of WP1 will be shared in the Operational Board of Data4lifesciences. This Project plan will be openly shared on the Data4lifesciences website and, when relevant, the work package will be actively and openly communicated within the NFU, related stakeholders, partners and projects like BBMRI, TraIT, and charity funds, as well as the wider community.

## 7. Risk plan

Below a risk matrix is given which identifies the major risks as can be seen at this moment in the project. The risk plan is to formally review the risk list every 6 months so that new risks can be added, hazard can be re-estimated and actions be taken.

Risk description	Probability	Impact	Action
1. HANDS 2.0 is not useful, practical or informative enough	4	8	Update HANDS with input from various people: experts, UMC policy makers, ICT specialists, researchers, funders and specialists. Pilot with research project.
2. HANDS 2.0 is not known enough and/or used enough	6	8	Communicate the existence of HANDS actively and persistently – demonstrate usefulness to researchers and UMCs
3. HANDS 2.0 does not help to lead to better data stewardship in UMCs	4	7	Find a means that better fits the need to obtain the goal.