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Horizon 2020
INFRADEV-1-2014 - Design studies

RICHFIELDS Working Package 13
Deliverable D13.3

Governance design for RI platform for consumer behaviour and lifestyle

Date delivered:
M37

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Deliverable lead beneficiaries:
Wageningen Economic Research

www.richfields.eu
#RICHFIELDS

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 654280.

Project	
Project acronym:	RICHFIELDS
Project full title:	Research Infrastructure on Consumer Health and Food Intake for E-science with Linked Data Sharing
Grant agreement no.:	654280
Project start date:	01.10.2015
Document:	
Title:	Governance design for RI platform for consumer behaviour and lifestyle
Deliverable No.:	D13.3
Authors:	Marc-Jeroen Bogaardt, Krijn Poppe, Trond Selnes
Reviewer:	Karin Zimmermann – Project Coordinator Pieter van 't Veer – Scientific Coordinator
Start date:	01.03.2017
Delivery date:	31.10.2018
Due date of deliverable:	31.07.2018
Dissemination level:	PU
Status:	Final

Change history:		
Version	Notes	Date
001	First outline draft	20.12.2017
002	First Draft	12.02.2018
003	Reviewed by Krijn Poppe. Incorporating his comments.	22.05.2018
004	Final draft	30.05.2018
005	Incorporating comments given at Phase 3 Workshop at 4th June in The Hague and after the workshop by e-mail	14.06.2018
006	Adapt final draft to D13.4 and D12.3	15.10.2018

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Karin Zimmermann

Project Coordinator

Prof Pieter van ’t Veer

Scientific Coordinator

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Summary

This report describes the **design of the governance structure** of the determinants and food intake research infrastructure (DI-RI). The DI-RI[1] will be a subset of the European research infrastructure on Food, Nutrition and Health (FNH-RI) which is being designed and developed currently. In this report it will referred as FNH's DI-RI. The governing body of FNH's DI-RI is a board of a foundation - already been established in 2018 during the project RICHFIELDS – with the formal name "STICHTING Food, Nutrition and Health Research Infrastructure". The foundation is based in Wageningen, the Netherlands.. The statutes of the foundation include the name, the goal, the procedures for the appointment and discharge of board members, the location and the decision making within the foundation.

The FNH's DI-RI is a not-for-profit organisation under Dutch law. The Board will guarantee the **neutral status** of the Research Infrastructure (RI) by avoiding a bias in the composition of the board from different interest groups. As the FNH's DI-RI will be a **collaboration** between public organisations (universities, public sector research institutes) and private companies (food manufacturers, supermarkets, app owners, etc.) located in different countries in Europe, it will not strive to have the European Research Infrastructure Consortium (ERIC) status because ERIC is about research infrastructures on a non-economic basis, while FNH's DI-RI will be part of a RI with an economic basis.

The collaboration concerns data sharing, data processing and data generation (via the Consumer Data Panel) by the RI and service provision in return. Universities, research institutes, app owners, food companies, retailers etc. have collected -and are still collecting - data about what people eat and drink or why they eat and drink that. We define this as food-related consumer behaviour data. The core of the FNH'S DI-RI is the consumer data platform for linking, processing and sharing data on dietary intake and its determinants. The **goal** of the collaboration is to provide integrated and harmonised data on food-related behaviour of consumers to others e.g. researchers that want to re-use it for their research. The data platform will be a module of the FNH-RI. The foundation shall own the intellectual property rights in the FNH-RI domain, which have been, or will be legally granted/transferred by the consortium partners to the foundation.

The general model of the FNH's DI-RI is a **hub and nodes Model** which works as a **network based** administrative organisation. The hub will be located at Wageningen University and Research and it manages and coordinates the operations. The nodes are national collaborative groups that also represents their own country with a membership of the foundation RI. As a foundation the RI is an independent legally non-profit organization for the purpose of serving the research infrastructure. Independence is important as it entails the ethical and legal commitments of the scientific community. The hub promotes communication within and among the national nodes, but these are free to choose their own research. They do however depend on each other in their common mission of making better use of dispersed resources and insights. As the FNH's DI-RI is a scientific organisation and scientists are the users, member states scientists and scientific organisations join

[1] In some other deliverables of the project RICHFIELDS the term 'Richfields RI' has been used instead.

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the FNH's DI-RI. To this end countries involved in the FNH's DI-RI will set up a national node in which the relevant and interested scientific organisation(s) of that country organise themselves as a node and appoint a Head of Node, that represents the country in the FNH's DI-RI governance.

There are two advisory committees: 1) the Scientific and Ethical Committee; 2) the Stakeholder Committee. **The Scientific and Ethical Committee SEAB** will consist of scientists appointed in their own right. They do not represent their own organization or country. The Board appoints the SEAB members and decide the rules for the further engagement in the SEAB: how long, how to deal with a replacement etc. The Research Infrastructure including its SEAB shall be periodically evaluated by an independent visitation commission. All scientific research, especially in relation to persons and to health, has to be cleared by SEAB on the basis of a research plan before it can start. Its advise should be sought by the FNH'S DI-RI management on all issues that link to ethical questions. SEAB will also advice on the protocols on matters relating to data security, transfer of data to third countries, assessing the genuineness of a request by data users and the rules of operation in the event of requests that may be ethically dubious or questionable, data subjects' requests, and complaints procedures. SEAB will have the right to advise when asked by the management of the FNH'S DI-RI, but also on its own initiative. **The Stakeholders Advisory Committee SAC** is the link between the FNH'S DI-RI and the consumer/ citizen and patients' organizations and other NGOs, the industry and other scientific communities and organizations. For members, SAC shall draw upon a range of stakeholders (consumer organizations, patient organizations, research institutions, the legal profession, IT professionals, commercial entities, non-governmental organizations, former politicians). It contributes to the decision-making process (the Board and director of the Foundation), together with the SEAB. The SAC ensures a societal awareness on needs and expectations on key issues, such as data protection, informed consent in research, research priorities, and other ethical, legal and societal issues.

Financing of the national nodes and their activities is independent from the central hub. Each national node is responsible for its own governance and financing. The annual contribution fee per node is given by the central hub (a board decision) and the national contribution can come from public, public-private or only private sources. The latter would be an option although very unlikely.

The **use of the individual micro data** by the users of the FNH'S DI-RI is already regulated by the GDPR and internally by the Ethical Committee and technical, organizational and security measures. In the micro data-lab of the FNH'S DI-RI the individual data of the consumer data platform will be made available for scientist to be re-used. The micro data-lab is a facility that grants researchers access to individual data that is privacy sensitive and where there is the risk that individual data gets published. Researchers get access to a micro data-lab if they submit a research plan that shows that access to individual data is essential for answering their research question.

External relationships are essential to the design of the governance structure. Through the external relationships the RI build trust and confidence in the scientific and ethical quality of the RI. The RI must thus have a demonstrated stronghold in ethics and law. For this to evolve, the FNH'S DI-RI deals with the data management rules: data storage, maintenance, access to the RI, access to and also sharing and re-using data and methodologies and services. The literature review in Deliverable

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13.2 shows that privacy, informed consent and ownership are the most frequent issues of ethical concern, and they are also essential to the external relations.

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1. Introduction

According to Annex 1 of the Description of Action "*a design has to be made for the governance structure of the research infrastructure that will be based on a lead organisation type or a network administrative organization type. This includes a governing body - like an international coordinating centre -, an executive management steered by an assembly of members or a board of a foundation. The governance should support the business model of the ICT- based research infrastructure and should balance the interests of the different stakeholders. Special attention will be given to the role of the industry as commercial entities in the governance structure. They are an important data provider and an important potential user of the RI. [..] Public health authorities as well as institutes involved in policy research are reluctant to share the governance of the RI with commercial interests. [..] Therefore the project will see whether a public-private partnership construction can be designed with a governance structure that balances these interests.*"

This report describes the design of the governance structure of the determinants and food intake research infrastructure (DI-RI) in which the above underlined elements are included specifically. The DI-RI[2] will be a subset of the FNH-RI. In this report it will referred as FNH's DI-RI.

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2. Governance of research infrastructures

What is exactly an international distributed research infrastructure?

The ESFRI (European Strategy Forum on Research Infrastructures) has defined a European distributed research infrastructure as "a research infrastructure with a common legal form and a single management board responsible for the whole research infrastructure, and with a governance structure including among others a strategy and development plan and one access point for users, although its research facilities have multiple sites" (ESFRI, 2011: 8).

According to the Organisation for Economic Co-operation and Development (OECD, 2014: 7-8) an international distributed research infrastructure is a multi-national association of geographically-separated distinct entities that jointly perform, facilitate or sponsor basic or applied scientific research, which should have all the following:

- An identity and a name.
- A set of international partners (funding agencies, research institutes, academic institutions, foundations, research-oriented organisations from the public or private sectors).
- A formal agreement by the partners to contribute resources, expertise, equipment, services or personnel towards achieving a common scientific purpose.
- A strategic plan or work programme.
- A governance scheme (for decision making) and a set of officers with well-defined responsibilities.
- A focus on the provision of services to its members and users.

And that research infrastructure may have the following (OECD, 2014: 7-8):

- An independent legal status.
- A common fund and rules for acquisition/spending of funds.
- A secretariat.
- A host institution.
- A central entry point for users.
- Policies for access by users to research resources and to data, and for managing any generated intellectual property.

2.1 Literature on governance of RIs and data platforms

Governance concerns coordination between organizations

Markus and Bui (2012) reviewed three theories of interorganizational governance (see Provan and Kenis, 2007; Hart and Moore, 1996; Gulati and Singh, 1998) to conceptualize the governance of interorganizational coordination hubs. An interorganizational coordination hub is an information technology (IT) based platform that is open to use by members of a

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defined organizational community. An example is Visa, the payment network that coordinates billions of transactions each year (Markus and Bui, 2012: 164). According to Markus and Bui (2012: 174) the governance of a platform as an interorganizational coordination hub will face three challenges. The first challenge means that an IT based platform must have a formal governance because many issues require legal formalization: financial commitments to IT products and service providers, intellectual property issues, risk liability. The governing organisation of the platform may play several social and technical roles. It operates the IT platform for the members or directly manage an IT services provider that operates the IT platform. The legal body that governs the IT platform can be a lead organization, a collective or member-owned organization, or an investor-owned organization (p. 176). The second challenge involves the heterogeneity of the participants. The members must be induced to participate actively for instance by contributing high-quality data. Because if only certain subgroups of the community participate (e.g. buyers and not suppliers), the IT platform will not be able to serve its purpose and will collapse (p. 173). This means that the governance arrangement must take into account the interests of the different parties and must ensure the IT platform is run fairly i.e. with equality or equity across all groups of participants. The third challenge concerns the centrality of IT and data. The platform needs formal governance to answer members' concerns about who owns the data, how the data are processed, and who can access the data (p. 174).

What does governance include in case of a public-private platform?

Public-private partnerships or collaborations refer to "forms of cooperation between public authorities and the private business with the primary aim to fund, construct, renovate, manage, and maintain an (*research*) infrastructure or the provision of a service" (EC, 2004, Green Paper on public-private partnerships) often with the aim of introducing private sector resources and/or expertise in order to help provide and deliver public sector assets and services. It could also for the purpose of delivering a project or service traditionally provided by the public sector.

According to Klievink et al. (2016) information platforms – as an ICT (Information and Communication Technology) innovation that is promising for transformation of governments from the outside-in - are being collaboratively developed and used by a collective of public and private organizations. Public-private information platforms enable businesses to pursue their own interest, transform business-government interactions and serve collective interests and public value (p. 67). Klievink *et al* argue that both the IT infrastructure and governance mechanisms should be addressed in interaction with each other when studying public-private platforms (p. 68). Three main elements are related to the governance of platforms. First the decision-making structure which is about who decides, how and on which components of the platform in terms functionality, design and implementation. Secondly the formal and informal mechanisms of control over the platform

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including input control (where an owner decides what goes on the platform), process control (methods and procedures prescribed to parties) and informal control (values, norms and trust). Thirdly the ownership structure, where a platform can be proprietary to a single firm or ownership is shared between multiple actors (p. 69)

The distributed RI should include at least a legal status, a governing body, a director, an executive management, financial sustainability, and rules for access the data

The establishment of an international distributed research infrastructure should involve at least four key issues (OECD, 2014: 11). First a legal status of the research infrastructure**.** In Europe there are several options of legal forms:

- A legal form under national law, such as a limited liability company, national association, private limited company, société civile according to French Law or Spanish Law;
- An European Economic Interest Grouping (EEIG-GEIE);
- An European Grouping of Territorial Co-operation (EGTC-GECT);
- A foundation (which has no members);
- An association (which has members);
- A legal European form (European Union Treaty);
- An international form such as an International Organisation;
- An open-ended international co-ordinating body.
- An European Research Infrastructure Consortium (ERIC).

Countries participating in an international distributed research infrastructure have the option to sign a non-binding Memorandum of Understanding (MoU) as a framework for co-operation governed by statutes established for that purpose. But this non-binding consortium is not a legal entity and can therefore not enter into contracts with third parties, e.g., enter into employment contracts or undertake procurement. As the development of the RI includes different phases – design, preparatory, implementation, operation – the legal status in the early phases may be served by a simple consortium or based on a MoU signed by a few institutions. And the final collaboration may require an intergovernmental agreement. The decision about the type of legal status may depend on the type of funding used in each phase (OECD, 2014: 12).

The second key issue concerns the governance of the RI. The OECD (2014: 14) defines the governance structure of the research infrastructure as a set of bodies, rules and procedures for making decisions, for carrying out administrative and managerial tasks, for dealing with financial matters, and for executing the scientific work programme, including managing relations with external users. Regardless the type of legal form, a common governance model used among international distributed RIs incorporates three elements (see Figure 1): (i) a governing body (such as a general assembly) representing the collective interests of the

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partners and that is the ultimate decision-making body, (ii) a director (or Board of Directors) in charge of implementing the decisions of the governing body, and (iii) an executive management (secretariat) in charge of operating the research infrastructure.

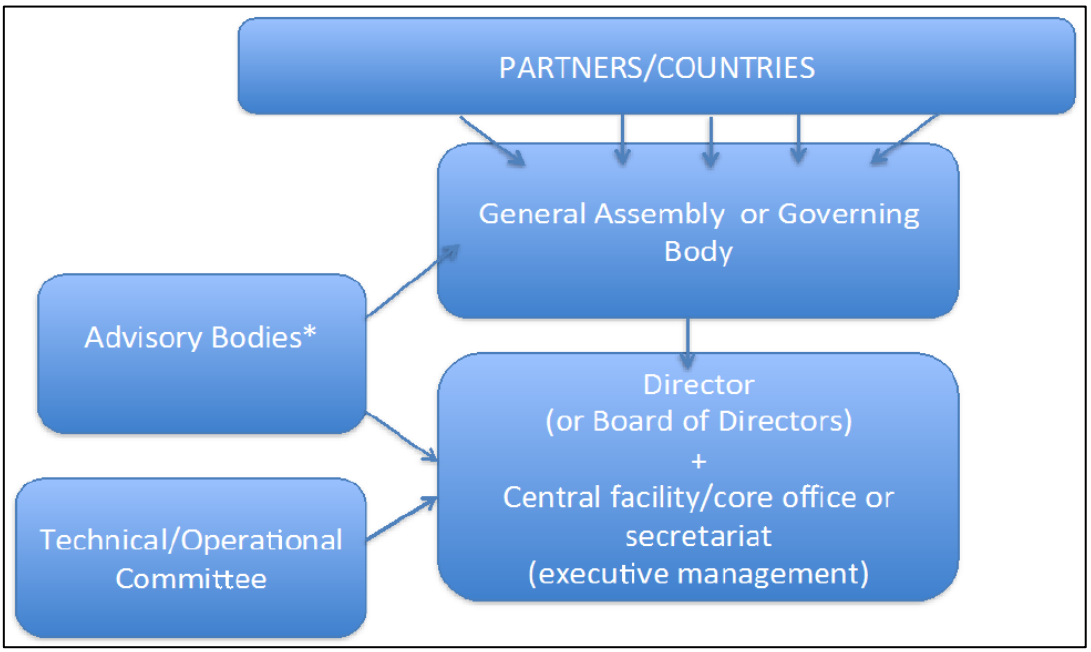

*Figure 2.1: Common governance structure of an international distributed research infrastructure (OECD, 2014: 15). * means the advisory boards can be administrative, financial, scientific etc. They deliver information and advice to the governing body and/or to the director, and are usually composed of persons external to the RI.*

In general the location of the central facility or headquarters of the RI is selected on scientific, financial and political considerations. The central facility is in charge of management of the research infrastructure and operational aspects – coordination of the activities, provision of core services, management of access to the infrastructure (OECD, 2014: 16). The central facility can be located in: a single location (at the host country), several locations (in case of shared central responsibility between several partners), or distributed among all of the different partners (if the activity itself is so distributed and requires an involvement of the staff in the scientific or administrative operations).

The third key issue concerns the financial sustainability of the RI. The funding entities of the international distributed RI can be: national funding agencies, ministries, scientific institutions and organisations, international organisations, foundations, associations, private companies. The contributions of the partners of the RI can cover all kinds of activities and can be made in cash or in kind (OECD, 2014: 17).

The fourth key issue involves the rules that will govern access to its resources. This implies access to scientific resources (e.g. observing time), access to data, access to tools.

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Influence of the characteristics of the data sharing on governance: commercial sensitivity of the data and risk of privacy infringement

By connecting four inter-organisational governance modes – market, bazaar, hierarchy and network (see e.g. Provan and Kenis, 2008) - with data governance, Broek and Veenstra (2015) illustrated that the governance mode of data sharing in inter-organisational collaborations is influenced by the characteristics of the data sharing, the coordination mechanisms and the control organisations have over their data within the collaboration. The commercial sensitivity of data and the risk of privacy infringement appeared to be important reasons for wanting to keep tight control over data. When personal data is involved, the coordination mechanism called for is strict control of a hierarchical nature (2015: 10). If the data sharing concerns commercially sensitive data, it is difficult for involved organisations to set up an purely commercially viable model for cross-organisational data sharing. Data collaborations involving personal data need to put a hierarchical governance mode in place in order to retain control over the data (2015: 11).

Governance structure as decision making structure

Sayogo and Gil-Garcia (2015: 2234) define the governance structure of an interorganizational information sharing initiative as the decision making structures that form within and across the formal and informal network of organizations that are created to collaboratively formulate and implement cross-boundary information sharing initiatives. In their study in the US on the role of several determinants of governance structures in the success of inter-organizational information sharing initiatives, Sayogo and Gil-Garcia (2015) showed that three determinants predict the success: knowledge of information needs of the participating organizations, knowledge about other participating organizations, and executive support and involvement which can manifest in the form of leadership.

General issues to be solved when exchanging data between organizations

Goethals (2008) focused on problems showing up when partnering companies decide to exchange data. These problems take a different form for different business-to-business data integration configurations. Goethals has identified the following eight issues which should be taken into account when deciding on an inter-organizational data integration configuration:

1) Partners have to define what information flows are valuable. Partners have to identify what information sharing practices add value.
2) The partners have a different perception of the objects on which they want to share data. Each involved organisations' viewpoint on the subject should be mapped of which data will be shared because each organisation may use the object in different tasks.

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3) When the information that companies want to share is known, partners have to define an appropriate data format i.e. determine a way to share data so that it offers necessary functionality.
4) To enable the information sharing investments are needed. Partners have to agree on who will bear the costs for installing, maintaining and upgrading systems.
5) Partners become dependent upon service levels provided by data sharing systems such as availability, system response time etc. The service levels should be in line with different users' requirements.
6) Partners must preserve or guarantee the value of data sharing activities. Partners must handle data in line with how other partners would like them to handle it so that they can build trust. This has to do with the quality of the data and also the faith of the sender in the receiver preserving the confidentiality of the data.
7) Data ownership must be unambiguous. A party decides what can or has to happen with the data and what cannot.
8) All the above mentioned issues have to be dealt with in the frame of changing relationships because partners that provide data and the parties that use data can change over time. Also, there can be changes in the agreement on which parties can access data: some parties can probably no longer access the data.

2.2 Governance structure of existing European RIs on health and food

BBMRI, EATRIS[3], ECRIN, ELIXIR, INFRAFRONTIER[4], and INSTRUCT[5] are all distributed research infrastructures being on the ESFRI Roadmap in the domain of health and food (ESFRI, 2016: 2). In this paragraph elements of the governance structures of the existing international distributed research infrastructures BBMRI, ECRIN and ELIXIR are briefly described to provide insights how they are being governed because these three are relevant for the FNH-RI. These insights has guided the design of the governance structure of the FNH'S DI-RI (see chapter 4 in this report).

2.2.1 BBMRI

The distributed Biobanking and BioMolecular resources Research Infrastructure (BBMRI) is one of the largest research infrastructures for health research in Europe by providing a gateway for access to biobanks and biomolecular resources coordinated by national nodes.

The participation in BBMRI and the governance of BBMRI are defined in the statutes of BBMRI. The interaction between BBMRI and its partners is defined in a partner charter that is agreed between national nodes and partners.

[3] EATRIS is the European advanced translational research infrastructure in medicine (http://eartis.eu).
[4] Infrafrontier is the European Research Infrastructure for phenotyping, archiving and distribution of model mammalian genomes (https://www.infrafrontier.eu/).
[5] Instruct is a pan-European research infrastructure in structural biology, making high-end technologies and methods available to all European researchers (see: https://www.instruct-eric.eu/).

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The distributed architecture of BBMRI enables distribution of some management tasks – e.g. common services – to the members/partners of BBMRI (BBMRI, 2012: 6). Figure 2 illustrates the governance and management structure of BBMRI.

The statutes allow the decision making body, the assembly of members and the director general – the chief executive officer and legal representative of the RI – to establish subordinate governance bodies and management structures as necessary when the RI grows and develops without having to make changes in the statutes.

The members are the countries – members states of the European Union, associated countries and third countries – and intergovernmental organizations that have signed the statutes of BBMRI. The assembly of members consist of officially appointed delegates of the participating members.

The executive management of BBMRI comprises the director general and the management committee. Together they plan and oversee all scientific and service activities of the RI.

A national node is an entity (not necessarily of legal capacity) designated by a member state, that coordinates the national resources – in this case biobanks and biomolecular resources – and links national activities with the European activities of the RI. Each national node has a director – national coordinator – appointed by an appropriate authority of the member state. Each member state – country – has established one national node. Each national node forms the interface with national, regional or organizational network(s) of biobanks and biological resources within the country, and coordinates their activities with those of the European BBMRI.

The common services are a key element of the RI as they provide users expertise, services and tools in specific areas of biobanking. The common services are place under the responsibility of the director general and are managed by a director who is appointed by the director general after consultation with the national delegates of the members state where the common service is located and financially supported by the member state.

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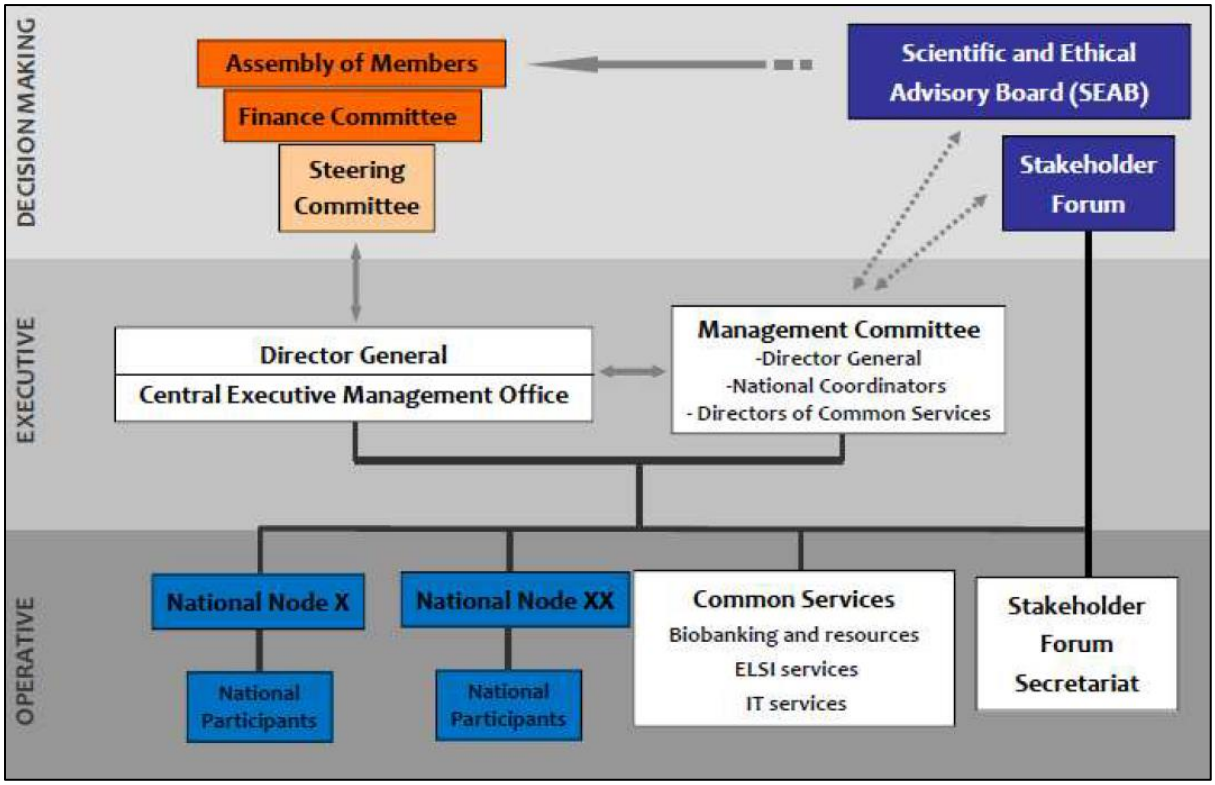

Figure 2.2: Governance structure of BBMRI (source: BBMRI, 2012: 38). The white boxes indicate facilities established under the ERIC legal framework.

2.2.2 ECRIN

The distributed European Clinical Research Infrastructure Network (ECRIN) promotes multinational, high-quality, transparent clinical trials by overcoming the obstacles caused by fragmentation and poor interoperability of the national, clinical research environment.

ECRIN has eight full member countries (Czech Republic, France, Germany, Hungary, Italy, Norway, Portugal and Spain) and one Observer Country (Switzerland). Member countries have access to the full range of ECRIN services and collaboration opportunities. Observer status, which lasts for a maximum of three years, grants similar support.

The organisation of ECRIN involves a core team, European correspondents, and national scientific partners. The core team of ECRIN is based in Paris and develops the strategy of the RI as well as common tools and procedures for ECRIN-supported trials, and links the national European correspondents. The national European correspondents, seconded to ECRIN by their local institutions, are based in each member of observer country. They link the national clinical research network to the ECRIN core team and other countries. They oversee the implementation of ECRIN's work in their respective countries. The national scientific partners are a network of clinical trial units (CTUs) and manage trials in-country. They host the European correspondents. The national scientific partners have a framework contract with ECRIN and provide services to ECRIN at non-profit costs.

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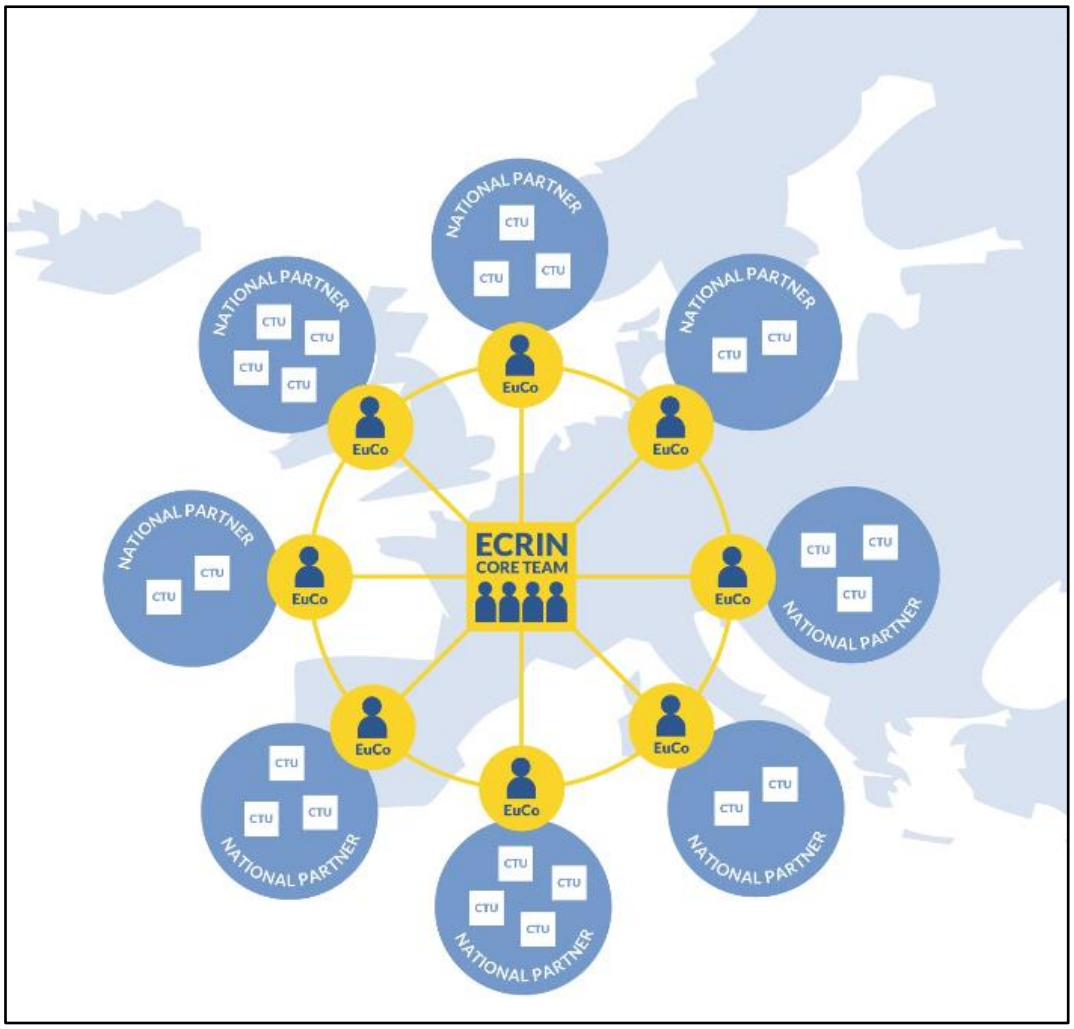

Figure 2.3: Organisational structure of ECRIN (source: http://eu-isciii.es/wp-content/uploads/2015/12/4-Gonzalo-Calvo-ECRIN-ISCIII-26-01-2016.pdf).

ECRIN is governed by the Assembly of Members, which is composed of a representative from the government of each member or observer country[6]. The Network Committee represents the national scientific partners and provides advice to the Assembly of Members and Director General. It is composed of one senior delegate of each national scientific partner of member and observer countries. The Steering Committee oversees activities and provides advice on budget, work plan and scientific/technical matters. It is composed of the chair and vice chair of both the Assembly of Members, two members from the Network Committee, as well as the Director General.

ECRIN is funded by the contributions of its member and observer countries (see Figure 4 below). These funds are primarily dedicated to supporting the organisation and developing its core competencies to enable the provision of operational support to multinational

[6] http://www.ecrin.org/who-we-are/governance

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trials. Country funding does not cover costs incurred by specific projects aimed at developing new tools and procedures, or multinational clinical trials where ECRIN provides trial management services. These projects are funded by grants from European funding bodies (e.g. Horizon 2020, Innovative Medicines Initiative 2) and services provided to industry sponsors, for example.

Income	**€**
Member country contributions (France, Germany, Hungary, Italy, Norway, Portugal, Spain) and local contribution for France	1,360,000
European Commission funded projects	582,978
Other income	54,316
Financial income	19,671
Total income for 2016:	2,016,965
Expenditures	
Salaries, social expenses and taxes	749,738
Other operational costs	935,974
Financial expenses	1,148
Total expenditures for 2016:	1,686,860
Net result	
Net result for 2016:	330,105

Figure 2.4: Financial report for 2016 (source: ECRIN Annual report 2016 http://www.ecrin.org/annual-reports . http://fr.zone-secure.net/50296/367148/#page=38

2.2.3 ELIXIR

The distributed infrastructure for life-science information (ELIXIR) consolidates Europe's national centres, services, and core bioinformatics resources into a single, coordinated infrastructure. ELIXIR is an inter-governmental organisation, which builds on existing data resources and services within Europe.

The structure of the RI is based on a hub and nodes model, with a single hub located in the UK, and a number of nodes located at centres of excellence throughout Europe, which coordinate nationally the bioinformatics services within that country.

The hub carries out scientific, technical and administrative coordination tasks in addition to the delivery of core services. These tasks are decided by the board of the RI and executed by the director, both of which are advised by advisory bodies[7].

[7] FAQs on Legal and Governance Issues of ELIXIR, January 2014.

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The nodes of the RI play a leading role in the provision of technical services. The head of nodes support the director in developing the ELIXIR programme, scientific strategy and grant-funding opportunities.

The legal framework of the RI is based on the ELIXIR consortium agreement. This consortium agreement includes covers the mission and strategy, the organisation and obligations of the consortium partners. The consortium agreement covers the following provisions: objective and tasks of the RI, membership, obligations of the members and the hub, the governance structure between the hub and the nodes and the internal governance structure of the hub itself, finance, nodes, intellectual property, liability etc.

The members of ELIXIR are sovereign states and EMBL (European Molecular Biology Laboratory), an intergovernmental organisation funded by 20 member states.

The hub, located in the UK coordinates the mission and activities. The hub handles the organisational, technical and infrastructure interactions with the nodes and other biological and medical research infrastructures and e-infrastructures.

The hub hosts the director and the staff. The director is responsible for the day-to-day operational, financial and administrative management of the RI in accordance with the decisions made by the board. The staff are responsible for managing the implementation of the ELIXIR programme, servicing the various boards and committees, external relations and communications, grant-application functions. The staff comprise legal and technical expertise, which is necessary for a large, distributed research infrastructure and the effective interfacing and coordination with other biological, health and e-infrastructures.

The board determines ELIXIR's overall strategy and policy in scientific, technical and administrative matters, in particular by making decisions that the director will execute. The board is composed of representatives from each of the consortium partners and include a scientific and an administrative delegate from each partner. Each member has one vote. The board is the highest decision-making body and has appointed a head of nodes committee, comprising the head of nodes appointed by each of the nodes. This committee supports the director in developing and implementing the scientific vision and programme for ELIXIR.

The board decides on issues that are of overall strategic importance to the RI, such as the financial plan, the budget and the programme of ELIXIR. It establishes and monitors rules and procedures, including those for the evaluation and selection of nodes. The board is advised by an independent Scientific Advisory Board.

The director is the executive body within the governance structure of the RI. He/she is appointed by the board to manage and administer the activities of the RI in accordance with the decisions of the board. The staff assist the director in his/her tasks.

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The nodes – national or international research institutes - sited throughout member states, provide the delivery of technical services. Each node is hosted by an institute that provides a set of services on behalf of or for ELIXIR. These services and the terms and conditions of

their delivery are specified in collaboration agreements. In some member states, the nodes consist of the national bioinformatics research infrastructures that comprise various institutes, which has established an overarching legal structure[8].

The nodes run the resources and services that are part of ELIXIR. This involves data deposition resources for depositing data safely and securely; added-value databases providing researchers with access to well curated data; bio-compute centres for cloud computing and analysis; services for the integration of data, software, tools and resources; training; and standards, ontology and data management expertise (ESFRI, 2016: 67).

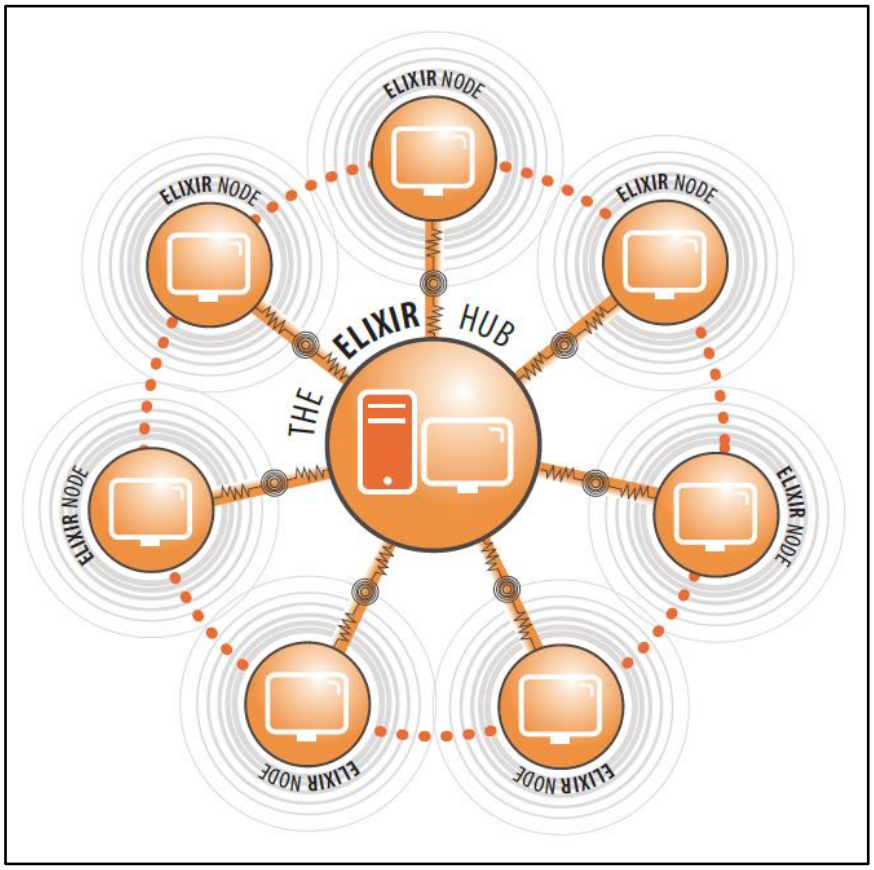

Figure 2.5: Organisation of ELIXIR structured on the basis of a hub and nodes model (source: https://www.elixir-europe.org/system/files/faq_on_elixirs_legal_framework_january_2014.pdf)

[8] FAQs on Legal and Governance Issues of ELIXIR, January 2014 (see also https://www.elixir-europe.org/about-us/governance/faqs#FAQ14).

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2.3 Conclusions: components of the governance structure

Based on the literature (see paragraph 2.1), the design of the governance structure of the FNH'S DI-RI should (at least) include the following components (some specified with elements from the descriptions of the governance structures of BBMRI, ECRIN or ELIXIR):

1) A decision making structure (who decides how and on what)

This includes the statutes, the decision making body and the executive management. It involves the description of the decision making on hub level and the decision making on national node level. For example the board of the FNH'S DI-RI decides which tasks – scientific, technical, administrative coordination - will be carried out by the hub (the director and the staff), decides on the strategy, the financial plan, the programme of the FNH'S DI-RI, establishes rules and procedures (e.g. for the selection of nodes).

2) Control mechanisms - formal and informal - over which resources and data goes on the RI, the methods and procedures prescribed to partners

3) An ownership structure of the RI

4) A governing organisation

This includes the governing body (the board), a director (implementing the decisions of the governing body) with support of an executive management (operating the RI).

5) A host institution

This concerns the hub which hosts the director and the staff.

6) An identity and a name

7) A set of partners

This includes the national nodes with all its partners.

8) A formal agreement by the partners to contribute data and resources

The consortium agreement includes the obligations of the partners.

9) A legal status of the RI (a foundation under national law)

10) Funds and rules for acquisition and spending of funds

This concerns the funding by contributions of member countries to national nodes. It involves also other financing sources e.g. funding by the European Commission for projects.

11) Policies (rules) for access by users to resources, data, tools/services of the RI

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For example, ECRIN is primarily accessible to clinical research but also open to industry sponsored clinical research project, originating from any country (ECRIN, 2015).

12) Policies for managing the generated intellectual property

For example, ECRIN can claim intellectual property rights (alone or shared with its service contributors) over tools, data, products or any other results developed or generated by ECRIN while carrying out the work programme (ECRIN, 2015).

13) Location of the central facility (management and operation of the RI) of the RI

Own building or move in with institute that is partner of the RI.

14) Control over the data due to the commercial sensitivity of the data and the risk of privacy infringement

For example, ECRIN has taken appropriate measures to insure the risks specific to its activities[9].

[9] Source: Commission Implementing Decision of 29 November 2013 on setting up the ECRIN as a ERIC.

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3. The design of the Determinants-Intake Research Infrastructure

3.1 Introduction

According to the Description of Action the objective of the project RICHFIELDS is to "*design a world class research infrastructure on food and health consumer behaviour and lifestyle that will serve as an open access, distributed data platform to collect, align and share existing data in order to enable researchers, policymakers and other stakeholders to develop, evaluate and implement effective food and health strategies, both at the level of individuals and populations*".

In order to design an appropriate governance structure of the FNH'S DI-RI, it should be clear what the FNH'S DI-RI looks like concerning its services offered to its customers, data sources and its suppliers and its functions such as data cleaning, data pseudonymisation, data storage, performance etc.

The FNH'S DI-RI will be a collaboration between public organisations (universities, public sector research institutes) and private companies (food manufacturers, supermarkets, app owners, etc.) located in different countries in Europe. The collaboration concerns data sharing, data processing and data generation (via the Consumer Data Panel) by the RI and service provision in return. Universities, research institutes, app owners, food companies, retailers etc. have collected -and are still collecting - data about what people eat and drink or why they eat and drink that. We define this as food-related consumer behaviour data. The core of the FNH'S DI-RI is the consumer data platform for linking, processing and sharing data on dietary intake and its determinants. The goal of the collaboration is to provide that integrated and harmonised data on food-related behaviour of consumers to others e.g. researchers that want to re-use it for their research. The data platform will be a module (subset or part) of the European research infrastructure on Food, Nutrition and Health (FNH-RI). The next sections present the description of the main elements of the FNH'S DI-RI (see also Figure 3.1).

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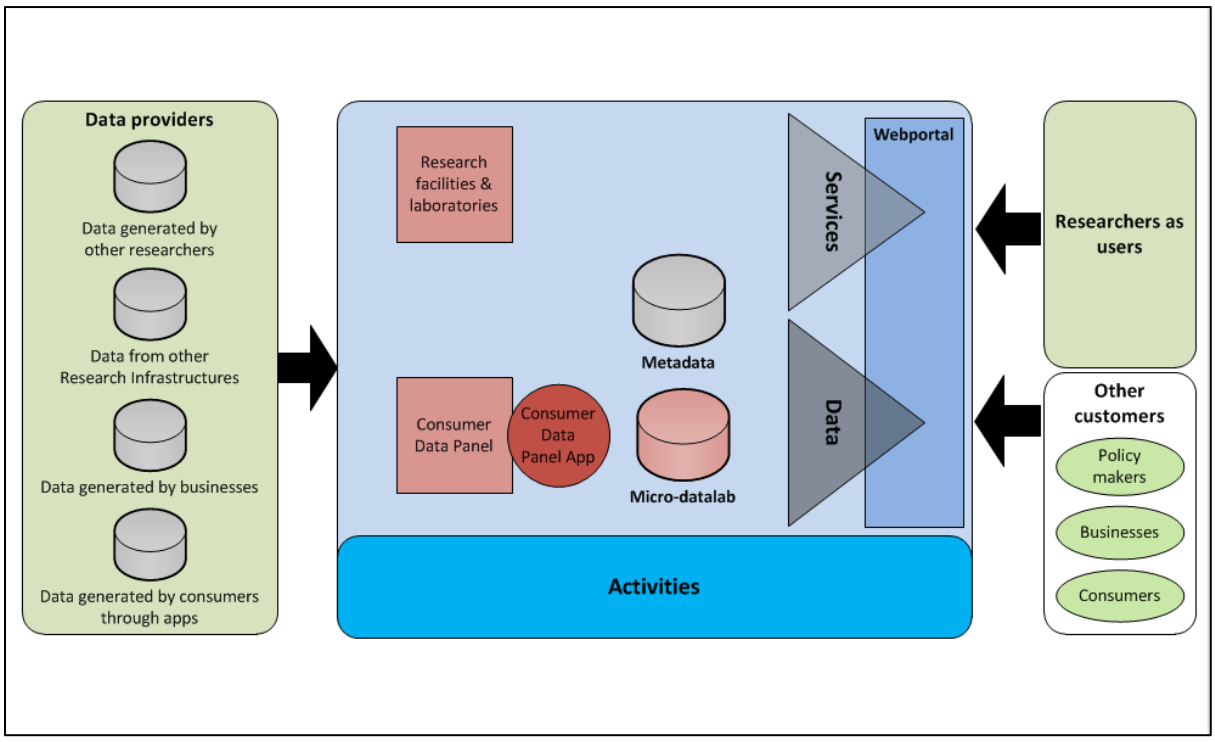

Figure 3.1 The main components of the research infrastructure: data suppliers, data, services (including facilities), activities, and researchers and other customers.

3.2 Researchers as users and other customers

The users of the FNH's DI-RI are members of the research community in Food, Nutrition and Health, with disciplines like food science, human nutrition, health, medicine, economics, econometrics, marketing, sociology, psychology, public administration, artificial intelligence and several related fields that study the behaviour of consumers in relation to food, lifestyle, nutrition and health. This community consists of professors, researchers, doctoral candidates, technical staff and students participating in research in the framework of their studies. The majority of these users works in universities and public research institutes, including academic hospitals.

But there are also researchers working in private research institutes (sometimes partly financed by public money) including research facilities and laboratories as well as with research labs in the food and health industry.

An user needs survey on FNH-RI (see Annex 3) especially about the need for a FNH-RI executed in the first half of 2018 confirmed that data customers see the need of sharing data. The survey showed that in general there is high agreement on the benefits a FNH-RI could provide. Information on the quality of the data, easy access to the data, up to date information on relevant data sets and compliance to standards were most important. Also the quality of the data is relatively important for future users. With the most important aspect is a description of the structure of the data and the least information on outliers. And

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there is high interest in assistance on best practise**.** The main interest in assistance related to working with data is on the topic of Extracting data from multiple internal and external sources. The interviewees stated that three main tools they wanted an overview of are: remote monitoring devices for health data, consumer panels, tools to do a survey. Furthermore the main barrier to data sharing was a lack of standards.

3.3 Data

The FNH'S DI-RI focuses on data of the two pillars 'Determinants' and 'Intake' of the DISH-model[10]. Determinants concern the question why do people choice, buy and eat and drink that food products. Determinants are factors or motives that influence people's food/dietary choices. Intake concerns the question what are people actual eating and drinking. To understand the determinants of food choice by the consumer and measure the intake of food and nutrients by the consumer, many types of data are relevant. Figure 3.2 shows five groups of aspects that have an influence on healthy eating. They range from the product characteristics and the product environment, to demographics, the social environment and consumer characteristics (see also Symmank et al, 2017).

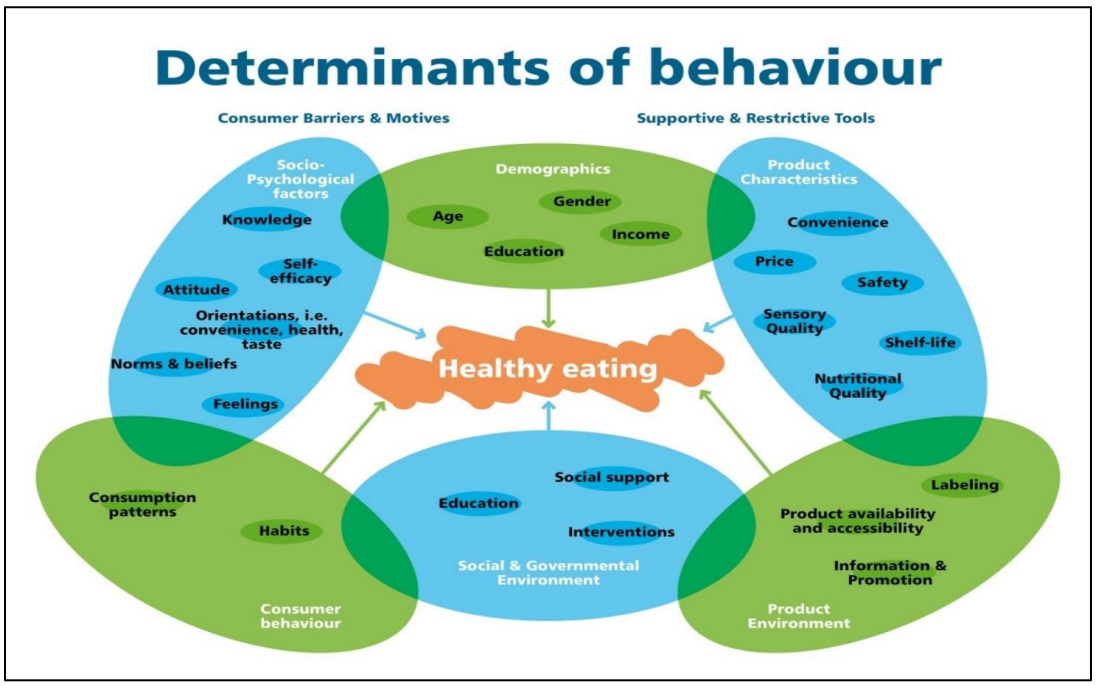

Figure 3.2. Determinants of food behaviour (developed by Snoek, Reinders and Zimmermann at Wageningen UR on the basis of a literature review).

The data that the FNH'S DI-RI provides to its users can come from many sources:

- gathered by the FNH'S DI-RI itself,
- from other Research Infrastructures,
- from research labs,

[10] See the FP7 project EuroDISH.

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- from researchers themselves,
- from open sources like public data, and
- from companies that are willing to share data with science.

These data are not only provided as raw data, but are linked with ontologies, and described with meta-data. Standard definitions for data are provided. Such data include shopping and eating behaviour, food composition data, sustainability aspects of food items etc. Data is typically on the micro level of individual consumers, but also describes the potential determinants of food choice. A large part of the data are data on individual consumers that, given the high sensitivity of the data from a privacy point of view, will be available in a micro-lab setting.

Managing the different types of data and make them accessible for scientists, makes it necessary that the FNH'S DI-RI develops an ontology and that harmonizes entities, food classification and description systems. This is fundamental to facilitate future data access and exchange.
Whilst past data collected by laboratories and experimental facilities may be difficult to incorporate into the FNH'S DI-RI, providing sufficient support and training to standardise their future data collection in such a way as to be more easily shared with the wider research community would increase future data sharing opportunities. The development of authoritative materials and standards must be a component of the FNH'S DI-RI to establish best practice and to help shape the research community moving forwards, thus making future data sharing activities easier. By developing harmonised Standard Operating procedures (SOPs), data management protocols, including calibration/standardisation protocols and improved approaches to obtaining ethical consent at the outset of research studies would increase future data sharing opportunities.

The FNH'S DI-RI data platform will be flexible enough to be able to respond to a dynamic ICT environment, however, careful consideration is needed on a case by case basis about the extent to which the data captured is reflective of the proposed research concepts, and of sufficient quality to be treated as a useful variable for research in the determinants of food behaviour domain.

Data relevant for the FNH'S DI-RI will have several levels of aggregation. Most attractive to study the behaviour of consumers is individual data on their behaviour and its potential determinants. However also more aggregated data and statistics are of scientific use.

3.4 Data providers

The providers of data on consumer behaviour related with the purchase, preparation and consumption of food are key-partners of the FNH'S DI-RI and can be categorized in three groups, according to the type of data:

1) Research-generated data from researchers of public and non-profit organisations, from other existing research infrastructures, and from laboratories and experimental facilities in Europe.
2) Business-generated data from researchers of businesses including food processors and food ingredient producers, retailers, marketing agencies (e.g. for loyalty cards), for-profit research

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institutes and labs, catering services and restaurants, and app developers, and from statistical organizations and commodity boards.

3) Consumer-generated data from citizens in which consumers provide data through questionnaires, surveys, apps on their smartphone, wearable sensors.

Currently in Europe a total of 37 research laboratories and facilities exists where consumer behaviour research takes place (see Figure 3.3). Four of them are classified as commercial applications (e.g., virtual stores offering services such as assortment testing for existing and novel products) that don't not produce research data that can be shared through the FNH'S DI-RI. The remaining 33 facilities are either run by academic institutions or industry, with public, private or public-private funding sources. The facilities differ by the type of stimuli being used: real foods vs. virtual foods vs. fake foods. The research facilities and laboratories cover the following three main areas of consumer behaviour research (source: D10.1):

1) food choice (including perception, preference, acceptance, and taste tests);
2) purchase decisions and possible determinants (store design, food labels, novel product launches);
3) consumption behaviour (preparation, serving portions, left-overs/food waste) and possible determinants (e.g., sensory properties of food, the role of social and physical environments etc.)

A first mapping revealed 37 research facilities and food laboratories across Europe that generate such data.

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Figure 3.3 Geographical overview of the mapped research facilities and laboratories in the EU (source: D10.1)

3.5 The FNH'S DI-RI App

The FNH'S DI-RI is operated as a method of citizen science in which consumers can share their data on food, lifestyle and health with the European research community. Consumers can share data from their apps and loyalty cards and participate in research through a central app that also manages their consents in a GDPR-proof way. Citizens (consumers) are being asked to provide their data, especially with their smart phone as a choice. Researchers can access these individual data through a strict micro-lab protocol. This way we create personalised feedback structures (see Figure 3.4 below). New ICT developments have made it much easier to monitor individual behaviour with apps, wearables and sensors. It is our goal that a large group of European citizens will use the platform. The FNH'S DI-RI App is the tool to access direct data from consumers for research purposes. This app collects consumer behaviour data related to purchase, preparation and

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consumption of food. Consumers are approached in local language and the national nodes are promoting the FNH'S DI-RI App.

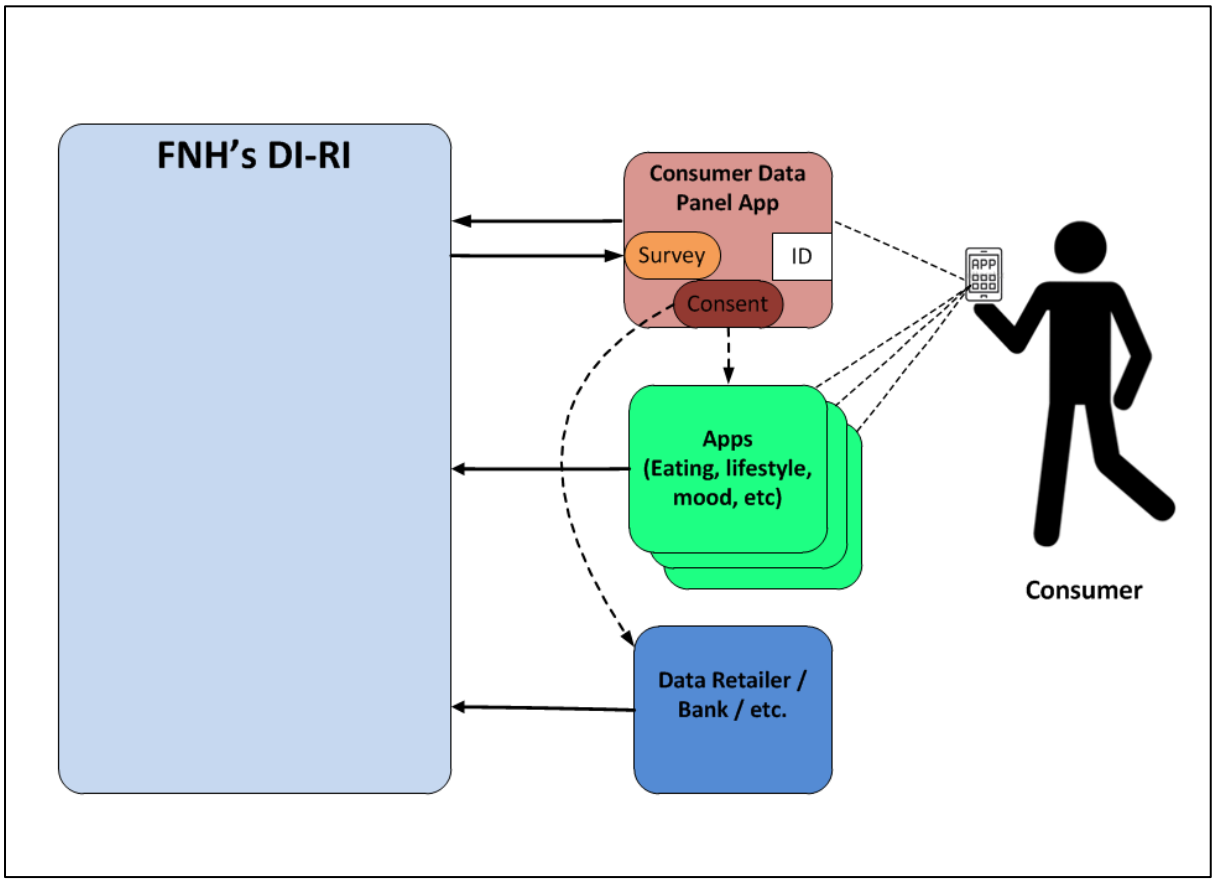

Figure 3.4 Data flows through Consumer Data Panel App of the FNH'S DI-RI

The purpose of the FNH'S DI-RI App is

- To collect in a very extensive framework determinant and intake related consumer data. This data comes from various apps and social media consumer are using. The data is unstructured (PASSIVE app user).
- To establish for the first time a broad European online research consumer panel for research. Consumer using the Richfield App can participate in research studies set up or supported by the Richfield-RI. The data collected is structured will be used for a specific purpose (research thesis) but will also be stored and provided for any other research purpose in future (ACTIVE app user).

Consumers will download the FNH'S DI-RI App on their smartphone or iPad. They will use their social media account to log in and share the data from other food-related apps with the data platform of the FNH'S DI-RI. Next to they also answer questions on food and health in their FNH'S DI-RI App which will be posed at irregular intervals. In return the FNH'S DI-RI

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inform them with a newsletter how their data was used in research. After one year participation detailed advice will be generated on their food pattern and how to make it more healthy.

3.6 Upcoming technology measuring food intake

The collection of such food-related consumer behaviour data is not only done with common or traditional methods – such as questionnaires, surveys, interviews, observations, experiments – and (self-tracking) apps on smartphones but also with the use of modern information technology such as (implantable) wearable sensors – ear-based chewing and swallowing detection systems – and wearable camera's (Vu et al., 2017; Fontana & Sazonov, 2014). For example researchers of the Tufts University in the US have developed a tooth sensor which can measure in real time a person's salt, sugar and alcohol intake (see Figure 3.5 below). The sensor sends data by radio waves signals to an application on a smartphone. Something similar has been developed at the Georgia Institute of Technology in the US where researchers (Lee et al, 2018) developed a stretchable oral sensor to wear in the mouth of a person to measure the amount of sodium the person consumes (see Figure 3.6 below). The sensor integrates with a miniaturized flexible electronic system that uses Bluetooth technology to wirelessly report the sodium consumption to a smartphone or tablet. The researchers plan to further miniaturize the system to the size of a tooth. According to the researchers[11], by monitoring sodium in real-time, the device could one day help people who need to restrict sodium intake and learn to change their eating habits and diet.

[11] Source: http://www.rh.gatech.edu/news/605924/flexible-wearable-oral-sodium-sensor-could-help-improve-hypertension-control

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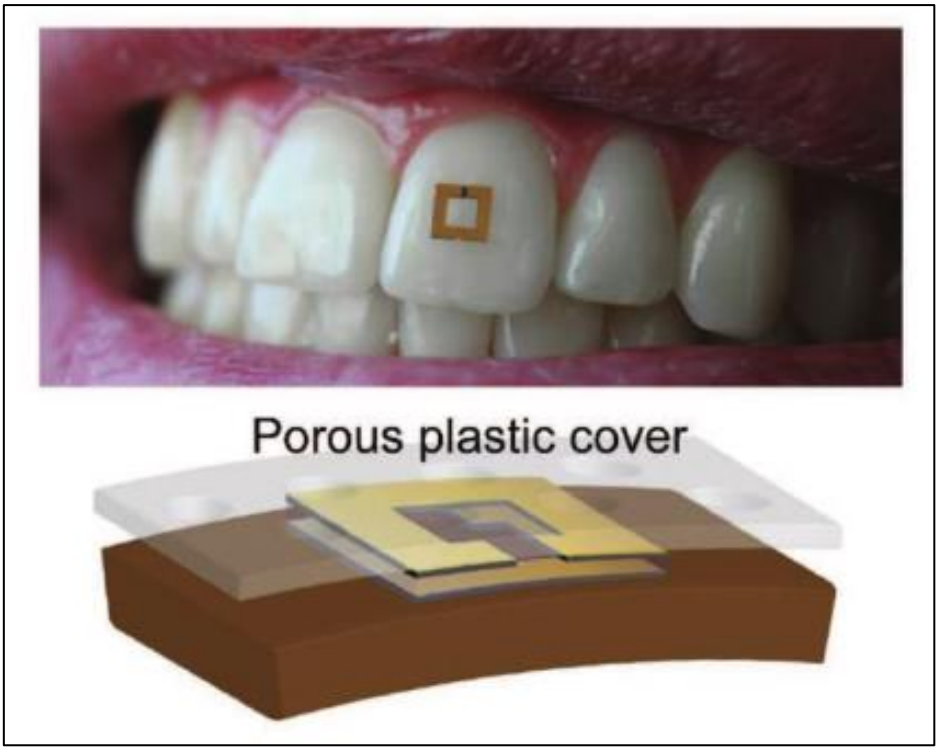
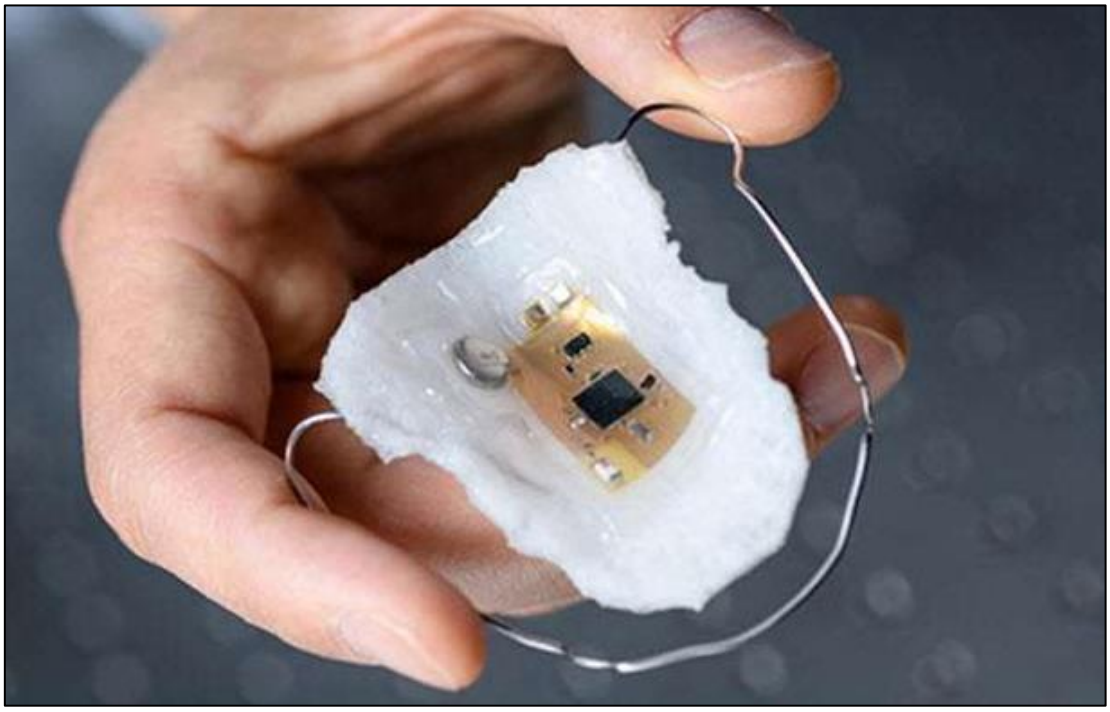


Figure 3.5. A sensor adhered to a human tooth for in vivo monitoring of ingested fluids (Tseng et al, 2018).



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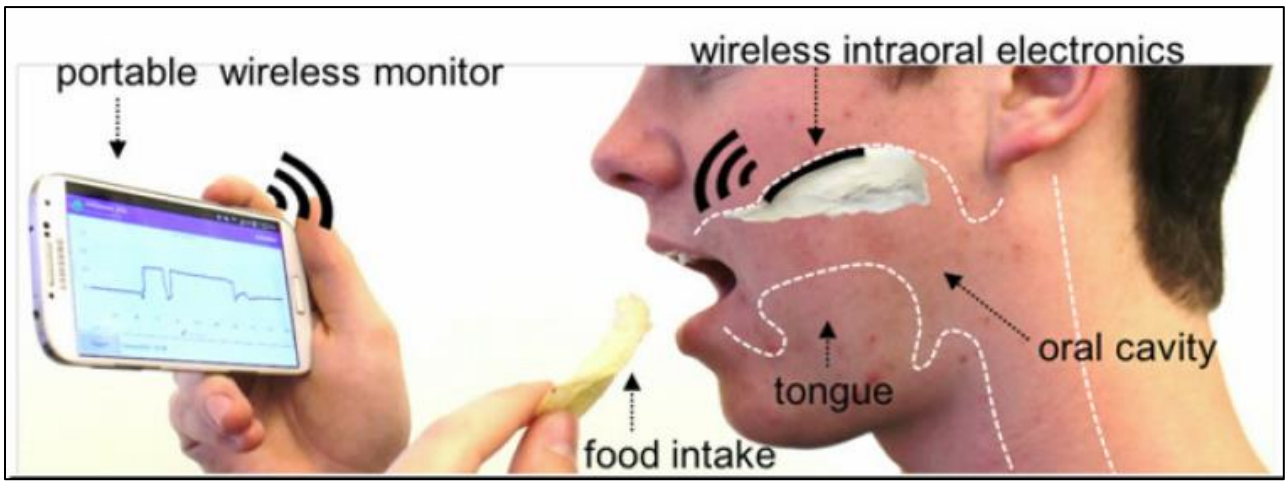

Figure 3.6. The intraoral electronics displaying quantification of sodium intake via real monitoring (Lee et al, 2018).

3.7 Services provided by FNH'S DI-RI

The FNH's DI-RI provides all kinds of services which help researchers to carry out their research more efficiently, makes it comparable and helps to standardize data. The services offered to the users consist of five categories:

1) Data catalogues and data management protocols

Access to high quality and harmonized integrated data

The FNH's DI-RI offers access to various data sets via a single entry point:

1. Research data on consumers food intake and its determinants generated by academic/public research and businesses/private research (that data are described in the meta-database).
2. Data from consumer apps concerning purchase, preparation and consumption of food.
3. Data from wearable devices monitoring food intake through passive sensors.
4. Data of existing research infrastructures such as EuroFIR information platform, Global Data Synchronisation Network (GS1 GDSN), ELIXIR, ENPADASI, GLOBODIET, ECRIN, BBMRI and PRECIOUS.

Access to micro data

The online Consumer Data Panel contains individual consumer behaviour data related to food intake and its determinants. Access to this personal data is only allowed for scientists having a clear research questions which is of public interest and is only for research purposes. The handling and customer care, interviewing and communication is done via the Consumer Data Panel App and a specific consumer programme is being designed for that purpose. This consumer panel includes 20,000 consumers in eight EU member states in 2020-2022. The panel will grow by 25% per year to 100,000 consumers EU wide in 2027 eventually. The App will also set the standard for future apps to be used for research purposes (App quality label).

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Researchers have access to micro datasets (= anonymized data of individual persons = personal data) from apps connected to the FNH's DI-RI via a special micro-dataset lab (physical access) which is located in the FNH-RI Hub, and later as well remotely in special labs of National Nodes. In these labs, analyses can be run, access to individual data is possible, but the data cannot be copied or leave the facility in any other way. Access to this personal data is only granted to public researchers with pre-defined research questions that undergoes an evaluation by an scientific and ethical committee. For some high level industrial member access to the micro data set is possible as well. However, the same rules will be applied regarding scientific and ethical requirements for access.

Access to labs and physical facilities

The FNH's DI-RI facilitates access to labs and physical research facilities for the members of the FNH's DI-RI by network and community building, by an internal member database with contact details and information about expertise/opportunities and by an model agreement for facility sharing or a guideline for facility sharing. The FNH's DI-RI is only an intermediary.

2) Research protocols which set and support best practices for research. The protocols can be downloaded

Access to research protocols, ontologies, semantic models and vocabulary/thesauri

In order to make datasets from different scientific groups and geographical areas compatible with each other, the FNH's DI-RI provides standardized research protocols for data collection (in form of a guideline) including ethical consent, legal compliance, and shared ontologies. The FNH's DI-RI also provides ontologies and semantic models.

Linking own data to other data sets

Data owners - especially app owners - can use the protocols to collect data. Since these data will be „standard" data because are collected through FNH's DI-RI protocols thus it's very easy to integrate it with other standard data. This brings added value to data owner through two ways: 1) to use it more easily for internal use 2) to sell it more easily since data is standard.

3) Standardised vocabulary/thesauri to describe the (un)structured data

4) Ontologies/semantic data models to describe and link your data by establishing concepts and their relationships

5) Training and consultancy services including our summer- and winter school to get first-hand knowledge on data use for advanced research

Strong excellence research community

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On a regular basis the FNH's DI-RI organizes conferences and thematic workshops to bring its members together. These events have a scientific focus – presentations of new research findings – and a network character to link public researchers with researchers from industry, app developers and other data suppliers and users. Non-RI members are considered as guests in order to enlarge the network.

Training & Support

The FNH's DI-RI offers online and physical/F2F training sessions for researchers from the public and private sector about using protocols and semantic, different analysis methods, how to get access to data via the FNH's DI-RI, how to provide access to one's own data sets via the RI Data Platform, how to use the micro data set lab.

Consulting and Analysis

Consulting and analysis for industry and policy makers on request. The focus is on requests that can be solved by using data available by the FNH's DI-RI including the micro data. The expertise of the network of FNH's DI-RI will be used to perform the requested analysis.

3.8 Activities of the FNH'S DI-RI

To provide the services defined in section 3.7 and to process the data from data providers to types of data that the researchers can access, many activities have to be carried out. These are listed in table 3.1 (see below). The activities can be classified in three main groups:

1 Data management (incl. storage of data)
2 Support to researchers and
3 Govern the research Infrastructure.

The data management activities deal with the data acquisition and making the data available to the users through the web portal. An important sub-activity is the acquisition of data. The delivery of services requires activities classified under Support to researchers. Last but not least the activities have to be organized and the FNH's DI-RI has to be governed. These activities are discussed in more detail in D12.3.

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Table 3.1. Activities of the FNH's DI-RI

Activity	Sub-activity	Remarks
Data management		
Develop and maintain ontology on Determinants and Food Intake data		
Manage / connect to data-sets from companies		
Manage / connect to data-sets from research labs		
Manage / connect to data-sets from other research infrastructures		
Maintain data model and database on provenance of data for contracts with companies (including ICT companies with apps) and research labs that provide data		
Engage consumers in joining the Consumer Data Panel	Manage consents	
Create and maintain a Consumer Data Panel App that consumers can download to manage consents and answer survey questions		
Organise relations with apps that provide data	Data diplomacy: keep track of developments in apps	*Maintain RIMS database on apps*
	Maintain protocols (API) for data exchange	
	Contract with apps for data exchange based on consents	
	Add option for integration in CDP app	
Provide feedback / personal advise to participating consumers		
Upgrade data with big data techniques	Knowledge attraction from corpus of text or different data sets with help of a semantic data model	
Set up a micro-datalab	Define access conditions	
Support Researchers		
Maintain the web portal		
Provide access to the data sets		
Provide access to the Consumer Data Panel micro-datalab	Maintain terms and conditions access policy	
	Handle registration and log in	
	Control compliance	
Support access to research facilities and labs		*Including standardisation etc.*
Provide data catalogues		

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Provide standardised vocabulary / thesauri		
Provide ontologies / semantic data models		
Provide training sessions, courses and consultancy services		
Govern the FNH's DI-RI		
Run the Foundation FNH-RI for management of the FNH'S DI-RI	Includes financial management, risk management, relation hub and national nodes	
Run projects to innovate the FNH's DI-RI		*Together with partners in the nodes: projects to make FNH'S DI-RI more mature*
Build up a FNH's DI-RI community and foster networking		
Organise conferences and wider dissemination		

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4 The design of the governance structure of the FNH'S DI-RI

4.1 Introduction

In this chapter we present the design of the governance of the FNH'S DI-RI as a distributed research infrastructure with its legal status, its hub-and-spokes organisational model, its internal organisational structure, the management of the data and services, and its external relationships.

Given the importance in the FNH's DI-RI of individual data on food intake by persons, data protection, ethical issues and intellectual property rights are critical aspects of the design. Much of the data and software represent sensitive information. Protecting such data and software is of pivotal interest, but at the same time we are facing a development where open data and open software are being promoted and demanded. The FNH's DI-RI will balance these interests.

4.2 Legal status of the FNH'S DI-RI

To realise the goals of the research infrastructure, a foundation for FNH's DI-RI has already been established in 2018 during the project RICHFIELDS. The foundation bears the formal name "STICHTING Food, Nutrition and Health Research Infrastructure" and is based in Wageningen, the Netherlands. The foundation is managed by a Board. The statutes of the foundation include the name, the goal, the procedures for the appointment and discharge of board members, the location and the decision making within the foundation. The FNH's DI-RI is a not-for-profit organisation under Dutch law.

The Board will guarantee the neutral status of the Research Infrastructure by avoiding a bias in the composition of the board from different interest groups. As the FNH's DI-RI will be a collaboration between public organisations (universities, public sector research institutes) and private companies (food manufacturers, supermarkets, app owners, etc.), it will not strive to have the European Research Infrastructure Consortium (ERIC) status because ERIC is about research infrastructures on a non-economic basis, while FNH's DI-RI will be part of a RI with an economic basis.

4.3 Ownership structure

The Foundation shall own the intellectual property rights in the FNH-RI domain, which have been, or will be legally granted/transferred by the consortium partners to the Foundation.

4.4 The Hub-and-nodes model

The general model of the FNH's DI-RI is a Hub and Nodes Model which works as a network based administrative organisation. The Hub manages and coordinates the operations of the FNH's DI-RI. The Nodes are national collaborative groups that also represents their own country (from EU member states and former EFTA countries) with a membership of the Foundation RI, which is the 'mother organization' of the Hub, the network that constitutes the research infrastructure. As a Foundation the RI is an independent legally non-profit organization for the purpose of serving the research infrastructure. Independence is important as it entails the ethical and legal commitments of the scientific community.

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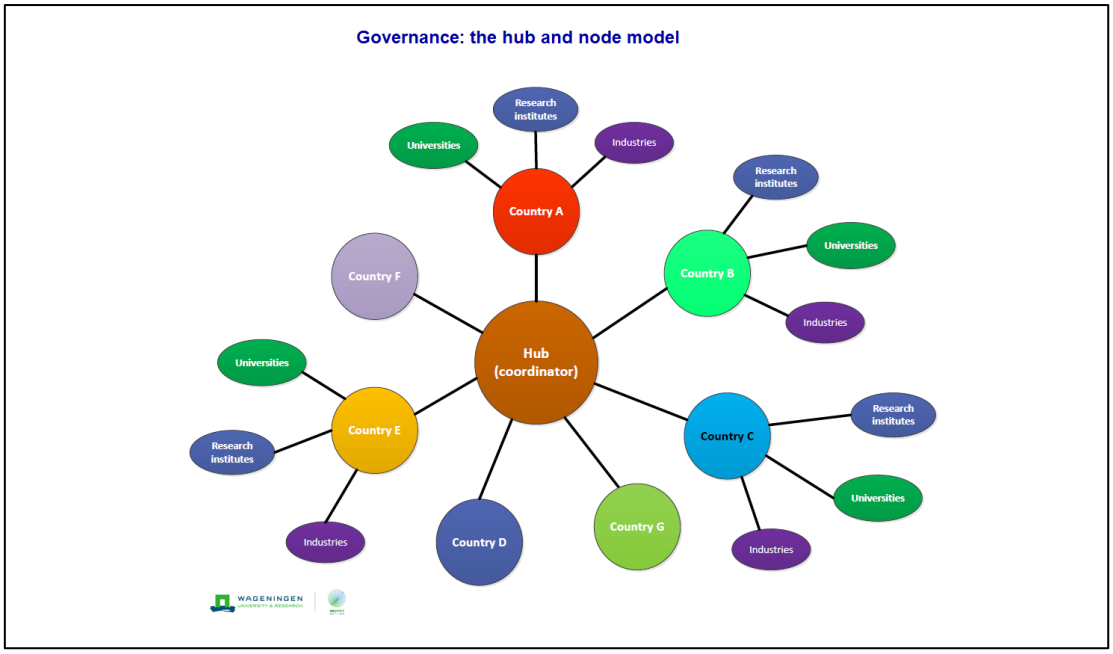

Figure 4.1: the Hub and node Model

The Hub is the central management centre and network coordinator of the facilities, resources and services offered by the FNH's DI-RI, and will be located at Wageningen University and Research. The Hub promotes communication within and among the national nodes. The Nodes are free to choose their own research. They do however depend on each other in their common mission of making better use of dispersed resources and insights. As the FNH's DI-RI is a scientific organisation and scientists are the users, member states scientists and scientific organisations join the FNH's DI-RI. To this end countries involved in the FNH's DI-RI will set up a Node in which the relevant and interested scientific organisation(s) of that country organise themselves as a node and appoint a Head of Node, that represents the country in the FNH's DI-RI governance. The Nodes also need to be recognized by their own government as a Node, by means of the signature of a minister. In principle the Node should be on the Roadmap of its own country to be or become a recognised research infrastructure. In absence of a national roadmap, the recognition of a relevant ministry is sufficient.

By fulfilling these requirements the Nodes are allowed to be members and also become involved in the decision making of the FNH's DI-RI.

The Nodes organise themselves as they judge the best way. The Nodes might be formal organisations, as a group of research institutes united in a foundation or scientific society. They might also be an informal group of research organizations that are loosely coupled for the purpose of being involved in the FNH's DI-RI. The Nodes can have members from outside universities and public research institutes such as private research institutes, research labs from food companies or service organisations and research funders (like ministries, funding agencies, patient organisations).

During the RICHFIELDS project the formation of national nodes in a number of countries has already been started. Currently (in September 2018) nodes are active in The Netherlands, Denmark, Italy, Slovakia and the UK. Nodes in a *statu nascendi* (early stage) are Slovakia, France, Spain. Other

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countries have also taken steps by and showing interest by organising a national workshop (Iceland, Finland, Sweden, Norway, Latvia, Belgium (Flanders))

The legal status as a Foundation allows the DI-RI to sign contracts with data suppliers and with scientists using its Consumer Data Platform/Microlab. Doing this through one of the main consortium partners of the current RICHFIELDS project or the project that is responsible for the construction is cumbersome and could be quite bureaucratic. It could lead to an unequal playing field between consortium partners or nodes. It could also lead to unclear situations for the partners. Therefore a foundation under Dutch law has been created, with a set of rules laid down in statutes (Consortium Agreement). As the ultimate aim is to construct a Food, Nutrition and Health RI, the whole Foundation is called FNH-RI, where the FNH'S DI-RI will be a part of.

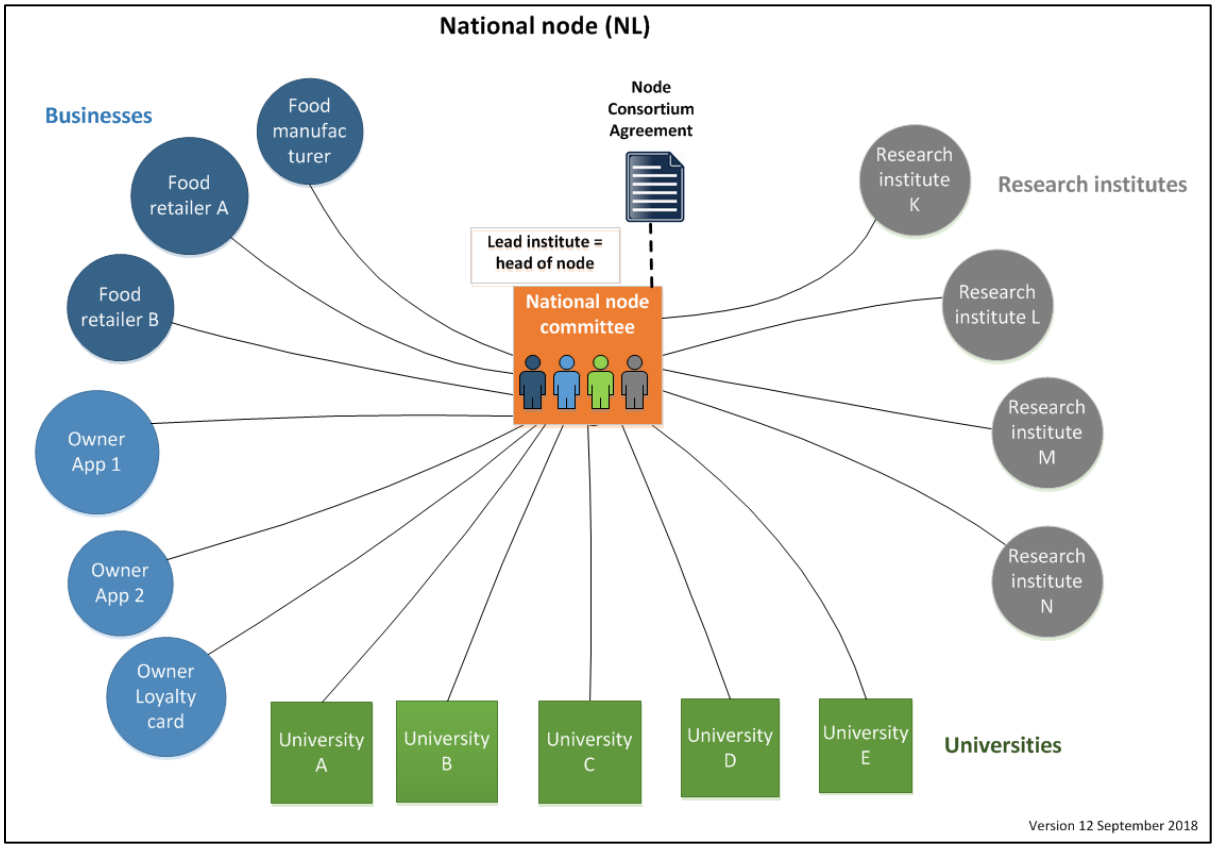

Figure 4.2 The organisational structure of a national node

4.5 The internal organisation

The governing organisation is the central hub, which consist of:

- Board
- Head of Nodes Committee
- A director and staff
- Advisory Committees

The internal organization is presented in figure 4.3. The main parts are then described further.

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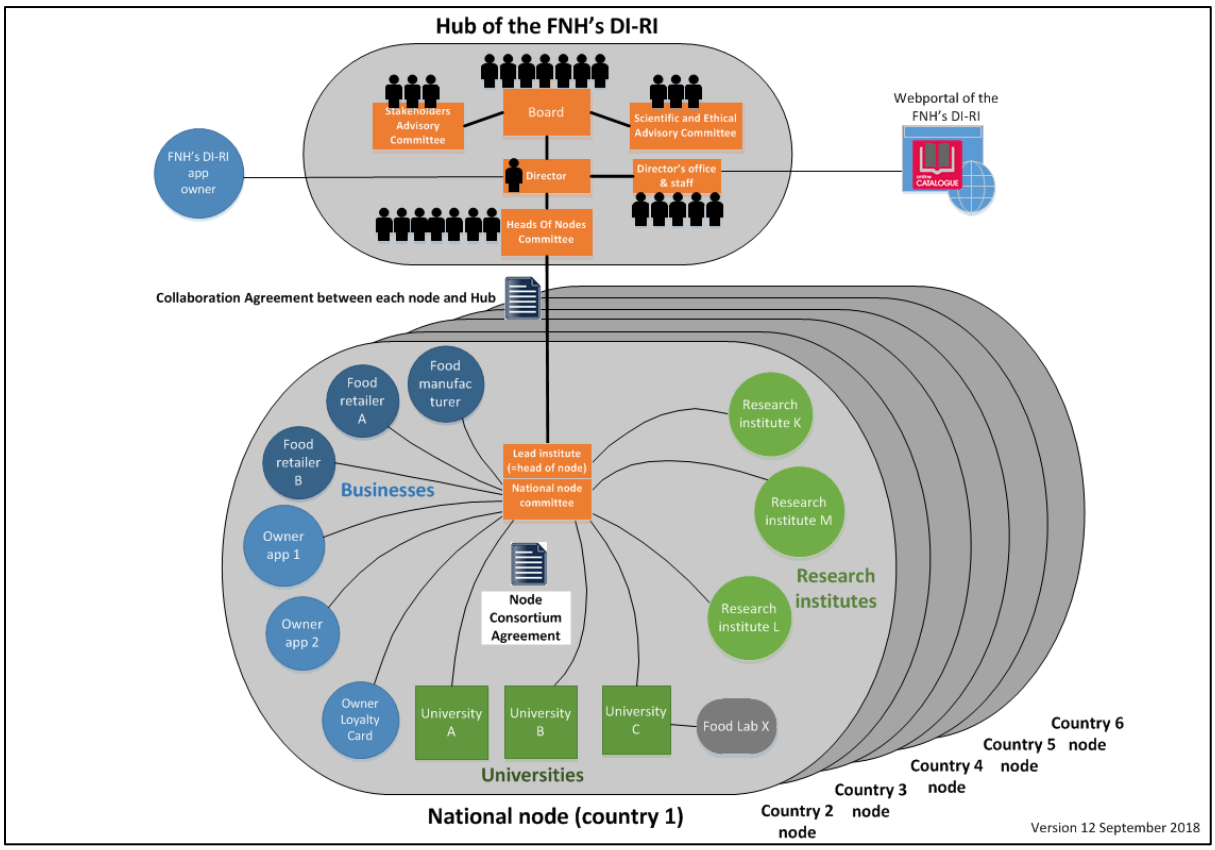

Figure 4.3 The internal organisation

4.5.1 Heads of Nodes

The Head of Nodes is the highest governance level of the FNH'S DI-RI, which sets the strategy and the agenda of the FNH'S DI-RI and appoints the offices of the Hub, the network administrative organisation. The Heads of Nodes meet at least once a year for a joint meeting to decide the strategy and agenda for the FNH'S DI-RI.

All Nodes are members of the Heads of Nodes. The Board may offer a candidate Node an "associate" status if it is decided that the Node is mature enough or has taken measures towards maturity.

The Heads of Nodes can all act as board members of the Foundation FNH-RI.

4.5.2 The Board

The Board is the decision making body for the joint operational decisions. The Board interacts with the national government of countries about their financial and other support of the FNH'S DI-RI. The Board also interacts with the Stakeholders Advisory Committee, which provides the Board with advice and expertise and financial support of the whole RI.

The Board consists of 5 till 7 persons which are voted in by the heads of the national nodes. A larger Board, say one composed of representatives from each country in Europe, will probably have negative implications for the decisiveness of the Board. In the beginning of the FNH'S DI-RI the Board will consist of the people representing the "founding" organisations. The Board shall establish an

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ethics policy which seeks to identify potential legal/ethical risks of sharing personal data and in particular sensitive data, and will provide guidance and principles concerning how these risks can be addressed. The Board will implement mechanisms to ensure that the Nodes are aware of their obligation to safeguard compliance of all relevant laws and regulations when handling, storing, or processing personally identifiable data resulting from research and from apps.

The Hub provides the services. Different levels of services similar to libraries:

- Researcher searches for datasets in the catalogue (metadata) and finds some relevant datasets, requests and receives the datasets from the FNH'S DI-RI.
- Researcher searches for datasets in the catalogue (metadata) and finds some relevant datasets, requests but have to come to the FNH'S DI-RI where he can examine the datasets.
- Researcher searches for datasets in the catalogue (metadata) and finds some relevant datasets, but has to request the data provider (as the FNH'S DI-RI do not have the datasets) to obtain the datasets from the data provider.
- Researcher searches for datasets in the catalogue (metadata) but does not find any relevant datasets, so he has to search somewhere else.

The Hub will also facilitate the development projects which are pivotal to the further improvement of the RI.

4.5.3 Advisory Committees

There are two advisory committees: 1) the Scientific and Ethical Committee; 2) the Stakeholder Committee.

The Scientific and Ethical Committee SEAB

SEAB will consist of scientists appointed in their own right. They do not represent their own organization or country. The Board appoints the SEAB members and decide the rules for the further engagement in the SEAB: how long, how to deal with a replacement etc. The Research Infrastructure including its SEAB shall be periodically evaluated by an independent visitation commission.

SEAB advises the Director of the Hub, the Board of the Foundation and the Heads of Nodes on all aspects of the FNH'S DI-RI: its objectives and the implementation of the Work Program. An annual report could be made available; as meetings could deal with issues regarding individual researchers, there could be too much privacy aspects to make those available. All scientific research, especially in relation to persons and to health, has to be cleared by SEAB on the basis of a research plan before it can start. The members (5 to 10) of this committee should be from the highest indisputable behaviour and have a trustworthy reputation in different member states.

SEAB will report to the highest level in the governance of the FNH'S DI-RI and have the right to publish decisions it takes. Its advise should be sought by the FNH'S DI-RI management on all issues that link to ethical questions. This includes collection new types of data from individual consumers and making data available for some research questions that have specific ethical aspects. As the outside world (like consumers on the social media) does not make much difference between types

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of data managed by the FNH'S DI-RI, be it individual consumer data or general statistics, it is important for the reputation of the FNH'S DI-RI that SEAB monitors all the activities of research infrastructure, not only those where individual data of consumers are involved. SEAB will also advice on the protocols on matters relating to data security, transfer of data to third countries, assessing the genuineness of a request by data users and the rules of operation in the event of requests that may be ethically dubious or questionable, data subjects' requests, and complaints procedures.

SEAB will have the right to advise when asked by the management of the FNH'S DI-RI, but also on its own initiative.

Stakeholders Advisory Committee SAC

The Stakeholders Advisory Committee SAC is the link between the FNH'S DI-RI and the consumer/ citizen and patients' organizations and other NGOs, the industry and other scientific communities and organizations. For members, SAC shall draw upon a range of stakeholders (consumer organizations, patient organizations, research institutions, the legal profession, IT professionals, commercial entities, non-governmental organizations, former politicians). It contributes to the decision-making process (the Board and director of the Foundation), together with the SEAB. The SAC ensures a societal awareness on needs and expectations on key issues, such as data protection, informed consent in research, research priorities, and other ethical, legal and societal issues.

One of the objectives of the FNH'S DI-RI is to improve the competitive position of the European industry. This makes it attractive for the FNH'S DI-RI to be in contact not only with the direct clients in research (through the operational processes and through the nodes in strategic decision making), but also with the industry as indirect user. Industry has much practical knowledge, runs scientific research labs and is willing to contribute data sets to the research infrastructure. Many users of the research infrastructure, being PhD students, will engage in their career with industry. In addition, industry will be a source of finance for the FNH'S DI-RI. This all makes some form of dialogue, representation and even influence (as advisors) logical. It makes the FNH'S DI-RI to some extent resemble a public-private partnership, an organisational form not uncommon in today's research landscape. Some of this dialogue with industry can and will take place in the nodes. As such, we will not rule out an organisational form which include industry. For SME and their industry organisations that might seem logical and it is also likely that a research lab of a big multinational takes part in activities of a node in the country where it works. But given the number of large food, health and ICT multinationals that are already active in European research programs, and have expressed a clear interest in the FNH-RI, it makes sense to organise them in a Stakeholders Advisory Committee. Participation of private industry in a research infrastructure on food and health is however a sensitive issue. It is of great importance to keep the involvement clear and transparent and outside the decision making bodies as damage to the reputation of the FNH'S DI-RI is a real risk. It is therefore in the interest of both the RI and the industry itself not to be involved in the decision making, other than by giving advice. Minutes of the meetings of the Stakeholders Advisory Committee and its advises to the Board of the Foundation and its director should be made public on the website of the Foundation. It is advised to do the same for the Board meetings itself.

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One of the considerations for the Foundation will be about how the citizens/consumers will be engaged. The ambition is to engage consumers/citizens in an active way. They can for instance share their data with the FNH'S DI-RI and they could see themselves as a commons that collectively owns that data set. In that view that consumer data platform could be organized as a data cooperative. For now we emphasize that the citizen involvement is very likely to grow in importance the coming years. Citizens, maybe with a background in consumer- and patient organisations, will participate in the Stakeholder Advisory Committee.

4.5.4 Director and Staff

The director and staff takes care of the daily management and will ensure the allocation of responsibilities for various tasks such as appointment of personnel (e.g. the DPO), conducting risk assessment, establishing robust security systems, the processes for obtaining data from various data suppliers and their level of integrity, overseeing the contractual agreements with researchers, transfer of data to third countries, and reporting and monitoring processes for GDPR compliance. The staff includes a legal officer and web developer for the portal. The director's office and staff take care of the daily operational work such as the maintenance web by webteam, help desk for researchers etc. Tasks may be delegated to nodes or their universities and research institutes or to self-employed individuals, but the Hub remains responsible for the results. Such a delegation of tasks might reduce administrative costs for the Foundation and it makes the FNH'S DI-RI more flexible. Besides, the necessary expertise might be only found at the nodes and their universities and research institutes. Sharing the work brings this expertise to the level of the FNH'S DI-RI and makes for instance standardization efforts more acceptable if the work is done by the best experts themselves. As much of the finance of the FNH'S DI-RI comes via the nodes from the member states, it makes it attractive that this money also flows back to organizations active in the nodes that secure the money in the first place.

As the FNH'S DI-RI concerns data on consumption behaviour and purchase habits of individual data subjects, according to the GDPR it would need a Data Protection Officer (DPO). It is not essential that the DPO is a staff member of the organisation where the headquarter of the FNH'S DI-RI is located. A DPO with appropriate professional qualifications can be appointed on the basis of a service contract. The officer will be responsible for providing advice on compliance with the GDPR, monitor compliance, raise awareness and act as a contact point for the supervisory authority. Freedom of information (FOI) is not specifically mentioned in the GDPR but the FNH'S DI-RI will put in place a mechanism that enables such requests to be handled efficiently and effectively. Although other options are possible the FNH'S DI-RI will have the DPO to act also as an FOI officer.

4.6 Financing the FNH'S DI-RI and nodes

Financing of the national nodes and their activities is independent from the central hub. Each national node is responsible for its own governance and financing. The annual contribution fee per node is given by the central hub (Board decision) and the national contribution can come from public, public-private or only private sources. The latter would be an option although very unlikely.

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4.7 Access by users to micro-data lab of FNH'S DI-RI

The Hub of the FNH'S DI-RI, which is the executive (management) level where all the work is coordinated, signs the contracts with data suppliers and with scientists who wants to use the micro-data lab.

The use of the individual micro data by the users of the FNH'S DI-RI is already regulated by the GDPR and internally by the Ethical Committee and technical, organizational and security measures. One of those organizational measures is the a micro-lab that the FNH'S DI-RI will make available for the scientists that user the individual data of the consumer data platform.

A micro-lab is a facility that many statistical offices run, to grant researches access to their individual data that is privacy sensitive or where there is otherwise a risk that individual data gets published. Researchers get access to a micro lab if they submit a research plan that shows that access to individual data is essential for answering their research question. They then have to sign a contract that stipulates that they are allowed to use the data (this can be done by remote access), but have to treat knowledge on pseudomised individual data as confidential and can only take out aggregated data (or scatter plots etc.) after having performed their results on the computer of the FNH'S DI-RI. This computer provides a lot of standard software to perform the research (statistical packages like SPSS, SAS; programming languages as R) and a researcher can bring in his own data sets that he want to link with the data of the FNH'S DI-RI. Once the research is ready, a staff member of the FNH'S DI-RI checks if the output file is in line with the contract and does not contain individual data (or tables made in such a way that individual data can be re-engineered by comparing tables). Data sets and interim results are archived with the FNH'S DI-RI in case future demand for the background data of a research paper arises. In this way the maximum guarantees are given to consumers and other data providers that files with individual data are not released by the FNH'S DI-RI and will not pop-up somewhere on the world wide web. Annex 3 provides a first design of the protocol for the Consumer Data Platform Micro-lab.

4.8 Policies for managing Intellectual property

For dealing with access and usage rights for the data and services intellectual property rights (IPR) are of great importance, as there are many types of organizations and data involved, as universities and research institutes claim ownership on the results from projects. Where this is often of limited value in social science (where it is hard to create a patent from a new insight) or software (where code from research projects often has to be rewritten from scratch to make it maintainable), projects can create commercial value in food or health that research institutes and university can commercialize. The FNH'S DI-RI keeps track of the ownership of the knowledge brought as input in a project and ownership of the results that a research consortium creates.

FNH'S DI-RI will also take measures to comply with the trend promoted by the EU towards E-science, open data, open software and open science including publishing in open access journals. As the FNH'S DI-RI is and will be heavily financed with public money, the FNH'S DI-RI will embrace this development of openness and restrict itself in exploiting IPR on its data. The willingness of citizens to contribute will benefit from a position in which results are also available to the public and research without exploitation rights.

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The FNH'S DI-RI consumer data platform is based on the idea that citizens – as consumers of food – are sharing their data for science production. This poses challenges regarding IPR: who is the owner and what is the nature of the collective goods. This social production of science has been called citizen science, which involves public participation and collaboration in scientific research with the aim to increase scientific knowledge. The collaboration with citizens will be organized by seeking advice from the Citizen Science Association (www.citizenscience.org).

Citizen science as public participation gathering, interpreting or analyzing data, implies the production by a collectivity. And according to intellectual property legislation, this collectivity will own the IPR of their inputs. Citizen science can cover public, private and common goods, and each have their own characteristics and must be carefully integrated in the RI. Data donated by a collectivity of users, who is interested in fostering and propelling scientific research, is a good example of a commons. This can enrich the goals of the FNH'S DI-RI. Making the public understand that the shared data will be part of a digital commons where all researchers, professional and amateur, have the right to access, could enhance public visibility and, therefore, increase digital assets of the FNH'S DI-RI while, at the same time, it accomplish the European Commission main objectives in the development of open science.

When obtaining, processing or disclosing data, the FNH'S DI-RI must follow certain legal rules which will be imposed by the owner of the data or the creator of the database, whoever it may be. In some cases the rules will not be set up at all, as for example in anonymous datasets. FNH'S DI-RI obtains primary data, for example via recording audio question and answers to customers in supermarket entrances. In this case a database does not exist. As the data is merely factual, there is no data rightholder but the FNH'S DI-RI has created a work subject to IPR, the set of recordings. The concept of IPR implies that the creation of that data, creates the IPR, without further registration needed. If the FNH'S DI-RI obtains primary data, processes it and inserts the data in a database created by the FNH'S DI-RI, then the IPR are the sui generis rights on the created database.

There can be cases where a third party supplies data to the FNH'S DI-RI without using a database format. For example, a freedom of access to information is exercised by a partner of the FNH'S DI-RI and the data obtained from this partner are pdf files non-machine readable. The FNH'S DI-RI parses the files, extracts the data and creates a database, in which it inserts the data. In this case, the supplier of the pdf is the rightholder of the pdf files IPR, if any, and the FNH'S DI-RI is the rightholder of the database structure IPR sui generis. When a third party provides data to the FNH'S DI-RI, data which is already inserted in a database. In this case the IPR of the content and right sui generis of the database are from the supplier.

In conclusion, the IPR on data obtained by the FNH'S DI-RI must be analysed case by case. It depends if it is a database (then there is a rightholder who arranged the data in the database) or primary data. And of course it makes a difference if this work was created by the FNH'S DI-RI itself or obtained from a partner. But all cases corresponds to one of the next possibilities:

- FNH'S DI-RI as creator of works from scratch.
- FNH'S DI-RI as creator using a third party pre-existing (derivative) work.
- FNH'S DI-RI as a mere user of third parties creations.

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The IPR clearance policy of the FNH'S DI-RI includes the following conditions:

1) For each of the three activities described above, where the FNH'S DI-RI uses third party works, the consent of the rightholder has to be obtained in a way there is no doubt this consent has been granted. Although verbal consents on IPR could be valid legally speaking, they should not be accepted as it is very uncertain they could be used as evidence in court in case of a legal conflict. Obtaining the permissions will depend on the data supplier and must be analysed case by case. Some suppliers will use a public license, where the conditions would be clearly stated, some public licenses will have not addressed all possible uses so the supplier should be contacted and some other suppliers will not express publicly the conditions and thus a direct contact will be needed in order to draft a document where the conditions are regulated**.**

2) For each of the activities described above where the FNH'S DI-RI is the collector of the data and the creator of the database, it will be expressed publicly in a way no doubt could arise, what are the permissions that the FNH'S DI-RI offers to the rest of the actors of the informational playground. Exploitation for profit is not the objective.

3) It has to be taken into account that, although there is a European legal framework related to intellectual property, every country has a specific normative. Thus, the FNH'S DI-RI operating in different member states, will need to assure with local experts that the proceedings designed to collect or publish data do accomplish local legal requirements. This complexity can be reduced somehow by running the website and databases from one site.

4.9 Appropriate technical, organisational and security measures

As the FNH'S DI-RI stores data and allows public and private actors access to the data, the Directive on e-commerce is applicable (Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market). The Directive regulates the limitation of liability of FNH'S DI-RI as a service provider that stores data. The FNH'S DI-RI is a data provider who hosts the information in a server managed by its organization in European Union territory. With this role the FNH'S DI-RI is considered an intermediary of the information society.

The Directive on e-commerce, and the interpretation made by the European Union Court of Justice, sets forth a limited liability by FNH'S DI-RI as data provider which will only be responsible once it is aware of facts or circumstances from which the illegal activity or information is apparent or the provider, upon obtaining such knowledge or awareness acts expeditiously to remove or disable access to the information (article 14 of the Directive 2000/31/EC). No prior control through filtering or monitoring should be installed in the server. Although the legislation and the jurisprudence may be clear, in practice what is important is not to be right but not to have a judicial case. Therefore, the incorporation of strict policies on IPR of the hosted data is very recommendable.

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The following list of issues related to scientific, ethical, privacy and data provenance aspects will be taken included in the technical, organisational and security measures of the RI (e.g. in an internal handbook or work flow management system):
1. Obtaining data. **1.1.** Identification of the authorship of the data and record this in the meta-data. **1.2.** Clearance of previous IPR and/or other terms and conditions. If consent on IPR, terms or conditions are not met, then the data should not be used.
2. Managing or processing data. **2.1.** Respect of third parties IPR and/or terms and conditions.
3. Publishing data. **3.1.** Respect of third parties IPR and/or terms and conditions. **3.2.** Related to data: for each dataset, machine readable and human readable metadata should be provided, indicating IPR and/or terms and conditions. **3.3.** Related to the data-platform: **3.3.1.** Provision of clear IPR and/or terms and conditions for the usage of the platform. **3.3.2.** Provision of clear proceeding for third parties IPR claims. **3.3.3.** Provision of a clear proceeding for privacy claims. **3.3.4.** Licence of the web page. **3.4.** Related to access of third parties to data: facilitate data mining or access of data through an API.
4. Deployment of software applications, if any. **4.1.** Appropriate IPR licence should be attached. **4.2.** Source code of the applications should be uploaded to a version control repository.
5. Specifically related to project that develop the FNH'S DI-RI or extend and maintain it: all key assets produced by the consortium members should be assigned to the inheriting institution if IPR on the assets could hamper future scientific developments contrary to European Union open science principles.

Table 4.1 Relevant IPR issues for the technical, organisational and security measures

4.10 Ethical issues and the GDPR

Essential issues of ethical concern includes personal data for research purposes, are privacy, informed consent and ownership of data. These concerns relates primarily to privacy of an individual as a result of the use of data containing personal data (namely identifiers such as name, telephone numbers, addresses, IP address, and biomarkers) and to an individual's right of control over his or her data. Both privacy and right of control are matters addressed by the European Union's General Data Protection Regulation (GDPR).

The GDPR identifies two parties who are required to comply with the GDPR. They are the 'controller' and the 'processor'. 'Controller' is defined as 'the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data' and 'processor' as 'a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller'. The definitions make clear that a controller or a processor can be an individual or an organization, it can be a private one or a public organization.

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The GDPR imposes obligations on all parties when it comes to processing personal data. Informed consent is key to legitimizing processing of personal data. Informed consent is a mechanism widely used in research to legitimize the use of an individual's data for a particular purpose(s). Purpose limitation is an important aspect of consents: processing is not allowed unless further data processing is compatible with the initial purpose for collection or for scientific or historical research purposes. That does not accommodate multiple data sets that are being used for purposes other than those for which the consent was sought. Mechanisms often utilised to enable re-purposing are blanket consent for all potential uses, and tiered consent allowing individuals to permit specific uses. Use of blanket consent (often used by app providers) is restrictive of individual autonomy. Consent permitting specific uses also poses problems for research using big data since it is impossible to predict the uses of the data sets in the future. In order to balance the interests of both the individual and the researchers governance structures that recognise the rights of individuals to withdraw from participation and an independent ethics committee that review requests for access to data to determine whether the request would meet the ethical parameters without compromising privacy may be helpful

Ownership of data is a complex concept. It could refer to the right to control data (namely, empowerment of the individual to control the means and ways in which his data is being utilized) and rights to benefit from the data (such as intellectual property rights that reside in the database and innovation from big data analysis. A related issue in respect to ownership is how a research infrastructure with vast quantities of data from different sources maintains data integrity and gives control to data subjects over their personal data through mechanism such as right to rectification and withdrawal of consent.

These ethical issues have several consequences for the design of the FNH'S DI-RI. The GDPR requires the FNH'S DI-RI to have a Data Protection Officer as the scientific protocols for the use of the individual micro data has to be strongly regulated, to prevent misuse and trust-problems with data suppliers and ensue that the citizens remain "owner" of their data. But also SEAC will play an essential role.

The FNH'S DI-RI will collect data from a variety of sources – data from apps, social media, loyalty cards etc. The FNH'S DI-RI Hub will work out a program for meeting the consent standards required by the GDPR where data is being processed for purposes other than originally envisaged. A close scrutiny of the consent forms and terms of use of the data suppliers will be needed for examining whether data subjects have consented to further processing. The privacy-sensitivity of the data is less restricted for science than for other purposes and in the absence of a clear guidance (even though the Recitals of the GDPR recognises the importance of data for research), the re-purposing of the kind envisaged by the FNH'S DI-RI will have to be examined on a case-by-case basis by the FNH'S DI-RI.

Through pseudonymisation the data cannot be attributed by its users to a particular data subject – citizen/consumer - without the use of additional information and this additional information has to be kept separately from the processed data by the controller. This makes pseudonymisation different from anonymization, in which this key is not stored. Although the additional data are kept

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separately it may still be possible for there to be security breaches - e.g. obtaining of the key to the additional information - which enable the linking of the additional data to the pseudonymised data. However, the discussion on the use of the concepts pseudonymisation versus anonymization is ongoing and for now we just establish the fact that the FNH'S DI-RI will make use of the best practice concerning these concepts and implement appropriate safeguards for unauthorised reversal of what we now call pseudonymisation: technical measures such as encryption and other organisational measures on the ways in which the de-identification key will be protected from access. The FNH'S DI-RI will also not supply more data to a researcher than (s)he needs for that research question, to minimize the risk of inference from the data. It might be decided to delete the directly identifying data, in order to minimize potential risks for security breaches. In circumstances where the FNH'S DI-RI has demonstrated inability to identify the data subject, it might benefit of the exemption from the rights to access, rectification, erasure and data portability allowed to data subjects by the GDPR.

4.11 Location of central facility (management and operation of FNH'S DI-RI)

Own building or move in with institute that is partner of the RI.

The foundation for FNH's DI-RI - formal name is "STICHTING Food, Nutrition and Health Research Infrastructure" – has already been established in 2018 during the project RICHFIELDS and is based in Wageningen, the Netherlands.

4.12 External relations

The essence of the external relationships is to build trust and confidence in the scientific and ethical quality of the RI by a demonstrated stronghold in ethics and law. For this to evolve, the FNH'S DI-RI deals with the data management rules: data storage, maintenance, access to the RI, access to and also sharing and re-using data and methodologies and services. The literature review in WP 13 Deliverable 13.2 showed that privacy, informed consent and ownership are the most frequent issues of ethical concern, and they are also essential to the external relations.

Currently the GDPR is new and much effort must be devoted to make the FNH'S DI-RI compatible with the way the regulation evolves. The new law will harmonize many of the national legal differences that used to dominate the scene, and much of the value added by the FNH'S DI-RI will be about how the services are delivered through the information and communication technologies. The GDPR imposes obligations on processing personal data and gaining informed consent is key to legitimizing processing of personal data. Informed consent is a mechanism in research to legitimize the use of an individual's data for a particular purpose(s). Current practice does not accommodate multiple data sets that are being used for purposes other than those for which the original consent was sought. But the FNH'S DI-RI will have to apply types of consent that allows re-use of data.

Not all of the challenges ahead can be defined in the (still important) internal technical, organisational and security measures in the form of (certified) handbooks and workflow management systems. It is also very much about developing a culture that is about collaboration and a societal focus. The FNH'S DI-RI needs a framing that put emphasis on terms like "international", "entrepreneurial" and "result-oriented" science. However, the User Survey shows that for instance sharing data is not very common in the mind-sets or practice of science. This is also a setting where

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the FNH'S DI-RI has to deal with IPR issues where universities and research institutes tend to claim ownership on the results from projects. Where this is often of limited value in social science (where it is hard to create a patent from a new insight) or software (where code from research projects often has to be rewritten from scratch to make it maintainable), projects can create commercial value in food or health that research institutes and university can commercialize. This results in keeping track of ownership of knowledge brought as input in a project and ownership of the results that a research consortium creates.

New concepts like pseudonymisation might provide a useful route for the FNH'S DI-RI to reduce risks but still maintain the usefulness of the data. Data can in any case not be attributed by its users to a particular data subject (person) without the use of additional information and this additional information has to be kept separately from the processed data by the data controller. Some form of joint data control might be needed. The GDPR recognizes the existence of joint controllers of data but does not give any methodology for assessing the risks involved. The Scientific and Ethical Board will be very important for ensuring good external relations by its active right to advise on its own initiative and publish the decisions it takes. Its advise will also be sought by the FNH'S DI-RI management on all relevant issue, including the collection new types of data and new types of consent from individual consumers. As the outside world (like consumers on the social media) does not make much difference between types of data managed by the FNH'S DI-RI, be it individual consumer data or general statistics, it is important for the reputation of the FNH'S DI-RI that the SEAC monitors all the activities of research infrastructure, not only those where individual data of consumers are involved. SEAC will advise on the protocols on matters relating to data security and usage, assessing the genuineness of a request by data users and the rules of operation in the event of requests that may be ethically dubious or questionable, data subjects' requests, and complaints procedures.

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References

BBMIR (2012). Business Plan. Version 21.1 (http://www.bbmri-eric.eu/wp-content/uploads/BBMRI-Business-Plan.pdf).

Broek, T. van den, Veenstra, A.F. (2015). *Modes of Governance in Inter-Organizational Data Collaborations*.

Commission Implementing Decision of 29 November 2013 on setting up the ECRIN as a ERIC. ECIS. Completed Research Papers. Paper 188.

ECRIN (2015). ECRIN-ERIC Internal rules of procedure. Last updated on June 18th 2015.

ESFRI (2011). Strategy Report on Research Infrastructures. Roadmap 2010. European Union.

Fontana, J.M., Sazonov, E. (2014). *Detection and Characterization of Food Intake by Wearable Sensors*. In: Wearable Sensors: Fundamentals, implementation and applications. 1e Edition. Academic Press. pp. 591-616.

Goethals, F.G. (2008). Important Issues for Evaluating Inter-Organizational Data Integration Configurations. In: *Electronic Journal Information Systems Evaluation*. Volume 11. Issue 3, pp. 185-196.

Klievink, B., Bharosa, N., Tan, Y-H. (2016). The collaborative realization of public values and business goals: Governance and infrastructure of public-private information platforms. In: *Government Information Quarterly*. Volume 33, pp. 67-79.

Lee, Y. et al. (2018). *Wireless, intraoral hybrid electronics for real-time quantification of sodium intake toward hypertension management*. In: PNAS. Volume 115, no. 21, pp. 5377-5382.

Markus, M.L., Bui, Q. (2012). Going Concerns: The Governance of Interorganizational Coordination Hubs. In: *Journal of Management Information Systems*. Vol. 28, No. 4, pp. 163-198.

OECD (2014). *International Distributed Research Infrastructures: Issues and Options*.

Provan, K.G., Kenis, P. (2008). Modes of network governance: Structure, management, and effectiveness. In: *Journal of public administration research and theory*, 18 (2), 229-252.

Sayogo, D.S., Gil-Garcia, J.R. (2015). Analyzing the Influence of Governance Structure Determinants on the Success of Inter-Organizational Information Sharing Initiatives. 48th Hawaii International Conference on System Sciences. In: IEEE Computer Society, pp. 2232-2241. DOI 10.1109/HICSS.2015.267.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 654280.

Stok F.M., Hoffmann, S., Volkert, D., Boeing, H., Ensenauer, R., Stelmach-Mardas, M., et al. (2017). *The DONE framework: Creation, evaluation, and updating of an interdisciplinary, dynamic framework 2.0 of determinants of nutrition and eating*. PLoS ONE 12(2): e0171077. doi:10.1371/journal.pone.0171077.

Symmank et al (2017) Predictors of food decision making: A systematic interdisciplinary mapping (SIM) review. Appetite, 110, 2017, 25-35.

Tseng, P., Napier, B., Garbarini, L., Kaplan, D.L., Omenetto, F.G. (2018). *Functional, RF-Trilayer Sensors for Tooth-Mounted, Wireless Monitoring of the Oral Cavity and Food Consumption*. In: Advanced Materials, Volume 30, issue 18. https://doi.org/10.1002/adma.201703257.

Vu, T., Lin, F., Alshurafa, N., Xu, W. (2017). *Wearable Food Intake Monitoring Technologies: A Comprehensive Review*. In: Computers, Volume 6. Issue 4.

Websites

http://www.bbmri-eric.eu

http://www.ecrin.org

http://www.elixir-europe.org

http://eu-isciii.es/wp-content/uploads/2015/12/4-Gonzalo-Calvo-ECRIN-ISCIII-26-01-2016.pdf

FAQs on Legal and Governance Issues of ELIXIR, January 2014 (see also https://www.elixir-europe.org/about-us/governance/faqs#FAQ14).

https://www.elixir-europe.org/system/files/faq_on_elixirs_legal_framework_january_2014.pdf

https://ec.europa.eu/research/infrastructures/index_en.cfm?pg=eric-landscape

http://www.rh.gatech.edu/news/605924/flexible-wearable-oral-sodium-sensor-could-help-improve-hypertension-control

https://ec.europa.eu/research/infrastructures/pdf/2016_charterforaccessto-ris.pdf

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