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Authors: Timotijevic, L.[1]; Astley, S.[2], Bogaardt, M.J.[3]; Bucher, T.[4] Carr, I.[5]; Copani, G.[6]; de la Cueva, J.[7]; Eftimov, T.[8]; Finglas, P.[9]; Hieke, S.[10]; Hodgkins, C.E.[1]; Korušić-Seljak, B.[8]; Klepacz, N.[1]; Pasch, K.[11]; Maringer, M.[12] Mikkelsen, B.E.[13]; Normann, A.[14]; Ofei, K.T.[15]; Poppe, K.[3]; Pourabdollahian, G.[6]; Raats, M.M.[1]; Roe, M.[2]; Sadler, C.[10]; Selnes, T.[3]; van der Veen, H.[3], van`t Veer, P.[12] and Zimmermann, K.[3]

[1] School of Psychology, University of Surrey, Guildford, GU1 7XH, Surrey, UK

[2] EuroFIR AISBL, Rue Washington 40, 1050 Brussels, Belgium.

[3] Wageningen Economic Research, Prinses Beatrixlaan 582 - 528 2595 BM, The Hague, The Netherlands

[4] School of Environmental and Life Sciences, Faculty of Science, The University of Newcastle, 10 Chittaway Road, Ourimbah, NSW, 2258, Australia.

[5] School of Law, University of Surrey, Guildford, GU1 7XH, Surrey, UK

[6] National Research Council of Italy, Institute of Intelligent Industrial Technologies and Systems for Advanced Manufacturing (CNR-STIIMA), Via A. Corti, 1 20133 Milano, Italy

[7]Javier de la Cueva & Asociados, Calle Rodríguez Marín 90, 28016, Madrid, Spain

[8]Computer Systems Department, Jožef Stefan Institute, Jamova c. 39, SI-1000 Ljubljana, Slovenia

[9]Quadram Institute Bioscience, Norwich, Norfolk, NR4 7UQ, UK.

[10] European Food Information Council (EUFIC), Rue des Deux Églises 14 (3rd floor), 1000 Brussels, Belgium.

[11]German Institute of Food Technologies (DIL e.V.), Prof.-von-Klitzing-Str. 7, D-49610 Quakenbrück, Germany

[12]Division of Human Nutrition and Health, Wageningen University & Research, Stippenweg 4, Building 124, 6708 WE Wageningen, The Netherlands

[13]University of Copenhagen, Department of Geosciences and Natural Resource Management, Rolighedsvej 23, DK 1958 Frederiksberg

[14]RISE - Research Institutes of Sweden, Frans Perssons väg 6, 412 76 Gothenburg, Sweden,

[15]Copenhagen Business College, Bispetorvet 1-3, DK -1167 Copenhagen K

kwof@niels.brock.dk

Corresponding author: Dr Lada Timotijevic, School of Psychology, Guildford, GU1 2NY, Surrey, UK; l.timotijevic@surrey.ac.uk; +44 1483 686946

ORCID: https://orcid.org/0000-0002-3154-0048

Short title: A research infrastructure on food behaviour & health

Abstract

Background: A better understanding of food-related behaviour and its determinants can be achieved through harmonisation and linking of the various data-sources and knowledge platforms.

Scope: We describe the key decision-making in the development of a prototype of the Determinants and Intake Platform (DI Platform), a data platform that aims to harmonise and link data on consumer food behaviour. It will be part of the Food Nutrition Health Research Infrastructure (FNH-RI) that will facilitate health, social and food sciences.

Approach: The decision-making was based on the evidence of user needs and data characteristics that guided the specification of the key building blocks of the DI Platform. Eight studies were carried out, including consumer online survey; interview studies of key DI Platform stakeholders; desk research and workshops.

Key Findings: Consumers were most willing to share data with universities, then industry and government. Trust, risk perception and altruism predicted willingness to share. For most other stakeholders non-proprietary data was most likely to be shared. Lack of data standards, and incentives for sharing were the main barriers for sharing data among the key stakeholders. The value of various data types would hugely increase if linked with other sources. Finding the right balance between optimizing data sharing and minimizing ethical and legal risks was considered a key challenge.

Conclusions: The development of DI Platform is based on careful balancing of the user, technical, business, legal and ethical requirements, following the FAIR principles and the need for financial sustainability, technical flexibility, transparency and multi-layered organisational governance.

Background

Currently, there are no international research infrastructures (RIs) to connect diverse data and science-related services in the field of food and health (nutrition) that would aid science in this domain (Brown et al, 2017; Snoek et al, 2018; Tufford et al, 2020). This commentary reports on the approach to decision making undertaken by a consortium of international scientists to develop the first international RI for food and health, which specifically focuses on dietary determinants and intake. Development of the "Determinants and Intake Platform" (DI Platform) aims to contribute to the larger Food Nutrition Health Research Infrastructure (FNH-RI[i]) by providing the prototype design of the consumer food data platform.

An international RI would unlock the potential of large-scale repositories of scientifically validated data in order to model and anticipate the complex relationships between food consumption, food production, demographic expansion, natural resource scarcity, climate change, and diet-related health outcomes such as obesity, cancer, cardiovascular diseases and malnutrition (JPI, 2015; MRC, 2017; EC, 2016, Willet et al, 2019; Tufford et al, 2020). Shifting global population towards healthy diet will not only reduce current health risks of major chronic diseases and mortality, but substantially reduce environmental degradation (Clark et al, 2019). The EAT-Lancet Commission (Willet et al, 2019) set out global scientific targets for healthy diet based on the best evidence available that meets nutritional standards while remaining within planetary boundaries. Western diets are falling substantially short of these targets (Bozeman et al, 2020), and considerable shifts in people's food-related behaviour is needed to achieve the recommended dietary patterns (Willets et al, 2019).

New multi-disciplinary approaches to research and innovation are required to link global science and establish evidence bases that can contribute to delivering long term impacts and realising these targets. According to the high-level conference for Food 2030 (EC, 2016), addressing consumer behaviour in terms of food purchase, preparation, consumption and handling of food and related non-food waste streams must be a priority in tackling these global challenges. In particular, the need to improve linkage of key research infrastructure and data/knowledge platforms such as national surveys and cohorts, omics including metagenomics, and deep phenotyping facilities and brain banks is highlighted: it is argued that not only would these linkages better support innovative food and nutrition research, but will also lead to the establishment of internationally leading trans-disciplinary centres of excellence in integrative nutrition, thus strengthening both cooperation and training in key challenge areas.(MRC, 2017).

This commentary aims to provide insight into the complex decision making on the design of DI Platform carried out within the RICHFIELDS project[ii] (funded by the EU under the "Research Infrastructures" funding stream). It was based on the evidence of user needs and data characteristics assessed in the projectthat guided the specification of the key building blocks of the DI Platform. It aims to highlight the rationale used for balancing of requirements for designing and implementing such an RI. The final design of the DI Platform is represented in the Figure 1 – the Minimum Viable Offer specifies the services offered. Currently, the discussions are ongoing within the scientific research community to eventually arrive at a future implementation of an effective and sustainable Food Nutrition and Health Research Infrastructure (FNH-RI), which will integrate health, food and social sciences as part of the European Roadmap of research infrastructures. DI Platform would form a part of the FNH-RI via its DATA services that aim to facilitate sharing of the data and resources on consumer food behaviours and their determinants. The data on environmental impact will not form a part of DI Platform, but will be linked through the FNH-RI with other relevant data platforms such as SUSFANS[1].

[1] www.susfans.eu/ Accessed 16/06/2021

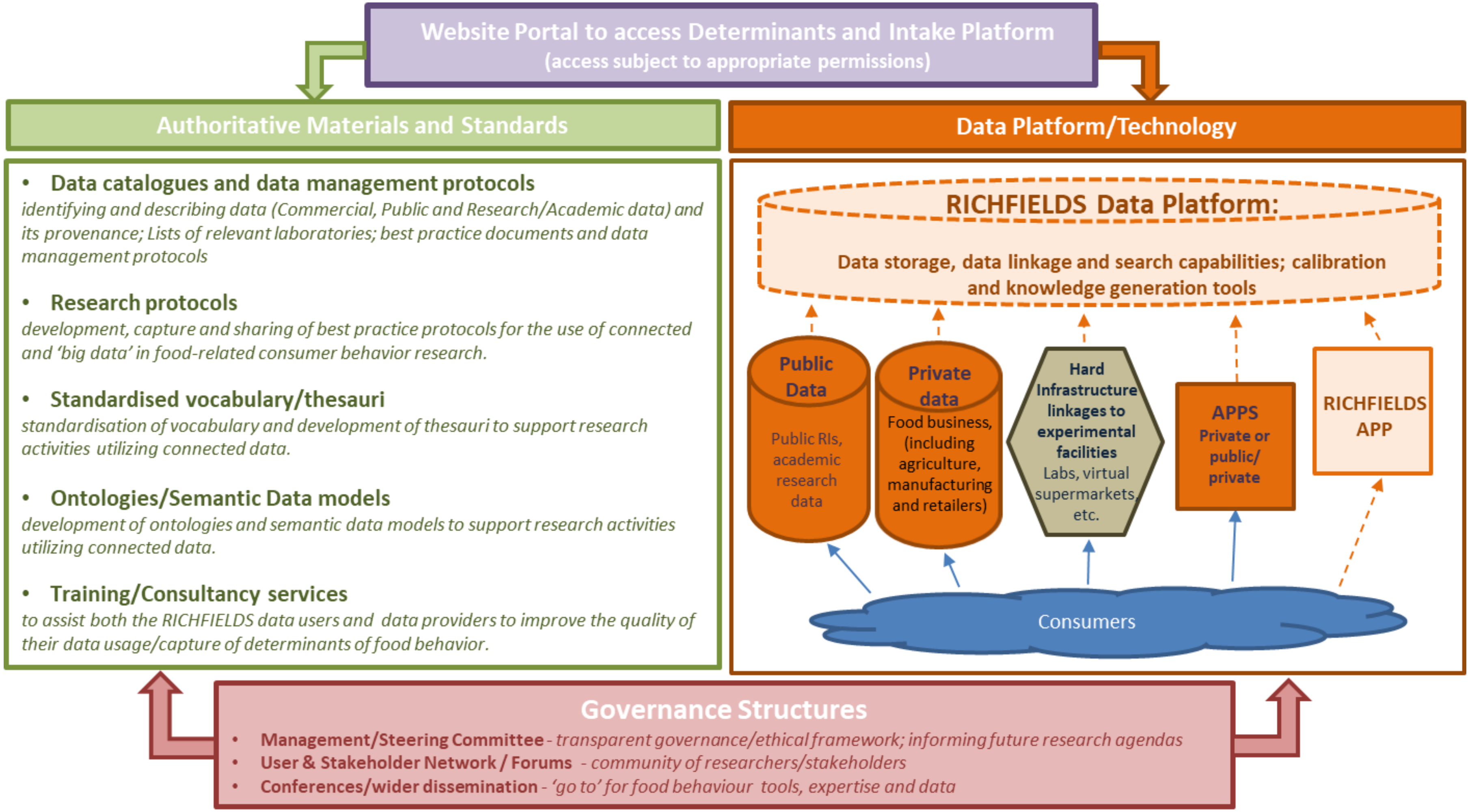

Figure 1 – in colour--

***Figure 1**: Minimum Viable Offer: Determinants and Intake Platform*

1. Approaches

The methodological approach for designing the DI Platform is described in Figure 2. As reusability and sharing of data between scientific users and societal stakeholders is core to the DI Platform, a series of studies were designed to (1) generate evidence about user needs; and (2) to evaluate the available data that could be harnessed to address the user needs.

The evaluation of user needs for data-services was based on two distinct functions that any user may have vis-à-vis the future RI: as data donators and as data users. The evaluation focused on four groups, i.e. (i) consumers, (ii) businesses, (iii) food and health science research facilities and laboratories, and (iv) existing RIs with a so-called ERIC status[2].

The evaluation of data was based on our understanding of the processes by which data are generated: through consumer behaviour (e.g. through apps), through business processes (e.g. generating sales data by retailers), and through scientific processes (e.g. by opening up research labs, facilities and the established international RIs and data-platforms such as BBMRI[3], ELIXER[4], EuroFIR[5], ENPADASI[6]).

In order to evaluate the evidence thus generated, we developed a set of criteria to be used in a harmonised and consistent way to inform the design of the DI Platform. These criteria we called the "Guiding Design Principles", further detailed below.

[2] We have decided to focus, in the initial instance, on ERIC RIs. This was a pragmatic decision because ERIC provides a legal structure widely recognised within the EU and therefore linking up of national RIs is better supported through the ERIC framework. The advantages of an ERIC structure include:

- a legal capacity recognised in all EU countries;
- flexibility to adapt to specific requirements of each infrastructure;
- a faster process than creating an international organization;
- exemptions from VAT and excise duty.

[3] https://www.bbmri-eric.eu/ Accessed 16/06/2021
[4] https://elixir-europe.org/about-us Accessed 16/06/2021
[5] https://www.eurofir.org/ Accessed 16/06/2021
[6] https://www.healthydietforhealthylife.eu/index.php/call-activities/calls/98-calls-site-restyling/514-enpadasi-2014-site-restyling Accessed 16/06/2021

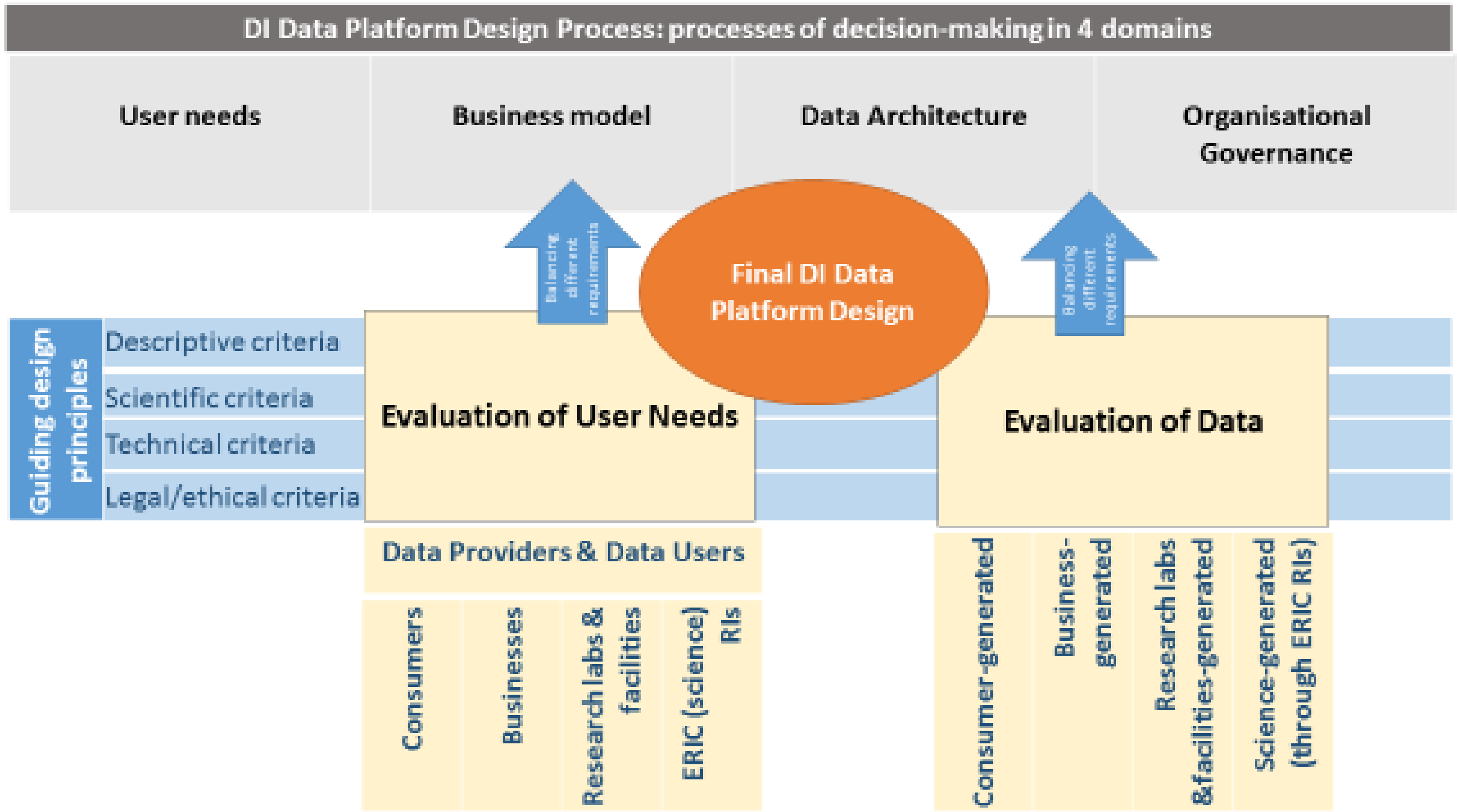

Figure 2. Overall methodological approach to the design of DI Platform. An inventory and evaluation of user needs and data requirements was made among four stakeholder groups. Four guiding design principles were used to integrate these into the key building blocks of the design of the RI.

2.1 Evaluation of User Needs

The research on user needs was based on a series of studies to address a) user willingness to share data; b) the conditions under which users would be willing to share; c) the user requirements vis-à-vis the DI Platform.

Study 1: A large-scale survey with European consumers (8 European countries: France, Italy, the Netherlands, Slovenia, Spain, Sweden, the UK, and Germany, N=8450) was a quantitative study exploring what type of food-related data (such as food purchase, recipes search, food consumption data) the consumers were willing to donate; to what group of stakeholders (e.g. scientists, government and industry) and for what purpose (e.g. for the purpose of publicly-funded research, for the purpose of developing and monitoring policies or to develop innovative food products). Participants were asked what types of food-related activities they performed on their computers and smartphones. It furthermore assessed the psycho-social factors influencing these data-sharing intentions including attitudes to science, subjective health status, health interest, values, trust, risk perception, reasons for sharing food-related data, privacy concerns, use of health apps, and demographic data as predictors of willingness to share data. The questions format was Likert-type 5-point scale. The participants filled an online questionnaire which took 35 minutes to complete. The questionnaire was developed in English and then translated, checked by native speakers and put into Qualtrics™. Data collection for each country was run separately.

Study 2: Semi-structured face-to-face interviews were conducted with representatives of four businesses, three labs/research facilities and four ERIC RIs (in total, N=11 interviews) to capture potential data donators' willingness to share data and their needs as potential users of DI Platform. The interview guide covered the topics of the purpose of generating the data; data structure; relevance of data content; challenges of using the data; data needs and how they can be addressed; challenges of sharing data with the research community; privacy policy and ethical issues. The results from the interviews were then synthesized and validated in a group interview with representatives from RIs, commercial, and research organisations (N=21).

Study 3: User needs elicitation through a series of three workshops with European stakeholders were carried out at different time points in the DI Platform design process. The stakeholders included researchers and scientists, business representatives (e.g. app/software developers, food retailers, food manufacturers); policy makers, and consumer organisations. The objective of the Workshop 1 (N=21) was to capture user needs in relation to the consumer-generated data, by eliciting users' assessments of validity and reproducibility of the data generated through consumer online behaviour (e.g. via the apps enabling food purchase, preparation and consumption). The objective of the Workshop 2 (N=34) was to elicit users' perceptions of the challenges associated with the DI Platform and the related solutions, with a specific focus upon: data architecture and interoperability; business model; and governance and ethics. The objectives of the Workshop 3 (N=29) was to elicit user requirements by eliciting the potential users' reactions to the first proposed design of the DI Platform (Figure 1).

Study 4: A survey of publicly funded scientists and professionals working in the domain of food and nutrition (a purposive sample of N=95) was carried out in order to identify the most important user requirements (e.g. domain specific data, tools and services) of the DI Platform. The online survey was sent to the corresponding authors that published in the field of food nutrition and health in the last 3 years (searchable by Pubmed or Scopus). The questions included the current use of search engines, use of publicly available data bases, incentives and barriers to data sharing, and user requirements of the platform. The question format were open questions, 7-point Likert scales and CATA questions.

2.2 Evaluation of Data

Study 5: Evaluation of consumer-generated data was carried out through desk research of the existing applications (apps) in the domain of lifestyle, with a specific focus on food purchase, preparation and consumption (Maringer et al, 2018). It examined scientific, technical and legal/ethical issues associated with the types of data being generated by consumers and the potential value of consumer-generated food behaviour data within the proposed RI.

Study 6: Evaluation of business-generated data was carried out in four case studies of two retail organisations and two public procurement organisations based on desk research and four face-to-face, semi-structured interviews (one from each case). The studies explored three important topic areas; (1) best practices of collecting data, (2) ICT technology used for data collection (3) stakeholder perspectives for sharing of data in data pools (Ofei et al, 2017; Hondo et al, 2017).

Study 7: Evaluation of science (facilities and labs)-generated data. Following the mapping of the laboratories and other research facilities (39 in total) across Europe used for studying consumer behaviour with smart sensing technology under controlled

conditions, two facilities were selected as case studies. In-depth, semi-structured interviews were conducted with representatives from two organisations with significant research and teaching facilities, with an aim to examine the type of consumer data being generated by different experimental facilities and laboratories and for what purpose (Mikkelsen et al, 2017). Examples included import and export software applications as well as smartcards, near field communication tools and data meshes. Each interview lasted 45-60 minutes.

Study 8: Evaluation of science generated data in ERIC RIs relevant to food and health domain. Four case studies were performed through desk studies designed to evaluate facilities, datasets, and tools linked to the relevant RIs to answer questions that are essential for the development of a consumer data platform focussing on: food composition and food attributes (EuroFIR[4]); standardized food intake from population based survey (GloboDiet, Aglago et al, 2017); clinical intervention (Qualify[7]); consumer diet, health and lifestyle (Precious[8]). The four RIs identified have well-established practices of generating huge amount of validated data in the broad domain of food and health (though not necessarily related to the data on determinates of food choice) and the evaluation of specialist labs that use innovative technologies to interrogate human food-related behaviour in controlled settings. Approaches to data access, data linking, governance and business models were explored with a view to defining the potential connection of these existing RIs with the proposed DI Platform.

2.3 Guiding design principles: the criteria for evaluation and decisions for the design

The guiding principles for DI Platform design drew upon the FAIR (findable, accessible, interoperable and re-usable) principles (Wilkinson et al, 2016), and applied them to the DI domain.

The Guiding Design Principles (evaluative criteria) were defined as follows:

1. **Descriptive criteria** related primarily to “findability” of data: can data be identified, characterised, classified.
2. **Scientific criteria** relate to the methodological validity and re-usability of the data: can the “big” data generate meaningful and valid information on food-related purchase, preparation and consumption.

[7] http://qualify-fp7.eu/ Accessed 16/06/2021
[8] https://www.eurofir.org/our-resources/past-projects/precious/ Accessed 16/06/2021

3. **Technical criteria** relate to the issues of data organisation, standardisation, inter-operability.
4. **Legal/ethical criteria** are concerned with the issue of data access and usability, based on legal and ethical compliance.

2. Findings

The section below reports on the findings. We provide information about the confidence intervals and means/standard deviations for quantitative studies (Study 1 and 4). The analysis of qualitative data – including interviews and workshops - was conducted following established standards for qualitative research (Reynolds et al, 2011) that emphasise transparency, reflexivity, comprehensiveness and responsibility, among other things. Several researchers analysed qualitative data: their notes were compared and the written summaries of the findings were cross-checked by all researchers involved in the interview process. A wider set of researchers from the overall project reviewed the analyses and provided comments and feedback on clarity, logic and structure.

3.1 Evaluation of user needs

Study 1: The cross-country survey indicated that consumers were more willing to share data with **universities** than with governments and companies (F (1, 7969) = 1194.950, p < .001, η^2 = .130). Three important variables predicted the willingness to share data: trust (medium to large positive effect), moral motives such as altruism (small to medium positive effect) and perceived risk of sharing data (small negative effect)(Table 1)

Table 1: Model predicting data sharing with University, Government and Companies

		Universities	Governments	Companies
β of the final model	Trust	.499	.433	.405
	Perceived risk in sharing data	-.118	-.100	-.030
	Moral motives	.210	.255	.279
Final model vs null	χ^2 (3)	3391.4, p < .001	3844.9, p < .001	3184.0, p < .001
Explained variance: final model (full model)	R^2	.42	.46	.41

Study 2 The results from the **four business case studies** suggested that it was important to gain access to new types of data that address the needs of businesses. Given the limitations and measurement problems of businesses' own data, the core value for businesses was in making integrated or linked data available through the use of the DI Platform services, in particular, access to the results and interpretations carried out by others. Some businesses were reluctant to share the data that contained sensitive information linked to competitive advantage. **Labs and facilities case studies** confirmed that there is a need for replicable data and standardisation that would enable greater connection between different types of data, with a particular emphasis upon the individual level data. Of particular value was the possibility to link with a wider, multidisciplinary academic community. It was nevertheless recognised that some barriers to this vision may exist, such as the current legal environment as national institutions and ethical committees require data handling that is not aligned with the idea of a sharing research infrastructure. The four **ERIC RIs case studies** indicated that data sharing with a DI Platform has potential; in most cases it would be essential to describe the governance of the data and any follow-up use (e.g. by an ERIC RI) as part of the research ethics application for a project. Finding the right balance between optimizing data sharing and minimizing ethical and legal risks was considered a key challenge for those data providers.

Study 3: Workshop 1 highlighted the need for clear characterisation of data (meta-data) in order for it to be useful in studying the determinants of food choice and that it ensured that data captured through apps and other online services was representative of populations of interest. **Workshop 2** highlighted the need for transparent and collaborative design process in order to gain legitimacy and attract future users/data donators. **Workshop 3** highlighted the main value offered by the DI Platform to allow access to scientifically validated, up-to-date, real-time, well-described data capturing diet, diet-related behaviour and health.

Study 4: The survey of **scientists and nutrition professionals** highlighted that information on the quality of the data (M=6.42, SD .92), easy access to the data (M=6.25, SD=1.06), up-to-date information on relevant data sets (M=6.08, SD=1.07) and compliance to standards (M=6.05, SD=1.04) were the most important user requirements. Only a small number of people already publicly share data (7%). The main barriers to sharing data are lack of standards, lack of incentives/recognition for data sharing, lack of trust between data providers and users, ownership issues and lack of time. The main incentives for sharing data include access to other shared data sets (30% of respondents), networking/collaboration (29%) and being referenced for sharing data (19%).

3.2 Evaluation of data

Study 5: The main limitation from a scientific perspective with respect **to consumer-generated data** in the **purchasing** domain was that it did not identify whether the purchased food was consumed or not, nor did it identify the individual that may actually consume the food. As a result, linking purchasing data to public health outcomes at an individual level would be of limited value. Similarly, whilst the food **preparation** data reflects consumers' motivation to gain knowledge and to develop skills in food preparation, this data can not be a proxy of consumption. In contrast to the consumer-generated food purchase and preparation data the majority of food **consumption** apps analysed had the potential to provide insight into habitual food consumption behaviours and how these change over time at an individual level. Many apps do not provide a true picture of people's habitual or typical food consumption behaviour because they are designed as behaviour change interventions (e.g. the user can set a goal of achieving a particular weight). A vital source for better understanding the possible drivers and barriers for people's food purchase, preparation and consumption behaviour was likely to come from associations between these data and other relevant social, health and lifestyle data(Maringer et al, (2018).

Study 6: The nature of the business–generated data is determined by business purpose for which data is collected, which may limit the potential usefulness of the data for scientific purposes. The DI Platform therefore would need to ensure data source diversity but balance this with a clear understanding of the value of the difference types of data generated within businesses. Furthermore, a number of retailers have already developed APIs (Application Programming Interfaces) for sharing data and these are potentially quick wins for the proposed RI in terms of data acquisition.

Study 7: The data collected in the past by research facilities and within labs is proprietary and typically not formatted, standardised or stored in a manner conducive to sharing outside the original purposes of the research study undertaken. In addition, the diversity of data generating devices including video and audio results in a wide variety of data types and thus increases the difficulty of post-hoc data integration.

Study 8: The case studies demonstrated that structures are in place to facilitate linkages between some of the existing ERIC RIs in the food and health domain and the proposed DI-

Platform and therefore data from these sources is possibly the most accessible form of research data. However, the development of a DI Platform ontology and the harmonization of entities, food classification and description systems would be fundamental to facilitate future data access/exchange between existing and new RIs. The development of authoritative materials and standards must be a fundamental component of the DI Platform offering to establish best practice and to help shape the research community moving forwards.

3. Design of DI-RI

Our design process was based on the evidence from the 8 studies, and addressed four design components:

A. User requirements
B. Business model - service offerings and value proposition
C. Data architecture - technical design
D. Organisational governance - political will, fair representation, legal/ethical considerations

The design process was iterative and reflexive, based on the Guiding Design Principles (Section 2.3) balancing often conflicting requirements of these core design components (Figure 3).

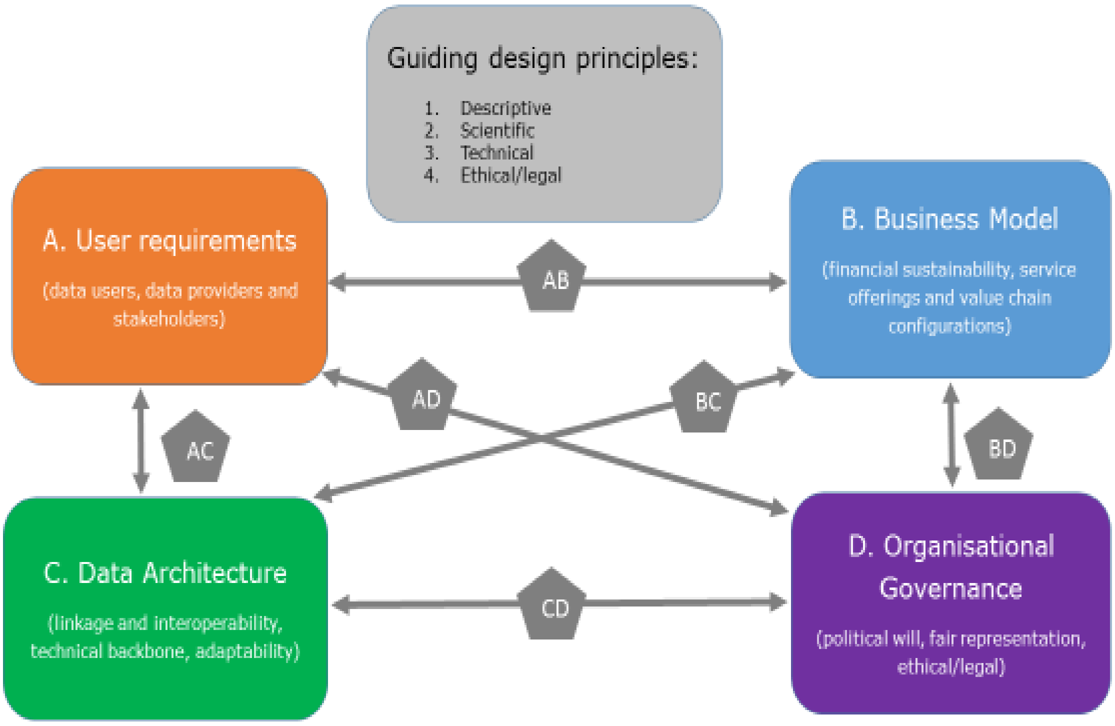

Figure 3. The design process: balancing the components of the design

It involved detailed examination of the evidence collated throughout the RICHFIELDS project and the generation of design options for each design element of the DI Platform [please see Table 2 for detailed summary of the linkages between evidence generated from different studies and the main considerations for the DI-Platform design]. This process was carried out by researchers who had not been directly involved in the evidence generation phases so as to avoid bias. The experts involved included those specialising in business model innovation; in governance/ organisational studies; legal (IP, data protection, data governance), ethics and technical design.

Following the Figure 3, the final design was based on the decisions made in the context of four main considerations: A) Who are the users and what needs should the RI satisfy? B) What business model should be adopted to ensure financial sustainability? C) How should the data architecture and technical backbone be developed to ensure the adaptive, effective and ethical RI? D) What organisational governance should ensure the RI's political sustainability?

Table 2: The relationship between the evidence generated in the studies 1-8 and the design considerations of user requirements, data architecture, business model and organizational governance.

	User Requirements	**Data Architecture**	**Business Model**	**Organisational Governance**
Study 1: Consumer survey on willingness to share data (cross-country)	Trust: respect consumer greater willingness to share with universities rather than government and businesses	Data security; protection of privacy – e.g. by design. Within meta-data specifically reference data owners and their entitlements.	To enhance trust in science and altruism - data-sharing for public good, adhering to legal and ethical standards. Consent by design.	Transparent, ethical and open risk governance. Ethics board to oversee data sharing. IP to model the concept of "the digital commons".
Study 2: Case studies (businesses; labs and facilities; ERIC RIs)	Access to new ways of interpreting data. Reluctance to share data – business sensitivity. Access to cutting-edge scientific methods and tools.	The system capable of connecting the existing data resources and knowledge bases.	Offer: Access to data summaries – aggregate data. Access to raw data depends on willingness to share Access to non-proprietary data.	Careful consideration of Conflict of Interests.
Study 3: Workshops	For all users, enhancement of scientific validity and harmonized approaches to data collection	Distributed system. Data is locally stored (does not leave the data holder) and the system enables connections between disparate data-sets. The system will support data standardization and interoperability.	Attract future users/donators. Free access to accredited researchers from the associated nodes.	Public-private funding with granulated data access. Governance model weighs up balance of different interests: political will, financial sustainability and requirement for scientific excellence.

	User Requirements	Data Architecture	Business Model	Organisational Governance
				Balance reputational risks (e.g. in terms of association with businesses), legal requirements for data protection and financial sustainability.
Study 4: Nutritionists/dietitians Survey (Cross-country)	Data quality, easy access, compliance to standards, networking.	Data sharing and access central.	Lower burdens for scientists in the process of data sharing.	Efficiency and cost-benefit based services.
Study 5: Consumer-generated data (via APPs)	Link purchasing and consumption data to context (i.e. public health)	Link food purchase, preparation and consumption behaviour. ICT system capable of recognizing the donator of data and the legal conditions under which contribution is made.	Association between APPs-generated data and other sources social, health, lifestyle data – distributed system.	Focus on joint understanding of drivers & barriers
Study 6: Business-generated data (via business processes)	Ensure data usefulness to science	Data source diversity & comparable values. ICT system capable of recognizing the donator of data and the legal conditions under which contribution is made. Intellectual Property license must be applicable to the data being extracted	Link the purpose for collecting business data to the needs of science	Use quick wins for data acquisitions.
Study 7: Labs and	Enable data sharing over	Make data generating	Post-hoc data	Joint services (between DI-

	User Requirements	Data Architecture	Business Model	Organisational Governance
facilities data	time - harmonisation	devices comparable.	integration	Platform and other labs/facilities) for integrated usage and data generation.
Study 8: ERIC-RIs data	Facilitate linkages between DI-Platform and ERIC RIs to harmonise data collection.	Ontology and harmonization of entities, food classification and description systems. Meta-data	Future access & exchange between existing and new RIs as part of the business model.	Collaboration (between DI-Platform and ERIC-RIs) to share and to co-design authoritative materials and standards as part of knowledge-sharing.

4.1 User requirements

The DI Platform will first serve the needs of the publically funded users, which will over time be extended to other stakeholders such as industry. The majority of the primary users work in universities and public research institutes, including academic hospitals. Secondary users will be 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.

Based on the results of Studies 1-8, we identified the following user requirements that would inform the design of our platform: data sharing for public good; access to cutting-edge scientific methods and tools; link purchasing, preparation and consumption data with context; harmonise data collection (over time and contexts) to enable linkages between data bases (e.g. ERIC-RIs); facilitate collaboration on the development of standards and knowledge services; enhance usefulness of business- and apps-generated data to science; network building and best practices sharing. Who should be the primary user of the RI and their related requirements required balancing of the ethical, financial and socio-political concerns. Access rights would depend on the kind of data donated or the degree of sharing ((e.g. if only pre-competitive data shared – access is then limited).

Defining the users and their needs is inextricably linked with the decisions about the financial and business model of the RI (Fig 3 AB link): what kind of access would be granted (e.g.

access to raw or aggregate data) and under what conditions (in exchange of data, for premium price or for some evidence of public good/ethical action).

4.2 Business Model

Six main categories of services are designed to be offered to the RI users namely data related services, knowledge related services, consultancy services, training, community building and networking and other services such as quality labels, personalised advice. The RI could be a funded through public and private entities.

The business model focused on three main elements: value proposition (service offerings), value chain configuration (key resources, key activities and key partners) and financial structure (revenue stream and cost structure). From the **value proposition** perspective, the service offerings should be compliant with the legal/ethical requirements and enabled through most up to date technological solutions. The design needs to address the current technical possibilities for managing user access, for instance, through "consent by design" or the data architecture that can ensure different level services/data are rooted to diverse users (Fig. 3. BC link). Similarly, the decision about the **value chain** would depend on technical issues, such as data architecture (Fig 3, BC link) and governance structure (Fig. 3, BD link). The technical solution will enable finely granulated and leveraged system which would be compliant with the current legal frameworks (e.g. GDPR, 2018). From a **financial angle**, the defined finance model is directly affected by the decisions about the main technical (Fig. 3, BC link), governance structure (Fig. 3, BD link) such as the public-private nature of the RI, and the main users/stakeholders who will be served as the customers of the DI Platform (Fig. 3, Link AB). The risks vary depending on the type of entities supplying data, the end users (e.g. research community within the public sector, research community within the private sector) and the financial sustainability of feasibility of the RI and the stakeholders (private and public).

4.3 Data Architecture

The data architecture was designed as a distributed system connecting the existing data resources and knowledge bases. Each new dataset connected with the DI Platform will be processed to extract new knowledge, which will be locally stored (in a form of an ontology linked with other existing ontologies such as ONS - Ontology for Nutritional Sciences, Pathway, Gene Ontology, Disease Ontology) to be further used for data harmonisation. It *means that the data processors will be able to access heterogeneous data in a harmonised way.*

The data architecture of the DI Platform (Figure 4) was designed using a modular concept, which will enable enough flexibility to adapt to any additional needs of the larger FNH-RI to which it will be connected via DATA services, as well as to any new technological advances. As food and nutrition data is heterogeneous, the data architecture supports not only the management of distributed data but also the management of semantics needed to support data standardisation and interoperability.

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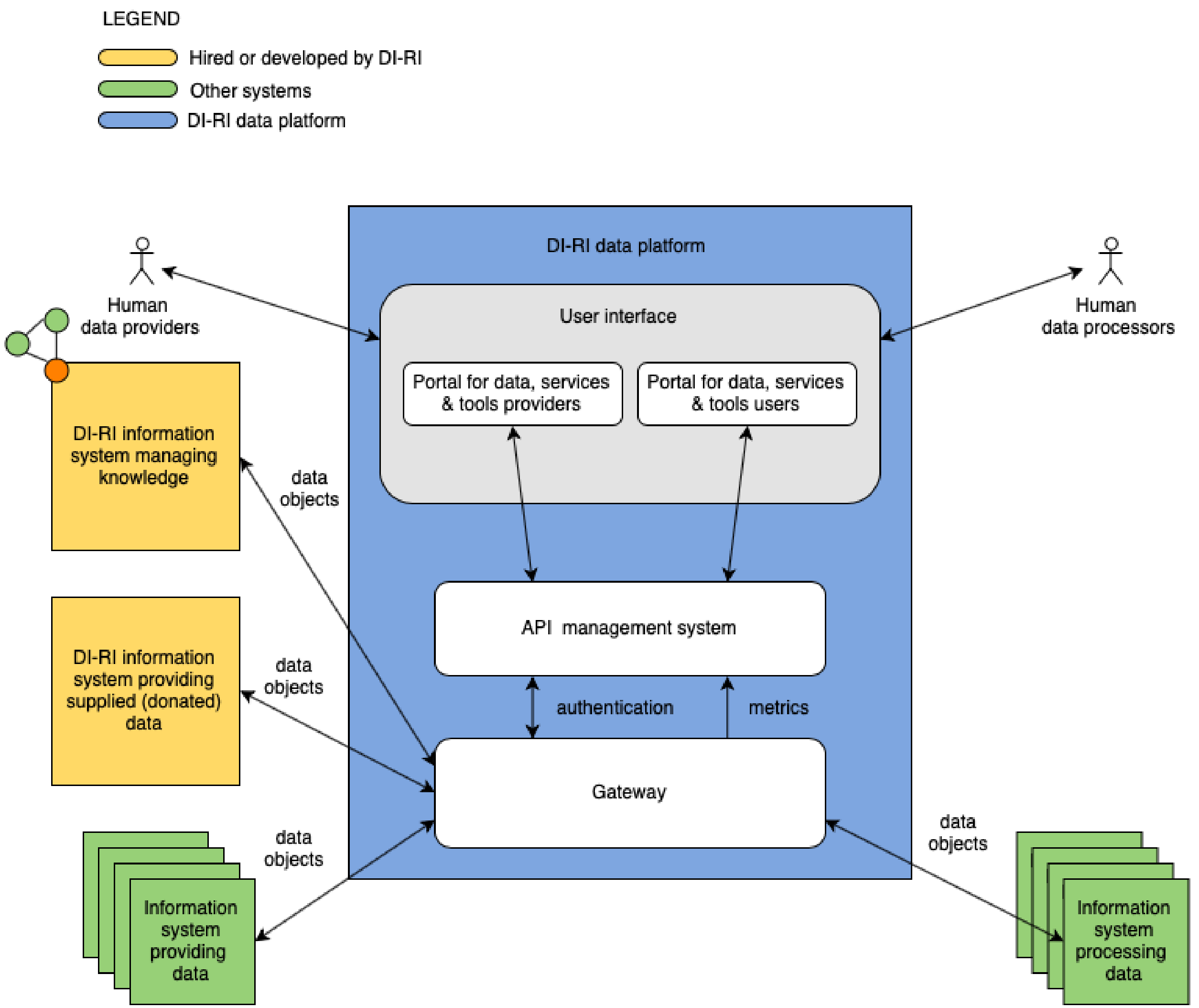

410 *Figure 4. Technical Design of DI Platform*

The data architecture of DI Platform is based on a distributed system, which connects data-providing systems with data-processing systems through web services. For each connected system providing data, the DI Platform automatically collects metadata needed to create knowledge (Eftimov et al, 2018) that is further used to support data standardisation and interoperability. In this way, we are able to handle different types of data (such as structured, semi-structured and unstructured data[iii]), being described and classified using different systems. In the project RICHFIELDS, for example, we developed advanced methods for food image recognition, which enables structuring of food information from photos (Mezgec and Koroušić Seljak, 2017) and linking it with already structured data such as EU-Menu Programme consumption data (EFSA[9]) and food composition data EUROFIR AISBL[4] (Mezgec et al, 2018). In recent years, several organisations and infrastructures, such as EUROSTAT[10], EUDAT[11] etc., have developed their own systems for data description and classification, which all require to be made interoperable, and this is one of the most relevant objectives of the European Open Science Cloud (EOSC) being tackled by the support of the Research Data Alliance (RDA)[12] and related projects like FNS-Cloud[13] (also connected with Zenodo[14] and other relevant food and nutrition platforms and infrastructures), Blue-Cloud[15], COMFOCUS[16], DAFNE[17] etc. However, each of these projects focuses on specific fields of food and nutrition, none of them on the food, nutrition and health aspects related to consumer science, which is the focus of FNH-RI. The linking will be facilitated through the FNH-RI search functionality under the DATA services option. Other examples of structuring data include i) extraction of dietary recommendations from scientific papers or reports published online (Eftimov et al, 2017a; Eftimov et al, 2017b) and ii) matching food composition data to food consumption data, where both systems are described using different systems, such as LanguaL and FoodEx2 (Koroušić Seljak et al, 2018). For data providers that are unable to provide data via web services, it will be possible to upload the data to the DI Platform local storage with the help of administrators. The DI Platform and its underlying data model need to comply with legal/ethics constraints (Fig. 3 CD link) and the business model (Fig. 3, BC link). The full operation of the data model is premised on the decisions about access and

[9] https://www.efsa.europa.eu/en/data/food-consumption-data Accessed 16/06/2021
[10] https://ec.europa.eu/eurostat Accessed 16/06/2021
[11] https://eudat.eu/ Accessed 16/06/2021
[12]https://rd-alliance.org/ Accessed 16/06/2021
[13] https://www.fns-cloud.eu/ Accessed 16/06/2021
[14] https://zenodo.org/ Accessed 16/06/2021
[15] https://www.blue-cloud.org/news/blue-cloud-position-paper-eosc Accessed 16/06/2021
[16] https://cordis.europa.eu/project/id/101005259 Accessed 16/06/2021
[17] http://dafne-anemos.hhf-greece.gr/ Accessed 16/06/2021

presumes an adequate ICT system capable of recognising the donator of data (Fig. 3, AC link) and the legal conditions under which such contribution is made. Crucial to the system's ability to extract data is meeting the requirements imposed by the GDPR (2018) and the Intellectual Property licence applicable to the datasets. Data provided by the DI Platform will include metadata that specifically references right holders/data owners and their entitlements.

4.4 Organisational governance

The organisational governance of the DI Platform is a Hub and Nodes Model which works as a network-based organisation, registered as a foundation. The Hub is the central part of the RI and the Nodes are the national partners. The highest decision making body is the Heads of Nodes Committee, with a Board for the daily management. The Nodes are national networks of centres of excellence. A Scientific Advisory Committee and Ethical, Legal and Societal Issues Advisory Committees ensure the scientific integrity and quality and an Industry Board takes care of the relationship with the involved stakeholders (see Figure 5)

The organisational governance reflects the need for international collaboration on data and services. DI Platform governance would be subsumed under the large FNH-RI governance structure. Compliance with the highest legal/ethical requirements is pivotal and enabled through up-to-date technological solutions (Fig. 3, CD link). However, developing a model of revenue and services flows between diverse stakeholders is hugely contingent upon the public-private responsibilities involved. Consequently the governance is linked to the business model (Fig. 3, BD link). We additionally considered the problem of conflict of interest (CoI) and the issue of credibility if the DI Platform granted access to commercial organisations, but balanced these against financial and political sustainability. Restricting access of some stakeholders could prevent political support necessary to achieve a global research infrastructure. Given the ambition to establish an RI that would be solely or partly public-sector (nation states and EU) – or structurally funded, the issue of fair balance of interests came to the fore. Relying upon nation states to fully support an RI may not be a realistic business model given that their willingness to pay may be driven by political rather than science-related factors. This could be further complicated by restricting access to the DI Platform to only a small group of users, e.g. publicly funded scientists rendering the RI exclusive and under-utilised, too expensive and consequently politically untenable. Were the private sector to be allowed into the decision making, organisational governance would need to adequately address the possible conflict of interest (Fig. 3 AD and BD links).

The adequate design of governance structures and processes also concerns who to involve in decision-making processes. Three rationales have been considered: economic, political and excellent science. Under the economic rationale, financial contribution would determine the decision-making power and level of access. Thus, for instance, the nation states who invest more can expect their scientists to benefit the most. This opens up the issue of how to manage private investment and the possible conflict of interest. The political rationale would see the development of bespoke arrangements for access for those countries which are unable or less able to pay and/or have a greater need to develop a science base. Finally, participation in decision-making could also be driven by excellent science – with decision-making roles being allocated to individuals with standing, rather than on cost-benefit basis; or it could be based on the principle of management of the digital commons – found in many other online digital infrastructures, such as Wikipedia and OpenStreetMaps. Our platform will combine all three rationales through 3 decision-making bodies: Assembly of Member States; Finance Committee and Head of Nodes Committee (represented by eminent scientists). Industry sponsoring in kind (i.e. data) and cash is welcome, but free access to the data is only possible for public researchers with their protocols for independent research, approved by the relevant advisory committees.

Ensuring a transparent data chain can partly be facilitated by the technological backbone of the RI (Fig. 3, CD link), where a metadata repository is organised to keep track of provenance data as well, but it is also inextricably linked to the way in which organisation is managed.

4. Conclusions

We set out to describe and explain the key approach and decision-making processes in the development of a DI Platform that would focus on big data about consumer food and health determinants and intake, generated via consumer apps, business processes and science. The highlighted balancing of the requirements illustrates the process that is characterised by uncertainty with respect to not only the technical possibilities that underpin such a research infrastructure, but perhaps more significantly, the political climate, the emerging and constantly evolving legal and ethical frameworks, and the uncertain financial and economic context. Ultimately, the development of a DI Platform requires flexibility, adeptness and internationalism to foster such long-term vision.

The ultimate aim of this long-term vision is to broaden the areas of scientific enquiry in food domain, by linking scientific enquiry relevant to food production (agriculture and food technology) and food consumption (food determinants, intake, nutrition and health). Linking of the science in these two domains will evaluate the adherence to the global health and sustainable diet, provide more accurate estimates of our progress towards achieving sustainable development goals (EAT-Lancet Commission Willett et al., 2019) and identify the trade-offs required (Tuomisto, 2019) The research community needs a research infrastructure that helps to generate transdisciplinary evidence and expertise in order to substantiate the citizen-centred food systems transition. In recognition of the need to link up and make inter-operable various data bases, knowledge platforms and tools, through harmonisation and, where appropriate, standardisation of nutrition and health concepts and data across Europe (see European Nutrition Report 2004, 2009), we are developing an over-arching Food, Nutrition and Health Research Infrastructure (FNH-RI). The DI-Platform development is part of this global initiative to set up Food Nutrition and Health RI (FNH-RI), contributing the much-needed data and knowledge on determinants and characteristics of consumer food-related behaviour.. Through FNH-RI, the scientific community will benefit by easy access to EU-wide data on food consumption, nutritional adequacy and health impacts, environmental footprints and food loss and waste; and will contribute to the vision to achieve affordable, healthy and sustainable diets across Europe.

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Authors Statement

Ethics approval and consent to participate: all studies reported within this manuscript were conducted according to the guidelines laid down in the Declaration of Helsinki. The procedures involving research study participants (Study 1) were submitted to the University of Surrey Ethics Committee. Based on the assessment of the study, formal ethical approval was not required. Online informed consent was obtained from all subjects.

Consent for publication: No individual person's data are contained in the publication.

Availability of data and material: The datasets generated and/or analysed during the current study are not publicly available. This is because the consent from the participants to re-purpose the anonymised data was given under the condition that the data would only be made available if relevant legal, professional and ethical approvals were provided. Anonymised data is available from the corresponding author on reasonable request.

Competing interests: The authors declare they have no competing interests.
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Study1,3&5; KL contributed to the design of DI Data Platform (business model); MM contributed to the Study1,3&5; BEM contributed to the design of DI Data Platform (user needs) and to the Study 3,4,6,7&8. AN contributed to the Study1,3&5; KTO contributed to the Study 3,4,6,7&8. KP led the overall DI Data Platform Design; GP contributed to the design of DI Data Platform (business model); MMR contributed to the DI Data Platform design and to the Study 13&5; MR contributed to the Study 3,4,6,7&8; CS contributed to the Study 3; PPV was the scientific lead of the DI Data Platform design process; KZ was the coordinator of the overall DI Data Platform design process.

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[i] https://fnhri.eu/ Accessed 16/06/2021

[ii] https://www.richfields.eu/ Accessed: 1[iii] Structured or relational data concerns all data, which can be stored in a relational database. Semi-structured data is a form of structured data that does not conform with the formal structure of data models associated with relational databases; however, it may have information associated with it, such as metadata tagging, that allows elements contained to be addressed (e.g. XML or JSON data). Unstructured data, such as text, PDF documents, media posts, photos, audio files etc., does not have a pre-defined data model, thus it is not a good fit for a relational database.

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