Intelligent ecosystem to improve the governance, the sharing, and the re-use of health data for rare cancers

Deliverable 8.2

Pilot Data Governance

8 February 2025

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

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This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Revision History

Revision	Date of Issue	Author(s)	Brief Description of Change
0	19/12/2023	E. Martinelli (INT)	ToC
0.1	21/12/2023	A. Trama, E. Martinelli (INT)	Revised ToC for distribution
0.2	07/03/2024	A. Trama, E. Martinelli (INT)	Added contributions by MSCI, ECCP, UPM
0.3	08/03/2024	E. Martinelli (INT)	Added contributions by MME
0.4	11/03/2024	A. Trama, E. Martinelli (INT)	Revised contributions and added contribution by UU
0.5	11/03/2023	A. Trama, E. Martinelli (INT)	Added clarifications from OUS, Final revision

Addressees of this document

This document is addressed to the whole IDEA4RC Consortium. It is an official deliverable for the project and shall be delivered at the European Commission and appointed experts.

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

TABLE OF CONTENTS

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

List of Figures

List of Tables

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Abbreviations and definitions

Abbreviation	Definition
CNIL	Commission nationale de l'informatique et des libertés en France
CoEs	Centres of Excellence involved in the IDEA4RC project
DGA	Data Governance Act
DPA	Data Processing Agreement
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
DSA	Data Sharing Agreement
EHDS	European Health Data Space
EHR	Electronic Health Records
EIA	Ethical Impact Assessment
ERN	European Reference Networks
EU	European Union
FAIR	The FAIR principles standing for Findable, Accessible, Interoperable and Reusable
GDPR	The General Data Protection Regulation
IDEA4RC	The European-funded project "Intelligent Ecosystem to improve the governance, the sharing, and the re-use of health Data for Rare Cancers"
IRB	Institutional Review Board
IT	Information Technology
NGO	Non-Governmental Organisation
NLP	Natural Data Processing
OECI	Organisation of European Cancer Institutes
PI	Principal Investigator
ROPA	Record of Processing Activities
WG	Working Group
WP	Work Package

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EXECUTIVE SUMMARY

The IDEA4RC Governance defines the regulatory, ethical and legal framework that shall be deployed within the IDEA4RC federated ecosystem (the Governance Layer developed in WP7) to enact the legal, ethical and data use conditions agreed by the IDEA4RC partners and required by their Institutional, National and European regulations.
Our aim is to provide an exemplary framework that could be exploited to similar ecosystems.
The governance relies on four main pillars:

1. IDEA4RC infrastructure is designed to allow secondary use of health data for research purposes and new knowledge generation and sharing (the infrastructure is not intended for direct use in the clinical practice)
2. the data are processed inside a secure data infrastructure - the FHIR capsule - within the data holder's premises: data never leave this environment
3. the data holder shall have control over the use of the data, i.e. shall be able to agree on and monitor the data use by internal and external users (i.e., decide who will be allowed to use the data, for which purposes, under which conditions), based on the lawful basis established by each individual data holder (in our case the IDEA4RC CoEs)
4. the governance framework shall be flexible to adapt to the evolving regulatory landscape consequent to the ongoing establishment of the EHDS.

In this context we have conducted an in-depth analysis of the legal and ethical requirements at each CoE and have defined:

1. the general ethical and legal conditions that must be met by IDEA4RC, and three possible scenarios for data use, depending on the lawful basis and on the individual CoEs legal and ethical obligations, and we have mapped these scenarios for IDEA4RC CoEs (chapter 2);
2. the legal and ethical requirements at each CoE (chapter 3), comprising:
    a. the requirements for data use and data processing agreements that are being defined by the Consortium with the advice of CoEs legal departments and DPOs, and whether data anonymisation might be required,
    b. the main aspects that shall be addressed in the IDEA4RC governance, including data use by commercial stakeholders (such as pharmaceuticals, market research companies, insurance companies)

3. The general legal and ethical framework that shall be implemented to ensure secure, lawful, privacy preserving, and at the same time as open as possible data use (chapter 4).

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1 INTRODUCTION

IDEA4RC aims to develop a federated ecosystem between the CoEs of the European Reference Network (ERN) on Rare Adult Solid Tumors (EURACAN) for the secondary use of data. More importantly, it aims to test the created ecosystem in the 11 EURACAN CoEs contributing to IDEA4RC with specific use cases defined in task 8.1 (D8.1).

In short, the use cases ask specific research questions related to the natural history, definition of predictive and/or prognostic factors, evaluation of treatment effectiveness and quality of care for 2 specific families of rare cancers, namely head and neck tumors and soft tissue sarcomas. This involves running a series of analyses in the federated environment which requires meeting the ethical and legal requirements for carrying out observational studies. Thus, this document aims to:

1) define the legal governance framework and the agreement for re-using data in the federated ecosystem,
2) describe the legal and ethical requirements needed to implement the use cases (i.e. run analyses in a federated ecosystem) in each of the CoE contributing to the ecosystem.

Furthermore, IDEA4RC initiated a discussion to define a governance to be used during and also after the end of the project, as an example of potentially useful FAIR governance for a federated system in the EHDS. This document therefore also includes a summary of the principles underlying future governance (after the end of IDEA4RC) currently under discussion.

The work reported in this document leverages the results of the co-creation activities (D2.1), and guidelines on how to comply with relevant legislation and promotes data reuse and ethics developed in D2.3. Furthermore, it provides the basis for defining the technical requirements for developing the data governance layer (Tasks 7.1-7.4) and the pilot implementation (WP9).

2 DATA GOVERNANCE LEGAL FRAMEWORK AND LEGAL AGREEMENT

The present section analyses the path towards the definition of the IDEA4RC data governance legal framework. IDEA4RC involves a federated infrastructure, therefore, this section will also analyse the application of the GDPR and the upcoming EHDS regulation in such an environment.

Following up on the work performed in Task 2.2 and reported in Deliverable 2.3, this section will delve deeper into the governance scenarios and the discussions at a project level intended to finalise the data governance legal framework.

Finally, it will further identify any ethical and legal risks to be addressed with regards to the governance, while also presenting the agreements in progress and suggested future solutions, including the proposal for a Unilateral Agreement.

2.1 Application of the GDPR in a federated infrastructure

The GDPR[1] constitutes the primary personal data protection legislation in the EU, providing for the requirements and the legal framework by which organisations processing and sharing personal data must abide. As such, the GDPR requires, among others, the following main elements:

A. Compliance with the data protection principles (lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity, confidentiality and accountability);[2]
B. The identification of a legal basis to process/share personal data;[3]

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) 2016 (OJ L).
[2] Article 5 GDPR.
[3] Article 6 GDPR.

C. The identification of the parties' roles (Data Controller/Data Processor), the corresponding obligations[4] and the ensuing contractual relationships[5];
D. The implementation of technical and organisational measures adequate to ensure the security of the processing/sharing.[6]

In particular, as far as the acceptable legal bases provided by Article 6 GDPR are concerned, those include the following:

1. Consent of the data subject, as long as it is explicit, specific, and freely given prior to the data processing;
2. Performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
3. Compliance with a legal obligation to which the controller is subject;
4. Protection of the vital interests of the data subject or of another natural person;
5. Performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
6. Legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

The legal basis might be different depending on the requirements of the national legislation, as further analysed in D2.3, as well as the legal and ethical rules applied by each CoE, therefore the governance implemented in IDEA4RC shall comply with such different frameworks.

In addition to the above, and considering that IDEA4RC involves the processing of health data, the conditions of Article 9 GDPR must also be considered. In particular, health data falls within the scope of special categories of personal data, as described in paragraph 1 of Article 9 GDPR, and, thus, requires special treatment. As per par. 2 (j) of the same article, the processing of such

[4] Articles 24, 26-31 GDPR.
[5] Articles 26 and 28 paragraph 3 GDPR.
[6] Articles 25, 32 GDPR.

special categories of personal data may be permitted considering specific circumstances (in particular the application of Article 89 GDPR in addition to national dispositions), among others, for scientific and research purposes, as long as the processing:

a. Is proportionate to the aim pursued;
b. Respects the essence of the right to data protection;
c. Provides for specific suitable measures to safeguard data subjects' rights and freedoms.

Article 89 GDPR further complements the framework for the processing of special categories of data for research purposes, requiring that further safeguards are put in place, including technical and organisational measures to ensure data minimisation, such as pseudonymisation or anonymisation techniques.

It is worth clarifying that the difference between anonymised and pseudonymised lies in the possibility to re-identify the data subject, particularly on whether the party in hold of the data has access to any additional information enabling it to re-identify the data subjects and/or has any legal means available to access such information.[7] Based on this distinction, pseudonymised data is still considered personal data, while data protection legislation is not applied to anonymised data.

In the context of the IDEA4RC project, the processing of personal data envisioned falls within the scope of "further processing of data", meaning that the data is processed "*for purposes other than those for which the personal data were initially collected*".[8] Unless the further processing of data is considered compatible with the purposes for which the data was originally collected, a separate legal basis is required.

The architecture of IDEA4RC is based on the federated learning approach. Federated learning ensures that any machine-learning algorithms are executed on multiple local datasets stored at isolated data sources in a decentralised collaborative learning setting. As such, no data used

[7] Case T-557/20 SRB v. EDPS [2023] ECLI:EU:T:2023:219 par. 88-94, 97-100.
[8] Recital 50 GDPR.

to produce the outputs ever leaves the local sites, while only aggregated data is shared with the Data User.[9]

In the IDEA4RC architecture, data never leaves their native secure processing environment, called the IDEA4RC capsules located at the respective CoEs and they are always processed locally. As such, no new secure processing environments are created at runtime. This collaborative approach allows for data analysis from multiple sources while keeping the data decentralised and secure. These services enable organizations to perform analytics on distributed datasets without the need to physically centralise or transfer the data since the CoEs will only share the aggregated results of each requested computation.

In view of the above, it has been crucial for the project to duly identify the roles of the partners and researchers involved, the relationship that would be established between them, and the additional measures they shall implement in order to ensure the security of the activities involving personal data. As per the GDPR, the roles in question are:

a) Data Controller: determines the purposes (how) and means (why) of processing personal data.
b) Joint Controller: two or more data controllers who jointly determine the purpose and means of processing.
c) Data Processor: processes personal data on behalf of the controller, under the latter's instructions.

It is worth mentioning that, according to the EU Court of Justice practice[10] and EDPB Guidelines[11], it is not necessary that a data controller actually has access to the data that is being processed, as long as they are meeting the rest of the requirements (i.e. defining the means and purpose). At the same time, the EHDS Regulation provides that Health Data Access Bodies and Data Users are joint controllers of the data processed pursuant to the Regulation.[12]

Taking the above into consideration, and in order to best align the envisioned architecture with the CoEs' needs and requirements, the three main scenarios analysed below were shared with

[9] Nguyen Truong et al, 'Privacy preservation in federated learning: An insightful survey from the GDPR perspective' (Computers & Security, Volume 110, 2021).
[10] Wirtschaftsakademie, C-201/16, ECLI :EU :C :2018 :388, paragraph 38.
[11] European Data Protection Board, 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR' (7 July 2021) available at <https://www.edpb.europa.eu/system/files/2023-10/EDPB_guidelines_202007_controllerprocessor_final_en.pdf> accessed 10 January 2025.
[12] Article 51 of the Draft EHDS Regulation.

their legal representatives and DPOs, who examined the possibilities in depth and provided feedback.

In addition to the above, a consultation with the CoEs' legal departments has been conducted in order to identify the legal basis that is most appropriate for each CoE, considering their status, national legislation and ad hoc dispositions. The legal bases identified can be summarised in the table below:

	Legal Basis
INT	Articles 9.2(j) GDPR and 6.1(c) GDPR, in addition to Art. 110-bis, 4th paragraph of the Italian Privacy Code and Garante provision no. 465 of 28 September 2023 (scientific research in accordance with Italian legislation)
CLB	Articles 9.2(j) and 6.1(f) of the GDPR (scientific research conducted in the legitimate interest of the fight against cancer)
APHP	Art. 9.2(j) and Art. 6.1(e) GDPR (scientific research in the public interest)
IIS-FJD	Under further consideration
VGR	Articles 9.2(j) and and Article 6.1(c) GDPR, further subject to an ethical review
MSCI	Articles 9.2(j) GDPR and Article 6.1(c) GDPR, and the Act of 20 July 2018, The Law on Higher Education and Science (scientific research in accordance with Polish legislation)
MUH	Articles 9.2(j) and 6.1(a), as stipulated by Act No. 372/2011 Coll (monitoring the proposed amendment to Act No. 372/2011 Coll.), further subject to a DPIA
OUS/NIPH	Articles 9.2(g) and 6.1(e) GDPR, in line with Section 19 of the Health Register Act, cf. Section 1-3 of the Cancer Registry Regulations (Possible to further apply 9.2(h), 9.2(i) and 9.2(j) of the GDPR) (processing necessary for a task carried out in the public interest)
MMCI	Articles 9.2(j) and 6.1(c) GDPR, further subject to a DPIA and data pseudonymisation
FPNS	Articles 9.2(j) and 6.1(c) GDPR, and provision 17.2.d of the LOPD GDD, further subject to data pseudonymisation (scientific research in accordance with Spanish legislation)

UKE	Articles 9.2(j) and 6.1(c) GDPR, and par. 6 Abs. 1 Nr 2 Gesundheitsdatennutzungsgesetz (scientific research in accordance with German legislation)

Table 1: Centres' of Excellence identified legal bases

As the project evolves, and taking into account regulatory developments, the above-identified legal bases may be subject to future changes to better respond to the legislative requirements.

2.1.1 GDPR Role Allocation Scenarios

The present section presents the three potential scenarios identified that would determine the role allocation among the project and the corresponding obligations of Data Holders and Data Users. The scenarios in question have been developed to address the GDPR requirements primarily prior to the entry into force of the EHDS Regulation.

As detailed in D2.3, once the EHDS Regulation is in place, the CoEs will have a common legal basis to perform research on health data pursuant to Articles 9 (2) (j) and 6 (1) (c) GDPR, as the EHDS introduces a legal obligation to make data available for research purposes.

Scenario 1 - The Data User acts as a Data Controller processing the data on its own

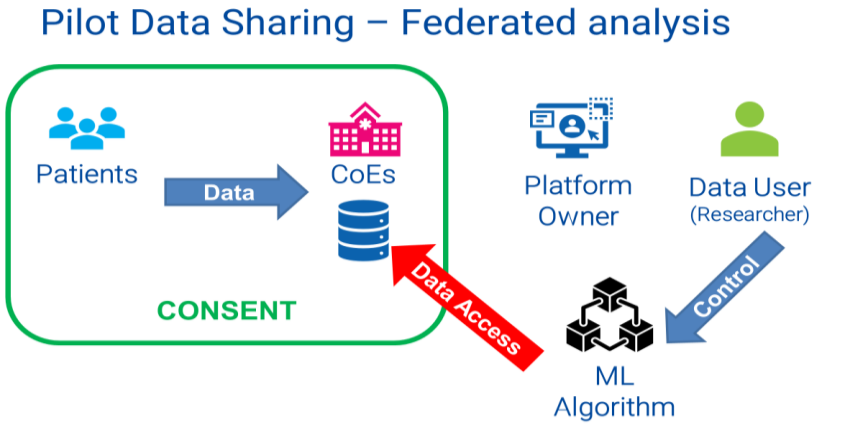

Figure 1: Presentation of Scenario 1

In this scenario, the CoEs have lawfully collected and processed patients' data for the provision of healthcare services based on the legal basis of their choosing, which in most cases has been consent. Said patient data is stored locally in a secure processing environment, namely in the IDEA4RC capsules.

In turn, the Data User has defined the purposes of the processing, by defining the research questions and the respective research objectives, and the means, by choosing to answer the research questions using the IDEA4RC platform and respective algorithms. Similarly, the Data User is controlling the algorithm that, in turn, directly processes the data located in the capsules, sharing only aggregated results with the Data User.

Based on the above, the Data User acts as a Data Controller processing directly the data, even though they do not have access to the raw data. In order to perform the above, the CoE would require a legal basis to allow the process of the data, in accordance with Art. 6 and 9 GDPR. Similarly, the Data User requires a legal basis to process the data.

Scenario 2 - The CoE is processing its own data

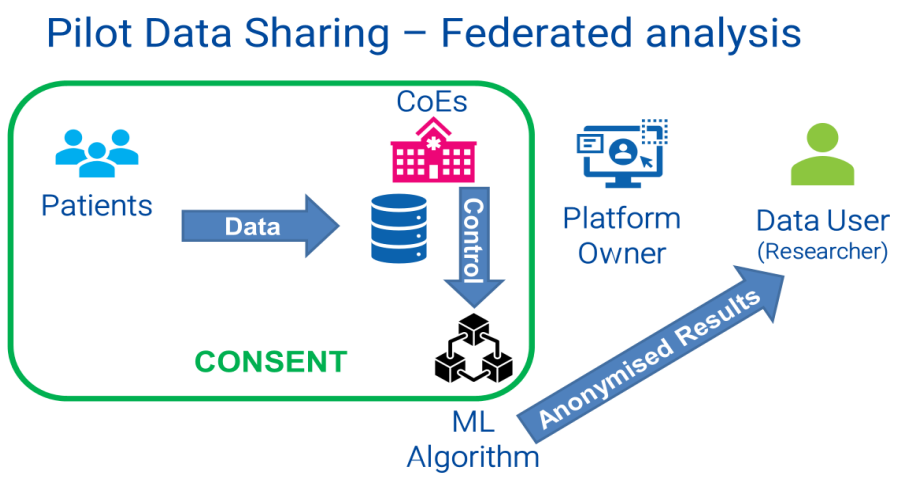

Figure 2: Presentation of Scenario 2

The premise of this scenario regarding the original data collection and processing remains the same as the one above. However, the difference lies in the control over the algorithm and the consequent roles allocated to the Data User and the CoEs.

In this scenario, again the Data User has defined the means and purposes of the research, and, hence, the data processing. However, the implementation of the algorithm is controlled by the CoEs, who might:

a) act under the Data User's instructions, for the purposes defined by the Data User, thus becoming a Data Processor; or
b) act as Joint Controllers along with the Data User.

The above scenario is further evolving as the project progresses, through a co-creation process with the CoEs' legal departments and competent authorities, as will be further reported in future deliverables. Already, the discussion is moving towards providing a set of predetermined algorithms approved by the CoEs that the researcher can utilise to perform the research, again receiving exclusively aggregated data, thus providing more control to the CoEs over the data processing activities.

In order to perform the above, the CoE and the Data User would require a legal basis to allow the process of/to process the data, in accordance with Art. 6 and 9 GDPR.

For both Scenario 1 and Scenario 2 the legal basis will be selected by each CoE individually. The CoEs have provided input on the legal bases that they have available for this action, as reported in the table above, and it was explicitly asked to consider it before they provided their responses.

In the case of Data Users, however, patients' consent is not an option, as the Data User is not envisioned to have access to the actual personal data (and thus the communication information of patients) but only to aggregated results. Thus, only the application of the research exemption is possible where that is foreseen in the national legislative framework.

Once the EHDS is in place, the legal basis is already defined and it will be "compliance with a legal obligation to which the controller is subject", in conjunction with the research exemption of Art. 9 (2) (j) GDPR.

Scenario 3 - The data is anonymised prior to its entry into the capsules

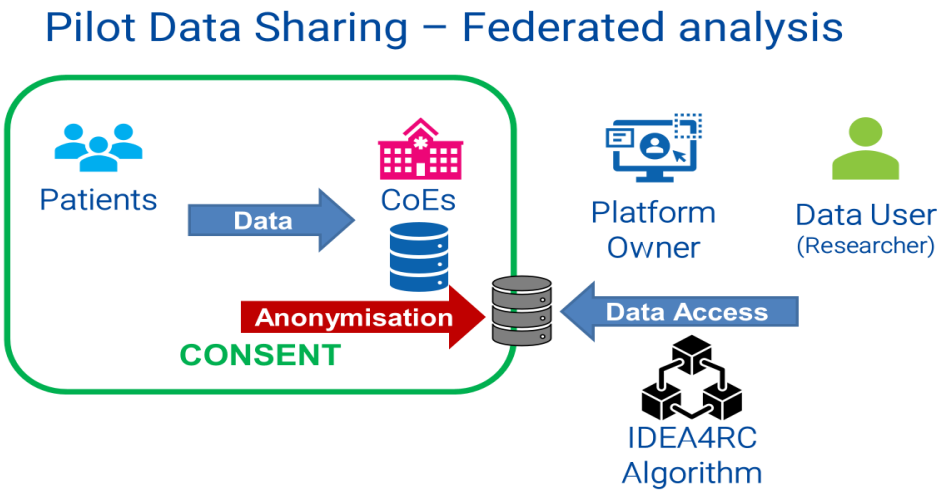

Figure 3: Presentation of Scenario 3

This scenario entails the anonymisation of the data before they enter the IDEA4RC capsules so that no natural persons can be identified using legal means. As such, the GDPR does not apply to any further use or sharing of the anonymised data. The respective CoE in hold of the data remains the only Data Controller and needs to have a legal basis solely to anonymise the data. In most cases, the anonymisation of the data is either covered by the patients' original consent, or is covered by the legal obligation, in line with Art. 6 (1) (c) GDPR, to adopt technical and organisational measures to ensure data protection provided by Article 32 GDPR and relevant national requirements.

Even though anonymisation would facilitate the legal management of the project's solutions, simplifying the agreements and documentation required, it is widely accepted that anonymisation can pose a number of problems. Data Protection Authorities already recognise that anonymisation may not always be possible altogether or in a way that the dataset remains useful. Since anoymisation entails lowering the risks of re-identification below a certain threshold, it is recogised that the context of the processing or the nature of the data may lead to insufficient mitigation of re-identification risks.[13] Datasets related to rare cancers may fall within the latter category, taking into account the frequently low number of patients' data held at one sole hospital.

Similarly, when anonymising data, it is essential to take into account the possibility of reverting anonymisation at a later stage due to the technological evolution.[14] As such, a periodical review and testing of the anonymised dataset to ensure it remains anonymous is required.

Based on the above, the majority of the CoEs within IDEA4RC have confirmed that indeed they are facing obstacles related to anonymisation, whether due to the amount of data held, or the CoEs' internal procedures, or the national Data Protection Authority's views on the topic. The lack of homogenised guidelines regarding anonymisation at an EU level (as the EDPB has only recently published relevant guidelines on pseudonymisation[15]) further accentuate the difficulties described above. As a result, the CoEs have opted to not pursue anonymisation as a whole.

[13] Agencia Española de Protección de Datos, '10 Misunderstandings related to Anonymisation', available at <https://www.aepd.es/guides/10-anonymisation-misunderstandings.pdf> accessed 10 January 2024.

[14] Ibid no 12.

[15] European Data Protection Board, 'Guidelines 01/2025 on Pseudonymisation' (16 January 2025) available at <https://www.edpb.europa.eu/system/files/2025-01/edpb_guidelines_202501_pseudonymisation_en.pdf> accessed 16 January 2024.

2.1.2 Views of the CoEs on the Scenarios

The above-described scenarios were shared and discussed with the CoEs and, in particular, their legal experts and DPOs with the aim of finding the most suitable solution for all. In view of this, a consultation period commenced, collecting the CoEs' views on the scenarios and their respective feasibility for their organisation. The table below presents the results of said consultation with the CoEs' legal departments and DPOs. Where the CoEs expressed their direct preference towards one of the above scenarios, this has been marked as green, while those that have been deemed feasible have been marked with blue. Where the CoEs are still reviewing their options, in coordination with the Ethical Approval Bodies, this has been marked as "To Be Determined" (TBD).

	IIS-FJD	CLB	VGR	MSCI	MUH	CRN	MMCI	FPNS	UKE	INT	APHP
Scenario 1	TBD		☑		☑	☑			☑		
Scenario 2	TBD	☑	☑	☑	☑	☑	☑	TBD	☑		☑
Scenario 3	TBD		☑		☑			TBD	☑	☑	

Table 2: Centres' of Excellence preferences regarding the agreement scenarios

Taking the above into consideration, it becomes apparent that the national and local legislation and guidelines result in a complete lack of homogeneity among the CoEs preferred solutions. While the majority leans towards Scenario 2, said lack of homogeneity entails the need to establish multiple types of agreements to accommodate each CoEs needs, as will be further analysed in Section 2.2

2.2 Governing data sharing and data access: proposed agreements

As required by the GDPR, any personal data processing or sharing process involving multiple parties must be adequately described in a formal agreement defining the rights and obligations of each party.

In centralised infrastructures, where data is transferred to and stored at a centralised environment, the relationship among the parties is defined through a traditional Data Sharing Agreement, detailing the roles of each party taking into consideration: (A) whether they have control over the data or they are following instructions (Data Controller - Joint Controller or Data Controller - Data Processor), (B) whether they are transferring or receiving the data (Data

Holder - Data Recipient), and (C) whether they are exporting data to a third country or importing data from a third country (Data Exporter - Data Importer).

On the other hand, in federated infrastructures, such as the one envisioned in IDEA4RC, the relationship of the CoEs with the Data User is not adequately described by the traditional data sharing agreements, since the Data User does not receive personal data but only the result of the data analysis in an aggregated form. As explained, a different relationship is established with the Data User in each of the scenarios presented above.

Of course, the capsule hosting the federated learning infrastructure ensures a secure environment, as required by the EHDS, and a privacy-enhancing technological solution, since raw data remains in the premises of the original data holder, while also limiting the capacity to extract personal data from the aggregated results. As such, federated learning ensures data protection by design and by default (Art. 25 GDPR).

Given the differences among the approaches adopted in each CoE as detailed in the above-described table, it was originally envisioned that each CoE would have to sign a different type of agreement with Data Users, depending on their preferred scenarios. In particular in the case of Scenario 3, the agreement to be signed would only describe the rights and obligations of the parties that are not relevant to personal data protection, primarily focusing on the terms and conditions of using the results. The agreements in Scenarios 1 and 2 in addition to said terms and conditions would include the personal data protection rights and obligations of the parties.

As the project evolved, an agreement on the basis of Scenario 2 has been decided, so as to avoid having multiple legal instruments governing the relationship between the parties. Said agreement between the pilot sites focuses on describing the datasets that shall enter into the IDEA4RC capsules, also highlighting the fact that only the aggregated results of the data analyses to be performed on the basis of predetermined algorithms will be shared with the other pilots.

In view of the above, and in order to avoid the need for multiple agreements, a different type of model has been researched and designed in the context of T2.2 and T10.1. The proposed model has adopted the form of a Unilateral Contractually Binding Commitment Agreement, enclosing all obligations entailed by each possible role, including rights for the data subjects, and requiring the signature of each party irrespectively of the other parties' signatures. As such,

each signatory party commits to comply with the requirements related to each role they assume in a research project, while easily extendable and modifiable Annexes are added to ensure that each role assumed is adequately described.

The above suggested approach is being further discussed with Data Protection Authorities and has been proposed as a complementary voluntary commitment to the CoEs, receiving their approval. If further adopted by Data Protection Authorities, it will significantly simplify and expedite the signature of the agreements beyond the project's lifecycle with parties outside the IDEA4RC Consortium.

In accordance with the Data Agreements to be signed, as well as the guidelines and policies defined in D2.3, the CoEs shall be able to perform the previously agreed research to answer the predetermined research questions (use cases). Of course, only authorised personnel shall have access to the IDEA4RC platform, based on their role and responsibilities within each CoE. In the context of the project, a number of documents related to the security of the solutions, their privacy-enhancing aspects, as well as several templates and additional information are provided to partners to facilitate their internal compliance procedures, including the performance of Ethical Approvals and DPIAs, where applicable.

It is worth noting that the agreements signed within the context of IDEA4RC might have to be modified and updated beyond the project's lifecycle in order to take into consideration the requirements and guidelines following the adoption of the EHDS Regulation. Once the EHDS is in place, the Commission is expected to design templates for the Data Access Applications (Art. 45 of the Draft EHDS Regulation), for the Joint Controllership Agreement to be signed between the Health Data Access Bodies and Data Users (Art. 51 of the Draft EHDS Regulation), as well as establishing a common application form, a common data permit template (see definition below), standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests (Article 53 of the Draft EHDS Regulation).

Following the entry into force of the EHDS Regulation and the issuance of ad hoc guidelines by the competent authorities, further changes are anticipated not only in relation to the agreements, but also with regards to the data governance model, the procedures and documentation required, as well as the policies that must be in place.

'Data permit' means an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data as described in the data permit definition of the EHDS regulation[16]. In IDEA4RC we address data permit for the secondary use purposes of health data based on conditions laid down in the EHDS Regulation (Art. 44-Art. 51 EHDS).

2.3 Ethical and legal risks

As demonstrated, ethical and legal compliance have been at the forefront of the project's activities since the beginning. Similarly, ethical and legal risks have already been considered, identified and reported in D2.3, while addressing existing and upcoming risks is a constant priority throughout the project. The present section summarises the risks previously identified and their main mitigation measures already in place.

First of all, the work performed in WP2 and WP10 aim precisely at ensuring, on one hand, that patients comprehend the IDEA4RC structure and goals, inspiring trust in the relevant ecosystem, while also ensuring that all IDEA4RC stakeholders are treated in an equitable manner, promoting transparency.

The identification of a legal basis for any processing and/or sharing performed within the project and prior to the entry into force of the EHDS Regulation has been a major part of the ongoing work performed. In order to address this, as well as to mitigate the risks from the lack of homogeneity among the CoEs due to local legislations, both bilateral and Consortium-level discussions and consultations have been performed, aiming to identify the requirements in each CoE and align the respective strategy.

Similarly, as previously discussed, the CoEs' legal experts and DPOs have already been called to describe the procedures they must follow within their organisation, the relevant requirements and documentation. This has allowed for the identification of the CoEs' needs and the preparation of relevant templates to assist them with complying with said requirements in a timely and homogeneous manner. Said templates shall also focus on assisting the IDEA4RC

[16] https://www.european-health-data-space.com/European_Health_Data_Space_Article_2_(Proposal_3.5.2022).html

coordination, as well as the CoEs with the identification and allocation of adequate access rights both at a Consortium level and a CoE level.

In addition to the above steps adopted at Consortium level, the CoEs have already identified, validated and, in most cases, commenced the necessary procedures to ensure legal and ethical compliance. Said procedures include the performance of Data Protection Impact Assessments, as well as the acquisition of Ethical Approvals, where required. Finally, the CoEs have established legal contacts within their organisations in charge of monitoring compliance in cooperation with the IDEA4RC partners.

Security is a central component of the IDEA4RC infrastructure, with ongoing effort present in all of the related activities aiming at ensuring data and platform security throughout their lifecycle. D2.4, D3.2, D4.4 further analyses the security measures envisioned for the IDEA4RC activities they will provide respectively the security and privacy by design approach of the overall architecture (D2.4), the specific security and privacy technical measures implemented into the IDEA4RC capsule (D3.2) and the specific security and privacy technical measures implemented into the IDEA4RC controller (D4.4).

Finally, the question of datasets ownership and intellectual property rights has already been addressed to an extent through the Consortium Agreement and shall be complemented by the work performed in WP11, in order to ensure proper attribution of rights and smooth performance of relevant actions.

The requirements, guidelines and policies established and reported in D2.2, D2.3 and D2.4 complement the above work performed in order to ensure a holistic approach towards ethical and legal compliance.

Of course, as already highlighted, the EHDS Regulation is expected to bring a number of updates and modifications to the IDEA4RC governance framework, in order to best align with updated legislation, guidelines and relevant templates provided by the Commission and/or competent authorities. As a result, regulatory and normative developments remain closely monitored in IDEA4RC in order to ensure compliance with evolving requirements.

2.4 Next steps

In order to finalise the procedures and best align the procedures among the CoEs, ad hoc meetings were organised with the 5 CoE that did not clarify the scenario to further discuss it in depth.

Based on the outcome of these discussions, the respective agreement drafts were developed and circulated accordingly to each CoE, in order to provide their inputs, finalise them and, ultimately, sign them.

Following the above discussions, the agreements have been developed and disseminated for a final review and signature. The signature procedure is ongoing and expected to be finalised in the beginning of 2025.

3 LEGAL AND ETHICAL REQUIREMENTS IN THE IDEA4RC CENTRES

Given the varying interpretations and contextual applications of EU regulations in EU Member States and in non-EU Countries that also host ERN EURACAN members, this section analyses the specific legal and ethical requirements needed to run the use cases and to work with technical partners of IDEA4RC in each of the eleven CoE contributing to IDEA4RC.

3.1 Work performed

In order to collect information regarding national legal and ethical frameworks to be applied in the different participating CoE, two actions have been carried out:

- Representatives from Participating CoEs were asked to fill a template of 10 slides proposing 7 questions (please refer to Appendix 1) to collect important information in order to set up the pilot studies. Questions included in the survey concerned: (1) formal agreement to use the data for running the use cases (2) data protection requirements, (3) cybersecurity requirements and cooperation with IDEA4RC technical partners, (4) ethical approval, (5) other requirements, (6) risk of delay in formal procedures, (7) commercial use of IDEA4RC data. The type of formal agreement is described in section 2.2.
- Some of the representatives were asked to set up a meeting to discuss in detail about information contained in the template.

Templates were received completed from 11 participating CoEs:

- Instituto Investigacion Sanitaria Fundacion Jimenez Diaz (IIS-FJD), Spain
- Centre de Lutte Contre le Cancer Léon Bérard (CLB), France
- Assistance Publique Hopitaux de Paris (APHP), France
- Västra Götalandsregionen (VGR), Sweden
- Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy (MSCI), Poland
- Fakultni Nemocnice v Motole (MUH), The Czech Republic
- Cancer Registry of Norway (CRN), Norway [previously Oslo Universitetssykehus HF (OUS)]
- Masarykuv Onkologicky Ustav (MMCI), The Czech Republic
- Fundación Profesor Novoa Santos (FPNS), Spain
- Universitaetsklinikum Essen (UKE), Germany

- Fondazione IRCCS Istituto Nazionale dei Tumori (INT), Italy

Meetings were organized with four participating centers:

- Fakultni Nemocnice v Motole (MUH), The Czech Republic – 31.10.2023 10:00 – 11:00
- Universitaetsklinikum Essen (UKE), Germany – 16.11.2023 15:00 – 16:00
- Cancer Registry of Norway (CRN), Norway [previously Oslo Universitetssykehus HF (OUS)] – 20.11.2023 13:00 – 14:00
- Centre de Lutte Contre le Cancer Léon Bérard (CLB), France – 20.11.2023 17:30 – 18:30

3.2 Results

- *Instituto Investigacion Sanitaria Fundacion Jimenez Diaz (IIS-FJD), Spain*

To obtain signatures of the agreement, it needs revision from the Legal Department and from the DPO. After the acceptance, the signatures circuit will start. It will be possible to sign the agreement electronically. Issues concerning data protections are still under verification. The project has already been evaluated and approved by the local EC. It is possible that a DPIA will be needed.

Possible delays for the agreement finalization may occur due to the overload at the Legal Department and DPO. Some doubts have been expressed about the possibility of commercial use of the data. The IIS-FJD Cybersecurity department has already evaluated the project and is in contact with the project coordinators to assess final concerns about the installation of the capsules.

- *Centre de Lutte Contre le Cancer Léon Bérard (CLB), France*

To finalise the agreement, the Legal department has to verify it after the project has been approved by the Chief Information Security Officer (CISO), IT director, DPO & EC. It is possible to sign the agreement electronically. The time frame envisioned is of 2 to 3 months. CLB will record the processing activity linked to the project, so they do not need a separate ROPA. Technical partners need to comply with Information System Security Policy (PSSI). PSSI is based on the ISO 27002. A direct data processing agreement should be signed with each technical partner involved in pilot implementation in CLB including a clause on CLB/ French security requirements. The following mandatory documentation is required for EC submission, CISO and DPO approval and global project management:

- GDPR compliance application in accordance with the French legal framework of MR-004 set up by the CNIL,
- Ethical approval of the project from the coordination team institution (INT),
- List of source variables used to generate aggregated results,
- Protocol, synopsis and agreement template,
- EIA.

EC approval will take up to 2 months depending on the project complexity. Possible delays may occur (more than 3 months), due to the review of the agreement. All documents mentioned should be provided by the consortium except the PSSI and the MR-004. There were some doubts expressed whether commercial use of the data is possible. Use of data by external users may be possible under specific conditions after project termination. Specific conditions: express agreement of the CLB on the nature of the study for which data are used, financial compensation for CLB and mention in publications for every study using CLB data. To be detailed later on with the CLB Valorisation officer.

- *Assistance Publique Hopitaux de Paris* (APHP), *France*

To finalise the agreement further details about the type of agreement (under discussion) are needed. It is possible to sign the agreement electronically.

Concerning data protection requirements: APHP would need

- ROPA and
- DPIA.

APHP does not anticipate they would need any support by the IDEA4RC technical partners for the extraction of data from unstructured sources (i.e. natural language processing). The building of the IDEA4RC cohorts is already authorized by the APHP IRB (n°CSE-22-21-EURACAN-IDEA4RC). An amendment including DPIA will be sent to the IRB. In order to make an ethical application APHP needs:

- Research protocol,
- DPIA,
- Declaration of interests.

Moreover, research projects must comply with a reference methodology or be subject to a request for authorization form the CNIL. APHP does not need EIA. EC will decide within two months of receipt of the requests. Possible delays may occur due to the revision of the

amendment by the EC. Commercial use of IDEA4RC data will be acceptable in APHP, it should be performed in accordance with the consortium agreement and only after signing a specific agreement with APHP.

- *Västra Götalandsregionen* (VGR), *Sweden*

After the acceptance of the draft of the agreement, the signatures circuit will start. There are no additional steps that need to be taken before the agreement is signed. It is not possible to sign the agreement electronically. Concerning data protection requirements: ROPA is not needed, DPIA is already finalized and accepted by local legal advisors and DPO. In terms of cooperation with IDEA4RC technical partners, VGR has a cybersecurity policy that applies based on data classification. For the software developers, there are regular tort liability according to commercial contracts. Direct DPA should be signed between the VGR and the technical partners if needs arise. The ethical approval was sent in January 2024. Possible delays may occur if ethical application is rejected or needs to be revised. EIA is not needed. No commercial use of IDEA4RC data is allowed by VGR.

- *Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy* (MSCI), *Poland*

The agreement signing process is as follows: after the acceptance from the legal department, the agreement has to be signed internally by PI, DPO, Legal Department, IT Department and then it could be signed by the Main Director. Estimated time – 2 – 4 weeks. It is possible to sign the agreement electronically. Concerning data protection requirements, MSCI needs:

- ROPA,
- DPIA,
- authorisation of local teams to access EHR.

Concerning cooperation with IDEA4RC technical partners, MSCI does not have a cybersecurity policy, all issues are considered on a case-by-case basis. Liability requirements for software developers will depend on the deployment strategy. Direct DPA should be signed between the MSCI and the technical partners. For IDEA4RC MSCI needs approval from the EC. In order to make an ethical application MSCI needs:

- study protocol (original in English, and summary in polish),
- information for study participants (if needed, not applicable in IDEA4RC),

- informed consent form (if needed, not applicable in IDEA4RC),
- declaration regarding the fulfillment of the obligation regarding personal data,
- CV of PI.

Meeting of the Bioethics Committee is once a month, so the process of obtaining ethical approval could take 4-8 weeks. MSCI does not need EIA. Possible delays may occur due to a long period of document verification by the legal department, DPO and IT department. Possibility and specific conditions for commercial use of IDEA4RC data are still under revision of the Legal and DPO department.

- *Fakultni Nemocnice v Motole (MUH), The Czech Republic*

Estimated time for signing the agreement is approximately 10 days. It is possible to sign the agreement electronically. Concerning data protection requirements, MUH needs:

- ROPA
- DPIA and admittance to EHR by the localized team members,
- approval from the pertinent individual for assent and data utilization.

In terms of cooperation with IDEA4RC technical partners, MUH would prefer to have direct DPA. MUH has a cybersecurity policy, it is in local language and it is not publicly available. The Security Policy of MUH must be observed when developing software. For the IDEA4RC project, MUH needs to obtain Ethical approval. In order to make an ethical application MUH need: project protocol, information for study participants and informed consent form (if needed), CV of PI and approval from head of department where the project will be implemented. Meeting of the Bioethics Committee is once a month, so the process of obtaining ethical approval could take 4-8 weeks. MUH do not need EIA. MUH does not report any risks of potential delays in formal procedures. Possibility and specific conditions for commercial use of IDEA4RC data has to be verified.

- *Cancer Registry of Norway* (CRN), *Norway [previously Oslo Universitetssykehus HF* (OUS)]

CRN from 01.01.24 is part of the Norwegian Institute of Public Health (NIPH) and has the possibility of signing the agreement electronically. Since the IDEA4RC project proposes a new technology, the following data protection requirements are necessary:

- ROPA
- DPIA

- risk analysis.

There were some doubts expressed concerning data processing, whether the output to be shared with others is anonymous, given that Norway is a small country, and the project concerning rare cancers.

Concerning cooperation with IDEA4RC technical partners, CRN do not have a preferred model of collaboration, but they need to have the necessary legal basis in place. CRN does not have a cybersecurity policy. For the software developers they need to see the risk assessment for the whole technical setup and CRN needs to get more overview of any licensing of the products developed and used. CRN will prepare an application to the EC since this is a new technical solution. For the application, CRN needs to provide a project description. The process of obtaining ethical approval normally takes 6-8 weeks from submission of the application until approval is granted (or rejected). CRN does not need EIA. There are also other requirements to comply with in terms of national jurisdiction: access to data from the CRN and other national health registries requires that the recipient meets certain conditions subject to Norwegian national law (which is GDPR-compliant, but might have requirements which are stricter on certain areas, see details in Appendix 3). Concerning commercial use of IDEA4RC data it depends on whether the data is anonymous or personal. Anonymous data is not restricted. Access to personal data for commercial use can be given provided the requirements in national law are fulfilled, together with legal basis and necessary ethical approval. The CRN can set certain conditions for the processing of the data, hereunder storage, deletion, further transfer etc.

- *Masarykuv Onkologicky Ustav (MMCI), The Czech Republic*

An internal agreement review procedure is the only requirement needed to sign the agreement. It is possible to sign the agreement electronically. Concerning data protection requirements: MMCI would need ROPA and DPIA. Concerning cooperation with IDEA4RC technical partners, MMCI doesn´t need to share data with them (MMCI will use its own model for extraction of data from medical records). Hence MMCI assumes that they do not need any agreement regarding cyber security policy with technical partners. MMCI will cooperate with technical partners in technical matters regarding the development of the "capsule" on the MOU and their integration into the federated IDEA4RC ecosystem. Local EC has already approved the project as a whole. Depending on the data use model - e.g., if pseudonymised data are put in capsules

- it will be necessary to obtain EC approval again. The meeting of the EC is once a month. MMCI does not need EIA. Possibility and specific conditions for commercial use of IDEA4RC data have to be verified.

- *Fundación Profesor Novoa Santos (FPNS), Spain*

The agreement signing process is as follows: a) EC approval: 2-6 months, b) DPO approval. The DPO`s decision is collegial in a committee (High Impact Committee on data protection). The approval could last 2-6 months. The current internal regulations are that SERGAS (Regional health services provider) propose a contract for the transfer of data to the other parties. For this reason, it is not usual for SERGAS to sign an agreement proposed by another party. It is possible to sign the agreement electronically, but it must be an advanced digital signature according to Spanish public administration regulation. Concerning data protection requirements in FPNS:

- ROPA is compulsory
- DPIA is recommended.

Other issues are mandatory:

- detailed list of variables,
- identification of all persons who may have access to the data.

In terms of cooperation with IDEA4RC technical partners, FPNS do not have a cybersecurity policy, no specific document has been drafted on this issue, although the policies are clear within the organization. For software developers there are liability requirements. According to Spanish data laws, a DPA is required for technology companies that may receive data from an institution. Concerning EC approval, some parts of the project have been approved or their approval is in progress. In order to obtain approval from the EC it is necessary to submit the project description in Spanish and in English. This description, which will be drafted by FNPS, must include: (a) General Information (who is promoter, the principal investigator within FNPS, all the centers involved, the person responsible for each center and the researcher within FNPS), (b) Objectives (Main and secondary objectives), (c) Type of study, (d) Methods, (e) Scope of the study (Selection of patients, recruitment of patients, sample size, end of the study, measurements and interventions, description of the intervention, timetable and expected date of completion, distribution of tasks among the members of research team, registry and

database statistical analysis, (f) ethical-legal aspects, (g) financial report/ source of funding, (h) commitment to publish the results, (i) Annex Variables.

Whole process could take 2-6 months. In FNPS EIA is recommended. Possible delays may occur due to the compulsory translation of legal agreement into Spanish. FNPS states that commercial use of IDEA4RC data is not possible.

- *Universitaetsklinikum Essen (UKE), Germany*

After acceptance by the legal department and DPO, the signatures circuit will start. The estimated time necessary to sign the agreement is 2-3 weeks, maximum 1 month. It is not possible to sign the agreement electronically. DPO from UKE did not raise any objections concerning data protection: it is not necessary to prepare ROPA and DPIA. UKE has a cybersecurity policy in place. Preferred model of collaboration with technical partners and liability requirements for the software developers is under verification. Approval by the EC is pending, UKE is waiting for the final response. Whole process normally takes 4 weeks. The UKE does not need an EIA. UKE does not report any risks of potential delays in formal procedures. Possibility and specific conditions for commercial use of IDEA4RC data has to be verified.

- *Fondazione IRCCS Istituto Nazionale dei Tumori (INT), Italy*

The agreement has to be revised and approved by the legal office. The legal office asks whether privacy issues have been reviewed by the DPO and whether an EC approval was obtained. It is possible to sign the agreement electronically. INT has a registry aimed at maintaining record of Processing Activities. At INT DPIA is compulsory, but INT already has DPIA for the federated learning approach. In terms of cooperation with IDEA4RC technical partners, INT has already signed direct processing agreements with technical aprtners. INT as Project Coordinator has already the EC approval for IDEA4RC. INT do not report any risks of potential delays in formal procedures, they have already worked with federated infrastructure and federated learning. Thus, no major problems are envisioned unless the conditions previously used (e.g. autonomous controllers) will change. The possibility and specific conditions for the commercial use of IDEA4RC data must be verified by legal experts.

A summary of the results presented for each center participating in IDEA4RC is provided in Tables 2-6 below.

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Table 3: Times and methods for signing the agreement, by IDEA4RC centers

IIS-FJD	CLB	VGR	MSCI	MUH	CRN	MMCI	FPNS	UKE	INT	APHP
Process of signatures (time)										
x	2-3 months	x	2-4 weeks	10 days	x	x	2-6 months	max 1 months	x	x
Electronic signatures										
Yes	Yes	No	Yes	Yes	Yes	Yes	Yes*	No	Yes	Yes

x – no data; * Advanced digital signature according to Spanish public administration regulations

Table 4: Data protection requirements, by IDEA4RC centers

IIS-FJD	CLB	VGR	MSCI	MUH	CRN	MMCI	FPNS	UKE	INT	APHP
ROPA										
Under review	Not needed	Not needed	Necessary	Necessary	Necessary	Necessary	Necessary	Not needed	Necessary	Necessary
DPIA										
Under review	Necessary	Necessary	Necessary	Necessary	Necessary	Necessary	Recommended	Not needed	Necessary	Necessary
Others										

Under verification	List of variables, CISO approval, IT director approval, DPO & Ethics committee approval	-	Authorization of local team to access EHR	Admittance to EHR by the localized team, approval from the pertinent individual for assent and data utilization	Risk analysis	-	Detailed list of variables, identification of all persons who may have access to the data	-	-	An amendment to the ethics committee

x – no data; - not applicable

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Table 5: Requirements for collaboration with technical partners

IIS-FJD	CLB	VGR	MSCI	MUH	CRN	IMCI	FPNS	UKE	INT	APHP
Model of collaboration with technical partners										
x	Direct agreement (data processing agreement)	Direct agreement (data processing agreement)	Direct agreement (data processing agreement)	Direct agreement	No cybersecurity policy and specific agreement	Direct agreement (data processing agreement)	Direct agreement (data processing contract)	Under verification	Direct agreement (data processing agreement)	x
Cybersecurity										
x	PSSI IT Security Policy	Cybersecurity policy on place	Cybersecurity issues are consider on case-by-case basis	Cybersecurity policy on place	No cybersecurity policy	No cybersecurity policy	Cybersecurity policy on place	Cybersecurity policy on place	To be verified	x
Liability requirements										
x	Compliance with CLB PSSI	Regular tort liability according commercial contracts	Yes, it will depends on the deployment strategy	No need regarding liability requirements	Risk assessment for the whole technical setup and overview of any licensing products developed and used	To be verified	Each partner must sent the specific information for the project (technical architecture and DPO)	Under verification	To be verified	x

x - no data

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Table 6: Ethical approval

IIS-FJD	CLB	VGR	MSCI	MUH	CRN	MMCI	FPNS	UKE	INT	APHP
Status										
Approved	In preparation	In preparation	In preparation	In preparation	In preparation	Approved	Some part approved, some in progress	In progress	Approved	Approved, amendment needed
Timeline										
-	Up to 2 months	2-3 months	1-2 months	1-2 months	6-8 weeks	1 month	2-6 months	1 month	-	2 months
Ethical Impact Assessment										
-	Necessary	Not necessary	Not necessary	Not necessary	Not necessary	Not necessary	Recommended	Not necessary	-	Not necessary

x - no data; - not applicable

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

Table 7: Commercial use of the data

IIS-FJD	CLB	VGR	MSCI	MUH	CRN	MMCI	FPNS	UKE	INT	APHP
Possibility										
To be verified	To be verified	Not possible	Under revision of legal team	To be verified	It depends whether data are anonymous or personal	To be verified	Not possible	To be verified	To be verified	Yes
Specific conditions										
To be verified	Express agreement of the CLB on the nature of the project, financial compensation for CLB and mentioned in publication for CLB and mentioned in publication for every project using CLB data. To be detailed later with the CLB Valorization officer	-	Under revision of legal team	To be verified	Anonymous data are not restricted, access to personal data for commercial use can be given provided the requirements of national law, legal basis and ethical approval	To be verified	-	To be verified	To be verified	In accordance with consortium agreement and only after signing a specific agreement with APHP

x - no data; - not applicable

3.3 Conclusions and Next steps

The CoEs are willing to contribute to the IDEA4RC platform, and will be able to sign an agreement for the use of the data defined by the Consortium and compliant to local and National ethical and legal regulations.

An agreed protocol for IDEA4RC use cases and templates for ROPA and DPIA shall be adopted and shared by all CoEs.

The time requested for approval and signature of the agreement and for approval of the protocol by EC varies among the different CoEs, thus the implementation of IDEA4RC in each CoE may be completed at different timings.

The use of data by commercial actors as well as the possibility to receive a financial compensation is debated.

These considerations and the different requirements for data provision to IDEA4RC due to Institutional and/or National ethical and legal frameworks will require the implementation of flexible data governance, adapted to each institution's legal and ethical policies.

3.3.1 Next steps

A Governance WG has been established in IDEA4RC dedicated to address ethical and legal requirements and to define the overall governance. This multidisciplinary WG is engaged in setting the basis to discuss with DPO, ECs and legal experts of the CoEs. Besides providing a shared governance framework and a template for the agreement for data use, this Governance WG will start working on ROPA and DPIA to share them with CoEs that requested them, to be able to discuss them at the Plenary Project Assembly Meeting of IDEA4RC, envisioned for April 29-30.

4 GOVERNANCE IN IDEA4RC

The IDEA4RC partners believed that an important aspect to obtain a satisfactory outcome of the efforts and resources invested in the project was to clarify, from the beginning and in all phases, the governance (whoever develops the strategy and defines the rules, thinks about how to collect the resources necessary to achieve the objectives and evaluate the results) of the ecosystem that is being built. This is also with the aim of guaranteeing fair and open access to the infrastructure on the basis of ethical principles.

Therefore, this section presents the discussion initiated with IDEA4RC partners on the governing bodies, rules and procedures for accessing and managing the IDEA4RC federated ecosystem.

Governance is expected to be updated as the project progresses through different implementation phases. Therefore, the governance presented here should be considered as a first draft.

4.1 Methods to define the IDEA4RC governance

The findings acquired through the first co-creation workshop, that took place in Venice in April 2023, and through semi-structured interviews with IDEA4RC partners made us aware of different expectations regarding the future data governance model for IDEA4RC. In particular, considerable variations were recorded regarding the following topics: (1) the openness of this data ecosystem to different type of actors, including commercial and non-commercial ones; (2) the conditions under which access to data about rare cancers via this data ecosystem should be allowed to third parties (for free versus in exchange of a (financial) contribution); how decisions about data permit applications should be made. The importance of these aspects was further highlighted when reviewing relevant governance approaches already in use, such as the data governance model used in the EURACAN registry https://euracan.eu/registries/starter/european-registry-governance/) and in other collaborative projects such as Survival and Prevalence of cancer patients in Europe -

[EUROCARE https://www.iss.it/en/eurocare-il-progetto], Transatlantic Australasian Retroperitoneal Sarcoma Working Group [TARPSWG https://tarpswg.org/tarpwg-governance/]). To tackle these aspects in the specific context of IDEA4RC and acquire a better understanding about the expectations that the IDEA4RC partners had regarding them, we followed a two-steps approach:

1. We conducted an opinion poll consisting of three questions about the topics mentioned above during the IDEA4RC Plenary Meeting that took place in Madrid on November 22, 2024. The survey (see Appendix 2) was deployed using Wooclap, an interactive online platform used to conduct opinion polls and surveys. All the participants (60) to the Plenary Meeting could answer the questions in real time. The results of this opinion poll were made sense of during the same meeting, as the participants were shown the results immediately thereafter and invited to reflect upon them, to discuss their choices, preferences, and doubts. The sociologist from University of Utrecht (UU) in attendance together with INT Coordination Team took detailed notes of the insights the participants shared. Inspired by focus group methodology, this approach allowed for the collection of rich insights about the participants' emerging perspectives about data governance, about the elements they were uncertain about, and about relevant differences in legislation and regulations between countries as well as institutions.

   Additional relevant insights were collected during the scenario validation workshop that the UU researchers organized in Madrid, on November 23, 2023. The three scenarios presented for validation entailed different levels of openness and suggested highly diverse potential future users for IDEA4RC, ranging from pharmaceutical companies, to regulatory bodies and patients. These insights were combined with perspectives and approaches identified in the relevant scientific and gray literature to design a more extensive survey.

2. To ensure high response rates, we developed a survey consisting of 48 questions, including a combination of multiple choice questions and open questions. These

questions were developed based on the insights acquired as described under step 1. We estimated that the survey would take a maximum 15 minutes to complete in a rigorous and thorough manner. The questions focused on four main topics: (1) the IDEA4RC users; (2) general rules for accessing and re-using data about rare cancers via IDEA4RC; (3) the IDEA4RC data access application and data permit; (4) financial or other contributions to access and re-use data about rare cancers via IIDEA4RC. To ensure the validity of the results, short explanations were included in the survey about the legal terms deemed most important. Some of the questions required the respondents to express agreement or disagreement regarding particular data governance aspects. Other questions asked the respondents to select one or multiple options they found most desirable regarding the future data governance of IDEA4RC. The open questions were meant to enable the respondents to provide insights different from or complementary to the options indicated in the multiple choice questions. The respondents were asked, for instance, to mention additional commercial or non-commercial stakeholders who they believed should be able to access, use and re-use data about rare cancers via IDRA4RC, or to indicate what kind of special privileges they believed the current IDEA4RC partners should enjoy in the first years after this data ecosystem becomes functional. The respondents were also able to share any additional ideas, comments, and suggestions they had about the data governance model of IDEA4RC at the end of the survey.

The initial survey was piloted internally among the UU university scholars and feedback was received from experienced survey developers, to ensure the validity and reliability of the data to be collected. Based on this feedback, we adjusted some of the questions to ensure their clarity, the logical sequence of the questions, and the overall structure of the survey, to make it more coherent and easier to fill in. The survey was developed and administered using the online platform Qualtrics and was distributed among the IDEA4RC clinical and technical partners in the period December 12, 2023 – January 26, 2024. A total of 62 people received the request to fill in the survey and they comprise all the professionals with clinical or technical tasks who participate directly to IDEA4RC

from the 11 CoEs that are involved in this project. To encourage respondents to answer as truthfully as possible, all responses were collected anonymously. 33 people out of 62 completed the survey, which constitutes a response rate of 53 %.

There are a number of limitations that need to be considered when interpreting the results described below. Whereas the above response rate is positive for a survey, it is nonetheless a limiting factor, as the wishes and preferences of almost half of our sample remain undocumented. Another limitation stems from the fact that the survey was distributed to both clinical and technical partners, without the possibility to distinguish between the insights representatives of each group shared. Yet, clinical and technical partners are likely to have different data governance expectations based on their specific interests, types of knowledge, skills, and tasks on the project.

4.2 Survey results

The IDEA4RC users

The majority of respondents (70%) agreed that both commercial and non-commercial actors should have access to the IDEA4RC ecosystem. Only 30% preferred to restrict access exclusively to non-commercial actors.

The majority (90%) of respondents believed that private research institutions, pharmaceutical companies, and health IT companies were appropriate users of the IDEA4RC ecosystem. Only a minority (20%) of those interviewed agreed in considering insurance companies as potential users. Finally, around half of the interviewees also consider marketing research companies and independent researchers as relevant users.

With regards to potential non-commercial users of IDEA4RC, competent authorities, healthcare professionals and researchers were recognized as eligible users by 80%, 73% and 61% of respondents, respectively. Some of the respondents emphasized that researchers should have experience in the medical field and even better in oncology or be experts in epidemiology, data science and biostatistics to access the ecosystem. Only

55% selected national and EU institutions as eligible users. However, this response may have been distorted by the fact that an option already existed that proposed competent authorities at regional, national and European levels as users of the ecosystem.

IDEA4RC is intended only for the secondary use of data, therefore not for the recovery of a specific patient's personal data for primary use (i.e. treatment). However, patients and patient advocates were also considered legitimate users of the ecosystem, albeit by a minority of respondents. In detail, 48% of respondents believed that patient organizations are suitable users and 33% underlined the importance of patient organizations being independent. Only 21% considered the individual patient or family member to be a relevant user of the ecosystem.

General rules for accessing and re-using data about rare cancers via IDEA4RC

All respondents agreed that the rules on how to access the IDEA4RC ecosystem should differ between commercial, non-commercial actors and IDEA4RC partners.

Commercial actors

Most respondents agreed that commercial actors should be allowed to query the IDEA4RC ecosystem as long as the study is approved by an ethics committee and the results are communicated to all data providers. Approximately 60% of respondents expressed a preference to allow commercial companies to interrogate the ecosystem under the supervision of a PI selected among IDEA4RC partners. Only 26% suggested that simple questions could be analyzed on behalf of the commercial actor by the current IDEA4RC coordinator.

IDEA4RC partners

Almost all (82%) respondents agreed that special rules are needed for IDEA4RC partners. The rule with the highest number of preferences (37% of respondents) was to guarantee exclusive access to the ecosystem to IDEA4RC partners for a few years (range from 2 to 5 years) after the end of the project. Only 15% chose the option to open the IDEA4RC

ecosystem only after a certain number of publications (range from 5 to 10). Further proposed special rules for partners included: free access to the ecosystem, low administrative burden, involvement in research performed with their data, approval of every study performed on the data. Most respondents (74%) agree that the special rules reserved for IDEA4RC partners should also apply if they collaborate on a study with a commercial actor, however they should make the collaboration public. While 67% of respondents agreed that IDEA4RC partners should be included as co-authors in publications from external actors using the IDEA4RC ecosystem, there were also a few notable exceptions. It was emphasized that in the ecosystem the data will be extracted automatically so no additional work will be necessary. Partners should be included in the acknowledgment but not be involved as authors unless they are clearly involved in the study and publication. Rather than the recognition of researchers, it was suggested to also consider the recognition of institutions since some of them have data valorization policies.

The IDEA4RC data access application and data permit

The governance proposed in the questionnaire included several phases: submission of a data access application, review of the data access application and approval of the data access application with issuance of a data permit. The terms data access application and data permit have been proposed based on the EHDS.

Most respondents (67%) agreed that the data access application should include major insights. Only a minority of respondents argued that a simple data access application with limited information, mainly relating to the data needed for the objectives of the study, would suffice. The information to include in the data access application included: name and CV of the PI, the study's rationale, objectives, hypothesis, the statistical plan and the data elements needed.

For the majority of respondents, the data access application should be examined by a multidisciplinary committee including mainly clinical partners of IDEA4RC and members of the ethics committees. Technical partners and legal advisors were considered

relevant by 60% of respondents, and only 29% of respondents said that patients should be part of the multidisciplinary committee reviewing the data access application. All agreed that the decision about the data access application should be made within a specific time interval ranging from 15 days to max 2 months.

Regarding data permit, 90% of respondents identified the DPO as the person in charge of approving/issuing it, 60% identified ethics committee members as best responsible for approving/issuing the data permit. A minority of respondents suggested data managers, statisticians, data scientists and patient representatives. We believe this is due to an unclear understanding of what data permit is. Respondents had different ideas about the time frame within which data permission should be issued, ranging from 3 months to 1 year.

Finally, it is worth mentioning that 50% of respondents agreed that it should be possible to appeal a data owner's decision not to make their data available, while the remaining 50% disagreed.

Financial or other contributions to access and re-use data about rare cancers via IDEA4RC

The majority of interviewees (82%) agreed on the need to ask for a financial contribution from new users (i.e., not data providers or CoEs contributing to IDEA4RC) to access the IDEA4RC ecosystem. According to 52% of those interviewed, only commercial actors should pay, while for the remaining 48% both commercial and non-commercial actors should be asked for a financial contribution. The majority of respondents (85%) suggested different pricing rates based on different categories of users (e.g. commercial, non-commercial), 56% suggested setting fees based on the type of study, 37% based on the financial profit that could arise from the results, 33% based on the level of development of the country where the user is based and 22% based on the social impact of the study. Everyone agreed that the financial contribution will be requested and used to ensure the functioning of the ecosystem from all points of view (assistance and updating of technical infrastructure, administrative costs, costs at local level borne by

data providers, etc.). Interestingly, 63% of respondents agreed that fees should be set and paid upon receipt of data permit; 33% suggested dividing the payment into 2 tranches: a first to be paid when the data is released and a second to be defined once the financial profit has been obtained.

4.3 Governance first draft

Based on the survey results, we developed the first draft of the governance as follows:

1) Data remain the property of the CoE contributing data to the IDEA4RC ecosystem
2) Each CoE is free to access and use its own data for research purposes
3) Access to the IDEA4RC data ecosystem is possible, based on specific rules, to
   - Each CoE contributing to the IDEA4RC data ecosystem
   - Third parties:
     i. non-commercial, including researchers (regardless of their area of expertise), health care professionals, competent authority, national and European Institutions,
     ii. commercial companies, including pharmaceutical companies, health IT companies, private research institutions, health insurance company, regulatory bodies
     iii. patients' organizations and patient advocates
4) Access to the IDEA4RC data ecosystem is based on a data access application (including name of the PI, brief CV of the PI, study background, objectives, hypothesis, statistical analyses, data needed, expected results, dissemination level)
5) The data access application is submitted to each CoE or to a central secretariat (to decide whether the federated infrastructure will have a centralized managed governance and by whom will be managed) .
6) The data access application is reviewed and approved from a scientific point of view by a Steering Committee

7) The data access application is reviewed by an ethics committee (to decide whether the EC of each CoE has to review the data access application or one EC can act on behalf of the others)
8) The data access application is approved by a legal representative on the basis of the EC opinion and scientific review, and the relevant agreement will be signed.
9) Commercial and non-commercial third parties, depending on the study, may be asked to contribute funding.
10) Commercial third party should work with an IDEA4RC PI (to be further discussed)
11) The fee rate will be specific for the type of third-party requesting data access and based on the type of study.
12) IDEA4RC partners (and future partners joining the data ecosystem) have free access to the data, exclusive access to the data ecosystem for 1 year before the ecosystem is open to external stakeholders, agreement signed una tantum (to be confirmed)
13) IDEARC consortium should be recognised in the publications (to be further discussed)

4.4 Next steps

To mitigate the shortcoming of the survey, the findings of this survey will be used to initiate a series of focus groups with representatives from each professional category. During these focus group sessions, clinical and technical partners will be invited to share separately their reactions, thoughts, needs, and preferences regarding the future data governance model of IDEA4RC. To make these discussions as useful as possible and to ensure the translation of the insights thus acquired into concrete decisions about the data governance model of this data ecosystem, the results of this survey will first be discussed with legal experts from each center of expertise. This will allow us to map the realm of possibilities available in regard to data sharing based on well-informed considerations and reflections about differences in national laws and regulations as well as the norms and expectations of each medical organization involved.

Focus groups will focus on the following issues that need further clarifications

- Central governance vs federated governance and responsibilities (from a legal point of view in a federated system):
    - to whom the data access application should be submitted (a centralised secretariat, a single hospital?)
    - by whom the data access application should be approved (Ethic committees? Legal representative? both)
    - do we need an EC approval, do we need the expert review? We should move from a user-based decision into a more formal decision based on hospital legal framework.
- Visibility requested by the hospitals (vs authorship rules)

5 SUMMARY OF CHANGES APPLIED TO ADDRESS REVIEWERS' RECOMMENDATIONS

REVIEWERS RECOMMENDATIONS

Overall, the deliverable needs to be revised for the next reporting period. Following the requested revision of the legal basis analysis in D2.3, its impact on scenarios 1-3 should be updated in this deliverable accordingly (see Recommendations R2). The deliverable needs to be revised for the next periodic report (see the related comments in section "2 Objectives and Workplan"). Following the requested revision of the legal basis analysis in D2.3, please update its impact on scenarios 1-3 in this deliverable accordingly.

R2 – Legal Analysis and GDPR Compliance: A) Revise the legal analysis in D2.3 to clearly identify the lawful basis for data processing under GDPR that are relevant for the project. Additionally, it should outline how the EHDS will alter the requirements for the processing grounds under the GDPR. This revision should support a systematic approach to identifying variability in Member State laws under the GDPR (and subsequently the EHDS) by elucidating the consequences of different legal options and the extent of national law for each option. Following this analysis, please update its impact on scenarios 1-3 in D8.2 for the next periodic report. B) In future deliverables, consistently identify and expand the role of each partner under the categories established by relevant regulations in line with the recommendations of independent ethics advisor (e.g., GDPR, EHDS). C) Ensure that the ethical advisor provides targeted advice to ensure legal analyses are precise and conclusive (See also comments of WP3 and WP12 in "Objectives and work plan") D) Consistently communicate that the objective of IDEA4RC is not to produce a medical device for clinical decision support (see also Comments regarding D2.1).

APPLIED REVISIONS

Document section	Revision applied
2.1 – page 11-12	Referenced the analysis of the legal bases that was performed in the updated version of D2.3.

	"*The legal basis might be different depending on* ***the requirements of the national legislation, as further analysed in D2.3, as well as*** *the legal and ethical rules applied by each CoE, therefore the governance implemented in IDEA4RC shall comply with such different frameworks.*"
2.1 – page 13	A reference to the EDPB Guidelines further explaining the concepts of data controllers and data processors was added. "*It is worth mentioning that, according to the EU Court of Justice practice* ***and EDPB Guidelines****, it is not necessary that a data controller actually has access to the data that is being processed, as long as they are meeting the rest of the requirements (i.e. defining the means and purpose).*"
2.1 – page 13 - 14	Provided the results of the consultation with the CoEs regarding the legal basis used in each site. A table was provided to summarise the findings.
Errore. L'origine riferimento non è stata trovata. – page 15	Added clarification regarding legal basis for data reuse, following the analysis reported in deliverable D2.3. "*…once the EHDS Regulation is in place, the CoEs will have a common legal basis to perform research on health data pursuant to Articles 9 (2) (j) and 6 (1) (c) GDPR, as the EHDS introduces a legal obligation to make data available for research purposes.*"
Errore. L'origine riferimento non è stata trovata. – page 16	Description of Scenario 2. Added clarification regarding the access to aggregated data only, i.e. non personal data. "*The above scenario is further evolving as the project progresses, through a co-creation process with the CoEs' legal departments and competent authorities, as will be further reported in future deliverables. Already, the discussion is moving towards providing a set of predetermined algorithms approved by the CoEs that the researcher can utilise to perform the research, again receiving exclusively aggregated data, thus providing more control to the CoEs over the data processing activities.*"
2.1.1 – page 17	The text related to the most anticipated legal bases was deleted, as the detailed analysis was provided above.
Errore. L'origine riferimento non è stata trovata. – page 17	For Scenario 1 and Scenario 2 added clarifications regarding the legal basis and the relevant reference articles of GDPR. "*….Once the EHDS is in place, the legal basis is already defined and it will be "compliance with a legal obligation to which the controller is subject", in conjunction with the research exemption of Art. 9 (2) (j) GDPR.*"

Errore. L'origine riferimento non è stata trovata. – page 18	Added clarification regarding Scenario 3 that makes available only anonymized data. It is further clarified that the CoEs will not pursue anonymization. "*In most cases, the anonymisation of the data is either covered by the patients' original consent, or is covered by the legal obligation, in line with Art. 6 (1) (c) GDPR, to adopt technical and organisational measures to ensure data protection provided by Article 32 GDPR and relevant national requirements.*"
Errore. L'origine riferimento non è stata trovata. page 19**Errore. L'origine riferimento non è stata trovata.**	Updated **Errore. L'origine riferimento non è stata trovata.** with the preferred scenarios selected by CoEs
2.1.2 – page 20	The text was updated since in the meantime the CoEs have decided to opt for Scenario 2. "*As the project evolved, an agreement on the basis of Scenario 2 has been decided, so as to avoid having multiple legal instruments governing the relationship between the parties. Said agreement between the pilot sites focuses on describing the datasets that shall enter into the IDEA4RC capsules, also highlighting the fact that only the aggregated results of the data analyses to be performed on the basis of predetermined algorithms will be shared with the other pilots.*"
2.3 – page 23	The actions towards ensuring compliance at a CoE level were expanded. "*In addition to the above steps adopted at Consortium level, the CoEs have already identified, validated and, in most cases, commenced the necessary procedures to ensure legal and ethical compliance. Said procedures include the performance of Data Protection Impact Assessments, as well as the acquisition of Ethical Approvals, where required. Finally, the CoEs have established legal contacts within their organisations in charge of monitoring compliance in cooperation with the IDEA4RC partners.*"
Errore. L'origine riferimento non è stata trovata. – page 24	Added the actions performed at date. "*Following the above discussions, the agreements have been developed and disseminated for a final review and signature.*"
3 – page 25	The concept of "*different adoption*" of EU regulations was clarified to "*varying interpretations and contextual applications*" of EU regulations.

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

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APPENDIX 1 - LEGAL AND ETHICAL REQUIREMENTS IN THE IDEA4RC CENTERS

Template sent to participating centers

Section 1

At the beginning, we ask you to confirm or change/modify contact details, so as to be sure that we will contact the appropriate people

Organisation			
	Name, surname	Job title	E-mail
Main contact person			
Legal department			
Data protection officer (or relevant expert in data privacy			
Ethics officer			
Other (if necessary)			

Section 2

This part contains questions related to data protection regulation and ethical issues

Question 1: DSA

a) Please provide us feedback about **data sharing agreement**

- Approved
- Not approved (if not approved, please provide feedback)

b) Please describe the steps that need to be taken (including who needs to be involved and estimated time) for **the agreement to be signed.**

c) Is it possible to **sign the agreement electronically** (preferred form)

- Yes
- No

d) Is there any **other issues** specific in your centre that need input from consortium?

- Yes
- No

Question 2: Data protection requirements

Are there any other documents, arrangements needed to meet your local **data protection regulations?**

a) ROPA

- Yes
- No

b) DPIA

- Yes
- No

c) Other (e.g. detailed list of variables, authorisation of local team members to access EHR?)

- Yes
- No

Question 3: Cybersecurity requirements

Please describe model **of cooperation with IDEA4RC technical partners**?

a) Whether a cybersecurity policy has been prepared

- Yes (please provide)
- No

b) Whether there is any liability requirements for the software developers (in our case IDEA4RC technical partners)?

- Yes (please specify)
- No

c) Whether there is preferred model of collaboration with technical partners (e.g. direct Data processing agreement)

- Yes (please specify)
- No

Question 4: Ethical approval

Please describe if you need **approval of ethical committee**

a) What type of documents you need in order to apply

b) How long does the process take?

c) Do you need **Ethical Impact Assessment (`EIA`)**

Question 5

Please indicate any other requirements to comply with legislative texts in **national jurisdiction**?

- Yes (please specify)
- No

Question 6

What **risks of delay in formal procedures** can you see locally, that might be relevant to IDEA4RC pilot implementation?

Question 7

Would secondary **commercial use of IDEA4RC data** be acceptable to your institution?

- Yes
- No

Are there any **specific conditions** for commercial data use?

Thank you

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APPENDIX 2 - IDEA4RC DATA GOVERNANCE SURVEY

Welcome to the IDEA4RC data governance model survey! This survey will take about 15 minutes to complete. There are no right or wrong answers, and we are interested in your personal views. Unless otherwise specified, you will be able to select only **one** option for the multiple-choice questions. We would be very grateful if you could fill in all the open questions that emerge based on your answers. The insights you share will be used for project-related and research purposes. We will treat your responses strictly **confidentially**. Before we share or publish data from this survey, we will remove or recode any personal or identifying information. Your participation is **voluntary**. Please feel free to contact Claudia Egher (c.egher@uu.nl) for any questions, comments, or concerns. Please confirm below that you agree to participate in this survey.

Answer	Percentage	Count
I agree to participate.	100%	33

Why is it important that you fill in this survey?

The insights you provide here are essential, as they will be used to determine the data governance model of IDEA4RC and, as such, they will function as a blueprint for similar initiatives, once the European Health Data Space regulation is approved.

To facilitate the sharing and re-use of data about rare cancers, which is vital to advance knowledge in this field, IDEA4RC is developing tools to automatise the data retrieval from already available sources (electronic health records). This will significantly reduce the work of manual data collection.

This survey is meant to systematically collect your views on who should be able to access the data ecosystem about rare cancers that we are developing together and based on what rules and conditions. In providing your answers, please also focus on the long-term future and the rules that you would consider appropriate,

if you had to personally request to access and re-use data about rare cancers from other data providers.

The four modules of the survey:

- The IDEA4RC users
- General rules for accessing and re-using data about rare cancers via IDEA4RC
- The IDEA4RC Data Access Application and Data Permit
- Financial or other contributions to access and re-use data about rare cancers via IDEA4RC

The IDEA4RC users

Q1. In your view, who should be able to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Only non-commercial actors	30%	10
Only commercial actors	0%	0
Both commercial and non-commercial actors	70%	23

Q2. In your view, which categories of commercial actors should be able to access and re-use data about rare cancers via IDEA4RC? You can select multiple options.

Answer	Percentage	Count
Private research institutes	100%	23
Pharmaceutical companies	91%	21
Medtech/health IT companies	91%	21
Insurance companies	22%	5
Marketing and/or socio-economic research companies	43%	10

Independent/self-employed researchers	52%	12

Q3. In your view, which categories of non-commercial actors should be able to access and re-use data about rare cancers via IDEA4RC? You can select multiple options.

Answer	Percentage	Count
Any researchers regardless of their area of expertise	61%	20
Only researchers with expertise in specific areas (e.g. epidemiology, genetics, data science, etc.)	33%	11
Any healthcare professionals (e.g. medical specialists (oncologists, oncological surgeons, radiologists), nurses, nurse practitioners, psychologists, etc.)	73%	24
Only specific types of healthcare professionals	9%	3
Any competent authority at the regional, national, and/or EU level	79%	26
Any national or EU institution	55%	18

Q4. In your view, in what areas should researchers have expertise, to be permitted to access and re-use data about rare cancers via IDEA4RC?

Medical filed, biostatistical, bioengineers, genomics
Data science, epidemiology, oncology, technical implementations...
Researchers should have expertise in defining relevant research questions for rare disease coming from clinical needs
Oncology, molecular biology, developmental biology, genetic, omics
Cancer
Epidemiology, biostatistics, data science, for instance
Oncology

I believe researchers should at least have some background in working with patient-based data and ethics formation.
Cancer, epidemiology, clinical research
Cancer
Fields related to the dataset in question

Q5. In your view, what types of healthcare professionals should be permitted to access and re-use data about rare cancers via IDEA4RC?

Healthcare professionals with responsibilities to defined clinical practice guidelines
The ones who deal directly or indirectly with cancers
Physicians, Scientists

Q6. In your view, what kind of patient actors should be able to access and re-use data about rare cancers via IDEA4RC? You can select multiple options.

Answer	Percentage	Count
Patient organizations, regardless of area of activity (e.g., advocacy, policy, drug development, patient care, family support, etc.)	48%	16
Patient organizations regardless of how they are funded and by whom	15%	5
Only independent patient organizations (receiving no or limited funding frompharmaceutical companies, health IT businesses, or any other commercial entity)	33%	11
Patient advocates (both patients and non-patients)	36%	12
Individual patients	21%	7

Family members of patients	21%	7
No patient actors should be able to access and re-use data about rare cancers viaIDEA4RC	33%	11

Q7. In your view, are there any additional commercial or non-commercial actors that should be able to access and re-use data about rare cancers via IDEA4RC? If yes, please mention them below.

No
No
Regulatory bodies e.g EMA
I think commercial actors in cooperation with non-commercial actors (academia) should be able to access and re-use data
Regarding commercial actors - I believe that they also should be able to re-use data via IDEA4RC but in previous questions I chose "only non-commercial actors" because I can´t agree with "default" access of commercial actors . It must be considered case by case whether commercial actor has legitimate reason for re-use of IDEA4RC data (e.g. research) and also other aspects of accesing data must be assesed - for example reimbursement for providing data, intellectual property rights (dedication to project or each institution providin data etc.).
Hospitals and Healthcare research organisations, in general
No
No
For transparency and trust, broad access including individual patients is important, but for any actor accessing the data, the support of researchers with expertise in oncology, epidemiology, genetics, data science should be

mandatory or at least available in order to guarantee the quality of the knowledge derived from the IDEA4RC data sets
No
None come to mind
There may be an access for patients, but with accessible information in plain language. Not survival curves without any context...
Students, Universities for educational purposes

General rules for accessing and re-using data about rare cancers via IDEA4RC

Q8. Do you agree or disagree that rules should be developed to determine how data about rare cancers can be accessed and re-used via IDEA4RC?

Answer	Percentage	Count
Agree	100%	33
Disagree	0%	0

Q9. In your view, should both commercial and non-commercial actors follow the same set of rules to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Yes	24%	8
No	76%	25

Q10. In your view, what specific rules should apply for pharmaceutical companies or other commercial actors to access and re-use data about rare cancers via IDEA4RC? You can select multiple options.

Answer	Percentage	Count

Simple queries should be conducted on behalf of the pharmaceutical company/commercial actor by the IDEA4RC coordinator.	26%	6
Pharmaceutical companies or other commercial actors should be allowed to query theIDEA4RC data provided that the scope of the query is approved by an ethical committee.	61%	14
Complex queries should be conducted by the pharmaceutical company or commercial actor under the supervision of a P.I. selected from among the IDEA4RC partners.	57%	13
The results obtained by the pharmaceutical company or commercial actor through simple and complex queries should be communicated to all data providers.	70%	16

Q11. Do you agree or disagree that special rules should apply to allow IDEA4RC partners to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Agree	82%	27
Disagree	18%	6

Q12. In your view, what special rules would be appropriate to allow the IDEA4RC partners to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Only IDEA4RC partners should be allowed to access and re-use data about rare cancers in the first year after the IDEA4RC infrastructure is fully functioning.	19%	5

Only IDEA4RC partners should be allowed to access and re-use data about rare cancers for a limited number of years after the IDEA4RC infrastructure is fully functioning.	37%	10
IDEA4RC should become open to other data users only after each IDEA4RC partner has performed the analyses needed to achieve a set number of publications.	15%	4
Other special rules should apply to allow the IDEA4RC partners to access and re-use data about rare cancers via IDEA4RC.	30%	8

Q13. In your view, what other special rules should apply, to allow the IDEA4RC partners to access and re-use data about rare cancers via IDEA4RC?

Need to have approval of the scientific comittee, bioethics comittee depending on structure
Free license to use IDEA4RC data
It is reasonable that access is limited to IDEA4RC partners for a limited number of years. Also, participating centres have an additional interest in data access for benchmarking and quality control and guidelines should be made for that
Ability to get involved in the research team if they are performed with there data
IDEA4RC partners should always have right to access and re-use their data (data of their patients). Their data should not be re-used by other partners or other subjects without their consent (for example consent of guarantor, PI etc.). But additionally to this I believe that partners should have

administratively easier access (for example they can submit short description of project they need data for, they should sign simple Data Transfer Agreement)

Q14. In your view, for how many years should the IDEA4RC partners be the only ones allowed to access and re-use data about rare cancers via IDEA4RC after the IDEA4RC infrastructure is fully functioning?

2-3
3
3
5
2-3
2 years, to allow for project specific research within the network and ensure enough time to publish
5 years
Depends on the outcome of the project, how well ithe platform functions
3

Q15. In your view, for how many publications should the IDEA4RC partners have performed the necessary analyses before opening IDEA4RC to other users?

10
5
It should be discussed within the consortium.

Q16. Do you agree or disagree that the IDEA4RC partners submitting a data access request should disclose if they (will) collaborate with a pharmaceutical company or another commercial actor on the study?

Answer	Percentage	Count
Agree	94%	30
Disagree	6%	2

Q17. Do you agree or disagree that the special rules to access and re-use data about rare cancers reserved for the IDEA4RC partners should apply also when an IDEA4RC partner collaborates for a study with a commercial actor (e.g., pharmaceutical company, medical technologies company, IT business)?

Answer	Percentage	Count
Agree	74%	20
Disagree	19%	5
Partially agree	7%	2

Q18. In your view, what special rules about the access and re-use of data about rare cancers that apply to IDEA4RC partners should be withheld when an IDEA4RC partner collaborates with a commercial actor for a study?

Each situation should be assessed independently.
The access to the data from the commercial actor should be restricted by the rules for commercial actors.

Q19. Do you agree or disagree that the IDEA4RC partners should be included as co-authors on the publications of external actors based on data about rare cancers accessed via IDEA4RC?

Answer	Percentage	Count
Agree	67%	22
Disagree	33%	11

Q20. In your view, why should the IDEA4RC partners not be included as authors on the publications of external actors based on data about rare cancers accessed via IDEA4RC?

Because data are automatically extracted by the EHe of the hospital, the partners received already funding from the Eu for the activities related to the data processing, the partners should be among the authors only if contributing to the development of the publication
Acknowledgement seems fairer, as the IDEA4RC partners would not be actively involved in the analysis for such a publication.
It is enough to be clearly cited; the authors' work regards analyses, not data collection.
Recognize the work done with an acknowledgement and list the partners in a working group to be cited.
Authorship should be limited to those who concretely contribute to a publication.
Although the data comes from the work we are performing, the research contribution will not. I believe we should be added to acknowledgements not as authors.
Because, it would not be clear who did what (e.g. data collection). Acknowledgements to the consortium or authorship as IDEA4RC consortium would be enough.
If we made the data available, we are just providing a dataset. We are not contributing to those specific research. When you publish a dataset, you expect to be cited, not included as an author.

Q21. In your view, why should the IDEA4RC partners be included as authors on the publications of external actors based on data about rare cancers accessed via IDEA4RC?

Because is thanks of their activity if the data are available.
I partially agree on this statement. It depends on the partners; data providers should be aware and review the publication so likely should be as co-authors. Partners providing the infrastructure maybe devote time on giving access etc., so maybe can be also considered. Partners preparing the data, delivering a solution etc. should be assessed similarly.
It should be defined the role of authors and their involvement in manuscript preparation, clear rules in governance guidelines in terms of publication.
IDEA4RC partners should be included as authors when data from their patients are used in the published study. This is part of the data valorization policies of many institutions.
As guarantors of data integrity. To provide knowledge of underlying data and methods of data retrieval help in interpretation of data.
Because they have put significant resources to collect and structure own data in a manner that can be interrogated by an external organization.
They are contributor so they have to be mentioned as mentioned as contributor.
If it was option I would choose "partially agree". In my opinion this is subject to "case by case" consideration. If only data are provided and there is no other participation I believe that dedication to project IDEA4RC and maybe also affiliation to institutions is sufficient. If more work is done then involved partners should be included as co-authors on the publications.
Because they participated in the development of the tool.
IDEA4RC partners should be included as authors only for those projects for which a specific protocol is prepared and accepted by the IDEA4RC Steering group.
I would not exclude an authorship. If partners are involved in projects with commercial partners I would agree under restricted conditions.

To ensure quality control on research questions and results achieved from the data.
Because they play a key role in any investigation is made using their data. At least they should be acknowledged.
I'm unsure here. Including IDEA4RC-partners as co-authors ensures the correct knowledge in the project, but may be an additional workload. Maybe it could be decided on a case by case basis whether partner(s) are co-authors or if IDEA4RC is just referenced.
As data providers. order of authorship according to number of patients issued from their institution, starting from third position ending third position before the end.

The IDEA4RC Data Access Application and Data Permit

Relevant definitions

In answering the questions in this module, we recommend that you consider the following definitions:

A **data access application** includes the information that a user must submit to request access to individual record data.
A **data permit** is a fixed-term permit from an authority to a user for the processing of personal data.

Q22. In your view, what information should be included in the data access application to obtain permission to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count

A simple data access application, containing only mandatory information about the data needed and the study's purposes.	12%	4
The data access application should include only the essential information in a study protocol.	15%	5
The data access application should include extensive information usually provided in a study protocol: the goal of the study; the type of data needed, the types of analyses to be performed, dissemination of the results methods (if applicable).	67%	22
Other information should be included.	6%	2

Q23. What kind of information should be provided in the study protocol included in the IDEA4RC data access application? You can select multiple answers.

Answer	Percentage	Count
The name of the principle investigator	100%	5
The C.V. of the principle investigator	80%	4
The study's rationale	100%	5
The study's objectives	100%	5
The study's main hypothesis	100%	5
The study's statistical plan	100%	5
An overview of the data analyses to be performed	100%	5
The types of researchers expected to perform the analyses	60%	3

Q24. In your view, what other information should be included in the data access application, to obtain permission to access and re-use data about rare cancers via IDEA4RC?

Ethical aspects, responsibilities of PI and his DOI etc.
Data listed into Article 46 of EHDS - https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022PC0197

Q25. In your view, what would be the most suitable approach to decide about the IDEA4RC data permit?

Answer	Percentage	Count
Each data holder (center of expertise) should be able to decide on a case-by-case basis whether it makes its data available or not.	30%	10
Decisions about access to data about rare cancers via IDEA4RC should be made at a centralized, IDEA4RC level by a multi-disciplinary committee established for this purpose.	64%	21
Decisions about the IDEA4RC data permit should be made using a different approach altogether.	6%	2

Q26. In your view, who should approve the IDEA4RC data permit at the level of each data holder? You can select multiple options.

Answer	Percentage	Count
Data protection officers	90%	9
Data managers	40%	4
Ethical committee members	60%	6
Disease experts	40%	4

Statisticians	20%	2
Data scientists	30%	3
Patient representatives	10%	1
Other actors	30%	3

Q27. In your view, what other types of actors should be involved in the IDE4RC data permit approval at the level of each data holder?

Depending on national regulation.
Patient representatives (only until the EHDS is not yet in force).
Each center probably already has a process for research data application. I think that requests to access data from IDEA4RC must use this existing process. This will probably be different in each center.

Q28. In your view, what approach would be most suitable to select the disease experts to be involved in the IDEA4RC data permit approval at the level of each data holder?

Only clinical experts directly contributing to IDEA4RC should be involved.	25%	1
Clinical experts members of EURACAN should be involved.	50%	2
Another approach should be used to select the disease experts.	25%	1

Q29. In your view, what other approach would be most suitable to select the disease experts to be involved in the IDEA4RC data permit approval at the level of each data holder?

EURACAN members and experts from specific sites.

Q30. You have indicated that neither the data holder, nor a centralized IDEA4RC committee should make decisions about the IDEA4RC data permit. In your view, what other actors or group of actors would be most suitable to make decisions about the IDEA4RC data permit?

To safeguard patient integrity each data holder must be mandated to make decisions on a case-by-case basis on data permit. The other option is that data holders provide a set of requirements under which data can be re-used (e.g. minimum number of patients in the data holders dataset for a given question).

Q31. Do you agree or disagree that it should be possible to appeal a decision made by a data holder not to make its data available for a study via IDEA4RC?

Answer	Percentage	Count
Agree	50%	5
Disagree	50%	5

Q32. What types of actors should be part of the IDEA4RC multidisciplinary committee assessing the data access applications? You can select multiple options.

Answer	Percentage	Count
IDEA4RC clinical partners	90%	19
IDEA4RC technical partners	62%	13
IDEA4RC legal advisors	67%	14
Ethical committee members selected from the IDEA4RC partners	90%	19
Patient representatives	29%	6
Other actors	0%	0

Q33. In your view, what other types of actors should be part of the IDEA4RC multidisciplinary committee assessing the data access applications?

NO ANSWER

Q34. Do you agree or disagree that decisions about the IDEA4RC data access application should be made within a specific time interval?

Answer	Percentage	Count
Agree	100%	33
Disagree	0%	0

Q35. In your view, what would be an appropriate amount of time for a decision to be made and communicated to an applicant about the IDEA4RC data access application?

Answer	Percentage	Count
15 days	16%	5
1 month	47%	15
2 months	38%	12

Q36. In your view, for what time interval should IDEA4RC data holders be allowed to release the date permit?

Answer	Percentage	Count
3 months	16%	5
3-6 months	25%	8
Maximum 1 year	44%	14
A different amount of time	16%	5

Q37. In your view, what different amount of time would be ideal to allow IDEA4RC data permit holders to access and re-use data about rare cancers?

It depends on the objectives of the study.
Clear governance rules should be applied and then the answer may be defined.
It should be considered case by case depending on the purpose for which data are shared.
Up to 5 years.

Financial or other contributions to access and re-use data about rare cancers via IDEA4RC

Q38. Do you agree or disagree that a financial contribution should be required, to allow access and re-use of data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Agree	82%	27
Disagree	18%	6

Q39. What types of actors should be required to make a financial contribution to be allowed to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Only commercial actors.	52%	14
Only non-commercial actors.	0%	0
Both commercial and non-commercial actors.	48%	13
None of the actors described above.	0%	0

Q40. In your view, what criteria would be most suitable to determine the financial contribution required to access and re-use data about rare cancers via IDEA4RC? You can select multiple options.

Answer	Percentage	Count
Different fee rates should apply for **different categories of data permit holders** (e.g., commercial, non-commercial, governmental actors).	85%	23
Different fee rates should apply depending on the **type of study** conducted (e.g., basic research, research with commercial potential).	56%	15
Different fee rates should apply depending on the **expected societal impact** of a study (e.g., substantial improvements in quality of life, advancement in fair access to good quality care)..	22%	6
Different fee rates should apply depending on the level of **economic development of the country** where the actor is based.	33%	9
Different fee rates should apply depending on the **financial profit** made by an actor from the development of a product (e.g., medical drug, technology, software, etc.) where data about rare cancers accessed via IDEA4RC were used.	37%	10
Different criteria should be used.	11%	3
The fee rate should be **the same** regardless of the type of actor, type of study, or expected study outcomes and long-term benefits.	4%	1

Q41. In your view, what other criteria should be used to determine the financial contribution required to access and re-use data about rare cancers via IDEA4RC?

The determination of the financial contribution should be defined based on costs and benefits.
Number of patients to be assessed in the study(ies).

Q42. In your view, for what purposes should the financial contribution required to access and re-use data about rare cancers via IDEA4RC be used? You can select multiple options.

Answer	Percentage	Count
The fee should be used to cover expenses related to the maintenance of the IDEA4RC technical infrastructure (both at the level of data holders and at the centralised level, i.e. orchestrator).	96%	26
The fee should be used to cover the administrative costs required to managetheIDEA4RC data permit.	89%	24
The fee should be used to update and improve the IDEA4RC infrastructure, so that more diverse types of data about rare cancers can become accessible.	74%	20
The fee should be used by each data provider as it sees fit.	15%	4
The fee should be used for different purposes than those mentioned above.	0%	0

Q43. In your view, for what other purposes should the financial contribution required to access and re-use data about rare cancers via IDEA4RC be used?

NO ANSWER

Q44. In your view, which approach would be most suitable to determine and pay the financial contribution required to access and re-use data about rare cancers via IDEA4RC?

Answer	Percentage	Count
The fee should be fixed and its payment made upon receiving the data permit approval, but prior to accessing the data.	63%	17
The fee should be fixed and its payment could be made any time during the period for which access to data is granted.	4%	1
The fee should consist of (1) a set obligatory amount and (2) an additional amount, to be determined and paid retrospectively, only if/when financial profit is made from products developed (also) through the use of data about rare cancers via IDEA4RC.	33%	9
A different approach than those mentioned above should be used.	0%	0

Q45. In your view, what other approach would be most suitable to determine the financial contribution required to access and re-use data about rare cancers via IDEA4RC and when it should be paid?

NO ANSWER

Q46. Do you agree or disagree that another kind of contribution than a financial one should be required, to allow access and re-use of data about rare cancers via IDEA4RC?

Answer	Percentage	Count
Agree	17%	1
Disagree	83%	5

Q47. In your view, what kind of non-financial contribution (e.g., service provision, expertise, tools, etc.) should be required to allow access and re-use of data about rare cancers via IDEA4RC?

I partially agree on the previous comments: financial contribution can be considered depending on the use scope, and other non-financial contributions can be done if it implies research that can benefit both IDEA and external actors.

Q48. You have reached the end of the survey. If there are other insights regarding the IDEA4RC data governance model that you would like to share, please write them down below.

There are missing information about profile of respondent and because the benefits of data usage are different and the contribution to produce the data set is strictly related to user profile, it was not possible to select the right answer, because the bottom "other" or "not applicable" was missed, in many question there were no clear definitions, in some questions there were missing information about general governance and decision making process allowing implementation, in some question free text options were missed.
Regarding the fees. Generally, I believe that non-profit (academic) researchers should have free access to data. However, I chose the option "both commercial and non-commercial actors" because even non-commercial actors - for example public bodies or non-profit organisation like EORTC, OECI, DIGICORE can conduct research projects which can have

commercial potential - for example data registries which can be exploited also by pharmaceutical sector. In such case the fees should be charged.
It should be aligned as much as possible to EHDS regulation to maximise the reuse of project results after the end of the project.
I think that we have a lot of confusion in IDEA4RC because we talk about what will happen during the project and after at the same time. When communicating about these questions, it's important to be clear about what phase we are talking about. For example, the data permit process would probably look completely different during the project (among project partners) and after (for other researchers). Our ethics committee can only approve the reuse of data within a clearly scoped project and timeframe, not for all use cases forever.

APPENDIX 3 – REQUIREMENTS FOR DATA GOVERNANCE FOR NORWAY

Article 9 Paragraph 4 of the GDPR states that member states may "maintain or introduce further conditions, including limitations, with regard to the processing of data concerning health". This also applies to EEA-countries including Norway.

The Norwegian Health Register Act contains overall and uniform conditions for making available and collating health information applicable to all health registers covered by the Act, such as the Cancer Registry of Norway. The conditions are to be understood as a clarification and visibility of the terms and elements that are currently either to be given weight according to the GDPR, the Health Register Act, the Health Research Act and the regulations covered by the Health Research Act, or which are given weight by the data controllers when they assess applications for access to data.

The regulations covered by the Health Research Act, refer to and set stricter and more specific requirements than the general rules on processing in the Personal Data Protection Regulation and the Health Research Act. The regulations also provide the data controllers with a supplementary legal basis for access and compilation.
The applicable conditions in Norwegian legislation making available direct and indirect information on health from health registries, including the Cancer Registry is listed below:

- *The information must be used for an expressly stated purpose that is within the purpose of the register.*
- *The disclosure must be in accordance with the obligation of confidentiality in that the data subject has consented or in that the disclosure is covered by an exception or dispensation from the obligation of confidentiality.*
- *The recipient must be able to prove that their own processing will have a legal basis according to Articles 6 and 9 of the GDPR.*
- *The use must be within the data subject's consent, in cases where consent has been obtained.*

- *The data subject must not have objected to the making available, in cases where the data subject has a right to object to this.*
- *No more information shall be made available than is necessary for the purpose of the recipient's processing.*
- *The information must be made available without name, national identification number or other directly identifiable characteristics, unless special reasons make it necessary for the recipient to obtain the information with such characteristics.*
- *The recipient must explain what suitable technical and organizational measures are to be put in place to safeguard information security (confidentiality of the information, integrity, etc.).*
- *Making it available must be safe from ethical, medical, and health-related considerations.*
- *For medical and healthcare research, the recipient must have received prior approval from the regional committee for medical and healthcare research ethics (REK).*