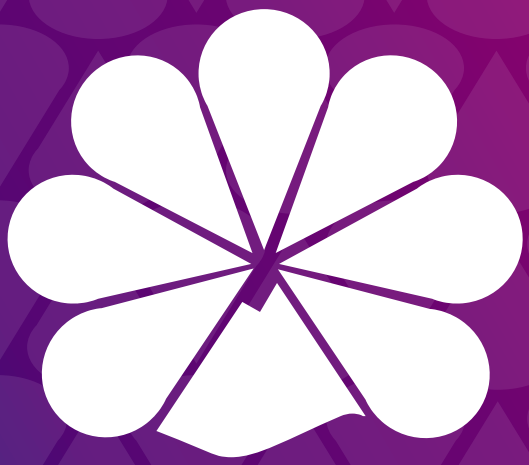

RADeep

Data Access Policy

Revision v1.0

Background

This Data Access Policy document applies to the RADeep registry. It covers the composition of the Data Access Committee (DAC) as well as the entire process to be followed for requesting and granting access to the data captured in the RADeep registry.

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1. Definitions and abbreviations

The **RADeep Consortium** is formed by:

- Vall d'Hebron Research Institute (VHIR) / Vall d'Hebron University Hospital (HUVH), Spain - Principal Investigator: Maria del Mar Mañú Pereira
- Hôpital Erasme (ERASME), Belgium - Principal Investigator: Béatrice Gulbis
- The Cyprus Institute of Neurology and Genetics (CING), Cyprus - Principal Investigator: Petros Kountouris

The Consortium is in charge of overall governance and global strategy of RADeep. A Consortium Agreement defines respective roles, rights and relations among parties forming the Consortium as well as their equal responsibilities on data protection in terms of General Data Protection Regulation based on the Joint Controllership of data (Art. 26 GDPR).

As per RADeep Consortium agreement, **RADeep Steering Committee** consists of one representative of each party of the Consortium (VHIR, ERASME, CING), one haematologist, one paediatrician, one laboratory specialist, 2 patients representatives, one IT and statistical analysis specialist, and one platform manager. The composition of the RADeep Steering Committee is available here: https://www.radeepnetwork.eu/governance/.
The RADeep Steering Committee is in charge of the common and transversal tasks for RADeep coordination and implementation of the different disease specific arms, as well as defining RADeep's Study protocol, including the establishment of the common data elements for rare anaemia disorders (CDE-RAD).
The RADeep Steering Committee is responsible for drafting the Policy for data access and publishing.

DAC: Data Access Committee

Health Care Provider (HCP) Institution : Any legal entity providing healthcare on the territory of a Member State of the European Union.

Data Providers: Legal entity situated in one of the Member States of the European Union, coordinating a patients' registry or a multi-center/national/regional network of HCPs or individual HCPs who have signed a Collaboration agreement with VHIR (acting as the RADeep coordinator) and provided patients' data to RADeep.

Data sharing: Sending personal data or making it accessible within the European Economic Area (EEA).

Data transfer: International transfer of personal data which involves sending personal data or making it accessible from an EEA country to recipients located outside the EEA.

Data subject : an identified or identifiable natural person
RAD: Rare Anaemia Disorder

Secretariat: a designated member from the RADeep consortium in charge of assessing the eligibility of data requests.

Data Requestor: Legal entity requesting data from RADeep, i.e. HCPs and research centres from both public and private institutions, patients associations, health authorities, or regulatory bodies.

2. Introduction to RADeep registry

RADeep supports the standardized collection of data of patients affected by any RADs at the European level, maximizing public benefit from data on RADs. RADeep guarantees data subjects rights and confidentiality, in agreement with the General Data Protection Regulation (GDPR) and applicable laws for cross-border sharing of personal data. RADeep has the following major objectives:

a) To collect and describe the demographics, disease-management, and treatment outcomes of patients diagnosed with RADs
b) To perform observational studies concerning research questions and to present outcomes in the fields of health related to organ damage and risk stratification for identification of trial cohorts for new drugs and/or development of research projects
c) To allow the re-use of data gathered in the platforms by other stakeholders (“Data Requestors”) in agreement with GDPR.
d) To promote harmonisation and best practices in the prevention, diagnosis, treatment and follow-up of RADs patients by the dissemination of reliable guidelines and the translation of research results into clinical practice.

3. Ethics and Data Governance

The RADeep registry has been approved by the ethics committees of the members of the Consortium, when needed. For further information, visit https://www.radeepnetwork.eu/.
The data governance standards in the RADeep registry comply with the GDPR.

In regards to the ownership of the Data:

- The patient participant (who is the ‘Data subject’) is the primary owner of the data. In case the patient participant is under the minimum age for consenting to the processing of his/her personal data (depending on national law), or subject physically or legally incapable of giving consent, parent(s) or legal guardian(s), is/are the primary owner(s) of the data.

Data Providers are Controllers of the data of the patient participant that they provide to RADeep and act as “data controller” at their site. In this sense, Data Providers undertake to comply at all times with their Data Protection obligations under the Collaboration agreement with VHIR and, in particular, Data Providers ensure that any personal data

- shared with RADeep are collected or obtained in a lawful or legitimate way in order to be shared according to the needs of RADeep, including (when allowed in the Collaboration agreement signed between RADeep and Data Provider) for the re-sharing with third parties, as well as they ensure that appropriate technical and organisational measures have been implemented with respect to the data provided to RADeep to ensure a level of security appropriate to the risk, in accordance with Article 32 of the GDPR.
- VHIR/HUVH, ERASME and CING, partners of RADeep, are Joint Controllers of the processing of the patient's data in RADeep, and also the "data processors", with responsibility for the protection of the data, its storage, use and access.
- When processed by a Data Requestor, the data become research data and the RADeep Consortium and Data Requestor are controllers of this data within the scope of their respective processing. Therefore, Data Requestor is also considered a Controller with respect to the patient's data which it processes in RADeep.

When approved by the DAC, data must be effectively anonymised or pseudonymised/de-identified prior to releasing them to Data Requestors.
A Data Sharing/Transfer Agreement must be in place with all the Data Requestors being granted access to the data. In this agreement, Data Requestors will ensure that they will use the data only in the research defined in their application, that they will treat datasets in confidence, and declare that they refrain from any attempt to re-identify data subjects through including, but not limited to, linkage with other datasets, use of publicly available databases. Furthermore, the data Sharing/Transfer agreement will lay out principles on publications, following the rules established in the RADeep Publications and Authorship Policy.

4. Data Access Committee (DAC)

COMPOSITION

The DAC comprises:

- Members of the Steering Committee
- One expert on legal issues
- One expert on ethical issues
- Biostatistician
- Representatives of Data Providers meeting the following criteria:
  - providing pseudonymised patient level data and
  - Being a National/Regional registry or multi-center Network disease related

FUNCTIONING

The DAC will meet remotely 6 times a year, if needed.
Members of the DAC can decide to name one permanent substitute. Substitutes' names and qualifications will need to be given to the RADeep Consortium. Substitutes will vote and have the same decision level as representatives in the DAC.
The term of the DAC members (other than members of the Steering committee) is two years, renewable.
Members of the DAC declare their conflict of interest when they join the DAC and update every

year.
Quorum: For a meeting to take place, 2/3 of DAC members will need to be present or represented by their permanent substitute.
Decisions will be made at a 2/3 majority of present DAC members. There will be no possibility to vote electronically, via email or other, as members need to participate in the discussion to have a clear understanding of different perspectives before they vote.

DAC members shall:

- Read all documents provided by the RADeep Consortium Secretariat at least two weeks ahead of the meetings, in order to make informed decisions.
- Be present or represented at at least 2/3 of the meetings
- Will receive no financial compensation for their participation in DAC meetings.

TASKS

The tasks of the DAC are divided into two main categories:

In regards to the RADeep general governance:

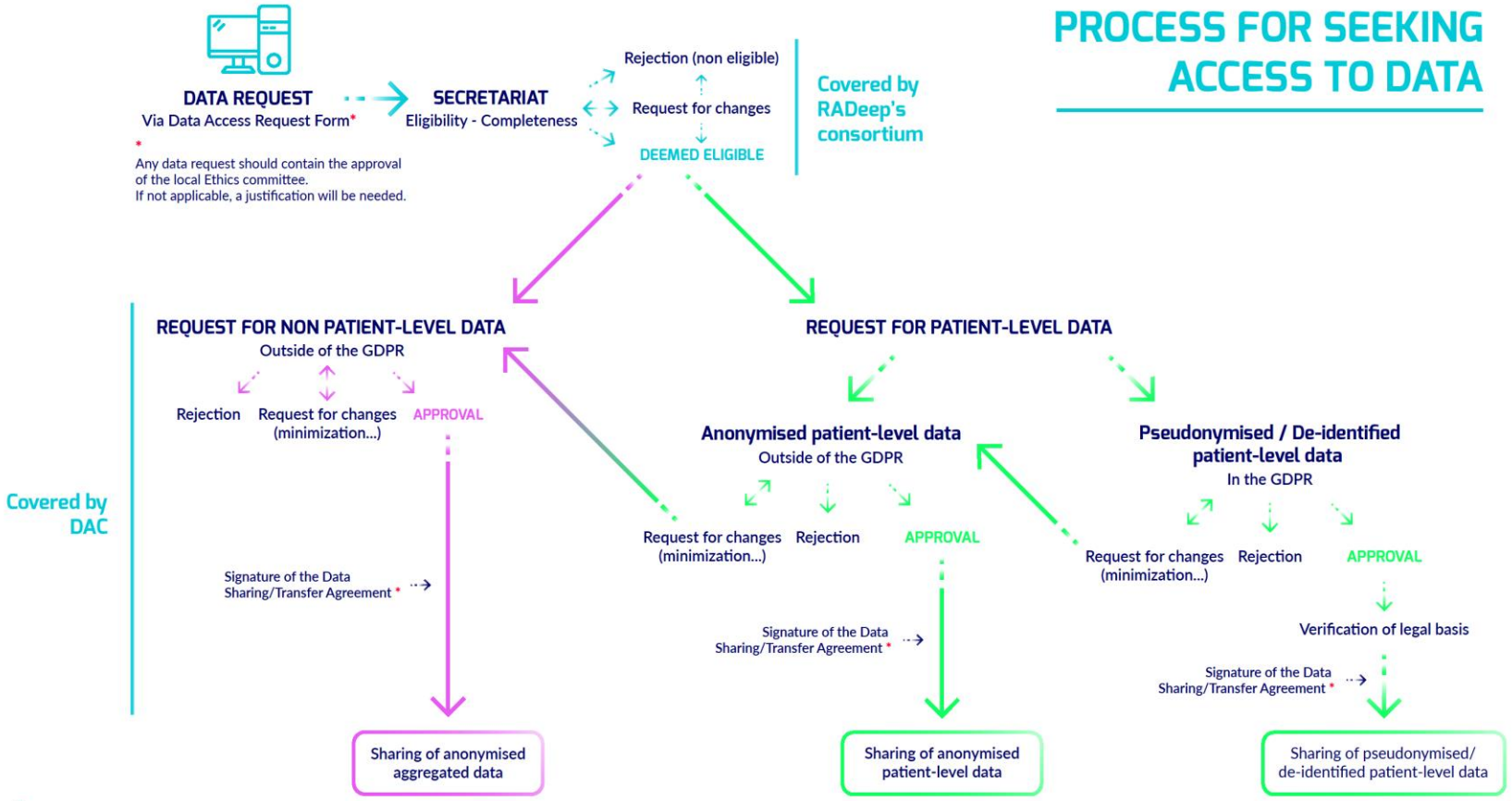
- Reviewing and approving the governance processes within DAC, as well as the Data Access Policy.
- Approving the protocol for data processing by the RADeep Consortium to obtain anonymized data for annual publications and website :
    - Epidemiological reports
    - Disease burden reports
- Reviewing the RADeep Publications and Authorship Policy, including policy for publications by the RADeep consortium, by Data providers and by Data Requestors.

In regards to the requests from Data Requestors:

The main role of the DAC is to review the requests of access to data in RADeep, following criteria listed below:

- The request is aligned with RADeep main objectives
- The project respects the principle of data minimization, i.e. requests only data needed to achieve its objective. If it is not the case, the DAC will issue an amendment request including a proposal of elements to be shared
- There is no major overlap with research led by the RADeep consortium. If it is the case, access to data could be delayed after publication.
- If the DAC detects any overlap with an ongoing project outside of the RADeep Consortium, it shall notify the concerned Data Requestor and seek synergy whilst respecting confidentiality.

5. Process for seeking Access to Data



*
Data will be used only for the purpose intended and approved;
EU legislation is respected
There will be no attempt to re-identify data, including merging RADeep data to other sources of data,
There will be no attempt to directly contact the data subjects, and
Principles on publications will be laid out in the data Sharing/Transfer agreement, following the rules established in the "RADeep Rules for publications" document.

- Data Requestor shall need to complete the Data Request Access Form which will be available on the RADeep website.
  Data Requestors can request the following type of data:

Pseudonymised / De-identified patient-level data	All the personal data that directly relates to the patient are removed and replaced by a pseudonym. Only the data provider is able to link the pseudonym to the patient's direct identifications. Pseudonymised data can be used to distinguish individuals and combine their data from different records. Their processing is subject to data protection regulations.
Anonymised patient-level data	This can be achieved by removing all information that could be used to indirectly identify a patient. It may be necessary to obfuscate data by slightly changing the original data. Anonymised data are no longer considered as personal data and are not subject to data protection regulations. Once anonymised, the process is irreversible.
Anonymised aggregated data	All the personal data that relate to the patient is processed in a manner that makes it impossible to identify individuals on the basis of the data. Anonymised data are no longer considered as personal data and are not subject to data protection regulations. Once anonymized, the process is irreversible.

- The completed forms shall be submitted to the Secretariat of the RADeep Consortium via coordination@radeepnetwork.eu
- the Secretariat will provide an acknowledgement of receipt to the Data Requestor
- The Secretariat will check the completeness of the Data Request Access form and the eligibility of the Request, taking into account following criteria:
  - Data Requestor is a legal entity, based in or outside the EEA
  - Data Requestor is appropriately qualified for use of the data (revision of curriculum vitae);
  - For patients organisations: Not-profit Organisations where patients and/or carers represent a majority in governing bodies, formally constituted and with a legal entity (Association Registration and Incorporation Status or bylaws), and representing one of the diseases covered by RADeep will be deemed eligible.
  - When required by a regulatory authority or by law, Data Requestor has obtained authorisation from their local ethics review committee / Institution Review Board in order to perform the research defined in the application.
- If needed, the Secretariat will ask for additional information or first necessary changes before forwarding to the DAC.
- Data requests will be compiled by the RADeep consortium Secretariat and sent for revision to members of the DAC at the latest two weeks before the meeting. The secretariat will also inform the DAC about rejections made on the basis of the eligibility criteria.

- Neither the RADeep consortium nor the secretariat will make suggestions on a potential approval or rejection of the request based on scientific content.
- The DAC will review requests and make a decision in meetings organised every 2 months by the Secretariat, following a yearly calendar shared in advance.
  Feedback will be provided in the format as listed below:
  - Approval
  - Rejection
  - Request for amendment
- The Secretariat shall provide the feedback from the DAC using the Feedback Form promptly after the DAC meeting.
- When data sharing is approved:
  - Pseudonymised patient-level data are subject to GDPR and for this reason, Pseudonymised data shall only be shared with respect to those patients for whom the Data Providers have obtained consent, or other legal basis under article 6.1 and 9.2 of the GDPR, that allows RADeep to share data with third parties.
  - Anonymised patient-level data and anonymised aggregated data are out of the GDPR and do not need additional levels of approval before being shared.
  - If granted access, the Data Requestor **always** needs to sign a Data Sharing/Transfer Agreement. A Data Sharing/Transfer agreement model will be accessible on the RADeep website https://www.radeepnetwork.eu/.

  The Data Sharing/Transfer agreement:
  - will ensure that Data Requestors treat datasets in confidence and refrain from any attempt to re-identify data subjects through including, but not limited to, linkage with other datasets, use of publicly available databases.
  - will ensure that Data Requestors only use the data for the research defined in their application
  - lays out principles on publications, as per rules established in the “RADeep Publications and Authorship Policy” document.
- The information about projects given access to RADeep data will be made publicly available on the RADeep website, https://www.radeepnetwork.eu/.

6. Levels of authorization to access data

Authorization to access data for members of the consortium:

	Data to be shared	Highest Data level to be shared	Access modalities	DAC request
Members of the RADeep Consortium for platform management	All data	Pseudonymised patient level	Authenticated*	No
Members of the RADeep Consortium when producing publications	All data	anonymised data	Authenticated*	Yes, approval for the protocol for processing of data

*Access of authorised users to the registry is controlled by assignment of a secure, individualised password.

Authorization to access data for Data providers:

	Data to be shared	Highest data level to be shared	Access modalities	DAC request / Data Sharing/Transfer agreement	Fee
Registry/Network Coordinator	All data in their Registry / Network	Pseudonymised patient level	Authenticated*	No	No
HCPs contributing directly or via a local or national Registry / Network	All data coming from their HCP	Pseudonymised patient level	Authenticated*	No	No
All Data Providers and their HCPs contributors, when acting as Data Requestors	All data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	No
	All data in RADeep for which the consent has been obtained or for which another legal basis under the GDPR allows the re-sharing of data.	Pseudonymised/De-identified patient level	Extraction	Yes	No

*Access of authorised users to the registry is controlled by assignment of a secure, individualised password.

Authorization to access data for Data Requestors:

	Data to be shared	Highest data level to be shared	Access modalities	DAC request / Data Sharing/ Transfer agreement	Fee
Non Contributing Researcher / Health Care Provider in the EU	All data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	Yes*
	All data in RADeep for which the consent has been obtained or for which another legal basis under the GDPR allows the re-sharing of data	Pseudonymised patient level	Extraction	Yes	Yes*
Non Contributing Researcher / Health Care Provider Outside the EU	All Data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	Yes*
Industry / Pharmaceutical company	All data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	Yes
Health Authorities / Regulatory bodies	All data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	No**
Patient organisation* **	All data in RADeep	Anonymised patient level data or anonymised aggregated data	Extraction	Yes	No

* A fee will be requested from Data Requestors, and may vary depending on analysis involved.
** Exceptions may apply
*** See eligibility criteria

7. Governance review

This document will be reviewed every year by the DAC and may be subject to change per regular vote as described in section 4.