RADeep

Publications and Authorship Policy

Revision v1.0

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The following guidelines must be used for each publication using data or results generated as part of the RADeep Registry.

1. Publications by the Steering committee

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. 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).
RADeep Steering Committee is responsible for drafting the Policy for data access and publishing.

The Steering committee is planning two publications per year (one on overall epidemiology / one on overall disease burden).
All publications will be published in Open access journals.
The Steering Committee will strive to publish in journals with flexible policy for large numbers of authors.
Protocols for RADeep publications will be submitted to the approval of the Data Access Committee.

1) Publications of the Steering Committee will be co-authored by:
- Members of the Steering committee and their team members.
- Data providers[1] whose data has been used to produce the publication, following minimal contribution criteria (See below*).
- Whenever a multi-center Registry/Network is included as a co-author, the HCPs contributing to this Registry can also be included as co-authors, provided that
    a) they participated in the most recent RADeep mapping exercise
    b) they made a minimal contribution*, following the same rules as apply at the level of the Registry/Network.
    c) Journal allows for the inclusion of a sufficient number of authors
- At least one author from each Data Provider contributing with the minimal criteria will be included, with order being set relatively to the total number of patients provided for the publication.

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[1] Data Providers are the participating registries or HCPs who have signed a Collaboration agreement with VHIR (as RADeep coordinator) and entered and/or transferred data to RADeep.

- Additional co-authors per Data Provider will be included relatively to the total number of patients they provided for the publication, and the possibilities offered by the journal.
- HCPs fulfilling the criteria of the minimal contribution but excluded as authors due to journal limitations in number will be listed in the annex of the publication, linked in Pubmed and cited on the RADeep website

* Minimal contribution to RADeep in order to be included as a co-author in a publication is a minimal percentage of patients relative to the total number of patients in current regular follow-up at the level of the Data Provider. Numbers of patients in current regular follow up per disease will come from a mapping exercise conducted yearly by the RADeep team, in collaboration with Data Providers. For the purpose of the RADeep study, a patient "in current regular follow-up" is a patient who has been tracked during the last two years. This active follow-up or tracking should include regular medical check-ups, which include physical examination, laboratory test, and imaging assessments. The regular medical check-up is determined by the characteristics and behavior of the illness. It is defined, in hematological diseases, according to international guidelines, as at least one medical visit or check-up in the last two years.

Only patients meeting the inclusion criteria for the publication will be considered in that calculation (e.g. percentage of patients with SCD enrolled on the platform (meeting the inclusion criteria for the publication) relatively to total number of patients with SCD (meeting the inclusion criteria for the publication) in current regular follow up by Data Provider)

Only patients with ALL relevant data elements for the publication will be considered, e.g. epidemiology vs disease burden.
Example of a publication on SCD:

Total number of patients with SCD followed by Data Provider (as per RADeep mapping), and, if Data Provider is a National Registry/Network, followed by HCPs contributing to Data Provider	Minimum number of patients with SCD to be enrolled in RADeep (with all data elements)
0 to 125 patients	50 % of patients need to be enrolled
125-250 patients	50% of first 125 patients and 40% of following 125 patients need to be enrolled
250-500 patients	50% of first 125 patients, 40% of following 125 patients, and 30% of following 250 patients need to be enrolled
More than 500 patients	50% of first 125 patients, 40% of following 125 patients, 30% of following 250 patients and 20% of following patients need to be enrolled

Eligibility: Minimal nb of patients
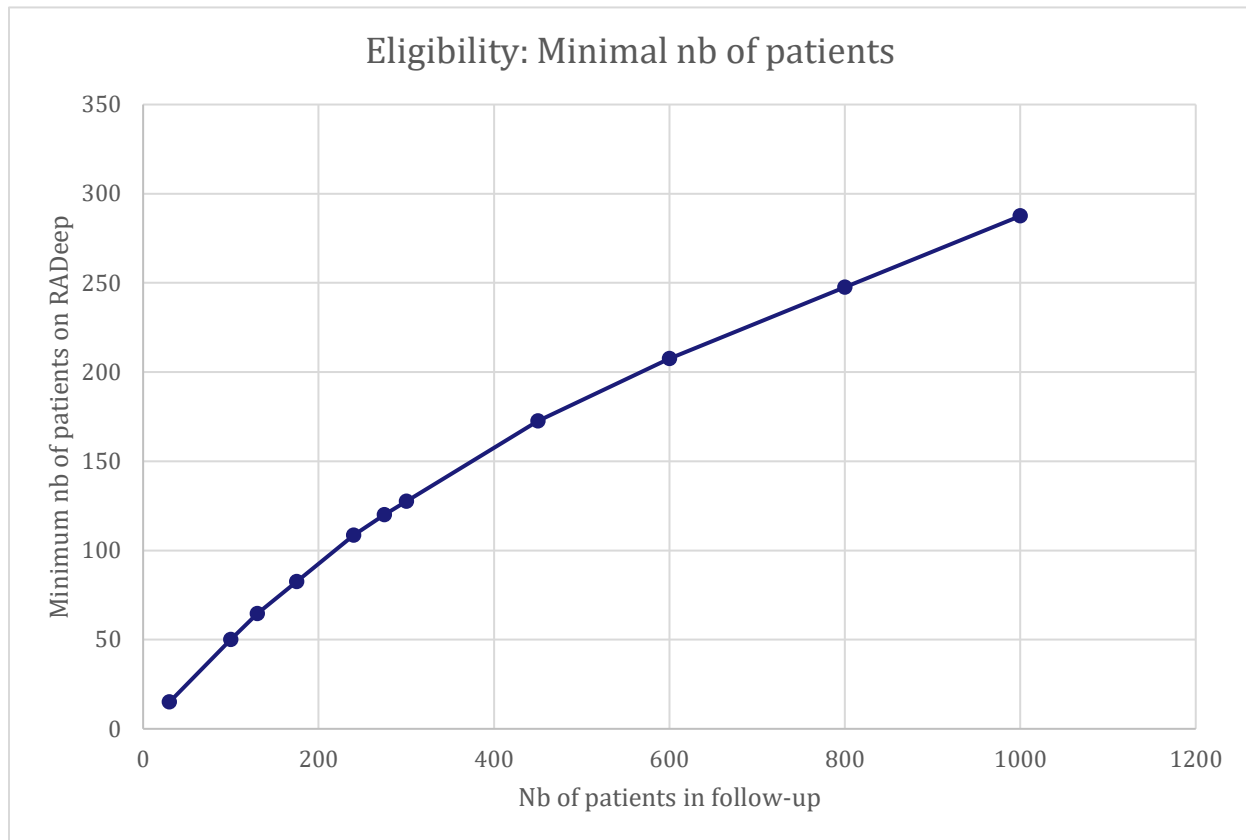
2) **Publications of the Steering Committee will include acknowledgement to :**
- ENROL
- The ERN-EuroBloodNet

2. Publications by Data Providers <u>on their own data</u>

Data Providers are the participating registries/networks or HCPs who have signed a Collaboration agreement with VHIR (as RADeep coordinator) and entered or transferred data to RADeep.

Data Providers (and, in the case of multi-centers Registries/Networks, individual Centers that they cover) can publish <u>their own data</u> without prior approval of the Steering committee.

In order to not jeopardize RADeep's objectives in the reporting and public dissemination of the results of the Project (linked to financial sustainability), Data Providers shall delay publications on epidemiology and overall disease burden reports on large local/national datasets to <u>after June of each year</u>, which is when the RADeep team plans to publish their reports on the RADeep data at European level.

Any publication made possible thanks to the support/added value of RADeep (CRF, codification, platform, standardization...) will need to include **acknowledgment** to RADeep, ENROL and the ERN-EuroBloodNet.

Any publications made possible thanks to the support/added value of RADeep (CRF, codification, platform, standardization...) will be encouraged to be published in Open access journals.

3.   Publications by Data Requestors

Data Requestors are any legal entity being granted access to RADeep data by the Data Access Committee.

The Data Access Committee will only grant access to Data Requestors if there is no conflict/overlap with research led by the RADeep consortium / Data providers.
If it is the case, access to data could be delayed **after** publication by RADeep.

All publications by Data Requestors will need to include **acknowledgement** to:
   •   RADeep, ENROL and the ERN-EuroBloodNet.
   •   All Data Providers whose data has been used for publication, following the alphabetical list of Data Providers by country.
Data requestors will also be encouraged to list / cite / acknowledge Individual Centers covered by multi-centers Registries/Networks, according to the list provided to RADeep by Data Providers.

All publications made possible thanks to data coming from RADeep will need to be published Open access.

Publications will be reviewed prior to publication by the Steering Committee to ensure:
   •   Use of data sets according to Data Sharing/Transfer agreement
   •   Inclusion of the acknowledgement
Scientific content of the publications will NOT be reviewed.

Rules for publications and text for acknowledgement will be included in the Data Sharing/Transfer agreement that will be signed between VHIR (as RADeep coordinator) and Data Requestor.

RADeep can become a collaborator of a publication instead of a Data Provider for a publication. In that case there can be a co-authorship and same rules will apply as the ones for RADeep publications.

4.   Governance review

This document will be reviewed by the RADeep Data Access committee every year and may be subject to change.