Data Access Policy (DAP)

Core Registry and e-Reporting of Rare Conditions (e-REC)

		Page
1	Data Access Committee	2
2	The Role of The Data Access Committee	3
3	Utility Of The Core Registry	3
4	Utility Of The e-REC	3
5	Role Based Access Rules	4
6	Ownership Of Data	4
7	Ethics & Data Governance	4
8	Research & Data Analysis	5
9	Process For Seeking Access To Data	5
10	Dissemination Of Data Analysis Activity	5
Appendix 1	Data Flow Within The Core Registry	6
Appendix 2	Data Flow Within e-REC	7
Appendix 3	Data Request Form	8
Appendix 4	Data Sharing Agreement	10
Appendix 5	Data Access Committee Feedback To Data Search Requests	16
Appendix 6	Overview of Data Access Approval Process	17

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This Data Access Policy (DAP) applies to the two registries (Core Registry and e-REC) that are run within the EuRREB project (https://eurreb.eu/). EuRREB is the merged continuation of two projects, EuRRECa (2018 – 2023) and EuRR-Bone (2020 – 2023). The DAP has been developed and updated by the Registries Team. It covers the entire process that will be followed for requesting access to the data in the two registries as well as the composition of the Data Access Committee (DAC) that will consist of a core DAC composed of Chair, the Registries Team, patient representatives, and representation from allied groups including ESPE, ESE, ECTS, and ISCBH. In addition, the DAC will rely on a group of experts who will be co-opted depending on the theme of the submitted application.

Name of system: Core Registry and e-Reporting of Rare Conditions (e-REC)

1. Data Access Committee (DAC):

Chair	Olaf Dekkers, Leiden University Medical Centre
EuRRECa PI	Faisal Ahmed, University of Glasgow & Leiden University Medical Centre
EuRR-Bone PI	Natasha Appelman-Dijkstra, Leiden University Medical Centre
Project Manager	Tess de Rooij, Leiden University Medical Centre
Chair Steering Committee	Agnès Linglart, Assistance Publique–Hopitaux de Paris
Endo-ERN ePAG	Arlene Smyth, Office for Rare Condition Glasgow
Endo-ERN representative	Pietro Maffei, Azienda Ospedaliera di Padova
ESPE Representative	Olaf Hiort, University of Lübeck
ESE Representative	Kristi Alexandraki, National and Kapodistrian University of Athens
ECTS Representative	Carola Zillikens, Erasmus Medical Centre, Rotterdam
ISCBH Representative	Ciara McDonnell, Children's Health Ireland, Dublin
ISCBH Representative	Adalbert Raimann, Vienna Bone & Growth Centre
ERN BOND ePAG	Tenna Toft, XLH Alliance, Denmark
Bone Expert	Roland Chapurlat, Université de Lyon
Bone Expert	Gabrielle Hausler, Vienna Bone & Growth Centre

Future Composition of the Committee

The current composition of the DAC reflects the Steering Committee of the EuRREB project, originally funded by European Union's Health Programme (2014-2020) and currently supported by the European Reference Network on Rare Endocrine Conditions (Endo-ERN) and Bone Conditions (ERN BOND). The composition fixed to a limited term of 4 years and the composition of the Committee will continue to reflect its principal stakeholders and supporters.

2. The Role of the DAC

The overall aim of the DAC is to promote the research use of the data that are being collected in the registries through a transparent and simple approach ensuring the long-term sustainability of the project. The DAC should advise on the maintenance of the highest levels of custodianship of the data. Whilst it should have a good knowledge of ethics and data protection, it should not act as another 'research ethics committee' which is a responsibility that rests at the level of the data controllers. The DAC should:

- Check that the proposed work complies with the terms and conditions of the ethics approval provided to the EuRREB project;
- Look for evidence of the third party who is requesting the data is appropriately qualified for use of the data;
- Advise on improving the projects and any overlaps with ongoing projects;
- Advise on the dissemination and publication plans;
- Ensure that the effort of all those involved is appropriately acknowledged;
- Aim to respond to all data requests promptly;
- Communicate to the requestor with appropriate feedback;
- Be aware of their own conflicts of interest;
- Treat all data requests confidentially;
- Review and advise on the governance processes within DAC.

For further reading, Cheah, P.Y., Piasecki, J. Data Access Committees. *BMC Med Ethics* **21,** 12 (2020). https://doi.org/10.1186/s12910-020-0453-z

3. The Utility of the Core Registry

It is expected that the Core Registry will solely be used to perform Secondary Research on the data that shall be collected during routine clinical care and this form of research is approved under its current ethics approval and have also been described in the participant information sheet. It is anticipated that, in time, these data will be used for the following purposes by a wide range of stakeholders:

a. Provide a source population for the conduct of clinical trials;
b. Provide the patient with details of their condition;
c. Provide information on specific interventions related to defined patient groups;
d. Provide for the follow-up of small patient populations;
e. Life-cycle assessment of the effectiveness and safety of interventions and medicinal products
f. Provide robust data on disease epidemiology, patients' characteristics and current standard of care;
g. Provide source population data that can be linked to other datasets on specific outcomes;
h. Facilitate the designing of pragmatic trials for rare conditions as well as post-authorisation studies.

4. The Utility of e-REC

e-REC is a 'light-touch' registry. The data collection system is designed to minimise the reporting burden on health care professionals and as it does not collect any identifiable data, it does not require informed consent. Its purposes include:

a. understanding the level of activity that is occurring amongst the participating centres;
b. provision of data to participating European Reference Networks such as Endo-ERN and ERN BOND for their continuous monitoring exercise;
c. understanding how many people are affected by a particular rare condition;
d. providing feasibility data for future studies;
e. understanding the process of diagnosis and initial presentation of rare conditions through secondary surveys.

5. Role Based Access Rules

The following broad groups of stakeholders will require access to the data in the Core Registry:

Patient	This group will have read-only access to their own individual data. In addition, they will be able to complete online questionnaires.
Clinical Contributor	This group will have access to all the cases at their centre. They will also be able to provide access to other members at their clinical team.
Centre Lead	Responsible for the governance at local centre and serves as the contact person of the local centre for the Registries Team.
Centre Administrator	Can create new users at centre and have read-only access to data.
Researcher	This user will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
Registries Team	Access to all data and provides role-based access.

The following broad groups of stakeholders will require access to the data in the e-REC:

e-REC Reporter	This group will have access to the data of newly encountered cases seen monthly in their centre.
e-REC Analyst	Will have read only access to the e-REC registry to perform analysis on data reported by all centres.
External Researcher	This user will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
Registries Team	Access to all data and provide role-based access.
European Commission	This stakeholder will have access to the aggregated data.

6. Ownership of Data

- In the Core Registry, the patient participant (who is the 'data subject') is the primary owner of the data and will grant each of the users and the Leiden University Medical Centre a nonexclusive licence to use such data for research purposes. In case the patient participant is under the age of 16 or 18 years (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 and will grant each of the users and the Leiden University Medical Centre a nonexclusive licence to use such data for research purposes.
- The Leiden University Medical Centre is the current owner of the e-REC and the Core Registry platforms.
- The institution of the clinician participant who has entered the data is the owner of the aggregated data of that patient participant and acts as the 'data controller' at the local centre.
- The Leiden University Medical Centre is the sponsor of the EuRREB registries and acts as the custodian of the data, acts as the 'data controller' of the registries and also as the 'data processor' with responsibility for the protection of the data, its storage, use and access
- When processed, the data become research data and are then the intellectual property of the investigator who is the 'third party'. This third party has to abide by the agreement reached in the Data Sharing Agreement whilst using the data supplied for the purpose stated in the Data Request Form.

7. Ethics & Data Governance

The Core Registry has been approved in the Netherlands by the institutional board of the LUMC 'research databases'. For further information visit https://eurreb.eu/registries/ethics-approval/.

- The data governance standards in the e-REC and the Core Registry comply with General Data Protection Regulation (GDPR).
- A research project using data from Registries will be considered to have ethics approval subject to the following conditions:
    - The research project is within the fields of research described in the application.
    - The research protocol has been subject to scientific critique by the Data Access Committee, is appropriately designed in relation to its objectives and is likely to add something useful to existing knowledge.
    - The processing of the data in the Core Registry will comply with the terms of informed consent from data subjects.
    - Research must be conducted in circumstances such that data subjects are not identifiable to the

external researchers. Data must be effectively anonymised or pseudonymised prior to release to external researchers.

- The researchers should undertake to treat datasets in confidence and not to attempt re-identification of data subjects through linkage with other datasets.
- A Data Sharing Agreement must be in place with all external researchers to ensure processing of the data in accordance with the terms of the ethics approval and any other conditions required by the Registries Team.

- Any research project that requires external researchers to be able to identify data subjects for linkage with other datasets, for collecting further data from subjects or for undertaking other research procedures involving subjects, is not covered by this approval. Such projects should be the subject of further project-specific application for ethics review.
- All centres who consider participating in the two registries (e-REC and Core Registry) should consider themselves as local data controllers and secure approval from local institution before contributing data.
- On approval of any research project by the DAC, approval from individual centres will be obtained before their data are shared for any research project. Whilst ethics approval already exists to use the data for research under the conditions mentioned above, local regulations may vary and individual centres may also want to check whether they need any additional approvals locally.

8. Research & Data Analysis

- The data in the Core Registry and e-REC shall undergo 6-12 monthly analysis by the Registries Team to provide progress reports to the DAC. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the DAC but shall be performed closely with the oversight of the DAC.
- All other analysis will require completion of a Data Sharing Agreement and the Data Request Form.
- It is anticipated that the data from the e-REC may be required for performing secondary surveys. These surveys will be brief and performed by the Registries Team on behalf of researchers and following approval by the DAC. The surveys will be designed jointly by the researchers and the Registries Team.

9. Process For Seeking Access To Data

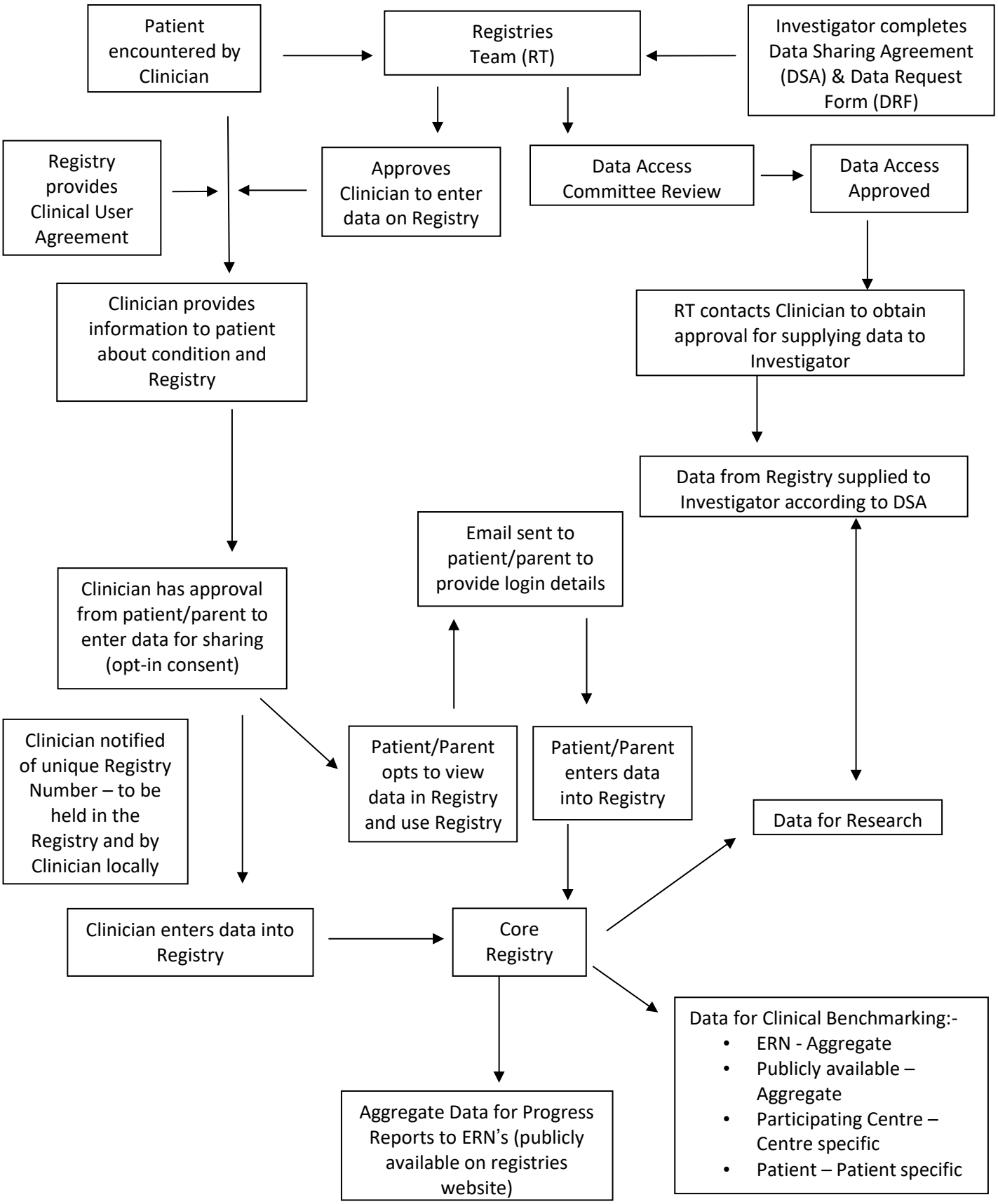
- Access to the data shall follow the path outlined in Appendix 1 and 2.
- The investigator shall need to complete the Data Request Form (Appendix 3) and the Data Sharing Agreement (Appendix 4).
- The completed forms shall be submitted to the Registries Team that will check their completeness and forward to the DAC.
- The DAC shall provide their feedback using the Feedback Form (Appendix 5)
- The process for seeking access is summarised in Appendix 6.
- In case the contents of a new application overlap with an existing active application, the investigators of the two applications will be jointly advised to discuss the overlap.

10. Dissemination Of Data Analysis Activity

- All approved requests for data analysis shall be available on the EuRREB website and shared with other parties as appropriate.
- Six monthly reports of all such 'research activity' will be obtained from investigators and a lay summary shall be posted on the EuRREB website and shared with other parties asappropriate.
- Acknowledgements and attribution of any publications should follow the conditions in Section 4.3 of the Data Sharing Agreement

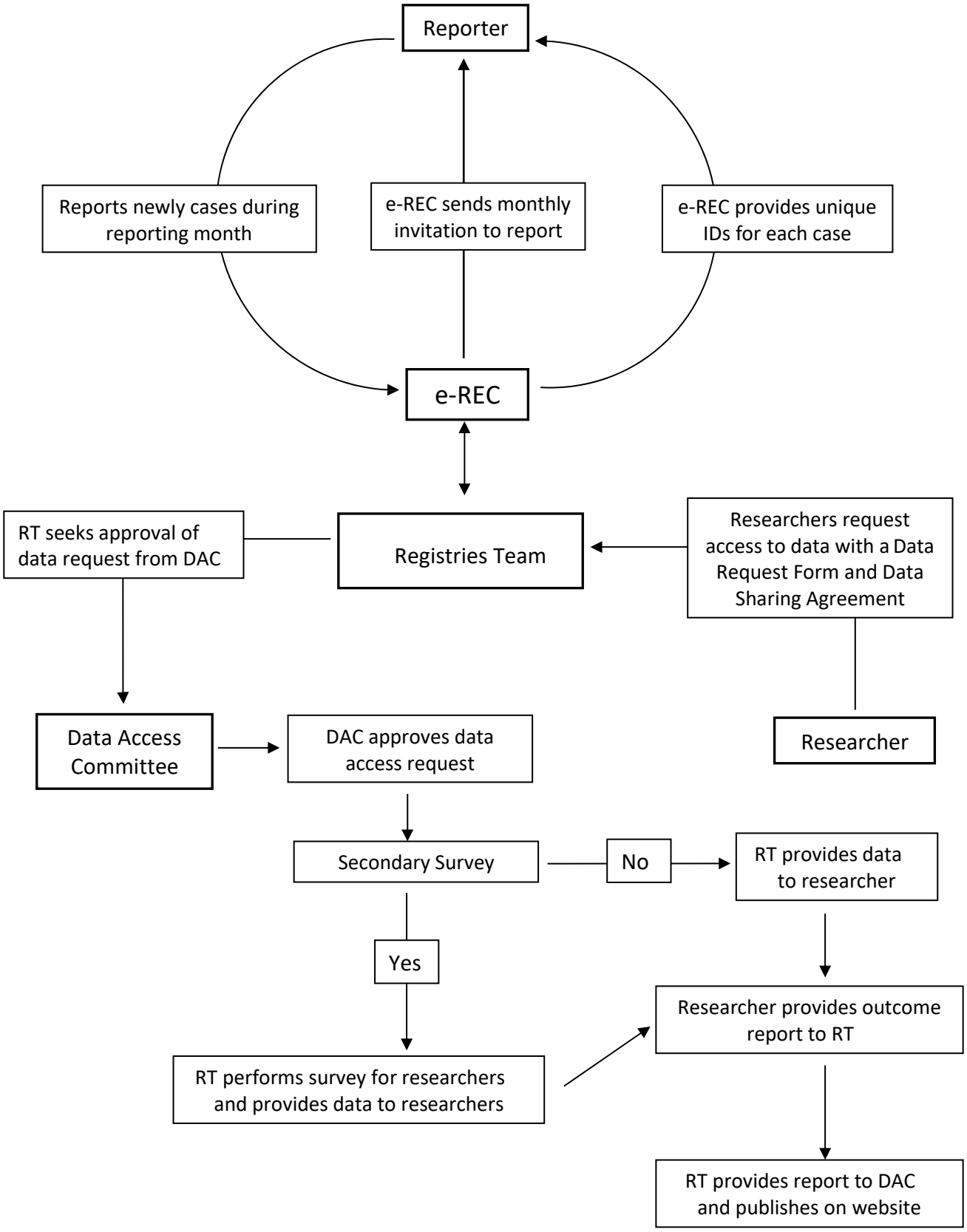
Appendix 1

Data Flow Within The Core Registry Platform



Appendix 2

Data Flow Within e-REC



Appendix 3
Data Request Form

The Data Request Form can be filled out online: https://forms.lumc.nl/lumc2/registries_data_request_form

Fields marked with * are mandatory

Before completing the form please read the following information:

- Discuss your data needs with the Registries Team. You can contact them at: registries@lumc.nl
- Take a look at the following information:
  - Obtaining Registry Data
  - Ethics Approval
- Please ensure the project has been fully discussed with all the co-investigators. The acknowledgement of receipt of application will be sent to all the investigators.

For help with this form, please contact us at:

registries@lumc.nl

Once completed please submit the form.

Details of Principal Investigator

1. Full name: *
2. Email address: *
3. Name of Institution: *
4. Location of Institution: *

Details of Co-Investigator

5. Full name:
6. Email address:
7. Name of Institution:
8. Location of Institution:

29. Please select from which registry data is required (multiple answers are possible) *
- ☐ Data requested from e-REC
- ☐ Data requested from the Core Registry

30. Full name of the project *

31. Short name of the project for communication purposes *

32. Has this application been discussed with all co-investigators?
The acknowledgement of receipt of application will be sent to all the investigators *
- ○ Yes
- ○ No

33. What is or what are the main reason(s) for requesting data access from the EuRREB Registries? *
- ☐ To assist with designing a new project
- ☐ To perform a survey of participating centres
- ☐ To obtain deidentified existing patient data from the registry
- ☐ Other

Funding and Other Organisations

34. Has the project been funded? *
- ○ Yes
- ○ No
- ○ Not applicable

38. Is there a plan to apply for (additional) funding? *
- ○ Yes
- ○ No

40. How will the data access costs be covered? *

41. Has this project been peer reviewed and approved by any organisation?
e.g., funding body, ethics body, regulatory agency, other formal organisation *
- ○ Yes
- ○ No

Details of Project

45. Background and rationale for support required (max. 500 words) *

46. What is the primary aim or hypothesis of the project? *

47. What are the primary outcomes that will be measured? *

48. What are the secondary outcomes that will be measured? *

49. Describe the methodology, including project design (max. 500 words) *

50. State the inclusion criteria of the cases that will be recruited *

51. State the exclusion criteria of the cases that will be recruited *

Details of Data

52. Specify the data that are required from the registries using the Data Request Justification of the Data Dictionary *

53. If applicable, please specify any data fields that are not currently collected in the registries, but will be necessary for your project (please refer to the Data Dictionary)

54. Specify whether the data need to be linked to source data *

- ◯ Linkage to source data is required (pseudonymised data) No
- ◯ linkage to source data is required (anonymous data)

56. What data analyses are planned? *

Participating Centres

57. Do you have any inclusion or exclusion criteria of the centres that will need to be approached? *
- ◯ Yes
- ◯ No
- ◯ Not sure

60. In case of missing data, will there be a need to contact participating centres? *
- ◯ Yes
- ◯ No

61. Please provide further details of how data will be exchanged with centres
Please discuss with the Registries Team who will help with completion. You will also be asked to complete a separate Data Sharing Agreement once the data request has been approved. *

62. Will participating centres need to be contacted for the project? *
- ◯ Yes, once
- ◯ Yes, more than once
- ◯ No
- ◯ Not sure

Ethics/IRB

65. Do the investigators intend to collect any biomaterial (including data) that are not collected as part of routine clinical practice? *
- ◯ Yes
- ◯ No

66. Do the investigators have ethics/IRB approval? *
- ◯ Yes
- ◯ No

Dissemination

70. Summary of project for the website (max. 200 words) *

71. Plain language abstract of the project (max. 100 words) *

72. How will this project improve the health of people with the condition that is being studied? *

73. Would you be interested in writing a short piece in the EuRREB newsletter? *
- ○ Yes
- ○ No

74. Will the project require collection of patient reported outcomes/surveys? *
- ○ Yes
- ○ No

77. List the expected outputs of the project and how they will be disseminated *

78. State the publication plan for authorship of abstracts and full papers, and how it compares to our recommendations *

79. Please provide the timeline of the project from start to above outputs *

Previous Data Requests

80. Have you received data from the EuRREB Registries previously? *
- ○ Yes
- ○ No

Wrap Up

85. Please add any additional/relevant information. The Registries Team may contact you for further clarification. Please add relevant files below.

86. Please add relevant files as attachments here:

87.

88.

89. Date of completion: *

90. Date of submission: *

Check your Data Request Form before submitting.

** = Input is required*

Appendix 4

DATA SHARING AGREEMENT

EuRRECa/EuRR-Bone

This document describes the minimum arrangements for data provision **by the Core Registry and e-REC**. It is to be used as the basis of agreements made about specific services with individual bodies.

THE UNDERSIGNED:

1. **Leids Universitair Medisch Centrum (LUMC),** having its registered office and principal place of business at Albinusdreef 2, 2333 ZA Leiden, the Netherlands, legally represented by H.B.M. Onstein, managing director division 2, hereinafter referred to as **"Supplier"**;

   and

2. XXXXX, having its registered office and principal place of business at XXXXX, in XXXXX, legally represented by XXXXX, hereafter referred to as the **"Recipient"**

The foregoing entities are solely referred to as "**Party**" and collectively referred to as "**Parties**".

WHEREAS:

I. The parties participating in the e-REC and/or the Core Registry own the rights to certain data and are willing to provide the Recipient with such data through Supplier for the purpose of executing the Research XXXXX (hereinafter: the **"Research"**) as set forth in **Annex 1**;

II. On behalf of these parties, Supplier enters into this Data Sharing Agreement with Recipient, to ensure adequate protection of the data;

III. With this agreement, the Parties aim to determine the terms and conditions upon which the Recipient agrees to conduct the Research and upon which the Supplier agrees to transfer the data.

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

Definitions

a) "**Controller**", "**Data subject**", "**Personal data**", **"Pseudonymised data"**, "**Processing**", "**Processor**" and "**Supervisory authority/authority**" shall have the meaning as in the General Data Protection Regulation (EU) 2016/679 (hereinafter: "**GDPR**").

b) "Data" means the data as identified in **Annex 1** which the Supplier will transfer to the Recipient. As far as the Data will contain Personal Data before the transfer they will be pseudonymised as described in **Annex 2** (see: Method of data storage and security measures (e.g. method of encoding)).

c) "Confidential information" means any proprietary information, know-how, data, or procedure related to the data and disclosed by Supplier to Recipient pursuant to its rights or obligations under this Agreement.

Clause 1. The processing of Personal Data

1.1 The Supplier will provide the Recipient with the Data in accordance with the terms of this Agreement. Parties are considered as Controller with regard to their own processing of the Personal Data for the purpose of the Research, and they will act in accordance with the GDPR and additional applicable national data protection laws.

1.2 Recipient shall implement appropriate technical and organizational measures to meet the requirements of the GDPR, with respect to the use of data, and shall manage and use the databases in accordance with the guidelines established by European data protection regulations.

1.3 The Supplier warrants and undertakes that:

a. the Personal Data have been collected, processed and transferred in accordance with the GDPR and additional national data protection laws;

b. the Data will only contain Pseudonymised data and no directly identifing Personal data;

c. it has obtained any regulatory or ethics approvals necessary to collect the Data and transfer the Data to the Recipient;

d. it has full authority to transfer the Data to the Recipient.

1.4 The Recipient warrants and undertakes that:

a. the Personal data will be processed in accordance with the laws applicable to the Recipient and the GDPR and any (additional) applicable national law;

b. the Data will be used for the sole purpose of the Research in accordance with the permitted uses of the Data specified in the informed consent form of the Data subjects from whom the Data were collected;

c. Data will only be shared with a third party when that is necessary for the purpose of the Research, in which case Recipient will enter into an agreement with that third party that includes at least the terms stated in this agreement;

d. the Data will only be processed outside the European Economic Area when the processing is in accordance with Chapter V of the GDPR;

e. appropriate technical and organisational measures are in place to protect the Personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected;

f. all Personal data will be treated strictly confidential and shall have in place procedures so that any third party it authorises to have access to the Personal data, including employees and (sub)Processors, will respect and maintain the confidentiality and security of the Personal data. Any person or organisation acting under the authority of the Recipient, including a (sub)Processor, shall be obligated to process the personal data only on instructions from the Recipient and in accordance with the permitted use under this Agreement. This provision does not apply to persons authorised or required by law or regulation to have access to the Personal data;

g. in the event a Data subject withdraws its consent or objects to the use of the Data, Recipient will – at the instruction of Supplier – immediately return or destroy the Data from that particular Data subject.

1.5 Under no circumstances will the identity of the Data subject, or any means to derive such identity, be provided to Recipient. Recipient shall not carry out any procedures with the Data (linking, comparison, processing) through which the identity of Data subject could be derived.

1.6 If either Party becomes aware of a Personal data breach, that Party shall promptly notify the other

Party/ies. In such a case Parties will fully cooperate with each other to remedy the Personal data breach, fulfil the (statutory) notification obligations timely and cure the damages. A Personal data breach refers to: 1) a Personal data breach according to applicable law in the territory where the Data are treated, and 2) a Personal data breach as meant in articles 33 and 34 of the European General Data Protection Regulation.

Clause 2. Confidentiality

2.1 Confidential Information is the sole property of the Supplier and shall be used by the Recipient solely for the purpose of the Research. The Recipient agrees not to disclose Confidential Information to third parties without the consent of the Supplier and under an agreement by the third party to be bound by the obligations of this Clause 2. The Recipient shall safeguard Confidential Information with the same standard of care that is used with Recipient's own confidential information, but in no event less than reasonable care.

2.2 The obligations under this Clause 2 shall not extend to any information:

- which is or becomes publicly available through no breach of this Agreement;
- which Recipient can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
- which Recipient receives from a third party which is not legally prohibited from disclosing such information; or
- which Recipient is required by law to disclose.

2.3 The obligations of this Clause 2 shall survive this Agreement for a period of three (3) years after termination or expiration of this Agreement. Upon the request of the Supplier, the Recipient agrees to return the Confidential Information to the Supplier or destroy, at the option of the Supplier, all copies of Confidential Information; provided, however, that Recipient shall be entitled to retain one (1) copy of Confidential Information solely to ensure compliance with its rights and obligations hereunder.

Clause 3. Ownership of data

3.1 Agreements about the ownership of the data are included in the Data Access Policy: https://eurreb.eu/wp-content/uploads/2024/11/EuRRECa-EuRR-Bone-Data-Access-Policy-v8.pdf

Clause 4. Publication

4.1 If data from the Core Registry and e-REC are used for a report or publication without any statistical or clinical input from the Registry project team the use of data must be acknowledged along with a disclaimer. The current recommended text for use in publications is available on the website: https://eurreb.eu/publication-guidelines/.

4.2 Personnel from the Registry PMT must be included as co-authors in any publication or report when statistical or clinical input and analysis has been required from the PMT. Submission for review must occur at least 30 days prior to the intended publication. A copy of published research based on data from the Core Registry and e-REC must be sent to the registry PMT.

The non-publishing Party shall be entitled to make editorial comments and/or to recommend delay for up to ninety (90) days to enable patent applications to be filed or to remove or alter all reference to any of their own Results or background (therein) they consider to be of a confidential nature. If no objection is received in writing within the ninety (90) days period, the publishing Party will be free to publish the manuscript or other form of disclosure submitted to the non-publishing Party.

4.3 The disclaimer to be included in publications and reports based on data from the Core Registry and e-REC that have not, with prior agreement, involved any statistical or clinical input from the registry project team is available on the website https://eurreb.eu/publication-guidelines /.

The source and data handling methods should be made clear in the 'Methods' section. The abstract should also include 'EuRRECa/EuRR-Bone' and 'Core Registry' or 'e-REC' which would

allow for searching for publications with these key words (as appropriate). Logos for inclusion in publications and reports are available on the Registries website: https://eurreb.eu/publication-guidelines/.

Data published in the Endo-ERN and ERN BOND reports are in the public domain, but EuRRECa/EuRR-Bone should be acknowledged as the source of the data and the disclaimer used.

Clause 5. Representations and warranties

5.1 Other than the warranties set out in section 1.3 the Data is provided by the Supplier to the Recipient without any warranties whatsoever, express or implied, including any warranties for merchantability or fitness for a particular purpose.

5.2 Nothing in this Agreement shall be construed as granting to Recipient, either expressly or by implication, any right or licence to the Data, under any patent, patent application, trade secret, know how, confidential information, trade or service mark, copyright, or other intellectual and/or industrial property rights Supplier possesses or may possess, nor any option to any such right or license.

Clause 6. Liabilities and indemnification

6.1 The Recipient assumes the risk of any damage, loss, or expense associated with or resulting from the conduct of the Analyses or Recipient's use of the Data, unless such damage or loss is caused by the gross negligence or wilful misconduct of the Supplier.

6.2 The Recipient will indemnify and hold the Supplier, its directors or employees harmless against all claims of any kind whatsoever that may arise or result from the use of the Data.

6.3 The Supplier shall not be liable toward the Recipient for any claims, costs or damages that may result, directly or indirectly, out of Recipient's use of the Data and/or Results, unless and to the extent that damage is caused by gross negligence and/or due to wilful misconduct by the Supplier.

6.4 The Parties shall in no case be liable for any indirect, incidental or consequential damages (including without limitation, lost business or profits, or loss of use of equipment) suffered by another party.

Clause 7. Duration and termination of the Agreement

7.1 This Agreement shall become effective on the date of the last Party's signature below, and shall remain in force for the period of the Research, unless terminated earlier in accordance with section 7.2. The Parties agree that the term may be extended by mutual written agreement prior to expiry of the term.

7.2 This Agreement can be terminated earlier by either Party with immediate effect by receipt of written notice:

a. Upon a material breach of this Agreement by the other Party, if it is not cured within thirty (30) days after the breaching Party has received written notice of such material breach.
b. in the event the other Party is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Party;
c. in the event the business of the other Party will be winded up or closed down;
d. in case of force majeure - as determined in clause 11 below - if the force majeure situation will last over ninety (90) days.

7.3 The Recipient agrees, on termination of this Agreement (whether as a result of its breach or otherwise), to cease all use of the Data and shall within fifteen (15) days return all Data to Supplier or destroy all Data at the sole discretion of Supplier, or to deal immediately with the Data in

accordance with Supplier's written instructions. However, Recipient may retain one (1) copy of the Data solely for reproduction purposes.

7.4 Clauses 1-6, 8 and this section 7.4 shall survive expiration or early termination of this Agreement, as well as any terms that by their nature would be expected to survive expiration or early termination of this Agreement shall survive such expiration or early termination.

Clause 8. Publicity

Neither Party will use the logo or name of the other Party or the name of an employee of the other Party, for promotional purposes, in any publicity, advertising or news release, without prior written approval of the Party whose name is to be used.

Clause 9. Modifications

Modifications, changes and extensions to this Agreement are only binding after these have been agreed upon in writing between the Parties.

Clause 10. Assignment

The rights and obligations as determined in the Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

Clause 11. Force Majeure

In case of force majeure the concerning Party is entitled to suspend the obligations for the duration and extent of the force majeure, provided that the other Party has been notified in writing of the force majeure. Force majeure situations will concern those situations which prevent the execution of the Agreement and which are not imputable to the concerning Party pursuant to law, Agreement or according to generally accepted standards and as a result will not be attributable to that Party.

Clause 12. Severability

The invalidity or unenforceability of any particular provision of this Agreement shall not affect any other provisions therein. The Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted.

Clause 13. Governing law

This Agreement shall be interpreted and governed by the laws of The Netherlands in any action. Any dispute relating to the interpretation or implementation of this Agreement which the Parties hereto have failed to settle amicably shall be exclusively referred to the competent courts of The Netherlands for settlement.

Clause 14. General Terms and conditions

No general conditions will apply to this Agreement.

IN WITNESS WHEREOF, the Parties hereto have by their authorized representative duly caused this Agreement to be executed as of the date hereinafter written.

Leids Universitair Medisch Centrum	**XXXXXXXX**
……	……
Date: ……	Date: ……
Name: ……	Name: ……
Title: ……	Title: ……

LUMC contact person / PI	**Recipient contact person / PI**
Name: Natasha Appelman-Dijkstra	Name: ……
E-mail: N.M.Appelman-Dijkstra@lumc.nl	E-mail: ……

LUMC Data protection officer	**Recipient data protection officer**
E-mail: privacy@lumc.nl	E-mail: ……

Annex 1: PROTOCOL

- **Original Grant applications:** available upon request (2018-2022 EuRRECa, 2020-2023 EuRR-Bone)
- **Data Request Form:** https://forms.lumc.nl/lumc2/registries_data_request_form
- **Ethics documents**: Approved protocols Coordinator, IRB approval, LUMC science committee regulations https://eurreb.eu/registries/ethics-approval/
- **Data Access Policy:** https://eurreb.eu/wp-content/uploads/2024/11/EuRRECa-EuRR-Bone-Data-Access-Policy-v8.pdf

Annex 2: Privacy Matrix

PRIVACY APPENDIX TO THE DATA SHARING AGREEMENT BETWEEN LUMC (Supplier) and XXXX (Recipient) (hereinafter: "main agreement")

PART I. Description of the data transfer

Data subjects The personal data transferred concern the following categories of data subjects:	Patients with rare endocrine, bone and mineral conditons whose data is included in the Core Registry and e-REC.
Purposes of the transfer(s) The transfer is made for the following purposes:	Conducting scientific research as described in the data request form.
Categories of data The personal data transferred concern the following categories of data:	See data request form.
Sensitive data (if appropriate) The personal data transferred concern the following categories of sensitive data:	See data request form, but in any case health data.
Method of transfer	Secured e-mail, e.g. Zivver or SURFfilesender.
Method of data storage and security measures (e.g. method of encoding)	The following measures will be taken as a minimum: all personal data will be coded and stored on the secured servers of the Recipient, to which only the research team has access. The key to uncode the data will be kept securely by the principal investigator of the local hospital. See data request form for any more specific security measures that will be taken for this study.
Authorized processors	See data request form.

Appendix 5

EuRRECa/EuRR-Bone Registries

DAC Feedback Form

Mandatory questions are marked with a star (*)

DAC members are requested to complete this form within 2 weeks. The feedback will be collated and sent to the DAC Chair and then anonymised and returned to the PI and also shared with the DAC.

1. Name of the PI (Study Lead) *

(Data Request Form - Q1)

2. Study Short Title *

(Data Request Form - Q4)

3. Name of DAC reviewer *

(will be removed for anonymous feedback)

Name

4. Comment on the composition of the co-investigators/study group *

5. Is there a clear funding plan? *

(Data Request Form - Q8-13)

- ◯ Yes
- ◯ No
- ◯ Unclear

6. Additional comments on funding plan

7. This study is relevant to: *

(Data Request Form - Q18 Background & Rationale)

- ☐ Advance scientific understanding
- ☐ Advance clinical care
- ☐ Developing new therapies
- ☐ Other

8. Additional comments on relevance of study

9. Is there a clear primary aim description? *

(Data Request Form - Q19)

- ◯ Yes
- ◯ No
- ◯ Unclear

10. Additional comments on primary aim

_____
_____
_____
_____
_____

11. Are the primary and secondary outcomes feasible? *

(Data Request Form - Q20-21)

- ◯ Yes
- ◯ No
- ◯ Unclear

12. Additional comments on outcomes

_____
_____
_____
_____
_____

13. Is the methodology/project design clear? *

(Data Request Form - Q22-24)

- ◯ Yes
- ◯ No
- ◯ Unclear

14. Additional comments on methodology/project design

15. Are the requested data sufficient to answer the primary aim? *

(Data Request Form - Q25-26)

- ◯ Yes
- ◯ No
- ◯ Unclear

16. Additional comments on data requested

17. Is the data analysis plan suitable? *

(Data Request Form - Q29-34)

- ◯ Yes
- ◯ No
- ◯ Unclear

18. Additional comments on data analysis

19. Is the timeline realistic? *

(Data Request Form - Q35-37 & Q50)

- ◯ Yes
- ◯ No
- ◯ Unclear

20. Additional comments on the timeline

21. Are the ethics/IRB processes adequate? *

(Data Request Form - Q38-41)

- ◯ Yes
- ◯ No
- ◯ Unclear

22. Additional comments on ethics/IRB

23. Comments on the project summaries

(Data Request Form Q42-44

24. Are the outputs ambitious enough? *

(Data Request Form - Q48-50)

- ◯ Yes
- ◯ No
- ◯ Unclear

25. Additional comments on outputs and dissemination plan

26. Please comment on the track record of the PI and the research team in general and in I-DSD/I-CAH/I-TS related studies? *

(Data Request Form Q51-55)

27. General comments to improve the project

28. Decision of the DAC member *

- ◯ Approved
- ◯ Revision _____
- ◯ Rejected _____

Appendix 6

Registries Data Access Committee Approval Proces