Data Sharing Agreement
for the ERN eUROGEN registry

This Data Sharing Agreement ("**Agreement**"), effective as of the date of last signature below (the "**Effective date**") is entered into by and between:

Stichting Radboud universitair medisch centrum, established at Geert Grooteplein 10, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands, legally represented by the undersigned

(hereinafter called ,,**Radboudumc**")

And

<Legal Name, address of the party that wishes to join the ERN eUROGEN registry>

(hereinafter called „the **Provider**")

Radboudumc and the Provider maybe be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS:

a) The overall goal of the European Reference Network (ERN) eUROGEN is to improve access to high quality healthcare for patients with rare urogenital diseases and complex conditions. ERN eUROGEN allows healthcare professional to work together to support patients with such rare and complex diseases, which require highly specialised care. ERN eUROGEN also aims to improve knowledge about rare urogenital diseases and complex diseases and to support clinical research for improved diagnosis, risk prediction and the development of innovative therapies. For these latter aims, the ERN eUROGEN registry was set up (the "**Purpose**");
b) The European Commission has previously decided to award a grant for the action entitled "**ERN eUROGEN registry**", number **946157** ("the Action")**.** The European Commission, as funding agency and Radboudumc as Coordinator, signed the Grant Agreement for the execution of the Action on May 13, 2020;
c) In the support of the Purpose, Radboudumc and the Provider may be engaged in various activities including, but not limited to, the conduct of future research studies (each a "**Study**" and collectively "**Studies**");
d) In support of the Purpose, Provider intends to contribute data to the registry that is set up as part of ERN eUROGEN (the ''ERN eUROGEN registry''), subject to the terms and conditions of this Agreement;

Definition

"**Data Protection Legislation**"	means: (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of Provider Data to which a Party is subject and the GDPR or all legislation enacted in each Country in respect of the protection of Personal Data; and (b) any code of practice or guidance published by a Regulatory Body from time to time;
"Data Access and Sharing Policy"	means the document that is attached to this Agreement as Attachment;
"GDPR"	means 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 repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119/1, 4.5.2016;
"Pseudonymisation"	means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person
"Regulatory Body"	means any competent governmental, statutory, regulatory or enforcement authority or regulator concerned with the activities carried on by any Party or any part, division or element thereof, in respect of the activities carried out pursuant to this Agreement.
"Study Data"	means study data entered in the ERN eUROGEN registry, a descriptive list of which is attached to this Agreement as Appendix 1;
"Steering Commitee" and "Advisory Board"	have the meaning that is described in the Data Access and Sharing Policy;

For the purposes of this Agreement, "**Controller**", "**Processor**", "**Data Subject**" and "**Process**" shall have the meanings set out in the GDPR and "**process**" "**processing**" and "**processed**" when used in relation to the processing of Provider Data, will be construed accordingly, and will include both manual and automatic processing. Any reference to "**Pseudonymised Data**" means study data that incorporates such categories of data as are listed in the GDPR.

NOW, THEREFORE, in consideration for the mutual promises and for valid consideration, the Parties agree to the following terms:

Section 1 Obligations of the Parties

1.1 Radboudumc

i. Radboudumc is the coordinator of ERN eUROGEN and the ERN eUROGEN registry. It has contracted with Castor EDC, a tradename of company Ciwit B.V. to allow the centralized storage of the Study Data. Given the fact that the Provider and Radboud jointly developed and determined the purposes and means of the ERN eUROGEN registry, Parties shall be joint Controllers. However, Radboud, as the central Party that coordinates the ERN eUROGEN registry, shall be responsible for the storage and the use of the transferred data as well as the administration of user rights in a compliant way with all applicable national, federal, state, and local statutes, legislation, directives, regulations, and rules pertaining to the activities contemplated herein, including without limitation the following: (i) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation, 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 - GDPR) the ICH GCP, requirements of the competent EC as well as generally accepted professional standards for clinical and research standard of care;

ii. Radboudumc shall ensure that appropriate technical and operational measures are in place to safeguard against any unauthorized or unlawful processing of the Study Data and against accidental loss or destruction of, or damage to the Provider sufficient to comply with its data security obligations set out in the GDPR, promptly, and in any event within 48 hours, notify the Provider about any actual or suspected breach of the Data Protection Legislation in relation to any Study Data processed as a result of this Agreement;

iii. Radboudumc shall provide the Castor EDC logindetails necessary for the actual upload of Study Data to the ERN eUROGEN registry;

1.2 The Provider

i. The Provider is responsible to obtain and maintain any required ethical approval or similar necessary for the provision of Study Data to the ERN eUROGEN registry;

ii. When providing Study Data, The Provider shall fully comply with with all applicable national, federal, state, and local statutes, legislation, directives, regulations, and rules pertaining to the activities contemplated herein, including without limitation the following: (i) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation, 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 - GDPR) the ICH GCP, requirements of the competent EC, generally accepted professional standards for clinical and research standard of care as well as any guidelines governing the performance of research in the hospital or other place where the data is collected;

iii. The Provider is responsible for obtaining any required informed consent from each Data Subject before enrolling the respective Data Subject into the ERN eUROGEN registry and before transferring any data from that Data Subject. To that regard the Provider shall use the patient information and consent form as approved by its competent ethics committee. The consent shall cover inter alia the transfer of pseudonymized data (i.e. removing all sensitive personal data, including but not limited to patient names, initials, and other personally-identifiable information, and leaving only a coded Data Subject number) to Radboudumc and for use within the ERN eUROGEN registry and in scientific research projects approved in accordance with the Data Access and Sharing Policy;

iv. The Provider shall ensure timely completion of the data as defined and in the way described in the ERN eUROGEN registry Protocol and Data Access and Sharing Policy (see Attachments). Provider shall have the responsible Investigator be available for query resolution;

v. The Provider agrees that upon prior notice Radboudumc or its designees on behalf of ERN eUROGEN will in accordance with applicable data protection laws, including but not limited to GDPR, and the patient informed consent be granted access to all documents necessary for auditing and monitoring purposes and that the responsible Investigator will be available for questions.

1.3 Both Parties

i. Notwithstanding the division of responsibilities set out in the clause above, the Parties shall be jointly responsible for the compliance obligations imposed by the Data Protection Legislation (Article 26 of the GDPR), and the Parties shall cooperate to do all necessary things to enable performance of such compliance obligations;

ii. Each Party shall not, by its acts or omissions, cause the other Party to breach its respective obligations under the Data Protection Legislation.

iii. If a Regulatory Body notifies one of the Party of an audit or other investigation of the Regulatory Body regarding the ERN eUROGEN registry the Party first notified shall inform the other Party promptly of such notification, including providing a copy of any correspondence received from such Regulatory Body with respect to the audit or investigation and provide the audit response or any other comments by the Regulatory Body to the other Party immediately upon receipt;

iv. Given the fact that Radboudumc will not have the key to the coded Study Data provided by Provider, The Parties agree that the Provider is primarily responsible for managing Data Subject requests exercising their rights under the GDPR and will comply with article 12 of the GDPR in order to respond to such a request.

v. However, the Parties acknowledge that Data Subjects are allowed to exercise their rights under the GDPR against both Parties. If a Data Subject makes a request to Radboudumc, Radboudumc will notify the Provider about the request without undue delay.

vi. Radboudumc will assist Provider in complying with its obligation to provide an answer to Data Subject requests.

Section 2 Data Ownership and Access

2.1 to the extent legal ownership of the Study Data is deemed possible, Radboudumc acknowledges that it shall not obtain any ownership rights to the Study Data provided by Provider.

2.2 The Study Data entered by the Provider will not be shared with third parties, except to the extent described in the Data Access and Sharing Policy;

2.3 As set out in the Data Access and Sharing Policy, the ERN eUROGEN Project Steering Committee together with the Advisory Board may grant access to third parties not belonging to ERN eUROGEN, who can request to access to the data upon the presentation of a research protocol that has to be approved by the Project Steering Committee together with the Advisory Board;

2.5 As described in the Data Access and Sharing Policy, requests from third parties for access rights to Provider's Study Data will be forwarded to Provider and provider may veto such requests for the reasons contained in the Data Access and Sharing Policy.

Section 3 Term

This Agreement shall begin on the date of last signature by the Parties and shall continue as long as the ERN eUROGEN registry exists or any study continues with use of the Study Data. Storage terms of he data is arranged for in the Data Access and Sharing Policy.

Section 4 Confidentiality

4.1 Each Party undertakes that it shall not disclose at any time during the Term or thereafter to any person any confidential information concerning the business affairs, customers, clients or suppliers, grant applications or other information of the other Party, of which it would be reasonably apparent to any third party that it is of a confidential nature (the "Confidential Information") of the other Party, except as permitted by the subsequent Clause;

4.2 Each Party may disclose the other Party's Confidential Information: to its employees, officers, representatives or advisers who need to know such information for the purposes of carrying out its obligations under this Agreement or fulfilling the Purpose. Each Party shall ensure that its employees, officers, representatives, or advisers to whom it discloses the other Party's Confidential Information comply with this Clause 4; and as may be required by law, court order or any governmental or Regulatory Body or authority.

4.3 No Party shall use the other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement or for fulfilling the Purpose.

Section 5 Amendment

No change, amendment or modification of this Agreement shall be valid unless set forth in a written instrument signed by a duly authorized representative of each Party.

Section 6 Governing law and jurisdiction

This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed and interpreted in accordance with the laws of the Netherlands. Each Party irrevocably submits to the exclusive jurisdiction of Arnhem, the Netherlands over any claim or matter arising under, or in connection with, this Agreement.

Section 7 Severability

In the event any provision of this Agreement is held to be invalid or unenforceable, the remainder of this Agreement shall remain in full force and effect as if the invalid or unenforceable provision had never been a part of the Agreement.

Section 8 Violation/Termination of Agreement

8.1 A Party (the 'Terminating Party') may terminate its involvement in this Agreement by giving ninety (90) days prior written notice to the other Party of its intention to terminate if that other Party (the 'Party in Breach') commits a material breach of the terms of this Agreement. The notice shall include a detailed statement describing the breach. If the breach is capable of being remedied and is remedied within the ninety (90) day notice period, then the termination shall not take effect. If the breach is of a nature such that it can be fully remedied but not within the ninety (90) day notice period, then termination shall also not be effective if the Party involved begins to remedy the breach within that period, and then continues diligently to remedy the breach until it is remedied fully. If the breach is incapable of remedy, then the termination shall take effect at the end of the ninety (90) day notice period in any event.

8.2 After termination of this Agreement, Radboudumc shall be allowed to keep the Study Data provided by Provider in the ERN eUROGEN registry for the terms set out in the Data Access and Sharing Policy, and may keep sharing that Study Data in accordance with the Data Access and Sharing Policy unless: a) the Provider terminated this Agreement in accordance with 8.1 above for a breach by Radboudumc of its data protection obligations or b) in the event that a relevant Data Subject withdraws his/her permissions to keep their Study Data in the ERN eUROGEN registry.

8.3 In the event of termination of this Agreement, the obligations which by their nature are intended to survive will survive the termination of this Agreement and will continue in full force and effect between Parties.

Section 9 Regulatory requirements

The Parties agree to comply with all applicable laws and regulations relating to the privacy of subject health information, including, but not limited to 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) ("GDPR") as each apply to the Parties and their activities.

Section 10 Authorship policy

If data from the ERN eUROGEN registry are used for a report or publication, the use of data must be acknowledged along with a statement as specified in the ERN eUROGEN registry Data Acces and Sharing Policy.

Section 11 Entire Agreement

This Agreement and the documents attached hereto and/or specifically referenced herein constitute the final, complete and exclusive Agreement between the Parties with respect to the subject matter of the Agreement, and it supersedes any and all prior or contemporaneous agreements, understandings, promises, or representations, whether oral or written, made between Radboudumc and the Provider concerning the subject matter of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement, in one original for each Party, as of the EFFECTIVE DATE.

The persons signing this Agreement confirm that they have the necessary authority to agree to the commitments and obligations inherent in participating in this Registry.

Stichting Radboud universitair medisch centrum	**Provider** < Name of Institution>
Name of authorized representative	Name of authorized representative of institution
Date and Signature	Date and Signature
Name of authorized representative	Name of authorized representative of institution
Date and Signature	Date and Signature

Appendix 1 Description of Study Data

This registry will entail different elements:

- The Common Data Elements developed by the European Platform on Rare Diseases providing basic information about patient status, care pathway, disease history, clinical and genetic diagnosis, consent for reuse and recontacting, and availability of biological specimens (see attachment 1.0 Common Data Elements). These data elements will be collected from all patients suffering from a rare urogenital disease or complex condition treated at a HCP at which implementation of the ERN eUROGEN registry was approved.
- A Clinical Practice Snapshot containing 6 disease-specific questions about the clinical procedures performed. These Clinical Practice Snapshot questions were developed according to the "ERN eUROGEN Data Element Development Protocol" (see attachment) including consensus among at least three clinical experts in the field as well as at least one European Patient Advocacy Group (ePAG) representative. They were developed for six of the expertise areas (see attachment 1.5 Clinical Practice Snapshot - PUV, 1.7 Clinical Practice Snapshot - ARM, 1.8 Clinical Practice Snapshot - KidTrans, 2.1 Clinical Practice Snapshot - AMS800, 3.1 Clinical Practice Snapshot - testicular cancer and 3.3 Clinical Practice Snapshot - adrenal tumours), and will initially be collected only from patients suffering from diseases from these disease areas. The Clinical Practice Snapshots will be developed for the other disease areas later.
- Patient Reported Outcome Measure (PROM) questionnaires.
    - To assess the quality of care, we will send the H-care survey to all patients, as seen in attachment F1. These will be directed to parents for patients under the age of 16 and to the patients themselves for patients aged 16 and older.
    - To assess health-related quality of life, we use the SF-36 questionnaire for patients from workstream 2 and 3 (functional urogenital disorders requiring complex surgery and rare urogenital tumors) and for patients from workstream 1 (rare congenital uro-recto-genital disorders) aged 18 or older, as seen in attachment F2.
    - For patients from workstream 1 under the age of 18, we will use the PedSql questionnaires directed at parents, with different versions available for different age groups of children, as seen in attachments F3 to F9. For the age group of 8 to 18, there is a questionnaire for both the child and the parents.
- Data elements on the follow-up of patients will be added to the registry in due time. The data elements to be collected and the timing of collecting them will be defined by experts in the field.

List of attachments (included by reference):

ERN eUROGEN registry Protocol
ERN eUROGEN Data Access and Sharing Policy
1.0 Common Data Elements
1.5 Clinical Practice Snapshot - PUV
1.7 Clinical Practice Snapshot - ARM
1.8 Clinical Practice Snapshot - KidTrans
2.1 Clinical Practice Snapshot - AMS800
3.2 Clinical Practice Snapshot - testicular cancer
3.3 Clinical Practice Snapshot - adrenal tumours
F1 H-care survey
F2 SF-36 questionnaire
F3 PedsQL infant
F4 PedsQL 2-4
F5 PedsQL 5-7
F6 PedsQL 8-12
F7 PedsQL 8-12, patient
F8 PedsQL 13-18
F9 PedsQL 13-18, patient