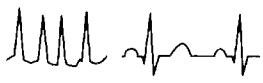
STOPSTORM CONSORTIUM AGREEMENT

FINAL VERSION 1.0

STOPSTORM: A PROSPECTIVE EUROPEAN VALIDATION COHORT FOR STEREOTACTIC THERAPY OF RE-ENTRANT TACHYCARDIA



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CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon

REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (hereinafter referred to as "Rules for Participation"), and the European Commission Multi-beneficiary General Model Grant Agreement and its Annexes, and is made on 1 May 2021, hereinafter referred to as the Effective Date

BETWEEN:

1. UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU), established in HEIDELBERGLAAN 100, UTRECHT 3584 CX, Netherlands, VAT number: NL004205315B01, represented for the purposes of signing the Agreement by Dean & Vice-president of Executive Board UMC Utrecht, Arno HOES.
the Coordinator

2. **FAKULTNI NEMOCNICE OSTRAVA (FNO)**, established in 17 LISTOPADU 1790, OSTRAVA PORUBA 708 52, Czech Republic, VAT number: CZ00843989,

3. **Institut klinické a experimentální medicíny (IKEM)**, established in Videnska 1958/9, PRAGUE 4 14021, Czech Republic, VAT number: CZ00023001,

4. **NEMOCNICE AGEL TRINEC PODLESI AS (NPO)**, established in KONSKA 453, TRINEC 739 61, Czech Republic, VAT number: CZ48401129,

5. **CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL (CAU)**, established in OLSHAUSENSTRASSE 40, KIEL 24118, Germany, VAT number: DE811317279,

6. **RUPRECHT-KARLS-UNIVERSITAET HEIDELBERG (UHEI)**, established in SEMINARSTRASSE 2, HEIDELBERG 69117, Germany, VAT number: DE811225433,

7. **CHARITE - UNIVERSITAETSMEDIZIN BERLIN (CHARITE)**, established in Chariteplatz 1, BERLIN 10117, Germany, VAT number: DE228847810,

8. **TECHNISCHE UNIVERSITAET DRESDEN (TUD)**, established in HELMHOLTZSTRASSE 10, DRESDEN 01069, Germany, VAT number: DE188369991,

9. **UNIVERSITAET zu LUEBECK (UZL)**, established in RATZEBURGER ALLEE 160, LUBECK 23538, Germany, VAT number: DE202095138,

10. **HERZZENTRUM LEIPZIG GMBH (ULEIHC)**, established in STRUEMPELLSTRASSE 39, LEIPZIG 04289, Germany, VAT number: DE161952414,

11. **CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS (CHUV)**, established in RUE DU BUGNON 21, LAUSANNE 1011, Switzerland, VAT number: CHE108910225TVA,

12. **Insel Gruppe AG (BERN)**, established in FREIBURGSTRASSE 18, BERN 3010, Switzerland, VAT number: CHE433951246MWST,

13. **UNIVERSITAT ZURICH (USZ)**, established in RAMISTRASSE 71, ZURICH 8006, Switzerland, VAT number: CH233525,

14. **Narodowy Instytut Onkologii im. Marii Sklodowskiej-Curie - Panstwowy Instytut Badawczy (NRIO)**, established in UL. W K ROENTGENA 5, WARSZAWA 02781, Poland, VAT number: PL5250008057,

15. **GORNOSLASKIE CENTRUM MEDYCZNE IM. PROF. LESZKA GIECA SLASKIEGO UNIWERSYTETU MEDYCZNEGO W KATOWICACH (GCM)**, established in UL ZIOLOWA 45-47, KATOWICE 40 635, Poland, VAT number: PL9542269625,

16. **AARHUS UNIVERSITET (AU)**, established in NORDRE RINGGADE 1, AARHUS C 8000, Denmark, VAT number: DK31119103,

17. **AARHUS UNIVERSITETSHOSPITAL (AUH)**, established in PALLE JUUL-JENSENS BOULEVARD 99, AARHUS 8200, Denmark, VAT number: DK29762929,

18. **CONSORCIO MAR PARC DE SALUT DE BARCELONA (IMIM)**, established in PASEO MARITIM 25-29, BARCELONA 08003, Spain, VAT number: ESS0800471E,

19. **SERVICIO MADRILENO DE SALUD (SERMAS)**, established in PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain, VAT number: ESQ2801221I,

20. **FUNDACION INVESTIGACIÓN HOSPITAL GENERAL UNIVERSITARIO DE VALENCIA (FIHGUV)**, established in AV TRES CRUCES 2, VALENCIA 46014, Spain, VAT number: ESG96792221,

21. **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL RE)**, established in VIA AMENDOLA 2, REGGIO EMILIA 42122, Italy, VAT number: IT01598570354,

22. **FONDAZIONE CENTRO NAZIONALE DI ADROTERAPIA ONCOLOGICA (CNAO)**, established in STRADA CAMPEGGI 53, PAVIA PV 27100, Italy, VAT number: IT03491780965,

23. **ISTITUTO DON CALABRIA (IRCCSDC)**, established in VIA SAN ZENO IN MONTE 23, VERONA 37129, Italy, VAT number: IT00280090234,

24. **UNIVERSITA DEGLI STUDI DI TORINO (UNITO)**, established in VIA GIUSEPPE VERDI 8, TORINO 10124, Italy, VAT number: IT02099550010, represented by the Director of the Department of Medical Sciences [redacted]

25. **FONDAZIONE IRCCS POLICLINICO SAN MATTEO (IRCCS OSM)**, established in VIALE GOLGI 19, PAVIA 27100, Italy, VAT number: IT00580590180,

26. **UNIVERSITEIT MAASTRICHT (UM)**, established in Minderbroedersberg 4-6, MAASTRICHT 6200 MD, Netherlands,

27. **ACADEMISCH ZIEKENHUIS LEIDEN (LUMC)**, established in ALBINUSDREEF 2, LEIDEN 2333 ZA, Netherlands, VAT number: NL003566213B01,

28. **ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM (AMC)**, established in MEIBERGDREEF 15, AMSTERDAM 1105AZ, Netherlands, VAT number: NL004627672B01,

29. **STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MAASTRO)**, established in Dr. Tanslaan 12, MAASTRICHT 6229 ET, Netherlands, VAT number: NL004210104B01,

30. **STICHTING CATHARINA ZIEKENHUIS (SCZ)**, established in MICHELANGELOLAAN 2, EINDHOVEN 5623EJ, Netherlands, VAT number: NL002655135B01,

31. **HARTERAAD (HART)**, established in PRINSES CATHARINA-AMALIASTRAAT 10, SGRAVENHAGE 2496 XD, Netherlands,

hereinafter, jointly or individually, referred to as "Parties" or "Party"

relating to the Action entitled

A PROSPECTIVE EUROPEAN VALIDATION COHORT FOR STEREOTACTIC THERAPY OF RE-ENTRANT TACHYCARDIA

in short

STOPSTORM

hereinafter referred to as "Project"

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Funding Authority as part of the Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Parties and the Funding Authority (hereinafter "Grant Agreement").

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Section: Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Rules for Participation or in the Grant Agreement including its Annexes.

1.2 Additional Definitions

"Consortium Body":

Consortium Body means any management body described in the Governance Structure section of this Consortium Agreement.

"Consortium Council":

The Consortium Council consists of representatives from all the consortium Parties and functions as the Project's general assembly.

"Consortium Plan"

Consortium Plan means the description of the action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the Consortium Council.

"Database"

Means a database built in order to collect, store, manage and analyse the clinical data collected in the frame of the Project.

"Data Management Plan"

Means the plan detailing the management of the data of the Project, as described in the Protocol.

"Funding Authority"

Funding Authority means the body awarding the grant for the Project.

"Defaulting Party"

Defaulting Party means a Party which the Consortium Council has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

"Needed"

means:

For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

"Software"

Software means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

2 Section: Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

3 Section: Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

A new entity becomes a Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

If

- the Grant Agreement is not signed by the Funding Authority or a Party, or
- the Grant Agreement is terminated, or
- a Party's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Consortium Council and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation in the Project.

4 Section: Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

Each Party undertakes to notify promptly, in accordance with the governance structure of the Project, any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

Each Party shall submit its contributions to the periodic reports in time and shall make sure that financial statements are completed and electronically signed by the deadline communicated by the Coordinator. Such deadline communicated by the Coordinator must be reasonable to enable the Parties to submit its contributions and complete the financial statements. The Parties understand 30 calendar days before relevant deadlines by the Funding Authority as reasonable enough. If a Party fails to meet its reporting obligations and causes a delay in the submission process of the periodic reports, the Coordinator shall be entitled to submit a periodic report without the respective Party's contribution in order to meet the deadline set out by the European Commission and to avoid any repercussions that may affect the entire consortium and result in termination of the Grant Agreement by the Commission.

4.2 Breach

In the event that a responsible Consortium Body identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Consortium Council, will give formal notice to such Party requiring that such breach will be remedied, if capable of remedy, within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the Consortium Council may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation in the Project.

4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

4.4

Since the Project consists of the performance of clinical research, the relevant Parties shall make appropriate additional contractual arrangements regarding the rights and obligations in respect of the performance of such clinical research in accordance with Applicable Law and this Consortium Agreement. In case of conflict between such clinical arrangements and the Grant Agreement or Consortium Agreement, firstly the Grant Agreement and secondly the Consortium Agreement shall prevail, except in case where this is not in the best interest of subjects included in the clinical research.

4.5

Each Party shall secure all necessary approvals from the relevant research ethics committees before undertaking any part of the Project requiring ethics committee approval and shall, if required, obtain properly signed informed consent and acknowledgement forms from any human subjects or their legal guardians who they will involve in the Project together with the consent for transferring the collected data and materials. Where any part of the

Project takes place in a hospital, the Party involved shall first obtain all necessary approvals and agreements from that hospital, when required.

5 Section: Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another Party, or to another Party's Affiliated Entity/ies under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliated Entities) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act .

A Party's aggregate liability towards the other Parties collectively, shall be limited to the amount of the relevant Party's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement or € 500.000 (five hundred thousand euro), whichever is the lowest. Any limitation or exclusion of liability does not apply if the damage concerned was caused by a wilful act or gross negligence or can otherwise not be excluded or limited by law.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory liability.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the competent Consortium Bodies of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the competent Consortium Bodies.

6 Section: Governance structure

6.1 General structure

The organisational structure of the Consortium shall comprise the following Consortium Bodies:

Consortium Council as the ultimate decision-making body of the consortium

Management Board as the supervisory body for the execution of the Project which shall report to and be accountable to the Consortium Council.

The Coordinator is the legal entity acting as the intermediary between the Parties and the Funding Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.

The Project Support Team assists the Management Board and the Coordinator.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Representation in meetings

Any Party which is a member of a Consortium Body (hereinafter referred to as "Member"):

- should be present or represented at any meeting;
- may appoint a substitute or a written proxy to attend and vote at any meeting;

and shall participate in a cooperative manner in the meetings.

6.2.2 Preparation and organisation of meetings

6.2.2.1 Convening meetings

The chairperson of a Consortium Body shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
Consortium Council	At least once a year	At any time upon written request of the Management Board or 1/3 of the Members of the Consortium Council
Management Board	At least every 6 months	At any time upon written request of any Member of the Management Board

6.2.2.2 Notice of a meeting

The chairperson of a Consortium Body shall give notice in writing of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

	Ordinary meeting	Extraordinary meeting
Consortium Council	45 calendar days	15 calendar days
Management Board	14 calendar days	7 calendar days

6.2.2.3 Sending the agenda

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body a written (original) agenda no later than the minimum number of days preceding the meeting as indicated below.

Consortium Council	21 calendar days, 10 calendar days for an extraordinary meeting
Management Board	7 calendar days

6.2.2.4 Adding agenda items:

Any agenda item requiring a decision by the Members of a Consortium Body must be identified as such on the agenda.

Any Member of a Consortium Body may add an item to the original agenda by written notification to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

Consortium Council	14 calendar days, 7 calendar days for an extraordinary meeting
Management Board	2 calendar days

6.2.2.5

During a meeting the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda.

6.2.2.6

Meetings of each Consortium Body may also be held by teleconference or other telecommunication means.

6.2.2.7

Decisions will only be binding once the relevant part of the Minutes has been accepted according to Section 6.2.5.

6.2.2.8

Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document, which is then agreed by the defined majority (see Section 6.2.3) of all Members of the Consortium Body. Such document shall include a reasonable deadline for responses.

Decisions taken without a meeting shall be considered as accepted if, within the period set out in article 6.2.4.4, no Member has sent an objection in writing to the chairperson. The decisions will be binding after the chairperson sends to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

6.2.3 Voting rules and quorum

6.2.3.1

Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.

6.2.3.2

Each Member of a Consortium Body present or represented in the meeting shall have one vote.

6.2.3.3

A Party which the Consortium Council has declared according to Section 4.2 to be a Defaulting Party may not vote.

6.2.3.4

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

6.2.4 Veto rights

6.2.4.1

A Member which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.2.4.2

Reserved,

6.2.4.3

A Member may veto decisions during the meeting and within 15 calendar days after the draft minutes of the meeting are sent. A Party that is not a Member of a particular Consortium Body may veto a decision within the same number of calendar days after the draft minutes of the meeting are sent.

6.2.4.4

When a decision has been taken without a meeting a Member may veto such decision within 15 calendar days after written notification by the chairperson of the outcome of the vote.

6.2.4.5

In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all its Members.

6.2.4.6

A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

6.2.4.7

A Party requesting to leave the consortium may not veto decisions relating thereto.

6.2.5 Minutes of meetings

6.2.5.1

The chairperson of a Consortium Body shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 16 calendar days of the meeting.

6.2.5.2

The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

6.2.5.3

The chairperson shall send the accepted minutes to all the Members of the Consortium Body and to the Coordinator, who shall safeguard them. If requested the Coordinator shall provide authenticated duplicates to Parties.

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 Consortium Council

In addition to the rules described in Section 6.2, the following rules apply:

6.3.1.1 Members

6.3.1.1.1

The Consortium Council shall consist of one representative of each Party (hereinafter Consortium Council Member).

6.3.1.1.2

Each Consortium Council Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2. of this Consortium Agreement.

However, Members of the Consortium Council who are not normally authorised to take legally binding decisions concerning the below-mentioned matters due to internal organizational rules or proxy regulations applicable at their institution, shall ensure they consult with their institution's legal office or relevant department in view of obtaining any necessary approval upon receiving the meeting agenda for the Consortium Council meetings or a written document according to the agenda and, in any case, prior to participating in any vote at such meeting. The meeting agenda identifying issues requiring a vote shall be circulated in due time to the Members of the Consortium Council leaving them a reasonable time period to consult internally as set out above, in order to obtain a proper mandate or special power of attorney due to be provided to the other members during the Consortium Council's meeting.

6.3.1.1.3

The Coordinator shall chair all meetings of the Consortium Council, unless decided otherwise in a meeting of the Consortium Council.

6.3.1.1.4

The Parties agree to abide by all decisions of the Consortium Council. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

6.3.1.2 Decisions

The Consortium Council shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. In addition, all proposals made by the Management Board shall also be considered and decided upon by the Consortium Council.

The following decisions shall be taken by the Consortium Council:

Content, finances and intellectual property rights

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Funding Authority
- Changes to the Consortium Plan
- Modifications to Attachment 1 (Background Included) in accordance with Section 9.1.2.
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2)

Evolution of the consortium

- Entry of a new Party to the consortium and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the consortium and the approval of the settlement on the conditions of the withdrawal
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the consortium and measures relating thereto
- Proposal to the Funding Authority for a change of the Coordinator
- Proposal to the Funding Authority for suspension of all or part of the Project
- Proposal to the Funding Authority for termination of the Project and the Consortium Agreement

Appointments

On the basis of the Grant Agreement, the appointment if necessary of:

- Management Board Members

6.3.2 Management Board

In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The Management Board shall consist of the Coordinator, Vice-Coordinator and the work package leaders.

The Coordinator shall chair all meetings of the Management Board, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

Minutes of Management Board meetings, once accepted, shall be sent by the Coordinator to the Consortium Council Members for information.

6.3.2.3 Tasks

6.3.2.3.1

The Management Board shall prepare the meetings, propose decisions and prepare the agenda of the Consortium Council according to Section 6.3.1.2.

6.3.2.3.2

The Management Board shall seek a consensus among the Parties.

6.3.2.3.3

The Management Board shall be responsible for the proper execution and implementation of the decisions of the Consortium Council.

6.3.2.3.4

The Management Board shall monitor the effective and efficient implementation of the Project.

6.3.2.3.5

In addition, the Management Board shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, if necessary, propose modifications of the Consortium Plan to the Consortium Council.

6.3.2.3.6

The Management Board shall:

- agree on the Members of the Project Support Team, upon a proposal by the Coordinator
- support the Coordinator in preparing meetings with the Funding Authority and in preparing related data and deliverables
- prepare the content and timing of press releases and joint publications by the consortium or proposed by the Funding Authority in respect of the procedures of the Grant Agreement Article 29.

6.3.2.3.7

In the case of abolished tasks as a result of a decision of the Consortium Council, the Management Board shall advise the Consortium Council on ways to rearrange tasks and budgets of the Parties concerned. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled.

6.4 Coordinator

6.4.1

The Coordinator shall be the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement. The Coordinator shall be responsible for hosting, maintenance and possible upgrading of the Database in accordance with the Data Management Plan.

6.4.2

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Funding Authority
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Funding Authority and fulfilling the financial tasks described in Section 7.3
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any project deliverable, the Coordinator may nevertheless submit the other 'Parties' project deliverables and all other documents required by the Grant Agreement to the Funding Authority in time.

6.4.3

If the Coordinator fails in its coordination tasks, the Consortium Council may propose to the Funding Authority to change the Coordinator.

6.4.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.4.5

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

6.5 Project Support Team

The Project Support Team shall be proposed by the Coordinator. It shall be appointed by the Management Board and shall assist and facilitate the work of the Management Board and the Coordinator for executing the decisions of the Consortium Council as well as the day-to-day management of the Project.

6.6 External Advisory Board (EAB)

An External Advisory Board (EAB) will be appointed and steered by the Management Board. The EAB shall assist and facilitate the decisions made by the Consortium Council. The Coordinator will ensure that a non-disclosure agreements executed between all Parties and each EAB member. The Coordinator is hereby granted a power of attorney to conclude such non-disclosure agreement on behalf of all Parties. Its terms shall be not less stringent than those stipulated in this Consortium Agreement, and it shall be concluded no later than 30 calendar days after their nomination or before any confidential information will be exchanged, whichever date is earlier. The Coordinator shall write the minutes of the EAB meetings and prepare the implementation of the EAB's suggestions. The EAB members shall be allowed to participate in Consortium Council meetings upon invitation but have not any voting rights.

7 Section: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

The financial contribution of the Funding Authority to the Project shall be distributed by the Coordinator according to:

- the Consortium Plan
- the approval of reports by the Funding Authority, and
- the provisions of payment in Section 7.3.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Funding Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Funding Authority.

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Return of excess payments; receipts

7.1.4.1

In any case of a Party having received excess payments, the Party has to return the relevant amount to the Coordinator without undue delay.

7.1.4.2

In case a Party earns any receipt that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Party earning such income. The other Parties' financial share of the budget shall not be affected by one Party's receipt. In case the relevant receipt is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

7.1.5 Financial Consequences of the termination of the participation of a Party

A Party leaving the consortium shall refund all payments it has received except the amount of contribution accepted by the Funding Authority or another contributor. Furthermore a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional direct costs occurring to the other Parties in order to perform its and their tasks.

7.2 Budgeting

The budget set out in the Consortium Plan shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.

7.3 Payments

7.3.1 Payments to Parties are the exclusive tasks of the Coordinator.

In particular, the Coordinator shall:

- notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts
- undertake to keep the Funding Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.
- With reference to Articles 21.2 and 21.3.2 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount from which the amounts retained by the Funding Authority for the Guarantee Fund and for the final payment have been deducted.

7.3.2

The payment schedule, which contains the transfer of pre-financing and interim payments to Parties, will be handled according to the following:

Funding of costs included in the Consortium Plan will be paid to Parties after receipt from the Funding Authority without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Funding Authority will be paid to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by a responsible Consortium Body to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party relating to any Deliverables/Results/work not completed in accordance with such Defaulting Party's obligations under the Grant Agreement and/or Consortium Agreement. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Funding Authority.

7.3.3 Reimbursement for patient enrolment

Each Party which enrols subjects to the prospective cohort study of the STOPSTORM Registry, will receive a reimbursement of EURO 10.000,- (ten thousand euro) per subject from the Coordinator based on actual, eligible, and auditable direct costs, as mentioned in the Grant Agreement Article 6 and Chapters 4-6. Of this total amount, 75% will be reimbursed by Coordinator for every subject which is enrolled in the prospective cohort study, and 25% when, as determined by the Management Board, the final data of each subject (mandatory requirements) has been collected and checked for quality as described in the Grant Agreement DoA part B Section 1.3.7 (Table 1.3 and Quality Assessment and Harmonisation) and as updated by the Management Board during the course of the Project. The percentages as mentioned in the previous sentence may be amended by the Management Board. Every Party is responsible for their own financial reporting to the EC for this reimbursement and will submit its reporting directly to the EC through the relevant portal. After approval of the EC the Coordinator will pay out the reimbursement to the Party concerned.

8 Section: Results

8.1 Ownership of Results

Results are owned by the Party that generates them.

8.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 26.2 with the following additions:

Unless otherwise agreed:

- each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s), and
- each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given:

  (a) at least 45 calendar days advance notice; and

  (b) Fair and Reasonable compensation.

8.3 Transfer of Results

8.3.1

Each Party may transfer ownership of its own Results following the procedures of the Grant Agreement Article 30.

8.3.2

It may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) to this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to a transfer to listed third parties according to the Grant Agreement Article 30.1.

8.3.3

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer. Any addition to Attachment (3) after signature of this Agreement requires a decision of the Consortium Council.

8.3.4

The Parties recognize that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give the full 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

8.3.5

The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.4 Dissemination

8.4.1

For the avoidance of doubt, nothing in this Section 8.4 has impact on the confidentiality obligations set out in Section 10.

8.4.2 Dissemination of own Results

8.4.2.1

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

For the avoidance of doubt, submissions of abstracts to scientific meetings and congresses will be excluded from the thirty (30) days prior notice, provided that such abstracts do not disclose details of the Project, and provided that the submission can be retracted if objections by other Parties occur. Such abstracts need to be sent to the other Parties upon submission. Any objection to an abstract shall be made within seven (7) calendar days after receipt of the notice.

8.4.2.2

An objection is justified if

(a) the protection of the objecting Party's Results or Background would be adversely affected

(b) the objecting Party's legitimate interests in relation to the Results or Background would be significantly harmed.

The objection has to include a precise request for necessary modifications.

8.4.2.3

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

8.5

The objecting Party can request a publication delay of not more than 60 calendar days from the time of receipt of the publication for review. After 60 calendar days following receipt of the publication for review the publication is permitted.

8.5.1 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.5.2 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree that includes their Results or

Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

In accordance with scientific customs, the Party's contributions will be expressly reflected in all written or oral public disclosures concerning Results by acknowledgment or co-authorship, as appropriate.

8.5.3 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

9 Section: Access Rights

9.1 Background included

9.1.1

In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2

Any Party may add further own Background to Attachment 1 during the Project by written notice to the other Parties. However, approval of the Consortium Council is needed should a Party wish to modify or withdraw its Background in Attachment 1.

9.2 General Principles

9.2.1

Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

9.2.2

Any Access Rights granted expressly exclude any rights to sublicense unless expressly stated otherwise.

9.2.3

Access Rights shall be free of any administrative transfer costs.

9.2.4

Access Rights are granted on a non-exclusive basis.

9.2.5

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

9.2.6

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these

rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

9.2.7

The requesting Party must show that the Access Rights are Needed.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions under a separate agreement.

Access rights to Results for internal (including clinical) research activities and educational purposes shall be granted on a royalty-free basis.

9.4.2

Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on Fair and Reasonable conditions under a separate agreement.

9.4.3

A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Reserved.

9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties under a separate agreement.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Consortium Council to terminate its participation in the consortium.

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period of time specified in Section 9.4.3.

9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

9.8

Reserved.

9.9 Specific provisions for Access Rights to Software

9.9.1 Definitions relating to Software

"Application Programming Interface"

means the application programming interface materials and related documentation containing all data and information to allow skilled Software developers to create Software interfaces that interface or interact with other specified Software.

"Controlled Licence Terms" means terms in any licence that require that the use, copying, modification and/or distribution of Software or another work ("Work") and/or of any work that is a modified version of or is a derivative work of such Work (in each case, "Derivative Work") be subject, in whole or in part, to one or more of the following:

a) (where the Work or Derivative Work is Software) that the Source Code or
b) other formats preferred for modification be made available as of right to any third party on request, whether royalty-free or not;
c) that permission to create modified versions or derivative works of the Work or Derivative Work be granted to any third party;
d) that a royalty-free licence relating to the Work or Derivative Work be granted to any third party.

For the avoidance of doubt, any Software licence that merely permits (¬but does not require any of) the things mentioned in (a) to (c) is not a Controlled Licence (and so is an Uncontrolled Licence).

"Object Code" means software in machine-readable, compiled and/or executable form including, but not limited to, byte code form and in form of machine-readable libraries used for linking procedures and functions to other software.

"Software Documentation" means software information, being technical information used, or useful in, or relating to the design, development, use or maintenance of any version of a software programme.

"Source Code" means software in human readable form normally used to make modifications to it including, but not limited to, comments and procedural code such as job control language and scripts to control compilation and installation.

9.9.2 General principles

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software as far as not modified by this Section 9.9.

Parties' Access Rights to Software do not include any right to receive Source Code or Object Code ported to a certain hardware platform or any right to receive Source Code, Object Code or respective Software Documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

The intended introduction of Intellectual Property (including, but not limited to Software) under Controlled Licence Terms in the Project requires the approval of the Consortium Council to implement such introduction into the Consortium Plan, unless it has been already introduced in the Proposal and/or attached in Annex 5 of this CA; in such a case, no further approval is needed.

The Parties are aware that where open source software is used for the implementation of the Project, the resulting software may be subject to open source licenses.

In the event that:

a) any Software which is Background has been used or introduced under an open source licence (including as Controlled License Terms), or

b) any Software which is Results has been made available, on agreement of the owning Party, under an open source licence (including as Controlled License Terms),

then, in respect of such Background or Results, the terms of the open source licence will prevail over the terms of this Section 9.9.

9.9.3 Access to Software

Access Rights to Software that is Results shall comprise:

Access to the Object Code; and,

where normal use of such an Object Code requires an Application Programming Interface (hereafter API), Access to the Object Code and such an API; and,

if a Party can show that the execution of its tasks under the Project or the Exploitation of its own Results is technically or legally impossible without Access to the Source Code, Access to the Source Code to the extent necessary.

Background shall only be provided in Object Code unless otherwise agreed between the Parties concerned.

9.9.4 Software licence and sublicensing rights

9.9.4.1 Object Code

9.9.4.1.1 Results - Rights of a Party

Where a Party has Access Rights to Object Code and/or API that is Results for Exploitation, such Access shall, in addition to the Access for Exploitation foreseen in Section 9.4, as far as Needed for the Exploitation of the Party's own Results, comprise the right:

to make an unlimited number of copies of Object Code and API; and

to distribute, make available, market, sell and offer for sale such Object Code and API as part of or in connection with products or services of the Party having the Access Rights;

provided however that any product, process or service has been developed by the Party having the Access Rights in accordance with its rights to exploit Object Code and API for its own Results.

If it is intended to use the services of a third party for the purposes of this Section 9.8.4.1.1, the Parties concerned shall agree on the terms thereof with due observance of the interests of the Party granting the Access Rights as set out in Section 9.2 of this Consortium Agreement.

9.9.4.1.2 Results - Rights to grant sublicenses to end-users

In addition, Access Rights to Object Code shall, as far as Needed for the Exploitation of the Party's own Results, comprise the right to grant in the normal course of the relevant trade to end-user customers buying/using the product/services, a sublicense to the extent as necessary for the normal use of the relevant product or service to use the Object Code as part of or in connection with or integrated into products and services of the Party having the Access Rights and, as far as technically essential:

- to maintain such product/service;
- to create for its own end-use interacting interoperable software in accordance with the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs

9.9.4.1.3 Background

For the avoidance of doubt, where a Party has Access Rights to Object Code and/or API that is Background for Exploitation, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

9.9.4.2 Source Code

9.9.4.2.1 Results - Rights of a Party

Where, in accordance with Section 9.8.3, a Party has Access Rights to Source Code that is Results for Exploitation, Access Rights to such Source Code, as far as Needed for the Exploitation of the Party's own Results, shall comprise a worldwide right to use, to make copies, to modify, to develop, to adapt Source Code for research, to create/market a product/process and to create/provide a service.

If it is intended to use the services of a third party for the purposes of this Section 9.8.4.2.1, the Parties shall agree on the terms thereof, with due observance of the interests of the Party granting the Access Rights as set out in Section 9.2 of this Consortium Agreement.

9.9.4.2.2 Results – Rights to grant sublicenses to end-users

In addition, Access Rights, as far as Needed for the Exploitation of the Party's own Results, shall comprise the right to sublicense such Source Code, but solely for purpose of adaptation, error correction, maintenance and/or support of the Software.

Further sublicensing of Source Code is explicitly excluded.

9.9.4.2.3 Background

For the avoidance of doubt, where a Party has Access Rights to Source Code that is Background for Exploitation, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

9.9.5 Specific formalities

Each sublicense granted according to the provisions of Section 9.8.4 shall be made by a traceable agreement specifying and protecting the proprietary rights of the Party or Parties concerned.

10 Section: Non-disclosure of information

10.1

All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during the term of this Consortium Agreement and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

10.2

The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for the duration of this Project and for a period of 4 years after the end of the Project:

- Not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations or to keep copies of electronically exchanged Confidential Information made as a matter of routine information technology back-up provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

10.3

The recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder. This obligation does not alter the status of the information as a Confidential Information and it is still to be treated as confidential in regards to any other Party.

10.5

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care

10.6

Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7

If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

10.8

The Coordinator shall be responsible for hosting, maintenance and possible upgrading of the Database in accordance with the Data Management Plan. The Database will be governed by the Registry Regulatory Document as included in Attachment 4 and all Parties will comply with said document.

11 Section: Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and

Attachment 1 (Background included)

Attachment 2 (Accession document)

Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2)

Attachment 4 Registry Regulatory Document

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

Other communication:

Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all Parties.

11.4 Assignment and amendments

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval. Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.1.2 require a separate written agreement to be signed between all Parties.

11.5 **Mandatory national law**

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.6 **Language**

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

11.7 **Applicable law**

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

11.8 **Settlement of disputes**

The parties shall endeavour to settle their disputes amicably.

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules.

The place of arbitration shall be Brussels if not otherwise agreed by the conflicting Parties.

The award of the arbitration will be final and binding upon the Parties.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

12 Section Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

Partner 1:

UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU)

Name [redacted]

Title: Dean and Vice-president of Executive Board UMC Utrecht

Date:

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 2:

FAKULTNI NEMOCNICE OSTRAVA (FNO)

Name(s): [redacted]

Title: Deputy Director for Science, Research and Education

Date: MARCH 31 [redacted] 22

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 3:
INSTITUT KLINCKÉ A EXPERIMENTÁLNÍ MEDICINY (IKEM)

Name: Ing. Michal Stiborek, MBA
Title: Director

Date: 31. 03. 2022

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 4:

NEMOCNICE AGEL TRINEC PODLESI AS (NPO)

Name: Radek Neuwirth

Title: MUDr.

Date: 31. 03. 2022

Signature:

Name: Yvona Placzkova

Title: Ing.

Date: 31. 03. 2022

Signature:

Organisation stamp (in blue):

Partner 5:

CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL (CAU)

Name [redacted]

Title: Head of Research Affairs

Date: [redacted]

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 6:

RUPRECHT-KARLS-UNIVERSITY HEIDELBERG (UHEI)

Name [redacted]

Title: Head of Department Legal issues of Research Funding / EU Research Officer

Date: [redacted]

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 7:

CHARITE - UNIVERSITAETSMEDIZIN BERLIN (CHARITE)

Name: [redacted]

Title: Faculty Business Director

Date: [redacted]

Signature: [redacted]

Organisation stamp (in blue):

Partner 8:
TECHNISCHE UNIVERSITAET DRESDEN (TUD)

Name [redacted]
Title: Head of Unit

Date: 05/04/2022

Signature:

Organisation stamp (in blue): [redacted]

Partner 9:

UNIVERSITAET ZU LUEBECK (UZL)

Name [redacted]

Title: President

Date: 22.03.2022

Sign [redacted]

Organisation stamp (in blue): [redacted]

Partner 10:

HERZZENTRUM LEIPZIG GMBH (ULEIHC)

Name [redacted]

Title: Medical Director of Leipzig Heart Center, Director of Leipzig Heart Institute

Date: 20.04.2022

Signature [redacted]

Organisation stamp (in blue):

Partner 11:

CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS (CHUV)

Name [redacted]

Title: General Director

Date: April 27 2022

Signature: [redacted]

Organisation stamp (in blue):

[redacted]

Partner 12:
INSEL GRUPPE AG (BERN)

Name [redacted]
Title: Director of Teaching and Research

Date: [illegible]

Signature:

Name [redacted]
Title: PD Dr. med.

Date: 31. MAR 2022

Signature: [redacted]

Name [redacted]
Title: [illegible]

Date: 22.4.2022

Signature [redacted]

[redacted]

Orga[redacted]

[redacted]

Partner 13:
UNIVERSITAT ZURICH (USZ)

Name [redacted]
Title: Vice President

[redacted]

Date: 17. MRZ. 2022

Signature: [redacted]

[redacted]

Organisation stamp (in blue):

Partner 14:

NARODOWY INSTYTUT ONKOLOGII IM. MARII SKŁODOWSKIEJ-CURIE – PAŃSTWOWY INSTYTUT BADAWCZY (NRIO)

Name: [redacted]

Title: Deputy Director for Scientific Matters

Date: 2022-03-31

Signature: [redacted]

Organisation stamp (in blue):

[redacted]

Partner 15:

GORNOSLASKIE CENTRUM MEDYCZNE IM. PROF. LESZKA GIECA SLASKIEGO UNIWERSYTETU MEDYCZNEGO W KATOWICACH (GCM)

Name: [redacted]

Title: Director

Date: [redacted]

Signature: [redacted]

Organisation stamp (in blue):

[redacted]

[redacted]

Partner 16:

AARHUS UNIVERSITET (AU)

Name [redacted]

Title: Head of AU Technology Transfer Office

Date: 24.03.2022

Sign [redacted]

Organisation stamp [redacted]

Partner 17:

AARHUS UNIVERSITETSHOSPITAL (AUH)

Name [redacted]

Title: Deputy Director

Date: 22.03.2022

Signatu [redacted]

Organisation stamp (in blue):

Partner 18:

CONSORCIO MAR PARC DE SALUT DE BARCELONA (IMIM)

Name [redacted]

Title: Manager

[redacted]

Partner 19:

SERVICIO MADRILEÑO DE SALUD (SERMAS)

Name [redacted]

Title: General Director HCSC/SERMAS

Date:

Si[redacted]

O[redacted]tamp (in blue):

Partner 20:

FUNDACION INVESTIGACIÓN HOSPITAL GENERAL UNIVERSITARIO DE VALENCIA (FIHGUV)

Nam[redacted]

Title: Manager FIHGUV

CIF: G96792221

Date: 29/03/2022

Sign[redacted]

Organisation stamp (in blue):

Partner 21:

AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL-RE)

Name [redacted]

Title: Director of the Research and Statistics Infrastructure Unit

Date: March 31st 2022

Signatu [redacted]

Organisation stamp (in blue):

[redacted]

Partner 22:

FONDAZIONE CENTRO NAZIONALE DI ADROTERAPIA ONCOLOGICA (CNAO)

Name [redacted]

Title: President

Date:

[redacted]

Partner 23:

ISTITUTO DON CALABRIA – IRCCS OSPEDALE SACRO CUORE DON CALABRIA (IRCCSDC)

Name: [redacted]

Title: Legal Representative

Date: 24/03/2022

Signature: [redacted]

Organisation stamp (in blu [redacted]

Partner 24:

UNIVERSITA DEGLI STUDI DI TORINO (UNITO)

Name [redacted]

Title: Director of Department of Medical Sciences

Date: 19th April, 2022

Signature:

[redacted]

Organisation stamp (in blue):

[redacted]

Partner 25:

FONDAZIONE IRCCS POLICLINICO SAN MATTEO (IRCCS OSM)

Name [redacted]

Title: General Director

Date:

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Partner 26:
UNIVERSITEIT MAASTRICHT (UM)

Name [redacted]
Title: Scientific director CARIM

Date: 19 April 2022

Signature:
[redacted]
Organisation stamp (in blue):
[redacted]

Partner 27:

ACADEMISCH ZIEKENHUIS LEIDEN (LUMC)

Name [redacted] [redacted]

Title: Business Manager, Division 4 LUMC

Date: [redacted]

Signature: [redacted]

Organisation stamp (in blue):

[redacted]

Partner 28:

ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM (AMC)

Name: [redacted]

Title: CFO of the Executive Board

Date: 06-05-2022

Signature: [redacted]

Organisation stamp (in blue): [redacted]

Read and acknowledged by: AMC Principal Investigator

Name: [redacted]

Partner 29:

STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MAASTRO)

Name: [redacted]

Title: CEO

Date: 8 april 2022

Signature: [redacted]

Organisatio[redacted]

Partner 30:

STICHTING CATHARINA ZIEKENHUIS (SCZ)

Name [redacted]

Title: Manager Education & Research

Date: 22-03-2022

Signatu [redacted]

Organisation stamp (in blue):

[redacted]

Partner 31:
HARTERAAD (HART)

Name [redacted]
Title: Director

Date: 6/4/22 [redacted]

Signatu[redacted]

Organisation stamp (in blue):

[redacted]

Attachment 1: Background included

According to the Grant Agreement (Article 24) Background is defined as "data, know-how or information (…) that is needed to implement the action or exploit the results". Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the project. This is the purpose of this attachment.

PARTY 1

As to **UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 2

As to **FAKULTNI NEMOCNICE OSTRAVA (FNO)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **FAKULTNI NEMOCNICE OSTRAVA (FNO)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 3

As to **INSTITUT KLINCKÉ A EXPERIMENTÁLNÍ MEDICINY (IKEM)**, it is agreed between the Parties that, to the best of their knowledge

No data, know-how or information of **INSTITUT KLINCKÉ A EXPERIMENTÁLNÍ MEDICINY (IKEM)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 4

As to **NEMOCNICE AGEL TRINEC PODLESI AS (NPO)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **NEMOCNICE AGEL TRINEC PODLESI AS (NPO)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 5

As to **CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL (CAU)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the German RAVENTA trial (NCT03867747) before RAVENTA is adapted to the prospective STOPStorm project as described in WP3 will be added to the retrospective patient database in the STOPStorm project as described in WP1	For site specific patient data within the RAVENTA trial there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the RAVENTA trial OR 2) the patient data is submitted anonymously into the STOPStorm database	The data will be used for publications as defined in the RAVENTA trial protocol and for further inhouse developments and subsequent publications if desired.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPStorm project as described in WP1	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPStorm database	The data will be used for further inhouse developments and subsequent publications if desired.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 6

As to **RUPRECHT-KARLS-UNIVERSITY HEIDELBERG (UHEI)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the German RAVENTA trial (NCT03867747) before RAVENTA is adapted to the prospective STOPSTORM project as described in WP3 will be added to the retrospective patient database in the STOPSTORM project as described in WP2	For site specific patient data within the RAVENTA trial there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the RAVENTA trial OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for publications as defined in the RAVENTA trial protocol and for further inhouse developments and subsequent publications if desired.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPSTORM project as described in WP2	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for further inhouse developments and subsequent publications if desired.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 7

As to **CHARITE - UNIVERSITAETSMEDIZIN BERLIN (CHARITE)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **CHARITE - UNIVERSITAETSMEDIZIN BERLIN (CHARITE)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 8

As to **TECHNISCHE UNIVERSITAET DRESDEN (TUD)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the German RAVENTA trial (NCT03867747) before RAVENTA is adapted to the prospective STOPSTORM project as described in WP3 will be added to the retrospective patient database in the STOPSTORM project as described in the respected work package	For site specific patient data within the RAVENTA trial there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the RAVENTA trial OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for publications as defined in the RAVENTA trial protocol and for further inhouse developments and subsequent publications if desired.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPSTORM project as described in the respected work package.	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for further inhouse developments and subsequent publications if desired.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 9

As to **UNIVERSITAET ZU LUEBECK (UZL)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **UNIVERSITAET ZU LUEBECK (UZL)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 10

As to **HERZZENTRUM LEIPZIG GMBH (ULEIHC)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **HERZZENTRUM LEIPZIG GMBH (ULEIHC)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 11

As to **CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS (CHUV)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS (CHUV)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 12

As to **INSEL GRUPPE AG (BERN)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **INSEL GRUPPE AG (BERN)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 13

As to **UNIVERSITÄTSSPITAL ZÜRICH (USZ)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **UNIVERSITÄTSSPITAL ZÜRICH (USZ)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 14

As to **NARODOWY INSTYTUT ONKOLOGII IM. MARII SKŁODOWSKIEJ-CURIE – PAŃSTWOWY INSTYTUT BADAWCZY (NRIO)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the Polish SMART-VT trial (NCT04642963) before SMART-VT is adapted to the prospective STOPSTORM project as described in WP3 will be added to the retrospective patient database in the STOPSTROM project as described in WP1	For site specific patient data within the SMART-VT trial there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the SMART-VT trial OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for publications as defined in the SMART-VT trial protocol and for further inhouse developments and subsequent publications if desired.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPSTORM project as described in WP1	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPSTORM database	The data will be used for further inhouse developments and subsequent publications if desired

This represents the status at the time of signature of this Consortium Agreement.

PARTY 15

As to **GORNOSLASKIE CENTRUM MEDYCZNE IM. PROF. LESZKA GIECA SLASKIEGO UNIWERSYTETU MEDYCZNEGO W KATOWICACH (GCM)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **GORNOSLASKIE CENTRUM MEDYCZNE IM. PROF. LESZKA GIECA SLASKIEGO UNIWERSYTETU MEDYCZNEGO W KATOWICACH (GCM)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 16

As to **AARHUS UNIVERSITET (AU)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **AARHUS UNIVERSITET (AU)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 17

As to **AARHUS UNIVERSITETSHOSPITAL (AUH)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
At Aarhus University Hospital an atlas based method for autosegmentation of substructures in the heart has been developed. It will be optimised to STOPSTORM patients within in current project.		

This represents the status at the time of signature of this Consortium Agreement.

PARTY 18

As to **CONSORCIO MAR PARC DE SALUT DE BARCELONA (IMIM)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **CONSORCIO MAR PARC DE SALUT DE BARCELONA (IMIM)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 19

As to **SERVICIO MADRILEÑO DE SALUD (SERMAS)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **SERVICIO MADRILEÑO DE SALUD (SERMAS)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 20

As to **FUNDACION INVESTIGACIÓN HOSPITAL GENERAL UNIVERSITARIO DE VALENCIA (FIHGUV)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the Spanish RANIT trial before RANIT is adapted to the prospective STOPStorm project as described in WP3 will be added to the retrospective patient database in the STOPStorm project as described in WP1	For site specific patient data within the RANIT trial there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the RANIT trial OR 2) the patient data is submitted anonymously into the STOPStorm database	The data will be used for publications as defined in the RANIT trial protocol and for further inhouse developments and subsequent publications if desired.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPStorm project as described in WP1	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPStorm database	The data will be used for further inhouse developments and subsequent publications if desired.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 21

As to **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL-RE)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL-RE)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 22

As to **FONDAZIONE CENTRO NAZIONALE DI ADROTERAPIA ONCOLOGICA (CNAO)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **FONDAZIONE CENTRO NAZIONALE DI ADROTERAPIA ONCOLOGICA (CNAO)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 23

As to **IRCCS SACRO CUORE DON CALABRIA (IRCCSDC)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **IRCCS SACRO CUORE DON CALABRIA (IRCCSDC)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 24

As to **UNIVERSITA DEGLI STUDI DI TORINO (UNITO)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **UNIVERSITA DEGLI STUDI DI TORINO (UNITO)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 25

As to **FONDAZIONE IRCCS POLICLINICO SAN MATTEO (IRCCS OSM)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **FONDAZIONE IRCCS POLICLINICO SAN MATTEO (IRCCS OSM)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 26

As to **UNIVERSITEIT MAASTRICHT (UM)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **UNIVERSITEIT MAASTRICHT (UM)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 27

As to **ACADEMISCH ZIEKENHUIS LEIDEN (LUMC)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Site specific treated patients and their data collected within the Dutch START trial(s) before START is adapted to the prospective STOPSTORM project as described in WP3 will be added to the retrospective	For site specific patient data within the START trial(s) there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the	Publication of this data is subject to the terms of the START trial protocol. The use of the data is only permitted for the Implementation of this consortium agreement and

patient database in the STOPSTORM project as described in WP1	START trial OR 2) the patient data is submitted anonymously into the STOPSTORM database	publication within this consortium. The use of the data outside this scope is not allowed. No duplication/ reproduction/ downloading rights.
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPSTORM project as described in WP1	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPSTORM database	Publication of this data is subject to the terms of the START trial protocol. The use of the data is only permitted for the Implementation of this consortium agreement and publication within this consortium. The use of the data outside this scope is not allowed. No duplication/ reproduction/ downloading rights.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 28

As to **ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM (AMC)**, it is agreed between the Parties that, to the best of their knowledge,

The following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
Site specific treated patients and their data collected within the Dutch STARNL trial(s) before STARNL is adapted to the prospective STOPSTORM project as described in WP3 will be added to the retrospective patient database in the STOPSTORM project as described in WP1	For site specific patient data within the STARNL trial(s) there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for data sharing within the STARNL trial OR 2) the patient data is submitted anonymously into	Use of the data is limited to further research and inhouse developments and subject to the terms of the STARNL trial protocol, Consortium Agreement and Registry Document

	the STOPSTORM database Publication of this data is subject to the terms of the STARNL trial protocol	
Individually treated patients under compassionate use and their data collected will be added to the retrospective patient database in the STOPSTORM project as described in WP1	For individual patient data there is no limitation for implementation under one of the following conditions: 1) the patient has not withdrawn his consent for individual data sharing OR 2) the patient data is submitted anonymously into the STOPSTORM database	Use of the data is limited to further research and inhouse developments and subject to the terms of the Consortium Agreement and Registry Document

This represents the status at the time of signature of this Consortium Agreement.

PARTY 29

As to **STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MAASTRO)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MAASTRO)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 30

As to **STICHTING CATHARINA ZIEKENHUIS (SCZ)**, it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of **STICHTING CATHARINA ZIEKENHUIS (SCZ)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 31

As to **HARTERAAD (HART)**, it is agreed between the Parties that, to the best of their knowledge

No data, know-how or information of **HARTERAAD (HART)** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

Attachment 2: Accession document

ACCESSION

of a new Party to

[Acronym of the Project] Consortium Agreement, version [..., YYYY-MM-DD]

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Grant Agreement]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]
Signature(s)
Name(s)
Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]
Signature(s)
Name(s)

Title(s)

Attachment 3: List of Third Parties for simplified transfer according to Section 8.3.2.

Partner 5 CAU: Third Party Universitätsklinikum Schleswig-Holstein (UKSH)

Partner 8 TUD: Universitätsklinikum Carl Gustav Carus Dresden (UKD)

Partner 9 UZL: Universitätsklinikum Schleswig-Holstein (UKSH)

Partner 18 IMIM: Fundació Institut Hospital del Mar d'Investigacions Mèdiques (FIMIM)

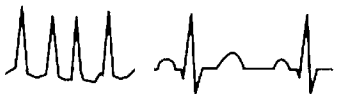
Partner 19 SERMAS: Fundación para la Investigación Biomédica del Hospital Clínico San Carlos (FIB HCSC)

Partner 26 UM: Academisch Ziekenhuis Maastricht (MUMC)

Attachment 4: Registry Regulatory Document

STOPSTORM Registry

Regulatory Document



STORM.eu

Final Version 1.1

February 21, 2022

Grant Agreement no.: 945119

Call/Topic identifier: H2020-SC1-BHC-08-2020-RTD-RIA

1) In this Regulatory Document the following terms have the meanings ascribed to them below:
   a) **Affiliated Third Party/ies**: means a party listed in Appendix E, which is affiliated to one of the Partners.
   b) **Coordinator**: means the Partner of the Registry who has been assigned this role. In this Registry, UMC Utrecht is the coordinator.
   c) **Controller:** means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data
   d) **Consortium Council:** the Consortium Council consist of one representative from all the consortium Partners and functions as the STOPSTORM general assembly.
   e) **Data:** means the observational and prospective (raw) data collected from Donors stored in the **STOPSTORM** Registry in Pseudonymized form. For the purpose of this Regulation, Data are considered Personal Data.
   f) **Database:** means the STOPSTORM Registry database containing the Data.
   g) **Dataset:** means the Data from the **STOPSTORM** Registry made available for the purpose of a Study.
   h) **Donor:** means any individual who's Data are transferred to the **STOPSTORM** Registry in compliance with the terms and conditions of this Regulatory Document.
   i) **Findings**: Results, data and information, whether or not they can be protected, which are generated as a result of a Study
   j) **GDPR**: means the General Data Protection Regulation (EU) 2016/679
   k) **Host**: means the third party hosting the Database without being part of the Consortium, the Host will be: Ciwit B.V. (Castor), with a legal address at George Westinghousestraat 2, 1097 BA Amsterdam.
   l) **Individual Findings**: means findings that are clinically relevant to the Donor.
   m) **Management Board**: the supervisory body for the execution of the STOPSTORM Registry which shall report to and be accountable to the Consortium Council.
   n) **Participant**: means each academic party providing Data in the STOPSTORM Registry, but which is not a party to the Consortium Agreement and that has signed the accession form attached hereto as **Appendix D**.
   o) **Partner**: Each Party of the STOPSTORM Consortium as described in the Consortium Agreement.
   p) **Personal Data:** means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
   q) **Project Plan**: means the project plan, detailing the aims and set-up of the STOPSTORM Registry attached hereto as **Appendix A**.
   r) **Pseudonymized:** 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 organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person
   s) **Regulatory Document:** means this regulatory document including its appendices and any

future amendments to it

t) **Researcher**: means a researcher of a Partner
u) **Results:** means all results, know how, data, findings and information and all intellectual property rights therein;
v) **Study:** a project of a Partner within the STOPSTORM Registry, using a Dataset, which is subject to approval of the Management Board.
w) **Study Proposal:** The document describing the scope, purposes and methodology of the project of a Partner within the STOPSTORM Registry, using the Database, which is subject to approval of the Management Board.

1) Background and purposes.

The background and purposes of the **STOPSTORM** Registry is described in Appendix A.

2) **Laws and Regulations**.

This Regulatory Document is drafted taking into account EU law and legislation. As the **STOPSTORM** consortium is an international collaboration, it is not feasible to implement all national laws of the Partners into this Regulatory Document. In collecting Data and making available the Data to the **STOPSTORM** Registry, each Partner requires to abide by its national law, including but not limited to data protection law. It is their individual responsibility to ensure that no Data is entered into the **STOPSTORM** Registry in violation of their national law and legislation and that all Data can be used for the purposes of the **STOPSTORM** Registry.

3) **Participants**.

Participants may become a member to this Regulatory Document (and not the Consortium Agreement) in order to submit Data. An academic party can become a Participant by signing the accession form attached hereto as Appendix D, which form will be signed by the Coordinator on behalf of the Partners and the Participant. Commercial third parties cannot become a Participant. However, commercial third parties can request access rights as specified in Article 5 section 9 through 11 of this Regulatory Document.

4) In the Project Plan, Affiliated Third Parties will be involved. Affiliated Third Parties may submit Data and receive access to Data. Affiliated Third Parties are not a party to the Consortium Agreement. In order for the Affiliated Third Parties to be able to submit and/or receive access to Data, it is hereby agreed that the Affiliated Third Parties have the same rights and obligations under this Regulatory Document as if they were a Partner. The Affiliated Third Parties do not have any rights under the Consortium Agreement. Academic parties listed in Appendix E can become an Affiliated Third Party by signing the accession form attached here to as Appendix D, which form will be signed by the Coordinator on behalf of the Partners and the Affiliated Third Parties. Additional academic parties may become an Affiliated Third Party in accordance with the Grant Agreement procedures for adding third parties to the STOPSTORM Registry.

1) Each Partner and Participant shall transfer into the **STOPSTORM** Registry pseudonymized Data of patients that consented to participate in the Registry and that are eligible to

participate in the **STOPSTORM** Registry. Consent shall be obtained in accordance with applicable national and European law.

2) Transfer of Data into the **STOPSTORM** Registry database and the use of such Data by the Partners within the scope of STOPSTORM, as determined by the Management Board, shall be free of charge. Costs for (where applicable) making available Data from the **STOPSTORM** Registry to Partners for the performance of analyses by the Partners for other research purposes outside the scope of STOPSTORM shall be determined by the Consortium Council.

3) The Data in the **STOPSTORM** Registry shall be used for research purposes only and not for any commercial purposes.

4) Each Partner and Participant shall remain the custodian of the Data it transfers into the **STOPSTORM** Registry. Transfer of Data into the **STOPSTORM** Registry shall not restrict any use of such Data by the Partner or Participant that has contributed such Data.

5) It is the responsibility and liability of each Partner and Participant transferring pseudonymized Data into the Database, to ensure such transfer is in compliance with the law, including but not limited to privacy laws and that such Data can be used for the purposes of the STOPSTORM Registry.

6) To ensure the lawful processing of the Data by the **STOPSTORM** Study Group, each Partner and Participant shall inform the Coordinator of specific obligations following from its national mandatory law, that may affect the processing of the Data in relation to the **STOPSTORM** Registry.

7) Data shall be made available from the **STOPSTORM** Registry on behalf of the **STOPSTORM** Consortium for Studies in accordance with **Section 5** hereof. After the STOPSTORM Registry is completed the Data in the STOPSTORM Registry will be made publicly available as determined by the Consortium Council, in an anonymized form. The form and procedure to anonymize will be determined by the Consortium Council.

1) The Coordinator shall, as a data processor be responsible for maintaining and hosting the **STOPSTORM** Registry in accordance with the GDPR and any applicable data protection provisions of national law of the Partners/Participants it is informed of. In this role the Coordinator shall act as a data processor on behalf of the Joint Controllers and shall process the Data in accordance with the terms set out in **Appendix B**.

2) Each Partner (including UMC Utrecht) and Participant is considered the Controller of its own Data and shall fulfil all obligations of Controller under applicable data protection law.

3) In respect of the use of the Data for the purpose of creating and managing the **STOPSTORM** Registry, the **STOPSTORM** Consortium Partners and Participants providing Data are considered to be joint controllers. In view of article 26 of the GDPR, the privacy arrangements between the Coordinator and each Partner and Participant has been determined in the privacy matrix attached to this Agreement as **Appendix C**. In respect of the use of the Data

for the purpose of performing a Study, the Partner conducting the Study shall be a separate controller. In the case of several Partners jointly performing a Study, these Partners will be considered joint controllers in accordance with Appendix C.

4) Partners and Participants shall ensure that the privacy of the Donors and the confidentiality of Data are protected in accordance with the statutory requirements applicable in their own country and the policies of the institution of which the Donor is a patient. The Coordinator shall not be responsible or liable for any failure of a Partner nor Participant to comply with national law and/or institutional policies with regard to the transferring of Data into the **STOPSTORM** Registry.

5) Each Partner and Participant shall use best efforts to ensure the accuracy of any Data that it places into the database and promptly to notify the Coordinator of any errors therein and, if so instructed by the Coordinator, correct such errors.

6) Partners and Participants shall transfer Data into the **STOPSTORM** Registry in pseudonymised form only, in accordance with the guidelines and instructions of the Consortium Council. The key to coded Data is held at each Partner's/Participant's own location for its own Donors and is the responsibility of the local investigator.

7) The Coordinator shall inform the Partners and Participants about the method of encoding and the location of the **STOPSTORM** Registry (and any changes to the location).

8) Data which will be provided to Partners for Studies will only concern pseudonymized Data.

Access by Partners and Participants

1) Each Partner and Participant remains the custodian of its Partner/Participant Data in the **STOPSTORM** Registry and is entitled to extract such Partner/Participant Data from the **STOPSTORM** Registry database for its own uses without the approval of the Management Board. Each Partner or Participant shall be responsible and liable for the processing of its own Data in accordance with applicable laws. However, each Partner and Participant is not allowed to submit its own Data (which is provided under Article 3 section 1) to another registry, unless approved by the Management Board. Such consent is not required if own Data is to be submitted to RAVENTA trial data base or a data repository mentioned in Attachment 1 of this Consortium Agreement.

Access by Partners Researchers

2) Each Partner shall be bound by this Regulation. The applicable conditions must be made known to the Researcher at least prior to the review of the Study Proposal.

3) Researchers requesting Data shall send their Study Proposal to the Coordinator who will submit this Proposal to the Management Board.

4) Making available Data shall be conditional to obtained approval from the Management Board and to the extent applicable to the permits and licenses required by the Researcher's national law.

5) If the Management Board approves a Study Proposal, the Researcher will receive a 'Mail of Approval', as attached hereto as **Appendix F**, explaining in layman's terms the terms and condition of this Regulatory Document with regard to receipt and use of the Data. In order to have an overview of all Studies performed, all 'Approval emails' will be stored with the Coordinator.

6) The Partner shall be considered a Controller under the GDPR in relation to the Dataset.

7) Access to Data shall at least be conditional to the following:
   a) The Partner shall be responsible for obtaining the permits and approvals necessary in its own country and the policies of its institution.
   b) The Partner shall use the Data for the approved Study only. In case of deviations or changes in the Study the Management Board shall have the right to terminate Access without any liability at its sole discretion.
   c) The Partner shall bear sole responsibility for the handling and use of the Data in accordance with applicable law and legislation.
   d) The Partner shall not duplicate the Data or have them duplicated.
   e) The Partner shall not disclose or provide access to the Data to any third party without the prior written consent of Management Board. For the avoidance of doubt, sub-processing of the Data by a third party is not allowed without prior written approval of Management Board.
   f) Findings must be shared with the research community at large and therefore be scientifically published in accordance with the Consortium Agreement and this Regulatory Document.
   g) The source of the Data will be properly acknowledged in publications.

8) Reserved.

Commercial Parties

9) Commercial parties will not be provided access to the STOPSTORM Registry or any individual Data derived from the STOPSTORM Registry. However, companies that make available Funding may request certain analyses, based on an analyses plan developed by (a group of) Partners in the form of investigator-initiated research, with reports and/or scientific publication as sole deliverable. Such Partners will first conclude appropriate written agreements with the commercial party concerned.

10) In deviation of sub 9 above, commercial parties may be granted access to certain fully anonymised aggregated data, subject to clause 11.2 and subject to all Partners involved in the Study agree and any additional conditions determined by the Management Board in consultation with such Partners.

11) In no event shall commercial parties own results of such analyses.

The publication of Findings generated with Data from the **STOPSTORM** Registry needs to comply with rules concerning authorship, as defined by the International Committee of Medical Journal Editors (ICMJE). To qualify as author, at least the following criteria apply to the contribution of the investigator in respect to the intended publication:

a) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
b) Drafting the work or revising it critically for important intellectual content; and
c) Final approval of the version to be published; and
d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Complaints of Donors relating to or arising from the **STOPSTORM** Registry shall be submitted to the institution of the Partner or Participant or Affiliated Third Party at which the Donor is a patient and/or where Data were collected.

If the Partners determine that the **STOPSTORM** Registry must be dissolved, the Consortium Council shall prepare a proposal that includes at least transfer, destruction or return of the Data. If the Data are maintained in another database after the **STOPSTORM** Registry is dissolved, the proposal shall contain provisions for access and use of the Partners, Participants and third parties. Any transfer of Data into another database shall be in compliance with the terms of the GDPR.

1. Participants may participate in Consortium Council meetings. All information which is disclosed during such meetings is "Confidential Information" and Participants will treat such information in accordance with this clause 9.

2. The Participant hereby agrees for the duration of the STOPSTORM Registry and for a period of four years after the end of the STOPSTORM Registry:

    a. Not to use Confidential Information otherwise than for the purpose for which it was disclosed;
    b. to ensure that internal distribution of Confidential Information by a Participant shall take place on a strict need-to-know basis; and
    c. to destroy, on request of the Coordinator all Confidential Information that has been disclosed to the Participant including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and

regulations or for the proof of on-going obligations or to keep copies of electronically exchanged Confidential Information made as a matter of routine information technology back-up provided that the Participant comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

3. The Participant shall be responsible for the fulfilment of the above obligations on the part of their employees involved in the STOPSTORM Registry and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the STOPSTORM Registry and/or after the termination of the contractual relationship with the employee or third party.

4. The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Participant can show that:

    a. the Confidential Information has become or becomes publicly available by means other than a breach of the Participant's confidentiality obligations;
    b. the Coordinator subsequently informs the Participant that the Confidential Information is no longer confidential;
    c. the Confidential Information is communicated to the Participant without any obligation of confidentiality by a third party who is to the best knowledge of the Participant in lawful possession thereof and under no obligation of confidentiality to the STOPSTORM consortium;
    d. the Confidential Information, at any time, was developed by the Participant completely independently of any such disclosure by the STOPSTORM consortium;
    e. the Confidential Information was already known to the Participant prior to disclosure, or
    f. the Participant is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order. This obligation does not alter the status of the information as a Confidential Information and it is still to be treated as confidential in regards to any other Party.

5. The Participant shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the STOPSTORM Registry as with its own confidential and/or proprietary information, but in no case less than reasonable care.

6. Participant shall promptly advise Coordinator in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

7. If Participant becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

    a. notify the Coordinator, and

b. comply with the Coordinator's reasonable instructions to protect the confidentiality of the information.

8. All results, information and intellectual property rights vested therein, which are generated by the Participant during attendance of the Consortium Council meetings or by using the Confidential Information, will be vested in the Partners in equal shares. Participant shall assign (or cause to be assigned) and does hereby assign fully to each of the Partners in equal shares all rights, title and interest in and to any such results, without payment of any additional compensation to Participant.

1) Without prejudice to the custodianship of the Data by the Partners and ownership in any software used for the **STOPSTORM** Registry, by any Partner or third party, the **STOPSTORM** Registry shall be owned by the Partners jointly.

2) Without prejudice to the rights of each Donor in respect to its personal data under the GDPR and/or the rights of the Donor according to applicable law relating to data protection in his/her country of residence, no Partner or Participant can withdraw its Data from the **STOPSTORM** Registry until the **STOPSTORM** Registry is dissolved, unless withdrawal is justified based on pressing circumstances, such as mismanagement of the **STOPSTORM** Registry, misuse of the Data or fraud.

1) The STOPSTORM Management Board (as defined in Appendix A – Description of action (Part B)) decides on requests for access to Data. Decisions will be made by the STOPSTORM Management Board in accordance with Article 6 of the Consortium Agreement.

2) The Coordinator is authorised by the Partners and Participants to and shall be responsible for:
   - Making the database available to Partners for the purpose of the STOPSTORM Registry.
   - Concluding agreements with commercial third parties on behalf of the Partners and Participants for providing fully anonymised aggregated data in accordance with article 5 section 9 of this Regulatory Document.
   - Processing and analysing the Data in the database in accordance with the Protocol and this Regulatory Document;
   - Concluding written agreements with third parties and parties providing services (e.g. maintaining, hosting, SAAS in relation to the database) and processing the Data for the purpose of the STOPSTORM Registry;

Since this is a registry and not a clinical trial, it is not the intention of the STOPSTORM Registry to find Individual Findings. However, in the event of Individual Findings, such findings will be reported to the Management Board. The Management Board will then report such Individual

Findings to the Partner or Participant from which the data is derived. With respect to data resulting from prospective cohort trials, the Partner or Participant involved in such trial will report the Individual Findings in accordance with the procedures laid down in such local trials.

This Regulatory Document shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

The parties shall endeavour to settle their disputes amicably. All disputes arising out of or in connection with this Regulatory Document, which cannot be solved amicably, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules.

APPENDIX A: PROJECT PLAN (and AMENDMENTS)

Project Information:
Start Date: May 1 2021
Duration: 6 years, April 30 2027
Coordinated by [redacted] (UMC Utrecht) Co-led [redacted] (CHUV)
Website: https://stopstorm.eu

All Partners:

Partner	*Partner Name*	*Acronym*	*Country*
1	Universitair Medisch Centrum Utrecht	UMCU	NL
2	Fakultni Nemocnice Ostrava	FNO	CZ
3	Institut klincké a experimentální mediciny	IKEM	CZ
4	Nemocnice AGEL Trinec-Podlesi a.s.	NPO	CZ
5	Christian-Albrechts-Universitaet zu Kiel	CAU	DE
6	Ruprecht-Karls-University Heidelberg	UHEI	DE
7	Charite - Universitaetsmedizin Berlin	CHARITE	DE
8	Technische Universitaet Dresden	TUD	DE
9	Universitaet Zu Luebeck	UZL	DE
10	Herzzentrum Leipzig GMBH	ULEIHC	DE
11	Centre Hospitalier Universitaire Vaudois	CHUV	CH
12	Insel Gruppe AG	BERN	CH
13	UniversitätsSpital Zürich	USZ	CH
14	Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy	NRIO	PL
15	Gornoslaskie Centrum Medyczne Im. Prof. Leszka Gieca Slaskiego Uniwersytetu Medycznego W Katowicach	GCM	PL
16	Aarhus Universitet	AU	DK
17	Aarhus Universitetshospital	AUH	DK
18	Consorcio Mar Parc De Salut De Barcelona	IMIM	ES
19	Servicio Madrileño De Salud	SERMAS	ES
20	Fundacion Investigación Hospital General Universitario De Valencia	FIHGUV	ES
21	Azienda Unita Sanitaria Locale Di Reggio Emilia	AUSL-RE	IT
22	Fondazione Centro Nazionale Di Adroterapia Oncologica	CNAO	IT
23	Istituto Don Calabria – Irccs Ospedale Sacro Cuore Don Calabria	IRCCSDC	IT
24	Universita Degli Studi Di Torino	UNITO	IT
25	Fondazione IRCCS Policlinico San Matteo	IRCCSOSM	IT
26	Universiteit Maastricht	UM	NL
27	Academisch Ziekenhuis Leiden	LUMC	NL
28	Academisch Medisch Centrum Bij De Universiteit Van Amsterdam	AMC	NL
29	Stichting Maastricht Radiation Oncology Maastro Clinic	MAASTRO	NL
30	Stichting Catharina Ziekenhuis	SCZ	NL
31	Harteraad	HART	NL

Background

Ventricular tachycardia (VT) is an unpredictable and potentially deadly condition and should be promptly treated with catheter ablation and medication, before irreversible and potentially fatal organ damage follows. Unfortunately, this combination of treatments does not prevent VT reoccurrence in 30-50% of VT patients and while they can undergo multiple invasive ablations, technical difficulties or refusal of the patient can lead to a lack of effective treatment options.

A promising novel, non-invasive treatment option for VT is stereotactic arrhythmia radioablation (STAR). Besides being non-invasive, STAR can also be used to reach locations that are inaccessible for catheter ablation, which may potentially improve effectiveness of overall VT treatment.

Small scale first in men/early phase trials have been performed for STAR, providing proof-of-concept for clinical safety and efficacy. However, patients with recurrent VT are not a homogenous group and each center deals with different inclusion criteria, imaging and/or target definition. Many questions remain and the available studies lack the power to clinically validate the approach and prepare for late stage phase III trials.

Approach

The STOPSTORM consortium sets out to consolidate all current and future European efforts to clinically validate STAR treatment by merging all data in a validation cohort study, standardising pre-treatment and follow-up, in order to collect the data sets and statistical power needed to unanimously establish clinical safety, efficacy and benefit for STAR.

The STOPSTORM consortium also sets out to refine protocols and guidelines, determine volumes of interest, define and model the optimal target region and target dose, also in relation to surrounding healthy tissues (i.e. organs at risk) and determine which patient population and underlying cardiopathies respond best to STAR.

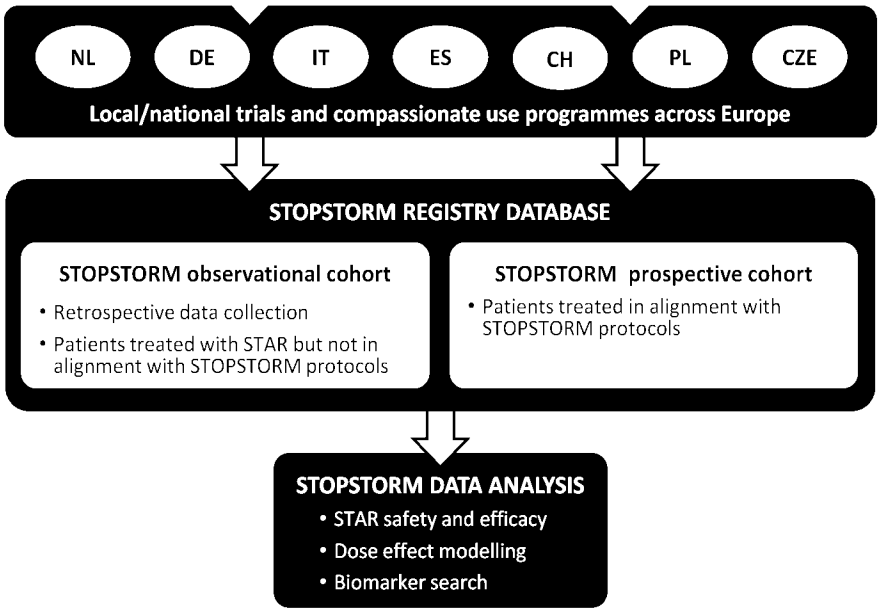


Figure 1. General depiction of STOPSTORM Approach

Main Aim of STOPSTORM Registry

There is initial evidence of safety and efficacy in preclinical and clinical studies on low numbers of patients (Gianni et al. 2020; Lloyd et al. 2020; Neuwirth et al. 2019; Robinson et al. 2019). The main aim of the STOPSTORM consortium is to create a prospective European validation cohort, in order to determine efficacy and safety in a large VT patient population treated at multiple centres and on various STAR delivery platforms. Outcomes will be measured as survival free from VT storm and incessant VT, reduction of sustained VT burden, incidence of toxicity, and adverse events due to STAR, as well as by long-term follow-up information on safety and efficacy, cardiac mortality (arrhythmic versus non-arrhythmic), and overall survival. Finally, we will formulate a consensus on patient selection, target definitions, and treatment design regarding the clinical use of STAR in mainstream clinical practice. STAR will be positioned as an adjunctive treatment to catheter ablation for refractory VT. Combined, this will enable us to design and perform a future phase 3 clinical trial.

STOPSTORM Registry Objectives

1. To implement a European registry infrastructure for collecting STAR data from all patients treated non-invasively for refractory VT:
    a. Observational data collection from patients who are being treated before the start of the prospective validation cohort, and from patients treated throughout the project who do not meet the inclusion criteria of the prospective validation cohort.
    b. Prospective data collection for 217 patients within the consortium in the period 2021-2023.
2. To harmonise and standardise STAR treatment across Europe.
3. To validate safety and efficacy of the procedure in a larger VT patient cohort, whilst also:

a. Deriving predictive factors for efficacy and outcome;

b. Learning which patients benefit most from STAR (e.g., impact of underlying heart diseases, stage of heart failure, size, and type of substrate); and

c. Modelling radiation dose-volume-response and derive recommendations for optimal dose prescription and target delineation.

4. To work towards a consensus statement and multidisciplinary guidelines for the clinical implementation of STAR, regarding external audit and end-to-end treatment protocols for the procedure, which will improve the QoL of VT patients.

Management and Board Structures

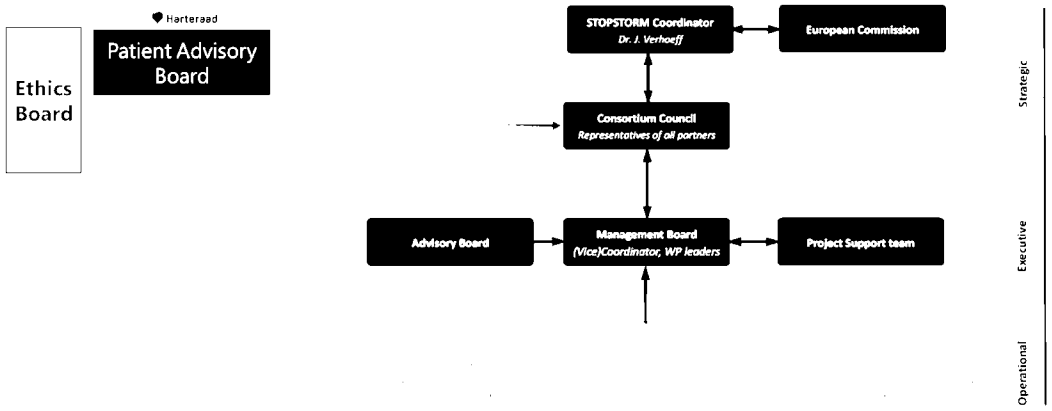


Figure 2. Management and Board Structures

Timeline

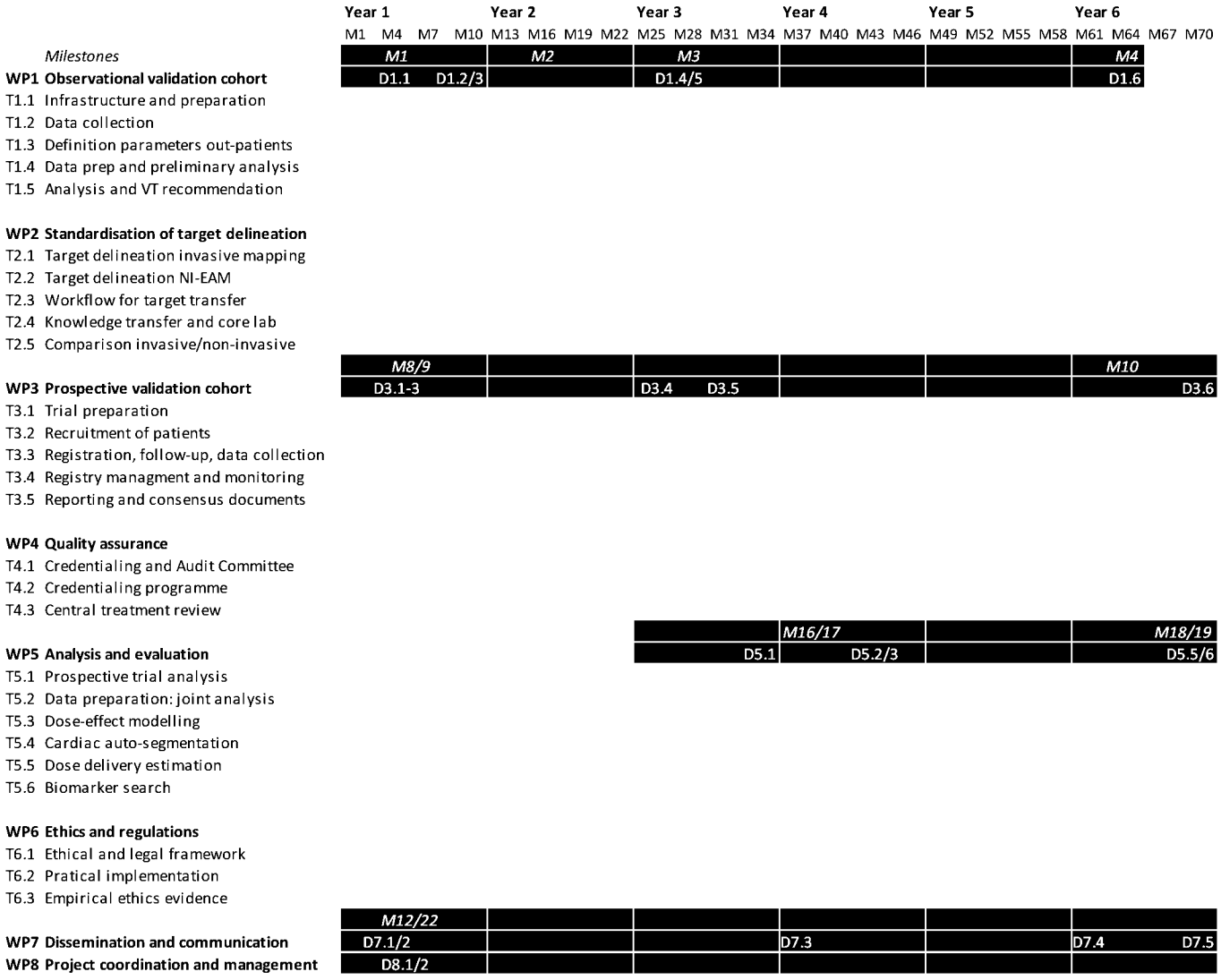


Figure 3. Timeline and GANTT Chart

APPENDIX B: SPECIFIC DATA PROCESSING TERMS (Processor)

Article 1. Definitions

1.1. In this Appendix B, capitalised terms shall have the meaning defined in the Regulatory Document of the **STOPSTORM** Registry. Additional capitalised words shall have the following meaning:

a.	Incident	i a complaint or request for information by a Donor with regard to the processing of Data by the Processor; ii an investigation or confiscation of Data by government officials or a suspicion that such may occur at some point in the future; and/or iii a personal data breach as meant in Article 4.12 of the GDPR.
b.	Sub-Processor	Any non-subordinate third party hired by the Processor to help process Data.
c.	Processor	The Coordinator.
d.	Controller	Each Partner and Participant making its Data available to the **STOPSTORM** Registry and submitting it in the database.

Article 2. The processing of the Data

2.1. The Processor shall only process Data on behalf of the Controller for the purposes outlined in the Regulatory Document or as additionally agreed otherwise between the Processor and the Controller.

2.2. Without prejudice to the provisions of Article 2.1, the Processor shall be allowed to process Data if it is required to do so by a statutory provision (including the court order or administrative decisions based on it). In such cases, the Processor shall to the extent permitted by law, notify the relevant Controller(s) of the intended processing of the Data and of the statutory provision prior to the processing. Processor shall minimise the extent of the enforced processing to the maximum extent possible.

2.3. The Processor shall process the Data in a proper manner, in accordance with the requirements to which it is subject under the GDPR and to the extent known to the Processor, the national privacy law of the Partners and Participants.

2.4. In processing the Data, the Processor shall reasonably ensure that its procedures shall not violate health care legislation.

Article 3. The security and monitoring of Data

3.1. To protect the Data from loss, unauthorised inspection or use, damage or any other form of unlawful processing, and to guarantee the availability of the Data when due, the Processor shall implement appropriate and effective technological and organisational measures, which, considering the current state of the art and the costs associated with it, shall be in accordance with the nature of the Data to be processed. These security measures shall include the following:

a.) measures designed to guarantee that only authorised employees can access the Data for the purposes outlined;

b.) measures involving the Processor only granting its employees and Sub-Processors access to Data through individual named accounts, with the use of said accounts being adequately logged and with the accounts concerned only granting their users access to those Data whose access is necessary for the legal person concerned;

c.) measures designed to protect the Data from unintentional or unlawful destruction, unintentional loss or changes and unauthorised or unlawful retention, processing, access or disclosure;

d.) measures designed to identify weaknesses with regard to the processing of Data in the systems used to provide services to the Controller(s);

e.) measures designed to guarantee that Data are separated in a sensible manner from the Data the Processor processes on its own behalf or on third parties' behalf;

f.) other measures agreed between the Controller(s) and the Processor.

3.2. The Processor's security measures shall comply with the requirements of the GDPR. Furthermore, the Processor has implemented an appropriate, written security policy for the processing of the Data.

3.3. Upon the request of a Partner and provided that such certificate is in place, the Processor shall submit a certificate issued by an independent and competent third party that confirms that the Processor's methods comply with the requirements arising from this article 3.

3.4. Each Partner is entitled to monitor (or have monitored) the Processor's compliance with this article 3 and shall enable such Partner to inspect the Processor's processing methods, but no more frequent than once per year, unless such Partner has reasonable doubts that the Data are not processed in accordance with the Regulatory Document, this or applicable law.

3.5. If, in response to such inspection, the Partner reasonably instructs the Processor to adjust or update its security policy, the Processor shall reasonably comply.

3.6. The Processor shall ensure that persons authorised to process the Personal Data on its behalf, have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

Article 4. Monitoring, obligation to provide information and incident management

4.1. When an Incident occurs, has occurred or may be about to occur, the Processor shall to the extent reasonably possible, undertake the activities necessary to undo the damage caused

by the Incident as soon as possible or minimise the consequences to the maximum extent possible.

4.2. In addition, the Processor shall notify the relevant Controller(s) without undue delay and to provide any relevant information on:
   a.) the nature of the Incident;
   b.) the Data that (may) have been affected;
   c.) the actual and likely consequences of the Incident; and
   d.) the measures which have been or will be taken to resolve the Incident or to minimise the consequences or damage to the maximum extent possible.

4.3. The Processor shall consult the relevant Controller(s) on further arrangements to be undertaken with respect to the Incident and to prevent future Incidents.

4.4. The Processor shall cooperate with the relevant Controller (s) any time, shall follow the reasonable instructions of the relevant Controller (s) and shall enable the relevant Controller (s) to conduct an appropriate investigation of the Incident, formulate a response to the Incident and take appropriate subsequent steps, including notifying the Dutch Data Protection Authority and/or the Donor.

4.5. The Processor shall at all times have written procedural guidelines in place covering the handling of Incidents and shall furnish the relevant Controller (s) with a copy of such procedural guidelines upon the request.

4.6. Alerts under this article 4 shall be addressed to chair of the relevant Controller (s) or any other designee indicated by the relevant Controller (s).

4.7. The Processor shall not provide third parties any information on Incidents, except in cases where the Processor is legally required to do so or the Parties have otherwise agreed.

Article 5. Obligation of cooperation

5.1. The Processor shall fully cooperate with the relevant Controller(s) to enable and the relevant Controller (s) to fulfil their obligations under the GDPR. The Processor and relevant Controller (s) shall agree on procedures to comply with the rights of Donors under the GDPR.

Article 6. The hiring of Sub-Processors

6.1. The Processor shall not outsource the processing of Data to a Sub-Processor without prior written permission from the Controller(s). The foregoing does not apply to the Sub-Processors listed in Appendix C.

6.2. If the Controller agrees to the hiring of a Sub-Processor, the Processor shall impose on the Sub-Processor minimally the same requirements under this Appendix B, the Regulatory Document (to the extent applicable) and applicable legislation.

6.3. The Processor shall remain fully responsible for the processing of the Data by the Sub-Processor as if it has performed the processing itself.

Article 7. Duration and termination

7.1. This Appendix B shall enter into force on the effective date of the Regulatory Document and terminate upon termination of the **STOPSTORM** Registry or so much earlier as foreseen in the Regulatory Document or this Appendix B.

7.2. Obligations which, by their very nature, are meant to continue to apply even after the termination of this Appendix B shall continue to apply after the termination of this Appendix B. Such provisions shall include those which arise from provisions governing confidentiality, liability, dispute resolution and applicable law.

7.3. Upon expiration of the initial term of the **STOPSTORM** Registry or upon earlier termination in accordance with the Regulatory Document, the Processor shall discuss with the Consortium Council the feasibility and possibility of continuing the **STOPSTORM** Registry or to destroy the Data.

Article 8. Retention period, restoration and destruction of Data

8.1. The Processor shall not retain the Data longer than strictly necessary for the **STOPSTORM** Registry and applicable law.

APPENDIX C: PRIVACY APPENDIX (Controller)

Description of the Data:

Data subjects The personal data transferred concern the following categories of data subjects:	Patients treated with cardiac SBRT for ventricular tachycardia.
Purposes of contribution of Data The Data is contributed for the following purpose.	The Data is contributed for the purposes of the STOPSTORM Registry which aims to collect data on patients treated with cardiac Stereotactic body radiation therapy (SBRT) for ventricular tachycardia.
Categories of Data and Sensitive Data The personal data transferred concern the following categories of data (For each category, the corresponding sensitive data are listed):	- Pseudonymized personal data (e.g. demographics, year of birth, etc.) - Gender - Age - Height - Weight - Special categories of personal data: • data concerning health: - Cardiac diagnosis (Ischemic/Non ischemic heart disease) - Medical history: o COPD o Diabetes o Heart failure type o NYHA class o coronary heart disease o previous heart infarctions o myocarditis o cardiomyopathies o valve anomalies o prior ablations o Other disease - ECOG performance status

	- Hospitalization
	- Drug usage
	- LVEF
	- Implanted device
	- Clinical examination
	  o Weight, heart functioning
	- ECG
	- Lung function tests
	- FDG-PET, MRI, Cardiac-CT, Transthoracic and Transoesophageal echocardiography, chest X-ray
	- ICD readouts
	- NIPS
	- Medication use
	- Blood test values, e.g.:
	  o Serum Troponin value
	  o NT-proBNP value
	  o Myoglobin value
	  o CK-MB value
	- CTCAE v5, PROMS, EQ5D
	Data concerning RT treatment and delivery:
	- Planning CT, structure set, treatment plan, treatment dose.
	- CBCT scans and flouroscopy images obtainded during treatment, treatment records.
	- VT ablation data.
	-

Method of transfer	CASTOR (Electronic Data Capture tool) to record the info in the eCRF. RIA Exchange(Research Imaging Architecture, based on XNAT) to collect all data (dicom and non-dicom files).

Method of data storage and security measures (e.g. method of encoding)	Clinical data will be stored in an electronic data capture software (eCRF): CASTOR. The **STOPSTORM** Registry database is compliant with GCP and GDPR. It is located in a secure and fully certified data center in the Netherlands. The **STOPSTORM** Registry database is certified to store medical data (ISO 9001 and 27001:2013). Pseudonymized Data will be entered[1]. This system will assign a unique study registration (USR) number to each patient, which will be used to code all study data (alphanumeric code). The eCRF system uses an electronic audit trail to log changes of important variables. A separate subject identification/enrolment log containing USR numbers with corresponding patient identifiers (name, date of birth, sex, and date of inclusion), i.e. the key to coded information, is held at each Partner or Participants for its own Donors to prevent a direct match between study data and patient identifiers and is the responsibility of the local investigator. Handling of Personal Data by the **STOPSTORM** Registry database is in compliance with the GDPR. Each Partner and Participant is responsible for correct Data input, their login accounts and local trial master files. All other data will be stored in two separate research archives: 1) Research Folder Structure for daily transfer and analysis 2) RT bulkstorage, frozen archive for backup Access to the Research Folder Archives is possible only from within the UMCU and is granted by different roles, such as researcher, data manager, cohort assistant, or coordinator. Such 'role-based'

[1] The process or pseudonymization is the responsiblity of each Partner and Participant. If a Partner or Participant has questions with regards to pseudonymization, please contact the Consortium Council.

	access to the system will avoid unauthorized data access and prevents users from performing actions they are not allowed to perform. Access to these archives will be restricted only to allowed researchers by Trial Office. Backups of all data are made daily and are stored in secured locations that are geographically dispersed.
Authorized sub-processors Identified at the Effective Date	CASTOR (Electronic Data Capture tool) RIA Exchange(Research Imaging Architecture, based on XNAT)

Privacy arrangements **The Partners and Participants providing Data are joint controllers with regard to the Personal Data that will be processed by virtue of the STOPSTORM Registry. In this context Parties determine and agree on- in accordance with article 26 of the GDPR- their respective obligations with regard to compliance with the GDPR.**	
Privacy obligation *(please mention below the applicable privacy obligations).*	*Please mention below with regard to each obligation: the name of the responsible Party, the personal data and processing activities involved and if necessary the arrangement(s) about how to fulfil the obligation.*
1. Provide information on the processing of the Personal Data to data subjects in accordance with article 13, 14 GDPR, The Medical Treatment Contracts Act (WGBO) and article 12 of the Medical Research Involving Human Subjects Act (WMO).	Each Partner and Participant is responsible for providing information on the processing of personal data to the patient in accordance with the GDPR.
2. Safeguarding that informed consent for the processing of the personal data is obtained or that another legitimate basis for the processing of the personal data is in place (article 6 GDPR).	Each Partner and Participant is responsible that informed consent from Donors is obtained and filed. These filed data may be subject to monitoring purposes.

3. Safeguarding that the data subjects can exercise their right to data portability (article 20 GDPR),	Each Partner and Participant shall include a local contact person in the patient information brochure. This right is not mandatory according to the GDPR. Donors can only exercise this right if so expressly included in the patient information brochure and technically possible.
4. Safeguarding the security of the Personal Data in accordance with article 32 GDPR and in accordance with other arrangements in this Agreement.	The Coordinator is responsible for maintaining the **STOPSTORM** Registry database. The **STOPSTORM** Registry database is compliant with GCP and GDPR. It is located in a secure and fully certified data center in the Netherlands. The **STOPSTORM** Registry database is certified to store medical data (ISO 9001 and 27001:2013). Pseudonymized Data will be entered[2]. A separate subject identification/enrolment log containing the key to coded information is held at each Partner or Participants for its own Donors and is the responsibility of the local investigator. Handling of Personal Data by the **STOPSTORM** Registry database is in compliance with the GDPR. Each Partner and Participant is responsible for correct Data input, their login accounts and local trial master files.
5. Comply with data breach obligations (articles 33 and 34 GDPR).	The Coordinator on behalf of the General Assembly and each Partner and Participant is responsible for data breaches in accordance with articles 33 and 34 of the GDPR Each Partner and Participant shall notify the Coordinator immediately if its login or password details are in advertently disclosed to a third party. In such case the data

[2] The process or pseudonymization is the responsiblity of each Partner and Participant. If a Partner or Participant has questions with regards to pseudonymization, please contact the Consortium Council.

	protection officer of the Coordinator shall be contacted: UMC Utrecht data protection officer is: [redacted] Tel. [redacted] E-mail: [redacted] If The Coordinator becomes aware of a data breach in respect of Data received from a Partner or Participant, it shall immediately without delay notify the relevant Partner's/Participant's data protection officer in writing and also by other appropriate and quick manners such as by calling. The Coordinator shall assist the Partner and Participant by appropriate technical and organizational measures, insofar as this is possible, for the fulfilment of the Partner's/Participant's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III of the GDPR and assist the Partner or Participant in ensuring compliance with the obligations pursuant to Articles 32 to 36 of the GDPR taking into account the nature of the processing and the information available.
6. Safeguarding that employees who have access to Personal Data are instructed by a binding agreement in accordance with Article 32 lid 4 GDPR, to process the Personal Data in conformity with the instructions of de Controllers to the Personal Data, including observing the duty of confidentiality with regard to the Personal Data.	All personnel involved in the registration and processing of the Data are registered as such in the delegation log form per Partner and Participant. The local investigator is responsible for the accuracy of the log form, which is kept in the local trial master file. Partner, Participant and Coordinator will safeguard that employees who have access to personal data are instructed by a binding agreement in accordance with Article 32 lid 4 GDPR, to process the personal data in conformity with the instructions of the controllers to the personal data, including

	observing the duty of confidentiality with regard to the personal data.

7. Safeguarding that engaged (sub) processors who have access to Personal Data are instructed by a binding agreement (data processor agreement) to process the Personal Data in accordance with the requirements stated in article 28 of the GDPR, including among others the documented instruction of the Controllers to the Personal Data and all other GDPR requirements applicable to the processor.	The Coordinator is responsible for the security level of the **STOPSTORM** Registry database. The Coordinator will safeguard that engaged (sub) processors who have access to personal data are instructed by a binding agreement (data processor agreement) to process the Data in accordance with the requirements stated in article 28 of the GDPR, including among others the documented instruction of the Controllers to the personal data and all other GDPR requirements applicable to the processor.
8. Safeguarding that: (1) regular monitoring takes place in order to assess if the processing of the Personal Data by the (sub) processor is in compliance with the data processor agreement entered into with the (sub) processor; and (2) that breach of the data processor agreement is addressed by appropriate measures.	The Coordinator together with the Consortium Council is responsible for monitoring any sub-processors and following up on any breaches by the sub-processors.
9. Safeguarding that the transfer of Personal Data takes place in accordance with the transfer requirements of the GDPR.	The Coordinator may transfer pseudonymized Data outside of the European Economic Area (in Switzerland as few Partners belong to this Country) under the following conditions 1) the Coordinator has put in place appropriate safeguards such as signing the Standard Contractual Clauses in accordance with decisions by the European Commission to safeguards such transfer, 2) such third parties are only allowed to process Data as defined in the Regulatory Document, and 3) Coordinator will on request provide information about the third party, where Data is transferred to, including copies of safeguards that is governing such transfer.

	Switzerland is also one of the approved countries by the Dutch Privacy authorities which applies adequately the rights of privacy law (EU-like). Only pseudynomized personal data will be shared with Partners or Participants.
10. Safeguarding the compliance with the requirements regarding retention periods, destruction, return and/or migration of the Personal Data.	All source data will be kept for a period of 15 years after termination of the registry, as will be the eCRF's, according to national Dutch regulations. During this time, the head of the department of Radiotherapy will be responsible, if the PI will not be available anymore.
11. Safeguarding that a Privacy Impact Assessment (PIA) is executed prior to the collection, including obtaining and further processing of the Personal Data (Article 35 AVG).	A PIA has been performed in collaboration with the Information Security Officer of the Coordinator. Each Partner and Participant is separately responsible for compliance with the PIA obligation, if so applicable.
12. Further agreements regarding privacy responsibilities.	If the arrangements in this matrix appear to be incomplete or incorrect, the parties shall amend this matrix so as to be compliant with the GDPR.

APPENDIX D: ACCESSION FORM

Accession of a new [Participant/Affiliated Third Party] to the STOPSTORM Registry

[**PARTY**], with principal place of business at [ADDRESS], acting exclusively for and on behalf of its Department of [DEPARTMENT], hereinafter referred to as "[**SHORT NAME**]", lawfully represented by [NAME], in her/his function as [FUNCTION];

hereby consents to become a Participant/Affiliated Third Party to the STOPSTORM Registry and accepts all the rights and obligations of a Participant/Affiliated Third Party as stated in the STOPSTORM Registry Regulatory Document starting [DATE].

UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU), established in HEIDELBERGLAAN 100, UTRECHT 3584 CX, Netherlands, lawfully represented by [Name]**,** hereinafter referred to as "**COORDINATOR"**

Acting on behalf of the STOPSTORM Consortium in accordance with Article 2 section 3 of the "STOPSTORM Registry Regulatory Document

[[Only applicable for Participants]: hereby certifies that the Consortium Council has accepted in the meeting held on [DATE] the accession of [**PARTY'S SHORT NAME**] to the consortium starting [DATE] as a Participant.]

Each Party agrees that this declaration of accession will be executed in electronic PDF format only and the Participant signing this declaration of accession explicitly acknowledges and agrees that its signature in such format shall be regarded as an original signature and that this declaration of accession shall be effective upon delivery by electronic mail to the Coordinator and thereafter shall be deemed an original signed agreement.

[Insert name of the new Participant/Affiliated Third Party]
Name(s):
Title(s):
Function(s):
Date and Place:

Signature(s):_____

UMC Utrecht
Acting as Coordinator of the STOPSTORM Registry in accordance with the Regulatory Document

Name(s):
Title(s):
Function(s):
Date and Place:

Signature(s):_____

APPENDIX E: Affiliated Third Parties

Partner 5 CAU: Third Party Universitätsklinikum Schleswig-Holstein (UKSH)

Partner 8 TUD: Universitätsklinikum Carl Gustav Carus Dresden (UKD)

Partner 9 UZL: Universitätsklinikum Schleswig-Holstein (UKSH)

Partner 18 IMIM: Fundació Institut Hospital del Mar d'Investigacions Mèdiques (FIMIM)

Partner 19 SERMAS: Fundación para la Investigación Biomédica del Hospital Clínico San Carlos (FIB HCSC)

Partner 26 UM: Academisch Ziekenhuis Maastricht (MUMC)

APPENDIX F: MAIL OF APPROVAL FORMAT

Dear Researcher,

The STOPSTORM Management Board has received in good order the study protocol [NAME PROJECT] you submitted to it. The proposal was subsequently discussed at its meeting dated [DATE].

The Management Board considered the following documents in its review:

- Protocol version [VERSION], dated [DATE].

The STOPSTORM Management Board has determined that the study falls within the main objectives as stated in article 2 section 1 of the 'STOPSTORM Registry Regulatory Document' which justifies the release of data for the execution of the aforementioned study protocol.

The Management Board reminds you of your duties with respect to the data. You are expected to:

(a) use the data in accordance with all applicable laws and regulations. You are fully responsible for this.

b) to make no attempt to trace the identity of the patients.

(c) use the Data only for the approved study protocol and in accordance with the terms of this STOPSTORM Registry Regulatory Document. In the event of deviations or changes to the study protocol as described above, the Management Board has the right, in its sole discretion, to terminate access to the Data without liability.

(d) not duplicate or cause to be duplicated the Data.

(e) not disclose or provide access to the Data to any third party without the prior written consent of the Management Board.

f) report on a regular basis the progress and results of the study protocol.

g) generally share results with the research community and therefore publish scientifically in accordance with the provisions of the STOPSTORM Registry Regulatory Document.

h) in the case of an Incidental Finding, report this to the Management Board.

On behalf of the STOPSTORM Management Board, I wish you luck with your research project.

In case of conflict between this e-mail and the STOPSTORM Registry Regulatory Document, the latter will prevail.

Sincerely,

[NAME]

Chair STOPSTORM Management Board