COOPERATION AGREEMENT FOR A COMPREHENSIVE CANCER INFRASTRUCTURE OR NETWORK

*The undersigned (in alphabetical order):*

[XYZ

duly represented by members of the Boards of Directors of (the) healthcare institutions in […..}

hereinafter referred to as 'Party' or collectively as 'Parties'

*taking into account that:*

* from the patient's perspective, it is necessary to cooperate in the field of multidisciplinary cancer care, since cooperation in the [region/nation] can maintain and improve the quality of this complex care;

1

With this cooperation agreement (hereinafter: Cooperation Agreement), the parties wish to give shape to the alignment and coordination of the various activities in the field of multidisciplinary oncology within OncoZON in order to cooperate with each other in a sustainable manner;

***declare* that *they have agreed as* follows*:***

**Definitions**

Board of Directors (BoD): Annex(es):

Budget:

Network Coordination Team (NCT) Annual plan (tumour) working group: Annual plan:

Annual report:

Annual report (tumour) working group:

Local oncology committee: local (tumour) working group:

MDT:

Multi-year plan:

Network:

Personal data:

Board of Directors (BoD):

Network Board(NB):

the decision-making body of

annex(es) to this agreement which is/are inextricably linked to and integral part of this agreement

annually drawn up budget for costs incurred and then divided between the Parties

the members of the NB charged with the task of supporting the

NB in all its activities

annual document to be prepared by each (Tumour) Working Group translating the strategy into concrete goals, results and activities

document to be prepared annually translating the strategy into concrete goals, results and activities

document to be prepared annually outlining the activities and topics named in the Annual Plan

annual document to be drawn up by the (tumour) working group summarising the activities and topics in the (tumour) working group's annual plan

the oncology committee of each of the Care Institutions the (tumour) working group of each of the Care Institutions

multidisciplinary team

strategic plan drawn up on the basis of the Vision Document for a number of years in which the plans and priorities are presented the collection of Care Institutions working together under this Cooperation Agreement abbreviation for

any information relating to an identified or identifiable natural person within the meaning of

Board of directors of a healthcare institution

the consultative body on which the Parties are represented, as further defined in article 3 paragraph 1



Regional (tumour) working group:

Cooperation agreement:

Vision document:

Patient pathway:

Care professional:

working groups at tumour-specific or tumour- transcending level, in which all Care Institutions are represented and which meet periodically

the present Agreement including all Annexes and any subsequent supplements or amendments thereto agreed in writing

document detailing the longer-term visions and ambitions, on the basis of which the annual and multi-year plan is drawn up

A documented patient pathway which specifies the processes, decisions, timings and professionals involved in standard patient pathways

Staff member involved in Care

# Article 1: Purpose and content of cooperation

* 1. The aim of this cooperation is to continue to provide and further optimise integrated, high-quality patient care in the field of oncology in the [] region, as close as possible to the patient's home environment.
  2. Within [] the parties aim to provide treatment for virtually any form of cancer.
  3. Within [] the parties wish to design and align care pathways and processes as efficiently as possible in order to continue to meet quality and volume standards in the future.
  4. In order to achieve this, the Parties shall give substance to the cooperation within [] by means of the mutual optimal coordination of the Care provided by the Parties. This coordination includes in any case:
     1. the policy concerning the organisationof Care within [], in which the Parties agree how and where the best possible Care can be provided to the patient;
     2. care policy, aligning guidelines and standards as much as possible, conducting MDTs and sharing expertise;
     3. How to facilitate quality registrations, scientific research and training at regional level.
  5. [] is a network cooperation without legal personality.
  6. This Cooperation Agreement is the basis for the policies and agreements made in the Vision Document, the Multiannual Plan and the Annual Plan of [] and the Annual Plan of the Regional (tumour) Working Groups.

# Article 2: Principles and conditions of cooperation

* 1. The autonomy of each healthcare institution will be maintained without sharing or transferring responsibility over the policies and management of their individual institutions.
  2. The Care by Parties is provided by oncologically specialised Care Professionals, who are each responsible for their own medical professional conduct. The Parties create the preconditions necessary for this.
  3. Patients’ free choice of doctors is respected at all times.
  4. Quality and continuity of care, as well as efficiency, determine whether patients or healthcare professionals will travel.
  5. Already existing cooperation initiatives and alliances, both regarding oncological care and non- oncological care between (the relevant) Parties will be respected.
  6. Bilateral agreements yet to be concluded between Parties within [] may not conflict with the provisions of this Cooperation Agreement. In the event of a conflict between already existing bilateral agreements between Parties within [] and this Cooperation Agreement, the Cooperation Agreement shall prevail.
  7. Already existing cooperation initiatives and associations within oncology between Parties and hospitals outside [] are respected.
  8. If, after signing this Collaboration Agreement, a Party wishes to enter into a collaborative initiative or partnership with a hospital outside [], it will be discussed in the BoD prior to doing so.
  9. Parties are open to other oncology care providers collaborating with/joining [].

# Article 3: Organisation and management of cooperation

* 1. [] is organised as shown in **Annex** 2 and consists of:

1. the BoD, which is the decision-making body and includes the chairpersons of the Boards of Parties;
2. the NB, which falls under the BoD and in which the Local Oncology Committees of Parties are represented;
3. the NB has a NCT for the purpose of preparing and developing (policy) proposals;
4. the Regional (tumour) Working Groups, which fall under the NB and make efforts to achieve regional Care Pathways and best practices, among other things;
5. the project organisation, which carries out projects as part of the further development of [].
   1. The composition, appointment, tasks and powers of the organisational units referred to in paragraph

1 within [] are laid down in the Organisational Regulations attached to this Cooperation Agreement as **Annex** 3.

# Article 4: Patient care cooperation

* 1. The parties aim to align Patient Pathways and standardise protocols within oncology.
  2. In the MDT, consultations take place between the Parties' Healthcare Professionals.
  3. The discussion of patients in the MDT Ieaves the primary care team unaffected.
  4. The Chief Practitioner is the Healthcare Professional, who is the actual director of the oncological treatment of the patient who is undergoing treatment at his/her Healthcare Institution, as described in that Healthcare Institution's Patient Pathway.
  5. Where referral is involved, referral will be made to a Healthcare Institution in the [] region that has been designated as a centre of expertise in this regard, with due regard for the patient's freedom of choice, as well as that collaborative initiatives and partnerships between a Party and hospitals outside [] are respected.
  6. Each Party independently contracts and claims for the care provided to its patients.
  7. [If, within the framework of the collaboration, the care provision to a patient is taken over by a Care Professional from another Care institution, the Care institution that terminates the care provision will close it administratively.] The taking over Care institution registers the patient as a new patient and also registers and declares the care provision from the moment it continues it].
  8. The parties will endeavour to continue the existing provision of Care within [] and expand it where appropriate.

# Article 5: Cooperation on training, research and quality registration

* 1. The parties aim to participate in patient-related studies for the purpose of stimulating oncological innovation in the region.
  2. If Healthcare Professionals at one of the Healthcare Institutions need to be trained as oncologists for work at their own Healthcare Institution in accordance with the national, professional qualitative and quantitative agreements on this subject, and this is not possible at their own institution, for example due to the minimum number of registered oncologists per medical discipline, Parties that do comply with the agreements will strive to have this training take place at their institution.

5.3. Cooperation within [] implies transparency with regard to jointly established quality indicators, to the extent permitted under applicable laws and regulations.

5.4. Parties shall pursue demonstrably uniform registration of data, with minimal registration burden for Healthcare Professionals.

# Article 6: Data sharing and privacy

* 1. In order to realise the objectives of the Vision Document, the Long-term Plan, the [] Annual Plan and the Annual Plan of the (tumour) Working Groups, Personal Data may be processed by Parties in the future and, if necessary, exchanged between Parties for the purposes of:
     1. uniformly recording and comparing quality indicators to evaluate and improve the quality of care, and;
     2. developing and conducting retrospective scientific research and teaching.

At the time Parties are going to exchange Personal Data as mentioned above with each other, Parties will make appropriate agreements to act in accordance relevant laws and regulations when exchanging Personal Data.

* 1. To realise the objectives of the Vision Document, the Long-term Plan, the Annual Plan and the Annual Plan of the (tumour) Working Groups, Personal Data will be processed by Parties and, if necessary, exchanged between Parties for the purposes of:
     1. the care-related referral of a patient to another Healthcare Facility, and; Care-related discussion of the patient case in the MDT.
  2. When Personal Data are processed for the purpose mentioned in Art. 6.2 sub a, the consent of the patient for this processing is assumed. The mutual exchange of this data between Healthcare Institutions involves traceability to the individual patient.
  3. When processing Personal Data for the purpose mentioned in Art. 6.2(b), the patient's consent to such processing is necessary. For this purpose, parties shall use an in

jointly established consent form. The mutual exchange of this data between Healthcare Institutions involves traceability to the individual patient.

* 1. Parties attach great importance to the protection of Personal Data whereby relevant laws and regulations as well as the resulting rights of patients will be respected. Patients will be informed by the attending specialist about the cooperation and the associated exchange of Personal Data.
  2. The exchange of Personal Data takes place exclusively through secure channels.
  3. With due observance of the laws and regulations concerning the processing of personal and patient data, parties will act in accordance with the attached Data Sharing Protocol **(Annex 4)** when dealing with exchanged Personal Data.

# Article 7: Complaint and disciplinary law, calamities

* 1. The Parties strive for an informal, low-threshold handling of complaints. Complaints will be dealt with in accordance the complaint scheme of the Party/parties concerned.
  2. Each Party handles patient complaints that see acts of their own Employees.
  3. If a patient's complaint is received by one Party that relates to the actions of a Staff Member of the other Party in the context of a cooperation between Parties, this complaint (or part of it) will, with the patient's consent, be carefully transferred to the responsible other Party.
  4. If, in the context of a cooperation between Parties under this Cooperation Agreement, a complaint by a patient is received by one of the Parties, but the complaint also concerns the other Party, the Party to whom the complaint is received shall, with the consent of the patient, notify the other Party without delay. The Parties then agree on how the handling and settlement of the complaint will take place in that case and agree this with the patient. If the patient does not give permission for the complaint to be dealt with jointly, the complaint shall be dealt with exclusively by the Party which received the complaint for what concerns it and shall not make a decision on (the part of) the complaint for which the other Party is responsible.
  5. If a patient files a disciplinary complaint against a Healthcare Professional of a Party involved in the work that takes place in the context of a collaboration between Parties under this Collaboration Agreement, the rules applicable within that Healthcare Institution for legal assistance and its costs apply.
  6. Reports of calamities and violence in the healthcare relationship will be handled by the reporting committee of the Party in whose hospital the treatment took place in the context of a collaboration between Parties under this Cooperation Agreement, unless the Parties involved agree otherwise in mutual consultation.
  7. With due observance of statutory regulations concerning privacy and (medical) professional secrecy, Parties shall inform each other about incidents, calamities, claims, (disciplinary) complaints, civil, administrative and/or criminal proceedings and/or procedures that relate to or (may) affect the mutual cooperation within [].

# Article 8: Financial aspects of cooperation

* 1. The Care Institutions will each independently negotiate and contract with [the health insurers/payers] with regard to the Care to be provided by them.
  2. The costs associated with this cooperation and the settlement (allocation key) thereof, including at least, but not exclusively, facility costs for meetings and other

meetings, costs related to the website and costs for working group support, are budgeted and set annually by the BoD.

* 1. *[The Parties agree to bear the costs of the cooperation jointly, each for an equal share. At the start of the agreement, each Party will therefore contribute of the costs].*
  2. The mutual settlement of products, deployment of personnel and provision of services shall be agreed upon by the Parties and laid down in bilateral agreements, if necessary.
  3. If, in the future, there are developments in this cooperation that entail new financial consequences for one or more Care Institutions, the Care Institutions will reconvene in the BoD to reach further agreements.

# Article 9: Staff

* 1. The employment law appointments of those involved in the cooperation will not change, but where necessary, as part of the cooperation, Healthcare Professionals may be exchanged or shared.
  2. Each Health Care institution where one or more Care Professionals involved in this cooperation agreement, other than in employment, are connected to this Health Care institution, is itself responsible for any contractual obligations towards this Care Professional, so that the implementation of this cooperation agreement does not suffer as a result. Other healthcare institutions can never be held liable for the absence of or having a faulty contractual relationship between the healthcare professional and the healthcare institution concerned.
  3. If Healthcare Professionals perform Care on a structural and regular basis at a Party other than the Healthcare Institution to which he or she is assigned, bilateral agreements between the Parties provide for this.

# Article 10: Evaluation

* 1. As soon as there is reason to do so, but at least once a year, Parties will evaluate the results achieved so far within the Network in the BoD with a view to the necessity or desirability of adjusting this Cooperation Agreement or the resulting agreements between Parties.
  2. Part of the (annual) evaluation is in any case the chosen structure, i.e. network cooperation without legal personality, whereby the Parties do not exclude the possibility that a joint legal form may become necessary in due course. Should this become opportune, it will be prepared and organised with due observance of the applicable laws and regulations.

# Article 11: Duration and termination of agreement

* 1. This Cooperation Agreement is entered into for an indefinite period and enters into force on the day this Cooperation Agreement is signed by all Parties.
  2. A Party may only terminate this Cooperation Agreement after prior consultation in the BoD of [] about its intention to terminate the Cooperation Agreement. A notice period of one year applies. Notice of termination must be given in writing to all Parties.
  3. If and when:
     1. one of the Parties has been declared bankrupt or has itself filed for bankruptcy;
     2. one of the Parties has applied for suspension of payment or has been granted suspension of payment;
     3. one of the Parties has ceased its business or professional activity;
     4. one of the Parties has taken a decision to dissolve or has been dissolved by court order. Dissolution does not include the case where one of the participating institutions ceases to exist due to merger or acquisition;

the other Parties shall jointly have the right to terminate this Cooperation Agreement in whole or in part vis-à-vis such Party(ies) without observing any notice period and therefore with immediate effect.

* 1. If circumstances of an external nature arise, as a result of which the continuation of this Cooperation Agreement cannot reasonably be demanded from one or more Parties, the Parties shall immediately consult with each other in the BoD about whether or not to continue the Cooperation Agreement in a modified form, as well as about the possible term of termination.
  2. Articles which by their nature are intended to remain in force after termination by a Party shall continue to apply in full to that Party. In any event, these are Articles 7, 12 and 13.
  3. For the Party terminating this Cooperation Agreement, the rights and obligations, as a result of an attributable failure in the performance of any obligation under this Cooperation Agreement that predates the termination, shall continue to apply in full.
  4. The Party terminating this Cooperation Agreement shall immediately destroy all documentation (including all business confidential information) made available by either Party, including all copies thereof.

# Article 12: Liability

* 1. The parties are each responsible and liable for their own actions.
  2. If a patient and/or a third party brings a claim against one of the Care Institutions for which the Party concerned is not responsible, that Care Institution, with the patient's consent, shall inform the other Party without delay. In addition, in that case, in compliance with legal regulations on privacy and (medical) professional secrecy, all relevant information must be provided to the other Care Institution by the Care Institution concerned.
  3. Each Party will cover by means of insurance and keep insured the liability risk for damages of patients and/or third parties that may arise from the care provided on the basis of the cooperation within the physical walls of its institution and/or by persons affiliated to it (by means of employment, official appointment or otherwise contractually) on terms which are customary in the healthcare market. If necessary, the Parties will inform their insurers of their obligations under this Cooperation Agreement and the Parties will promote that the liability risks arising from this Cooperation Agreement are covered by insurance.
  4. Parties will also adequately insure themselves for the consequences of liability for damages other than patient damages caused in the context of treatment, such as liability for damages to Employees of Parties and accidents.

# Article 13: Confidentiality clause

* 1. In principle, the parties will keep confidential all information (including Business-Confidential Information as well as Personal Data) gathered or exchanged in the context of this Cooperation Agreement and will only use it in the context of the Cooperation Agreement and, consequently, share it with those who are directly involved in this cooperation and/or actually direct this cooperation.
  2. Information will only be shared to the extent necessary to perform the work.
  3. Business confidential information within the meaning of this Cooperation Agreement is information that a Party or Parties holds from one or more other Party(ies) or the cooperation under this Cooperation Agreement. In any event, business confidential information means (but is not limited to) information regarding (future) strategies and/or policies, financial

8

data, quality data, data on origin and number of patients and all other company data.

* 1. A Party or Parties shall only disclose or allow others to disclose, make available for inspection or make available to third parties information gathered or exchanged in the context of this Cooperation Agreement (in whole or in part) if the relevant Party, Parties or data subject(s) to whom such information relates have given their prior written consent.

13.S. The parties undertake to apply at least the same care to the security of information gathered or exchanged under this Cooperation Agreement as applies to the security of their own information.

# Article 14: Disputes

* 1. Disputes regarding compliance and implementation of this Cooperation Agreement and any agreements based on it or resulting from it shall be submitted to the BoD for decision.
  2. If no resolution of the dispute is reached between the Boards of Directors of the healthcare institutions concerned, the AB will appoint an independent mediator by majority vote.
  3. If mediation does not lead to resolution of the dispute then the Party(ies) shall be free to apply to the appropriate court.

# Article 15: Other provisions

* 1. In the event that one or more provisions of this Cooperation Agreement are or become invalid, the other provisions will remain in full force. The parties undertake to replace the invalid provision by a valid provision that matches the purpose and purport of the invalid provision as closely as possible.

1S.2. Amendments to this Cooperation Agreement shall only be made in writing.

* 1. The Care Institutions are not entitled to transfer the rights and obligations arising from this Cooperation Agreement to a third party, except with the prior written consent of the other Care Institutions.
  2. The provisions as set out in the preamble form a whole with the content of this Cooperation Agreement.
  3. All annexes form an integral part of this Cooperation Agreement.

9

Thus agreed and signed

[place, date)

.

# ANNEX 1: Cooperation agreements (multidisciplinary) oncology

APPENDIX 2: Organisational structure []

# ANNEX 3: [] organisational regulations

**Article 1: Board of Directors: composition, appointment, duties and powers**

* 1. Except with regard to the tasks/competencies delegated to other entities/persons in this Agreement, the leadership of the Network is vested in the BoD, consisting of one representative, being the chairman BoD, of each Healthcare Institution.
  2. The BoD shall appoint from among its members a chairman, i.e. a director of one of the Care Institutions, for a term of office of three years at a time.
  3. The BoD has the following duties:
     + Appointing the NCT of [], on the nomination of the NB. The chairman of the NCT, is admitted to the BoD as a member, but has no voting rights. This member does not count in the quorum;
     + Review and adopt policies formulated by the NB;
     + Review and adopt the proposals of redistribution or concentration of care formulated by the Regional (tumour) Working Groups in case of changing (voIume) standards;
     + Adopt the annual Budget, prepared by the NB;
     + Determine the allocation of portfolios within the NCT, upon nomination by the NCT.
  4. Each Healthcare Institution is entitled to nominate a director and an alternate as a member of the

BoD, through written notification to the chairman of the BoD.

* 1. The BoD meets at least twice a year to decide on the Budget, and policies and/or amendments to it.
  2. The chairman of the BoD is responsible for preparing an agenda and sending it to the members in a timely manner. The notice period for the meeting of the BoD shall be seven calendar days.
  3. The chairperson determines the venue, chairs the meeting and is responsible for drafting the minutes. The chairperson is assisted in this by the chairperson of the NCT.
  4. Each member of the BoD has one vote, except for admitted members to the BoD. A member of the

BoD may be represented by another member of the BoD or an alternate member by written authorisation.

* 1. The BoD may take decisions, which are binding for each of the participating hospitals. If a decision cannot be taken at the meeting due to insufficient attendance of members of the BoD, i.e. less than half, the agenda item shall be dealt with for decision-making at the next meeting.
  2. Decisions concerning the Network may also be taken by the members of the BoD outside a meeting if necessary by telephone, e-mail, etc., and confirmed at the next meeting and thus recorded in the minutes. Per decision taken outside a meeting, it will be agreed whether the decision takes effect immediately or not.
  3. Matters that exceed the medical content policy and/or may have financial/organisational consequences for the Care Institutions must be approved in advance by the BoD of the Care Institutions.

**Article 2: Network Coordination Team (NCT): composition, appointment, duties and powers** 2.1. The NCT consists of up to 6 members. The NCT is composed of:

* 1. NCT members are medical specialists, managers with oncology care experience and expertise or policy advisers with oncology care expertise.
  2. Preferably, one member of the NCT is a manager or policy advisor with experience and expertise of oncological care in one of the Healthcare Institutions.
  3. A representative of [] will chair the NCT.
  4. Members also serve on the NB.
  5. Members are nominated by the [] and appointed by the BoD.
  6. The NCT is supported by a policy advisor.
  7. The NCT's powers are policy-making, informing and coordinating in nature. The NCT supports the NB and coordinates consultation and coordination between the local oncology committee and the NB.

The chairman of the NCT also chairs the NB.

* 1. The NCT has the following duties:
     + Implement the policy as adopted by the BoD with its own mandate within the established frameworks;
     + formulate strategic policy proposals within the objective of the cooperation which, after consideration in the NB, are submitted to the BoD for decision-making;
     + Prepare draft Annual Plan of [];
     + annually adopt [] draft budget and draft financial statements;
     + initiating and coordinating [] activities as laid down in the established Multiannual Plan (including annual plan and report). This includes the activities of the NB and the Regional (tumour) Working Groups;
     + Implement portfolios as named in the Annual Plan;
     + Report to the BoD on the progress and implementation of its activities and activities carried out under its responsibility, such as those concerning the NB and Regional (tumour) Working Groups.
  2. The NCT meets once a month by videoconferencing and at least four times a year physically.
  3. The NCT organises a policy afternoon or evening once or twice a year.
  4. The chairman of the NCT has a term of three years, with the possibility of renewal.
  5. The other NCT members are appointed for two years, with the possibility of renewal.
  6. Members of the NCT resign according to a roster drawn up on the basis of seniority and 'roof-tile construction'.
  7. The composition of the NCT will strive for proportional representation of the [].

# Article 3: The NB: composition, appointment, duties and powers

* 1. Within [], decisions are made in the NB, which are then ratified by the BoD.
  2. The NB is composed of the chairs and managers/policy advisers oncology of the local oncology committees of the Healthcare Institutions. The NB has a decisive role in shaping the joint care policy on multidisciplinary oncology care in the region.
  3. A maximum of two people per Healthcare Institution sit on the NB: a medical specialist and a medical specialist or manager/policy advisor.
  4. NCT members sit on the RONBC on behalf of their hospital (Article 2.5).
  5. The NB meets once a quarter. If necessary or desired, additional consultations can be scheduled via video in the interim or additional consultations can take place following the NCT video consultations.
  6. The tasks of the NB are as follows:

14

* + - drawing up a Multiannual Plan with a scope of 3 years. This Multi-Year Plan requires the approval of the BoD.
    - Each year, the NB derives an Annual Plan from the Multi-Year Plan which includes:

the intended joint activities, spearheads and emphases of cooperation in that calendar year;

per Regional (tumour) Working Group an Annual Plan defining concrete goals, outcomes and activities for the working group, such as ambitions for the future in terms of patient care, best practices, performance outcomes quality standards, training and research;

the staffing, facilities and (financial) resources required for the implementation of the Annual Plan at each participating institution and the individual contributions of participating institutions to it; consistency and alignment with activities of the previous, ongoing Annual Plan.

* 1. The Annual Plan is translated into a Budget and submitted to the BoD. As soon as possible after approval of the Budget by the BoD, each partner ensures that staffing, facilities and (financial) resources are made available within its own institution in accordance with [] Annual Plan and Budget.

# Article 4: Regional (tumour) working groups : composition, tasks and competences

* 1. The Regional (tumour) Working Groups are the heart of []: from all Healthcare Institutions, Healthcare Professionals from the Local (tumour) Working Groups are delegated to the various Regional (tumour) Working Groups.
  2. The Regional Working Groups are both tumour-specific and cross-cutting.
  3. All Healthcare Institutions are represented in the Regional (tumour) Working Groups.
  4. In principle, a maximum of 3 mandated persons per Healthcare Institution are delegated to the Regional (tumour) Working Groups. Preferably, the chairman of the local (tumour) working group is one of the mandated delegates.
  5. The mandated persons have the power of attorney to make decisions on behalf of the Local (tumour) Working Group.
  6. For each Regional (tumour) Working Group, additional delegates/specialisms may be invited in addition to the three delegates per Healthcare Institution.
  7. In consultation with the Regional (tumour) Working Group and depending on the topic, the number of maximum mandated people may be deviated from and the Working Group opened to all interested parties.
  8. Each delegate is responsible for providing substantive feedback on the results and agreements of the Regional (tumour) Working Group to their own Local (tumour) Working Group.
  9. The elected chairman of the Regional (tumour) Working Group has a term of office of three years with the possibility of one renewal (i.e. a maximum of six years).
  10. Each Regional (tumour) Working Group prepares an Annual Plan (tumour) Working Group and an Annual Report each year, based on an established format, which respectively sets out the plans for the coming year and reviews the activities of the past year.
  11. Recurring themes in the Annual Plan (tumour) Working Group and Annual Report are: best practices, care pathways, analysis outcomes, studies (including inclusion rates), changing (volume) standards,

training/education, Service Level Agreements, patient satisfaction/patient participation and communication.

* 1. The Regional (tumour) Working Groups discuss the Clinical Guidelines in useand take stock of how their content relates to developments in the region. This inventory, including

any recommendations, is reviewed through the NB and presented to the BoD for decision-making.

* 1. The leaders of each Regional (tumour) Working Group (consisting of the chair, the vice-chair and a member) meet with the NCT of [] at least once a year. During this meeting, the Regional (tumour) Working Groups report on the progress and ambitions of the Regional (tumour) Working Group and, based on new developments and insights, the strategy for the coming period is adjusted.
  2. The Regional (tumour) Working Groups are supported by a policy officer employed by []. The policy officer takes care of the entire organisation of the Regional (tumour) working groups and provides substantive support during the working groups and preparation for the working groups.

# Article 5: Project organisation

* 1. The project organisation concerns a separate component in [], which, like the Regional (tumour) Working Groups, falls under the NB.
  2. The projects aim to develop and implement sustainable and widely applicable improvements in [].
  3. For each project, a project leader and project staff are appointed who are responsible for the outcome and implementation of the project. The project members are appointed by the NB.

# ANNEX 4: Patient data processing and management protocol / Data sharing protocol

**Data sharing protocol on [] cooperation agreement**

This Data Sharing Protocol is based on the Model Processor Agreement Healthcare Sector Organisations, version date 11 December 2017.

Article 1: **Definitions**

* 1. In this Data Sharing Protocol (Protocol), the following capitalised terms mean the following:

*General Data Protection Regulation*

*(GDPR)*

*Incident*

*Staff member*

*Party Parties*

*Personal data*

*Cooperation agreement Subprocessor*

*Processor*

Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (GDPR).

i a complaint or (information) request from a Data Subject regarding the processing of Personal Data;

ii an investigation or seizure by government officials of the Personal Data or a suspicion that this is about to take place;

 a Personal Data breach as referred to in Article 4 under 12 GDPR;

ÏV any unauthorised access, deletion, mutilation, loss or any other form of unlawful processing of the Personal Data.

the natural person engaged by the Parties for the execution of the Cooperation Agreement and employed by or for one of the Parties

Member Party to the Cooperation Agreement

Multiple Parties to the Cooperation Agreement

Any information about an identified or identifiable natural person within the meaning of Article 4 under 1 GDPR

Cooperation agreement []

Any non-subordinate third party involved by Processor in the processing of Personal Data under the Agreement, other than Employees

the processor referred to in Article 4(8) GDPR

*Controller* The processing controller referred to in article 4 subsection 7 GDPR

* 1. The aforementioned and other terms shall be interpreted in accordance with the GDPR.
  2. Where this Protocol refers to certain standards, this always means the most current version thereof. If the standard in question is no longer maintained, the most up-to-date version of the logical successor to the standard in question should be read instead.

# Article 2: Subject matter of this Protocol

* 1. This protocol relates to the processing of Personal Data by the Parties in the context of the implementation of the Cooperation Agreement and/or the bilateral healthcare cooperation agreements on the joint treatment of patients with specific oncological conditions.
  2. This Protocol forms an inseparable part of the Cooperation Agreement. To the extent that the provisions of this Protocol conflict with the provisions of the Cooperation Agreement, the provisions of the Cooperation Agreement shall prevail.

# Article 3: Personal Data processing

* 1. The parties guarantee that they will only process Personal Data in the context of the Cooperation Agreement to the extent that:
     + This is necessary for the execution of the Cooperation Agreement; or
     + this Is necessary for the implementation of the bilateral care cooperation agreements on the joint treatment of patients with specific oncological conditions.
  2. Without prejudice to the provisions of the first paragraph of this Article 3, Parties shall be allowed to process Personal Data originating from one or more other Parties if a statutory regulation (including judicial or administrative orders based thereon) obliges them to do so.
  3. The parties will process the Personal Data demonstrably, in a proper and careful manner and in accordance with its obligations as Processing Controller under the GDPR, and other laws and regulations.
  4. The Parties shall not, unless they have obtained express prior written consent from one or more other Parties to do so, process any Personal Data by themselves or by third parties in countries outside the European Economic Area ("EEA").
  5. Parties shall ensure that involved Employees have signed a confidentiality agreement and shall allow the other Parties to inspect this confidentiality agreement upon request.

# Article 4: Personal data security and control

* 1. Parties will demonstrably take appropriate and effective technical and organisational security measures, which, given the current state of the art and the costs involved, correspond to the nature of the Personal Data to be processed, to protect the Personal Data against loss, unauthorised access, mutilation or any form of unlawful processing, as well as to guarantee the (timely) availability of the data. The measures include in any case:
     + measures to ensure that only authorised Employees have access to the Personal Data for the purposes set out, and;
     + measures whereby Employees, Processors and Sub-processors only have access to Personal Data through named accounts, with the use of those accounts being adequately

logged and where the relevant accounts allow access only to that Personal Data to which access is necessary for the relevant (legal) person, and;

* measures to protect Personal Data against accidental or unlawful destruction, accidental loss or alteration, unauthorised or unlawful storage, processing, access or disclosure, and;
* measures to identify weaknesses with regard to the processing of Personal Data in the systems deployed, and;
* measures to ensure the timely availability of the Personal Data.
  1. Parties demonstrably process in accordance with ISO27001 and/or NEN 7510 and have implemented an appropriate, written security policy for the processing of Personal Data, which in any case sets out the measures referred to in the first paragraph of this Article 4.
  2. Parties demonstrably comply with the security requirements for network connections as described in NEN7512.
  3. Parties demonstrably comply with logging requirements as described in [].
  4. Parties demonstrably comply with the requirements of other NEN standards to the extent they have been declared applicable to healthcare.

# Article 5: Duty to inform and incident management

* 1. As soon as an Incident regarding the Personal Data relating to processing under the Cooperation Agreement occurs, has occurred or might occur, Parties are obliged to immediately notify the other Party or Parties thereof, providing all relevant information on:
     + the nature of the Incident regarding the Personal Data processed under the Cooperation Agreement;
     + the (potentially) affected Personal Data;
     + the identified and likely consequences of the Incident in respect of the Personal Data on processing under the Cooperation Agreement; and
     + the measures taken or to be taken to resolve the Incident regarding the Personal Data processed under the Cooperation Agreement or to limit the consequences/damage as much as possible.
  2. Without prejudice to the other obligations in this article, the parties shall be obliged to take measures that can reasonably be expected of them to remedy the Incident regarding the Personal Data processed under the Cooperation Agreement as soon as possible or to limit the further consequences as much as possible.
  3. Parties shall investigate the Incident regarding the Personal Data processed under the Cooperation Agreement in order to formulate a correct response and take appropriate follow-up steps regarding the Incident, including informing the Personal Data Authority (AP) and/or the Data Subject.
  4. Parties are not allowed to provide information about Incidents regarding the Personal Data relating to processing under the Cooperation Agreement to data subjects or other third parties, except to the extent that such Party or Parties are legally obliged or have otherwise agreed to do so.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Article 6:** | **Liability** |  | | | | |
| 1.20. Parties | are each | responsible | and liable | for | their own acts | as |

Controller.

* 1. To the extent that the Parties are jointly and severally liable towards third parties, including the data subject, or are jointly fined by the Personal Data Authority, they are obliged towards each other, each for the part of the debt which concerns him in their mutual relationship.
  2. Any limitation of liability under the Cooperation Agreement shall furthermore lapse for the Party concerned in case of intent or gross negligence on its part.
  3. The parties shall ensure adequate liability cover.

# Article 7: Duration and termination

* 1. This protocol shall commence on the date of signature of the Cooperation Agreement and its duration shall be equal to the duration of the Cooperation Agreement, including any extensions thereof.
  2. This protocol is an integral and inseparable part of the Cooperation Agreement.
  3. Obligations under this Protocol which by their nature are intended to continue even after termination of the Cooperation Agreement shall survive termination of the Cooperation Agreement. These include, for example, those arising from the provisions on confidentiality, liability, dispute settlement and applicable law.

# Article 8: Retention periods and intellectual property rights

* 1. The Parties shall not retain Personal Data for longer than strictly necessary, including statutory retention periods or any agreement on retention periods between the Parties.
  2. To the extent that the (collection of) Personal Data is protected by any intellectual property right, the Parties grant each other permission to use the Personal Data in the context of the execution of the Cooperation Agreement.

# Article 9: Final provisions

* 1. In the event of nullity or voidability of one or more provisions of this Protocol, the remaining provisions shall remain in full force and effect.
  2. In all cases not covered by this protocol, the Parties shall decide by mutual agreement.
  3. This protocol is governed by [country] law.
  4. The parties will endeavour to resolve conflicts by mutual agreement. This includes the possibility of ending the dispute through mediation or arbitration to be determined by mutual agreement.
  5. Disputes on or in connection with this Protocol shall be referred only to the court or arbitrator(s) designated for that purpose in the Cooperation Agreement.

# APPENDIX 5: Rules for information exchange between Healthcare Institutions within [CCI]

When exchanging business confidential information as mentioned in Article 13, the following ground rules should be followed.

# Rules for sharing company confidential information

1. There is one person in each Healthcare Institution ultimately responsible for access to business confidential information, including financial data, strategic data and data on patient origins and numbers. Under their supervision, the use of business confidential information is kept to a minimum and includes only information necessary for collaboration.
2. They decide on access to business confidential Information for those who are (directly) involved in the cooperation and actually drive the cooperation. With reference to the relevant article of the cooperation agreement, these are:
   * members of the BoD and NB,, the relevant partnerships, the management of departments and services involved in oncological care and specific functions concerning Oncology in Healthcare Institutions;
   * persons who, upon approval of the parties, coordinate and/or perform specific tasks and/or activities in the context of the cooperation.
3. The exchange of business confidential information is done in a secure manner at all times.

General Rules

1. Where possible, (highly) business confidential information is processed by an independent third party, and only provided in less detailed and aggregated form to the relevant Healthcare Institutions.
2. Business confidential information obtained in the context of the cooperation will be treated as absolutely confidential.
3. Company confidential information is stored/kept in a place accessible only to the agreed circle of users.
4. Business confidential information will not be used for any purpose other than that for which it was obtained.
5. Company confidential information is not disseminated within its own organisation beyond what is strictly necessary and remains within the agreed circle of users.
6. If the business confidential information is no longer needed, it should be returned and/or any copies destroyed.
7. The parties guarantee that the exchange of business confidential information will not go beyond what is strictly necessary and may not raise competition law concerns