

HARTWIG MEDICAL FOUNDATION – GUIDING PRINCIPLES

These Guiding Principles were most recently updated as per 1 September 2026. Hartwig Medical Foundation (**Hartwig**) may amend these Guiding Principles from time to time.

1. MISSION

1.1 Hartwig is a non-profit organization with the mission to improve cancer patient care. We support treatment decisions through a combination of innovative software, clinical data analyses, and molecular diagnostics. This enables patients to timely receive the right treatment while generating valuable data that supports research and the continuous improvement of care. There is still a great deal of progress to be made in this field, for instance through better use of information and data that are already available in this respect.

How does Hartwig aim to achieve its mission?

1.2 Hartwig aims to achieve its mission by collecting and collating genetic and clinical data (including treatment data) (**Hartwig Data**) from cancer patients in a database (the **Hartwig Medical Database**). Hartwig Data is always stored secured and in encoded form. Hartwig is provided with the encoded clinical data by several hospitals, treatment centers and research or governmental institutions with whom Hartwig collaborates. The genetic data is in most cases generated by Hartwig itself.

1.3 When a patient undergoes broad molecular testing, it is considered best practice to ask the patient for consent for re-use of their data. Hospitals, treatment centers and research institutions may agree that Hartwig, under the condition of a patient's informed consent, may store the generated encoded genetic data as well as clinical data in the Hartwig Medical Database in accordance with applicable laws and regulations.

1.4 The extensive, centralized information in the Hartwig Medical Database offers many options and opportunities in the cancer research field. That is why Hartwig makes data from the database available — under strict conditions — to certain parties, such as researchers and scientists. They can use the information from the Hartwig Medical Database to generate more knowledge on tumor growth and tumor characteristics, drug efficacy, patient stratification for drugs and to conduct further research on the relation between a specific genetic aspect and the responsiveness of a patient to a certain treatment. In this document, the term 'treatment' should be read as including medication.

2. CORE VALUES

Hartwig applies the following core values:

- 2.1 Patient centric. Hartwig aims to improve care and treatment of current and future cancer patients. Hartwig is transparent in using the informed consent of the patient as the basis for data access and data re-use of the patient's data for research purposes.
- 2.2 Innovation. Hartwig aims at contributing to scientific research, in order to promote the development of new more effective treatment methods and, thus, to contribute to the usage and development of safe, effective and affordable treatment.
- 2.3 Integrity. Hartwig handles data, including patients' personal data, in a reliable, careful, secure and transparent manner.
- 2.4 Reliability. Hartwig seeks to be a reliable partner for hospitals, treatment centers (and thus for patients), research institutions, academic institutions and experts, in order to promote scientific and social advances in the field of cancer.
- 2.5 Fairness. Hartwig values and operates in accordance with the FAIR principles. This means that the data stored in the Hartwig Medical Database are findable, accessible, interoperable and reusable.

3 SAFEGUARDING THE CORE VALUES

- 3.1 The aforementioned core values are essential for Hartwig. They are non-negotiable and underlie all of Hartwig's decisions. Hartwig translates the core values into specific arrangements and goals as far as possible, and safeguards them from a variety of perspectives, namely (i) social, (ii) ethical, (iii) legal, and (iv) contractual. Below, each of these perspectives will be further elaborated.

Social sphere

- 3.2 Society needs new, more efficient methods of research into cancer and cancer treatment and development. The collection and exchange of data plays a central role here. A great deal is already possible in terms of technology — including the use of electronic patient records and eHealth applications — and a tremendous amount of information is available. Applying the available technology to the available information — in the right way — can lead to a huge step forward in the field of healthcare innovation.
- 3.3 Patients have an expectation for their data to be used ethically and effectively to improve the way we care for and treat cancer patients, as well as supporting research endeavors when consent is provided for this. The practicalities of this in the fragmented health data landscape have meant that data is not always available, shareable or integrate-able. In accordance with the FAIR and CARE principles Hartwig aims to help break down these barriers and enable efficient and timely analysis of these data while respecting data sovereignty. Hartwig does this in collaboration with many national and international parties to ensure systems change is achieved. Upcoming regulations like EHDS will further strengthen and support a safe exchange of data. As well as ongoing efforts to enable the federation of analysis and data to support international analysis which are crucial to equitable outcomes and robust (cross) validation of findings.

3.4 To ensure a sustainable health system it is essential to routinely re-assess currently re-imbursed tests and treatments for their effectiveness and potential new biomarkers. To support this type of care evaluation Hartwig gathers relevant and rich clinical data including treatment and treatment outcome. To this end, Hartwig shares the data collected about cancer patients in the Hartwig Medical Database, and makes this data available for scientific and healthcare research under the appropriate legal, ethical and security conditions.

3.5 An important difference with existing initiatives is that Hartwig stores results from molecular (including DNA/RNA/A/Proteomics) analysis of biological human materials together with corresponding clinical data, rather than the biological materials itself. This makes Hartwig's activities essentially different from those of biobanks. Hartwig facilitates research through harmonized national data, this kind of data enables the advancement of comprehensive research in cancer genomics and improvement of cancer care. Hartwig therefore regularly monitors the results and permissibility of its activities. Hartwig engages (legal) assistance where necessary or desirable.

Nature of the data

3.6 Naturally, Hartwig is aware that it has personal, sensitive and confidential data at its disposal. In a society where technology, including Artificial Intelligence, is widely available and information is shared to an increasing extent, patients, hospitals, treatment centers and research institutions must be able to rely that Hartwig handles this data carefully and securely.

3.7 In Hartwig's view, it goes without saying that data is to be collected and stored as securely as possible, taking account of the state of the art and the latest insights in the field of data security.

3.8 Hartwig only makes available encoded data for researchers and scientists to whom data in the Hartwig Medical Database is made accessible.

3.9 Furthermore, Hartwig only stores patient data in the Hartwig Medical Database if and to the extent that this is possible pursuant to the applicable legislation and regulations. In addition, Hartwig ensures that no superfluous (personal) data is stored in the database. Hartwig outsources its data processing and storage to a reputable IT company/cloud services provider whose extensive expertise includes the data security field, whereby Hartwig itself retains control of the Hartwig Medical Database at all times. In this respect, Hartwig agrees upon strict (security) arrangements with the IT company/cloud services provider.

Data access requests

3.10 Hartwig also handles the assessment of requests for access to data in its database with due care. Each request is tested and assessed by independent bodies of Hartwig (the Scientific Council and the Data Access Board) using a clear, publicly accessible protocol (as laid down in the Rules of Procedure Data Access Requests).

3.11 Hartwig is aware that publishing scientific articles is an important way to advance research into cancer treatment. However, with a view to careful data handling, not every research plan automatically qualifies for access to data from the database.

- 3.12 The involved research plan must relate to innovative scientific and/or healthcare-economic research aimed at improving the collective healthcare system, improving/developing new treatment methods, the effective and efficient use and off-label use of existing cancer medication, and/or improving/developing safe, effective and affordable cancer medication. The research must be relevant, novel, feasible, and of social and/or scientific value. Moreover, the purpose of the research must align with Hartwig's mission and core values.
- 3.13 If Hartwig decides that Hartwig Data can be made available to a researcher, scientist or other party, it always makes available only a specific set of data (not the whole Hartwig Medical Database) that is needed for and may only be used for the approved specific research purpose. In the agreement that is entered into by and between Hartwig and the research institution, the institution agrees to comply with strict requirements governing the use and protection of the data made available by Hartwig, and confirms that all involved researcher(s) and any recipients of the data comply with these requirements as well.
- 3.14 As Hartwig is aware that supply chain responsibility is highly important, Hartwig's contracting parties are also required to apply the above guiding principles, such as the purpose limitation requirement.
- 3.15 If Hartwig itself wishes to make use of Hartwig Data in the Hartwig Medical Database – other than in the context of internal quality management, verification and logistic processes – or engages third parties for the use of Hartwig Data from the Hartwig Medical Database, the same rules and protocols apply to Hartwig as to external parties. One of the implications of this is that Hartwig, too, must submit its Hartwig Data use requests to the Scientific Council, Data Access Board and Hartwig's Board for assessment.
- 3.16 Hartwig also makes available statistical information based on the Hartwig Data in the Hartwig Medical Database. The Rules of Procedure Data Access Requests do not apply to requests for statistical and aggregated information based on the Hartwig Data from the Hartwig Medical Database.

Publications further to a data access request

- 3.17 Hartwig is not involved in the research performed by a researcher, scientist or other party to whom Hartwig Data is made available by Hartwig pursuant to a data access request. The publication of research results based on the Hartwig Data made available by Hartwig is important for scientific advances and, as such, is supported by Hartwig. However, in the event of such publication, Hartwig is not involved in or responsible for the content of any publication.
- 3.18 Hartwig, however, applies a Publication Policy, acknowledging the sources of the data that have contributed to the published results.

Collaboration

- 3.19 Hartwig is aware that social and scientific advances cannot be made without collaboration. That is why Hartwig seeks to collaborate with patient advocacy organizations, hospitals, treatment centers, academic institutions, interest groups and experts, where possible. The basic principle here is that each party does what it is good at. Hartwig brings parties together and facilitates the

appropriate and efficient use of medical and research data. Supply chain responsibility plays a central role here. Each link in the chain must handle the other parties' data and interests in an ethical manner.

- 3.20 Where possible, Hartwig also promotes collaboration in scientific research. If the same research plan emerges from various centers or research institutions, Hartwig may advise the respective parties to join forces in a single research project.

Ethical sphere

- 3.21 There is a growing awareness in society on the value of personal data, including medical data. This means that there is a greater need for openness and participation regarding the use of personal data. Hartwig is aware of this and considers transparency about the use of data to be of great importance.
- 3.22 Hartwig is, for example, fully open about what it does with personal data and why. Hartwig describes this inter alia in its Privacy Statement. Furthermore, ethical aspects are taken into account when Hartwig assesses requests for access to data in its database.

Informed consent

- 3.23 In principle, Hartwig only works with consent from patients and strives to offer patients options for controlling the use of their data. Under the applicable legislation and regulations and particularly, the General Data Protection Regulation (GDPR), the genetic data and clinical data that are processed by Hartwig qualify as 'special categories of personal data'. Hartwig has designed its processing activities and policies in such way that these comply with the strict requirements that apply to this type of data.
- 3.24 However, in extraordinary cases Hartwig works with data from patients whose biological human material was taken quite some time ago (for instance in case of retrospective studies). In those cases, the informed consent pursuant to which the biological human material was obtained is inadequate to serve as a sufficient legal basis for Hartwig's activities (which, after all, were not known about when the relevant biological human material was taken, as Hartwig did not yet exist at that time).
- 3.25 In so far as possible, in such cases Hartwig will proceed to attempt to obtain adequate informed consent or to arrange for it to be obtained. However, that is not always possible or practically feasible, for example where the patient in question has died in the interim, and may even be undesirable, for example when the patient is very ill. Under certain circumstances, the public interest that Hartwig seeks to serve, justifies Hartwig working with personal data in these situations as well in so far as the patient did not object to that at the time. Obviously, an important condition in this respect is that the privacy and medical interests of any patients concerned are sufficiently safeguarded in accordance with these Guiding Principles. In these situations Hartwig only acts after the interests involved have been carefully balanced.
- 3.26 In addition, Hartwig is aware that processing of personal data could be hampered or obstructed in the event that patient data is not or insufficiently pseudonymized, or if sufficient or sufficiently clear informed consent has not been obtained. In such cases, Hartwig can imagine that a socially

compelling research interest may justify overriding possible privacy objections. The nature and objectives of the research play an important role in this regard. Research into a ground-breaking method of treatment at an advanced stage may more readily provide such justification than research with a less direct social benefit/interest. Obviously, this is subject to the condition that legal limits are respected and that the invasion of privacy is so minor that the patient can still trust that his or her data will be handled with due care. Hartwig is aware that continuous vigilance is required to safeguard the privacy of patients. The patient and the hospitals, treatment centers and research institutions are entitled to this, and must be able to trust that data will be handled with due care.

- 3.27 The Data Protection Officer of Hartwig assists in this respect. Where possible, Hartwig also seeks to collaborate with interest groups. For example, Hartwig believes that patients' associations have a role to play in sharing their thoughts about participation and control options for patients, particularly with regard to retrospective studies.
- 3.28 When access to data in the database is requested, a careful assessment is made as to whether the intended use of the data falls within the scope of the patient's informed consent. Hartwig exercises restraint, where the informed consent is insufficiently clear.
- 3.29 On the other hand, Hartwig strives for a proportionate application of applicable legislation and regulation to avoid scientific research being unnecessarily obstructed. Without scientific research, the development of new, better or more efficient treatment methods would be impossible. To conduct such scientific research, responsible sharing of patient data is necessary.

Commercial use

- 3.30 In accordance with the legal requirements for processing personal data, Hartwig works in the public interest, with a clear non-profit motive. This means, for example, that Hartwig ensures that Hartwig Data from the Hartwig Medical Database are only used in accordance with its objectives (i.e. scientific research in the public interest).
- 3.31 If commercial parties, such as pharmaceutical companies, can contribute to Hartwig's mission, Hartwig will wish to facilitate this.
- 3.32 However, this would only be possible in the event that the research of commercial parties predominantly serves a public interest.
- 3.33 Hartwig will assess whether this requirement is met in each specific case. Naturally, requests from such parties for the provision of data must also pass the same test via the Data Access Board and the Scientific Council on the basis of the Rules of Procedure Data Access Requests. Hartwig will never permit the use of data for marketing or other purely commercial purposes.

Fees

- 3.34 Hartwig makes Hartwig Data in the Hartwig Medical Database available to researchers or scientists for free.

3.35 Hartwig may request a fee if a request for data requires disproportionate effort on the part of Hartwig. These fees are directly fed back to the foundation and are thus fully applied in furtherance of Hartwig's objectives and mission: the advancement of scientific research into cancer and cancer treatment.

3.36 Data will never be 'sold'. All that is provided is a contractual right to use specific data from the database for a specific research question.

Patients' control options

3.37 The basic principle is that, at all times, the patient retains control of the data relating to him or her.

3.38 Specifically, this means that a patient always has the option of accessing his or her data, having it deleted from the Hartwig Medical Database, withdraw consent previously given and object to the further use of the data. When a patient decides to withdraw his/her consent or to have deleted his/her data from the database, this only has future effect. This means that Hartwig will delete the patient's data from the database and will no longer use it. However, it is not possible for Hartwig to undo previous use of this patient's data by Hartwig and/or researchers to whom the data of this patient have been made available further to a data access request.

3.39 The Hartwig Data in the Hartwig Medical Database are stored in encoded form and no directly identifying data of patients. The key that is required to identify the Hartwig Data in the Hartwig Medical Database may remain at the hospitals, treatment centers, research institutions or governmental organizations that provide Hartwig with the data. Therefore, these hospitals, treatment centers and research institutions have an essential role in offering and implementing the control options to the patients. In this respect, Hartwig makes arrangements with the involved hospitals, treatment centers and research institutions.

Legal sphere

3.40 Hartwig takes a great deal of care in setting up, using and providing access to the Hartwig Medical Database. Hartwig knows and respects its legal limits and what it can and cannot do under, inter alia, the GDPR, the Dutch GDPR Implementation Act (Uitvoeringswet Algemene verordening gegevensbescherming) (UAVG) and the Medical Treatment Contracts Act (Wet op de geneeskundige behandelingsovereenkomst). Hartwig has its methods legally assessed in collaboration with a designated team of attorneys.

3.41 In the event that Hartwig encounters gray areas in the legislation and regulations, it applies proportionality and carefully assesses the limits of what is permissible where that is necessary to advance cancer research and development. In doing so, Hartwig applies the following principles in any event:

- patients' right to privacy is always respected. Personal data is processed in a careful and transparent manner;
- data in the database are encoded. Researchers that receive Hartwig Data from the Hartwig Medical Database always receive encoded data;
- the technical and organizational protection and security of data is essential;
- the data used are adequate, up to date, relevant and not excessive;

- Hartwig uses and/or provides data from the database exclusively for the purposes for which Hartwig received the data. Therefore, data is always used to foster advances in cancer treatment and research. The data provided or stored never exceed what is necessary for those purposes;
- in principle, Hartwig only processes data on the basis of informed consent of the patient. If, as regards prospective studies, no valid consent has been obtained, Hartwig cannot and will not proceed to store or provide patient data until the moment that sufficient informed consent that covers the processing has been obtained. Where retrospective studies are concerned, Hartwig applies the principles described in above;
- Hartwig processes personal data of patients within appropriately located and regulated processing environments, for example data from European citizens is only processed in the geo-located European Economic Area (EEA). If it is necessary to take the data outside the EEA, when it makes data available to foreign researchers, Hartwig will guarantee a sufficient security level for the data. The receiving party must, at the very least, comply with all data protection principles that apply within the EEA.

3.42 As well as complying with the applicable legislation and regulations, Hartwig seeks alignment with codes of conduct drafted on a self-regulation basis, such as 'Human Tissue and Medical Research: Code of Conduct for Health Research' (Gedragscode Gezondheidsonderzoek) drawn up by the Foundation Federation of Dutch Medical Scientific Societies. As long as it does not interfere with Hartwig's mission, Hartwig applies the 'best practice' principle when handling data, thus doing more rather than less where possible, even when less is permissible.

Contractual sphere

3.43 As long as it is in line with Hartwig's mission and core values, Hartwig applies the basic principle that Hartwig Data from the Hartwig Medical Database should be accessible to everyone.

3.44 Partners must share and conform to Hartwig's mission and core values and must agree to the strict conditions that Hartwig imposes with regard to patient privacy and data protection.

3.45 Hartwig also safeguards its core values contractually, by, for example, making clear arrangements about matters as data use in its collaboration agreements and license agreements. In addition, the Rules of Procedure Data Access Requests are contractually incorporated into the relevant agreement, thus assuring compliance with the safeguards included therein. Consent and transparency obligations are, where relevant, contractually imposed on parties that receive data, and these parties are furthermore subject to contractual restrictions on what they can do with the data. Use for marketing purposes is excluded, for example, and it is not possible to sell data or make data available to others. Arrangements of a more practical nature are also made, for example regarding the transfer of clinical data, the supply of samples and the manner in which data is provided in encoded form.

3.46 Hartwig also puts transparency first and foremost vis-a-vis its partners, for example regarding expectations, progress, costs and conditions in respect of the collaboration. In addition, Hartwig is prepared to make template agreements available to interested parties, if so requested with a view to transparency or for other reasons.