

**Statutes of  
the  
"European Health Data Alliance e.V."**

**In the version valid from 4 December 2023**

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### **Preamble**

The European Health Data Alliance (EHDA) is a non-profit association established with the aim of promoting the development of citizen-centred health data spaces in Europe. The Alliance sees itself as a trailblazer so that companies, interested (research) organisations and the public can ) institutions, service providers and service providers can successfully develop pioneering health-related projects with regard to the European Health Data Space (EHDS). "HEALTH-X dataLOFT", "GAIA-X-MED" and "TEAM-X" are consortia funded by the Federal Ministry for Economic Affairs and Climate as part of the "Gaia-X" programme. The EHDA takes up the technical and organisational Gaia-X data room solutions developed in the consortia as secure processing environments (sVU) and invites European partners to further develop them in cross-border and cross-sector use cases.

Against this background, it is to establish an association "European Health Data Alliance e.V.", the purpose of which is to realise the tasks and objectives outlined above and to bundle and coordinate the corresponding activities of its members.

The core tasks are the further development of the available technical and organisational solutions for data-based healthcare services and the expansion of the technological basis as a blueprint for the development of EHDS-compliant data spaces that are also Gaia-X-compliant and ensure syntactic and semantic interoperability. These serve as secure processing environments (sVU) in trustworthy supply and research scenarios. In addition, the tasks include the further development and exchange of expertise, the development and coordination of solution options for technical and organisational challenges, as well as their transfer to the member companies, politicians and the public. An important field of activity in order to position the awareness and diversity of data utilisation scenarios in society.

With selected founding members from all areas of research, industry, healthcare and patient advocacy, the EHDA is in a central position to be an advocate and driver of future EHDS-compliant and preferably Gaia-X-compliant data room technologies.

To this end, the EHDA develops the interests of various stakeholder groups for the development of suitable standards for patient-centred health data spaces in different application scenarios. The EHDA brings together the interests of patients, researchers, insurers, medical service providers, healthcare providers, pharmaceutical companies and MedTech, as well as other market participants, such as providers of data fidelity models and AI algorithms.

A central goal for the development and expansion of EHDS-compliant health data spaces is to ensure interoperability and the provision of interface knowledge relating to health data from all areas: Data from clinics, concomitant therapy, electronic patient records and data from wearables and other everyday companions should be manageable and available in a standardised and secure manner thanks to the infrastructures developed in the German Gaia-X health lighthouse projects. Citizen-centricity and data sovereignty are technologically secured, are centrally anchored in the statutes and are reflected in the governance structure of the association.

To this end, the EHDA collects and develops specifications and best practices. They enable the creation of a pan-European technical and organisational solution space for the realisation of various supply and research scenarios through federated data spaces with EU-compliant data protection standards, innovative data analysis options and the option for the development, training and implementation of AI algorithms ("compute-to-data"). This creates intelligent solutions and secure processing environments in which algorithms can learn from real data in compliance with data protection regulations without jeopardising the privacy of citizens. At the same time, these solutions take into account the relevant requirements and reservations of data holders.

In addition, the association carries out joint public relations work for the development of EHDS- and Gaia-X-compliant interoperable European health data spaces. In addition, the EHDA acts as a think tank for the development of innovative models of digital healthcare. The focus here is also on citizen-centredness, data sovereignty and intersectoral compatibility, always with the aim of improving care models based on the methods and technologies.

**§ 1**

**Name and registered office of the organisation**

The association shall bear the name "European Health Data Alliance". It is to be entered in the register of associations and will then bear the suffix "e.V.". The registered office of the association is Berlin.

**§ 2**

**Purpose, tasks and objectives of the organisation**

(1) The purposes of the organisation are:

1. The support / promotion of the operation and further development of various health data room technologies within the framework of EHDS-compliant Gaia-X technologies, secure processing environments (sVU). Key technical and organisational activities are discussed, coordinated and supported.
2. The pooling and coordination of the interests and activities of the members of the association in relation to sVUs for collaborative health data spaces.
3. To stabilise the structures and results developed within the "HEALTH-X dataLOFT", "GAIA-X-Med" and "TEAM-X" consortia and to establish them permanently and independently beyond the funding period.
4. To utilise and further develop data room technologies for application scenarios in supply, industry and research.
5. The international alignment of established data room technologies in accordance with the guidelines of the European Health Data Spaces (EHDS) as well as current and future national and international, in particular European, standards and regulations.

(2) The tasks and objectives of the organisation are in particular

1. To promote the development and use of innovative, open and participatory sVUs and to translate research findings more quickly into validatable research results and thus into improvements in care.

2. The management, coordination and implementation of projects in research, care and prevention to promote the purpose of the association with the aim of quickly transferring new research results into practice and thus sustainably improving care for citizens and patients.
  3. The integration and expansion of existing and the development of new data infrastructures for primary and secondary data utilisation in accordance with the EHDS in research, healthcare, rehabilitation and prevention (taking into account the associated personnel issues).
  4. The coordination, implementation and further development of the establishment of centralised and de-centralised infrastructures.
  5. The establishment of national and international co-operations and strategic alliances within the framework of the statutory tasks and objectives.
  6. Offering and providing centralised services for the members of the association.
  7. The support and promotion of projects in the context of national and international, in particular European initiatives, such as Gaia-X and EHDS.
  8. The promotion of cooperation with institutions from the scientific field, civil society, in particular client and consumer protection organisations politics and industry.
  9. The organisation suitable event formats such as seminars, symposia or workshops (also with external cooperation partners).
  10. Carrying out public relations work within the scope of the statutory tasks and objectives.
  11. Promoting the exchange of experience between members.
- (3) The association is authorised to undertake all transactions and measures that appear suitable to serve the objectives and purpose of the association.
- (4) The members and the bodies of the Association are committed to the tasks and objectives set out in the preamble to these Articles of Association and to the purpose of the Association. The members of the Association shall also promote the purposes, tasks and objectives of the Association through membership fees.

### **§ 3**

#### **Acquisition and termination of membership**

- (1) Only legal entities can members of the association.  
Natural persons can only be accepted as honorary members in accordance with paragraph 2. Admission to the association must be applied for in writing to the Executive Board. The Executive Board decides on the application for admission at its own discretion. It does not have to give reasons for rejecting the application to the applicant.
- (2) The Board of Directors may decide with the resolution on the acquisition of membership or at a later date that a member be accepted as an honorary member without voting rights. Members may be accepted as honorary members in accordance with paragraph 1 if this is justified by special reasons at the discretion of the Board of Directors.
- (3) Membership is lost through death or dissolution of the legal , voluntary resignation or formal expulsion. Resignation must be communicated to the Executive Board in writing; it can only take place with a notice period of six weeks to the end of each year. Expulsion is possible if the member's behaviour is detrimental to the association. It is carried out by the Executive Board. An appeal may be lodged with the General Meeting within a period of four weeks after notification of the expulsion decision.

### **§ 4**

#### **Membership fees**

- (1) All members are obliged to annual membership fees in accordance with the membership fee regulations, the amount of which is determined by the General Assembly. The funds raised by the members and government bodies are to be used exclusively for the purposes of the association.  
  
The membership fee regulations may stipulate that a one-off admission fee must be paid upon admission to the association. Further details are set out in the membership fee regulations.
- (2) The obligation to pay contributions begins with the start of membership in accordance with § 3 Para. 1.
- (3) Honorary members are exempt from the obligation to pay contributions.

## **§ 5**

### **Organs of the organisation**

The organs of the association are

1. the Management Board,
2. the Supervisory Board and
3. the general meeting.

## **§ 6**

### **Composition of the Executive Board**

- (1) The Executive Board consists of up to five members.
- (2) The following designation and appointment rights exist:
  1. The five members of the Executive Board are initially elected and appointed by the founding members by a simple majority at a general meeting.
  2. One member of the Executive Board must be a representative
    - a. A small or medium-sized enterprise within the meaning of EU Recommendation 2003/361 and
    - b. of a legal entity under private law.Two board members must be representatives of public corporations (universities) or charitable and other non-profit organisations.
  3. From 4 December 2025, two years after foundation, the following designation and appointment rights apply:



- a. Up to four members of the Executive Board can be elected and appointed by the founding members at a general meeting by a simple majority. Association members who are not founding members have no voting rights in this election.
  - b. If the EHDA e.V. has at least three other members at the time of the appointment of the Executive Board, a member of the Executive Board must be appointed by the General Meeting by election. The founding members have no voting rights in this election.
  - c. If the EHDA e.V. has at least six other members at the time of the appointment of the Executive Board, two members of the Executive Board must be appointed by the General Meeting by election. The founding members have no voting rights in this election.
  - d. If the EHDA e.V. has fewer than three other members at the time of the appointment of the Executive Board, the additional member of the Executive Board shall be nominated and appointed by the General Meeting in accordance with these Articles of Association, whereby in this case the other members who are not founding members shall also be entitled to vote.
- (3) The rights of nomination and appointment in accordance with paragraph 2 above also include the right to dismiss the respective member of the Executive Board at any time. The nomination, appointment and dismissal shall be made in writing to the Chairman of the Supervisory Board.
- (4) The regular term of office for members of the Board of Directors is three years to the end of the year. By way of derogation, the term of office for members of the Executive Board who were appointed when the association was founded is only two years to the end of the year. Re-nomination and re-election are permitted.

(5) One member of the Executive Board must be a representative

1. A small or medium-sized enterprise within the meaning of EU Recommendation 2003/361 and
2. of a legal entity under private law.

Two board members must be representatives of public corporations (universities) or charitable and other non-profit organisations.

## **§ 7**

### **Power of representation, duties and internal organisation of the Management Board and management**

- (1) In accordance with Section 26 (1) BGB, the Executive Board has the status of a legal representative of the association and represents the association in and out of court. The Executive Board is responsible for all business and measures of the association that are not expressly assigned to another body of the association. In particular, it also manages the day-to-day business of the association.
- (2) If the Executive Board consists of several persons, the association shall be represented jointly by two members of the Executive Board. If only one member of the Management Board is in office, this member shall represent the association alone. The Supervisory Board may authorise members of the Executive Board to represent the association individually and release them from the restrictions of Section 181 BGB. If a declaration of intent is to be submitted to an association, it is sufficient to submit it to a member of the Management Board.
- (3) The Executive Board may appoint one or more managing directors, who do not have to be members of the Executive Board, to handle day-to-day business. The managing directors act as special representatives within the meaning of Section 30 BGB on the basis of a written authorisation to be issued by the Executive Board.
- (4) The members of the Board of Directors elect a Chairman and a Deputy Chairman from among their number.

- (5) The Executive Board generally makes its decisions by consensus. If this unanimity is not achieved, the Executive Board decides by resolution, which requires a simple majority of the members of the Executive Board in office to be effective.
- (6) The Management Board must report to the Supervisory Board on its activities to an appropriate extent and at appropriate intervals and obtain recommendations from the Supervisory Board.
- (7) In order to fulfil its duties, the Executive Board may form committees at any time, even temporarily, which may also include representatives of the members of the association and external third parties.
- (8) The members of the Executive Board may receive remuneration and / or reimbursement of expenses, the amount of which is decided by the Supervisory Board.
- (9) The Executive Board shall adopt its own rules of procedure.
- (10) The Executive Board may appoint an Advisory Board to support its tasks.

## **§ 8**

### **Composition of the Supervisory Board**

- (1) The Supervisory Board consists of up to five members.
- (2) The following designation and appointment rights exist:
  - 1. The five members of the Supervisory Board are initially elected and appointed by the founding members at a general meeting by simple majority.
  - 2. One member of the Supervisory Board must be a representative
    - a. A small or medium-sized enterprise within the meaning of EU Recommendation 2003/361 and
    - b. and a legal entity under private law.

Two Supervisory Board members must be representatives of public corporations (universities) or charitable and other non-profit organisations.

3. From 4 December 2025, two years after foundation, the following designation and appointment rights apply:
  - e. Up to four members of the Supervisory Board may be elected and appointed by the founding members at a general meeting by simple majority. Association members who are not founding members have no voting rights in this election.
  - f. If the EHDA e.V. has at least three other members at the time of the Supervisory Board appointment, one member of the Supervisory Board must be appointed by the General Meeting by election. The founding members have no voting rights in this election.
  - g. If EHDA e.V. has at least six other members at the time of the Supervisory Board appointment, two members of the Supervisory Board shall be appointed by the General Meeting by election. The founding members have no voting rights in this election.
  - h. If EHDA e.V. has fewer than three other members at the time of the Supervisory Board appointment, the additional member of the Supervisory Board named in these Articles of Association shall be nominated and appointed by the General Meeting, whereby in this case the other members who are not founding members shall also be entitled to vote.
- (3) The rights of nomination and appointment pursuant to para. 2 above also include the right to dismiss the respective member of the Supervisory Board at any time.
- (4) The regular term of office Supervisory Board members is three years to the end of the year. By way of derogation, the term of office of Supervisory Board members who were appointed when the Association was founded is only two years to the end of the year. Re-appointment and re-election are permitted.

- (5) One member of the Supervisory Board must be a representative
1. A small or medium-sized enterprise within the meaning of EU Recommendation 2003/361 and
  2. of a legal entity under private law.
- Two Supervisory Board members must be representatives of public corporations (universities) or charitable and other non-profit organisations.

## **§ 9**

### **Tasks and internal organisation of the Supervisory Board**

- (1) The Supervisory Board monitors and advises the Executive Board and decides on the discharge of the Executive Board members.
- (2) The members of the Supervisory Board elect a Chairman and a Deputy Chairman from among their number.
- (3) The Supervisory Board generally makes its decisions by consensus. If this unanimity is not achieved, the Supervisory Board decides by resolution, which requires a simple majority of the Supervisory Board members in office to be effective.
- (4) In order to fulfil its duties, the Supervisory Board can form committees at any time, even temporarily, which can also be made up of representatives of the members of the association and external third parties.
- (5) The members of the Supervisory Board may receive remuneration and/or reimbursement of expenses, the amount of which is decided by the General Meeting.
- (6) The Supervisory Board adopts its own rules of procedure.

**§ 10**

**Tasks and internal organisation of the General Meeting**

- (1) The General Meeting is responsible for
1. Discussion of the further development of EHDA e.V,
  2. the discussion of an annual report by the Board of Directors, which must be accompanied by a statement by the Supervisory Board,
  3. the discharge of the members of the Supervisory Board,
  4. the election and dismissal of members of the Executive Board (§ 6),
  5. the election and dismissal of members of the Supervisory Board (§ 8),
  6. determining the amount of remuneration and / or reimbursement of expenses for the members of the Supervisory Board (Section 9 (5)),
  7. the amendment of the Articles of Association of the Association,
  8. the dissolution of the association.
- (2) In matters that fall within the remit of the Executive Board or the Supervisory Board, the General Meeting may adopt recommendations. For their part, the Executive Board and Supervisory Board may obtain a recommendation from the General Meeting on matters that fall within their remit.
- (3) Each member has one vote at the General Meeting and may be represented at the General Meeting by a proxy authorised in writing.
- (4) Notwithstanding para. 3, honorary members and members who are not or only partially obliged to pay membership fees in accordance with the Association's membership fee regulations or who are fully or partially in arrears with the payment of their membership fee at the time of the General Meeting are not entitled to vote. Such members are nevertheless entitled to attend and speak.

- (5) The resolutions of the General Meeting are passed by a simple majority of the members present and entitled to vote, unless these Articles of Association provide for a different quorum.
- (6) Resolutions of the General Meeting that relate to an amendment to the Articles of Association of the Association or the dissolution of the Association require a majority of  $\frac{3}{4}$  of all existing members and, from 1 January 2026, an additional half of the founding members.
- (7) The General Meeting meets at least once a year and whenever the Executive Board or the Supervisory Board decide to do so.
- (8) The General Meeting is chaired by the Chairman of the Supervisory Board, who issues invitations to the General Meeting with a notice period of at least fourteen days, starting on the day after the invitation is sent to all members. For the inaugural meeting of the association, the general meeting elects a chairman from among its members.
- (9) All questions relating to the conduct of the General Meeting, including the election procedure and the minutes, are decided by the Chairman of the General Meeting. The minutes of the General Meeting are signed by the Chairman of the General Meeting and the secretary.

## **§11**

### **Liability**

- (1) Board members or special representatives are only liable to the association for damage caused in the fulfilment of their duties in the event of intent or gross negligence. Sentence 1 of this paragraph also applies to liability towards members of the association. If it is disputed whether a member of an executive body or a special representative has caused damage intentionally or through gross negligence, the association or the member of the association shall bear the burden of proof.

- (2) If board members or special representatives are obliged to compensate another party for damage they have caused in the performance of their duties in accordance with the first sentence of paragraph 1 above, they may demand that the association release them from liability. Sentence 1 of this paragraph shall not apply if the damage was caused wilfully or through gross negligence.

## **§ 12**

### **Final provisions**

- (1) These Articles of Association were adopted at the general meeting of the association on 4 December 2024. They come into force on 4 December 2024.
- (2) In the event of the dissolution of the Association, liquidation shall be carried out by the last incumbent Board of Directors.
- (3) Any assets remaining after liquidation are divided equally between the founding members

**End of the statutes of the European Health Data Alliance e.V.**