

## **Articles of Association**

### **“National Registry for Gene and Cell Therapies Germany”**

#### **Preamble**

- (1) Gene and cell therapies represent an important and innovative growth area in the treatment of previously difficult-to-treat or, in part, incurable diseases. They are already applied in various medical fields and indications, or are in advanced stages of clinical development. The approval of new gene and cell therapy products often occurs on the basis of limited data. Therefore, the centralized, systematic, and objectively independent collection and provision of real-world data on the efficacy and long-term safety of these new treatments is an important responsibility of the community.
  - (2) To fulfill this responsibility across products, medical fields, and applications, the boards of academic societies that already implement gene and cell therapies in routine care in Germany have joined forces to establish a joint “National Registry for Gene and Cell Therapies”, which collects application data for all gene and cell therapies (excluding conventional hematopoietic stem cell transplantation without gene therapy) in Germany and makes these data available to all interested parties under regulated conditions.
  - (3) By formalizing the registry as a registered nonprofit association under German law (eingetragener Verein, e. V.), the preparatory work from the INTEGRATE-ATMP<sup>1</sup> innovation fund project and the associated academic INTEGRATE-ATMP consortium can be utilized to enable the systematic collection, provision, and analysis of gene and cell therapy application data, as also outlined in the National Strategy for Gene and Cell Therapies<sup>2</sup>.
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#### **§ 1 Name, Registered Office, and Fiscal Year**

- (1) The association bears the name **“National Registry for Gene and Cell Therapies Germany” (Nationales Gen- und Zelltherapieregister Deutschland)**. Upon registration in the Register of Associations, it shall carry the suffix “e. V.” (eingetragener Verein) in the German designation.
  - (2) The registered office of the association is Heidelberg, Germany.
  - (3) The fiscal year of the association shall correspond to the calendar year.
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<sup>1</sup> <https://integrate-atmp.de/>; last accessed on 03 February 2025.

<sup>2</sup> [https://www.bihealth.org/fileadmin/GZT/NationaleStrategie\\_GCT\\_DE.pdf](https://www.bihealth.org/fileadmin/GZT/NationaleStrategie_GCT_DE.pdf); last accessed on 03 February 202

## § 2 Purpose and Nonprofit Status

- (1) The purpose of the association is the promotion of public health and public healthcare.
  - (2) The association exclusively and directly pursues charitable purposes within the meaning of the “tax-privileged purposes” section of the German Fiscal Code (Abgabenordnung). The purposes of the association are in particular realized through:
    - the systematic collection, storage, and transparent provision of application data on the efficacy and safety of gene and cell therapies (across products and indications) to designated stakeholders (academia, science, regulatory authorities, health insurers, pharmaceutical industry, relevant professional societies and registries, patient organizations, and, where applicable, others) within a joint registry;
    - improvement of data quality in the field of gene and cell therapies through standardization of data collection and documentation in the registry;
    - promotion of automated, secure transfer of application data from local storage systems to the central core or meta-data registry while ensuring data protection;
    - promotion of knowledge transfer among research institutions, clinicians, therapists, regulatory authorities, pharmaceutical industry, and patients;
    - collaboration with national ministries, authorities, institutions, as well as international registries, research institutions, and organizations;
    - organization of expert events, symposia, and conferences on gene and cell therapies;
    - promotion of public health education and awareness of the benefits and risks of gene and cell therapies for the general public and affected patient groups;
    - development of diagnostic and therapeutic standards based on registry data and evaluation of national and international therapy recommendations in consultation with relevant professional societies;
    - support of research and development in gene and cell therapies;
    - preparation of overview projects on the application of gene and cell therapies and the economic impact of these therapies (e.g., international benchmarking);
    - support of scientific projects on gene and cell therapies across various indications (e.g., identification of class effects such as secondary malignancy risk after CAR-T cell therapy, AAV safety, etc.);
    - promotion of interoperability of data transfer with existing disease-specific or disease-group registries and definition of core datasets for transfer to the National Registry for Gene and Cell Therapies.
  - (3) The association acts selflessly; it does not primarily pursue its own economic interests.
  - (4) The association’s funds may only be used for purposes in accordance with the articles of association. Members shall not receive any benefits from the association’s funds.
  - (5) No person shall be favored by expenditures unrelated to the purposes of the association or by disproportionately high remuneration. Services of third parties shall be procured based on adequate offers at market conditions.
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### **§ 3 Membership**

- (1) Membership is open to any natural or legal person supporting the association's objectives. Members are primarily designated, elected, or appointed by stakeholders in the field of gene and cell therapies (For further details, see Section 6, paragraphs (14) and (15)).
- (2) Admission of new members is decided by the board upon written application by simple majority at its discretion. Newly admitted members shall be introduced at the next general meeting, at least once annually.
- (3) Members have the right to participate in decision-making, activities, and experience exchange in accordance with the statutes.
- (4) Each member undertakes to support the association's objectives and actively contribute to its tasks. Members must comply with resolutions and directives of the association's organs.
- (5) Members consent to public disclosure of their membership (e.g., on the association website) and may indicate their membership publicly.
- (6) Membership terminates through resignation, reelection, expulsion, loss of legal capacity, or death.
- (7) Resignation may occur at any time via written notice to the board, subject to a minimum two-month notice period before the end of the fiscal year.
- (8) Members may be expelled by board resolution for important reasons if continued membership is deemed unreasonable. Grounds include, but are not limited to, arrears in dues exceeding six months or gross violation of association interests. Members shall have the opportunity to be heard before expulsion and may appeal to the next general meeting within one month.
- (9) Members must provide the board with a valid postal and email address and notify changes promptly. All communication may occur in writing or electronically via email.

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### **§ 4 Contributions / Accountability Report**

- (1) The association may levy contributions from its members, the amount of which shall be determined by the General Assembly in a schedule of contributions.
- (2) Contributions shall be paid annually. The amount of the contribution shall be determined at the annual General Assembly.
- (3) The auditor appointed by the General Assembly, or in the event of their impediment, their deputy, shall audit the accounting records and the annual financial statements prepared by the Executive Board, report the results of the audit at the General Assembly, and provide a recommendation regarding the resolution on the discharge of the Executive Board.

- (4) The Executive Board is responsible for the proper use of the association's funds. The Board shall submit an annual budget, which shall be adopted by a simple majority vote at the annual General Assembly.
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## **§ 5 Organs of the Association**

The organs of the association are:

1. The General Assembly (§ 6)
  2. The Executive Board (§ 7)
  3. The Management (§ 9)
  4. The Scientific Advisory Board (§ 10)
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## **§ 6 General Assembly**

- (1) The General Assembly is the supreme body of the association. It shall convene at least once a year.
- (2) The General Assembly shall be convened by the Executive Board. The invitation shall be sent in writing or by email, observing a minimum notice period of two weeks. Written invitations shall be sent to the address last communicated in writing by the member; invitations by email shall be sent in text form to the email address last provided by the member in text form. The agenda shall be sent to all members prior to the General Assembly. The date of dispatch shall be decisive for the notice period. If a member requests the inclusion of an item on the agenda for resolution by the General Assembly, such request must be submitted in writing or by email to the Executive Board at least one week prior to the meeting. Any resulting change to the agenda shall be communicated to all members without delay via the Management, and at the latest at the beginning of the General Assembly. Motions concerning the election or removal of Board members, amendments to the Articles of Association, or dissolution of the association that were not announced in the timely invitation are excluded from an agenda amendment and may only be considered at the next General Assembly.
- (3) The General Assembly shall decide on all fundamental matters of the association's activities. Its tasks include, in particular:
  - Election and discharge of the members of the Executive Board;
  - Approval of the annual report and discharge of the Executive Board and the Management;
  - Adoption of rules of procedure for the Management and the association's bodies;
  - Appointment of members of the Scientific Advisory Board upon proposal of the Executive Board;
  - Determination of the membership fee;
  - Decision on the budget of the Management and the Executive Board, as well as other reports of the Executive Board;
  - Decision on the association's membership in other associations and federations;

- Amendment or adoption of new Articles of Association and any schedule of contributions;
  - Resolution on complaints against the exclusion of members;
  - Election of auditors;
  - Dissolution of the association;
  - Any other tasks delegated to the General Assembly by law or elsewhere in the Articles of Association.
- (4) All members of the association are entitled to participate in the General Assembly. A duly convened General Assembly shall be quorate if at least one-third of the voting members are present or participate in a written circulation procedure. Resolutions shall be adopted by a simple majority of the members present, unless otherwise stipulated in the Articles of Association.
  - (5) A voting member may be represented by another member holding a written proxy, whereby a member may exercise a maximum of two votes (their own and one on behalf of another member). The proxy must be presented in writing to the chairperson of the meeting no later than at the start of the General Assembly. Each proxy must be granted separately for each General Assembly. Proxy representation is not permitted for resolutions conducted via the circulation procedure.
  - (6) The General Assembly shall be chaired by the 1st Chairperson, or in their absence by the 2nd Chairperson, or alternatively by the Treasurer. Should none of these be present, the Assembly shall elect a chairperson from among its members. At the beginning of the General Assembly, a minute-taker shall be elected and any changes to the agenda shall be announced by the chairperson.
  - (7) Communications in text form pursuant to paragraphs 3–5 shall be deemed equivalent to written form within the meaning of § 126b BGB (German Civil Code).
  - (8) Minutes of the resolutions passed by the Assembly shall be prepared, signed by the chairperson and the minute-taker. The minutes must record the time, place, participants, agenda, matters resolved in the order of discussion, the full text of the resolutions, and voting results. The Management shall distribute the minutes to all members by email within four weeks of the Assembly; the minutes shall be archived.
  - (9) An extraordinary General Assembly shall be convened if 25% of the voting members of the association request it in text form, specifying a justified agenda. The requested agenda must be adopted. The procedures of the preceding paragraphs shall apply accordingly, with a minimum notice period of two weeks.
  - (10) The General Assembly may be held in person or virtually/online. Virtual meetings may be conducted via video conference or chat room, with member access restricted to authorized login credentials and a session-specific access code. The access code shall be sent via a separate email immediately before the meeting, at most three hours prior. Members shall not share access credentials with non-members. Resolutions may also be adopted via a written circulation procedure. For such procedure, the Executive Board shall set a deadline for members to submit their votes in text form. A resolution is valid if at least half of the voting members cast their vote within the deadline. Invalid votes are considered cast and counted as abstentions. The result of the circulation procedure shall

be communicated to members within 14 days after the deadline. Invalid circulation procedures may be repeated, if necessary, multiple times.

- (11) All votes and elections, including those conducted in virtual meetings, must comply with the five fundamental principles of elections: free, equal, secret, universal, and direct.
- (12) The General Assembly elects an auditor and a deputy auditor for each financial year, who shall neither be members of the Executive Board nor employees of the association. Re-election is permissible.
- (13) The association may adopt rules of procedure governing procedural details of the General Assembly.
- (14) The General Assembly consists of members with and without voting rights.

**Members with voting rights include:**

- a. Representatives of professional societies applying products in the field of gene and cell therapies. Each society may appoint up to three representatives. If cases from the society's specialty account for more than 50% of all registrations in the National Gene and Cell Therapy Registry, two additional voting members may be appointed. The society determines the election and rotation of its representatives. Rotation is generally envisaged every two years.
- b. Representatives of independent academic disease-specific or method-specific registries related to commercial gene and cell therapies, affiliated with the joint registry. One voting representative per registry. Election and rotation determined by the registry itself. Registries should preferably be organized as registered associations but this is not mandatory.
- c. One patient representative per therapeutic field, admitted upon direct written request or proposal by the respective medical society.

**Members without voting rights include:**

- a. Trade associations of pharmaceutical companies (e.g., vfa (Verband Forschender Arzneimittelhersteller), BPI (Bundesverband der Pharmazeutischen Industrie e. V.), Pharma Deutschland e. V.), each may appoint up to two representatives on written request.
- b. Representatives of outpatient physicians organized as registered associations. One per therapeutic field per association.
- c. Representatives of scientific study groups in gene and cell therapies. One representative per active clinical study group.
- d. Two representatives each from the National Association of Statutory Health Insurance Funds and the Association of Private Health Insurance.
- e. Up to two representatives from the Technology and Methods Platform (TMF e. V.) and the Research Data Portal for Health (FDPG, Forschungsdatenportal Gesundheit).
- f. Two representatives each from German regulatory authorities and specialized ethics committees (PEI and BfArM).
- g. Other specialized representatives in gene and cell therapies affecting the national registry, upon written request.

## § 7 Executive Board

- (1) The Executive Board consists of:
  - a) the 1st Chairperson;
  - b) the 2nd Chairperson;
  - c) the Treasurer;
  - d) up to a maximum of 12 further board members.

The board members listed above under a–c constitute the Executive Board within the meaning of Section 26 of the German Civil Code (BGB). Two board members acting jointly are authorized to represent the association. By resolution of the General Assembly, board members may be exempted from the restrictions of Section 181 of the German Civil Code (BGB).

- (2) The composition of the Executive Board shall be as follows:
  - Two representatives per professional society applying products in the field of gene and cell therapies. If cases from a society’s specialty account for more than 50% of all registrations in the National Gene and Cell Therapy Registry, an additional board member may be appointed. Should the total number of board members exceed 15 due to newly admitted societies, the number of representatives shall be reduced to one per society in the subsequent General Assembly.
  - Two representatives of the INTEGRATE-ATMP consortium leadership for a total of six years after the association’s founding, to ensure smooth transfer of project outcomes to the association. The term ends automatically unless the General Assembly decides otherwise in the interim.
  - One representative of the Berlin Institute of Health (BIH) for three years after the association’s founding, to ensure coordination with the National Strategy for Gene and Cell Therapies. The term ends automatically unless otherwise resolved by the General Assembly.
  - Two representatives of the German Society for Gene Therapy e. V. (DG-GT), representing basic science and translational research in gene and cell therapies. Should the total number of board members exceed 15 due to new societies, the number of representatives shall be reduced to one per society in the subsequent General Assembly.
- (3) Only voting members of the association are eligible for election to the Executive Board.
- (4) The Executive Board shall manage the association’s affairs and represent the association in and out of court. Its duties include, in particular:
  - a) Preparing and convening the General Assembly; setting the agenda;
  - b) Executing resolutions of the General Assembly;

- c) Maintaining the accounting records;
  - d) Preparing the budget, annual financial statements, and annual report, and may engage qualified third parties for these tasks;
  - e) Entering into and terminating employment or service contracts;
  - f) Exercising the right of instruction over employees;
  - g) Deciding on the admission and exclusion of members;
  - h) Adopting amendments to the Articles of Association required by the registry or tax authorities.
- (5) Members of the Executive Board shall be elected by the General Assembly for a term of three years. A single re-election is permitted. Board members shall be elected for each office in a separate voting procedure. Incumbent board members remain in office until their successors are elected.
- (6) The Executive Board may appoint experts and working groups to advise it in fulfilling the association's objectives. The Board shall also elect, by simple majority, an external scientific advisory body for the National Gene and Cell Therapy Registry (see § 9).
- (7) Members of the Executive Board shall serve on a voluntary basis. Board members shall be reimbursed for reasonable expenses incurred in the course of association activities. The Board may delegate portions of its responsibilities to the Management; details may be regulated in separate rules of procedure.
- (8) Executive Board members shall be liable to the association only for willful misconduct or gross negligence. Should a board member be held liable by a third party in connection with their board activities, the association shall indemnify the board member, provided the member did not act willfully or with gross negligence.
- (9) Further duties of the Executive Board arise from the association's Data Access and Data Use Charter.

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## **§ 8 Meetings and Resolutions of the Executive Board**

- (1) Executive Board meetings shall be convened by the Chairperson as needed, but at least twice per year.
- (2) Invitations shall be sent in writing or by email at least one week in advance by the 1st Chairperson, or alternatively by the 2nd Chairperson. The notice period may be shortened with the consent of all board members, which is deemed granted upon attendance at the meeting. Meetings may also be held remotely or electronically (e.g., via videoconference).

- (3) The Executive Board shall be quorate if at least three board members are present. Resolutions are adopted by simple majority of votes cast. In the event of a tie, the vote of the Chairperson, or alternatively the 2nd Chairperson, or further alternatively the Treasurer, shall decide.
- (4) Resolutions may also be passed in writing or by email (circulation procedure) if all board members consent to this procedure. Casting a vote in the circulation procedure shall be deemed approval.
- (5) All Executive Board resolutions, including those passed via circulation, shall be recorded in minutes and preserved.

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## **§ 9 Management**

- (1) The Management shall assist the Executive Board in fulfilling its tasks. The Management is responsible for personnel and financial administration of the registry and reports regularly to the Executive Board and the General Assembly.
- (2) The Management shall be appointed by the Executive Board with a two-thirds majority, following prior advertisement if necessary. Proposals may be submitted by the General Assembly. The Manager should possess experience in the application of gene and cell therapies and in establishing and operating medical registry systems. They shall be provided with an employment contract and appropriate remuneration.
- (3) The Manager shall participate in regular Executive Board and General Assembly meetings and may submit proposals for strategic development.
- (4) Tasks of the Management are regulated in the Rules of Procedure for the Management.

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## **§ 10 Scientific Advisory Board**

- (1) The association shall establish an external Scientific Advisory Board to advise the organs of the association on substantive matters. The Board may also be called upon to resolve internal disputes.
  - (2) The Advisory Board shall consist of up to 10 external experts.
  - (3) Members of the Advisory Board shall be appointed by the General Assembly upon proposal of the Executive Board for a term of three years. Reappointment is permitted. The Advisory Board shall elect a Chairperson.
  - (4) The Scientific Advisory Board shall assess and advise on the association's strategic and scientific activities and support the long-term advancement of its work.
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## **§ 11 Public Statements of the Association**

- (1) Public statements and communications of the association shall be made by the Executive Board.
  - (2) Decisions pursuant to paragraph 1 shall be adopted by simple majority. In the circulation procedure, voting shall occur by email; non-response shall be deemed abstention.
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## **§ 12 Scientific Publications**

- (1) Members shall ensure that authorship of scientific publications using data or biospecimens from association members complies with DFG Guidelines on Good Scientific Practice. Details regarding authorship order shall be regulated in the Data Access and Data Use Charter.
  - (2) The “National Registry for Gene and Cell Therapies” must be explicitly cited in all publications using registry data.
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## **§ 13 Dispute Resolution**

- (1) Disagreements between the association, its organs, and members shall be resolved amicably through mediation. The Scientific Advisory Board shall act as the mediation body.
  - (2) The mediation procedure shall follow the rules of the German Society for Law and Informatics e. V. (DGRI), substituting a medical mediator for the technical mediator.
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## **§ 14 Amendments to the Articles of Association**

- (1) Amendments to the Articles of Association may only be adopted by the General Assembly unless required by the registry or tax authorities. In the latter case, the Executive Board may also adopt the amendment to the articles of association (cf. Section 7, paragraph (4), letter h)
  - (2) A resolution to amend the Articles of Association requires a two-thirds majority of members present.
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## **§ 15 Dissolution of the Association**

- (1) The association may only be dissolved by a General Assembly convened for this purpose.
  - (2) A resolution to dissolve the association requires a three-quarters majority of members present.
  - (3) Upon dissolution or termination of the association, or upon loss of tax-privileged status, the assets of the association shall be transferred to a public law entity or another tax-privileged corporation for the promotion of public health.
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## **§ 16 Final Provisions**

- (1) Should individual provisions of these Articles of Association be invalid or become invalid, the validity of the remaining provisions shall remain unaffected.
- (2) The founding professional societies agree that an interim Executive Board shall be appointed for the prompt establishment of the association. The interim Board shall hold all rights and duties set out in § 8. The interim Board and its deputy shall be elected at the founding assembly by a simple majority of the participating society representatives. They shall represent the association legally, effect the registration with the registry, and convene the constituent General Assembly of all § 6 members, which shall then elect the permanent Executive Board, its deputies, and auditors in accordance with §§ 7 and 8.
- (3) These Articles of Association shall enter into force upon the appointment of the interim Board and the holding of the founding assembly. They shall be registered with the association registry immediately thereafter. This shall also apply to amendments.
- (4) Should modifications or supplements be required for registration or tax recognition, the interim Board is authorized to make such changes, which must be approved at the next General Assembly.
- (5) Should any provision of these Articles be invalid or become invalid, a provision closest to the intended purpose shall apply.

Articles of Association Version 2: Founding Assembly 30.06.2025, following amendments by the Executive Board meeting on 17.09.2025.

**Note:** This document is a translation of the original German version of the Statutes of the Association. In case of any discrepancies between the German and English versions, the German version shall prevail.