

Constitution of the RD-Connect Community

Document History

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Preamble

RD-Connect was established in November 2012 through a grant from the European Commission under the seventh framework programme (FP7), Grant Agreement number 305444. The consortium involved 30

partner organizations from Europe, the United States and Australia and 25 associated partners. The consortium was coordinated by Newcastle University, UK (2012-2017) and the Centro Nacional de Análisis Genómico, Centre for Genomic Regulation (CNAG-CRG), Spain (2018) and brought together over 100 experts. This multidisciplinary group included clinical academics, geneticists, bioinformaticians, ethicists and patient representatives to develop mechanisms to solve the problem of siloing and under-use of data in rare diseases, in particular clinical, phenotypic and omics data from individuals with rare diseases. This was tackled by developing an integrated platform of tools and resources developed to improve data analysis, sharing and linkage.

Within the European rare disease community, RD-Connect has been highlighted as a successful infrastructure that is facilitating and accelerating research and diagnosis. This has been demonstrated through the number of RD-Connect tools and resources being given IRDiRC Recognized Resources label:

- The RD-Connect Genome Phenome Analysis Platform
- The FAIR Guiding Principles document for scientific data management and stewardship
- International Charter of Principles for sharing Bio-Specimens and Data
- Guidelines for the informed consent process in international Rare Disease Research

The European Commission under FP7 funded RD-Connect for six years from November 2012 until October 2018. The RD-Connect consortium made the decision in May 2017 to continue the RD-Connect brand and community as well as to seek funding to support the individual assets.

Funding for individual assets is being obtained on an ongoing basis. To continue the RD-Connect mission and vision more broadly and keep the community together under a unified strategy, the founders of RD-Connect now develop this RD-Connect Constitution to create an open, inclusive community for all interested parties. This will provide a means to maintain and further develop the RD-Connect infrastructure both within and outside Europe, cement its position as a global resource for rare disease research and data sharing, and maintain the RD-Connect Community as a whole in a spirit of openness and collaboration.

A list of funding sources for individual RD-Connect assets and for the community as a whole is maintained at www.rd-connect.eu/funding.

Article I Mission

1.1 The mission of the RD-Connect Community is to promote, facilitate and accelerate rare disease research by maximizing the availability and (re)use of rare disease data and biosamples through provision of infrastructure, tools and services to share, analyse and link datasets and biosamples in a secure and regulated way.

Article II Vision

2.1 The vision of the RD-Connect Community is to build an open community that works to improve rare disease research, offering rare disease researchers and patients a recognized, authoritative, sustained and continuously developed reference resource for accessing, analysing and exchanging data and biosamples and sharing expertise.

Article III Organization and Affiliation

- 3.1 This organization is known as the RD-Connect Community. It is a community of individuals committed to collaborating on a platform of tools and resources to facilitate data sharing, analysis and reuse in rare disease research.
- 3.2 The RD-Connect Community is organized as an independent, non-governmental, not-for-profit, international association of interested parties who work together to support rare disease research and data sharing. It is not controlled by any individual healthcare provider, research institution, research funder, disease advocacy organization, company, or other single entity. It is initially established as an unincorporated association among entities interested in pursuing RD-Connect's goals.
- 3.3 The views of RD-Connect Community members do not necessarily represent the views of the institutions and organizations with which members are affiliated.
- 3.4 The RD-Connect Community may hereafter be referred to as "the Community" or "RD-Connect"

Article IV Guiding Principles

- 4.1 RD-Connect is founded on the following principles:
 - 4.1.1 **Collaboration:** a full and unreserved commitment to working together to improve human health and advance research into rare diseases.
 - 4.1.2 **Patient benefit:** a commitment that all activities will serve the ultimate goal of making a difference to patients with rare diseases, as outlined in the IRDiRC Vision.
 - 4.1.3 **Multidisciplinarity:** a recognition of the need to work across academic fields to achieve progress in rare disease research and an acknowledgement of the value of contributions from all stakeholders.
 - 4.1.4 **Freedom of scientific enquiry:** the encouragement of openness of datasets, biosamples, and software to reuse without competition or protectionism, to enable scientific enquiry that exploits the full potential of the resources to bring benefit to patients and science as rapidly as possible.
 - 4.1.5 **Reciprocity:** giving back. A commitment that feedback of results will be channelled to institutions and patients.
 - 4.1.6 **Respect for privacy and autonomy:** an acknowledgement that rare disease patient datasets may contain personal information and that best practice in security, stewardship and consenting will be used at all times to protect participants' privacy.
 - 4.1.7 **Recognition and attribution:** an understanding that rare disease datasets and samples are precious resources that have been freely and altruistically donated by patients and that the intellectual investment of investigators involved in the creation of datasets that are reused by others is substantial, and that both patients and originating investigators therefore deserve due acknowledgement.

Article V Activities

- 5.1 The core activities of RD-Connect are as follows:

- 5.1.1 Sustaining a **multidisciplinary community** promoting and enhancing rare disease research and data sharing
- 5.1.2 Providing tools and services for **analysis and stewardship of rare disease data**, in particular omics data, clinical and phenotypic data, through the **Genome Phenome Analysis Platform** and associated tools
- 5.1.3 Involving **patients** and working closely with the **patient organizations** to ensure that data sharing in the rare disease community leads to progress for patient benefit
- 5.1.4 Supporting discovery of and access to quality rare disease biosamples through the **RD-Connect Sample Catalogue**
- 5.1.5 Supporting the discovery of information about rare disease biobanks and registries through the **RD-Connect Registry & Biobank Finder**
- 5.1.6 Educating the rare disease field on key issues in the field through **international meetings and conferences**.
- 5.1.7 Working on activities in support of the **IRDiRC 2017-2027 Vision** of enabling all people living with a rare disease to receive an accurate diagnosis, care, and available therapy within one year of coming to medical attention.
- 5.1.8 Creating educational materials and undertaking **training and educational activities** to teach the rare disease community about data analysis and stewardship
- 5.1.9 Developing and promoting **best practice standards** and policies for rare disease data sharing, data stewardship and data analysis
- 5.1.10 Developing and contributing to an **ethical, legal and societal framework** for the rare disease field.

Article VI Membership

- 6.1 Membership of the RD-Connect Community is open to individuals, academic research groups and organizations active in the field of rare disease research and is subject to approval by the Executive Committee.
- 6.2 Membership of the RD-Connect Community may be assigned on an individual, research group or organizational basis. To apply for membership, a completed membership application should be submitted to the administrative office of the Chair of RD-Connect. Membership applications will be approved by the Executive Committee.
- 6.3 By signing the Membership Agreement, members of the RD-Connect Community commit themselves to adhering to and promoting the Mission, Vision and Guiding Principles of RD-Connect as defined in the Constitution.
- 6.4 On approval of membership by the Executive Committee, members will receive an electronic membership certificate. Members will be listed on the RD-Connect website if requested (www.rd-connect.eu). Organizational members may be requested to provide their logo for the RD-Connect website. Individual members may be requested to provide a photo and biographical details if they would like these to be displayed publicly.

- 6.5 Members who wish to terminate their membership should contact the Chair of the Executive Committee in writing. Membership will cease after 30 days from receipt of the termination request and the member's information will be removed from the web site within this period.
- 6.6 Members commit themselves to a collaborative approach to other members, including timely and open sharing of information about research projects, funding opportunities and other opportunities that might support the aims of the RD-Connect Community. All members are expected to contribute to the sustainability of the consortium.
- 6.7 Members will have the opportunity to nominate or be nominated to sit on the executive committee described in Article VIII.
- 6.8 Voting: The membership will vote on new appointments to the executive committee and other areas of importance to RD-Connect specified by the executive committee. Each individual member of the Community has one vote including when representing a research group or institution. Where not otherwise stated, decisions must be passed by a two-thirds majority of a quorate meeting. Where a decision is required during the period between annual meetings, this may be taken virtually, at the discretion of the Chair, with the same quorum and majority requirements.
- 6.9 Quorum: a vote can only be considered if at least two thirds of the membership participate (in person or virtually).
- 6.10 Members will have access to reports, including financial reports, newsletters, work plans and updates on activities.
- 6.11 Members must not, whether knowingly or negligently, act in a way which could bring the RD-Connect Community into disrepute, lead to a possible loss of public confidence, or damage the interests of the Community.
- 6.12 If a member is found to be acting contrary to the Mission, Vision or Guiding Principles or to have otherwise taken actions that have brought, or could possibly bring, the RD-Connect Community into disrepute, the member will be contacted by the Chair of the Executive Committee in writing to request an explanation of the reasons for their actions and how this can be resolved. The member will be given a period of 30 days to resolve the issue(s) or explain why they feel they have not contravened the obligations. If the member does not comply or the explanation is deemed unsatisfactory then they will be asked to remove the RD-Connect logo and any other association from any publishable materials, i.e., websites, newsletters, etc. and their membership will be terminated forthwith following a two thirds vote of the Executive Committee.
- 6.13 Members will not claim to be a member of RD-Connect without first having received confirmation of their membership.
- 6.14 Members must comply with all relevant known national and international data protection, privacy and ethical laws and guidelines.

Article VII Membership Meetings

- 7.1 All members will be invited to periodic membership meetings. It is aimed to hold membership meetings annually, subject to availability of funds and administrative support and at the discretion of the Executive Committee. Any costs of attendance at membership meetings are not reimbursed by RD-Connect.

- 7.2 The date of the membership meeting will be set by the Executive Committee, who will also set the time and the place. This will be announced at least six months in advance.
- 7.3 Special meetings: Special meetings (either in person or virtual) may be called by the Executive Committee.
- 7.4 Notice: Notice of meeting agendas and supporting documents for each meeting will be given to each member, by (electronic) mail, not less than seven (7) days before the meeting.

Article VIII Executive Committee

- 8.1 The Executive Committee is responsible for providing overall policy and strategic direction to the RD-Connect Community, oversees activities and progress, and delegates responsibility for day-to-day operations to the appropriate Members. The Executive Committee will have no more than 15 and not fewer than 8 members. The Executive Committee receives no compensation. Members of the Executive Committee are elected as private individuals and not as representatives of their home institution or organization.
- 8.2 The Executive Committee will always include at least one representative of EURORDIS, one additional patient representative, one representative from the host institution of the RD-Connect Genome Phenome Analysis Platform, the Sample Catalogue and the Registry & Biobank Finder. The remaining members of the committee should be elected from interested parties.
- 8.3 EURORDIS are responsible for appointing an appropriate patient representative, and be responsible for providing appropriate support and training if required.
- 8.4 All Executive Committee members will serve 2-year terms, but are eligible for re-election, with at least three Executive Committee positions up for rotation every 2 years.
- 8.5 Election of new Executive Committee members or election of current Executive Committee members to a second term will occur as the first item of business at the annual meeting.
- 8.6 Meeting: the Executive Committee will meet at least annually and ideally monthly, either in person or virtually, at an agreed upon time and place. An option to join remotely should be in place whenever possible.
- 8.7 Quorum: a meeting must be attended by at least two thirds of the Executive Committee members before business can be transacted or motions made or passed.
- 8.8 Voting: each member of the Executive Committee has one vote. Where not otherwise stated, decisions of the Executive Committee must be passed by a two-thirds majority of a quorate meeting. Where a decision is required during the period between annual meetings, this may be taken virtually, at the discretion of the Chair, with the same quorum and majority requirements.
- 8.9 An Executive Committee meeting requires that each Executive Committee member have written notice of the agenda at least seven (7) days in advance.
- 8.10 There will be three officers of the Executive Committee consisting of a Chair, Chair-Elect and Past Chair working as part of Troika. All posts will be held for two years. Their duties are as follows:

8.10.1 The Chair will convene regularly scheduled Executive Committee meetings, will preside or arrange for the Vice-Chair or other members of the Executive Committee to preside at each meeting. The Chair will serve a 2-year term of office.

8.10.2 The Chair-Elect will assume the role of Chair following a 2-year term of office, and will chair subcommittees on special subjects as designated by the Executive Committee.

8.10.3 After 2 years in office the Chair will become the Past Chair. The Past Chair will support the new chair and ensure continuity of knowledge and process.

8.11 When a vacancy on the Executive Committee exists, nominations for new members may be received by the Chair's Office two weeks in advance of an Executive Committee meeting. These nominations will be sent out to the members to be voted upon and results announced at the next Executive Committee meeting. These vacancies will be filled only to the end of the particular Executive Committee member's term.

8.12 Resignation from the Executive Committee must be in writing and received by the Administrative Office. An Executive Committee member will be removed from the Executive Committee if s/he has excess absences from regular Executive Committee meetings following a three-quarter vote of the remaining Executive Committee members following an appeal. An Executive Committee member may be removed for other reasons by a three-quarter vote of the remaining Executive Committee members following an appeal. All appeals must be submitted to the Chair of the Executive Committee on request.

8.13

Article IX Subcommittees and Advisory Boards

9.1 The Executive Committee may create subcommittees and advisory boards as needed, such as fundraising, conference, etc. These may be standing bodies or bodies convened for a specific, time-limited purpose. A list of subcommittees and the corresponding members will be available on the RD-Connect website.

9.2 The Executive Committee Chair appoints all subcommittee and advisory board chairs upon agreement by the Executive Committee. All subcommittees and advisory boards will report to the Executive Committee.

9.3 Advisory Boards will be required to report and provide recommendations to the Executive Committee based on the remit of the advisory board as defined by the Executive Committee.

9.4 Bodies formally constituted by the Executive Committee and their membership are listed on the RD-Connect website.

Article X Assets, branding, trademark and licensing

10.1 The RD-Connect name and logo ("RD-Connect brand") is trademarked. The trademark is held by CNAG-CRG in good faith on behalf of the RD-Connect Community of members.

10.2 The RD-Connect brand may be used to designate tools and resources ("assets") developed by RD-Connect members for the benefit of the rare disease community and in line with the Founding Principles of RD-Connect. Use of the brand is subject to approval by the Executive Committee. RD-

Connect assets developed within the period of the original EU funding may continue to use the RD-Connect brand for as long as they continue to meet the Founding Principles.

- 10.3 In general it is expected that RD-Connect assets will be made available to the community under an appropriate open source license. Licensing conditions for any asset bearing the RD-Connect brand will be evaluated by the Executive Committee.

Article XI Administrative Office to the Executive Committee

- 11.1 The Administrative Office to the Executive Committee will be provided by CNAG-CRG until such a time when this role is transferred to another member organization who can take over the administrative and financial responsibility for this role and whose role is agreed by a two-thirds vote of the Executive Committee.
- 11.2 The Administrative Office will provide the Chair of the Executive Committee with administrative support to ensure efficient communication between the Chair, other members of the Executive Committee, the membership and the Administrative Office.
- 11.3 The Administrative Office will provide an ongoing support role to the Executive Committee and members, including administrative support, communications support (website, newsletter), and project management support where required and dependent on sufficient funding available to support these roles.
- 11.4 The Administrative Office is responsible for supporting the activities of the Executive Committee, coordinating the implementation of the strategic priorities, fiscal procedures, supporting the development of donations/fundraising and grant plans and providing annual activity and financial reports to RD-Connect Community members. The Executive Committee must approve the annual reports.
- 11.5 The Administrative Office will provide all supporting documentation and information to the Executive Committee at their regular meetings.
- 11.6 The Administrative Office will be responsible for keeping records of Executive Committee actions, including overseeing the taking of minutes at all Executive Committee meetings, sending out meeting announcements, distributing copies of minutes and the agenda to the Executive Committee and members, and assuring that records are maintained. The Administrative Office will also provide an annual report to the Executive Committee describing the activities and financial status of the Administrative Office.
- 11.7 The fiscal year will be the calendar year (1st January – 31st December). Annual reports will be submitted and reported to the Executive Committee showing income, expenditures, justifications, and pending income. The financial records of RD-Connect are public information and will be made available to the membership, Executive Committee members and the public.
- 11.8 The Administrative Office will also be responsible for planning and delivering all meetings (virtual and in person) of the Executive Committee, as well as any other meetings deemed necessary by the Executive Committee.

Article XII Publication Policy

- 12.1 All publications involving work by members that was supported by RD-Connect, or data that was accessed through RD-Connect should follow the RD-Connect publication policy (June 2018). Members are encouraged to use open-access options for publication whenever possible.

Article XIII Conflict of Interest

- 13.1 RD-Connect wishes to promote independence, objectivity and a fair balance of representation in all its activities. Members of the Executive Committee, and of advisory boards and subcommittees (where applicable), are expected to disclose their financial or in-kind relationships with their organizations, industry and any other organization that could represent a potential Conflict of Interest. Full disclosure is expected even when it is not clear whether a relationship or affiliation constitutes a conflicting interest.
- 13.2 RD-Connect recognizes that these relationships do not necessarily imply bias or decrease the value of participation in professional activities.
- 13.3 Disclosure of these relationships is necessary for others to make an informed decision about the impact of the disclosed relationship. All relationships over the previous two calendar years and the current year (including future commitments which are foreseen over the coming year) must be disclosed. Executive Committee members and subcommittee members are required to renew their disclosures on an annual basis.
- 13.4 Members of the RD-Connect Community should maintain the highest personal and professional standards in conducting activities. Members have an obligation to act in the public interest and in the interests of the Community, and should be willing to educate the scientific and lay communities.

Article XIV Date of Activation of Constitution and Interim Officers

- 14.1 When approved by at least two-thirds of the votes cast by the Executive Committee, this Constitution will become active and adopted at the time of the business meeting.

Article XV Amendment of Constitution

- 15.1 This Constitution may be amended when necessary by a two-thirds majority of the Executive Committee. Proposed amendments must be submitted to the Administrative Office to be sent out with regular Executive Committee announcements

Article XVI Dissolution of RD-Connect

- 16.1 The dissolution of RD-Connect will be decided by an affirmative vote by written ballot of three-fourths (3/4) of votes of the members of the RD-Connect. The procedure on dissolution will follow that outlined for proposing amendments in Article VI.
- 16.2 If RD-Connect is wound up, all of its assets which would otherwise be available to its members generally shall be transferred on its winding up either to another body with objects similar to that of RD-Connect or to another body the objects of which are the promotion of charity and anything incidental or conducive thereto (whether or not the body is a member of RD-Connect).

This Constitution was approved following a meeting and vote of the Executive Management Committee of RD-Connect as constituted under the original FP7 consortium on 12 June 2018.