

MODEL AWARD AGREEMENT

with the legal entities selected in the context of the Clinical Trials Call issued by Fondazione Telethon for the implementation of Work Package 4 of the Grant Agreement awarded by HaDEA following the call for proposals no. HORIZON-HLTH-2023-DISEASE-07-01

Not Binding

TABLE OF CONTENTS

RECITALS	3
Article 1 (<i>Subject Matter, value of the Recitals and Annexes</i>)	4
Article 2 (<i>Definitions</i>)	5
Article 3 (<i>Duration</i>)	8
Article 4 (<i>Funding Scheme - Lump Sum</i>)	8
Article 5 (<i>Milestones and Associated Contribution Tranches</i>)	9
Article 6 (<i>Indicative Project Budget</i>)	10
Article 7 (<i>Eligibility criteria and research modalities</i>)	11
Article 8 (<i>Project Management, Project Documentation and Payments</i>)	12
Article 9 (<i>Relationship with the Partners' consortia</i>)	13
Article 10 (<i>Role and Obligations of the Sponsor</i>)	14
Article 11 (<i>Coordinating Investigator</i>)	15
Article 12 (<i>Platform management and Communications</i>)	15
Article 13 (<i>Publications and Data Sharing</i>)	16
Article 14 (<i>Documents Required to Activate the Project</i>)	16
Article 15 (<i>Content of the Partnership Agreement and related declarations</i>)	16
Article 16 (<i>Termination or revocation of the Award Agreement and of the Contribution –Liability of the Beneficiary</i>)	17
Article 17 (<i>Monitoring and Valorisation of Research Results</i>)	18
Article 18 (<i>Checks and audits</i>)	19
Article 19 (<i>Privacy</i>)	19
Article 20 (<i>Confidentiality and classified information</i>)	20
Article 21 (<i>Conflict of interests</i>)	21
Article 22 (<i>Applicable Law and Dispute Settlements</i>)	22
Article 23 (<i>Final provisions and Annexes</i>)	22

AWARD AGREEMENT

between

FONDAZIONE TELETHON ETS (tax and VAT code no. 04879781005), with registered office in Rome (Italy), Via Varese 16/B (postal code no. 00185), registered in the Italian Register for the Entities of the Third Sector on the 1st April 2022, rep. no. 1217, represented by Mr./Ms. [...], born in [...], on [...], in his capacity of special attorney appointed on [...] by means of [...], acting as member of the ERDERA Partnership appointed as responsible of the implementation of the grant agreement awarded by HaDEA in the context of the call for proposals no. HORIZON-HLTH-2023-DISEASE-07-01;

(hereinafter even referred to as «**Fondazione Telethon**», «**FTELE**» or «**Granting Authority**»)

and

[...] (tax and VAT code no. [...]), with registered office in [...] (postal code no. [...]) at [...] no. [...], registered with the Companies Register of [...] at no. [...], represented by Mr. [...], born in [...], on [...], in his capacity of special attorney appointed on [...] by means of [...], in its quality of leader of the consortium of legal entities formed by [...], [...], [...] and [...];

(hereinafter referred as «[...]», «**Beneficiary**», «**Consortium**» or, with specific reference to the legal entity signing this agreement as leader of the Consortium, «**Sponsor**» or «**Lead Beneficiary**»),

(Fondazione Telethon and the Beneficiary are hereinafter referred to collectively as «**Parties**» or individually as «**Party**»)

RECITALS

- A)** On the 12th January 2023, the European Commission, supported by the European Health and Digital Executive Agency (hereinafter also referred to as «**HaDEA**»), has issued the call for proposal (hereinafter also referred to as «**Main Call**») no. HORIZON-HLTH-2023-DISEASE-07-01, aimed at awarding a grant for supporting initiatives direct to foster research in the area of rare diseases and to strengthen the healthcare system's capacity to cure such illness statuses;
- B)** The Main Call has been awarded to the European Rare Diseases Research Alliance (hereinafter also «**ERDERA Partnership**» or simply «**ERDERA**»), a European partnership bringing together more than 170 public and private organisations in 37 countries around a single objective, it being to translate cutting-edge science into tangible benefits for the thirty million Europeans affected by a rare disease;
- C)** Following the award of the Main Call, HaDEA and the ERDERA Partnership signed a grant agreement by means of which the same ERDERA Partnership has been appointed as beneficiary of the grant (hereinafter also «**Grant Agreement**»);
- D)** Furthermore, the entities forming the ERDERA Partnership stipulated a consortium agreement in order to regulate their reciprocal obligations in the context of the activities direct to the implementation of the Grant Agreement (hereinafter also referred to as «**ERDERA Consortium Agreement**» or simply «**ERDERA CA**»);
- E)** As entity included in the ERDERA Partnership and therefore recipient of the funds issued under the Grant Agreement, FTELE contributes to the achievement of ERDERA's objectives by implementing the "Work Package 4" (hereinafter also referred to as «**WP4**»), according to the provisions of Annex I, Part "A", of the same Grant Agreement;

Version of 18 September 2026

- F) In the context of the aforementioned WP4, FTELE is identified as the entity responsible for managing clinical trial call (hereinafter «**Clinical Trial Call**») and implementing a mechanism of financial support to the third parties which have presented the best proposals in the context of the aforementioned Clinical Trial Call («**Financial Support to Third Parties**» or «**FSTP**»), according to the provision of the Grant Agreement;
- G) In particular, FTELE is responsible for implementing the cascade funding activities set out under WP4, including, the operational management of funding, technical-scientific monitoring of funded projects, and disbursement of contributions in accordance with the procedures established in the Grant Agreement and in this award agreement (hereinafter also referred to as «**Award Agreement**»);
- H) Research projects funded under this Award Agreement are therefore carried out within the framework of ERDERA and shall be implemented in compliance with:
- (i) the provisions of the Grant Agreement concluded with HaDEA, due to the powers delegated to it by the European Commission;
 - (ii) the applicable Horizon Europe rules;
 - (iii) the provisions of this Award Agreement, which govern the management, monitoring, and disbursement of fundings;
- I) According to article 6.2, paragraph D (“*Other cost categories*”), no. 1.3, of the template of annotated grant agreement included in the Main Call documentation (hereinafter «**Annotated Grant Agreement**» or «**AGA**»), «*Unless otherwise specified in the Grant Agreement, the financial support provided by the beneficiaries may take any form (e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities); for the purposes of the EU grant, these remain however actual costs*»;
- J) Based on the aforementioned provision of the AGA and according to the confirmation letter received by the Project Officer of the European Commission on [...], the Clinical Trial Call issued by FTELE for the implementation of WP4 shall be subject to a “lump sum” funding scheme, according to the provisions of this Award Agreement and without prejudice for the rules on budget management, reporting and monitoring contained in the Grant Agreement;
- K) On [...], FTELE has issued the Clinical Trial Call no. [...], having as object «[...]», by means of Clinical Trial Notice published on [...] through the Smart Simple Platform managed by FTELE and through [...];
- L) The Clinical Trial has been awarded to the Beneficiary whose proposal was selected through the evaluation process as the highest-ranked proposal submitted under the same Clinical Trial Call;
- M) Given the result of the Clinical Trial Call, by means of this Award Agreement, the Parties intend to regulate their reciprocal obligations with reference to the implementation of the subject of the Clinical Trial awarded by FTELE in the context of WP4.

Based on the above, by means of this Award Agreement, the Parties, as represented and domiciled above, agree as follows:

Article 1

(Subject Matter, value of the Recitals and Annexes)

1. This Award Agreement sets out the terms under which FTELE awards a non-repayable lump-sum financial contribution to beneficiaries selected through the FSTP mechanism of ERDERA – Project No. 101156595, funded under the Horizon Europe programme under call HORIZON-HLTH-2023-DISEASE-07, and defines the rights and obligations of the parties regarding the implementation of the approved research project.

2. The Recitals, the documents cited thereto and the Annexes referred to in article 19 constitute integral and substantial part of this Award Agreement.

Article 2

(Definitions)

1. For the purposes of this Award Agreement and the related Grant Agreement, the terms listed below shall have the meanings ascribed to them herein:
 - a) «**Annotated Grant Agreement**» or «**AGA**»: the template of the Grant Agreement, included in the documentation of the Main Call, containing notes and indications on the rules applicable to the same Main Call and to the phase of execution of the Grant Agreement;
 - b) «**Award Agreement**»: this funding agreement, to be concluded between FTELE and the Beneficiary, including all its annexes, and any subsequent formally approved amendments, supplements or appendices;
 - c) «**Beneficiary**» or «**Consortium**»: the legal entity, whether acting individually or as part of a partnership, selected by FTELE under the Financial Support to Third Parties mechanism, Party to this Award Agreement and responsible for implementing the funded project;
 - d) «**Budget**»: the overall estimate of the resources required to implement the Project, broken down by eligible cost categories for evaluation, descriptive and project consistency purposes only, with no relevance for financial reporting;
 - e) «**Clinical Trial**» or «**Interventional Clinical Trial**»: a clinical study that fulfils the definition of a clinical trial under Regulation (EU) No. 536/2014 and in which participants are prospectively assigned to receive one or more investigational medicinal products in order to evaluate their safety, efficacy, pharmacokinetics, pharmacodynamics, or other health-related outcomes;
 - f) «**Clinical Trial Notice**»: the public notice by means of which FTELE has issued the Clinical Trial Call direct to the selection of the Beneficiary;
 - g) «**Clinical Trial Scientific Committee**» or «**CTSC**»: the independent body responsible for the scientific evaluation of all proposals;
 - h) «**Contribution**» or «**Funding**»: the financial support granted by FTELE to the Beneficiary for the implementation of the Project, disbursed in the form of a lump sum, within the limits and subject to the conditions set out in this Award Agreement;
 - i) «**Clinical Trials Information System**» or «**CTIS**», which supports the flow of information between Clinical Trial sponsors, European Union Member States, European Economic Area countries and the European Commission;
 - j) «**Coordinating Investigator**»: the Principal Investigator nominated by the Consortium's partners who is responsible for the scientific leadership and coordination of the Project and serves as the primary scientific contact with Scientific Secretariat, the CTSC, and FTELE. The Coordinating Investigator and the Sponsor may belong to the same institution or to different consortium partners. If the Coordinating Investigator and Sponsor are different institutions, the Coordinating Investigator will co-sign the Award Agreement;
 - k) «**Co-Sponsor**»: the party of the Consortium potentially appointed, in the same Consortium's proposal, for supporting the Sponsor in the fulfillment of its obligations under this Award Agreement, which can be entrusted by the Sponsor with specific tasks in the context of the activities aimed at initiating,

Version of 18 September 2026

managing, conducting and financing the Project in accordance with Regulation (EU) no. 536/2014, pursuant to applicable national legislation, and in compliance with a specific co-sponsorship agreement. The Co-Sponsor shall not be entitled to receive directly any amounts payable by FTELE and shall sign this Award Agreement for acknowledgment and acceptance;

- l) **«Co-Sponsorship Agreement»**: where applicable, the agreement between the Sponsor and the Co-Sponsor that governs the allocation of their respective responsibilities, roles and obligations, and that is signed by both parties;
- m) **«Dissemination and Communication»**: the activities aimed at making the results of the Project public, as provided for in this Award Agreement and in accordance with the provisions of the Horizon Europe Model Grant Agreement;
- n) **«Project Documentation»**: the documents submitted by the Sponsor to FTELE for the purpose of verifying the progressive achievement of the Project Milestones;
- o) **«ERDERA»** or **«ERDERA Partnership»**: the European Rare Diseases Research Alliance, funded under the Horizon Europe programme, governed by the relevant Grant Agreement concluded between the European Commission and the beneficiary consortium, in which FTELE participates as a beneficiary;
- p) **«ERDERA Clinical Trial Call»** or **«ECTC»** or **«Clinical Trial Call»**: the Call for proposals issued by FTELE in order to implement the Work Package 4 assigned to it under the Grant Agreement and consisting of cascading procedures aimed at selecting qualified entities to develop clinical trials in the field of rare diseases;
- q) **«ERDERA Consortium Agreement»** or **«ERDERA CA»**: the consortium agreement signed by the entities composing the ERDERA Partnership and regulating their internal relationship in the framework of the Horizon Europe Grant Agreement;
- r) **«European Commission»**: the political and independent branch of the European Union;
- s) **«Financial Rules»**: the Regulation no. 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the European Union;
- t) **«Financial Support to Third Parties»**, **«FSTP»** or **«Cascade Funding»**: the mechanism for financial support to third parties provided for under the Horizon Europe programme, whereby FTELE grants contributions to entities external to the ERDERA consortium for the implementation of specific research activities selected through competitive procedures;
- u) **«Fondazione Telethon»** or **«Granting Authority»** or **«FTELE»**: the entity named “*Fondazione Telethon ETS*”, established under Italian Legislative Decree no. 117/2017 and having its registered office in Rome (Italy), Via Varese no. 16/B, acting as a beneficiary of the ERDERA action, funded under the Horizon Europe programme and as the entity granting Financial Support to Third Parties;
- v) **«Grant Agreement»** or **«GA»**: the Horizon Europe Grant Agreement, signed between HaDEA and the ERDERA Partnership, serving as the normative and regulatory reference for general principles, including provisions on Open Science, dissemination, communication, intellectual property, ethics and controls;
- w) **«Good Clinical Practice»**: international standard of ethical conduct and scientific quality for the design, conduct, recording, and reporting of clinical trials involving human subjects;
- x) **«HaDEA»**: the European Health and Digital Executive Agency, in its role of signing party of the Grant Agreement, due to the powers delegated to it by the European Commission;

Version of 18 September 2026

- y) «**Horizon Europe**»: the European Union framework programme for research and innovation established by Regulation (EU) 2021/695 and its subsequent amendments;
- z) «**Implementation Period**»: the timeframe between the start date of the Project and its completion, as indicated in this Award Agreement, subject to any expressly authorised extensions;
- aa) «**Intellectual Property (IP)**»: the set of industrial and intellectual property rights, including by way of example patents, know-how, models, software and research results, generated in the course of implementing the Project;
- bb) «**Lead Beneficiary**» or «**Sponsor**»: the party of the Consortium designated as Sponsor and entrusted by the other Consortium's members with the power of signing the Award Agreement on behalf of the same members, which is responsible for the initiation, management, conduct, and financial accountability of the Project in accordance with Regulation (EU) 536/2014 and applicable national legislation, as well as for the correct implementation of the Award Agreement by all partners, and which is potentially assisted by a Co-Sponsor;
- cc) «**Lump Sum**»: a form of funding not based on the reporting of actual costs incurred, whereby disbursement of the contribution is subject solely to the achievement and validation of the Project Milestones, as set out in this Award Agreement;
- dd) «**Main Call**»: the call for proposals no. HORIZON-HLTH-2023-DISEASE-07-01, aimed at awarding a grant for supporting initiatives direct to foster research in the area of rare diseases and to strengthen the healthcare system's capacity to cure such illness statuses;
- ee) «**Milestones**»: the intermediate and/or final results, of a scientific, technical or procedural nature, that are clearly identifiable, verifiable and measurable, the achievement of which is a condition for the positive assessment of the Project and for the disbursement of the Contribution;
- ff) «**Model Grant Agreement**» or «**MGA**»: the template of the Grant Agreement, included in the documentation of the Main Call, without additional notes and indications on the rules applicable to the same Main Call and to its execution phase, which represents the standard contractual document used by the European Institutions in order to grant funds or other form of financing measures to interested operators;
- gg) «**Partners**»: the legal entities participating in the implementation of the funded project under the coordination of the Sponsor, which is entrusted by the same Partners to represent the latter in the relationship with FTELE and to sign the Award Agreement in their behalf;
- hh) «**Consortium Funding Agreement**»: the agreement governing the relationship between the Sponsor and its Partners;
- ii) «**Project**»: the set of research activities approved by FTELE to be realised under this Award Agreement, following the selection of the Beneficiary in the context of the Clinical Trial Call issued by FTELE, as described in the project proposal and in any documents annexed to this Award Agreement;
- jj) «**Project Budget**»: the document containing the breakdown of the estimated costs that the Beneficiary deems necessary for the implementation of the Project subject of this Award Agreement and that the same Beneficiary has submitted together with its application in the context of the Clinical Trial Call, in order to allow FTELE to evaluate the sustainability of the implementation approach proposed by the same Beneficiary;
- kk) «**Project Documentation**»: the documents submitted by the Sponsor to FTELE for the purpose of verifying the progressive achievement of the Project Milestones;

Version of 18 September 2026

- ll) «**Scientific Secretariat**»: the secretariat responsible for the management of the Clinical Trial Call issued by FTELE;
 - mm) «**Subcontracting**»: the assignment to third parties of limited and ancillary activities in relation to the Project, in compliance with the principles of economy, transparency and best value for money, without delegation of scientific or managerial responsibility for the Project;
 - nn) «**Work Package 4**» or «**WP4**»: the specific work package which FTELE is responsible for implementing under the provisions of the Grant Agreement, including the obligation to issue the Clinical Trial Call in the area of research and implementation of cures against rare diseases.
2. Words and expressions which the previous paragraph defines in the singular form are considered to be defined also in the plural form, and vice versa.

Article 3

(Duration)

1. This Award Agreement shall be effective from the date of its signature and until the completion of the activities included in the Project described in Annex “A”. In any case, the Award Agreement shall cease to produce effects and shall be considered to be fully terminated, at the latest, **on the 30 June 2034**.
2. Projects shall start on the first day of the calendar month immediately following the month in which Milestone 1, as referred to in article 5, paragraph 1, letter a), of this Award Agreement, is achieved and approved by FTELE, subject to any extensions expressly authorised in accordance with the applicable provisions of the European Commission.
3. Milestone 1 must be completed within **6 months** from the date of the Award Agreement being signed. Failure to meet this deadline, unless duly justified and expressly authorized in writing by FTELE before it expires, will result in action being taken by FTELE in accordance with Article 16.

Article 4

(Funding Scheme - Lump Sum)

1. The contribution is granted in the form of a lump sum, pursuant to the provisions contained in article 6.2, paragraph “D”, no. 1.3, of the AGA and in compliance with the reporting modalities set forth in this Award Agreement.
2. Lump sum funding consists of the disbursement of a predetermined fixed amount, which is not based on the actual costs incurred by the beneficiaries nor on the amount of reported expenditure, but is exclusively linked to the achievement of the expected results, as defined by the Project milestones provided for in following article 5.
3. In particular, the lump sum scheme has the following main characteristics:
 - a) the contribution is not calculated based on actual costs incurred by the Beneficiaries;
 - b) the Beneficiary is not required to submit documentation on financial reporting of costs, but only documentation showing the correct implementation of the Project, as provided for in article 8. In this respect, the actual costs incurred by the Beneficiary do not serve as a basis to determine the grant amount, without prejudice to the submission of the documents above;

Version of 18 September 2026

- c) payments are made exclusively upon achievement of the Milestones set out in the technical annex, attached as **Annex “A”** to this Award Agreement, and subsequent approval by FTELE;
 - d) the progress monitoring of the Project is technical-scientific in nature and is aimed at verifying the achievement of the expected results and outputs.
4. The total amount of the contribution granted to the Project shall be structured in predetermined tranches, each associated with the achievement of the planned Milestones, as governed by the specific provisions of the following article 5 of this Award Agreement.
5. In the event of non-achievement, partial achievement, or non-compliant achievement of the Milestones, FTELE reserves the right to:
- a) proportionally reduce the amount of the contribution;
 - b) suspend disbursement of payments;
 - c) revoke, in whole or in part, the funding granted.
6. It is understood that the lump sum scheme does not exempt the Beneficiary from complying with the principles of sound financial management, as better provided for in the subsequent articles, with specific reference to:
- a) economy;
 - b) efficiency;
 - c) transparency;
 - d) best value for money;
 - e) absence of conflicts of interest.
7. The Beneficiary declares and agrees that it has not received by HaDEA, the European Commission or other European Institutions any fund or other financing measure which can determine duplication of the financing included by this Award Agreement.

Article 5

(Milestones and Associated Contribution Tranches)

1. The total Contribution is structured in predetermined percentage tranches, each associated with the achievement of the following Milestones:
- a) **Milestone 1:** regulatory and ethics approvals required to initiate the Clinical Trial (e.g. CTA authorisation and ethics committee approval: **20%**;
 - b) **Milestone 2:** first participant first visit («FPFV»): **20%**;
 - c) **Milestone 3:** last participant first visit («LPFV»): **25%**;
 - d) **Milestone 4:** last participant last visit («LPLV»): **15%**;
 - e) **Milestone 5:** clinical study report: **15%**;
 - f) **Milestone 6:** entry of study results in the Clinical Trials registry: **5%**.
2. The achievement of a Milestone does not automatically entitle the Beneficiary to disbursement of the corresponding tranche of Contribution, which remains in all cases subject to assessment and validation by FTELE.

Article 6

(Indicative Project Budget)

1. The Parties acknowledge and agree that the Beneficiary has presented an indicative Project Budget together with the application submitted in response to the Clinical Trial Notice, which serves the sole purpose of providing an indicative representation of the allocation of resources, at the evaluation stage, in relation to:
 - a) the scientific objectives of the Project;
 - b) the approved research activities;
 - c) the overall structure of the Project and the planned Milestones.
2. The Project Budget:
 - a) has been submitted with reference to all the entities participating in the Project;
 - b) is broken down according to the cost categories provided for in the Clinical Trial, for informative and descriptive purposes only;
 - c) does not constitute a binding expenditure plan for the implementation of the Project;
 - d) shall serve, during the implementation of the Project, for the only purposes referred to in the following paragraphs of this article.
3. For the above descriptive purposes, the Project Budget is structured according to the following indicative cost categories:
 - a) personnel of clinical and research staff at all participating sites;
 - b) costs of the investigational medicinal product (IMP), including for ATMPs, manufacturing costs up to and including Phase I/II batch production (GMP-compliant), but excluding Phase III-scale manufacturing costs, which are not eligible;
 - c) Clinical Trial insurance;
 - d) clinical site costs, including screening, monitoring, data collection, patient visits;
 - e) regulatory costs, with specific reference to:
 - (i) ethics committee submissions and Clinical Trial Authorisation (CTA) fees, which are eligible for all Projects;
 - (ii) EMA scientific advice fees, provided that:
 - EMA provides fee waivers for certain categories of applicants and products, including paediatric studies (under the Paediatric Regulation), products with Orphan Drug Designation (ODD), and academic/non-commercial sponsors. It is hereby understood and agreed between the Parties that, should the Beneficiary be qualified for a waiver by EMA, it shall be expected to apply for it and, having obtained such waiver, the corresponding costs will not be eligible for ECTC funding;
 - for applicants that do not qualify for any EMA fee waiver (e.g. SME sponsors without ODD or paediatric designation), EMA scientific advice fees are eligible and must be included in the Project Budget;

Version of 18 September 2026

- f) data management and biostatistics costs, including costs associated with the data collection and management service;
 - g) “*Patient and Public Involvement and Engagement*” (PPIE) activities, which are costs associated with patient partner participation, including PAO staff time, travel and subsistence, translation and interpretation, reimbursement of out-of-pocket expenses, and costs of developing patient-facing materials. PPIE costs must be adequately budgeted and described in the “*Patient Involvement Plan*”, as provided for in Annex “A” and in the Budget;
 - h) costs of multinational clinical trial management support structure (e.g. ECRIN, c4c, CVBF or equivalent), it being understood that the Beneficiary is required to include or contract an organisation with proven experience in multinational trial coordination, such as those mentioned above;
 - i) project management and coordination costs, including costs of the sponsor institution for fulfilling its regulatory and legal obligations;
 - j) dissemination and open access publication costs;
 - k) costs relating to subcontracting of activities by the Beneficiary to other entities;
 - l) 25% flat rate of the Project's eligible direct costs, as set out in the final approved budget, excluding subcontracting costs and internal core facilities of direct costs.
- 4. The Project Budget does not give rise to any assessment of cost eligibility, nor does it entail any obligation to report financially, justify actual costs incurred, or determine documentary, accounting or financial controls on the same Project expenditure by FTELE.
 - 5. The budget is therefore not a parameter for determining, reducing or recovering the contribution granted, without prejudice to the application of the provisions of this Award Agreement on technical-scientific assessment, Project Documentation and payments. Therefore, the Beneficiary shall not be entitled to request an increase of the amounts granted under this Award Agreement due to a change of the circumstances existing at the moment of submission of the application or for any other reason whatsoever that may potentially cause variations of the costs borne by the same Beneficiary for the implementation of the Project.
 - 6. Any reallocation of the contribution granted shall be permitted exclusively in the form of a transfer of budget between Partners, subject to the prior written approval of FTELE.
 - 7. In any case, the Beneficiary must ensure its compliance with the mandatory budget requirements set out in article 4.2. of the Clinical Trial Notice.

Article 7

(Eligibility criteria and research modalities)

- 1. The Beneficiary acknowledges and agrees that, during the whole duration of this Award Agreement, the same Beneficiary shall be obliged to grant that the research objectives, the implementation procedures and the operative activities are carried out in compliance with the eligibility requirements provided for in the Clinical Trial Notice and by the related documentation as well as by the Grant Agreement and related attachments.
- 2. Furthermore, the Beneficiary shall grant compliance with the further ethical standards and requirements, the gender mainstreaming values provided for in article 14 of the Grant Agreement and in the corresponding section of Annex 5 to the same Grant Agreement as well as the eligibility criteria set out in article 5 of the Clinical Trial Notice. To this end, the Beneficiary shall acknowledge fulfilment of the

Version of 18 September 2026

eligibility requirements, in accordance with applicable Italian and European Union law, declaring compliance with the aforementioned requirements and principles, as well as the requirements provided for in article 137 et seq. of the Financial Rules.

3. FTELE reserves the right to carry out verifications on the fulfilment of the requirements and principles referred to in the previous paragraph, including after the disbursement of the grant funding. If any breach of these requirements or principles is identified during this verification process, FTELE shall notify the relevant authorities, and take any necessary measures in accordance with applicable law.
4. Without prejudice for the above, the Beneficiary shall also ensure that the implementation activities are compliant with the technical specifications regarding the Project indicated in Annex “A” of this Award Agreement.

Article 8

(Project Management, Project Documentation and Payments)

1. The implementation of the funded Project is managed through the submission of Project Documentation related to the Project. This is consistent with the lump sum funding scheme and is aimed at monitoring the technical-scientific progress of the activities, as well as the achievement of the planned Milestones.
2. At the end of each relevant period, the Coordinating Investigator may submit the Project Documentation signed by the Lead Beneficiary and certifying that one or more project Milestones have been achieved during the relevant period.
3. Such Project Documentation is technical-scientific in nature and is aimed at verifying the achievement of the planned Milestones. The latter does not entail any financial reporting obligations, nor the submission of accounting documentation or proof of expenditure.
4. In the course of evaluating the Project Documentation, FTELE shall assess whether the Milestone or Milestones associated with the reference period:
 - a) have been fully achieved, in compliance with the Project objectives and specifications;
 - b) have not been achieved or have been achieved only partially or not in compliance with the Project objectives and specifications.
5. Upon positive verification of the Milestones’ achievement, payment of the associated contribution tranche shall be made within **60 (sixty) days** of the end of the reference period, subject to the terms and conditions set out in the following paragraphs.
6. In the event of non-achievement, partial achievement, or non-compliant achievement of a Milestone, FTELE reserves the right, based on the technical-scientific assessment carried out, to:
 - a) fully withhold the contribution tranche associated with the affected Milestone;
 - b) adjust the disbursable amount proportionately to the level of Milestone achievement, where technically assessable.
7. All payments are in any case subject to:
 - a) positive validation of the Project Documentation by FTELE;
 - b) prior transfer of funds by the European Commission under the ERDERA project to FTELE.
8. No automatic right to payment shall arise in favour of the Beneficiaries in the absence of a positive verification of achievement of the planned Milestones.

Version of 18 September 2026

9. Given the Lump Sum scheme on which this Award Agreement is based upon, the Parties agree that no accounting documentation will be required by the same Beneficiary in the context of the monitoring and progress reporting obligations provided for in this article. The verification on the exact performance by the Beneficiary of the activities entrusted to it shall be carried out on the basis of the deliverables and technical documentation concerning the concrete implementation of the Project.
10. Without prejudice for the provision contained in the previous paragraph, if required by HaDEA and/or the European Commission on occasion of checks and audits on the activities subject of the Award Agreement or if other relevant circumstances so require, FTELE reserves the right to request to the Beneficiary all the necessary documentation in order to concretely verify the exact implementation of the Project, the completion of the Milestones described in Annex “A” and to achieve overall indications as to the modalities through which the funding has been spent by the same Beneficiary, according to article 20.1, letter (c), point (ii), of the Grant Agreement.
11. In cases referred to in previous paragraph 10, the Beneficiary shall provide all the documentation required by FTELE and shall cooperate with its potential audits and verifications by fully disclosing any information available, including Partner’s documentation. FTELE in turn reports such documentation to the European Commission.

Article 9

(Relationship with the Partners’ consortia)

1. Disbursement of the contribution shall be made exclusively to the Sponsor, who shall be responsible for the subsequent distribution of funds to the Partners in accordance with the contribution allocation approved during the selection process and formalised in this Award Agreement.
2. The internal arrangements between the Sponsor and its Partners shall be governed by a Consortium Funding Agreement signed by all Partners and attached to this Award Agreement.
3. Any changes to the internal distribution of the contribution between the Sponsor and the Partners shall only be permissible upon submission of a reasoned request and express approval by FTELE and may not under any circumstances result in an increase in the total amount of the contribution granted or affect the achievement of the Project milestones.
4. FTELE shall not assume the role of party to the internal contractual arrangements between the Sponsor and the Partners and shall assume no responsibility with regard to the performance of provisions contained in such arrangements, without prejudice to its right to authorise or refuse changes to the contribution allocation.
5. Notwithstanding any other provisions contained in the previous paragraph, the Sponsor and the Partners shall be jointly and severally liable to FTELE for the proper implementation of the Project and the fulfilment of all obligations arising from this Agreement. This joint and several liability shall extend to any damage, losses, penalties, recoveries, reimbursements, repayments, costs, or expenses incurred by FTELE due to any act, breach, delay, non-compliance and non-performance attributable to the Sponsor and/or one of its Partners. The allocation of responsibility among the Sponsor and its Partners does not exclude their joint and several liability toward FTELE.
6. The total contribution granted to the Project is distributed between the Sponsor and the Partners as defined and approved during the selection process.
7. The distribution of the contribution among participating entities is set out in the Shares Allocation attached as **Annex “E”**, which forms an integral part of this Award Agreement.

Article 10

(Role and Obligations of the Sponsor)

1. The Sponsor shall be the legal entity responsible for the initiation, management, conduct and financial accountability of the Clinical Trial in accordance with the EU Regulation no. 536/2014 and any applicable national legislation.
2. The Sponsor is legally and regulatorily responsible for:
 - a) the Clinical Trial, including submission of the Clinical Trial Application through CTIS;
 - b) pharmacovigilance reporting;
 - c) safety oversight;
 - d) trial monitoring;
 - e) quality management and fulfilment of Good Clinical Practice obligations across all participating clinical sites;
 - f) the distribution of the contribution to the Partners in accordance with the approved allocation and the Indicative Project Budget;
 - g) compliance by itself and the Partners with the provisions of this Award Agreement.
3. The Sponsor shall possess, either directly or indirectly through formalised agreements with qualified third parties the expertise, infrastructure, and operational capacity required to fulfil a Sponsor role for a multinational phase I/II Clinical Trial.
4. The Sponsor shall receive by the Partners the necessary financial documentation to enable consolidated reporting to FTELE.
5. The Sponsor ensures that the Partners, and the Coordinating Investigator, are informed of the obligations arising from this Award Agreement and remains solely responsible towards FTELE for the overall implementation of the Project.
6. FTELE assumes no responsibility in relation to the internal arrangements between the Sponsor, the Coordinating Investigator and the Partners.
7. In the event that the proposal of the Consortium to which the Clinical Trial Call has been awarded identifies a Co-Sponsor of the Clinical Trial project, the Sponsor shall act as representative of the Consortium towards FTELE and the Co-Sponsor shall support the Sponsor in the fulfilment of its obligations under this Award Agreement. The respective obligations of the Sponsor and the Co-Sponsor shall be governed by a Co-Sponsorship Agreement attached to this Award Agreement. The provisions contained in this paragraph do not prejudice the scientific role of the Coordinating Investigator according to article 11 of this Award Agreement.
8. Where the Sponsor acts jointly with the Co-Sponsor, the funding shall be transferred exclusively to the Sponsor and the relationships between FTELE and the Co-Sponsor will be managed through the Sponsor.

Article 11

(Coordinating Investigator)

1. The Coordinating Investigator shall be responsible for the scientific leadership and coordination of the Project, serving as the primary scientific contact for ERDERA programme management.
2. In particular, the Coordinating Investigator is responsible for:
 - a) the scientific, technical and organizational coordination of the Project, including scientific reporting and communication with evaluation bodies;
 - b) timely submission of all scientific deliverables, and other documents required by the Scientific Secretariat and FTELE to certify the achievement of the Milestones;
 - c) coordinating scientific activities and serving as the primary interface with the Scientific Secretariat, the CSTC, and FTELE on scientific and project implementation matters.
3. The Coordinating Investigator shall represent the Consortium in scientific interactions with the Scientific Secretariat, the CTSC and FTELE.
4. The Coordinating Investigator shall sign the Award Agreement together with the Sponsor for acknowledgement and confirmation of having read, understood and undertaken its terms.
5. In the event of a coincidence with the Sponsor, the provisions of this article shall also apply to the Sponsor.

Article 12

(Platform management and Communications)

1. The operational management of the Project and communications between the Coordinating Investigator and FTELE shall take place through distinct channels, as specified below.
2. The Smart Simple IT platform is used by FTELE for:
 - a) submission of the project proposal at the application stage;
 - b) management and submission of the Project Documentation certifying the achievement of the Milestones.
3. The project proposal and the documentation submitted at the application stage shall remain archived on the Smart Simple platform as the official project records.
4. Communications via Dedicated Email Address
5. Formal communications other than the submission of the Project documentation certifying the achievement of the Milestones, including in particular:
 - a) submission of requests to amend the Project;
 - b) submission of requests to amend the contribution allocation;
 - c) transmission of clarifications, supplementary documents or additional information;must be sent exclusively via the dedicated email address indicated by FTELE.
6. Amendment requests shall be deemed correctly submitted and shall take effect only upon express written approval by FTELE. Such requests shall include, without limitation, changes to the Project timeline, budget allocation, Milestones, deliverables, Consortium composition, key personnel or any other substantial aspect of the Project. Any such amendments shall be subject to, and implemented in accordance

Version of 18 September 2026

with, the relevant Grant Agreement and any applicable rules, guidelines or requirements of the European Commission.

Article 13

(Publications and Data Sharing)

1. Beneficiaries are required to ensure the dissemination of scientific results generated by funded projects in compliance with the provisions of the Horizon Europe Model Grant Agreement (MGA), in particular articles 17 and 38 and Annex 5.
2. In accordance with article 17 MGA (Dissemination: Open access to scientific publications) and Annex 5 MGA (Open science), peer-reviewed scientific publications arising from the project must be made available open access. In particular, where beneficiaries choose to publish research results, they must ensure immediate open access to publications in accordance with the procedures set out in the MGA.
3. With regard to research data, beneficiaries are required to manage them responsibly and, where possible, to make them accessible in accordance with the FAIR principles (Findable, Accessible, Interoperable, Reusable), applying the Horizon Europe principle of “as open as possible, as closed as necessary”, as set out in Annex 5 MGA, taking into account the need to protect intellectual property, confidentiality, personal data protection and applicable legislation.
4. Pursuant to article 38 MGA (Visibility of EU funding), in all dissemination and communication activities and in every publication, presentation or other scientific material, beneficiaries must clearly and visibly include the following acknowledgement: this project is funded within the European Rare Diseases Research Alliance (ERDERA) partnership under the Horizon Europe research and innovation programme.
5. FTELE may request information from beneficiaries on publications and dissemination activities for the purposes of scientific monitoring and fulfilling reporting obligations to European institutions.

Article 14

(Documents Required to activate the Project)

1. Following the successful conclusion of the evaluation phase and the subsequent technical-scientific support and accompaniment phases, the formal start of the Project is subject to the submission and verification of the documentation set out below. This includes the final version of the Co-Sponsorship Agreement, where required.
2. This Award Agreement is signed exclusively by the Sponsor, in its role of single contact point of FTELE.
3. Project Partners do not sign this Award Agreement but grant a mandate to the Sponsor and undertake specific commitments through the documentation referred to in this article.
4. Signature of the Award Agreement does not constitute authorisation to initiate the Clinical Trial. Confirmation that all required approvals are in place remains a prerequisite for activation of the Clinical Trial and release of the funding instalment linked to the First Participant First Visit (FPFV) milestone.

Article 15

(Content of the Partnership Agreement and related declarations)

1. By means of a Partnership Agreement, attached to this Award Agreement as **Annex “D”**, each Partner:

Version of 18 September 2026

- a) grants a mandate to the Sponsor to sign the Award Agreement with FTELE and to manage the relationship with the Foundation;
- b) undertakes to implement the Project activities allocated to it in accordance with the approved proposal and the relevant milestones;
- c) undertakes to carry out the Project activities assigned to it in accordance with the approved proposal and the planned milestones;
- d) declares acceptance of the lump sum funding scheme, acknowledging that the contribution is not based on actual costs incurred and that payments are subject solely to the achievement and validation of the Milestones;
- e) declares the absence of double funding for the activities covered by the contribution;
- f) undertakes to cooperate with the Sponsor and to provide the information required for project monitoring;
- g) set forth the rules governing their reciprocal relationship in the context of the activities aimed at implementing the provisions of this Award Agreement and to the realization of the Project.

Article 16

(Termination or revocation of the Award Agreement and of the Contribution – Liability of the Beneficiary)

1. If the Beneficiary commits a material breach of any obligation under this Agreement including failing to submit the complete required documentation or carrying out other acts or omission that prevent the activation of the Project, the initiation of funded activities or determine a significant delay in the completion of the Milestones, to an extent that the breach cannot be remedied by means of the reduction mechanism provided for in article 4, paragraph 5, of this Award Agreement, FTELE shall be entitled to terminate this Agreement. In this case, the Beneficiary must repay all the amounts received under this Award Agreement, together with applicable interests and expenses.
2. In the event of termination of this Award Agreement, FTELE shall be entitled to the reimbursement of the funding already transferred to the Beneficiary. In this case, at its sole discretion, FTELE may request either:
 - a) full reimbursement of the amounts paid in the event that the Milestones achieved, and the deliverables submitted by the Beneficiary are deemed by the same FTELE non-compliant with the technical documentation or useless to the European Commission, HaDEA or to FTELE itself, according to a discretionary evaluation carried out by the latter;
 - b) partial reimbursement in the event that the Milestones achieved, and the deliverables submitted comply with the technical documentation and are considered to be useful for the European Commission, HaDEA or to FTELE in the context of the overall implementation of Project.
3. The assessment of the technical compliance of the deliverables and of their utility for FTELE and the European Commission, as well as the subsequent quantification of the sums to be reimbursed shall be referred to the exclusive and discretionary evaluation of FTELE, which shall decide on this matter after consulting with the European Commission, if needed.
4. In the event of a breach pursuant to the previous paragraphs, FTELE will send a notice to the Beneficiary, setting a deadline for the latter to submit clarifications. After reviewing the Beneficiary's response, FTELE will conduct an assessment. If the issues have not been resolved, FTELE will terminate the agreement by sending a written notice to the Beneficiary.

Version of 18 September 2026

5. In the event of failure to meet the eligibility requirements set forth in article 7 of the Award Agreement, the Beneficiary shall forfeit the right to the contribution granted by means of an express decision issued by FTELE, which may be notified at any time and without prior notice. Such forfeiture shall entail the Beneficiary's obligation to fully repay the whole Contribution, including all sums already disbursed.
6. The Beneficiary will lose the funding, and the granted contribution will be revoked if it no longer meets the eligibility requirements set forth in article 7 of this Agreement.
7. A claim for indemnification shall also arise if breaches, delays, or omissions attributable to the Beneficiary result in FTELE's failure to meet Milestones, deliverables, deadlines, or any other obligation undertaken with the European Commission within the scope of the Project, whether directly or indirectly.

Article 17

(Monitoring and Valorisation of Research Results)

1. In order to monitor the implementation of funded projects and promote the development of the research results generated, FTELE, as the entity responsible for managing the financial support to third parties activities under the ERDERA partnership, shall carry out technical-scientific monitoring of the projects, in line with the lump sum funding scheme and the applicable provisions of the Horizon Europe Model Grant Agreement.
2. Such monitoring activities are aimed at assessing the achievement of Milestones, analysing the results obtained, and identifying any potential opportunities for the scientific, clinical or pre-competitive development and valorisation of research results, including in a perspective beyond the formal completion of the project.
3. All intellectual and industrial property rights over results generated within the project, including, by way of example and without limitation, results relating to therapeutics, diagnostics, clinical data, databases, software, materials, know-how and other results susceptible to industrial application (hereinafter "Results"), remain with the beneficiaries and the responsible researchers in accordance with applicable national and international law, subject to the rights of any third parties involved.
4. FTELE does not acquire intellectual property rights over the Results. However, in line with the objectives of the ERDERA action and the Horizon Europe programme, beneficiaries undertake to protect and valorise the Results where the conditions are met, including by exploring opportunities for development, technology transfer or collaboration with industrial partners or other suitable entities.
5. In order to allow proper assessment of protection and valorisation opportunities before disclosure of the Results, beneficiaries undertake to submit any scientific manuscripts, presentations or other forms of communication of the Results to the competent internal structures of their organisation for the necessary intellectual property checks.
6. Where, during the duration of the project or thereafter, agreements are concluded with third parties relating to the Results or the intellectual property associated therewith, or agreements that significantly affect the manner of use, publication, protection or exploitation of the Results, beneficiaries are required to notify FTELE within 60 days of signing, in order to allow assessment of the overall impact on the project and on the obligations arising from the funding.
7. In order to enable assessment of the impact of funded research, beneficiaries also undertake to keep FTELE informed of significant events following the conclusion of the Project, such as, by way of example, the initiation of a subsequent clinical study, the filing of patent applications, the obtaining of other intellectual property titles, the creation of start-ups, or the conclusion of option, licence or collaboration agreements relating to the Results.

Article 18

(Checks and audits)

1. By virtue of this Award Agreement, the Beneficiary acknowledges and agrees that the European Commission and HaDEA, acting either directly through their own bodies or through FTELE, shall be entitled to carry out all the necessary checks and audits to verify the technical compliance of the deliverables and the reports submitted, the proper implementation of the Project and its compliance with the obligations under this Award Agreement as well as the respect of the provisions on cost reporting contained in the documentation of the Main Call, in the Grant Agreement, in the Clinical Trial documents and in this Award Agreement. For such purposes, the European Commission and HaDEA may also enlist the assistance of external independent experts.
2. Such checks may be carried out even after the time limit of the funding and shall include checks on the use of funds at any level of the consortium, including at individual partner institutions. They shall be formally notified to the Beneficiary concerned and shall be deemed initiated on the date of receipt of such notification.
3. The Beneficiary shall fully cooperate with the checks procedures by promptly providing all requested documentation (including complete accounts, individual salary statements or other personal data) within the deadline set forth by the European Commission, HaDEA or FTELE, granting access to its premises. The Beneficiary shall also participate, where necessary, in meetings with the staff of the European Commission, HaDEA or FTELE. The Beneficiary shall ensure that all requested information is readily available, accurate, precise, complete, and provided in the required format, including electronic format.
4. Upon completion of the review, a report shall be drafted. The European Commission, HaDEA or FTELE, will formally notify such report to the Beneficiary concerned, which has thirty days from receiving notification to make observations. The report will be in the language of this Award Agreement, unless otherwise agreed by the European Commission, HaDEA or FTELE.
5. Should the Commission, including through FTELE and by means of its own audits, deem the checks and audits to be unsatisfactory, the Beneficiary may be subject to recovery measures in accordance with the Grant Agreement.
6. In any case, the Beneficiary agrees to provide any document requested by the European Commission.
7. For all of the aspects not expressly regulated in this article, the provision of article II.25 of the Grant Agreement and of related Annex 5 shall apply to the Beneficiary.

Article 19

(Privacy)

1. In the context of the implementation of projects funded through the financial support to third parties (cascade funding) mechanism, each beneficiary and FTELE shall act as independent data controllers with respect to the personal data processed by each, in relation to their own purposes and responsibilities, pursuant to applicable personal data protection legislation.
2. Beneficiaries are informed of and accept that personal data provided in the course of the application, the project design support phase, and the implementation of funded activities shall be processed by FTELE exclusively for purposes related to the management, monitoring and disbursement of funding, as well as for compliance with the obligations set out in the Horizon Europe programme and the applicable Model Grant Agreement.

Version of 18 September 2026

3. Beneficiaries undertake, in the conduct of research activities, to comply with and ensure compliance by all parties involved in the project, including persons authorised to process data, with the provisions of Regulation (EU) 2016/679 (GDPR), Legislative Decree 196/2003 and its subsequent amendments, as well as any other applicable national, international, or European Union legislation on personal data protection.
4. FTELE shall ensure that personal data will be:
 - a) processed lawfully, fairly and in a transparent manner in relation to the data subjects;
 - b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;
 - c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
 - d) accurate and, where necessary, kept up to date;
 - e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and processed in a manner that ensures appropriate security of the data.
5. It is understood that FTELE does not process personal data as data processor on behalf of the beneficiaries, nor does it carry out any delegated processing activities relating to research data. In particular, FTELE does not access and is not made recipient of personal data of patients or other parties involved in research activities, except, where strictly necessary, in aggregated and anonymous form.
6. Beneficiaries undertake to ensure that, in the context of technical-scientific monitoring, audits, checks or information requests by FTELE, no unauthorised personal data or data exceeding the purposes of the funding is communicated or shared, nor information capable of enabling direct or indirect identification of the data subjects.
 - a) Beneficiaries may grant their personal access to personal data only if it is strictly necessary for implementing, managing and monitoring the agreement with FTELE.
 - b) Any further processing of personal data, as well as any involvement of third parties in the processing, remains under the sole responsibility of the beneficiaries, who undertake to ensure full compliance with applicable law and to indemnify FTELE against any liability arising from non-compliant processing.

Article 20

(Confidentiality and classified information)

1. All information and data, of whatever nature, relating to the management of the funding, the implementation of the project, and the relationships between the beneficiaries and FTELE under the financial support to third parties (cascade funding) mechanism must be kept strictly confidential and used solely for purposes related to the correct implementation of the project and the obligations arising from the funding.
2. Beneficiaries undertake not to communicate or disclose to third parties the confidential information referred to in this article without the prior written consent of FTELE, except for communication to project partners, provided this is limited to what is strictly necessary and subject to equivalent confidentiality obligations.

Version of 18 September 2026

3. FTELE may disclose sensitive information to its staff and either to the Granting Authority or to EU institutions and bodies.
4. Beneficiaries also undertake to ensure compliance with confidentiality obligations by responsible researchers, collaborators, consultants, employees and any other party who, in whatever capacity, gains access to confidential information in the context of the project.
5. The confidentiality obligation starts from the date in which the Project formally begins and remains in force throughout the duration of the funding and thereafter, until the confidential information legitimately enters the public domain for reasons not attributable to the beneficiaries or FTELE. If Beneficiaries request, FTELE may agree to keep such information confidential for a longer period.
 - a) information that must be disclosed pursuant to legal obligations, safeguarding of the European Union financial interests, orders of competent judicial or administrative authorities, or to comply with transparency and reporting obligations under applicable European Union law, including those connected to the Horizon Europe programme, is excluded from the confidentiality obligation;
 - b) the confidentiality obligation no longer applies if the disclosing party agrees to release the other party and the information becomes publicly available, without breaching any confidentiality obligation;
 - c) beneficiaries and FTELE must handle classified information in accordance with the applicable national, EU, or international on classified information.
 - d) deliverables which contain classified information must be submitted according to special procedures agreed with FTELE and the Granting Authority.
 - e) classified information may not be disclosed to any third party (including participants involved in the action implementation) without prior explicit written approval from FTELE.
 - f) action tasks involving classified information may be subcontracted only after explicit approval (in writing) from FTELE.
 - g) breach, even partial, of the confidentiality obligations set out in this Section constitutes a serious default and may result in the adoption of the measures provided for in this Award Agreement, including suspension or revocation of funding, without prejudice to FTELE's right to claim compensation for any damage suffered.

Article 21

(Conflict of interests)

1. The Beneficiary must take all measures to prevent any situation in which the impartial and objective application of the Award Agreement could be compromised due to family, political, national, or economic interests, or any other direct or indirect interest of one or more of the Partners, of the Sponsor or of the single people operating in the context of the same Beneficiary.
2. If a situation arises that constitutes or could lead to a conflict of interests, the Beneficiary must formally notify FTELE immediately and take all the necessary measures to resolve this situation. FTELE may verify that these measures are appropriate and may request that additional measures be taken by a specific deadline.
3. If the Beneficiary breaches any of its obligations under this article, the grant may be reduced, or this Award Agreement may be terminated according to article 15.

Version of 18 September 2026

4. The Consortium undertakes to adopt and implement adequate internal procedures and organizational measures to ensure the authenticity, integrity, and impartiality of the Project and related results. In any case, the Consortium shall maintain and apply its own internal policies and procedures to this end.

Article 22

(Applicable Law and Dispute Settlements)

1. Except for the provisions contained in this Award Agreement, in the Grant Agreement, in the documentation of the Main Call and in any other further European Union provisions, this Award Agreement shall be governed by the applicable Italian Law.
2. If a dispute concerns the interpretation, application, performance, validity or termination of the relationship between FTELE and the Beneficiary, the parties must bring action before the Court of Rome.

Article 23

(Final provisions and Annexes)

1. The Parties acknowledge that the following Annexes contain binding provisions concerning the implementation modalities of the subject of this Award Agreement and agree that the provisions contained thereto constitute integral and substantial part of the same Award Agreement:
 - a) **Annex “A”**: Technical annex on the content of the Project to be implemented by the Beneficiary;
 - b) **Annex “B”**: Grant Agreement between the ERDERA Partnership and HaDEA, comprehensive of all its attachments;
 - c) **Annex “C”**: Horizon Europe Work Programme 2023 – 2025 General Annexes, published along with the call for proposal;
 - d) **Annex “D”**: Partnership Agreement by means of which the Partners participating to the Project implementation appoint the Sponsor;
 - e) **Annex “E”**: Shares Allocation, subdivision of the shares of the contributions included in the Award Agreement among the Partners, the Coordinating Investigator, and the Sponsor which have been selected at the end of the Clinical Trial Call;
 - f) **“Annex F”**: the Consortium Funding Agreement, which contains the Consortium internal financial and governance arrangements;
 - g) **“Annex G”**: where applicable, the Co-Sponsorship Agreement governing the relationship between Sponsor and Co-Sponsor;
 - h) [...] *[Insert reference to any other potential Annexes]*.
2. The Grant Agreement is subject to the terms of the grant and the Grant Agreement, of the Main Call, and related attachments.
3. In the event of any conflict between the provisions of this Award Agreement and those of the Grant Agreement or of the documentation of the Main Call, the latter shall prevail.
4. In the case described in the previous paragraph, the provisions of the Grant Agreement that do not conflict with the Grant Agreement or with the documentation of the Main Call shall be applied.
5. The Beneficiary acknowledges and agrees that, in the performance of this Award Agreement, it will be bound by the contractual obligations under articles 12, 13, 14, 17.2., 18 and 20 of the Grant Agreement.

Version of 18 September 2026

The bodies mentioned in article 25 of the Grant Agreement (e.g. HaDEA, the Court of Auditors, European Anti-Fraud Office) can exercise their rights also towards the Beneficiary.

6. The provisions of the Grant Agreement concerning Financial Support to Third Parties will be applicable in this Award Agreement.
7. Any amendment to this Agreement must be made in writing and with the mutual consent of all Parties involved.

[...], [...] (*Insert the place and date of signature*)

FONDAZIONE TELETHON ETS

in its quality of member of the ERDERA
Partnership and Granting Authority

[...]

Special Attorney/Legal representative

[...]

in its quality of Sponsor of the Beneficiary

[...]

Special Attorney/Legal representative

For acknowledgment and acceptance

[...]

in its quality of Coordinating Investigator

[...]

Special Attorney/Legal representative

[*To be inserted in the event of appointment of a Co-Sponsor by the Beneficiary*]

For acknowledgment and acceptance

[...]

in its quality of Co-Sponsor of the Beneficiary

[...]

Special Attorney/Legal representative
