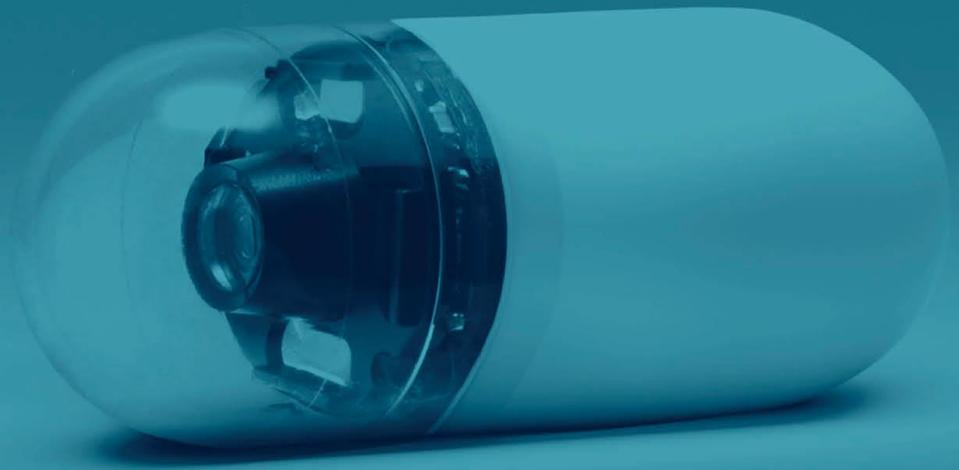


CaixaResearch Consolidate

Call

2021



Rules for
participation

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Executive Summary

"la Caixa" Foundation (hereinafter, "LCF") launched the Innovation Programme in 2015 jointly with Caixa Capital Risc as a strategic collaborator. Its first initiative, the Validate Call, has supported leading biomedical research projects and researchers boost their innovation potential through valorisation and training actions. Continuing with its commitment to help the results from ground-breaking research that meets societal needs and reach the market, **LCF extends its Innovation Funding Scheme in response to existing needs** in the biomedicine innovation ecosystem.

For this purpose, the CaixaResearch *Consolidate* Call (hereinafter, the "Call") is born as a new line of the innovation Calls. The Call wishes to **support disruptive Life Sciences** projects that have a clear roadmap to commercialisation, that include a robust ongoing valorisation plan or valorisation activities, and are at a stage of development closer to the market. This implies an advanced level of development and maturity, at a Technology Readiness Level (TRL) of 4 or greater (in contrast to the TRL 1 to 4 expected for projects applying to the CaixaResearch *Validate* Call). This Call will offer financial and non-financial support to bring the Assets through key technology transfer and business milestones to a stage of investment readiness.

The Call will consider applications for projects led by Spanish and Portuguese public or non-profit legal entities (universities, research centres, hospitals) **that own or co-own** the Assets resulting from the research activity.

In order to diligently respond to the needs of the projects, the Call will be permanently open (with a maximum of 3 cut-offs per year). The evaluation process will comprise two steps. (1) The application is initiated with a letter of intent; (2) Pre-selected applications will then be invited to submit a full proposal that will undergo a deeper evaluation process concerning the following criteria: (a) Unmet medical need, (b) Technical feasibility, (c) Assets' Development roadmap, (d) Assets' Business Case, (e) Team and implementation, and (f) Responsible Innovation.

Preamble

The "la Caixa" Foundation is supporting the Iberian biomedical research and innovation ecosystem through a range of grants and funding programmes. Moreover, **LCF's current Strategic Plan reflects the firm commitment to the translation of research results into society** as either new products or new companies.

Currently, many research Projects are unable to successfully go through the so-called "Valley of Death" of the innovation process. During the journey that a technological or highly innovative concept must follow until it reaches the market, there is a strict gap left by the availability of early-phase (mainly public grants) and late-phase (mainly private investment) financing resources. This is a high-risk stage in which many entrepreneurs lack enough financing to continue advancing their Projects.

In order to respond to this need, the innovation programme was created in 2015. Currently, it is articulated **into two schemes, CaixaResearch *Validate* and *Consolidate* calls, which aim to provide support to different stages of biomedical knowledge and the technology transfer process**, from research centres to the market, hence contributing to the progress of the well-being of people and society.

A. Rules for Participation

1

Aims

1.1. With CaixaResearch *Consolidate*, LCF aims to increase the capacity of Projects to successfully advance the development of the Asset into commercialisation with the ultimate aim of providing innovative solutions for health through:

- » Facilitating technologies with very high potential to reach market and respond to societal needs.
- » Ensuring that researchers leading ground-breaking Projects can successfully achieve their entrepreneurial goals.
- » Strengthening innovation that is society-oriented in the Iberian biomedical research ecosystem.
- » Triggering a cultural change in the research ecosystem that fosters license agreements with existing companies and the creation of new health-based companies.

1.2. Specifically, the Call seeks to support Projects from public or non-profit legal entities in their development of results from scientific research (the "Assets") into further transferability and/or commercialisation stages in which they are able to attract commercial investment (the "Projects"). Therefore, selected Projects will be supported according to their specific necessities, nature, and maturity stage in order to achieve the:

- » Completion or execution of valorisation actions through a defined point-of-value in the development plan, including prototyping, validation or testing with end users;
- » Design and/or completion of a business plan;

- » Design of strategies to access main stakeholders (end users, buyers, distributors, etc.);
- » Establishment of a plan to make the product, technology, or service attractive for investors and potential licensees in the biomedical sector.

2

CaixaResearch *Consolidate* general framework

WHAT?

LCF will fund excellent Projects of proven social relevance and with ground-breaking innovation potential for the creation of services or products in the area of Life, Medical, and Health Sciences.

WHO?

Public or non-profit entities based in Spain or Portugal that own the assets resulting from research activity.

HOW?

The programme offers financial support of up to EUR 300,000 for a maximum of 24 months, as well as ad-hoc non-financial support, reducing existing barriers and facilitating access to training, existing networks, and key expertise.

WHEN?

The Call will be permanently open for applications and a maximum of three cut-offs per year will be established for the review and selection of Projects.

WHY?

To drive the transformation of scientific knowledge into value for society.

Participating in the Call entails the full acceptance of these Rules for Participation, their interpretation lying within the corresponding jury during each stage of the Call.

3.1. Submission of **Projects will be accepted all year round**.

3.2. Cut-off points will be defined based on the volume of applications received and will be notified accordingly. A maximum of three cut-offs per year for the review and selection of proposals will be announced.

3.3. The evaluation process will consist of **two different stages**: 1) The **Pre-selection** of applications based on a Letter of Intent; and 2) The **Selection of proposals** based on a full proposal submitted by pre-selected candidates (**Full Proposal**). Pre-selected Projects will be decided upon within approximately one month from each cut-off, and selected Projects will be announced within a maximum of five months after the cut-off.

3.4. To provide equal opportunities for all projects applying at any time of the year, attention will be put into the homogeneous distribution of the yearly budget allocated for this call throughout that year's cut-offs. However, the final total amount assigned in each cut-off will depend ultimately on the quality of the projects applying as a result of the evaluation process.

3.5. LCF holds the right to modify the scheduling of the Call due to logistical requirements.

Projects

4.1. Eligible Projects must be from the Life Sciences field, following the Life Sciences categorisation of the [European Research Council Peer Review Evaluation Panels](#) for reference.

4.2. Within the scientific areas defined above, the Assets may belong to one of the following **business areas**:

- » Pharmaceuticals and Medical Biotechnology
- » Medical Technologies (medical devices and diagnostics)
- » Digital Health

4.3. The Call is aimed at disruptive Projects in a mature stage of transferability to the market, (e.g., those that may be deemed to have achieved a Technology Readiness Level (TRL) equal to or greater than 4 as defined by the [European Commission](#)). Therefore, **only Projects that have already performed significant valorisation activities, including proof of concept validation, for the research underlying the Asset will be considered eligible**.

4.4. Assets must have IP registration or any other proven protection strategy, including the application of measures to protect trade secrets.

4.5. Projects must provide a clear answer to an existing unmet medical need and comply with the principles of Responsible Research and Innovation.

4.6. Projects must have a clear focus on innovation: Projects are expected to develop a roadmap for the successful transfer of the Asset to the market (Development Roadmap), with specific relevant milestones to advance on this path in the context of the grant. It is required that the teams clearly identify the appropriate valorisation actions and human resources that will lead to that purpose.

4.7. Projects that have not participated in the CaixaResearch Calls are eligible to participate in CaixaResearch *Consolidate* provided that they meet the eligibility requirements and are at the appropriate development stage. In this case, prior participation in acceleration or innovation programmes will be positively valued.

4.8. Projects under *Validate or Consolidate Calls* can apply to the Call as long as the Valorisation Plan of the Assets has been approved by the Programme Office before the application.

Beneficiary

4.9. The Beneficiary will be the entity that owns or co-owns the Assets, whose main activity is located and registered in Spain or Portugal and has submitted the application form in its own name.

4.10. Beneficiaries must be public or non-profit organisations: including universities and university foundations, research centres, technological centres, hospitals, and hospital foundations.

4.11. Projects may be submitted by a consortium of legal entities from any EU Member State, as long as they are led and represented by one of them that shall adopt the role of Beneficiary for the purpose of the Call and that will have to own or co-own the Assets. In case of a consortium, all members of the consortium must abide by the eligibility criteria.

4.12. LCF shall hold the right to declare a Project as non-eligible if the ownership of the assets is not majority-owned by the Beneficiary and/or non-profit institutions (i.e. the Beneficiary, either by itself or together with other non-profit institutions must own more than 50% of each Asset).

Linked Third Party

4.13. In case the Beneficiary had incorporated, before the term of the Grant and as a result of its participation as awardees in *Validate Call*, or incorporates during the term of the Grant (but not before the signature of the Project Agreement), a Spin-off Company, the Beneficiary may declare the Spin-off Company as a Linked Third Party for the execution of the Project. Such a declaration will be made upon application to the Call with regard to

existing Spin-off Companies, or immediately after incorporation, for those incorporated during the Project (in these cases the Engagement Letter duly executed together with an explanation of the impact on the Full Proposal, if any, shall be submitted within one month from the notice of incorporation given to LCF).

4.14. Spin-off Companies that have been incorporated before the signature of the Project Agreement will not be accepted as Linked Third Parties unless the Project had previously participated and been awarded a grant in *Validate Call*.

4.15. The representation of the Linked Third Party for the purposes of the Call will correspond to the Beneficiary. The Beneficiary must ensure that its obligations under the Call also apply to the Linked Third Party. The Beneficiary remains responsible towards LCF for any activities carried out by the Linked Third Party under the Project.

4.16. The Linked Third Party may declare the costs it incurs for developing the Project, provided that any such costs fulfil -mutatis mutandis- the general and specific conditions for eligibility set out in sections 7.1 and 7.3. To prevent any doubt, mutatis mutandis means that (i) costs declared by the Linked Third Party would have to be eligible as if they were incurred by the Beneficiary itself and (ii) no cost inherent to the Spin-off Company's activity and not derived specifically from the execution of the Project will be considered (e.g., company management and governance costs and salaries are not eligible; personnel costs are eligible if they are related to personnel working for and assigned to the Project).

Project Leader

4.17. The Project Leader (PL) must be an individual with tertiary qualifications (university graduate, professor, or doctor).

4.18. The Project Leader is expected to commit to the development of the proposal by being dedicated primarily to the Project.

4.19. Proven experience in technology transfer activities is required and prior participation in acceleration or innovation programs will be positively valued.

4.20. The Project Leader may be the leader of the research Project (i.e., Principal Investigator) that generated the Assets.

4.21. The **Project Leader may be involved in more than one application per call, but may not be Project Leader in more than one.**

4.22. The Project Leader will be provided with sufficient scientific and administrative support by the Beneficiary to ensure the proper management and development of the Project.

5.1. To initiate the submission process, Project Leaders will need to complete the online application forms available on the LCF application platform (<https://grants.lacaixafoundation.org/>) and provide the required documentation. Incomplete applications or those presented on paper or via any other channel may be considered ineligible.

5.2. Applications must be completed in English. LCF reserves the right to request for the translation of official documents into English, when reasonably justified.

5.3. The Project Leader will require the agreement of the Beneficiary to be able to submit the application. This will be done by an online check by the Organization Manager on LCF's call management online system. In case of projects including Co-owners of Assets and/or consortia, all Co-owners and partners will be required to provide their acceptance at the Full Proposal stage through the above-mentioned online system for the submission of the application. All acceptances are required to be made before the deadline for applications.

It is recommended that invitations for acceptance are not sent until the general data and proposal information, and the composition of the consortia (where applicable), are filled in, as changes to this information/composition will require the re-approval of all other members in the proposal.

The Organization Manager will have access to the information of the applications, including without limitation the budget, the composition of the consortium (where applicable), and the evaluation report.

5.4. To accelerate the proposal evaluation process, the application process will entail two steps: the initial submission of a **Letter of Intent**, and the subsequent submission of a **Full Proposal**. **Only pre-selected Projects will be invited to submit a Full Proposal.**

5.5. A template for the Letter of Intent will be available in the call website (<https://fundacionlacaixa.org/en/call-consolidate-programme-description>).

The following information will be requested:

- » General data and proposal information
- » Aim and potential impact
- » Scientific rationale and implementation
- » Development roadmap and market potential

5.6. For pre-selected Projects a template for Full Proposal will be available on the LCF application platform. The following information and documentation will be requested:

- » General information about the Project
- » Project leader and team
- » Implementation and transfer potential
- » Responsible Innovation

- » Resources and budget where applicants shall include the distribution of the budget among the Consortium Partners and Linked Third Parties (if applies).
- » Documentation on valorisation activities (PoC, prototypes, preclinical/clinical assays, etc). Max. 5 pages.
- » Reference/support letters from the TTO office of equivalent institution (if available).
- » Business Plan (if available).
- » Patent or IP strategy information.
- » In case the Beneficiary had incorporated a Spin-off Company: the public deed of incorporation, the technology transfer agreement, a shareholders' engagement letter (including a statement on accepting the Spin-off Company to be declared as a Linked Third Party, if applicable) (the "Engagement Letter"), and any other document that may be deemed necessary for this purpose, upon specific request from LCF (e.g., agreements signed with the Spin-off Company, the shareholders' agreement, an updated statement on the shareholders).
- » Acceptance of the Co-owner of the Assets via the call management online system as explained in paragraph 5.3 above.

5.7. Full Proposal must be consistent with the Letter of Intent. Material or substantial deviations will render the Full Proposal ineligible. In all other cases, LCF reserves the right to exclude a Project from the selection process if the information provided in the Full Proposal shows discrepancy with respect to the information provided in the Letter of Intent.

6

Evaluation Process and Criteria

The evaluation process is composed of two stages: pre-selection and selection. In each stage, eligibility checks will be conducted by the Call Programme Office. All pre-selected applications will be revised to ensure the fulfilment of the criteria published in these Rules for Participation. Any application that does not fulfil the criteria published in these Rules for Participation or that do not have the mandatory documents will be rejected, and notification will be sent to the applicant.

Pre-selection process

6.1. Eligible proposals will be reviewed by innovation experts (internal and external) in four main perspectives. Evaluators will be asked to review the overall quality and feasibility of the Projects, with an emphasis on the criteria governing the review process:

- » Unmet medical need: Projects need to prove the potential impact of their solution in meeting unmet medical needs.
- » Scientific rationale: Projects need to present the technical relevance of the scientific concept underlying the Asset to address the unmet need in the specific therapeutic area.
- » Development Roadmap: Projects will need to ensure their financial feasibility and sustainability through major milestones.

» Business Case: Projects must present their market potential and business strategy to achieve commercialisation stages.

6.2. Applicants will be notified as to whether or not their applications have been short-listed. Pre-selected Projects will be invited to submit a Full Proposal to the next phase of the call.

6.3. If required, LCF may carry out a thorough assessment of the Project by an independent external consultant in order to evaluate specific aspects of the proposal (as intellectual property strategy, regulatory roadmap strategy, etc...), as well as the planned financial and development milestones.

Selection process

6.4. Pre-selected applicants will be invited for an interview with the Innovation Selection Board. The Innovation Selection Board will be composed of experts from different sectors of the innovation and biomedical ecosystem and members from LCF and Caixa Capital Risk (hereinafter, "CCR"). The interviews will be held in English.

6.5. The evaluation will start when members of the Innovation Selection Board receive and review the full proposals. Evaluators can request further information or documentation on the Projects through the Call Programme Office.

6.6. In order to be evaluated, the Project Leader must attend the interview and cannot delegate such participation to a team member.

6.7. The general aim of the interviews is to assess more precisely the quality, consistency, and soundness of the Projects.

6.8. The Innovation Selection Board members will review the Projects and will separately enter the specific comments considering each evaluated criterion. The evaluation criteria dimensions are listed below:

- » Unmet Medical Need: to evaluate to what extent the Asset addresses an unmet medical need, considering the proposed solution to address this need and the impact on the stakeholders involved.
- » Technical Feasibility: to evaluate the scientific rationale behind the Asset, considering the scientific fundamentals underlying the proposal, the current stage of development and the possible technical limitations linked to the development of the Project.
- » Assets' Development Roadmap: to evaluate to what extent the stated actions and milestones contribute to the advancement of the roadmap and how the participation in the Call implies a decisive impetus for the roadmap's advancement.
- » Assets' Business Case: to evaluate the commercial potential of the Asset, considering the correct identification of the market opportunity, the added value in comparison to existing solutions and the proposed Business Model.
- » Team and Implementation: to evaluate the capabilities of the proposed team and commitment of the project leader to successfully lead the Project.

- » Responsible Innovation: to what extent social responsibility is considered in the Project conception, design, development, and outcomes.

6.9. After interviewing all the candidates, the Innovation Selection Board will have the option to further discuss the quality and relevancy of proposals and accordingly propose a final list of prospective participants that can be selected and the suitability of the requested budget.

6.10. The CaixaResearch *Consolidate* Coordination Committee, composed of members from LCF and CCR, will be the body responsible for selecting the final list of funded proposals and the distribution of the allocated budget among them, which will be presented to the governing bodies of LCF.

6.11. All pre-selected applicants will be informed via email on whether or not the proposal was accepted for funding. Rejected proposals will receive an evaluation report to help applicants improve the quality of the Project submitted.

6.12. In case the proposal is improved upon and re-submitted, the Project will undergo the evaluation process under the same conditions as the rest of the proposals. After three unsuccessful attempts, LCF reserves the right to discard the application to the corresponding three next cut-offs of the Call.

6.13. LCF holds the right to declare the call void and not to award any grant in case the projects does not reach sufficient quality and/or relevancy or due to other considerations in terms of pertinence, adequacy, timing, etc. at LCF's discretion as promoter of the Call.

Complementary documentation for awarded Projects

6.14. The Projects that receive the Valorisation Grant shall be required to submit the following complementary documentation **before the signature of the Project Agreement** (as defined in clause 7.4):

- » Keep and make available to LCF all documentation required in order to comply with the provisions outlined in regulations on preventing money laundering and financing terrorism, which includes:
 - / Legal documents proving that the legal representative is entitled to act on behalf of the organization and copy of his/her ID, passport, residence permit or ID valid in the country of origin including a photograph.
 - / Copy of the deeds evidencing the name, legal form, address and legal purpose of the Organization
 - / Beneficial owner deed or certificate executed by the legal representative of the Organization including the full name, National Identity Card Number (DNI) and, optionally the positions, of the persons who directly or indirectly hold more than 25% of the voting rights of the Organization. If no one holds more than 25% of the voting rights, the full name, National Identity Card Number (DNI) and, optionally the position,

of all the members of the Executive Board (for associations), members of the Board of Trustees (for foundations) and directors or members of the organization's governing body must be specified.

Regarding Consortium Partners, information detailing the members of the governing bodies may be required. The Organization Manager will be responsible for uploading such information in the system in the name of all Consortium Partners.

Complementary information and/or documentation may be required, especially for those organizations located in high risk countries pursuant to the list of high risk third countries identified by the European Commission at any given time and/or equivalent lists.

Checks against the international lists of sanctioned persons will be performed on the basis of international economic and financial sanctions imposed by the United Nations, the European Union, Spain and/or the U.S. Department of the Treasury's Office of Foreign Assets Control ("**Sanctions**").

Award of the Valorisation Grant and signature of the Project Agreement will be subject to successful verification of the requirements applicable in the field of prevention of money laundering and financing terrorism including successful verification via the above-mentioned checks against the list of sanctioned persons. This is mandatory for receiving the Grant throughout the whole term of the Agreement.

- » Certificate from the Spanish Tax Agency or the equivalent tax authority that certifies that the Beneficiary fulfils its tax obligations.
- » Certificate of the Spanish Social Security or the equivalent authority that certifies that the Beneficiary fulfils its obligations in accordance with current labour regulations.

7

Support to Projects

CaixaResearch *Consolidate Call* will offer the following resources to the selected Projects:

Financial resources

7.1. A grant of up to EUR 300,000 for 24 months (the "Grant"). LCF may consider, by way of exception, a Grant amount above this limit, subject to availability of funds made available for the Call and the specific needs of the Project.

7.2. The Grant may cover expenses such as:

- » Technological development of the Asset.
- » Consulting, feasibility, and market study services.
- » Evaluation studies needed for regulatory approval.
- » Hiring of personnel destined to the development of the Project.
- » Management of intellectual property strategies.

- » Overhead expenses up to a maximum of 10% of the total budget.
- » Travel or representation expenses.

7.3. Costs derived from concepts that are not directly related to the Project's milestones or that do not directly contribute to the successful development of the Asset will not be accepted.

7.4. Payments will be made in various instalments, in accordance with the payment plan defined for each Project. Selected Projects will sign an agreement with LCF that will be prepared in collaboration with the Project Leader and that will define the payment, follow up, reporting, and reimbursement terms and conditions (the "**Project Agreement**").

7.5. A rigorous follow-up system will be implemented to assure the accomplishment of the valorisation actions and the achievement of proposed milestones. The financial support payments will be linked directly to this follow-up system.

7.6. The funds pertaining to the Project will be transferred to the Beneficiary. In case of consortia and/or the participation of Linked Third Parties, the Beneficiary will be responsible for distributing the funds as specified in the Project Agreement.

7.7. The Beneficiary will also be responsible for justifying the costs incurred by all Consortium Members and Linked Third Parties, as well as those costs derived from subcontracting, if applicable.

Non-financial

7.8. Each Project will be assigned a Project Manager from LCF or selected third entity who will permanently and closely monitor the Project development.

7.9. If requested by the Beneficiary, LCF may assign a mentor to the Project.

7.10. Additionally, each Project will have the possibility to rely on LCF or an affiliated entity for additional non-financial support, which may include the following activities:

- » Access to the experts' network to receive support in specific aspects (IP, business administration, etc.).
- » Training for specific valorisation and business abilities.
- » Guide and support from a panel of experts involved in the Programme.
- » Other justifiable actions will be considered upon request.

The Project Agreement will set up the KPIs (key performance indicators), the payments and the frequency of the follow-up meetings. The specific needs of each Project will be taken into account when negotiating the agreement.

8.1. Follow-up of Projects

- » For any paperwork or consultation throughout the duration of the Grant, the Project Leader may contact the LCF Project Manager (hereinafter "LCF Project Manager") or LCF.
- » LCF will provide a username and password to access the follow-up platform. The details of the Grant awarded will be kept up-to-date, and any action carried out with the funding of the Grant awarded must be reported even after the period of validity for the funds of the grant has ended.
- » The LCF Project Manager will request that the Project Leader schedules regular follow-up meetings which include the prior submission of:
 - An economic report. The incorrect justification of expenses might delay further financial support.
 - A report on the achieved milestones detailed in the agreement signed between the Beneficiary and LCF. Delays or alterations to the work plan will be carefully evaluated by the Project Manager and may impact the payment plan or lead to early termination of the Project Agreement in case of material and/or unjustified alterations.

8.2. Key performance indicators (KPIs)

Mid-term payments will be contingent upon the achievement of personalized KPIs and milestones that will be defined in detail in the agreement signed between the Beneficiary and LCF.

B. General Annex

9

IP Rights, Protection and Maintenance of the Assets

9.1. IP Rights

Under no circumstances will the Call be construed as an assignment or transfer of any industrial and/or intellectual property right held or owned by the Beneficiary prior to the Project or of any other industrial and/or intellectual property right obtained as a result of the development of the Project.

At the time of application to this Call and at least until the award of the Grant, all intellectual and/or industrial property rights over the Assets shall be owned by the Beneficiary and, where appropriate, the Co-owner(s). To prevent any doubt, this requirement shall be deemed to be met in the case of a transfer of the assets by means of a license of use and exploitation to a Spin-off Company as referred to in above.

9.2. Protection and maintenance of the Assets

The Beneficiary and, where appropriate, the Co-owner(s) of the Assets (and/or, if appropriate, the transferee of the Asset/s, except where indicated otherwise) will make their best efforts to protect and maintain the Assets by taking on the following actions:

- » Monitor the application proceedings for the grant of intellectual and industrial property rights, as well as keep and maintain the rights granted on the Assets within the necessary or recommended national authorities.
- » In the event of the Assets not being suitable for protection under intellectual or industrial property rights, to keep the Assets under reasonable trade secret protection measures.
- » In the event of the Assets being transferred by means of a license, hold a subsidiary right for the defence and protection of the rights protecting the Assets, in case of inactivity of the licensee:
 - if there is a breach or alleged breach of the rights protecting the Assets by third parties (the "Third Party Breach"); and/or
 - when a third party has filed a claim for an alleged breach of a prior right (the "Third Party Claim").
- » Such right for defence and protection of the rights protecting the Assets shall consist of the following:
 - to immediately inform the other parties of such Third-Party Breach or Third-Party Claim, identifying the known facts as well as the details of the individual or legal person that has committed said Third Party Breach or attaching a copy of the Third-Party Claim and identifying any other known facts;
 - to request and subsequently deliver to LCF, in due time and form, the relevant reports on the viability and appropriateness of (a) carrying out any legal actions, notices, legal proceedings, and/or any procedures that are applicable in the relevant jurisdiction in order to defend its interests, in the case of a Third Party Breach; and (b) the legal actions to be taken in the relevant jurisdiction in order to defend its interests in the case of a Third Party Claim; and
 - to take on, as the case may be, the organisation and management of the proceedings and disburse any applicable costs and fees within the exercise of its rights in the case of the Third-Party Breach or its rights for the defence against the Third-Party Claim.

10

Exploitation

10.1. The Beneficiary may exploit the Assets as follows:

- » Direct exploitation: direct exploitation of the Assets by the Beneficiary; or
- » Exploitation by transfer of the Assets to a third party or by means of a license of use and exploitation; or
- » Exploitation by means of an incorporation or participation as a shareholder of a Spin-off Company and the transfer of the Assets to such Spin-off Company by means of a license of use and exploitation.

10.2. The exploitation of the Assets shall be made in market conditions and will ensure the adequate diffusion and social return.

10.3. The Beneficiary will communicate in advance to LCF the proposed terms and conditions for the exploitation of the Assets. LCF will have the right to oppose such exploitation in the event it is not carried out in market conditions or the dissemination and social return is not guaranteed through the exploitation.

In case one or more of the indicators established in these Rules for Participation are achieved, LCF will be entitled to the reimbursement of the awarded Grant in accordance with the reimbursement procedure detailed below and subject to the specific term and conditions of the Project Agreement. The reimbursed money will be reinvested in LCF's research and innovation programmes.

11.1. Indicators

- » **Recurring Payment:** Any payment obtained by the Beneficiary from the exploitation of the Assets by means of (i) direct exploitation by the Beneficiary; or (ii) royalties derived from exploitation by a Spin-off Company or a third-party licensee; or (iii) dividends obtained from the shares owned by the Beneficiary in the Spin-off Company or a third-party transferee. To prevent doubt, Recurring Payment excludes any Lump-sum payment described below.
- » **Lump-sum payment:** (i) The sale by the Beneficiary of the shares owned in the Spin-off Company or a third-party transferee; or (ii) the assignment by the Beneficiary of the Asset resulting from the Project.

11.2. Reimbursement protocol

The following payments will be due by Beneficiary to LCF until the full reimbursement of the Grant in each of the cases described below. To prevent doubt, the amount to be reimbursed shall not accrue interest between the award of the Grant and the full reimbursement.

- » **Recurring Payment:** An amount equal to five per cent (5%) of any Recurring Payment received by the Beneficiary as described in Section 11.1 above.
- » **Lump-sum payment for the sale of shares by the Beneficiary:** the amounts defined below in the event of the sale of the Beneficiary's shares in the Spin-off Company or an entity that exploits the Asset/s:
 - If the sale price of the shares of the Beneficiary is equal to or exceeds five (5) times the awarded Grant, the whole amount of the Grant shall be reimbursed to LCF.
 - If the sale price of the shares of the Beneficiary is less than five (5) times the awarded Grant, the Beneficiary will reimburse the amount of the Grant in proportion to the ratio between the sale price of the shares of the Beneficiary and five (5) times the awarded Grant.
 - The reimbursement shall be paid in one instalment within two (2) years from the sale of the shares of the Beneficiary.
- » **Lump-sum payment for the transfer of the Asset by the Beneficiary:** The Beneficiary will reimburse to LCF any lump-sum payment for the transfer of the Asset(s) up to the whole amount of the Grant, less any payment made by the Beneficiary as a result of any recurring payment or sale of shares as referred to above.
 - The reimbursement shall be paid in one instalment within two (2) years from the transfer of the Asset by the Beneficiary.

- » Alternatively, and at LCF's choice, the amount due as reimbursement of the Grant may be capitalized by LCF in shares of the Spin-off Company.

In the event that the exploitation of the Asset(s) did not occur under any of the above-mentioned models, the parties will do their best efforts to agree on an equivalent reimbursement protocol.

11.3. Reimbursement term

LCF's right to the reimbursement of the awarded Grant as provided above will terminate after twenty (20) years from the signing of the Project Agreement provided that, if the reimbursement had started during the last four (4) years of the referred term, the right will continue in force for an additional term of five (5) years from the first reimbursement.

Non-reimbursement

11.4. The obligation to reimburse the Grant shall not apply when the owners of the Asset/s can prove, to the entire satisfaction of LCF, the impossibility and/or inability to exploit the Asset/s due to circumstances beyond their control during the period of protection of the rights over the Asset/s.

Compatibility with *Validate Call*

11.5. Should the Project (or a derivation thereof) were included in an application to *Validate Call* (or past editions of *CaixaImpulse*) and became awarded under such Call, the Parties hereby declare and acknowledge that (i) the rules for participation of any such former *CaixaImpulse Call* will not supersede or modify in any way these Rules for Participation or any agreement signed as a consequence thereof; and (ii) these Rules for Participation will not supersede or modify in any way the rules for participation of the former edition of *CaixaImpulse Call* or any agreement signed as a consequence thereof. Therefore, the terms and conditions established therein shall remain fully in force.

11.6. In the event that the same event or indicator creates an obligation for the Beneficiary to reimburse LCF for both *Validate Call* (or former editions of *CaixaImpulse*) and for this Call, the reimbursements corresponding to both calls shall be accumulated so that the Beneficiary jointly reimburses the amounts corresponding to both calls. For the sake of clarity, the free-of-charge right to subscribe up to the 1% of the shares of the Spin-off Company shall not accumulate in terms of percentage; i.e. the right will exist under both calls but up to a maximum of 1% of shares.

11.7. Potential applicants should not apply at the same time to this Call and to *Validate Call*. Should that happen, the proposal will be excluded from *Validate Call* and only the proposal submitted to this Call will continue its course.

11.8. Potential applicants are informed that should they apply to this Call and become awarded under it, they will not be allowed to apply to *Validate Call*.

12

Subscription Right

12.1. If the exploitation of the Assets is to be carried out by means of a Spin-off Company as provided in 10.1 above, LCF or any entity within the Criteria Group, at the discretion of the Criteria Group, shall have the free-of-charge right to subscribe shares of the Spin-off Company, in accordance with the following:

- » If the Spin-off Company (i) has not been incorporated at the time of signature of the Project Agreement, or (ii) has been incorporated, but has not been transferred the Assets as of the time of signature of the Project Agreement, LCF or any entity within the Criteria Group, at the discretion of the Criteria Group, shall have the free-of-charge right to subscribe, at nominal value, 1% of the shares of the Spin-off Company, (a) upon its incorporation, or (b) within three months from the signature of the Project Agreement, or (c) within one month from the transfer of the Assets, whichever is later.
- » If the Spin-off Company has been incorporated and has already transferred the Assets as of the time of signature of the Project Agreement, LCF or any entity within the Criteria Group, at the discretion of the Criteria Group, shall have the free-of-charge right to subscribe 1% of the shares of the Company at nominal value, within three (3) months from the signature of the Project Agreement.
- » The Beneficiary shall notify FBLC of the incorporation of the Spin-Off Company and/or the transfer of the Assets with a minimum anticipation of two (2) months to allow LCF or the Criteria Group to exercise the subscription right established in this clause. Otherwise, the three-month term referred to above shall commence as from the time the Criteria Group has knowledge of any such situation.

12.2. The Beneficiary shall ensure that the Spin-off Company and its shareholders are first aware of, and expressly accept, the rights granted to LCF or any entity within the Criteria Group in accordance to the foregoing and adhere, where applicable, to the obligations derived from these Rules for Participation, which shall be included in the terms of the Engagement Letter as described in 5.6 above. This provision shall also be deemed to apply to the reimbursement described in Clause 11 above, where applicable.

13

Other Obligations

13.1. Obligations of the Beneficiary

Within the framework of the Call, and without prejudice to any other obligations set forth in these Rules for Participation, the Beneficiary will:

- » Sign the Project Agreement.

- » Exploit the Assets in market conditions. In case the exploitation of the Assets is not carried out in market conditions, LCF will have a right to veto such exploitation.
- » Refrain from entering into any agreements and/or undertaking any exploitations of the Assets and/or taking any other actions or inactions which may hinder or prevent the compliance with these Rules for Participation by the Beneficiary, the Co-Owner(s) of the Assets (if applicable), and their successors and assignees, including, but not limited to, any actions or inactions which would be incompatible with honouring LCF's reimbursement rights and LCF's participation rights.
- » Keep LCF informed about any exploitation of the Assets and provide LCF with any information and documentation needed so as to enable LCF to exercise its reimbursement rights and/or monitor the reimbursement, including, but not limited to, a copy of the Assets' transfer agreements entered into with third parties and any accounting and supporting documents which may be reasonably requested by LCF for the aforementioned purpose (e.g., account books, details on royalties or other payments made by transferees, turnover and net sales information, etc.).
- » Keep LCF informed in case the exploitation of the Assets is to be carried out by a Spin-off Company or a third-party and provide LCF with any information and documentation needed so as to enable LCF to exercise its rights to reimbursement as provided in Section 11 above.
- » Use the entire amount of the Grant to develop the Project, in accordance with these Rules for Participation.
- » Manage the funds that LCF allocates for the grant and be responsible for the distribution of the budget to the Consortium Partners, where applicable.
- » At the request of LCF, provide an audit report and/or statement, as well as any additional information, documentation and/or clarification that LCF may deem pertinent to allow its auditors and/or advisors to evaluate the correct allocation of the grants awarded. The cost of this audit report and/or statement will be paid by LCF, subject to prior approval of the corresponding budget, unless irregularities are detected as a result of it, in which case the Beneficiary would bear the cost. Any such request may take place at any time.
- » Manage the Project with due diligence, monitor the task carried out by the Project Leader and his/her team, and inform LCF on the progress and results achieved by the Project.
- » Observe and comply with the justification of expenses submitted within the execution of the Project.
- » Assume the social and ethical implications of the Project in accordance with the research personnel's ethical code, also taking into account the gender dimension.
- » Indicate the support received from CaixaResearch through materials, publications, and dissemination activities developed within the framework of the Project.
- » Prepare regular financial and milestones reports reflecting the development of the Project and attend an annual follow-up meeting with its LCF Project manager.
- » After the execution of the Project, deliver the final report to LCF.
- » Provide any information that LCF may require in order to promote, publish, and/or disseminate the CaixaResearch Programme, in particular those transactions that, as a result of their nature, may be subject to coverage by the media, and consequently give coverage to the Beneficiaries' results and/or the results achieved by any of its participants, e.g., research and development activities, marketing, transaction and turnover results, securing investments, whether through their own resources (share

capital or reserves) or transfer of shares, participations, securities, or rights to purchase and subscribe shares, participations, or securities, etc. Without prejudice to the foregoing, the information provided as a result of the obligation described herein may be treated as confidential upon express request from the Beneficiary.

- » Report additional funding raised for the Project from third parties in follow-up reports provided to LCF.

13.2. Obligations of the Project Leader

Within the framework of the Call, the Project Leader will abide by the following obligations, without prejudice to any other obligations set forth in these Rules for Participation:

- » Respect and comply with all obligations and duties pursuant to these Rules for Participation.
- » Use the entire amount of the grant to execute the Project, always in accordance with these Rules for Participation.

14

Representations and Warranties

14.1. The Beneficiary represents and warrants that it is an entity that has been incorporated and lawfully exists in accordance with the laws of Spain and Portugal and is duly authorised to apply for this Call and carry out the obligations set out in these Rules for Participation.

14.2. The Beneficiary and the Project Leader represent and warrant that:

- » these Rules for Participation are legal and valid obligations which bind them and are enforceable in all of their terms and conditions.
- » the application, execution, and compliance with these Rules for Participation do not contravene any contract, documents, or agreements, verbal or written, to which they are party or to which they are bound, nor do they infringe upon any laws or regulations of any courts, governmental or administrative entities, or any other body that may have jurisdiction over them.

15

Breach and Liability

15.1. Breach

- » In the event of a remediable breach by the Beneficiary and/or the Project Leader of the obligations and/or representations and warranties contained in these Rules for Participation, LCF shall notify the breaching party, requesting that the latter correct the infringement within a maximum period of thirty (30) days following the receipt of such notification.
- » If after the aforementioned 30-day period no remedy had been provided, LCF will be entitled to choose between demanding forced compliance or terminating these Rules

for Participation, and LCF will have the right, in both cases, to claim for the corresponding compensation for the damages caused by the infringement.

- » Notwithstanding the foregoing, if LCF resolved that the Beneficiary had not used the Grant in accordance with the specified purposes provided in these Rules for Participation, the Beneficiary shall be obliged to return the Grant in full, without prejudice to compensation for damages to which LCF could be entitled. Likewise, if the justification of expenses of the Project were less than the amount of the Grant awarded, the Beneficiary shall be obligated to reimburse the amount corresponding to the part of the Grant not justified.

15.2. Liability

The Beneficiary and the Project Leader will hold LCF and any entity of the Criteria Group harmless in relation to any costs, damages, and/or expenses (including reasonable legal fees) that may result from the breach or defective compliance of their obligations under these Rules for Participation. Notwithstanding the above, the Beneficiary will be solely responsible before the Project Leader and LCF and CCR for any costs, damages, and/or expenses (including reasonable legal fees) resulting from the breach of the Beneficiary's obligation to use the amount of the Grant.

16

Duration

16.1. The rights and obligations set out in these Rules for Participation shall start on the date the Beneficiary accepts and adheres thereto, which shall be formalised through the execution of the Acceptance Letter (the "**Effective Date**").

16.2. The rights and obligations set out in these Rules for Participation shall terminate once any of the following events occur:

- » Mutual written agreement between LCF and the Beneficiary.
- » Failure to comply with the duties regarding protection and maintenance of the Assets, as provided in Section 9 above, effective upon LCF's notice of non-compliance, which may be remedied within the time frame provided upon LCF's discretion.
- » Reimbursement of the Grant to LCF, when applicable.
- » Sufficient evidence, to the entire satisfaction of LCF, of the following:
 - failure to implement the Project within the 3-year term granted to that end, unless such failure is attributable to the Beneficiary, in which case Section 15.1 of these Rules for Participation shall apply; and/or
 - failure to implement the Project, including, without limitation, the exploitation of the Assets, unless such failure is attributable to the Beneficiary, in which case Section 15.1 of these Annexes to the Rules for Participation shall apply.

16.3. Without prejudice to the above, the following sections shall be valid for twenty-five (25) years following the termination of the Rules for Participation: 9.1 (Intellectual and industrial property rights), 9.2 (Protection and maintenance of the Assets), 10 (Exploitation), 11 (Reimbursement), 17 (Confidentiality), 18 (Data Protection), 19 (Publicity and Dissemination) and 20 (Miscellaneous).

17.1. The confidentiality of the applications presented is guaranteed throughout the entire process. In any case, the general characteristics of the applications may be disseminated and, in due course, the name of accepted Projects (and logo, if applicable), a brief description, the Beneficiary and its logo, the name of the Project Leader and his/her photo, may be published through, without limitation, press releases, emails, brochures, and websites to communicate information about the Call.

17.2. The information content and the results of the Project, as well as any other information and documentation exchanged within the framework (including information and documentation regarding other Project participants) of the Call shall be considered confidential information (the "**Confidential Information**").

17.3. LCF, the Beneficiary, and the Project Leader, as well as any other person attending the activities, shall undertake, unless prior authorisation in writing is received from the other parties, to:

- » keep the Confidential Information strictly confidential and not to disclose it to any Third Parties;
- » not use the Confidential Information for any purpose other than the development of the Project;
- » restrict access to the Confidential Information exclusively to those employees, collaborators, and/or professional advisers that, under the obligation of confidentiality, need to access the Confidential Information strictly for the development of the Project; and
- » return the Confidential Information without keeping any copies or summaries when the Programme is terminated.

17.4. The confidentiality obligations described in the section above shall not be applied to the Confidential Information if:

- » the information is in the public domain before or at the moment at which it is received or obtained, and it is in the public domain by no fault or negligence of the receiving party;
- » the information is obtained without being subject to any confidentiality obligation; and
- » the disclosure of the information is required by law or judicial order, in which case said disclosure request must be previously notified, in advance, to the other party, so that the latter can implement the actions it considers necessary to prevent or limit the disclosure.

17.5. The obligations and commitments set in this section shall extend to information to which the Parties have had access as a result of their participation in the activities and events carried out within the framework of the Call, including, but not limited to, the activities and events offered under LCF mentoring and expert advice programmes.

18.1. The applicants authorize LCF to access, use, and share information from the Projects submitted to the Call, including any and all documents referred to therein, whether submitted at the time of the application or at a later stage, for the purposes of this Call and to the extent necessary, including, but not limited to, the evaluation, selection, and monitoring of the Projects. The applicants warrant to LCF that such information and documentation can be shared and used for these purposes.

18.2. With regard to identifying and/or professional information of individuals linked to the Projects (including the Project Leader, other team members, and representatives), the applicant organizations, when submitting the Proposals, warrant having informed those persons on the information indicated in the sub-section below and, where applicable, having obtained the necessary consent of those persons for their inclusion in the applications submitted to this call. Any and all personal data collected within the framework of this Call (including data submitted in the applications) will be processed for the purpose of managing the participation of the applicant organizations in it, the basis of such processing being the performance of the resulting relationship, and such data will be stored until the end of the applicable statutory limitation periods.

18.3. Personal data will be communicated only if needed to comply with legal obligations. LCF hires service providers located outside of the European Economic Space, with all guarantees required by applicable regulations. The data subjects can ask for more information and/or exercise their rights of access, rectification, erasure, restriction, portability, and objection before the Data Protection Officer of the "la Caixa" Foundation at Avinguda Diagonal 621–629, 08028 Barcelona, Spain, or at the e-mail address dpd@fundacionlacaixa.org. Data subjects are also entitled to lodge a complaint before the Spanish Data Protection Agency.

19.1. Publicity

LCF will be entitled to disclose the results of the Beneficiary's Project where relevant, in international, national, and/or regional media considered to be the most suitable and on all those platforms where examples of excellence and good practice in the area of innovation are required. For this purpose, the general characteristics of the applications may be disseminated and, in due course, the name of the accepted Project, a brief description, the Beneficiary, and the name of the Project Leader may be published through, without limitation, press releases, emails, brochures, and websites. To prevent doubt, LCF will not be required in any case to pay any compensation to Beneficiaries for the dissemination and publication of the results of the Projects.

19.2. Dissemination

The Beneficiary shall promote the maximum dissemination of the Grant, subject to a previous agreement with the LCF through the LCF Project Manager:

- » The Project Leader and the Beneficiary shall, in due course, provide LCF with information regarding communication and dissemination actions, materials, events, and activities that they develop in relation to the Project during their participation in the Call, so that they may be duly notified and/or represented and can request changes and/or approve of brands and logotypes.
- » The responsible party shall make reference to the Grant awarded by LCF (reference, CODE, and logo whenever possible) in any actions, results and communication and dissemination materials which are carried out in relation to the Project and the Grant (e.g., e-mails, letters, brochures, posters, advertisements, graphic material, pamphlets, apps, social networks, publications, reports, patents, licenses, scientific articles, etc.) and also in any acts and activities which are organised or in which the winner participates in relation with the Project (e.g., workshops, courses, interviews, press releases, Project, and/or results presentations, scientific congresses, etc. and all support material).
- » The correct reference is "The project leading to these results has received funding and support from the "la Caixa" Foundation under the Grant < code reference>". LCF will provide the specific code reference for each Project.
- » The LCF's online channels to link to or mention are:
 - Twitter: @FundlaCaixa and/or @CaixaResearch (<https://twitter.com/CaixaResearch>, <https://twitter.com/FundlaCaixa>)
 - Instagram: @fundlacaixa
 - Facebook: @CaixaResearch
 - LinkedIn: Fundación Bancaria "la Caixa"

Any dissemination of the results of the Project shall indicate that such dissemination only reflects the author's view and that LCF is not responsible for any use that may be made of the information that it contains.

20.1. Assignment

The Beneficiary may not assign, subrogate, or delegate, totally or partially, the rights derived from the Grant without the prior written consent of LCF.

20.2. Business ethics

The Beneficiary and the Project Leader shall be responsible for ensuring strict compliance with the regulations that are applicable to the activities carried out while developing the Project, undertaking to expressly indemnify and hold LCF harmless in the event of a claim.

In the fulfilment of its obligations by virtue of these Rules for Participation, the Beneficiary, including their employees and representatives, and the Project Leader shall carry out their activity in accordance with business ethics principles and in accordance with all applicable laws in Spain, in particular with national anti-corruption regulations (Criminal Code), the European Union, the OECD, and the European Council, and which may be applied to said activities.

20.3. Applicable Law and Jurisdiction

These Rules for Participation shall be governed by the laws of Spain.

Any controversy or dispute that may arise with regards to the interpretation or execution of these Rules for Participation shall be submitted to the exclusive jurisdiction of the Courts of the City of Barcelona. The Beneficiary and the Project Leader hereby waive any other jurisdiction to which they may be entitled.

Participation in the CaixaResearch *Consolidate* Call and the execution of the Acceptance Letter entail the full acceptance of these Rules for Participation and the adherence to all terms and conditions included herein, their interpretation lying within the corresponding jury during each stage of the Call. Failure to meet deadlines or procedures established in these Rules for Participation will entail the disqualification of the participants from the Call.

Additional Information

LCF CaixaResearch *Consolidate* Call website contains structured and additional information to this Rules for Participation (<https://fundacionlacaixa.org/en/innovation-consolidate-call>).

Applicants may also find a FAQ section and directly contact LCF for further queries by using the following contacts:

- » Questions and answers:
ci_info@fundaciolacaixa.org

Glossary

- » **Assets:** results from scientific research and/or innovation activities.
- » **Beneficiary:** the entity that owns or co-owns the Assets and whose main activity must be located and registered in Spain or Portugal. The Beneficiary will be responsible for submitting the application form.
- » **Innovation Programme:** the Programme launched by LCF, articulated in two schemes, *Validate* and *Consolidate*, and which aims to provide support to different stages of the biomedical knowledge and technology transfer process, from basic research and innovation centres to the market, hence contributing to the progress of the well-being of people and society.
- » **Co-owner:** any legal or natural person that co-owns the Asset(s) jointly with the Beneficiary and, as the case may be, other co-owners.
- » **Consortium Partner:** a member of a consortium in Projects in consortium according to Section 4.11.
- » **Grant:** the grant to be awarded to each Project under the Call for up to EUR 300,000 for 24 months from the signing of the Project Agreement.
- » **Engagement Letter:** the letter to be signed by the shareholders of the Spin-off Company whereby they declare their acknowledgement and acceptance of the Rules, the application made by the Beneficiary to the Call, and the statement on accepting the Spin-off Company to be declared as a Linked Third Party, if applicable.
- » **IP Rights:** industrial and/or intellectual property rights held or owned by the Beneficiary prior to the Project or of any other industrial and/or intellectual property rights obtained as a result of the development of the Project.
- » **Linked Third Party:** the Spin-off Company, if declared as such by the Beneficiary in accordance with Section 4.13. A company incorporated before the signature of the Project Agreement will not be accepted as Linked Third Party unless the Project has

previously participated and has been awarded a grant in *Validate Call (former CaixaImpulse Validate)*.

- » **Organization Manager:** person appointed by the Beneficiary (or by the Consortium Partners) to represent it, upload and manage its supporting documentation, and accept the submission of Proposals on its behalf on the LCF calls management online system.
- » **Project:** projects in a mature stage of transferability to the market (e.g., those that may be deemed to have achieved a Technology Readiness Level (TRL) which have performed significant valorisation activities of their research, from public or non-profit legal entities in their development of Assets into further transferability and/or commercialisation stages in which they are able to attract commercial investment.
- » **Project Agreement:** the agreement to be entered into between LCF and the Beneficiary for the development of the Project receiving the Grant, under which they will define the payment, follow-up, reporting, and reimbursement of specific terms and conditions, among other things.
- » **Recurring Payment:** for the purposes of the reimbursement of the Grant, includes any gross amount received by the Beneficiary as payment of (i) direct exploitation of the Assets by the Beneficiary; or (ii) royalties derived from the exploitation of the Assets by a Spin-off Company or a third-party licensee; or (iii) dividends obtained from the shares owned by the Beneficiary in the Spin-off Company.
- » **Spin-off Company:** the company whose purpose is the development of the Project and/or exploitation of the Asset. A company incorporated by the Beneficiary before the application to the Call may be considered a Spin-off Company only if it had been incorporated within the eighteen (18) months preceding the application to the Call. For the purposes provided in these Rules for Participation, (i) the Spin-off Company may include third parties as shareholders and (ii) a company in which the Beneficiary held more than 50% of the share capital will not be considered as a Spin-off Company.
- » **Transfer:** shall mean either the licensing of IP Rights on the Assets to a third party as provided in Section 10.1 or the assignment of the Assets as provided in Sections 11.1 and 20.1.