



Rules for Participation

**CAIXAIMPULSE CONSOLIDATE
2019**



"la Caixa" Foundation

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Executive Summary

The “la Caixa” Banking Foundation (hereinafter, “LCBF”) launched its CaixaImpulse Programme in 2015. Its first initiative, the CaixaImpulse 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 groundbreaking research meet societal needs, **LCBF is extending its CaixaImpulse Funding Scheme in response to existing needs** in the biomedicine innovation ecosystem.

To this end, the CaixaImpulse *Consolidate* Call (hereinafter, the “Call”) is born as a new line of the **CaixaImpulse** programme with Caixa Capital Risc as a strategic collaborator. The CaixaImpulse *Consolidate* Call wishes to **support society-relevant 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 a Technology Readiness Level (TRL) of 4 or greater (in contrast to the TRL 1 to 4 expected for Projects applying to the CaixaImpulse Call). This Call will offer financial and non-financial support to bring the Assets 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 a Project’s needs, the Call **will be permanently open** (with a maximum of 3 cut-offs per year). The evaluation process will be comprised of 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) Implementation feasibility, (b) Appropriate development roadmap, (c) Transfer potential of the Asset, and (d) Social Impact and Responsible Innovation.

The Call will provide financial support of up to EUR 300,000 for a maximum of 24 months. Once the Projects achieve specific key performance indicators (KPIs), financial support will be reimbursed to LCBF to ensure the sustainability of the programme. In addition, the non-financial and *ad-hoc* needs of each Project will be considered.



Preamble

The “la Caixa” Banking Foundation is supporting the Iberian biomedical research ecosystem through a range of grants and funding programmes. Moreover, **LCBF’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 CaixaImpulse Programme was created in 2015. Currently, it is articulated into **two schemes, CaixaImpulse Validate and CaixaImpulse Consolidate, 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 CaixaImpulse Consolidate, LCBF 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 groundbreaking 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 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

CaixaImpulse *Consolidate* general framework

WHAT?

LCBF will fund excellent Projects of proven social relevance and with groundbreaking 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

General calendar

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

3.2. Cut-off moments 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 as described in Clause 5.5 (**Full Proposal**). Pre-selected Projects will be decided upon within approximately one month after each cut-off, and selected Projects will be announced within a maximum of **three** 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. LCBF holds the right to modify the scheduling of the Call due to logistical requirements.

4

Eligibility Criteria and Requirements

Projects

- 4.1. Eligible Projects have to fall into the scientific area of Life, Medical, and Health Sciences:
- » **Life Sciences:** Biomathematics, Cell Biology, Human Biology, Biochemistry and Molecular Biology, Human Physiology, Genetics, Immunology, Microbiology, and Neurosciences.
 - » **Medical and Health Sciences:** Clinical Sciences, Epidemiology, Medical Specialities, Nutritional Sciences, Pathology, Pharmacodynamics, Pharmacology, Preventive Medicine, Psychiatry, Public Health, Surgery, and Toxicology.
- 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 research 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 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 seek a clear social impact and answer an existing societal medical need**. Projects that do not define a relevant potential social impact are not eligible.
- 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 evaluate the efficacy or safety of products, therapies, medical devices, or diagnostic systems needed for the regulatory approval of the asset are eligible.
- 4.8. Projects that have not participated in the CaixaImpulse Programme are eligible to participate in CaixaImpulse *Consolidate* provided they meet the eligibility requirements and are at the appropriate TRL stage.

4.9. Projects under the CaixaImpulse Programme can apply to the Call as long as the Valorisation Plan of the Assets has been approved by the Programme Office before the application.

4.10. Projects that evaluate the efficacy or safety of products, therapies, medical devices, or diagnostic systems of for-profit organizations are not eligible for this Call.

Beneficiary

4.11. The **Beneficiary is 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.

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

4.13. Projects may be submitted by a consortium of legal entities from all EU Member States, as long as they are led and represented by the Beneficiary, which owns or co-owns the Assets. In case of a consortium, all stakeholders must abide by the eligibility criteria.

Linked Third Party

4.14. In case the Beneficiary had incorporated, or incorporates during the term of the Grant, 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 LCBF).

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 LCBF 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.** The **Project Leader may or may not be the leader of the research Project** (i.e., Principal Investigator) that generated the Assets.
- 4.20.** The **Project Leader may be involved in more than one application, but can be Project Leader in only one.**
- 4.21.** 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. The Beneficiary will inform LCBF about the link with the Project Leader.

5

Application Process

- 5.1.** To initiate the submission process, Project Leaders will need to complete the online application forms available on the LCBF application platform (www.CaixaImpulse.com) 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.** LCBF reserves the right to request for the translation of official documents into English, when reasonably justified.
- 5.3.** 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.**
- 5.4.** A template for the Letter of Intent will be available on the LCBF application platform. The following information and documentation will be requested:
- » General information and Project description
 - » Team and Scientific and technical feasibility
 - » Transferability and market potential
 - » Social relevance and potential impact
 - » Letter from the Beneficiary informing about the link with the Project Leader and its commitment with regards to the Project.
- 5.5.** For pre-selected Projects invited to submit a Full Proposal in the electronic platform, the following additional documentation may be requested:
- » **Development stage of the project:**
 - » 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).
 - » Project leaders' CV (max 1 page).
 - » 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 LCBF (e.g., agreements signed with the Spin-off Company, the shareholders’ agreement, an updated statement on the shareholders).

» Gantt chart (linked to proposed milestones).

» **Compliance of the Beneficiary with the legal and regulatory requirements:**

- » Accreditation document.
- » A certificate from the Tax Agency assuring that the applicant centre has fulfilled its obligations with regards to taxation, valid at the moment of application.
- » Social Security Certificate, valid at application date, assuring that the applicant centre has fulfilled its obligations with regards to employment.
- » Copy of the power of attorney certifying the capacity of the representative to act on behalf of the Beneficiary.
- » Acceptance letter¹ duly signed (template provided).
- » Certification of data validation² (template provided).
- » In case of consortia and/the participation of Linked Third Parties as provided under 4.13 and 4.14, the distribution of the grant between the members of the consortium (template provided) and/or the Spin-off.

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 CaixaImpulse 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 assigned to be remotely reviewed by innovation experts (internal and external) in three main perspectives. Evaluators will be asked to review the overall quality and feasibility of the Projects, with an emphasis on ensuring the robustness of a specific area according to their expertise:

- » **Technology transfer:** Projects need to present the relevance of the scientific concept underlying the Asset and provide a solid Assets’ development strategy within their business area.
- » **Financial attractiveness:** Projects will need to ensure their financial feasibility and sustainability and present their market potential.
- » **Societal impact:** Projects need to prove their social relevance in solving a specific societal need.

1 This letter shall declare that all entities that co-own the Assets (including the Beneficiary and, when applicable, all stakeholders forming the Consortium) agree with these Rules for Participation and the appointment of the Beneficiary of the Programme as their representative.

2 This letter shall declare that the Beneficiary entity certifies that the provided documents correspond to the original documentation of the Institution.

- 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.

Selection process

- 6.3.** Pre-selected applicants will be invited for a face-to-face interview with the Innovation Selection Board. The Innovation Selection Board will be composed of experts from different sectors of the innovation and biomedical ecosystem.
- 6.4.** 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 CaixaImpulse Programme Office.
- 6.5.** Candidates will be invited to Barcelona to present their Projects in a face-to-face interview. The interviews will be held in English.
- 6.6.** In order to be evaluated, the Project Leader must attend the face-to-face 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 score the Projects between 1 (very poor) and 5 (exceptional) for each evaluated criterion. The evaluation criteria dimensions are listed below:
- » Team and Implementation feasibility (35%)
 - » Assets' Development roadmap (30%)
 - » Assets' Transfer potential (20%)
 - » Social impact and Responsible Innovation (15%).
- 6.9.** Each Member of the Innovation Selection Board will score the proposals individually. A ranking of the best proposals will be generated accordingly.
- 6.10.** After interviewing all the candidates, the Innovation Selection Board will have the option to further discuss the quality and relevancy of proposals of the ranking and accordingly propose a final list of selected participants.
- 6.11.** The LCBF Coordination Committee will be the body responsible for validating the final list of funded proposals.
- 6.12.** 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.
- 6.13.** 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, LCBF reserves the right to discard the application to the corresponding three next cut-offs of the Call.

CaixaImpulse *Consolidate* 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”). LCBF 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 LCBF 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 LCBF or selected third entity who will permanently and closely monitor the Project development.
- 7.9. If requested by the Beneficiary, LCBF may assign a mentor to the Project for the first year in the Programme.

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

- » Access to the CaixaImpulse 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 CaixaImpulse Programme.
- » Other justifiable actions will be considered upon request.

8

Follow-up of Projects

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 LCBF Project Manager (hereinafter "**LCBF Project Manager**") or LCBF through the email address caixaimpulse@fundaciolacaixa.org.
- » LCBF will provide a username and password to access the CaixaImpulse follow-up platform (www.fblcresearch.com). 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 LCBF Project Manager will request that the Project Leader schedule 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 LCBF. Delays or alterations to the workplan 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 LCBF.

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 (or, if appropriate, the licensor of the Assets) 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 LCBF, 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 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 LCBF the proposed terms and conditions for the exploitation of the Assets. LCBF 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.

11

Reimbursement

In case one or more of the indicators established in these Rules for Participation are achieved, LCBF 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 LCBF'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. To prevent doubt, Recurring Payment excludes any Lump-sum payment described in 11.2 below.
- » **Lump-sum payment:** (i) The sale by the Beneficiary of the shares owned in Spin-off Company; 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 LCBF 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:
 - » If the sale price of the shares of the Beneficiary in the Spin-off Company is equal to or exceeds five (5) times the awarded Grant, the whole amount of the Grant shall be reimbursed to LCBF.
 - » If the sale price of the shares of the Beneficiary in the Spin-off Company 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 LCBF 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 LCBF's choice, the amount due as reimbursement of the Grant may be capitalized by LCBF 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

LCBF'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.

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 10.3 above, **LCBF or any entity within the Criteria Group**, at the discretion of the Criteria Group, **shall have the right to subscribe shares of the Spin-off Company**, in accordance with the following:

- » If the Spin-off Company (i) had not been incorporated at the time of the application to the Call or (ii) had been incorporated, but had not been transferred the Assets as of the time of the application to the Call, **up to 1% of the shares, at nominal value**, within one (1) month from the signing of the Project Agreement.
- » In any other case, **up to 1% of the shares of the Company (i) at the post-money valuation of the last financing round** or (ii) in the absence of any financing round, at nominal value, within one (1) month from the signing of the Project Agreement.

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 LCBF 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 5.5 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, the Beneficiary will abide by the following obligations, without prejudice to any other obligations set forth in these Rules for Participation:

- » Sign the Project Agreement.
- » Exploit the Assets in market conditions. In case the exploitation of the Assets is not carried out in market conditions, LCBF 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 LCBF's reimbursement rights and LCBF's participation rights.
- » Keep LCBF informed about any exploitation of the Assets and provide LCBF with any information and documentation needed so as to enable LCBF 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 LCBF for the aforementioned purpose (e.g., account books, details on royalties or other payments made by transferees, turnover and net sales information, etc.).
- » Keep LCBF informed in case the exploitation of the Assets is to be carried out by a Spin-off Company or a third-party and provide LCBF with any information and documentation needed so as to enable LCBF to **exercise its rights to reimbursement as provided in Section 11 above**.
- » For a period of five (5) years after the date on which the final report is due, keep and make available to LCBF all original documentation which may be required to justify the expenses incurred. **During this period, LCBF reserves the right to conduct random financial audits to the Projects.**

- » Use the entire amount of the Grant to develop the Project, in accordance with these Rules for Participation.
- » Manage the Project with due diligence, monitor the task carried out by the Project Leader and his/her team, and inform LCBF 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 the CaixaImpulse Programme 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 LCBF Project manager.
- » After the execution of the Project, deliver the final report to LCBF.
- » Provide any information that LCBF may require in order to promote, publish, and/or disseminate the CaixaImpulse 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.

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, LCBF 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, LCBF will be entitled to choose between demanding forced compliance or terminating these Rules for Participation, and LCBF will have the right, in both cases, to claim for the corresponding compensation for the damages caused by the infringement.
- » Notwithstanding the foregoing, if LCBF 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 LCBF 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 LCBF 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 LCBF 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.

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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 LCBF and the Beneficiary.
- » Failure to comply with the duties regarding protection and maintenance of the Assets, as provided in Section 9 above, effective upon LCBF's notice of non-compliance, which may be remedied within the time frame provided upon LCBF's discretion.
- » Reimbursement of the Grant to LCBF, when applicable.
- » Sufficient evidence, to the entire satisfaction of LCBF, 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

Confidentiality

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. LCBF, 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 LCBF mentoring and expert advice programmes.

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Data Protection

18.1. The applicants authorize LCBF 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 LCBF that such information and documentation can be shared and used for these purposes.

18.2. With regards 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. LCBF 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

LCBF 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, LCBF 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 LCBF through the LCBF Project Manager:

- » The Project Leader and the Beneficiary shall, in due course, provide LCBF 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 LCBF (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 CaixaImpulse Grant <code reference>"**. LCBF will provide the specific code reference for each Project.
- » The LCBF's online channels to link to or mention are:
 - » Twitter: @FundlaCaixa and/or @CaixaCiencia (<https://twitter.com/CaixaCiencia>, <https://twitter.com/FundlaCaixa>)
 - » Instagram: @fundlacaixa
 - » Facebook: @obrasociallacaixa
 - » LinkedIn: Fundación Bancaria "la Caixa"
- » The LCBF websites are:
 - » <https://obrasociallacaixa.org/es/investigacion-y-becas/>
 - » www.CaixaImpulse.com
- » Any dissemination of the results of the Project shall indicate that such dissemination only reflects the author's view and that LCBF is not responsible for any use that may be made of the information that it contains.

19.3. Open Access and Open Data Policy

- » The Beneficiary and the Project Leader shall comply with Open Access Policy concerning the publication of the results of the Project, which promotes the dissemination of the results and allows the results to reach citizens and thus involve them in the process of transforming society.
- » Consult the Open Access and Open Data policy here:
 - » https://obrasociallacaixa.org/documents/10280/692563/politica_acceso_abierto_ca.pdf/8f3de439-aa93-4ad8-a116-aacab2a94fbd
- » In the event that human genotype/phenotype data were generated within the framework of the Project, they shall be deposited with priority in the European Genome-phenome Archive (EGA) <https://ega-archive.org/> or in a similar archive.

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Miscellaneous

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 LCBF.

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 LCBF 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 CaixaImpulse *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

LCBF CaixaImpulse *Consolidate* Call website contains structured and additional information to this Rules for Participation (web page).

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

- » Questions and answers: +34 900 22 30 40
- » info@caixaimpulse.com

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.
- » **CaixaImpulse Programme:** the Programme launched by LCBF, articulated in two schemes, CaixaImpulse *Validate* and CaixaImpulse *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.
- » **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 4.14.
- » **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 LCBF 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:** a company incorporated by the Beneficiary for the development of the Project. This term will be also deemed to include those companies incorporated by the beneficiary during the two (2) years 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.