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Co-Lab AcceiBio

Open Call 2024 for Drug Discovery Projects

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Rules for Participation

Content

Scope

AccelBio is a the Collaborative Laboratory ("AccelBio)" whose main purpose is to accelerate biomedical innovation in Portugal. Its primary objective is to foster the successful transfer of scientific knowledge to the economy through the development of products and businesses in biotechnology.

The AccelBio Open Call ("Open Call") is a competition which will select projects with the most promising prospects of transitioning from research into clinical product candidates. The ultimate goal of the Open Call is to capitalize on the best Portuguese discoveries, transforming them into innovative drug assets.

The transition from early-stage to late-stage in a drug development project is a critical aspect of the innovation process. It often faces challenges related to lack of preclinical/translational expertise and insufficient financial support and is often referred to as - the "valley of death" of drug development. AccelBio aims to provide researchers with an understanding of the drug development process and industry requirements in order to transform a good scientific idea into a clinical product candidate.

The Programme is open to any Portuguese public or non-profit legal entity (universities, research centres, hospitals) who may wish to submit proposals of projects from their research activity with potential to be made into assets with clinical therapeutic potential. Eligible Proposals must have potential as pharmaceutical therapies mainly in the following therapeutic areas: oncology, neurosciences, infectious diseases, immunology, metabolism and/or cardiovascular.

The projects selected by Open Call will gain a financial award to pay for services and consumables of up to 50 000€ as well as help in preparing a comprehensive value creation plan. This plan is developed with the support of the AccelBio team and has the duration of 18 months. It shall encompass a set of experiments required to drive a drug discovery project effectively to pre-clinical candidate stage.

Glossary

AGREEMENT shall mean the agreement entered into between AccelBio and the Beneficiary Institution for the development of a Selected Project receiving the Support, under which they will define the experiments, follow-up, reporting, IP conditions, among other specific terms and conditions.

APPLICANT INSTITUTION shall mean any Portuguese public-sector or non-profit organisation that owns or co-owns the Asset/s. The Applicant Institution will be responsible for submitting the application form.

ASSET/S shall mean the results from scientific research owned or co-owned by the Applicant Institution as identified for the purpose of or developed under the Selected Project.

BENEFICIARY INSTITUTION shall refer to the Applicant Institution that has been selected to enter the Programme, and therefore is the beneficiary of the Grant and responsible for complying with the Agreement.

CONFIDENTIAL INFORMATION shall mean the information and the results from scientific research identified for the purpose of or developed under the Selected Project as well as any other information and documentation exchanged within the framework of the Programme.

CO-OWNER shall mean any entity or individual that co-owns the Asset/s jointly with the Applicant Institution and, as the case may be, with other co-owners.

ELIGIBLE PROPOSALS shall mean Proposals that fulfil all the eligibility criteria to be submitted to the Open Call.

EVALUATION COMMITTEE shall mean the group of experts that will be in charge of the reviews of the applications.

EVALUATION PHASES shall mean the phases after eligibility check of the proposal, where all qualified Proposals will undergo an independent evaluation by experts (Evaluation Committee) to determine the final Beneficiary Institutions. The evaluation process is composed of two phases: pre-selection and selection. The Pre-selection phase consists in a remote evaluation conducted by up to four (4) external evaluators comprising the Evaluation Committee. The evaluation criteria, each assigned varying weights, include: asset, need, team, finance and business case and social impact. The Selection phase consists in the invitation of Pre-selected applicants to participate in a remote presentation and interview conducted by the Evaluation Committee. The evaluation will rely on the assessments conducted by the members of the Evaluation Committee, with each member providing a qualitative evaluation.

SUPPORT shall refer to the support to be awarded to each Selected Project under the Open Call.

FINAL REPORT shall mean a report submitted by the Project Leader to AccelBio, within three (3) months of the end of the Selected Project term. The Final Report shall give evidence of compliance with the development and execution of the Selected Project after each Stage and should include an executive summary, main results and goals from the Selected Project, baseline reviews (scope, schedule, and budget) lessons learned, and next steps.

IP RIGHTS shall mean industrial and/or intellectual property rights to scientific research results owned or co-owned by the Applicant Institution prior to the Selected Project, and/or obtained as a result of the development of the Selected Project. For clarity, it is emphasized that the Open Call will prioritize projects that do not possess existing IP but have the potential to generate new intellectual property.

OPEN CALL shall mean the AccelBio Open Call that aims to provide support in 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 wellbeing of people and society.

PROJECT shall mean a project under which an Applicant Institution proposes to develop Asset/s into further transferability and/or commercialisation stages in which they are able to attract commercial investment.

PROJECT LEADER or PL shall mean the individual in charge of leading the Selected Project. The Project Leader does not necessarily have to be the principal investigator of the group that discovered or obtained the Asset/s, but the one who undertakes to lead the Selected Project and participate in the mandatory activities developed in the framework of the Open Call.

PROJECT TEAM MEMBERS shall mean the members of the Beneficiary Institution that carry out specific activities of the Selected Project.

PROJECT TERM shall begin on the starting date indicated in the Agreement and shall end eighteen months after. Unless AccelBio concedes a temporary extension (max. 6 months) for the Selected Project.

PROPOSAL shall mean the proposal of a Project (related to drug discovery) to develop the Asset/s into further transferability and/or commercialisation stages in which they are able to attract commercial investment and that is submitted by an Applicant Institution within the framework of the Open Call.

SELECTED PROJECT shall mean the Proposal selected to be awarded a Grant under the Programme.

TEAM refers to the researchers from the Beneficiary Institution who will collaborate with the Project Leader in developing the Selected Project.

THERAPEUTIC AREAS refer to distinct fields or categories of medical conditions and diseases for which specific projects are being developed.

VALORISATION PLAN refers to a strategic plan outlining both an experimental approach and a business strategy for the Selected Project, aimed at optimizing the translation of innovative research into drug products and, ultimately, their commercialization.

Rules of participation

Aims and framework of the Open Call

a. Through the AccelBio Open Call, AccelBio aims to support researchers in converting scientific knowledge into products or businesses that create value for society by:
   i. Supporting and guiding defined activities, guiding assets from discovery through pre-clinical validation.
   ii. Enhancing the capacity of Project Leaders and their teams to transition assets from the lab to the market successfully.
   iii. Introducing industry best practices and knowledge to academic labs.
   iv. Instigating a cultural shift in the research ecosystem, enabling researchers to achieve their entrepreneurial goals.
b. To support Project Leaders and Selected Projects in their journey, AccelBio has established a comprehensive program built on three pillars:
   i. Technical Support: Each project is paired with a translational researcher who collaborates with the Project Leader and team to formulate a Value Creation Plan. This plan guides the execution of proposed activities, such as validation and testing, prototyping, and business strategy design.
   ii. Financial support: Experiments are conducted either at AccelBio Associates Labs or at the Beneficiary Institution, with funding support of up to €50,000 for consumables and services. All the consumables and/or services and must be acquired by AccelBio. Nevertheless, The Beneficiary Institution remains the key source of biological insights, interpretation of experimental results, research tools, scientific steering, and creativity.
   iii. Expert Advice: Project Leaders and teams benefit from specialized training in valuation and business skills, including project management, technology evaluation, license agreement negotiation, business creation, and fundraising. The project will encompass industrial good practices, such as robust quality control, outcome-driven project management, the understanding of target druggability, compound lead and drug likeness, and the ability to operate across multiple disciplines needed to successfully carry out drug discovery projects. AccelBio will actively guide the progress of activities, fostering collaboration and creating opportunities for business development.

Target and general requirements

Eligible Projects

a. The Selected Projects will be supported according to their specific needs, nature, and maturity stage in order to:
   iv. Characterise an Asset/s and identify its potential value to society and its market potential.
   v. Complete or execute value creating activities through a defined point-of-value in the development plan, including target validation, HIT discovery, lead optimization and pre-clinical studies.
   vi. Design strategies to access main stakeholders (end users, companies, investors etc.).
   vii. Establish a plan to make the product(s) attractive for investors and potential licensees in the biomedical sector.
b. Eligible Projects must be from the life sciences field, related to human health and drug discovery. Within the Scientific Areas, the Asset/s must belong to one in the following therapeutic areas: oncology, neurosciences, infectious diseases, immunology, metabolism and/or cardiovascular.
c. The following Projects are non-eligible for this Call:

viii. Fundamental research projects without a clear definition of activity aimed to generate an Asset to be transferred to the society as a solution to an identified unmet clinical need.
ix. Projects presenting assets without possibility to generate new IP.

Applicant Institution

d. The Applicant Institution will be the entity that owns or co-owns the Asset/s, whose main activity is located and registered in Portugal, and which has submitted the application form in its own name.
e. Applicant Institutions must be public-sector or non-profit organisations, including universities and university foundations, research centres and technological centres.
f. The Applicant Institution must provide the Project Leader with sufficient scientific and administrative support to ensure the proper management and development of the Selected Project.
g. The Applicant Institution must assure financial capacity to develop the project together with AccelBio.

Project Leader

h. The Project Leader must be an individual linked to the Applicant Institution with tertiary qualifications (university graduate or PhD holder). The Project Leader does not need to be the leader of the research (i.e. principal investigator) that generated the Asset/s.
i. The Project Leader is expected to commit to the development of the Selected Project.
j. The person acting as Project Leader may be involved in more than one application per call but may not be appointed as Project Leader in more than one Proposal per call.

Evaluation process

The AccelBio management team will conduct an initial eligibility check to ensure compliance with the criteria outlined in the Rules of Participation. Proposals failing to meet these criteria or lacking mandatory documents will be rejected, and the Applicant Institution will be promptly notified. Proposals may be declared ineligible at any point between submission and Agreement signature if any breach of the Rules of Participation is identified. Following the eligibility check, all qualified Proposals will undergo an independent evaluation by experts (Evaluation Committee) to determine the final Beneficiary Institutions. The evaluation process is composed of two phases: pre-selection and selection (the "Evaluation Phases").

Pre-selection: Each application will undergo a remote evaluation conducted by up to four (3) external evaluators comprising the Evaluation Committee. The evaluation criteria, each assigned varying weights, include:

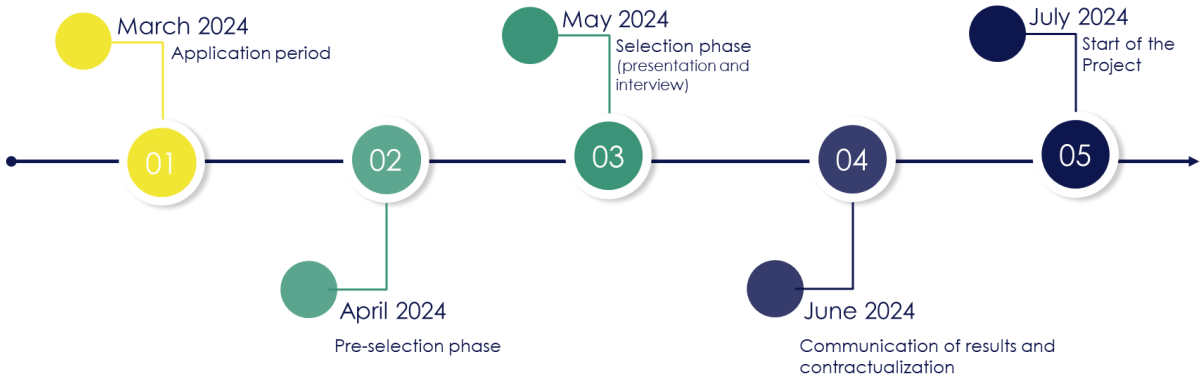
- ASSET: Assessment of the quality of science and the novelty or originality of the Asset/s (30%);
- NEED: Evaluation of the unmet clinical need addressed by the Asset/s (20%);
- TEAM: Examination of the suitability of the team to develop the proposed project (10%);
- FINANCE: Assessment of the financial sustainability for project development (20%);
- BUSINESS CASE and SOCIAL IMPACT: Scrutiny of the strategy, needs, and expected outcomes pertaining to the business case and social impact (20%).

Selection: Pre-selected applicants will be invited to participate in a remote presentation and interview conducted by the Evaluation Committee. Both the presentation and interview will be remote. The evaluation will rely on the assessments conducted by the members of the Evaluation Committee, with each member providing a qualitative evaluation. Further details on the evaluation process can be found in the Guidelines for Evaluation.

Application process

a. Applications must be submitted to geral@accelbio.pt using the template provided here.
b. Applications must be completed in English.
c. The Project leader must submit an official document from the Applicant Institution stating its support to the application.
d. Application process will entail two steps: the initial submission of a Proposal (pre-selection phase), and the subsequent invitation for a presentation and interview (selection phase) with the Evaluation Committee in case of pre-selection.

Calendar



Project follow-up

To ensure effective oversight and evaluation of the resources allocated through the Open Call, AccelBio has established a series of procedures for monitoring and supporting project activities. Initially, AccelBio will organize a kick-off meeting before project commencement to align stakeholders and clarify objectives. Subsequently, online questionnaires will be distributed to obtain feedback and assess progress.
Additionally, the AccelBio Translational Researcher may request follow-up meetings to monitor ongoing developments and schedule a final meeting to review project outcomes. Within three (3) months of the project's conclusion, the Project Leader (PL) is required to submit a comprehensive Final Report to AccelBio. This report will document project milestones, achievements, lessons learned, and future steps, following a provided template.
AccelBio emphasizes the importance of implementing a robust quality management system for project success. Together with the Project Leader and their team, AccelBio will establish and adhere to quality standards, including the development of Standard Operating Procedures (SOPs) and Study Plans for each task. A deviation management process will address any deviations from established procedures, ensuring consistency and reliability in project execution.
Furthermore, AccelBio will create a dedicated SharePoint platform to facilitate seamless communication, document sharing, and project management. This centralized hub aims to enhance collaboration, streamline information exchange, and promote transparency throughout the project lifecycle.

IP rights, asset protection and maintenance

AccelBio's business model is firmly rooted in harnessing the significant scientific potential in Portugal, largely untapped, to create drug discovery assets with robust intellectual property (IP). These assets will be transformed into commercially appealing programs with multiple exit options and a high return on investment. The Open Call targets very early drug discovery projects, enhancing academic research groups with industry-standard drug discovery capabilities, including target validation, assay development, high-throughput screening, in silico modelling, medicinal chemistry, in vitro and in vivo testing, IP support, and business development. This support aims not only to validate drug discovery assets but also to evolve them into commercially appealing programs by generating valuable IP, a comprehensive data package, and executing a viable commercial strategy.
Successful projects are expected to result in licensing or partnering agreements with pharmaceutical or biotech companies, and potentially the creation of new investable companies.
Participation in the Open Call operates on a risk-sharing model. Academic groups gain access to drug discovery capacities necessary for developing and de-risking their promising projects in alignment with the value creation plan. Revenues generated through the exploitation of drug discovery assets will be shared between CoLAB AccelBio (including associate members contributing their capacities) and the Beneficiary Institution. The terms governing IP sharing will be defined and agreed upon the Agreement signature.

Obligations

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

a. sign the Agreement;
b. exploit the Asset/s in market conditions. If the exploitation of the Asset/s is not carried out in market conditions, AccelBio will have a right to veto such exploitation;
c. refrain from entering into any agreements and/or undertaking any exploitations of the Asset/s and/or taking any other actions or inactions which may hinder or prevent the compliance with these Rules of Participation by the Beneficiary Institution, the Co-Owner(s) of the Asset/s (if applicable), and their successors and assignees, including, but not limited to, any actions or inactions which would be incompatible with honouring AccelBio's participation rights;
d. keep AccelBio informed about any exploitation of the Asset/s and provide AccelBio with any information and documentation needed so as to enable AccelBio to exercise its rights;
e. use the entire Support to develop the Selected Project, in accordance with these Rules of Participation;
f. manage the Selected Project with due diligence, monitor the task carried out by the Selected Project Leader and their team, and inform AccelBio on the progress and results achieved by the Selected Project;
g. assume the social and ethical implications of the Selected Project in accordance with the research personnel's ethical code, also considering the gender dimension;
h. indicate the support received from the Open Call through materials, publications, and dissemination activities developed within the framework of the Selected Project;
i. prepare regular milestone reports reflecting the development of the Selected Project and attend follow-up meetings with its AccelBio Translational Researcher;
j. deliver the Final Report to AccelBio after execution of the Selected Project;
k. provide any information that AccelBio may require in order to promote, publish, and/or disseminate the Open Call, in particular those transactions that, due to their nature, may be subject to coverage by the media, and consequently give coverage to the Beneficiary Institution's 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 Institution;

l. report additional third-party funding raised for the Selected Project in follow-up reports submitted to AccelBio.

Obligations of the Project Leader

Within the framework of the Open Call, the Project Leader is obliged to:

m. use the entire Support to execute the Selected Project, always in accordance with these Rules of Participation;

n. respect and comply with any other obligations and duties pursuant to these Rules of Participation.

Breach and liability

Breach

a. In the event of a remediable breach by the Beneficiary Institution and/or the Project Leader of the obligations, representations, and warranties contained in these Rules of Participation, AccelBio shall notify the breaching party. The latter is requested to correct the infringement within thirty (30) days following the receipt of such notification;

b. If, after the aforementioned 30-day period, no remedy has been provided, AccelBio will be entitled to choose between demanding forced compliance or terminating these Rules of Participation. In both cases, AccelBio retains the right to claim corresponding compensation for the damages caused by the infringement;

c. Notwithstanding the foregoing, if AccelBio determines that the Beneficiary Institution has not used the Support for the specified purposes outlined in these Rules of Participation, the Beneficiary Institution shall be obliged to compensate AccelBio and reimburse the amount corresponding to the misused Support;

Liability

The Beneficiary Institution and the Project Leader shall not hold AccelBio liable for any costs, damages, and/or expenses (including reasonable legal fees) arising from the breach or defective compliance of their obligations under these Rules of Participation.

Duration

a. The rights and obligations set out in these Rules of Participation shall start on the date the Beneficiary Institution accepts and adheres thereto, which shall be formalised by submitting the Proposal through the website of AccelBio (the "Effective Date");

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

   x. mutual written agreement between AccelBio and the Beneficiary Institution;

   xi. failure to comply with the duties regarding protection and maintenance of the Asset/seffective upon AccelBio's notice of non-compliance, which may be remedied within the time frame provided at AccelBio's discretion;

xii. failure to implement the Selected Project, including, without limitation, the exploitation of the Asset/s, unless such failure is attributable to the Beneficiary Institution;

a. Without prejudice to the above, the following Sections shall be valid for ten (10) years following the termination of the Rules of Participation: IP Rights, asset protection and maintenance, Obligations, 9 Breach and liability, Confidentiality, Data protection and Publicity and dissemination.

Confidentiality

a. The confidentiality of the presented applications is ensured throughout the entire process. However, general characteristics of the applications may be disseminated, and subsequently, information such as the name of accepted Selected Projects (and logo, if applicable), a brief description, the Beneficiary Institution and its logo, the name of the Project Leader, and their photo, may be published through various channels, including but not limited to press releases, emails, brochures, and websites. This dissemination aims to communicate information about the Open Call;
b. The information content, results of the Selected Project, and any other exchanged information and documentation within the framework of the Call, including details about other Selected Project participants, shall be treated as confidential information, hereinafter referred to as 'Confidential Information;
c. Unless prior authorisation in writing is received from the other parties, AccelBio, the Beneficiary Institution, and the Project Leader, as well as any other person attending the activities, shall undertake to:
    i. keep the Confidential Information strictly confidential and not to disclose it to any third parties;
    ii. not use the Confidential Information for any purpose other than the development of the Selected Project;
    iii. 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 Selected Project;
d. The confidentiality obligations described in this section above shall not be applied to the Confidential Information if:
    i. 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;
    ii. the information is obtained without being subject to any confidentiality obligation;
    iii. 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;
e. The obligations and commitments set out 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 Open Call.

Data protection

a. The applicants will be duly informed, within the framework proposal submission, about the processing of their personal data concerning its application, as well as the exercise of their rights regarding the protection of personal data in accordance with the provisions of article 13 and following of the European General Data Protection Regulation;
b. Notwithstanding the foregoing, for illustrative purposes, the applicants are likewise informed that AccelBio will access, use and share information from the Proposals submitted to the Open Call, including the

processing of any personal data or 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 Open Call and to the extent necessary, including, but not limited to, the evaluation, selection, and monitoring of the Selected Projects. The applicants warrant to Accelbio that such information and documentation can be shared and used for these purposes;

c. With regard to the identification and/or professional information of individuals linked to the Selected Projects (including the Project Leader, other team members, and representatives), the applicant organisations, when submitting the Proposals, warrant that they have informed those persons on the information indicated in the sub-section below and, where applicable, obtained the necessary consent of those persons for their inclusion in the applications submitted to this Open Call. All personal data collected within the framework of this Open Call (including data submitted in the applications) will be processed by AccelBio for the purpose of managing the participation of the applicant organisations, 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.
d. Personal data will not be transferred to third parties, except to those third parties whose intervention is necessary for the correct management of the Open Call, as well as when the disclosure of personal data is legally mandatory. Furthermore, personal data will not be subject to automated decisions. In the event that AccelBio needs to contract the services of suppliers located outside the European Economic Area, those contracts can only be carried out after complying with all of the requirements established by the data protection regulations and applying the guarantees and safeguards necessary to preserve their privacy.

Publicity and dissemination

Publicity

Where relevant, AccelBio will be entitled to disclose the results of the Beneficiary Institution's Selected Project 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 Selected Project, a brief description, the Beneficiary Institution, and the name of the Project Leader may be published through, without limitation, press releases, emails, brochures, and websites. To prevent doubt, AccelBio will not be required in any case to pay any compensation to the Beneficiary Institution for the dissemination and publication of the results of the Selected Projects.

Dissemination

The Beneficiary Institution shall promote the maximum dissemination of the Support, subject to a previous agreement with AccelBio through the Project Manager:

a. The Project Leader and the Beneficiary Institution shall, in due course, provide AccelBio with information regarding communication and dissemination actions, materials, events, and activities that they develop in relation to the Selected Project during their participation in the Call, so that they may be duly notified and/or represented and can request changes and/or approve brands and logotypes;
b. The responsible party shall make reference to the Support awarded by AccelBio (reference, CODE and logo whenever possible) in any actions, results and communication and dissemination materials which are carried out in relation to the Selected Project and the Support (e.g. emails, letters, brochures, posters, advertisements, graphic material, pamphlets, apps, social networks, publications, reports, patents, licences, scientific articles, etc.) and also in any acts and activities which are organised or in which the winner participates in relation with the Selected Project (e.g. workshops, courses, interviews, press releases, project and/or results presentations, scientific congresses, etc. and all support material);

c. The correct reference is "The project leading to these results has received Support from CoLAB AccelBio under the Grant <code reference>". AccelBio will provide the specific code reference for each Selected Project.
d. AccelBio's online channels to link to or mention are:
   i. Instagram: @colab_accelbio
   ii. LinkedIn: CoLAB AccelBio
e. Any dissemination of the results of the Selected Project shall explicitly state that it reflects only the author's views, and AccelBio bears no responsibility for any use of the information it contains. Importantly, no dissemination should compromise the protection of results under intellectual property. This means that any dissemination of abstracts, presentations, publications, or any other materials related to the Selected Project must be previously discussed and approved by AccelBio to ensure that the intellectual property is not compromised.

Miscellaneous

Any question related to the Rules for participation in the Open Call 2024 for Drug Discovery Projects should be addressed to the e-mail: geral@accelbio.pt.