



# **PHOENIX-OITB**

## **Open Call 2**

### **Application Guide**



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 953110

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## Abbreviation List

API	Active Pharma Ingredient
cGMP	Current Good Manufacturing Practice
EC	European Commission
EU	European Union
GA	Grant Agreement
gGmbH	EN: non-profit company with limited liability under German law DE: gemeinnützige Gesellschaft mit beschränkter Haftung
ICH	International Council of Harmonisation
IPR	Intellectual Property Rights
LIST	Luxembourg Institute of Science and Technology
OECD	Organisation for Economic Co-Operation and Development
OITB	Open Innovation Test Bed
QbB	Quality-by-Design
RTO	Research and Technology Organisation
SbD	Safety-by-Design
SEP	Single Entry Point
SMEs	Small and Medium Enterprises
SSbD	Safe-and-Sustainable-by-Design
TRL	Technology Readiness Level

## 1. Introduction to PHOENIX and PHOENIX-OITB

Nanopharmaceuticals have the potential to drive the scientific and technological uplift, offering great clinical and socio-economic benefits to the society in general, industry and key stakeholders and patients. Nevertheless, affordable and advanced testing, manufacturing facilities and services for novel nanopharmaceuticals are main prerequisites for successful implementation of these advances to further enhance the growth and innovation capacity.

The establishment of current good manufacturing practice (cGMP) in nanopharmaceutical production at large scale is the key step to successfully transfer nanopharmaceuticals from bench to bedside (from lab to industrial scale). Due to the lack of resources to implement GMP manufacturing at-site, the upscaling and production of innovative nanopharmaceuticals is still challenging to main players of the EU nanomedicine market, start-ups and SMEs. To allow successful implementation of the nanopharmaceuticals in the nanomedicine field, there is an urgent need to establish a science- and regulatory-based Open Innovation Test Bed (OITB). PHOENIX aims to enable the seamless, timely and cost-friendly transfer of nanopharmaceuticals from lab bench to clinical trials by providing the necessary advanced, affordable and easily accessible PHOENIX-OITB.

PHOENIX-OITB is a unified body and an operational structure to sustainably coordinate the value chain that merges all services necessary to develop nanopharmaceutical solutions and products for end-user. The structure of PHOENIX-OITB is legally represented by Phoenix gGmbH, which acts as the Single-Entry-Point (SEP) to the services of the OITB. The PHOENIX-OITB will be a non-profit company with limited liability under German law and it will ensure the long-term sustainability and professional management of end-user projects.

PHOENIX-OITB aims at offering a consolidated network of facilities, technologies, services and expertise for all the technology transfer aspects from characterisation, testing, verification up to scale up, GMP compliant manufacturing and regulatory guidance. PHOENIX-OITB offers facilities compliant with pharma quality guidelines, to SMEs, start-ups and research laboratories for scale-up, GMP production and testing of nanopharmaceuticals.

For more information visit [PHOENIX website](#).

## 2. PHOENIX-OITB Open Call 2






PHOENIX-OITB's mission is to offer a Single Entry Point (SEP) for a consolidated network of facilities, technologies, services and expertise for all the technology transfer aspects from characterization, testing, verification up to scale-up, GMP compliant manufacturing and regulatory guidance in the field of nanopharmaceutical development, framing the OITB clearly within the nanomedicine field.

The Open Call 2 will contribute to validate and demonstrate the effectiveness of the services and to evaluate the operational set up of the OITB throughout execution of Pro-Bono Demo Cases.

### 2.1. Services Provided under the Open Call 2

PHOENIX-OITB's concept and implementation strategy are designed to cover a wide range of nanopharmaceutical manufacturing methods, formulations and administration routes so that most methods and services of interest are available to the end-user.

The services and expertise provided by the PHOENIX-OITB include production and characterisation under GMP conditions, safety evaluation, regulatory compliance and commercialisation boost. The PHOENIX-OITB service portfolio is divided in five different categories. Each category includes a list of services, all of which together cover the different topics needed for the development of nanopharmaceuticals from early stage to entry into clinical trials.

Service Category	Services Included	List of Services
<b>Physico-Chemical Characterization</b>  	Services needed to perform an accurate physicochemical characterization, including techniques to characterize not only nanoparticles but also small and large molecules (synthetic or biological ones) as well as the characterization of the conjugated.	Surface Properties, Moisture/Dry Mass, Size & Size Distribution, Morphology, Structure, Composition, Chemical stability, Particle Concentration, Drug (API) Release Kinetics, Free/Encapsulated API Sterility.
<b>In vitro Characterisation</b>  	Services that permit an extensive <i>in vitro</i> characterisation of the nanomedicine under development, allowing specific and critical questions to be answered related to its toxicity, like cytotoxicity, cell viability, sensitization & irritation, etc. This category confers the data needed to enter into the next category: <i>in vivo</i> experiments.	Composition, uptake and localisation, Bioactivity, Immunocompatibility, Immune response, Extraction of targeted cells, (A)cellular reactivity & cytotoxicity, Cell viability, Cellular structure, uptake & localisation, Inflammatory response, Endocytosis/Exocytosis, Sensitation & Irritation, Cytotoxicity, Genotoxicity, Nanomechanical properties of cells & tissues, Dose metrics, Microbial evaluation, Transcriptomics, Metabolomics, Proteomics, Gene expression
<b>In vivo Characterisation</b>  	Services that allow to cover part of the pre-clinical <i>in vivo</i> characterisation of the nanomedicine under study. Most of the assays available follow OECD/ICH test guidelines.	Biodistribution, Haemocompatibility, Pharmacokinetics, Pharmacodynamics, Acute, Sub-scute & Repeated dose systemic toxicity, Reproductive toxicity.
<b>Manufacturing</b>  	Services needed for the scale-up until the GMP manufacturing of a nanopharmaceutical.	Manufacturing of liquid, semi-solid, solid nanoparticle formulations with a special focus on extended release parenterals, lipid based nanoformulations and nanovesicles, liposomes, solid lipid nanoparticles, crystalline nanoparticles, polymeric nanoparticles, inorganic nanoparticles, On-site lyophilization and fill and finish capabilities.
<b>Innovation</b>  	Services that help the customer reach its goals. Transversal and complementary services to the ones in the other categories, equally necessary when developing novel nanopharmaceuticals.	Training, Regulatory Support & Guidance, IPR & Business Support, QdB, SbD and SSbD Support.

For more information please refer to the PHOENIX-OITB [Service Portfolio](#) available online.

Under the scope of the Open Call 2, service *categories Physico-Chemical Characterization, In vitro Characterisation, In vivo Characterisation and Manufacturing* will be offered to the applicants.

## 2.2. General Overview of the Open Call 2 Process

The submission period is from **11 March 2024** to **03 May 2024**. During this time, questions on the application process can be addressed to [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu).

The Evaluation Committee, composed of PHOENIX consortium members with technical expertise, will assess the quality of the presented offers from **06 May 2024** to **31 May 2024** for the first stage and from **01 July 2024** to **14 July 2024** for the second stage<sup>1</sup>.

PHOENIX-OITB Open Call 2 is subjected to a **two-stage submission procedure** with the **evaluation procedure** organised in several steps:

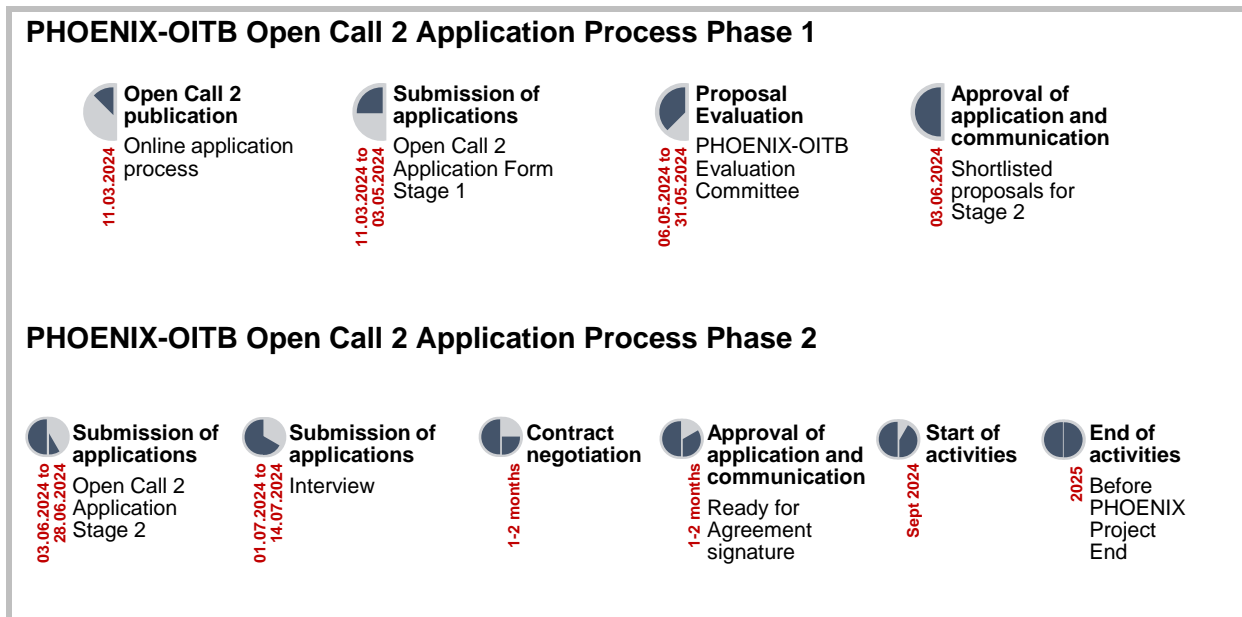
- first stage: short proposal (5 pages)  
submission from 11.03.2024 to 03.05.2024  
evaluation from 06.05.2024 to 31.05.2024
- second stage: detailed proposal (10 pages) and interview  
submission from 03.06.2024 to 28.06.2024  
evaluation from 01.07.2024 to 14.07.2024

At the end of the first stage evaluation process (**31.05.2024**), applicants will be informed of the outcome of their application by email. Successful proposals will be ranked and shortlisted candidates will be invited to the second stage. Other proposals will be allocated in a reserve list (longlisted candidates) or rejected. Invitation to second stage does NOT constitute a formal commitment to funding. Successful candidates from stage one who fail to interview, to sign the agreement, to provide methods or technologies to transfer or to provide convincing preliminary data will be excluded from further evaluation (agreement termination).

Please note that all information provided will be treated confidentially and stored only for the purpose of this call.

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<sup>1</sup> please note that dates for evaluation are tentative and are subject to change according to Committee's availability



At the end of the evaluation process, Pro-Bono Demo Cases will be chosen among all the submitted proposals to benefit from the services offered by the PHOENIX-OITB. At the end of the activities, the successful applicants must provide feedback following the form that will be provided by the PHOENIX-OITB: This feedback will be solely used for improving the services, their implementation and extend, whenever applicable. Please note that if no application will be listed eligible to be granted during the open call period, PHOENIX-OITB intends to launch a second call following the same guidelines specified in this document.

### 2.3. Language and Formatting

English is the official language for the PHOENIX-OITB Open Call 2. Submissions done in any other language will not be eligible for evaluation. All official communications between the applicant and PHOENIX-OITB will be done in English. It will be the only official language during the whole execution of the PHOENIX-OITB project.

The reference font for the body text of proposals is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions). The minimum font size allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used. This applies to the body text, including text in tables. Text elements other than the body text, such as headers, foot/end notes, captions, formula's, may deviate, but must be legible. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). In addition, figures, schemes and photos are encouraged to be provided to make clearer the aim of the proposal taking in account its final length (**max. 5 pages**).

### 2.4. Origin of the Funds

This call uses funds obtained within the scope of the PHOENIX-OITB project funded by the European Union's Horizon 2020 research and innovation programme under grant agreement (GA) No 953110. No additional funding will be dedicated to support this call by the PHOENIX consortium or its beneficiaries. Successful applicants will be supported up to 100% for the coverage of service costs.



### 3. Open Call 2 Application Terms & Conditions

#### 3.1. Open Call 2 Announcement

The Open Call 2 will be published on the PHOENIX-OITB website on **11.03.2024** and will close on **03.05.2024**.

#### 3.2. Admissible Applications

Any legal entity (SMEs, start up or RTOs) and research group, from now on called the “Applicant”, based in the European Union or [associate countries of H2020](#) can apply to this call. Consortia between entities are not allowed. Multiple application per entity will be allowed.

Certain criteria must be followed to ensure the application is considered for evaluation. This includes:

- a completed admission accompanied by the relevant administrative forms, proposal description and any supporting documents specified in the open call 2. Check the standard admissibility criteria for details of supporting documents required under Section 7.1 [Annex I: Application Form – Stage 1](#) and Section 7.2 [Annex II: Application Form – Stage 2](#).
- a page limit which will apply to proposals/applications and must not exceed the maximum number of pages indicated in the application guideline
- proposals/applications must be received before the submission deadline

#### 3.3. Submission

Applicants will be required to complete the Application Form Stage 1 and 2 available online in the [PHOENIX project webpage](#) following the specified Open Call 2 guidelines. Figures, schemes, and additional documents attached to support the application cannot contain additional information or case study than the ones the applicant presents in the main body of the Open Call 2 application. A pdf version of the Application Form Stage 1, complete in all the required parts, needs to be sent via email to [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) before the Open Call 2 deadline (**03.05.2024**).

Upon the submission of the Application Form, a Confirmation Email will be sent to the applicants confirming the receipt of the proposal. In case of non-receipt of the Confirmation Email, it is advised to contact the PHOENIX-OITB.

## 4. Selection of Applications

### 4.1. Evaluation Committee

Evaluation of each submitted application will be carried out by an Evaluation Committee consisting of **6** experts from the PHOENIX-OITB consortium partners. They will have specific expertise in the different areas of knowledge and/or highly specialized staff belonging to PHOENIX-OITB. A consensus report regarding the proposal evaluation, will be provided by the Evaluation Committee at the end of the evaluation period.

### 4.2. Eligibility Criteria

An application will be eligible if it fulfils the following prerequisites:

- it is submitted before the submission deadline date, following the requested submission procedure
- all the required fields in the application form (Section 7.1 [Annex I: Application Form – Stage 1](#) OR Section 7.1 [Annex II: Application Form – Stage 2](#)) are complete
- the applicant is based in the European Union or [associated countries of H2020](#)

Moreover, the Evaluation Committee will ensure that, overall, Open Call 2 applications follow the criteria below

- it is submitted by a legal entity as SME, start-up, academia or RTOs (no natural person)
- it presents a [Technology Readiness Level](#) higher than 3

### 4.3. Proposals Evaluation

The Evaluation Committee will evaluate each proposal following three main criteria as described below. Each award criteria will be rated on a scale from 0 to 5 (half point scores may be given):

**0** – Application fails to address the criterion or cannot be assessed due to missing or incomplete information.

**1 – Poor.** The criterion is inadequately addressed or there are serious inherent weaknesses.

**2 – Fair.** The application broadly addressed the criterion, but there are significant weaknesses.

**3 – Good.** The application addresses the criterion well, but a number of shortcomings are present.

**4 – Very good.** The application addresses the criterion very well, but a small number of shortcomings are present.

**5 – Excellent.** The application successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

The threshold for individual criteria is 3 (out of 5) and the overall threshold is 10 (out of 15). In order to be considered for support, the application must score above both individual and overall thresholds.

Criteria	Description	Max. Points
Excellence	Challenges to be overcome.	5
	Description of the proposed solution.	
	Description of current state-of the art.	
	Alignment with the services provided by PHOENIX-OITB.	
	TRL level	
	Regulation, standardization and certification issues.	
Implementation	Work plan description.	5
	Risk management.	
Impact	Competitive advantages.	5
	Market opportunity.	
	Go-to-market strategy.	
	Key exploitable results.	

The scoring will take into account the average score of the members of the Evaluation Committee. At least 75% of the members of the selection board need to participate in the evaluation to assign a final score.

The Evaluation Committee evaluate each application in a transparent and fair way, respecting the [confidentiality](#) of any information identified as confidential at the time it is provided. Evaluations will be performed applying the highest ethical and moral standards. At the end of each evaluation period, the Evaluation Committee will provide a consensus report regarding the proposal evaluation.

The applicant's contact person (as provided in the form) might be **contacted during the evaluation** process to provide further clarification on all aspects of the application. Upon consideration of the problem and the proposed services, the Evaluation Committee may suggest different services or make observations on the proposal.

If the proposal is awarded, the details of the services will be discussed during the contracting period with staff from the PHOENIX-OITB responsible of the service(s) and an implementation agreement will be signed. A Non-disclosure Agreement (NDA) will be signed after the successful completion of the second stage by the awarded applicant and PHOENIX-OITB. Upon request, PHOENIX-OITB commits to sign an NDA after the first stage with the shortlisted candidates invited to the second stage of the Open Call 2.

The decisions of the Evaluation Committee shall be final and, upon proposal of the Committee, PHOENIX-OITB coordinator LIST may declare the call null and void, without the obligation to assign the established services, when the applications submitted do not fulfil the expectations in terms of completeness, excellence and fitness to the call.

#### 4.4. Proposals Prioritization

In case of multiple applications achieve the exact same score, prioritization criteria will be followed to furtherly evaluate and rank the proposals:

- GMP proposals will be prioritized over no GMP proposals
- TRL 4 or 5 proposals will be prioritized over TRL 3 proposals

- High clinical relevance (high medical need or unmet medical need) will be prioritized over low clinical relevance
- Diversity of services offered for the awarded proposal will be also taken into consideration.

#### 4.5. Communication of the results

The applicants will be informed about the decision made by the Evaluation Committee by the end of **03.06.2024** (Stage 1) via email. Besides, the final decision will also be published on the PHOENIX-OITB website (<https://www.phoenix-oitb.eu>). If the application is successful, the PHOENIX-OITB consortium will enter into **contract negotiations** with regard to the specific terms of the service(s).

Applicants believing that the proposal rejection was based on a flaw in the selection procedure, can submit an **objection** following the procedure detailed below. The objection procedure is not meant to question the judgement made by the evaluators, but it will concern procedural shortcomings. Objection requests should be raised within **7 days** from the communication of the proposal evaluation results. If an objection is submitted after the specified deadline, it will be rejected without further examination. An initial reply will be sent no later than two weeks after the deadline for objection requests. This initial reply will indicate when a definitive reply will be provided after the Evaluation Committee will examine the eligibility of the objection and recommend an action based on its decision. Only if there is clear evidence of a shortcoming that could affect the eventual awarding decision, it is possible that all or part of the proposal will be re-evaluated.

Objection requests will be subject to some conditions:

- Objection must be related to the evaluation process and limited to procedural aspects and not on the merits of the proposal. Objection must relate to the evaluation procedure, admissibility or eligibility checks and demonstrate a procedural irregularity. Mere repetitions of the content of the proposal or disagreements with the result or reasoning of the evaluation will not be considered.
- Objections must be sent via email to [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) within the specified deadline (email subject: PHOENIX-Open Call 2 Objection).
- Re-evaluations will only be carried out if the objector demonstrates that the procedural irregularity affects the final decision on the successful proposals. Thus, for example, a problem relating to one of the evaluation criteria will not lead to a re-evaluation if, even by adding the maximum points under this criterion, the final score of the proposal would remain below the threshold for funding.
- Re-evaluations will be made on the proposal as it was originally submitted; no additional information will be admitted. Re-evaluations will be partial (limited to the criterion affected by the error) or full (when the whole evaluation has been recognised as flawed).
- The score following a re-evaluation will be regarded as definitive and may be lower than the original score.
- All requests for review will be treated as confidential.

## 5. Implementation of Tests for Case Studies

The Open Call 2 schedule and timeline shall not exceed the PHOENIX-OITB project run time.

### 5.1. Applicants' commitment

During the execution of the tests, the applicants shall comply with the following requirements:

- Each applicant will be the recipient of one or more of the selected services, as described in the [catalogue of PHOENIX-OITB](#) and [Section 2.1 Services Provided under the Open Call](#)
- The applicants will not transfer or assign directly or indirectly any portion of the support to other ends not included in the initial application.
- The applicants will take part in the demo-case study in accordance with the rules and requirements of the call and in accordance with the agreed support for each case study according to the contract.
- The applicants will designate a person to lead the communication between the applicant and the PHOENIX-OITB consortium partners throughout the duration of the demo-case study. In addition, a principal investigator will be responsible for the management of the demo-case study and replying to any request of information within the scope of the demo-case study.
- The applicants will supply any information requested by the PHOENIX-OITB consortium service providers for the purpose of ensuring that these requirements comply with any written request or direction received from the European Commission concerning the proper management of the demo-case study.
- The applicants will not be entitled to require further supporting for the mere reason that they disagree with the results of the support by the PHOENIX-OITB.
- The applicants will comply with dissemination and communication requirements as described in the Confidentiality and Communication Rules relating to the Open Call 2 published together with the application documentation of the PHOENIX-OITB call. All applicants are aware that the PHOENIX consortium partners are obliged to comply with the Open Data and Open Access rules of the EC provided for in the European Union's Horizon 2020 research and innovation programme. Details can be found in the [Annotated Model Grant Agreement](#).
- The applicants are requested to fill and submit a feedback form at the end of the activities about the service provided by PHOENIX-OITB

## 6. Confidentiality, Communication Rules and IPR

### 6.1. Confidentiality and Communication

All the information submitted by applicants will be handled only by the PHOENIX-OITB project team involved in the Open Call 2. The identity of the sender and the content of the proposal will be treated strictly confidential within the Evaluation Committee of PHOENIX-OITB. The application will be evaluated by a team of experts (Evaluation Committee) from the PHOENIX-OITB. PHOENIX-OITB will perform the work impartially applying the highest ethical and moral standards.

The application document will be stored on a web-based, password protected data platform to which only the PHOENIX-OITB Evaluation Committee have access for the duration of the project. Data with regard to the proposal may also be exchanged between the PHOENIX-OITB Evaluation Committee by way of corporate email.

Confidential information disclosed by the applicant must be marked as confidential. The applicant shall disclose to the PHOENIX-OITB consortium confidential information, in its sole discretion, if the applicant deems necessary or desirable for the purpose of assessing the application and execution of the case study. The PHOENIX-OITB consortium will strictly apply to confidentiality rules as laid down in its consortium agreement and will not use confidential information of applicants for any purpose other than to meet the objectives of this Open Call 2.

Media files need to be of high resolution but do not need to disclose IP. The applicant of the selected demo case is aware of this and authorizes the EC and PHOENIX-OITB to publish, in whatever form and whatever medium, with the applicant's prior approval, information related to the use case while underlying IP and other sensitive information will remain confidential.

When filling the application form, applicants are asked to confirm that no conflict of interest could arise in connection with this Open Call 2. This will ensure to prevent any situation where the impartial and objective selection of the proposal is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ("conflict of interest"). Applicants who cannot confirm that there is no conflict of interest, will not be considered for the selection.

Any communication or publication under the Open Call 2 should clearly indicate that the development or technology has received funding from the European Commission within the scope of the PHOENIX-OITB (GA no 953110) displaying the EU logo on all printed or digital material, including websites and press releases. In addition, it must be specified that it reflects only the author's view and that the EC and PHOENIX-OITB are not liable for any use that may be made of the information contained therein.

The applicant of the selected case study will, throughout the duration of their involvement with PHOENIX-OITB, take appropriate measures to engage with the public about such involvement and to highlight the financial support of the EC.

## 6.2. Intellectual Property Rights (IPR) conditions

1. The proposal submitted to this Open Call 2 should be solely based on original work by the applicants and their foreseen developments should be free from any third-party right, or, if this is not the case, such rights should be clearly stated.
2. Before entering into the demo-case study, applicants will be requested to identify their respective background in a separate list. This will be essential for the modifications of and derivative works to the background, as well as for the joint results use and exploitation – if applicable.
3. If the tests performed during the Open Call 2 result in any improvement or enhancement for the company, the company will share this information with the PHOENIX-OITB project in order to report on the impact of the project.
4. If applicable, a joint ownership agreement will be drafted to define terms and condition for handling jointly owned intellectual assets.

Reference: [European IP Helpdesk](#).

## 6.3. Confidentiality Statement from the PHOENIX-OITB Evaluation Committee

The content of the PHOENIX-OITB Application Form is to be treated as Confidential.

Disclosing Party	The party who discloses the Confidential Information via PHOENIX-OITB Open Call 2 Application Form
Receiving Party	PHOENIX-OITB
Confidential Information	Shall collectively refer to all non-public information or material disclosed or provided by Owner to the Receiving Party, either orally or in writing concerning any aspect of the business or affairs of the Owner or its affiliates including without limitation, any information or material pertaining to products, formulae, specifications, designs, processes, plans, policies, procedures, employees, work conditions, legal and regulatory affairs, assets, inventory, discoveries, trademarks, patents, manufacturing, packaging, distribution, sales, marketing, expenses, financial statements and data, customer and supplier list, raw material, costs of goods and relationship with third parties. Confidential Information also includes any notes, analyses, compilations, studies or other material or documents prepared by the Receiving Party which contain, reflect or are based, in whole or in part, on the Confidential Information (e.g. Open Call 2 Evaluation Form).
Involved Parties	Open Call 2 Applicants and PHOENIX-OITB

Access to PHOENIX-OITB Open Call 2 Application Form - thus Confidential Information - will be restricted to the minimum number of PHOENIX project member necessary for a proper evaluation thereof and each member to whom such access is permitted shall abide by the terms of Confidentiality. The access to this document is restricted to the PHOENIX-OITB Evaluation Committee and may be disclosed to additional PHOENIX-OITB project members

(service provider PHOENIX project member and PHOENIX project managers for communication purposes) only if they:

- need to know details in order to evaluate the implementation of the required services and
- are bound by an obligation of confidentiality to the beneficiary

The use of Disclosing Party's sensitive information by the PHOENIX-OITB Evaluation Committee will be restricted only to the proposal evaluation and Open Call 2 application process.

The Receiving Party shall take all actions reasonably necessary to ensure that the Confidential Information remains strictly confidential and is not disclosed to or seen, used or obtained by any person unrelated to PHOENIX project. Those who received this document shall not use for any purpose or benefit whatsoever or disclose to any person at any time any Confidential Information provided by Disclosing Party. The Disclosing Party's Confidential Information should be treated with the same degree of care one uses to protect their own Confidential Information, but in no event with less than a reasonable degree of care.

The Confidentiality Obligation no longer apply if:

- the Disclosing Party decides or agrees to release the Receiving Party,
- the Confidential Information becomes publicly available (without breaching any Confidentiality Obligation)
- the disclosure of the Confidentiality Information is required by EC, international or national authorities\*.

\* This policy is not intended to prevent disclosure where disclosure is required by law.

Herewith, on behalf of the PHOENIX Open Call Evaluation Committee, I confirm and state that the PHOENIX Open Call 2 Confidentiality Statement presented above will be duly followed. We agree to abide by the requirements of the Confidentiality Statement and inform the Disclosing Party if any violation (unintentional or otherwise) of the Confidentiality Statement has occurred.

Upon successful completion of the evaluation process, a specific Confidentiality Agreement is intended to be signed between the Disclosing Party and Receiving Party prior to establishing Implementation Agreement.

Place, Date (DD/MM/YYYY) and Signature

Überherrn, 10/10/2022

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Chair of Evaluation Committee

Dr. Nazende Günday-Türel, PHOENIX-OITB Scientific Coordinator



## 7. Annexes

### 7.1. Annex I: Application Form – Stage 1

This section shows the information and fields required in your application.

Follow the [link](#) to download the Open Call Stage 2 Application Form. Fill in and complete the form in all its part and send a pdf version by mail to [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) before the deadline 03 May 2024.

In case of questions or technical issues, please contact us at [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu).

#### Instructions

Fill out the information as requested. Proposals must be complete and contain all mandatory parts to fulfil admissibility requirements.

English is the official language for the PHOENIX-OITB Open Call. Submissions done in any other language will not be evaluated. All official communication between the applicant and PHOENIX-OITB will be done in English. It will be the only official language during the whole execution of the PHOENIX-OITB project.

The reference font for the body text of proposals is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions). The minimum font size allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used. This applies to the body text, including text in tables. Text elements other than the body text, such as headers, foot/end notes, captions, formula's, may deviate, but must be legible. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). In addition, figures, schemes and photos are encouraged to be provided to make clearer the aim of the proposal taking into accounts its final length (**Section “D. Case Study Application” max. 5 pages**).

Figures, schemes, and additional documents attached to support the application cannot contain additional information or case study than the ones the applicant presents in the main body of the Open Call application.

**A. Applicant Information**

The information in this questionnaire will be shared with the members of the Evaluation Committee only for the purpose of assessing the application. You will be asked for authorisation to use of your data at the end of the application form under the “**Authorisation and Privacy Notice**” paragraph.

<b>Applicant Name, Registration Number and Date (when applicable)</b>	
<b>Postal address</b>	
<b>Country</b>	
<b>Telephone number</b>	
<b>Website</b>	
<b>Email</b>	
<b>Service of application (multiple choice possible)</b> *Please review the <a href="#">Service Portfolio</a> for more details on each service offered.	<input type="checkbox"/> Physico-Chemical Characterisation <input type="checkbox"/> <i>In vitro</i> Characterisation <input type="checkbox"/> <i>In vivo</i> Characterisation <input type="checkbox"/> Manufacturing

Provide contact information for each of the following:

	Queries with regards to the application form ( <u>Principal Investigator</u> )	Technical Specifications and Quality Assurance	General Inquiries
<b>Name and Position</b>			
<b>Telephone</b>			
<b>Cell phone (optional)</b>			
<b>Email</b>			

**B. Applicant Presentation**

**Provide an elevator pitch-type presentation of your company (main goals, markets, sectors, R&D efforts, etc.). You can attach documents to support your presentation.**

EXAMPLE

**Background**

**Key background that you bring into the case study (e.g. Intellectual property, freedom-to-operate, patents, industrial design, process designs).**

EXAMPLE

**Expertise and resources**

**Name the key resources that you will provide to execute the case study (e.g. person-hours, materials, machinery, a description of the associated skills and prior experience). Will cooperation with other links in the supply chain be required? Please, include any images or documents that may help illustrate your point.**

EXAMPLE

**C. Case Study Outline (Publishable Section)**

<b>Pro-bono Demo Case Acronym</b>	
<b>Full title</b>	

**Publishable Summary of the Case Study - Needed Service**

**Which PHOENIX-OITB service do you think will help you solve the problem and how?**  
\*Brief description of the problem to be solved with the PHOENIX-OITB service

EXAMPLE

**D. Case Study Application (Confidential to PHOENIX-OITB Section)****i. Excellence**

Explain the clarity and pertinence of the proposal objective within the PHOENIX-OITB service.

**Provide a description of the problem (with quantification) and challenges to overcome. Please describe the business need for your proposed solution and the associated market including some quantification (market size, growth strategy, potential access to investors, etc.)**

**Provide a detailed description of the needed service to be developed in collaboration with the PHOENIX-OITB (including a description of the functionality, size, etc.).**

**How do the PHOENIX-OITB services help you solve the challenge(s) described?**

**Describe how your final product goes beyond the state-of-the-art.**

Please describe the [TRL](#) positioning of your proposed solution and the change from current state

Will the final product be subjected to any policies and/or regulatory requirements?

## ii. Implementation

Explain the quality and effectiveness of the proposal plan.

Please provide a detailed description of the proposed work plan (key inputs and outputs, milestones and time schedule).

Please provide a detailed description of the technological, business and managerial risks together with a mitigation strategy.

**iii. Impact**

Explain which are the potential impacts and outcomes that may derive from your participation in the Open Call.

**Can any societal, environmental and economic impacts outside your company itself be expected? How your product provides a competitive advantage with respect to competitors?**

**How the target market(s) will be penetrated (tools, resources and timeframe)? Are channels to reach the market(s) identified?**

**What are the expected results to be exploited. Please describe your Return On Investment and the global economic value creation.**

EXAMPLE
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**iv. Additional documentation**

Please merge all the figures with relative caption in one image file to add in the box below. Use the text box to provide additional information and explanations.

**Please, provide any other relevant documentation, when applicable.**

--



### E. Authorisation and Privacy Notice

Please carefully read the text below and then indicate your consent at the bottom of the page.

The data are collected on behalf of PHOENIX project and PHOENIX-OITB gGmbH to allow the management of the application submission and the review, evaluation and selection processes for the PHOENIX-OITB Demo Cases.

The personal data, including but not limited to full name, telephone number, position, organization name and credentials, are collected to allow the PHOENIX-OITB Evaluation Committee to manage the submission, review, scheduling or administration of your information. The personal data provided will be stored in the PHOENIX-OITB internal server and shared with the Evaluation Committee members, beneficiaries that will provide the services of interest and the project managers for communication purposes. The information provided may also be shared with the European Commission upon request.

The information and data provided in the Application Form will be stored for a period of 5 years after the termination of the PHOENIX Project. After this period, your data will be destroyed or anonymized. Any personal data held by us for marketing and service update notification will be kept unless a notification for the cancellation of these data is sent.

Please contact us at [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) for any inquiries.

I, the undersigned [ENTER FULL NAME], CERTIFY that the information stated above is true, correct, and complete to the best of my knowledge. Likewise, I confirm that my legal entity consents to this application and has no objection to the information contained herein being shared with the Evaluation Committee, European Commission and that there is no conflict of interest.

- I have read the privacy notice above and consent to the processing of my data.
- I read and understood the application guidelines.
- I confirm that the provided information are correct and accurate.
- Herewith I confirm that I agree the title/acronym/publishable abstract of this proposal can be published in the PHOENIX project website and can be showcased for PHOENIX project and PHOENIX-OITB dissemination purposes.

Full Name	Signature	Date (DD/MM/YYYY)
Click or tap here to enter text.	X	Click or tap to enter a date.
Full title/Position		
Click or tap here to enter text.		

**F. Letter of Intent**

This letter is to **confirm** that [ENTER FULL LEGAL ENTITY NAME], represented by [ENTER NAME OF LEGAL REPRESENTATIVE] is committed to participate in the PHOENIX-OITB Open Call 2.

I, the undersigned, hereby confirm

- the legal entity commitment to participate in the PHOENIX-OITB Open Call
- that no conflict of interest in connection with the proposal in object are present
- my knowledge that false declaration may lead to rejection, suspension or termination of the granted service

<b>Full Name of the Legal Representative</b>	<b>Signature of the Legal Representative</b>	<b>Date (DD/MM/YYYY)</b>
Click or tap here to enter text.	X	Click or tap to enter a date.
<b>Full title/Position</b>	<b>Legal entity Stamp</b>	
Click or tap here to enter text.		

## 7.2. Annex II: Application Form – Stage 2

This section shows the information and fields required in your application.

Follow the [link](#) to download the Open Call Stage 2 Application Form. Fill in and complete the form in all its part and send a pdf version by email to [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) before the deadline 28 June 2024.

In case of questions or technical issues, please contact us at [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu).

### Instructions

Fill out the information as requested.

Proposals must be complete and contain all mandatory parts to fulfil admissibility requirements.

English is the official language for the PHOENIX-OITB Open Call. Submissions done in any other language will not be evaluated. All official communication between the applicant and PHOENIX-OITB will be done in English. It will be the only official language during the whole execution of the PHOENIX-OITB project.

The reference font for the body text of proposals is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions). The minimum font size allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used. This applies to the body text, including text in tables. Text elements other than the body text, such as headers, foot/end notes, captions, formula's, may deviate, but must be legible. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). In addition, figures, schemes and photos are encouraged to be provided to make clearer the aim of the proposal taking into accounts its final length (**Section B. to E. max. 10 pages**).

Figures, schemes, and additional documents attached to support the application cannot contain additional information or case study than the ones the applicant presents in the main body of the Open Call application.

**A. Applicant Information**

The information in this questionnaire will be shared with the members of the Evaluation Committee only for the purpose of assessing the application. You will be asked for authorisation to use of your data at the end of the application form under the “**Authorisation and Privacy Notice**” paragraph.

<b>Applicant Name, Registration Number and Date (when applicable)</b>	
<b>Postal address</b>	
<b>Country</b>	
<b>Telephone number</b>	
<b>Website</b>	
<b>Email</b>	
<b>Service of application (multiple choice possible)</b> *Please review the <a href="#">Service Portfolio</a> for more details on each service offered.	<input type="checkbox"/> Physico-Chemical Characterisation <input type="checkbox"/> <i>In vitro</i> Characterisation <input type="checkbox"/> <i>In vivo</i> Characterisation <input type="checkbox"/> Manufacturing

Provide contact information for each of the following:

	<b>Queries with regards to the application form (<u>Principal Investigator</u>)</b>	<b>Technical Specifications and Quality Assurance</b>	<b>General Inquiries</b>
<b>Name and Position</b>			
<b>Telephone</b>			
<b>Cell phone (optional)</b>			
<b>Email</b>			

<b>Pro-bono Demo Case Acronym</b>	
<b>Full title</b>	

**Publishable Summary of the Case Study - Needed Service**

**Which PHOENIX-OITB service do you think will help you solve the problem and how?  
\*Brief description of the problem to be solved with the PHOENIX-OITB service**

EXAMPLE

**B. Objective(s)**

Please provide an extensive description of the proposal objective(s).

EXAMPLE

**C. State of the art**

Please provide an extensive explanation of the proposal background and state of the art.

EXAMPLE

**D. Implementation**

Please provide an extensive explanation of the quality and effectiveness of the proposal.

EXAMPLE



**E. Impact**

Please provide an extensive clarification of the proposal potential impacts and outcomes.

EXAMPLE

**F. Additional documentation**

Please merge all the figure with relative caption in one image file to add in the box below. Use the text box to provide additional information and explanations.

**Please, provide any other relevant documentation (when applicable).**

EXAMPLE

### G. Authorisation and Privacy Notice

Please carefully read the text below and then indicate your consent at the bottom of the page.

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Please contact us at [open-call@phoenix-oitb.eu](mailto:open-call@phoenix-oitb.eu) for any inquiries.

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- I have read the privacy notice above and consent to the processing of my data.
- I read and understood the application guidelines.
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<b>Full Name</b> Click or tap here to enter text.	<b>Signature</b> X _____	<b>Date (DD/MM/YYYY)</b> Click or tap to enter a date.
<b>Full title/Position</b> Click or tap here to enter text.		