



## ANGELINI FOR FUTURE 2021

### Supports for Independent Research in Rare Diseases

### CALL FOR PROPOSALS

#### Introduction

Angelini Pharma is an international group, leader in health care and well-being, committed to help patients, doctors and caregivers in the fight against diseases with constant and prevalent attention in the areas of Pain and Inflammation and Mental Health. Angelini Pharma has made research its core business to improve patients' health and quality of life.

INCIPIT, Italian Network for Paediatric Clinical Trials, is a no profit consortium composed by the Italian main children's hospitals, the largest departments of paediatrics and national and international paediatric therapeutic networks coordinated by Italian institutions with the aim to support the planning, conduction and completion of all types of clinical studies in the paediatric population.

In this context, Angelini and INCIPIT, sharing the scope to promote high quality research on drugs, are now launching the first edition of call for proposals - **Angelini for Future 2021**- to support independent research projects proposed by European investigators working in public or private non-profit healthcare organizations. In this joint collaboration, Angelini allocates 300 K€ to fund up to two research projects either in late preclinical phase or in early clinical phase and INCIPIT provides the expertise to prepare the call, to manage the evaluation process of the research projects and to perform monitoring of the scientific results.

The aim of this initiative is to support research investigating drug repurposing in rare diseases or in conditions with high-unmet medical needs in CNS, targeting the paediatric population. Although there are over 7,000 rare diseases, only around 400 have licensed treatments. Drug repurposing is a good option for these diseases, which are affecting small populations, and has the potential to deliver new treatments with drugs already available but not yet specifically studied in these patients.

#### Eligibility criteria

**Therapeutic area:** This call is in support of research project focusing on rare diseases (in Europe a disease is considered to be rare when it affects 1 person per 2000) or on conditions with high unmet medical needs in CNS with the aim to identify and to develop new uses of existing drugs in the paediatric population.

**Host Institution:** Only research proposals submitted by Investigators employed by public and private non-profit Research Institutions (Academia, Research Foundation and non-profit organizations) are eligible.

**Applicants:** Applicants must hold a professional degree in Science (PhD, MD, PharmD, etc.)



## Project

**Project description:** Proposals should address key outstanding questions either in preclinical phase or in early clinical phase.

**Project duration:** The duration of the proposed research project can be 18 months (maximum).

**Budget:** Total amount up to 300k€ will be allocated by Angelini Pharma to fund up to two projects. The project proposal will need to come with the allocated budget sheet. A maximum of 100,000 € for research expenses is allowed for proposals addressing preclinical study. The funding will be provided by “Angelini for Future” upon signature of a contract as described in the agreement.

## Evaluation

**Grants will be awarded on a competitive basis.**

The scientific evaluation and selection of applications for funding will be managed through a strict, meritocratic and transparent process. INCIPIT scientific officers will identify and appoint a Scientific Committee (SC) for the selection process based on expertise and independence from the applicants. SC will be composed by qualified and internationally recognized experts selected among the most eminent scientists in the fields of the proposals. Members are required to submit a declaration of conflict of interests upon their appointment. Each individual must declare any interests, which may potentially cause a conflict in the course of fulfilling their duties and responsibilities as a scientific committee member.

A review session will complete the evaluation process in order to guarantee impartiality and transparency.

A summary of each proposal’s evaluation will be made available to the applicant of that proposal.

**Evaluation criteria:** Scientific Committee evaluates each application using a scoring methodology based on:

- scientific merit of the proposal
- progress and prospective impact to benefit patients
- well-designed studies
- skills and experience to carry out the research

## Terms of the award

The research projects will be assessed and up to two of these will be selected by May 2021.

The funds will be released based on a specific agreement provided by Angelini.

The proponent will be the sponsor of the research activities. Full ownership of all intellectual property (IP) rights arising from funded research belongs to the Host Institution/grantee, according to IP regulations.



### Rules for Applying

- “Angelini for future” intends to sponsor research project promoted by public or private non-profit organizations that meet the criteria set forth here and applicable regulations.
- Angelini Pharma strives to avoid conflict of interest; therefore, each member of Scientific Committee shall declare have no conflict of interest with Angelini Pharma such as personal activity, relationship or business involvement interferes, or appears to interfere as well as applicant researchers shall declare have no conflict of interest with Angelini Pharma and members of Scientific Committee. Furthermore, Organizations to which any directors of Angelini Pharma and their spouses and family or first- or second-degree relations may belong may not apply. They will inform promptly Angelini Pharma in case of any conflict of interest.
- Any proposed projects on Angelini Pharma’s products or research conducted jointly by Angelini Pharma and external partners, in which Angelini Pharma obtains information, data, intellectual rights or other benefits in exchange for founding, are excluded from this programme.
- The payment of grants does not imply any commercial relation and must not intend to induce or encourage the prescription, use or purchase of Angelini Pharma products.
- The applicant’s organizations assume responsibility for the research project and for potential breaches of rights by third parties.
- The researchers can submit the proposal starting from February 1<sup>st</sup> until March 31<sup>st</sup> via PEC or e-mail [research@incipit-ped.net](mailto:research@incipit-ped.net) and they’re asked to include all necessary information such as:
  1. Sponsor contact details
  2. Letter of request
  3. Detailed Project description and purposes together with the requested budget according to the forms provided by INCIPIT
  4. Letter of support from host institution
  5. Declaration of commitment:
    - a) to start research project within 60 days of the date on which the grant is paid and the commitment to inform Angelini confirming that the research project has been started to the email address: [research@incipit-ped.net](mailto:research@incipit-ped.net);
    - b) to confirm the availability and allocation of the funding to be received for conducting the project results;
  6. Declaration of the project independency from Angelini Pharma; the winning organizations must be the actual beneficiary of research projects carried out independently and shall maintain full responsibility of projects, their content and all other aspects in compliance with applicable regulations.
- Angelini Pharma will not have access and will not examine any proposal.
- The documentation applied won’t be returned to the applicant by INCIPIT.
- In compliance with Farindustria Code, Code of Practice EFPIA and IFPMA disclosure the documentation related to the winning organizations are published on Angelini Pharma website.
- The host institutions of each proponent will be asked to declare the implementation of specific anticorruption plans according to the national law where required. (e.g. Italian “Piano per la Prevenzione della Corruzione”)



### **Confidentiality**

INCIPIT will treat your proposal confidentially, as well as any related information, data and documents received. Scientific Committee members are also bound by an obligation of confidentiality.

### **Privacy of personal data**

Personal data will be processed exclusively for the purposes indicated in this Call and in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, as well as the provisions of the legislative decree 30 June 2003, n.196, as modified by the legislative decree 10 August 2018, n.101.

Angelini Pharma and INCIPIT will act as Autonomous Data Controller towards the respective competences. The parties have determined the purposes and means of processing of personal data through an agreement of Joint Controlling, defining the respective responsibilities for compliance with the obligations under the GDPR, towards the contents and objectives of the present call.

#### **Key dates and deadlines**

- **Opening date:** January 29<sup>th</sup> 2021. Information and application forms will be available upon request to [research@incipit-ped.net](mailto:research@incipit-ped.net)
- **Closing date:** March 31<sup>st</sup> 2021 at 5 pm. Complete applications must be received at [research@incipit-ped.net](mailto:research@incipit-ped.net) email address by March 31<sup>st</sup> 2021 at 5 pm.
- **Evaluation:** April-May 2021. During this period applications will be reviewed and selected.
- **Award:** May 2021. Selected applicants will receive notification letter