ANGELINI PHARMA INDEPENDENT RESEARCH GUIDELINES

This document provides guidelines for the scientific and academic research community interested in submitting an Investigator Initiated Trial (IIT) proposal through angelinipharma.com. We strongly recommend reviewing the information in its entirety before submitting a proposal.

At this time, Angelini Pharma will be prioritizing review of new Investigator Initiated Trial ideas in the context of COVID-19.

MISSION

ANGELINI PHARMA is committed to improve patients' health and quality of life through bold pursuits in science aimed at the advancement of disease knowledge that addresses unmet medical needs surrounding our therapeutic areas with the goal of advancing patient care. The mission of Angelini Pharma includes support to high-quality research that is initiated and executed by external investigators and/or public or public-like institutions as well as no-profit bodies, research organizations, scientific societies or associations (together, "Institutions").

Angelini Pharma IIT Program does not exclude and will not interfere with the medical and scientific research independently conducted by Angelini Pharma as part of its R&D activity. Should any application made under the Angelini Pharma IIT program overlap with research activities independently conducted by Angelini Pharma, Angelini Pharma will continue its independent research regardless of the support eventually provided under the IIT Program, preserving the confidentiality, non-use and non-disclosure obligations concerning confidential data included in the IIT submission.

ABOUT ANGELINI SUPPORT TO IIT

The Angelini Pharma IIT Program provides an opportunity to academic and community-based physicians and/or Institutions interested in conducting their own independent research in the disease areas where Angelini Pharma operates to apply for an unconditional support aimed to help advance the medical and scientific knowledge in the same disease areas . Any qualified researchers and Institutions who are interested in conducting their own independent research with Angelini Pharma unconditional support are welcome to apply for proposals.

All proposals are reviewed by Angelini Pharma medical staff based on rigorous ethical and scientific merit of the proposed research, clinical value, study design meets ethical guidelines, experience and qualification of the investigator and research site, with the purpose of ensuring patient safety, alignment with Angelini Pharma values and research priorities.

TYPES OF ELIGIBLE RESEARCH

The research proposal compliant with applicable local laws, rules, guidelines and regulations must align with the robust medical and scientific governance company's system. Depending on each therapeutic area's current interests, this may include but not be limited to:

- Preclinical and clinical studies;
- Observational studies, e.g. epidemiological studies or outcomes studies;

- Other research focusing on products (medicinal or not), devices, solutions and systems (including screening tools) relevant for the prevention, diagnosis or therapy of a particular disease and that, as such, may fall within the scope of the National Health Service.

Election of IIT proposals worthy of Angelini Pharma's unconditional support will be to the sole discretion of Angelini Pharma.

INVESTIGATOR RESPONSIBILITIES

IIT must be conceived and developed by external investigators or third-party public or public-like institutions or no-profit research organizations. All responsibility for the conduct of IIT pertain to the investigator and their institution, including ensuring that the study is conducted under the appropriate ethical, legal, and regulatory guidelines including ICH/GCP Guidelines. The applicants are not an employee of Angelini Pharma or its affiliated entities and Angelini Pharma, its affiliated entities, directors, officers and agent will not interfere with the designing, planning and execution of the relevant IIT.

PROCESS

Angelini Pharma receives, reviews, and responds to unsolicited proposals from health care professionals (HCPs), scientists, and Institutions for research support. The application process occurs through the **Application Form** available at angelinipharma.com/investigator-initiated-trials/, allowing the proposals to come into Angelini Pharma via a simple, user friendly website.

After filling the online Application Form, you will receive an email to confirm — by means of a direct link — the sending of the application for participation; the Application will be considered received by Angelini Pharma when, after clicking on said link, you'll be addressed to a webpage, confirming its successful upload.

The contact details requested in the application form (First and Last name, contact number, email, Institution name and address) are intended to be used with the sole purpose to allow Angelini to follow up your proposal.

In case of a negative feedback, your personal data will not be stored, and will be permanently deleted by Angelini.

The application does not ensure nor guarantee approval. Through the internal governance process, all proposals are carefully considered and evaluated, and decisions are made by Angelini Pharma discretionally, based on criteria mentioned above. Angelini Pharma strives to provide a response to your application within four weeks of submission to the portal. Applicant will be notified of approval or denial of an IIT submission.

All submissions will be considered confidential and will not be disclosed to any third party other than the staff involved in the reviewing, election and follow-up process. Copy of each submission will be kept by Angelini Pharma for administrative and legal purposes only, for the time statutorily required.

In the event Angelini Pharma and/or any of its affiliate already have a research plan in progress which plan overlaps with the object matter of the IIT application, then Angelini Pharma will continue

its independent research activity. In doing so, Angelini Pharma and/or the relevant Affiliate will also evaluate the possibility to establish a joint research effort outside and beyond the IIT program.

PHASE	EXTERNAL APPLICANT	ANGELINI PHARMA
Application & Review	-IIT submission through the Application Form on angelinipharma.com	- Review of the IIT proposal - Following the review of the IIT proposal, you may be asked to submit your CV and/or any documentation confirming the capabilities to perform the trial together with a full protocol and final study budget for further evaluation - Books and records. Angelini must prepare and maintain records that accurately and reasonably detail and document the process - Communication of decision to decline or approve the study proposal within 4 (four) weeks
Negotiate, finalize, and execute contract that defines roles and responsibilities of the approved IITs. The contract shall only be finalized if the IIT is approved by an Ethics Committee where such approval is required		
IIT Execution and Reporting	- IIT Conduction The progress of IIT will be collected in a study memorandum provided to Angelini Pharma	- Approve final budget and payment milestones and completion of the final study report - Issue drug shipment (when applicable) - Check on the study memorandum the consistency with the agreed support request
	- Results Reporting	- The agreed financial support is linked with defined milestones and shall only be paid if these milestones are achieved.

DISCLOSURE

Angelini Pharma is committed to transparency in its interactions with healthcare professionals and health care organizations/institutions. Consistent with applicable laws and/or codes of practice applicable to the pharmaceutical industry, we track all transfer value provided to HCPs and HCOs without compromising patient data or confidentiality.

NOTE

This application form is not to be used for Grants, Donations, Charitable Contributions or collaborative study requests. The intent of this tool is not to collect adverse events either actual or potential that should be reported through the normal channel in place in your country.