

IIT 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.

1. 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.

2. 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.

3. 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:

- Observational clinical studies (prospective and retrospective) e.g. epidemiological studies or outcomes studies;
- Interventional clinical studies (clinical trials);
- 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.

4. WHICH REQUESTS ARE NOT IN SCOPE?

This application form is not to be used for Grants, Donations, Charitable Contributions or collaborative study requests.

5. 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.

It is the responsibility of the Sponsor/Proposer to handle actual or potential adverse events, which should be reported through the normal channel in your Country.

6. PROCESS

Angelini Pharma (Angelini Pharma S.p.A. and its affiliate established in the country of the applicant or of the Institution on behalf of which the application is made) receives, reviews, and responds to unsolicited proposals from health care professionals (HCPs), scientists, and Institutions for research support.

The application process occurs only through the **Application Form** available at angelinipharma.com, allowing the proposals to come into Angelini Pharma via a simple, user-friendly website.

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 Pharma to follow up your proposal.

You will be asked to provide your Curriculum vitae and the study synopsis according to the template provided and downloadable from the Homepage.

If your application has been correctly submitted ((after completing the online form and clicking on the "virtual button" to send the proposal, You will receive an email to confirm the sending of the application for participation by means of a special link), you'll be addressed to a webpage, confirming its successful upload, and You will receive a confirmation email. Angelini Pharma strives to provide a response (approval or denial) to your application within 8 (eight) weeks from successful submission of the proposal.

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

In case of a positive feedback, your personal data will be stored for a period of 12 (six) months to carry out the IIT agreement negotiation.

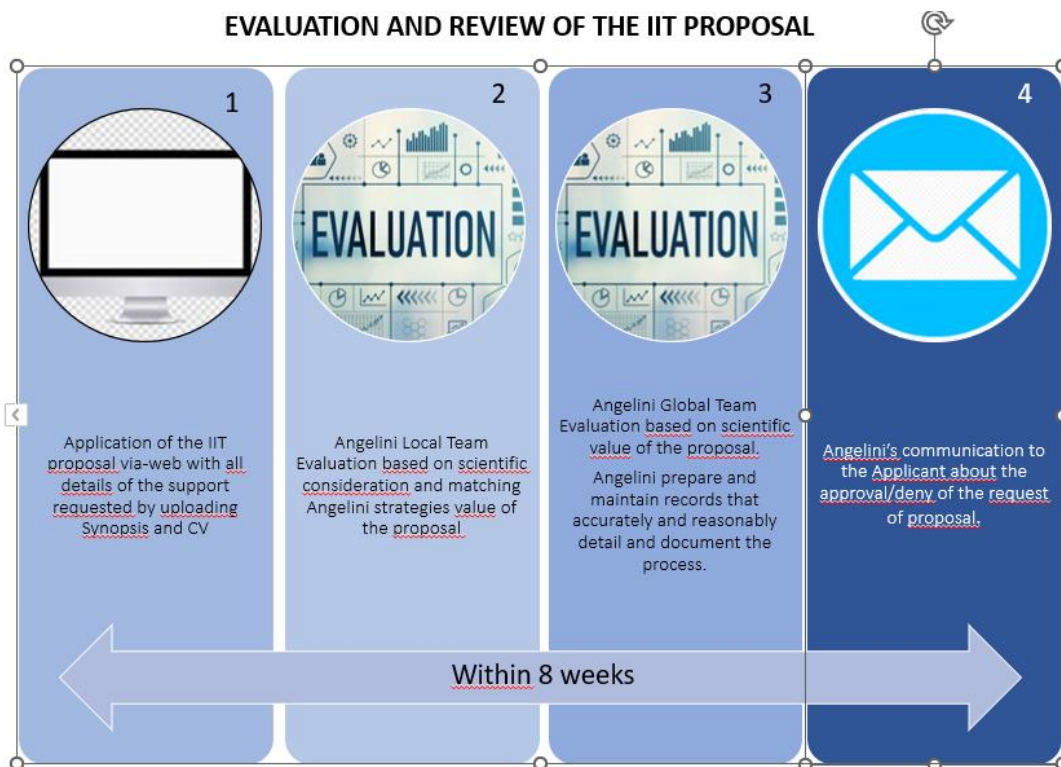
The application does not ensure nor guarantee approval. Through the internal governance process, all proposals are carefully considered and evaluated, and decisions are made by Angelini Pharma discretionally, based on criteria mentioned above.

All submissions will not be disclosed to any third party other than the staff involved in the reviewing, election and follow-up process. Your proposal could be sent to the Licensor or Marketing Authorization Holder (MAH) of the licensed product involved in the IIT proposal for which Angelini Pharma S.p.A. or its affiliates are not the Licensor or MAH, in order to receive by them merely a favorable opinion on the IIT proposal.

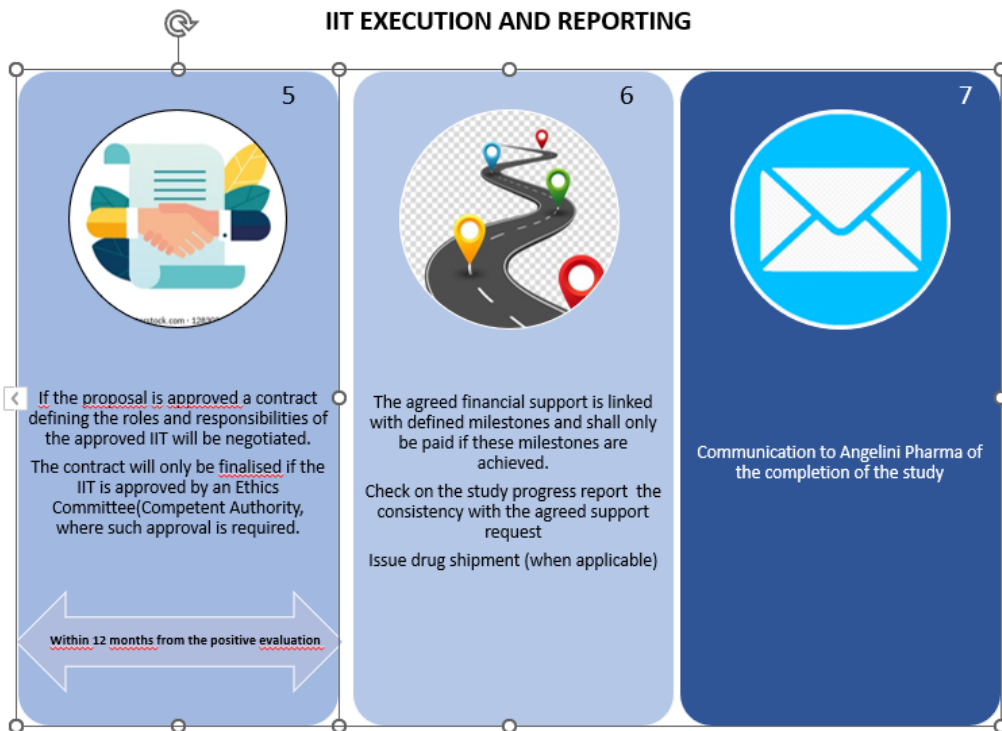
If necessary, your data may also be transmitted in accordance with the law to tax authorities, police and judicial and administrative authorities, for the assessment and prosecution of crimes, prevention and protection from threats to public security, to allow Angelini Pharma to ascertain, exercise or defend a right in court, as well as for other reasons related to the protection of the rights and freedoms of others.

In the event Angelini Pharma S.p.A. 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.

EVALUATION AND REVIEW OF THE IIT PROPOSAL



IIT EXECUTION AND REPORTING



8. 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.