RIS guidelines

RIS ANGELINI PHARMA INDEPENDENT RESEARCH GUIDELINES

This document provides guidelines for the scientific and academic research community interested in submitting Research Initiated Studies (RIS) 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 RIS 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 RIS program overlap with research activities independently conducted by Angelini Pharma, as a part of our commitment, Angelini Pharma will continue its independent research regardless of the support eventually provided under the RIS Program; by preserving the confidentiality, non-use and non-disclosure obligations concerning confidential data included in the RIS submission.

2. ABOUT ANGELINI SUPPORT TO RIS

The Angelini Pharma RIS Program provides an opportunity for academic and community-based researcher/physician and/or Institutions, to apply for an unconditional support. The RIS Program is for all those who are interested in conducting their own independent research in the disease areas where Angelini Pharma operates, to give our contribution to the improvement of 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 via unconditional support are welcome to apply for proposals.

All RIS proposals are reviewed by Angelini Pharma S.p.A. non-clinical staff, based on rigorous ethical and scientific merit of the proposed research, study design in line with guidelines, experience and qualification of the investigator and research site, with the purpose of ensuring an 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 robust scientific governance company's system. Depending on each therapeutic area's current interests, this may include but not be limited to:

- Non-clinical 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 RIS 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

RIS 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 RIS pertain to the investigator and their institution, including ensuring that the study is conducted under the appropriate ethical, legal and regulatory 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 RIS.

6. PROCESS

Angelini Pharma S.p.A. 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 (i.e. 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 Home page.

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 60 (sixty) calendar days from 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 (twelve) months to carry out the RIS 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 and as per internal standard procedures.

All submissions will not be disclosed to any third parties other than the staff involved in the reviewing, selection and follow-up process. Your proposal could be sent to the company that is the licensor/owner of the intellectual property of the medicinal product to which the RIS refers, in order to receive its favorable or unfavorable assessment on the RIS.

In case Angelini Pharma S.p.A. and/or any of its affiliate already have a research plan in progress that overlaps with the object matter of the RIS application, then Angelini Pharma will continue its independent research activity.

PHASE	EXTERNAL APPLICANT	ANGELINI PHARMA
Application & Review	- RIS submission through the Application Form on angelinipharma.com	• Review of the RIS proposal • Following the review of the RIS proposal, you may be asked to submit your CV and/or any documentation confirming the capabilities to perform the research study together with a detailed protocol and a comprehensive 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 60 calendar days
Negotiate, finalize, and execute contract that defines roles and responsibilities of the approved RISs. The contracts shall only be finalized if the RIS is approved by an Ethics Committee, where such approval is required		
RIS Execution and Reporting	- RIS Conduction The progress of RIS will be collected in a study	• Approve final budget and payment milestones and completion of the final study report

	memorandum provided to Angelini Pharma	• 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.

7. DISCLOSURE

Angelini Pharma is committed to transparency in its interactions with research 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.