

Application for Investigator Initiated Trials (IITs) Initial application

Dear investigator,

Thank you very much for considering applying for a research grant with us. This document summarises relevant information to guide you through the application form. For any questions, please do not hesitate to contact support_clinical_proposal@fresenius-kabi.com.

What we would consider

- Clinical and preclinical study applications from the U.S. and Canada with Fresenius Kabi products for clinical nutrition, intravenous fluid management, generic injectables, biosimilars, and infusion delivery solutions
- Studies exploring new indications
- Real world and observational studies

What we do not consider

- Studies where the product is contraindicated
- Studies from third party firms exclusively that are without relevance to our products or strategic initiatives
- General educational and training activities are not included in the IIT evaluation program and are handled separately
- Studies founded or co-founded by direct competitors of Fresenius Kabi
- Studies where it appears that the risk:benefit ratio is too high

What to consider beforehand

The application process starts with the **initial application**. The initial application will only require basic information about your projected study to keep your initial efforts low and allow a speedy evaluation.



Please prepare to provide the following information for initial application:

- **Contact information** and institution of the applicant
- At least one and up to three **research articles** showing your **expertise** relevant for the current application. Please provide full citations, DOIs or Pubmed-IDs
- If your study is supervised by a senior researcher, please also provide contact details of your **supervisor**
- The preliminary **title** of the study with no more than 200 characters
- A brief rationale and **scientific background** of your study with no more than 3500 characters
- The study's **hypothesis** (max. 1500 characters)
- Primary (max. 200 characters) and secondary **endpoints** (max. 1500 characters)
- A brief description of the main characteristics of your **study population** (e.g., demographics, diseases) (max. 1500 characters)
- A **description of treatment arms** including the number of patients per arm, the intervention, dosing, and duration, if the study is interventional. Please also check whether the planned intervention is approved according to the product information

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- The **study design** (interventional, observational, randomization, blinding, single- or multicentre, etc.)
- The planned **sample size** and a short justification for it (power calculation, max. 1500 characters)
- The current **status** of the study, i.e., whether a protocol or ethics approval is already available. Please note that for initial application these documents are not required
- The overall **funding** requested from Fresenius Kabi
- The **Fresenius Kabi products** and number of units you would like to request (if any)
- Other **sources of funding** for the study (if any)

Application process

If Fresenius Kabi is interested in the concept proposal, the investigator will be asked to submit a full study protocol. Fresenius Kabi will notify the investigator after the internal review(s) of the protocol.

Please note that the invitation for a full submission does not guarantee support of your study as the final decision about supporting your study will be taken after the full submission.

An overview of the application process is shown in the figure below:

Intended timeline

