**Submission to Mölnlycke IIS Program**

Send the completed form to: InvestigatorInitiatedStudies@molnlycke.com

Acknowledgement receipt of your submission of the IIS proposal will be automatically generated.

Information to be completed for IIS **concept** proposals

**Contact Details**

|  |  |
| --- | --- |
| Completed by  |  |
| Investigator name  |  |
| Name of institution  |  |
| Address  |  |
| Telephone  |  |
| Email  |  |
| Have you had discussions about the research with a Mölnlycke representative ahead?  | *If so, please list the name(s) of the person(s). In this way, we will make sure to align with the named person(s) to facilitate streamlined communication with you.* |

**Study information needed for concept proposal**

|  |  |
| --- | --- |
| Study synopsis | *Please add to the application* |
| Study title |  |
| Study design  | *A brief summary of major study design features i.e.* in vitro*, animal or clinical study, follow up times and study end point* |
| Please describe how your study will add value to the existing evidence on this topic/area  |  |
| Main objective |  |
| Secondary objective(s) |  |
| Primary endpoint(s) |  |
| Materials and methods |  |
| Indication to be investigated  |  |
| Study population  | *For clinical/animal study describe target population, indication studied and inclusion/ exclusion criteria’s* |
| Number of patients to be enrolled  |  |
| Short description of statistics including a justification for the number of subjects to be enrolled  |  |
| Product(s) to be investigated and (if applicable) comparator(s)  |  |
| Study duration (how long will each patient be treated and followed up?)  |  |
| Planned start date (first patient enrolled)  |  |
| Planned end date (last patient completed)  |  |

**Support requested**

|  |  |
| --- | --- |
| Requested monetary support (euro)  |   |
| Requested product support |   |

**Add additional documents to the application of IIS concept proposal:**

* Study synopsis
* Curriculum vitae (CV) for all participating investigators

Additional information to be completed for IIS **full** proposals

**Contact Details**

|  |  |
| --- | --- |
| List all investigators involved in the study |  |
| List all study centre(s) | *The site(s) where the research will be conducted.* |

**Study information needed for IIS full proposal**

|  |  |
| --- | --- |
| Study protocol | *Please add to the application.* |
| List secondary endpoint(s) |  |
| List explorative endpoint(s) |  |
| Planned report date |  |
| Planned publication & presentations dates |  |

**Additional information needed**

|  |  |
| --- | --- |
| Please list publications within this area | *At very high level, if there are any similar study published.* |
| Please list previous, ongoing, and planned number of clinical trials/research |  |
| Please list if there are any ongoing or planned competitive studies |  |
| Please list funding history |  |
| Please define if your research is funded by other third parties or if you plan to request further support by any other person/institute/company? |  |
| Please state the industry code applicable to this proposal (e.g. MedTech Code, local codes…) |  |

**Support requested, shall be updated if changed at the time of submission of the concept proposal**

|  |  |
| --- | --- |
| Requested monetary support (euro)  |  |
| Requested product support |  |

**Add additional documents to the application of IIS full proposal:**

* Full study protocol
* Budget details:
	+ Full study cost and how much of the full study cost the IIS funding request is. Use the template for prospective or retrospective study
	+ Product request. Use the product consumption template to estimate the required number of products.
* A copy of the EC/IRB approval (if applicable and ready)
* A copy of regulatory authority approval (if applicable and ready)
* Curriculum vitae (CV) for all participating investigators