IPSEN ISS FAQS

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1. ABOUT ISS SUPPORT

1.1 Who may apply for ISS support?

The following types of individuals/organizations are eligible to submit requests for ISS support:

- Healthcare professionals
- Researchers
- Cooperative groups
- Research institutions
- Universities or colleges

1.2 How do I apply for ISS support?

To apply for ISS support, click here. ISS support requests must be submitted at least 90 days prior to work commencing on the project (protocol).

1.3 What type of information is needed for submission?

The following information is required for application submission:

- Principal Investigator's CV (detailing qualifications, experience in research, training on good clinical practices, and publications)
- Accreditation Number
- Outline or Synopsis Form: study title, objectives, hypothesis, study design, study population (inclusion and exclusion criteria), sample size, study treatment (if any), endpoints, and timelines
- Study Budget Estimate and amount (if any) of financial support requested and/or if required, product details

1.4 Is a protocol required at the time of first submission step?

A protocol is not required at first submission step.

1.5 Why does Ipsen request so much information during submission?

Ipsen assesses several factors during the ISS proposal review in order to make an informed decision. These factors include study design, rationale, strategic interest, scientific merit, site capabilities, budget alignment, and risks.

1.6 How long does it take for the initial submission to be reviewed?

Please note that our normal processing time for a new complete ISS submission is a minimum of 12 weeks. Typically Ipsen will confirm initial interest within 4 weeks of submission of the study outline. Following receipt of the full synopsis, a decision will typically be communicated within 8 weeks. This timeline assumes all information about a proposed study is available when you submit your application and that any questions arising can be addressed in a timely manner.

1.7 Can investigators submit study proposals for animal research and any other non-clinical research?

Yes. Ipsen accepts ISS submissions for both clinical and non-clinical research.

1.8 Do investigators have to submit a study proposal if requesting drug only?

Yes. Proposals are required even if the request is for drug only.

1.9 Who reviews the ISS submissions?

Ipsen assesses several factors during the ISS proposal review in order to make an informed decision. These factors include study design, rationale, strategic interest, scientific merit, site capabilities, budget alignment, and risks.

The assessment is undertaken by subject matter experts including Medical Affairs, Global Patient Safety, Biometry, Legal and any ad hoc subject matter experts. The final assessment will be done by the relevant Governance Body.

2. NEW USER REGISTRATION

2.1. How do I register?

To register, open the ISS website found here.

- Select the Register for New Account link

- Enter the required information and click Register

- You will receive an email to activate your account
- To connect enter your email address and password entered during the registration
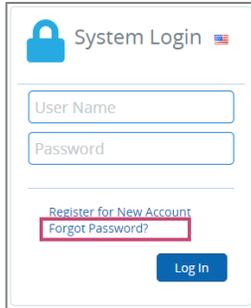
2.2. How do I update my profile?

To update your profile, click the Profile Global Tool icon and then select Profile.

2.3. What do I do if I cannot remember my password?

Click the Forgot Password? link on the login page.

2.4. Whom do I contact for additional support?

For additional support, contact InvestigatorSponsoredStudies@Ipsen.com.

2.5. How do I give my Study Coordinator access to my projects?

If the PI/Sponsor would like access for their study coordinator they will need to contact the PM at Ipsen to have that individual added. Once they have been added as a resource to the system they will also need to be manually added to the study in the role of Investigator or Sponsor Representative.

3. APPLICATIONS

3.1. Can I use any internet browser to use Visiontracker?

Visiontracker is a web-based system that can be used on any operating system or browser. For optimal performance, we recommend using Chrome.

3.2. How long does a Visiontracker session last?

The system will log you out if there is no activity for 45 minutes.

3.3. How can I view or open a saved application?

You can view and open saved applications from your Workbench and in Portfolio Search.

3.4. How do I print my application?

You can print your application by using the gear icon on your Workbench or in Portfolio Search through the Actions menu.

3.5. How do I attach a document?

You may add documents on the Attachments node. To upload a new document, select New Supporting Material in the Actions menu.

In the Post Attachment window, click Attach File and select the file from your computer. Choose the Attachment Type from the drop-down menu and click Post to upload the attachment.
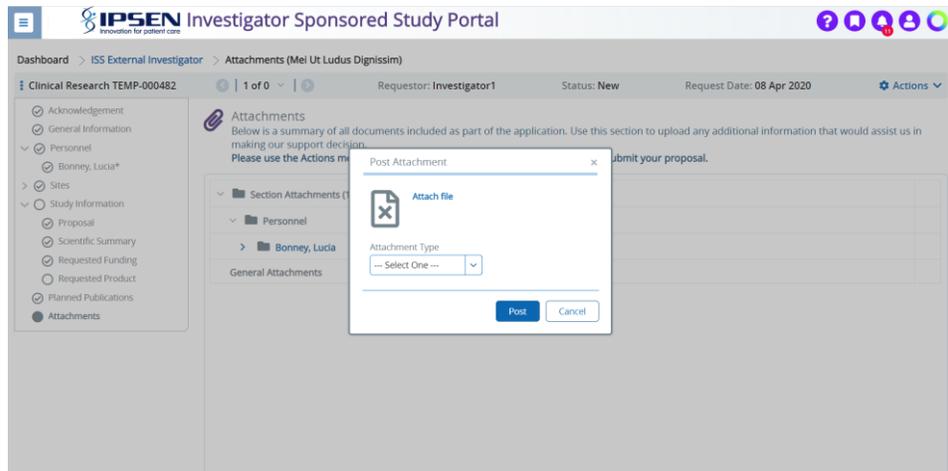
3.6. What happens after the outline has been submitted?

If the outline is endorsed, the applicant will receive a request to submit a full synopsis.

3.7. What type of attachments are required during the study life cycle?

The following attachments **may** be required during the study life cycle:

- The principal investigator's CV
- The GCP training certificate
- Study Budget
- Protocol and amendment(s)
- Regulatory documents (IEC/IRB and/or Competent Authority approval)
- Informed consent templates approved by IEC/IRB
- Invoices
- Final Study Report
- Drug Destruction Certificate
- Publications

4. POST APPROVAL

4.1. What happens after a study synopsis is endorsed?

If the synopsis is endorsed, the applicant will receive first a request to submit the protocol and then a request to submit corresponding regulatory information.

4.2. What is expected once the project has been endorsed and the contract has been executed?

The applicant will submit regular project status updates while the study is active.

4.3. What happens if there is a change in the product, protocol or budget (amendment)?

The investigator will submit an amendment for changes to the protocol or budget. To submit an amendment:

1. Open the application
2. Select Create Amendment in the Actions menu

3. A new Amendments node will appear in the table of contents
4. Enter the Description of the change in the free text box
5. Select the Reason for the change from the drop-down menu
6. Upload any protocol or budget amendments, as well as any supporting materials
7. Click the Actions menu and select Submit Amendment

4.4. What is expected of the applicant after the study is completed?

The applicant will submit a final study report, product, and financial reconciliation, as well as any publications associated with the study.