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**IIT APPLICANT WORKING GUIDE**

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I. INTRODUCTION

The purpose of this guide is to provide guidance to Investigator-Sponsors applying online for Ferring support of Investigator Initiated Trials (IIT’s).

REGISTERING IN VISIONTRACKER

Investigators must register/create an account in Visiontracker at the time of first use. This account may be used for all Investigator Initiated Trial applications submitted by the researcher to Ferring.

II. HOW TO REGISTER AND LOG-IN

To register and receive a User ID and password for the Ferring study system, begin by accessing the appropriate web link to Visiontracker:

- Ferring web link:
  
  https://ferring.envisionpharma.com/vt_ferring/#Login

REGISTER TO RECEIVE A USER ID AND PASSWORD

1. Click the Need a User ID link.

2. Complete the Registration form. Required fields are marked with an * [asterisk].
3. Click OK when complete.

4. Clink OK when confirmation of registration request box appears

LOGIN WITH USER ID AND PASSWORD
An email with your User ID will be sent to the email address provided during registration. If the message is not received in 20 minutes, search your Junk E-mail folder, in case it was classified as junk mail.

A second email will be sent containing a temporary password.

1. Log in using the new User ID and the temporary password.
NOTE: Notice the Forgot Password link; in the future, if you require a new password, click this link and follow the procedure below.

2. The temporary password works only once. You must create a new password prior to logging again. Follow the on-screen instructions.

If a password does not meet the security requirements, the system will provide messages to guide you.

3. The following screen will appear after you have successfully created a new password.
III. HOW TO SUBMIT AN APPLICATION

1. Log in to the Visiontracker system.
2. From the Task List tab click on New Application.
3. From the New Application, select a grant or study type using the drop-down menu; then click OK.

4. Review and scroll down to accept the New Study application agreement; click the Accept box at the bottom of the text and then click OK.
MAIN NAVIGATION TABS
The main navigation tabs display at the top of the screen. Begin with the Main tab and complete all the fields under each tab.

![Main Navigation Tabs]

Each tab contains required fields. All required fields are marked with an * [asterisk].

- Main
- Study Design
- Support
- Attachments

To switch from one tab to another, click on the intended tab or use the arrow at the bottom of the page to switch to the next tab in the series.

SAVE STUDY APPLICATION

1. Enter a Study Title and then click the Save button.

   - A Save confirmation displays. It contains a temporary application number. This is the study application’s identification number prior to submission.

   - A new number will be assigned after the completed application has been submitted.
ATTACHMENTS
Original Budget, CV, and Protocol Attachment(s)

To attach the original budget, CV, during the original submission follow these steps below.

If you have an attachment that is not one of these three types of attachments, or if you are attaching a document after the original submission, see the section titled Additional Attachments below.

1. Click on the Attachments tab.
2. Click on the paperclip icon.
3. A pop-up window appears; click the Browse button.
4. Navigate to the appropriate folder on your computer, click to highlight the file name, then click the Open button.
5. At the next screen, enter a description of the attachment (optional).
6. Click OK.

SUBMIT APPLICATION

1. When complete, click the Submit button.
• When the submission is successful, a new number is assigned to the completed application.

• Please record this number for future inquiries. An acknowledgement confirmation email will also be sent.

• Red text indicates items that must be completed before the system will accept the study application.
  – Click on each main tab and search for fields shown in red. These required fields must be completed in order for the system to accept the study application.

• Once corrected, click the **Submit** button again.

**TIPS**

• Click **Copy** to automatically copy information entered during registration (such as email address, address, etc.) into the Sponsor-Investigator section on the **Main** tab and the Legal/Contracting Contact Information for Primary Site on the **Support** tab.

• Click **Save** every 15 minutes to prevent loss of any data entered.

• Be sure your study application is complete and accurate before submitting. Submitted applications cannot be edited.

• The **Submit** button identifies any missing required fields, which change to red text.

• Click **Save** to hide the red text.

• **Caution**: Do not click **Submit** until you are ready to submit because you will not be able to make any changes once all required fields are complete. **You cannot edit the study after it has been submitted. You will then need to contact support to have an admin from Ferring open the study for you if additional edits need to be made.**

To locate previously completed applications click the **All My Applications** tab.
**The Copy Application** link is used to copy a previously submitted study application.

**Support**: The icons called “Add” allow you to add entries under the support tab, which then display on the grid.
ADDITIONAL ATTACHMENTS

If you are attaching a document after the original submission or you are not attaching the original budget, CV, and protocol documents. Follow the steps below.

1. Click on the Attachments tab.

2. Click the Post New link with the paperclip icon, under the Additional Attachments section.

3. A pop-up window displays; click the Browse button.

4. Navigate to the appropriate folder on your computer, click to highlight the file name, then click the Open button.
5. At the next screen, **select the type of publication** from the drop-down menu. In this example, an Abstract is being attached.

![Selecting the type of publication](image)

6. Enter a description of the attachment (optional).

7. Click **OK**.

### IV. HOW TO PROVIDE ADDITIONAL STUDY INFORMATION

You will be notified via email if additional information is required for your Investigator Sponsored Trial/Investigator Sponsored Submission (ISS/IST).

1. Click the link in the email message and **log in**.
2. From the **Task List** tab, locate the study requiring additional information.
3. Click the **Additional Info Required** link.
   - This link allows you to edit the application.

4. Add the requested information and click the **Submit** button when finished.
   - This study application disappears from your Task List after submitting it.
V. HOW TO SUBMIT STUDY STATUS UPDATES

Active studies require updates periodically. You will be notified via email when a Study Status Update is required.

1. Click the link in the email message and **log in**.
2. The **Task List** will display, locate the study requiring additional information.
3. Click the **View or Add Status Updates** link.

![Study Status Update screenshot](image1)

4. Scroll to the **Study Status Update** section and click the **Add** link.
   - The pop-up window for **Study Status Updates** appears.

![Study Status Update pop-up](image2)

5. Fill in current patient enrollment and study details.
   - The first column, **Actual / Most Current Dates**, contains the information that was entered during the last study status update.
The *Updated Dates* column is the new information to be submitted during the current study status update.

6. Adverse Event reporting, **all SAEs** (whether initial or follow-up) must be reported to Ferring within 24 hours of first knowledge using the **SAE form** available on Ferring’s IIT System. Click on the **safety mailbox link** to send notification.

7. All other (non-serious) adverse events experiences shall be provided to Ferring, along with enrollment/milestone study status updates, on at least a quarterly basis.

8. You can add **Supporting Documents** by clicking on the **Post New** and uploading your attachments

9. **Click OK** when your study status updates have been entered.

10. Click the **Submit** button (not shown) to send notification to the company and complete the study status update
Navigate to the location on your computer where the invoice is stored and *click to highlight* the file name, then click *Open*.

1. At this last screen, *enter a description* and click *OK*.
VIII. HOW TO REQUEST DRUG SUPPLY

If you require additional product, follow the process below.

1. **Log in** to the Visiontracker system.
2. Locate the study by using either the **Task List** or **All My Studies** tab.
3. Click the **View or Add Status Updates** link.
4. Click on the **Study Status Updates** tab.
5. Scroll to the section titled **Additional Product Request** and click the **Add** link.

6. **Select the product** from the drop-down list.

**TIP:** You may scroll to the right to locate the drop-down menu button, if you do not see it.
7. Complete the form; required fields are marked with an * [asterisk].
8. Click **OK** when finished.
9. Click the **Submit** button.

## IX. HOW TO SUBMIT A PUBLICATION/PRESENTATION

Submit your publications for a study by following the process below.

1. **Log in** to the Visiontracker system.
2. Locate the study using either the **Task List** or **All My Studies** tab.
3. Click the **View or Add Status Updates** link.
4. Click on the **Attachments** tab.

5. Under the **Additional Attachments** section, click the **Post New** link near the paperclip icon.

6. A pop-up window appears; click the **Browse** button.

7. Navigate to the appropriate folder on your computer, click to highlight the file name, then click the **Open** button.
8. At the next screen, **select the type of publication from the drop-down menu**. In this example, we are attaching an Abstract.

9. Enter a description of the attachment (optional).

10. Click **OK**.
X. FREQUENTLY ASKED QUESTIONS (FAQS)

1. HOW CAN I GET HELP?

To receive technical support while using the Visiontracker system contact the Envision Technology Solutions (ETS) help desk. ETS provides technical support for the Ferring Visiontracker application program.

There are several ways to contact the Envision Technology Solutions (ETS) help desk.

A) From the web screen:
   1. Click the Contact Us link (left corner of the web page).
   2. Select Technical Support from the Address to field.
   3. Select a Subject from the drop-down menu.
   4. Select a Related to item from the drop-down menu.
   5. Type your Message into the box.
   6. To attach a screen shot or other documentation, click the Browse button, navigate to the file location, click on the file name, and then click the Open button.
   7. Click Send.

B) Email the ETS help desk: visiontracker_general_requests@envisionpharmagroup.com

C) Call the ETS help desk:
   - USA Hotline: +1 860 266 4944 (9 AM – 4 PM EST)
   - Europe Hotline: +44 1403 322 075 (9 AM – 4 PM GMT)

2. WHAT IF I CAN’T LOGIN?

Double-check that you have your user ID entered correctly into the User ID field.

- If you have forgotten your password, click on the Forgot Password link. The system will send a temporary, one-time-use password. After you have received your new password and login, you will be required to create a new password. You can then log in with the new password.
- If you do not recall your User ID, email the ETS help desk:
  visiontracker_general_requests@envisionpharmagroup.com
3. WHAT IF I HAVE A QUESTION ABOUT MY SUBMISSION?

Submit email to Ferring via mailbox us1grantsandIT@ferring.com

4. WHAT IF I WANT TO ADD MORE INFORMATION AFTER I CLICK SUBMIT?

Unfortunately, you cannot edit it any further after you have submitted the study application.

If Ferring requests additional information from you, they can open-up the study application to allow you to add more information.

You may send Ferring a message explaining why you need to make changes to the study application already submitted via mailbox us1grantsandIT@ferring.com.

1. Click on the Contact Us link on the left side of the web page.

   ![Contact Form]

2. A Contact Form will appear. Required fields are marked with an * [asterisk].
3. From the *Address to field, select the Appropriate Medical Affairs Office from the drop-down menu.
4. Select a *Subject from the drop-down menu.
5. Select a *Related to item from the drop-down menu.
6. Type your *Message into the box.
7. To attach a screen shot or other documentation click the *Browse* button.

8. Navigate to the file location, *click on the file name*, and then click the *Open* button.

9. Click *Send*. 
5. HOW LONG DOES MY VISIONTRACKER SESSION LAST?

Your web session will time out after 90 minutes and you will be prompted to reenter your Username and Password information. Like many other Web applications, this time limit exists for security purposes.

If using Internet Explorer, you might try refreshing the browser memory. However, if you left the browser window open for more than 90 minutes with an incomplete study proposal:

1. Press **F5**, then click the **Logout** button in the left column.
2. **Exit** out of the **browser**, completely shutting it down.
3. **Open** Internet Explorer again and **log in** to the web link.
4. Press **F5** and see if your data were recovered.

We recommend that Investigators save their work often to avoid this issue. When stepping away for a while, investigators should log off the system rather than leave the browser window open.

6. HOW DO I PRINT MY SUBMITTED APPLICATION?

Here is one way to print your submitted application.

1. **Log in** to the Visiontracker system.
2. Click on the **All My Applications** tab.
3. **Click on the Tracking Number** of the study you wish to print.

4. Click on the **print** icon, located in the top right corner.

5. A PDF file is automatically created for you to print or save.

6. To print, **click the Open button**.
• You may see a security warning; if so, **click Allow** to give you permission to open the file.

7. When the file opens, **click the File menu** and then **click Print**.

    The study application will print to the printer that you have previously configured as your default printer.
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<th>Abbreviation</th>
<th>Description</th>
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<td>IIT</td>
<td>Investigator Initiated Trial – A clinical or non-clinical study independently initiated, developed and conducted by an external investigator, which is not under FPI sponsorship, and for which funding and/or other support from Ferring is requested.</td>
</tr>
<tr>
<td>Investigator</td>
<td>Individual or Institution seeking funding and/or a Ferring product for an IIT.</td>
</tr>
<tr>
<td>IND/IDE</td>
<td>Investigational New Drug Application/Investigational Device</td>
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<tr>
<td>RA</td>
<td>Research Agreement</td>
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