

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



For questions please contact support.montblanc@bayer.com.

Please note: All user names in Mont Blanc will consist of First Name.Last Name followed by the standard ending @Bayer.com (i.e., first.last@bayer.com). This username is not a valid email address. This username will give you access to the Bayer-developed system.

Contents

How to submit study updates.....	2
General Information:.....	2
Clinical Trial Registration:	2
Event Milestones:	3
Payment Milestones.....	3
Patient Metrics	3
Documents	4
Study Operations Manager (Site Personnel):.....	5
Study countries.....	6
IIR Support.....	6
IIR Medicinal Product	6
Additional Study Drugs / Comparators	6
Investigator Log	6
How to submit a protocol amendment	7

After successful login to [Mont Blanc](#), the approved study can be viewed and to provide updates to the study, please go to the section “[Study Info](#)”.

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



How to submit study updates

1. Please go to the section “Study Info”.

The screenshot shows the top navigation bar with 'IIR Study Concepts', 'Home', 'Study Info' (highlighted with a red box), and 'Library'. Below the navigation bar is a 'STUDY SELECTOR' section with a search box containing 'All Studies' and a '+ Create' button. To the right, there is a section titled 'All IIR Study Concepts' with a 'Save View As' button.

2. Click on the study number hyperlink, this brings you to the study.

Study Number	Study Type	Lifecycle State	Product
IIR-FR-00013 ★	Investigator Initiated Research	Candidate	BAY 597939, Rivaroxaban Factor Xa Inhibitor
IIR-FR-00012 ★	Investigator Initiated Research	Project / Trial Started	BAY 597939, Rivaroxaban Factor Xa Inhibitor

3. You will then find the following sections in Mont Blanc:

General Information

- Clinical Trial Registration
- Event Milestones (7)
- Payment Milestones (2)
- Patient Metrics (2)
- Documents (4)
- Study Operations Manager (2)
- Study Countries (1)
- IIR Support
- IIR Medicinal Product/Substance Support
- Additional Study Drugs / Comparators (0)
- Investigator Log (0)

General Information:


This section shows the information that was entered in the study concept.

Clinical Trial Registration:

Here you can enter Clinical Trial Registration numbers like: EuDraCT, IND/ IND Exemptions, IRB Number, ClinicalTrials.gov or other country registration number

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



To enter a number, click on the  button in the upper right corner, then the information in this section can be entered. After you have entered the number(s), please click on “Save”.

Investigator Initiated Research: IIR-FR-00013 ★ CANDIDATE



▼ Clinical Trial Registration

EuDraCT

IND / IND Exemptions

IRB Number

ClinicalTrials.gov

Other Country Specific Registry Number

Event Milestones:

To update planned or actual dates, please double click in the field that needs updating and select the new date from the calendar function.

Please note: the original finish date will not change after an updated new planned date or actual date has been entered.

▼ Event Milestones

Milestone ▲	Baseline Finish Date	Original Finish Date	Planned Finish Date	Actual Finish Date	Cc
1. EC / HA Approval, Animal...		31 Jul 2019	31 Jul 2019		
2. FPFV (IIR-FR-00013)		01 Aug 2019	08 Aug 2019		
3. LPFV (IIR-FR-00013)		19 Sep 2019	19 Sep 2019		
4. LPLV (IIR-FR-00013)		26 Sep 2019	26 Sep 2019		
5. Study Report (IIR-FR-00013)		31 Oct 2019	31 Oct 2019		
6. Trial Publication (IIR-FR-0...		31 Dec 2020	31 Dec 2020		
7. Study Closed (IIR-FR-000...		31 Dec 2020	31 Dec 2020		

Payment Milestones

This section is for your information only.

Patient Metrics

When patients have enrolled, entered or completed treatment, please update the patient numbers directly in the table, by making a double click in the field.

If you miss a specific metric type (e.g. total entered treatment), please click on the create button and create a new metric type.

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



+ Create		Q		
Metric ID	Metric Type	Planned	Actual	Study Country
Total Completed	Total Completed		100	5 France
Total Enrolled	Total Enrolled		100	0 France

Documents

In this section, all documents uploaded will appear in Mont Blanc for this study.

1. To upload another one, please click on +Add

Documents						
+ Add		Q	Show in Library			
Name	Documen...	Type	Subtype	Classifica...	Status	
Budget	VV-01078	Study Conc...	IIR Documents	Budget	In Progress	
CV	VV-01006	Study Conc...	IIR Documents	Investigator...	In Progress	

2. Click "Upload"

Search: Documents

Q Scope

+ Add filter All Documents

Upload Sort by Modified Date (Newest First) 1-19 of 19 1 of 1

Budget VV-01078 IIR-FR-00013 IN PROGRESS

3. Click "Choose" and select a document from your local drive.

Upload File (Step 1)

Upload new file

Choose

Choose document type

Search for and select a document type, subtype, or classification

Cancel Next

4. Choose a document type, by typing in a specific word like "protocol", then click Next.

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



Upload File (Step 1) ✕

Upload new file

2019_08_05_IIR to be migrated_v1_J.xlsx

Choose document type

Central Trial Documents > Product and Trial Documentation > Protocol 🔍

02.01.02 To describe the objective(s), design, methodology, statistical considerations and organization of a trial. Usually also gives the background and rationale for the trial, but these could also be provided in other protocol referenced documents. Includes Special Protocols.

5. And click “Save”

Upload File (Step 2) ✕

General*

Name* 2019_08_05_IIR to be migrated_v1_J

Title

Type Central Trial Documents

Subtype Product and Trial Documentation

Classification Protocol

Content* Non Confidential

Require Certified Copy? Yes No

Version 0.1

Study* IIR-FR-00013

Study Country Depends on Study 🔍

Study Site 🔍

Milestones

Upload another

6. Then you can upload another document or click “Close”.

Study Operations Manager (Site Personnel):

In this section, other Site Personnel can be given access to the study. This user first needs to complete the registration template on this portal <http://iirportal.bayer.com> before you can select

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



them.



IIR Investigator Registration

Select one of the following that best describes your role:

Investigator (Primary Investigator for the study)

Site Personal (Staff personal who supports the Investigator)

First Name*

Last Name*

Email*

Study countries

All participating countries should be added in this section.

Please click on the “Create” button to list another country.

▼ Study Countries

<input checked="" type="button" value="+ Create"/>	<input type="text"/>	<input type="button" value="Q"/>
Study Country Name ▲	Study Number	Country
France	IIR-FR-00013	France

IIR Support

This section contains the information from the study concept but can be updated by the Bayer Responsible Person. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

IIR Medicinal Product

This section contains the information from the study concept but can be updated by the Bayer Responsible Person. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

Additional Study Drugs / Comparators

This section lists all additional study drugs / comparators that are used in the study as mentioned in the General information section. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

Investigator Log

This section is the place where Bayer documents that an investigator has changed during the lifecycle of the study.

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



How to submit a protocol amendment

If you would like to submit an amendment to the protocol, please go to section “IIR Protocol Amendment” and click on the create button:

▼ IIR Protocol Amendment

+ Create Show in Tab

Then select the amendment category (Minor or Major) and click “Save”

- Major amendments include change to inclusion/exclusion criteria, primary endpoint and in study design (including drug dosage/exposure and number of study subjects)
- Minor amendments include e.g. change of contact details

Cancel Save + Create

▼ Details

Protocol / Amendment* Protocol Amendment

Amendment Category*

Then you will see another task bar, this is just a reminder not to forget to upload some documents. You can **complete** the task now or later, however, please upload the necessary documents under Attachments.

! Please Upload Required Documentation 26 May 2021

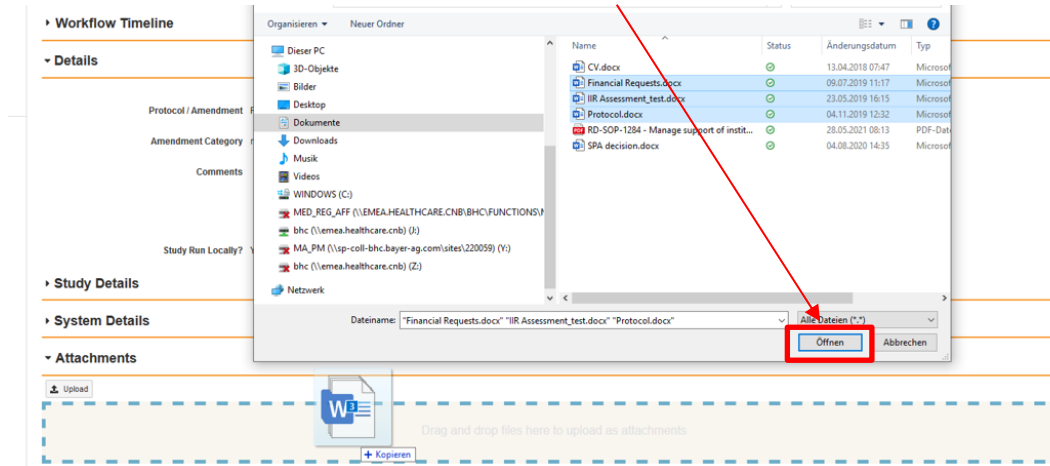
Go to Attachments, click “Upload”

▼ Attachments

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?



Select documents from your local drive, you can upload more than one document and drag & drop it to “Attachments” section or alternatively click “open”



Once the documents are available at the latest then complete the task:

▼ Attachments

Download All Upload

ISCS supporting documents for review.docx

Protocol.docx

! Please Upload Required Documentation 26 May 2021

Complete

Now an email is sent to the IIR Responsible and will start the review cycle.

For questions please contact support.montblanc@bayer.com.