

Mont Blanc – Investigator Initiated Research (IIR): How to submit an IIR Study concept?



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

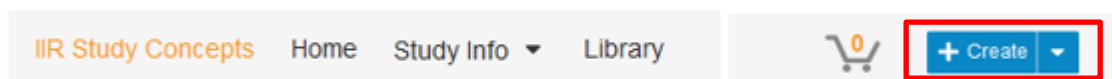
Please login to [Mont Blanc](#), and open the “IIR Study Concepts” tab

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 user name is not a valid email address. This user name will give you access to the Bayer-developed system.

Prior to submitting your concept please ensure you have the following available for upload

- IIR Assessment Form (for [clinical](#), [preclinical](#), [Covid-19](#))
- CV
- Budget (if applicable)

Please open the “IIR Study Concepts” tab. Click the “Create” button at the top **RIGHT**.



Submit a new study concept

Please fill in all required information, which can easily be identified by the yellow color of the fields.

Most of these entries should be made in the section “IIR Proposal”.

IIR Proposal

Study Number

Nominated Investigator*	<input type="text"/>	Short Title*	<input type="text"/>
Nominated Organization*	<input type="text"/>	Protocol Title*	<input type="text"/>
Investigator's Degree		Therapeutic Area	
Product(s) Used in Study*	<input type="text"/>	Indication Group*	<input type="text"/>
Related Product*	<input type="text"/>	Indication*	Depends on Indication Group
Bayer prod./subs. used as Comparator* <input type="radio"/> Yes <input type="radio"/> No		Study Phase*	<input type="text"/>
Please enter Bayer prod./subs.:	<input type="text"/>	Blinding*	<input type="text"/>
Non-Bayer prod./subs. used as Comparator* <input type="radio"/> Yes <input type="radio"/> No		Control*	<input type="text"/>
Please enter Non-Bayer prod./subs.:	<input type="text"/>	Primary Country*	<input type="text"/>
Study Type*	<input type="text"/>	Planned Number of Countries*	<input type="text"/>
Prospective / Retrospective*	<input type="text"/>	Planned Number of Patients/Subjects*	<input type="text"/>
Preclinical Part Included? <input type="radio"/> Yes <input type="radio"/> No		Planned Number of Sites*	<input type="text"/>
Human Material Included? <input type="radio"/> Yes <input type="radio"/> No		Study Ownership IIR*	<input type="text"/>

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Please select the type of support you are requesting from Bayer.

▼ IIR Support

Support Requested from	<input type="text" value="Bayer*"/>
Total Study Cost	<input type="text" value="Analytical"/>
Financial Amount Requested	<input type="text" value="Financial"/>
	<input type="text" value="Medicinal Product/Substance"/>
	<input type="text" value="Equipment"/>
	<input type="text" value="Other"/>
Currency	<input type="text" value=""/>

You can select multiple entries from the list. (i.e Financial and Medicinal Product/Substance)

If Study Drug is requested (labeled: Medicinal Product / Substance in the list), please also complete the next section:

▼ IIR Medicinal Product/Substance Support

Medicinal Product/Substance request	<input type="radio"/> Yes <input type="radio"/> No
Please enter Bayer prod./substance	<input type="text"/>
Est. Amount / Unit (Bayer Med. Product)	<input type="text"/>
Placebo Requested	<input type="radio"/> Yes <input type="radio"/> No
Amount of Placebo (unit as Med. Product)	<input type="text"/>
Comments	<input type="text"/>

The next step is important!

Please click on the save Button in the upper right corner of the form:

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Cancel Save + Create **Save**

Instructions
IIR Proposal
IIR Support
IIR Medicinal Product/Substance Support

Now the status of your concept submission can be viewed as “Initiated”:

IIR: IIR-FR-00016 ★ INITIATED

However, please do not click on the “Complete” button at this stage.

Task: Complete Information **Complete** !

Workflow Timeline

- The next step is to upload your CV and a completed IIR Assessment Form (for [clinical](#) or [preclinical](#) studies) and Budget information if applicable

You will find a new section in the submission for: “Submitted Documents”

Submitted Documents

+ Add

Click on the section title and then on the small gray “Add” button.

Then click “Create”

Search: Documents

Fields All Documents

Filters

Create Document Name (A-Z) 1-16 of 16

Then you have two options: “Upload” or “Document from Template”.

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- With “**Document from Template**” you will be able to work **on-line on the IIR Assessment Forms** (clinical or preclinical)
- By selecting “Upload” you can select a document from your local drive.

Both options are explained below:

A: Create a Document from Template

Please select “Document from template” and click “Continue”

The screenshot shows a dialog box titled "Create Document" with a close button (X) in the top right corner. Below the title, there is a label "Select Creation Method." followed by a dropdown menu. The dropdown menu is currently set to "Document from Template". At the bottom of the dialog box, there are two buttons: "Cancel" and "Continue". The "Continue" button is highlighted with a red rectangular box.

On the next screen you are asked to “choose a document type”. Please either select or type: “**Study Concept Form/ Assessment Form**”

The screenshot shows a web application interface for "IIR Study Concepts". The navigation bar includes "Home", "Study Info", and "Library". The main heading is "Create Document from Template (Step 1)". Below this, there is a section titled "Choose document type" with a search input field containing the text "Select a document type, subtype, or classification". A dropdown menu is open, showing a list of document types. The first item, "Study Concept Documents > IIR/ISCS Documents > Study Concept Form/ Assessment Form", is highlighted with a red rectangular box. Other items in the list include "Study Concept Documents > IIR/ISCS Documents > Budget" and "Study Concept Documents > IIR/ISCS Documents > Documentation of Sponsor Capabilities (incl. CV)".

Then open the go to “Choose template” and you will find three templates for “pre-clinical”, “clinical” and “COVID-19” studies, select the right template and click “next”

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Create Document from Template (Step 1)

Choose document type

Study Concept Documents > IIR/ISCS Documents > Study Concept Form/ Assessment Form

Choose template

Select a document template

- COVID_Clinical IIR_Assessment Form_v.3.0
- IIR assessment form clinical IIR
- IIR assessment form preclinical IIR

Cancel Next

On the next screen please enter a Name for the document and click “Save”

Cancel Save

General*

Name*

Title

Type Study Concept Documents

Subtype IIR/ISCS Documents

Classification Study Concept Form/
Assessment Form

Content Non Confidential

Version 0.1

Milestones

After you clicked “Save” you will automatically return to the study concept and see the document you have created under “Submitted Documents”, in the example the name of the document is “IIR XYZ”.

Submitted Documents

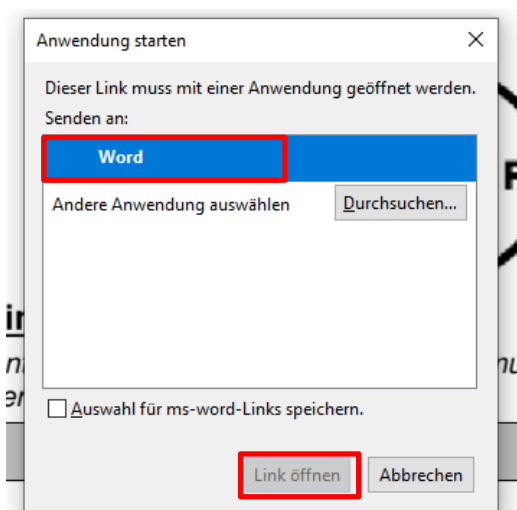
+ Add

Name	Document Number
IIR XYZ	WV-01573

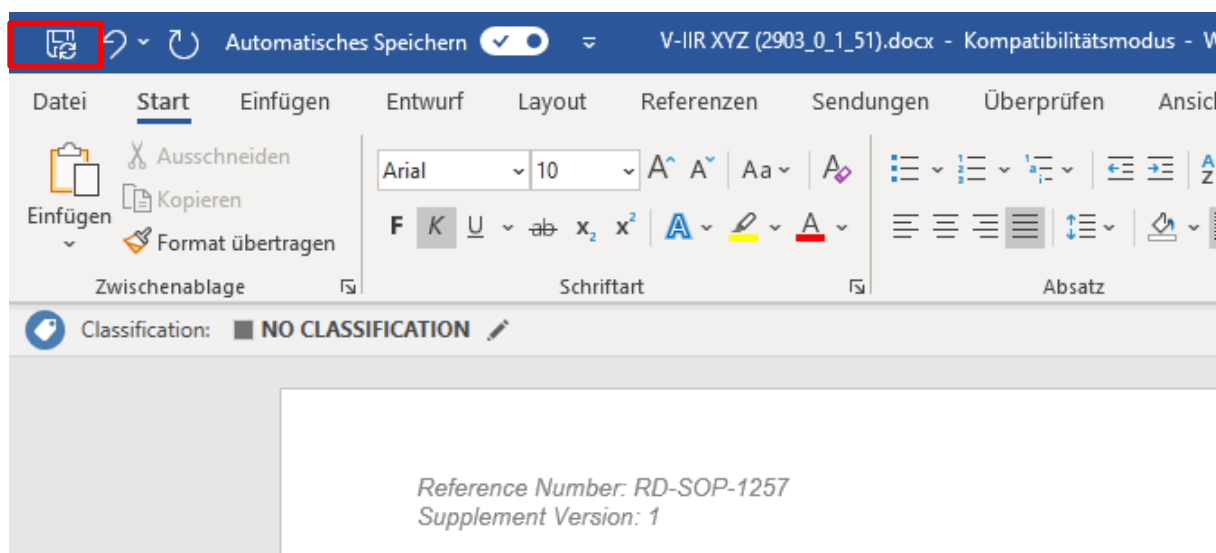
To complete the template, please click on the blue link under “Name” (IIR XYZ) this will open the document.

Now click on “Edit” and the document will be checked out and open in Word, please select Word or another application and click “open Link”

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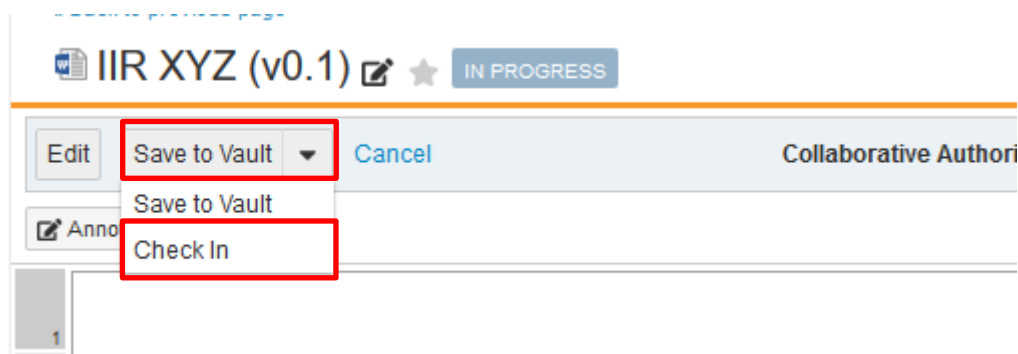


The document will open in Word, please complete the document, and use the save icon in Word.

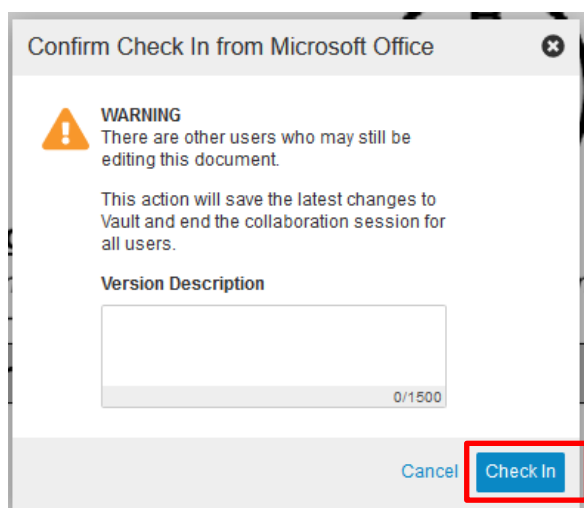


Go back to Mont Blanc and select under the drop down: “Save to Vault” the option “Check in”.

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You can enter a Version Description, then click “check in”, now the document is available in Mont Blanc.



Please go back to the study concept you can do this easily when you open the section “Study Concept Information” and click on the blue link behind the number that looks like this: IIR-FR-00071

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INFORMATION Edit Fields

General

Name IIR.XYZ

Title

Type Study Concept Documents

Subtype IIR/ISCS Documents

Classification Study Concept Form/ Assessment Form

Content Non Confidential

Document Number VV-01573

Created By IIR Investigator2 on 26 May 2021 8:35 AM CEST

Last Modified By IIR Investigator2 on 26 May 2021 8:35 AM CEST

Version 0.1

Lifecycle Base Doc Lifecycle

Status In Progress

Milestones

Document Date

Study Type

Global ID 22856_2903

Global Version ID 22856_2903_3482

Communication Log

Document Link

Document Version Link

Contracts & Budgets

Study Concept Information

Comments

IIR/ISCS Study Concept Identifier [IIR-FR-00071](#)

Now you can upload further documents, e.g. from your local drive.

B: Create a Document from your Local Drive

Under Submitted documents, first click “add” then click “create”

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Search: Documents

Fields

► Filters

Document Name (A-Z)

Then select “upload” and click “continue”

Create Document

Select Creation Method.

Upload

Click “Choose” and select a document from your local drive

Upload Files (Step 1)

Drag and drop files to upload here

Files for upload cannot exceed 4 GB in size. Files over 4 GB and Audio/Video files over 4 GB will not be rendered. [Learn more.](#)

or choose files to upload

Choose document type and field values

Document Type

Select a document type, subtype, or classification

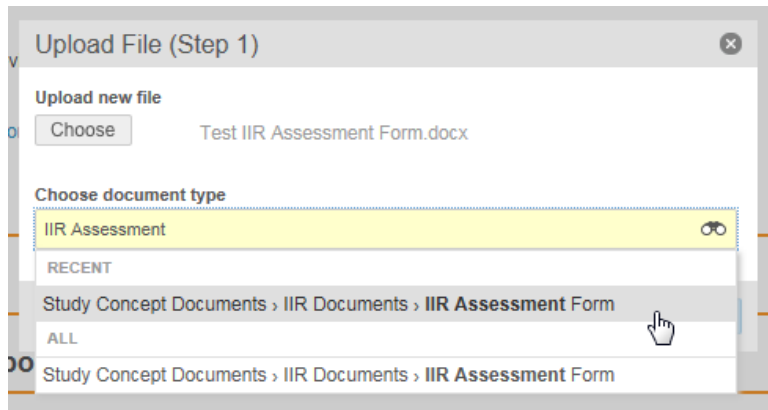
Name	Änderungsdatum	Typ	Größe
Test IIR Assessment Form.docx	09.05.2019 10:56	Microsoft Word D...	13 KB

Please choose a document type, then the following options will be available:

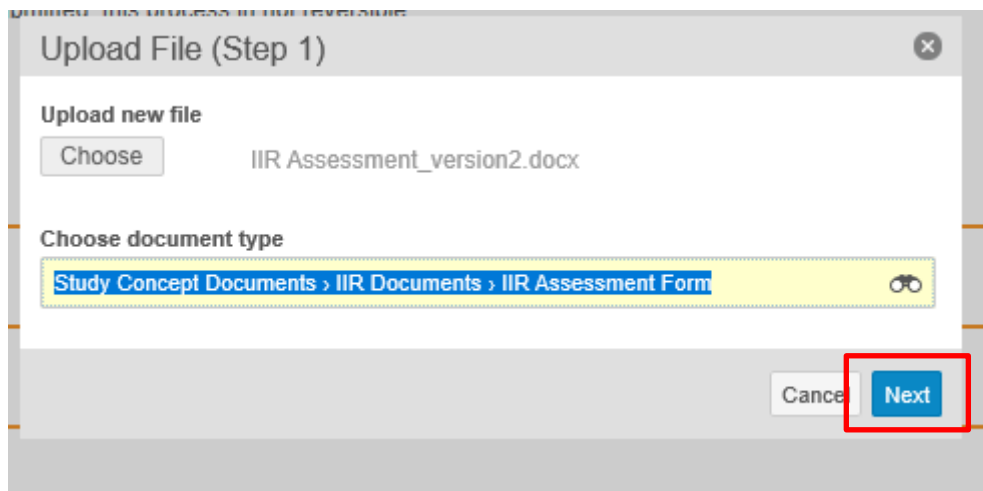
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- IIR Assessment Form
- Budget
- Investigator CV
- Study Publication
- Other miscellaneous documents



Then click “Next”



In the “Next” window you can leave the entries as they are and click “Save”.

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Upload File (Step 2)

General*

Name* IIR Assessment_version2

Title

Type Study Concept Documents

Subtype IIR Documents

Classification IIR Assessment Form

Content* Non Confidential

Version 0.1

Milestones

Document Date

Study Type

Study Concept Information

Upload another

The document upload is complete. Repeat the same steps to upload your CV and a Study Budget if applicable, please

Click “Close” to complete this step for your concept submission.

Search: Documents

Upload Sort by Modified Date (Newest First) 1-10 of 10 1 of 1

Document Name	ID	Status
IIR Assessment_version2	VV-01104	IN PROGRESS
Budget	VV-01078	IN PROGRESS
Financial Requests	VV-01007	IN PROGRESS
1. CV	VV-00997	IN PROGRESS
Financial Requests	VV-00998	IN PROGRESS

Close

All uploaded documents will be visible in the “Submitted Documents” Section:

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Submitted Documents

Name	Subtype	Classification
Test Curriculum Vitae	IIR Documents	Investigator CV
Test IIR Assessment Form	IIR Documents	IIR Assessment Form

Please review and edit your submission by clicking the **“Complete”** button on the top of the **“Concept Submission”** form:



Please confirm your entries are correct in the pop-up window. If everything is correct, click

Click Complete to Submit for Review

Clicking Complete below will forward your Study Concept to the Bayer IIR committee for formal review. Please ensure you have uploaded the required documents before clicking Complete.

Study Type*
Interventional

Prospective / Retrospective*
Prospective

Short Title*
Interventional clinical Study on Xarel

Protocol Title*
Interventional clinical Study on Xarelto

Study Phase*
Phase I

Primary Country*
France

*Required to proceed

Cancel **Complete**

“Complete” again.

The concept status has been updated to **“Submitted”**. Bayer will review the submission and a representative will contact you.

IIR: IIR-FR-00016 ★ SUBMITTED

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An email will be sent to you as confirmation that Bayer has received the study proposal and will now review it.



Study Concept **IIR-FR-00016** has been submitted

Dear IIR Investigator2 We confirm that Bayer has received the submitted study proposal. The proposal will now be reviewed in the Bayer electronic approval system (Mont Blanc) and we will provide further feedback about the outcome.

Request Title: Interventional clinical Study on Xarelto Product: BAY 597939, Rivaroxaban Factor Xa Inhibitor

For any questions you may have regarding the IIR process in Mont Blanc, please write an e-mail to IIR-Support@bayer.com or contact the company system responsible for IIR at following address:

Bayer AG

Medical Affairs & Pharmacovigilance, Pharmaceuticals

Business Excellence

13342 Berlin Germany

Kind regards, Vorstand: Werner Baumann, Vorsitzender | Liam Condon, Hartmut Klusik, Kemal Malik, Wolfgang Nickl, Stefan Oelrich, Heiko Schipper

Vorsitzender des Aufsichtsrats: Werner Wenning

Sitz der Gesellschaft: Leverkusen | Amtsgericht Köln, HRB 48248

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