



Investigator Quick Reference Guide

General Notes and Tips

- You will need to click the **Save** button at the bottom right corner of any form in order for your information to be saved.
- FastTrack has a security timeout feature when the system is idle for an extended period of time. You will be required to log back into the system after sixty minutes of inactivity. If you are working on a record and leave it open while performing other tasks, we recommend that you navigate to the bottom of the record, and click the **Save** button. This will prevent you from losing any data you have already entered.
- * [Asterisks] indicate a required field.
- This document will indicate up to 5 values in drop-down lists within FastTrack; where the value lists are longer than 5 this will be noted.
- It is recommended that you save as you go. You don't have to have all the required fields populate; the draft will be available for you on your home page when you are ready to come back to it.
- You will not be able to move onto the next page if a required field has not populated.
- Once you've completed a section, you can move back and forth by clicking the tabs at the top of the page or clicking on the back bottom at the lower left of the page.

We are committed to providing you with answers to your questions and concerns. Please contact us using the information below, and we will respond to your inquiry as quickly as possible.

Study Support

Please contact BMS via FastTrack

Technical Support

Main Number: +1 844 439 5499 US only. For Outside US, please see the International numbers at the end of the guide.

Main Email: hd-sci-apps@bms.com



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Registering for Access and Logging In

To register for access to the website, navigate to <https://fasttrack.bms.com/>

You will first need to register for the FastTrack portal.



FastTrack Access

Country
USA

Enter your BMS account information below

Email:
Email *

Password: [Forgot password?](#)
Password *

Don't have an account yet? [Click here](#)

You will then be asked to complete your profile in the system. The first section covers “Your details”. These fields will be mandatory:
First Name, Last Name, Institution Name, Institution Address, City, Postal Code, State/Province.

Next, you will be asked to provide “Your professional details”.
These fields will be mandatory:
Title, Profession, Email Address and Password.

When you have completed these fields, simply click Submit and you will be brought to your Home page.



Your professional details

Title *

Profession *

Therapeutic Area

Create sign-in details

Your email address *

Choose a password *

Retype your password *

[Cancel](#)

[Register](#)



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FastTrack Access

Country

USA ▼

Your details

Salutation

Please select ▼

First Name *

Last Name *

Institution Name *

Institution Address *

Enter your email address and your password. If you have forgotten your password, you can click the **“Forgot your password?”** link to have it reset and resent to you. If you have forgotten your email address used to set up this account, US investigators call +1 844 439 5499. For Investigators outside the US, please see the list at the end of the guide for International numbers.





Submitting New Investigator Sponsored Research Concept

When creating a new request, you will first be asked to provide the Investigator's Information. There will be a box to check if you are the primary investigator. Checking this box will remove the requirement to identify a role, first name, last name and email as this information will be taken from the investigator profile that you provided when first registering.

If you are not the Primary Investigator, you must complete this section.

Enter the Investigator's Information

My Role*

This is a mandatory field with a drop-down list. You will be asked to choose between the following values:

- Co-Investigator
- Regulatory Document Coordinator
- Site Legal Contact
- Study Site Coordinator
- Sub-Investigator
- Other

Investigator First Name* This is a mandatory field.

Investigator Last Name* This is a mandatory field.

Investigator Email* This is a validated mandatory field – for email format.

Enter the Institution Information

The institution will auto-populate from your primary investigator profile. If this is not the correct institution, you will need to enter all mandatory fields. There is also a set of "Institution Address" fields below the Institution Name (i.e. Institution Address Line 1, etc.) and above the Shipping Address fields. There is also a checkbox that says "Shipping Address same as Institution Address?" If this is checked, the Shipping Address fields below will become hidden and not need to be entered. Otherwise, these can be entered manually just like the Institution address fields.

Institution* This is a mandatory field.

ShippingAddressLine1* This is a mandatory field.



- ShippingAddressLine2 This is NOT a mandatory field.
- Shipping City* This is a mandatory field.
- Shipping State / Province* This is a mandatory field for the US/Canada
- ShippingPostalCode* This is a mandatory field.

STUDY DETAILS

StudyType* This is a mandatory field. You will be asked to choose between the following values:

- Interventional
- Non-Interventional without Patients
- Non-Interventional with Patients

Study Subtype* This is a mandatory field. The study subtype values change dependent upon the study type. You will be asked to choose between the following values, by study type:

Study Types			
	Interventional	Non-Interventional without Patients	Non-Interventional with Patients
Sub-Types	Interventional	Prospective	Prospective
		Retrospective	Retrospective
		Prospective and Retrospective	Prospective and Retrospective
			Registry

Short Title* This is a mandatory field.

TherapeuticArea* This is a mandatory field with a drop-down list. You will be asked to choose between the following values:

- Cardiovascular Disease
- Immunoscience
- Metabolic Diseases
- Neuroscience
- Oncology



Disease Area*

This is a mandatory field with a drop-down list. You will be asked to choose from an extensive list of values.

Phase*

This is a mandatory field with a drop-down list. You will be asked to choose from an extensive list of values.

Planned Start Date* This is a mandatory field with a pop-up calendar to select a date.

Planned # of Sites* This is a numeric value mandatory field

Planned Trial Duration (# of Months)* This is a numeric value mandatory field.

Planned # of Patients Enrolled* This is a free-form mandatory field.

Local BMS Contact Name This is NOT a mandatory field.

Requested Resource*

This is a mandatory field with a drop-down list. You will be asked to choose between the following values:

- Funding
- Drug and Funding
- Drug
- Other

If you select “Funding” or “Drug and Funding” then two additional fields will appear that are also mandatory:

- Total Budget Requested
- Budget Currency

Primary Compound*

This is a mandatory field with a drop-down list. You will be asked to choose from an extensive list of values.

Primary Indication*



This is a mandatory field with a drop-down list. You will be asked to choose from an extensive list of values.

If you need to request additional compound(s), you will check a box and an additional Compound and an additional Indication field will appear. Both will be mandatory and will be an extensive drop-down list of values.



Study Rationale: Provide a brief description of the medical question and the rationale of how this trial addresses the question. Provide a rationale for the dose schedule outlined for all treatment arms. Reference any non-labeled indication.

* This is a free-form mandatory field

Primary Objective: Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.

* This is a free-form mandatory field

Primary Endpoint*

This is a free-form mandatory field

Hypothesis*

This is a free-form mandatory field

Study Assessments: Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures.

This is a not a mandatory field.

Secondary Objective

This is a not a mandatory field.

Data and Statistical Plan: Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The range of sophistication will depend on a number of factors, including the size and complexity of the study.

* This is a free-form mandatory field

References: List references, studies, and sources that support the study design.

This is a not a mandatory field.

Will you receive funding from other sources?*

This is a yes/no mandatory radio button selection. If you choose yes, you will be asked to specify.

Will a government review be required?*

This is a yes/no mandatory radio button selection. If you choose yes, you will be asked how many reviews the study will undergo



Targeted Patient Population: Specify age, gender, and other demographic information for the trial population.

This is a not a mandatory field.

Estimated Contract Review Time: Provide this in number of weeks or months.

This is a not a mandatory field.

Specify the dose, schedule, duration, and any pre-medications, etc.

This is a not a mandatory field.

Participating Countries*

There will be a drop-down country list to choose from for this response.

How often does your IRB/IAC meet?*

This is a mandatory field with a drop-down list. You will be asked to choose between the following values:

- Daily
- Weekly
- Bi-Weekly
- Monthly
- Bi-Monthly
- Other

If you answered "Other", you will need to provide a short description –which will be a mandatory field.

Sample Size Calculation*

* This is a free-form mandatory field.

Sample Size Justification: The sample size must reference the primary endpoint.*

* This is a free-form mandatory field.

List any correlative studies.*

* This is a free-form mandatory field. If there are no correlative studies please enter N/A.

Key Inclusion Criteria: List the inclusion criteria necessary to support the trial design and drug safety requirements.

* This is a free-form mandatory field.



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Key Exclusion Criteria: List the exclusion criteria necessary to support the trial design and drug safety requirements.

* This is a free-form mandatory field.

Secondary Endpoint

This is a not a mandatory field.

Would you like to add planned publication information to this request?*

Yes No

This is a yes/no mandatory radio button selection. If you choose yes, then an additional tab at the top will appear and you will be required to specify the planned publication indicated after the SUSAR section below.

Add SUSAR Contacts Below

SUSAR: Suspected Unexpected Serious Adverse Reaction

If needed, you can add multiple SUSAR Contacts here by clicking "+Add SUSAR Contact".

SUSAR Contact Name*

* This is a free-form mandatory field.

SUSAR Contact Email*

* This is a validated mandatory field – for email format.

Country

There will be a drop-down country list to choose from for this response.



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Enter the Planned Publication Information Below

Publication Type*

This is mandatory when you choose the Yes radio button for planned publications. You will be required to choose from one of the following drop-down values:

- Abstract
- Manuscript
- Poster
- Other

Planned Publication Date*

This is a mandatory field with a pop-up calendar to select a date.

Planned Journal Title

This is a not a mandatory field.

Planned Congress Name

This is a not a mandatory field.

Add Related Documents Below

Curriculum Vitae*

This is a mandatory field requiring you to upload a file.

The following fields are NOT mandatory; however you are free to upload any additional documents.

- Other Curriculum Vitae
- References/Relevant Literature
- Supporting Document(s) 1 -4



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International contact numbers for BMS Help Desk

Help Desk Phone Numbers	Toll Free
Argentina	0800 666 1071
Australia	1 800 506 758
Austria	0800-005910
Belgium	0800 764 18
Brazil	0800 891 5625
Bulgaria	0808 101 3509
Canada	866 909 5700
China - North	10800 713 1387
China - South	10800 130 1345
Colombia	1 800 518 1050
Czech Republic	800-143583
Denmark	808 898 69
Dominican Republic	1 866 685 1182
Egypt	8000000567
France	0800 911 214
Germany	0800 180 1681
Greece	00800-12-8174
Holland/Netherlands	0800 023 2647
Hong Kong	800 930 344
Hungary	06800 16 920
India	000 800 100 3451
Indonesia	001 803 015 203 5739
Ireland	1800936294
Italy	800 874 029
Italy - Latina	800 874 029
Italy - Anagni	800 874 029
Japan	00531 13 1432
Korea	308 132 264
Malaysia	1800 81 4462



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Mexico	1 800 267 4357
Norway	800-111-65
Peru	0800 53 963
Philippines	1800 1116 0970
Poland	00-800-1213633
Portugal	800 863 249
Puerto Rico	1 800 723 7223
Romania	800 896868
Russia	8-10-8002-6984011
Saudi Arabia	800 844 2544
Singapore	800 1301 705
Slovakia	0800-001604
Spain	900 931 312
South Africa	080 09 83157
Sweden	020 793 303
Switzerland	0800 894 178
Taiwan	801 14 8913
Thailand	001 800 13203 5739
UK	0808 101 3509
United Arab Emirates (UAE)	80004445767
US	888 930 5700



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