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Overview of Bristol-Myers Squibb (BMS.com) Independent Research

**Purpose**

Use this job aid to access and learn about research opportunities through Bristol Myers-Squibb (BMS).

**Navigating to Research Opportunities**

1. First, navigate to [www.bms.com](http://www.bms.com).
2. Select **Researchers & Partners** from the menu located on the left.
3. Select **Independent Research**.
You can now select from the different research opportunities offered at BMS.

**Investigator Sponsored Research**

You are automatically redirected to the FastTrack Portal. Please use the guide titled “...” on the SharePoint site to learn more.
Area of Interest and Competitive Research Grants

It is highly recommended that you click on information on competitive research grants link first to see if there are any RFPs/competitive research grants available for your therapeutic area of interest.

Areas of Interest

Bristol-Myers Squibb seeks Independent Research applications across all therapeutic areas. Our areas of interest outline additional criteria to help guide the scientific community. All concept applications submitted that best align with our interest will be considered & evaluated.

The criteria will include, but not be limited to:

- Specific therapeutic area of interest
- The type of science we are seeking
- We may include a specific window of time for all concept applications to be submitted.

We also post general request for proposals (RFPs) that do not have the same type of restrictions as the competitive research grant process.

You can now filter to find areas of interest.

1. Filter to select your region using the drop-down fields.

If you find a desired area of interest:

2. Click the RFP link and access the FastTrack Portal

Please login or follow the “How to Register for FastTrack” guide.
Competitive Research Grants

The Bristol-Myers Squibb Competitive Research Grant process includes the submission of a concept application that meets the required criteria posted. Competitive Research Grants we post will include specific criteria that must be met for your application to be considered.

Here you will see if there are research grants available.

Below you have the option to begin a new application through FastTrack or access the Investigator Inquiry Form. The Investigator Inquiry Form allows you to submit questions about Investigator Sponsored Research, as well as requests for more information about becoming a clinical researcher for Bristol-Myers Squibb.

Please login or follow the “How to Register for FastTrack” guide.
Creating your ID and Password on the BMS Portal

**Purpose**

Use this job aid to register for FastTrack in order to submit a request for Investigator Sponsored Research. FastTrack is the new portal solution to standardize and streamline business operations for Investigator Sponsored Research (ISR), Non-Clinical Research (NCR), Named Patient Program (NPP), and Data Sharing Requests.

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.

**Technical Support**

Main Number: +1 844-439-5499 (US only)

*For Outside US, please see the “International BMS Help Desk Phone Number Guide”*

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

**Registering for Access**

1. Navigate to [https://fasttrack.bms.com](https://fasttrack.bms.com)
2. Select the country you wish to register in

3. Select **Click here** next to “Don’t have an account yet?” to register an email and password

**BMS Privacy Statement**

Before creating and registering a User ID, you must read and agree to the BMS Privacy Statement. Please click here to review and agree to the [BMS Privacy Statement](#)
4. Read and Agree to the BMS Privacy Statement
5. Agree to the criteria listed in the Privacy Statement. Once you agree to each statement, select, **Continue to Create User ID**
6. Enter your details and your professional details. All mandatory fields are marked with an asterisk (*)
7. Create your sign-in details. All mandatory fields are marked with an asterisk (*)
8. Click **Register**

---

*Please note: all mandatory fields must be entered before clicking Register*

---

Here is an example of what a home page will look like. You are brought to your FastTrack homepage. You are now ready to create your request!

*Please see your respective guide for details on how to create your request*
Investigator Sponsored Research Request Submission

Purpose

Use this job aid to submit a request for Investigator Sponsored Research (ISR). This guide will take you through all of the tabs required to submit a request successfully.

This submission guide is for proposals supporting patient enrollment. If your proposal is NOT enrolling patients, STOP HERE.

Please navigate to the Non-Clinical Research (NCR) form as NCR requests do not involve proposals that relate to patient recruitment or patient related data.

General Notes and Tips

Below you will find general notes and tips for when you are creating an ISR Request.

- * [Asterisks] indicate a required field within the interface
- You will not be able to move on to the next page if a required field is not completed
- Periodically click Save (located at the bottom right corner on any form) in order to save your information. If you do not have all the information, which is necessary to submit your request, click Save and a draft will be available for you on your homepage when you are ready to return to the form. The forms do not auto-save.
- FastTrack has a security time-out feature. After sixty (60) minutes of inactivity, you will be required to log back into the system.
  - If you are working on a record and leave it open while performing other tasks, it is recommend that you navigate to the bottom of the record and click Save to prevent you from losing data you have entered
- You can return to any section of the form at any point by clicking the tabs at the top of the page or clicking Back in the lower left of the page

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<td><em>For Outside US, please see the “International BMS Help Desk Phone Number Guide”</em></td>
</tr>
<tr>
<td><strong>Main Email:</strong> <a href="mailto:hd-sci-apps@bms.com">hd-sci-apps@bms.com</a></td>
</tr>
</tbody>
</table>
Log-in to FastTrack

1. Navigate to https://fasttrack.bms.com
2. Select your country
3. Enter your email address and your password
   • If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide at the end of this guide.
4. Click Submit

Create New Investigator Sponsored Research Proposal

Once you have logged in, you will want to create a new request. To do this:

1. Click Create New Request
2. Select ISR: Clinical

Now, you can submit the New Investigator Sponsored Research Request through FastTrack.

Submitting New Investigator Sponsored Research - Clinical Study Proposal Form

When creating a new request, you will provide the Investigator’s information first. There will be a box to check to indicate 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 auto-populates from your investigator profile.

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

1. Investigator & Institution Info

   Enter the Primary Investigator’s Information

   ![Image of the Investigator’s Information section]

   **My Role**

© 2018 BRISTOL-MYERS SQUIBB COMPANY. Version-072318
This is a mandatory field with a drop down list. You will 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 mandatory field and must be submitted in a valid email format.

**Enter the Institution Information**

From your Primary Investigator Profile, the institution auto-populates. If this is not the correct institution, you will need to re-enter all mandatory fields.

**Institution Name***
This is a mandatory field.

**Institution Address Line 1***
This is a mandatory field.

**Institution Address Line 2**
This is NOT a mandatory field.

**Institution City***
This is a mandatory field.

**Institution State/Province***
This is a mandatory field for the US/Canada.

**Institution Postal Code***
This is a mandatory field.
- **Institution Country**
  This is a mandatory field. You will search for the country within the database. Once you select the appropriate country, click **Done**.

There is a checkbox that says, “Check this box if the shipping address is the same as the address of the institution above”. If you select this checkbox, the shipping address fields automatically populate and hide, meaning you do not need to enter the address. Just like the Institution address, these fields can be entered manually.

- **Shipping Address Line 1**
  This is a mandatory field.

- **Shipping Address Line 2**
  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**.

- **Shipping Postal Code**
  This is a mandatory field.

Click **Next** to continue
2. Request Details

- Enter the Details of Your Request Below

<table>
<thead>
<tr>
<th>Study Type*</th>
<th>Study Subtype*</th>
<th>Short Title*</th>
<th>Therapeutic Area*</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a mandatory field. Choose one of the following values:</td>
<td>This is a mandatory field. The study subtype values change depending on the study type. Choose one of the following study types:</td>
<td>This is a mandatory field.</td>
<td>This is a mandatory field with a drop-down list. Choose one of the following values:</td>
</tr>
<tr>
<td>- Interventional</td>
<td>- Interventional Prospective</td>
<td>- Cardiovascular Disease</td>
<td>- Neuroscience</td>
</tr>
<tr>
<td>- Non-Interventional without Patients</td>
<td>- Interventional Retrospective</td>
<td>- Immunoscience</td>
<td>- Oncology</td>
</tr>
<tr>
<td>- Non-Interventional with Patients</td>
<td>- Interventional Prospective and Retrospective</td>
<td>- Metabolic Diseases</td>
<td>- Virology</td>
</tr>
</tbody>
</table>
- **Disease Area***
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

- **Phase***
  This is a mandatory field with a drop down list. Choose an option from the 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 mandatory field.

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

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

- **Local BMS Contact Name***
  This is a NOT a mandatory field.

- **Requested Resource***
  This is a mandatory field with a drop-down list. Choose one of the following values:
  - Funding*
  - Drug and Funding*
  - Drug
  - Other

*Note: If you select something other than “Funding” you see the above fields.*
If you select “Funding” or “Drug and Funding”, two additional, mandatory fields appear. Click the link and download the required budget template.

Complete the form and upload the completed budget template to attach it to this submission.

- **Primary Compound**
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

- **Primary Indication**
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

Click **Next** to continue, or see below.

A checkbox says, “Check this box to request additional compound.” If you select this checkbox, an option to search for a Compound name and Indication appear.
3. Additional Request Details

Enter the Details of Your Request Below (continued)

- **Study Rationale**
  This is a free-form mandatory field. 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.

- **Primary Objective**
  This is a free-form mandatory field. Provide the main goal of the study and the study population. Provide a detailed definition that links to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.

- **Primary Endpoint**
  This is a free-form mandatory field.

- **Hypothesis**
  This is a free-form mandatory field.

- **Study Assessments**
  While not mandatory, this field will help the BMS team better understand and assess your request. Specify type and frequency of safety, efficacy, and outcome measures. Also, indicate the method(s) used to assess measures.
- **Secondary Objective**
  This is a not a mandatory field.

- **Data and Statistical Plan**
  This is a free-form mandatory field. Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The level of detail required will depend on a number of factors, including the size and complexity of the study.

- **References**
  This is not a mandatory field. List references, studies, and sources that support the study design.

- **Will you receive funding from other sources?**
  This is a yes or no mandatory radio button selection. If you choose yes, please explain.

- **Will a government review be required?**
  This is a yes or no mandatory radio button selection. If you choose yes, specify how many reviews the study will undergo.

- **Targeted Patient Population**
  This is a not a mandatory field. Specify age, gender, and other demographic information for the trial population.

- **Estimated Contract Review Time**
  This is a not a mandatory field. Provide this in number of weeks or months.

- **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. Choose one of the following values:
  - Daily
  - Weekly
  - Bi-Weekly
  - Monthly
  - Bi-Monthly
  - Other (you will need to provide a short description - which is a mandatory field.

- **Sample Size Calculation***
  This is a free-form mandatory field.

- **Sample Size Justification***
  This is a free-form mandatory field. The sample size must reference the primary endpoint.

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

- **Key Inclusion Criteria***
  This is a free-form mandatory field. List the inclusion criteria necessary to support the trial design and drug safety requirements.

- **Key Exclusion Criteria***
  This is a free-form mandatory field. List the exclusion criteria necessary to support the trial design and drug safety requirements.

- **Secondary Endpoint***
  This is not a mandatory field.

- **Strategic Partnership Research Program***
  This is not a mandatory field.
Would you like to add planned publication information to this request?*
This is a yes or 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 Suspected Unexpected Serious Adverse Reaction (SUSAR) section below.

Add Suspected Unexpected Serious Adverse Reaction (SUSAR) Contacts Below

The acronym SUSAR stands for Suspected Unexpected Serious Adverse Reaction.

SUSAR Contact Name*
This is a free-form, mandatory field.

SUSAR Contact Email*
This is a mandatory field and must be entered in a valid email format.

Country*
This is a mandatory field. A drop-down list of countries to choose from is available for this response.

Click Next to continue.

4. Planned Publication Information

Enter the Planned Publication Information Below
This is mandatory when you choose the “Yes” radio button option for planned publications.

Publication Type*
This is a mandatory field. 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.

Click **Next** to continue.

- **Add Related Documents Below**

- **Curriculum Vitae***
  This is mandatory, 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

Click **Submit**.

- **5. Submit the Request**

After you complete the mandatory fields and submit, your homepage will display a success message at the top of the page and a tile of the request displays under Current Requests. Please check your email for a confirmation of your submission.*

---

*Note: You may need to refresh your screen to see the success message. 
The above image is just for informational purposes only*
Name Patient Request Submission

Use this job aid to submit a request for Named Patient Program Research. This guide will take you through all of the tabs required to submit a request successfully.

---

This submission guide is for proposals enrolling a patient in an Early Access Patient Program. If your proposal is NOT enrolling patients, STOP HERE.
Please navigate to the appropriate submission guide for further instruction.

---

**General Notes and Tips**

Below you will find general notes and tips for when you are creating an ISR Request.

- * [Asterisks] indicate a required field within the interface
- You will not be able to move on to the next page if a required field is not completed
- Periodically click **Save** (located at the bottom right corner on any form) in order to save your information. If you do not have all the information, which is necessary to submit your request, click **Save** and a draft will be available for you on your homepage when you are ready to return to the form. The forms do not auto-save.
- FastTrack has a security time-out feature. After sixty (60) minutes of inactivity, you will be required to log back into the system.
  - If you are working on a record and leave it open while performing other tasks, it is recommend that you navigate to the bottom of the record and click **Save** to prevent you from losing data you have entered
- You can return to any section of the form at any point by clicking the tabs at the top of the page or clicking **Back** in 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.

---

**Technical Support**

**Main Number:** +1 844-439-5499 (US only)

*For Outside US, please see the “International BMS Help Desk Phone Number Guide”*

**Main Email:** hd-sci-apps@bms.com
Log-in to FastTrack

1. Navigate to https://fasttrack.bms.com
2. Select your country
3. Enter your email address and your password
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide at the end of this guide.
4. Click Submit

Create New Named Patient Program

Once you have logged in, you will want to create a new request. To do this:

1. Click Create New Request
2. Select Named Patient Program

Now, you can begin to submit the New Named Patient Program Request.

A dialog box appears with the programs available in your country.

3. Select your desired program.

By selecting the desired program, FastTrack populates the request form for that specific chosen program. As all Named Patient Programs are unique, this guide will take you through the tabs (not necessarily specific fields) required to successfully submit a request.

Submitting New Named Patient Program

When creating a new request, you will provide the Investigator's information first. There will be a box to indicate if you are the Primary Investigator, which will prepopulate the Investigator profile information. If you are not the Primary Investigator, you will need to manually enter the Investigator's information and your role.

If you are not the Primary Investigator, you must complete this section.
1. HCP & Institution Info

Enter the HCP’s Information

My Role*
This is a mandatory field with a drop down list. You will choose between the following values:

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

HCP First Name*
This is a mandatory field.

HCP Last Name*
This is a mandatory field.

HCP Email*
This is a mandatory field and must be entered in email format.

Enter the Institution Information

From your Primary Investigator Profile, the institution auto-populates. If this is not the correct institution, you will need to re-enter all mandatory fields.
Institution Name*
This is a mandatory field.

Institution Address Line 1*
This is a mandatory field.

Institution Address Line 2
This is NOT a mandatory field.

Institution City*
This is a mandatory field.

Institution State/Province*
This is a mandatory field for the US/Canada.

Institution Postal Code*
This is a mandatory field.

Institution Country*
This is a mandatory field. You will search for the country within the database. Once you select the appropriate country, click Done.

There is a checkbox that says “Check this box if the shipping address is same as the address of the institution above”. If you select this checkbox, the shipping address fields automatically populate and hide. These fields can also be entered manually, if needed.

Shipping Address Line 1*
This is a mandatory field.

Shipping Address Line 2
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.
Shipping Postal Code*
This is a mandatory field.

Click Next to continue.

2. Request Details

Enter the Details of Your Request Below

These fields are specific to the program that you selected. All fields with an asterisk (*) are mandatory fields.

Add Additional Compound

Indication*
This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

Compound Name*
This is a mandatory field with a searchable list.

Compound Quantity*
This is a free-form mandatory field.

Compound Unit*
This is a free-form mandatory field.
Enter Pharmacist Information

- **Pharmacist Name***
  This is a free-form mandatory field.

- **Pharmacist Phone Number***
  This is a free-form mandatory field.

- **Pharmacist Email***
  This is a free-form mandatory field.

Click **Next** to continue.

3. Patient Details

Patient eligibility will be determined by Bristol-Myers Squibb in accordance with established policies and procedures. Bristol Myers Squibb’s acceptance and processing of this application does not guarantee that access to investigational product will be provided. Do not include the patient’s name or submit any patient-identifying information to BMS.

Enter Patient Information Below

- **Patient Initials***
  This is a free-form mandatory field.
- **Patient Gender***
  This is a mandatory field. Select from the drop down list.

- **Patient Age at Enrollment***
  This is a free-form mandatory field.

- **Date of Diagnosis***
  This is a mandatory field. A pop-up calendar appears to select a date.

- **Patient Height (cm)**
  This is a not a mandatory field.

- **Height Assessment Date**
  This is not a mandatory field. A pop-up calendar appears to select a date.

- **Patient Weight (kg)**
  This is not a mandatory field.

- **Weight Assessment Date**
  This is not a mandatory field. A pop-up calendar appears to select a date.

- **Has the patient participated in a BMS study in the past***?
  This is a yes or no radio button mandatory field.

- **Patient Medical History***
  This is a free-form mandatory field. Provide patient medical history, current physical condition, and rationale for the request. Include a detailed summary of the disease.

- **Patient Current Treatments***
  This is a free-form mandatory field. List patient's current treatments, concomitant medications (including herbals), and outcomes in this field.

- **Has the patient had any prior treatments***?
  This is a yes or no radio button mandatory field. If you select “no”, you may continue. If you select “yes”, then you will be asked to enter additional details about the previous treatment.

Click **Next** to continue.
4. Proposed Treatment Plan

**Enter Treatment Plan**
Enter the proposed treatment plan details (in addition to the treatment being requested).

- **Product**
  This is not a mandatory field.

- **Treatment Dose**
  This is not a mandatory field.

- **Treatment Route**
  This is not a mandatory field.

- **Planned Duration of Treatment**
  This is not a mandatory field.

- **Treatment Plan Comments**
  This is not a mandatory field.

Click **Next** to continue.

5. Patient Eligibility Questions

**Please Answer the Questions Below**
This section will be specific to each Named Patient Program. Answer all mandatory fields denoted with an *(asterisk).*

Click **Next** to continue.
6. Related Documents

Add Related Documents Below

Curriculum Vitae
This is mandatory, requiring you to upload a file. The following fields are not mandatory; however, you are free to upload any additional documents:

- Other Curriculum Vitae
- File Upload(s) 1-4

Click Submit.

5. Submit the Request

After you complete the mandatory fields and submit, your homepage will display a success message at the top of the page and a tile of the request displays under Current Requests. Please check your email for a confirmation of your submission.*

*Note: You may need to refresh your screen to see the success message.
The above image is just for informational purposes only
NCR Request Submission

**Purpose**

Use this job aid to submit a request for Investigator Sponsored Non-Clinical Research (NCR). This guide will take you through all of the tabs required to submit a request successfully.

---

*This submission guide is for proposals that do NOT enroll patients.*

If your proposal DOES involve enrolling patients, STOP HERE.

Please navigate to the Investigator Sponsored Research (ISR) form as ISR requests do involve proposals related to patient recruitment and patient related data.

---

**General Notes and Tips**

Below you will find general notes and tips for when you are creating an ISR Request.

- *[Asterisks] indicate a required field within the interface
- You will not be able to move on to the next page if a required field is not completed
- Periodically click Save (located at the bottom right corner on any form) in order to save your information. If you do not have all the information, which is necessary to submit your request, click Save and a draft will be available for you on your homepage when you are ready to return to the form. The forms do not auto-save.
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Main Email: hd-sci-apps@bms.com
Log-in to FastTrack

1. Navigate to https://fasttrack.bms.com
2. Select your country
3. Enter your email address and your password
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide at the end of this guide.
4. Click Submit.

Create New Investigator Sponsored Non-Clinical Research Proposal

Once you have logged in, you will want to create a new request. To do this:

1. Click Create New Request
2. Select ISR: Non-Clinical

Now, you can submit the New Investigator Sponsored Non-Clinical Research Concept through FastTrack.

Submitting New Investigator Sponsored Non-Clinical Research - Clinical Study Proposal Form

When creating a new request, you will provide the Investigator’s information first. There will be a box to check to indicate 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 auto-populates from your investigator profile.

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

1. Investigator & Institution Info

   Enter the Primary Investigator’s Information

   My Role*
   This is a mandatory field with a drop down list. You will 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 mandatory field and must be submitted in a valid email format.

**Enter the Institution Information**

From your Primary Investigator Profile, the institution auto-populates. If this is not the correct institution, you will need to re-enter all mandatory fields.

**Institution Name**
This is a mandatory field.

**Institution Address Line 1**
This is a mandatory field.

**Institution Address Line 2**
This is NOT a mandatory field.

**Institution City**
This is a mandatory field.

**Institution State/Province**
This is a mandatory field for the **US/Canada**.
- **Institution Postal Code**
  This is a mandatory field.

- **Institution Country**
  This is a mandatory field. You will search for the country within the database. Once you select the appropriate country, click **Done**.

There is a checkbox that says “Shipping Address same as Institution Address?” If you select this checkbox, the shipping address fields automatically populate and hide, meaning you do not need to enter the address. Just like the Institution address, these fields can be entered manually.

- **Shipping Address Line 1**
  This is a mandatory field.

- **Shipping Address Line 2**
  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**.

- **Shipping Postal Code**
  This is a mandatory field.

Click **Next** to continue.
2. Request Details

Enter the Details of Your Request Below

- **Study Type***
  This is a mandatory field. Choose MTA.

- **Short Title***
  This is a mandatory field.

- **Therapeutic Area***
  This is a mandatory field with a drop-down list. Choose one of the following values:
  - Cardiovascular Disease
  - Immunoscience
  - Metabolic Diseases
  - Neuroscience
  - Oncology
  - Virology

- **Disease Area***
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

- **Phase***
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

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

This is a mandatory field with a drop-down list. Choose one of the following values:

- Funding*
- Drug and Funding*
- Drug
- Other

*Note: If you select “Funding” or “Drug and Funding”, two additional, mandatory fields appear. Click the link and download the required budget template. Complete the form and upload the completed budget template to attach it to this submission.

**Local BMS Contact Name**

This is a NOT a mandatory field.

**Primary Indication**

This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

**Primary Material**

This is not a mandatory field.
Primary Compound*
This is a mandatory field. Search for the value within the database.

Quantity*
This is a free-form mandatory field.

Unit*
This is a free-form mandatory field.

Click **Next** to continue, or see below.

A checkbox says, “Check this box to request additional compound.” If you select this checkbox, an option to search for a Compound name and Indication appear.

**Add Additional Compounds Below**

- **Compound Name**
  This is a mandatory field with a searchable list.

- **Compound Quantity**
  This is a free-form mandatory field.

- **Compound Unit**
  This is a free-form mandatory field.

- **Indication**
  This is a mandatory field with a drop-down list. Choose an option from the extensive list of values.

Click **Next** to continue.
3. Additional Request Details

Enter the Details of Your Request Below (continued)

- **Study Rationale***
  
  This is a free-form mandatory field. 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.

- **Primary Objective***

  This is a free-form mandatory field. Provide the main goal of the study and the study population. Provide a detailed definition that links to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.

- **Primary Endpoint***

  This is a free-form mandatory field.

- **Hypothesis***

  This is a free-form mandatory field.

- **Study Assessments***

  While not mandatory, this field will help the BMS team better understand and assess your request. Specify type and frequency of safety, efficacy, and outcome measures. Also, indicate the method(s) used to assess measures.
- **Secondary Objective**
  This is not a mandatory field.

- **Secondary Endpoint**
  This is not a mandatory field.

- **Data and Statistical Plan**
  This is a free-form mandatory field. Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The level of detail required will depend on a number of factors, including the size and complexity of the study.

- **References**
  This is not a mandatory field. List references, studies, and sources that support the study design.

  Click **Next** to continue.

## 4. Related Documents

- **Add Related Documents Below**

  ![Related Documents Image]

- **Curriculum Vitae**
  This is mandatory, 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

  Click **Submit**.
5. Submit the Request

After you complete the mandatory fields and submit, your homepage will display a success message at the top of the page and a tile of the request displays under Current Requests. Please check your email for a confirmation of your submission.*

*Note: You may need to refresh your screen to see the success message. The above image is just for informational purposes only.
Data Sharing Research Request

**Purpose**

Use this job aid to submit a request for Data Sharing Research. This guide will take you through all of the tabs required to submit a request successfully.

*This submission guide is to request data collected by BMS from a previously completed BMS Sponsored Study. If this does not apply to your study, STOP HERE. Please navigate to the appropriate request submission guide for more information.*

**General Notes and Tips**

Below you will find general notes and tips for when you are creating an ISR Request.

- * [Asterisks] indicate a required field within the interface
- You will not be able to move on to the next page if a required field is not completed
- Periodically click **Save** (located at the bottom right corner on any form) in order to save your information. If you do not have all the information, which is necessary to submit your request, click **Save** and a draft will be available for you on your homepage when you are ready to return to the form. The forms do not auto-save.
- FastTrack has a security time-out feature. After sixty (60) minutes of inactivity, you will be required to log back into the system.
  - If you are working on a record and leave it open while performing other tasks, it is recommend that you navigate to the bottom of the record and click **Save** to prevent you from losing data you have entered
- You can return to any section of the form at any point by clicking the tabs at the top of the page or clicking **Back** in 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.

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Log-in to FastTrack

1. Navigate to https://fasttrack.bms.com
2. Select your country
3. Enter your email address and your password
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide at the end of this guide.
4. Click Submit

Create New Data Sharing Research Proposal

Once you have logged in, you will want to create a new request. To do this:

1. Click Create New Request
2. Select Data Sharing

Now, you can submit the New Data Sharing Request through FastTrack.

Submitting New Data Sharing Request for BMS Sponsored Study Data

When creating a new request, you will provide the Investigator's information first. There will be a box to check to indicate 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 auto-populates from your investigator profile.

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

1. Investigator & Institution Info

   Enter the Primary Investigator’s Information

   - Enter the Primary Investigator's Information
     - Check this box if you are the primary investigator.
     - [My Role]
       - [Select role] –
     - [Primary Investigator First Name]
     - [Primary Investigator Last Name]
     - [Primary Investigator Email]
My Role*

This is a mandatory field with a drop down list. You will 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 mandatory field - for email format.

Enter the Institution Information
From your Primary Investigator Profile, the institution auto-populates. If this is not the correct institution, you will need to re-enter all mandatory fields.

- **Institution Name**  
  This is not a mandatory field.

- **Institution Address Line 1**  
  This is a mandatory field.

- **Institution Address Line 2**  
  This is NOT a mandatory field.

- **Institution City**  
  This is a mandatory field.

- **Institution State/Province**  
  This is a mandatory field for the **US/Canada**.

- **Institution Postal Code**  
  This is a mandatory field.

Click **Next** to continue.

### 2. Request Details

#### Enter the Details of Your Request Below

- **Title of Proposed Research**  
  This is a free-form mandatory field. Enter a name for your research proposal. This identifies your research proposal on this site.

- **NCT Number/BMS Protocol Number**  
  This is a free-form mandatory field. Provide the identifiers of the Bristol-Myers Squibb requested studies.
Study Rationale and Methodology/Research Proposal Summary*
This is a free-form mandatory field. Provide a brief description of the research question and the rationale of how this study addresses the question. Provide a rationale and references, if applicable.

Research Proposal Lay Language Summary*
This is a free-form mandatory field.

Hypothesis*
This is a free-form mandatory field.

Primary Objective*
This is a free-form mandatory field. Provide the main goal of the study and the study population. Provide a detailed definition that links to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section. Novel or unconventional endpoints may require explanation in the rationale section. The primary endpoint will be linked to the justification of the sample size.

Secondary Objective
This is a not a mandatory field.

Publication/Communication Plan*
This is a free-form mandatory field. Please describe how and where the results of the proposed research plan will be shared.

Study Design*
This is a free-form mandatory field.

Study Design Lay Language Summary*

Secondary Objective
This is a not a mandatory field.

Publication/Communication Plan*
This is a free-form mandatory field. Please describe how and where the results of the proposed research plan will be shared.

Study Design*
This is a free-form mandatory field.

Study Design Lay Language Summary*
This is a not a system mandatory field; however, you will need to complete this for consideration.

**Study Population***
This is a free-form mandatory field. Provide a description of the study population(s) for the proposed research. This may include but is not limited to:

- Study arms
- Inclusion/exclusion criteria for any cohort or subgroup analysis

**Data and Statistical Plan***
This is a free-form mandatory field. Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculations. The range of detail required will depend on a number of factors, including the size and complexity of the study. At a minimum, the statistical assumptions surrounding the reporting of the primary endpoint should be included.

**Funding Sources***
This is a free-form mandatory field. Please identify the funding source(s) being used or anticipated for use for the proposed research. This may include donations or grants (including research grants from governments, government agencies, funding from employers, or other forms of funding (e.g. commercial organizations).

**Software Requirements***
This is a free-form mandatory field. Please identify any specific software requirements needed to run the analysis.

**Provide any other important information/considerations***
This is a not a mandatory field.

**Does the Investigator have a conflict of interest??**
This is a drop-down mandatory field. Choose either Yes or No. If you choose “no”, you may continue the request. If you choose “yes”, the following will appear:

"Investigator Conflict of Interest Disclosure: Please provide information regarding any relationship(s) (financial or other) that reasonably will, or could be perceived to, influence any aspect of the proposed research. This should include, but not be limited to,
financial relationships with Bristol-Myers Squibb or other pharmaceutical or biotechnology companies within the last three years; board memberships, editorial positions; consultancies, whether paid or unpaid; employment; grants; patents; royalties; stocks or shares (including options). For any identified conflicts of interest, please describe how these conflicts will be addressed. “

This is a mandatory field.

Click Next to continue, or see below.

3. Team Members

Enter Team Members

This is only applicable if you choose to add additional team members to the request during the “Request Details” section.

Would you like to add team members to the request?*

This is a mandatory radio button field. Choose either Yes or No.

If you choose “yes”, the following will appear:

- Team Member Name*
  This is a mandatory field.

- Employer/Company*
  This is a mandatory field.

- Post/Position*
  This is a mandatory field.

- Experience/Qualifications*
  This is a free-form mandatory field.

- Does this person have any conflicts of interest?*
  This is a mandatory field. If you choose “no”, you may continue the request. If you choose “yes”, the following will appear:
“Conflict of Interest Disclosure: Please provide information regarding any relationship(s) (financial or other) that reasonably will, or could be perceived to, influence any aspect of the proposed research. This should include, but not be limited to, financial relationships with Bristol-Myers Squibb or other pharmaceutical or biotechnology companies within the last three years; board memberships, editorial positions; consultancies, whether paid or unpaid; employment; grants; patents; royalties; stocks or shares (including options). For any identified conflicts of interest, please describe how these conflicts will be addressed.”

This is a mandatory field.

Click Next to continue.

4. Planned Publication Information

Enter the Planned Publication Information Below
This is mandatory when you choose the “Yes” radio button option for planned publications.

- **Publication Type***
  This is a mandatory field. 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.

Click Next to continue.
5. Document Upload

Add Related Documents Below

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Curriculum Vitae</td>
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<tr>
<td>Add File...</td>
</tr>
<tr>
<td>Other Curriculum Vitae</td>
</tr>
<tr>
<td>Add File...</td>
</tr>
<tr>
<td>References/Relevant Literature</td>
</tr>
<tr>
<td>Add File...</td>
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<tr>
<td>Supporting Document 1</td>
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<td>Add File...</td>
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<td>Supporting Document 2</td>
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</table>

Curriculum Vitae*
This is mandatory, 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

Click Submit.

5. Submit the Request

After you complete the mandatory fields and submit, your homepage will display a success message at the top of the page and a tile of the request displays under Current Requests. Please check your email for a confirmation of your submission.*

*Note: You may need to refresh your screen to see the success message.
The above image is just for informational purposes only!
Submit Progress Reports

**Purpose**

Use this job aid to submit Progress Reports in Fast’Track. Refer to your study agreement for details on timelines for when the Progress Report is due.

---

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.

**Technical Support**

**Main Number:** +1 844-439-5499 (US only)

*For Outside US, please see the “International BMS Help Desk Phone Number Guide” found on the FastTrack portal*

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

---

**Login to FastTrack**

5. Navigate to [https://fasttrack.bms.com](https://fasttrack.bms.com)

6. Select your **country**

7. Enter your **email address** and your **password**
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide found on the FastTrack portal.

8. Click **Submit**

**Open Request**

On your homepage:
1. Click anywhere within the tile or click the **View** button of the program for which you wish to submit a progress report.

   The details of the request are opened.

2. **Select Progress Reports**

3. **Click Submit New Progress Report**

   A dialogue window appears.

4. Enter any notes including PI name, BMS assigned Protocol # and type of progress report

5. Select applicable document(s) to upload

6. **Click Submit**
The Progress Report's date, notes, and a link to download the file now shows within the Progress Reports tab.

**ISR Accrual Submissions**

**Purpose:**
Use this job aid to submit ISR Accruals.

After you login successfully into the FastTrack Portal and you are able to see your existing studies, click on the “view” button of the study you wish to enter monthly accrual data to (see screen shot example below):

![Screen Shot Example](image)

The details of your request will display, click on the word “Accruals” link (see screen shot example below):
The Accruals screen will display. Click on the “Submit Accrual Update” button to submit your first accrual and also to update any previous entries (see screen shot example below):

The Submit New Accrual Update screen will display. Populate the data and click “Submit” (see screen shot example below).
Please note that the **Actual date** should be updated as appropriate to the date when the milestone occurred. Also, **Best Est** means "best estimate". This is, according to you, the best estimation you can make on the date for this milestone to occur. **Best Est** should not be changed once applied, as they are discussed and agreed at study activation. If the study is running late or early, a specific discussion should be done with BMS to change the **Best Est** dates. Some field descriptions are:

**Total Number of Patients to be Accrued** is the number of patients planned to be recruited as per protocol.

**Number of Patients Accrued to Date** means "patients enrolled and treated". These are the numbers of patients who received at least one dose of treatment.

**Number of Patients Actively on Study** are the patients receiving the treatment at the time the sheet is being completed.

**First Planned First Visit**: this is the date when the first patient receives the treatment for the first time (eg: the randomization date or D1 of the first cycle for this first patient).

**Last Patient First Visit**: this is the date when the last patient receives the treatment for the first time (eg: the randomization date or D1 of the first cycle for this last patient).

**Last Patient Last Visit**: this is the date when the last patient receives the treatment for the last time or the last visit of follow up depending on your study.
Submit Amendments

Purpose
Use this job aid to submit Amendments to your study.

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.

**Technical Support**

Main Number: +1 844-439-5499 (US only)

*For Outside US, please see the “International BMS Help Desk Phone Number Guide” found on the FastTrack portal*

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

Login to FastTrack

1. Navigate to [https://fasttrack.bms.com](https://fasttrack.bms.com)

2. Select your country

3. Enter your email address and your password
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide found on the FastTrack portal.

4. Click Submit

Open Request
On your homepage:

7. Click anywhere within the tile or click the **View** button of the program for which you wish to submit an amendment.

The details of the request are opened.

8. Select **Amendments**

9. Click **Submit New Amendment**

A dialogue window appears.

10. Indicate what kind of amendment you're submitting
11. Enter any notes including PI name and the BMS assigned Protocol #
12. Select applicable document(s) to upload
13. Click **Submit**

![Amendments tab screenshot]

The Amendment’s date created, Status, Amendment Type, notes, and a link to download the attached file shows within the Amendments tab.
Request Additional Team Members

**Purpose**

Use this job aid to view a study. In order to add a new team member, the owner of the study needs to contact the assigned Protocol Manager.

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.

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**Login to FastTrack**

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2. Select your country
3. Enter your email address and your password
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide found on the FastTrack portal.
4. Click Submit

---

**View Team Members**

---

**Open the Request**

---
On your homepage:

1. Click anywhere within the tile or click the View button of the program for which you wish to submit a request for a new team member to be added.

The details of the request are opened.

2. Select Sites & Team

To add a new team member, which allows another person to see the study, the owner of the study needs to contact the assigned Protocol Manager.

The “Add New Site” button has nothing to do with requesting a new team member. This button/functionality is part of adding/managing multiple sites.
Create a Message

**Purpose**

Use this job aid to create a message. Messages are used to communicate with the Protocol Manager letting them know that they have a message. When the Protocol Manager responds, you will receive an email notification.

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.

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**Login to FastTrack**

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2. Select your country
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   - If you have forgotten your password, 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 users call +1 844 439 5499. For users outside the US, please see the International BMS Help Desk Phone Numbers Guide found on the FastTrack portal.
4. Click Submit

**Open Request**

On your homepage:
1. Click anywhere within the tile or click the **View** button of the program for which you wish to send a message

The details of the request are opened.

2. Select **Messages**

3. Click **Create a Message**

A dialogue window appears.

4. Enter the message you wish to send, including PI name and the BMS assigned Protocol #

5. Click **Send Message**

A message sent notification appears at the top of the screen and your message shows within the **Messages** tab.
NPP Drug Resupply

**Purpose**
Use this job aid to request drug re-supply for a Named Patient Program. This guide will walk you step-by-step on how to request drug re-supply for a patient in a named patient program. All screen shots are for example only.

**Login to FastTrack**
1. Navigate to [https://fasttrack.bms.com](https://fasttrack.bms.com)
2. Select your **country**
3. Enter your **email address** and your **password**
   - If you have forgotten your password, 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 use the International BMS Help Desk Phone Numbers Guide at the end of this guide.
4. Click **Submit**

**Drug Re-Supply**

**Choose Program**

On your homepage:

1. Click anywhere within the tile of the named patient program corresponding to the patient for whom you would like to reorder supplies
- **Choose Patient**

  The next screen will show you all patients in that study.
  
  2. Select the patient that you wish to request drug re-supply

- **Request New Shipment**

  3. Click **Shipments**

  4. Click **Request New Shipment**
5. Click the drop down arrow and select the shipment site

The Request New Shipment box appears

---

Reach out to the assigned Protocol Manager, if you not able to see the request new shipment button.

---

6. Complete the form with the order quantity requested. Add any comments, if necessary

A confirmation appears and the system will redirect you to the shipments tab.

---

You can track the status of your shipment by checking the status of your request. The status will change from “Submitted” to “Ready to Ship” after your request is verified. Once shipped, the status will change to “Processed” and the “Date Shipment Processed” field will be filled in.
Submit Your Publications – (coming soon)

Managing Documents – (coming soon)

EU Data Protection Concerns
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