Frequently Asked Questions

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

The BMS Help Desk is no longer available via email. If you would like to contact the BMS Help Desk via phone:

*Main Phone Number: +1 844-439-5499 (USA Only) option - 1, 1, 1, 3, *, 8 If you are outside of the USA, please refer to the phone numbers on pages 28-32.*

General HCP Questions

Q: How do I Register for FastTrack?

A: Navigate to FastTrack using https://fasttrack.bms.com. Select the **Country** you wish to register in. Within **Create an Account**, enter your personal, institution, and login details. Before creating and registering a User ID, you must read and agree to the Bristol Myers Squibb (BMS) Privacy Statement and the criteria listed in the Privacy Statement. Once you agree to each statement, select **Register**.

Please open the link above using Google's Chrome browser. Microsoft's Internet Explorer browser does not support FastTrack.

All mandatory fields are marked with an asterisk

You will receive a welcome email from FastTrack where you will find the link to log in to FastTrack.

Please check your spam folder if you have not received a welcome email

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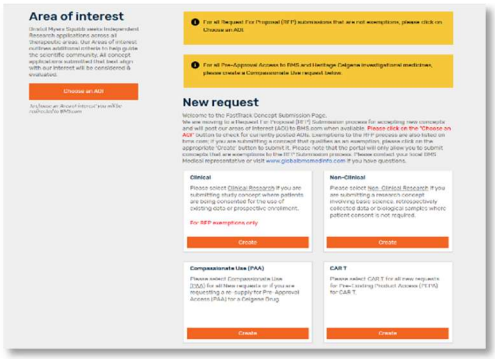
Q: How do I Log in to FastTrack?

A: Navigate to FastTrack using https://fasttrack.bms.com. Select your **Country** of registration. Enter your **email address** and **password**, then click **Submit**.

Q: How do I Create a New Request?

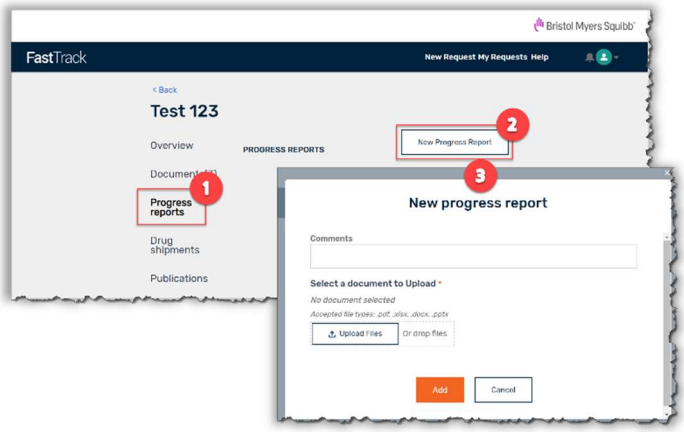
A: Once you have logged in to FastTrack, click **New Request** from the top menu. Determine the appropriate program and select **Create.** Fill out the required information and submit your request.



All mandatory fields are marked with an asterisk. The New Request screen is the default if you have never saved or submitted a request through FastTrack.

Q: How do I Submit Progress Reports for NCR?

A: After clicking the study tile, select **Progress Reports** from the left menu. To submit a progress report, select **New Progress Report** and enter the data. When complete, click **Add**.



Progress Reports apply to only Non-Clinical: Investigator Sponsored Research (NCR) studies

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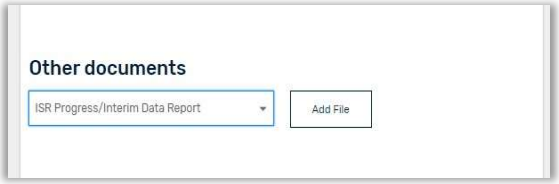
Q: How do I Submit Progress Reports for ISR?

A: After clicking the study tile, select **Documents** from the left menu. To submit a progress report, select **ISR Progress/Interim Data Report** under **Other documents** and click **Add File**. Select a document to upload and when complete, click **Add**.



Progress Reports apply to only Investigator Sponsored Research (ISR) studies

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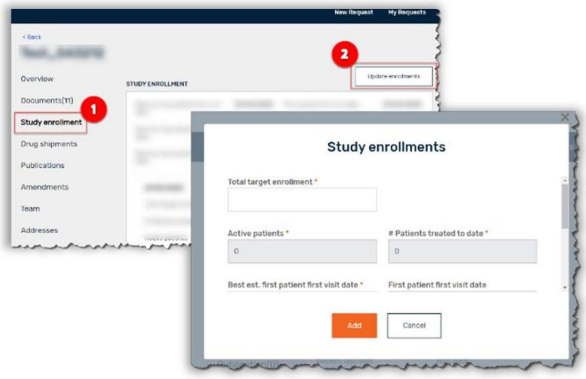
Q: How do I Submit Enrollment (Accruals)?

A: After clicking the study tile, select **Study Enrollment** from the left menu. To update, , select **Update Enrollments** and enter the data. When complete, click **Add**.



Enrollment (Accruals) apply to only Clinical: Investigator Sponsored Research (ISR) studies that are enrolling patients

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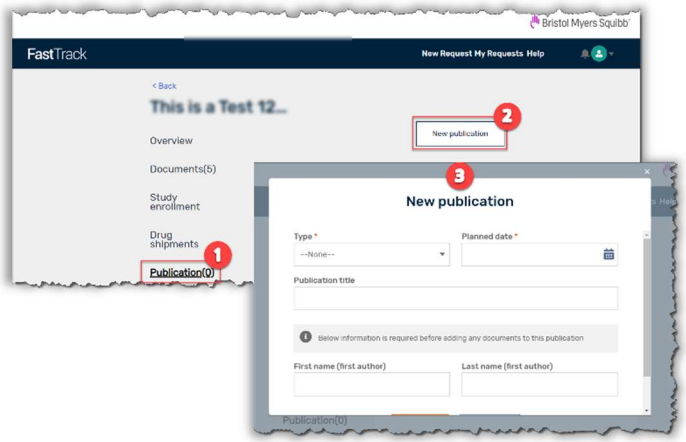
Q: How do I Submit Publications?

A: After clicking the study tile, select **Publications** from the left menu. To submit a publication, select **New Publication** and enter the data. When complete, click **Add**.

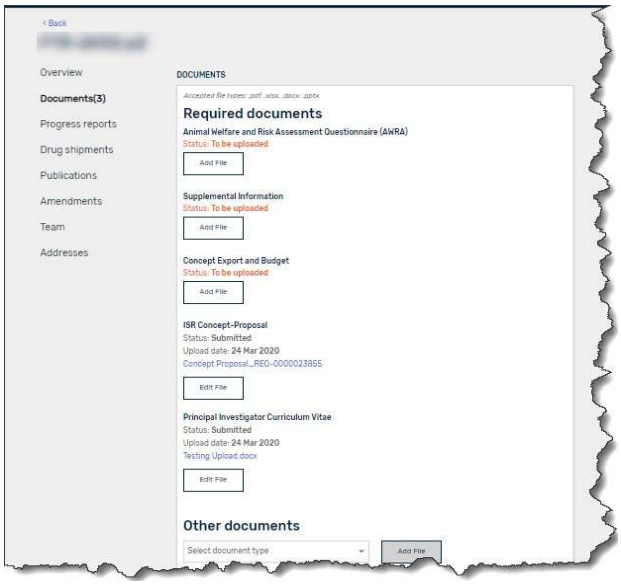


Publications do NOT apply to Compassionate Use studies

Q: How do I View/Edit/Upload/Add Documents?

A: After clicking the study tile, select **Documents** from the left menu. To submit a document or form, select **Add File** under **Required Documents** or **Other Documents** after selecting a document type. The documents will be submitted once you select a document to upload and click **Add**.

To resubmit a document, click **Edit File**.



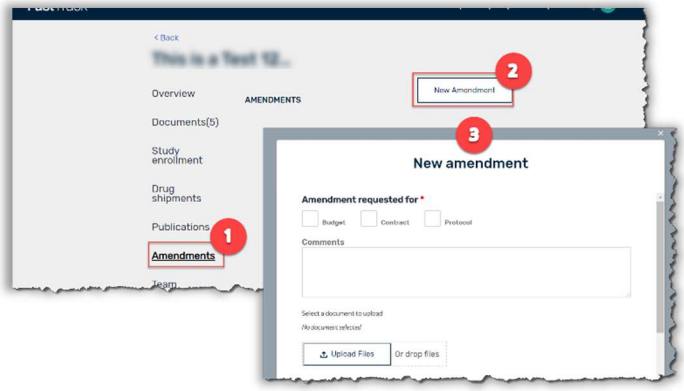
Each program has specific placeholders available for document upload

Q: How do I Submit the Final Study Report (FSR)?

A: Similar to uploading or adding documents (see above), after clicking the study tile, select **Documents** from the left menu. To submit the Final Study Report, select **Add File under Required Documents**. The documents will be submitted once you select a document to upload and click **Add**.

Q: How do I Request an Amendment(s)?

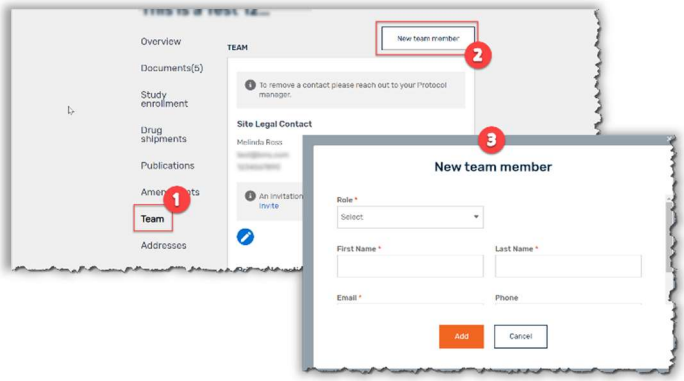
A: After clicking the study tile, Select **Amendments** from the left menu. To submit an amendment, select **New Amendment** and enter the data. When complete, click **Add**.



Amendments do NOT apply to Compassionate Use (PAA) studies and apply to specific requests.

Q: How do I Add Additional Team Members?

A: After clicking the study tile, select **Team** from the left menu. To add another team member, select **New Team Member** and enter the new team member's data. When complete, click **Add**.



The user should confirm first that the new team member being added has already registered for a FastTrack account before proceeding with adding the person as a new team member.

Q: How do I Add/Change a Drug Re-Supply Address?

A: After clicking the study tile, select **Drug Shipments** from the left menu. To set-up a drug shipping address, click **Add a drug shipping** address, then **Add Drug Shipment Address,** and submit the address data. Drug shipments to the newly added address will be available after BMS verifies the site details.

Q: How do I Submit a Drug Re-Supply Request?

A: After BMS verifies the site details, select the study tile. Then select **Drug Shipments** from the left menu. To submit a drug re-supply, click **New Drug Shipment** and submit the drug and quantity data, add in any comments, and validate the obligation to submit adverse events. When complete, click **Add**. Select the appropriate BMS verified site shipping address radio button of drug shipment location. When complete, click **Add** then **Place Order** to submit the request.

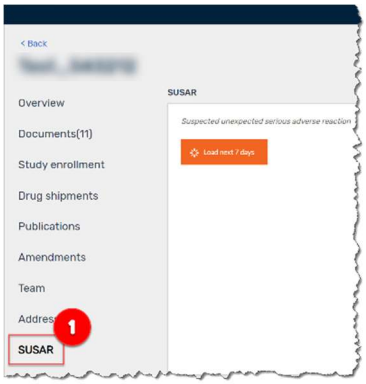
SUSARs apply to only Clinical: Investigator Sponsored Research (ISR) and Compassionate Use studies

Q: How do I change my password and log out?

A: To **change your password, update your profile** or log out of the system please click on arrow next to the **profile icon** on the right side.

Q: Where do I View Suspected Unexpected Serious Adverse Reaction Events (SUSARs)?

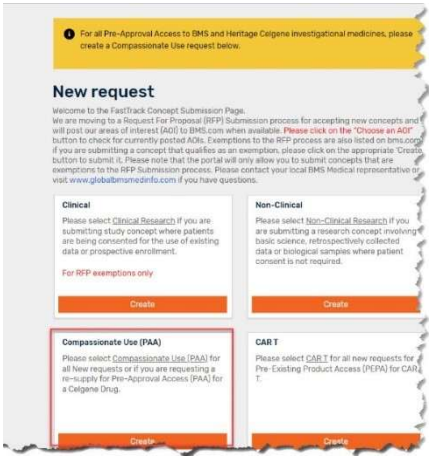
A: After clicking the study tike, select **SUSAR** option from the left menu. To see recent Adverse Events reported relative to the study, click **Load Next 3 Documents**.



Pre-Approval Access (PAA) Questions

Q: What is Pre-Approval Access (PAA)?

A: This is an important topic for Bristol Myers Squibb (BMS). We know that many of the patients seeking access to our **investigational medicines** are facing a serious or life-threatening illness and often have no further treatment options or a clinical trial available to them. We welcome unsolicited requests for **Pre-Approval Access (Compassionate Use)** from the physicians treating these patients and we take great care to have each patient's case assessed by a physician on our staff. The goal of PAA is to ensure that **eligible patients can obtain access** to our investigational medicines.



Q: Who can submit a Pre-Approval Access request?

A: A **licensed physician** who is solely responsible for the **oversight and use of the Investigational Medicinal Product (IMP)** must submit the request for the treatment of the patient. The physician must have appropriate expertise and facilities for the administration of the **IMP, monitoring, managing,** and **reporting Adverse Event (AE)/Serious Adverse Event (SAEs).**

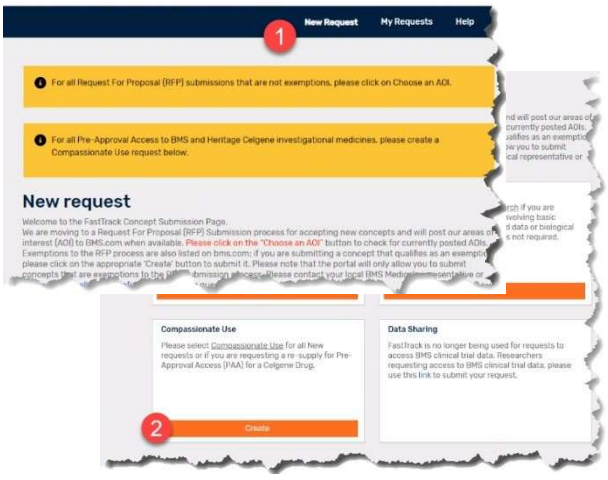
Q: What patients are eligible for Pre-Approval Access?

A: Specific eligibility criteria must be met for access outside of a clinical trial. The **illness must be serious or life-threatening**. There are **no other viable options** (including approved products or active clinical trials). There is sufficient evidence that the **potential benefit to the patient would likely outweigh the potential risks** based on what is known at the time.

Q: How do I create a Pre-Approval Access Request

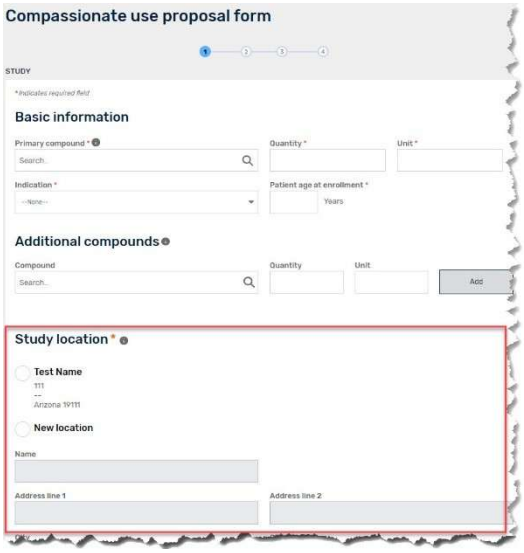
A: NOTE: You will need to register for FastTrack – see "How do I register for FastTrack" in Section 3 - General HCP Questions

log into FastTrack (https://fasttrack.bms.com/login) with your email and password and click on "**New Request**" on the top bar. "New Request" is used when submitting a new single patient request for PAA. Scroll down and select the **Create button** in the box **"Compassionate Use" to** complete the Compassionate use proposal form and **submit**. The **fields with an asterisk*** are mandatory.



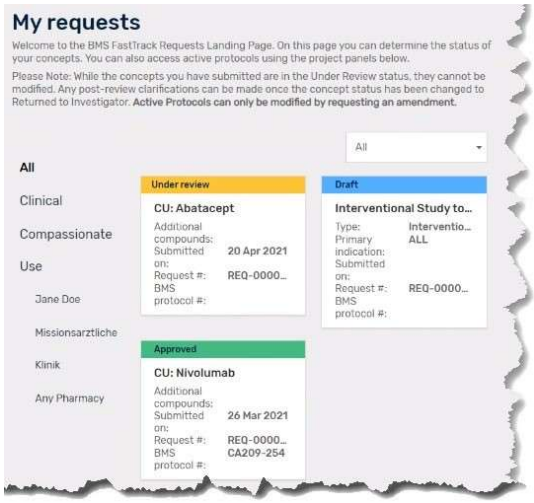
Q: What is the Study Location?

A: The **Study location** included in this section is the **institution** where the patient is going to be treated. The **Curriculum Vitae (CV)** to upload must be current and include the place where the patient will be treated. If you don't work where the patient will be treated, please have the **Overseeing Physician** complete the request.



Q: Where do I find my draft and submitted PAA request?

A: If you **Save and Close,** you can find your request listed under the **My Request tab** in **Draft** status (blue heading bar). When you **Submit,** you will get a pop-up to indicate a successful submission, and you will find your request with **"Under review"** status (yellow heading bar). When it is accepted by BMS Medical you will see the **Approved** status (green heading bar).



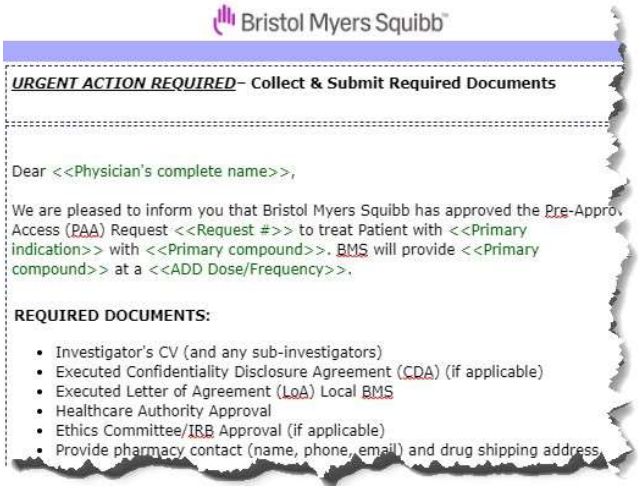
Q: What happens after I submit my Request?

A: You will receive an **email confirming** that the request is submitted. BMS will assess the request and will communicate the **approval or rejection by email**.

Q: What will occur if my PAA request is approved?

A: When the request is approved, you will receive **an initial approval email** indicating the documents required by BMS prior to providing drug supplies. **Each country will have different requirements** regarding the documents needed prior to providing drug.
Below are some examples of documents which may be required for your country:

- Letter of Agreement
- Confidentiality Agreement
- Health Authority Approval
- FDA 3926
- Ethical Board Approval
- Import permit / Import authorization


Bristol Myers Squibb

***URGENT ACTION REQUIRED*– Collect & Submit Required Documents**

Dear <<Physician's complete name>>,

We are pleased to inform you that Bristol Myers Squibb has approved the Pre-Appro Access (PAA) Request <<Request #>> to treat Patient with <<Primary indication>> with <<Primary compound>>. BMS will provide <<Primary compound>> at a <<ADD Dose/Frequency>>.

REQUIRED DOCUMENTS:

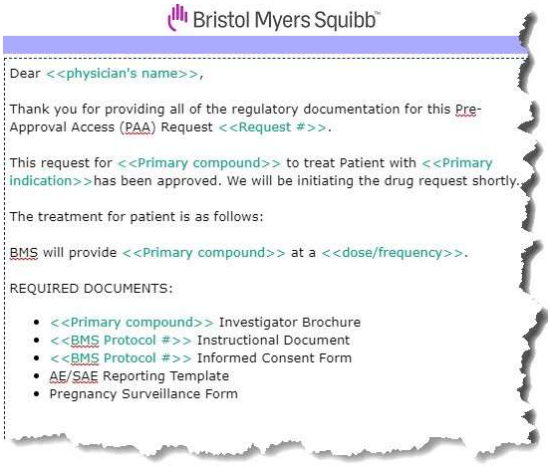
- Investigator's CV (and any sub-investigators)
- Executed Confidentiality Disclosure Agreement (CDA) (if applicable)
- Executed Letter of Agreement (LoA) Local BMS
- Healthcare Authority Approval
- Ethics Committee/IRB Approval (if applicable)
- Provide pharmacy contact (name, phone, email) and drug shipping address

With each new request, you will receive a copy of the **safety reporting guidelines** as part of your PAA request. Please ensure you have read and understood the safety reporting by signing the **Letter of Agreement.** This indicates you will comply with the reporting requirements.

Q: What happens after the documents receive final approval?

A: Once all the documents requested are received, the final approval email will be sent by BMS**.** The email will also contain the following documents:

- Investigator Brochure
- Serious Adverse Event Reporting Form
- Pregnancy Surveillance Reporting Form
- Depending on the asset, you may receive additional safety documents with your initial approval email.


Bristol Myers Squibb

Dear <<physician's name>>,

Thank you for providing all of the regulatory documentation for this Pre-Approval Access (PAA) Request <<Request #>>.

This request for <<Primary compound>> to treat Patient with <<Primary indication>>has been approved. We will be initiating the drug request shortly.

The treatment for patient is as follows:

BMS will provide <<Primary compound>> at a <<dose/frequency>>.

REQUIRED DOCUMENTS:

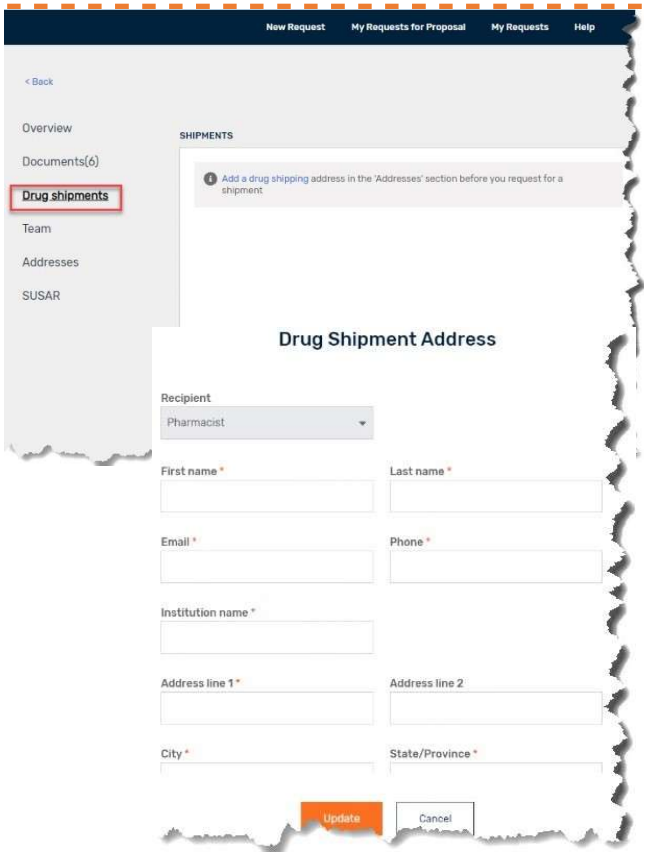
- <<Primary compound>> Investigator Brochure
- <<BMS Protocol #>> Instructional Document
- <<BMS Protocol #>> Informed Consent Form
- AE/SAE Reporting Template
- Pregnancy Surveillance Form

BMS will keep in regular contact while you have a patient receiving drug supply for PAA.

Q: How do Drug Shipments (Initial and re-supply) work for PAA?

A: The **BMS Drug Shipment team** initiates the first drug shipment once all required documents have been received by BMS. The drug shipment takes **7-10 business days** to arrive.

When completing the drug request form, please be sure to enter and complete **General Mailing Address** and **Drug shipment address.** The Drug shipment address will be used for all drug shipments, so this will need to be complete and accurate. The pharmacist's full contact information is also required.



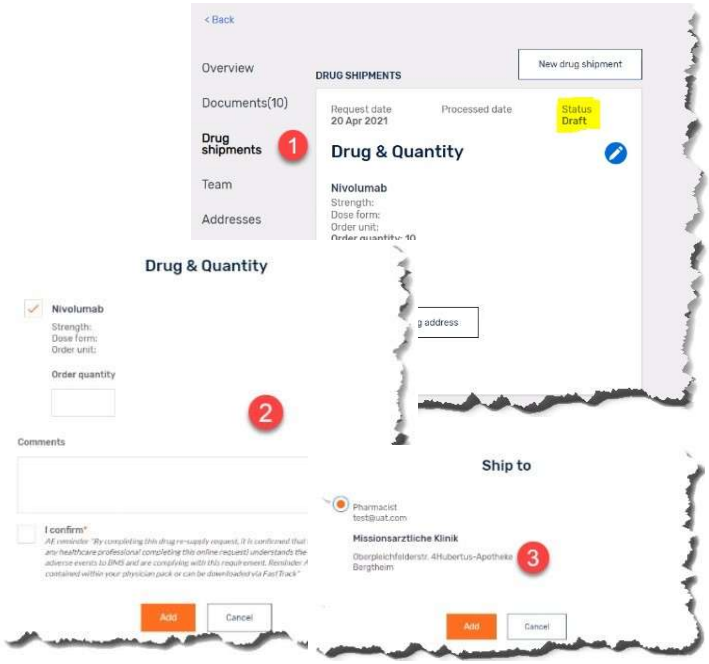
Q: How do we prepare and store study drug for PAA?

A: How to best prepare and store the study drug will be described in the **Investigational Brochure/s (IB),** which will accompany the **final approval letter**. Please follow the instructions included in the IB to store and prepare the study drug. If you require the IB to be re-sent, please reach out to your BMS PAA Trial Manager.

Q: How do we handle Re-Supply of Drug for PAA?

A: Resupply of drugs can be completed by a site team member with access to the request in FastTrack.

- Open the Approved request on the My **Requests** page.
- Select **Drug Shipments** to the left of the screen.
- Select **New Drug Shipment**. The required drug will be preselected based on the initial drug shipment completed.
- Enter 3 months' supply for the **Order quantity** needed.
- The drug re-supply request has been entered; however, it is still in a draft status and will need to be submitted.
- Select **shipping address** and a pop-up will appear.
- Select the address for drug shipment.
- Select **Add to save the information**. You will be returned to the Drug Shipments screen,
- Click the big orange submit button to **submit the request**.
- The request status will change from Draft to Submitted.



Note: **Order quantity** means the number of boxes of drugs needed. BMS will provide **3 months' supply** within one shipment. However, due to regulatory, local laws or complexities, this can be adjusted with endorsement by Patient Access Operations leadership.

Q: What happens if my patient on PAA experiences a Safety Event?

A: Please complete the **Adverse Event form** provided to you as part of your final approval email and send it to **worldwide.safety@bms.com**. Refer to the Reporting Safety Information and Product Quality Complaints Training provided to you with the initial approval email for more information.

Q: When does my patient have to stop treatment on PAA?

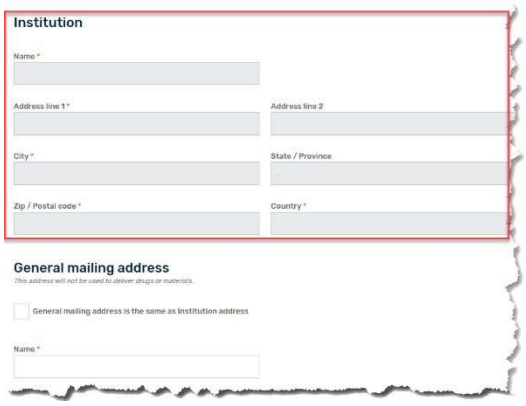
A: Reasons for stopping treatment include (but are not limited to): **disease progression**, **adverse events**, **withdrawal of consent**, reimbursement of the product in the market, and **physician opinion**.

Q: What happens when my patient on PAA no longer needs treatment?

A: If your patient no longer requires treatment, please inform BMS. All drugs which have been shipped to your designated pharmacy **MUST be destroyed** as per local policy. You cannot use the drug for any other patient, however, exceptions can be made in rare circumstances by BMS **BMS will require confirmation** that all drugs have either been provided to the patient or destroyed. If you are required to inform your **Health Authority** that the patient is no longer taking this medication, please inform them

Q: What is the meaning of Institution on the request form?

A: Where **Institution** is listed on the **request form**, please complete this with information regarding where the **patient** will be receiving **treatment**. If the patient is currently being seen at a different hospital, please only include where the **treatment** will occur.



Q: Do I need to enter patient initials and if yes, where do I enter this information?

A: Patient initials are no longer allowed to be in the Request submission form as this is a privacy issue. The field has been removed. BMS will refer to **All patients** by their Request number (REQ#), which is unique per the submitted request. This can be easily seen on the **My Requests** screen which lists all your requests. For PAAs, please ensure you are reviewing the Compassionate Use (PAA) requests.

Q: How do I know what drug has been assigned to the correct patient?

A: When the drug is shipped, a packing list will accompany the shipment. The **REQ number** from Fastrack is present on the packing list. Should you have two patient requests that require the same drug to be shipped, these will arrive in one shipment. You will be provided with one packing list for the patient requests, the REQ numbers for both patients will be present on the packing list.

Q: How do I know the dose for pediatric patients, elderly or special populations, etc.?

A: Dosing is determined by the **HCP**. This information is sent in the **PAA Final Approval Letter** to the HCP.

Q: Why is the Investigator Brochure being provided and do I need to follow it?

A: We provide the **Investigator Brochure (IB)** with the final approval email for your reference. The IB has the relevant information regarding the drug supplied, including **both preparation** and **storage details**. Only the IB needs to be followed to ensure the safety of patients.

Q: Can we keep the drug for other patients if this patient stops treatment?

A: If a patient stops treatment the drug needs to be **destroyed,** and the site needs to send a **confirmation drug destruction form to BMS Trial Manager**

Q: What is meant by the question 'Patient Has Participated in a BMS Study'?

A: If the patient has taken a **BMS product** on either a **BMS sponsored** or **Investigator Sponsored Research** study, answer this question with a **yes**.

Q: What information is required as part of the request?

A:

- **Patient information** to assess suitability for the drug.
- **Patient lab assessments** on the request form – all labs to be provided.
- **Treating Physician information** as the Primary Investigator.
- **General mailing address** is for the Physician, not the drug shipment.
- **Pharmacy contact information**- please include full contact information for the pharmacist in charge and a specific email and phone number for the pharmacy, not the hospital's general phone number.

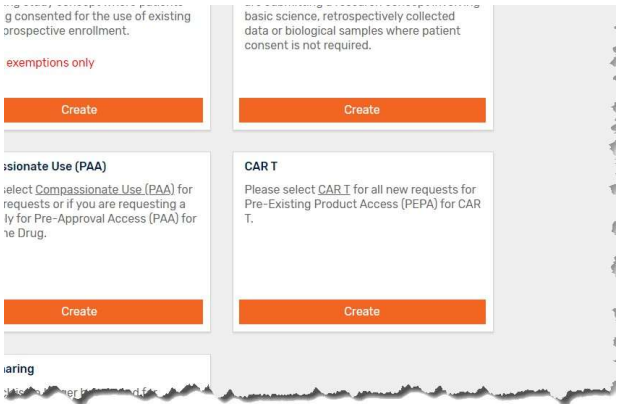
Q: What are the maximums when placing re-supply order?

A: The standard is **three cycles** or **three months'** worth of supply.

Pre-Existing Product Access (PEPA) Questions

Q: What is Pre-Existing Product Access (PEPA)?

A: Pre-Existing Product Access enables physicians to provide patients for whom autologous CAR T product was for use under an existing clinical trial program for which the patient is deemed no longer eligible. The goal of PEPA is to enable patients **to obtain access** to their pre-existing CAR T product.



Q: Who can submit a Pre-Existing Product Access request?

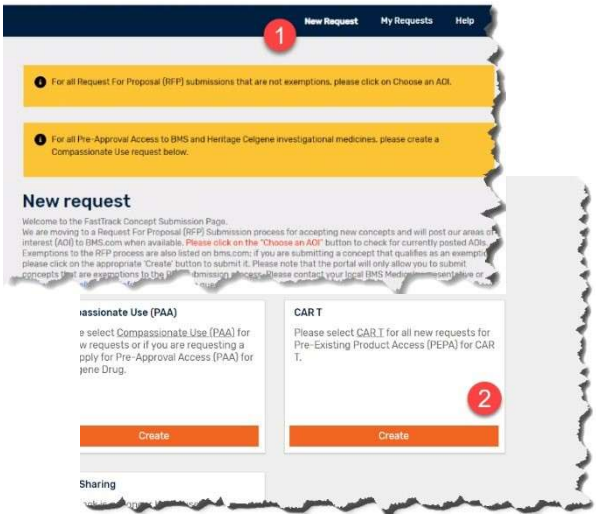
A: A **licensed physician** who is solely responsible for the **oversight and use of the CAR T** for the treatment of the patient must submit the Request. The physician must have prior experience handling CAR T and the treatment site must be REMS certified for the relevant **BMS CAR T product** to ensure **monitoring, managing,** and **reporting Adverse Event (AE)/Serious Adverse Event (SAEs).**

Q: What patients are eligible for Pre-Existing Product Access?

A: Patient must have an **existing BMS autologous CAR T product** originally manufactured for use under an existing clinical trial program for which the patient is deemed **no longer eligible**. The **illness must be serious or life-threatening**. There are **no other viable options** (including approved products or active clinical trials). There is sufficient evidence that the potential **benefit to the patient would likely outweigh the potential risks** based on what is known at the time.

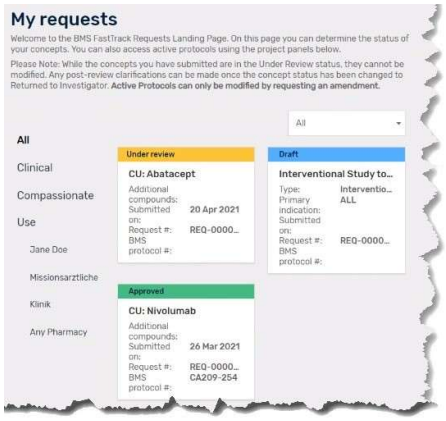
Q: How do I create a Pre-Existing Product Access Request

A: Once you log in FastTrack (https://fasttrack.bms.com/login) with your email and password, click on **New Request** on the top bar. A New Request is used when making a PEPA request for different patients. After scrolling down, select the **Create button** in the box **"CAR T"**. Complete the **Pre-existing Product** proposal form and **submit**. The **fields with an asterisk*** are required.



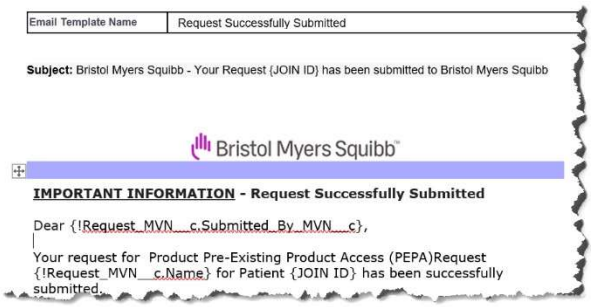
Q: Where do I find my submitted PEPA request?

A: If you **Save and Close,** you can find your request listed under the **My Request tab** in **Draft** status (blue heading bar). If you **Submit,** you will get a pop-up to indicate a successful submission, and you will find your request with **"Under review"** status (yellow heading bar). When it is accepted by BMS Medical you will see the **Approved** status (green heading bar).



Q: What happens after I submit my Request?

A: You will receive an **email confirming** that the request is submitted. BMS will assess the request and will communicate the **approval or rejection by email**.



Email Template Name	Request Successfully Submitted

Subject: Bristol Myers Squibb - Your Request {JOIN ID} has been submitted to Bristol Myers Squibb

Bristol Myers Squibb

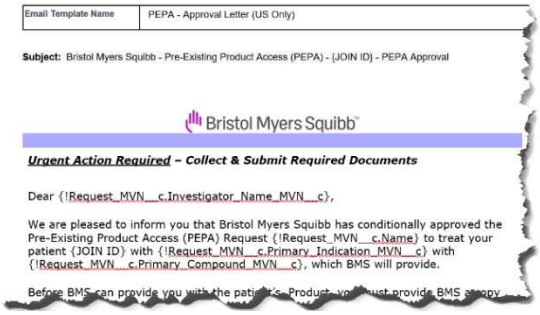
IMPORTANT INFORMATION - Request Successfully Submitted

Dear {!Request_MVN__c.Submitted_By_MVN__c},

Your request for Product Pre-Existing Product Access (PEPA)Request {!Request_MVN__c.Name} for Patient {JOIN ID} has been successfully submitted.

Q: What will occur if my PEPA request is approved?

A: In case the Request is approved, you will receive a **pre-approval email** indicating which documents are required to be received by BMS prior to being able to provide the product. **Each country may have different requirements** regarding what documents are required for collection. An example of a document which may be required for your country is the Health Authority Approval.



Email Template Name	PEPA - Approval Letter (US Only)

Subject: Bristol Myers Squibb - Pre-Existing Product Access (PEPA) - {JOIN ID} - PEPA Approval

Bristol Myers Squibb

***Urgent Action Required* – Collect & Submit Required Documents**

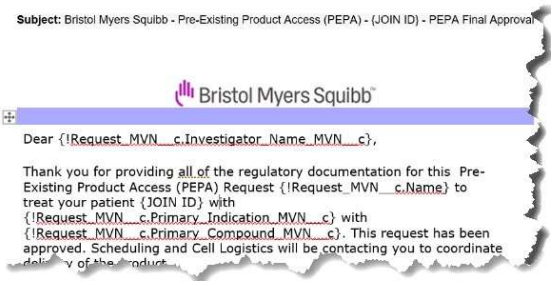
Dear {!Request_MVN__c.Investigator_Name_MVN__c},

We are pleased to inform you that Bristol Myers Squibb has conditionally approved the Pre-Existing Product Access (PEPA) Request {!Request_MVN__c.Name} to treat your patient {JOIN ID} with {!Request_MVN__c.Primary_Indication_MVN__c} with {!Request_MVN__c.Primary_Compound_MVN__c}, which BMS will provide.

Before BMS can provide you with the patient's Product, you must provide BMS a copy

Q: What happens after the documents receive final approval?

A: Once all the documents are completed, final approval will be sent by BMS. At this point, **Scheduling and Cell Logistics** will contact you to coordinate delivery of the product.



Subject: Bristol Myers Squibb - Pre-Existing Product Access (PEPA) - {JOIN ID} - PEPA Final Approval

Bristol Myers Squibb

Dear {!Request_MVN__c.Investigator_Name_MVN__c},

Thank you for providing all of the regulatory documentation for this Pre-Existing Product Access (PEPA) Request {!Request_MVN__c.Name} to treat your patient {JOIN ID} with {!Request_MVN__c.Primary_Indication_MVN__c} with {!Request_MVN__c.Primary_Compound_MVN__c}. This request has been approved. Scheduling and Cell Logistics will be contacting you to coordinate

Q: What Happens if my patient on a PEPA experiences a Safety Event?

A: Pursuant to the Letter Agreement, you agree to **report to BMS all serious adverse events (SAEs)** and pregnancy (refer to Attachment C to the Letter Agreement – Adverse Event Definitions), regardless of causality, via electronic mail to **worldwide.safety@BMS.com** or facsimile **1-609-818-3804**. All AEs must be reported from the administration of the nonconforming product under this Letter Agreement **through 90 days after** the administration of the Product.

Q: What is the meaning of Institution on the request form?

A: Where **Institution** is listed on the **request form**, please complete this with information regarding where the **patient** will be receiving **treatment**. If the patient is currently being seen at a different hospital, please only include where the **treatment** will occur. The **treatment** site must be REMS certified for the relevant **BMS CAR T product**.

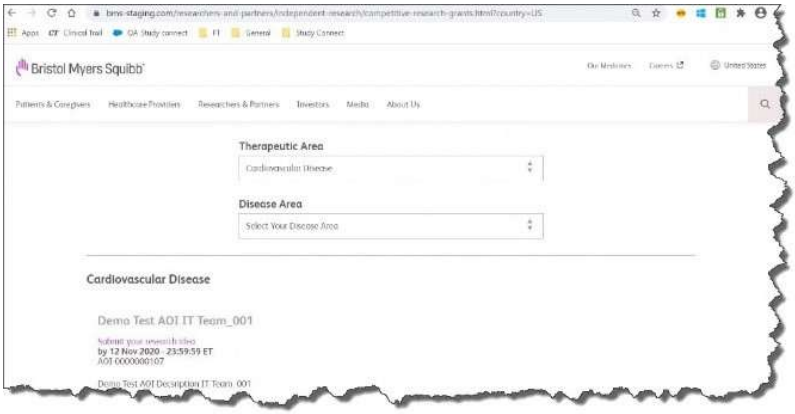
Q: Do I need to enter patient initials and if yes, where do I enter this information?

A: Patient initials are no longer allowed to be in the Request submission form as this is a privacy issue. The field has been removed. BMS will refer to **patients** by their Request number (**REQ#)**, which is unique per the submitted request and/or by the **Join ID**. This can be easily seen on the **My Requests** screen which lists all your requests. For PEPAs, please ensure you are reviewing the **Pre-Existing Product Access (PEPA) requests**.

Request for Proposals (RFP) Questions

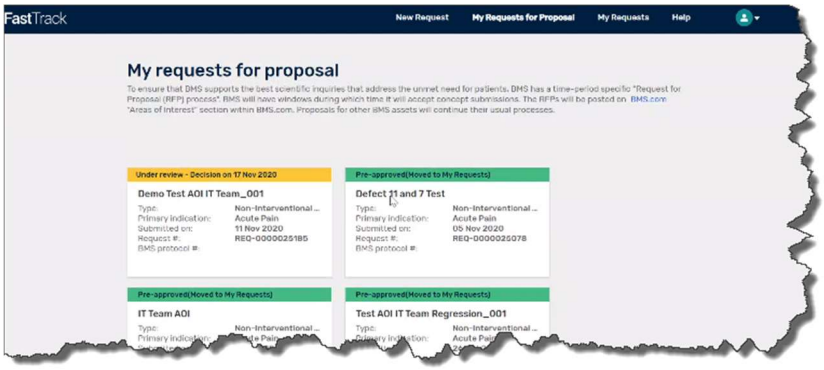
Q: What is RFP?

A: Bristol Myers Squibb (BMS) utilizes a **Request for Proposal (RFP) Submission Cycle** for all investigator sponsored research proposals (ISRs) that focus on investigating BMS marketed and investigational therapies. Any exemptions to the RFP process are posted to BMS.com & periodically updated.



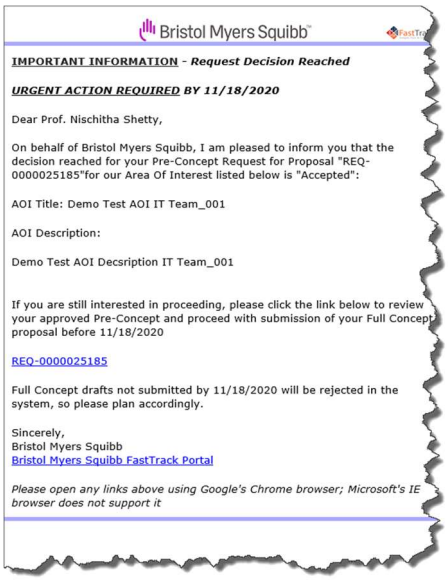
Q: How do I Submit for an RFP?

A: From **BMS.com**, select an **Area of Interest (AOI)** based on Therapeutic and Disease Area to submit a related clinical research concept. You will click the link and sign-in to the portal to complete a one-page **Pre-concept Submission** before the deadline. Then you will be able to see the pre-concept in **My Request for Proposal.** After a review period, if your concept is selected, you will be asked via email to complete the **Full Concept Submission**. Full Concept submissions can be found in **My Request**.



After the decision process, approved full concept submissions are assigned a Protocol Manager who will facilitate the Study Planning phase.

Q: What can I Expect When I Submit an RFP



Bristol Myers Squibb

IMPORTANT INFORMATION - ***Request Decision Reached***

URGENT ACTION REQUIRED BY 11/18/2020

Dear Prof. Nischitha Shetty,

On behalf of Bristol Myers Squibb, I am pleased to inform you that the decision reached for your Pre-Concept Request for Proposal "REQ-0000025185"for our Area Of Interest listed below is "Accepted":

AOI Title: Demo Test AOI IT Team_001

AOI Description:

Demo Test AOI Decsription IT Team_001

If you are still interested in proceeding, please click the link below to review your approved Pre-Concept and proceed with submission of your Full Concept proposal before 11/18/2020

REQ-0000025185

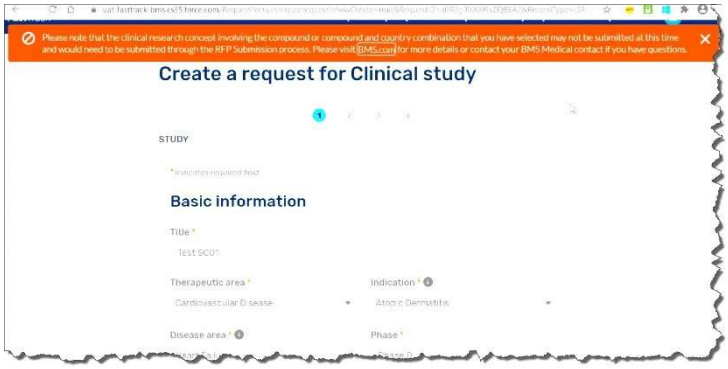
Full Concept drafts not submitted by 11/18/2020 will be rejected in the system, so please plan accordingly.

Sincerely,
Bristol Myers Squibb
Bristol Myers Squibb FastTrack Portal

Please open any links above using Google's Chrome browser; Microsoft's IE browser does not support it

A: Based on the RFP Cycle and its timings, you will be able to see an AOI on **BMS.com** to begin submitting your short pre-concept. Please note that you will receive a message that you are leaving BMS.com. This is part of the normal process to bring you to the FastTrack portal. In order for your research concept to be considered during the RFP cycle, it must be submitted to BMS prior to the **Pre Concept Submission End Date.** Decisions on preconcepts will be communicated to submitters after the **Pre Concept Submission End Date.** Potential investigators whose pre-concepts are accepted will receive a notification which will provide the deadline or **Full Concept Submission End Date** for submission of the full concept. All full concepts that are received by BMS by the **Full Concept Submission End Date** will undergo a competitive review process and grants for ISRs will be awarded based on evaluation criteria that includes scientific merit, feasibility, and methodology. Decisions will be communicated to all full concept submitters at the end of the review process and a formal auto-notification will be sent by email to all submitters on the same date.

Q: Are there Exemptions to the RFP Process?



Please note that the clinical research concept involving the compound or compound and country combination that you have selected may not be submitted at this time and would need to be submitted through the RFP Submission process. Please visit BMS.com for more details or contact your BMS Medical contact if you have questions.

Create a request for Clinical study

STUDY

Basic information

Title *

Therapeutic area *

Cardiovascular Disease

Indication *

Atopic Dermatitis

Disease area *

Phase *

A: Exemptions to the RFP process for those types of concepts that may be submitted any time are posted to **BMS.com** based on the **Primary Investigator's Country Location**, **Therapeutic Area**, **Disease Area**, and/or **Primary Compound** as specified in the posted exemptions. If you try to submit a non-exempt clinical research concept, you will get a warning message explaining this study needs to be submitted through the **RFP Submission process**.

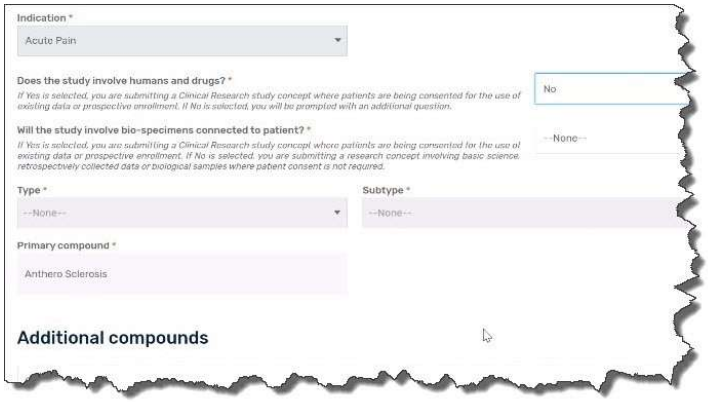
If your concept does not fall within the specified exemptions and there is no open RFP cycle for the relevant Primary Compound, you may request to submit an "off-

cycle" concept. Please contact your BMS Medical representative with your proposal. If accepted for formal review following the initial intake, you will be provided with a personalized link to submit your concept through the FastTrack submission portal.

If you have questions, contact your **BMS Medical contact.** You can use this **Investigator Inquiry Form.**

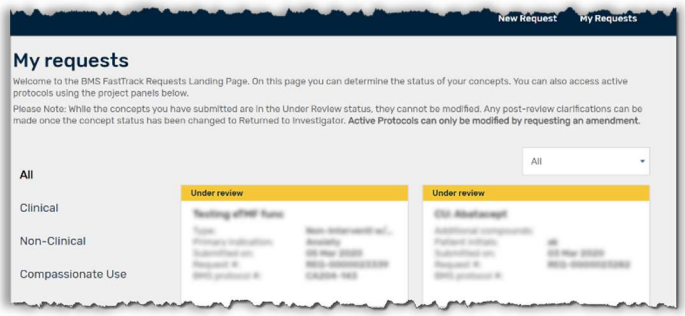
Q: For RFP, explain Human versus non-Human Studies

A: If the clinical study involves **Humans** or **Human Tissue**, BMS needs to have a **disclosure statement** on file. It is important that you choose the correct answer at this point in the submission process. Later in the study phase, the **disclosure statement** may be used to show that BMS has consent for the clinical study.



Q: How do I Find a Specific Study?

A: After logging in to FastTrack, the new home page will default to **ALL** studies on a screen titled **My Requests**. Studies are shown separately as their own tile. The color shows the status of the study.



Technical Help Questions

Q: Who do we contact about EU Data Protection?

A: You may contact our **EU Data Protection Officer** at EUDPO@bms.com to exercise any data privacy rights that you may have, as well as to raise any concerns or questions about the handling of your personal data by BMS™.

Q: How do I Contact the BMS Help Desk?

A: We are committed to providing you with answers to your questions and concerns as quickly as possible.

The BMS Help Desk is no longer available via email. If you would like to contact the BMS Help Desk via phone:

Main Phone Number: +1 844-439-5499 (USA Only) option - 1, 1, 1, 3, *, 8 If you are outside of the USA, please refer to the phone numbers on pages 28-32.

Common Help Desk Numbers

Country		Number
	Belgium / Belgique / België	0800 816 71
	Brazil / Brasil	08000 474 056
	Canada	844 439 5499
	China / 中国	400 881 1485
	France	0805 540 097
	Germany / Deutschland	0800 101 5430
	Italy / Italia	800 925 001
	Japan / 日本	012 091 4105
	Spain / España	900 810 939
	United Kingdom	0800 032 8019
	Algeria / Algérie / لجزائر	983 200 513
	Argentina	800 266 1569
	Australia	1 800 099 940
	Austria / Österreich	08000 706 102
	Bahrain / البحرين	800 816 83
	Belgium / Belgique / België	0800 816 71

	Brazil / Brasil	08000 474 056
	Bulgaria / Republika Bălgarija	00800 120 4444
	Canada	844 439 5499
	Chile	800 395 251
	China / 中国	400 881 1485
	Colombia	01 8000 125 394
	Czech Republic / Česká Republika	800 050 176
	Denmark / Danmark	802 52 505
	Ecuador	1 800 000 472
	Egypt / مصر	0800 000 9138
	Estonia / Eesti Vabariik	8000 044 822 (Landlines Only)
	Finland / Suomi	0800 417 461
	FOT / DOM/TOM	00 33 1 58 83 83 68
	France	0805 540 097
	Germany / Deutschland	0800 101 5430
	Greece / Ελλάδα	00800 4414 3410 (Landline only) 210 607 4359

	Hong Kong / 香港	301 34 736
	Hungary / Magyarország	06 809 81 583
	India	000 800 440 5114
	Ireland	1800 800 012
	Israel / יִשְׂרָאֵל	1809 344 260
	Italy / Italia	800 925 001
	Japan / 日本	012 091 4105
	Korea / 대한민국	0809 080 957
	Kuwait / الكويت دولة	222 804 17
	Luxembourg / Lëtzebuerg	800 850 89
	Mexico / México	01 800 436 0226
	The Netherlands / Nederland	0800 220 0032
	Norway / Norge	800 58 222

	Oman / عُمان سلطن	800 77 238
	Peru / Perú	0800 777 39
	Poland / Polska	800 707 447
	Portugal	800 784 734
	Puerto Rico	844 439 5499
	Qatar/قطر	8000 193
	Romania / România	0800 400 740
	Russian Federation / Российская Федерация	8800 555 6489
	Saudi Arabia / السعودية العربية المملكة	800 844 5328
	Singapore / Singapura	1800 723 1415
	South Africa	0800 000 602
	Spain / España	900 810 939
	Sweden / Sverige	020 109 194
	Switzerland / Schweiz	0800 200 356

	Taiwan / 中華民國	0800 666 508
	Thailand /ประเทศไทย	00 1800 294 211
	Tunisia / Tunisie / تونس	00 33 1 58 83 83 68
	Turkey / Türkiye	0216 282 1586
	المتحدة العربية الإمارات دولة UAE /	8000 444 1057
	Venezuela	0800 100 3349

Change History

Change Type	Author	Date/Time	Description
Logo update	Rod Faigao	July 7, 2025	BMS Trademark logo updated to Registered