

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.

*If you would like to contact the BMS Help Desk via email, please include your question, issue, and contact information and send it to hd-sci-apps@bms.com. If you would like to contact the BMS Help Desk via phone, use the phone numbers listed below and selecting options **1, 1, 1, 3, *, 8**.*

*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 below.*

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.

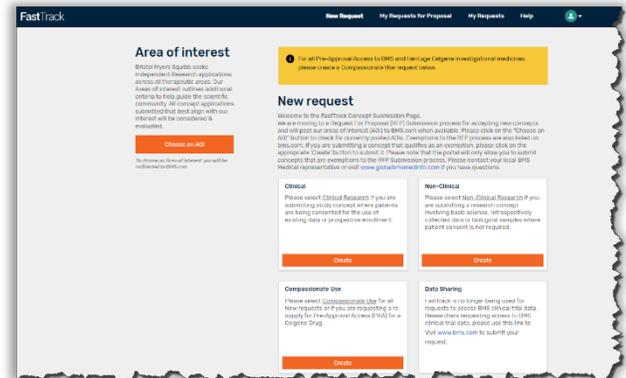
Please check your spam folder if you have not received a welcome email

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?

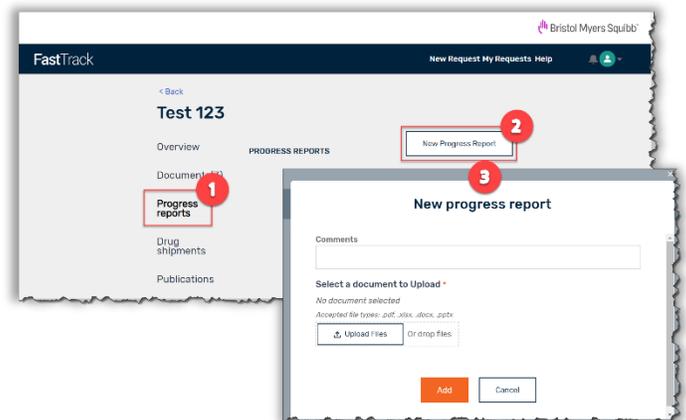
A: Once you have logged in to FastTrack, click **New Request** from the top menu. Determine the appropriate program and select **Create**. Fill out the required information and submit your request.



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?

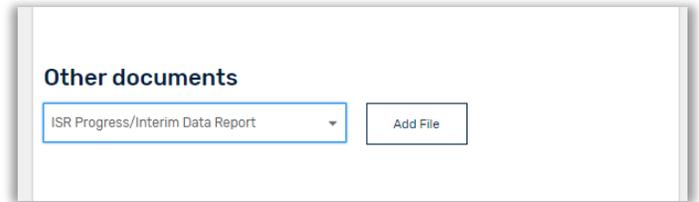
A: After clicking the study tile, select **Progress Reports** from the left menu. To submit a progress report, select **New Progress Report** and enter the data. When complete, click **Add**.



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

Q: How do I Submit Progress Reports for ISR?

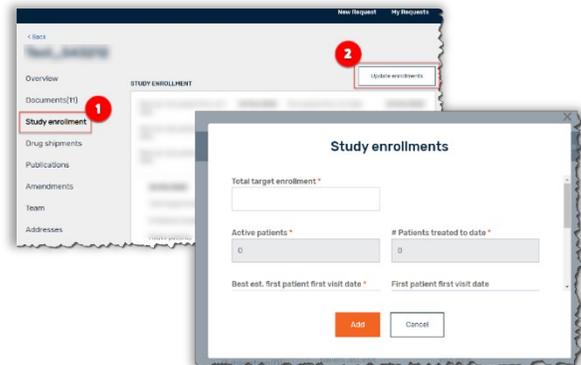
A: After clicking the study tile, select **Documents** from the left menu. To submit a progress report, select **ISR Progress/Interim Data Report** under **Other documents** and click **Add File**. Select a document to upload and when complete, click **Add**.



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

Q: How do I Submit Enrollment (Accruals)?

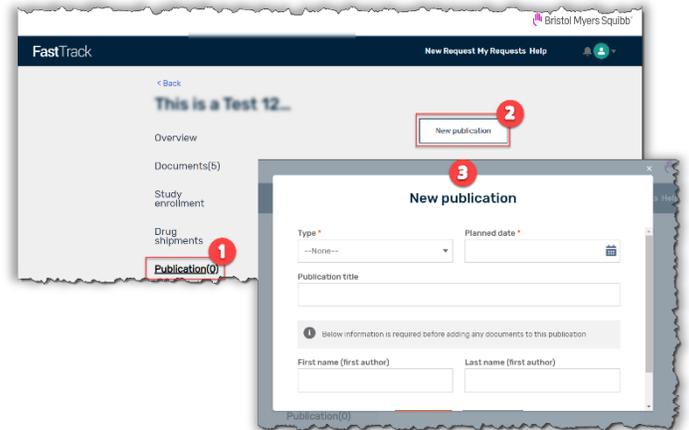
A: After clicking the study tile, select **Study Enrollment** from the left menu. To update accruals, select **Update Enrollments** and enter the data. When complete, click **Add**.



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

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**.

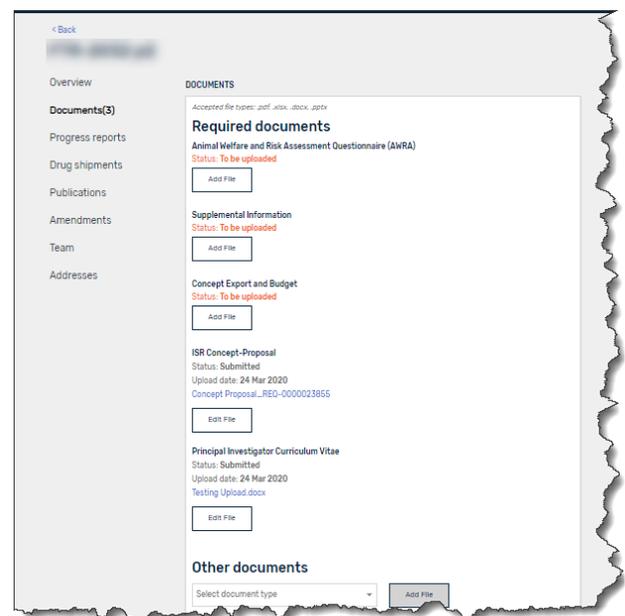


Publications do NOT apply to Compassionate Use studies

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

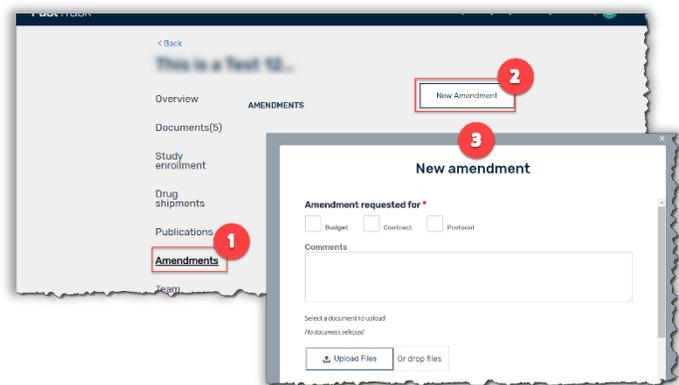
Q: How do I Submit the Final Study Report (FSR)?

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)?

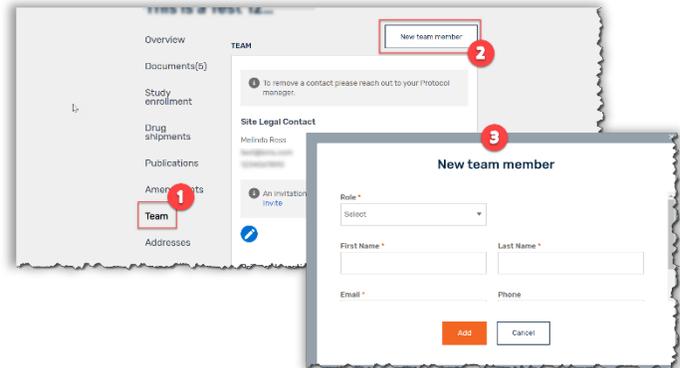
A: After clicking the study tile, select **Amendments** from the left menu. To submit an amendment, select **New Amendment** and enter the data. When complete, click **Add**.



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

Q: How do I Add Additional Team Members?

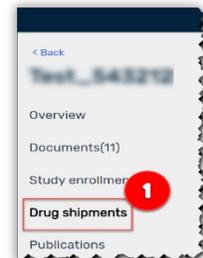
A: After clicking the study tile, select **Team** from the left menu. To add another team member, select **New Team Member** and enter the new team member's data. When complete, click **Add**.



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.

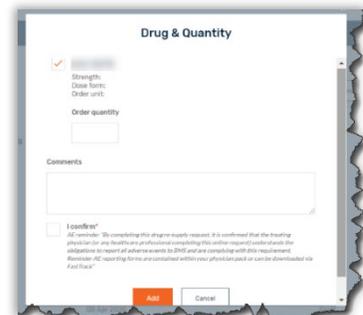
Q: How do I Add/Change a Drug Re-Supply Address?

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.



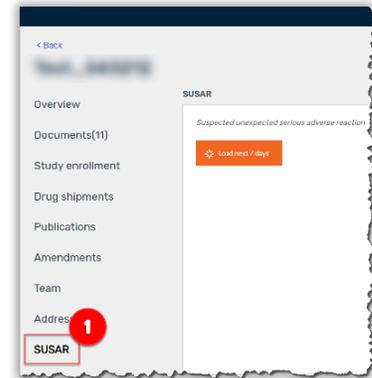
Q: How do I Submit a Drug Re-Supply Request?

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.



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

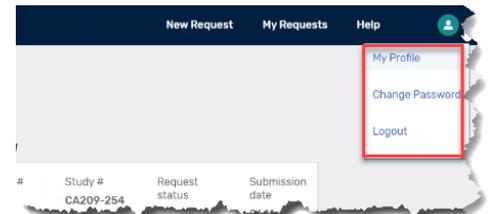
A: After clicking the study tile, select the **SUSAR** option from the left menu. To see recent Adverse Events reported relative to the study, click **Load Next 3 Documents**.



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.



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.

1 For all Pre-Approval Access to BMS and Heritage Celgene investigational medicines, please create a Compassionate Use request below.

New request

Welcome to the FastTrack Concept Submission Page. We are moving to a Request For Proposal (RFP) Submission process for accepting new concepts and will post our areas of interest (AOI) to BMS.com when available. Please click on the "Choose an AOI" button to check for currently posted AOIs. Exemptions to the RFP process are also listed on the page. If you are submitting a concept that qualifies as an exemption, please click on the appropriate "Create" button to submit it. Please note that the portal will only allow you to submit concepts that are exemptions to the RFP Submission process. Please contact your local BMS Medical representative or visit www.globalbmsmedinfo.com if you have questions.

| | |
|--|---|
| <p>Clinical</p> <p>Please select Clinical Research if you are submitting study concept where patients are being consented for the use of existing data or prospective enrollment.</p> <p><i>For RFP exemptions only</i></p> <p>Create</p> | <p>Non-Clinical</p> <p>Please select Non-Clinical Research if you are submitting a research concept involving basic science, retrospectively collected data or biological samples where patient consent is not required.</p> <p>Create</p> |
| <p>Compassionate Use (PAA)</p> <p>Please select Compassionate Use (PAA) for all New requests or if you are requesting a re-supply for Pre-Approval Access (PAA) for a Celgene Drug.</p> <p>Create</p> | <p>CAR T</p> <p>Please select CAR T for all new requests for Pre-Existing Product Access (PEPA) for CAR T.</p> <p>Create</p> |

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

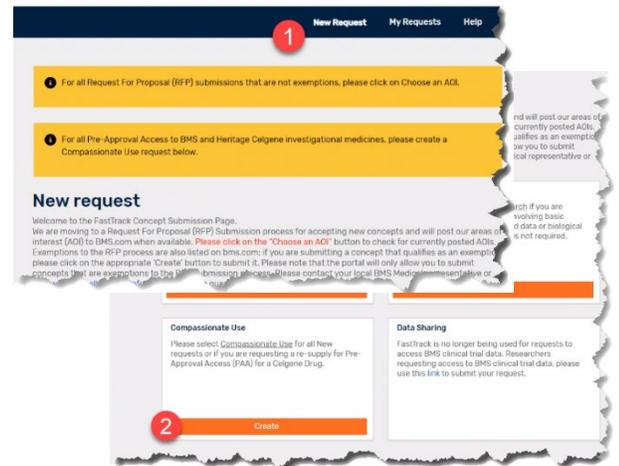
A: A **licensed physician** who is solely responsible for the **oversight and use of the Investigational Medicinal Product (IMP)** for the treatment of the patient must submit the request. The physician must have appropriate expertise and facilities for the administration of the **IMP, monitoring, managing, 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. Once approved, there is a plan by BMS to make the medicine available commercially in the country from which the request was received. Enough of the investigational medicine is available. Additional criteria regarding the therapy may impact eligibility like its development program, the patient, or other circumstances.

Q: How do I create a Pre-Approval 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 PAA request for different patients or if a **resupply for a PAA is already approved** by BMS in a different system. After scrolling down, select the **Create button** in the box **“Compassionate Use”**. Complete the proposal form and **submit**. The **fields with an asterisk*** are required.



Q: What is the Study Location?

A: The **Study location** included in this section is the **center**, 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 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).

My requests

Welcome to the BMS FastTrack Requests Landing Page. On this page you can determine the status of your concepts. You can also access active protocols using the project panels below.

Please Note: While the concepts you have submitted are in the Under Review status, they cannot be modified. Any post-review clarifications can be made once the concept status has been changed to Returned to Investigator. Active Protocols can only be modified by requesting an amendment.

| All | Under review | Draft |
|-------------------|--|--|
| Clinical | CU: Abatacept Additional compounds: Submitted on: 20 Apr 2021 Request #: REQ-0000... BMS protocol #: | Interventional Study to... Type: Interventio... Primary Indication: ALL Submitted on: Request #: REQ-0000... BMS protocol #: |
| Compassionate Use | | |
| Jane Doe | | |
| Missionsärztliche | | |
| Klinik | Approved CU: Nivolumab Additional compounds: Submitted on: 26 Mar 2021 Request #: REQ-0000... BMS protocol #: CA209-254 | |
| Any Pharmacy | | |

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**.

Bristol Myers Squibb™

IMPORTANT INFORMATION - Request Successfully Submitted

Dear Jane Sample,

Your concept REQ-0000026672 has been successfully submitted for consideration by BMS.

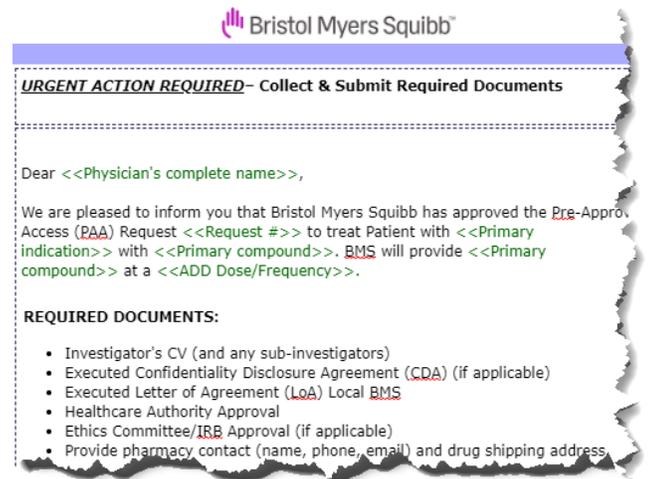
We look forward to reviewing your submission and we will strive to provide a decision to you within four weeks, unless the concept has been submitted as part of a Competitive Research program or assistance program.

Q: What will occur if my PAA 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 drug supplies. **Each country will have different requirements** regarding what documents are required for collection. Below are some examples of documents which may be required for your country:

- Investigator CV
- Letter of Agreement
- Confidentiality Agreement
- Health Authority Approval
- FDA 3926
- Ethical Board Approval

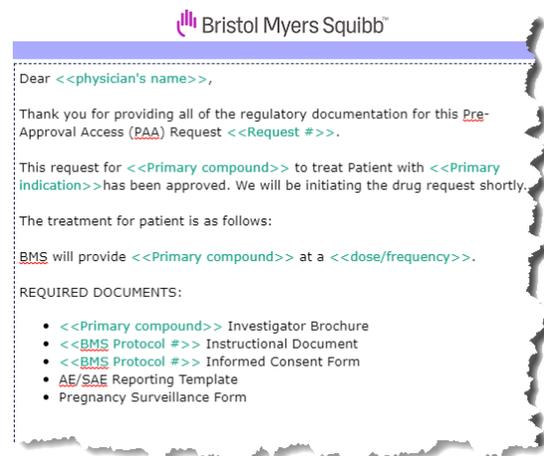
With each new request, you will receive a copy of the **safety reporting guidelines** as part of your pre-approval request. Please ensure you have read and understood the safety reporting by signing the **Letter of Agreement**. This indicates you will comply with the reporting requirements.



Q: What happens after the documents receive final approval?

A: Once all the documents are completed, final approval will be sent by BMS with the **Patient Instruction Documentation** and **Drug Shipment**. In the email, documents that may be included are Patient Instructional Document, Patient Informed Consent Form, Investigator Brochures, Serious Adverse Event Reporting Form, and Pregnancy Reporting Form. This will be dependent on the drug requested.

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 finalized and received. After all required documents are sent to BMS, the drug shipment takes **7-10 business days** to arrive. The status can be checked via the **drug shipment tab** in Fastrack.

When completing the initial 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 recipient should be the pharmacist's contact information.

Please note that the **clinical stock** will be provided for all requests approved via **Pre-Approval Access** and may differ from commercial stock and other compassionate access stock.

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**. In addition, this information may be contained within the **patient document** for BMS products. Please follow the instructions included in the IB to store and prepare the study drug. If you require this to be re-sent, please reach out to your BMS contact.

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. First, select **Drug Shipments** to the left of the screen; then select **New Drug Shipment**. The required drug will be preselected based on the initial drug shipment completed. Only enter the **Order quantity** needed. The drug shipment request has been entered but it is not yet complete. Select **Choose shipping address** and a pop-up will appear. Select the address for drug shipment. Then select **Add**. You will be returned to the Drug Shipments screen, click the big orange 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 only provides a **2-3 months' supply** within one shipment. Please refer to the Appendix for resupply quantities per drug

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

A: Please complete the **AE/SAE form** provided to you as part of your final approval email and send it to worldwide.safety@bms.com. In addition, we provide an **AE/SAE training presentation** for you and your colleagues to review.

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

A: When you receive the **final approval email** from BMS, you may have a **Letter of Agreement (LoA)** with information on how long BMS will provide treatment. This may include how long patients can receive treatment with a particular drug that is being supplied. Reasons for stopping treatment include (but are not limited to): **disease progression, adverse events, withdrawal of consent, and physician opinion.**

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

A: If your patient no longer requires treatment or has completed the protocol treatment duration, please inform BMS. All drugs which have been shipped to your designated pharmacy **MUST be destroyed** as per local policy. You cannot use them for any other patients. **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 and provide BMS a copy.

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.

Institution

Name *

Address line 1 * Address line 2

City * State / Province

Zip / Postal code * Country *

General mailing address
This address will not be used to deliver drugs or materials.

General mailing address is the same as Institution address

Name *

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 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 on the **HCP**. The **PAA requests** are reviewed and approved with comments on the dosing to the **PTM**. 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 stock provided as part of the Pre-Approval Access (PAA) request. The IB has the relevant information regarding the stock supplied, including **both preparation and storage details**. Do not reference the Package Insert (PI) as commercial stock is not being supplied. 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** which the PTM uploads into the request and pushes to eTMF.

Q: What is meant by the question ‘Patient Has Participated in 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: Enter **Patient information** to assess suitability for the drug. Enter **patient lab assessments** on the page – all labs to be provided. Add **Treating Physician information** as the Primary Investigator. The **general mailing address** is for the Physician, not the drug shipment. **Pharmacy contact details**- please include details for the pharmacist in charge and a specific 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 **two cycles** or **two months’** worth of supply. Consult the table below for **maximums** when HCPs and pharmacists place a **re-supply order**. See table below:

| Brand | Compound Name | Product Strength/Dose Form | Order Unit (Max Qty Allowed) |
|---------|------------------|--|--|
| Orencia | Abatacept | <ul style="list-style-type: none"> 250 mg vials for IV infusion (not avail in kits in Italy) 125 mg pre-filled syringes for SC administration | <ul style="list-style-type: none"> 3 vials (IV) 1 box (4 syringes) |
| Eliquis | Apixaban | <ul style="list-style-type: none"> 0.5mg tablet kits <p>Doses available based on pt. weight:</p> <ul style="list-style-type: none"> 0.5mg 1mg 1.5mg 2mg 3mg 4mg | <ul style="list-style-type: none"> Order unit = 1 kit Max qty to order: 12 (3 months of drug) 14 bottles per kit - 1 kit is 1 week dosing |

| | | | |
|-----------|-----------------------------------|---|--|
| Onureg | Azacitidine tablets | <ul style="list-style-type: none"> 200 and 300 mg | <ul style="list-style-type: none"> 3 bottles of 300 mg for 3 cycles 1 bottle of 200 mg for dose modifications Note: Bottles of 14 tablets |
| Nulojix | Belatacept | <ul style="list-style-type: none"> 250mg vials | <ul style="list-style-type: none"> 8 vials per box QTY: 1-2 boxes |
| | BET Inhibitor | <ul style="list-style-type: none"> 0.25 mg tablets (30 tablets per bottle) 2mg tablets (30 tablets per bottle) | <ul style="list-style-type: none"> 8 bottles of 2mg 12 bottles of 0.25mg Note: pediatric dosages must be confirmed with medical/clinical team |
| Sprycel | Dasatinib | <p>US label:</p> <ul style="list-style-type: none"> 20-50-70 mg 60 tablets per bottle 80-100-140 mg 30 tablets per bottle <p>Turkey label:</p> <ul style="list-style-type: none"> 20-50-70 mg 30 tablets per bottle Pediatric PAA - 10mg/mL bottle, Powder for Oral Suspension; Oral Syringe/PIBA kit | <p>US label:</p> <ul style="list-style-type: none"> 20-50-70 mg 60 tablets per bottle <p>Turkey label:</p> <ul style="list-style-type: none"> 2 bottles of 50 mg tablets per month <p>Pediatric PAA:</p> <ul style="list-style-type: none"> 4 bottles max 10 syringe/PIBA kits max |
| Empliciti | Elotuzumab | <ul style="list-style-type: none"> 300-400 mg vials | <ul style="list-style-type: none"> 10 vials per box Both strengths for 3 cycles |
| Idhifa | Enasidenib (resupply only) | <ul style="list-style-type: none"> 50-100 mg 30 tablets per bottle | <ul style="list-style-type: none"> 3 bottles of 100 mg 1 bottle of 50 mg for dose modifications for IDHIFA related toxicities. |
| Inrebic | Fedratinib | <ul style="list-style-type: none"> 100 mg caps 120 caps per bottle | 3 bottles |
| Yervoy | Ipilimumab | <ul style="list-style-type: none"> 200mg/vial 5mg/mL | <ul style="list-style-type: none"> 4 vials per box QTY: 1-2 boxes(1 box for Turkey) |

| | | | |
|---------------------------------|-----------------------|--|--|
| Revlimid | Lenalidomide | Turkey label: <ul style="list-style-type: none"> • 5-10-15-25 mg capsules • 21 capsules per box | 3 boxes of 25 mg Or 3 boxes of 10 mg |
| Reblozyl | Luspatercept | <ul style="list-style-type: none"> • 25–75 mg vials • 1 vial per box | 6 of each strength |
| Opdivo | Nivolumab | <ul style="list-style-type: none"> • 100mg/vial (10mg/ml) | <ul style="list-style-type: none"> • 5 vials per box • QTY: 2 boxes |
| Pomalyst (Imnovid in Turkey) | Pomalidomide | <ul style="list-style-type: none"> • 1-2-3-4 mg caps • 21 caps per box | 3 boxes of 4 mg |
| | Rela+ Nivo FDC | Fixed Dose Combo(FDC): Rela 80mg/Nivo 240mg vials | <ul style="list-style-type: none"> • 2vials per kit • QTY: 1 kit for 4 weeks |
| | Relatlimab | 80mg | <ul style="list-style-type: none"> • 4 vials • QTY:1-2 boxes |
| Istodax | Romidepsin | 270mg or 10mg | <ul style="list-style-type: none"> • 9 vials per box • QTY: 3boxes |

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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?

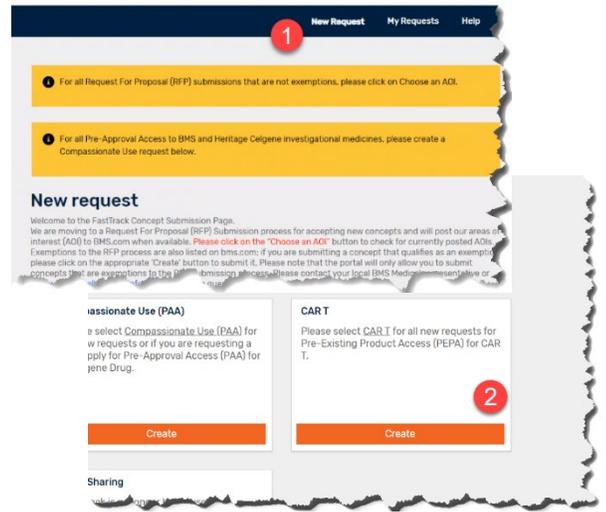
A: A **licensed physician** who is solely responsible for the **oversight and use of the CAR T** for the treatment of the patient must submit the Request. The physician must have prior experience handling CAR T and the treatment site must be REMS certified for the relevant **BMS CAR T product** to ensure **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.

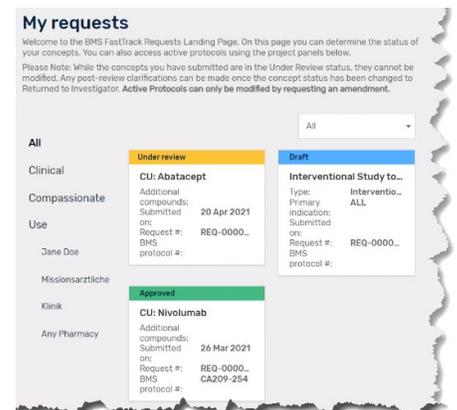
Q: How do I create a Pre-Existing Product Access Request

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.



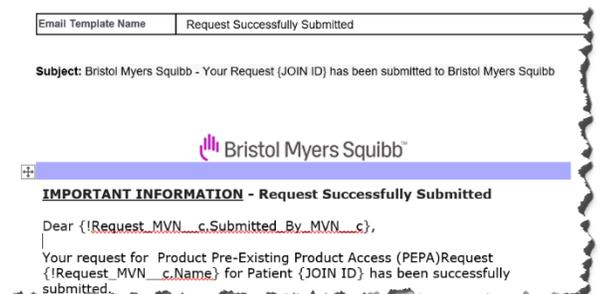
Q: Where do I find my submitted PEPA request?

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).



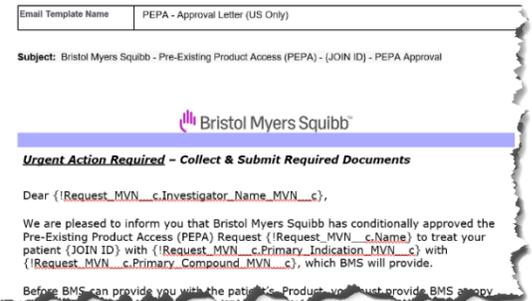
Q: What happens after I submit my Request?

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**.



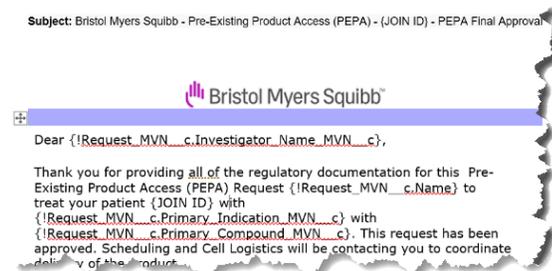
Q: What will occur if my PEPA request is approved?

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.



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.



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**.

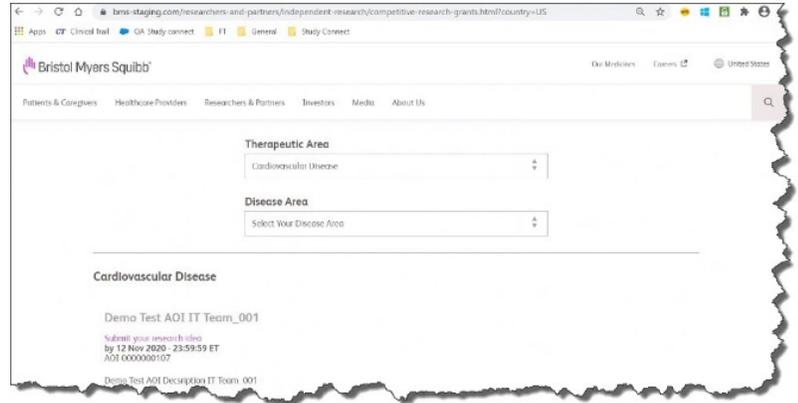
Q: Do I need to enter patient initials and if yes, where do I enter this information?

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

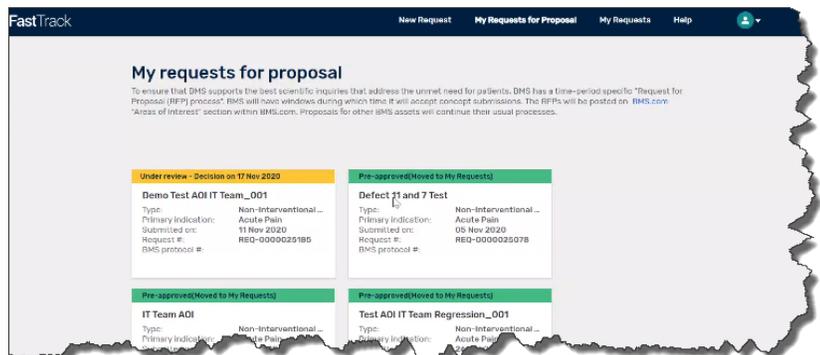
Q: What is RFP?

A: Bristol Myers Squibb (BMS) will be moving from a rolling submission process to 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](https://www.bms.com) & periodically updated.



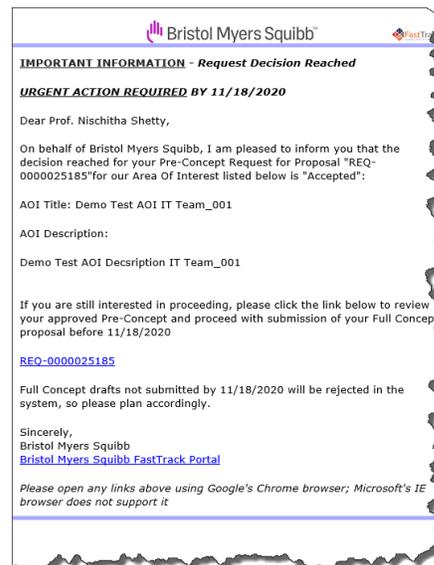
Q: How do I Submit for an RFP?

A: From [BMS.com](https://www.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.



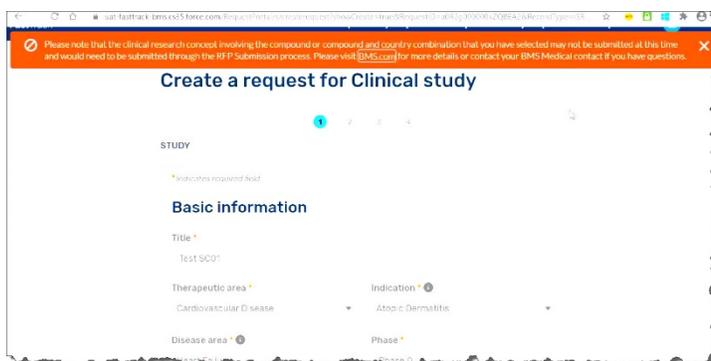
Q: What can I Expect When I Submit an RFP

A: Based on the RFP Cycle and its timings, you will be able to see an AOI on [BMS.com](https://www.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 pre-concepts will be communicated to submitters within 3-4 weeks 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 3-4 month 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?

A: Exemptions to the RFP process for those types of concepts that may be submitted any time are posted to [BMS.com](https://www.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 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.

The screenshot shows a form with the following fields:

- Indication ***: Acute Pain
- Does the study involve humans and drugs? ***: No
- Will the study involve bio-specimens connected to patient? ***: --None--
- Type ***: --None--
- Subtype ***: --None--
- Primary compound ***: Anthero Sclerosis
- Additional compounds**: (empty field)

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.

The screenshot shows the 'My requests' page with the following details:

- Header:** New Request, My Requests
- Section:** My requests
- Welcome message:** Welcome to the BMS FastTrack Requests Landing Page. On this page you can determine the status of your concepts. You can also access active protocols using the project panels below.
- Note:** Please note: While the concepts you have submitted are in the Under Review status, they cannot be modified. Any post-review clarifications can be made once the concept status has been changed to Returned to Investigator. Active Protocols can only be modified by requesting an amendment.
- Filter:** All
- Categories:** Clinical, Non-Clinical, Compassionate Use
- Under review panels:**
 - Panel 1:** Testing of... (Details: Type, Reviewer, Request #, BMS product ID)
 - Panel 2:** C... (Details: Additional compounds, Requester, Request #, BMS product ID)

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.

If you would like to contact the BMS Help Desk via email, please include your question, issue, and contact information and send it to hd-sci-apps@bms.com. If you would like to contact the BMS Help Desk via phone, use the phone numbers listed below and selecting options **1, 1, 1, 3, *, 8**.

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 |
|  | USA | 1 844 439 5499 |

Additional Phone Numbers

| Country | | Number |
|---|--------------------------------|---------------|
|  | Algeria / Algérie / الجزائر | 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 |

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| | | |
|---|-------------------------------------|--|
|  | 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 |

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| | | |
|---|--------------------------------|------------------|
|  | India | 000 800 440 5114 |
|  | Ireland | 1800 800 012 |
|  | Israel / ישראל | 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 |

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| | | |
|---|---|---------------------|
|  | 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 |
|  | United Kingdom | 0800 032 8019 |
|  | USA | 1 844 439 5499 |
|  | Venezuela | 0800 100 3349 |

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