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

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 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.

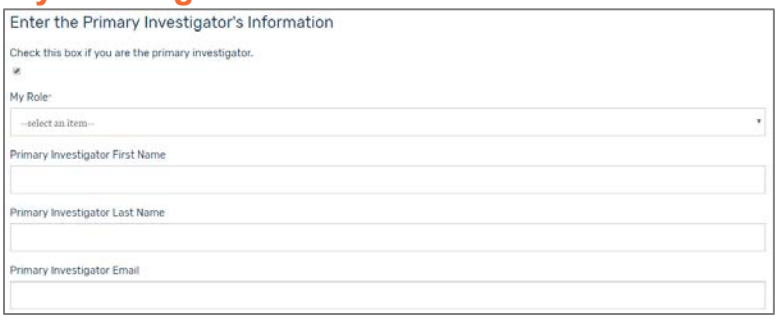
Submitting New Investigator Sponsored Research - Clinical Study Proposal Form

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



My Role*

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

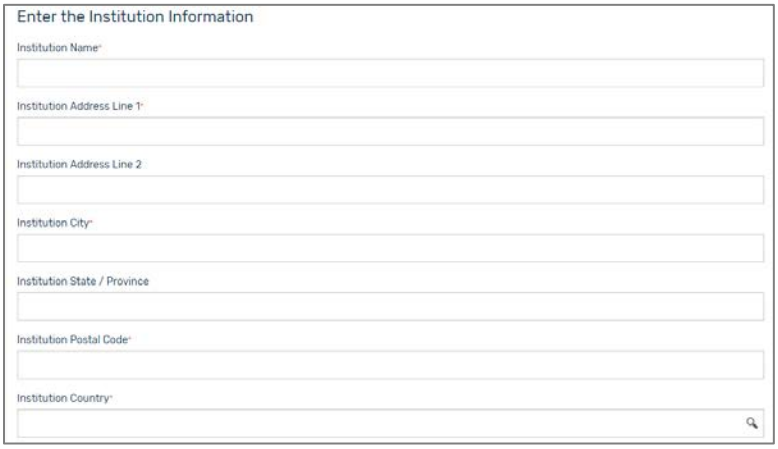
- Co-Investigator
- Regulatory Document Coordinator
- Site Legal Contact
- Study Site coordinator
- Sub-Investigator
- Other

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.

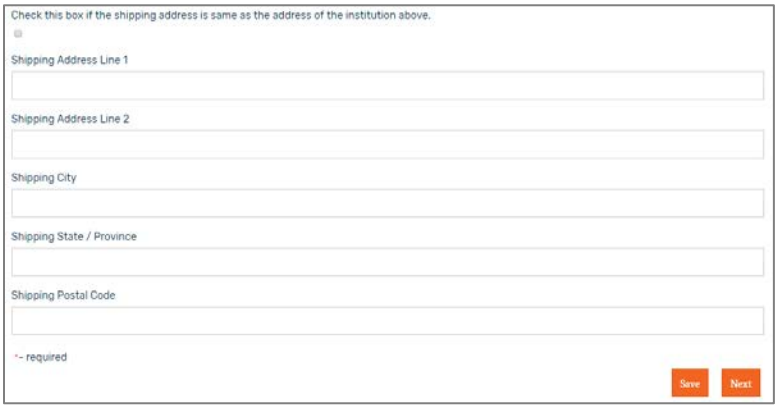
Institution Address Line 2
This is NOT a mandatory field.

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, "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.

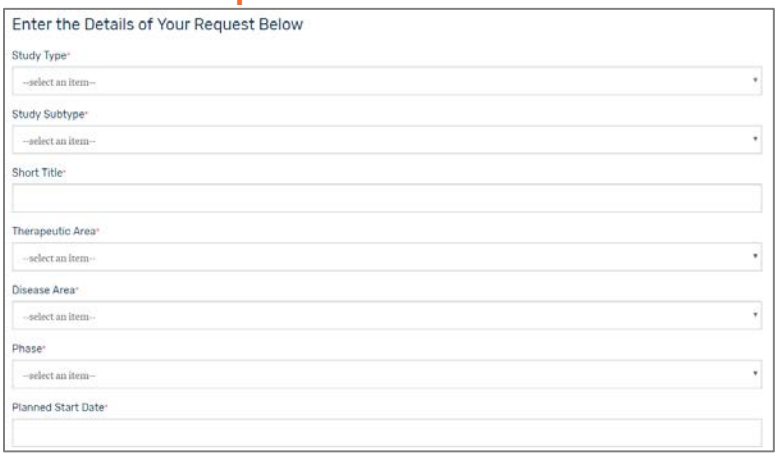
- **Shipping State/Province***
  This is a mandatory field for the **US/Canada.**

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

Click **Next** to continue

2. Request Details

Enter the Details of Your Request Below



Study Type*

This is a mandatory field. Choose one of the following values:

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

Study Subtype*

This is a mandatory field. The study subtype values change depending on the study type. Choose one of the following study types:

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

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*

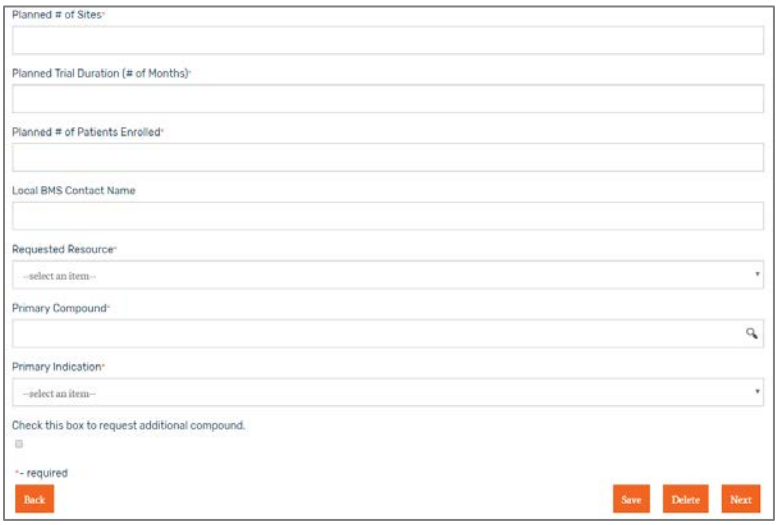
This is a mandatory field with a drop-own list. Choose an option from the extensive list of values.

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.

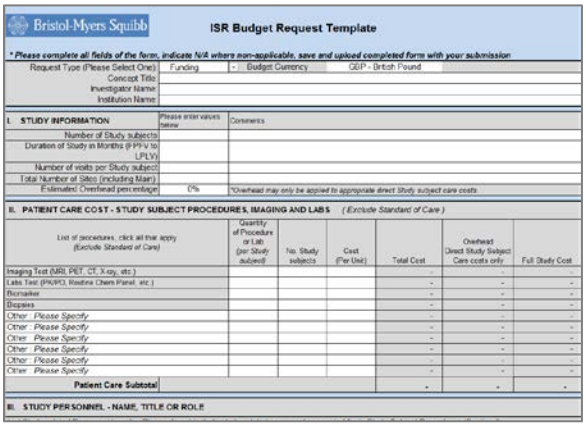
Local BMS Contact Name

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



Bristol-Myers Squibb

ISR Budget Request Template

** Please complete all fields of the form, indicate N/A where non-applicable, save and upload completed form with your submission*

Request Type (Please Select One)	Funding	Budget Currency	GBP - British Pound
Concept Title			
Investigator Name			
Institution Name			

I. STUDY INFORMATION	Please enter values below	Comments
Number of Study subjects		
Duration of Study in Months (FPI-V to LPLV)		
Number of visits per Study subject		
Total Number of Sites (including Main)		
Estimated Overhead percentage	0%	*Overhead may only be applied to appropriate direct Study subject care costs*

II. PATIENT CARE COST - STUDY SUBJECT PROCEDURES, IMAGING AND LABS *(Exclude Standard of Care)*

List of procedures, click all that apply (Exclude Standard of Care)	Quantity of Procedure or Lab (per Study subject)	No. Study subjects	Cost (Per Unit)	Total Cost	Overhead Direct Study Subject Care costs only	Full Study Cost
Imaging Test (MRI, PET, CT, X-ray, etc.)				-	-	-
Labs Test (PK/PD, Routine Chem Panel, etc.)				-	-	-
Biomarker				-	-	-
Biopsies				-	-	-
Other : Please Specify				-	-	-
Other : Please Specify				-	-	-
Other : Please Specify				-	-	-
Other : Please Specify				-	-	-
Other : Please Specify				-	-	-
Other : Please Specify				-	-	-
Patient Care Subtotal				-	-	-

III. STUDY PERSONNEL - NAME, TITLE OR ROLE

**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.*

- **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.

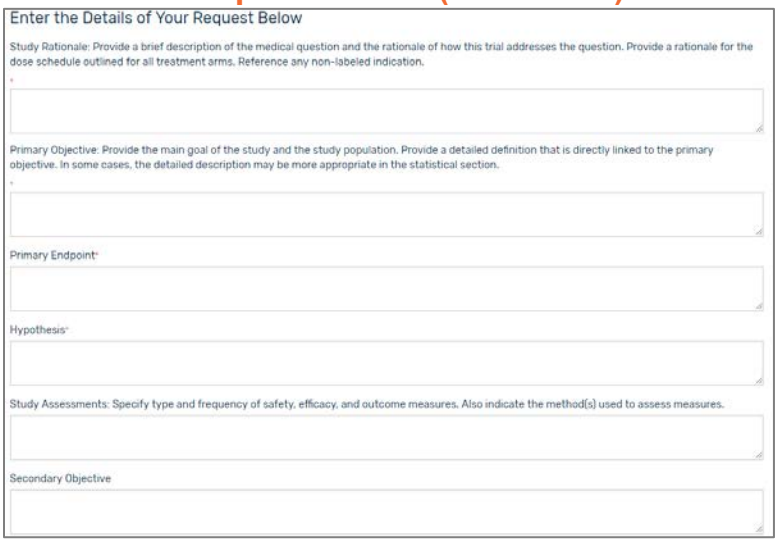
- **Compound Name***
  This is a mandatory field with a searchable list.

- **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*

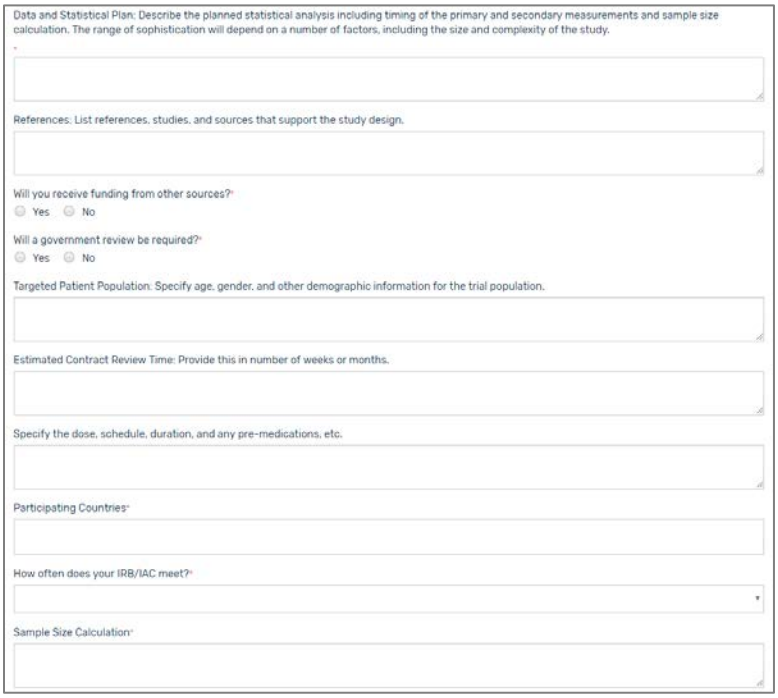
This is a free-form mandatory field.

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 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.

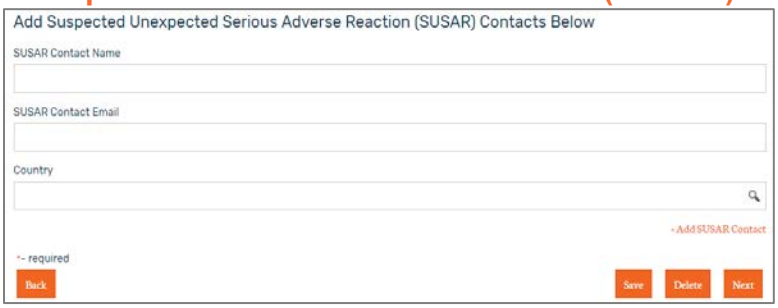
Strategic Partnership Research Program

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.

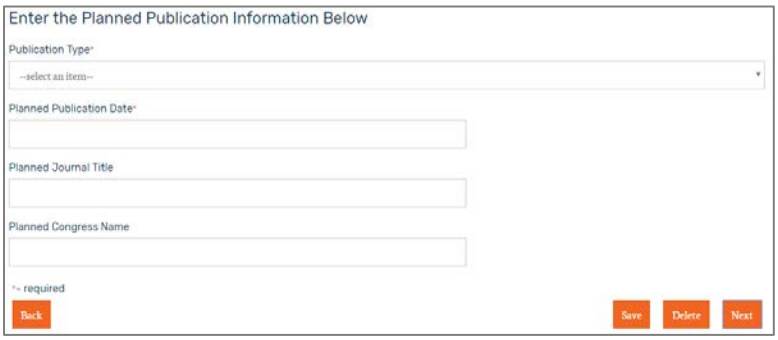
SUSAR Contact Email*
This is a mandatory field and must be entered in a valid email format.

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

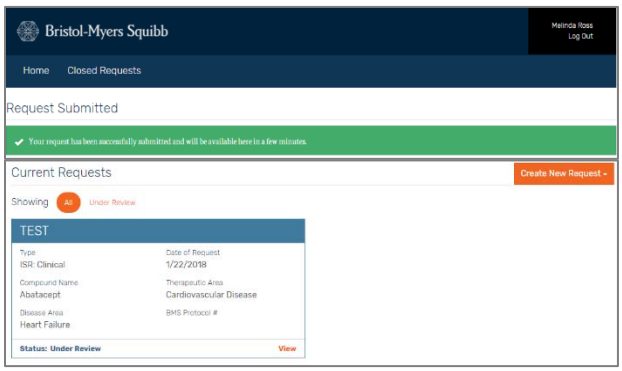
Curriculum Vitae*
This is mandatory, requiring you to upload a file. The following fields are not mandatory; however, you are free to upload any additional documents:

- 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

International Phone Number Guide

Whether you are in the office, field working, or travelling, you can contact the BMS Service Desk in different ways.

Procedure

If you are Office based you can dial ***BMS** (1) from any office phone.

*Please note: The ****BMS*** *(*267) in-office shortcut is currently unavailable in Caracas (CRC).*
For Bothell (BOT) and Seattle (SLE) sites, please dial 1BMS (1267)
*For Santiago (SCL) please dial *BMS* (*267*)*

Self-Service, chat and Service Desk phone numbers are available on 411.bms.com under contact a Service Desk or on each application page.

After selecting the language, select option one (1) and then option four (4) for FastTrack.

SERVICE DESK CONTACT NUMBERS			
Country		Number	Speed Dial
	Algeria / Algérie / الجزائر	983 200 513	N/A
	Argentina	800 266 1569	*BMS
	Australia	1 800 099 940	*BMS
	Austria / Österreich	08000 706 102	*BMS
	Bahrain / البحرين	800 816 83	N/A
	Belgium / Belgique / België	0800 816 71	*BMS
	Brazil / Brasil	08000 474 056	*BMS
	Bulgaria / Republika Bălgarija	00800 120 4444	N/A
	Canada	844 439 5499	*BMS

	Chile	800 395 251	*BMS*
	China / 中国	400 881 1485	*BMS
	Colombia	01 8000 125 394	*BMS
	Czech Republic / Česká Republika	800 050 176	*BMS
	Denmark / Danmark	802 52 505	*BMS
	Ecuador	1 800 000 472	N/A
	Egypt / رصم	0800 000 9138	N/A
	Estonia / Eesti Vabariik	8000 044 822 (Landlines Only)	N/A
	Finland / Suomi	0800 417 461	*BMS
	FOT / DOM/TOM	00 33 1 58 83 83 68	*BMS (Guadeloupe only)
	France	0805 540 097	*BMS
	Germany / Deutschland	0800 101 5430	*BMS
	Greece / Ελλάδα	00800 4414 3410 (Landline only) 210 607 4359	*BMS
	Hong Kong / 香港	301 34 736	*BMS
	Hungary / Magyarország	06 809 81 583	*BMS

	India	000 800 440 5114	*BMS
	Ireland	1800 800 012	*BMS
	Israel / יִשְׂרָאֵל	1809 344 260	*BMS
	Italy / Italia	800 925 001	*BMS
	Japan / 日本	012 091 4105	*BMS
	Korea / 대한민국	0809 080 957	*BMS
	Kuwait / تيوكلا قلود	222 804 17	N/A
	Luxembourg / Lëtzebuerg	800 850 89	N/A
	Mexico / México	01 800 436 0226	*BMS
	The Netherlands / Nederland	0800 220 0032	*BMS
	Norway / Norge	800 58 222	*BMS
	Oman / عُمان فنطلس	800 77 238	N/A
	Peru / Perú	0800 777 39	*BMS
	Poland / Polska	800 707 447	*BMS
	Portugal	800 784 734	*BMS
	Puerto Rico	844 439 5499	*BMS

	Qatar / رطق	8000 193	N/A
	Romania /România	0800 400 740	*BMS
	Russian Federation / Российская Федерация	8800 555 6489	*BMS
	Saudi Arabia / المملكة العربية السعودية	800 844 5328	*BMS
	Singapore / Singapura	1800 723 1415	*BMS
	South Africa	0800 000 602	*BMS
	Spain / España	900 810 939	*BMS
	Sweden / Sverige	020 109 194	*BMS
	Switzerland / Schweiz	0800 200 356	*BMS
	Taiwan / 中華民國	0800 666 508	*BMS
	Thailand /ประเทศไทย	00 1800 294 211	*BMS
	Tunisia / Tunisie / سنوت	00 33 1 58 83 83 68	N/A
	Turkey / Türkiye	0216 282 1586	*BMS
	UAE / دولة الإمارات العربية المتحدة	8000 444 1057	*BMS
	United Kingdom	0800 032 8019	*BMS
	USA	1 844 439 5499	*BMS

	Venezuela	0800 100 3349	*BMS (N/A for AVM)