

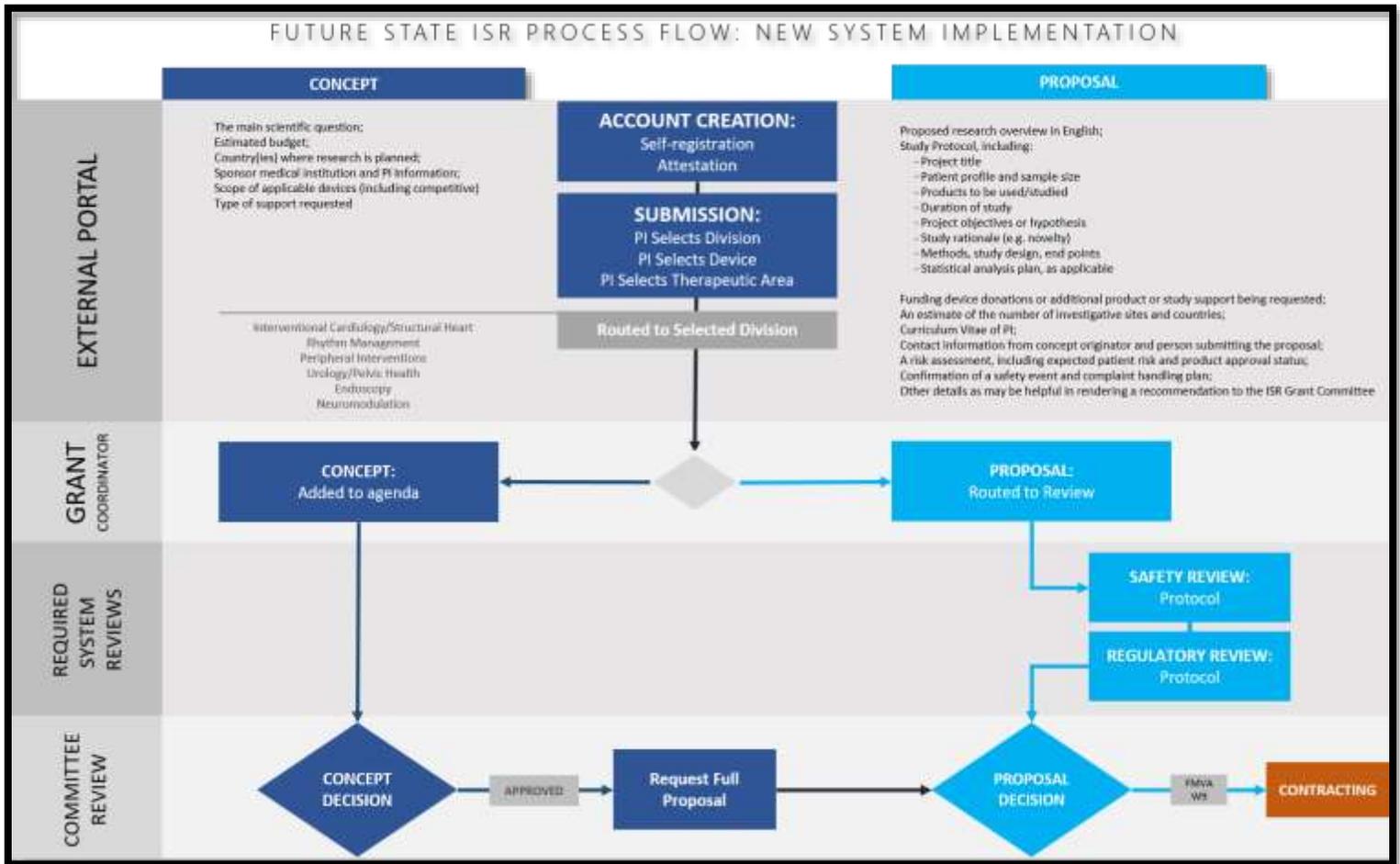
INVESTIGATOR SPONSORED RESEARCH (ISR)

Step-by-Step System Process and System User Guide

Table of Contents

1. Submission process summary and flow.....	3
2. Home Page.....	5
3. Registration.....	6
4. Sign on and Password Reset	9
5. Home Page Navigation	11
6. Submit New Study Request	12
6a. Concept submission	13
6b. Proposal submission (approved concept).....	19
6c. New Proposal.....	21
7. Approved Proposal	29
8. Milestones.....	31
10. Help.....	33

1. Submission process summary and flow



Submission Process Summary:

1. Access the ISR portal <https://qa-bsc-isr-portal.corp.idea-point.com/>
2. Click “Log-In” on the right corner of the screen (see p. for further detail)
 - a. Upon successful sign on, you will arrive at your ISR home page. From the home page you are able to:
 - Edit your profile
 - Create a new submission
 - View in progress submissions

3. Select Create Submission
 - a. You have the option of submitting to the ISR committee as a concept first, or go directly to a full proposal:
 - i. Concept - a high level summary of the research for which you would like support with a rough budget; submitted to get committee feedback prior to investing your time in a full proposal. (recommended for most submissions)
 - ii. Proposal - a detailed description of the research for which you would like support including protocol and line-item budget.
 - b. Attach required files
 - c. Submit
4. The Investigator Sponsored Research Committee will review and a BSC representative will contact you following the next committee meeting with a decision and next steps.

2. Home Page

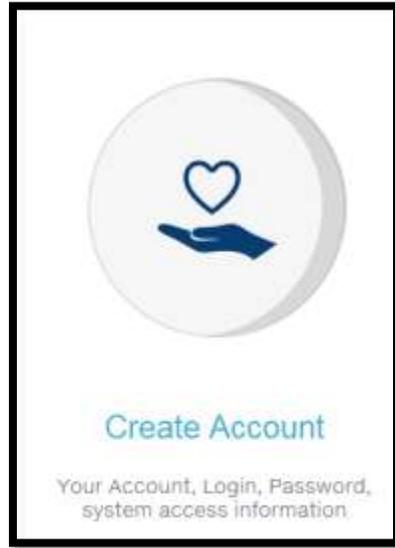
The ISR website URL address is: <https://qa-bsc-isr-portal.corp.idea-point.com/>



3. Registration

If you do not already have a user ID and password to the ISR website:

1. Click the “[Create Account](#)” link from the sign on page.



2. Fill in all the required fields.

Create New Account

Please fill out the necessary information below to create an account for this Portal.

First Name *

Last Name *

Email Address *

Country *

Password

Re-Type Password

If you are associated to an institution, type in the field below and select from the popup.

3. Enter Data Privacy Notice code shown on your screen and click on [Create Account](#).

Data Privacy Notice

BSC collects and processes personal information, including your name, business address, business contact information, and the institution with which you are affiliated (collectively, "Personal Information"). BSC will use the Personal Information to manage and track the submission, review, approval of investigator sponsored research (ISR) requests. BSC and certain authorized third parties will use appropriate safeguards to protect your Personal Information from improper or unauthorized access or disclosure, such as Access Control and Authentication Procedures, Pseudonymization / Encryption of Personal Data in Motion; Workstation Security a Network Security Measures.

You may (1) access your Personal Information collected about you, (2) have inaccuracies corrected, and (3) request the discontinuation of the use and disclosure of your Personal Information by contacting the Boston Scientific Global Privacy Office at GlobalPrivacy@bsci.com or if you are a European Resident, contacting the EU Data Protection Officer at EuropePrivacy@bsci.com.

You may refuse to provide Personal Information to BSC or withdraw your consent to use your Personal Information, although if you do so you may no longer be able to use the Boston Scientific ISR database. Finally, you have the right to lodge a complaint with the data protection authority of your country [see EU list] where you believe that your rights have been violated.

BSC collect, store and process your information on servers located in the United States. Your information will be accessible to the companies of the Boston Scientific Group, where this is necessary to manage the ISR and to third party supporting this objective.

To lawfully transfer information to the United States, BSC has adhered to the EU-U.S. and Swiss-US. Privacy Shield.

Your personal information will be kept on these servers for so long as you have an account on IdeaPoint or longer if necessary to comply with a legal obligation (eg of transparency).

By clicking 'Create Account' below, you agree:

- that BSC and its affiliates may process your Personal Information for the purposes described above;
- that your Personal Information may be disclosed to third parties by BSC, including other BSC affiliates or third parties appointed to carry out services on behalf of BSC.

By clicking 'Create Account' below, you also agree to the following (US only):

- You attest that you have not been disbarred by the FDA.

 Enter the code shown:

[Create Account](#)

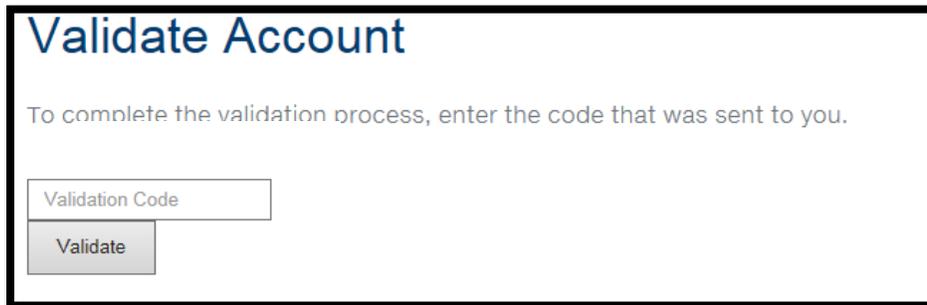
Once you have successfully created your account, the following message will appear:

Account Validation

Thank you!

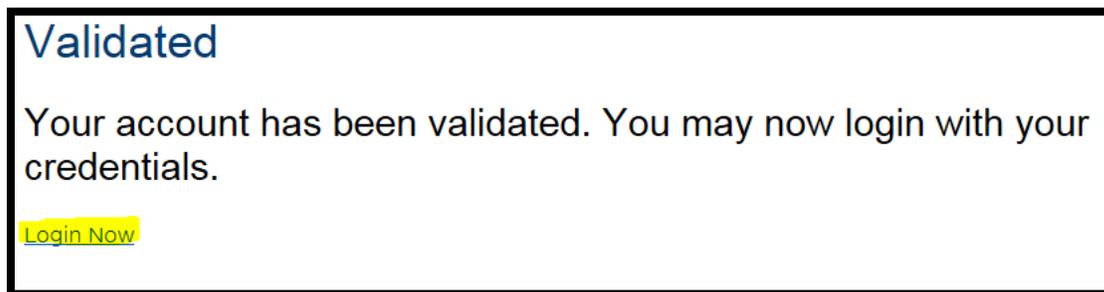
We are attempting to validate the information you entered. You will receive an email shortly with further instructions.

4. You will receive an email notification from no-reply@idea-point.com to continue the process of your account.
 - a. Click on the link and enter your validation code.



The screenshot shows a web form titled "Validate Account" in blue text. Below the title is a grey instruction: "To complete the validation process, enter the code that was sent to you." There is a text input field with the placeholder text "Validation Code" and a grey "Validate" button below it.

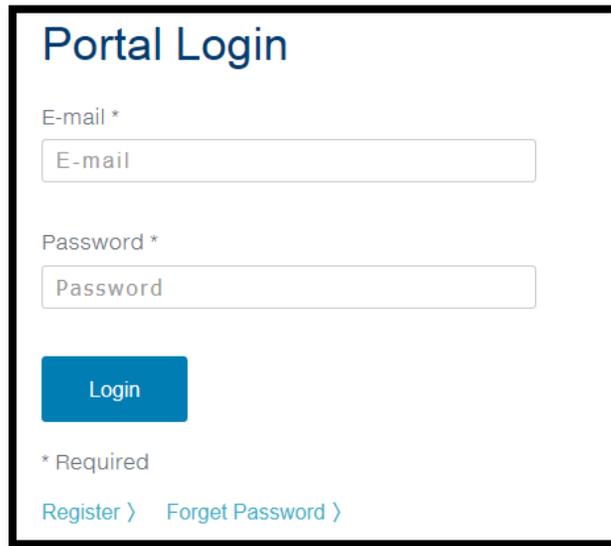
5. Once your account is validated you can Login to the system by simply clicking on **Login Now**



The screenshot shows a confirmation message with the heading "Validated" in blue. The text reads: "Your account has been validated. You may now login with your credentials." Below this text is a yellow button with the text "Login Now" in blue.

4. Sign on & Password Reset

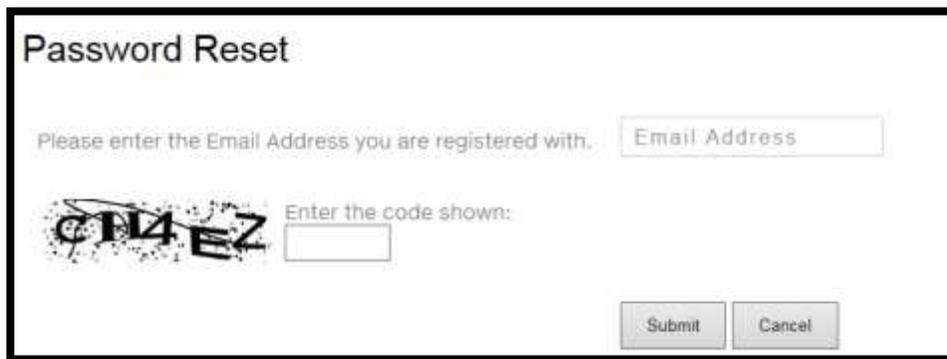
Enter your email and password into the designated area fields of the sign on page.



The screenshot shows a 'Portal Login' form. It has a title 'Portal Login' in blue. Below the title are two input fields: 'E-mail *' and 'Password *'. The 'E-mail *' field contains the placeholder text 'E-mail'. The 'Password *' field contains the placeholder text 'Password'. Below the input fields is a blue 'Login' button. At the bottom of the form, there is a note '* Required' and two links: 'Register >' and 'Forget Password >'.

Password Reset

1. To retrieve your password, click on “[Forget Password](#)”
2. Enter your Email address and the provided code shown and click [Submit](#).



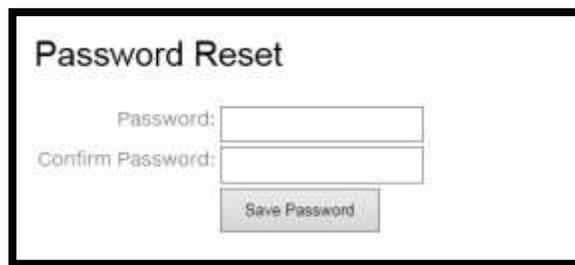
The screenshot shows a 'Password Reset' form. It has a title 'Password Reset'. Below the title is a text prompt 'Please enter the Email Address you are registered with.' followed by an 'Email Address' input field. Below that is a CAPTCHA image showing the text 'C14EZ' with a small box next to it labeled 'Enter the code shown:'. At the bottom right of the form are two buttons: 'Submit' and 'Cancel'.

- An email with your Reset code will arrive shortly, once received you need to enter the code that was sent to you and click on [Validate](#)



The screenshot shows a form titled "Password Reset". Below the title, it says "Please enter the code that was sent to you:". To the right of this text is a text input field labeled "Code". Below the input field are two buttons: "Validate" and "Cancel".

- You can now enter a new password and click on [Save Password](#).



The screenshot shows a form titled "Password Reset". Below the title, there are two text input fields. The first is labeled "Password:" and the second is labeled "Confirm Password:". Below these fields is a button labeled "Save Password".

- Once your password has been successfully saved you will be guided back to the login page.

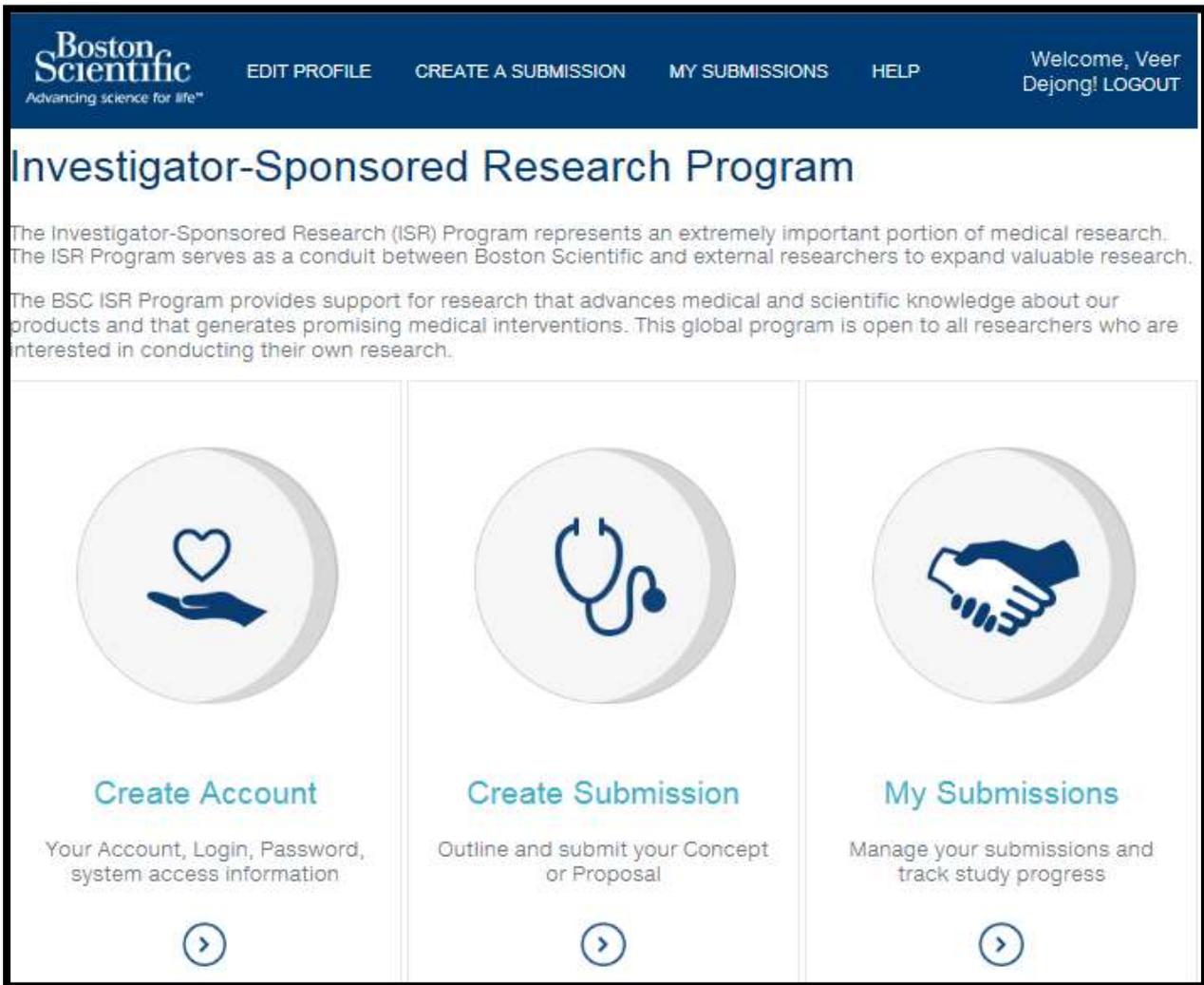


The screenshot shows a page with a green success message at the top: "Password Reset" followed by "You have successfully changed your password. You may now use your new password to login." Below this message is the "Portal Login" section. It contains two text input fields: "E-mail *" and "Password *". Below the input fields is a blue button labeled "Login". At the bottom left, there is a small asterisk and the text "* Required".

5. Home Page Navigation

Upon successful sign on, you will arrive at your ISR home page. From the home page you can:

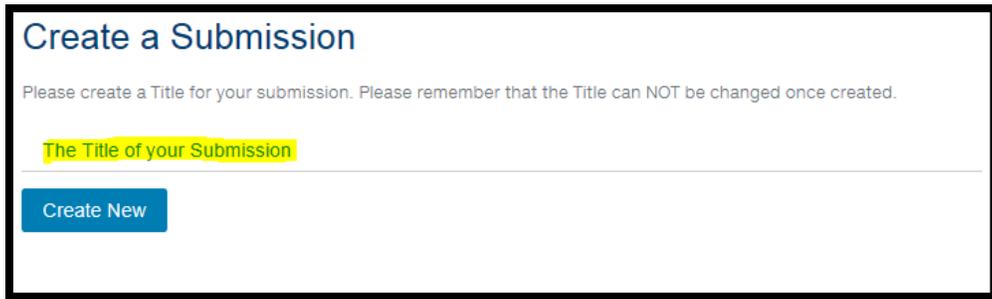
- Edit profile
- Create a submission
- View in progress submissions
- Request Help
- Log out



6. Submit New Study Request

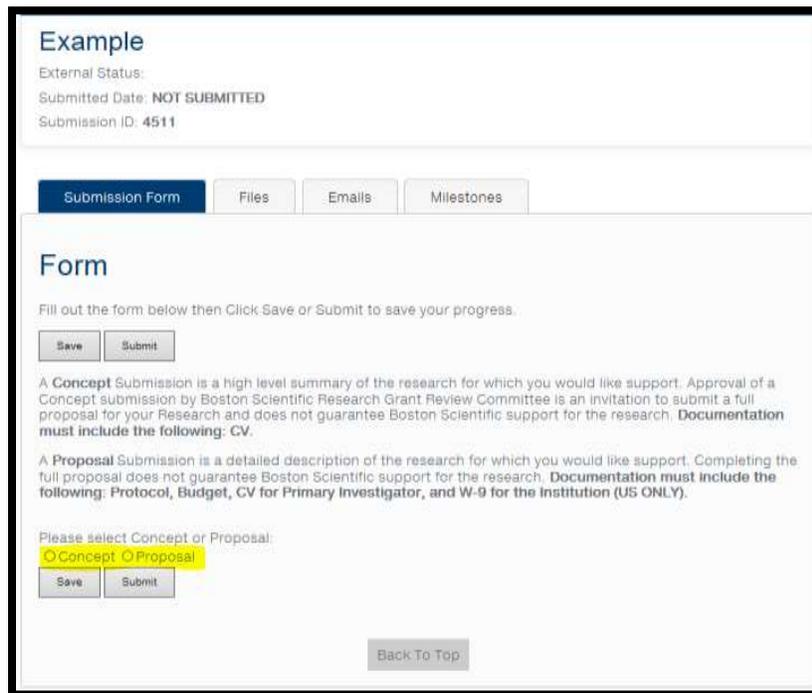
To submit a new study

1. Select “[Create Submission](#)”
2. Enter The Title of your Submission and select “[Create New](#)”



The screenshot shows a web form titled "Create a Submission". Below the title is a message: "Please create a Title for your submission. Please remember that the Title can NOT be changed once created." There is a text input field containing the text "The Title of your Submission". Below the input field is a blue button labeled "Create New".

You will be taken to a page in which you can choose to submit a concept or a proposal. It is recommended to submit a concept prior to submitting a full proposal if possible. Submitting a concept will allow Boston Scientific to review your submission at a high level. If your study fits current Boston Scientific areas of interest and is strategically aligned, the committee would request a full proposal submission.



The screenshot shows a web page titled "Example". It displays submission details: "External Status:", "Submitted Date: NOT SUBMITTED", and "Submission ID: 4511". Below this is a navigation bar with buttons for "Submission Form", "Files", "Emails", and "Milestones". The "Submission Form" button is active. The main content area is titled "Form" and contains instructions: "Fill out the form below then Click Save or Submit to save your progress." There are "Save" and "Submit" buttons. Below this is a section explaining the difference between a Concept and a Proposal submission. At the bottom, there is a section titled "Please select Concept or Proposal:" with radio buttons for "Concept" and "Proposal". The "Concept" radio button is selected. There are "Save" and "Submit" buttons below the selection. A "Back To Top" button is located at the bottom right of the form area.

6a. Concept submission

To submit a concept:

1. Select Concept
2. Indicate if you are the Primary Investigator by selecting [Yes](#) or [No](#).
3. Select Therapeutic Area (Dropdown list)
4. Select [Disease state](#)
5. Select [Products](#)
6. Fill in Concomitant [Medications/Devises](#) as applicable.

A **Concept** Submission is a high level summary of the research for which you would like support. Approval of a Concept submission by Boston Scientific Research Grant Review Committee is an invitation to submit a full proposal for your Research and does not guarantee Boston Scientific support for the research. **Documentation must include the following: CV.**

A **Proposal** Submission is a detailed description of the research for which you would like support. Completing the full proposal does not guarantee Boston Scientific support for the research. **Documentation must include the following: Protocol, Budget, CV for Primary Investigator, and W-9 for the Institution (US ONLY).**

Please select Concept or Proposal:

Concept Proposal

Concept

Are you the Primary Investigator?

Yes No

Strategic Alignment

* Therapeutic Area

Interventional Cardiology/Structural Heart ▼

* Disease State

▼

* Products

▼

Concomitant Medications/Devises

▲

▼

7. Check the box(s) for type of support you are requesting
 - To add additional products, click on the + button, another screen will appear where you can choose from a dropdown list.
 - Once the additional product is requested please add the quantity.
 - To enter more products, repeat this process.

The screenshot shows a web form titled "Support Requested". It includes a question: "What type of support are you requesting from Boston Scientific?" with three radio button options: "Financial" (checked), "Product" (checked), and "Other" (unchecked). Below this are four input fields: "Estimated Budget" (text), "Currency" (dropdown), "Product requested" (dropdown), and "Quantity" (text). At the bottom, there is a table header for "Additional Products Requested" with columns for "Product", "If Other", and "Quantity". The first row of the table contains three icons: a plus sign (+), a pencil (edit), and a trash can (delete). A blue arrow points to the plus sign, and a red circle highlights it. To the right of the table, there is a pagination control showing "Page 1 of 0" and "No records to view".

The screenshot shows a modal form titled "Add New". It contains three input fields: "Product" (dropdown), "If Other" (text), and "Quantity" (text). Below the fields is a note: "(*) required". At the bottom right, there are two buttons: "Submit" and "Cancel".

8. Fill in the Study Summary Section and provide:

- Main Scientific Question.
- Study Design
- Projected number of subjects
- Primary country. I
 - To add **other Sites and/or Countries**, click on the **+** button, another screen will appear where you can choose other countries from a dropdown list and enter the site name(s).
 - Once the country and site are selected you must select **submit**.
 - To enter more countries and sites, repeat this process.

The screenshot shows the 'Study Summary' form. It includes fields for 'Main scientific Question', 'Study Design', 'Projected Number of Subjects', and 'Primary Country'. Below these is a table for 'Other Sites/Countries' with columns for 'Countries' and 'Sites'. A blue arrow points to the table header, and a red circle highlights the '+' button in the table's toolbar. The table currently shows 'Page 1 of 0' and 'No records to view'.

The 'Add New' dialog box is shown, featuring a 'Countries' dropdown menu and a 'Sites' text input field. A note indicates that both fields are required. At the bottom, there are 'Submit' and 'Cancel' buttons, with a blue arrow pointing to the 'Submit' button.

9. Legal Statement:

- Read legal statements
- Acknowledge the statements by checking the box's

10. **Click the Save button.**

Legal Statement

* I certify that I am qualified to practice medicine or qualified to conduct this study

* I understand that completing this form expresses my interest in conducting this study, but does not guarantee support for this Investigator Sponsored Study

- If you are submitting a Concept please upload your CV in the "Files" tab above.
- If you are submitting a Proposal please upload your CV, Budget, and Draft Protocol in the "Files" tab above.

Please be sure to save your changes before leaving the page.

Save Submit

Back To Top

You will know your Concept has been successfully saved when the below message appears and your Concept receives a unique Submission ID number.

Boston Scientific
Advancing science for life™

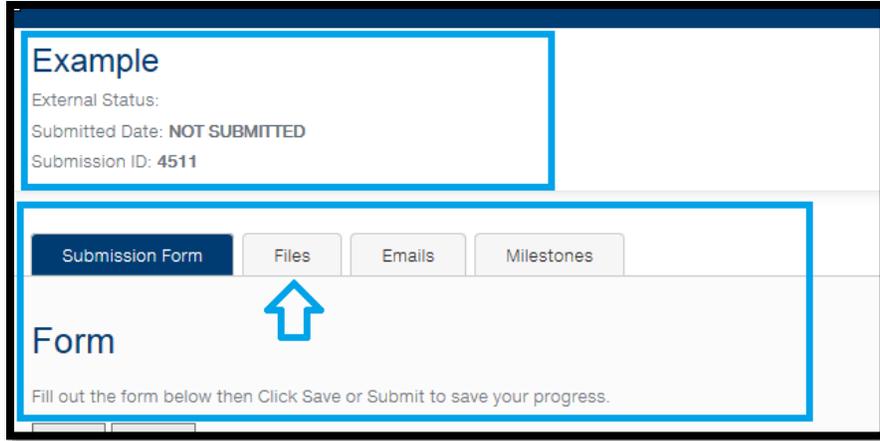
EDIT PROFILE CREATE A SUBMISSION MY SUBMISSIONS HELP

Welcome, Veer Dejong! LOGOUT

This request has been saved but not submitted. Please come back to complete at a later time.

The final step required before submission is complete is to upload your CV.

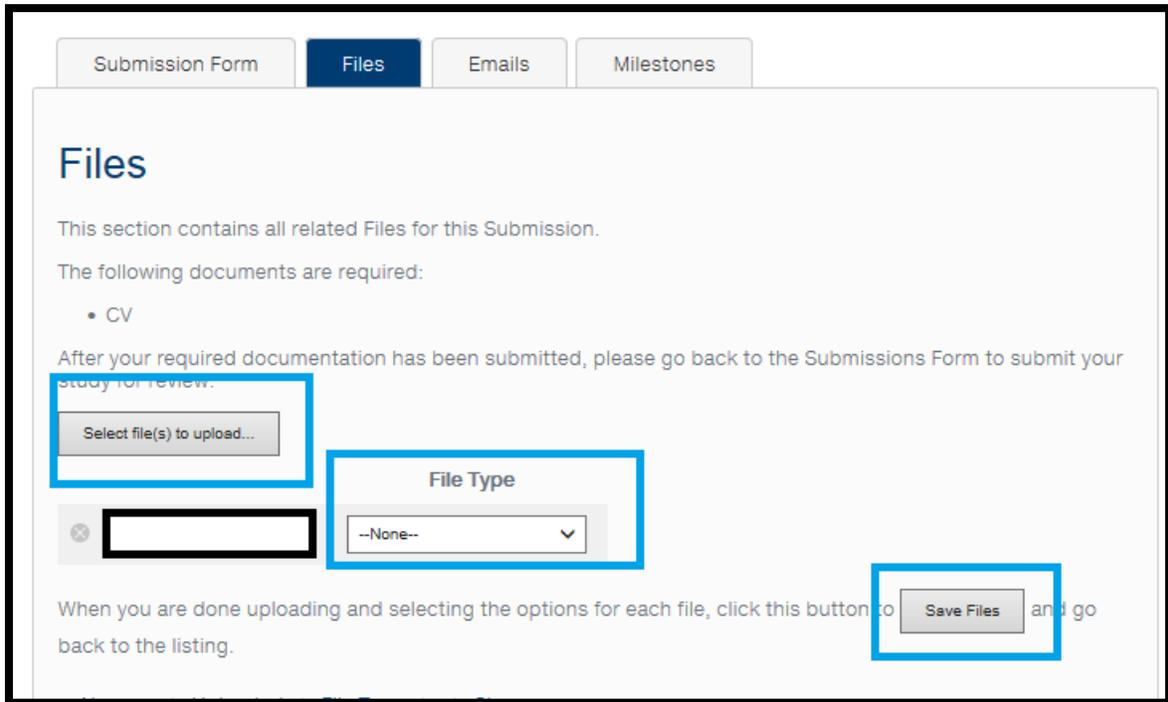
11. Select the Files Tab and click on Select file(s) to upload your CV



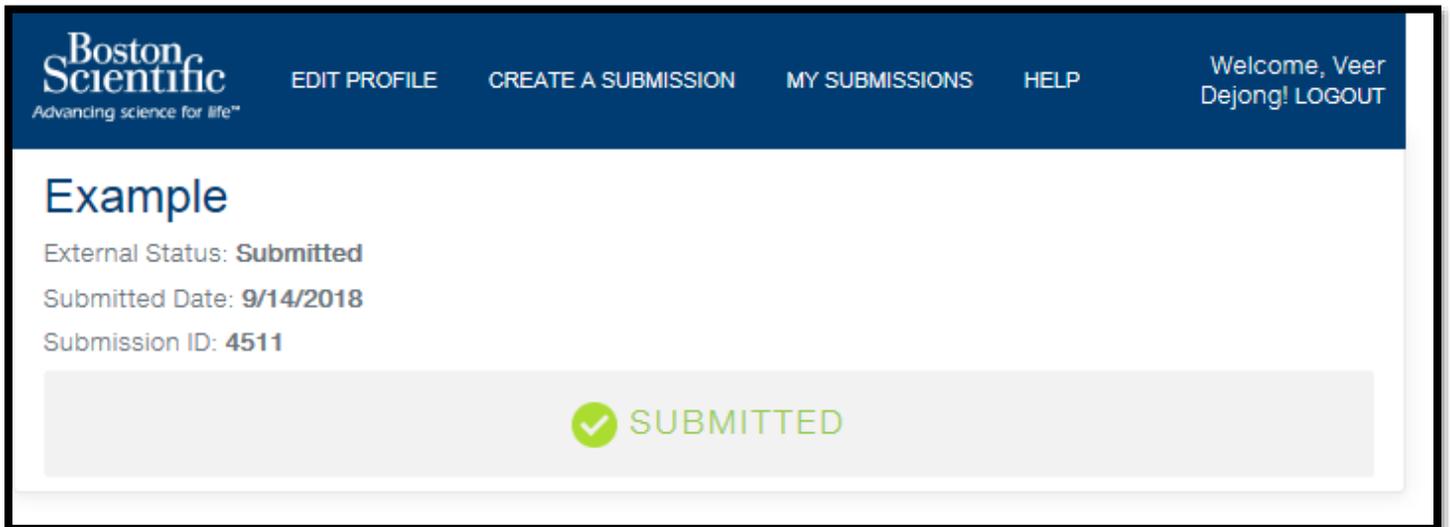
12. Click on “Select file(s) to upload – add your CV

13. Select the File Type from the dropdown list

14. Click on Save Files



15. Once your CV has been uploaded, go back to the Submission Form tab, scroll down and click on submit. You will see if your concept has been successfully submitted if you see below notification.



Note: You will be notified from a Boston Scientific representative once your study has been reviewed.

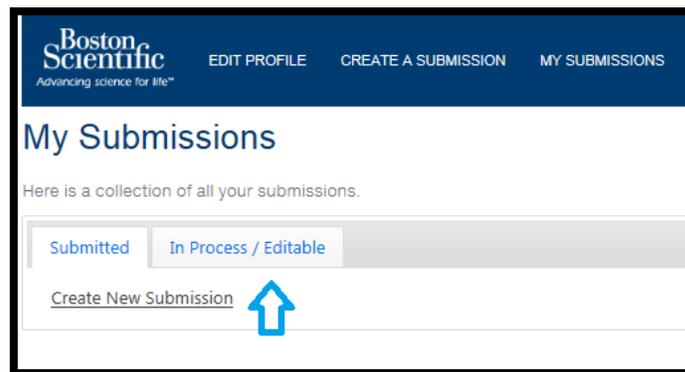
6b. Proposal submission (Approved Concept)

To access an approved concept:

1. Login to your account and go to My Submissions



2. Click on the tab "In Process / Editable"



3. Click on the study Title
 - a. The approved concept will indicate an “**Editable Until**” date. If you are unable submit your proposal before the date indicated, kindly reach out to your Grant Coordinator.

Here is a collection of all your submissions.

Submitted	In Process / Editable			
<u>Title</u>	<u>Current Status</u>	<u>Date Submitted ↓</u>	<u>Editable Until</u>	
Example	Concept Approved	9/14/2018	12/14/2018	



< 1 >

6c. New Proposal Submission

1. To submit a new study, select “[Create Submission](#)”



2. Enter The Title of your submission and select “[Create New](#)”

The screenshot shows the 'Create a Submission' form. The title of the form is 'Create a Submission'. Below the title, there is a message: 'Please create a Title for your submission. Please remember that the Title can NOT be changed once created.' The input field contains the text 'The Title of your Submission', which is highlighted in yellow. Below the input field, there is a blue button labeled 'Create New'.

You will be taken to a page in which you can choose to submit a concept or a proposal.

3. Select proposal and submit.

The screenshot shows a web interface for a submission form. At the top, it says "Example" and provides "External Status: Submitted Date: NOT SUBMITTED" and "Submission ID: 4511". Below this are four tabs: "Submission Form" (active), "Files", "Emails", and "Milestones". The main content area is titled "Form" and contains instructions: "Fill out the form below then Click Save or Submit to save your progress." There are "Save" and "Submit" buttons. The text explains that a "Concept Submission" is a high-level summary and that a "Proposal Submission" is a detailed description. It notes that documentation for a proposal must include a Protocol, Budget, CV for the Primary Investigator, and W-9 for US institutions. At the bottom, there is a radio button selection for "Concept" (selected) and "Proposal", with "Save" and "Submit" buttons. A "Back To Top" button is located at the bottom right of the form area.

4. Indicate if you are the Primary Investigator by selecting [Yes](#) or [No](#).
5. Select Therapeutic Area (Dropdown list)
6. Select [Disease state](#)
7. Select [Products](#)
8. Fill in Concomitant [Medications/Devises](#) as applicable.

Are you the Primary Investigator?
 Yes No

Strategic Alignment

* Therapeutic Area: Interventional Cardiology/Structural Heart

* Disease State: [Dropdown]

* Products: [Dropdown]

Concomitant Medications/Devices: [Text Area]

9. Check the box(s) for type of support you are requesting

- To add additional products, click on the + button, another screen will appear where you can choose from a dropdown list.
- Once the additional product is requested please add the quantity.
- To enter more products, repeat this process.

Support Requested

What type of support are you requesting from Boston Scientific? Financial Product Other

* Estimated Budget: [Text Field]

* Currency: [Dropdown]

* Product requested: [Dropdown]

* Quantity: [Text Field]

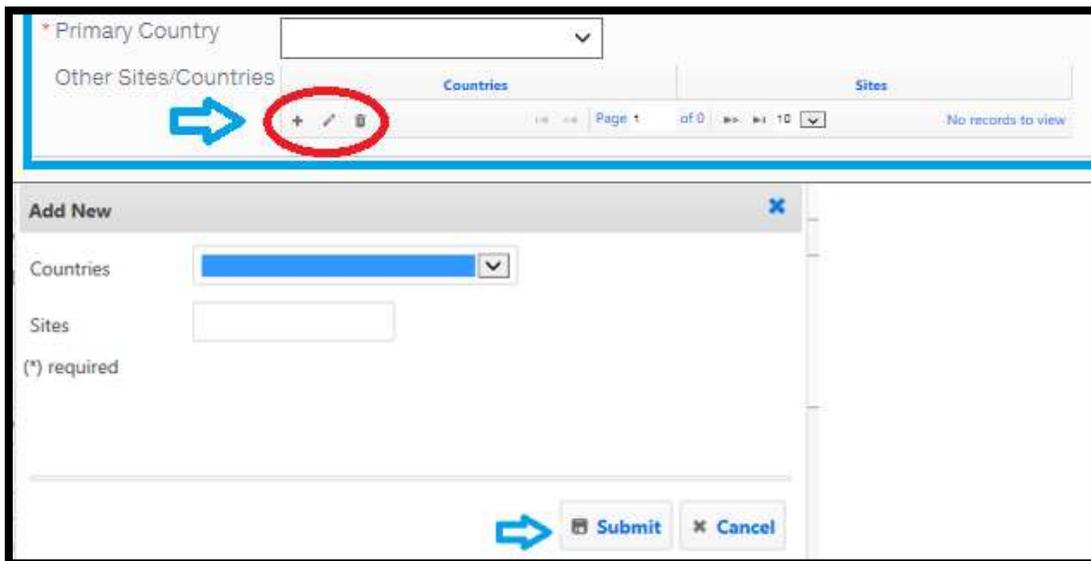
Additional Products Requested

Product	If Other	Quantity
Page 1 of 0		
No records to view		

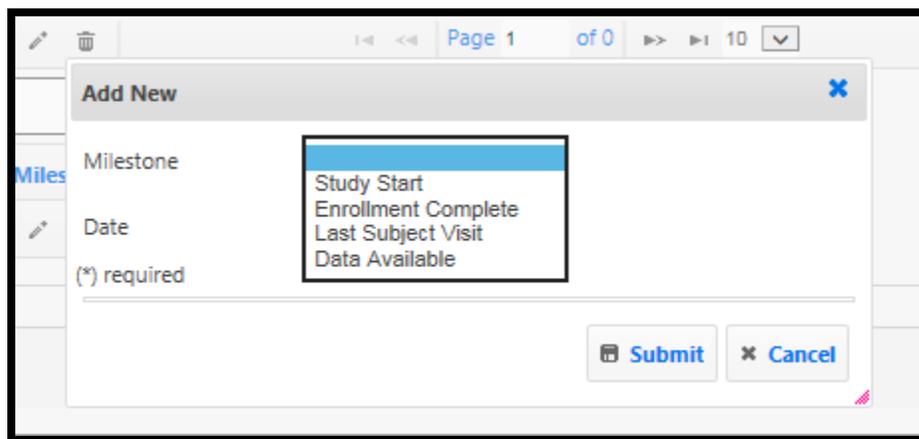
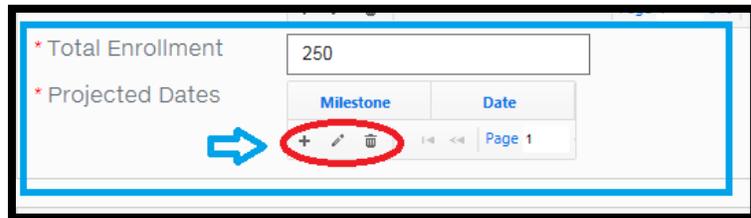


10. Fill in the Study Summary Section and provide:

- Main Scientific Question.
- Study Design
- Research Design Setting
- Statistical analysis
- Main Efficacy Measurement
- Regulatory Status
- Primary country
 - To add **other Sites and/or Countries**, click on the + button, another screen will appear where you can choose other countries from a dropdown list and enter the site name(s).
 - Once the country and site are selected you must select [submit](#).
 - To enter more countries and sites, repeat this process.



- Total enrollment (planned subjects to be enrolled)
 - Projected dates.
 - To enter your Projected dates, please click on the + button, another screen will appear where you must add your Expected milestone and estimated date. Once the required information has been entered you must select [submit](#).
 - To enter all, please repeat this process.



- Publication strategy:
 - Manuscript submission
 - Conference Presentation
 - Proposed timelines
- Safety and complaint Reporting
- Organizational overview
- Legal Statement

11. Legal Statement:

- Read legal statements
- Acknowledge the statements by checking the box's

12. **Click the [Save](#) button.**

Legal Statement

* I certify that I am qualified to practice medicine or qualified to conduct this study

* I understand that completing this form expresses my interest in conducting this study, but does not guarantee support for this Investigator Sponsored Study

- If you are submitting a Concept please upload your CV in the "Files" tab above.
- If you are submitting a Proposal please upload your CV, Budget, and Draft Protocol in the "Files" tab above.

Please be sure to save your changes before leaving the page.

Save Submit

Back To Top

Your Proposal will receive a unique Submission ID – if your concept was approved and you are submitting as a proposal, the Submission ID will remain the same.

The final step required before submission is complete is to upload your CV, budget, study protocol and a W9 (US ONLY) for the institution.

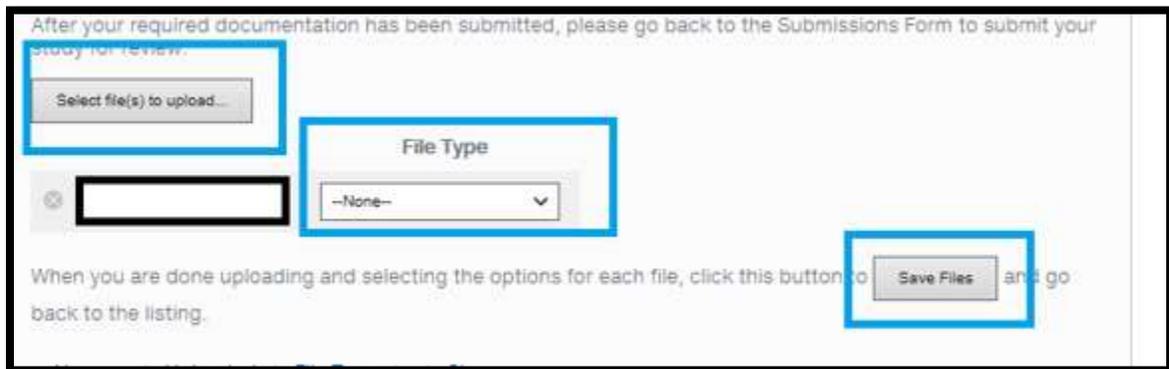
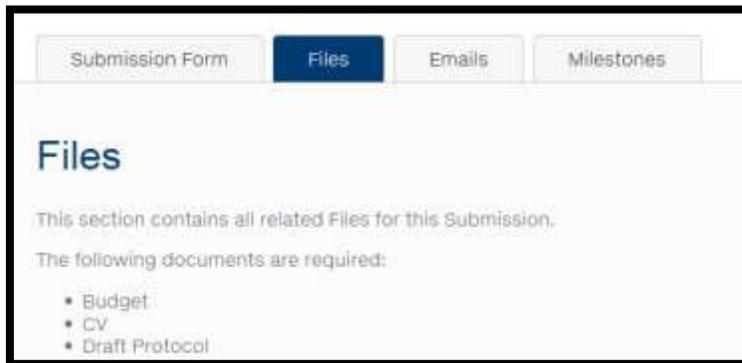
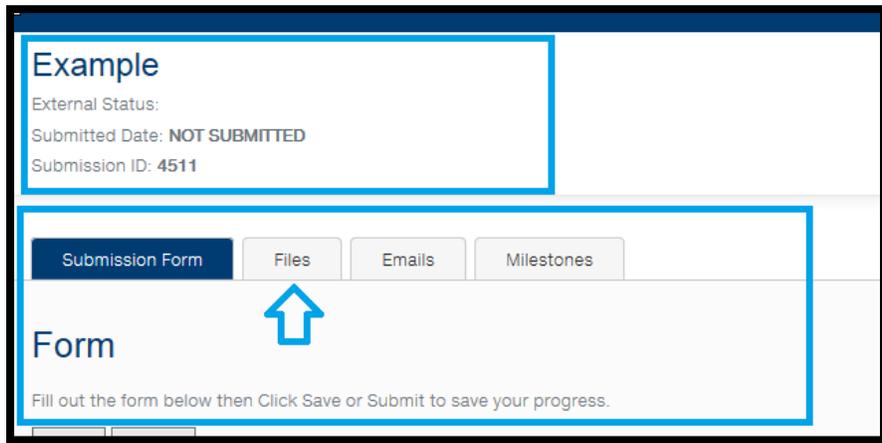
Note: When submitting your budget please keep in mind the list of non-payable items as per BSC's policy:

Non- Payable Items:

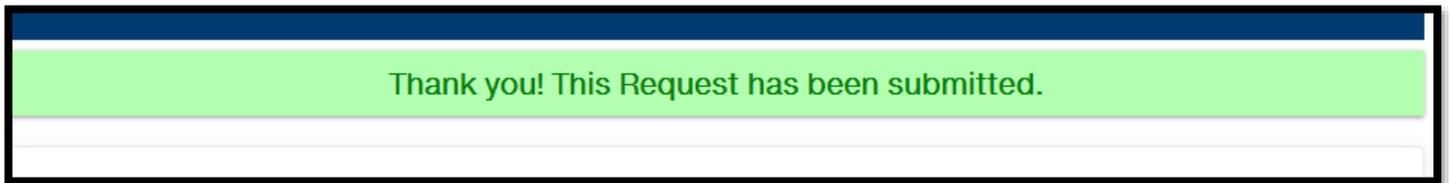
- Proposal design fees
- Protocol development fees
- Reporting AEs or SAEs to IRB and FDA, or other regulatory agencies
- Directly paying of salaries to investigators, study personnel or third-party vendors etc. This would not include Time and Effort that is included in the overall budget.
- Services rendered in the normal care of patients regardless of participation in the research
- Record storage/long term storage
- Archiving (beyond study closure)
- Time and effort for writing and publishing
- General education and training activities
- Fees or expenses related to routine operations
- Capital expenses; and
- Facilities Expenses.

To upload the required documents:

13. Select the Files Tab
14. click on Select file(s) to upload the required documents.
15. Select the File Type from the dropdown list
16. Click on Save Files



17. Once all required documents have been uploaded, go back to the Submission Form tab, and click on [save/submit](#). You will see if your proposal has been successfully submitted if you see below notification.

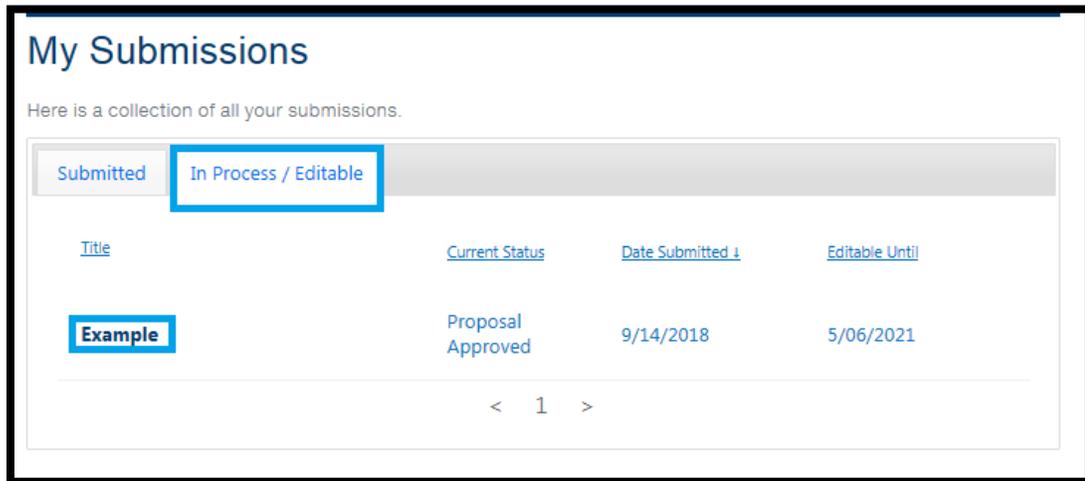


Note: You will be notified from a Boston Scientific representative once your study has been reviewed.

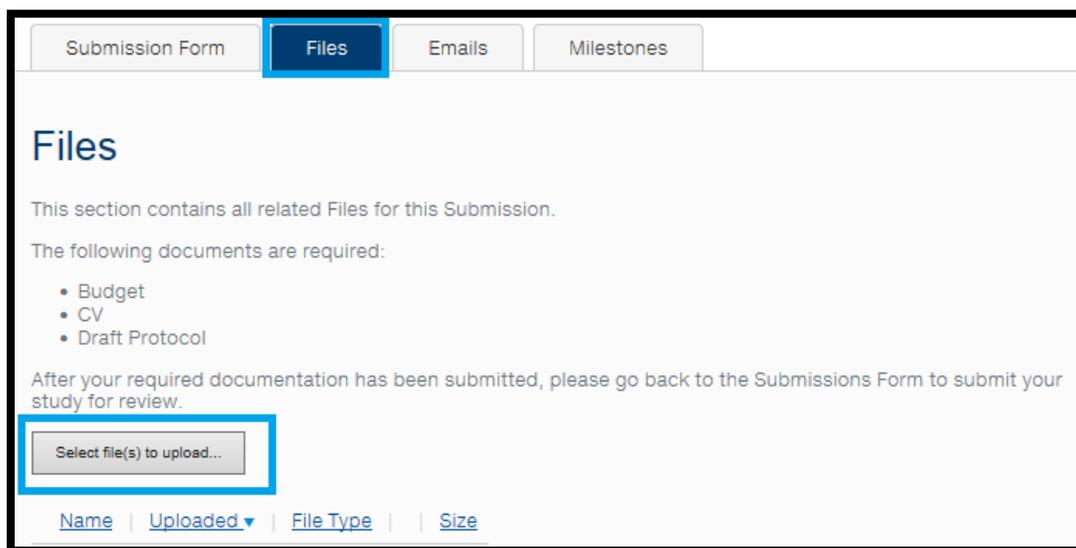
7. Approved Proposal

To follow-up on your submission, login in to the ISR portal and click on the [In Process/Editable tab](#).

- Review your study by clicking on the study Title.



- Files can always be uploaded by clicking on the [Files tab](#).
- Select your file which you would like to upload and indicate what you are uploading and click on save files.



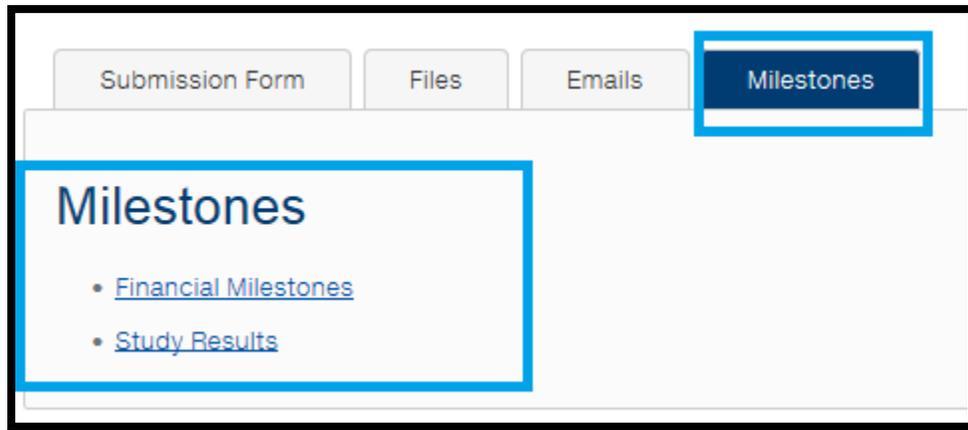
The screenshot displays a web interface for file management. At the top, a header reads "File Type". Below this, a file named "76065706.docx" is shown with a close icon. A dropdown menu is open, listing the following file types: "--None--", CV, Budget, Draft Protocol, Protocol Amendment, Notification of Closure, Draft Abstract, Draft Manuscript, Final Abstract, Final Manuscript, Status Update Report Form, Final Study Report, IRB Approval, and Miscellaneous. To the right of the dropdown, a "Save Files" button is highlighted with a blue box. Below the dropdown, there is a table with columns for "Name" and "Uploaded". The text "Clinical_Feb2018.pdf" is visible at the bottom of the table. A "Save Files" button is also highlighted with a blue box to the right of the dropdown menu.

8. Milestones

Upon completion of a Milestone or a Study Result you will be required to confirm they are complete.

To access Milestones or Study Results and Indication Completion:

1. Click on the [Financial Milestones Link](#) or [Study Results](#).



Note: The Milestones or study results will be divided in separate columns which will indicate a [Planned Date](#), an [Actual Date](#), [A complete \(Y/N\)](#), a [Comments](#) and an [Editable Until](#) column.

2. Select the row you are planning to edit and click on the pencil.
 - a. A New Window will appear where you can select if you completed the row you selected. You must select [Yes](#) to sign off for completion and add a [comment with the completion date](#). Once this has been filled it, please click on Save.
 - b. If you wish not to edit the selected row, simply click on cancel.
 - c. If your milestone is delayed you will be required to notify your Grant Coordinator for BSC to understand the progress of the Study. "As Agreed in ARTICLE II – Institution's Responsibilities - [Section 2.02 Reporting of The Agreement](#)".

Submission Form Files Emails **Milestones**

Milestones

- [Financial Milestones](#)
- [Study Results](#)

Milestone	If Other	Planned Date	Actual Date	Complete (Y/N)	Comments	Editable Until
Contract Executed		11/26/2018		Yes		
25% Enrollment		5/27/2019		No		11/27/2019
Interim Report		3/30/2019		No		9/30/2019

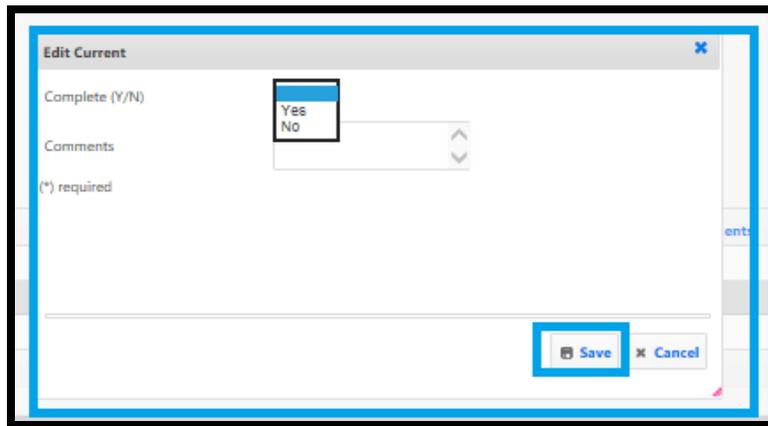


Edit Current [X]

Complete (Y/N)

Comments

(*) required



9. Help

For additional questions, please contact your research areas site coordinator.

Research Areas	Suggested or actual address
Neuromodulation	BSN.ISR@bsci.com
Urology and Pelvic Health	UroPH.ISR@bsci.com
Peripheral Intervention	PI.ISR@bsci.com
Rhythm Management / Electrophysiology	RM.ISR@bsci.com
Interventional Cardiology	IC.ISR@bsci.com
Endoscopy	Endogrants@bsci.com