



PIRMA *User Guide*

Version 2.0

November 2025



Table of Contents

<u>What is PIRMA</u>	4
<u>Access to PIRMA</u>	5
<u>PIRMA Home Page</u>	6
<u>PIRMA Users</u>	7
<u>Setting up a New Project in PIRMA</u>	8
<u>Defining Risks in PIRMA</u>	9-10
<u>Entering New Risks in PIRMA</u>	11-12
<u>Updating Risks in PIRMA</u>	13-14
<u>Entering Risk Mitigation in PIRMA</u>	15
<u>Updating Mitigations in PIRMA</u>	16
<u>Exporting in PIRMA</u>	17
<u>Closing a Project in PIRMA</u>	18



What is PIRMA

Peripheral Interventions Risk Management Application

- PIRMA is a web-based risk management application.
- One of the Peripheral Interventions (PI) New Product Development Initiatives is “Pulling Risk Forward (PRF)”
- The **PIRMA** tool is the PI-PRF Risk Management tool for repositing, tracking, quantifying and mitigating project risks.
- Using **PIRMA** for Risks is required for all PDP and TDP projects. It is also required for all sustaining projects where the risks are being captured and will be mitigated.
 - If you have a unique exploratory project (sometimes called an umbrella project number) that includes other projects that share a project number but you would prefer to separate their risks, we can work with you to set up separate entries in PRIMA. Please contact the PI PMO PIPMOTeam@bsci.com if you have any questions about this.



QUICK
TIPS

- Here is the link to **PIRMA** - [PIRMA -Dashboard \(bsci.com\)](https://bsci.com/PIRMA-Dashboard)
- It can also be reached from the PI PMO SharePoint site homepage or by searching “PIRMA” in Lexicon



Peripheral Interventions Risk Management Application PIRMA | PPIM

Definition

Project Risk Management Application for documenting the Project Risk Register, as well lessons learned and best practices. The Project Probability and Impact Matrix (PPIM) provides a standard method to calculate risk scores based upon combination of probability and impact ratings.

To request access to PIRMA, contact Peripheral Interventions Project Management Office (PI PMO)

Source: PLCP Web

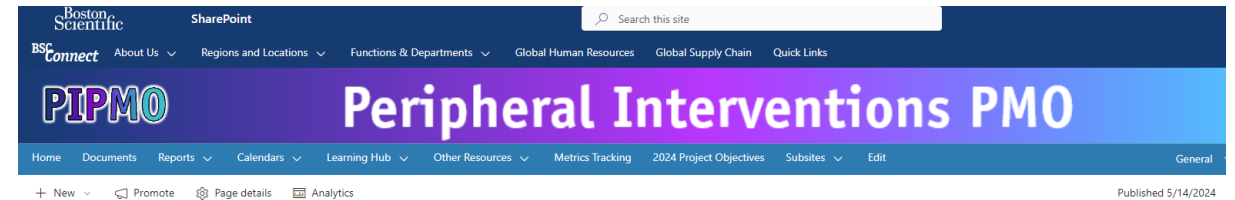
[Click here for the PIRMA login and handbook](#)



[Click here for the PIRMA Template](#)

Related Lexicon Links

- [Risk Management](#)
- [Project Risk Register](#)
- [Risk Register](#)



Welcome to the PI PMO!

Affectionately referred to as “Pipmo.” This site is our one-stop shop for resources, templates, events, and more. You can use the links in the header to navigate the entire site, or use the links to the right to navigate directly to our most popular resources.

[Submit feedback on our intranet site!](#)

Quick Links

- [PIRMA](#)
- [Boston Scientific's PLCP](#)
- [PI NPD Excellence site](#)
- [What is a PMO?](#)
- [Brand standards & BSC templates](#)
- [Video conferencing resource site](#)

Use our Request Portal to request support from the PMO team!

[Go to Request Portal](#)



PIRMA Home Page

[PIRMA -Dashboard \(bsci.com\)](https://bsci.com)

Boston
Scientific

PIRMA

Risk Resources

Risk Metrics

Search Lessons Learned

Permissions

Launch Cadence

Admin

Time & Money

Add New User

Logged In as Hannah Campbell

My Projects

Add New Project

Projects I own or am designated as a team member.

Project Name	Status	Phase	Risk & Mitigations	Lessons Learned & Best Practices
Filter	Filter	Filter		
S0000	On Hold	TDP: Plan	View	View
Test/Learning Environment	Active	Define	View	View
SURECHOICE	Active	Plan	View	View
S10038 PI VIP Blockwise-Sterling/Ranger	Active	Plan	View	View

1 through 4 of 4 recordsPer page: 10Export to .csv

All Projects

Projects displayed varies by job title/role (i.e. PI group can see all PI projects). You are assigned to PI.

Project Name	Project Owner	Status	Phase	Project Status in PPM	Risk & Mitigations	Lessons Learned & Best Practices
Filter	Filter	Filter	Filter	Filter		
S6474 Eluvia 200 + Fortnight	Rosalie Waldron	Active	Plan	----	View	View
Ideal Product Flow	Rosalie Waldron	Active	Sustaining	----	View	View
S6124 Ranger .035 PDP	Orla Sugrue	Active	Confirm	Active	View	View
Eluvia 5mm	Orla Sugrue	Cancelled	Plan	----	View	View

Search
using
filter bar
to see
more
projects

Click on “view” to open the project



If you cannot find a project you think you should be able to see in PIRMA, please contact [PI PMO](#)



PIRMA Users

Roles & Responsibilities

- General overview of tasks and responsibilities of PIRMA users

Tasks	PMO Support	Project Manager	Project Team	Risk & Mitigation Owners
Add new users	X			
Create new project	X			
Assign project owner	X			
Assign project team members		X		
Enter Risks		X	X	
Enter Mitigation		X	X	
Assign Risk and Mitigation owners		X	X	
Review and Monitor risks and mitigation		X	X	X
Manage / update risks				X
Manage / update mitigation				X



QUICK
TIPS

While Project Managers are typically responsible for overseeing risk management process, entire project team is responsible for identifying, mitigating and reporting project risks!

- If you are new to PIRMA and cannot see any projects, the PMO team will need to add you to the system.
- To add a new project into PRIMA, please contact the PMO team through the [PIPMO mailbox](#) so they can initiate the set up.
- Information needed by PMO to add a new project is:
 - Project Manager/Owner Name
 - Project name – format
 - Division – PI, or IC etc.
 - Franchise – Arterial, Venous, IO, Coronary Therapies, Watchman, Cork projects, Devoro Integration, SHV
 - Organization (optional) NPD or Sustain Eng

- Once project set up is complete, the PM can add team members and risks. If you can't find a team member in PIRMA yet, please contact PMO

The screenshot displays the PIRMA interface for editing project information. The main panel shows project details for 'S6474 Eluvia 200 + Fortnight', including Project Status (Active), Franchise (Arterial), Project Phase (Plan), Organization (NPD), Division (PI), and Project Status in PPM (None). A 'RISKS' tab is visible. The 'Risk Summary' section shows a total of 111 project risks, with 43 open risks. Below this, there are charts for 'Risk Response Strategy Totals' and 'Risk Category Totals'. The 'Edit Project Information' modal is open on the right, showing fields for Project Name, Project Phase, Division, Franchise, Organization, Project Status, Project Status in PPM, Project Owner, and Team Members. The Team Members field lists Fintan Waldron and Rosalie Waldron. The modal has 'Close' and 'Save' buttons at the bottom right.

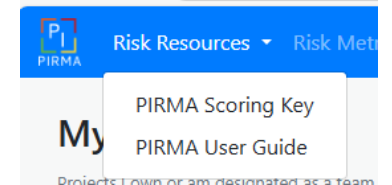
Field	Value
Project Name*	S6474 Eluvia 200 + Fortnight
Project Phase*	Plan
Division	PI
Franchise	Arterial
Organization	NPD
Project Status*	Active
Project Status in PPM	-----
Project Owner	Rosalie Waldron
Team Members*	Fintan Waldron, Rosalie Waldron



Defining Risks in PIRMA

Impact and Probability Scoring

- Before entering Risks, review the PIM Scoring Key, Impact Ranking Key, and the Impact Score Definitions to determine how to define and rank the project risks.
- Risk scoring key is in PIRMA Homepage navigation bar under Risk Resources



Probability and Impact Matrix (PIM) Scoring Key

Probability Ranking Key		
Ranking	Description	Probability of occurrence
5	Almost certain	>90%
3	Possible	Coin flip (50:50)
1	Rare	<10%

Impact Ranking Key

Ranking	Description	Definition
5	Critical	If not retired, will terminate project.
3	Medium	If not retired, results in a change in AOP – e.g., meaningful impact to project cost or schedule.
1	Very low	If not retired, likely to have limited impact (e.g., delay of single-digit months, cost within acceptable margins for team to manage) but no change to AOP; team able to mitigate/monitor without escalating to leadership.

Impact Score Definitions

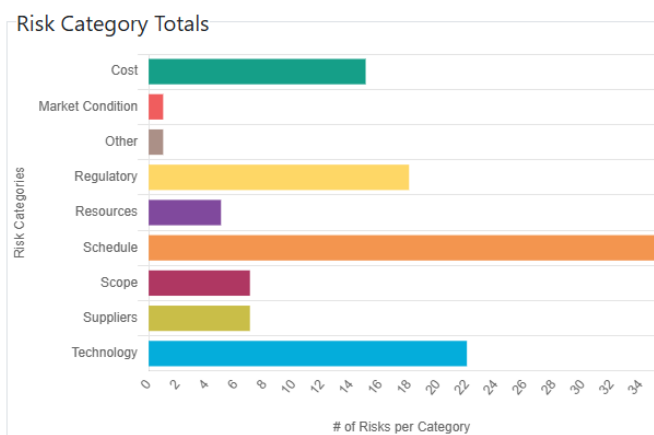
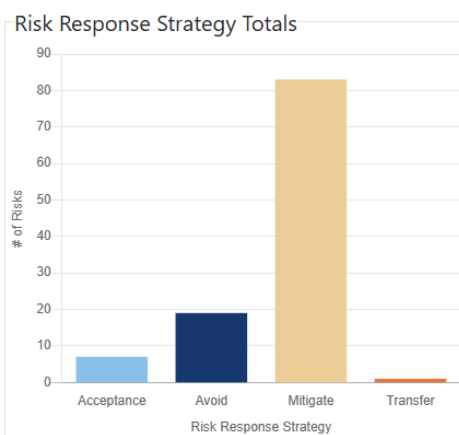
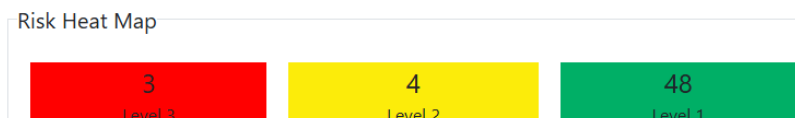
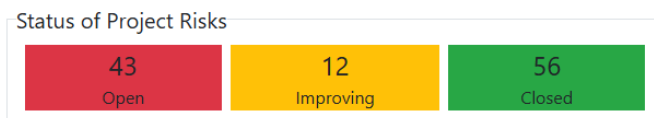
Rank	Very low - 1	Medium - 3	Critical - 5
Impact	Risk will <u>not</u> meaningfully impact cost or schedule if not retired	Risk will result in meaningful impact to project cost or schedule if not retired	Risk will lead to project termination if not retired
Outcome	<p>No change to AOP</p> <p>Limited impact, risk may:</p> <ul style="list-style-type: none">Impact performance of the product (within the contract)Impact schedule but incur delays within single-digit monthsIncrease cost within reasonable margin to be managed by team <p>Project team capable of monitoring/mitigating risk without elevating to leadership</p>	<p>Entails a change in AOP</p> <p>Team may need to recontract project terms and conditions given meaningful impact on project cost and schedule</p> <p>Team may need to request additional funding / resources from leadership to support mitigation of risk</p>	<p>Risk kills project if not retired</p> <p>Example: if sole supplier of a critical component terminates partnership, could lead to project failure</p>



Defining Risks in PIRMA

Risk Level

- Risk level is automatically assigned based on Impact Ratings and Risk Levels



Impact	Critical (5) (Project Killer)	3		
	Medium (3) (Impact to AOP)	28	4	
	Very Low (1) (Team can manage)	8	10	2
		Rare (1) <10%	Possible (3) 50%	Almost Certain (5) >90%
		Probability		



All level 3 risks will be highlighted as “red” in the heatmap.

Level 3: Any risk with Impact rating of 5.

Level 3: Any risk with Risk score of 15 or higher.

Level 2: Any risks with Risk score of 8 to 12 and impact of less than 5.

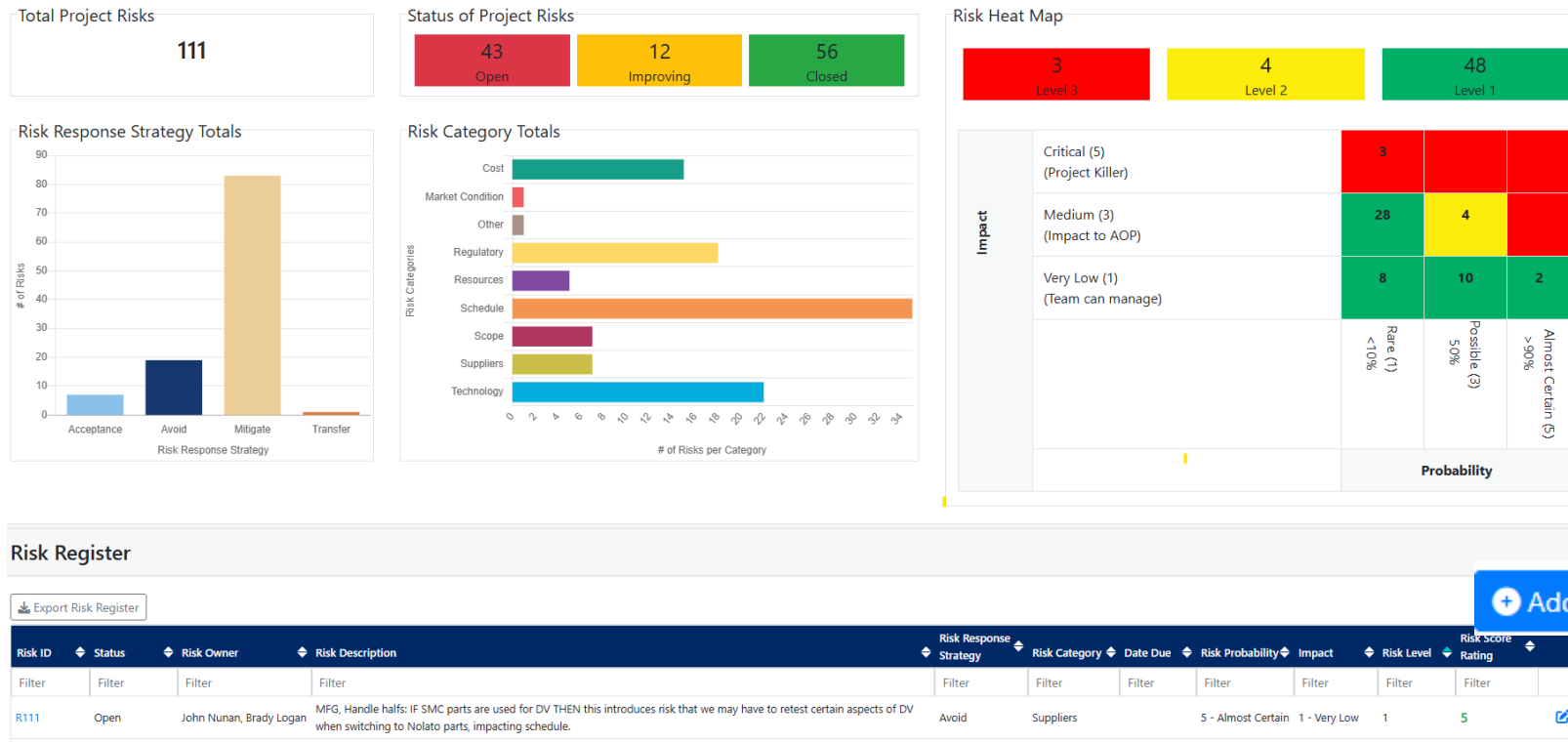
Level 1: Any risks with Risk score of 6 and below and impact of less than 5.

Risk Register											
<div>Export Risk Register</div> <div>Add Risk</div>											
Risk ID	Status	Risk Owner	Risk Description	Risk Response Strategy	Risk Category	Date Due	Risk Probability	Impact	Risk Level	Risk Score Rating	
Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	
R111	Open	John Nunan, Brady Logan	MFG, Handle halves: IF SMC parts are used for DV THEN this introduces risk that we may have to retest certain aspects of DV when switching to Nolato parts, impacting schedule.	Avoid	Suppliers		5 - Almost Certain	1 - Very Low	1	5	



Entering New Risks in PIRMA

- Once the project is set up, project team can add a risk by selecting the **Add Risk** Button in the Risk Register section





Entering New Risks in PIRMA

- Fill in the required fields and desired optional fields.

Risk Analysis Key

Probability Ranking Scale		Impact Ranking Scale	
1	Rare < 10%	1	Very low <i>Risk will not meaningfully impact cost or schedule if not retired</i> <i>No change to AOP</i> Project team capable of monitoring/mitigating risk without elevating to leadership
3	Possible Coin flip (50:50)	3	Medium <i>Risk will result in meaningful impact to project cost or schedule if not retired</i> <i>Entails a change in AOP</i> Team may need to recontract / request additional funding and resources
5	Almost certain > 90%	5	Critical <i>Risk will lead to project termination if not retired</i> <i>Risk kills the project if not retired</i>

Risk Responses Key	
Mitigate	Take action to reduce the probability and impact of the risk event to an acceptable
Avoid	Change plans to eliminate the threat
Accept	Used for risks for which the probability and impact cannot be further reduced by practical/realistic means
Transfer	Shift the risk consequence and responsibility for mitigation to a third party. (*this does not eliminate the risk)

Risk Identification

Date Identified* 2024-06-05 Owner* Select owner(s)

Description*

Please use 'If, Then' format to describe specific risk and identify impact. Example: IF test fails late in program, THEN we expect a 6 month delay.

Risk Response Planning ⓘ

Risk Response Strategy* Not Set Risk Due Date

Action To Be Taken:

Project Specifics

Project Phase* Not Set Risk Category* Not Set

Monitoring & Control

Status* Not Set

Is the Risk Materialized ? Unknown

Contingency:

Comments:

Risk Analysis ⓘ

Probability* Not Set Impact* Not Set

Risk Score Rating 0

Risk Trigger: Expected Outcome:

Risk Trigger Date

Attachment

Upload Attachments

Choose File No file chosen




While it is not mandatory to add "Risk Due Date" when entering new risk, it is strongly recommended to add due date as more details are available. This date will be used to send automated reminders to risk owners.



Updating Risks in PIRMA

First edit option

- The first way to update an existing risk, is select the Risk edit button in the far-right column in the Risk Register 
- A box will open allowing for quick changes to the risk.

Risk Register											
<div>Export Risk Register</div> <div>Add Risk</div>											
Risk ID	Status	Risk Owner	Risk Description	Risk Response Strategy	Risk Category	Date Due	Risk Probability	Impact	Risk Level	Risk Score Rating	
Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter
R100	Open	John Nunan	Molding, Rack and Clip: IF we do not begin making progress soon for the rack and clip mold at Nolato, THEN we will delay our unit builds for mechanical DV and commercial readiness waiting for a commercial mold to be manufactured impacting commercialization timing and potential submission.	Mitigate	Schedule		3 - Possible	3 - Medium	2	9	

Edit Risk R3

Status *
Open

Owner *
5

Description *
resources

Risk Category *
Resources

Date Due
📅

Probability *
2 - Unlikely

Impact *
2 - Low

Cancel Edit Save Changes



Only the information shown in the Risk Register can be edited using this option. To edit all the risk fields, use the second edit option.



Updating Risks in PIRMA

Second edit option

- To update an existing risk, select the Risk ID from the Risk Register

- Select Edit

Edit

Delete

History

Home / Project Test/Learning Environment / Risk R5 / Edit Risk R5

Cancel Save

Risk Identification

Date Identified* 2021-11-02 Owner* Select owner(s)

Description* Supply Chain issue with pump molds long lead times

Please use 'If, Then' format to describe specific risk and identify impact. Example: IF test fails late in program, THEN we expect a 6 month delay.

Project Specifics

Project Phase* Define Risk Category* Suppliers

Risk Analysis

Probability* 4 - Likely Impact* 4 - High

Risk Score Rating 16

Risk Trigger: shipping delays Expected Outcome:

Risk Trigger Date

Risk Response Planning

Risk Response Strategy* Mitigate Risk Due Date 2022-02-23

Action To Be Taken:

Monitoring & Control

Status* Open

Is the Risk Materialized ? Unknown

Contingency:

Comments:

Attachment

Upload Attachments Choose File No file chosen

There are no attachments uploaded for this risk



Updating Risks in PIRMA

When the Risk has Materialized

1. Within section *Monitoring & Control* set *Risk Materialized* to “Yes”.
2. Close the section *Monitoring & Control* by entering a comment

EditDeleteHistory

Closed on Aug. 21, 2025, 11:30 a.m.

Risk Identification

Date Identified02 Jun 2025

Risk OwnerJustine Adamek

Risk DescriptionIf PQS needs modification to support use for Immunobead, then updates to PQS would be required resulting in additional resource load

Risk Response Planning ⓘ

Risk Response StrategyMitigate

Risk Due DateNone

Action To Be TakenConfirmed PQS will need additional modification as it currently does not have controls for GMP/IMP and does not have development procedures. PQS is also not set up for in house testing. Pending additional PQS resource.

Project Specifics

Project PhaseTDP: Plan

Risk CategoryTechnology

Monitoring & Control

StatusClosed

Risk MaterializedYes

Contingency-

CommentsRealized risk - we will need to expand PQS system, but resource load has been accounted for and approved in AOP 2026.

Risk Analysis ⓘ

Probability5 - Almost Certain

Impact1 - Very Low

Risk Score Rating 5

Risk Trigger

Expected Outcome

Risk Trigger Date

AttachmentThere are no attachments uploaded for this risk

Boston Scientific General – Access Limited to all Internal BSC Personnel.

15



Entering Risk Mitigation in PIRMA

Mitigate = Take action to reduce the probability and impact of the risk event to an acceptable

- To add a mitigation to a risk, open the risk and under the Risk Response Planning section
- Select “Mitigate” from the Risk Response Strategy dropdown
- A new Mitigation section will appear to fill in

Risk Response Planning ⓘ

Risk Response Strategy*

Mitigate ▼

Risk Due Date

Action To Be Taken:

Mitigation 1

Mitigation Description *

Owner *

Select owner(s)

Due Date

Click to select Date

Status *

Not Set ▼

Notes

ⓘ Delete Mitigation


+ Add Mitigation






Updating Mitigations in PIRMA

First and second edit options

Similar to Risks, Mitigations can be edited by:

1. Select the Mitigation edit  button in the far-right column in the Mitigation Register.
2. To update an existing mitigation, select the Risk ID from the Risk Register. Select “Edit” button, this will open the risk and mitigation for editing

- Export the Risk Summary image (including the total project risks, status of project risks, and risk heat map) using the button 
- Export the Risk Register as an excel using the button 
- Export the Mitigation Register as an excel using the button 
- Export the Risks & Mitigations together as a csv using the navigation bar button

Export Risk+ Mitigation Register



Mitigation Description						
	A	B	C	D	E	F
1	Mitigation Description	Owner	Due Date	Status	Related Risk	Notes
2	TBD	Kylee Vonderharr	02 Feb 2022	On Track	R1	
3	TBD	Kylee Vonderharr		On Track	R3	
4	TBD	Kylee Vonderharr		On Track	R4	
5	work with supplier for quicker delivery	Hannah Campbell	22 Feb 2022	Closed	R5	
6						

A	B	C	D	E	F	G	H	I	J	K	L
Risk ID	Risk Status	Risk Owner	Risk Description	Risk Category	Probability	Impact	Mitigation Description	Owner	Due Date	Mitigation	Mitigation Notes
R1	Open	Kylee Vonderharr	LMR Plan and shelf life	Cost	4 - Likely	3 - Medium	TBD	Kylee Vonderharr	2-Feb-22	On Track	
R2	Closed	Kylee Vonderharr	Cobalt upclassification	Regulatory	2 - Unlikely	2 - Low					
R3	Open	Kylee Vonderharr	resources	Resources	2 - Unlikely	2 - Low	TBD	Kylee Vonderharr		On Track	
R4	Open	Kylee Vonderharr	Biocompatibility findin	Schedule	4 - Likely	4 - High	TBD	Kylee Vonderharr		On Track	
R5	Open	Kylee Vonderharr	Supply Chain issue with	Suppliers	4 - Likely	4 - High	work with supplier for qui	Hannah Campbell	22-Feb-22	Closed	
R7	Improving	Bobbie Lundberg	test	Resources	4 - Likely	4 - High					



Closing a Project in PIRMA

- PIRMA is a “living tool” that is intended to be updated as a project progresses
- If the project is ready to close, please update the risks and mitigations first, then update the project status to Launched
- If the project is moving to On-Hold or Cancelled, then also update the project status

Edit Project Information

Project Name*

Test/Learning Environment

Project Phase*

Define

Division

PI

Franchise

IO

Organization

NPD

Project Status*

Active

Not Set

Active

Cancelled

On Hold

Launched



Thank you!

Please send questions to PIPMOTeam@bsci.com