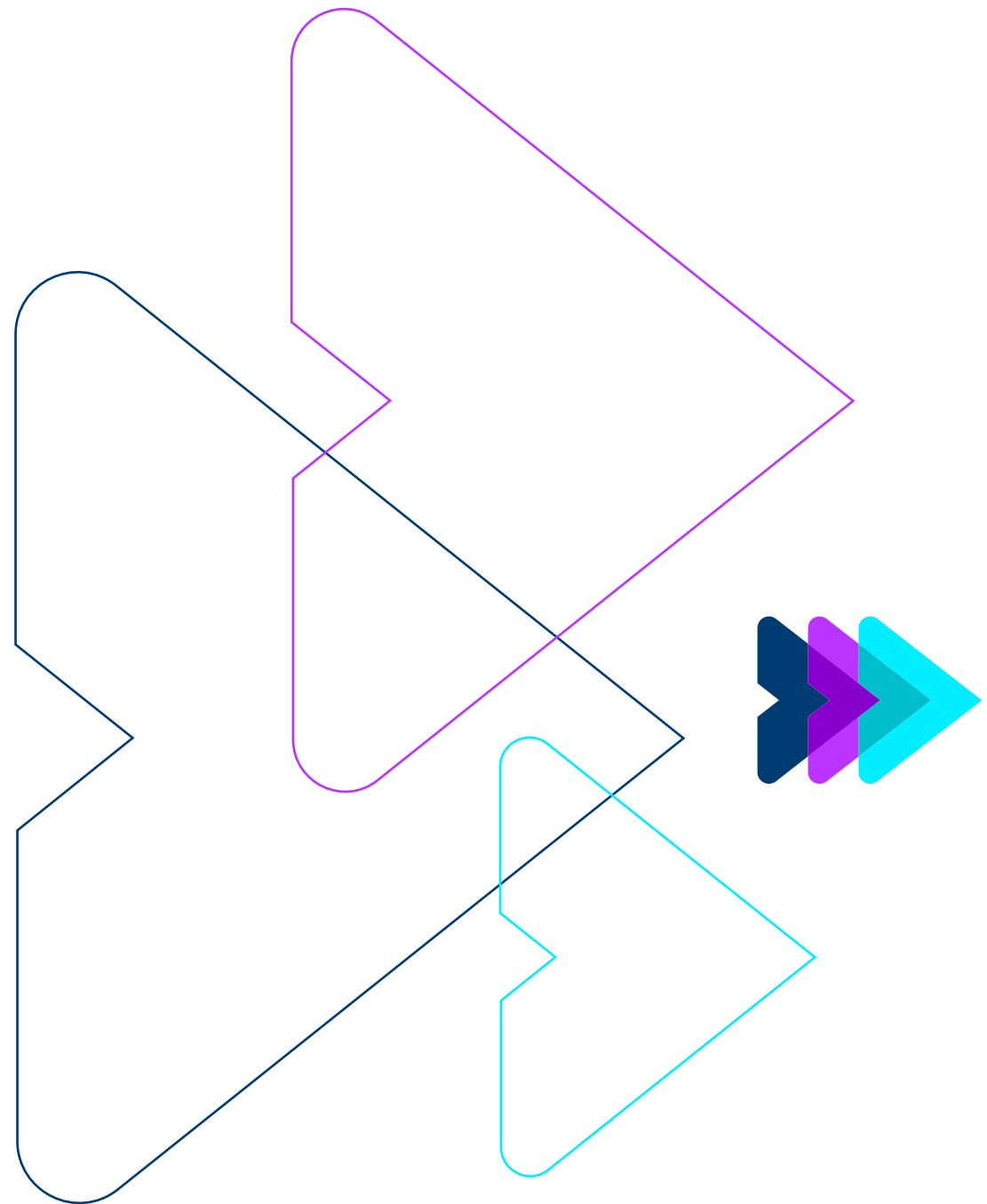
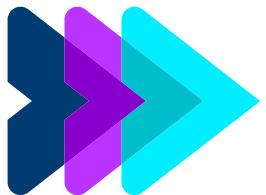




# **PIRMA** User Guide

Version 2.0

November 2025





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- 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](mailto:PIPMOTeam@bsci.com) if you have any questions about this.





# Access to PIRMA

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- 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

[azplcpapw00001.bsci.bossci.com/plcp/lex/](https://azplcpapw00001.bsci.bossci.com/plcp/lex/)

**Global PLCP/Lexicon Web**

Navigate the Product Life Cycle Process (PLCP)  
Business Strategy & Portfolio

**PIRMA** June 3, 2024 Edition 23508 entries in Lexicon. Windchill data as of 6:00pm EDT May 28, 2024

The BSC Lexicon. Type in the box above; press enter (or click Go!)

## Peripheral Interventions Risk Management Application

**PIRMA | PPIM**

### Definition

Project Risk Management Application for documenting the Project Risk Register, as well as 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](#)

[azplcpapw00001.bsci.bossci.com/plcp/lex/](#)

**Boston Scientific SharePoint**

**PIPMO** Peripheral Interventions PMO

Published 5/14/2024

Home Documents Reports Calendars Learning Hub Other Resources Metrics Tracking 2024 Project Objectives Subsites Edit

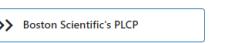
+ New Promote Page details Analytics

### Welcome to the PI PMO!

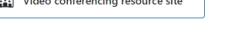
Affectionately referred to as “Pipmo.” This site is our one-stop shop for resources, templates, events, and more. You can use the links in the header to navigate the entire site, or use the links to the right to navigate directly to our most popular resources.

[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)

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Risk Resources ▾ Risk Metrics Search Lessons Learned Permissions Launch Cadence Admin Time & Money Add New User

Logged In as Hannah Campbell

**My Projects**

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	<a href="#">View</a>	<a href="#">View</a>
Test/Learning Environment	Active	Define	<a href="#">View</a>	<a href="#">View</a>
SURECHOICE	Active	Plan	<a href="#">View</a>	<a href="#">View</a>
S10038 PI VIP Blockwise-Sterling/Ranger	Active	Plan	<a href="#">View</a>	<a href="#">View</a>

1 through 4 of 4 recordsPer page: 10 ▾ [Export 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	-----	<a href="#">View</a>	<a href="#">View</a>
Ideal Product Flow	Rosalie Waldron	Active	Sustaining	-----	<a href="#">View</a>	<a href="#">View</a>
S6124 Ranger .035 PDP	Orla Sugrue	Active	Confirm	Active	<a href="#">View</a>	<a href="#">View</a>
Eluvia 5mm	Orla Sugrue	Cancelled	Plan	-----	<a href="#">View</a>	<a href="#">View</a>

Search using filter bar to see more projects

Click on “view” to open the project



QUICK TIPS  
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



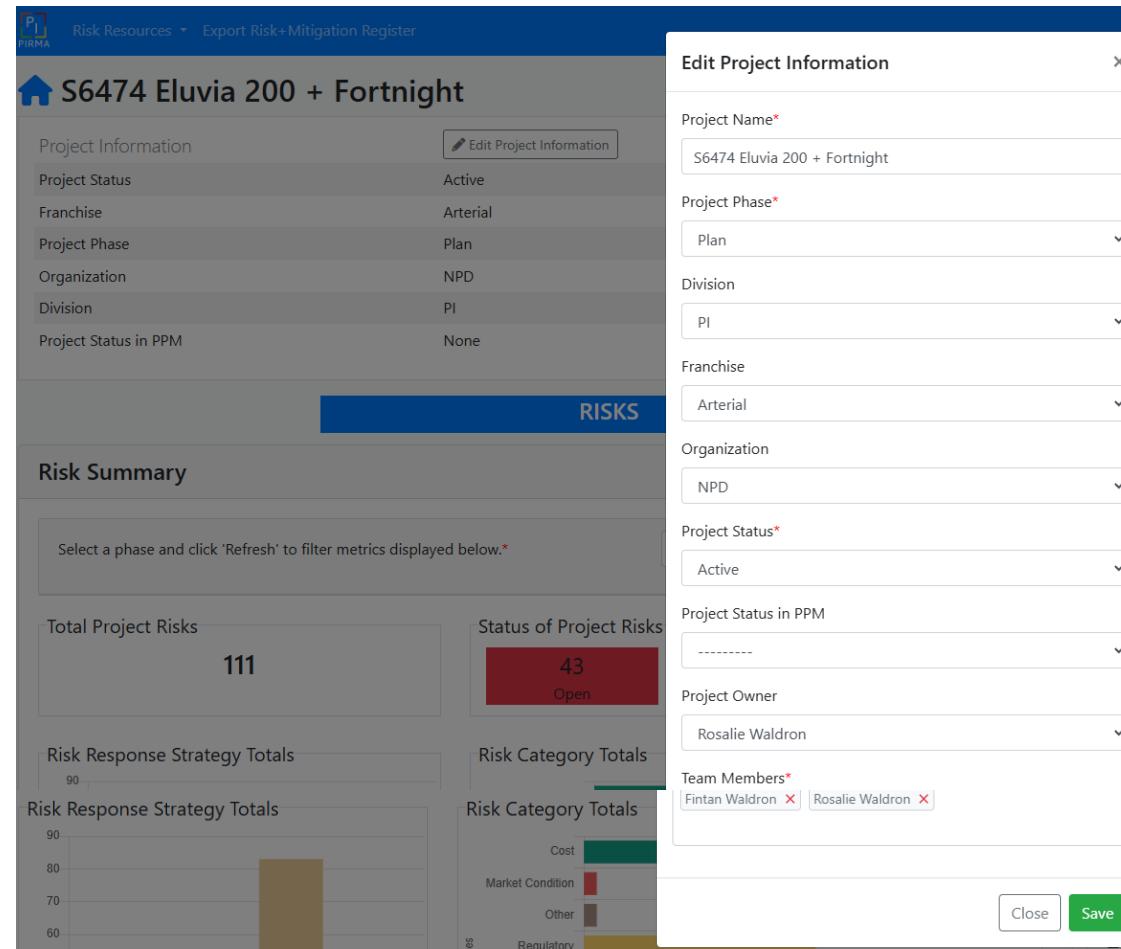
QUICK TIPS While Project Managers are typically responsible for overseeing risk management process, entire project team is responsible for identifying, mitigating and reporting project risks!

- 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



# Setting up a New Project in PIRMA

- 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



Risk Resources | Export Risk+Mitigation Register

## S6474 Eluvia 200 + Fortnight

**Project Information**

Project Status	Active
Franchise	Arterial
Project Phase	Plan
Organization	NPD
Division	PI
Project Status in PPM	None

**RISKS**

**Risk Summary**

Select a phase and click 'Refresh' to filter metrics displayed below.\*

**Total Project Risks** 111

**Status of Project Risks** 43 Open

**Risk Response Strategy Totals**

**Risk Category Totals**

**Team Members\***

**Project Information**

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 X Rosalie Waldron X

**Close** **Save**

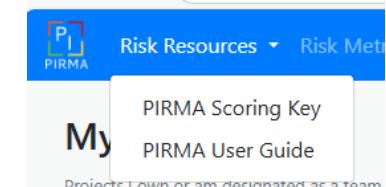


# Defining Risks in PIRMA

## Impact and Probability Scoring

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

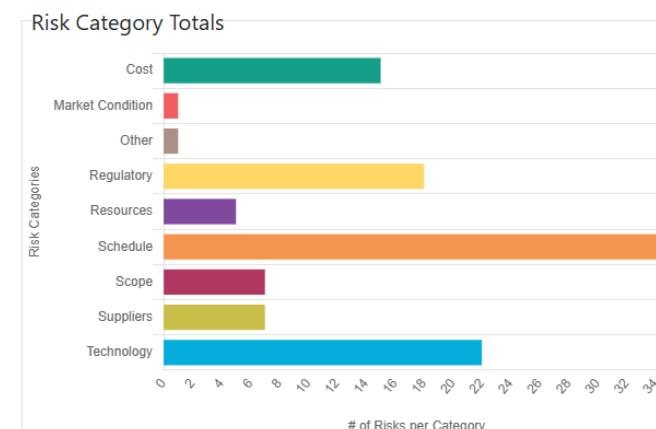
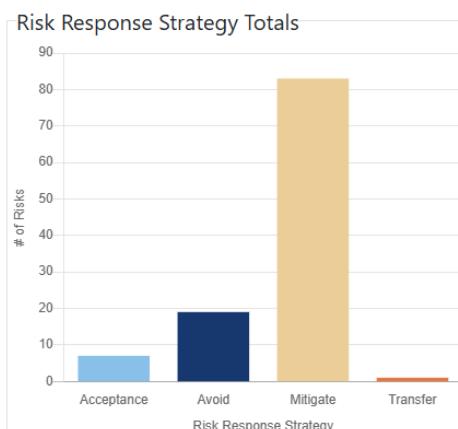
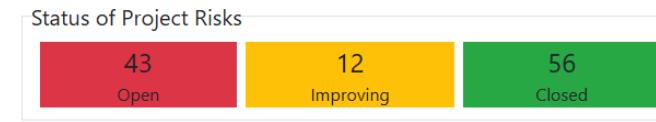


# Defining Risks in PIRMA

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## Risk Level

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



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

Export Risk Register Add Risk

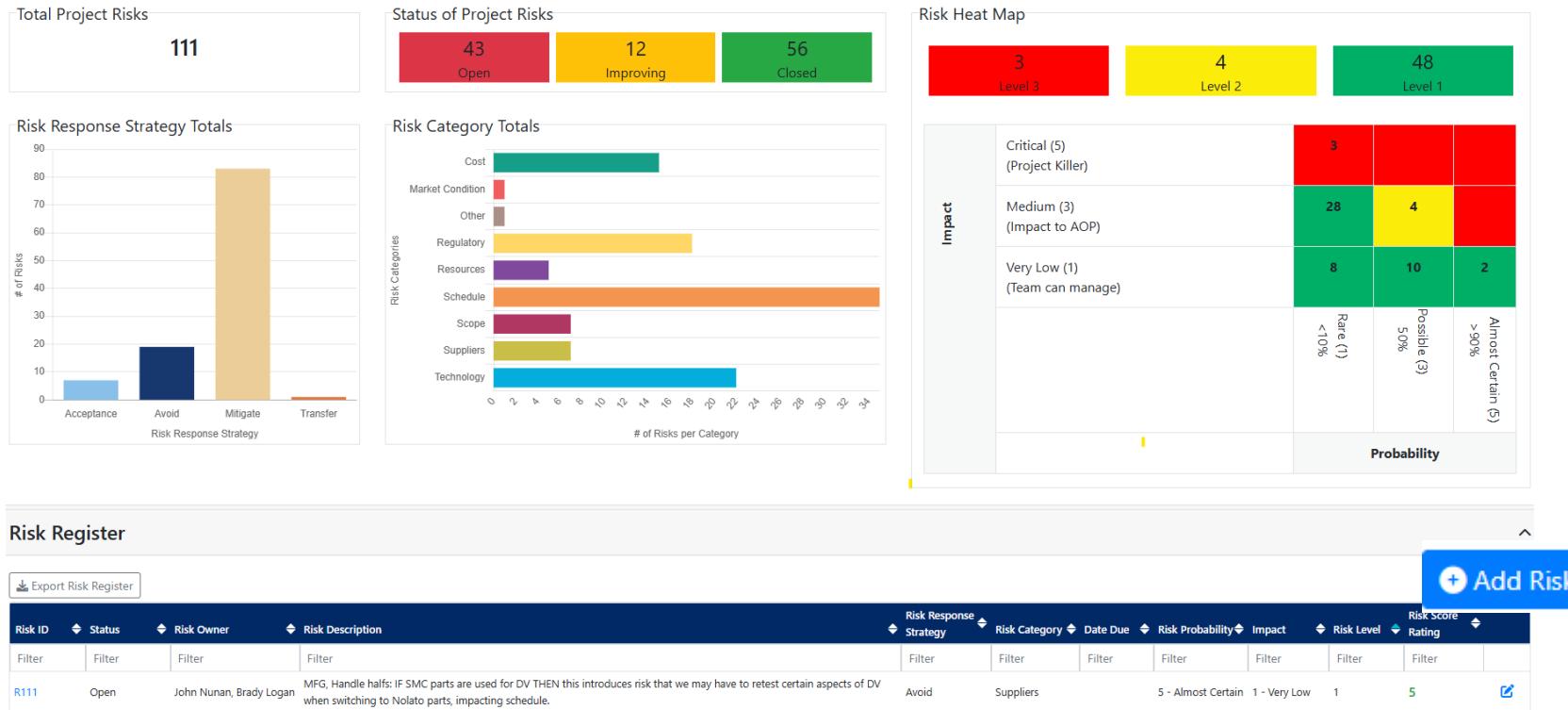
Risk ID	Status	Risk Owner	Risk Description	Risk Response	Risk Category	Date Due	Risk Probability	Impact	Risk Level	Risk Score	Rating
Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter	Filter
R111	Open	John Nunan, Brady Logan	MFG, Handle halfs: IF SMC parts are used for DV THEN this introduces risk that we may have to retest certain aspects of DV when switching to Nolato parts, impacting schedule.	Avoid	Suppliers	2024-06-15	5 - Almost Certain	1 - Very Low	1	5	<input checked="" type="checkbox"/>



# Entering New Risks in PIRMA

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- 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

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- Fill in the required fields and desired optional fields.

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)

Diagram illustrating the flow of risk entry:

- Risk Identification:** Fields include Date Identified (2024-06-05), Owner (Select owner(s)), and Description (Text area with placeholder: "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."). A blue arrow points from the "Risk Responses Key" table to this section.
- Risk Response Planning:** Fields include Risk Response Strategy (Not Set) and Risk Due Date (Text input).
- Project Specifics:** Fields include Project Phase (Not Set) and Risk Category (Not Set).
- Monitoring & Control:** Fields include Status (Not Set), Is the Risk Materialized? (Unknown), Contingency (Text area), and Comments (Text area).
- Risk Analysis:** Fields include Probability (Not Set) and Impact (Not Set). A blue arrow points from the "Risk Response Planning" section to this section.
- Final Summary:** Shows Risk Score Rating 0, Risk Trigger, Expected Outcome, Risk Trigger Date, and 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.





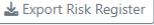
# Updating Risks in PIRMA

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## 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

Risk ID	Status	Risk Owner	Risk Description	Risk Response	Risk Category	Date Due	Risk Probability	Impact	Risk Level	Risk Score
Filter	Filter	Filter	Filter	Strategy	Filter	Filter	Filter	Filter	Filter	Rating
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 \*

Owner \* 

Description \*

Risk Category \*

Date Due 

Probability \*

Impact \*



QUICK  
TIPS

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

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## 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

**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 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

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

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

[Edit](#) [Delete](#) [History](#)

<b>Risk Identification</b>	<b>Project Specifics</b>	<b>Risk Analysis</b>
<b>Date Identified</b> 02 Jun 2025	<b>Project Phase</b> TDP: Plan	<b>Probability</b> 5 - Almost Certain
<b>Risk Owner</b> Justine Adamek	<b>Risk Category</b> Technology	<b>Impact</b> 1 - Very Low
<b>Risk Description</b> If PQS needs modification to support use for Immunobead, then updates to PQS would be required resulting in additional resource load	<b>Risk Score Rating 5</b>	
<b>Risk Response Planning</b>	<b>Monitoring &amp; Control</b>	
<b>Risk Response Strategy</b> Mitigate	<b>Status</b> Closed	<b>Risk Trigger</b>
<b>Risk Due Date</b> None	<b>Risk Materialized</b> Yes	<b>Expected Outcome</b>
<b>Action To Be Taken</b> Confirmed 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.	<b>Contingency</b> -	<b>Risk Trigger Date</b>
	<b>Comments</b> Realized risk - we will need to expand PQS system, but resource load has been accounted for and approved in AOP 2026.	<b>Attachment</b> There are no attachments uploaded for this risk



# Entering Risk Mitigation in PIRMA

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**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 i

Risk Response Strategy*	Risk Due Date
Mitigate	
Action To Be Taken:	
<input type="text"/>	

Mitigation 1

Mitigation Description *	Owner *	Due Date	Status *	Notes
<input type="text"/>	<input type="text"/> Select owner(s)	<input type="text"/> Click to select Date	<input type="text"/> Not Set	<input type="text"/>

Delete Mitigation

Add Mitigation



## 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



# Exporting in PIRMA

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

[Export Risk+Mitigation Register](#)



A1	Mitigation Description	Owner	Due Date	Status	Related Risk	Notes
1	Mitigation Description					
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	TBD	Kylee Vonderharr		On Track	
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 w/Suppliers	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 x

Project Name\*  
Test/Learning Environment

Project Phase\*  
Define

Division  
PI

Franchise  
IO

Organization  
NPD

Project Status\*  
Active

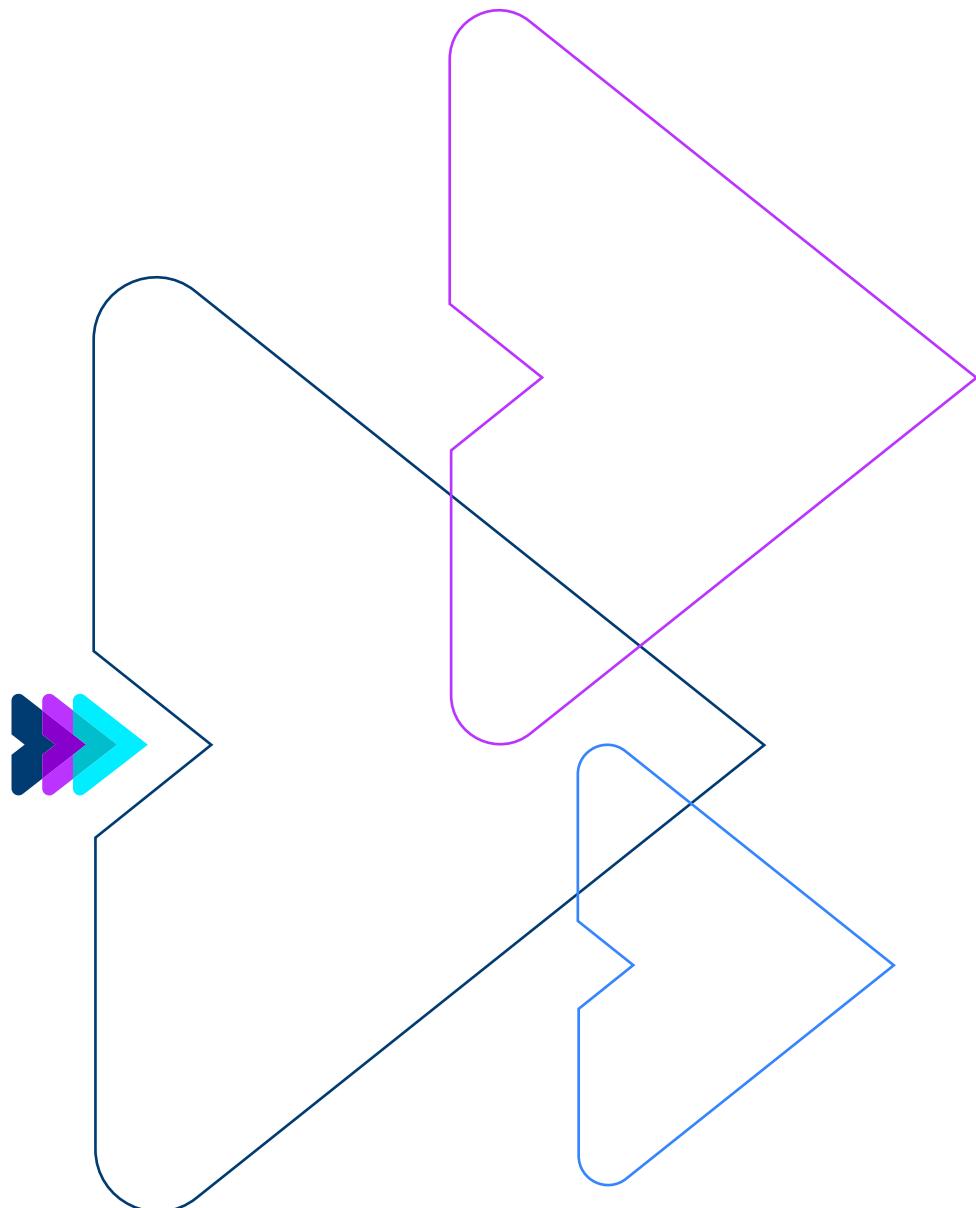
Not Set

Active

Cancelled

On Hold

Launched



**Thank you!**  
Please send questions to [PIPMOTeam@bsci.com](mailto:PIPMOTeam@bsci.com)