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INHOUSE Supply Point Evaluations & Decisions in SANITY

SANDOZ

CONTENT

1 SPC Business Process

* key differences 'old versus new'

2 Structure in SANITY

3 Requesting SPC Submission

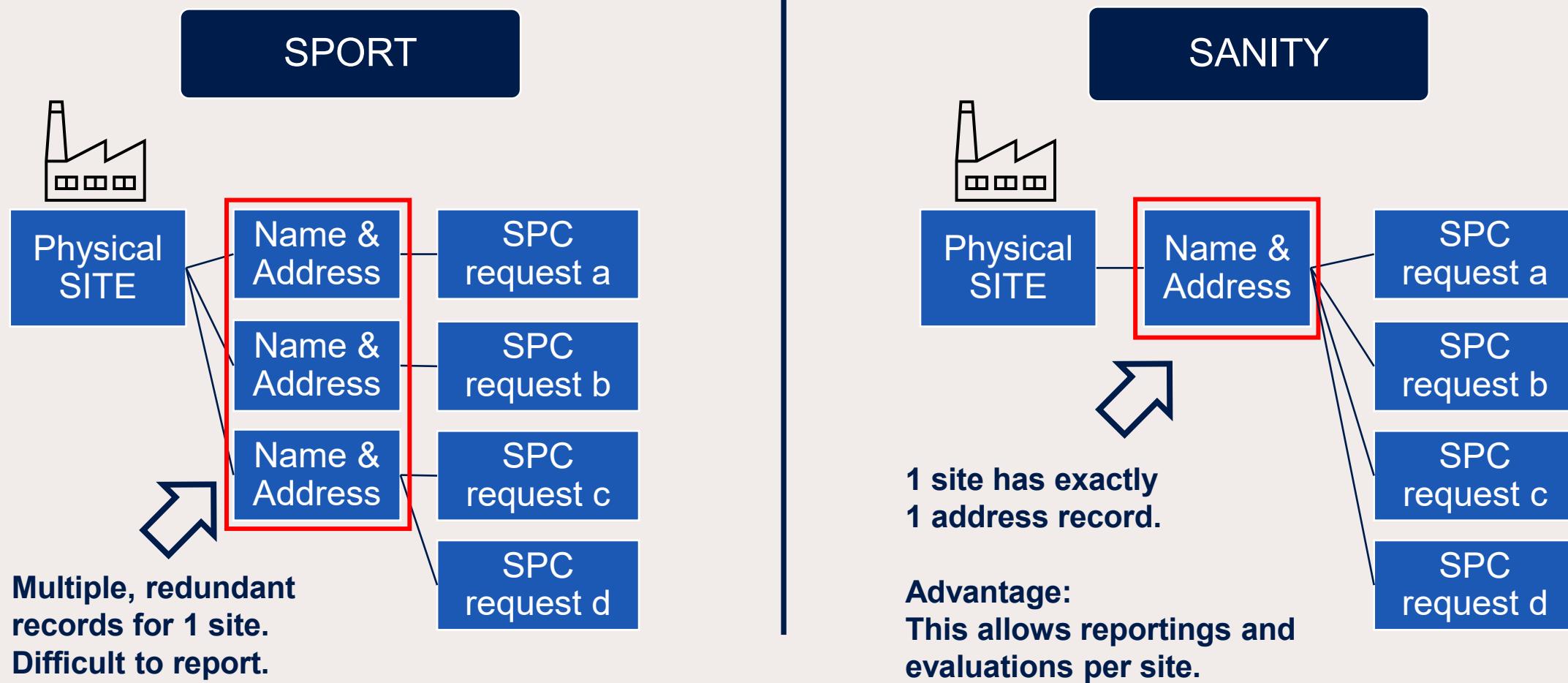
4 Transparency on SPC Submissions

5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

SPC Business Process: Key difference SPORT versus SANITY



CONTENT

1 SPC Business Process

2 Structure in SANITY

- * SPC Stage Gates
- * SANITY structure

3 Requesting SPC Submission

4 Transparency on SPC Submissions

5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

SPC Stage Gates in SANITY



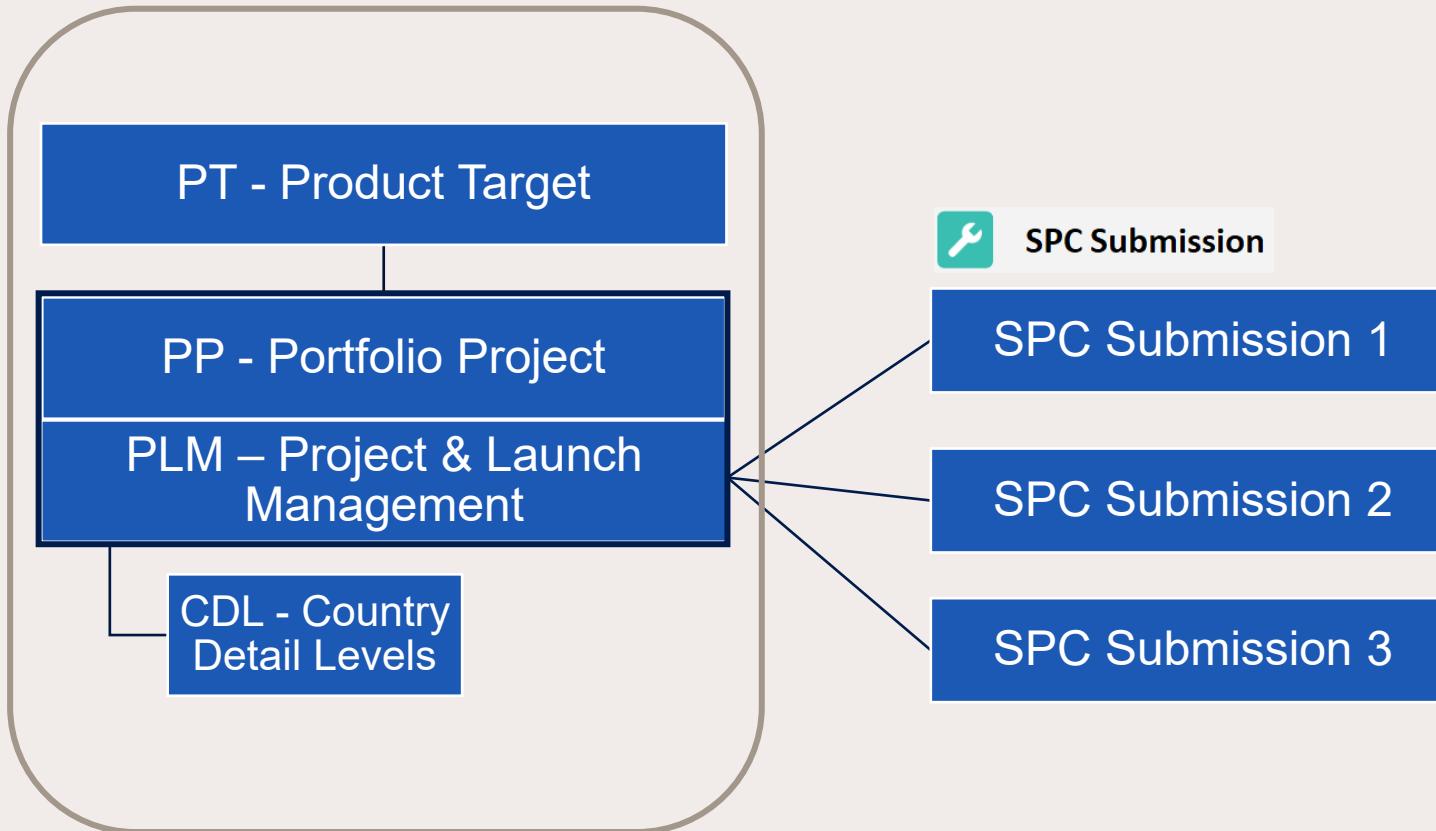
SPC Submission

SANITY SPC Submissions STAGE GATES & RESPONSIBILITIES:



STRUCTURE IN SANITY

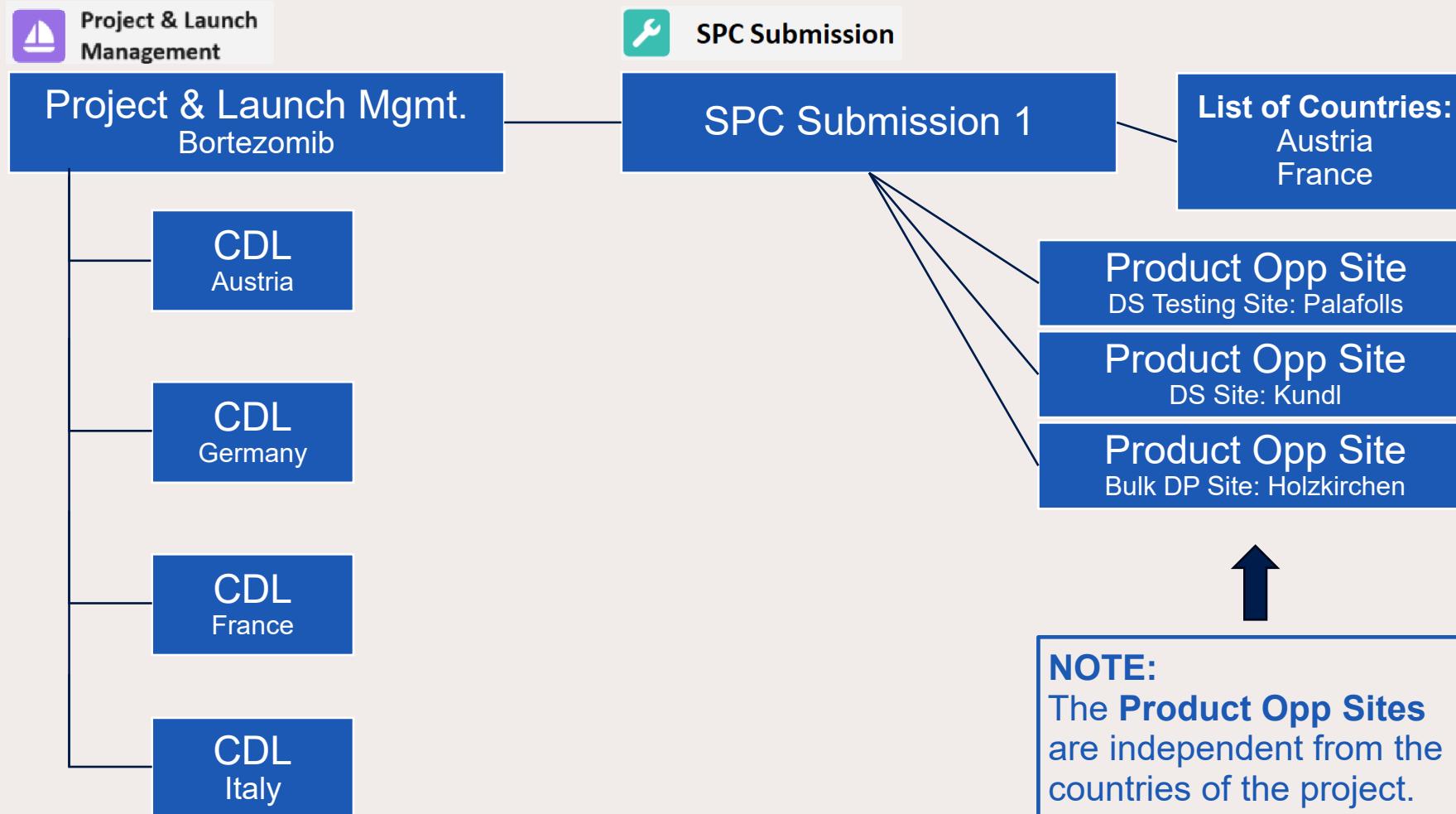
The SPC Submissions are linked to the PLM (Project & Launch Management)



- The **Core Structure** (PT, PP, PLM, CDLs) needs to be available to create a SPC submission.
- The **Project & Launch Management** is starting point to request a SPC submission.
- SPC Submissions are linked to the **Project & Launch Management**.

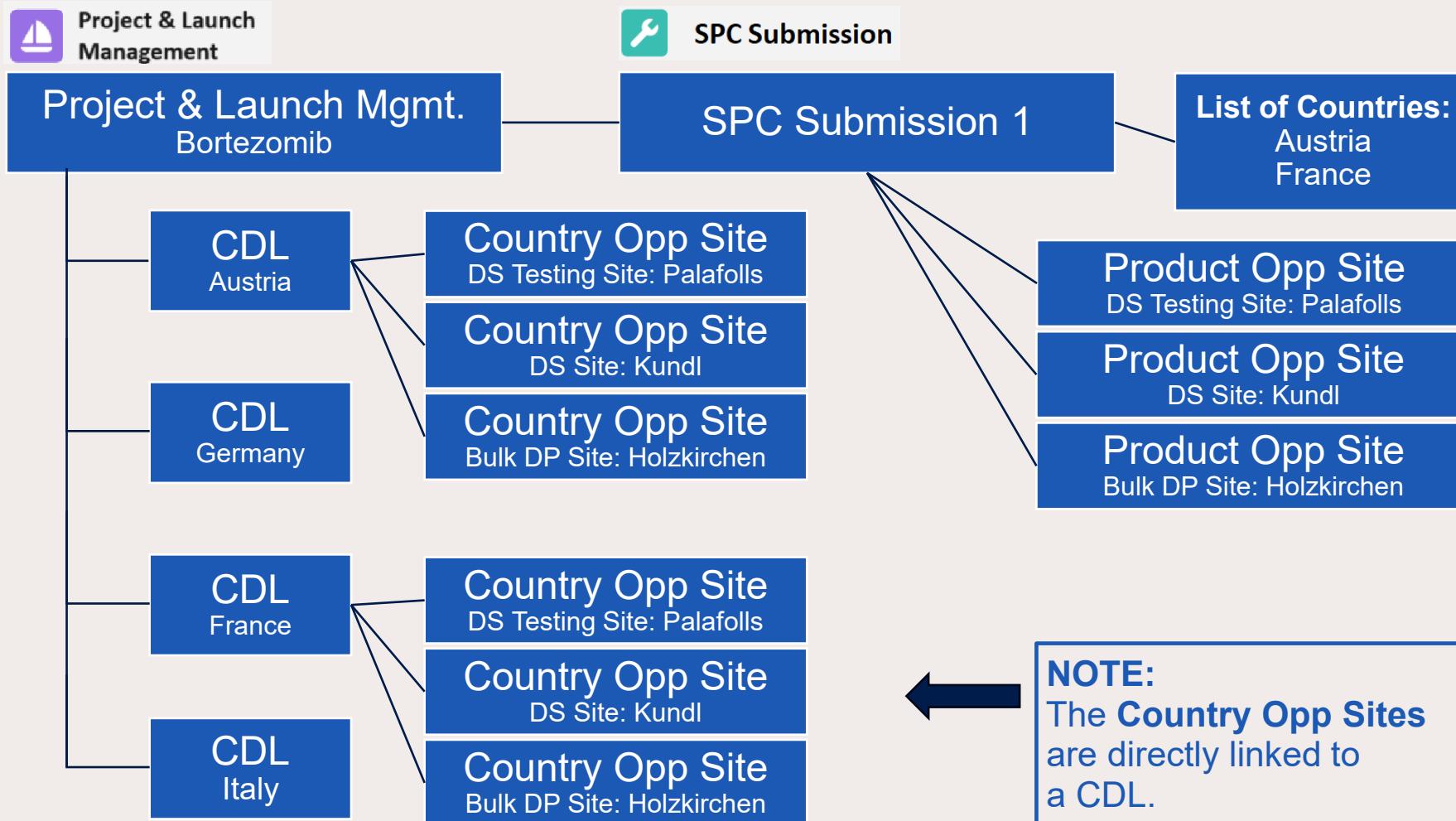
SUBMISSION

BEFORE APPROVAL: Sites are not linked to CDLs



SUBMISSION

AFTER APPROVAL: Sites are linked to CDLs



CONTENT

1 SPC Business Process
2 Structure in SANITY

3 Requesting SPC Submission

- * Requesting sites
- * Replacing a site
- * Submitting for evaluation

4 Transparency on SPC Submissions

5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

How to request a SPC Submission: Starting Point: Project & Launch Management



Project & Launch
Management

1

Open the Project &
Launch Management

2

„New SPEED SPC“

The screenshot shows the 'Project & Launch Management' interface for the product 'Ibuprofen FCT (302252) SDC DEHO'. Step 1 highlights the title bar. Step 2 highlights the 'New SPEED SPC' button in the top navigation bar. Step 3 highlights the 'SPC Wizard' window that opens after clicking the button.

Project & Launch Management
Ibuprofen FCT (302252) SDC DEHO

Overall Traffic Light Active Pre-Launch Countries Launched Countries Country Status Blank Interest Stage Blank Country Stages

0 4 25 35 Approved, In Registration, Launched, Active

Request Forecast Update Cancel Forecast Requests Edit Request Feedback **New SPEED SPC**

Details Project Timeline [In-House] Budget Team **[In-House]**

SPEED SPC Submissions (0)

Selected Sites & Scopes (No Countries) (0)

Sites & Scopes & Countries (0)

Supply Point Evaluations Home SPC Submissions

Speed SPC Wizard

New SPEED SPC request

Product API : Bortezomib
Dosage Form : LYVI
Project Strengths : 3 mg LYVI

SPC Wizard opens

SPEED SPC Wizard

Step 1: New SPEED SPC request

Speed SPC Wizard

New SPEED SPC request

Countries Selection

Selected Countries

Scopes Selection

SPC Request Creation

Close

Product API : Ibuprofen
Dosage Form : FCT
Project Strengths : 200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT

* Submission Type
New Launch

* Request Driver
Portfolio Development

* Request Rational
field: Request Driver

* Background
field: Request Rational

* Proposed Timeline
field: Proposed Timeline

Comments
field: Comments

Next

To skip the wizard without saving.

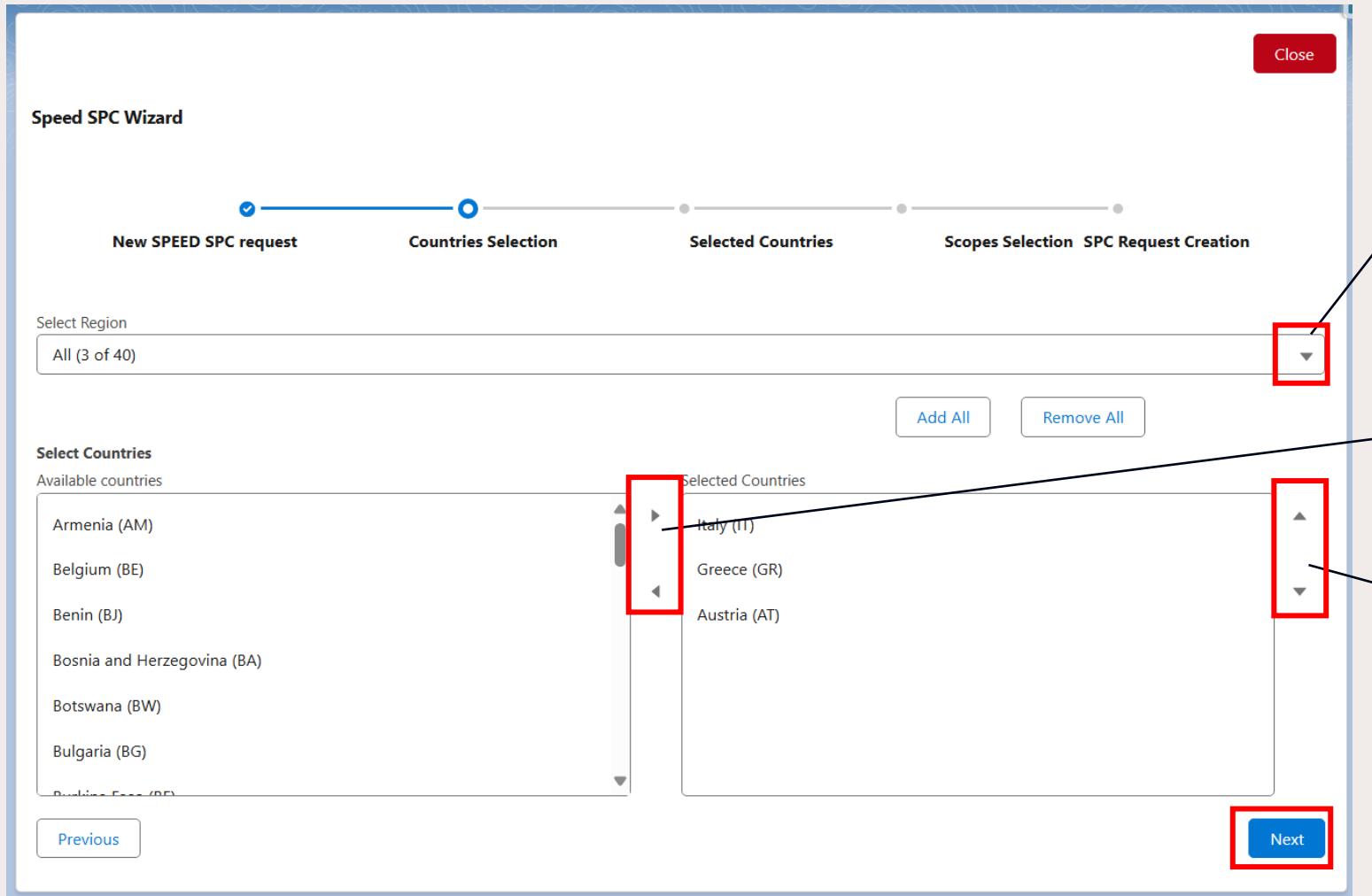
Mandatory to select one of the 4 options:

- New Launch
- Supply Chain Change
- Tech Transfer
- Scope Extension

Move to next step.

SPEED SPC Wizard

Step 2: Country Selector



Select region to make the number of available countries easier to handle

Mark the countries first, then you can select or de-select them

Marked countries can be sorted using these arrows

SPEED SPC Wizard

Step 3: Selected Countries

Close

Speed SPC Wizard

Progress Bar:

New SPEED SPC request Countries Selection **Selected Countries** Scopes Selection SPC Request Creation

Selected Countries

Europe : Portugal (PT),Romania (RO),Slovakia (SK),Slovenia (SI),Spain (ES)

NAmer : United States (US)

Previous

Change needed?
'Previous' brings you
back to step 2.

Useful to x-check
your selection

Next

In the next step, you
can specify the sites

SANDOZ

SPEED SPC Wizard

Step 4: Scopes Selection

Speed SPC Wizard

New SPEED SPC request Countries Selection Selected Countries Scopes Selection SPC Request Creation

Close

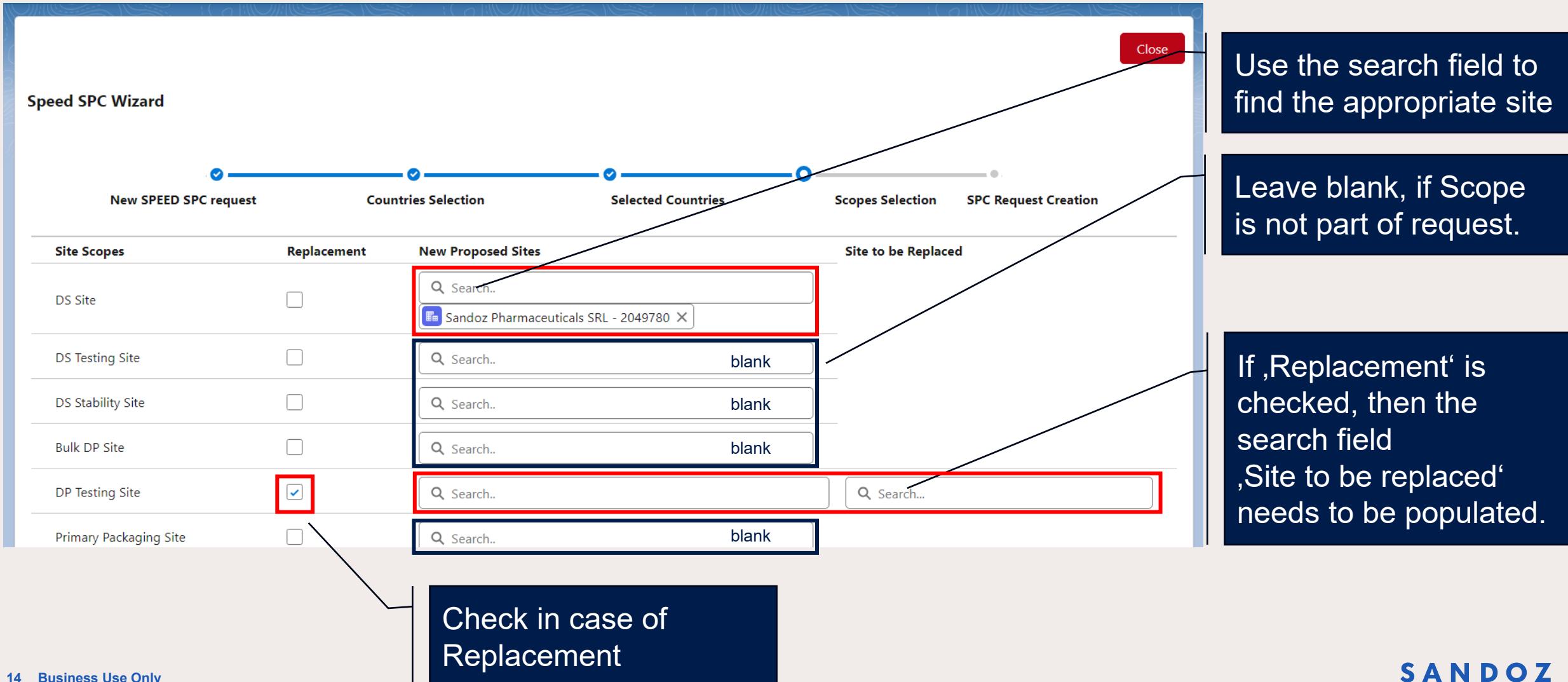
Site Scopes	Replacement	New Proposed Sites	Site to be Replaced
DS Site	<input type="checkbox"/>	<input type="text"/> Search...  Sandoz Pharmaceuticals SRL - 2049780 X	
DS Testing Site	<input type="checkbox"/>	<input type="text"/> Search... blank	
DS Stability Site	<input type="checkbox"/>	<input type="text"/> Search... blank	
Bulk DP Site	<input type="checkbox"/>	<input type="text"/> Search... blank	
DP Testing Site	<input checked="" type="checkbox"/>	<input type="text"/> Search...	<input type="text"/> Search...
Primary Packaging Site	<input type="checkbox"/>	<input type="text"/> Search... blank	

Use the search field to find the appropriate site

Leave blank, if Scope is not part of request.

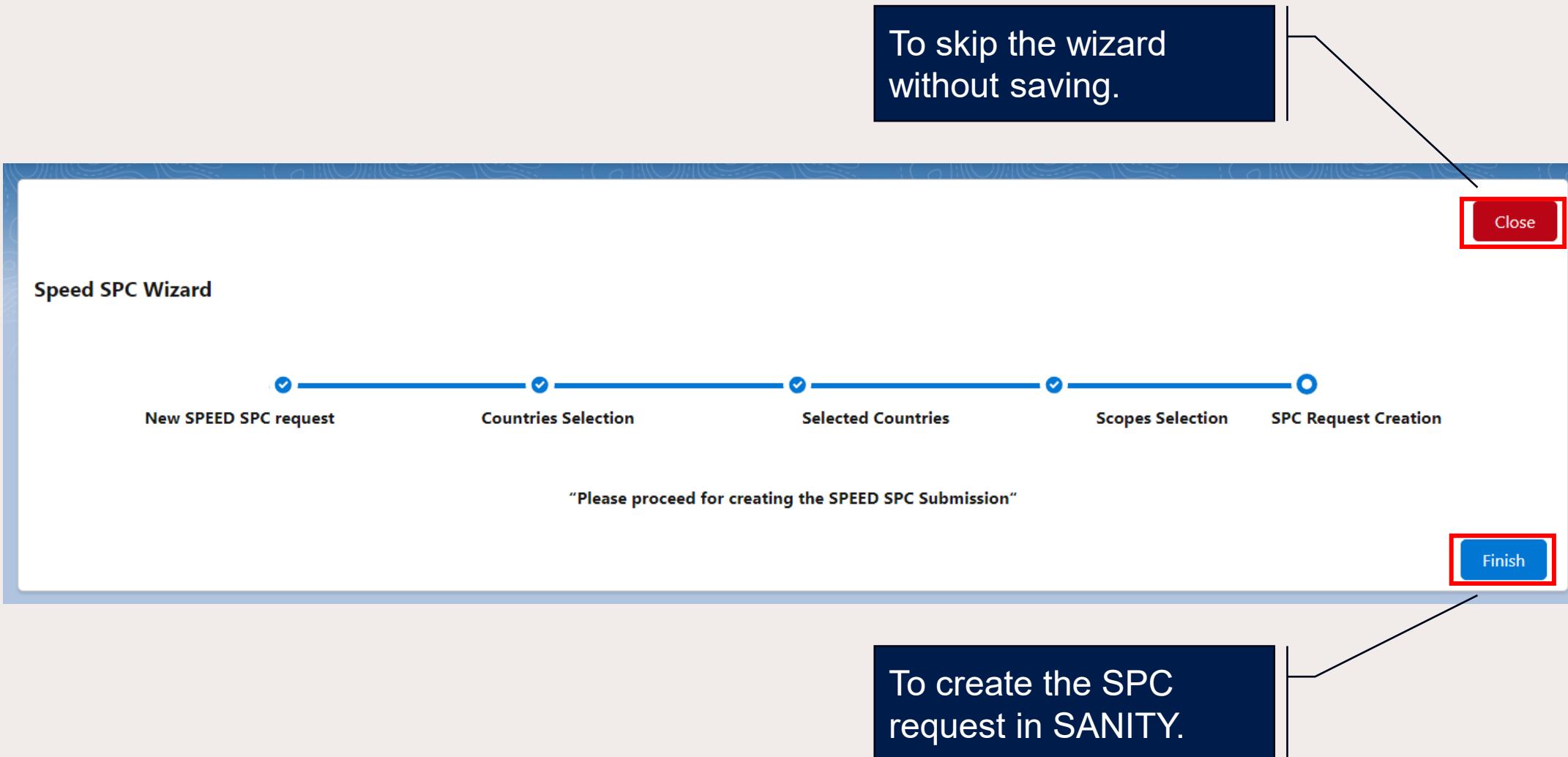
If 'Replacement' is checked, then the search field 'Site to be replaced' needs to be populated.

Check in case of Replacement



SPEED SPC Wizard

Step 5: SPC Request Creation



SPC Submission



SPC Submission

SPC Submission
[SPC00000195] Ibuprofen FCT [New Launch]

SPC Stage Gate SPEED Submission Subtype New Launch SPEED Evaluation Lead

SPEED Follow-Up Activities Approved

Request Information

General Information

SPC Submission Name	[SPC00000195] Ibuprofen FCT [New Launch]	SPC Stage Gate	SPEED
Product API & Dosage Form	Ibuprofen FCT	SPEED Requestor	Global In-House SPC Requestor BIO & SM Test User
Project Strength(s)	200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT	SPEED Evaluation Lead	

Submission Information

Request Rational	field: Request Driver	Background	field: Request Rational
Request Driver	Portfolio Development	Proposed Timeline	field: Proposed Timeline
		Comments	field: Comments

Countries

Countries in Selection: Italy (IT);Greece (GR);Austria (AT);Paraguay (PY);

Submission Type

SPC Stage Gate

Text fields from Wizard

Selected Countries

SPC Submission



SPC Submission

SPC Submission
[SPC00000195] Ibuprofen FCT [New Launch]

> Countries

Financials & Timelines

Financials	Launch + 5 Yr Net Sales	USD 0.00
Target Launch(es)	Target Regulatory Submission(s)	
First Technical Batch Date	Request Assignment Date	
First Patent Expiration	Planned Implementation Date	

Scopes (Roles)

DS Site	Under Evaluation	Bulk DP Site	Unchanged / Not Requested
DS Testing Site	Unchanged / Not Requested	DP Testing Site	Unchanged / Not Requested
DS Stability Site	Unchanged / Not Requested	Primary Packaging Site	Unchanged / Not Requested
Secondary Packaging Site	Unchanged / Not Requested	Release Site	Unchanged / Not Requested
DP Stability Site	Unchanged / Not Requested	Import Testing Site	Unchanged / Not Requested
Device Assembly Site	Unchanged / Not Requested	Sterilization Site	Unchanged / Not Requested

please use the sections below to see the sites and select/reject the ones where multiple sites are indicated for the same scope (role)

Sites Under Evaluation (multiple sites for same scope need selection) (1)

1 item • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link	Site Role	Replacement Site	Site Status	Site Comm...
1 DS Site: Sandoz Pharmaceuticals SRL - 2049780	DS Site		Under Evaluation	<input type="checkbox"/>

[View All](#)

Selected Sites (0)

Rejected Sites (0)

Financial information from Portfolio Management

Scopes selected in Wizard

Use this section to select / reject sites, if you have multiple sites per scope under evaluation

SPC Submission

Adding Sites



SPC Submission

You can add Sites
for further Scopes
to the same Submission

SPC Submission
[SPC00000195] Ibuprofen FCT [New Launch]

SPC Stage Gate: SPEED Submission Type: New Launch Submission Subtype: SPEED Evaluation Lead:

+ Follow Add Site (highlighted with a red box) Submit for Evaluation

SPEED Follow-Up Activities Approved Rejected Stopped

SPC Submission

Prepare to Submit for Evaluation



SPC Submission

SPC Submission
[SPC0000195] Ibuprofen FCT [New Launch]

+ Follow Add Site Move To Follow-Up Activities

Project Strength(s)	200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT	SPEED Evaluation Lead
Owner	Evaluation Leads	
Submission Information		
Request Rational	field: Request Driver	
Request Driver	Portfolio Development	
Background	field: Request Rational	
Proposed Timeline	field: Proposed Timeline	
Comments	field: Comments	

Attachment Acknowledgement

Attachment Acknowledgement

Files (1)

forecast for SPC submission
21-May-2025 • 18KB • pdf

[View All](#)

Prior to submission,
you need to

- Upload the file(s) with forecast information
- Flag the checkbox 'Attachment Acknowledgement'

SPC Submission

Where to find the Forecast information



Project & Launch Management

Project & Launch Management

SDC SILJ

Request Forecast Update Cancel Forecast Requests Edit Request Feedback New SPEED SPC ▾

Created by [redacted] on 03.02.2015 at 22:11

Molecule

Country Status: Blank

Country Stages: Tentative approval / IP Hold, In Evaluation, Active, Discontinued, Approved, In Registration, Evaluated

Quip URL

PLM responsible(s): Owner: Antonio Vujicic, PM: Antonio Vujicic

PLM ID: PLM-416078-01

Unique ID: 416078

Yearly Launch Information

Speed Forecasting Information

The chart displays the cumulative forecast net sales for different countries over a six-year period. The total sales increase significantly from 2026 to 2031, reaching approximately 22 million units. The legend identifies the countries contributing to these sales.

Year	CA Canada	CL Chile	HK Hong Kong	AU Australia	CH Switzerland	DK Denmark	EE Estonia	ES Spain	FR France	IE Ireland	IT Italy	LT Lithuania	LV Latvia
2026	~3M	~1M	~1M	~1M	~1M	~1M	~1M	~1M	~1M	~1M	~1M	~1M	~1M
2027	~4M	~2M	~2M	~2M	~2M	~2M	~2M	~2M	~2M	~2M	~2M	~2M	~2M
2028	~5M	~3M	~3M	~3M	~3M	~3M	~3M	~3M	~3M	~3M	~3M	~3M	~3M
2029	~6M	~4M	~4M	~4M	~4M	~4M	~4M	~4M	~4M	~4M	~4M	~4M	~4M
2030	~7M	~5M	~5M	~5M	~5M	~5M	~5M	~5M	~5M	~5M	~5M	~5M	~5M
2031	~8M	~6M	~6M	~6M	~6M	~6M	~6M	~6M	~6M	~6M	~6M	~6M	~6M

Sum of Forecast Net Sales (converted)

Year

Forecast Country

- CA Canada
- CL Chile
- HK Hong Kong
- AU Australia
- CH Switzerland
- DK Denmark
- EE Estonia
- ES Spain
- FR France
- IE Ireland
- IT Italy
- LT Lithuania
- LV Latvia

[View Report](#)

As of Today at 18:19

Click on **View Report** to be able to download as excel file.

After downloading the report as excel file, please delete all countries in the excel file which do not belong to your SPC Submission.

SPC Submission Submitting for Evaluation



SPC Submission

'Submit for Evaluation' hands the submission over to the SPC Manager for evaluation.
Evaluators and Requestors will receive an email notification.

SPC Submission
[SPC0000195] Ibuprofen FCT [New Launch]

SPC Stage Gate: SPEED | Submission Type: New Launch | Submission Subtype: SPEED Evaluation Lead | SPEED Evaluation Lead

The request has been submitted for evaluation and is now under the responsibility of the evaluators.

SPEED → Follow-Up Activities → Approved → Rejected → Stopped

The action button changes from 'Submit for Evaluation' into 'Move To Follow-Up Activities', and the orange message on the SPC Submission indicates the change of responsibilities.

SPC Submission
[SPC0000206] Acetylcysteine POS [New Launch]

SPC Stage Gate: SPEED | Submission Type: New Launch | Submission Subtype: SPEED Evaluation Lead | SPEED Evaluation Lead

SPEED → Follow-Up Activities → Approved → Rejected → Stopped

Project & Launch Management

Where to find Sites & Submissions



Project & Launch
Management

The screenshot shows a project management interface with the following details:

- Project & Launch Management** header.
- Acetylcysteine POS (301998) SDC DEHO** project identifier.
- Request Forecast Update** and **Cancel Forecast Requests** buttons.
- [In-House] Supply Chain** tab is selected.
- SPEED SPC Submissions (4)** section with 4 items, updated "vor ein paar Sekunden".
- SPC Submission**, **SPC Stage Gate**, **Countries i...**, **SPEED Requestor**, and **SPEED Evaluat...** filters.
- View All** button.
- Sites and Scopes per Country** visualization:
 - Record Count: 0, 0.4, 0.8, 1.2, 1.6, 2.
 - Algeria: DS Site (blue bar).
 - Greece: DS Site (blue bar), Import Testing Site (dark blue bar).

All SPC Submissions with Stage Gate

If you want to filter for certain SPC Stage Gates, you can use 'View All'

Graphical representation for quick overview

Project & Launch Management

Where to find Sites & Submissions



Project & Launch
Management

Project & Launch Management
Acetylcysteine POS (301998) SDC DEHO

Request Forecast Update Cancel Forecast Requests Edit Create Risk & Issue New SPEED SPC Initiate

Details Risks & Issues Team Project Timeline Assessments [In-House] Budget **[In-House] Supply Chain** Countries & Fcsts More ▾

SPEED SPC Submissions (5)
5 items • Filtered by Record Type • Updated 4 minutes ago

Sites & Scopes & Countries (10+)
10+ items • Updated a few seconds ago

SPC Country Opp S...	SPC Country Opp Site: Site Name	SPC Country O...	SPC Count...	SPC Count...	SPC Country Opp Site: SPC Submission
1 SPC-Country-Site-00366	Hexal AG - 2045908	DS Site	Austria	Effective	[SPC00000139] Acetylcysteine POS [New Launch]
2 SPC-Country-Site-00367	Sandoz Private Limited (Kalwe) - 1073	DS Testing Site	Austria	Effective	[SPC00000139] Acetylcysteine POS [New Launch]
3 SPC-Country-Site-00348	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Spain	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
4 SPC-Country-Site-00349	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Romania	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
5 SPC-Country-Site-00350	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Algeria	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
6 SPC-Country-Site-00351	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Portugal	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
7 SPC-Country-Site-00352	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Slovenia	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
8 SPC-Country-Site-00353	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Slovakia	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
9 SPC-Country-Site-00354	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Spain	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]
10 SPC-Country-Site-00355	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Romania	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]

[View All](#)

To see this table, please scroll down
in '[In-House] Supply Chain'

Link opens the
SPC Submission

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
-
- 4 Transparency on SPC Submissions**
 - * Choosing the right APP
 - * List Views with SPC Submissions
-
- 5 Evaluating SPC Submissions
- 6 Site Status
- 7 Contact Persons

Supply Point Evaluation & Decision: Choosing the right APP



The image shows the SANITY app launcher interface. Step 1 highlights the 9-dot menu icon in the top-left corner. Step 2 highlights the search bar containing 'supply'. Step 3 highlights the 'In-House Supply Point Evaluations' app in the list of results.

- 1 Hover with your mouse over the 9 dots
- 2 Type 'supply' in search field
- 3 Select In-House Supply Point APP

Supply Point Evaluation & Decision: Finding the SPC Submissions



In-House Supply
Point Evaluations

Search... Home Accounts Project & Launch Management SPC Submissions

SPC Submissions Open Requests Assigned to Me

1 item • Sorted by SPC Submission Name • Filtered by My spc submissions - Record Type, SPC Stage Gate • Updated a few seconds ago

SPC Submission Name ↑	Product Opportunity	Prod... ↓	SPC ... ↓	Submission... ↓	Sub... ↓	Created By
[SPC00000174] citrin -X LDP [Supply Change]	citrin -X LDP- Sandoz Dev	SPEED	Supply Change	Global In-House SPC Manager BIO &		

SPC Submissions All Requests Submitted for Evaluation

3+ items • Sorted by SPC Submission Name • Filtered by Evaluation Leads - Record Type, Owner Alias • Updated a few seconds ago

SPC Submission Name ↑	Product Opportunity	Product API & Dosage Form	Pro... ↓	Submission ... ↓
[SPC00000160] Zolpidem tartrate FCT [Supply Change]	Zolpidem tartrate FCT- SDC DEHO	Zolpidem tartrate FCT	Supply Char	
[SPC00000189] Glucosamine hydrochloride ASP [Supply Change]	Glucosamine hydrochloride ASP- SDC INHY	Glucosamine hydrochloride ASP	Supply Char	
[SPC00000190] Iron gluconate APW [Supply Change]	Iron gluconate APW- SDC DEHO	Iron gluconate APW	Supply Char	

SPC Submissions All Requests Under Evaluation

3 items • Sorted by SPC Submission Name • Filtered by All spc submissions - Record Type, SPEED Evaluation Lead, Assigned For Evaluation • Updated a few seconds ago

SPC Submission Name ↑	Product Opportunity	Product API & Dosage F...	Produc... ↓	Submission ... ↓
[SPC00000188] Vonoprazan fumarate FCT [New Launch]	Vonoprazan fumarate FCT- SDC ATKU	Vonoprazan fumarate FCT	New Launch	
[SPC00000192] Iron gluconate APW [Tech Transfer]	Iron gluconate APW- SDC DEHO	Iron gluconate APW	Tech Transfer	
[SPC00000193] Acetylcysteine GOSO [Tech Transfer]	Acetylcysteine GOSO- SDC DEHO	Acetylcysteine GOSO	Tech Transfer	

SPC Submissions All Approved Requests

3+ items • Sorted by SPC Submission Name • Filtered by All spc submissions - Record Type, SPC Stage Gate • Updated a few seconds ago

You are the **Evaluation Lead** of these SPC Submissions

All Submissions which are not assigned yet to an **Evaluation Lead**

All Submissions which are assigned to an **Evaluation Lead**

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
- 4 Transparency on SPC Submissions

5 Evaluating SPC Submissions

- * Taking ownership
- * Evaluation
- * Closing the SPC Submission

6 Site Status

7 Contact Persons

Supply Point Evaluation & Decision: Finding the SPC Submission



The screenshot shows a Salesforce page for "In-House Supply Po...". The top navigation bar includes a search bar, a star icon, a plus sign, a question mark, a gear, a bell, and a user icon. The main menu items are Home, Accounts, Opportunity Detail & Diligences, and SPC Submissions (which is highlighted with a red box and circled with a blue number 1). A sidebar on the right lists "Select SPC Submissions", "Search for API", and "Open the SPC Submission".

The main content area displays "SPC Submissions All" with a search bar containing "acetylcy". It shows two items:

SPC Submission Name	Record Type	Business Timing View	Requested SPC date
[SPC00000154] Acetylcysteine POS [Supply Change]	SPEED SPC Submission		
[SPC00000139] Acetylcysteine POS [New Launch]	SPEED SPC Submission		

Each row has a checkbox next to it. The first row is highlighted with a red box and circled with a blue number 3, indicating the target item.

SPC Submission Record: Take ownership by changing the owner



SPC Submission

Change the owner

SPC Submission [SPC00000195] Ibuprofen FCT [New Launch]

+ Follow Add Site Change Owner Move To Follow-Up Activities

SPC Stage Gate SPEED Submission Type New Launch Submission Subtype SPEED Evaluation Lead

SPEED Follow-Up Activities Approved Rejected Stopped

Request Information

General Information

SPC Submission Name	[SPC00000195] Ibuprofen FCT [New Launch]
Product API & Dosage Form	Ibuprofen FCT
Project Strength(s)	200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT

SPC Stage Gate SPEED
SPEED Requestor Global In-House SPC Requestor BIO & SM Test User

SPEED Evaluation Lead
Owner Evaluation Leads

SANITY Linked Items

Project & Launch Management Ibuprofen FCT (302252) SDC DEHO

Product Opportunity Ibuprofen FCT- SDC DEHO

Portfolio Project Ibuprofen FCT (302252)

Attachment Acknowledgement

NOTE:
A mail notification gets automatically sent to the SPEED Evaluation Lead.

Fields get updated automatically

SPC Submission Record: Submission Information



SPC Submission

SPC Submission [SPC00000206] Acetylcysteine POS [New Launch]

SPC Stage Gate SPEED	Submission Type New Launch	Submission Subtype	SPEED Evaluation Lead Global In-House SPC Manager BIO & SM TestUser
SPEED		Follow-Up Activities	Approved

Request Information

General Information

SPC Submission Name	[SPC00000206] Acetylcysteine POS [New Launch]
Product API & Dosage Form	Acetylcysteine POS
Project Strength(s)	100 mg POS; 200 mg POS

SPC Stage Gate	SPEED
SPEED Requestor	Global In-House SPC Manager BIO & SM TestUser
SPEED Evaluation Lead	Global In-House SPC Manager BIO & SM TestUser
Owner	Global In-House SPC Manager BIO & SM TestUser

Submission Information

Request Rational	field: Request Rational
Request Driver	Portfolio Development

Background	field: Background
Proposed Timeline	field: Proposed Timeline
Comments	field: Comments

Values provided
in Wizard

SPC Submission: Selecting a Scope for evaluation



SPC Submission

SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

Sites Under Evaluation (multiple sites for same scope need selection) (4)

4 items • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1 DS Site: Medical-Sanitary Public Institution - T	DS Site		Under Evaluation	
2 DS Site: SANDOZ PRIVATE LIMITED - 2066169	DS Site		Under Evaluation	
3 DP Testing Site: WESSLING Hungary Kft - T	DP Testing Site		Under Evaluation	
4 DS Site: WUHAN GRAND HOYO - TMP-4464	DS Site		Under Evaluation	

[View All](#)

Selected Sites (0)

Rejected Sites (0)

Select Site to
change status

Product Opp Site: Decision made through Status change



Product Opp Site
SANDOZ PRIVATE LIMITED - 2066169

Site Status Under Evaluation Edit

Replacement Site

Site Role DS Site

Product Opportunity [Acetylcysteine POS- SDC DEHO -3](#)

SPC Submission [\[SPC00000206\] Acetylcysteine POS \[New Launch\]](#)



Available Options:

- Under Evaluation
- Selected
- Rejected

SPC Submission record: Review your decisions



SPC Submission

SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

Sites Under Evaluation (multiple sites for same scope need selection) (2)

2 items • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1 DS Site: Medical-Sanitary Public Institution - T	DS Site		Under Evaluation	
2 DS Site: WUHAN GRAND HOYO - TMP-4464	DS Site		Under Evaluation	

[View All](#)

Selected Sites (1)

1 item • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1 DP Testing Site: WESSLING Hungary Kft - T	DP Testing Site		Selected	

[View All](#)

Rejected Sites (1)

1 item • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1 DS Site: SANDOZ PRIVATE LIMITED - 2066169	DS Site		Rejected	

[View All](#)

MULTIPLE SITES PER SCOPE

- In SPC Stage **SPEED**, multiple sites for 1 scope are allowed
- If you select 1 of these sites, then all other sites of same scope are automatically 'rejected'

SPC Submission record: Stage ,Follow-Up Activities'



SPC Submission

Next, you need to change the SPC Stage into Follow-Up Activities.

The screenshot shows the SPC Submission record for submission [SPC00000206] Acetylcysteine POS [New Launch]. The top navigation bar includes 'Follow', 'Add Site', 'Change Owner', and a button 'Move To Follow-Up Activities' which is highlighted with a red box and circled with a blue number 1. Below the navigation bar, there are fields for 'SPC Stage Gate' (SPEED), 'Submission Type' (New Launch), 'Submission Subtype', 'SPEED Evaluation Lead' (Global In-House SPC Manager BIO & SM TestUser), and a progress bar with stages: SPEED, Follow-Up Activities, Approved, Rejected, and Stopped. A large blue arrow points from the 'SPEED' stage to the 'Follow-Up Activities' stage. The 'Follow-Up Activities' stage is currently selected.

! Pre-requisite is to have maximum 1 site per site scope !



SPC Submission record: Stage ,Follow-Up Activities'



SPC Submission

In Stage Follow-Up Activities,

- You can change the Submissions Information
- You can not change the site selections any more

The screenshot shows the SPC Submission software interface for a submission named [SPC00000206] Acetylcysteine POS [New Launch]. The top navigation bar includes the SPC Submission icon, the submission ID, and tabs for SPEED, Follow-Up Activities (which is active), and Approved. Below the tabs are sections for Request Information, Evaluation Information, Team, and Follow-Up Activities. The Request Information section is currently selected. It contains fields for General Information, Submission Information, and a large area for Comments. The Submission Information section is highlighted with a red box. A blue callout box labeled "Submission Information" points to this red box. The right side of the interface shows a dark sidebar with various icons.

SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

SPEED Follow-Up Activities Approved

Request Information Evaluation Information Team Follow-Up Activities

General Information

SPC Submission Name	[SPC00000206] Acetylcysteine POS [New Launch]
Product API & Dosage Form	Acetylcysteine POS
Project Strength(s)	100 mg POS; 200 mg POS

SPC Stage Gate Follow-Up Activities

SPEED Requestor	Global In-House SPC Manager BIO & SM TestUser
SPEED Evaluation Lead	Global In-House SPC Manager BIO & SM TestUser
Owner	Global In-House SPC Manager BIO & SM TestUser

Submission Information

Request Rational	field: Request Rational
Request Driver	Portfolio Development

Background	field: Background
Proposed Timeline	field: Proposed Timeline
Comments	field: Comments

Submission Information

Supply Point Evaluation & Decision: Closing the SPC Submission



SPC Submission

SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

SPC Stage Gate Follow-Up Activities Submission Type New Launch Submission Subtype SPEED Evaluation Lead
Global In-House SPC Manager BIO & SM TestUser

SPEED Follow-Up Activities Approved Rejected Stopped

A large blue arrow points from the main interface down to the 'Close SPC Submission' dialog.

Close SPC Submission

Please select the final stage, and please note that you will not be able to move the stage back after the closure.

Approved — The request is approved and all the selected sites in the background will be created for each country in scope for the submission.

Rejected — The request is negatively closed with the with no further actions and no site record created in the background.

Stopped — The request is negatively closed with the with no further actions and no site record created in the background.

Finish

A large blue arrow points from the main interface up to the 'Close SPC Submission' dialog.

SPC Submission: Sites & Scopes Per Country



SPC Submission

SPC Submission
[SPC0000206] Acetylcysteine POS [New Launch]

SPEED Follow-Up Activities Approved

Request Information Evaluation Information Team Follow-Up Activities **Sites & Scopes Per Country**

Sites & Scopes per Country

Record Count

Country	Site Scope
Algeria	DP Testing Site
Austria	DS Site
Belarus	
Greece	
Hungary	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	

[View Report](#) As of Today at 9:44 AM C

[Effective] Sites & Scopes per Country (10+)

10+ items • Sorted by Country • Filtered by Site Status • Updated a few seconds ago

SPC Country Opp Site Name	Site Name	Site Scope	Country	Site Status
1 [DP Testing Site] Prod Opp L-6345 [DZ]	WESSLING Hungary Kft - T	DP Testing Site	Algeria	Effective
2 [DS Site] Prod Opp L-6346 [DZ]	WUHAN GRAND HOYO - TMP-4464	DS Site	Algeria	Effective
3 [DP Testing Site] Prod Opp L-6345 [AT]	WESSLING Hungary Kft - T	DP Testing Site	Austria	Effective

This navigation item gets generated during approval

Note:
In the approval step, new records will be generated for each site, site scope and country.

List with 1 record per site, site scope and Country

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
- 4 Transparency on SPC Submissions
- 5 Evaluating SPC Submissions

6 Sites

- * Possible values for Site Status
- * Requesting a new Site

7 Contact Persons

Sites Status Possible values



Product Opp Site

Manually selectable Site Status

- Under Evaluation
- Selected
- Rejected

Product Opp Site
Novartis Pharma Services Inc. - 2070543

Site Status	Under Evaluation	
Replacement Site		
Site Role	Release Site	

Automatically assigned Site Status

- Effective
This is the status right after approval.
It is not intended to replace this first site yet.
- To be replaced
If a new site has been selected, then the first site moves into 'To be replaced'.
- Dismissed
If a third site replaces the second site, then the first site moves into 'Dismissed'.





If a site is not available in SANITY

You can request the creation of a Site from the SANITY support team

Following information is required

- Account Name (Company Name)
- Billing Street
- Billing City
- Billing Zip/Postal Code
- Billing Country

Mail to: sanity.support@sandoz.net

CONTENT

- 1 SPC Business Process**
- 2 Structure in SANITY**
- 3 Requesting SPC Submission**
- 4 Transparency on SPC Submissions**
- 5 Evaluating SPC Submissions**
- 6 Site Status**

7 Contact Persons

- * Help to identify the right project
- * Help to setup a new site in SANITY

SPC Submission - Contact Persons

PROJECTS

Global Commercial Operations Team

- ✓ Help to identify the right project in SANITY
- ✓ Creating new projects in SANITY

➤ Nancy Kapoor, nancy-1.kapoor@sandoz.net

➤ Santhos Itikyal, santhosh_reddy.itikyala@sandoz.com

SANITY USAGE

Training Manager, SANITY Support Team

- ✓ Help how to use SANITY
- ✓ Technical challenges in SANITY
- ✓ Creating new projects in SANITY

➤ Bernhard Hauth, hauthbe3@sandoz.net

➤ sanity.support@sandoz.net

SITES

SANITY Support Team

- ✓ Providing extracts from SANITY
- ✓ To create a new site in SANITY

Important: Validation, if the site does not exist yet in SANITY, must be done before requesting the support team.

➤ sanity.support@sandoz.net

Following site information is required

- Account Name (Company Name)
- Billing Street
- Billing City
- Billing Zip/Postal Code
- Billing Country

S A N D O Z