

1. Partner Selected

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^ Scope Extension (Secondary) Deal Context:

Scope Extension Deals (Amendments to an already existing Agreement):

Scope Extension Deals upon creation by Business Operations would commence from the governance stage 'Partner Selected' (*Because the partner is already selected for the same product - INN, API & Dosage form combination, there is no need for early evaluation and partner selection process required again*) and already have a Product Opportunity DD (PSB Selected) linked to the BD Opportunity DD record on which the PSB & DRB Assessment & Approval for the initial deal were carried out. You could find this Opportunity DD record under 'Associated records & Status' section on the BD Deal page. BD and DD Teams will use the same Opportunity DD record to do the DRB feedback and approval for the scope extension deal. **Please don't create a new Opportunity DD record for Scope Extension Deals.**

As per the audit recommendations, all the risk assessments and approvals for a given product with a given partner covered under a parent agreement should all be available on one opportunity evaluation record ideally.

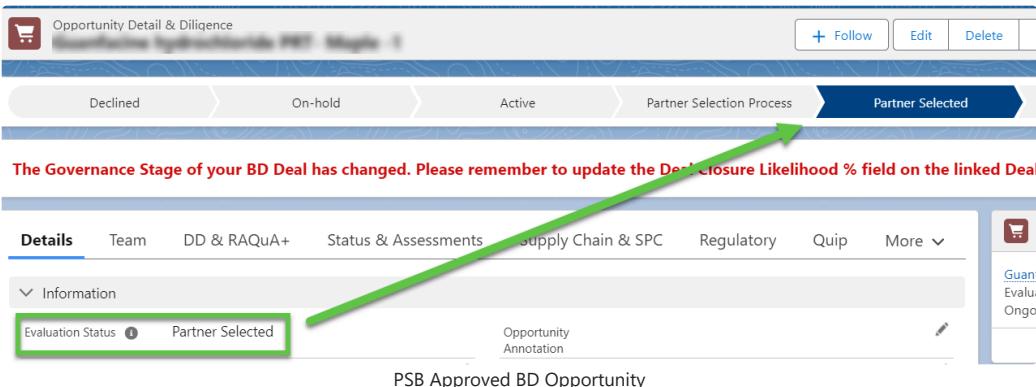
Please follow the instructions in [Step 3.3](#) to initiate separate DD and choose 'Confirmatory Evaluation/DRB'. Please note that, under the parent Opportunity DD there could be multiple Due Diligence records as many number of evaluations carried out. All would refer to the same Product Opportunity (Evaluation) Team set-up.

Before proceeding with DRB Feedback, BD Manager and DD Manager will update the Product Opportunity (Evaluation) Team by

1. Unchecking the 'Active Team Member' checkbox for the Team members who are not relevant for the ongoing evaluation.
2. Update 'Include in Feedback' and 'Include in Approval' checkboxes for the rest.
3. Add new team members when required with the instructions from [Step 3.4](#).

Upon completion of the team set-up for scope extension deals, the opportunity record is expected to have all the Product Opportunity (Evaluation) Team members who were involved in the risk assessment of the product offered by the partnership opportunity across all scopes and all strengths, including all the amendment opportunities.

^ Step 4.1. Update Discontinuation reason for Declined Partnership Opportunities



The screenshot shows the 'Opportunity Detail & Diligence' page for a deal. At the top, there's a navigation bar with 'Opportunity Detail & Diligence' and icons for '+ Follow', 'Edit', 'Delete', and a search bar. Below the navigation is a horizontal timeline with stages: Declined, On-hold, Active, Partner Selection Process, and Partner Selected. A green arrow points from the 'Partner Selected' stage to the 'Evaluation Status' field. The 'Evaluation Status' field is highlighted with a green border and contains the text 'Partner Selected'. Below the timeline, a red message reads: 'The Governance Stage of your BD Deal has changed. Please remember to update the Disclosure Likelihood % field on the linked Deal'. The bottom of the screen shows a footer with 'PSB Approved BD Opportunity'.

Responsibility: BD Manager;

Evaluation status of the BD Partnership opportunity DD record, which was **fully PSB approved**, would automatically be moved from 'Partner Selection Process' to 'Partner Selected'.

Consequently, Evaluation status of all the other BD Partnership Opportunity DD records under the BD Deal, would automatically be '**Declined**'.

For history tracking & documentation purposes, BD Managers are expected to record the reason for discontinuation of the declined BD opportunities, as follows.

When you scroll down on the Opp. DD record until the end, you will find the **System Information** section. Upon expanding the section, you could fill the following info.

1. **Discontinuation reason (Picklist)** - Choose the appropriate reason in the picklist
 2. **Discontinuation reason (text)** - Use this field to verbally record the reason for not going with this partnership opportunity.
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↖ Step 4.2. Update Milestones/Financial Obligations

Note on updating Probability to achieve on Estimated date:

1. The 'Probability to achieve on Estimated date' should be updated to 100% only if the milestone is achieved in reality and if the payment could be processed by the Invoice processing team.
2. Probability to achieve on Estimated date for 'License fees' Signature milestones will be automatically updated to **100%** upon marking the deal **'Contract Signed'**.
3. Probability to achieve on Estimated date for all milestones on a **stopped/on-hold** deal will be automatically updated to **0%**.

Basket deal cases:

If you have cases, wherein you owe collective amount to the partner for 2 or more products (meaning 2 or more BD deal records on SANITY),

1. Either split the amount and record on SANITY
 2. Or record the obligation collectively on the key product of the basket
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Responsibility: BD Manager;

Consulted: Finance BPA, Partner;

BD Managers are expected to record the identified financial obligations to be paid to the BD Partner/Supplier for a given BD Deal, with an estimated timeline to achieve such milestones as follows.

1. On the BD Deal record, Click on the 'Milestones' Tab
2. Next to the 'Financial Obligations' related list, click on the 'New' button.
3. Select the record type 'BD Budget'

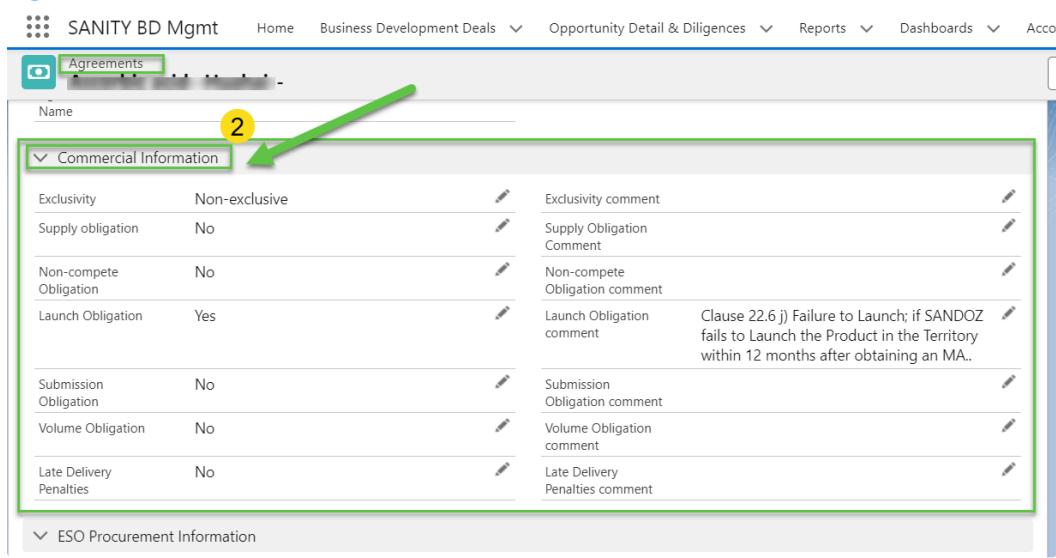
Fill in the following 10 fields mandatorily

1. Estimated date to achieve
2. Timing of milestone/payment in sequence
3. Cost Class
4. Cost Detail
5. D&R Relevance (Y/N)
6. Cost Type
7. Event Name
8. Cost Amount (& Currency)
9. Probability to Achieve on Estimated date
10. Business case/CAR (Select the CAR of the BD Deal)

Note:

1. If you have 10 milestones, you could use the 'Timing of Milestone/Payment in Sequence' field to denote the sequence of payment from 1 to 10. This would help you sort the milestones in the sequence of payment, when you see in reports/dashboards.
2. For detailed dependencies on 'Cost Class', 'Cost Detail', 'Cost Type' and 'D&R relevance', please refer here: [Financial Obligations - Cost Structure set up on SANITY.xlsx](#)
3. For doubts on 'D&R Relevance (Y/N)', please reach out to your Finance BPA.
4. Update 'Region' & 'Country' fields as appropriate
5. The terms 'Financial Obligations' and 'Milestones' are used synonymously in SANITY nomenclature.
6. Recording 'Regulatory fees' that could be paid from Local Organization on SANITY is subject to the reporting requirements in the region/alignment with Finance BPA.

^ Step 4.3. Recording Commercial Info. & Singing Entity on the Agreement



The screenshot shows the SANITY BD Mgmt application. The top navigation bar includes links for Home, Business Development Deals, Opportunity Detail & Diligences, Reports, Dashboards, and Accounts. The 'Agreements' tab is currently active. Below the tabs, there's a search bar and a list of agreements. A green arrow points to a section titled 'Commercial Information', which is enclosed in a green box. A yellow circle with the number '2' is placed over the 'Commercial Information' label. The main content area displays various obligation types (Exclusivity, Supply obligation, Non-compete Obligation, Launch Obligation, Submission Obligation, Volume Obligation, Late Delivery Penalties) with their respective status (e.g., Non-exclusive, No, Yes) and comments.

| Exclusivity | Non-exclusive | Exclusivity comment |
|-------------------------|---------------|--|
| Supply obligation | No | Supply Obligation Comment |
| Non-compete Obligation | No | Non-compete Obligation comment |
| Launch Obligation | Yes | Launch Obligation comment Clause 22.6 j) Failure to Launch; if SANDOZ fails to Launch the Product in the Territory within 12 months after obtaining an MA.. |
| Submission Obligation | No | Submission Obligation comment |
| Volume Obligation | No | Volume Obligation comment |
| Late Delivery Penalties | No | Late Delivery Penalties comment |

Click on the image to maximize

The screenshot shows the SANITY BD Mgmt software interface. At the top, there's a navigation bar with links like Home, Business Development Deals, Opportunity Detail & Diligences, Reports, Dashboards, and Account. Below that is a header for 'Agreements' with a sub-header 'Workshop - Sandoz - Restricted BD IP - Protection'. The main area has tabs for Details, Milestones, Teams, and All Related. Under Details, there's a section for Contract Information. A green arrow points to the 'Sandoz Signing Partner' field, which contains 'RCH080 - Sandoz AG'. A yellow circle with the number '4' is placed over this field. Other fields in this section include 'Target FDF' (with a value of 4), 'Contract effective date' (19.08.2024), 'Owner' (with a blue profile picture), 'Signature Date (Reporting)' (19.08.2024), and 'Estimated Expiration Date'.

Responsibility: BD Manager;

1. On the **BD Deal** record, under '**Associated Records & Status**' Section, click on the **Agreement** record.
2. Update all fields on the left side under '**Commercial information**' section, once finalized with the partner.
3. Wherever marked yes, please update the respective '**comment**' field on the right side.
4. Upon deciding the Sandoz Signing Entity for the deal and after alignment with the entity, **please update 'Sandoz Signing Partner'** field at the top left.

If at this point in time, you don't have a decision on which entity would you sign your deal with, please remember to update this information, whenever you confirm with the respective signing Entity. This is very crucial for tracking IP Ownership or Funds Flow Approval.

↖ Step 4.4. SPC Submission

Responsibility: BD Manager;

Consulted: ESO Functions;

Approvers: Supply Point Committee;

SPC stands for **Supply Point Committee** and is composed of the ESO department leadership. It's essential when the BD Deal is in the '**Partner Selected**' stage. SPC evaluates all the partners or suppliers involved in the BD Deal. After a detailed evaluation by the different involved departments, the ESO SPC Manager collects the assessments and presents them to the committee. The SPC will then be responsible for approving the partners/suppliers, which will allow the product's commercial launch.

For collecting inputs from the partner on the supply chain network, please use this: [Sandoz ESO Supply Chain Questionnaire 2023.docx](#)

4.1. Creation of SPC Submission record by BD

BD Manager leading the Deal is expected to create SPC Submission record on SANITY, which will be taken over by **ESO SPC Manager** who will then build a team for the respective business units to collect feedback post which **ESO QA Manager** will perform the evaluation and provide feedback for the specific BD Deal.

1. Click on the "**SPC & Agreement**" tab
2. In the '**SPC Submissions**' related list click "**New**". You will be redirected to the '**New SPC Submission**' page

3. Fill in the following fields:
 - a. **Launch Date** - to be populated with the date the product is planned to be launched
 - b. **Requested SPC Date** - to be populated with the date you wish to have the SPC meeting
 - c. **Day 1 / IP Launch Country** - select the appropriate option from the picklist
 4. After filling in all the fields click on "**Confirm**", and the SPC Submission record will be created
 5. If you have changed your mind and do not wish to create a new SPC Submission record, click "**Return**"
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-
-

4.2. Updating SPC Submission information by ESO SPC Manager

On the SPC Submission record, ESO SPC Managers are expected to record the following inputs:

1. **SPC #** - the number of the SPC Submission for the deal or the legacy number from an old system
2. **# of SKUs** - the number of SKUs to be considered during the BD Deal
3. **ESO Projected Launch Date** - to be decided after the ESO Lifecycle Manage and Launch Execution teams review the 'BD Planned Launch Date'
4. **Order Mgt Centre** - stands for 'Order Management Centre' and should be filled in as a part of additional Supply Chain information
5. **SRM/location** - stands for 'Supply Relationship Manager' and should be filled in as a part of additional Supply Chain information

The screenshot shows the "SPC & Agreement" tab of a Business Development Deal record for "Paracetamol DEV". The "SPC Submissions (0)" section is visible. The form contains fields for "Launch Date" (2023/02/13), "Requested SPC date" (2023/02/13), and "Day 1 / IP Launch Country" (None). Buttons at the bottom are labeled 5 ("Return") and 4 ("Confirm").

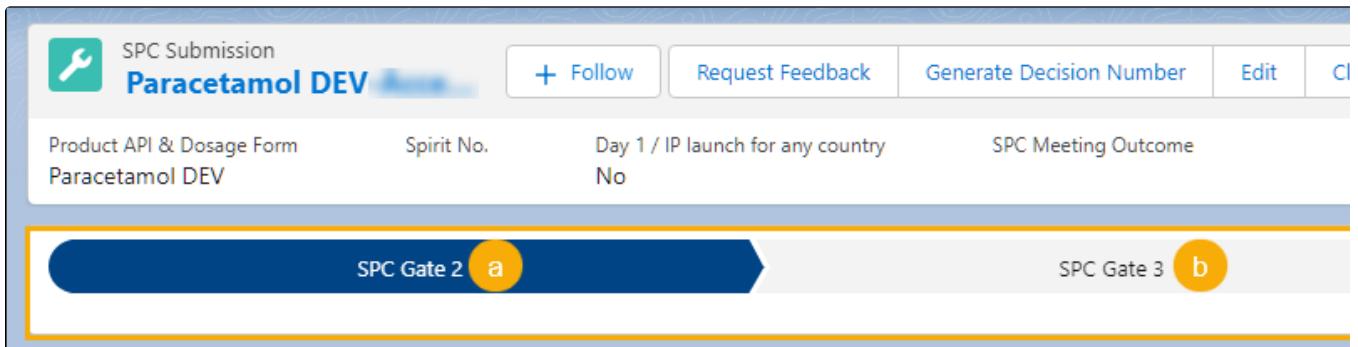
The screenshot shows the "SPC Submission" record for "Paracetamol DEV". It includes sections for "Activity History", "Additional Details" (with fields 6 and 7 for JustificationTxt and Risks/concerns), "Decision" (with fields 8 and 9 for ESO Recommendation and SPC Meeting Outcome), and "System Information" (with fields 10 for Record Type, Name, Owner, Last Modified By, and Created By).

6. JustificationTxt - to
 7. Risks/concerns - to there are no risks in
 8. ESO Recommendation presents the evaluat
 9. SPC Meeting Outco
 10. SPC Submission Na
-
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SPC Submission Stages

An SPC Submission record has two stages, in line with Supply Point Committee as follows. The SPC Stages can be easily seen or changed in the Path component of the SPC Submission record.

1. **SPC Gate 2** - this is the selected stage when the SPC Submission record is created. Here, ESO SPC Manager will start the process of evaluating the partners/suppliers involved in the deal and then, present the findings to the committee
2. **SPC Gate 3** - if the committee endorses the basic evaluation, the record moves to this second stage. Along with this, the 'SPC Meeting Outcome' field is set to 'SPC 2 under evaluation'. Here, the team created by ESO SPC Manager carries out a more detailed evaluation of their functions and submits their assessments. Lastly, ESO SPC Manager presents to the committee again, and the committee will decide on approving or rejecting the SPC Submission



Refer here for detailed steps on SPC Team set-up, Assessment, Site evaluation and how to access & use SPC Dashboard:

[SPC Assessment & Dashboard](#)

↖ Step 4.5. Trademarks/Trade Dress assessment

Responsibility: BD Manager;

Consulted: Legal Brand Protection;

Answer the following 6 questions from BD Project License Summary to determine, if

- Self-assessment from the BD Manager would suffice or
- You require an assessment from Legal Brand Protection (LBP)
 - Groeschel, Susanne <susanne.groeschel@sandoz.net>
 - Foot, Nicholas <nicholas.foot@sandoz.net>

| # | Trademarks & Trade Dress Assessment | (Y/N) |
|---|--|-------|
| 1 | Partner's brand name/Trademark(s) used in the final product | |
| 2 | Final product involves special medical devices like inhalers, auto-injectors or syringes | |
| 3 | Final appearance of the product is unknown until deal signature | |
| 4 | Product appearance (color, shape, imprint, embossment) is uncommon or identical to Ox. | |
| 5 | Primary packaging (e.g., syringe, nasal spray, eyedrops, vial) is uncommon or identical to Ox. | |
| 6 | Secondary Packaging (e.g., labels, inserts, boxes, wraps) is uncommon or identical to Ox. | |
| | If any of the above answers is 'Y', then DRB feedback from Legal Brand Protection (LBP) is required. | |
| 7 | DRB Feedback secured from LBP | |
| 8 | Follow-up required post contract signature | |

If-assessment of Trademarks & Trade Dress for Small Molecules BD Opportunities

out, if you require an assessment from LBP by answering the following 6 questions

Trademarks assessment:

1 Partner's brand/name to be licensed in or used in the final product?

No

Yes

Trade dress assessment:

2 Final product involves special medical devices like inhalers, auto-injectors, syringes or special patches

No

Yes

BD Managers are always encouraged to request Partner for pictures to Compare Ox Product & How Partner's final product will look like.

3 Final product appearance is unknown until deal signature

No

Yes

Request DRB Feedback from LBP explaining the situation & then mark 'Resolution needed after signature' In the contractual risk Mitigation section on SANITY.

BD Manager to assess using the following 3 criteria to determine if LBP's feedback is required

| | |
|----------------------|-----------------------------------|
| 4 Product appearance | Color, Shape, Imprint, Embossment |
|----------------------|-----------------------------------|

| | |
|---------------------|--------------------------------------|
| 5 Primary Packaging | Syringe, Nasal spray, Eyedrops, Vial |
|---------------------|--------------------------------------|

| | |
|-----------------------|-------------------------------|
| 6 Secondary Packaging | Labels, Inserts, Boxes, Wraps |
|-----------------------|-------------------------------|

All 3 are common and clearly distinctive from Ox.

If appearance of any of these 3 are uncommon or identical to Ox.

No need to request LBP for DRB Feedback!
BD Manager's self assessment would suffice

There is a dedicated section for 'Trademarks' on the BD Project License Summary document ([Standard template here](#)).
Please update your inputs as required.

^ Step 4.6. Contract Preparation & Review

Responsibility: BD Manager;

Consulted: Legal; Patents & Other business functions based on the deal requirements;

- Prepare a draft of the relevant Contract (LSA or Product Annex to Framework LSA etc.) ("Initial Draft") by using the relevant templates or the Product Annex template as attached to the relevant Framework Agreement.
- Access the latest [Global Legal owned Templates here](#).
- Include deal specific terms, conditions and mitigations in the Contract as aligned internally and discussed with the Partner
- Check if a functional review of the Initial Draft (e.g. by Patents, Regulatory, Quality, etc.) is necessary, depending on the risks and specific circumstances of the deal, which would require related material adaptations of the Global Contract Template.
- Request a review of the Initial Draft by Legal, prior to sharing it with the Partner. Upon review by Legal and other relevant functions, if applicable, share the Initial Draft with the Partner & negotiate
- Upon complete review by Legal and other required functions on the contractual terms, please send an email to Sandoz Signing Entity attaching the below 2 confirmations along with the finalized contract (PDF) in execution version.
 - CAR Approval
 - DRB Approval

- Implement changes received from the Sandoz signing party, if any, and align them with Legal & Partner
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In case of a new Framework LSA, request a suitable template from Legal. Global Contract Templates may be adapted to local market needs, local legal requirements, or other deal specifics by the relevant BD Manager in consultation and alignment with Legal. For deals in responsibility of the US BD team, US Legal will provide tailored Contract templates as needed.

Any exceptions (e.g. usage of a previously concluded contract, partner's template, etc.) shall be discussed and agreed with Legal, it being understood that the use of a partner's template shall only be considered under exceptional circumstances and require that BD Manager has, despite reasonable efforts, including escalation to the Regional BD Head, not been able to convince the Partner to use the Sandoz LSA Template and BD and Legal agree that the Partner's template is materially comparable to the Sandoz LSA Template.

Upon requesting DRB Feedback, the BD Deal will automatically move to '5) Confirmatory Evaluation'. Please [update Deal Closure Likelihood % as appropriate.](#)



Next: 5) Confirmatory Evaluation