. Early Evaluation

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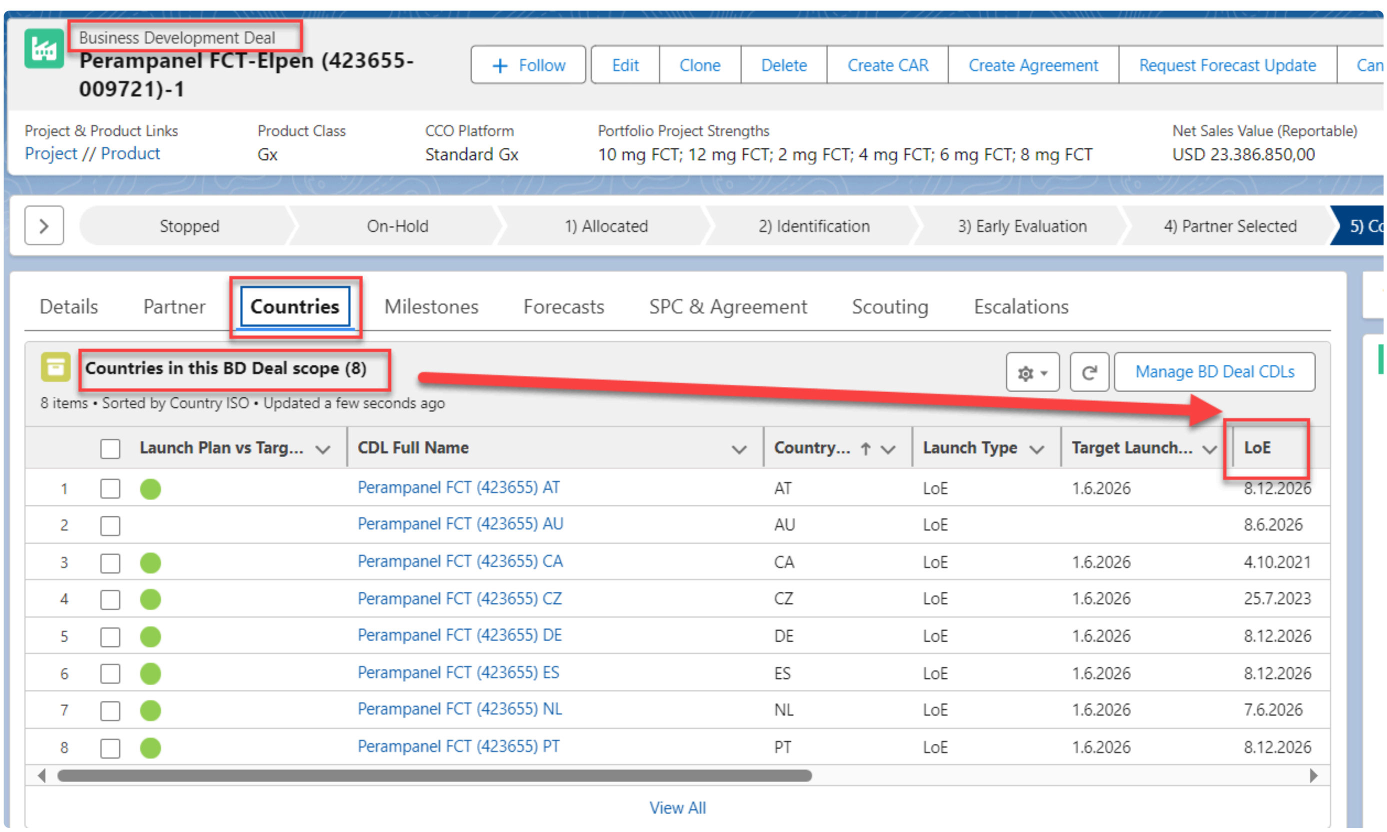
Step 3.1: Initiate IP Assessment (Calibration of earliest possible launch date)

Responsibility: BD Manager;
Consulted: Patents;

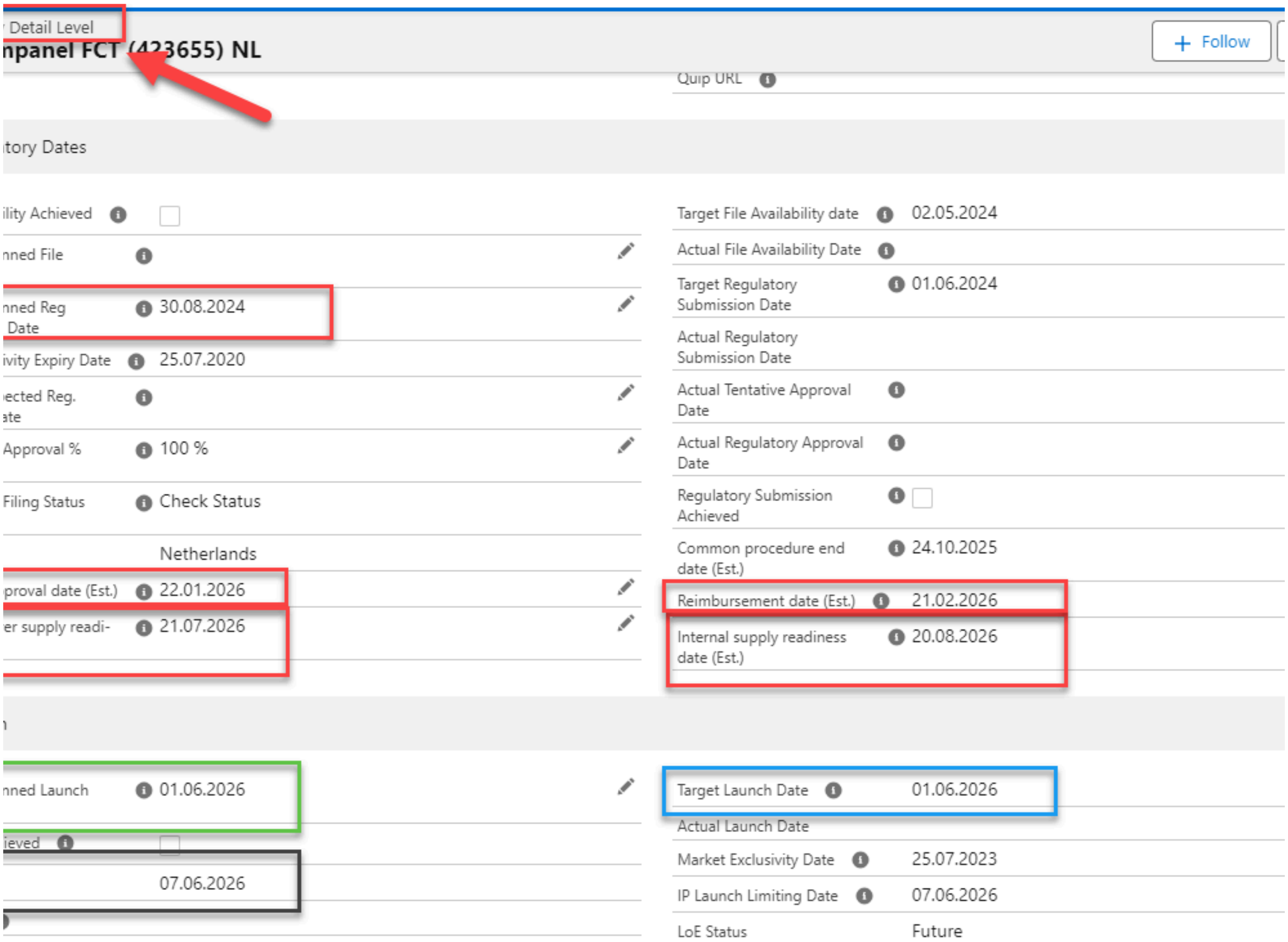
- Collect from the Partner IP relevant Information (with IP Questionnaire).
- Reach out to Patents team to talk to an IP attorney for Initial IP Assessment on LoE/Earliest possible launch date for each of the countries in scope of the deal execution and initiate FTO assessment.

<u>Launch Timeline Transparency:</u>

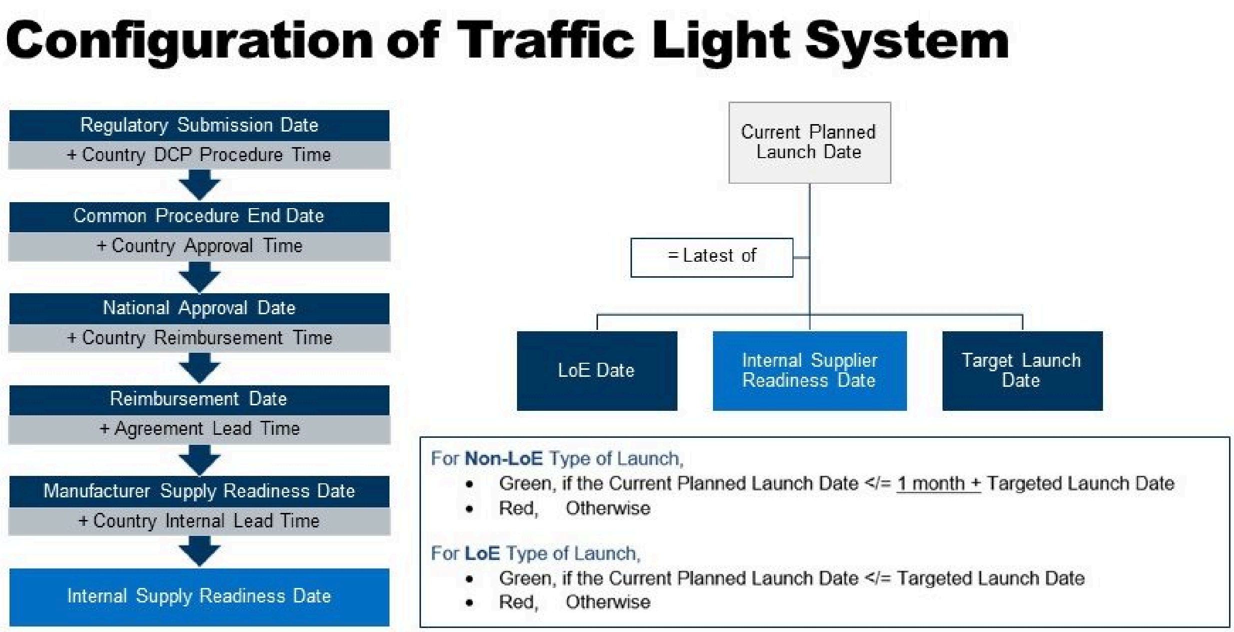
- For all countries officially selected at GPC, the LoE date is recorded in **Eagle IP** (Patents specific digital system) by Patents. This information from Eagle IP is synchronized with 'Country records' on parent Product Target, which then are transcended to 'Country Detail Level' (CDL) records on BD Deal. You could find this information on CDL records available under 'Countries' tab of the BD Deal record as shown below.



Ensure the availability of **Regulatory Submission Dates**, **LoE** or Market Formation Date and **Target Launch Dates** on the system for the individual countries in scope at this stage of the project and kindly reach out to **<u>Global Business Operations</u>** or **<u>Portfolio</u>** for missing details.



These highlighted dates along with Regulatory assumptions in calibration of earliest possible (Current Planned) launch date, as follows:

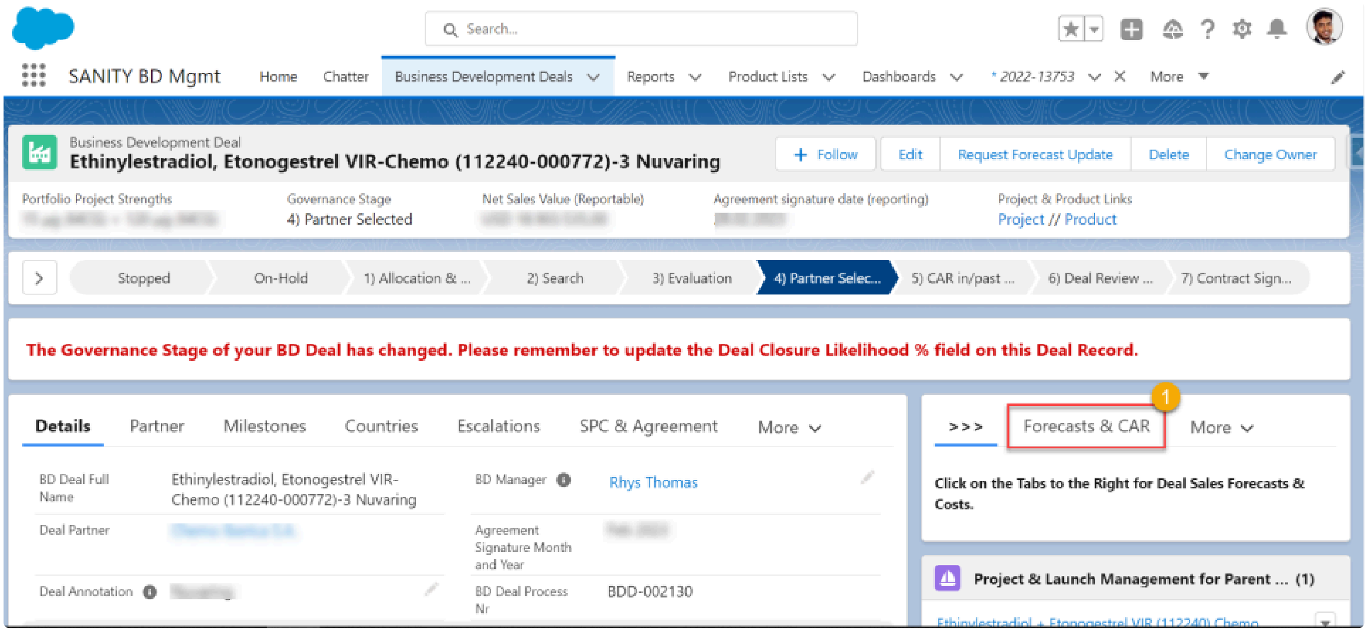


While choosing between partnerships, BD is recommended to prioritize the Partner who allows Sandoz to launch earliest or on the Targeted launch date.

Step 3.2: Preparation of draft CAR

Responsibility: BD Manager;
Consulted: Finance BPA, Business Operations;

1. To initiate negotiation of commercial offers with the Partner, start preparing a business case with Selection/Investment forecasts available on the BD Deal record.



2. Ensure you have the '**Countries in BD Deal**' field reflecting all the countries for which you look forward to include in the Business case.

Knowledge nugget:

- *Adding a country to the 'Countries in BD Deal' field, automatically inherits the CDL record from the Parent Portfolio Project (if the country exists in the Parent Portfolio Project) or creates a new **CDL** for the newly added country (if the country doesn't exist in the Parent Portfolio Project).*
- *The newly added CDL also connects the **forecasts** attributed to the country in scope of the BD Deal increasing the Sales value and helping you with preparation of the Business case.*
- ***If you miss forecasts for a specific country, the first thing to do is to check if that country has been added to the 'Countries in BD Deal' field.** After adding a country, it takes 20 minutes to inherit the right CDL and associated forecasts to the deal.*

3. If you see no forecasts as a result of #1 even after adding countries in scope of the deal, it means Forecasts are missing. Please '[Request Forecast Update]' in this case.

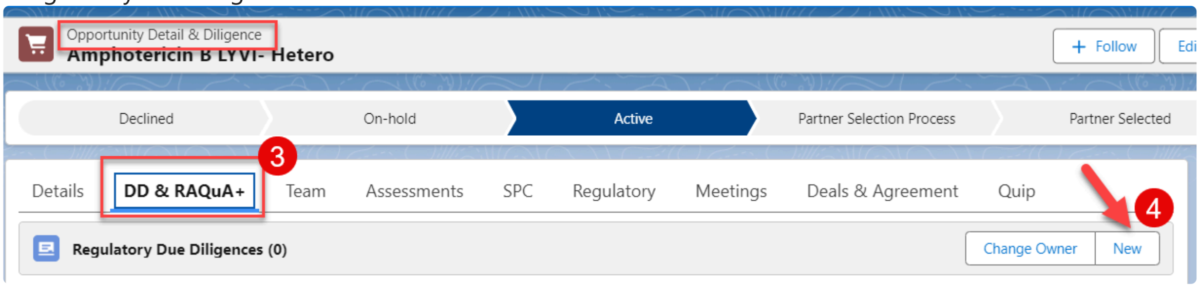
4. If you see forecasts as a result of #1, follow the instructions here to finish [CAR Preparation.]

Step 3.3: Internal DD Kick-off (+Reduced PSB)

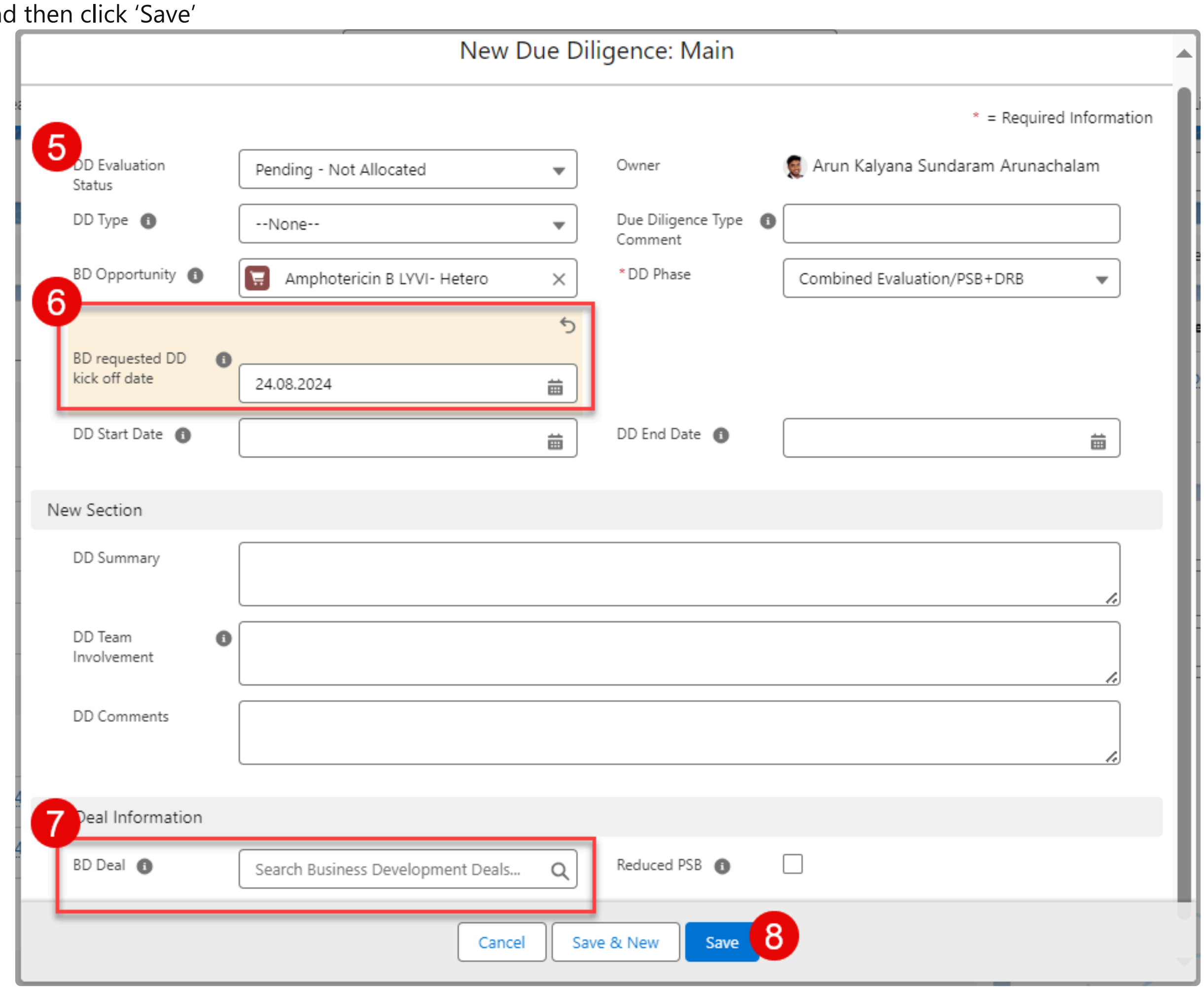
Responsibility: BD Manager & DD Manager;

BD Manager is expected to reach out to DD & BD Execution team requesting an internal DD kick-off meeting to initiate early evaluation of the opportunity via the following steps:

1. On the BD Deal record, please go to the '**Partner**' Tab.
2. Open the **Opp. DD** record for which you would like to initiate DD
3. Click the "**DD & RaQUA+**" tab
4. Under "Regulatory Due Diligences" click "**New**".



5. This will open a new window to create a new DD record, which would commence with '**DD Evaluation Status**' as '**Pending-Not allocated**'
6. Add the requested date for internal DD kick-off meeting on the '**BD requested DD kick-off date**' field (This is the date on which BD wishes the Due Diligence to be kick-started, considering the availability of Dossier, BD License Project Summary, Supply Chain Information, Financial checks, etc.
7. Please go to BD Deal Information and select the right '**BD Deal**' *(from the list of BD Deal records connected to the parent portfolio project)* for which you request for Due Diligence. *Note: The reason that this cannot be automated is because, multiple deals with different territories could be connected with the same partnership opportunity for contract amendment deals. So Due Diligence records need to be mapped to the right deal.* You could also make use of the comments fields to provide more information on Dossier availability, #partners in consideration or other information that might help DD and improve transparency across functions.
8. And then click 'Save'



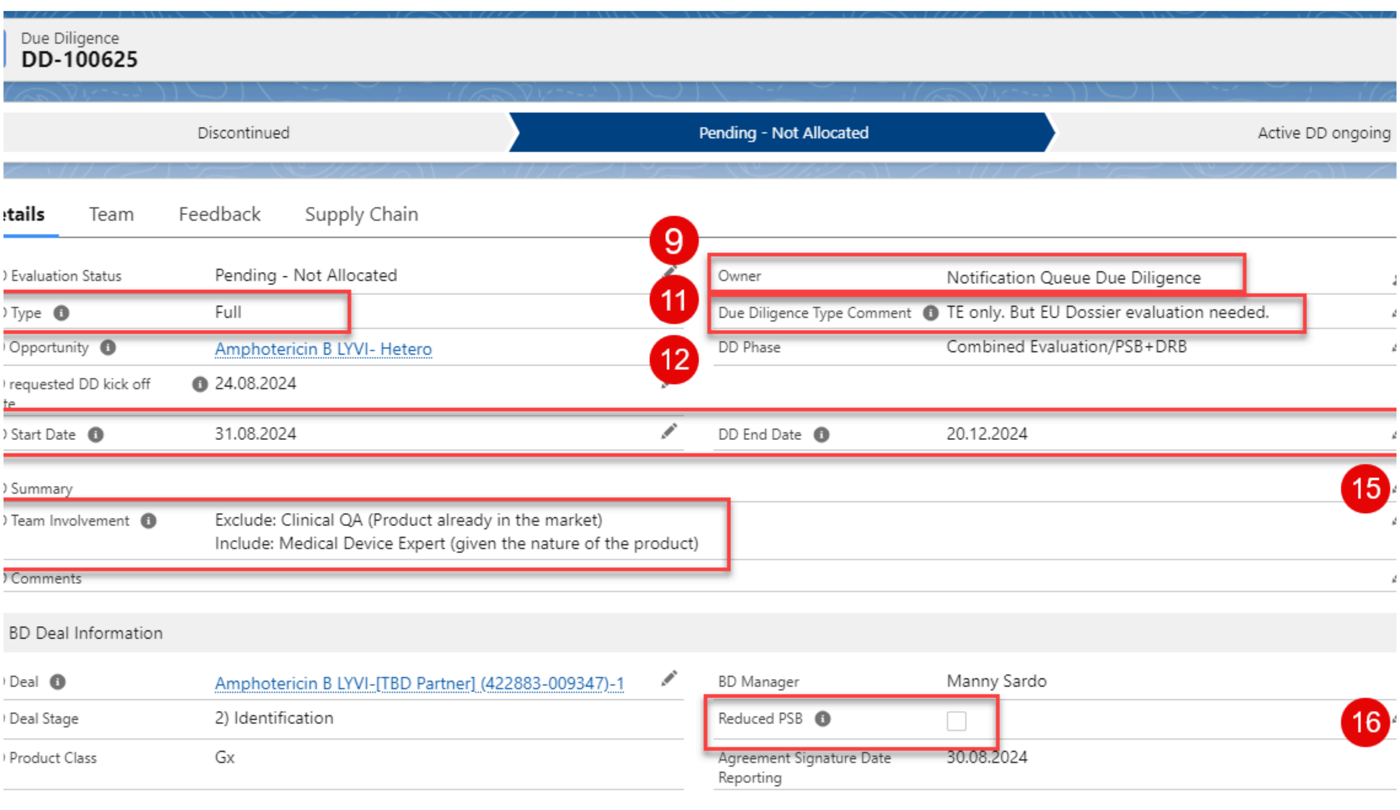
9. Upon completing the creation of DD record, the ownership will go to the **DD&BD Execution's Notification Queue Due Diligence**', which will then be transferred to the DD Manager who will be nominated by the Head of DD&BD Execution through an internal alignment.

DD Manager will then update the **Evaluation Status** from 'Pending not allocated' to 'Active DD Ongoing', once the DD Manager starts working on Due Diligence and then

10. Update the **DD Type** to 'Partial' or 'Full'
11. Explain the rationale for Partial/full Diligence on **DD type comment**
    a. E.g. "Territory Extension" or "Early Stage Deal" for 'Partial'
    b. Or "New Partner" or "Dossier Ready" for 'Full'
12. Choose 'Combined Evaluation/PSB+DRB' for **DD Phase**, unless there is going to be a separate Due Diligence for PSB and DRB, in which case, choose 'Early Evaluation/PSB' and 'Confirmatory Evaluation/DRB'. *Note: Most of the Small Molecules due diligence process carry combined due diligence, given the nature of diligence. The split is specifically facilitated for Biosimilars.*
13. Record Estimated the below dates and then update these fields with actual dates, once DD is begun & completed. This is important to improve reporting and transparency.
    a. '**DD Start Date**' - DD Manager starts working on DD
    b. '**DD End Date**' - DRB Approved
14. **DD Team Involvement** is a field with great significance for governance. Should the DD Manager decide there are changes to the ideal team set-up and
    - if one of the core functions need not be involved (E.g. Clinical QA for late stage deals or for products already in the market) or
    - if one of the extended functions need to be involved

    please record these deviations on the Involvement of functions in this field.
15. **DD Summary** field is dedicated for Biosimilars to signify your 'go/no-go' recommendations for the partner. For Small Molecules, this is captured as part of the DRB Feedback process, on the 'Opportunity Assessment' record (Feedback) created for Due Diligence.
16. **DD Comments** field is free text for BD and DD Managers to capture miscellaneous information or status updates.
17. DD Project documentation is set-up in DD **Project** folder in **Quip**. and linked under '**Quip**' section on the Opportunity DD Record.

Upon completion of DD, please update the **Evaluation status** to 'DD Finished' and 'DD End Date' with the actual date of closure.



Reduced PSB

There will be a leaner risk assessment process in the event of

- assessing a time critical launch opportunity,
- MA granted opportunity,
- In-distribution or In-licensing opportunity with a strategic partner with who we manage Alliance exclusively or
- if the partnership to be assessed is the only source available for the territory with acceptable timeline.
- any other opportunity that BD, ESO and DD&BD Execution Team together deems qualifying for reduced PSB.

16. This could only be decided by the 'DD & BD Execution' Team. DD Manager could tick the **'Reduced PSB' checkbox** on the DD record.

Note: BD Manager shouldn't update this checkbox for compliance reasons, but could request DD Manager to do so to depict DD Manager's acknowledgement for leaner evaluation process.

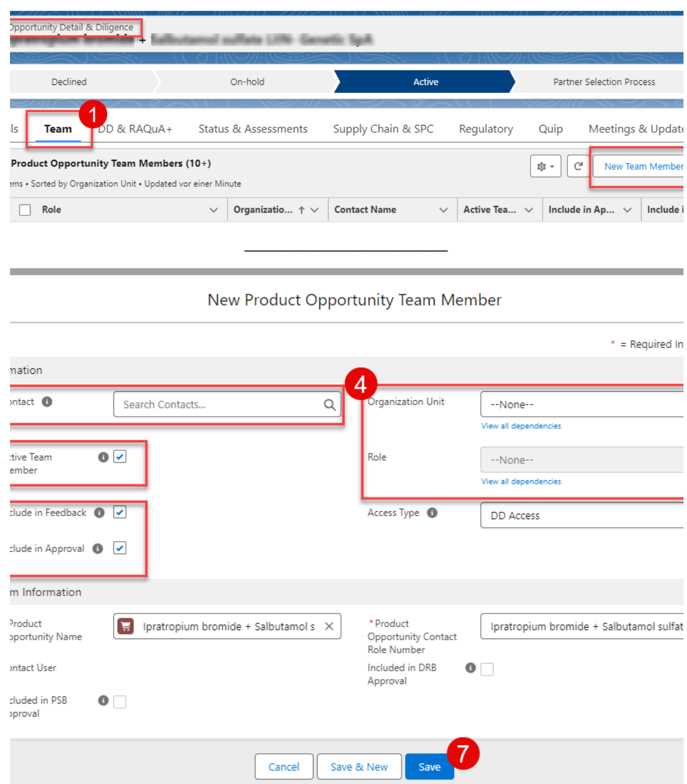
Opportunities that qualify for 'Reduced PSB' would suffice to have only DD Manager involved in the **PSB Feedback** process as written in PSB/DRB/CAR Approval for different BD Deal Types. However, there will not be any changes to the ideal list of functions to be involved in PSB Approval, DRB Feedback & DRB Approval for 'Reduced PSB' opportunities.

Step 3.4: DD Team Nomination & Set-up

Responsibility: BD Manager, DD Manager;
Consulted: DD & ESO Functions, Legal, Patents, Portfolio/Platforms;

Internal kick-off is expected to happen ideally 2 weeks after BD Manager reached out to DD Manager. In the event of delay potentially caused by limited bandwidth of the DD&BD Execution team, DD Manager aligns with BD Manager on the possible timeline for Due Diligence. DD & BD Execution Manager will set-up the internal kick-off meeting with all Functions who would be involved in the assessment of the BD Partnership opportunity (Including BD&L, Regulatory, Clinical, cQA, ESO Functions, MS&T, NPS&L, SC, QA, etc.). These functional members will be nominated by the respective functional heads based on the internal alignment within the function. Once decided, **Set up the Product Opportunity Team on SANITY.**

1. Go to the "**Opportunity Detail & Diligence**" record and click the "**Team**" tab
2. Click "**New Team Member**" on the "**Product Opportunity Team**" section, this opens up a pop-up window
3. Use an existing contact or create a new "**Contact**" *(If a contact you are searching for is missing on SANITY, reach out to Business Operations and please understand that, to be able to request feedback or approval or add a member to the Product Opportunity Team, he/she needs to have an active 'User account' and a 'Contact record' on SANITY.)*
4. Select their respective "**Organization Unit**" and "**Role**"
5. Tick "**Active Team Member**" if the person is actively involved in this opportunity
6. Tick "**Include in Feedback**" and "**Include in Approval**" to include the person in either Feedback or Approval requests or both, as per the guidelines



Significance of '**Access Type**' field:

- For '**Special**' access type (restricted) BD Deals,
  - selecting '**Full access**' provides this team member read only access for BD Deal & Opp. DD;
  - selecting '**DD access**' here provides this team member read only access only for Opp. DD record;
- For '**General**' access BD Deals (Small Molecules), this field doesn't matter as nothing is restricted anyways.

here: [PSB/DRB/CAR Approval for different BD Deal Types](). An example has been provided below.

ization Unit	Active Team Member	Include in Feedback	Include in Ap
ligence	☑	☑	☑
tory	☑	☑	☐
l	☑	☑	☐
l QA	☑	☑	☐
	☑	☑	☑
A	☑	☑	☐
	☑	☑	☐
Chain	☑	☑	☐
s	☑	☑	☐
o	☑	☑	☐
ement	☑	☑	☐
s	☑	☐	☑
	☑	☐	☑
al BD Head	☑	☐	☑
latforms*	☑	☐	☑

ote that these checkboxes are only a prelinimary list of who provides Feedback

7. Click "**Save**" and then repeat steps 2 to 7 to include more team members

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When you add a new team member to an opportunity, they will receive an **email notification**, similar to the one below, informing them that they are an active team member in that opportunity.

New Team Member

Rita

ear Sanity User,

ou have been added as a team member on the [Amiodarone hydrochloride LIVI - PHAROS]() .

ank you

- All Small Molecules Deals by default have 'General' access unless & until this is explicitly changed on the deal for restricted projects.

Adding Team Members

- DD Manager adds the Technical Functions
  E.g. Regulatory, Clinical, Clinical QA, ESO Functions including NPS&L, MS&T, SC and QA
  If applicable, also the extended team members from Medical, Toxicology, SDC Experts, Device & Scientific Affairs, etc.
- BD Manager adds the Non-technical Functions
  E.g. Patents, Finance, Portfolio, BD Regional Head, Legal & ESO Procurement

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Other Helpful links:

- [Set-up Product Opportunity Evaluation Team on SANITY]()
- [Contact Product Opportunity Team in one Email]()

Step 3.5: Recording Supply Chain Info.

Responsibility: BD Manager;
Consulted: ESO Functions & Partner;

Once BD Manager receives the list of supply chain sites and addresses from the partner, the BD Manager will create the required Site Accounts on SANITY following Step 5.1. and then adds the Site accounts as Product Opportunity Sites pertaining to the partnership opportunity.

Step 3.5.1. [Creating a Site Account on SANITY]()
Step 3.5.2. [Adding a Site Account as a Product Opportunity Site]()

Please find below the chart that depicts the list of business functions responsible for updating the required Supply Chain related information on SANITY at different stage gates of the Project.

count Info. Management on SANITY	Evaluation			Negotiation			Implementation			Product in tl	
	Source	Verify	Change	Source	Verify	Change	Source	Verify	Change	Source	Verif
ise Partner				BD			BD				
Production Site											
ntermediate Site											
· Site (E.g. Micronisation)											
or bulk manufacturing site				BD			ESO LCM	BDRA	ESO LCM		
ary packaging Site											
ndary packaging Site	BD										
nalytics Site					BDRA	BDRA					
ı Release Site				ESO SPC							
etesting Site											
lity							PM	PM	PM		
obiological				BD							
nportation site										Subject to alignm Syste	
bution site											
sor of Clinical Study											
cal Site	BD			BD	cQA	BD	cQA	cQA	cQA		
nalytical site											
. Statistical site											
lopment Site for non-integral cal device component											
ıfacturing site for non-integral cal device component	BD			BD	QA	BDRA	PM	QA	PM		
mbling site for medical device ponents											
lopment site for drug product ug device combination											

Step 3.6: PSB Feedback (Early Risk Assessment)

Responsibility: BD Manager;
Consulted: DD Manager, Partner, CCO Governance & Process; Business Operations; All Functions who are requested PSB Feedback;

In alignment with the DD & ESO Functions, facilitate seeking inputs from the partner to allow risk assessment by the Functions.
You could also use the standard templates available below for

- ESO Questionnaire 2024
  - Sandoz ESO Supply Chain Questionnaire 2023.docx
  - Technical Questionnaire_TRAQ_V06_15FEB2024.docx
  - FRM-8137205 Ver 2.0_ License Partner Questionairre.docx
  - FRM-8137228 (3) Manufacturer Questionairre Ver.3.0.docx

Once ready with the assessment,

1. **BD** will **Request PSB Feedback** after doing the preliminary checks.
2. **Functions** will **Provide PSB Feedback** on the Opportunity Assessment records.

Potential doubts/asks for help from BD:

- For list of functions to be included in the PSB Feedback, please refer here: PSB/DRB/CAR Approval for different BD Deal Types
- If a Functional member is new to digitally recording the assessment/approval on SANITY, please share this link: BD Onboarding for Functional Members for a quicker onboarding, which includes everything they need to know.
- Refer here for Handling Inactive Team Members Error message during Feedback/Approval
- If a specific function/member has been missed out while requesting PSB feedback, Request PSB Feedback individually.
- Both BD or Functions could easily Access/Track the status of Feedback requests.

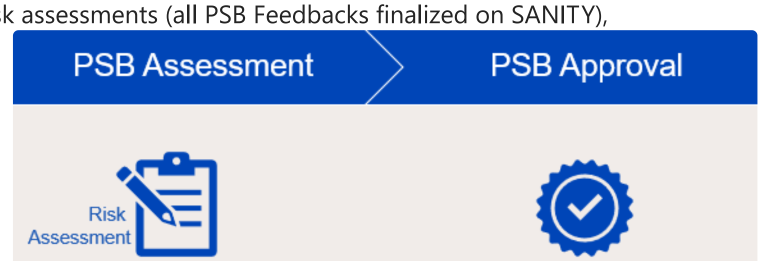
- If a functional member you requested PSB feedback is ooo or if another member is to be replaced, please Reassign the Feedback Request.

Only if you tried all the above links and still require help, contact *Business Operations.*

Step 3.7: PSB Approval

Responsibility: BD Manager;
Consulted: DD Manager, CCO Governance & Process, Business Operations;
Approvers: Partner Selection Board (DD, ESO NPS&L, BD Head, Patents & *CCO Platforms)

Only upon completion of risk assessments (all PSB Feedbacks finalized on SANITY),



1. BD will **Request PSB Approval** after doing the preliminary checks via the guidelines here.
2. Functions & BD Head will
   a. Either provide **Provide PSB Approval** on the Product Opportunity Team Member records.
   b. Or **Reject a PSB Approval Request** Or **Request for broader discussion**. which will automatically raise a Meeting Agenda Item for discussion in the monthly PSB/DRB Meeting.

Potential doubts/asks for help from BD:

- For list of functions to be included in the PSB Approval, please refer here: PSB/DRB/CAR Approval for different BD Deal Types
- If a Functional member is new to digitally recording the assessment/approval on SANITY, please share this link: BD Onboarding for Functional Members for a quicker onboarding, which includes everything they need to know.
- Refer here for Handling Inactive Team Members Error message during Feedback/Approval
- If a specific function/member has been missed out while requesting PSB approval, Request PSB Approval individually.
- Both BD or Functions could easily Access/Track Approval Requests.
- If a functional member you requested PSB Approval is ooo or if another member is to be replaced, please Recall/Reassign an approval request.

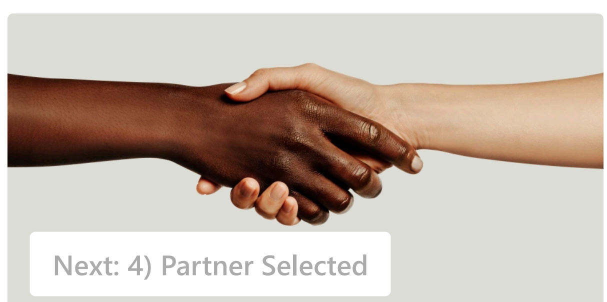
Only if you've tried all the above links and still require help, contact *Business Operations.*

Upon complete approval at PSB, automatically

- the BD opportunity will be moved to 'Partner Selected'
- the BD Deal will be moved to '4) Partner Selected'.

Please remember to manually

- update BD Project License Summary Document
- Deal Closure Likelihood % as appropriate



Next: 4) Partner Selected