5. Deal Approval

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Finance needs to possess an oversight of all Small Molecules BD Deals approaching contract signature/amendment (that might have a financial impact). So it is important to secure approval from Finance either at CAR or at DRB.

⌃ Should BD request DRB Approval (Step 6.1) or CAR Approval (Step 6.2) from Finance?

If your deal does not require investment/payment to the partner via margin price or profit share (in the event of no CAR),

- **Step 6.1.** please add Finance BPA to the Product Opportunity Team and request DRB Approval via SANITY. This is only in the event of a BD Deal requiring no explicit investment. E.g. Territory Extension signed with no additional cost or covered in 10% CAR buffer from the initial deal.
- and then please discuss with Business Operations to
  - Either delete CAR record on SANITY, in case of no CAR forecasts and no FOs
  - Or keep CAR record on SANITY, Update 'Financial Obligations relevance' as 'No', clone Portfolio Forecasts as CAR Forecasts (if required) and mark CAR signed with appropriate comments.

Else

- **Step 6.2.** please prepare a CAR and secure CAR Approval as advised below.

In case of doubts, always reach out to Finance BPA to decide on CAR preparation. Please keep Finance posted for any changes in Payment terms (Timeline/collection agreed), Supply prices & markup agreed, P&L impact, Insurance policies or Launch Timeline, to facilitate this oversight.

∧ Step 6.1: DRB Approval

Responsibility: BD Manager;
Consulted: DD Manager, CCO Governance & Process, Business Operations;
Approvers: Deal Review Board (DD, ESO NPS&L, BD Head, Patents & Legal)

Only upon completion of all contractual risk reviews for the DRB risk assessments (all DRB Feedbacks finalized on SANITY),

1. BD will **Request DRB Approval** after doing the preliminary checks.
2. Functions & BD Head will
   a. Either provide **Provide DRB Approval** on the Product Opportunity Team Member records.

   b. Or **Reject a DRB 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 DRB 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 feedback, Request DRB 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*.

⌃ Step 6.2: CAR Preparation, Approval & Digitization

Responsibility: BD Manager;
Consulted: Finance BPA & Business Operations;
Approvers: Regional Finance or SIRC or BoD

CAR stands for Capital Appropriation Request or Capital Allocation Request. An investment proposal to MAL for decision making on the expenditure for deal execution. **Any Small Molecules BD Deal requiring investment definitely needs CAR Preparation, Approval & Digitization.**

Step 6.2.1. CAR Preparation

To start with CAR Preparation, ensure you have Selection/Investment Forecasts (potentially Assumption based Forecasts) already linked to the BD Deal. Ensure to include all required countries in '**Countries in BD Deal**' field to automatically inherit Portfolio FCs into BD Deal scope. Once you have the required forecasts in scope of the BD Deal available for Extraction, please look out for '*Is Assumption Based?*' Checkbox field under each of the Forecast & Actuals record to help differentiate, if the Forecast Request records are established from *SPIRIT* or *SANITY*.

Please lease refer here for step by step instructions & also the **latest CAR Templates** on Extraction of Forecasts from SANITY & Preparation of CAR

Step 6.2.2. CAR Approval

Upon preparation of CAR and reviewing FOs, submit the CAR for approval from the approval body specific to investment thresholds and the region.

- <5mUSD: 1. Regional Portfolio Head, 2. Global/Regional BD Head and 3. Global BD&L and M&A Finance Head
- >5mUSD: SFGC (Sandoz Finance & Governance Committee)
- >100mUSD: BoD (Board of Directors)

For more details on MAL approval, please refer to [Sandoz MAL](#)

Step 6.3.3. CAR Digitization

Responsibility: Accenture DST;

Lead Time: 2 Business days (after the acknowledgement of request on SANITY Chatters)

1. Double check, if all the **FOs** part of **CAR Excel** are reflected on **SANITY** and create the missing ones until they match exactly.
2. Update 'Financial Obligations Relevance' field on the CAR record as 'No', if there are no financial obligations to the partner and 'Yes', otherwise.
3. Upload the fully approved CAR PDF (should contain signatures of all parties as advised in MAL guidance) and final CAR Excel Sheet
   a. Partially approved CARs (pending signatures) shouldn't be requested for digitization on SANITY.
   b. Only the final CAR Excel sheet should be uploaded replacing obsolete versions. Final sheet is the one that is approved.
4. Use the chatter functionality on SANITY to request CAR Digitization from Data Stewards (Accenture Colleagues who are trained to translate info. from CAR Excel to SANITY Forecasts) like below:

If your digitization request notification is received, your request will be acknowledged usually within 1 business day. However, we recently have issues with Salesforce notifications failing. So, Please **track the status of your request** in **[BD CAR Tracker - Quip](#)**.

- If your deal is '**Unallocated**', it is probably because there are overwhelming requests and will be picked up in due time.
- If your deal is '**Pending Inputs from BD Manager**', the data stewards require more input from you on clarification of
  - Inputs for Financial Obligations Relevance 'Y/N' field
  - Discrepancies in first forecasted launch year
  - SKU Specific details missing
- if your deal is '**Picked up by SANITY DST**', it is in progress. ETA is maximum 1 day.
- if your deal is **missing** in the Quip document, it is probably because the salesforce chatter notification failed. Kindly write an email to Data Stewards with BD Ops Manager in cc. (within 2 days preferably or as early as possible).

Chatter requests only to the Business Operations will not be progressed. BD Managers are expected to directly leverage the external consultants to streamline Operations and involve Business Operations Team, only when required.

5. BD Managers will be notified upon digitization and marking the CAR '***Signed***', who are then expected to review CAR Status, CAR Amount, NPV, IRR, Payback, Gross Margin & Supply costs. Revert back to data stewards for any discrepancies.

Note: For OTC Brand products or for business cases, where Net Sales Value needs to reflect L+10, please refer here: CAR for 10 years horizon

⌄ What are the results of CAR Digitization?

1. Complete creation of SKU Specific CAR Forecasts on SANITY which helps auto-calculate **Gross margin** on Forecast level & also on holistic level.

*Under '**Sales Value**' section on the BD Deal Record,*

2. **Deal value forecast source** Field is updated from 'Value from Portfolio Forecasts' to 'Value from CAR'
3. '**Launch +5 Year Net Sales**' Field reflecting the L+5 Sales value from the approved CAR .
4. '**Launch +10 Year Net Sales**' Field reflecting the total forecasted sales value from L+10 yr time horizon from the approved CAR
5. '**Net Sales Value' (Reportable)** Field reflecting
   a. L+10 Sales Value for Deals with Product Class - differentiated Gx/Biosimilars/Matured brands.
   b. L+5 Sales Value for Deals with Product Class - Gx.

6. **Total CAR Amount** reflecting
   a. Either the value from 'Total approved Budget (CAR or IH)' field on the CAR record, if it exists
   b. Or the value from the sum of all milestones (FOs) amount or value
7. **CAR Attractiveness** is a verbal measure of CAR Score calibrated as follows:

CAR Field	Weightage/Rating	0	2.5	5	7.5	10
Total Net Sales (mUSD)	33.34%	<15	15<x<40	40<x<100	100<x<130	130<x<300
NPV (mUSD)	33.33%	< 3	3<x<5	5<x<15	15<x<25	>25
IRR(%)	33.33%	<15%	15% <x<22%	22% <x<35%	35% <x<50%	>50%

CAR Score = 0.3334 * Rating for Total Net Sales + 0.3333 * Rating for NPV + 0.3333 * Rating for IRR

CAR Attractiveness (based on CAR Score) = Very Low (<2), Low (2 to 5), Medium (5-7) and High (>7)

8. Translation of values from CAR Excel Sheet to 'Business case/CAR' record on SANITY: **NPV, IRR, Core ROS, CAR Amount & Payback**

⌄ How should BD request CAR digitization for Basket CARs?

Basket CARs are approved by Finance in the event of basket deals
- either combining two or more distinct products in one agreement
- or same products with different dosage forms which are reflected as 2 or more BD Deals on SANITY.

Because a BD Deal on SANITY constitute to a one product specific to a combination of API, INN & Dosage form.

It is very important to **split the CAR** in such cases. Being the project lead responsible for enhancing transparency and reportability on such basket CARs, BD Managers should be responsible for splitting the basket CARs into product specific CARs as follows with the help of Finance BPA, before requesting for CAR digitization from Data Stewards.

- For approval, you could have used one consolidated CAR Excel Sheet. But,
- For digitization, you need to split the basket CAR sheet into product specific CAR Excel Sheets

1. Split the SKU specific forecasts in the 1_forecast tab into appropriate Deal specific CAR sheets
2. Split the NPV, IRR, Core Ros%, CAR Amount and Payback for each product with the guidance of BPA and record them on the CAR Excel Sheets
3. Upload the individual product specific CAR Excel Sheet & the (combined) signed CAR (consolidated) PDF on SANITY Files section for each of the deal and request CAR digitization via chatter from each of the deal record.

⌄ Step 6.3: Contract Signature

Responsibility: BD Manager;
Consulted: Legal, Sandoz Signing Entity, BD Head;

Prior to finalization of the Contract, please ensure that
1. The deal already has all the required approvals
    a. Mandatorily GPC, SPC, PSB, CAR & DRB
    b. Other approvals required subject to Deal Type & Thresholds
2. BD License Project Summary (In-licensing Checklist) is fully complete (except in case of Early stage deals)

3. Risks identified during DRB are reflected in the BD License Project Summary and mitigated in the contract
4. Confirm that Financials in final contract and SANITY are in correspondence with the completely approved CAR

Upon complete review from Legal, Patents & Other relevant business functions who needed to review the contractual terms & associated risks, initiate Contract sign off process, which shall be executed in accordance with the contract management procedure of the respective signing party, either via
1. Sending hard copy with ink signatures based on the agreement requirements
2. Docu-sign - digital signature.

Receive signed originals of the Contract from the Sandoz signing party and send them to the Partner for signing. And then obtain an original of the Contract where applicable with the countersignature(s) from a Partner(s). In case of a digital signature, all the signatories will automatically receive a copy of the agreement upon complete=ion of the signature process.

Contract Management guidelines recommended from Legal here.

Please note that, the **date of last signature** on the contract is considered as the **Actual Agreement Signature date.**
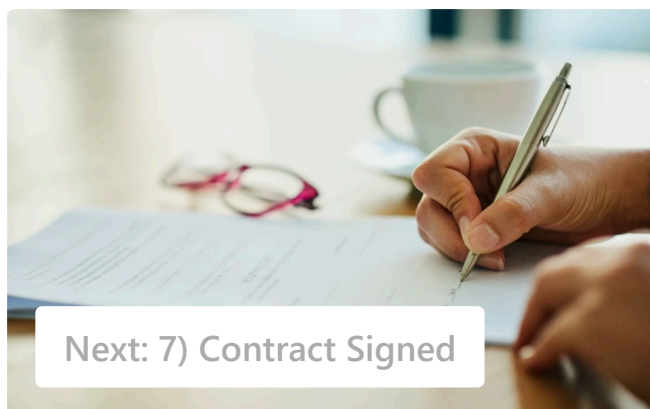
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Refer here for latest contact details: Invoices contacts for Sandoz AG and Hexal AG.xlsx

- For Hexal AG contracts, first reach out to Regional Head ESO Procurement Europe to get a CLM ID and then send the contract with the CLM ID to Head Legal Assistant Germany. This CLM ID should be added on the Agreement object
- For Local deals this is handled by the BD Manager, except in US where it is handled by Legal. Upon receipt of CLM IDs this will need to be recorded on the Agreement object in SANITY
- For Canadian contracts this applies only for those who allow sharing of information with affiliates. CA is uploading the contracts on a local excel database

Please update the BD Project License Summary Document completely with all relevant information at this stage.

You signed the deal with the partner. Great! To be able to reflect this on SANITY, please follow the next steps (7.1) to ensure deal compliance to the process and data quality checks.

Next: 7) Contract Signed