

# **Feature Overview**



# Introducing: ICSM CMO Collaboration – Enable Clinical Trial Collaboration in SAP Business Network - CSC-47278

## **Feature Description**

This feature introduces the entitlement Industry Solution Life Sciences and related functionality. When enabled, the buyer can share clinical trial relevant information with the supplier as part of sub-contracting purchase orders or stock transport orders for efficient collaboration in the manufacturing and distribution of the clinical finished goods. Clinical trial data originates in the SAP Intelligent Clinical Supply Management industry solution.

## **Key Benefits**

Enable high degree of clinical supply chain process automation in combination with the SAP Intelligent Clinical Supply Management industry solution. Avoid manual information channels by using SBN to exchange clinical trial data with associated orders and ship notices.

Audience:

**Buyer and Supplier** 

**Enablement Model:** 

High Touch

Applicable Solutions:

SAP Business Network

## Prerequisites, Restrictions

### **Prerequisites**

- SAP S4HANA OP 2022
- SAP Intelligent Clinical Supply Management (ICSM)
- SAP Business Network Supply Chain
- Entitlement for Clinical Trials Add-On
- Buyer has a valid SAP Business Network for Supply Chain Application Gateway configuration for accessing the BTP Launchpad
- Supplier has entitlement through a Supply Chain Collaboration with a buyer that has Clinical Trials Add-on entitlement for the Life Sciences application.

### Restrictions

- SAP Integration Suite, managed gateway for spend management and SAP Business Network
  - The integration supports only SAP S/4HANA.
  - The PCN release status is supported from cXML version 1.2.060 and later.

# **CMO Collaboration in Clinical R&D | Context**

Current Life Sciences market dynamics and customer pain points highlight need for more integrated and streamlined collaboration in clinical ecosystem

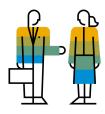
### **Market Dynamics:**

- <u>Industry Standard Research Reports</u> highlight that Life Sciences companies (sponsors) outsource almost 2/3<sup>rd</sup> of their manufacturing activities to CMOs
- This figure is even higher for SMEs ~ 80%
- Outsourcing manufacturing, packaging and distribution is projected to increase due to increased demand for biologics and Cell & Gene therapies (ATMPs) with a decreasing share of blockbuster drugs

### **Customer Challenges:**

- Non-integrated approach resulting in silos, broken data-flows and no connectivity to the external supply network
- Higher inventory carrying costs for both sponsors and CMOs
- Sponsors still using inefficient manual processes to exchange information and collaborate with their CMOs, CDMOs, CROs especially for packaging, label design and approval, shelf-life management etc.
- Expensive and hard-to-maintain custom integrations
- Missing harmonized approach to clinical and commercial landscapes and processes based on customer feedback from SAP Life Sciences ISBN Event 2022
  - Sponsors want to utilize their existing investments made in the commercial world
  - They do not want to have separate onboarding for partners in commercial v/s clinical world

# **CMO Collaboration in Clinical R&D | Value Proposition**





- Accelerate product development and go-to market with CMOs
- Lower TCO by leveraging existing customers' SAP Business Network instances
- Increased transparency in production, inventory and material flow
- Improve collaboration with business partners by sharing orders and inventory information
- Optimized inventory and lower inventory carrying cost
- **Easy integration** with S/4 through pre-packaged content
- Harmonized processes for clinical and commercial supply chains
- **Reduce time-to-value** by simplifying, automating and standardizing procurement processes



### **Vendors**

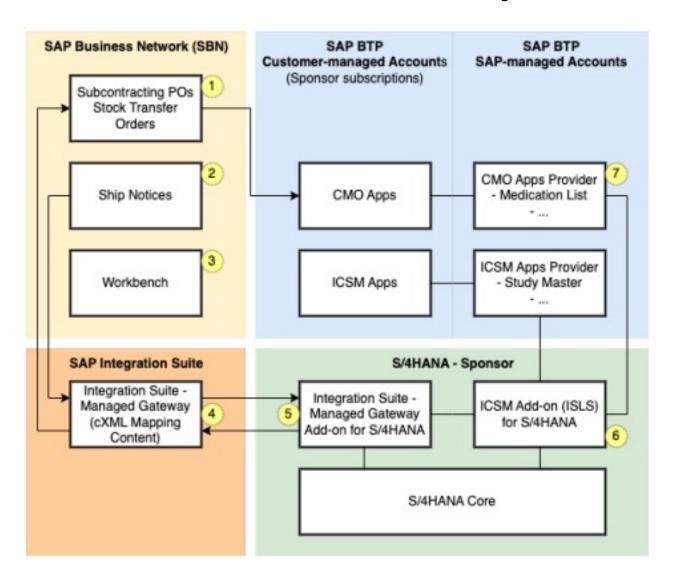
- Increased transparency in inventory and material flow
- Improve collaboration by access to orders and inventory information
- Optimized inventory and lower inventory carrying cost
- Easy onboarding for vendors
- Native integration with SAP Business Network Supply Chain

# **CMO Collaboration in Clinical R&D | Overview of Scope**

ICSM CMO Collaboration with SAP Business Network Supply Chain

	ICSM	will be integrated with SAP Business Network SCC to offer CMO user a portal based access to their relevant information	
	Enhance SBN SCC with clinical trial parameters for subcontracting purchase orders		
		External Packaging	
		Label service order (overprinting)	
		External relabeling for shelf-Life extension	
		Consumption of components and finished goods manufactured confirmation	
	Stock Transport Orders		
		Distribute components to CMO	
		Goods movement tracking of clinical finished goods	
		□ From CMO to Sponsor	
		□ From packaging CMO to other CMO for further distribution	
		□ To CMO for relabeling (shelf-life extension)	
	SAP Business Network SCC Integration for		
		Medication list display and extraction	
		Study master data visibility for a CMO	
		BOM display	
		Clinical finished goods or component materials scrapping or blocking	
		Stock visibility for clinical finished goods and components	

# **Solution Overview and Summary of Enhancements**



#### SAP Business Network (SBN4SC):

- · Supplier onboarding is managed using standard SBN processes.
- · (1) Subcontracting PO is extended with ICSM specific content, navigation link to a medication list app. Stock transport orders are extended with relevant ICSM specific content and features where applicable.
- (2) Related ship notices are extended with ICSM specific content, ability to confirm medication kit packaging details at handling unit level.
- · (3) Workbench filters, work lists, and downloads are extended with relevant ICSM specific content.

#### **SAP Integration Suite:**

· (4) SBN/SCC cXML message definitions and mappings for purchase order / stock transport order and ship notice are extended with ICSM data.

### S/4HANA (Sponsor):

- (5) Integration Suite Managed Gateway add-on for purchase order / stock transport order and ship notice is extended to manage additional ICSM content, manage virtual goods receipt, manage medication kit creation and packaging information.
- · (6) ICSM add-on has functions that are called by the ICSM-related enhancements, such as providing ICSM specific content for SBN subcontracting purchase orders and related stock transport orders. The add-on will also include the back end functionality for CMO-facing apps such as the medication list app that will be based on SAP BTP.

**SAP BTP** (provider and subscriber account setup shown here is tentative and may change)

 $\cdot$  (7) BTP based apps for use by CMOs, such as display of medication list, BOM, study master, shipment notification etc.. These apps are linked from the CMO supplier accounts in SBN so that a CMO can directly navigate to a BTP based app and use their SBN identity for authentication.

# **Enablement Steps & Notes**

Enable the entitlement for Life Sciences Add-on

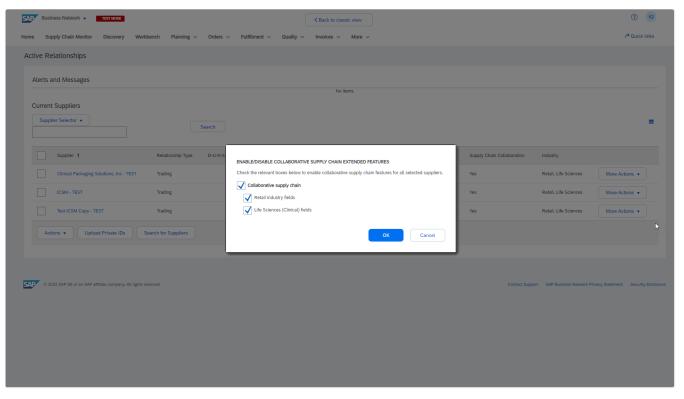
The	he following settings will affect integration behaviors between AN and Ariba Buyer.				
✓	Download PO Confirmations (ConfirmationRequest)				
✓	Download Ship Notices (ShipNoticeRequest)				
✓	Download PO Statuses (StatusUpdateRequest)				
✓	Download Notifications (NotificationRequest)				
	Upload CSV Payment Proposals/Payment Batch				
	Sign all Invoices with Esignature				
	Enable tax invoicing for UAE				
	Label both CXML and PDF invoice documents as 'Tax Invoice' for Australia and New Zealand				
	Download Supplier Data (OrganizationDataChange applicable only to Open Network customers)				
<b>~</b>	Allow Quick Enablement				
<b>~</b>	Send VendorID, SiteID and SiteAuxID in outgoing documents				
<b>✓</b>	Allow Multiple Private ID's per Supplier				
	Add missing vendor records based on vendor compound keys in documents				
	Allow Supplier to enter service details for OC				
	Copy accounting information from parent line in purchase Order to child lines in Service Sheet.				
	Allow suppliers to create invoices directly from service POs without a service sheet.				
<b>✓</b>	Allow buyer to activate Supply Chain Collaboration features.				
	Allow buyer to enable quality collaboration features.				
	Enable Planning collaboration for Forecast and Manufacturing visibility processes.				
	Enable Inventory collaboration for Supplier managed and Replenishment processes.				
	Allow buyer to activate Industry Solutions.				
	✓ Life Sciences				

ENTITLEMENT INFORMATION

## **Enablement Steps & Notes**

Enablement to display Life Sciences(Clinical) relevant fields.

- Login as a Buyer.
- Navigate to More -> Supplier Enablement -> Active Relationships.
- Select supplier with whom clinical trial relationship needs to be enabled.
- Select Actions button and choose Enable/Disable Supply Chain Collaboration option.
- Select option Life Sciences(Clinical) fields.



# **Feature Details Permissions Available for Buyer**

Permissions	Description
Life Sciences / ICSM: Clinical BTP Apps Full Access	Life Sciences / ICSM: Clinical BTP Apps Full Access
Life Sciences / ICSM: Clinical BTP Apps Restricted Access	Life Sciences / ICSM: Clinical BTP Apps Restricted Access
Life Sciences / ICSM: Clinical Stock Transport Orders Access	Life Sciences / ICSM: Clinical Stock Transport Orders Access
Life Sciences / ICSM: Clinical Subcontracting Purchase Orders Access	Life Sciences / ICSM: Clinical Subcontracting Purchase Orders Access
Life Sciences / ICSM: Goods Receipt Access for Clinical Purchase Orders or Stock Transport Orders	Life Sciences / ICSM: Goods Receipt Access for Clinical Purchase Orders or Stock Transport Orders
Life Sciences / ICSM: Ship Notice for Clinical Purchase Orders Access	Life Sciences / ICSM: Ship Notice for Clinical Purchase Orders Access
Life Sciences / ICSM: Ship Notice for Clinical Stock Transport Orders Access	Life Sciences / ICSM: Ship Notice for Clinical Stock Transport Orders Access

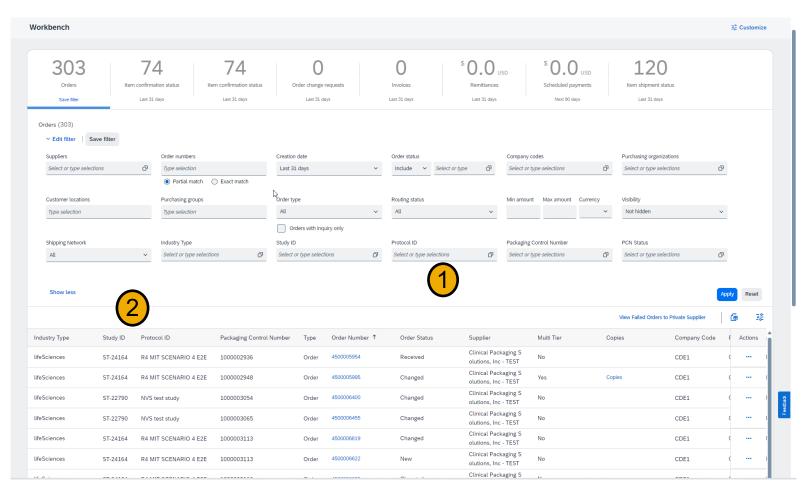
 Depending on the permissions assigned to the buyer user the buyer user will be able to access relevant data.

# **Feature Details Permissions Available For Supplier**

Permissions	Description
Life Sciences / ICSM: Clinical BTP Apps Full Access	Life Sciences / ICSM: Clinical BTP Apps Full Access
Life Sciences / ICSM: Clinical BTP Apps Restricted Access	Life Sciences / ICSM: Clinical BTP Apps Restricted Access
Life Sciences / ICSM: Clinical Stock Transport Order Confirmation Access	Life Sciences / ICSM: Clinical Stock Transport Order Confirmation Access
Life Sciences / ICSM: Clinical Stock Transport Orders Access	Life Sciences / ICSM: Clinical Stock Transport Orders Access
Life Sciences / ICSM: Clinical Subcontracting Purchase Order Confirmation Access	Life Sciences / ICSM: Clinical Subcontracting Purchase Order Confirmation Access
Life Sciences / ICSM: Clinical Subcontracting Purchase Orders Access	Life Sciences / ICSM: Clinical Subcontracting Purchase Orders Access
Life Sciences / ICSM: Goods Receipt Access for Clinical Purchase Orders or Stock Transport Orders	Life Sciences / ICSM: Goods Receipt Access for Clinical Purchase Orders or Stock Transport Orders
Life Sciences / ICSM: Goods Receipt Creation Access for Clinical Purchase Orders or Stock Transport Orders	Life Sciences / ICSM: Goods Receipt Creation Access for Clinical Purchase Orders or Stock Transport Orders
Life Sciences / ICSM: Report Consumption for Clinical Subcontracting Purchase Order	Life Sciences / ICSM: Report Consumption for Clinical Subcontracting Purchase Order
Life Sciences / ICSM: Ship Notice Creation for Clinical Purchase Orders Access	Life Sciences / ICSM: Ship Notice Creation for Clinical Purchase Orders Access
Life Sciences / ICSM: Ship Notice Creation for Clinical Stock Transport Orders Access	Life Sciences / ICSM: Ship Notice Creation for Clinical Stock Transport Orders Access
Life Sciences / ICSM: Ship Notice for Clinical Purchase Orders Access	Life Sciences / ICSM: Ship Notice for Clinical Purchase Orders Access
Life Sciences / ICSM: Ship Notice for Clinical Stock Transport Orders Access	Life Sciences / ICSM: Ship Notice for Clinical Stock Transport Orders Access

 Depending on the permissions assigned to the supplier user the user will be able to access relevant data and perform assigned actions.

# New Filters And Columns In Workbench Worklists For Buyers And Suppliers



The filters and columns are introduced in the following workbench tiles –

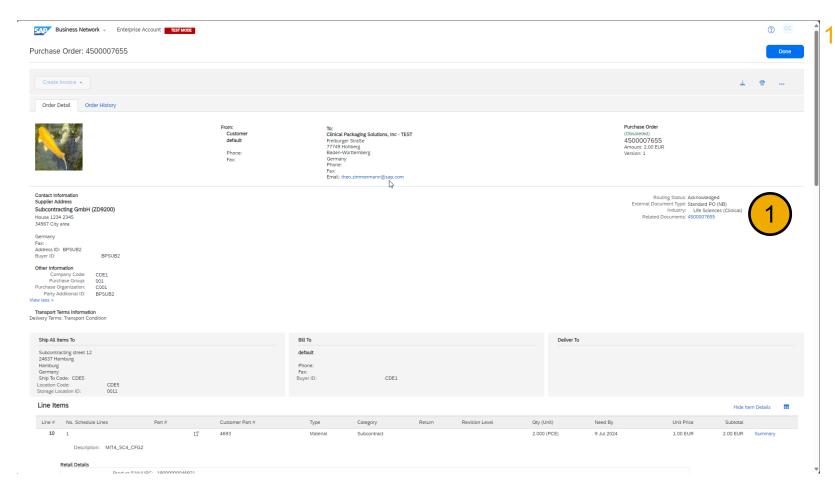
Orders, Item confirmation status, Item shipment status on the buyer side.

New Orders, Changed Orders, Orders, Orders, Item to confirm, Item to ship on the supplier side.

The screen shot on the left shows Orders tile for buyer

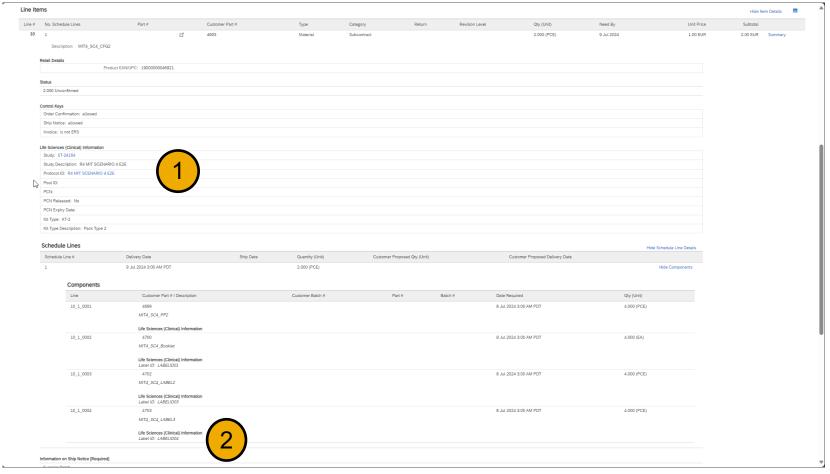
- Five new filters Industry Type, Study ID, Protocol ID Packaging Control Number, PCN Status Filters.
- 2. Five new columns Industry Type, Study ID, Protocol ID Packaging Control Number, PCN Status (Except in Orders tile).

# Changes on Order Details Page For Buyers And Suppliers



1. A new attribute "Industry: Life Sciences (Clinical)" in the purchase order detail screen identifying the order as belonging to Life sciences (clinical) industry.

# Changes on Order Details Page For Buyers And Suppliers



- Sciences (Clinical) Information is introduced under line items section providing information relevant to the clinical trials. The following fields are available in the section Study ID and description, Protocol ID, PCN ID (Packaging Control Number), PCN Expiry Date, PCN Release Status, Kit Type and description, Pool ID, Medication sequence number ranges.
- 2. A new section *Life*Sciences(Clinical) Information
  is introduced under
  components with field *Label ID*.

## Changes on Ship Notice UIs For Buyers and Suppliers

### RETAIL DETAILS Product EAN/UPC: 19000000046921 Best Before: Expires By: Free Goods Quantity: Unit: European Waste Catalog ID: LIFE SCIENCES (CLINICAL) DETAILS Study ID: ST-24164 Study Description: R4 MIT SCENARIO 4 E2E Protocol ID: R4 MIT SCENARIO 4 E2E PCN: 1000002836 PCN Expiry Date: 2026-04-19 SEQUENCE NUMBER RANGES From To Count 2521 2535 15 Sequence Numbers (Required Quantity: 15.000) Sequence From Sequence To Add New Range

The screen shot on the left shows create ship notice UI for supplier

- 1. Life sciences (Clinical)
  relevant fields introduced –
  Study ID, Study Description,
  Protocol ID.
- 2. Possibility to select medication sequence numbers when not using Handling Units.

Assigning Medication Sequence Numbers for HUs In Ship Notice Creation.

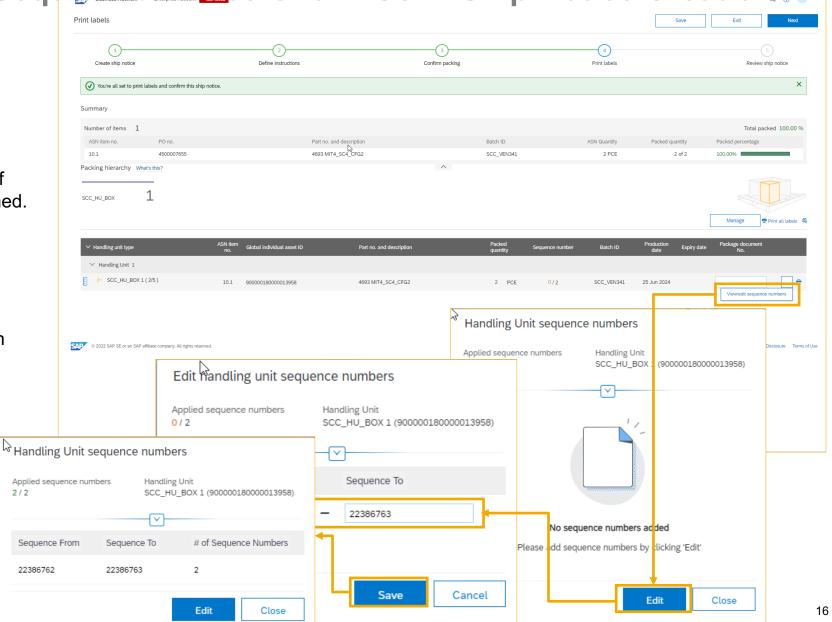
A supplier user can select View/Edit sequence Numbers option in the Packing Wizard.

A pop-up will display shown information of the medication sequence numbers assigned.

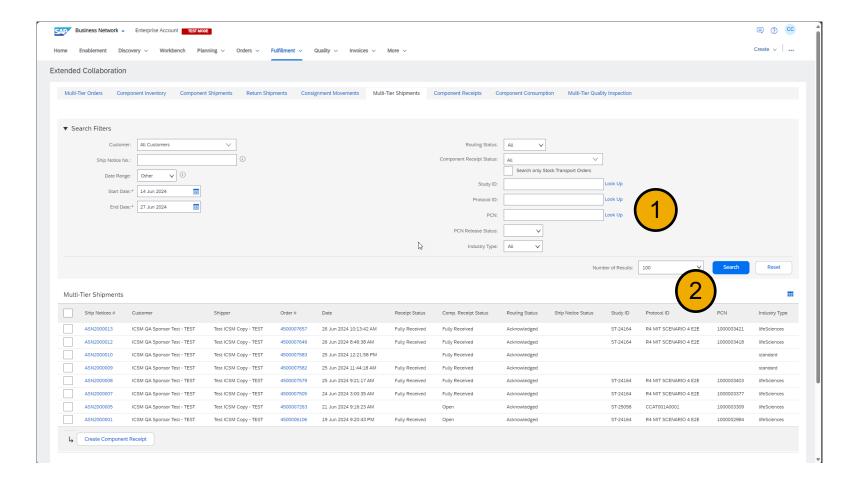
Select Edit option to enter the medication sequence numbers associated with the Handling Unit.

Select Save option to save the Medication sequence numbers associated with the **Handling Unit** 

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# **Changes on Multi-Tier Uls For Suppliers**



The filters and columns are introduced in the following UIs– *Multi-Tier Orders, Multi-Tier Shipments* on the supplier side.

The screen shot on the left shows Mult-Tier Shipments UI for Supplier

- 1. Five new filters *Industry Type, Study ID, Protocol ID PCN, PCN Status Filters*.
- 2. Four new columns *Industry Type, Study ID, Protocol ID PCN.*

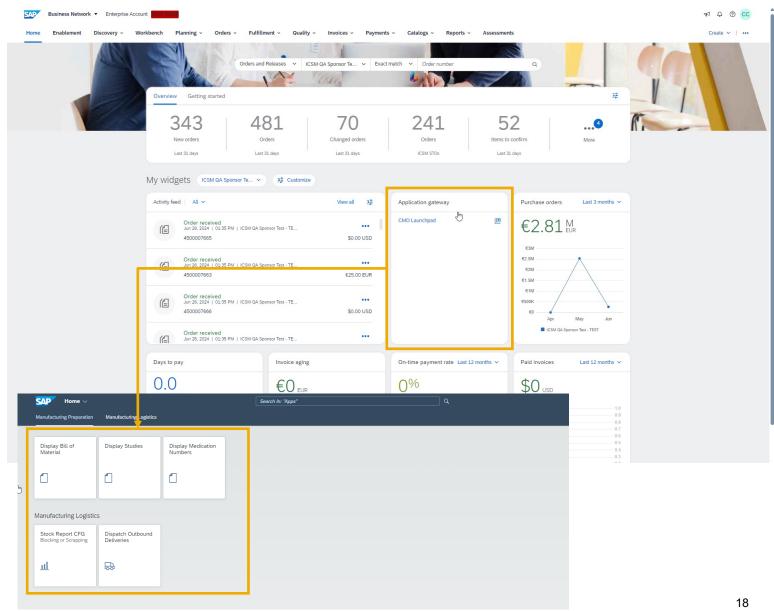
# Navigating to BTP Apps from the Supplier Home Page on SAP BN

A supplier user can select CMO launchpad link configured in the Application Gateway widget.

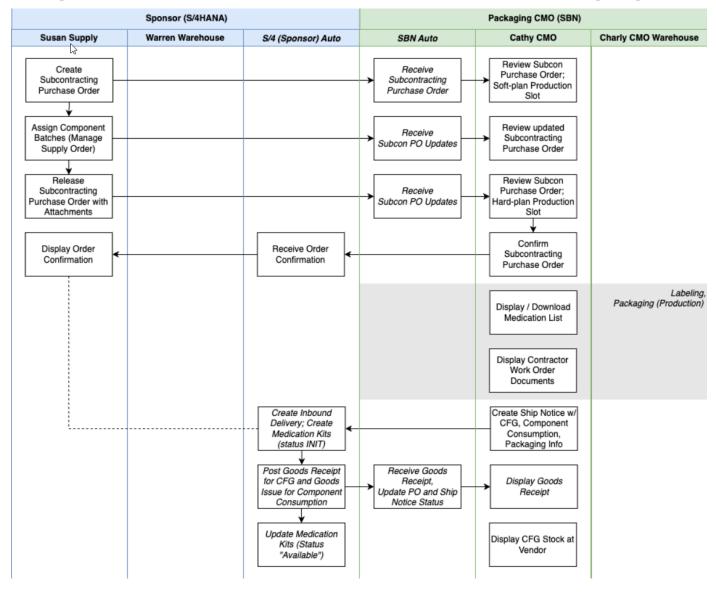
A window will display with the BTP launchpad and the 5 Fiori Apps delivered for CMO collaboration.

Supplier user will be able to access the data in different Fiori Apps and look at the data or perform actions.

Note: The visibility of data and ability to perform actions in the BTP app depends on the permissions assigned to the user in SAP BN.



# **Subcontracting Purchase Order For CFG External Packaging**



# Thank you.



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