

Providing Final Assessment (iPM)

Learning Objectives

After completing this unit, you'll be able to

- Identify information to be provided on the PSG Document for the evaluation
- Finalize an assessment in SANITY
- Know how to communicate with the GPfM for questions related to the evaluation

Adding information in the PSG Document for the Evaluation request

Now, as the responsible iPM to provide the product strategy, you will need to include the project-specific information in the PSG document on the "Quip" tab on the Opp D&D.

In general, all fields with "iPM and ESD" in the "**Responsible**" or "**Resp function**" column **(6)** on the right side and "1" in the "**Earliest PSG to be available**" **(7)** column of the Quip doc, should be completed.

You will find information to complete on the following tabs:

1. "Development & Technology"
2. "Timelines & Supply Chain"
3. "Clinical"
4. "TPC"
5. "Development Budget_selection" or "Development Budget"

Teno

PSG_Gate

Spreadsheet

Edit

View

Insert

Format

Data

Sources

Share 8/6

Open in Quip

Locked

Registered

	A	N	O	P	Q	R	S	T	U	V	W
1	fumarate (TAF) - Bictegravir + Emtricitabine HCl - CAPSULE										
2	Timelines						Comments / Help	Responsible	Earliest PSG to be available		
3	Scope	ZA	IN	SI	CN	MT	dark green = must win; light green = win opportunistically				
4	Rx status						e.g. phase III, registered or marketed,	Portfolio GPM	0		
5	Rx MA actual (assumed) date (dd.mm.yyyy)	07.07.2020					Italic if RLD not approved and launched yet, include assumption date based on innovator status (study phase / registration) and write (assumption) behind	actual: RA assumed: ESD	1		
6	regulatory strategy	generic					generic, 505B2, 10B ...	RA	1		
7	Data exclusivity (y)	0					CN DE not to be considered for strategy setting	std assumption	1		
8	Market exclusivity (y)	0						std assumption	1		
9	Approval + reimbursement (tentative time)	60					US: 30mo until TA; 10 mo registration;	std assumption	1		
10	CoPP needed	N					RU: CoPP registered needed, Requested for EAEU procedures starting in 2021 CN: see intranet, registered is mandatory TR: see scenarios on intranet. ... Yes it's needed, CPP registered from any country (marketed is not a must) but there are different scenarios that in case product is still not registered anywhere we can submit in TR without CPP and provide it later during product submission phase. In case product is already registered anywhere in the world and we submit without it we get rejection in first month after submission. It is for sure needed at least before granting approval from turkey, means in last DL they will ask for it MX: Regulation to be checked frequently; Not enforced by COFEPRIS, not applied. Recently signed Treat between US, CA and MX increase for 10 years data protection in Mexico.	std assumption	1		
11	CoPP availability date										

Instructions

Product Strategy Summary

Product General

Sandoz Trade dress

Development and Technology

Timelines & Supply Chain

Clinical

TPCs

Dev_Budg_selection

Development Budget

Count: 2

Finalizing the Evaluation - Feedback to GPfM

Upon finalization of the Evaluation, the Opportunity Assessment record needs to be set to final.

On the opportunity assessment record:

1. Set the "**Assessment Status**" to "Final"
2. Set "**Feedback Value**" to "Not Relevant / Not Applicable"
3. Click "**Save**"

Opportunity Assessment
Assessment-102737

Details Historical Assessments Record History & Activity

* Opportunity Diligence [redacted] X Owner Search Contacts... Q

Product Opportunity Team Search Product Opportunity Team... Q Function Development

* Feedback Type Portfolio Selection Role Development Manager

Summary

Overall Assessment

Assessment Status Final 1

* Feedback Value Not Relevant / Not Applicable 2

Risks --None--

Feedback Status Due Date 26/01/2021

Status

This field is calculated upon save

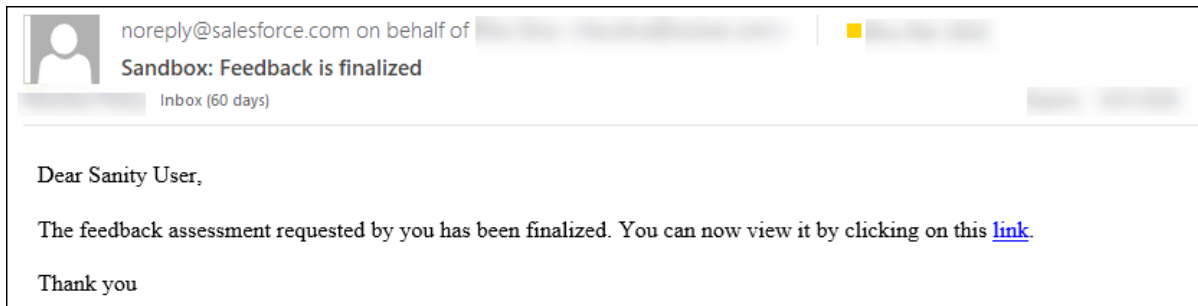
Detailed Feedback

Feedback

Cancel Save 3

Receive Feedback for evaluation (GPfM)

The respective Opportunity D&D owner (GPfM) will receive an email similar to the one below, letting them know the assessment has been finalized.



Further Questions (iPM/GPfM)

For further questions related to the product strategy assessment, the respective GPfM will get in contact with the iPM and ESD via comments in the Product strategy document itself or via email.

To send your question or answer via the Product Strategy document:

1. Click on the Comment's icon
2. Write your question/answer after tagging the person you want to reach
3. Click "Send"

