

Forecasting & Planning Tool
User Guide

Emerga Market Report

WHY SHOULD I USE THIS TOOL?

The stated purpose of this Tool is to allow Project Managers and Global Program Leaders to make more efficient and informed decisions during planning and forecasting Meetings with their teams. To meet this purpose, this Tool will enable Planning Teams to:

- 1. Learn to identify which development decisions are most impactful to an asset's value*
- 2. Understand how those decisions impact that value or create further risk*
- 3. Evaluate and communicate that asset value to/from other functions in the organization*

WHEN SHOULD I USE THIS TOOL?

The Tool is designed to be used in the context of a development planning team Meeting, both during early stage development (R2 / D1) and late stage development (D2 / D3). Please note that it is not intended for individual use, nor is it intended to replace any more accurate forecasting tools currently used by the Project or Portfolio teams. The Tool guides development teams through three phases of the Meeting: create greater alignment & intentionality during planning; generate insights regarding which development decisions are most important; and support commitment to action from the team following the Meeting.

Ultimately, it is the role of the Project Manager and Global Program Leader to guide the team through the Meeting's use of the Tool, and to hold team members accountable to outcomes following its use.

WHAT SHOULD I EXPECT AS OUTCOMES OF THE TOOL?

The Tool is action-oriented, as it will provide each team member with clarity of how their function's actions directly impact the value of the asset under development. Because of this, each team member will be responsible for taking at least one action after the Meeting and measuring the success of that action based upon its impact to the business.

While this action depends on the individual, there are five behaviors that this Tool promotes:

- 1. More informed planning at each stage of asset development*
- 2. Prioritization of investments and decisions based upon relative impact*
- 3. Greater accountability for project risks and outcomes*
- 4. More timely information and feedback to other stakeholders at Santen*
- 5. Creation of reasonable scenarios and backup plans in the case of setbacks*

WHAT SHOULD I PROVIDE MY TEAM BEFORE THE MEETING?


In order to facilitate the planning stage at the beginning of the Tool's Meeting, each team member will complete individual pre-work in advance of the Meeting. This pre-work will inform each team member about the Tool and what he or she can expect to achieve by using the Tool. To send and process this pre-work, follow these four steps:

1. **3 weeks** before the Meeting, send each member a briefing, found [<HERE>](#)
2. Allow each team member **2 weeks** to complete the packet
3. Each member sends you their briefing, so you understand the team's current thinking
4. As you begin the Meeting, use each of those briefings to inform the team's total plan

HOW SHOULD I BEGIN MY MEETING? – PLANNING STAGE

How I complete the asset's Scientific Background?

You will first define what you know about the Target Product Profile in the "Scientific Background" portion of the Tool's Planning Page. This area captures given information about the product, such as its *Disease Area* or *Acquisition Cost*, which will create a general baseline for the scenarios that you will construct. Please note, if a detail of the exact target profile is not available, choose the closest possible option.


SCIENTIFIC BACKGROUND

PROJECT NAME	DE-126	Disease Area	Glaucoma	Formulation	FP/EP3 Dual Agonist
Target Indication	BOTE	Project Start Date	2016	Target Launch Date	2020
Current Stage	Phase II	LOE	2030	Administration	Eye Drops
In-Licensed/ Acquisition Period	Phase I	In-Licensed/ Acquisition Cost (\$M)	25		

How do we answer the Alignment & Planning questions?

This area of the Tool appears identical to the pre-work briefing that each individual completed beforehand. The goal here is to create a *common* answer to each of the questions on this page. Where you focus your attention on the decisions within the Tool later will depend on what the team believes to be most important here. And each of the questions depends upon the response the question just before.

There are two important suggestions for efficiently completing each of these questions:

- A. Where individual responses are similar, reduce time by entering their common response
- B. Where individual responses are most different, spend more time to reach a compromise

ALIGNMENT & PLANNING				
Given our stage of development, what business metrics are most important to our success?	Metric 1	Metric 2	Metric 3	Notes
What is our goal or purpose for using this Tool?				
What do we already know about this asset? What further information do we need to know?				
What are the primary assumptions & risks that might strongly affect our project's outcomes?	Assumption 1	Assumption 2	Assumption 3	Notes
What decisions or investments do we think will have the biggest impact on identified business metrics and assumptions/risks?				
What opportunities do we have to apply this evaluation onto our current asset's development?				

How do I know when I am finished with my Planning Stage?

The Planning Stage acts as your hypothesis, which you will test across different scenarios involving product development decisions. Most important here is both that your team agrees upon each response and that each response has enough detail that you can act upon it. Do not move on to the Scenario Pages until you have filled in all three *Metrics* and all three *Assumptions* because you will come back to these decisions at the end.

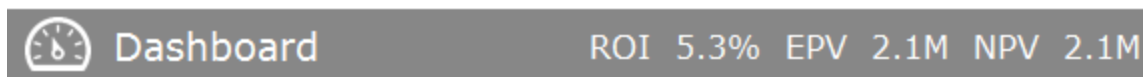
HOW DO I TEST DIFFERENT SCENARIOS? – GENERATING INSIGHTS

Each of the scenario tabs will allow you to create a different development plan, beginning from R0 / R1 / R2 through the completion of D3. These plans will include both research & development decisions, as well as commercial and manufacturing decisions to construct the asset's market value.

How do I interpret my Dashboard?

At the top of every Scenario Page, you will find the three metrics that you chose during Alignment & Planning. These metrics will change in value as you change parameters and decisions below. Whenever you change or make any decision note the effect on the Dashboard metrics. It is the best guide of how impactful each decision is on the asset's value.

PROJECT NAME : DE-126




How do I complete Scenario 1 – Base Case?

While each Scenario will contain the same development and commercialization decisions, Scenario 1 will act as the baseline for each of the other two scenarios your team will construct. It is important to begin with this page first, following your Planning & Alignment.

Your team will first make all development decisions starting in R0 and ending in Phase III. There are two steps to filling out these decisions most accurately:

1. Complete those decisions in previous development phases first, to reflect the known parameters of the development process to this current point
2. Then complete decisions for the current phase and future phases, to reflect the most likely development plan that your team constructs

	Scenario 1 - Base Case	Scenario 2	Scenario 3
 DEVELOPMENT PLAN	R0/R1/R2	P1	P2/P2b
Additional Biomarker & Diagnostic	\$2M		
Formulation Administration	Subcutaneous		
Trial Size (Number of Patients)	25	250	1500
Change in Observation Period	+ 6 months	- 6 months	0 months
Multinational Trials		Local	Local
Additional Indications Study		Yes	
Phase IIb Study		+ Competitive	
Dose Frequency		Medium	
# of Primary Endpoints Met			1
# of Secondary Endpoints Met			2
Comparator Type			Active
Regulatory Success			90%

If you acquire the asset in middle or late stage development: you will make early stage development decisions that reflect those decisions of the former company. Those clinical trial decisions will not impact your estimation of R&D costs or time-to-launch, as they have already been completed.

	R0/R1/R2	P1	P2/P2b	P3	
PTS	100%	100%	100%	100%	Cumulative POS: 0
Time Required (Years)	0	0	0	0	Expected Launch Date: 0
R&D Cost (\$M)	0	0	0	0	Total R&D Expense: 0
FTEs Cost (\$M)	0	0	0	0	Total FTE Expense: 0

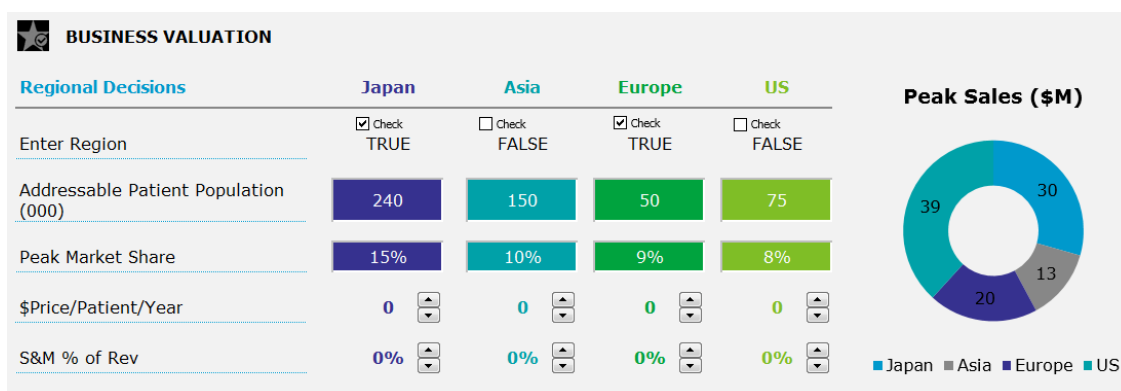
Below your clinical development decisions, you will find a table of the PTS, Time Required, R&D Cost, and FTE Cost for each Phase of development, as well as their cumulative effects for the entire development project. If your team feels any of these numbers are significantly

different from reality, or you wish to reflect known information, you may manually adjust each of these values.

If you acquire the asset in middle or late stage development: You will notice that time required and cost incurred for those phases are not included in the tables, to account for trials completed externally.

How do I account for regional differences as I launch this drug product?

Once you complete the clinical trial decision, you will choose which regions you wish to enter, how much patient volume you expect in each region, and how you wish to support the launch with pricing and marketing investment. Each of these decisions will have a baseline value, estimated by the Tool. However, the price and volume decisions here are primarily independent of clinical development decisions, so your commercial team members should provide guidance as necessary to reach a realistic estimate.



What commercial planning decisions do I need to make on a global scale?

Regardless of which geographic regions you enter, some decision will impact the value of the asset across all regions. Those decisions your team will make last, and are located at the very bottom of the Scenario Page. Each of these decisions will also contain baseline, suggested values, but you should manually update them based upon reasonable guidance from your commercial or manufacturing team colleagues.

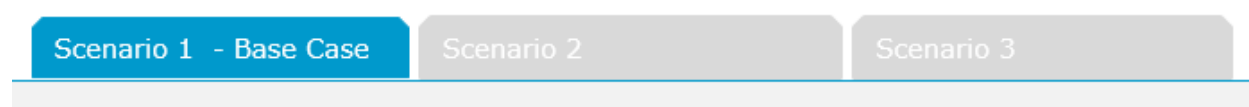
Global Decisions			
Avg. Penetration/Uptake Rate	10%	Medical Affairs Involvement	Late Stage Breakeven: 0
Avg. Patient Compliance Rate	80%	Royalty	12% ROI: 0
Discount/Rebate %	0%	Discount Rate - EPV	6% EPV: 0
\$ Avg. COGS/Patient/Year	80	Discount Rate - NPV	12% NPV: 0

How do I construct Scenario 2 and Scenario 3?

Once your team is confident that Scenario 1 is both an accurate picture of development decisions already made and a reasonable picture of the development plan through product launch, you may use Scenario 1 as the *baseline* for Scenario 2 and 3. To copy its decisions and values on to the other two pages, select the Commit Baseline Values button.

<PLACEHOLDER FOR COMMIT BUTTON SCREENSHOT>

Once selected, you may move to either of the other two Scenario by selecting that tab at the top of the Scenario Page.



When changing decisions on Scenario 2 or Scenario 3, remember to use your Dashboard metrics as your guide. If your team is attempting to create a *Best Case* Scenario, test which decision under your team's control will maximize those Dashboard metrics. If your team is attempting to create a *Worst Case* Scenario, test which decisions that could occur most decrease those Dashboard metrics.

How do I best compare the results across Scenarios 1, 2, and 3?

The Reports Page is the easiest way to compare results from one scenario to another. All data on this page is a result of the decisions made in the clinical development plan and in the commercial decision.

Guidance on interpreting this page:

- A. Start with the Summary Table at the top, which displays each of the primary metrics Santen uses today to analyze its business success. Note where you see the biggest differences from one Scenario to the next.
- B. With those differences in mind, look to the detailed reports below for explanations. Each of these detailed reports break up the critical metrics into their yearly values post launch.
- C. If you are focusing on a few specific decisions in the scenarios that impact those metrics of interest, adjust those decisions on the Scenarios pages. Then come back to this Reports Page to see their relative effects.

HOW DO I SUPPORT OUTCOMES? – COMMIT TO ACTION

Once you have finished constructing your three scenario, the last page you will complete is the Commit to Action Page. Here, the purpose is to generate insights from your original hypotheses, and commit individual to specific action following the Meeting.

How do I test whether the Tool supports my team's hypotheses for development?

On the top half of the Commit to Action Page, you will find 6 items listed directly from your Action & Planning responses: the 3 primary metrics and the 3 primary assumptions.

1. For each primary metric, mark whether it has been *validated* or not, meaning that your scenario analysis supports this as critical to this program's success or proves that another metric is more important.
2. For each assumption, repeat this process, indicating whether that assumption is correct based upon your analysis or requires adjustment.
3. For each item that has been validated, indicated as a Yes, explain why your scenario analysis supports that validation. What have you learned that leads to this outcome?
4. For each item that has not been validated, indicated as a No, explain why your analysis disproves that hypothesis. What have you learned that leads to this outcome?

Hypothesis	Validated?	Further Insights
0	Yes	
0	Yes	
0	No	
0	Yes	
0	No	
0	Yes	

How do individuals on my team commit to actions?

As the final step in every Meeting, each individual on the team should think of *one action* they can take that would support the insights just created above. With greater clarity of the project critical metrics and what impacts them, what can the individual do to support that metric? With greater clarity on project assumptions, what can the individual do to support that assumption?

Each action requires four criteria to be considered complete:

1. A clear description of the action
2. The name of the individual accountable for the action
3. The expected date by when the action will be complete
4. An estimation of what the action's impact will be on the business

Commitment	Individual Accountable	Expected Completion Date	Expected Outcome
Present data supporting narrow label design to clinical operations team.	Sagar	Feb 31, 2017	Decrease time to IND by 2 months.
Commitment 2			
Commitment 3			
Commitment 4			
Commitment 5			

When all individuals have entered an action into the Tool, select the Mail icon beside the actions chart. This icon will open your primary e-mail client and populate an e-mail with each of the individual commitments, names, dates, and outcomes. You may then send this e-mail directly to the team as a summary and confirmation of all commitments made by individuals.

It is your responsibility as the PM or GPL to follow-up with these individuals at their expected completion dates to assess the impacts that their actions have had.