



BOSU

— LIFE SCIENCE

Pillars to support SMBs in the race for launch

A BASE life science whitepaper
Published January, 2021

BASE life science

www.baselifescience.com

© 2021 BASE life science. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, including photocopying and recording, or by any information storage or retrieval system.

The race for launch – ensuring commercial readiness in Europe

Most pharmaceutical and biotechnology companies are launching their first drug in the US and subsequently in Europe, aligned with the launch sequencing theory's current state, implying to launch first in the countries with a higher willingness to pay [Nicolas Houy & Izabela Jelovac]. After the first market go-live, the company would have to launch in another country. Whether the company is choosing to launch itself in Europe or license, the likelihood of having all countries being launched or just a few ones, the company will need to set up a minimum of technologies and processes.

At BASE, we have supported multiple companies implementing their processes and tools over the last couple of years. For the first drug launch, an organization does not need all the shiny whistles but at least the following:

- CRM tool to manage the interactions with the various HCPs
- Business intelligence capabilities to gather insights from the data

- Business processes on customer related to customer management
- Segmentation and targeting process must be ready from day 1 to focus the activity
- KOL identification and management for the medical teams
- Digital assets management capabilities to present a coherent message to HCPs across channels
- Transparency reporting tools to ensure compliance with the sunshine act and other transparency laws

This whitepaper provides best practices applicable to companies trying to launch their first product in the market in Europe. For each of the pillar capabilities mentioned, we detail the essential points to tackle when commercializing a product in Europe.



Managing HCPs as a first step

Starting with the most apparent system commercial team would think of, the CRM. As a central piece of the overall landscape and the tool used for the field force's daily job. As such, this tool must be available quickly and be easy to use. The first best practice for a small to a medium-sized company is to leverage the software vendor's knowledge and limit the configuration. Off-the-shelf solutions with limited specificities but available quickly provide more value than something 100% the needs but require months of development.

The second best practice is to keep the more complex processes outside of the system. Typically, account plans are challenging to integrate fully within the CRM system. The crucial accounts must be flagged similarly to Key Opinions Leaders, while documentation of the account plans should be kept outside of the system. The process will mature with the organization, hence focusing on the system

fields may be detrimental to adoption in the short run. After a launch in multiple countries, reexploring the module to engrain working conduct within the organization could be favourable.

The third strategy is to focus on data. Having the right HCPs within my territory will ultimately determine the success of the failure. Hence, focusing on findings, determination of the appropriate data provider for the market in scope is a crucial activity. The territory management should not be complex to start with but should ensure the HCPs are available for the field force to select.

Finally, the fourth-best practice related to CRM is to focus on the field force as a channel. Whether the field force will remain the significant channel is under profound discussion but for the upcoming years, at least for a launch, using a workforce to raise awareness will remain an essential part of the strategy.



Creating insights from your data

While the CRM system is getting ready for the first countries, a launch organization should start planning how to efficiently retrieve insights from all the interactions and touchpoints that the company will have with HCPs. Business Intelligence relies on data, but initially requires a shared understanding of the data point. Hence the initial step must be to align the various stakeholders on the definition of the entry point. It should be evident for every user what interaction means and how to facilitate it according to Standard Operational Procedures. Should a phone call be recorded? There is no right or wrong, but consistency is key to analyze the data effectively.

The second perspective is to key the metric calculation simple. Having a directional view quicker is more important than having the exact number when in a launch mode. These details could easily be refined later. The example of field days is a striking one. Knowing the number with an extreme value of accuracy will not provide a lot of value. In launch mode, the critical aspect is to ensure that the field force is in the field and not crawling under internal calls and training.

From this point, keeping a simple architecture is more straightforward and will favour speed while maintaining the required quality. If you are using a standard CRM, maybe the standard SFDC reporting is enough in the first phase. Sure, there are many limitations around those reports, but the essential data can be covered without any significant complications. On top of that, it is all real-time with segregation of data built-in, which would save you a lot of time and hassle.

Defining a standard way of working

When recruiting the field force, whether a field market access function, a medical affair representative or a key account manager, it should be anticipated that explicit company guideline will be necessary to steer the process. Even the top talent and most diligent employees would need a strategy providing them with adequate knowledge of the correct approach. Despite being capable of adopting the right mindset and defining suitable tactics to reach goals efficiently, they still require explicit strategies and company guidelines for working conduct before feeling comfortable enough to hit the field. Defining the business process or more precisely, the business framework in which the various users should play is an essential part of a launch strategy. Each business activity should have a clear strategy, where tasks and approaches are explicitly defined. How does the company want the field force to act in front of the customer? There should probably always be an opening statement about the novelty and the innovation brought to the patient. Maybe, it is a simple statement of the sense of purpose linked to the patients. Regardless of the case, it is vital to create a standard way of executing calls, and this is valid for all the business processes. In addition to defining the business process, it is essential to distribute them. Communication of the ways of working is always a challenge for any company. BASE has explored multiple manners to document and distribute those instructions, and a playbook in slides format has been proven to be the more effective way to share the information. This format avoids the lengthy activity to create standard operating procedures while still enabling to provide guidance and a policy to the users.

Focusing on the right customer

An essential activity of the commercial organization is to drive the organization towards the right customers. Segmentation is key, and companies must address each target group differently to effectively capture the intended audience's interest. Therefore, big pharma companies rely on complex targeting models based on thousands of data points, not available for small or medium-sized companies. This lack of data should not mask the value of the segmentation. There is a need for the marketing team to guide the field force towards the more interesting HCPs. It does not mean that the field force has no influence, they can provide precious feedback, but it is the marketing team's responsibility to provide a view on those segments.

BASE's recommendations include focusing on key attributes from both HCPs and HCO while sticking to them for the entire process from territory creation to frequency definitions. In the initial phase, choosing 3 to 5 key aspects that matter for your customer should be enough. Some of the dimensions may be function-specific, but the company's importance should be aligned regardless of the function. Typically, there should be a notion of the importance of the HCPs or HCO within the universe. An HCPs being a top prescriber for the disease in the district would be essential. Another critical dimension to understand would be the HCP or HCO's attitude towards the product or the company. Finally, another point should drive the content presented to the HCPs or the messages that must be received.

Of course, many other attributes could be tracked, such as his preferred channel of contact. Another trendy one is whether the HCP is open to virtual visits. Whatever the final model is, the goal should remain to guide the customer journey and ensure the company can move from point A to point B.

Naturally, companies should not forget the availability of data. Typically, the attitude or behaviour of a specific HCPs towards your active pharmaceutical ingredient may be tough to track.

When data on HCPs are scarce and time is short in launch mode, enabling the field force to collect more information in a structured format is essential. CRMs vendors have been providing survey functionalities to directly capture the content in the CRM and make it available for the marketing team to analyze the new data and make sure the segmentation is updated.

Delivering the right message through your assets

Once the segments are well defined, the company can focus on the capabilities required to deliver the right message to those various segments. It is crucial to create assets that can add values for the HCPs and provide the right message. Nevertheless, in Europe, most of the promotional material must internally be approved within a Medical/Legal review (MLR). Due to this legal requirement, companies must ensure that an MLR system is put in place. Few companies try to keep the process done via email, but it is a sure way to create a nightmare for both teams.

The US has a particular way of dealing with the MLR process with the FDA 2253 Form specifies certain aspects that are not relevant for the other countries. Given this reality, both the standard operating procedure and the system must be flexible enough to provide speedy approval while ensuring compliance. Developing a workflow that enables that flexibility may require a little bit of upfront work but is definitively worth it when the implementation strikes in.

Ensuring that all the expenses are reported

Since sunshine act stroke in the US, more and more countries have been enforcing transparency laws. Therefore, most companies are subject to spend reporting when they hold a marketing authorization, requiring newly set up companies to disclose all data points. One of the key challenges we have observed in BASE is the lack of ownership. Companies typically not start by creating a compliance officer position, and therefore, the entire process lacks a captain. Without a clear process owner, there is a significant risk that data gets lost.

Having an owner does not necessarily mean that a giant monster should be built. The process could still rely on manual actions based on an extract from the expenses system and the CRM. If the company has a clinical trial system, it is usually possible to map it in a way or another. Typically, BASE recommends focusing on the process and leaving the large systems out of the equation initially. The value of transparency reporting systems lies in the integration, and at the start, there is not enough stability to perform any integrations.



About the Authors



Luca Morreale, Head of Operations, Switzerland

Highly motivated consultant focused on solving commercial and pricing challenges for Life Sciences companies through advisory, assessment or implementation services. Luca is pragmatic & result-driven with a strong ability to lead a team in a complex environment to achieve project goals. Additionally, he is capable of providing insights on both a strategic level as well as an operational level.

 (+41) 76 50 38 714  lumo@baselifescience.com



Baptiste Mercier, Partner, Head of Customer Engagement, Denmark

As head of Customer Engagement, Baptiste is an expert at helping our customers create real business value from their commercial, medical, digital marketing and market access platforms and data. Baptiste has more than 15 years of experience with CRM in pharma and is PMP, ITIL, Salesforce, Veeva, and OCE certified.

 (+45) 60 53 66 53  bmer@baselifescience.com