

Preparing a product for market means placing as much data as possible into the public domain in order to provide credible support to the marketing strategy. The job of the field-force representative is made considerably more difficult without peer-reviewed publications to back up the claims being made on the detail aid.

This is where publication planning comes in. The area is a complex one and is greatly influenced by the therapeutic area and by the novelty of the product concerned. This fact sheet gives some basic insights into this field.

1 The need for publications planning

Publications planning – or a publications strategy – has the very clear objective of publishing or presenting all good preclinical and clinical data as efficiently as possible, bearing in mind the need to balance speed with the quality of journals and congresses.

The aim is to support the product when it is launched but this process continues well after launch to maintain this support and to fill any gaps in the data or address specific issues. There is, however, a crucial element missing in this description in that underlying the planning process is the need to reflect the product profile and product messages in all that is published and presented.

Publications planning should never be considered in isolation. It is the core of the overall communications strategy for the product, in that it drives the content of the multifaceted communications media used to bring the product to the attention of physicians.

2 What is It?

Publication planning is driven jointly by medical and marketing, usually within the commercial team, although it often starts earlier, either in research or in the team handling the commercialization of early-stage products. The process identifies the key data for the product from the preclinical and clinical research program and seeks to publish and present those data in a way that reflects the product profile and positioning to best effect. That, in essence, is the most difficult part because it requires real insight and understanding of the therapeutic area, the product and its competitors in order to create an effective and credible strategy.

Linked to this is the generation of the “deliverables”. This includes the writing of manuscripts and scientific posters, the scheduling of abstract submissions and journal supplements, and the collection of information on key journals and congresses. However, not wishing to undervalue the skills involved, this is essentially the process-driven part of publications planning and is, arguably, the “easy bit”.

3 How to organize the planning process

The publication committee is core to the planning process and brings together personnel representing all key parts of the product development team, such as medical, preclinical research, clinical research, marketing, market research, and regulatory. A strong chairperson with the necessary vision, and the ability to steer an often disparate group of people towards a common goal, is an enormous asset.

Publications planning for a new product needs a starting point. This starting point should involve an audit of all the available information available so far. For example:

Preclinical studies

Completed, ongoing, planned studies; details of any data that have been presented or published anywhere, either by the drug company's research personnel or by independent investigators, whether subcontracted or working independently.

Clinical studies

Completed, ongoing and planned studies from Phases I onwards; details of any presented or published data.

Published papers and abstracts

A search for all mentions of the new product in published papers and abstracts, carried out via Medline and other on-line databases.

Surprising as it may sound, not all pharmaceutical companies have this information to hand when they start the publication planning process, usually because the research and development team has had little direct communication with the commercial team. However, without a clear starting point, the planning process will be flawed.

Additional information that can usefully be gathered at the start includes:

Congresses

A list of major national and international congresses, ideally with some grading of these by those with an ability to judge, such as key opinion leaders.

Journals

A list of key journals in the field, their lead times, circulations and impact factors, and the view of opinion leaders as to the ones most highly regarded; it is also valuable to know which opinion leaders are on the editorial boards of which journals.

Competitor intelligence

A list of all the main competitor products, their pharmacologic properties and availabilities; comparisons with the new product are also useful to have.

How all this information is stored is a matter of practicality and personal preference. A table in a word-processing package, or a spreadsheet, are useful tools but a database is better, particularly if a number of different report formats can be created to generate the planning document (see Section 4).

The publication committee meetings themselves need to be very focused, as it is usually difficult to get everyone together on a regular basis. Getting bogged down in reviewing abstracts or manuscripts is not a good idea. The task of reviewing material can be

carried out by assigned committee members outside the meeting, and a communication network set up via e-mail.

4 What tools are required?

Complex planning is enhanced by good tracking, coordination and communications tools of some kind.

Few pharmaceutical research programs are sufficiently complex to require the use of Microsoft Project[®] to track the progress of publications and presentations. While it is the most popular project management software around, MS Project is a very complex program and is only worth considering if there is someone already expert in it, and then only for the lovely Gantt charts it can draw.

A means of storing information on studies and their outputs is essential, but the creation and maintenance of a database can often be more time and trouble than it is worth. A clinical research program with a relatively small number of studies (eg, 20) does not need a database to keep a record of the outputs. However, the publications committee will need a document with up-to-date information, and it saves considerable effort if this can be generated directly from the word-processing or spreadsheet software used to store the information.

A relational table database, such as MS Access[®], is a practical alternative but needs someone very familiar with the program in order to create and maintain the database and to generate the document directly from the database itself. The database field structure can become quite complex, depending on how detailed it needs to be. Multiple presentation of data, and the publication of data from more than one study, can make the whole thing problematical.

Many agencies extol the virtues of their own publication planning and tracking software. This is usually a suite of databases (eg, studies, published papers, journals, congresses), but there is an element of the “emperor’s new clothes” about these offerings, as they tend to provide more in look than they do in terms of utility and can be costly to set up and time-consuming to maintain. Such software is no substitute for the brainwork required in creating the strategy.

Where specialist software can be useful is in communicating publications plans to affiliate companies around the world, since the information can be shared via a company intranet. However, this is a spin-off of the publications planning, not a fundamental part of it.

5 Product profiling and messaging

If there is currently no clear profile for the product or a list of messages that support the profile, this needs to be remedied sooner rather than later. Although not necessarily the domain of the publications committee, it does impinge on its work, and some pharmaceutical companies link the two very clearly.

An inconsistent approach to the product profiling and messages can give competitors an advantage and will serve only to confuse the medical profession. Ideally, all posters and manuscripts should be reviewed in draft form specifically to ensure that they present the information in a way that is in keeping with the product profile and messages. This does not mean that they need to have a marketing “spin” put on them, and they certainly should not read as if all were written by one person; but if there is a specific way to describe, for example, the product’s mode of action, this should be reflected in any information that is put into the public domain.

Publications can subsequently be linked to the product profile or messages they support. In this way, gaps in the supporting data will begin to appear and action can be taken to fill them.

6 Why use an agency?

An agency can provide personnel with the skills a pharmaceutical company either does not have or is not able to spare. There are a great many tasks that the agency can take care of, but there are few agencies with personnel who have the right insight into the planning process and who are able to provide real added value.

On a basic level, the agency can sort out all the data, create the database, and produce the planning document. They can facilitate the committee meetings, prepare agendas and minutes, and support the chairperson.

Those with the right skills can do much more, such as:

- Make recommendations for prioritizing the presentation and publication of data
- Critique the data itself and provide something of a reality check on its credibility
- Identify gaps in the data, particularly when it comes to supporting the product profile
- Suggest different analyses or ways of cutting the data to best effect

An agency is also well placed to deal with congress secretariats and journals in setting up presentations and publications. Of course, the agency will also want to handle the outputs – the manuscripts and posters – but there is no harm in spreading these tasks around, even using freelance writers.

There are two main areas to be wary of. The first has already been mentioned – the use of sophisticated and expensive software to support your planning when it adds little to the efficiency of the planning process itself. The second is the use of pseudo-science in making publications planning sound mind-bogglingly complicated, which it isn’t.

7 The pitfalls

In no particular order of importance, here are some of the possible pitfalls that can adversely affect the publications planning process:

Not starting soon enough

Initiating publications planning is a task for the commercial team as soon as it is created. Ideally, the process should have been started by the research team as the product goes into Phase II and before the final decision to commercialise the product has been made.

Having unrealistic expectations

This covers a range of concepts, such as:

- Believing that every study is a worthy contribution to the *New England Journal of Medicine*
- Assuming that the medical profession is suddenly going to be gripped with anticipation by the new product
- Expecting the road to the publication of clinical data to be a smooth one – it rarely is!

In theory, effective publications planning can result in almost all of the available new data being available at launch in good quality journals, but that is always difficult to achieve given the numerous factors that can prevent this from happening.

Colleagues doing their own thing

Research colleagues, whether or not part of the committee, may be inclined to handle the presentation and publication of their own data themselves because they do not feel bound by the committee's remit.

Ineffective publications committee

The publications committee members pulling in different directions, or an ineffective chairperson, will make the whole process very difficult. A good agency can help in bringing the various factions together, but there needs to be a firm belief in the committee's role and endorsement from on high to make it work.

Lack of a commercial angle

Failing to support the product profile through the publications planning is a seriously retrograde step. It will be too late to do this once the publications start appearing in print.

An ineffective agency

The agency should help the committee chairperson to drive the planning process and give the support required to make it all happen. However, the agency also needs to have the right insight into the product and therapeutic area to offer real support and added value.

8 Linking to the communications strategy

Publications planning described here applies to original data, but there is an extension to this process – often called a secondary publications strategy – which involves priming the market with papers on issues relevant to the new product (even without mentioning it) and/or re-publishing data in the form of review articles. This can be an important strategy, particularly where the product is in a very competitive field and the differentiators are what will make the product sell.

In Section 1, it was mentioned that the publications planning process is the core of the marketing strategy for a new product. Studies generate authors, who become product advocates, who in turn make good speakers. Indeed, the clinical program is the first opportunity to create a group of physicians – the investigators – who are likely to endorse the use of the product. Congress symposia and other means of reaching physicians will reflect the product profile and messages and will utilize the published (and unpublished) data. Having a clear view on how that data should be unveiled is fundamental to a consistent approach to marketing a new product.

**If you have any comments on this fact sheet, please contact
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