Creating an effective regulatory plan

Regulatory strategy in a nutshell

It is very common—especially early in development—to be required to deliver multiple regulatory submissions for multiple regulatory agency interactions—Including:

- orphan applications,
- scientific advice, and
- the paediatric investigation plan (PIP).

The timing and content of these regulatory deliverables will depend on the timing of your other development activities, including when you plan to submit your marketing authorization application (MAA). Therefore, preparing and submitting a successful MAA requires a carefully considered regulatory strategy - starting at least 2–3 years in advance.

It is often difficult to prioritize what to focus on first, and how to conduct regulatory agency interactions in the most efficient way. A clear regulatory plan is invaluable to ensure you adhere to best practices for MAA planning and effectively streamline all your regulatory submissions before you get to MAA filing.

It is always a good idea to write a regulatory plan in Phase 1 and then again at least 2 years before you submit your MAA. The former will help you plan your early-to-mid-phase regulatory interactions and the latter will make sure you have identified everything that is needed to file the MAA.

We have written numerous regulatory plans across different therapeutic areas and modalities.

How we can help you devise your regulatory strategy

We can write a regulatory plan for your product to make sure you have an orchestrated approach when delivering your regulatory objectives, that align with your overall development plan. The areas covered in the regulatory plan will depend on what activities you have already completed and how close you are to filing an MAA.

In most cases, the regulatory plan will cover the following aspects:

All regulatory milestones in the lead up to your MAA filing

The timing and scope of all the major regulatory milestones through to submission of the MAA (orphan, scientific advice, PIP, Rapporteur and European Medicines Agency [EMA] meetings). Effective timelines will help you efficiently allocate resources and integrate your development activities.

Evaluation of existing guidance and the prevailing approvals landscape, and analysis of near-term competitors in late-stage clinical development.

- All of these factors can impact the development strategy and MAA submission.
- Evaluating these aspects will help you understand where there may be risks to your development plan and how these can be mitigated or avoided.
- Collecting this information also has an economy of scale regarding designing clinical trials.

Orphan designation and maintenance strategy for rare diseases

The overall orphan registration and maintenance strategy, in addition to recommendations for protocol assistance to gauge acceptance of the proposed strategy.

- This is key to ensuring that you maximize product exclusivity and commercial return.
- It is not always appreciated that orphan maintenance at MAA submission is a higher and more important hurdle than getting the designation.
- The strategy for demonstrating significant benefit against the standard of care can be complex and should be evaluated during protocol assistance with the Committee for Orphan Medicinal Products.

Paediatric development

An outline of the structure and strategy for the PIP, plus recommended submission timing and potential challenges during the evaluation.

- It is often the case that a PIP can take 1 year to agree with the Paediatric Committee.
- It is not possible to file an MAA without an agreed PIP – this is a significant undertaking that should be carefully planned and executed.
- In particular, the regulatory plan will help to identify deferrals where possible so that the PIP does not delay the MAA filing; similarly, waivers may be possible to avoid some, or all, of the requirements related to a PIP.

Scientific advice and protocol assistance

Priorities and timing for scientific advice and protocol assistance (for rare diseases), depending on the phase of development. Often it is necessary to take multiple rounds of scientific advice – it is usually better to take the Committee for Medicinal Products for Human Use (CHMP) advice for medicines that are destined for a central approval via the EMA. However, national advice may be feasible and add some value, especially where the Medicines and Healthcare products Regulatory Agency (MHRA) is concerned post-Brexit.

Regulatory benefits, incentives and fee reductions

Opportunities for fee reductions, through incentives available to:

- orphan drugs,
- cell and gene therapies, and
- and small or medium enterprises.

CHMP advice fees run into the tens and sometimes hundreds of thousands of Euros – we can help you avoid some or all of these costs using fee derogations. As a recognised SME, we can act as the orphan sponsor and provide small or medium enterprise status to reduce fees.

As part of the regulatory plan, we will advise your strategy for maximizing regulatory and orphan exclusivity and obtaining the paediatric exclusivity reward – either an extension to the supplementary protection certificate (6 months for non-orphans) or an extension to orphan exclusivity (2 years).

We can also evaluate the MAA content for Module 1 in the EU, to ensure you have identified all mandatory components – especially the supply chain and Qualified Person release strategy, risk management plan and qualified person for pharmacovigilance.

We have produced regulatory plans for numerous products across different modalities (small molecule and biologics plus cell and gene therapies) and therapeutic areas. We will write a coherent and well-thought-out regulatory plan, which will make best use of your resources, reduce delays in your development programme and avoid excessive agency fees.

Your roadmap to working with Somerville Development Partner

Initial conversation

It is always a good idea to start with an open-ended discussion about your needs and challenges, and we can give you some preliminary advice on how to approach your regulatory interactions in Europe and the US.

Project scoping

To provide a specific proposal for how we would approach your project, we require access to some of your project details. Therefore, we always recommend signing a confidentiality agreement before discussing the scope of your project.

Next, we will provide a scope of work for you to review. Once this is agreed, we will start work on the project.

Kick-off

We will assign an experienced consultant to act as your Regulatory Lead from the very beginning—your expert will take overall responsibility and accountability for your project from start to finish.

Your Regulatory Lead will always be someone who has:

- 10–15 years of experience
- tenure in established pharmaceutical and biotechnology companies, and
- been the regulatory lead on a global project team.

Your Regulatory Lead will be your primary point of contact and will also draw on support and expertise from additional consultants, as needed.

We ask that you securely share all product-related documents so that we can conduct a detailed evaluation of the data. This will enable us to provide informed recommendations for how we will deliver the project.

The most common documents we request include:

- study protocols,
- the investigator brochure,
- clinical study reports,
- briefing books from prior regulatory interactions, and
- meeting minutes from prior regulatory interactions.

This also means that we can repurpose as much content as possible to reduce costs.

We will agree the timelines, overall project delivery and desired outcomes with you. We will also identify the relevant stakeholders who will need to review and provide input into the project.

Delivery

During the project, we look out for your best interests and work to help you achieve your corporate objectives. We work as a partner and proactively identify issues, solutions and opportunities, rather than acting as a passive or transactional vendor.

Our consulting team will produce the agreed deliverables to the required timetable.

We will meet with you as often as needed to discuss the progress of the project and request any additional information. We will also meet—as necessary—to discuss review cycles, final signoff and submission.

Every project we work on undergoes peer review, as well as quality control of the final submission. That way we effectively draw on all additional experience from among our team of life sciences experts.

Feedback

Feedback is very important to us, so most of all we want to hear your thoughts on how the project went.

Getting in touch

We always welcome the opportunity to discuss a potential project with you!

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