Taking scientific advice and protocol assistance (PRIME and ILAP)

Scientific advice and protocol assistance in a nutshell

Scientific advice is how sponsors can receive feedback on key aspects of their development plan from either national agencies (including the Medicines and Healthcare products Regulatory Agency [MHRA]) or the Committee for Medicinal Products for Human Use (CHMP).

Where scientific advice concerns a designated orphan medicinal product developed for a rare disease, it is referred to as protocol assistance.

Scientific advice and protocol assistance are critical to the successful development of a new medicine for approval in the EU and UK.

We have submitted numerous scientific advice requests across different therapeutic areas and modalities.

Questions to ask the regulatory authorities

We will work with you to identify which aspects of your development plan require advice from the regulatory agencies, and at which point in the development. Priority questions may include some of the following aspects:

- Evaluation of the potential for conditional, accelerated or exceptional circumstances approval.
- Design of the pivotal (Phase 3) study.
- Orphan maintenance strategy.
- Strategy for generating non-clinical data prior to and after submission of the marketing authorization application (MAA).
- Details of the manufacturing of the commercial material.
- Experimental validation and experimental design optimisation.

We have conducted numerous scientific advice procedures both at a national and EU level, via the European Medicines Agency/CHMP.

How we can help you prepare for scientific advice/protocol assistance

The timing and strategy for scientific advice will depend on the timing of your clinical trials and MAA. Fee reductions are also important, and our approach is to minimize the required fees you pay as much as possible. We have supported numerous advice procedures and can:

- draft the questions and company positions for the briefing book,
- prepare and submit the advice package to the agency, and
- prepare for meetings with the agency during the advice procedure.

In addition to the above, we also offer the following services for Small and Medium Enterprises (SMEs) and clients developing a small molecule/biologic for the US market:

- As a recognised SME, we can act as the orphan sponsor and provide small or medium enterprise status to reduce fees.
- We can support the preparation of Food and Drug Administration questions and briefing books.

While there is value in taking national advice, we always recommend taking CHMP advice, since this is the committee that will ultimately evaluate any product which is submitted for centralized approval.

Regulatory pathways offering enhanced support

You can integrate scientific advice with pathways that are designed to provide enhanced regulatory support – including:

- The PRIority MEdicines initiative (PRIME) in the EU.
- The Innovative Licensing and Access Pathway (ILAP) in the UK.

PRIME is usually reserved for products with early clinical proof-of-concept data and the bar for acceptance is high – around 80% of applications are rejected. The endorsement that acceptance onto the PRIME scheme brings is analogous to breakthrough therapy designation.

Conversely, ILAP (conducted by the MHRA) is designed for products earlier in development and has a higher rate of acceptance. During ILAP, the MHRA will provide several 'tools' to help sponsors, including supporting the development of the target development plan.

We can advise you on how to approach PRIME and ILAP for the greatest return on your resources and with the greatest likelihood of getting accepted onto a scheme.

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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