

A Guide to Scientific Advice

The European Medicines Agency (EMA) can provide scientific advice to medicine developers to help support the development of high-quality, effective, and safe medicines. This advice can prove very valuable when it comes to designing and performing appropriate tests and studies.

In fact, according to an EMA review, following scientific advice recommendations for a previously non-acceptable study increased the probability of a positive Marketing Authorization Application (MAA) outcome from 41% to 84% (n=118).

Scientific advice can be requested at any time up to MAA submission, but early scientific advice can ensure that your development is designed efficiently and maximize the potential of a successful MAA.

So how does scientific advice work?

First



The medicine developer presents that way it plans to develop the medicine and identifies questions and possible solutions.

Then



The EMA responds to the specific questions posed by the medicine developer.

Scientific advice is most useful when:

- Developing an innovative medicine with insufficient EU guidelines
- Developing new or repurposed medicines for which there is an unmet medical need
- Choosing to deviate from scientific guidelines in the development plan
- Possessing limited knowledge about medicine regulation

Types of questions addresses can relate to:



Quality aspects



Non-clinical aspects



Clinical aspects



Methodological issues



Overall development strategy

Regulatory experts can help determine if you would benefit from scientific advice and support you in developing questions to ensure you receive the best advice from the EMA.

Contact Allucent's A-team of experts to learn more.