FMAG Consulting

Facilitated **M**edical **A**ccess **C**onsulting

Who is behind FMAG Consulting?

Florence MAHLBERG- GAUDIN, PhD, acts as a consultant at *FMAG Consulting*. Over 25 years in academic research and R&D pharmaceutical industry in USA and France, she has gained extensive experience and expertise by effectively contributing to several projects in various therapeutic areas, at all stages: drug discovery, nonclinical development, translational research, new drugs registration and market access, as well as post-marketing follow-up.

FMAG Consulting motivations and main interests: Healthcare improvement, innovation, young companies and start-ups, international health product development and market access strategy, company success.

How can FMAG Consulting help you?

The know-how of FMAG Consulting can benefit any stage of your health innovation project, from early discovery to post-marketing. Our goal is to provide recommendations and support to best value your product. Anticipation, optimization of time and cost, awareness of regulatory and access context with an integrated vision of the dataset guide our approach.

Nonclinical development programme

FMAG Consulting goal: to help you design, optimize and implement your nonclinical programme in an integrated approach to best address and anticipate clinical, regulatory and market access issues, on due time and for the best value.

Concretely:

- Advise on the strategy and operational implementation of your nonclinical development programme, including CMC, pharmacology, toxicology, and pharmacokinetics
- Provide support to create your study protocols, from design to report and publication
- Identify gaps and needs, set priorities

Regulatory Dossiers

FMAG Consulting goal: to help you present your product in a concise, coherent and robust way, to get the most out of your data and convince regulatory assessors

Concretely:

- Help you to produce sound documents for Pre-IND, IND, NDA and CTD files, answers to questions and meetings with regulatory authorities
- Coach your teams to be prepared for advisory boards, appeal and hearing meetings with public health authorities, including benefit/risk reevaluations, risk management plans…

Market Access

FMAG Consulting goal: be prepared for access to the market and get the best value of your product

Concretely:

- Help you to design and integrate your access strategy early in the development,
- Support your access strategy implementation through the identification and coordination of key actors and needed expertises to provide appropriate medico-scientific evidence supporting claims (*cohort studies, drug utilization, real life medical practice, meta-analysis,..)*
- Build your Health Technology Assessment dossier
- Train for meetings with HTA agencies

Project Management

FMAG Consulting goal: to facilitate your project management, by providing tools to lead complex interdisciplinary projects in a multi-cultural/ international environment, with a results-oriented and continuous improvement mindset.

Concretely:

- Facilitate your collaborations and interactions with your partners (project team, investigators, key opinion leaders, experts, CRO's …) at national and international levels.
- By analyzing each situation, we help you find the best solution.

Looking forward to working with you and facilitating access to your health innovation

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