NDA Advisory Board

If you are looking for answers to your drug development concerns, the top level advice from NDA's Advisory Board is unmatched in the market. This unique group is comprised of some of Europe's most distinguished regulatory and HTA experts - leaders in their fields.

Using our Advisory Board allows you to get competent, unbiased answers and input into your development program, reducing risks and improving your chances for success.

The aim of this is to facilitate a fast and positive outcome to your drug development program.

Some of our Advisory Board members

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NDA

Integrated Regulatory & HTA Advice

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NDA is a leading regulatory, pharmacovigilance and HTA consultancy. We offer advice throughout the lifecycle of your product, from early development, through scientific advice and regulatory review, to market access and into the post-authorisation phase. Our team of over 100 specialist consultants, in collaboration with our unique Advisory Board, can give you the best advice and support to get your drugs to market, and keep them there.

Regulatory approval no longer guarantees the success of a new drug. The next hurdle is gaining payer approval from each individual health care system across the EU.

The future lies in addressing regulatory and HTA issues at the same time, something NDA has taken the lead on for the past few years. Our team has considerable experience of guiding pharmaceutical companies of all sizes on the direction and corrective actions needed to meet the needs of both regulators and payers in the major markets.

Integrated regulatory and HTA advice increases your chance of drug approval and reaching the patients.

An integrated approach with the NDA Advisory Board

NDA's Advisory Board comprises the most prominent and well-respected experts in the field of regulatory, HTA and pharmacovigilance. Each has been selected for their unique experience and all have worked in senior roles within regulatory agencies, payer healthcare bodies, academia or industry.

The combined HTA and regulatory expertise provides top-level integrated advice in a single consolidated report. This is a unique service to the pharmaceutical industry. Some regulatory agencies offer "integrated" advice - parallel regulatory and HTA Advice without the opportunity for regulators and payers to come together to discuss and conclude what would satisfy the requirements of both.

At NDA, our thinking and advice is truly integrated. Our Regulatory and HTA Advisory Board experts discuss each project and the questions that the company seeks advice on. The outcome is a clear cut development approach which will satisfy both payers and regulators.

Better still, this advice is completely independent, risk free and impartial. The advice received will help the client better understand the authority's expectations and make the most of formal agency advice. Clients leave with a well researched and thought-through integrated and consolidated report on the specific situation in question.

The NDA difference

NDA has offered integrated regulatory/HTA advice to several pharmaceutical companies for many years. All positively cite the benefits reaped and have revised their development programs as a result. Some have adapted internal development processes as a result. Most have used our advice to help develop the right questions and drive the agenda to enable them to seek parallel regulatory and HTA advice from the regulators and payers.

NDA regulatory & HTA expertise

The scope of the NDA Advisory Board is broad. It ranges from integrated feedback on phase I-III requirements, preparing or providing alternative assessments to parallel EMA/HTA advice. We can provide general strategic advice on likely approaches to be adopted by health technology bodies and payers in certain therapeutic areas, considering todays's environment, plus likely future developments. In addition to specific comments on a clinical programme, including input on endpoints, comparators, population etc, we can support with: positioning in the treatment pathway; starting and stopping rules; necessary additional analyses such as modelling or QALY calculations; follow-up studies and data collection to support/extend reimbursement.

Why integrated advice from NDA?

- To enable informed decision making resulting in more focused and efficient product portfolios.
- To modify development programs to simultaneously meet the needs of multiple stakeholders and reduce the duplication of efforts.
- To facilitate the constructive resolution of internal differences of opinion and ensure internal commitment to agreed decisions.
- To assess in-licensing opportunities to reduce investment and development risk.
- To increase the value of products in the eye of investors through unbiased, independent assessment of the products' development potential.