NDA Advisory Board

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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.

Our Advisory Board provides 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.

Contact us

NDA Advisory Services Ltd

Prime House, Challenge Court
Barnett Wood Lane
Leatherhead
Surrey KT22 7DE
UK
T +44 (0)1372 860 610
E info@ndareg.com

NDA

NDA Advisory Board

Regulatory Scientific Advice
Joint Regulatory/HTA Advice
Re-submission Advice
Oral Explanation Rehearsals
Post-approval Advice
Risk Management Plans

NDA Advisory Board

Looking for a way to align your development programs to the requirements of regulators as well as payers?

The NDA Advisory Board can provide you with unique insights into what the Agencies are looking for from the leaders in their field.

The pharmaceutical industry is changing. The uncertainties are even greater. We operate in a global landscape needing broader thinking. And we can no longer plan for regulatory needs alone. Let us help you to reduce the unknown and arm you with the expertise needed to get good medicines to patients.

The NDA Advisory Board represents the complete European knowledge on all regulatory, Health Technology Assessment (HTA) requirements. Our Board is completely unique. Nowhere else in the world will you get the Agency insights our team have, that is independent and impartial. All members are selected for their distinguished contributions to regulation and HTA, coupled with their dedication to positive and cost effective drug development.

25%
of MAAs fail

How will the NDA Advisory Board provide value to your company?

Approximately **25% of applications to the centralised European procedure fail**. An approval from the regulators is also no longer a guarantee for market access. HTA requirements are different from the regulatory requirements and even varies among the Agencies themselves

For over ten years NDA has provided unbiased Regulatory, and more recently HTA advice to the industry, improving the quality of several hundred development programs. This has created a **unique scientific capability without comparison**.

The NDA Advisory Board provides you with the information and confidence you need to efficiently take your product to market.

The NDA Advisory Board:

- Enable informed decision making
- Help you understand the requirements of regulators and payers within your development program
- Help to effectively resolve internal differences of opinion
- Assess your in-licensing opportunities to reduce investment risk

38%
of positive opinions were supported by NDA

How the Advisory Board can help YOU

Today NDA supports 90% of the world's top 30 companies. 38% of products recently receiving positive opinions in the EU centralised procedure got there with the help of NDA.

Examples of NDA Advisory Board activities:

- **Joint advice** on HTA and regulatory plans to enable a strategy considering the full outcome of your program
- **Assessments on internal plans** in relation to varying requirements of different therapeutic areas as well as different jurisdictions
- **Pre-submission reviews** of HTA / regulatory dossiers to provide advice, enabling informed development strategy decisions
- **Advice during the review process** to answer questions or provide clarifications enabling increased understanding
- **Advice on the appropriate design** of post approval study commitments, including market access schemes
- **Development due-diligence** in the face of acquisitions or in-licensing
- **Oral Explanation rehearsal** advice to development / regulatory teams

Reduce your risks
↓
Increase your efficiency
↓
Improve your business