



## Importance of Excellence in Scientific and Regulatory Communications

The ever-changing complexities of the regulatory world demand excellence in communicating science, data, development program goals and intentions, as well as how foreseen risks are being managed.

These complexities also mean that drug development companies must engage candidly with regulators and lead the scientific conversation with clarity and flexibility, yet be poised to negotiate their position.



While we work with global companies to strategize and execute successful engagements with regulators at critical junctures such as Oral Explanations and FDA Advisory Committee meetings, excellent communications are the backbone of streamlined, efficient programs achieving approval and market access.

A number of potential pitfalls await companies with even the most solid science and robust datasets. To avoid costly delays along the path to regulatory approval and commercialization, companies need to:

### 1. Communicate internally

To ensure alignment of clinical goals and regulatory approvability with the reality of a product's potential market value and accessibility the company needs efficient internal communication. The danger lies in a narrow focus on just regulatory considerations: A product may be effective but if there is no place in the market or doubtful economic defense of pricing, the company is wasting time and money. Development plans must be based on all considerations, requiring careful coordination and collaboration across all divisions.

### 2. Communicate with regulators

Unfortunately, too many companies engage with regulators much too late, or not at all, or lack the candor and skill needed to usher a product smoothly through the approval process. Excellent communication means asking the right questions, clarifying any questions from the regulators and responding in a collaborative and transparent manner. Remember that specific expertise in your company's product is rare, hence it's critical to clearly shape the story of not just the data but also the program, goals and risk management commitments.

### 3. Communicate globally

Just as internal divisions must be aligned, regional requirements vary in Europe and across the globe. Companies risk costly mistakes and a need to "redo" when they don't share knowledge freely internally. This is particularly important for US/EU programs. Learnings from multiple regulatory authorities or groups of payers must be transferred so there is no duplication of effort – or waste of time – on the other side of the pond. Constructive interactions speed efficiency.

## 4. Engage physicians, patients and advocacy groups

Get the community involved early, including doctors and potential study sites as well as patients and advocacy groups. Communicating with these stakeholders also demands delivering the messages behind the data in a concise and compelling manner to a wide variety of physicians, KOLs and other influencers. With such deep knowledge of one's product, it's a daunting challenge to distill the information, refine the message and keep it brief and clear for the audience.

## 5. Negotiate with payers

Companies put enormous effort into developing slide decks, internal FAQs and value proposition documents. This plethora of planning and information is to no avail if the company does a poor job of interacting with payers. In addition to understanding the audience around the table and their goals, the company must respond deftly to questions, defend the data, and communicate persuasively. Every interaction is an opportunity and certainly, when it's time to negotiate pricing, excellence in communications is critical.

## How we can help

NDA Group supports life science companies all over the world with the single aim to streamline the global development and commercialization process in order to accelerate patient access to important medical therapies.

Whatever regulatory hurdle you're facing — a Type B meeting, a document submission, or a SAG hearing — our industry-leading professionals will help you strategize and execute successful engagements with any global authority. We'll help you optimize every regulatory interaction and shape the dialogue about your product to create a more direct path to approval.

In the US, our Principals and Communications Strategists are particularly experienced at preparing for FDA Advisory Committee meetings, in addition to pre-IND, end of phase 2, pre-NDA/BLA, PMA, and mid- and late-cycle review meetings. In Europe, we assist with Scientific Advice Group meetings, Oral Explanations, PRAC meetings and preparation for intense pricing negotiations. We offer our clients an unparalleled breadth of global experience and expertise to drive efficient product development and health authority interactions across the US and Europe.