# The Art of the Possible: Translating Emotion into Data

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**When anecdotes become evidence, patients gain even more power in the R&D process.**

It is exciting to see multiple elements of the healthcare ecosystem activating and adapting to the idea that patients are taking a more central role in the development, regulatory review, and clinical use of advanced biopharmaceutical products. This phenomenon has been building over time, for sure, but it feels like the time has truly come. We are, as a collective group of participants in the complex process of making new medicines, moving beyond theory and exploring the art of the possible. Longstanding practices are changing, and conventional methods are being reevaluated. Patient groups are building entirely new functional capabilities. Biopharmaceutical companies are institutionalizing methods for seeking and integrating patients' perspectives into their drug discovery and development plans. At the same time, FDA is working to develop new systems to infuse the perspectives of patients into the regulatory review process.

It's hard to overstate the potential significance of these developments.

Starting at the beginning of the process of creating a new medicine, partnerships with patient groups will give academic and industry researchers access to high fidelity information from patients informing the choice of molecular targets and design goals for new drug development programs.

Once a medicine is in development, involving patient groups in the design of study protocols and endpoints will be critical to ensuring that multi-year programs costing many tens of millions of dollars actually yield data that are useful and important—not only to regulators, but also to the patients who will be living with that medicine.

FDA will increasingly look to patients for both qualitative and quantitative input as they evaluate the risk-benefit tradeoff for new medicines under review. This is a critical perspective that is most appropriately gauged by those directly affected by both the benefit and the risk.

Finally, after a new medicine reaches the market, patient groups will be the most effective agents to assure its correct placement on formularies and determine appropriate restrictions or limitations on its use.

All of this sounds wonderful, but new capabilities need to be created by all of the players to make it happen. I am quite familiar with the changes we at Alkermes, and others in industry, are driving in our companies. Like any other important change, it requires vision and a team of like-minded, energetic individuals dedicated to the mission. What is more fascinating and intriguing to me are the profound changes that are happening within the patient groups themselves.

In my view, a "state-of-the-art" patient group five years from now will have a broad range of new competencies and expertise and will be, by necessity, quite well-funded. Small organizations founded to raise money to fund basic academic research and patient information services will likely need to evolve. Otherwise they will face the potential of being eclipsed by larger organizations that can fund basic and clinical research, sponsor and manage large patient registries, collaborate with industry, advocate to affect government policy, interact with FDA to shape regulatory policy, develop new tools to measure patient preferences in scientifically rigorous ways, and negotiate with insurers and other payers—among other things. While there is no one-size fits all approach, there are many models emerging among the patient groups and it is exciting to see existing models being challenged and best practices being shared and replicated.

So, this is happening. Right now. And we all—patient groups, industry, FDA, payers—are the ones making it happen.

At the core of this transformation, as we elevate the perspective of the patients, is the idea of developing the methodologies and tools to translate emotion into data. Patients, their families, and the advocacy organizations that serve them already tap into a tremendous reservoir of human emotion. Those of us who discover and develop new medicines, the teams at FDA who review them, and the gatekeepers who decide who ultimately will gain access to them all need to understand that emotion. One of the best ways to do that is to translate it into the common language of science. Then, anecdote becomes evidence and gains even more power. The most impactful patient groups will be those who can rigorously capture emotion as data and then use it to drive the changes they desire.

A "state-of-the-art" patient group five years from now will have a broad range of competencies and expertise, including:

- **Funding basic and clinical research**
- **Sponsoring and managing large patient registries**
- **Collaborating with industry**
- **Advocating to affect government policy**
- **Interacting with FDA to shape regulatory policy**
- **Developing new tools to measure patient preferences**
- **Negotiating with insurers and other payers**