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Good Science Presented Well Generates Approvals

Getting a pharmaceutical or medical device approved for marketing requires good data above all else. Without good data, any application has little chance of success.

But – what is good data? Is it simply having results that are statistically significant? Or having trials done well? It is much more than that.

An FDA or EMA application must tell a compelling, truthful story. A story which, above all else, says, "this product is the essence of good science presented well." Good science because the work must be done well and have acceptable results. And presented well, because the total package must make sense. Look at your business situation this way. These Agencies are science-based, focused on protecting public health. They issue and enforce regulations that characterize their commitment to protecting the public in putting the drug onto the market and beyond.

This means the regulators care a great deal about the science behind your drug. Working with a regulatory consultant that has an excellent understanding of the science and how to present it properly is the surest and best path to approval.

However, it is crucial that the underlying science is good.

What Is Good Science?

Everything you do with your drug program is about meeting the dynamics of a regulated industry. One of the primary ways to meet those dynamics is by having good science behind your drug development process.

With that in mind, what is good science in the practical sense? Good science is using good clinical practices to derive data that you can believe and trust. This is true whether the data turns out to be favorable or not.

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Unfortunately, despite all efforts, not every drug has favorable data. The data that comes out of the clinical trials may not be the data that you would like to see. That's the reality of the drug development process. Good science does not create the data you want. Good science creates data upon which you can depend – favorable or unfavorable.

Working with a regulatory consultant that has an excellent understanding of the science behind your drug and how to present it properly to the FDA is the surest and best path to approval.

A good example of data with good science behind it that took a drug in a different direction is the drug Latisse.

This is a drug that was originally tested to treat increased eye pressure (glaucoma) in elderly people. It worked, but it had an unexpected and highly noticeable side effect. People in the clinical trials reported that their eyelashes were getting so long that they were touching the lens of their glasses. This was how the Sponsor discovered that Latisse makes eyelashes grow longer and thicker.

Even though Latisse was approved to help manage glaucoma, it seemed to show lots of promise in the "cosmeceutical" market. The Sponsor restudied the drug and now it is an FDA-approved treatment to grow eyelashes for people with inadequate or not enough eyelashes.

Every drug should have good, and therefore reliable, science that underlies it. So, even if the data is not that pretty, sometimes – with the help of a well-qualified consultant – you can still make a good case to the FDA.

What Is Bad Science?

Bad science is the converse of good science.

Bad science is work being done poorly or not at all. For example, failure to comply with good clinical practices (GCPs) at some crucial point or points. Perhaps the clinical trial was designed incorrectly, or maybe there was bad conduct during the clinical trial. For whatever reason, GCP was not followed during the drug development process, and that led to bad science being performed.

The primary problem with bad science is that the resulting data is unreliable. This is true whether the data is favorable or unfavorable. Practically speaking, favorable and unfavorable data produced by bad science are equally bad because the data is unusable and cannot be presented to the regulatory agencies.

Here is an unfortunate example of the broader impact of bad science. In September 2016, the Chinese Food and Drug Administration (CFDA) announced that nearly 80 percent of the country's clinical trials included falsified data. This self-disclosure is commendable and is, at the very least, a critical shot across the bow of the Chinese pharmaceutical manufacturing sector – an industry rife with questionable business practices that include inadequate quality controls and intentional misrepresentation of clinical trial outcomes.

When you have an intelligent path – based on good science – you are well-positioned to tell a persuasive story to the FDA and EMA/local national agencies.

Good Science Presented Well Wins

One aspect of drug development is that you are building a story. You are taking a product and slowly walking it through the necessary steps to say "Hey, this product works. It works in the right people and the right way."

We all know people who are good at telling a joke, and we know people who are terrible at telling a joke. The people who are good at telling jokes are good partly because they are good at telling stories. When dealing with regulators, you must be good at telling the story of your drug development program. That is good science presented well.

One way of looking at the drug approval process is that regulations and guidance draw a box that delineates the parameters in which your drug must fit. Unfortunately, there are many drugs that don't fit inside that box. Even if they have good science behind them, their data leaves them at least partly outside of that box.

This is where the presented well piece of the puzzle comes in. If you have good data, and you explain your data well, then it is much easier for the Agencies to understand your product and approve it.

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The Value of an Excellent Regulatory Consultant

A lot of companies are not sure what's the right path to follow when dealing with the regulators, and that is understandable. Every drug is different. Every disease is different. Even if you've done this before, figuring it out again is a challenge. That's why you want to work with people who know what they're doing and have a long, proven history of dealing with the drug approval process.

Imagine that you are planning to go on a hiking trek in a vast area where you have never been before and don't know where you are going. You would want an experienced guide. The same principle is true when working with any regulatory Agency. You want to have an experienced guide, someone who has walked the path before, to get you where you want to go. Therefore, an excellent regulatory consultant is one with a good scientific background and an understanding of how to present data so you can get to where you want to go.

An excellent regulatory consultant will help their clients develop the good science behind their product's story. This is accomplished by providing the necessary advice and feedback.

For instance, if a protocol is not designed correctly or if the method used for internal audits is not quite right, the regulatory consultant should inform their client along the journey toward the creation of good science. The right regulatory consultant understands that Sponsors are in the challenging position of having to figure out which organization is the right partner for their journey to market approval. The Sponsor's position is challenging because they are dealing with time and budget pressures to get to the next milestone on the regulatory continuum.

Win with ProPharma

One of our mantras at ProPharma is "science minds over regulatory matters". It means that we understand where you are in your business and the pressures you are operating under. We know where you need to go, and we know how to get you there as efficiently and as cost effectively as possible.

There are many consultants out there who try to shorten the process and then end up failing their clients. There are also some who take far too long. What you and your consultant must do is find the right balance between what works, what doesn't, and how to get the desired result. That's what an excellent partner should be, a consultant that understands your strengths and matches them up against their strengths.

Many of our clients make a product that doesn't fit perfectly into the box which the Agencies want it to fit. One of our core strengths is explaining, using science, why the product is okay despite the difficult fix. We leverage your good science to present a convincing story. That story explains why this is a good case for the Agencies to change that rigid square into a flexible rectangle that includes your product. That is because, even though your product doesn't fit within the rigid square, as long as your product is still safe and efficacious, it should be approved.

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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