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Case Study

# Disclosure as a Service Case Study

## Small but Growing Biotech Manages Disclosure, Maintains Compliance and Keeps its Promise to Patients

February 2019

# A Small but Growing Biotech, Passionate About Patients, with Disclosure Needs

A 500-employee pharmaceutical company may be considered small but this biotech, in terms of number of trials, is steadily growing. According to its senior director of clinical processes and systems, “Our pipeline is robust and healthy. We have a number of ongoing trials. If I were toput a number plus or minus five, we’re looking at about 25 today.”

He emphasizes the organization’s dedication to helping the patient. “That’s been the primary focus,” he says. “The mission pretty much speaks to the volume of what we do as a biotech pharmaceutical company, so it’s always about the patient. And that’s been the foundation of the company, that certainly is the principle and the belief of our CEO, and the culture of the company is pretty much based on that.”

While most large sponsors place a high priority on transparency, smaller sponsors are not as quick to jump on the bandwagon. This one is an exception. The director says the intent of trial disclosure is to bring awareness to patients about what the organization is doing in terms of, for example, its therapeutic areas. “By really being transparent, we’re helping the patients become aware of what we do as a company. So I think that’s really the main driver for this. That’s why I think we’re so passionate about being very, very transparent when it comes to trial disclosure and transparency. We really want to make sure that we’re delivering on our promise to the patient.”

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# The Desire – but Not the Expertise or Resources – to Manage Disclosure

For this biotech, the big challenge was both a lack of expertise and resources needed to manage registration of trials and posting results. “We just didn’t have the bandwidth to be able to take on all the associated work related to disclosure,” the director says. While he is the sole employee tasked with disclosure, he does work with a cross-functional team represented by clinical operations, regulatory affairs and legal.

As a senior staff member he approached the project by assessing the current state to determine what was needed to get up to speed for 100 percent compliance. For him, that was the tipping point. He points out that clinical trial disclosure is a heavily regulated area, particularly in Europe. Given the fact that the company conducts global trials, he says compliance was “front and center in my mind.”

## What If… the Repercussions of Noncompliance

In addition to running afoul of regulatory agencies, the director says a lack of transparency would damage the organization’s brand. Referring to the FDAAA Trials Tracker, which publicly tracks compliance of sponsors, he says: “We certainly do not want to be one of the companies that get published on that website. So we looked into how best we can manage this in order to be compliant.”

# For a Small Sponsor, Outsourcing is the Name of the Game

As a small biotech, the company relies on an outsourcing model. “We heavily outsource all of our trials. And that comes with the territory of being a small company,” says the director. “We don’t have deep pockets, if you will, to be able to employ all the necessary people that we need to be tasked with this project. “Keeping in mind that we outsource all of our clinical trials,” he continues, “it made business sense to use a third-party vendor for trial disclosure as well. So it’s really keeping it aligned with the primary business model of outsourcing. It was a logical move to outsource disclosure with a company that really understands disclosure and trial registration.”

He says that, prior to partnering with Citeline, the company did not have technology in place. “Everything was done via email,” he says. “That’s how we were reviewing study records, and I knew that it was not an optimal way of managing disclosure. We needed a more robust solution.”

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# Word of Mouth Leads to Not Just a Solution, but a Partner, for Disclosure as a Service

"And that's where Citeline came in," he says. "Citeline is synonymous with expertise in trial disclosure and registry. We basically made a decision based on the experiences that I've heard from other companies."

Getting executive buy-in can present another obstacle for sponsors large or small. Not so for this organization. "Well, to be perfectly honest," he says, "this is probably one of the very few projects where I could really say from inception to blessing and the green light to go ahead, it really happened with 24 to 48 hours.

"It was really quick. The moment we decided to outsource this and submit the proposal, the next thing I know, we were drafting and reviewing and approving the contracts. Not much convincing was needed on my part to really get this going. I mean I was pretty pleased with the engagement from our upper management. And by that I'm talking about all the way to the executive committee members." He says this is a reflection of how committed the organization is to being compliant with disclosure.

The director explains that it's not the typical vendor-client relationship. Both parties have forged that relationship into a partnership. "Awesome" and "excellent" are words he uses to describe the Citeline staff, adding, "I truly, truly appreciate it. I couldn't be more pleased with the engagement that we've established.

"I repeat myself all the time," he says, "how pleased I am with the partnership. Citeline has really delivered and really exceeded my expectations. The team is really committed to helping us out."

In particular, he cites Francine Lane, Citeline Senior Director Product Management, for her expert recommendations regarding regulations, registration and results postings, including some of the pitfalls. "Based on what we are learning now, the organization will be an expert in trial disclosure. And I don't think we would be able to achieve that without the help and partnership with Citeline."."

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The Director says the company's level of pain managing disclosure compliance prior to TrialScope Disclose was about 95 percent. He describes it visually, with a smiley face being the least amount of pain and a frown being the most. "I was frowning before Citeline. I'm now in the smile range," he says with a smile. "Even though we're not there yet, I think we're certainly moving the needle towards that 100 percent compliance. It's just a question of time."

# A Word of Advice

The director offers a suggestion to sponsors seeking help with clinical trial disclosure. His advice? Really understand what the vendor can deliver.

"Citeline," he says, "has really been active in this space and I think there's a lot to be said about being out there in the public and is working to do what is right for companies like us. I've seen enough of Citeline's articles to know that it is front and center, working to partner with NIH and the European public domains to be in a position to help clients like us, including some of the bigger pharmas that are challenged with the disclosure. Citeline has been instrumental in bringing us up to speed on where we need to be in terms of transparency."

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## About Citeline's TrialScope Disclose

TrialScope Disclose is the global leader in clinical trial disclosure and transparency management technology, supporting 13 of the top 15 industry clinical trial sponsors worldwide. TrialScope Disclose provides proven solutions that optimize the eciency of disclosure activities, maximize trial data transparency, and foster more informed, engaged patients through open research sharing.

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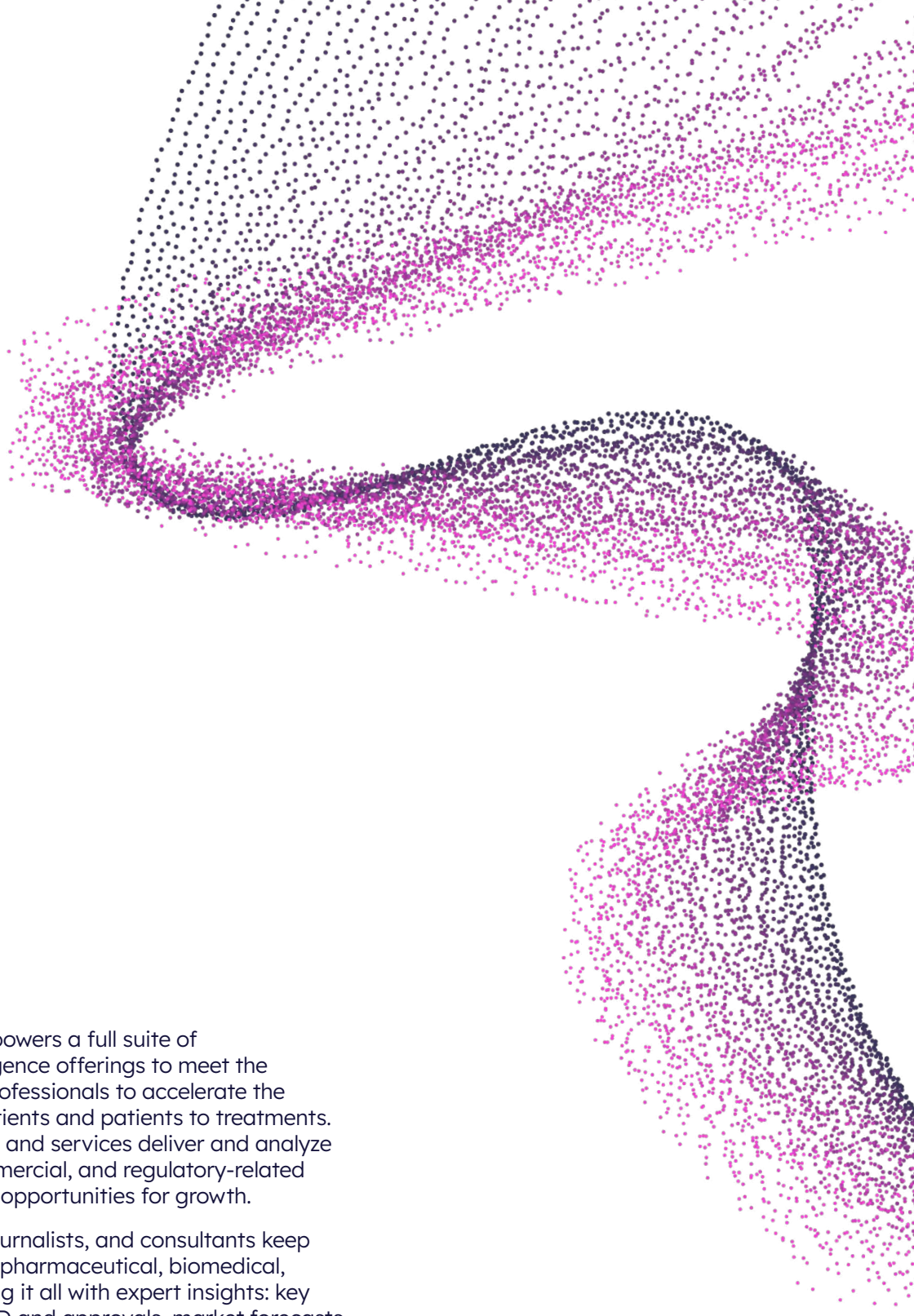

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