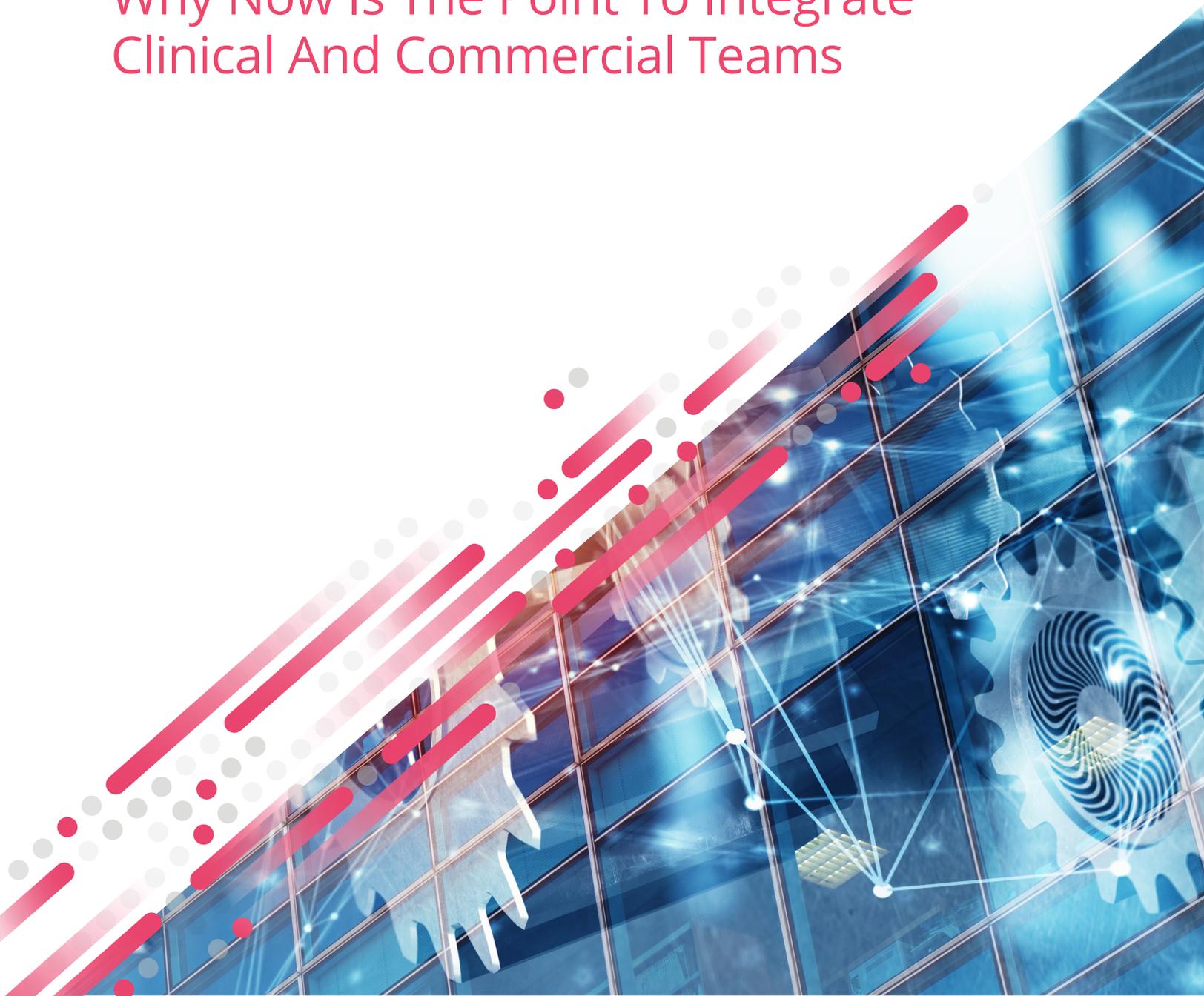


AN IDEA WHOSE TIME HAS COME: Why Now Is The Point To Integrate Clinical And Commercial Teams





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The EU's well-trodden route for commercializing medical devices is now permanently altered. Regulatory changes in Europe mean companies can no longer use the region as a springboard for rolling global commercialization plans, forcing them to rethink how to efficiently get devices to market. In this new, more demanding environment, for manufacturers there are big benefits to integrating their clinical and commercial teams.

Traditionally, developers of medical devices have been able to defer big investments in clinical trials until after their products are on the market and generating sales. The deferral was enabled by the path to market available in Europe.

At one time, companies needed little more than a quality management system to obtain a CE mark and start selling devices in Europe. The rules have tightened up somewhat since then, but today Europe still offers companies the chance to bring devices to market based on limited data. Importantly, CE markings awarded to devices in Europe also serve as keys to other countries such as Australia, enabling businesses to quickly start generating sales in multiple geographies.

Now, Europe is set to shed its reputation as the gateway to global medical device markets through a radical regulatory overhaul. Adam Steadman, vice president of clinical development at Syneos Health, said that while at one time European market access rules did not address “whether a device worked, whether it was safe,” beginning next year, the requirements in the region will be “in many ways tighter than in the US.”

The upshot is that now, more than ever, companies need to think differently. Strategies that worked well in the past will simply not work in the future. In this new environment, the concept of integrating clinical and commercial teams and putting an Asset Strategist at the center of the resulting broader group is gaining traction.

To understand the emerging landscape, *Medtech Insight* sat down with Steadman to discuss how market changes are driving clinical-commercial integration and how device developers can adapt to the new normal.



Adam Steadman,
vice president of
clinical development at
Syneos Health

How will the incoming European medical device rules affect commercialization strategies?

Historically you had time to play with because you had a product you could legally market in Europe very quickly after development and so you could commercialize it rapidly once the CE mark was applied. Companies used to start selling devices in Europe, use the CE marks to access Australia and New Zealand, and only consider the US and more complex markets like China and Japan once they had launched commercial products and started generating revenue.

You didn't need to have clinical-commercial integration because there wasn't much of a clinical aspect to it. But the rules in Europe have become tighter and tighter, and next year they're going to become very tight.

Commercialization is a completely different story now. You will no longer be able to leave clinical trials until later, which you used to be able to do. Now, there is much greater demand on clinical evidence. This will drive the need for closer clinical and commercial integration in many companies that historically didn't work that way.

Why are integrated clinical-commercial teams well suited to this new environment?

Integrated teams increase the likelihood of generating the right clinical data required to clear newly raised regulatory barriers and meet reimbursement requirements. Clinical staff that are disconnected from their commercial counterparts risk running studies that fail to generate the evidence needed to support the planned sales and marketing strategy.

Eliminating silos reduces that risk. Our integrated teams define the claims a company hopes to make about a device and the revenue-generation methodologies and work back from there, saying, “What do we need to do from a clinical perspective to generate the required evidence?” This means thinking about the data needed for regulatory purposes, the evidence that will get payers to pay for the device and have confidence that it’s going to do what it should do and influence the prescribers and hospital systems to use their device.

For example, say a company is developing an intensive care device it hopes will reduce the average stay in the ICU from three days to two days, thereby saving 10,000 ICU nights a year. That’s the kind of information we have to generate from a clinical perspective so that we can use it as a commercial marketing claim.

How does clinical-commercial integration work in practice?

It takes many forms, depending on the needs of the device developer. Sometimes it can be just a tiny touchpoint between clinical and commercial groups, such as asking somebody in the reimbursement team to help a sponsor choose the right endpoints for a clinical study.

At the other end of the spectrum, the integration forms an overarching full-service delivery. When we joined our clinical and commercial organizations, we developed the Biopharmaceutical Acceleration Model (BAM). The recognition that we have this ability to deliver an asset from lab to life is the catalyst for the development of the Syneos One organization.

When we can identify early on an asset (or device) that will benefit from the strength across the entire Syneos Health organization, we assign an Asset

Strategist. The Asset Strategist is responsible for ensuring the clinical and commercial objectives the sponsor has are met within our work. Syneos Health can handle all the clinical work and a complete brand launch. In these cases, we may put a Syneos One project leadership team in place with members across the clinical and commercial functions. They will work together to establish what clinical data will be needed to support the desired product label and pricing, and oversee every step in the process. In addition to the clinical oversight, the Asset Strategist helps engage commercial leadership to provide branding, marketing, sales people, CRM systems, advertising campaigns, pricing and market access strategies, you name it.

Why would a device developer want to outsource that wide range of activities?

Building commercial infrastructure from scratch is theoretically possible but in practice it could take years. We can wrap infrastructure around a product and get moving really, really quickly. So one thing we do is give you infrastructure when you need it.

The second thing we provide is optionality, so that you are completely free to develop your infrastructure however you want in the future. If you plan to develop products for years to come, you can build your own clinical, commercial and regulatory departments. But if you’re a single-product operation with an early exit strategy, you’re not going to build infrastructure to get a single product cleared or approved.

Yet, even focused single-asset operations can end up needing internal infrastructure. You may have an idea of how you’re getting commercialized, how you’re going to exit or how you’re going to sell or partner the product off with somebody else. But

very often it may work out completely differently. So we're providing that optionality, which allows you to move in whichever direction you need.

Why opt for full-service delivery over a patchwork of smaller providers?

For a small company to create such a patchwork, they'd have to find and contract with many disparate organizations. They'd have to go out and get a reimbursement expert, a company to manage their sales and a company to manage marketing. They'd need to go and individually work with advertising agencies and a public relations house. And they'd need to do that for all of the markets around the world that they want to enter.

We can provide and integrate all of these global services in one place. That brings many benefits. Firstly, you don't have to go and find where to locate, qualify and sometimes audit these services yourself. That saves a lot of time and energy up front.

Secondly, the end-to-end service model is more efficient. You have a lot of efficiencies when it comes to contracting and invoicing. You've got consolidated buying power from a customer's perspective, spending more money in one place. And there's a lot more scope to customize the whole process to exactly what the customer needs.

An external third-party relationship is a lot harder to manage than an internal relationship. If I can IM somebody who's in our reimbursement department, it's a lot more effective than having to deal with a different company that's in a different part of the world. You've got a team that's running in the same direction instead of seven, eight, nine disparate teams doing different things. That frees companies from the need to create infrastructure to manage multiple service providers.

Don't clients need infrastructure to manage the multiple Syneos Health teams they work with?

That was one of the things we thought about right up front. We've broken down commercial launches into 71 components. Each one of those components can be a huge exercise on its own. And that's before you factor in the clinical work. So there is a huge amount of work to manage and coordinate.

We worked out that for the bigger engagements, where you have a small sponsor team and a big service-provider team, you really need somebody who sits in the middle of that within the service provider.

Syneos One is our end-to-end offering that gives customers true control and ownership of their asset. Our Syneos One team of experienced Asset Strategists identifies timesaving efficiencies from strategy to development and execution, and clinical to commercialization.

The Asset Strategist helps the customer strategize what they need to do and how they need to do it. The Asset Strategist then leads with the key functions across our organization to be able to deliver that work program effectively with speed, clear accountability and a de-risking of the sponsor's investment into one partner versus many providers – ultimately helping our customers maximize their ROI.

Are small, one-shot operations the biggest beneficiaries of clinical-commercial integration?

The end-to-end Syneos One offer I just described has already achieved success with small to midsized companies. But when you look at commercial and clinical integration more generally, we also have larger pharma and device organizations seeking

our support to assist them with novel strategies, life cycle management of assets and other initiatives that also fit into this Syneos One model.

So I don't think our service offerings are limited by the size of our customers. How you compile it as you put them together and actually use them might be different, but the services ultimately apply to all companies.

Is integration already the norm at larger organizations?

No, not necessarily. When we started doing this integration work, I spoke at a conference and said that one of the amazing things was as a CRO, for the first time ever, we're actually looking way beyond the clinical aspects. We're seeing all the commercial aspects. We're now getting to see the overarching perspective that a pharma company or a device company actually sees that we as a CRO never saw because we only handled part of the process.

The interesting feedback I got on that comment from device and pharma companies was, well,

we're no different, because we're all in our own silos within these businesses. So at Syneos Health we're actually getting rid of those silos within the device and pharma companies to the point that we're giving them a better strategic approach to developing their products than they very often have themselves.

If we think about it, Syneos Health is the only company in the biopharmaceutical services industry purpose-built to create greater success for our customers. At Syneos Health, clinical and commercial live under the same roof and constantly share real-world knowledge and insights that lead to getting the job done better, smarter and faster. How we work and collaborate together is called the Biopharmaceutical Acceleration Model, or BAM. And this integration of our work, across clinical and commercial is how we will win together, and win more than our fair share of business – because we help organizations move faster from clinical trial to commercialization because we are thinking about their end commercial goals, from the very first interaction we have with them.

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