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CASE STUDY

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How a best-practice strategy for sourcing ancillary materials reduced risk, spending and workload in a global diabetes trial

It's impossible to run a global clinical trial of an investigational diabetes drug without ancillary materials. And as one leading multi-national pharmaceutical company recently learned, managing ancillaries can be a challenge every bit as complex as the trial itself.

The wide variety of equipment, instruments and consumables that are collectively known as ancillaries are clinical trial necessities. A trial cannot begin unless investigator sites have supplies of both the investigational drug and the ancillary components.

While all trials require ancillaries, diabetes trials typically require a high level of these products in order to administer the investigational medicinal product (IMP). Examples include lancets, test strips and glucose meters, refrigerators for storing supplies, laptops for site administrators and even electronics such as iPhones and wearable devices that go home with study patients.

Challenges

The Sponsor and its Procurement Team were facing a daunting set of challenges: Ancillary supplies for clinical trials were being treated as an afterthought. It was difficult to calculate annual spending on ancillaries. A stream of ancillary crises was impacting team workload. Moreover, there was no formalized strategy in place for the management of ancillary products.

- **Ancillaries as an afterthought.** With the Sponsor understandably focused on supplying IMP, ancillaries weren't given the priority or the attention they deserved during the planning stages of the trial. With ancillaries being treated as an afterthought, sourcing was conducted just before the study began, amplifying the challenge of ensuring that materials reached investigator sites in time. What's more, the failure to prioritize ancillaries continued to impact the study as it went on and sites required resupplies of these items.

- **Poor spending visibility.** The exponential growth and complexity of the sponsor's clinical trials in recent years led it to outsource key functions of clinical ancillary management to specialized service providers, in this case Contract Research Organizations (CROs). Faced with fragmented spending patterns and the discovery that the cost of ancillaries was often buried within invoices, the Procurement Team was finding it difficult to accurately report the annual spend on ancillaries.
- **Workload issues.** On a day-to-day basis, the Procurement Team was managing last-minute requests for ancillaries, many of which required immediate attention. The team frequently had to "save the day" when CROs were unable to source certain ancillaries, particularly items that were complex in nature and/or in short supply. Having to address a high volume of urgent requests was taking time away from critical tasks and exacerbating the team's already heavy workload.
- **No ancillary management strategy.** Finally, the Procurement Team acknowledged that the stream of problems it faced was a consequence of not having a formalized global strategy for managing ancillaries.

Making changes

A thoughtful examination of the issues led the Procurement Team to identify the need to:

- **Establish a best-practice global sourcing strategy for ancillaries** focused on transparency in sourcing practices and spending. Reflecting the latest research about top-notch procurement organizations, the team agreed to expand its purview beyond a traditional sourcing role by adding analytics-based insights to the plan as a means of protecting the business from risk.

Research indicates that procurement teams are becoming trusted advisors to the business, driving suppliers to innovate and, often times, protecting the business from risk.

- **Retain the services of several providers experienced in sourcing and managing ancillaries for global clinical trials.** These providers would be part of an ancillary management team that would include Procurement personnel and their Clinical Operations (Clin Ops) colleagues.
- **Consider how leading procurement organizations add value beyond that of cost reduction.** Research indicates that procurement teams are becoming trusted advisors to the business, driving suppliers to innovate and, often times, protecting the business from risk. The team worked together on how to influence the business in this way.

Research: How leading procurement organizations add value

Research conducted by The Hackett Group, Inc.[1], a consultancy group that specializes in business improvement, has identified five ways in which world-class procurement organizations are providing value beyond that of cost reduction. These include:

In addition, findings from a 2018 survey conducted by consulting firm Deloitte[2] revealed the top business strategies procurement organizations should adopt, along with the biggest challenges facing them.

Top 3 business strategies that procurement teams should deploy
1. Cost reduction
2. New products/Market development
3. Managing risks

Top 3 challenges facing procurement teams today
1. Limited supply chain transparency beyond Tier 1 suppliers
2. Insufficient skills & capabilities to deliver on procurement strategy
3. Inability to maximize digital technologies

1. The Hackett Group: 2014 Procurement World-Class Performance Advantage research
2. Deloitte: The Global Chief Procurement Officer Survey 2018, Leadership: Driving innovation and delivering impact

Actions taken

The Procurement Team selected several providers to manage the company's ancillary sourcing from end to end. Expectations and deliverables for these experienced providers, including Thermo Fisher Scientific, were:

- Working with CROs as an extension of the Sponsor's clinical team
- Securing competitive, transparent pricing of ancillary supplies
- Meeting all current ancillary needs for global clinical trials
- Providing detailed spending reports

The Procurement Team also agreed to conduct regular meetings with the providers to facilitate open communication and review progress on an ongoing basis. The meetings initially focused on ensuring that the providers agreed on roles and responsibilities and working methodologies. Over time, however, metrics – both financial and non-financial – became a centerpiece of the meetings.

Metrics measurement

Visibility of ancillary supplies & spend, minus additional work
Continued cost savings & avoidances, including volume discounts
Standardization of products across trials
Standardization of products across trials

Non-financial metrics
No more "save the day" calls
Reduction in number of suppliers
Structured, transparent & simpler processes – including fewer touchpoints between Clin Ops & Procurement • Redeployment of internal resources • Dedicated clinical services supply chain team • Global partner with scale required for growth

Partnering with Thermo Fisher Scientific

Thermo Fisher Scientific was selected as a provider based upon its more than 30 years of clinical supply chain experience and breadth of service offerings, including a clinical ancillary management service.

Thermo Fisher Scientific immediately assigned a dedicated Clinical Ancillary Management (CAM) team to partner with the sponsor's Procurement and Clin Ops personnel.

Their objectives included:

- Designing a client-specific, commonly sourced ancillary items catalogue
- Providing initial and ongoing demand management and supply scheduling
- Supporting the import/export of ancillaries in places where local sourcing wasn't the best option
- Ensuring that Ancillary Supply Chain Managers were an integral part of the Sponsor's project team
- Offering regular and periodic updates on ancillary projects
- Providing a quarterly summary of spending and cost savings
- Adding value in the provision of additional services, such as distribution of supplies to sites

Ancillaries are not commodities and sourcing them is merely the first in a series of steps that must be taken before these products can reach clinical sites.

Necessary steps for sourcing ancillaries

Challenges	Actions
Import/export	CAM team gathers detailed information upfront to help expedite the customs clearance process for every country participating in a global clinical trial, ensuring that all ancillaries comply with local regulations.
Translation needs	CAM team works with suppliers to ensure that instructions are readily available in all local languages.
Information delivery	For some trials, electronic copies of instructions, as well as physical instructions, are needed. Thermo Fisher Scientific has an innovative e-label solution to facilitate the production & delivery of clinical trial information – patient inserts, videos, podcasts – electronically.
Regulatory guidelines	Regulatory guidelines change constantly & vary from country to country. When considering an ancillary for a trial in a particular country, CAM team confirms the regulatory guidance for acceptability and/or sources an alternate product when necessary.
Timelines	It's essential to focus on upfront planning in order to identify & mitigate risks across the procurement and supply chain. CAM team anticipates & proactively addresses risks across the supply chain, ensuring supply of IMP & ancillaries to patients & sites, keeping clinical trials on track & avoiding unnecessary delays.
Recalls	Ancillaries are commercially available items so recalls can & doh appen. CAM team verifies that suppliers have a defined recall process with an associated tracking system. This is critical to mitigate risk & handle recalls.

Thermo Fisher Scientific scorecard

Thanks to the contributions of the CAM team, the Sponsor achieved every financial and non-financial objective in three years, as measured by pre-established metrics.

Financial

- **Make ancillary supplies/spend visible:** Designed a catalogue of 'commonly sourced items'
- **Achieve cost savings/avoidances:**
  - Year 1 - 17%
  - Year 2 - 20%
  - Year 3 - 24%
- **Standardize products across trials:** An analysis of historical trial needs provided the data necessary to standardize ancillaries

Non-financial

- **End "save the day" calls:** A clearer strategy prompted proactive ordering in anticipation of trial and patient needs.
- **Reduce number of suppliers:** Suppliers were reduced by half and working relationships with them improved, resulting in fewer one-off requests.
- **Create structured, transparent & simpler processes with fewer Clin Ops/Procurement touchpoints:** Clearly defined roles and responsibilities empowered teams to take action, eliminating the need for consults and resulting in faster turnaround on requests.
- **Redeploy internal resources:** New processes led to greater efficiencies, with sponsor resources no longer needed to monitor clinical ancillary management for trials.
- **Establish dedicated clinical services supply chain teams:** A dedicated Thermo Fisher Scientific team kept the Sponsor informed at all times.
- **Choose a global partner with scale required for growth:** CAM team and Thermo Fisher Scientific's extensive global network offered all the resources required to meet the Sponsor's growth expectations.

Conclusion

A sound ancillary management strategy requires a clear understanding of a study's design and end-to-end requirements, in-depth knowledge of international regulations and rigorous proactive planning.

Executing the strategy requires full collaboration between the key players – in this case, the Sponsor, CROs and providers that included the Thermo Fisher Scientific CAM Team. The Thermo Fisher Scientific CAM Team joined the project with a clear understanding of the Procurement Team's needs and a commitment to meeting those needs. Those efforts paid off. As a result, the team's best practice sourcing strategy for sourcing ancillary materials reduced risk, spending and workload in a global diabetes study on time and without any trial delays.

Thanks to a sound strategy and solid execution, the Sponsor was able to achieve its most important objective – that of ensuring that waiting patients received the ancillary products they needed to participate in a global diabetes study.

References

1. The Hackett Group. (2014). Research Alert: How World-Class Procurement Organizations Outperform; Focus on Becoming Trusted Advisors, Driving
2. Supplier Innovation [Press release]. Retrieved from **https://www.businesswire.com/news/home/20140814005636/en/Research-Alert-World-Class-Procurement-Organizations-Outperform-Focus**
3. Deloitte. (2018). Leadership: driving innovation and delivering impact: The Deloitte Global Chief Procurement Officer Survey 2018. **http://images.content.deloitte.com.au/Web/**

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