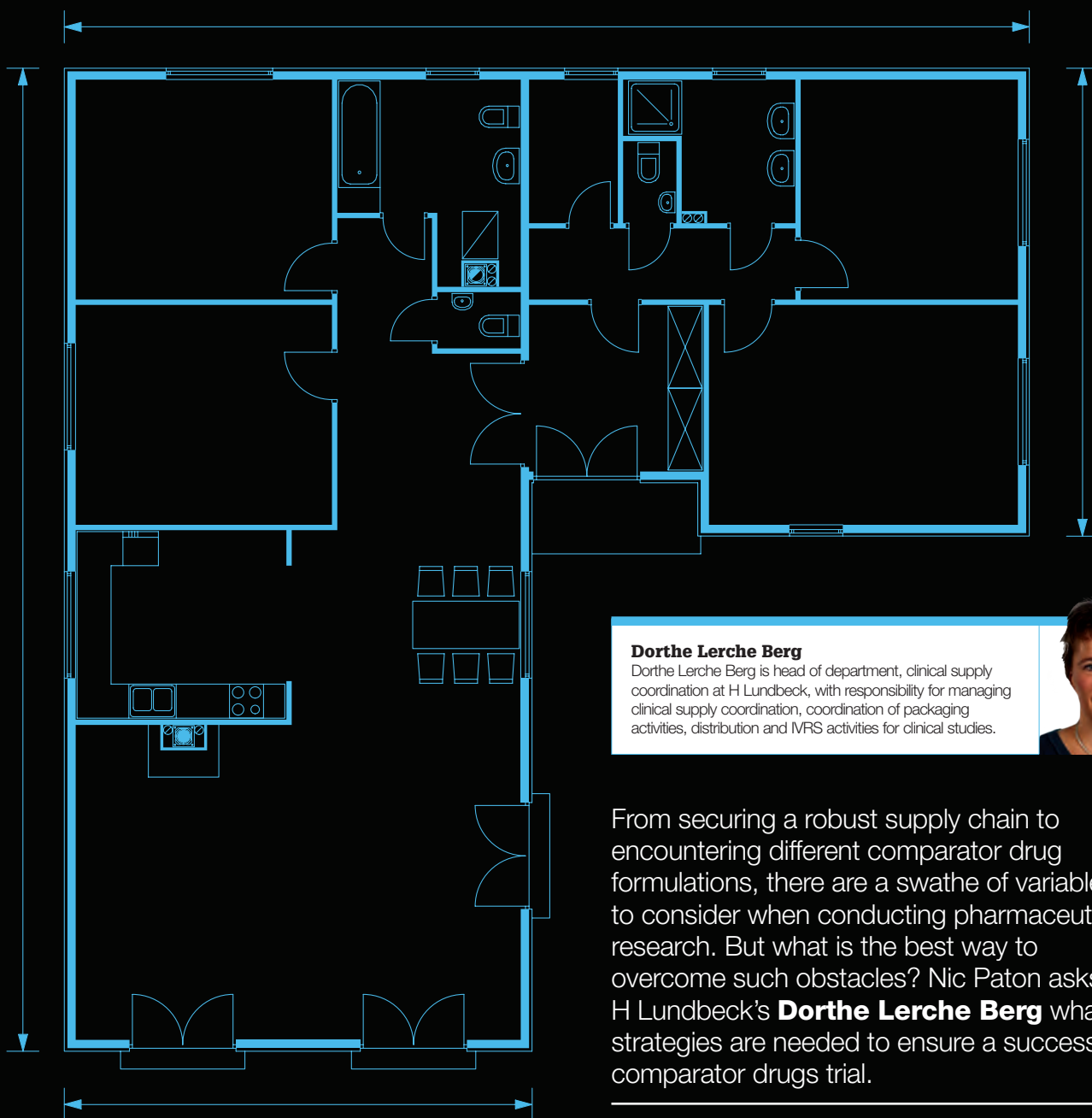


# Best laid plans



**Dorthe Lerche Berg**

Dorthe Lerche Berg is head of department, clinical supply coordination at H Lundbeck, with responsibility for managing clinical supply coordination, coordination of packaging activities, distribution and IVRS activities for clinical studies.



From securing a robust supply chain to encountering different comparator drug formulations, there are a swathe of variables to consider when conducting pharmaceutical research. But what is the best way to overcome such obstacles? Nic Paton asks H Lundbeck's **Dorthe Lerche Berg** what strategies are needed to ensure a successful comparator drugs trial.

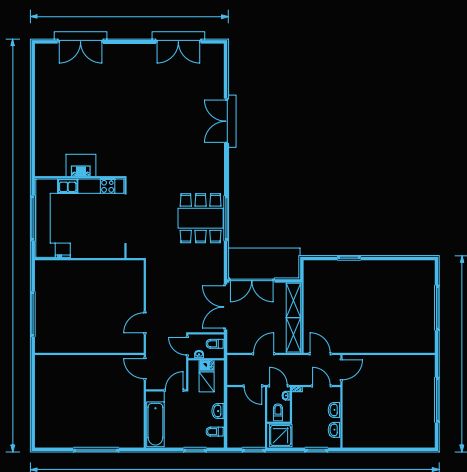
In an increasingly tightly regulated pharmaceutical environment, it is only natural that everyone – the public, politicians, pharmaceutical firms, regulators and clinicians – will want compelling evidence that new drugs coming off the production line compare favourably with existing drugs in terms of safety, efficacy and cost. To this end, comparative effectiveness trials are becoming an ever-more important part of the R&D mix for pharmaceutical firms when it comes to drug development.

With potentially billions of dollars of investment riding on the success or failure of new product streams, being able to demonstrate the value of new therapies and drugs, not to mention being able to make the strongest business case possible for their inclusion within hospital and government formularies, is absolutely paramount.

Yet sourcing and supplying comparator drug trials is not straightforward. It will normally require a lot of careful thought and strategic planning to get right, as well as to ensure it doesn't end up costing a fortune, argues Dorthe Lerche Berg, head of department, clinical supply coordination, at pharmaceutical company H Lundbeck.

"The challenges, unfortunately, can be myriad," she says. "Some of the most fundamental include the need to ensure you have obtained the necessary pedigree and product documentation for the comparator, the need to be 100% sure your supply chain is secure to guard against the introduction of possible counterfeit comparators and the need to look at issues around possible delays or interruptions in resupply throughout the course of the trial. Other issues that can be problematic include fluctuating patient enrolment, unexpected changes in the regulatory climate or a breakdown in supply chain or partnership relationships."

And it is the strength and robustness of the partnerships or relationships you forge in this context that can often make the difference between success or expensive failure, stresses Berg, whether this is simply the relationships within your internal supply chain or, as with many smaller firms, the partnership struck with a specialised company to source and manage comparator studies.



“In Europe, the comparator is not that expensive compared with the US but lead times in the US for sourcing comparators are often much shorter than in Europe. So you have to decide what is most important for you, cost or lead time?”

“A big pharmaceutical company will probably have a dedicated department for sourcing comparators or finding companies that specialise in that area,” she adds. “For a smaller firm, it may make sense to take this process externally.”

### Crucial decisions

Berg stresses the importance of having the right relationship with a partnering company.

“It will be a close association with critical decisions to be made in areas such as the timing of supplies,” she says. “It is important you have a robust plan that can meet your timelines. You need to have access to specialised knowledge, whether in-house or through a partner. For example, in Europe the comparator is not that expensive compared to the US but lead times in the US for sourcing comparators are often much shorter than in Europe. So you have to decide what is most important for you, cost or lead time, for example?”

The issue of ‘pedigree’ – does the potential partner have the appropriate capacity, do they completely understand the documentation required, can they meet the regulatory requirements – will be another vital consideration.

“Within Europe, the EU Clinical Trials Directive established standardisation of research activity in clinical trials throughout the European Community,” says Berg. “But there will be different requirements in other countries.”

It is also vital to have strategies in place to mitigate risk. These will need to include looking at how to ensure the supply chain is robust and secure, how to guarantee that counterfeits will not enter the supply chain and how to minimise delays.

“You need to ensure that risk, within the context of what you are doing, has been absolutely defined and agreed with the stakeholders,” says Berg.

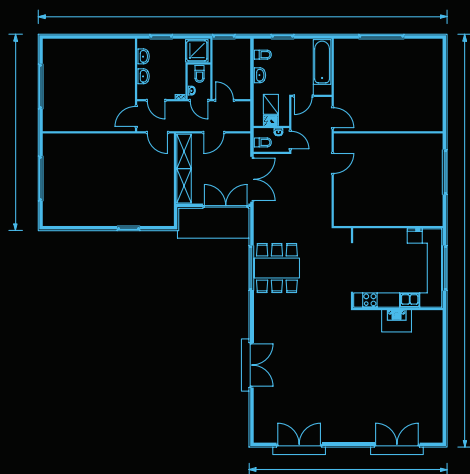
### Supply and demand

Another important question that will need to be addressed is that of central or local sourcing.

“It will very much depend on the strategic approach the company is taking,” says Berg. “One approach that is right for one company may not necessarily be right for another. So it is important to be having conversations with the different stakeholders within the internal supply chain. There has to be an agreement about costs and timelines, so it is important to define your strategy and then incorporate that into your sourcing of comparative studies.”

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"Whether you follow a central or local approach will, again, often depend on your supply chain. For some companies, it might be better to have four or five local suppliers rather than one global one. And when setting the comparator sourcing strategy, it is very important to ensure that quality is paramount."

Particularly in the current uncertain economic environment, it is imperative to have planned for the possibility that things may change unexpectedly, perhaps regarding the availability of the comparator, or fluctuations in patient enrolment, for example.

"This is something that needs to be discussed internally at an early phase," explains Berg. "You need to be looking at any risks associated with running short of supplies, as things will often change."

"You have to build an element of flexibility into your plan, and you need to be in very close contact with the people on the clinical side and be up to speed with how the trial is designed, to ensure any changes or fluctuations are spotted as early as possible."

This requires extensive planning and forecasting, and the ability to manage information from as early a stage as possible. Within this is the ability to source comparators at short notice.

"Right from the beginning you need to have a strategy in place that has contingencies for this sort of eventuality," explains Berg. "You always need a plan B and alternatives. Things can always go in a different way to how you expect; suddenly the market and availability can change."

"So you can have a situation where, when you start the study, the availability of your comparator is one month delivery. But then suddenly availability goes up to three months for delivery."

"You cannot just sit on your hands because you already have the study running, so you need a plan B within your strategy. You have to have pre-planned what you might do in this eventuality or simply have a plan of where else you are going to go in the market." >>



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“You need to be 100% sure your supply chain is secure to guard against the introduction of possible counterfeit comparators and you need to look at issues around possible delays or interruptions in resupply throughout the trial.”

### Single sourcing

There is also the issue of whether you intend to go down the single sourcing route or not. As with most things, there are both benefits and drawbacks, cautions Berg.

“If you opt for single sourcing, there will be many advantages,” she explains. “It will often cut your costs and reduce your administration. You may, for example, only need one batch with one expiry date.

“So, it can be a much more efficient way to manage things. However, some countries will not approve single-sourced

### Key tips for designing comparator studies

- Plan your options in advance, including the availability or limitations for sourcing the desired comparator.
- Evaluate any regional variations of and requirements for comparators, including dosage form, strength and intra-country regulatory agreements, packaging, reformulation, blinding and any re-labelling needs.
- When considering single sourcing, carefully weigh up the pros (one comparator source, a simplified supply chain, more consistency of data, greater flexibility) and cons (regulatory approval, country variability).
- Assess required pedigree and product documentation of any potential partners.
- Assess how you or your partners will mitigate risk (such as delays or counterfeits) and/or respond to the unexpected, such as fluctuating patient enrolment or the need to source comparators at short notice.
- Ensure your strategy and approach is robust and flexible and always have a plan B.

comparator studies because their requirements are different, or you may be required to use a product from a specific country as a comparator, or there may not be exactly the same formulation in different countries, so you may have to do studies to show that the formulation meets the requirement of that market, which can cause some challenges.” ■

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