



What can sourcing do for Drug Safety?

At a time of unprecedented change and with Safety's workload increasing in both volume and scope, the question must be, what can sourcing do for Drug Safety?

There is no shortage of evidence to suggest that more resources are, and will be, engaged in the business of Safety as AE reporting rates continue to increase (26% average increase year on year since 2006¹) driving us to look throughout our organisations, and beyond, for the capability we need to deliver what will be required of us. Inevitably, there is also clear evidence that ill-construed strategies, poor sourcing decisions, and poorly executed sourcing implementations can cause far greater problems than they resolve.

Sourcing is not just about contracting with service providers to perform activities that could be conducted in-house (outsourcing) but is also about leveraging organisational operations owned by the sponsoring company (internal sourcing) which may be situated in low-cost countries.

So, what can Sourcing do for Drug Safety? Sourcing, when considered and approached correctly, can help to deliver the optimal solution; to ensure that patients and business, alike, are protected. Or it can make a whole lot of trouble for us.

The key then, to ensuring you get to the right answer, is to take a strategic view of sourcing, that is, to consider sourcing as one potential element in achieving the desired capability and capacity to operate an effective PV system.

Establish a clear plan before action

Reactive sourcing decisions taken in isolation can be dangerous. What is required is a clear direction for Safety, a thorough consideration of how we deliver what is required of us today, and what is likely to be required of us in the medium-term. In this context, we can then consider how best to satisfy all requirements, and include in this the potential for contribution from a whole range of people and organisations.

Business logic needs to prevail in its simplest form. We need to determine:

- What are we seeking to achieve, both today and in the future?
- What needs to be done?
- How does it need to be done?
- Who can do it (options)?
- Who should do it (business case)?
- How do we organise the components of the solution?

The opportunists amongst us may well be tempted by the offer of services from an emergent outsourcing supply base, or the chance to place our problems in the hands of someone else². Both are fine if they are triggers to stimulate the business logic above. Without it, value may not be the result of any changes. Indeed, significant risk and cost could easily be added to the business of Safety.

¹ Data source: WCI **pvnet**™ Annual Reports 2007-2009.

² 31% of Pharmaceutical organisations surveyed ranked 'increasing their organisation's regulatory compliance' as one of the top three drivers for adopting an Outsourcing strategy [WCI PV Sourcing Survey, 2009].



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Capitalise on untapped resources

Local staffing constraints in established markets are cited as one of the biggest drivers towards off-shoring PV activities, so how can we utilise our resources at hand, whilst leveraging new opportunities? Untapped resources are everywhere. In the extended PV organisation, in the wider organisation at large, in our suppliers, our partners, and in an emerging supply base.

The commercial implications of Safety have never been better understood than today. From a new product submission, to reputation in the market, a good safety record is imperative. With this in mind, Safety should be on the career path of a far wider community. In fact, it could become one of the default roles expected in the progression of all clinical development staff.

The potential for academia to become a greater source of Safety talent will follow as Safety activities progress in Signal Detection and Risk Management. Each of these areas is of far greater interest to the intellectually curious than the (relatively) straightforward processing and investigation of adverse events.

Each of the above will likely deliver more of the senior resources required, but whilst they do have the potential to deliver some capacity into the more traditional safety activities, it is in the medical expert roles that the need is currently most apparent. Segmentation of activities will enable the lesser qualified to contribute, such that the more qualified can accommodate a greater total throughput, leveraging the junior resource.

As Safety is often a geographically distributed activity, it is worth considering how to get the best out of the total global team, before embarking on local recruitment strategies. Several leading companies now operate a single Safety workload by therapeutic area, with regional teams working down a shared AE list in order, effectively delivering a 24 hour activity and levelling out local/regional peaks and troughs in workload. The continued evolution of technology in safety systems makes such solutions far more accessible than ever before.

Delivering expertise where it is needed most

Increasingly, global focus on continual lifecycle benefit/risk analysis is requiring us to reallocate staff, asking them to take on different roles with evolving skill sets in our businesses (e.g. managerial capabilities needed for leading cross-functional Safety Management Teams). With these knowledgeable individuals in short supply a well considered sourcing strategy can provide the fundamental basis for releasing the right resources for such activities. Exploring low-cost, single case processing by implementing a well thought through Affiliate and/or Outsourcing operating strategy is one way of achieving continued regulatory compliance whilst leveraging the scarce skills within our organisations.

Be wary of those offering easy solutions

How should we respond when we are asked why we are not taking advantage of 3rd party offers to outsource aspects of our Safety activity and hence save cost? Or how we plan to?

To respond to the increasing pressure from numerous stakeholders, Safety must have a clear and well considered view of the longer term operating model which clearly focuses on the specific needs of the company and its ever emerging portfolio.



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There is a range of answers to this, not unreasonable, challenge. The fundamental points to remember are about avoiding increasing the risk to the patient, avoiding increasing the risk of non-compliance, and ensuring total cost is the figure under consideration, not just transactional cost.

At this point in the conversation, share the key points from *'Establish a clear plan before acting'*

Considering the future not just the present

The first point to consider in the development of any operational model is what is, and what will be, required of that model. This requires a consideration of how volumes, portfolio, geographical spread and regulations are changing now, and in the near term, and how this will affect the capabilities we need and our costs, compliance and resourcing in the years to come.

Of course, it is also worth understanding what others are doing, and considering what the supply base may look like in years to come. Both of these will inevitably impact our decisions and our ability to execute successfully.

Take control of Safety's destiny

No community is better placed than the Safety team to develop the view of future requirements, and the best way to develop the organisation is to be ready. Never has the need for a strategy for Safety been more pronounced.

So, now is the time to act, and to start the thinking process to take account of how requirements are evolving, consider what the options are, and to develop a clear route map to ensure continuing compliance, progressively less risk to patients, and the role Safety has to play in the future success of the business.