

Sourcing Pharmacovigilance activities – Strategic or Tactical imperative?

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Almost everyone has a point of view about the pros and cons of sourcing pharmacovigilance (PV) activities, but what is the actual utilisation of PV sourcing in industry, and what sourcing models are global organisations implementing now, and in the near term? This paper summarises the findings of a recent WCI survey¹ which answers the aforementioned questions and also captures industry's experiences to date; valuable insight for organisations implementing a PV sourcing strategy.

Importantly, PV sourcing is not just about contracting with external service providers (e.g. BPOs or CROs) (*outsourcing*) but it is also about leveraging organisational operations owned by the sponsoring company (*internal sourcing*) which may be situated in low-cost countries.

Currently, 70% of Pharmaceutical organisations outsource at least one PV activity. This level is expected to increase to 80% by 2012. However, no clear pattern exists within industry of a common sourcing model dominating in the near term. Some organisations will bring outsourced activities in-house, establishing their own off-shore capabilities. Other organisations will move PV activities from Global HQ offshore, establishing enhanced regional case processing centres and/or outsourcing through external providers to low-cost destinations like India and China (Figure 1). The measured variation in sourcing approaches across both large and small organisations is indicative of an immature market still in the process of establishing industry norms.

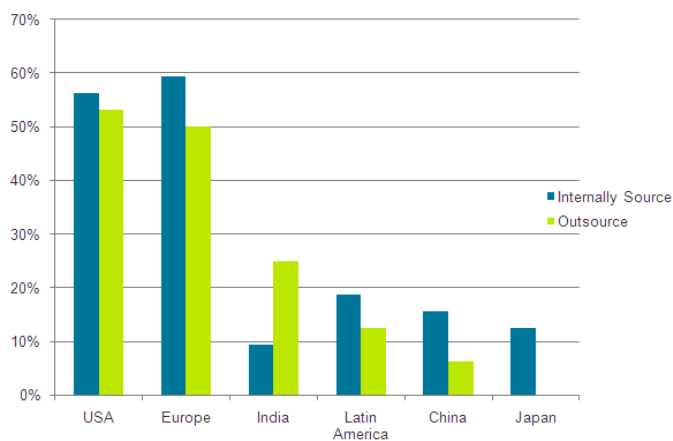


Figure 1a: Geographical distribution of current PV sourcing activities

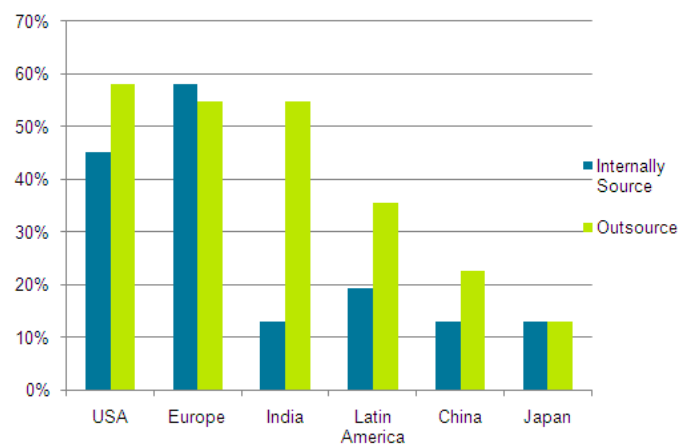


Figure 1b: Expected geographical distribution of PV sourcing activities by 2012

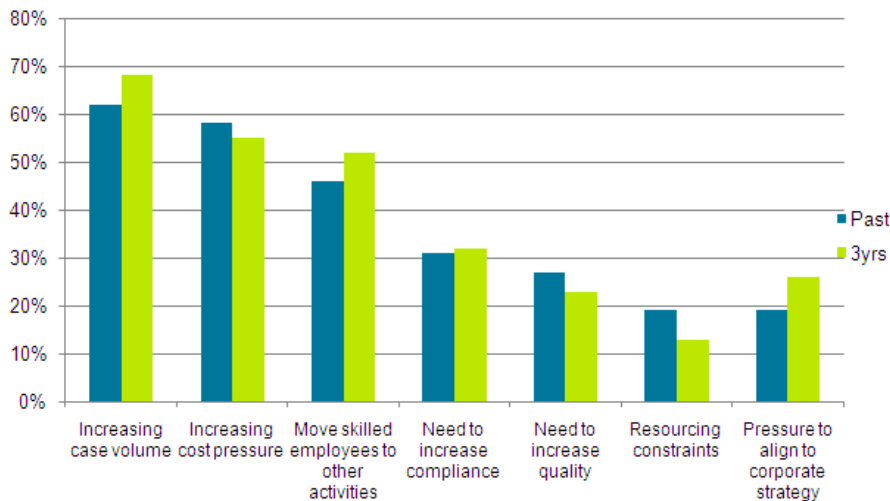
- Currently, the USA and Western Europe dominate as regions for sourcing PV activities
- By 2012, India, Latin America and China are expected to experience rapid growth in PV outsourcing

Organisations will continue to leverage their established resources through internal sourcing; however, some organisations will reduce the number of their case processing centres, preferentially locating them in low cost countries (e.g. Latin America and India).

¹ WCI PV Sourcing Survey 2009 (respondents were 33 pvnet and pvconnect Heads of Safety from Global Pharmaceutical organisations)

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What is driving industry to consider PV sourcing?



- Increasing case volume and cost pressure were reported as the most important reasons to consider PV sourcing
- Industry drivers were the same for both large and small Pharmaceutical organisations
- Industry drivers are not expected to change over the next three years

Figure 2: Current and near term drivers of PV sourcing. Percentage of organisations surveyed ranking each driver as 'very important'

What activities are PV organisations currently sourcing?

Sourcing of single case handling activities was found to dominate sourcing strategies for most organisations (Figure 3). In the next 3 years, sourcing of individual case safety reporting will become even more commonplace with greater than 80% of organisations outsourcing spontaneous cases.

- Over 50% of respondents currently outsource certain clinical case handling activities, a further 5% fully outsource their clinical case requirements (the entire process, end-to-end, is managed external to the organisation)
- Over 45% of respondents currently outsource certain spontaneous case handling activities, a further 10% fully outsource their spontaneous case processing requirements

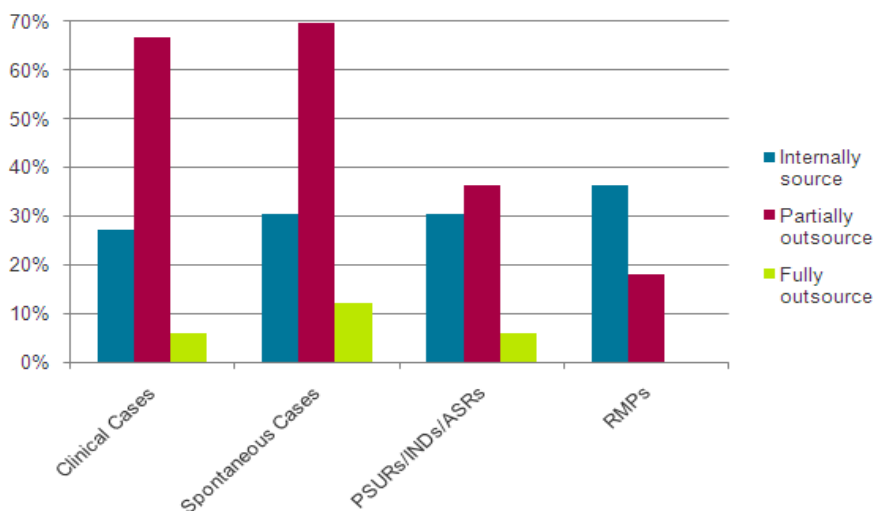


Figure 3: Distribution of sourcing models organisations are expecting to adopt by 2012 to process their core PV activities.

Partial outsourcing; where certain steps in a process are outsourced to an external vendor (e.g. case data entry). *Full outsourcing;* where all process steps are outsourced.

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What segmentation strategies are PV organisations choosing when deciding what products/activities to source?

Tactical sourcing currently dominates Industry practices (Figure 4) with 65% of organisations sourcing an ad-hoc mixture of activities and products. Tactical sourcing, whilst usually employed as a short-term solution to overcome volume spikes, can lead to an increase in sourcing costs and management requirements. Tactical sourcing, if employed on a large scale, significantly increases PV sourcing complexity.

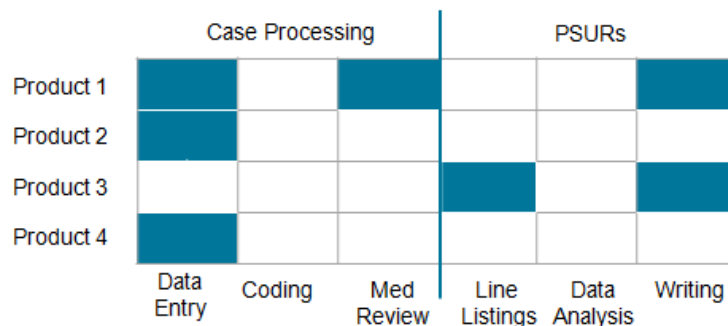


Figure 4: Example of an organisation employing tactical sourcing; ad-hoc product and activity sourcing increases management complexity.

What are PV organisations looking for from Outsourcing providers?

Total cost, volume flexibility and understanding of PV regulations were identified as the most critical criteria when organisations are selecting PV outsourcing vendors. However;

- 60% of respondents underestimated total transaction costs (activity + management costs)
- 30% overestimated their vendor's flexibility and capability
- 50% underestimated the time taken to fully implement PV sourcing activities in their organisation
- 25% of companies overestimated their service provider's quality levels

Sourcing, when considered and approached correctly, can help to deliver the optimal solution; to ensure that patients and the business, alike, are protected. However, past experiences suggest much can be learned and improved on when developing a sourcing strategy. Organisations experienced in sourcing PV activities believe that whilst sourcing brings significant benefits to their organisations they would have:

- Optimised their internal processes before sourcing them – don't source problems
- Approached PV Sourcing with a detailed plan incorporating a slow and cautious scale-up
- Allowed more time for implementation and transitioning of their own organisation
- Emphasised and resourced their internal change effort
- Kept high risk activities in-house as they gained experience of their vendor's capabilities
- Ensured greater alignment of sourcing activities across the global PV organisation

Planning and implementing a strategic sourcing initiative has many facets which need to be placed into the context of industry's macro drivers (Figure 5) and an organisation's own corporate strategy and attitude to risk. The key then, to ensuring the right approach, 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.

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Little or no strategic assessment of how all macro drivers affect a firm over both the short & long term

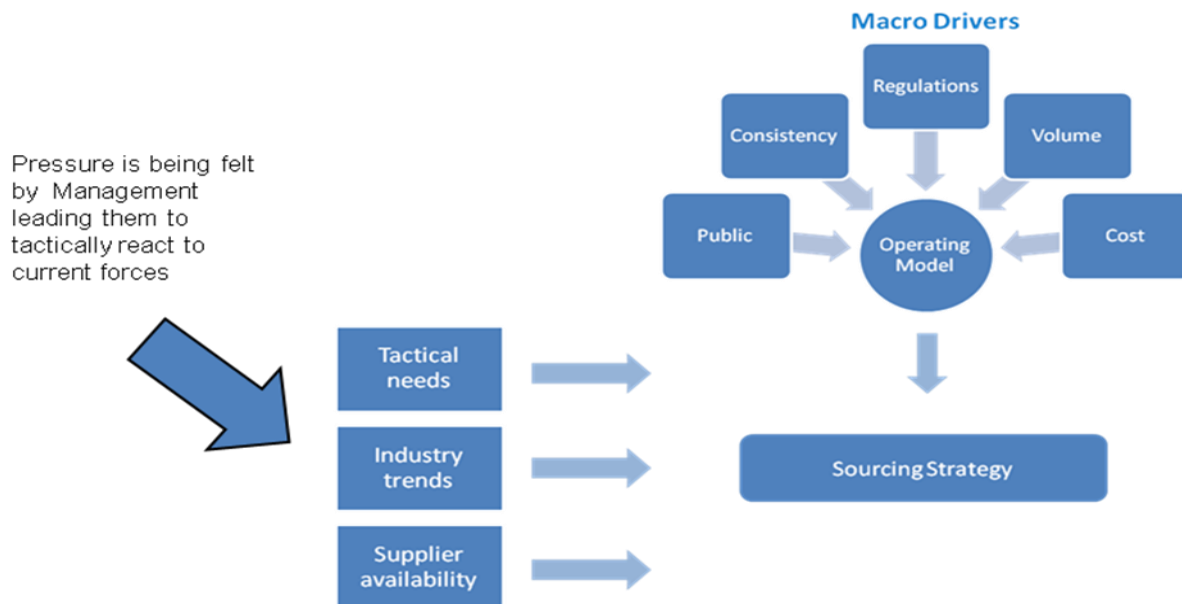


Figure 5: Tactical versus Strategic PV sourcing. Short term needs and supplier availability are driving PV sourcing initiatives rather than a holistic assessment of the firm's current and future needs and capabilities.

Irrespective of the final sourcing model selected, establish a clear plan before action and consider the future, not just the present:

1. Establish a clear strategy
 - What are we seeking to achieve, today and in the future?
 - What needs to be done?
 - How do we organise the components of the solution?
2. Optimise your internal processes
 - Do not look to source problems
3. Communicate and manage the change process
4. Establish clear responsibilities at process interfaces
 - Sourcing Procurement
 - Ongoing Vendor Management
 - Metrics
 - Continuous Improvement
5. Train providers and agree levels of quality to keep internal re-work and QC to a minimum

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