

LIFE SCIENCES

Pharmacovigilance

Drug safety
Change management
Process design
Process best practice
Organisational and
technology alignment
Performance and
compliance improvement

pharmacovigilance for the future

why

wci

**“we create
responses
to emergent
needs”**

Client Situation

As the dust of mergers settled, AstraZeneca emerged assessing the impact of its marketing and development plans on pharmacovigilance. ‘Dramatic’ was the conclusion. In 2002, the Clinical Drug Safety team processed over 50,000 individual adverse event (AE) case reports globally. Broadly harmonised, but with a lot of local variation, the system funnelled reports worldwide from seven collecting sites in Europe and the USA to a central database. It worked. However, continuing growth in the products and drugs portfolio would take the annual case report figure well past the 100,000 mark by 2007. Growing a quality workforce to match was currently a fanciful notion. AstraZeneca’s Clinical Drug Safety team decided they must re-engineer their case handling process to achieve the vast productivity increase approaching whilst maintaining the highest quality.

AstraZeneca’s challenge was to establish a smooth, timely, case-handling process that collected data into one global database. The data had to be consistent in structure and meaning, compliant and of the highest quality. The system needed to be fully operational by Q1 of 2004 and future proof, so that by 2007 productivity was at least 25% higher to prevent a backlog. Success would bring annual savings of \$3.3 million, as well as a sound basis for confident growth. AstraZeneca asked WCI to help.

The Solution

The key to effective solutions is not so much process technology itself, as communication. To work, everyone at every site must support the solution. Wide and genuine consultation about how to solve the

productivity problem and set up a system that will last, focuses people on the future; and if the consultation is done with foresight they feel that they are influencing both the direction and character of change and, as such, accept its necessity.

Once established communication must continue, or the change process rapidly loses credibility. The world class communications package was to be the cornerstone of AstraZeneca’s achievement in successfully implementing a new case-handling process at all seven sites – on time, on the same day.

The Project team made up of senior AstraZeneca Drug Safety people and WCI consultants began work in May 2003 beginning with face-to-face meetings. Supervision was from a Director level Steering Committee. The project would analyse and baseline current practice, design the new solution and implement it. The baseline period set for monitoring case-handling productivity was January – June 2003. After developing assessment measures, the team focused on three sites that together handled 85% of all cases. Through interviewing and documentation review, the case-handling process was mapped – a month’s work at each site. Inevitably, different sites measure different things. The results were shared and made accessible, attracting comments, ideas and consolidating buy-in from all levels of stakeholder and contributor. Results were reviewed in detail by the Project team after each investigation.

In Process Design, the team looked to incorporate best practice, remove

unnecessary steps and to seize opportunities for enhancement through the most appropriate technology. The new global process has nine core stages:

- Receipt Log
- Triage
- Data Entry
- Quality Review
- Evaluation
- Medical Review
- Complete
- Report
- Archive

Cases are classified on pre-set criteria, prioritised and routed accordingly.

Planning and preparation for implementation began in September 2003. Three implementation work-streams were defined; a sponsor from the Global Drug Safety Leadership Team was designated accountable for the output of each work-stream.

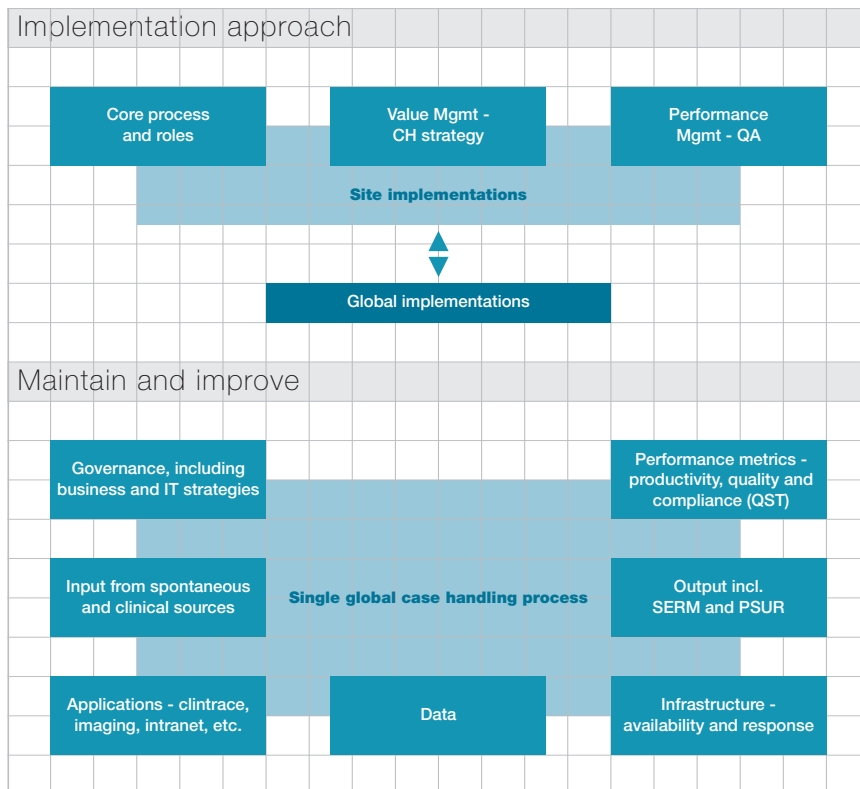
The Core Process and Roles Team evaluated and re-worked guidelines and documentation and laid down a training strategy. Value Management defined and developed the new global case-handling strategy governance mechanism, together with new IT and communication strategies. Performance Management and Quality Assurance laid down measures and targets of global performance for compliance, reporting quality and frequency and productivity. Communication and training was developed to match. Training for everyone involved or affected began at once with implementation taking place on 1 February 2004.

“we increased throughput by 30% with no increase to cost”

“we deliver lean compliant processes to life science companies”

“we have defined the future of drug safety and how to get there”

Model for Success



Benefits

AstraZeneca met the challenge. The new case-handling system was implemented on time, with the new system in operation on the same day at all seven sites across the world. In 2004, workload handled to specification increased by 30% and pharmacovigilance staff by 5%. The transition was smoother due to the

new system and the communications around it; there is a good understanding that standards and processes are the same across the globe and trust is growing internally and externally.

To summarise, the key steps to success were:

- A measurable business case, clear, measurable objectives and a mandate from the top
- Communication that keeps people in the loop, focuses them forward, and doesn't tail off on launch day. The mantra is 'maintain and improve'

AstraZeneca had the foresight to realise that recruitment could never keep pace with the increasing workload in PV and from the start they involved the 'people who knew.' Buy-in at the right level with people who were valued and respected was essential. A well planned and considered communications schedule ensured staff were strongly receptive to the 'continuous improvement' approach and AstraZeneca now change, refine and update things piecemeal as the system runs.

Dr. Barry Arnold, Global Head of Drug Safety at AstraZeneca commented; "The team assigned by WCI to support the project demonstrated a highly professional and customer-focused approach. It has been acknowledged by all AZ members of the team that WCI contributed significantly to the success of the project, with WCI ultimately ensuring that the project was completed in a successful manner, meeting all objectives and completing to the agreed budget and timelines defined beforehand." AstraZeneca recognised they needed to be savvy in improving processes and allocating resources, not just now, but going forward too. The Clinical Drug Safety Team has now been asked by top management to stretch towards a 50% productivity improvement. The new system and processes mean they are confident in achieving it.

“the process transformation achieved outstanding results”

Dr. Barry Arnold, Global Head of Drug Safety, AstraZeneca



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to assure compliance and boost performance



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