

LIFE SCIENCES

Pharmacovigilance

Risk management  
Signal detection  
Periodic reporting  
AE handling

is your drug  
safety effective  
today and ready  
for tomorrow?

why



**“we balance  
performance  
and compliance,  
enabling our  
clients to be  
more effective  
and efficient in  
drug safety”**

**“we have worked with 17 of the top 20 life science companies to transform drug safety effectiveness”**

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

**Why this is important**

Pharmacovigilance is becoming increasingly business critical. Ensuring the safest possible use of drugs is a company responsibility that is required by regulators and markets alike. Recent product withdrawals, litigations and increasing public and regulatory pressures have added further visibility to Pharmacovigilance departments, reconfirming the significance of product safety to the value of the pharmaceutical business. Life science companies have much to gain from reviewing their drug safety processes and adopting a far more proactive approach. It is no longer enough to report in a timely manner. Now you must anticipate and mitigate risk. The price to pay for non compliance is high – warning letters that risk the global reputation of the drug safety teams and product withdrawal which can cost an organisation millions and put jobs at risk. Drug safety processes must be 100% reliable, cost efficient and release management capability. The aim? To create and implement an effective risk strategy ready for the re-focused regime.

The model for success looks at how drug safety processes will evolve to meet the new challenge. WCI understand the importance of having a sound understanding of the effectiveness of safety processes as well as conformity to current operating practices. In such a highly regulated, fast moving and constantly changing environment such as life sciences it is obligatory to take a proactive approach. Our model for success has been developed based on our experiences working with life science organisations and represents the movement from a reactive and reporting stance to a proactive and risk based approach to pharmacovigilance. What is clear is that there is a need for organisations to refocus – to invert the triangle and both anticipate and mitigate risk.

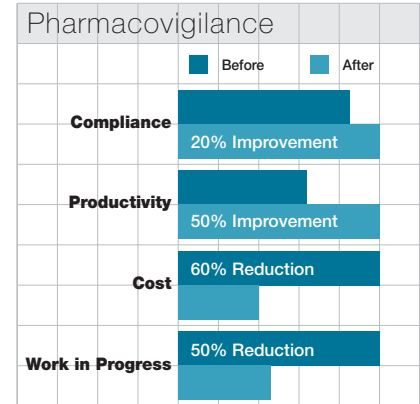
**Our drug safety capabilities include:**

- assessment and audit
- PV system redesign (process, organisation and tools)
- performance metrics implementation
- project and change management
- application selection and implementation

- pvnet (large sized company PV forum) and pvconnect (mid sized company PV forum)

**Benefits**

WCI’s approach to and understanding of pharmacovigilance supports a number of benefits for the life science organisation.



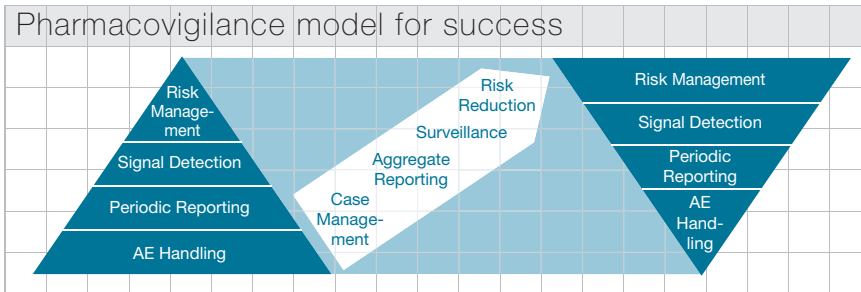
**Proof of Solution**

*“WCI’s ability to understand processes and critical interfaces is a significant contribution to understanding how we fulfil our regulatory regulations in an effective manner.”*

Ernst Weidmann, Head of Global Safety, Bayer

*“with the growth in AE volumes in excess of 23%, the old process would not have handled the increasing case load and maintained compliance with the current headcount! We are delighted with the new processes and the WCI team.”*

Dr Edmundo Muniz, Director of Worldwide Pharmacovigilance and Epidemiology, Eli Lilly



Simplify what you do

to assure compliance and boost performance

we facilitate two successful forums; pvnet and pvconnect

**For further information:**

Europe: +44 (0) 2392 268133  
 USA: +1 212 792 4267  
 info@wcigroup.com  
 www.leancompliance.com