

Pharmacovigilance Quality Assurance in the NHS:

Improvement through partnering
with professional membership
Quality Organisations



What creates the urgency in PV?

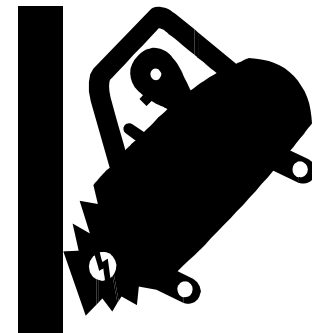


- Patient safety is paramount over science and society (ref.ICH GCP).
- We work in a very emotive environment. We attract the highest level of media attention and regulatory overview.



A picture of the situation within a non-commercial environment

- Insufficient funding to use sophisticated IT support of the processes such as a safety database.
- Absence of detailed training program for researchers.
- Little hands on monitoring of participating sites compared to commercial sector - gives rise to problems when managing safety reporting in multicentre study.



A picture of the situation within a non-commercial environment

- Poor information flow from shared-care centres, GPs and Hospice - difficult to keep within reporting timelines.
- Systems are inadequate to detect and report serious breaches of GCP.
- Systems are inadequate to deal with urgent safety issues.



A picture of the situation in a non-commercial environment

- Failure to report SUSARs within the expected 7/15 day timelines
- Inadequate PV technical contracts/agreements
- Non compliance with SOPs and Policies
- We need to be careful because we always state the bad without mentioning our achievements



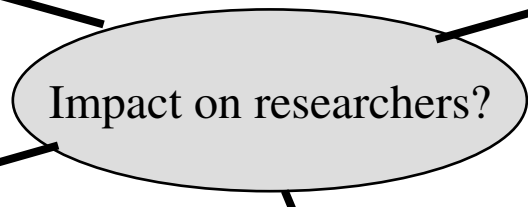
How Are Personnel Affected?



Unfamiliar environment – stress is evident

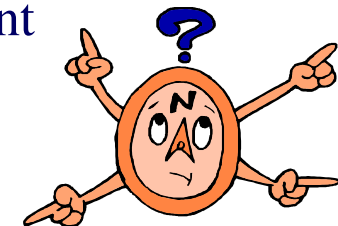
Huge responsibility on researchers

overwhelmed by the regulatory requirements and the quantity of paperwork



Imminent regulatory inspection - induces **panic** and **anxiety**

PV systems are at their infancy – this causes **confusion** within the team about PV responsibilities, event identification and reporting requirements.



The MHRA Expectations

- Concerns over lack of on going monitoring of safety information in academic trials and in particular monitoring of AEs / SAEs for increase in frequency.
- MHRA are aware of the constraints within the non-commercial settings, but same regulations apply for both commercial and non-commercial organisations.
- Quality and standards for PV are the same in the to commercial sector as within NHS and academia.

The impact of Inspection findings



- Repeated poor Inspection performance can lead to re-& possibly unannounced inspections in future
- Learn from experience gained during inspections to plan for the future
- Build or plan compliance **AND** effectiveness into your processes
- Expect to budget for and invest in Quality Assurance activities and resources

What can an individual do to achieve compliance?



- Each person must be aware of what he/she must do well to succeed.



- Be aware of the whole PV system and how your role fits in.

What can an individual do to achieve compliance?



- Protocols should be designed to make PV recording vs. reporting requirements.



- Realistic review of options/resources etc.



- Focus on developing your knowledge and skills continuously.

What can the team do?

- **Focus on systems and process.**



Definition of a process:

- a set of activities which convert selected inputs into a specified output. The activities are controlled by regulations or company constraints and involve people and machinery.

Definition of a system:

- a group of independent but interrelated processes to accomplish a set of specific functions.



- **Focus on Links with Systems outside the NHS:**

- local competent authorities and European Agency
- Ethic committees
- Data management boards

- **Map the PV system within your NHS Trust**

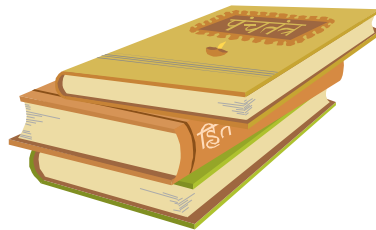


- A clear focus on what has to be done and skills required.
- Allocate adequate resource
- Identify where the risks occur
- Plan how best to improve the system

What can your department do?

Definition

Quality Assurance is a planned and systematic pattern of all actions necessary to provide adequate confidence that the product optimally fulfils customer's expectations.



What can your department do?

- Implement your PV system, and measure how well you do.
- Focus on QA and Quality management
- Identify your QA universe
- Define your QA roles and responsibilities



An exercise

- Split attendees into two groups
- In one group each individual will do the exercise
- Within the other group do the exercise in teams of four people
- List the activities in the PV system (5 min).
- List who is involved (2 min).
- Examples of what we produced



One prepared earlier.

- Record adverse events in patient notes
- Fill out SAE form
- Collect, collate and evaluate SAEs
- Add to safety database
- Report SUSARs to Competent authorities
- Distribute information to Ethics Committees
- Fill out page in CRF
- Add CRF data in CT database
- Reconcile CT database with Safety database
- Produce and distribute 6 monthly reports
- Produce and distribute Annual Safety Reports
- Produce end of study reports
- Update Investigator Brochure
- Update the Developmental Core Data Sheet
- Overall safety evaluation
- Ensure correct safety information in the informed consent



Who is involved

- Sponsor
- Local Competent Authority
- EMEA
- Ethics Committees
- Investigator
- Investigator site staff
- Clinical data management
- Call Centres



These can be in up to seven different locations

Lessons Learned From the Exercise



- The PV system is complex
- Need to define the boundary of your PV system
- Look at the system at different levels
- The List of activities to produce the same objective varies between NHS Trusts
- Your PV system will have common activities with others but there will also be significant differences
- Process mapping should be a continuous activity and not just a one off activity.

Process versus System Audits

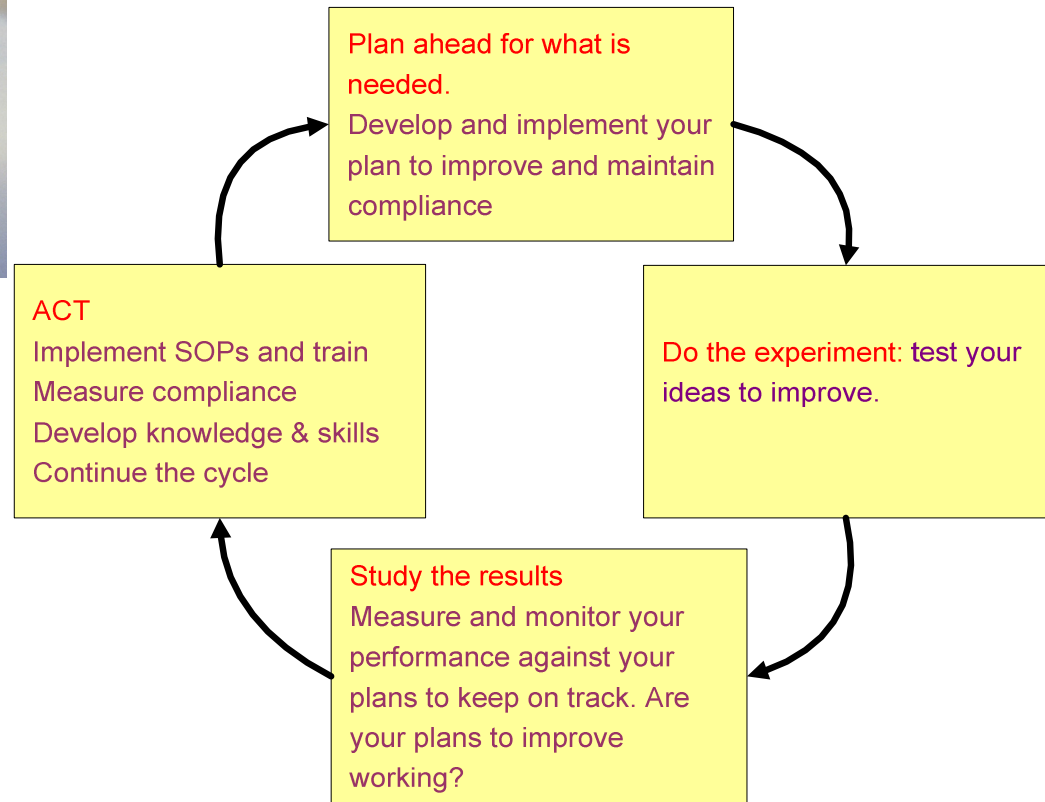
Understand the terminology¹ to plan the methodology

- Process Audits
 - Examines an activity to verify that the inputs, actions & outputs are in accordance with defined requirements”
- Systems Audits
 - Does not necessarily mean “database audits” in the PV world.
 - Otherwise know as management audits
 - Assesses whether controls exist, are adequate, are being implemented and whether they really work?





Continuous Improvement



British Association of Research Quality Assurance

BARQA Membership is open to all those
involved in Research Quality Assurance





How Can BARQA Help?

- We can work together to provide targeted training on PV QA for NHS
 - Provide training to ensure QA functions are developed within your organisations
 - Training courses: process mapping,
 - Seminars
 - Continuing Professional Development initiatives
- Updates on new developments through existing NHS members of the BARQA Committees e.g. GPvP committee
- Networking opportunities e.g. annual BARQA Conferences
- Forum to publish e.g. QUASAR



BARQA Webpage (accessible to non/members)

- WWW.BARQA.COM



Good Pharmacovigilance (GPvP) Committee Webpage



- **Introduction** to the Committee and **objectives**
- **Contact details** - if you have an interest collaborating with GPvP please contact the Chairman, allison.a.jack@gsk.com or Secretary, Helen Politis-Norton helen.politis.norton@spcorp.com
- **Breaking news** – latest information of Pharmacovigilance Specific Legislation/Guidance/Hot topics
 - Committee **“Top Tips”** – 4 presentation slides on general PV topics
- **Courses and training** – forthcoming BARQA courses
- **Discussion forum** – allow BARQA Members to discuss PV-related issues. Messages and responses can be anonymous. The views and opinions expressed in the Discussion Forum are strictly those of the Committee Members and not the opinion or policy of their respective employers or organizations
- **Publications** - BARQA specific



**A long journey starts with a
small step**

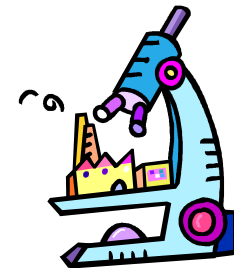
Look after the pennies and the pounds would look after themselves: true or false?



- Each individual focuses on doing things right first time.
- We must work as a team to make sure the whole system works
- The regulatory authorities must inspect all sponsors to ensure their PV system fits with National and European PV systems.
- So we need to look after both the pennies and the pounds.

Explore how quality management techniques can be developed.

- Develop your knowledge of the standards used in pharmacovigilance
- Develop and broaden your auditing skills
- Develop techniques for continuous improvement
- Broaden your quality management skills



This can be achieved through partnering with BARQA

- QA training for investigator and team on BARQA courses
- Networking within BARQA membership: e.g. QA Support for R&D management

