



# How introduction of a Quality Assurance Lead can improve the Quality Assurance Culture in a CRF

Author: Terese Hale, CRF Nurse Manager

## Quality Assurance

Investment and training in Quality Management Systems

Link roles with responsibility for calibration and validation of CRF equipment

Use of UKCRF QA documents including Quality Manual, Deviation guidelines, Audit checklists

Improved systems and processes for study set up, including Standard Operating Procedures, Risk Assessments, Risk Management & Escalation plans

Senior management support for Quality Assurance

Responsibility for quality assurance (QA) forms part of the CRF Nurse Managers role. However, there was no delegated lead taking responsibility for development of QA in the CRF.

The infrastructure needed to be developed within the team and supported to improve. A CRF Nurse Manager was tasked to undertake a scoping survey, & produce a gap analysis on the current state of QA in the CRF. This included investigation of CRF nursing and administrative staff in the application and adherence to QA processes, reviewing current systems and processes and improving knowledge through collaboration with other CRF's and QA Managers.

This identified gaps where investments could be made to improve the QA within the CRF.

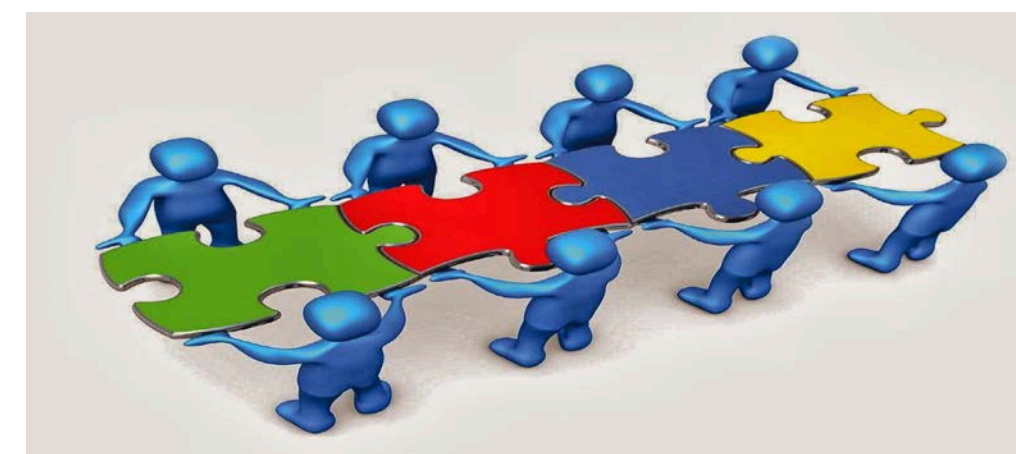
Development of QA Link roles within the nursing & admin team to support QA

Regular interactive SOP Meetings with all CRF team to discuss new and revised SOP's.

Regular interactive deviation meetings with all team to discuss new deviations & outcomes of CAPA's

QA training forms part of the CRF Induction for all new staff

Internal monitoring appropriate to risk undertaken by QA lead and link roles



“Caring for People,  
Keeping People Well”