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Quality assurance on a budget from a non-commercial perspective

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Abstract

The Research Governance Framework and the Medicines for Human Use (Clinical Trials) Regulations both state that NHS organisations should have defined processes in place in order to ensure the quality of studies being conducted within their institutions. The Department of Health considers research a priority and provides around £1 billion a year to fund research. This is additional to money granted by public bodies such as the Medical Research Council. So NHS trusts must increasingly be able to demonstrate robust Quality Assurance (QA) systems in return for this investment. But there is a growing need to ensure that the systems in place make most of a limited budget.

This presentation will suggest methods to ensure quality assurance on a budget from a non-commercial perspective. The Medicines and Healthcare products Regulatory Agency (MHRA) advocates a risk based approach to monitoring studies and this can be transposed into QA systems. For example, self-monitoring of low risk studies can reduce costs and allow trial monitors to focus on higher risk studies and by performing trend analysis on audit reports, training sessions can be arranged on a particular topic for an organisation if there are similar findings across a number of studies. By focusing more closely on mitigating high risk factors across a study or organisation, a higher level of QA is ensured.

Biography

Lucy H H Parker is the Clinical Research Governance Manager and is responsible for, the Governance section of the Joint Research and Enterprise Office of St George's, University of London and St George's Healthcare NHS Trust. Previously, she was a Research Governance Manager in the Joint Research Compliance Office for Imperial College London and Imperial College Healthcare NHS Trust, one of the first Academic Healthcare Science Centres in the United Kingdom. With over 8 years in research management, she has a wealth of experience in non-commercial research. She has a particular interest in data management systems.