

# The Clinical Audit Function – How Well Are Our Internal Customers Served?

(A Study of Internal Stakeholders' Perception)

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This article sets out to provide the readers an overview of my MSc research project entitled "The Clinical Quality Audit Function in Drug Development: a Study of Internal Stakeholders' Perception", including an extract of the results.





When the time came to start my research project (the last and significant part of the MSc programme), I instantly knew what I wanted to focus on! The questions WHY?, WHEN?, HOW? and many others (of a similar nature) had been on my mind since I got involved with and started analysing the notion of quality and its different connotations.

I have seen an array of quality functions at work throughout my career in clinical research. Yet, I did not get a sense that they were always being celebrated for the work they did and fully understood by the people directly affected by the outcomes of their efforts. Also, I was unsure how success and the magnitude of impact of the quality-enhancement efforts were being measured and evaluated. Hence, I set about investigating!

Naturally, being in an auditing/QA role for some time I focused on clinical quality audits and further narrowed the scope of my research to trial-specific auditing. My research project aimed to establish the key elements/attributes of the trial-specific audit function (Phase I of research) and study how they were perceived by sponsor drug development teams (Phase II of research). The research also sought to identify the possible methods of evaluation of the effectiveness and quality of internal audits.

So how did I get the feedback I was after? Firstly, I spoke to a number of quality colleagues (13 to be precise) of different length of experience and geographic location and background to get as broad a perspective as possible. This was to learn what they thought the clinical quality audit function's attributes were. Based on the results of the first phase of my investigation, a survey was created that went out to the clinical drug development community. The purpose of this second phase of the research was to measure the attitude towards trial-specific auditing, achieved by surveying the perceptions i.e. to learn what the clinical colleagues thought the clinical audit function did and how well it was doing it.

This research into the perceptions of the internal trial-specific audit function provides a reminder that internal audits are in place not purely because of the expectations of the regulatory authorities. The audit function is also a service provider and as such should ensure it expends appropriate time and effort on determining what its customers' expectations are, and perpetually look for efficient ways of meeting, if not exceeding them. I believe that any function making up the mosaic of the drug development processes is compelled to review how it is perceived by its stakeholders, as it is only through this review that hindrances preventing it from performing to its fullest capabilities can be identified. The assessment of effectiveness and quality of audits should form a natural part of the service quality assessment processes, despite the apparent difficulties in achieving objective assessment (as perceived by the audit professionals

interviewed). Only once the quality criteria have been established and the results of auditing evaluated against them, can one truly demonstrate the value of the contributions audits make to the Research & Development efforts of drug development companies. And contribute they unequivocally do, as underscored by the results of this research (see Figures 1-4 on pages 26 & 27 which contain an extract of the results).

The question that sprang to mind after perusal of the information gathered during this research project was whether organisations are fully embracing what internal audits have to offer. After all, you cannot inspect quality into a product! This idea is prominent in Dr. William Edwards Deming's 14 principles of management: "quality does not come from inspection; mass inspection is unreliable, costly and ineffective"<sup>1</sup>. It is rather simple actually – devise effective mechanisms for ensuring that quality risk signals gathered through various quality evaluation efforts (quality control i.e. monitoring, quality assurance i.e. audit or self-reported lapses of quality, whether actual or near-misses) are escalated to the right decision makers, at an optimal time, and any actions taken continuously evaluated for effectiveness. Why? Because without fully understanding the gaps and the associated risks, ill-conceived decisions may be taken, potentially or actually endangering the patients relying on the industry to supply safe and efficacious medicines. All employees of drug development companies, their service providers and product suppliers have a primary obligation to the public to ensure, individually and collectively, that the medicines brought to the market are of the "required quality standard"<sup>2</sup> i.e. fit for purpose.

The project results are by no means generalisable due to the limitations of the design of the research and the relatively low survey response rate (32 respondents – Phase II of research). Nevertheless, they are an indicator of the status quo and provide food for thought for both the auditing community and their customers. Furthermore, they provide a basis for additional research in this area which is recommended, extending the focus to external stakeholders and other types of audit (such as vendor and system).

**Disclaimer:** This was an independent academic research project not commissioned by any third party. The information presented in this article is intended for informational purposes only and does not replace independent professional judgment. Statements of fact and opinions expressed are those of the author individually and, are not the opinion or position of Janssen, Pharmaceutical Companies of Johnson & Johnson or its affiliates.

## REFERENCES

- 1 Deming, W. E. cited in Gabay, R. Deming's 14 Principles. QUASAR, Issue 111, 2010, p. 10.
- 2 Reflection paper on risk based quality management in clinical trials, European Medicines Agency, 2011

## Extract of Results

Figure 1

- LS1** The actions resulting from audits are beneficial for the trial/development programme it just makes good business sense to audit.
- LS2** The timing of audits is appropriate and allows timely actions to be taken to ensure that quality is improved over time as the trial progresses.
- LS3** Audit observations are utilised to bring about changes at the trial design/ set up level so as to ensure similar deficiencies are not repeated.
- LS4** Audits are not about finding individuals to blame for mistakes but the outcomes are used to critically review the underlying processes, using appropriate root cause identification approaches.
- LS5** It is clear to me what the clinical audit function does and why.
- LS6** There are efforts made to ascertain if the quality/compliance issues identified during audits are systemic i.e. spanning across different sites and/or trials.
- LS7** Corrective and preventive actions are carried out following the completion of a sufficient number of audits so as to ascertain the extent of the issues identified; teams use e.g. the Pareto analysis.
- LS8** Individual audit outputs feed into the continual improvement efforts of the company.
- LS9** Audits are helpful in improving the work I do i.e. audit actions improve the effectiveness of processes.
- LS10** Audits are a positive experience offering an opportunity to evaluate the 'health' of the trial/clinical site/development programme.
- LS11** Audits enhance the team's awareness of regulations, GCP and other guidelines.
- LS12** I can approach the audit department to seek help in interpreting the requirements/guidelines.
- LS13** Audits bring about and maintain the state of inspection readiness.

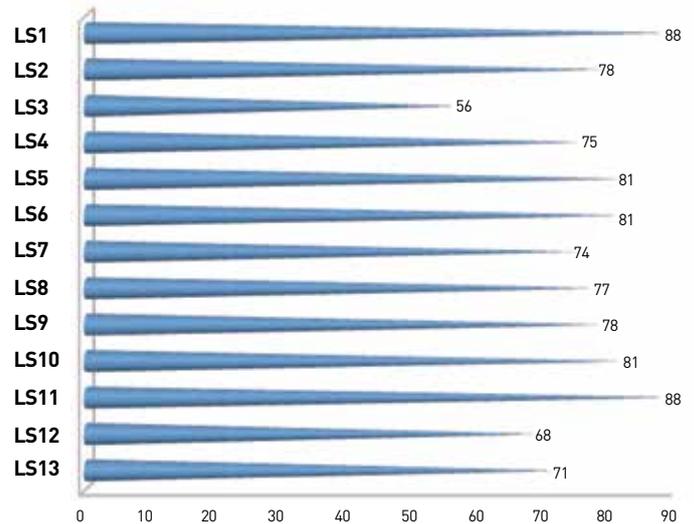
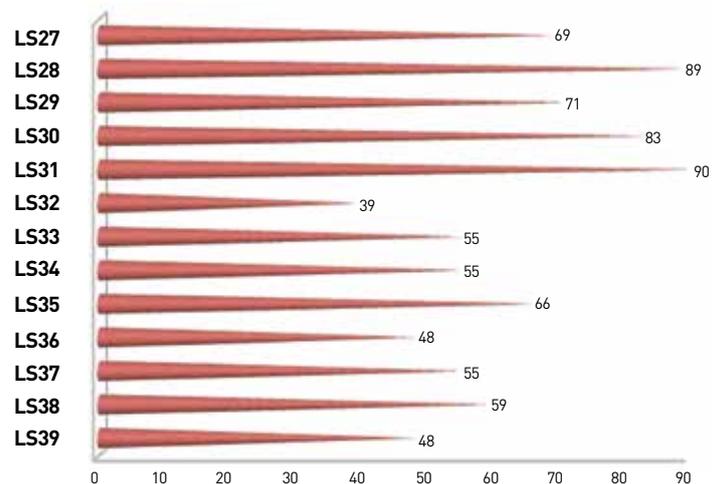


Figure 2

- LS27** Auditors possess sufficient knowledge about the audited trials and the associated processes.
- LS28** Auditors communicate effectively with the clinical team prior, during and after the audit.
- LS29** Auditors are open to discussions and listen to explanations.
- LS30** Auditors explain areas of actual or potential non-compliance.
- LS31** Auditors are professional and represent the company well.
- LS32** Auditors proactively seek feedback on the audit conduct.
- LS33** Auditors are flexible in approach and appropriately refocus during the audit to identify areas of the highest possible risk.
- LS34** Auditors communicate the right level of detail i.e. are not too detailed/too high-level.
- LS35** Auditors focus on the main areas of actual or potential non-compliance.
- LS36** Auditors are consistent.
- LS37** Auditors are objective.
- LS38** Auditors are open to different interpretations of the applicable requirements/expectations.
- LS39** Auditors bring to the table progressive knowledge of the regulatory environment.



Figures 1 & 2 relate to Phase II of the research and contain the %\* of respondents who Strongly or Slightly agreed with the statements related to:

- Trial-specific Audits/Audit Programmes (LS1-LS13) – Figure 1;
- Auditors (LS27 – LS39) – Figure 2.

The associated Likert Scale style questions were designed to evaluate the perception of the different aspects and attributes of the trial-specific audit function and auditor attributes. Full results are available in the thesis.

\* Calculations include the respondents who had an opinion on the statements only.

## Biography



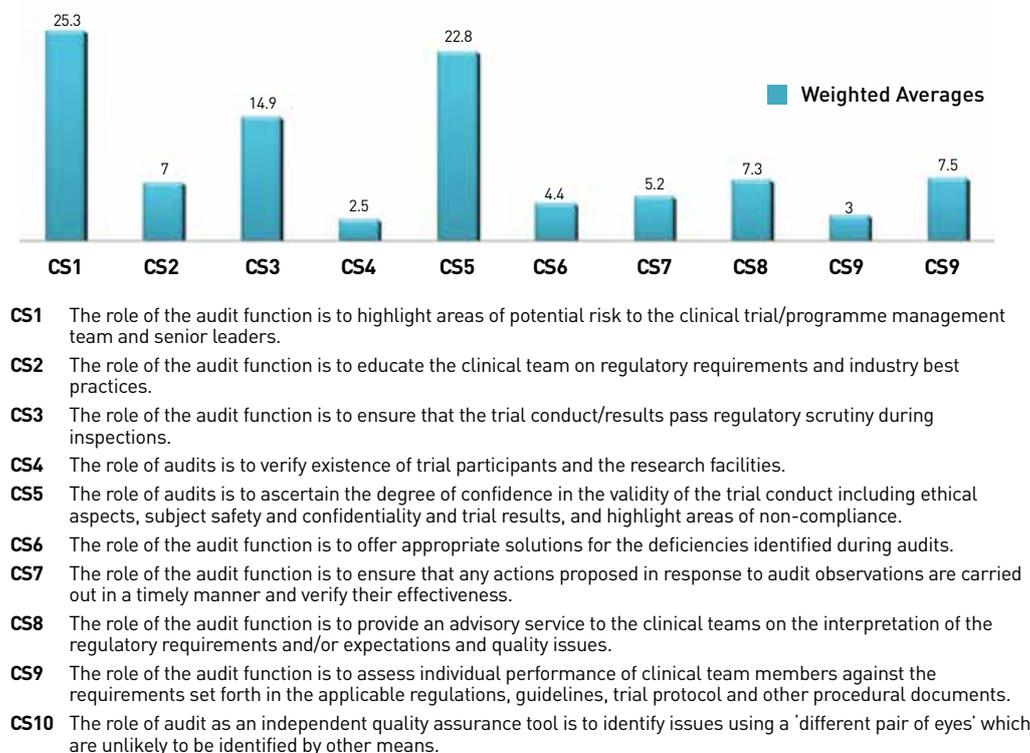
Katarina is a recent graduate from the Masters of Science (MSc) programme in Quality Management in Scientific Research and Development. She embarked on the journey of her MSc studies in 2009, when already working in clinical research for four and quality assurance for one year. Katarina is now a clinical quality auditor at Janssen, Pharmaceutical Companies of Johnson & Johnson. She started discovering clinical research and quality assurance within Phase I commercial organisations.

She had always had a strong inclination towards the world of academia and found that the MSc programme allowed her to take a step back and think over what she was doing out there in the 'real world' as a QA professional.

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Figure 3

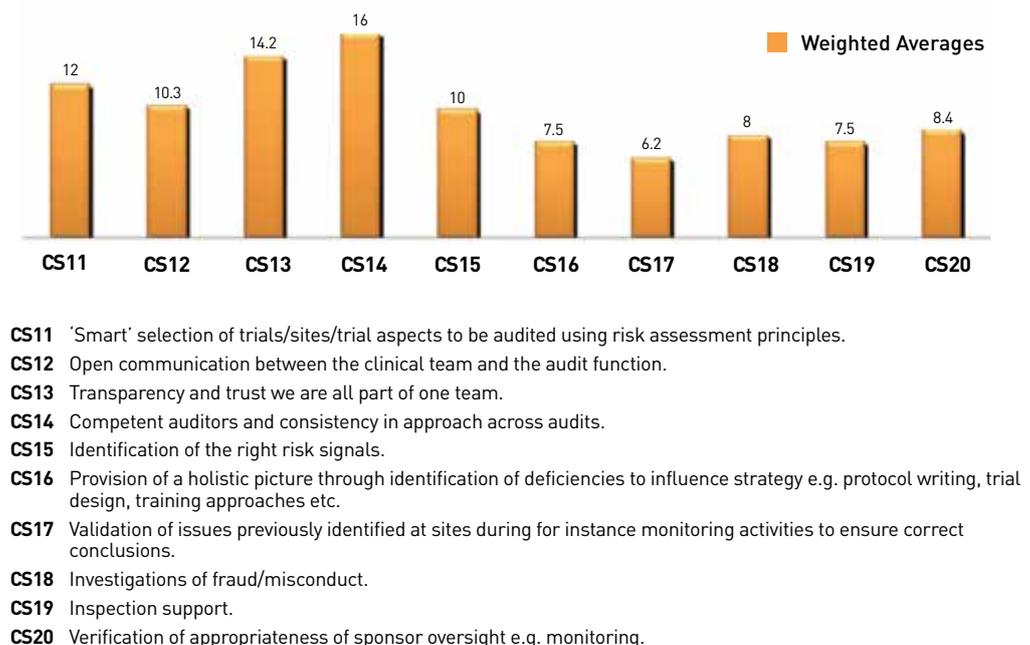
Question Identifier: B1 When talking about clinical trial-specific auditing, what statements best describe the role of the audit function in your opinion?



- CS1** The role of the audit function is to highlight areas of potential risk to the clinical trial/programme management team and senior leaders.
- CS2** The role of the audit function is to educate the clinical team on regulatory requirements and industry best practices.
- CS3** The role of the audit function is to ensure that the trial conduct/results pass regulatory scrutiny during inspections.
- CS4** The role of audits is to verify existence of trial participants and the research facilities.
- CS5** The role of audits is to ascertain the degree of confidence in the validity of the trial conduct including ethical aspects, subject safety and confidentiality and trial results, and highlight areas of non-compliance.
- CS6** The role of the audit function is to offer appropriate solutions for the deficiencies identified during audits.
- CS7** The role of the audit function is to ensure that any actions proposed in response to audit observations are carried out in a timely manner and verify their effectiveness.
- CS8** The role of the audit function is to provide an advisory service to the clinical teams on the interpretation of the regulatory requirements and/or expectations and quality issues.
- CS9** The role of the audit function is to assess individual performance of clinical team members against the requirements set forth in the applicable regulations, guidelines, trial protocol and other procedural documents.
- CS10** The role of audit as an independent quality assurance tool is to identify issues using a 'different pair of eyes' which are unlikely to be identified by other means.

Figure 4

Question Identifier: B2 When talking about clinical trial-specific auditing, what statements best describe the most important aspects/attributes of the audit function in your opinion?



- CS11** 'Smart' selection of trials/sites/trial aspects to be audited using risk assessment principles.
- CS12** Open communication between the clinical team and the audit function.
- CS13** Transparency and trust we are all part of one team.
- CS14** Competent auditors and consistency in approach across audits.
- CS15** Identification of the right risk signals.
- CS16** Provision of a holistic picture through identification of deficiencies to influence strategy e.g. protocol writing, trial design, training approaches etc.
- CS17** Validation of issues previously identified at sites during for instance monitoring activities to ensure correct conclusions.
- CS18** Investigations of fraud/misconduct.
- CS19** Inspection support.
- CS20** Verification of appropriateness of sponsor oversight e.g. monitoring.

The associated Constant Sum Questions were designed to measure the perceived relative importance of the different aspects/attributes/role of the trial-specific audit function and auditor attributes. Full results are available in the thesis.