

Towards an Integrated Approach to Benefits Realisation Management – Reflections from the Development of a Clinical Trials Support System

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"We know what we do, and often we know why we do what we do; but what we don't know is what we do does." -Michel Foucault

Abstract: The aim of our research project, described in this paper, was to develop a purpose-built clinical trials support system [CTSS], which would be sufficiently comprehensive, integrated and flexible, so as to support the vast majority of research studies that were to be managed and conducted by one UK-based health authority. Whilst at the start of this project, it was reasonably clear what major clinical activities the system would need to be able to support, it was less clear what benefits the system should be expected to deliver, nor how these benefits were related to specific aspects of the system's functionality. Moreover, whilst it was recognised that the introduction of the CTSS would engender fairly significant organisational changes, it was less easy to articulate the nature of the changes, nor how they might ultimately relate to the realisation of benefits. Consequently, it was agreed at the project's outset that an explicit benefits' realisation approach should be integrated into the system's development activity. The aims of this paper are threefold: 1] to describe the CTSS project, paying particular attention to why it justified the inclusion of a benefits realisation approach; 2] to provide a description of, and justification for, the benefits management approach adopted; 3] to provide a provisional assessment of the effectiveness of this approach. In addressing these objectives, it was envisaged that our paper would make an important contribution to the literature by providing one of the few first-hand accounts of the conduct of benefits' management practices, and certainly the first in the context of clinical trials support systems. Moreover, the paper provides new insights into the integration of benefits realisation and structured development tools and practices: we describe how the benefits dependency network has been successfully related to use case diagrams.

Keywords: Benefits realisation, Software development, Clinical trials, NHS.

1. Introduction

A considerable amount of time, money, effort and opportunity has been wasted upon IT investments that have ultimately failed to deliver any appreciable benefit. Whilst estimates of the level of failure vary, over the past thirty years they have tended to stay uncomfortably high. For example, it has been suggested that in the late 1970s only 20% of projects '*achieved something like their intended benefits*' [Eason, 1988], whilst by the late 1980s, it was estimated that up to 70% of IS project fail [Hochstrasser & Griffiths, 1991]. By the late 1990s, Clegg *et al* [1997] estimated that: '*up to 90% of all IT projects fail to meet their goals*', whilst more recently still the British Computer Society [BCS, 2004] concluded that '*only around 16 per cent of IT projects can be considered truly successful*'. There is also an established stream of research to suggest that the root cause of this problem is the failure of project teams to explicitly consider the organisational impacts and implications of a new piece of software and to proactively manage the associated organisational change [Clegg *et al*, 1997; Doherty and King, 2001]. The typical IT project team will focus upon delivering a technical solution, and only worry about its organisational impacts, once it is operational [Ahn & Skudlark, 1997; Eason, 2001; Doherty *et al*, 2003; Markus, 2004; Peppard & Ward, 2005].

One potentially important mechanism for proactively managing the social and organisational impacts of an IT project, to ensure that it ultimately delivers value, is through the initiation of an explicit benefits realisation programme. Such approaches have been defined as '*the process of organising and managing, such that the potential benefits arising from the use of IT are actually realised*' [Ward & Elvin, 1999]. A clear link between the high incidence of IT failures and the absence of formal and explicit '*benefits realisation*' approaches may

well have already been established [e.g. Farbey et al, 1993; Ward et al, 1996; Remenyi et al, 1997], but there is little evidence that organisations have been able to translate the academic research prescriptions with respect to the realisation of benefits, into effective working practices [NAO, 2006]. Indeed, Farbey et al [1999a] have explicitly highlighted the urgent need for benefits management approaches and practices to be developed for, and adopted within, the NHS, but to date there is little evidence that this advice has been heeded. Benefits realisation appears to be a good example of the often substantial gap between management theory and practice [Pfeffer and Sutton, 2002]. Consequently, there is a pressing need for new contributions that present insights into how benefits-oriented practices might best be operationalised and incorporated into systems development projects.

To help fill this notable gap in the literature, a KTP-funded, research project was initiated to help develop new benefits management approaches, and to explore how these could best be integrated and applied in support of the development, implementation and operation of a clinical trials support system [CTSS]. The remainder of the paper is organised into four parts. First, we provide a brief review and critique of the relatively small, but growing, body of literature related to the realisation of benefits from the investments in information technologies. Moving on, we then outline the research method adopted for the empirical part of this study and summarise the key findings. Finally, we explore the theoretical and practical implications of this work, paying particular attention to the lessons that might be learned to improve the realisation of business benefits in future IT projects.

2. Literature review

The aim of this section is to critically examine the link between organisational change and benefits realisation before reviewing the literature with respect to the application of explicit benefits realisation approaches.

2.1 Benefits realisation and organisational change

A major problem with the vast majority of information technology evaluation exercises is that they tend to be oriented towards the *'what'*, rather than the *'how'*: they focus on identifying the benefits that the project team anticipate [hope?] the resultant system will deliver, rather than attempting to understand how these desired outcomes will be realised. Moreover, such *'wish-lists'* of benefits are typically framed in financial or economic terms. Indeed, the emphasis on the financial and economic contribution of information systems is very evident in the literature. For example, Ballantine et al, [1996] note that *'studies have tended to concentrate on the financial techniques used to evaluate investments'*, and that *'financial reviews of cost / savings'* are the most common aspect of evaluation procedures. Similarly, Farbey et al, [1999b] note that the debate about systems evaluation has been primarily concerned with *'Value for IT money'*. Consequently, systems evaluation is often defined in these terms. For example, Willcocks [1992] defines systems evaluation as the *'process of establishing by quantitative and / or qualitative techniques the worth of IS / IT projects to the organisation'*.

Unfortunately, there is very significant gap between simply specifying the desired outcomes of a prospective software development project, in financial terms, and ultimately establishing the veracity of such cost savings or improvements to revenue, once the system is operational. This is partially because it is far less easy to effectively measure the outcomes of a system's project, in financial terms, than it is to make pre-investment predictions. However, probably, the more significant reason that anticipated benefits, whether financial or otherwise, rarely translate into actual benefits is that project teams typically fail to recognise the critical role of organisational change. For the past twenty years researchers have been flagging up the importance of organisational change. As Strassman [1990; p 519] reflected: *'computers add value only if surrounded by appropriate policy, strategy, methods for monitoring results, talented and committed people, sound relationships and well designed information systems'*. More recently, Melville et al [2004] commented that *'improvements in process and organisational performance [from IT] are conditional upon appropriate complementary investments in workplace practices and structures'*. Consequently, a fundamental purpose of any investment appraisal must be to explicitly establish the scope and implications of such organisational change [Lubbe & Remenyi, 1999]. Whilst there is a strong recognition amongst researchers, and perhaps practitioners also, that effective benefits delivery is predicated on well focused organisational change, there is little evidence that this understanding has been translated into a suite of well focused and commonly used tools and techniques, as discussed below. Indeed, there is a very significant gap in the literature, with respect to empirical accounts of the application of benefits-oriented approaches.

2.2 Benefits realisation approaches

It is unlikely that benefits will simply emerge, as if by magic, from the introduction of a new technology. Their realisation needs to be carefully planned and managed [Lin & Pervan, 2003; Markus, 2004]. Unfortunately, to date, there have been fairly few attempts to create specific tools, methods and approaches that are specifically suited to this task. One of the few exceptions to this rule has been the work conducted by researchers at the UK's Cranfield University [e.g. Ward & Elvin, 1999; Ward and Daniel, 2006], who have created a number of prospective methods, of which their benefits dependency network is probably the most widely recognised. However, even where such tools have been developed, there is very little suggestion that they are being actively used in systems development projects [Lin & Pervan, 2003]. Consequently, it is essential that the effectiveness of such tools is critically evaluated in systems development projects, and the results reported in the literature, to promote wider interest in their use.

3. Research context, objectives & approach

The aim of this section is to briefly describe the research context, in terms of the organisation and IT application, before articulating the study's objectives, and describing the research methods and approaches utilised.

3.1 Research context

No new medicinal drugs can be prescribed to patients without them being thoroughly tested beforehand, through the conduct of a formal clinical trial. Moreover, it is also good practice – and in most cases mandatory - for clinical procedures and practices to also be formally trialled before being enacted upon patients. Whilst the safety arguments for clinical trials make them an essential element in the evolution of clinical knowledge and practice, they are by no means straightforward undertakings, as they are time consuming, resource-intensive and they generate very significant amounts of data that need to be captured, stored, analysed and retrieved in an efficient and effective manner. Consequently, there is a very strong rationale for providing clinical trials with dedicated and comprehensive computer-based support to facilitate effective data management practices, and to ensure that the investigating team can gain access to the information that they require in a timely and accurate fashion. Unfortunately, relatively few clinical projects have access to such dedicated and comprehensive systems, and they typically have to make do with a combination of end-user generated, database or spreadsheet-based systems, that are tailored to the needs of a particular trial, but are then effectively redundant. However, such systems do not typically cover all of the clinical investigators' data processing requirements, and it is not unusual for them to have to out-source some specialist tasks, such as patient randomisation, and resort to paper-based record keeping, for others. Against this backdrop, the rationale for Health Authorities to either develop, or buy, a fully integrated and comprehensive clinical trial support system [CTSS] is strong.

The clinical trials support system in question is being developed by University Hospitals of Leicester, on behalf of the NHS research community of Leicestershire, Northampton & Rutland. It has been designed to standardise, integrate and, where possible, automate the conduct of clinical trials, within an NHS environment, by providing web-enabled, real-time support to all clinical research staff, as and when required. Given the fairly broad scope of the system, in the first instance it was envisaged that the systems' development effort would focus upon the following important areas of functionality:

- **Trial registration:** Once a new research contract has been secured, the first task to be performed, from a system's perspective, is to create a detailed description of it on the CTSS. More specifically, the Principal Investigator or the Trial Manager is required to record the following details: the research centres involved, the research staff and their roles, the trial treatment arms [e.g. active drug or placebo], the recruitment parameters [which define the sample], the patient trial data [e.g. blood pressure, white cell count, patient weight, ECG or MRI results etc] and the randomisation approach that is to be applied.
- **Patient randomisation:** To ensure that there is no bias in the allocation of patients to the treatment arms of a specific trial – for example, allocating the active drug to the least healthy patients and the placebo to the healthiest – it is important that the allocation process is randomised. The patient randomisation module has been designed to ensure that this service is delivered in a secure and accurate fashion.
- **Electronic data capture [EDC]:** Once a trial goes live, it will be necessary to collect, on an on-going basis, the patient-related data that will be needed to ultimately interpret the effectiveness, or otherwise, of the drug or procedure, under investigation. The EDC module has been designed to facilitate the collection and validation of such data, at the point at which it is generated: this is

an important development, as the web-enabled nature of the CTSS will enable patient data to be captured at a number of different clinics or surgeries, at the same time.

- **Adverse events reporting [AER]:** When a patient, on a trial, appears to suffer a harmful reaction to their drug regime or treatment, it is important that the research team and the regulatory authorities are informed immediately, so that they can determine an appropriate response; for example, the trial could either be suspended or even abandoned. The AER module has been designed to collect a detailed picture of such adverse events, and ensure that they are reported to the appropriate authorities, and acted upon, in a timely fashion.

In terms of progress, the project has been underway for just over a year, and thus far, all the information requirements have been gathered and the design has been specified – through the production of use case models - for each of these four modules. Moreover, the software has been developed and tested for the ‘*trial registration*’ and the ‘*patient randomisation*’ modules, and the coding is now also under way for the ‘*electronic data capture*’ module.

The specification and compilation of the functional software was relatively straight forward, as most of the stakeholders, who are experienced clinical researchers, had a clear idea of how they wanted the system to perform. However, it has been less easy to establish the measurable benefits that should ultimately be delivered [from this IT investment] and the exact nature of the organisational changes, upon which benefits realisation would ultimately be predicated. Consequently, there was a clear rationale for the adoption of a benefits realisation approach, which has become the focus for the research project, explored in this paper. More specifically, the following two research objectives, for this project, were established:

- to explore how benefits management approaches can best be adapted and applied in the context of a live systems development project;
- to provide a provisional assessment of the effectiveness of this approach.

In addressing these objectives, it was envisaged that our paper makes an important contribution to the literature by providing one of the few first-hand accounts of the conduct of benefits’ management practices, and certainly the first in the context of clinical trials support systems.

3.2 Research approach

The research method adopted on this project can best be described as a single case study approach [Yin, 1994]. The detailed design of the research strategy was very strongly influenced by the fact that one member of the research team was actively employed on the project, in the role of the ‘*Management Information Analyst*’ [MIA]. More specifically, he was heavily involved in the development and implementation of the CTSS, playing a key role in the: capture of users’ requirements, the systems design and the writing of XML code. In this position he had unrestricted access to a wide variety of relevant information and key personnel, through which he was able to gain unique insights into this increasingly important phenomenon. The research approach adopted was, however, more akin to ‘*action research*’ than ‘*participant observation*’, as he was given a very specific brief to research and apply benefits realisation methods on this project.

When conducting a case study, Darke et al [1998] suggests that data should be collected in a variety of ways, including ‘*formal interviews, questionnaires, observation, and document analysis*’, so that the findings can be triangulated. More specifically, when working on each case study site, the following data collection techniques were employed:

- **Document reviews:** The MIA had access to a wide variety of documents, including IT, marketing and corporate strategy reports, staff communication documents and detailed design documents.
- **Interviews:** Formal interviews or informal discussions were conducted with a wide variety of stakeholders, associated with the project, ranging from clinical and clerical users through to very senior managers. The main objectives of the interviews were twofold: 1] to understand how the users’ requirements so that these could be translate into benefits-oriented design documents; and 2] to gain critical feedback on the application and impacts of our benefits-oriented approaches.
- **Observation:** Being an active participant in the project, the principal researcher was able to observe their day to day execution at very close quarters, including participation in the vast majority of important project meetings.

A series of note-books were compiled to ensure that a complete, coherent and contemporaneous set of evidence was captured. Furthermore, the advice of Nandhakumar & Jones [1997: 118] was followed and

time was set aside to periodically ‘*step back from the research context*’, to write-up key findings and objectively review them with the other researchers.

4. Research findings

The presentation of the research findings is structured around the two specific research objectives, as previously highlighted.

4.1 The benefits realisation approach

There were three major aspects to the benefits realisation approach adopted on the CTSS project, to date, namely the benefits dependency network, the benefits-oriented use case diagram and the benefits-oriented prototyping. Each of these three innovative new approaches is described below:

- **The benefits dependency network:** The benefits dependency network [BDN] [Ward & Elvin, 1999] was chosen as our main tool, as it is probably the best established of the benefits realisation tools, and it is particularly useful for critically evaluating the targeted benefits, and the means by which these will be achieved, at a project’s outset. More specifically, it has been designed as a means of enabling ‘*the investment objectives [of a specific IT project] and their resulting benefits to be linked in a structured way to the business, organisational and IS / IT changes, required to realise those benefits*’ [Ward & Daniel, 2006]. It has proved to be a very useful tool on the CTSS project, as it has helped to focus the thoughts of the project stakeholders, as well as all the team members, on the system’s overall purpose, as well attainment of specific benefits and value from the system, once operational. At the time of the project’s conception and initiation most of the discussion focused upon the high level drivers for the system, in particular: cost reductions, greater regulatory compliance, and improved competitive positioning, by being in a better position to win research funding. However, through developing the BDN, the project team were encouraged to explicitly consider how such high levels investment objectives might best be achieved.

The BDN was not a document that was created at a certain point in time, and then remained constant from thereon. Rather it was a document that evolved, over time, through an on-going process of review and refinement, in line with the stakeholders’ growing understanding of the scope and potential of the system.

A copy of the BDN, as it currently stands has been provided [see figure 1]. Perhaps the most interesting issue to emerge from this document is the strong focus on improving the Trust’s competitive positioning. The UK’s National Health Service hospital trusts, being public sector institutions, are not normally considered to be engaged in the cut and thrust of market competition. However, as hospital trusts will be in competition with each other, and other research organisations, when seeking to secure research funding, it is important that they take steps to ensure that they are in the best position to compete effectively. One particularly effective tool in the competitive armoury of any organisation engaged in clinical research is a CTSS, as this sends important signals to the funding bodies about the organisation’s ability to effectively undertake and manage clinical trials.

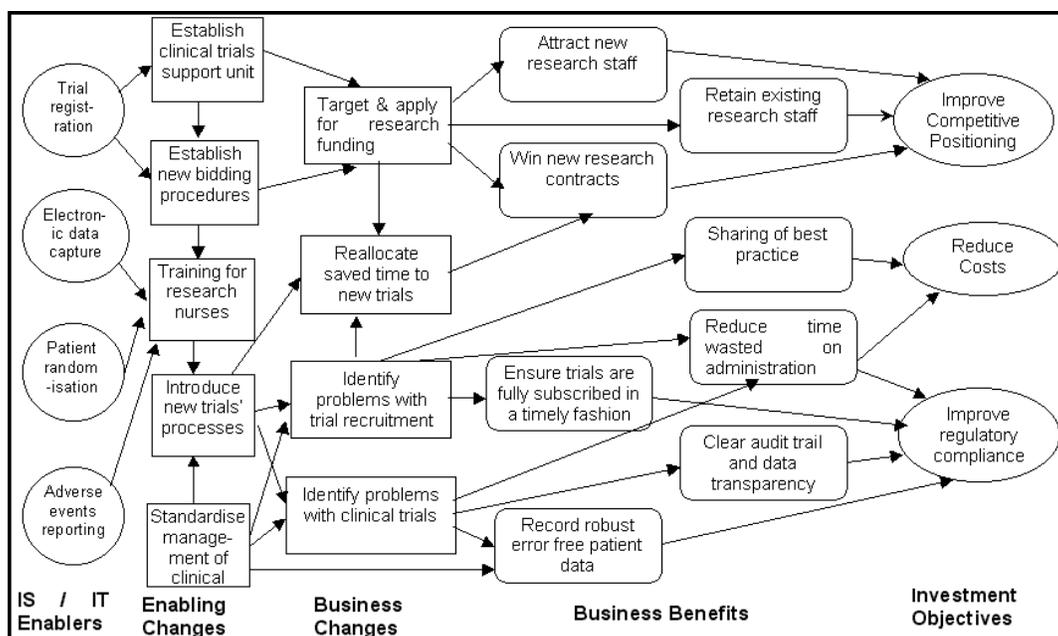


Figure 1: Benefits dependency network for the CTSS

- Benefits-oriented 'use cases':** The creation of a benefits dependency network was recognised as being an important first step towards ensuring that the CTSS project maintained a clear focus on the delivery of value. However, at an early stage in the project, the team realised that it would be very easy for that benefits' focus to be lost once the focus of the project switched from the specification of information requirements, to the more technically-oriented aspects of systems development – in particular the software coding. Consequently, an important aspect of the research agenda was to explore the potential of linking the benefits identified in the BDN to the design documentation, from which the coding was to be conducted. As the primary design tool, we had elected to adopt 'use cases' [Schneider & Winters, 1998], which can be defined as a means of establishing the sequence of transactions between an actor and a system that support the activities of the actor. The standard 'use case' description [see table 1] doesn't have any explicit links with benefits, so we have modified it, so that the software developers can see how their programmes relate to the attainment of benefits [see table 2]. This link between systems design and benefits is an important one, as it helps to keep the focus on benefits realisation, throughout the systems development. However, it does not help in terms of detailing the requisite organisational change, upon which the attainment of benefits is dependent. To this end, the research team are currently exploring ways of integrating the organisational change into their 'use case diagrams' [Schneider & Winters, 1998].

Table 1: The standard use case specification

Facet	Description
Name	Case Name
Goal	An overview of the case's primary objective
Primary actor	Uses the main functionality of the system
Pre-conditions	List of conditions that have to be met before the case can be invoked
Post-conditions	List of conditions, if any, that will be true once the case has been successfully concluded
Main course of action	A step by step account of how the use case scenario should unfold, assuming that everything runs according to plan
Alternative courses of action [extensions]	An account of how the use case will respond to unusual situations or problems.

Table 2: The modified use case specification, as applied in the context of a specific CTSS function

	Description
Name	Adverse events reporting
Goal	To record adverse events on trial.
Primary actor	Principal investigator or Chief investigator
Pre-conditions	Patient for whom adverse event is reported should be registered on the trial
Post-conditions	CTSS records the adverse events and alerts the trial sponsors
Main course of action	The primary actor will try to log on to the CTSS. On successful authorisation, the primary actor will try to access the adverse event reporting functionality. The CTSS will then validate if the primary actor is eligible to access the adverse events reporting functionality. On successful verification, the primary actor would be asked to enter the patient id for whom the adverse event is reported, the adverse event description, what action will be taking on the patient and whether the trial needs to be stopped. On submitting this information, the CTSS will create an automated alert to inform the trial sponsors.
Alternative courses of action	3a. The primary actor would be asked to review their staff ID entered and try again. 4.a The primary actor would be asked to review the patient ID entered and try again.
Benefits linkages	Prompt information sharing and action– a full description of the adverse event must be captured and validated and then sent to all relevant parties immediately. The recipients' of the information must acknowledge that they have read and understood the report and will then be prompted to enter their response. Reduce time wasted on administration: It is essential that details of the adverse event be recorded in real time, at the point at which it was recognised, and then automatically relayed to all the relevant parties, to reduce the need for any administrative intervention. Clear audit trail and data transparency: In order to comply with regulatory requirements, it will be essential that a full and accurate record of the adverse event, and any resultant courses of action, are captured and securely stored, as an audit trail.

- **Benefits' oriented prototyping:** The final tool to be deployed by the project team, to help ensure that the CTSS ultimately met its investment objectives, was through the use of benefits' oriented prototyping. Whilst 'use case' specifications and diagrams had been drawn up to provide guidance to the programmers, the resultant software was regularly reviewed with project stakeholders, so that their requirements could be tested and refined on a regular basis. An important element of these review sessions was to invite the stakeholders to consider how likely it was that the software, in its current state, would support the attainment of the specified benefits, and then suggest enhancements to the software that would improve the likelihood of benefits realisation. Moreover, the prototyping sessions were also used as a forum for exploring the stakeholders' views as to the nature of the organisational change that would be necessary to leverage these benefits, and this feedback was used to modify the BDN, and to develop the organisational change strategy.

4.2 Critique of the benefits realisation approach

From a research perspective, one of the most interesting aspects of adopting a benefits realisation approach is that it allows the capabilities and limitations of our approach to be critically assessed in the context of a 'live' IT development project. Whilst the project is still on-going, it is not possible to make any definitive assessments. However, it has been possible to develop the following, highly '*provisional*' list of findings, with respect to our approach:

- It proactively encourages stakeholders to explore the multitude of relationships that exist between technology, organisational change and benefits;
- It keeps benefits very firmly on the agenda, and it facilitates benefits-oriented communications between a range of system's stakeholders;
- It helps bridge the gaps in understanding and expectations that often arise between the system's designers, the software developers and the end-users;
- Each of the three developed tools has been found to be useful in its own right, but they deliver maximum value when applied in unison.

- Whilst the tools, developed and trialled thus far, have been found to be very useful, others will be needed to model the specified organisational changes, at a more detailed level.

Because of the highly provisional nature of this list, we will seek to develop and validate it in the coming months.

5. Concluding remarks

Ciborra [2004] argues that the prescribed use of systems development methods is very often subverted by the developers themselves who are apt to intervene, tinker and drift. In this project the team's tinkering has come in the form of experimenting with a number of benefits management practices. Thus far we have found these interventions and practices to have been very helpful, as they have helped to maintain the team's focus on benefits and organisational change, and they have also proved to be very helpful in terms of stimulating focused communication amongst all the stakeholders. Unfortunately what we don't know at this stage is - to paraphrase Michel Foucault - the ultimate effects of what we have done. However, we do believe that we have made an important academic contribution, by adapting and proactively applying benefits realisation practices, in a live project. Moreover, our experiences may be of interest to other IT practitioners who are also looking to make benefits the focal point of their software development efforts.

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