

Evaluation of Innovation In Healthcare – A Practice based Review of Governance and Project Management Issues

Purpose of Document: The purpose of this document is to provide an outline of the key areas of governance and project management relating to the successful delivery of innovation evaluation projects in the NHS and other healthcare provider organisations. The content is not intended to be exhaustive but is intended to highlight the kind of issues a project team may face and to signpost some possible solutions for consideration and action. The content is based on experience working with and feedback from a selection of innovation evaluation projects over a twelve-month period.

The First Question: Before planning the implementation of an innovation evaluation project it is essential to ensure that the decision to proceed with the project as an evaluation and not as a clinical investigation (clinical trials of devices are referred to as clinical investigations) or clinical trial is the correct one. In most cases this will be straightforward as the medical technology in question will be CE marked and used for its intended purpose. This means that the project will be defined as a post-marketing study which will further define it as a product evaluation project. In practice projects of this type fit a description of 'evaluation in use'. Such projects do not need Research Ethics Committee (REC) or Trust R&D approval. More on this below

Where there's any doubt queries can be raised and resolved quickly by the Medicines and Healthcare product Regulatory Agency (MHRA) – the Competent Authority for the regulation of Medical Technology in the UK. Useful advice can also be obtained from the HRA around definitions and when innovation evaluation is acceptable as a project methodology. Links to both websites which also give full accounts of how Medical Devices regulation (Including when a clinical investigation is required) operate in the UK is included in the References/Sources at the end of this document.

Project Manager (PM) Role and Engagement

The purpose of the PM, is to coordinate and where necessary support the initiation, start-up and delivery of the project by the clinical teams at participating sites and to act as a communications conduit between the site(s) and the Sponsor, Funder and Clinical Lead Site/Team. Specifically, to act as a link between the CI group and the PI group(s).

The PM should be selected on his/her ability to work with and advise participating organisations in relation to governance and project delivery requirements. Similarly, the PM will need to be available to conduct monitoring/audit as deemed necessary by the project team. It is also not unusual for PMs to provide direct 'hands on' support to site staff however, how this is organised will depend on additional factors such as contract status with the host organisation. Trust site advice may need to be sought on this point.

Projects of this type will require flexibility in terms of working time as this may be fragmented and irregular as well as, in the case of multi-site projects, a willingness to travel around an area, often at short notice and at times to suit the availability of the clinical team(s). The PM should be engaged prior to the commencement of the project – engaging part way through as a reaction to set-up and delivery problems is to be avoided where possible.

The PM should have a professional background such that enables insight into NHS the structure of various NHS/other Healthcare Provider organisations and should also have insight into key issues surrounding innovation governance.

Allocation of time for the PM should be based on:

A full analysis of the protocol including the nature/complexity of the technology involved

Site selection criteria including previous site selection assessment and previous exposure, if any, to the technology within the wider market

Project Feasibility assessment at the site including local staffing, resources and logistics and previous site performance. If previous site/staff experience is limited or historic, a higher allowance of time will be needed (see below)

As a rule of thumb, a 'ball-park' figure can be reached by evaluation of the number of sites, anticipated site visits x2 to 3 as a minimum during set-up, an additional initiation visit and on-going project review/monitoring/audit visits to each site (at least bi-monthly to monthly on average); remember to include a budget for travel expenses/parking. The former at £0.45 per mile, the latter at anywhere from £2-£5 per visit.

Cost site visits at an average of 1-2 hrs hence for a project over 12 months we can expect around 10-16 site visits per site so budget for between 10-32 hrs per site.

Admin/communications hours will be on average an additional 1hr per week per site per visit on plus project level admin at around 1-2 hrs per week. Obviously, the complexity and success or otherwise of the project at site will influence whether costs are at the lower or higher end.

Also, consider whether the PM may need to provide more direct support to clinical teams such as for example assisting with setting up clinic/clinical interventions or uploading anonymised data as this will involve additional time and travel expenses.

Once all these points have been reviewed, a decision can be made as to whether to opt for an externally contracted project manager or a specific time allocation to an internal project manager. This will depend on organisational structure and an assessment of time and cost effectiveness and efficiency. Note that the PM should be available for the duration of the project and for the end of project evaluation process.

PM host: It is important to consider who will host the PM. Some organisations employ PMs within their staff teams and some engage PMs via organisational associate arrangements. This should be clarified in advance, ideally prior to the approach to the site(s), in discussions between the sponsor and funder organisations.

Additional points for consideration

It is common practice for a number of organisations, including industry, universities, provider organisations, innovation networks and patient organisations to work together to launch and deliver projects. Although this rich organisational tapestry is compelling and mutually beneficial to all it can create a complex communication environment. The PM is well placed to ensure that lines of Communication with and between local sites, lead site, sponsor, funder technology initiator and all key stakeholders are clear and fully understood.

Advance clarification concerning delegation of duties/responsibilities between the PM, lead site team, local site teams, sponsor etc. is a singularly important issue as it will avoid task duplication or omission. Where multiple site clinical teams are active and are perhaps supported by external clinical staff for example from the lead site, it needs to be clear where responsibilities for delivery lie. As a rule of thumb, local clinical teams deliver the project at site and external clinical staff support them to do so – essentially a within site role. The role of the PM is to support organisational level staff at site and within key stakeholder organisations such as RD&I Managers, sponsors – essentially to work across and between organisations.

Some Governance Basics to Remember

The first priority is the safety and well-being of research participants and that includes both patients, carers and staff

The NHS organisation retains a duty of care to its patients and staff whether or not they are involved in an innovation project

The project protocol is the primary document for delivering the project. It is the responsibility of all participants to ensure the project is run in accordance with the protocol including any amendments

The protocol must be compliant with all aspects of applicable regulation

The project must not incur financial costs for the NHS

Medical technology innovation evaluation projects are not research and do not require Research Ethics Committee approval or Medicines and Healthcare product Regulatory Agency (MHRA) notification of no objection

Medical technology innovation evaluation projects do need NHS Organisation agreement/permission to proceed but may follow a different organisational pathway to research projects

As medical technology innovation evaluation projects are not research projects, formal written informed consent is not a stipulation however it is good practice to discuss participation with the patient/client and ensure they agree to participate. A simple information form, given to the participant at the point of enrolment, and a positive response will suffice.

General Innovation Governance Issues

Organisational agreement/permissions: The first issue to resolve with sites will probably concern the pathway for organisational approval of a technology/innovation evaluation project. Experience has shown that the differences between research study permission and evaluation project site approvals/permissions are not always clearly understood.

Consequently, some sites treat all externally initiated evaluation projects as if they were a type of research project. However, technology innovation projects have more in common with audit/service evaluation than research and consequently should be managed as such.

Systems for set-up, initiation and delivery of innovation projects may well be covered by local policy and procedure. The person approached as local investigator or the Research, Development and Innovation (RD&I) Office where there is one or Audit/Effectiveness Lead Manager (see below) will be able to advise. Expect some minor delays until the governance position is clarified and fully understood by the key players within and out-with the Trust.

As the pathways are somewhat different, at some sites, R&D Offices do not deal with projects of this type. In such situations it is essential to identify as quickly as possible who else will lead locally on the governance process, particularly organisational permission/agreement. At some sites this will be via an audit/effectiveness department and/or lead or sometimes it will be the clinical lead for a specific directorate who has delegated authority. As understanding as well as structure of the process are often variable and approaches inconsistent, it is important to visit and assess the site early, identify all the key people and meet with them. It would be accurate and reasonable to assume that each site will be slightly different.

Anecdotally speaking, the greatest consistency and easiest set-ups tend to be at sites where innovation is allocated along-side R&D, that is, essentially, where organisations have established RD&I offices. In such circumstances, the general principles of innovation governance and site agreement tend to be better understood. However, it is always wise to account for the possibility that even in such organisations optimal governance arrangements for innovation project management may not always be particularly well understood or that you may be dealing with a relatively junior/new member of the team. In mitigation it is also worth noting that many sites report that innovation evaluation type projects are relatively few in number and consequently local experience and also organisational memory can be limited.

Study Documentation: Protocol and Protocol Amendments: The protocol should describe the evaluation in full including a full schedule of events and interventions. It should also include details of how to report adverse events. Protocol amendments occurring after project initiation should be avoided. To do otherwise requires significant additional work to ensure agreement remained in place and that agreements covered the amended documentation.

In addition to the protocol, the minimum document requirements for a technology innovation evaluation are as follows:

Patient Information Form: As noted above, formal written consent is not required but it is best practice to inform the participant of the project and provide a summary so the patient can decide to either participate or decline the invitation.

Project Site File: A file will be held at each site with all project related documentation included. As with research projects there are usually two files, one containing data collection proforma including any questionnaires and one containing a copy of the protocol, key communications such as agreements and organisational permission/agreement to proceed and all study documents including blank copies of data collection proforma and questionnaires.

Data Collection Proforma: Collects all the necessary data for participating individuals. May be electronic or paper copy. Remember that any copies or uploads leaving site must be fully anonymised.

Recruitment log: Will be held locally and should list all the enrolled participants at the site. Note that as with all study documentation, a complete list of all participants should also be maintained centrally, usually at the lead site (Lead Investigator).

Screening log: Is used to formally screen clinic lists in order to identify referral patterns and is particularly useful in situations where enrolment to target is expected to be challenging or is below target. The log will identify whether there is an issue with the numbers of patients who meet the inclusion criteria or whether busy staff are simply unable to make the approach to potential participants in time. This is routine practice in many research studies and is a transferable, simple and useful management tool for evaluation projects.

Adverse Event (AE)/Serious Adverse Event (SAE) Reporting: It is essential that an agreed process for reporting and acting on AEs/SAEs is in place. The Incident Reporting procedures within provider organisations are generally acceptable however any such events should also be reported to the Lead Investigator and Sponsor and a process defined in order to ensure this happens.

Medical Engineering – Organisational Indemnity: When using new equipment, an NHS organisation completes a local register which ensures NHS indemnity is in place to cover the use of the product within its area of responsibility. Similarly, any electrically powered equipment must be safety tested prior to delivery to the clinical area, both need to be in place even for equipment training purposes. With regard to the former, once again, different organisations have different and sometimes additional requirements (national NHS Procurement registration) which means it can be difficult to put together a suite of documents that would enable registration at all sites to proceed quickly. Also, delay in the delivery of equipment from initiators/suppliers can be a major cause of project initiation delay and cause significant confusion.

Tissue Collection and Material Transfer Agreements: There are two key points here:

As with patient data ensure any tissues leaving site are anonymised

Where possible and where tissues are being transferred to a different site, ensure details of tissue management arrangements are written into the protocol. In this way, local approval of the protocol will include agreement to the transfer and use of tissue.

Where this is not feasible or has been overlooked a simple written agreement can be organised. Whether the former or latter approach is adopted the following elements should be covered:

Tissue collection, storage at collection site, transfer arrangements, arrangements for receipt at receiving site, storage at receiving site, details of analysis, and arrangements for disposal or return as appropriate.

Data Confidentiality: The Patient Information Form (PIF) will need to be reviewed and agreed at each site. However, stakeholder/patient review may only need a single review at the lead/first site and an agreement put in place with other sites to accept the outcome. However again, in order to avoid significant delay, it is well worth finding out in advance whether sites have internal systems and who manages the process as this can again vary from organisation to organisation. Note that data collection paperwork and software must be designed to ensure that no patient identifiable data leaves site i.e. all data leaving site is fully anonymised. Depending on where data is to be processed and analysed, particularly if there are multiple sites collecting data and transferring it to a central point, it may be necessary to develop a bespoke remote access data collection platform. Any such requirement will need to be fully costed.

Management issues

This section has been divided into two main elements. The first concerns activities relating generally to site set-up and the second to on-going project management activities; it should be noted however that there is often overlap and certain areas of activity will be re-initiated during the course of the project. Ultimately, as with any other project, the goal is to achieve completion of the project safely, within budget, to agreed timeline and to enrolment/recruitment target.

Site selection

Although the site selection process should be led by the CI/LI the PM is ideally placed to support the set-up process and help coordinate site selection. It is essential that wherever possible objective, assessable criteria are applied to site selection. Experience has shown that various factors, mostly concerning local service configuration, access to a suitable patient population and workload/staff deployment issues can have a very significant impact on achieving enrolment/recruitment targets.

It is important to be able to justify which sites are considered and what the selection process involves. Similarly, on what objective basis are certain sites to be included or not included i.e. is the selection essentially geographical or are other factors such as previous performance, previous clinical partnerships and joint working, personal knowledge and professional relationships to be considered? Also, are additional factors such as similarity of service configuration and available patient population key selection criteria?

Feasibility - Level 1 and level 2 Feasibility Assessment

Level 1 feasibility involves consideration of whether the technology, in its current form, is generally compatible with clinical service arrangements in the NHS and/or wider healthcare provider organisations i.e. is it in principle possible to deliver the project successfully in the UK and will the innovation translate in 'up-scale' terms to the wider healthcare economy?

Level 2 feasibility involves an assessment at each site to ensure that a project can be delivered there. It will involve a review of the site at both an organisational level i.e. does the site host the relevant services with sufficient capacity and does the clinical team have sufficient expertise (capability) in the area of practice? Also, has the site and team delivered before or are they a new/up and coming centre with little or no established track record of delivery in this field (but showing promise)? Also, does the organisation treat sufficient numbers of the target patient population, have sufficient availability of appropriately trained staff, possess an adequate clinical environment including space and accommodation as well as factors such as geographical location in relation to clinical teams and other sites and availability and timing of accessible clinics? All these factors will need to be taken into account. Other factors of interest will concern training needs, logistical support requirements, population dispersion and geographical dispersion of clinics and an assessment of the clinical team in terms of motivation to deliver.

Risk Assessment: This is a crucial part of study set-up planning and on-going management. Risk includes a number of domains including health and safety, equipment safety and storage and clinical intervention but also includes the potential for organisational risk including reputational risk and from the point of view of the sponsor, the risk of failure to deliver which incurs cost and delay. Aspects of risk such as those existing at an organisational level can be assessed as part of level 1 feasibility and on-going day to day risk as part of level 2 feasibility initially and then longer term as part of the protocol requirements.

Ensure any environmental issues such as safe storage of equipment/chemicals, disposal systems etc. are addressed. Also, ensure that any health and safety issues relating to the equipment, environment or any concerns relating to patient and/or staff safety are flagged to the sites and formally risk assessed locally.

Once again, the PM, if engaged early enough, is well placed to support site feasibility. Optimal timing of feasibility is essential and should include audit of relevant activity at site/patient population suitability (screening) and should be completed prior to but also as close as possible to initiation at the site (out of date data is as bad as no data).

Recruitment planning (RP)

This element links partly to Level 2 feasibility but expands to cover additional on-going local factors. The primary content of the RP should cover total numbers of participants needed to meet local enrolment targets with a breakdown by month to allow for recruitment/enrolment monitoring. It should also include wherever possible an Escalation Procedure to address underperformance.

If not already completed as part of site selection or feasibility, RP should involve an audit of potential participants, a review of staffing and physical resources available to support the project including contingency planning for emergencies such as long-term staff absence, mitigating geographical factors such as population/site dispersion and deployment of clinical teams and research/innovation support staff.

Consequently, the RP should include a comprehensive contingency plan supported by agreed contingency funding. For example, the RP needs to consider and account for issues such as staff withdrawal, staff absence, reconfiguration of service provision - what if the patients receive care at other locations e.g. GP Practices or NICE guidance changes and other treatment alternatives become available? In such circumstances, will the innovation still be 'fit for purpose'. Hence, if and when service provision reconfigures towards a more community based model focussing around for example GP led services, how will the technology in its current form apply and/or adapt? This is likely to be a key finding with a wide range of new and emerging technologies and could in some situations, form the core of the project outcome evaluation.

In other words, what is the plan B? Overall, if not considered, such factors can impact significantly on a project time line.

The RP should include contingency in terms of time and budget for any additional update or contact between Sponsor/CI and local sites i.e. re-submission of project documentation and repeat of meetings with clinical teams, research office staff, admin, finance and medical engineering staff where protocol changes/amendments have taken place.

NB – Tools/templates for site selection, project and site feasibility assessment and recruitment planning are readily available from research based networks and research active organisations and can be adapted on a bespoke basis for each project.

Finance: Innovation evaluation projects must be fully costed and adequately financed. Many projects fail because the funding does not match the full economic cost. It is wise to seek advice on this from organisationally based finance teams and fully scope the project to ensure all events are identified and costed.

As a general principle, a staged payment approach based on recruitment/enrolment activity and performance is generally acceptable to most provider organisations however be aware that if it is necessary to recruit additional people to open and run the project additional 'priming' funding may be required 'up-front'.

Timelines and momentum: The importance of seeking to maintain momentum in any project cannot be overstated. Contact via email can be slow. This is generally a result of workload and that many staff support dispersed clinics in the community as well as hospital based services or vice versa. Office/admin time for local staff/teams will generally be limited and project leads should be sensitive to that. Direct contact by phone or face to face is still by far the best method of information transfer and getting out to the sites is extremely important. Again, the PM is ideally placed to lead on this.

Note that effective early contact and planning, early and open/honest disclosure of the impacts on practice and workload are essential to avoiding delay.

Staff changes and organisational memory: RP must also account for possible key changes to site personnel both in the RD&I management side and the clinical side by ensuring site succession planning is in place both centrally and at each site.

Clinic Space/Equipment Storage Space: On a very practical level, clinical space is often at a premium and storage space for equipment can be equally problematic. It is well worth including an assessment of the environment as part of initial level 2 site feasibility.

Additional workload: It is very important that from the first exploratory visit to and discussion with sites, beginning as part of site selection and feasibility, any additional workload and timing issues in clinics etc. are clearly described. If a project delivery budget is available to the site it should be agreed in advance how this money will be spent i.e. extra clinic support staff, admin support etc. Projects should always be fully costed and funding allocations sufficient to cover the full costs and, where possible, include a reasonable sum towards infrastructure costs that clinical teams can invest locally.

Information Management, Data Collection and Confidentiality: For the avoidance of doubt and in order for the project to conform to the requirements of the Data Protection Act (DPA), unless specifically consented for, where data is being transferred off-site or will be accessed at any location other than by the participants local health care team, any and all personal identifiable data should be removed and only fully anonymised data transferred from the primary sources e.g. case notes, local clinical databases etc. to project level data collection forms or IT platforms.

Logistics: Arrangements for delivery and collection of any samples, data collection sheets etc. must be arranged and agreed. Where possible, details should be included in the project protocol or at the very least in written site agreements. Deliveries and collections can be arranged on an ad-hoc or scheduled basis dependent on local circumstances. Depending on how complex the logistical arrangements are this can be done by project team staff but it may be necessary to cost in a courier service.

Training: The timing of any training is very important. Project and/or equipment training should be planned well in advance giving sites reasonable notice, should obviously take place before project initiation but not so much in advance that refresher training could be required before project go live – this is reported frequently as a problem by both project and clinical teams. Re-training incurs significant time and expense, particularly when factoring in how difficult it can be to get all the necessary people together for a training session(s).

John Hugh Wardle, Associate Project Manager, Innovation Agency.

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JH LS Consulting Ltd Company Reg. 08994843

References/Sources

Health Research Authority (HRA)

<http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/questions-and-answers-medical-devices/>

Medicines and Healthcare product Regulatory Agency (MHRA)

<https://www.gov.uk/topic/medicines-medical-devices-blood/clinical-trials-investigations>

North West Coast Innovation Agency

<http://www.innovationagencynwc.nhs.uk/>