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Review article

PROspectiVe imaging research DEsign and coNducT (PROVIDENT): Considerations for clinical trials and studies using imaging (Part I)

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ABSTRACT

Objectives: Imaging is used in a wide range of contexts in clinical research projects, but adds complexity to the design, conduct and analysis. This paper is the first of two in which we use a consensus approach to bring together multidisciplinary perspectives on the challenges in conducting prospective clinical trials and research studies that include imaging. In this first part we consider challenges in ethics, participant information and consent, recruitment, trial/study and site set-up, training and trial or study conduct.

Key findings: Effective communication with patients regarding the purpose, benefits and risks, and potential future use of imaging data is essential to build trust and support informed participation. Transparency around data handling, including de-identification processes and the right to withdraw consent, underpins ethical research practice. Successful recruitment requires strong collaboration between clinical and imaging teams to ensure clarity, consistency, and efficiency. To reduce participant burden, flexibility should be offered in scheduling and scan requirements, taking into account accessibility and personal commitments. Site setup and staff training benefit from feasibility assessments that evaluate equipment capabilities and identify specific imaging training needs. Clearly defined roles and responsibilities of key personnel support streamlined workflows and accountability. Communication of planned changes to procedures during the study to all stakeholders is key to avoid delays and risks to data integrity. Effective monitoring of procedures, radiation doses (where applicable) and data quality should be pre-planned.

Conclusion: These considerations derived from a multidisciplinary team will be useful for funding applications, protocol design, trial implementation, conduct, commercialisation and uptake of new imaging techniques.

Implications for practice: Many prospective imaging studies could be improved by the upfront awareness of potential challenges and understanding of real-world examples these considerations provide.

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Introduction

Medical imaging plays a key role in the diagnosis and management of many diseases. Imaging may be used for diagnosis, study inclusion, to guide treatment, to assess treatment response and to monitor disease over time. However, using imaging adds complexity to the design, conduct and analysis of prospective clinical research studies, including clinical trials, in part due to the multi-disciplinary aspects of gathering, processing, using and storing imaging data, requiring input from a wide range of specialities. These include clinicians, nurses, radiographers, radiologists, patient representatives, trial managers, methodologists, statisticians, computational scientists, Picture Archiving and Communication System (PACS) and/or image repository managers, medical physicists and other stakeholders.

The aim of this consensus project was to bring together multidisciplinary perspectives to identify and provide considerations for addressing the challenges associated with the design, conduct and analysis of prospective clinical research studies that incorporate imaging as an integral component.[1,2] Imaging plays a variety of roles in clinical research, whether for diagnostic purposes, measuring efficacy and/or safety outcomes, informing inclusion criteria or acting as the intervention under investigation. We did not limit the scope of this project to clinical trials; logistical issues arise in other study designs such as observational studies, agreement studies, and laboratory studies. To avoid the lengthy and repetitious 'clinical trials and studies', throughout we have used 'trial' and 'study' interchangeably.

This research was initiated and led by the Imaging Studies Working Group of the National Institute for Health and Care Research (NIHR) Statistics Group.[3] As statisticians with a key role in the design and analysis of prospective imaging studies with a combined experience of over 85 years, we are aware of particular challenges in imaging studies that can be mitigated by timely identification and planning.

We address potential hurdles in the five stages of a prospective clinical study life-cycle. Firstly, funding or budget application where imaging studies can have additional processes and costs that may not be anticipated by research teams. Secondly, the study protocol detailing study planning, ethics approval, conduct, reporting, and appraisal highlighting imaging-related issues. Thirdly, the detailed planning for study implementation including operational challenges outside of protocol, particularly relevant to multi-disciplinary imaging studies. Fourthly, conduct during the study relating to imaging. Finally, we consider commercialisation and uptake of novel image techniques or processes.

Methods

The NIHR Statistics Imaging Studies Working Group (KB, NP, SM, TN, EH) instigated five multidisciplinary workshops (conducted Nov 2023 to Feb 2024) to identify the specific operational challenges that imaging studies present and to group these into domains. A total of 30 professionals with experience of imaging studies, including academic and commercial researchers, radiologists, radiographers, medical physicists, clinicians, patient advocates, trial managers, health economists, research nurses, methodologists, statisticians, and those with central and individual site perspectives, attended at least one workshop each. Patient advocates were members of the NIHR-Leeds Biomedical Research Centre or the NIHR Biomedical Research Centre at the Royal Marsden/The Institute of Cancer Research Patient and Public Involvement and Engagement (PPIE) Groups who had direct experience of taking part in research involving imaging. Each meeting lasted 1.5 h; following a general introduction, two breakout groups were created to discuss at least two different domains; participants joined the subgroup in which they were most experienced or interested. Each subgroup discussion was attended by at least five participants.

We presented initial ideas to prompt reflection on contributors' own experiences and facilitate discussion, with the content being updated in real time based on the feedback of the group. Updates to the domains and subdomains were made during the meetings by article authors acting as facilitators; no recordings of meetings were made, no quotes reported, considerations were added or amended following the group discussion with no comments attributed to individual participants and no analysis was performed. This approach is similar to previous publications.[4,5]

Prior to the workshops, based on the experiences of the working group of statisticians involved in imaging research, we identified nine key domains within prospective imaging clinical research studies to present at the first meeting: recruitment; ethics and consent; protocol; trial and site set-up; training; trial or study conduct; image interpretation and quantification; scanner imaging acquisition; and data flow and storage. Attendees suggested additional major topics (domains) to include in the first workshop, then discussed challenges under each domain over subsequent meetings; all suggestions were considered valid as they reflected real-world experience, we did not ask attendees to rank domains or challenges. As a result of workshop input, four additional domains were identified: quality assurance and quality control (QA/QC); health economics (HE) decision modelling; costings for running a trial; and commercialisation. As many specific domains have bearing on the protocol, we have not included a separate protocol domain to avoid duplication (only 12 separate domains are presented). As all of the authors and workshop participants are UK-based, a few of the considerations presented are more relevant for UK-based research, but the majority are broadly applicable.

Domains and considerations

In this first part, we present the points to be considered and relevant examples from the workshops in 5 of the 12 domains (Table 1), with the remainder discussed in the companion publication PROVIDENT Part II[6] (Table 2 summarises all 12 domains). Key subdomains and considerations were identified for each domain, together with real-world examples that illustrate potential pitfalls or highlight best practice.

Ethics, participant information & consent

Ethics

Researchers have a duty of care to participants including respecting their involvement, reducing - and being transparent about - possible risks, and being fair by considering and reducing implicit biases that might influence recruitment of certain participants.[7]

Careless wording in project titles and participant-facing documentation has potential to cause undue distress. For example, if a potential participant is approached to take part in a clinical study titled "Towards Improved Cancer Diagnosis" they might mistakenly believe this meant they had cancer.

Clinical trials often lack representativeness, with selective participation occurring via both direct and indirect mechanisms.[8] An example of direct selection might be exclusion of those with contra-indications to imaging. Indirect selection can result from a variety of sources including long scan times or additional appointments needed, which can act as an impediment for some to participate, particularly those from commonly under-represented groups. Considering how to optimise fairness and

Table 1
Split of domains between PROVIDENT Parts I & II.

Part I	Part II
Ethics, participant information & consent	Imaging acquisition and processing
Recruitment	QA/QC
Trial and site set-up	Image interpretation and quantification
Training	Data flow & storage
Trial or study conduct	HE decision model within prospective clinical trial Commercialisation

Abbreviation: HE, Health economic; QA/QC, Quality assurance/quality control.

representativeness is important, whilst recognising limitations of trial and health service contexts.

Participant information

The extent to which potential participants are informed about the study may be one of the most influential factors for recruitment into imaging studies.[9] Sometimes the imaging aspects of a trial are given relatively little attention or space in the participant information sheet (PIS), due to a primary focus on treatment and clinical data collection. Despite well-founded concerns over PIS length, fully informed consent requires transparency about the purpose, risks, procedures and time burden of imaging. This is required from an ethical perspective and giving potential participants this information up front can increase study retention rates.

Participants need sufficient information to plan their involvement, such as how long imaging will take and details about appropriate clothing or their privacy. A participant video can be a powerful tool to convey this information; a quick response (QR) code linking to the video could be included in the imaging study's PIS.

It is best if the PIS clearly explains the purpose of any imaging to be conducted, and indicates whether this might differ for some participants, such as healthy controls. Relevant information may include what are you looking for, its potential clinical significance, whether imaging results may affect participants' future care, what will happen if something unexpected is found. Identifying incidental findings can potentially be beneficial; however, knowledge of them can also have a negative impact for participants, so they should be made aware of this, and of procedures for addressing such findings, before agreeing to take part in the research.[10,11]

Full transparency necessitates informing participants regarding additional radiation exposure and frequency of scans, and the need for injections, if any.[12] Even if radiation is not involved it is best not to assume that this is common knowledge; a survey found that 57 % of patients mistakenly thought that magnetic resonance imaging (MRI) used radioactive materials while computerised tomography (CT) involved no radioactivity.[13] Stating the clinical study phase, such as whether this is an early or exploratory phase study, or whether the study results could directly influence routine clinical practice, allows participants to gauge how much impact their involvement will have.

The PIS should include information on the planned imaging procedure:

- Where will the scans be performed, is this the same location as the clinical assessments?
- What exactly will happen during the imaging visit?
- What happens if the scan cannot be performed on the day, will participants be recalled?

It is important to inform participants about what will happen to both their images and any image-derived data:

- Where will images and data be stored?
- Who will have access to images and data during the study?
- Will they be shared with others in future – for what purpose?
- Will images/data be made available for commercial use and/or artificial intelligence (AI) training?
- Can participants and/or their care team request access to the images/data?

See Example A for an excerpt from a real PIS and some suggested improvements.

Consent

It is important to obtain clear, unambiguous consent to store and use for research purposes both images and image-derived data, and to ensure that the wording around the level of de-identification of images and image-derived data is consistent with what will happen during the study. It can be difficult to explain the difference between pseudonymisation and anonymisation, but it is not accurate to tell participants that their images and data will be 'completely anonymised' if this is not the case. It is best if consent specifically includes procedures such as sharing and hosting of images and data. Future proofing consent for research use beyond the original trial including archiving and sharing of images requires careful consideration of transparent wording and whether and how to include potential future follow-up, AI-based research and commercial research as explicit separate consent.

A defined process for destroying or deleting both images and image-derived data is recommended for participants withdrawing consent for data storage, with appropriate processes and documentation that recognise imaging data are often stored separately from other study data. It is helpful to define roles and responsibilities with respect to the destruction process in the protocol or imaging manual. Note that it is not always possible or necessary to destroy data that have already been collected, and that rules around consent may differ depending on context.[14]

Recruitment

Many different factors can affect a potential participant's ability or decision to take part in an imaging study. Some factors adversely affecting recruitment, such as contraindication to the imaging modality, may be unavoidable, but others could potentially be avoided or ameliorated; all should be considered at the planning stage. Gaining additional health information, free imaging, and altruistic benefit to society were found to be key factors that influenced participants' decision to enrol in a CT imaging clinical trial.[15] Possible drug use or contrast injection, possible premedication, and personal availability/time commitment were key factors that influenced patients' decision not to enrol. Ionizing radiation is of great concern to participants;[9,12] therefore, explaining the level of risk is important (see Participant Information). In a brain MRI study, sociodemographic, lifestyle, and clinical characteristics affected completion rates.[15] Claustrophobia occurred in 1.7 % of patients and led to a loss of data in 0.8 % of cases. Whilst procedures could be designed to minimise the potential for claustrophobia, and teams could give consideration to whether, for example, contrast was strictly necessary to meet study objectives, it will not always be possible to fully eliminate such concerns.

Example A: Real-world challenges in ethics, recruitment, and trial conduct

For this example, we consider a multicentre trial of a new pharmacological treatment for inflammatory arthritis where inflammation and damage in several different joints were measured using validated semi-quantitative scoring systems to assess features visible on ultrasound, MRI and radiographs. These imaging-derived scores formed secondary trial outcomes. (This example is a synthesis of real-world issues arising from different trials with this design that the authors have worked on.)

For examples relating to trial and site set-up & training please refer to Example B.

Ethics, participant information & consent

Consider the following sentence taken from the Participant Information Sheet:

'An ultrasound examination of the joints and tendons will be performed at some visits. This will last approximately 45 min'

This could have been improved with more specific information:

'An ultrasound examination of your joints will be performed at the start of treatment and at 12 & 24 weeks afterwards. This will be performed by a trained professional called a sonographer. This will last approximately 45 min. During the scan, the sonographer will place a probe on the skin over your shoulders, elbows, wrists, hands, knees, ankles and feet. They will gently press the probe down to measure how much inflammation they can see in your joints, and will record scores on a paper sheet that only identifies you by your assigned trial ID number. No images from this ultrasound scan will be stored.'

Recruitment

The trial struggled to recruit to target; more than one third of those who failed screening were ineligible for MRI, many due to allergies to contrast materials. Contrast-enhanced measurements were not a key element; making these optional would have improved recruitment rates.

Trial or study conduct

The entire ultrasonography team changed during the course of the trial. Although the new team underwent a calibration exercise against an expert reader, there was considerable heterogeneity of scoring within the same participants over time, likely due to the change in staff. Regular monitoring of the ultrasound scores during the trial could have picked this up earlier. However, because the clinical staff tasked with monitoring the data quality for the trial needed to remain blind to imaging, the ultrasound data were not reviewed until after the trial had ended. In this case, arrangements could have been made for regular independent data quality assessments during the follow-up period.

Communication between clinical teams

Recruitment into imaging studies is challenging, as communication with participants (identification, consent, imaging and treatment) is split between different clinical teams who need to work closely together.

Often, the team leading the research won't be the first point of contact with participants, and so trialists may need to identify patients from other clinic lists or through primary care health provider lists.[4]

Engagement with local radiology departments is important to ensure clinical scanners have sufficient resources, capacity and capability to participate in the study e.g., reserved scan slots, radiographer time, and radiologists with the relevant speciality,[16] as specialist scans may require imaging at a different hospital and specialist staff who are trained to perform the imaging. Efficient scheduling and combining imaging visits with other clinic visits where possible may help relieve the burden on sites and participants and improve capacity for research imaging.

Another area where communication is important is around radiation exposure; referrers must inform radiology that the participant is part of a trial and supply relevant clinical information to allow the correct dose to be administered, and dose over time to be audited, where appropriate.

Reducing barriers for participants

Improving the accessibility of imaging can positively affect recruitment and representativeness of participants in imaging studies; this requires clear understanding of the potential difficulties for participants so that accommodations can be made, where possible. PPIE is critical to help anticipate and understand patient needs.[9,12,15]

Participant health, age, and mobility can affect the accessibility of research imaging, especially if there are multiple scans per clinic visit. Some people have extra caring responsibilities and/or work commitments, reducing the time they have available to attend scans; allowing out-of-hours scanning may increase the accessibility for many participants. Remuneration can help participants with travel and care costs and gives a tangible demonstration of appreciation for participation in research imaging.[17]

Reducing barriers (see Table 3) can enable participation from under-represented groups thus increasing fairness, representativeness and generalisability of a study, and can inform ongoing clinical practice whilst recognising limitations of trial and health service contexts.

Example A presents a real-world issue affecting recruitment.

Trial and site set-up

Research scan acquisition and analysis protocols are often more complex than those used in clinical practice and can be difficult for sites to implement, particularly when investigating a novel imaging modality or technique.[18,19] It is important to identify which key members of the research team will handle imaging aspects and to establish clear responsibilities and scope of work.

Site selection and accreditation

Not all sites will conduct imaging similarly, so we recommend running feasibility site surveys to understand local settings, site equipment including vendor, software and imaging capability, how sites will be able to implement trial procedures, and whether appropriate site and operator licenses are in place.[20–22] There may

Table 2
Domains, subdomains and items to consider for design and conduct of prospective imaging trials.

PROVIDENT PART I	
Subdomain	**Items to consider**
Ethics, participant information & consent	
Ethics	Explaining the purpose, risks and uncertainties of imaging; communicating potential future out-of-scope use of images or data; careful wording in participant-facing documents around diagnoses; potential for imaging eligibility and processes to affect fairness & representativeness.
Participant information	Provision of adequate information regarding imaging to participants, including: Sufficient detail around what will happen during imaging visits; why the imaging is being performed; the potential risks; the potential benefits; what will happen to images and derived data.
Consent	Transparency around levels of de-identification and image/data storage locations; consent to archive/share images and data; processes and responsibilities regarding withdrawal of consent for storage of images and derived data; consent for future use, follow-up, AI applications, commercial access.
Recruitment	
Communication between clinical teams	Recruitment can be challenging as participant contact and trial processes can be split between clinical and imaging teams; effective communication and co-ordination is key, particularly with local radiology departments to ensure efficient scheduling.
Reducing barriers for participants	PPI involvement is essential to help anticipate and understand patient needs. Measures to improve accessibility and attractiveness of research include: Providing adequate information; reducing clinic visits, limiting scan durations, offering flexible scanning schedules, remuneration, consideration of mobility issues, caring responsibilities and work commitments, continuity of care.
Trial and site set-up	
Site selection and accreditation	Run feasibility site surveys to understand local settings; establish what imaging equipment they have and their capabilities, and how they will be able to implement trial procedures. How to ascertain whether sites meet a certain threshold of knowledge.
Establishing the right team	Identify key imaging personnel for your study and document in a delegation log, defining responsible personnel for each element.
Site initiation	Engage site imaging personnel involved and summarise key trial documents, including imaging manual and data flow. In addition to QA/QC processes to set-up/approve a site, test locally all stages of acquisition, processing and transferring of images and imaging data.
Training	
Clinical staff	Any specialist training for the clinical staff is required e.g., annual MR safety training and MR knowledge to answer patient questions.
Imaging technology	Training re imaging technology (e.g. how to acquire new scanning sequences). Consider training encompassing different responsibilities of the site team.
Safety	Research team members may require imaging-modality-specific safety training, both for their own safety and participants' safety.
Image interpretation	Training required for scoring, analysing or reporting of images for the trial and whether standard/certified training is available or an ad-hoc training for the trial needs to be devised.
Data capture	Training on (electronic) data capture systems or CRFs that capture imaging data (e.g. clear guidance to readers/scorers on how to complete scoring sheets, conventions (i.e. 0 if none, avoid blank data fields).
Readers	How to train/qualify new readers during study i.e. whether baseline treatment is enough or whether training should be targeted to achieve good agreement with ongoing readers, and consider inter-reader reliability.
Trial or study conduct	
Engagement	Establish clear responsibilities for trial imaging components, linked to specific team members. Ensure communication in advance any changes to imaging and data acquisition to key team members, including statisticians.
Monitoring processes	Anticipate problems early by site visits and monitoring of imaging protocol compliance. Build into protocol and establish ongoing real-time transfer of scans into imaging repository during recruitment. Consider plan to ensure timeliness of trial reporting, if the trial radiologists are not available.
Monitoring data	Imaging data should be subject to the same level of scrutiny as clinical data. Off-protocol imaging and its impact on patient management. Compatibility with existing data when changes to scanning and imaging acquisition processes are made.
Safety	Which adverse events are to be deemed relevant to the trial; whether adverse event rates can be affected by participant information about possible diagnoses; procedures to allow images and/or derived data for specific participants to be released to and reviewed by the clinical team early, either due to incidental findings or participant emergency care needs.
PROVIDENT PART II	
Subdomain	**Items to consider**
Imaging acquisition & processing	
Availability of scanners and staff	Whether there is sufficient site capacity to accommodate additional research scans. The potential for decommissioning of specific equipment, technology or software; the need to document reproducibility with each change or update.
Scanner calibration, imaging protocols and manuals	Sources of variability that could impact the variability of acquired images, between or within study participants; the need to standardise image flow process across all sites; the degree to which imaging acquisition protocol should be prespecified.
Procedures for de-identifying images	Standards and procedures may differ across centres; different sites may treat metadata differently and leave behind identifiers or strip out important clinical information; difference between anonymisation and pseudonymisation; testing processes in advance avoids delays and risks to confidentiality; principal investigator oversight is key to ensuring these procedures are adequately resourced.

(*continued on next page*)

Table 2 (*continued*)

PROVIDENT PART II	
Subdomain	**Items to consider**
QA/QC	
QA/QC program	Consider if a QA program should be in place throughout the study and how often image QC checks should be performed and reviewed centrally. At each site, consider QA checks to identify potential artifacts and the requirements for within-site consistency checks. Define a site accreditation process required for sites to start imaging into the study.
Image interpretation and quantification	
Burden	Whether planned scoring/analysis can be completed within trial timelines, including assessment of inter- and/or intra-reader reliability; even automated methods will incur a time burden.
Personnel	Inclusion criteria for image readers; whether trial-specific training is needed; procedures for introducing new readers due to staff turnover.
Interpretation methods and procedures	The number of readers, rules around reliability; adjudication procedures; the number and ordering of reads; subjective elements of quantitative analysis; how final scores will be determined if multiple readers are planned; budget and contracts for scoring/analysis and hosting of scoring platforms.
Responsibility for quality control of images during trial	Who will determine image quality, and which criteria will be used; who specifies rules around participant recall if image quality is poor and has responsibility for recall.
Data flow & storage	
Data flow	Using flow diagrams to illustrate the transfer of images and derived data between departments, institutions, sites and external contractors; need for procedures, protocols, permissions and/or contracts, data protection impact assessments; testing the flow processes in advance; transferring in regular batches rather than at the end of the trial; early engagement with information security teams within clinical and non-clinical institutions.
Data storage	Ensuring adequate capacity, budget, access, security and archiving arrangements for storage of images and derived (meta)data; effective user acceptance testing of electronic or paper case report forms capturing imaging data; compatibility between standard care imaging forms and research protocol; compatibility between clinical and imaging forms and databases; maintenance of blinding of readers and/or clinical staff to imaging data; validation of imaging data to same high standard as clinical data.
HE decision model within prospective clinical trial	
Model costings	Establish focus of commissioner of decision model costing requirements (e.g. national or local costing). Decide cost model for standard imaging i.e. nation-wide or local costing.
	Identify costs for imaging not part of standard of care, including any costs for roll-out of new infrastructure and scanners for imaging.
	Opportunity costs for reconfiguring patient care pathways.
Model outcomes and comparisons	Consider most appropriate HE model outcomes to meet HE claims (e.g. time to diagnosis, number of tests, diagnostic accuracy etc.).
	Consider variation in standard of care pathways between sites, where imaging is compared to standard of care.
Costings for running a trial	
Standard costings	Costing informed by nationally-agreed reference standard costs for standard imaging.
Costs for trial delivery	Costs additional to standard care required to enable trial delivery including: New imaging scanners, sequences and methods; staff and staff training; image acquisition and processing; image interpretation and quantification; and data flow.
Commercialisation	
Access to scanners	Commercial needs including: access to clinical care scanners; manufacturer permissions to install new commercial imaging sequence methods on imaging hardware.
Access to participant images	Commercial use conditions including: Legal agreements, permissions and conditions; image de-identification.
Regulatory needs	Regulatory pathway of new technology and intended markets (e.g. UK, EU, USA) needs to be planned in advance to ensure study design is suitable for regulatory purposes.
	Commercial establishment of: any potential differences between international regulators in requirements for validation of imaging biomarkers; best strategy for comparison to current practice where standard of care varies; extending use by reproducibility studies across different sites/scanners/software; post market surveillance requirements.
Clinical guideline inclusion	Company needs include: up-front clarification of HTA approval requirements to plan evidence acquisition; plan for wider clinical utility of imaging to expand longevity; communication on statistical outcomes to avoid misperception that non-inferiority results are without benefit.
Market positioning, Innovation opportunities	Impact of local health systems including: Separate decision making creating small market place, except for e.g. National screening programmes; different processes to integrate new imaging systems to hospital PAC and electronic patient record systems.
Pathways to NHS adoption	Adoption requires consideration of barriers to clinical uptake including: Mixture of manufacturers and age of equipment within each hospital; cost of set up of new imaging and software into hospitals; difficulties to persuade staff to use novel imaging unless in clinical guidelines, due to workload pressure stifling time for innovation; lack of nationwide platform for sharing images; difficulty of reconfiguring clinical pathways and care.

be differences in information technology (IT) systems and specifications (see Part II: Imaging Acquisition and Processing[6]).

Consider if a site accreditation process (with study-specific training) is required (see Training, Part II: Quality assurance/quality control (QA/QC)[6]).

Establishing the right team

Identify all key members of the research team, establish clear responsibilities and scope of work i.e. who is going to do what. Responsibilities of those in key roles (for example, ionising

Example B: Real-world challenges in site set-up & training

For this example, as an example of good practice, we consider METRIC, a multi-centre prospective cohort diagnostic accuracy study comparing magnetic resonance enterography (MRE) with ultrasonography (US) in newly diagnosed and relapsing Crohn's disease patients (ISRCTN 03982913).[36,37] Trial outcomes included diagnostic accuracy metrics, interobserver variation and diagnostic impact. MRE and US were performed by two blinded independent radiologists.

Trial and site set-up

Participating sites in METRIC needed to meet *a priori* criteria, including: a sufficiently experienced lead radiologist with established inflammatory bowel disease (IBD) practice; experience of performing and interpreting both of the imaging modalities to be used in the trial; access to conventional imaging techniques; willingness to allocate sufficient study specific appointments to allow both MRE and US to be performed within 21 days of recruitment; at least two radiologists/appropriately trained radiographers and a gastroenterologist to be responsible for ensuring adherence; IBD service staff had agreed to support the trial and adhere to trial processes, including imaging acquisition, blinded reporting, quality assurance processes, sharing of imaging data and reports and administrative/ethical requirements.

The imaging protocol was flexible: MRE and US were performed by the usual clinical radiographer or sonographer team at each site, and the MR imaging platform used was decided by the lead site radiologist according to availability and local practice. Therefore, the exact imaging parameters varied but a minimum standard data set was acquired.

Training

Competence and training requirements for the study were pre-specified in the protocol to ensure appropriate expertise in small bowel imaging in the NHS. Radiologists requirements included: To have a declared interest in gastrointestinal radiology, experience of $\geq$20 of each procedure, hold FRCR and, if not consultant, to have undergone $\geq$12 months of sub-speciality gastrointestinal radiological training. Sonographers were eligible to perform US if they had completed training in small bowel US, and perform small bowel US in their usual clinical practice ($\geq$20 examinations). A two-day US training workshop before trial commencement was run to standardise US technique and agree on reporting enteric findings. Furthermore, training on CRF completion was provided by the central trials unit to the recruitment sites to ensure appropriate data collection.

radiation (Medical Exposure) Regulations [IR (ME)R] practitioner, operator and referrer) are particularly important to consider.[23] Identify if formal agreements with a central/imaging lab are needed. A statement of work, which describes tasks, required resources and special requirements in detail, can support the study throughout changes of staff.[24]

Table 3
Considerations to reduce barriers to participation.

Careful planning to reduce participants' barriers should include consideration of:
Covering participant concerns about imaging in patient information sheet
Reducing clinic visits where possible
Offering flexibility of time schedules for imaging and clinic visits
Continuity of staff conducting all of a participant's scans.
Reducing scan times or use of contrast (i.e. contrast injections) where possible
Reducing anxiety e.g. participants bring own music to play in MRI scanner
Planning for additional evaluation of contra-indications for contrast
Ensuring participant-facing imaging staff are trained in cultural sensitivity and awareness
Understanding any cultural or religious practices that may cause participants concern regarding timing of scanning appointments, specific imaging methods and/or pre-requisites for scanning processes such as removal of clothing or metal objects
Community outreach to increase awareness and understanding of different medical imaging techniques and processes

Consider additional support required: imaging network, complex imaging analysis resource (e.g. modelling), imaging staff (physicist, research radiographer), building of phantoms. Check if technical validation for all sites is required; accreditation requirements can be complex.[25] Identify who will complete central review/scoring if needed. Radiologists outside of the study team who report scans should be added to the delegation log.

Site initiation

At the Site Initiation Visit/Launch visit: Engage the relevant site imaging personnel; include imaging components in the training delivered (see Part II: Image interpretation and quantification[6]); summarize key trial documents, including the imaging manual and data flow diagram.

In addition to QA/QC processes to set-up/approve a site, test locally all processes of acquisition, processing and transferring of images and imaging data; clinical and imaging data may be collated and transferred separately so data flows for the study should reflect this.

Remember that most research is conducted in stretched radiology departments, with limited scanner availability, especially if scan appointment is required at short notice, so it is important to understand each site's constraints.

Example B presents the criteria sites had to meet to be included in a multi-centre diagnostic imaging study.

Training

With imaging technologies advancing rapidly, training can reduce recruitment barriers by increasing the number of experienced trialists and their familiarity with study procedures, which may differ from routine clinical practice. Training may be needed at different levels to meet imaging manual procedures: imaging acquisition, image processing (de-identification, cataloguing, uploading onto local and central host platforms), image interpretation, and data capture system.[26,27] Formal, benchmarked training on new machines and standardisation of technologies can lag behind trial needs and the approaches used in initial sonographer training[28] may be insufficient; we would recommend ensuring there is documented evidence of competency in the procedures outlined in the manual for all relevant staff prior to recruitment. There may be an ongoing need for regular modality-specific staff safety training to ensure both researchers' and participants' safety around equipment and during scanning procedures.

Example C: Real-world challenges in trial conduct

STREAMLINE Lung investigated the use of Whole Body MRI (WB-MRI) to identify whether lung cancers had spread (staging for metastasis) beyond the initial tumour site, to enable better and more timely cancer treatment (ISRCTN 50436483).[38,39]

The trial compared the diagnostic staging pathways of WB-MRI (and any additional tests required to make a treatment decision) to the standard NICE guideline pathway (CT plus any additional tests required), with trial outcomes including diagnostic accuracy, time to diagnosis, number of tests, cost of testing and patient experience of different pathways.

Trial conduct: safety

Processes were defined in the protocol to ensure that any important clinical findings from WB-MRI imaging would be available to clinicians for urgent patient management, regardless of usual trial processes. Specific imaging findings likely to trigger immediate release of imaging findings were identified. In addition, a process to make available free text radiologist reports in event of for example a recruited participant presenting to hospital with collapse, where WB-MRI findings could potentially change patient management.

Figure. 1 highlights some considerations around training for imaging studies. Example B shows how one trial ensured participating radiologists and sonographers were sufficiently trained to take part.

Trial or study conduct

Challenges in imaging studies frequently require multidisciplinary planning to optimise image quality and number of evaluable scans, as studies are affected by multiple components such as occasional shortages of positron emission tomography tracers, scanner availability, scanner readiness for research imaging or staff absences, to name a few.[16,29]

Trialists need to proactively plan for changes during the trial, particularly in long-term studies, including changes to staff, equipment, scientific evidence, and standard of care clinical practice.[27] Frequent monitoring of all aspects of the study enables timely adjustment of methods and trial processes. Delays can be reduced by planning real time upload and transfer of scans in the protocol rather than at the end of the trial. Consider the impact on image reporting and timelines if the trained and nominated trial radiologist is not available when reporting is required.

Engagement

It is important to identify all key members of your research team with respect to imaging and establish clear responsibilities and scope of work (see also Trial and site set-up).

When changes in imaging processes and data acquisition are required, these need to be discussed with key research members including statisticians, trial monitors and database managers, so the consequences for conduct, data integrity and statistical design can be considered. Regular research team meetings can facilitate multidisciplinary communication.[30] Changes should be documented appropriately (e.g. changes in delegation logs, protocol, imaging manual or statistical analysis plan).

Monitoring processes

Similarly to clinical aspects of the study, regular monitoring of trial imaging components is needed to enable timely reaction to emerging challenges.[27,31] Imaging trial teams may consider early monitoring and site visits to assess compliance with the imaging protocol and anticipate potential problems. It is important to monitor that timings of imaging acquisition and radiology reports comply with the protocol, and to ensure that radiation dose constraints are not exceeded (where applicable). If scan images are collected centrally, regular scan transfer enables more effective quality checks (see Part II: QA/QC[6]) and completeness than end of trial transfer. Central repositories and platforms such as Extensible Neuroimaging Archive Toolkit (XNAT[32]) may facilitate this.

Monitoring data

Imaging data should be subject to the same level of scrutiny as clinical data and be considered part of the trial master file.[33,34] Reports to governance committees should include imaging data collection monitoring metrics such as imaging acquisition success, image QC and image processing, scoring/measurement progress. These metrics should be regularly discussed within the study team.

Ideally, imaging processing, assessment, data entry, verification and data lock should occur prior to unblinding (where relevant). However, it is sometimes challenging or impossible to blind the site reviewer to treatment assignment due to the referral process: note that this may introduce bias in the image interpretation. Off-protocol imaging and its impact on participant care may need to be considered in outcome definitions and statistical analysis.

When making changes to scanning and image acquisition processes, considering compatibility with existing data may be important as it can affect analysis.

Safety

For some imaging studies, it can be challenging for researchers to identify which adverse events (AEs) are relevant to the trial, for example did a new imaging diagnostic test directly cause the AE, or did it arise as a consequence of downstream management decisions informed by the test?

Providing information to research participants about potential diagnoses is important for transparency but in clinical practice people may not be as well informed, which may increase the rate of reporting of some AEs during the study for a given pathway above what would be seen in practice.

It is possible that imaging may reveal incidental findings in some participants, or that images may prove helpful in guiding the management of participants who experience a medical emergency. It is best if procedures for reviewing images for safety, and communicating images and/or imaging findings in such circumstances, are clearly defined in the protocol, particularly if some of the research team are intended to remain blinded to imaging results during the trial.[10,35] These processes could also be highlighted in a data flow diagram (see Part II: Data Flow & Storage[6]).

Examples A & C present challenges relating to the conduct of real trials.

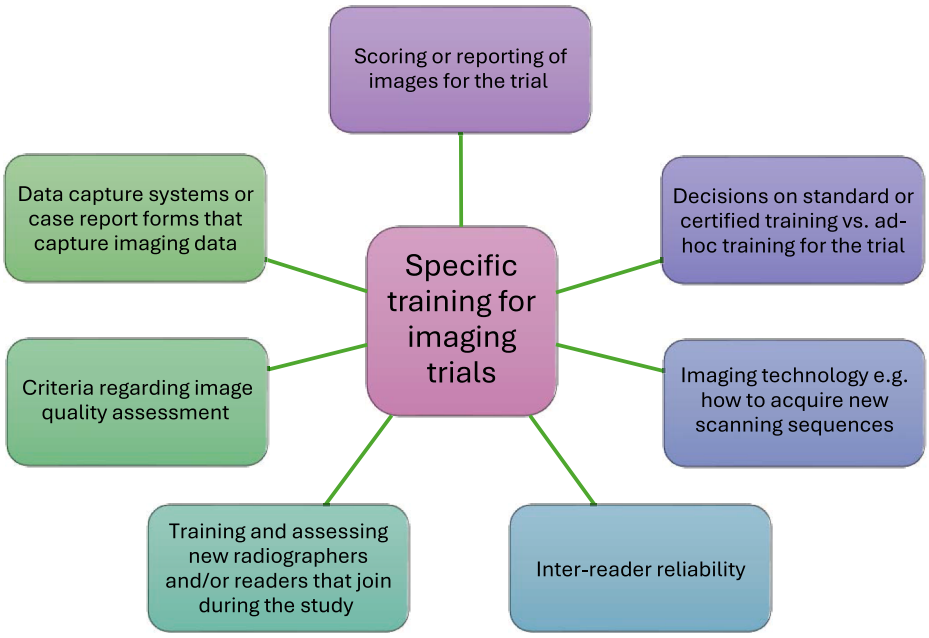

Figure 1. Considerations for training in a prospective imaging trial.

Discussion

We have drawn on a multidisciplinary team to identify challenges in the design and conduct of prospective imaging studies. We present 12 domains with specific examples to demonstrate how these challenges may impact on study success. Our main recommendation is that identifying potential pitfalls at the early stages of imaging study design will enable investigators to avoid problems that can be costly in terms of time, funding and data integrity, and thus improve research quality and efficacy. Although our collective experience is based mostly on studies conducted in UK health systems, we believe the challenges discussed here are transferable to other healthcare systems.

Trials and studies that involve imaging clearly pose different challenges with respect to design and conduct compared to those that do not. The specific operational challenges will depend on the role imaging has in the study.

Imaging can introduce additional concerns and barriers for potential participants and explaining the motivations for conducting imaging, the procedures involved and the potential risks in accessible language and in sufficient depth can be difficult without risking overloading them with information. However, it is important to consider and, where possible, resolve these issues in advance to facilitate recruitment and to promote equity in research. Establishing the right team and integrating the different roles within it, recognising the specialist skills needed to acquire, process, interpret, and manage images and derived data, and providing comprehensive training for key team members regarding imaging-specific processes are all important for study success. Clear communication and delegation of responsibilities will aid smooth running of the trial.

Understanding these specialist challenges means they can be addressed and incorporated in study documents such as the protocol and imaging manual early on to improve trial delivery; considerations should be made as early as the grant application stage.[26] As with any prospective research study, it is important to review the methodological aspects, and trial or study conduct, at regular intervals throughout the study.

This paper provides important considerations to improve the design and conduct of prospective studies including imaging. We hope that this paper and its Part II companion[6] will be most useful to research teams during the planning phase for a new research project. Future work will address challenges in the statistical design and analysis of imaging studies.

Ethics approval and consent to participate

Not applicable.

Availability of data

Not applicable.

Author contributions

KB: Conceptualisation, Methodology, Visualisation, Supervision, Writing- Original Draft preparation, Writing- Reviewing and Editing, Project AdministrationNP: Conceptualisation, Methodology, Visualisation, Supervision, Writing- Original Draft preparation, Writing- Reviewing and Editing.

PC: Methodology, Visualisation, Writing- Reviewing and Editing.

SD: Methodology, Visualisation, Writing- Reviewing and Editing.

AR: Methodology, Visualisation, Writing- Reviewing and Editing.

SM: Conceptualisation, Methodology, Visualisation, Supervision, Writing- Original Draft preparation, Writing- Reviewing and Editing.

TN: Conceptualisation, Methodology, Visualisation, Supervision, Writing- Original Draft preparation, Writing- Reviewing and Editing.

EMAH: Conceptualisation, Methodology, Visualisation, Supervision, Writing- Original Draft preparation, Writing- Reviewing and Editing.

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Conflict of interest statement

None.

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