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| ARTIFICIAL INTELLIGENCE  RADIOLOGY IMAGING  EVALUATION STUDY/ TRIAL  IMPLEMENTATION CHECKLIST  *This document has been collated by the Scottish Radiology Transformation Programme (SRTP) AI Steering Group as a best endeavours approach, based on current experience and available information, to assist NHS Boards in piloting radiology AI solutions, should they wish to use it. The content within this form has not been formally consulted and may be updated, as and when new versions become known, or work is commissioned to provide a more formal approach to AI use within NHSScotland.*  For reasons of audit-compliant clinical and research governance, stringent patient safety, robust project design, and to obtain publishable results/ outcomes, at this stage in NHS Scotland (November 2022), it is recommended that new AI imaging projects i.e. solutions not yet evaluated nor purchasable by any NHS Board, are conceived and delivered as evaluation studies or trials to build the case for the adoption of the AI software as a clinical tool/ medical device.  There are two key phases included in the Radiology AI Evaluation Toolkit, the **Proposal Phase** and the **Project Phase**.  The **Proposal Phase** ensures that once a Radiology need has been identified that the appropriate exploration, scoping and governance approvals are in place before it enters the Project Phase. The **Project Phase** involves the Implementation of the relevant AI solution being trialled into clinical deployment and ensures an appropriate evaluation is completed to ensure results and evidence from the study are appropriately recorded.  This document is available to guide NHS Boards through both of these phases. An overall explanation of the purpose and detail included within the Radiology AI Evaluation Toolkit can be found in Section 3 of the **AI Radiology Imaging Playbook** | | | |
| **Action** | **Notes/Guidance** | **Date Completed** | |
| 1. **Proposal Exploration Phase (Should We?)**   **This is a data gathering step to determine whether the proposal addresses an appropriate clinical problem and if there is both financial and clinical resource to pursue.** | | | |
| 1. Complete section 1-4 of the [AI Project Proposal Form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) and submit to local service management. | Will provide an overview of the project proposal |  | |
| 1. Review national AI radiology [registry](https://www.radiology.scot.nhs.uk/projects/artificial-intelligence/) | Will give insight into other similar AI projects being carried out across the country. |  | |
| 1. Source potential funding (body) for study | Within service/Board, or external e.g. [Our councils – UKRI](https://www.ukri.org/councils/) |  | |
| 1. **Project Scope (Could We?)**   **A more in depth look at the scope, resources and benefits of the proposal** | | | |
| 1. Complete [Verification Template](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Verification-Template-V1.0-1.docx) | This is to determine if the software is designed and developed as per the specified requirements. It will assess historical, external evidence and ensure that the identified algorithm is appropriate and safe for use. |  | |
| 1. Review clinical safety approach and complete documentation | See Specification document here: [**DCB 0160**](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems). Identify and engage with Clinical Safety Lead/Officer to discuss. Documentation requires updating throughout project. |  | |
| 1. Map the current clinical work flow and the proposed workflow involving AI. | This will ensure the entire pathway is considered at the beginning of the project which will aid evaluation and study design. |  | |
| 1. Complete Section 5 of the [AI Project Proposal Form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) | Explain funding source, costs, and assess (clinical and financial) benefits & risks of solution to service, Board and patient. In complement to Study Summary/Brief document |  | |
| 1. **Initial Governance Approval (Can We?)**   **Proposal approval to move to the project phase** | | | |
| 1. Clinical Governance Group/Clinical Director approval | Submit draft Project Proposal and clinical safety documentation. Agree service/clinical lead and service sponsor for proposal. If possible, identify Project Manager from Service e.g. CSM. |  | |
| 1. Imaging Governance Group (clinical + systems management/IT) approval | Submit AI [Project Proposal Form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) + Study Summary/Brief (with lead and sponsor details completed). Assess technical feasibility of solution at this stage e.g. connection, data sharing, integration.  If no CSM (see item 6), if possible, identify Project Manager from Imaging Systems management team). |  | |
| 1. R&D/Innovation Governance Group approval | If research project submit proposal to governing R&D/Innovation team |  | |
| 1. Assess if [Data Protection Impact Assessment](https://www.informationgovernance.scot.nhs.uk/wp-content/uploads/2019/02/IGPACK-Template-for-DOC02b-DPIA-Data-Protection-Impact-Assessment-v201901.docx) (DPIA) is required and complete | To assess patient impact of sharing their data with industrial research partner (potential supplier. Implementation Preparation – Contractual Arrangements”. R&D/Innovation and Information Governance can advise/assist. |  | |
| 1. **Finance**   **(funding bid can be submitted when project approved in principle by service)** | | | |
| 1. Request funding bid costing assistance from R&D/Innovation/R&D Finance Team | To include R&D, Safe Haven, eHealth, clinical/healthcare, imaging staff resource allocation e.g. consultant, nursing, **project manager**, eHealth/IT costs, and other clinical costs associated with study e.g. bloods, tissue, etc. |  | |
| 1. Submit funding bid (internal/external) | Await favourable outcome before can progress. |  | |
| 1. **Project Initiation** | | | |
| 1. Write an Investigator Brochure for solution. | R&D/ Innovation can advise. [See section 7 here](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-clinical-practice-e6r2-4-step-2b_en.pdf). Start with initially drafted [Project Proposal](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) and [Verification Form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Verification-Template-V1.0-1.docx) as a basis. |  | |
| 1. Write a trial/study participant consent form, Participant Information Sheet (PIS), participant letter, GP letter (if appropriate) | If patients or patient identifiable data will be involved. R&D/Innovation can advise.  Useful Links:  [Advice if project research or not](http://www.hra-decisiontools.org.uk/research/)  [NIHR clinical toolkit](https://www.ct-toolkit.ac.uk/routemap/)) |  | |
| 1. Ask for Patient Group input to these elements of the Local Information Pack | Patient Liaison/Experience Team may assist. |  | |
| 1. Write a [Study Protocol](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/) | R&D/Innovation can advise. Base on Study Brief/Summary and Funding Bid submission. To include aims, objectives and method of study, evaluation criteria and data/evidence gathering method. |  | |
| 1. Complete (but don’t submit - yet) [IRAS application](https://www.myresearchproject.org.uk/) form. Extract to PDF when drafted. | Based on Study Protocol. Identify Clinical Safety Officer and other specialists required for study/trial assurance. |  | |
| 1. “Sponsor” review of Study Protocol and IRAS application (R&D) | Sponsor usually = R&D. |  | |
| 1. [Research Ethics Committee](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/) approval  [Impact assessment](https://www.adalovelaceinstitute.org/project/algorithmic-impact-assessment-healthcare/) from the Ada Lovelace Institute provides useful information on impact assessment and accountability | REC approval is required. Submit Study Protocol, Investigator Brochure, Participant Consent Form, PIS, Letters. Include in Protocol, patient group input to information pack. Submit once Sponsor review complete.  **Takes >60 days.** |  | |
| 1. MHRA approval (via IRAS). | Submit IRAS application. Submit once Sponsor Review complete. Synchronised submission with REC submission. REC approval on condition of favourable REC outcome. |  | |
| 1. An IT System Security Risk Assessment/ Risk Triage will be required, and may result in the completion of a System Security Policy document (SSP). | Again, if not done at this point, will be required during “E. Implementation Preparation – Contractual Arrangements”. The eHealth/IT Security Manager can advise. As most solutions are now Cloud-based, this template should be used. |  | |
| 1. Submit [project form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) to the [national registry](https://forms.office.com/Pages/ResponsePage.aspx?Host=Teams&lang=%7Blocale%7D&groupId=%7BgroupId%7D&tid=%7Btid%7D&teamsTheme=%7Btheme%7D&upn=%7Bupn%7D&id=veDvEDCgykuAnLXmdF5Jmm5xZDbLPc1OkZ2QsSnL6AtUNlRKS0Y2VUdNTUZLM1NFN0gxRkFUTkNBMy4u&wdLOR=cB4564A9C-444D-4FC6-8007-CCDF804F196E) | This will inform future projects |  | |
| 1. **Implementation Preparation – Contractual Arrangements** | | | |
| 1. Collaboration Agreement required | R&D/Innovation can advise/ assist. |  | |
| 1. Data Processing Agreement (DPA) required | R&D/Innovation can advise/assist. Base on detail within DPIA. |  | |
| 1. Service Level Agreement (SLA) | If the study/trial involves the AI solution running as a “live” clinical service i.e. replacing the “traditional” service for a period of time within the study, an SLA will be required detailing support and contingency arrangements e.g. hours of operation, contact details, response times, triage and escalation, etc. R&D/Innovation and eHealth/IT can advise/assist in drawing together an SLA. Otherwise, if retrospective or parallel study, not required. |  | |
| 1. **Implementation Preparation – Data Setup** | | | |
| 1. First Meeting with PACS/CRIS/eHealth/ IT team and the Industrial Research Partner. | Architecture overview. Discuss connection testing and integration requirements. Implementation plan; arrange integration meeting; decommissioning/end of study plan. |  | |
| 1. Firewall and VPN Change Request | Place a request to eHealth/IT make changes to the Firewall and, potentially, enable a Virtual Private Network (VPN) connection. To be advised by Industrial Research Partner and eHealth/IT Network Specialists. |  | |
| 1. First PACS/CRIS/AI Solution Integration Requirements Meeting | With Industrial Research Partner, PACS/CRIS/eHealth/ IT team, PACS and CRIS suppliers. Commence specification of integration requirements. Implementation plan. |  | |
| 1. Technical readiness plan | When will the solution be ready to use |  | |
| 1. **Implementation Preparation – Clinical Readiness** | | | |
| 1. First Meeting to discuss incorporating study into clinical service | “As is” clinical service processes vs “To Be” (with AI). Staff and other resources required. Roles, responsibilities and allocation (time; should be costed in funding bid) to study.  Decommissioning/end of study/back to “business as usual” plan. |  | |
| 1. First Meeting to discuss training approach | In person, onsite, “classroom”, video, user guide. |  | |
| 1. First Meeting to confirm support/escalation process | With Industrial Research Partner, eHealth/IT/PACS/ CRIS team, clinical team. Should be as per SLA (see item 23). |  | |
| 1. Ensure video and user guide produced. | Include support/escalation arrangements. |  | |
| 1. Deliver training (onsite, classroom) | Include support/escalation arrangements. Include video and user guide resources. |  | |
| 1. Clinical Readiness Plan | When will the service be ready to commence. Issues, risks. |  | |
| 1. Contact Participant GP/GP letter | As per Information Pack provided to REC. Involve GP/inform in advance as deemed relevant to study design. Inform of start date and that their patient involved, for example. Share PIS and Consent Form (if GP responsibility). |  | |
| 1. Service pre-deployment briefing | Start date, clinical processes/ procedures, evaluation/ validation and data gathering process and requirements (as per **Study Protocol**), support/escalation process, PIS & Consent Form (if service responsibility). |  | |
| 1. Patient Experience & Public Involvement | If new technology, consider patient stakeholder engagement. Each heath board has a dedicated PEPI team who can support this |  | |
| 1. Consider carrying out a [validation](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Validation-Template-V1.0.docx) of the algorithm prior to deployment | This will test the algorithm on local data and provide data on model accuracy, |  | |
| 1. **Clinical Deployment** | | | |
| 1. First Evaluation Study Progress Review Meeting | End of week 1. Review evidence/evaluation data gathering progress. Review service performance impact. Clinical and general issues/risks. Update clinical risk log. |  | |
| 1. **End of Study (as defined in Protocol)** | | | |
| 1. Submission of an ‘End of Trial Declaration’ to the MHRA and REC. | Sponsor (R&D) |  | |
| 1. Archiving of essential documents for at least five years. | Sponsor (R&D) |  | |
| 1. Inform stakeholders that the study has ended. | Include GP and patient bodies |  | |
| 1. Disconnect and remove AI solution and return systems to pre-project state. |  |  | |
| 1. Perform an end of study team debrief | Include lessons learned, draw conclusions and reflect on study design |  | |
| 1. **Evaluation/Write up** | | | |
| 1. Publish results where clinical trial/study registered e.g. clinicaltrials.gov | Sponsor (R&D) | |  |
| 1. Write up an Evaluation Report | Include statistical analysis, technical assessment, qualitative assessment and health economics.  Conclusions and lessons learned | |  |
| 1. Consider journal publication |  | |  |