**Scottish Radiology Transformation Programme****Radiology AI Validation and Evaluation Playbook**  
  
**A focus on Why and How AI solutions should be validated and evaluated in radiology services**

Contents

[Introduction 4](#_Toc129003850)

[About this Resource 4](#_Toc129003851)

[Summary 5](#_Toc129003852)

[Chapter 1: Context 6](#_Toc129003853)

[What is Artificial Intelligence 7](#_Toc129003854)

[AI Lifecycle and Scope of Playbook 8](#_Toc129003855)

[Why AI is important in Health and Care 8](#_Toc129003856)

[Key Drivers for the use of AI in Health and Care 9](#_Toc129003857)

[Supply and Market for AI Solutions 11](#_Toc129003858)

[Key Strategic Links for the use of AI in Scotland 13](#_Toc129003859)

[Chapter 2: The WHY 14](#_Toc129003860)

[Why the use of AI in Radiology is Important 15](#_Toc129003861)

[Key Drivers for the use of AI in Radiology 16](#_Toc129003862)

[Strategic Approach to using AI in Radiology 16](#_Toc129003863)

[Chapter 3: The WHAT 18](#_Toc129003864)

[Strategic Objectives in Radiology AI 19](#_Toc129003865)

[Radiology AI Needs, Priorities and Value 20](#_Toc129003866)

[Typical use cases for AI in Radiology 22](#_Toc129003867)

[Radiology AI Challenges and Mitigations 24](#_Toc129003868)

[Chapter 4: The HOW 26](#_Toc129003869)

[Pre-Requisites for Radiology AI 27](#_Toc129003870)

[AI Legislation and Standards 30](#_Toc129003871)

[Ethics 31](#_Toc129003872)

[Bias, fairness and transparency 32](#_Toc129003873)

[Introduction to the Radiology AI Evaluation Toolkit 38](#_Toc129003874)

[Radiology AI Evaluation Toolkit Contents 39](#_Toc129003875)

[Phases of Conducting an AI Pilot in Radiology 40](#_Toc129003876)

[Stage 1: Radiology Imaging Need Identified 41](#_Toc129003877)

[Stage 2: Exploration Phase 42](#_Toc129003878)

[Stage 3: Scoping Phase 44](#_Toc129003879)

[Stage 4: Governance Approval Phase 46](#_Toc129003880)

[Stage 5: Implementation Preparation Phase 48](#_Toc129003881)

[Stage 6: Clinical Deployment Phase 50](#_Toc129003882)

[Stage 7: Evaluation Phase 51](#_Toc129003883)

# Introduction

About this Resource

Artificial intelligence (AI) refers to the development of computer systems that can perform tasks that typically require human intelligence, such as visual perception, speech recognition, decision-making, and natural language processing. AI systems are designed to simulate human intelligence and can learn from experience and improve their performance over time. AI encompasses a broad range of techniques and approaches, including machine learning, deep learning, natural language processing, computer vision, and robotics.

The purpose of this document is to provide context as to the importance of using Artificial Intelligence (AI) in radiology to transform the service. It also details a recommended process (in the Radiology AI Evaluation Toolkit) for imaging departments within health boards looking to engage in the initiation and evaluation of an AI radiology project in Scotland. This guidance has been developed based on the experience of clinical leads and subject matter experts who are familiar with the use of AI in radiology.

It is important to note that this document does not provide the information required to procure and maintain an AI solution in a live clinical workflow.

This document is intended to provide guidance to health boards and innovation teams on how best to pilot AI radiology imaging solutions with an aim of achieving a more consistent approach to the piloting and deployment of AI solutions into clinical workflows across Scotland. A consistent approach to piloting AI solutions in radiology will enable clinical areas of best value to be demonstrated and support the National Adoption of an AI solution.

The Scottish Radiology Transformation Programme (SRTP) is an ambitious programme of work that aims to transform the way that radiology services are delivered in Scotland. The vision for Radiology in Scotland is:

*“A world class, person-centred, sustainable radiology service that continually improves the health and wellbeing of the people of Scotland”*

The SRTP is supporting this vision through various projects or workstreams, including technology and workforce solutions that enable a distributed model of care and Artificial Intelligence.

The aim of the SRTP AI project is to put in place a structured nationally co-ordinated approach to piloting AI solutions to help ensure maximum benefit and avoid duplication of effort.

This playbook has been collated by the SRTP AI project as a best endeavours approach, based on current experience and available information, to assist health boards in piloting AI solutions in radiology, should they wish to use it. The content and documents within the Playbook and Toolkit have 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 NHS Scotland.

# Summary

This document will aim to answer the Why, the What and the How of using AI in radiology as follows:

* **Part 1 – The WHY?** 
  + explain why AI is important to alleviate demand and capacity issues within radiology departments across Scotland
* **Part 2 – The WHAT?** 
  + detail what AI radiology Imaging solutions are currently being piloted across Scotland
  + highlight the areas of need in radiology that AI can potentially support
  + provide information and assurance to radiology stakeholders on the potential and benefits of AI, ensuring that the potential of AI is not hampered by undue concerns of AI use
* **Part 3 – The HOW?** 
  + detail the process and documentation available in the **Radiology AI Evaluation Toolkit** to assist with deploying and evaluating AI Pilots
* **Part 4 – Recommendations & Next Steps** 
  + Explain intentions, opportunities and next steps for AI in radiology

# Chapter 1: Context



What is Artificial Intelligence

It is important to document what we mean by Artificial Intelligence before defining its use and importance in the radiology service.

Scotland’s AI Strategy defines Artificial Intelligence as:

“Technologies used to allow computers to perform tasks that would otherwise require human intelligence, such as visual perception, speech recognition, and language translation.”

Artificial Intelligence has the potential to make a significant difference to health and care, where there are already a broad range of techniques that can be used to carry out or augment health and care tasks that have previously been completed by humans. For this reason, the playbook intends to focus solely on the use of AI in Radiology. Additionally, Radiology is the area within healthcare with the most AI focus at present.

Artificial intelligence has developed rapidly over the past 20 years transforming how we use technology within our homes, communicate with people and prevent fraud. The use of AI within healthcare is still at a relatively immature stage with early advances allowing more accurate diagnosis and treatment plans, enhancing patient outcomes.

There are several risks associated with introducing AI into any service including:

* **Technological risks (dataset shift – the type of images used to train the data is different from the images encountered in clinical practice. This may be due to difference in disease prevalence, imaging equipment and protocols)**
* **Ethical risks (fairness, trustworthiness, transparency, safety)**
* **Automation bias (clinician overconfidence in AI)**
* **Clinical and Data Governance (including security and privacy)**

AI Lifecycle and Scope of Playbook

A high-level view of the product lifecycle for AI identifies five stages as illustrated in Figure 1. Whilst all areas of the product lifecycle for AI are important, this playbook intends to focus on the **Evaluate** stage as this is currently the most pressing issue that has not yet been defined nationally. It is assumed that guidance will be provided from other areas of NHSS, particularly on the Adopt and Maintain stages.

**Figure 1: The Product Lifecycle for AI**

Why AI is important in Health and Care

Artificial Intelligence has the potential to improve healthcare and will make it possible for many tasks to be automated or assisted, quality to increase and release staff to focus on the more complex processes and interactions that technology will never master.

Across clinicians, data scientists, managers and governments, there is an aspiration that AI will contribute to the transformation of healthcare delivery over the coming years.

To provide context, the following overarching guidance is currently available for the use of AI in the Public Sector/ Healthcare:

* [Office for Artificial Intelligence – A guide to using artificial intelligence in the public sector](https://www.gov.uk/government/publications/understanding-artificial-intelligence/a-guide-to-using-artificial-intelligence-in-the-public-sector)
* [UK National AI Strategy](https://www.gov.uk/government/publications/national-ai-strategy/national-ai-strategy-html-version)
* [Scotland’s AI Strategy](https://www.scotlandaistrategy.com/)
* [Society of Radiographers – Guidance on AI](https://www.sor.org/getmedia/26c8052b-86e7-4900-8057-d0852f9e5094/AI-Guidance-for-clinical-imaging-and-therapeutic-radiography-workforce-professionals_LLv1)
* [Royal College of Radiologists AI Policy](https://www.rcr.ac.uk/press-and-policy/policy-priorities/artificial-intelligence)
* [AI: How to get it right report - NHS Transformation Directorate (england.nhs.uk)](https://transform.england.nhs.uk/ai-lab/explore-all-resources/understand-ai/artificial-intelligence-how-get-it-right/artificial-intelligence-how-to-get-it-right/)
* [NHS Long Term Plan » The NHS Long Term Plan](https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/)

Key Drivers for the use of AI in Health and Care

Key Challenges in Health and Care

NHS Health and Care services are facing significant challenges that have been addressed in the NHS Long Term Plan and the NHS Scotland Recovery Plan. A summary of how these plans are responding to the challenges and how AI can assist are summarised below.

**The NHS Long Term Plan (January 2019)**

|  |  |
| --- | --- |
| **Response to Challenge** | **Can AI assist?** |
| The NHS will increasingly be **more joined up and coordinated in its care** | * Indirectly |
| The NHS will increasingly be **more proactive in the services it provides** | * AI solutions can provide predictive prevention (tailored screening, case finding and early diagnosis) |
| The NHS will increasingly be **more differentiated in its support offer to individuals** | * AI provides tailored prevention via a digital approach to support individuals |

**The NHS Scotland Recovery Plan (August 2021)**

|  |  |
| --- | --- |
| **Response to Challenge** | **Can AI assist?** |
| Innovation and Re-Design | * Centre for Sustainable Delivery (CfSD) priority is to increase diagnostic capacity in which AI plays a central role in helping to address increasing volume and complexity of diagnostic procedures |
| Outpatient and Diagnostic Procedures | * Innovation in diagnostic procedures, for example the use of AI, is required to help address backlogs and alleviate workforce pressures |
| Cancer | * AI can potentially support an optimal pathway for early cancer diagnosis as well as reduce the target waiting times for diagnosis and treatment of cancer |

Key Use Cases for AI in Health and Care

Artificial Intelligence can be used in health and care to:

* apply clinical best practice, eliminate unwarranted variation across the whole pathway of care and between the different regions in Scotland, speed up diagnosis and treatment, and support patients in managing their health and condition.
* use predictive techniques to support local health systems to plan care for populations.
* link and analyse clinical, genomic, and other data to support the development of new treatments to improve the NHS

A summary of the areas of care in which automated tasks could make a difference is presented in Figure 2.

**Figure 2: Use cases for AI in health and care (***as detailed in NHSX Report – Artificial Intelligence: How to get it right - October 2019***)**

This range of potential use cases for AI in health and care highlights the scale of the opportunity presented by AI for the health and care sector.

Supply and Market for AI Solutions

The use of AI in health and care has a large focus on the need for AI to address demand issues, however it is important to understand that the AI industry is building what the NHS needs in terms of supply of AI solutions.

Investors are committed to AI in healthcare

According to a report published in January 2022 by the Market Data Forecast the Global Artificial Intelligence in the healthcare market was valued at **$7.4 billion** in **2021** and is projected to reach **$48.77 billion** in **2027**.

The report explained that one of the main trends in AI in the healthcare market is the increase in the number of new IT companies offering solutions for the medical sector, which in itself is the result of the availability of increased venture capital financing for these companies.

Industry is building AI and regulators are approving it

As of 5th October 2022, there were 521 Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices approved for use in health care by the FDA (U.S Food & Drug Administration) and over 240 CE-marked medical devices in Europe

Diagnostics, and in particular radiology, are well served

Approximately 75% (392 out of 521) of FDA approved AI products are for radiology.

Radiology is well-served to drive forward the use of AI because:

* Radiology data is available in a standardised digital format
* AI is used primarily in image pattern recognition, which for some time has been the mainstay of AI (facial recognition, automated vehicles etc), and Radiology relates to interpretation of images

Key Strategic Links for the use of AI in Scotland

The current AI landscape is cluttered; however, it is important to note key stakeholders who are driving forward the use of AI in Scotland at a national and strategic Level. This playbook has been developed in line with the following national strategies.

# Chapter 2: The WHY



Why the use of AI in Radiology is Important

As the radiology service in Scotland continues to face increasing system pressures, the use of digital technology to enable enhanced working has never been so important. Artificial Intelligence is rapidly being seen as a key area to help alleviate the pressures radiology services are under across Scotland and reduce the gap between demand and capacity for reporting images.

Artificial Intelligence was identified in the Target Operating Model as one of the areas that could help towards making the radiology service more sustainable and address the current workforce and operational challenges being faced by radiology departments across Scotland.

The Royal College of Radiologists (RCR) provided their position statement on Artificial Intelligence in July 2018 which stated that:

AI potentially represents one of the most fundamental changes in medical care since the inception of the NHS, and strongly welcomes the introduction of appropriately regulated and governed uses of AI related technologies to enhance clinical practice.

There are a number of challenges and opportunities that are currently being faced by the radiology service as detailed in the below table.

| Challenges in Radiology without the use of AI | Opportunities of using AI in Radiology |
| --- | --- |
| Predictions of increasing radiology demand | Higher clinical accuracy with greater consistency and coverage (using Clinical Decision Support). Approved AI solutions would contribute to meeting demand. |
| Metrics on backlogs and waiting times for various modalities/aspects of the radiology service | Better turnaround times leading to better patient outcomes |
| Workforce shortages | The use of **technology** to deliver **benefit** to **patient care** and support **workforce pressures** (through workload prioritisation and standardisation of reporting) |
| Clinician burnout | Advancing radiology into things like digital biomarkers, prognosis and prediction rather than old-fashioned diagnostic etc. |
| Variability | AI **focussed on routine, repeatable tasks**, enabling staff to focus on more **complex processes and patient care** (through autonomous reporting and radiomic analysis) |

Key Drivers for the use of AI in Radiology

It is important to note that artificial intelligence is dependent on good quality and standardised national data, which will in turn inform future workforce planning requirements and the impact that artificial intelligence will have on providing a more sustainable radiology service in the future.

Key drivers for the use of artificial intelligence in radiology to help achieve a sustainable and resilient radiology service are:

Strategic Approach to using AI in Radiology

The Radiology Target Operating Model (approved by Health Board Chief Executives in 2021) reiterated the need for an innovative service that continually strives to improve, and benefits from emerging technologies with the following Digital Technology related recommendation:

“Safe and effective use of Artificial Intelligence to enable enhanced working as part of the professional toolkit.”

It is important to note the commitment that the Target Operating Model makes to AI as playing a pivotal role in driving forward service re-design.

Key initiatives for Artificial Intelligence committed to in the Target Operating Model Roadmap include:

1. Assessing the role of artificial intelligence in radiology to develop a nationally agreed approach for radiology services in Scotland.
2. National agreement on the ethical position of artificial intelligence within radiology services.
3. Following the nationally agreed approach, develop, test and implement artificial intelligence within radiology services in Scotland.

This playbook provides guidance on how to validate and evaluate AI within radiology as part of commitment 1 & 3.

# Chapter 3: The WHAT



Strategic Objectives in Radiology AI

The following are strategic objectives for using AI within radiology, any AI related work should align to as many of these objectives as possible.

Radiology AI Needs, Priorities and Value

For an AI project to be successful, it must meet the needs of radiology services at a local, regional and national level. If AI technology is deployed for technology’s sake, users of AI will only evidence that the technology can work, not that it can be used to address wider demand and capacity issues.

Due to the effects of the recent Covid-19 pandemic on the health service there is a greater need now, more than ever, to ensure that innovation projects, for example - AI pilots, are aligned with national strategic priorities to ensure maximum value and efficiency from AI capabilities.

In September 2021, a needs survey was sent out to radiology imaging departments and diagnostic management teams across Scotland to ascertain the biggest backlogs in terms of acquisition and reporting on a local basis.

Participants were also asked if they were aware of any AI opportunities which they thought could be considered address the issues identified. ​

The conclusions from this review are detailed in the table below with expected timelines as to when AI is likely to make a difference to the radiology service by.

0-2 years

3-5 years

5+ years

| **Radiology Need​** | | **AI Intervention** | **How can AI help** |
| --- | --- | --- | --- |
| Computed Tomography (CT) Pulmonary Embolism Detection​ | Analysis of CT scans upon acquisition to assess for pulmonary embolism, ensuring this life-threatening finding isn't sitting unreported in a backlog. | | * Allow faster and more accurate detection of PE to reduce mortality​ * Aid prioritisation of scans and improve workflow​ |
| MSK Plain Film Reporting​ | Provide an analysis of A&E MSK radiographs to A&E clinicians and radiologists reducing error and recall rates and increasing reporter confidence. | | * Quicker interpretation of plain films​ * Create a triage system to improve workflow​ |
| Chest X-Ray prioritisation for Lung Cancer​ | ​Will examine for lung cancer at the point of chest x-ray acquisition allowing the immediate request of a CT scan improving the national optimal lung cancer pathway. | | * Prioritise abnormal chest x-rays for immediate reporting​. * Speed up the lung cancer pathway |
| DEXA Acquisition​ | Interrogates historical CT scans or hip x-rays to calculate BMD as a surrogate of DEXA scan and identify patients at risk of osteoporosis | | * Reduce the DXA backlog by using an AI calculated BMD * Further risk stratifies patients allowing clinicians to prioritise treatment. |
| Thrombectomy Support ​ | Analysis of CT scans to find large vessel intracranial occlusions, aiding clinicians in the decision for thrombectomy. | | * Will support the national thrombectomy service. |
| Breast Screening | AI will perform the second read of the mammogram, supporting the screening service. | | * Workload reduction, easing workforce pressures. * Improved accuracy of breast cancer detection |
| Prostate MRI Reporting​ | Improve standardisation of reports by automatically calculating prostate volume and segmenting the lesion.  This information can be linked to the targeted biopsy software. | | * Reduce inter-observer variability in prostate lesion detection​ and increase reporting time.  Improve the accuracy of MRI image segmentation​ * Improving biopsy accuracy. |
| MRI Acquisition Time​ | Reconstruction of under sampled MRI data reducing acquisition time and improving image resolution | | * Reduction in scanning time and increased throughput of MRI patients. |
| MSK MRI Reporting​ | ​Analysis and pathology detection of MSK MRIs | | * Reduction in reporting time and increase in reporting accuracy. |

These findings demonstrate the range of potential from AI solutions, and the need to evaluate these in a structured and timely way to determine how to turn this potential into consistent contribution to the workload challenges currently experienced in Radiology – hence benefiting patient outcomes.

Typical use cases for AI in Radiology

The following Use Cases have been identified as typical use cases for AI in radiology. The expectation is that an AI product should align to one or more of the below use cases in order to demonstrate value.

Primary use cases of AI within radiology

| **Name** | **Description** | **Examples** | **Benefit to NHS** |
| --- | --- | --- | --- |
| Image analysis | AI algorithm can analyse medical images to detect abnormalities or patterns that are difficult for radiologists to detect. | Mammogram feature detection  CXR analysis | Improve accuracy  Speed up diagnosis  Reduce the need for repeat imaging |
| Clinical Decision Support | The use of artificial intelligence to aid interpreting images by providing automated suggestions, identifying abnormalities and highlighting critical findings | Provide follow up imaging or treatment suggestions  Lung cancer pathway | Increased accuracy  Improved efficiency  Consistency of reports.  Enhanced diagnostic confidence |
| Decision Referral | AI analyses medical images and patient data to provide a recommendation to the radiologist on whether to refer the patient for further imaging or follow-up. | Osteoporosis detection and referral for osteoporosis investigation.  Pulmonary nodule analysis and risk assessment | Standardisation and consistency of referrals.  Better patient outcomes |
| Improve accuracy | AI provides an additional opinion on a set of images, detecting some abnormalities that may be missed by humans | CXR analysis for NG tub placement or skeletal analysis for fracture. | Improve patient outcome and diagnostic certainty |
| Workload optimisation (Triage & Risk) | Analyses images and prioritises urgency based on severity to aid timely reporting | Lung cancer diagnosis.  Large vessel occlusion in stroke | Patients receive timely care. |
| Autonomous reporting (workload reduction) | Artificial intelligence will produce a RIS report without human intervention when the threshold for high confidence normal has been met. | Normal chest x-ray and normal CT brain reporting | Significantly reduce workload.  Improve staff wellbeing |
| Optimized radiology dosing | AI dose optimisation systems reduce radiation without losing diagnostic information | Reduction of CT dose | Specific benefit in paediatric CT. |
| Radiomic classification of disease | Deep image analysis allows characteristics to be analysed that aren’t identifiable by humans | Cancer prognosis in mesothelioma and glioma | Precision medicine  Improved prognostication |
| Big data analysis | Examining [big data](https://www.techtarget.com/searchdatamanagement/definition/big-data) to uncover information. This can predict hospital admissions, worsening of chronic disease and provide real-time monitoring of patients | Intelligent planning and scheduling | Efficient working  Improve population health management and enable more targeted interventions |
| Diagnostic Screening | AI can reliably detect diseases at an early stage. | Breast cancer  COPD | Earlier diagnosis of long terms conditions preventing complications and improving patient outcome\s |
| Image reconstruction |  | Cardiac CT and vessel analysis | Reduce reporting time |

Secondary use cases of AI within radiology Imaging

Education – trainee and clinician support

Using natural language processing for sense checking with right/left errors and typographical mistakes

Radiology AI Challenges and Mitigations

The use of artificial intelligence within health care is relatively new and therefore unknowns and challenges remain. The following challenges have been identified within radiology, specifically when looking to introduce artificial intelligence into the clinical radiology service. However, it is important to note that work is being progressed to navigate each of the challenges presented.

| **AI Challenge** | **Explanation of Challenge** | **Challenge Mitigation** |
| --- | --- | --- |
| Lack of standardised pathways, processes and coding | Requirement for standardised pathways, processes and coding that are not yet available and would be required for national adoption of AI solutions. | The National Data Project within SRTP is progressing the quality of National Data including coding standardisation.  The adoption of a National RIS would accelerate standardised Coding. |
| Lack of national RIS and national AI platform that AI would interact with. | Each AI solution will need to be tailored to individual health board's IT, creating expense and technical difficulty. | NHS Scotland moving towards a National RIS and PACS. |
| Crowded landscape/ duplication of effort. | Risk of local site adoption and evaluation collecting data that has already been evaluated without enhancing total knowledge. | AI Radiology Imaging Playbook and AI Evaluation Toolkit aims to provide a streamlined approach to the evaluation of AI Pilots/ Projects and therefore avoid duplication of effort. |
| Workforce pressures. | Difficult to trial and adopt new technology to transform the radiology Service due to current work pressures. | Education and training can reduce the learning curve and increase uptake. Pilot programs will identify issues before wider adoption. |
| IR(ME)R regulations. | Regulations currently state that artificial intelligence can only be used if a human will interpret the results. AI auto-reporting cannot yet be used in radiology. | Updated IRMER regulations are expected to come into force early 2023. |
| Potential lack of funding for AI solutions to be piloted | Difficult to gather data to create effective business cases. | Streamlined approach to evaluation of AI pilots will allow value of AI pilots to be realised and sufficient evidence to support a business case to demonstrate the value of implementing AI. |
| Lack of good prospective evidence to allow national adoption to be progressed | Most artificial intelligence algorithms have good data on accuracy but lack patient centred and economic outcome data | AI radiology Imaging Playbook and AI Evaluation Toolkit aims to provide a streamlined approach to the evaluation of AI Pilots/ Projects and therefore provide real world evidence that supports national adoption of an AI Solution. |
| Lack of policy, standards, guidance and consistency in all aspects of the radiology AI process. | Without policy, standards and consistency it is difficult to compare and evaluate different AI solutions and ensure they are safe effective and reliable. | Developing standards and guidelines, collaborating with stakeholders, implementing peer review and validation, establishing regulatory oversight, providing education and training, and conducting clinical trials. |
| Absence of a clear architecture and approach to radiology AI. | Without clear architecture different health boards will implement AI independently, leading to issues with national adoption and procurement. | The formation of a clinical advisory group will provide a clear clinical approach to uptake of AI. Procurement of a national platform and infrastructure will aid adoption. |
| Cost of AI products | There is a lack of clear business models to justify AI deployment. There is little health economic evidence to support installation |  |

# Chapter 4: The HOW



Pre-Requisites for Radiology AI

As previously noted, the interest in artificial intelligence technology is increasing which in turn creates a fast paced and ever-changing landscape. Guidance, regulations and frameworks are constantly being reviewed and developed to keep up to date with new AI technology and evidence that AI algorithms present.

In addition to the documentation provided in the Radiology AI Evaluation Toolkit, the following areas displayed in Figure 3 provide a signpost to useful information relating to evaluating and deploying AI pilots/ solutions that are out with the scope of the SRTP AI Project.

It is important to note that these specific set of considerations are relevant as of November 2022 and are subject to change given the developing AI landscape.

**Figure 3: Pre-Requisites for Radiology AI**

Education

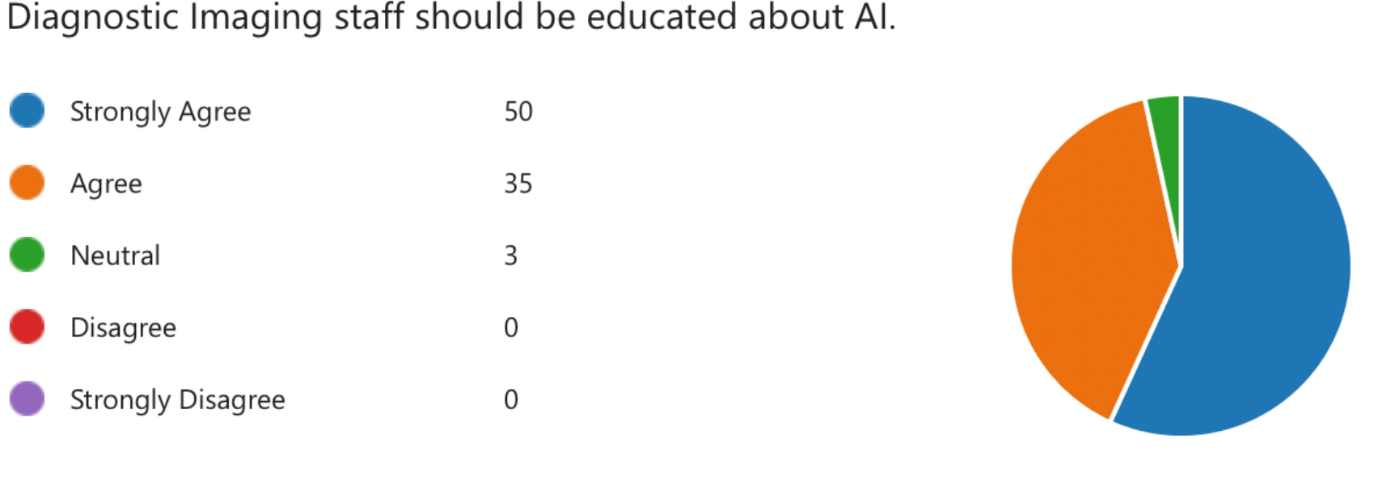
In May 2022 the SRTP AI Project in partnership with NVIDIA hosted an AI Education event. The aim of the event was to cover AI imaging basis and highlight the three main AI projects in radiology.

Over 300 people registered and attended the event.

There was a survey that was completed by 88 attendees to assess the attitudes of the Scottish radiology health care workforce towards the use of AI.

Some important takeaway points from the survey were:

* Radiology trainees do not feel they get appropriate education regarding AI in their training.
* Radiologists think they should be educated more on a number of things mainly the advantages of AI, limitations of AI and how to prepare for the integration of AI.
* 44% of respondents have basic understanding of AI and 36% have intermediate understanding which suggests that more needs to be done to ensure the workforce is prepared for the implementation of AI in radiology.
* Overwhelmingly, respondents felt that diagnostic staff should be educated about AI (Graph 1).
* Respondents also overwhelmingly felt that AI can help radiology (Graph 2).
* Respondents also commented that AI in radiology needs a lot more transparency and it is not simply the workforce that should be educated however also the public.



Education is an important aspect for the use of AI in radiology to be effective and users of AI to be engaged. Education can:

* Demystify AI terminology
* Highlight upcoming use cases
* Reduce uncertainty and fear surrounding AI implementation

Workforce

The SRTP AI Project is supporting the delivery aspects of the National Workforce Strategy in this playbook.

Key action within the Workforce Strategy is to “assess and identify the role of AI in delivering health and social care services to address demand and capacity issues”.

Link to strategy - [Health and social care: national workforce strategy - gov.scot (www.gov.scot)](https://www.gov.scot/publications/national-workforce-strategy-health-social-care/)

Other considerations for workforce are:

* Understand how AI will work within current/ future workforce regulations to assist staff and how this will look.
* Understand work NES are doing in this area
* Understand impact AI might have on staff and roles – advice and involvement – links with Advancing Practice & Workforce Planning.

Patient Involvement

If NHS Scotland is looking to use AI within radiology, we need to be aware that the specific roles of artificial intelligence within the patient pathway should be explained to the patient as part of the informed consent process. These open dialogues will address major sources of uncertainty about AI. SRTP would recommend health boards involving their local Patient Experience and Public Involvement Team (PEPI) to undertake patient/ public engagement sessions. This will ascertain any concerns/ queries ahead of rolling out an AI solution and inform the use of language in patient documents.

Clinical Pathways

Artificial intelligence algorithms will be added into established clinical pathways and act as an adjunct to improve clinical and patient flow. Well delineated pathways of care are a prerequisite to the addition of artificial intelligence and they will provide a basis for examining the effects of AI on the pathway as a whole and not just the accuracy and efficiency of the model.

AI Legislation and Standards

The UK does not currently have any explicit AI Legislation. The [European AI Act](https://artificialintelligenceact.eu/the-act/) is being developed, which will be the first to legislate specifically for AI (sector agnostic), however this will not apply to the UK and has therefore not been considered as part of the Radiology AI Playbook or Toolkit. This is a rapidly changing and complex area.

IR(ME)R Regulations 2017

The Ionising Radiation Medical Exposure Regulations (IR(ME)R) are set at a UK wide level and are enforced on a devolved level. Currently the IR(ME)R regulations state that radiation can only be used if a human will interpret the images, this therefore restricts the use of auto-reporting for AI.   
The IR(ME)R regulations are currently being reviewed and updated regulations are expected to come into force late 2022/ early 2023.

<https://www.cqc.org.uk/guidance-providers/ionising-radiation/ionising-radiation-medical-exposure-regulations-irmer>

Medical device regulation

In the UK, the medical device market is regulated by the [Medicines and Healthcare Products Regulatory Agency (MHRA)](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency). Medical devices must be registered with MHRA and comply with UK MDR 2002 regulations. UKCA or (until December 2024) EU CE certification is required, before they can be placed in the UK market. You can use a medical device in a clinical investigation or clinical trial without this certification.

Broadly, an AI product will require regulatory medical device approval where it is intended to treat, cure, prevent, mitigate or diagnose disease in a human. This is called ‘software as a medical device’.

Software as a medical device is classified based upon the clinical risk (I, IIa, IIb and III); the higher the classification, the higher the risk. Most radiology AI falls into classes I and IIa, with some in class IIb.

The AI vendor (often called the ‘manufacturer’) must state the intended purpose of their product and operate a medical device vigilance system to report problems or risks associated with the use of their device.

You should:

* Ensure that the intended purpose is suitable for your requirements.
* Verify that the AI vendor has the required UKCA or CE mark and that the classification is appropriate for your intended use.
* Ask the vendor to declare the details of any adverse incidents (problems with the use of their product) and ensure the product is suitable and safe for your needs.

The UK is establishing a Multi Agency Advisory Service (MAAS) for developers and adopters of AI in healthcare. When MAAS is available, you should contact the team with any enquiries about AI regulation.

Standards

Whilst not mandatory, AI vendors should comply with ISO13485 (Medical Devices – Quality Management System – Requirements for Regulatory Purposes) and ISO14971 (Medical Devices – Application of Risk Management to Medical Devices). This will provide you with confidence and assurance that the vendor has committed to a rigorous quality and risk management approach.

From a safety risk management perspective, the vendor should comply with DCB-0129 and you (as the healthcare organisation) should comply with DCB-0160.

The new British Standard – BS30440 Validation Framework for the Use of AI within Healthcare – is under public consultation and provides you with useful guidance on evaluating AI.

Standards for AI are constantly and rapidly evolving. More information, including an up-to-date database of AI standards in healthcare, can be found on the [AI Standards Hub](https://aistandardshub.org/).

Ethics

Scotland doesn’t currently have an ethical framework for artificial intelligence that you can apply to the evaluation of AI in radiology. However, guidance is available from across the UK, and governance mechanisms for healthcare data are well-established.

[Scotland’s AI Strategy](https://www.scotlandaistrategy.com/) incorporates some overarching domain-agnostic ethical principles for Scotland’s adoption of AI. In the health and care sector, the long-established [Caldicott Principles](https://www.gov.uk/government/publications/the-caldicott-principles) in combination with [UKGDPR](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/) ensure that patient information is kept confidential and used appropriately.

In a research context, ethical governance is provided by local and regional ethics committees who can be accessed through your local Research, Development and Innovation departments. If you are evaluating AI across multiple health and care entities, then you may use the national [Patient Benefits and Privacy Panel (PBPP)](https://www.informationgovernance.scot.nhs.uk/pbpphsc/) or [Integrated Research Application System (IRAS)](https://www.myresearchproject.org.uk/) processes.

At a national level the guidance for AI is evolving. The Ada Lovelace Algorithmic Impact Assessment is the only healthcare AI ethical assessment tool currently available in the UK. Its primary purpose is to provide a framework for discussing ethics.

The links below provide useful guidance on ethics in data, AI and healthcare.

* [Ada Lovelace Institute – Algorithmic Impact Assessment](https://www.adalovelaceinstitute.org/project/algorithmic-impact-assessment-healthcare/)
* [UK Government – Understanding artificial intelligence ethics and safety](https://www.gov.uk/guidance/understanding-artificial-intelligence-ethics-and-safety)
* [UK Government – Ethics, transparency and accountability framework for automated decision-making](https://www.gov.uk/government/publications/ethics-transparency-and-accountability-framework-for-automated-decision-making)
* [UK Government – Data ethics framework](https://www.gov.uk/government/publications/data-ethics-framework)
* [Alan Turing Institute – Understanding artificial intelligence ethics and safety](https://www.turing.ac.uk/sites/default/files/2019-06/understanding_artificial_intelligence_ethics_and_safety.pdf)
* [Open Data Institute – Ethics canvas](https://theodi.org/article/the-data-ethics-canvas-2021/)
* [NHS Digital – Digital inclusion for health and social care](https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion)

This guidance will be updated to include further details from Scottish Government when available, with the expectation that radiology would adopt the relevant ethical frameworks into their AI evaluation process.

For now, we recommend that you use the Ada Algorithmic Impact Assessment in combination with the existing data and research ethics mechanisms where applicable. You should ensure that ethics are discussed your stakeholders, before you commence an AI pilot.

Bias, fairness and transparency

What is bias?

Bias exists where the outcomes of an AI model for one group within a population are systematically less favourable than for other groups within the same population, without there being a relevant difference between the groups that justifies that difference. Those groups can be patients of a particular gender, race, age or other protected characteristic, for example. They can equally be different radiology scanners, manufacturers, hospitals or even clinical protocols.

Bias exists for a number of reasons, but typically:

* Humans often label or annotate the training data, build the AI models and validate the algorithmic outcomes. Humans tend to be biased, whether intentionally or otherwise.
* The data used to train an AI model isn’t representative of the population, or isn’t balanced to achieve a ‘fair’ outcome for all groups, perhaps because it is incomplete or has been poorly selected
* The AI model was trained on one population, but then deployed in another with different characteristics, or those characteristics change over time (e.g. recalibrating a CT scanner, or updating it with new software that changes the data).

The importance of addressing bias

As a public body, the NHS has a legal duty under the Equality Act 2010 and the Public Sector Equality Duty, to identify and consider the potential impact of its activities, upon equality. It is also required to give due regard to the need to eliminate discrimination, advance equality of opportunity and address health inequality. The [Equality and Human Rights Commission](https://www.equalityhumanrights.com/) has produced a useful [Guide to Artificial Intelligence in Public Services](https://www.equalityhumanrights.com/en/advice-and-guidance/artificial-intelligence-public-services), that further explains the role of equality in AI.

You should use an Equality Impact Assessment to help you identify and consider mitigations against human population bias. Your local equality and diversity team can help, and they should be consulted before evaluating AI in a live clinical setting.

As a clinician and healthcare professional, you have a legal duty of care and candour towards patients and colleagues. You must consider whether the output from an AI product is biased and therefore whether the accuracy, quality or relevance of that result may be compromised.

Ultimately bias, if left unchecked, may cause patient harm.

Managing bias

Scotland’s Future Forum has produced useful advice in Scrutinising the Use of Artificial Intelligence: A Toolkit. This will prompt you to ask the right questions when considering sources of potential bias. The [Algorithmic Transparency Reporting Standard](https://www.gov.uk/government/publications/algorithmic-transparency-template) from the [Centre for Data Ethics and Innovation](https://www.gov.uk/government/organisations/centre-for-data-ethics-and-innovation) may also guide your assessment of the fairness and transparency of both the AI product and your use of AI within clinical care.

You should ask the vendor to:

* Provide a breakdown of the different population sub-groups and volumes within their training data, and their rationale for selecting those subgroups.
* Show you evidence of the performance of their product on different population sub-groups, and on your local (target) population.
* Explain how the AI model works (model ‘explicability’) and which features in the underlying data influence the model outcome (using tools such as SHAP, LIME, saliency maps, etc.) so that you can make your own judgement about bias.
* Describe how they’ve mitigated bias and only proceed with your evaluation if you feel that the residual bias is acceptable.

You should also:

* Understand the intended use of the AI product and how that might apply to your local population, to identify risks of bias or inequality.
* Insist that in addition to generating an outcome, the AI product should generate a ‘confidence level’ or some other measure of quality and confidence, so that you can identify bias and choose whether and how to use the result.
* Require that your vendor is able to detect and report bias automatically within their product, and present up-to-date bias data to you in a useful and informative way.
* During commissioning and product calibration, use data that can uncover potential bias.
* Continuously assess outcomes for safety, performance and bias, and install systems of control to assess the impact of changes (e.g. scanner software upgrade).

Remember that a ‘population’ isn’t just patients. It can include scanners, scanner manufacturers, etc.

Technology & Architecture

When you use AI to deliver a better clinical service for staff and patients, it’s likely that you’ll have to redesign parts of that service to maximise the impact. This is true, even when evaluating a product in advance of procurement and adoption. The [Scottish Approach to Service Design](https://www.gov.scot/publications/the-scottish-approach-to-service-design/) and the [Digital Scotland Service Standard](https://www.gov.scot/publications/digital-scotland-service-standard/) will help you do this in a way that keeps your focus on the user and on patients.

Introducing AI seldom happens in isolation, and you should consider how you can evaluate ‘once for Scotland’. From a digital perspective, it will help if you can proceed in a way that supports [Scotland’s Digital Strategy](https://www.gov.scot/publications/a-changing-nation-how-scotland-will-thrive-in-a-digital-world/) and [Scotland’s Digital Health and Care Strategy](https://www.gov.scot/publications/scotlands-digital-health-care-strategy/).

Although you can deploy AI products individually, it may be more efficient and effective to evaluate and ultimately adopt AI using a platform. The market for AI platforms in radiology is rapidly maturing. They provide access to a wide range of AI products from different vendors, through a single portal that’s integrated once into your clinical systems and your radiology workflow. A platform isn’t always the correct solution, especially for complex clinical pathways or where AI forms only part of the overall product. You should consider the usability, practicality and cost of deployment before choosing your approach.

Cyber security and resilience are paramount. Most AI technologies are deployed in the cloud, and Scotland has a cloud-first adoption strategy for the public sector. AI vendors should host their solutions in the European Economic Area, with ISO27001 and CyberEssentials Plus certifications where possible. You should speak to your local information security advisor who will help you assess security risks using the NHS Scotland Information Security Risk Assessment Tool, and then complete a System Security Policy document if necessary.

It's common for AI evaluation to include some form of health technology assessment, economic assessment or other statistical analysis of effectiveness and value. You may be comparing two or more different vendors and wish to compare outcomes. This is typically delivered by a university or specialist commercial organisation. The data used in this analysis must be deidentified to protect patient confidentiality. You should engage with a [regional safe haven](https://www.nhsresearchscotland.org.uk/research-in-scotland/data/safe-havens), or Scotland’s [national safe haven](https://www.isdscotland.org/Products-and-Services/eDRIS/), to ensure analysis is performed in a secure data environment. Your local research and innovation team can help.

Always speak with your eHealth team before evaluating an AI product. They are best placed to advise on matters relating to technical integration, data, security, resilience, systems capacity, architecture, etc. It’s likely that you’ll turn to them when you have a technical enquiry or problem during an evaluation. They are a finite resource, so it’s important to engage early and ensure they have the capacity and knowledge to support you.

Data flows and volumes are an important consideration when evaluating AI in radiology, particularly where images are travelling to and from a cloud-based product. Consult your eHealth team to ensure the network has sufficient capacity.

You should consider whether you want AI results to be deposited in your main PACS/RIS or in an isolated area during an evaluation, and which image types and SOP classes you want to use for AI results derived from the original image.

The Royal College of Radiologists (RCR) have produced guidance that “sets out standards that a department should meet when integrating AI into already established systems, producing a safe and seamless system with the patients at the centre”.

Recommendations of the Guidance are:

1. Artificial intelligence must be integrated in reporting (radiology information system [RIS] and picture archiving and communication system [PACS]) workflows seamlessly and in a way that does not add extra burden to radiologists.
2. The accuracy of the AI algorithms must be clearly declared for radiologists and others making decisions on patient management.
3. AI findings must be communicated to the RIS via existing, widely used global technical standards (HL7 and/or FHIR).
4. AI findings must be communicated to the PACS using existing, widely used global technical standards (DICOM).
5. The workflow must be robust enough to ensure AI analysis is complete and available on PACS before a human reporter starts image interpretation.

Link to guidance documentation:

[Integrating artificial intelligence with the radiology reporting workflows (RIS and PACS) (rcr.ac.uk)](https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr212_integrating-ai-with-ris-pacs.pdf)

Procurement

Procurement of AI solutions is an area that is out of scope for this Playbook. However, it is important that consideration is given to the procurement process when an AI pilot/ study is being initiated, to understand what procurement requirements may be required once an AI pilot has been completed.

The UK Government has published [guidance on public sector procurement of AI](https://www.gov.uk/government/publications/guidelines-for-ai-procurement), which will help you to consider the question of ‘procurability’ when completing your AI product evaluation.

The National Procurement Team would recommend that anyone looking to undertake an AI Pilot gets in contact with the following national procurement leads to have a discussion about the potential procurement of an AI product should the evaluation study be successful:

| Name | Role | Email |
| --- | --- | --- |
| Paul Hornby | Head of Strategic Sourcing & Commercial, National Procurement | [paul.hornby@nhs.scot](mailto:paul.hornby@nhs.scot) |
| Jim Binnie | IT Procurement  (DPS Contact) | [Jim.Binnie@nhs.scot](mailto:Jim.Binnie@nhs.scot) |
| Adriana Roemmele | R&D Project Procurement Lead | [adriana.roemmele@nhs.scot](mailto:adriana.roemmele@nhs.scot) |
| Kate Henderson | Procurement Programme Manager – National Infrastructure Board | [Kate.Henderson@nhs.scot](mailto:Kate.Henderson@nhs.scot) |

Dynamic Procurement System

The Dynamic Procurement System (DPS) has been set up for Radiology Imaging Software. This was driven predominantly by a requirement to run a mini competition procurement for stroke thrombectomy with Mike Conroy (NHS Tayside) and Paul Armstrong (NHS GGC). The software will need to have EU CE or UKCA marking to be eligible for this.

The DPS has been set for four years and new suppliers can submit a response during the term to get added, unlike a framework where suppliers are fixed for the term. The following documentation is currently available to provide information on:

* Minimum Standards Criteria
* DPS Instructions to Bidders
* A list of the suppliers who are currently on the DPS as of November 2022.



Making the case for adoption

Ultimately, you are evaluating an AI product because you believe it will deliver a benefit to the NHS or to patients. The decision on whether to proceed beyond the evaluation is likely to reside with a number of stakeholders, including those outside of the radiology team. They will compare your evidence against other potential interventions to decide which provides best value for money, so it’s important that your value case provides sufficient information to build a business case for adoption (or otherwise).

The evidence required for an affirmative decision to adopt AI will vary between health boards, and even between departments. It is likely to depend upon the cost, impact and risk of implementation. Scotland has made a [commitment to delivering value-based healthcare](https://www.gov.scot/publications/delivering-value-based-health-care-vision-scotland/pages/1/), so you should consider whether adopting an AI product will meet those aims.

The minimum requirement is typically an [SBAR](https://learn.nes.nhs.scot/3408) but more costly, complex or risky adoptions might require a full business case, the format for which is outlined in the [Scottish Capital Investment Manual](https://www.pcpd.scot.nhs.uk/Capital/scimpilot.htm). The Royal College of Radiologists also provides useful [guidance on developing a business case](https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCR%2812%29_business.pdf). If you are evaluating for a ‘once for Scotland’ solution, then you should engage with the [Accelerated National Innovation Adoption](https://www.nhscfsd.co.uk/our-work/innovation/accelerated-national-innovation-adoption-ania-pathway/) pathway. It provides a mechanism to assess the suitability and readiness of an AI product for national adoption, including the value case.Whatever form your business case takes, it should:

* Specify and quantify, unambiguously, the problem you are trying to solve and why it is a priority for the radiology department, health board and/or Scotland.
* Explain exactly which parts of the problem will be solved by the AI product (preferably, with evidence), and describe any other work that will have to be done to realise the benefit (e.g. digitisation of associated processes, pathway or protocol changes, etc).
* Describe and quantify the benefits, explain to whom they will accrue and how you will prove that they have been delivered. Benefits tend be ‘cashable’ (e.g. they release cash for other purposes) or ‘non-cashable’ (e.g. they improve individual efficiency). Think about the overall cost and quality of care. Remember that you must validate the benefit with the person to whom it will accrue.
* Describe and quantify the costs and resources that you’ll need to fully adopt the product into clinical or operational service, including the timing of costs (recurring versus non-recurring), who you think should pay those costs and whether they have agreed!
* Produce a high-level adoption plan. For a simple business case this needn’t be more than a list of milestones and a short description of the work necessary for each. For a more comprehensive business case this may require a full and detailed work plan.
* Describe any risks, quantify them and suggest mitigations. Pay particular attention to safety risks.
* Explain your assumptions and any work you’ll need to do to validate those assumptions, and any external dependencies.
* Describe alternatives to the AI product (e.g. service optimisation) and what would happen if you did nothing (i.e. didn’t resolve the problem).
* Confirm that you have stakeholder and governance support.

Introduction to the Radiology AI Evaluation Toolkit

One of the key initiatives for artificial intelligence identified in the Radiology Target Operating Model roadmap is:

Following the nationally agreed approach, develop, test and implement artificial intelligence within radiology services in Scotland.

This Radiology AI Evaluation Toolkit provides a suggested process and documentation on how to validate and evaluate AI within radiology as part of this key initiative.

It is important to note that the Radiology AI Evaluation Toolkit **does not** currently provide information or documentation to support the evaluation of an AI solution into a live clinical deployment.

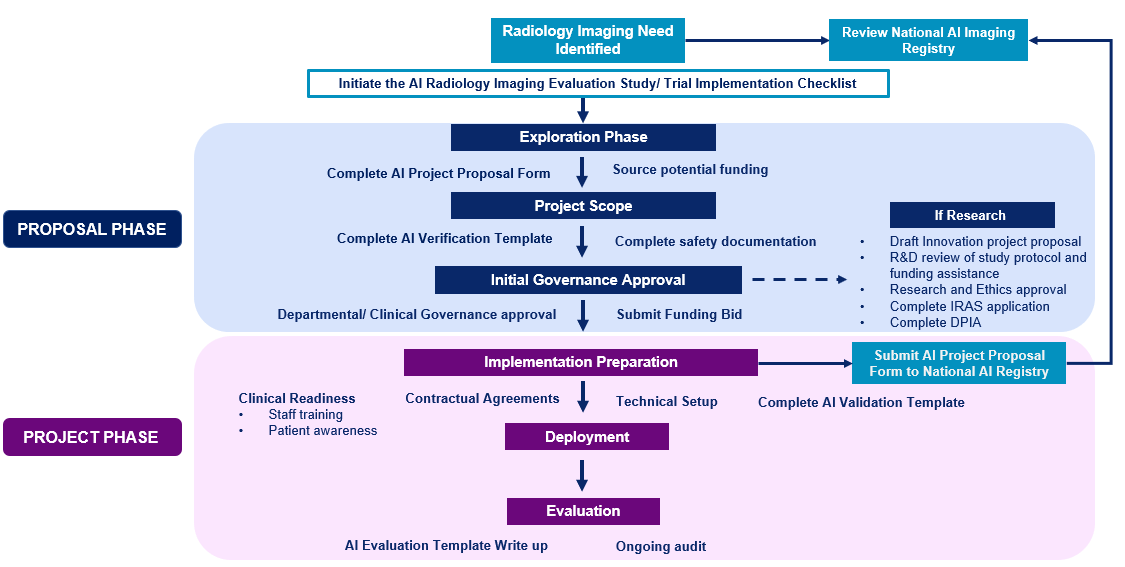
For reasons of audit-compliant clinical and research governance, stringent patient safety, robust project design, and to obtain publishable results/ outcomes, at this stage in NHS Scotland (November 2022), it is recommended that new AI imaging projects i.e. solutions not yet evaluated nor UKCA marked 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.

The Radiology AI Evaluation Toolkit can be found here: [Artificial Intelligence – Scottish Radiology Transformation Programme](https://www.radiology.scot.nhs.uk/projects/artificial-intelligence/)

Radiology AI Evaluation Toolkit Contents

The overarching document that is available to guide users through the toolkit is the **Radiology Imaging Evaluation Study/ Trial Implementation Checklist.**

The process flow detailed in Figure 4 provides a summary of the Radiology AI Evaluation Toolkit contents.



**Figure 4: Summary of Radiology Imaging Evaluation Study/ Trial Implementation Checklist**

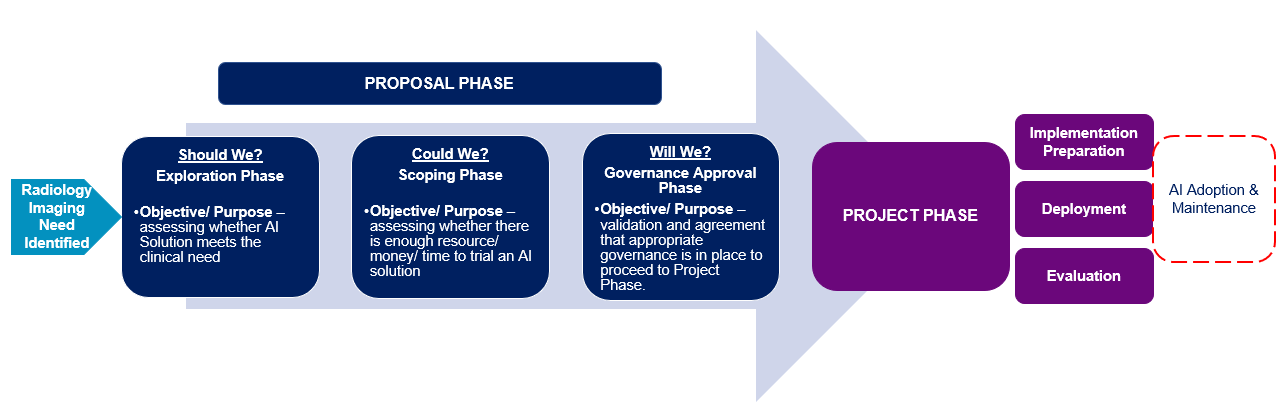
Phases of Conducting an AI Pilot in Radiology

There are two key phases included in the Radiology AI Evaluation Toolkit, the **Proposal Phase** and the **Project Phase** as displayed in Figure 5.

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.

**AI Adoption and Maintenance** is out of scope for this Playbook.



**Figure 5: Phases of Conducting an AI Pilot in Radiology**

Stage 1: Radiology Imaging Need Identified

Purpose

Given the growing number of AI products available it is essential that an appropriate need is identified at the beginning of the process. This will allow a product to be found that fits the need rather than the other way around.

Scope

This initial step is instrumental in having a successful evaluation process. Key stakeholders should be involved early on to describe and elicit the main problems that this AI will address.

High level steps, rational and considerations

1. Key stakeholders input into developing a clear and specific need. The need can be based around any of the clinical uses cases described previously in the playbook ( Pg 22.) It should be designed and reviewed both by clinician and management staff to ensure it encompasses all needs. Ensure sufficient evidence be presented to demonstrate the need for the system, including consideration of existing interventions
2. Review available products to determine if suitable products exist.

Stage checklist

✅ Identify the need(s)

✅ Options appraisal of suitable AI products

Stage 2: Exploration Phase

Purpose

This is a data gathering phase to determine whether the proposal addresses an appropriate clinical problem and if there is both financial and clinical resource to pursue.

Scope

Information required to complete this Phase:

* General information relating to Project (description/ title/ start date/ project lead), estimated project costs.
* Information to support Situation, Background, Assessment and Recommendation Report
* Benefits of the proposed study/ evaluation.
* Confirmation of what eHealth Strategic Aims the Project will deliver.
* Details of AI vendor and product.

High level steps, rational and considerations

High Level Steps to complete this Phase include:

1. The [National AI Registry](https://www.radiology.scot.nhs.uk/projects/artificial-intelligence/) should be consulted to assess if similar projects have been undertaken elsewhere in the country.  If similar project available contact the responsible clinician to use their experience to develop the proposal.
2. 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) will provide an SBAR of the clinical problem, detailing the expected benefits from the solution.  It should be used to provide an initial overview of the proposed AI project for submission to local service management or R&D teams.
3. At this stage there should be basic plan regarding how the proposal will be funded.

Stage checklist

✅ Define the clinical question

✅ Review the National AI Imaging Registry

✅ Complete sections 1 – 4 of the AI Project Proposal Form

✅ Consider funding options (see external links below)

Outputs

* Completed AI Project Proposal Form approved by local clinical lead/management.
* By the end of this Phase the project team will be able to answer the question – Should we proceed to the Scoping Phase?

Links to external guidance

* The [UKRI](https://www.ukri.org/opportunity/) hold opportunities for funding from the Medial Research Council and Innovate UK
* The [NIHR](https://www.nihr.ac.uk/researchers/funding-opportunities/) have pump primer funding opportunities available
* Stage 3 funding through NHS AI lab is currently closed.

Supporting documents from the Toolkit

The [National AI Register](https://www.radiology.scot.nhs.uk/projects/artificial-intelligence/) has been developed by the SRTP AI Project to develop an understanding of the artificial intelligence projects currently underway in radiology services. The register is kept up to date by SRTP AI Clinical Lead - Mark Hall, however the content within the Register is dependent on health boards and innovations teams making the SRTP team aware of what AI Projects they have in progress. Health boards and innovation teams are therefore encouraged to follow the below steps to ensure the SRTP AI Project has an oversight of on-going AI projects within the radiology service and to provide support where required.

The [Project Proposal form](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Project-Proposal-Form-V1.0-1.docx) will provide an SBAR to form as a basis for project design and governance approval

Stage 3: Scoping Phase

Purpose

This phase involves a more in-depth review of the scope, resources, and benefits of the AI proposal.

Scope

Information required for this Phase relating to AI product looking to be trialled including:

* Name of manufacturer
* Method of deployment
* Device certification
* Product standards
* Available evidence of product performance from manufacturer
* Any known evidence gaps that AI project will address

High level steps, rational and considerations

High Level Steps and rational for completing this Phase include:

1. Verification of the proposed AI solution will reduce the risk of project failure.
2. This Phase will assess historical, external evidence and ensure that the identified algorithm is appropriate and safe for use and this document will provide confidence to governance groups that correct process have been followed.
3. In this phase we will further explore funding source and costs.
4. As part of the scoping phase, we begin the process of clinical risk management, a process that will continue for the duration of the project.

Stage checklist

✅ Complete the verification template

✅ Initiate the clinical safety approach and start documentation

✅ Map the current and proposed workflow pathways

✅ Complete section 5 of the AI project proposal form

✅ If appropriate request funding bid costing assistance from innovation or R&D finance team.

Outputs

* AI Verification Template completed; supplier input will be required.
* Current and proposed workflow pathways mapped.
* Complete section 5 of the AI Project Proposal Form.
* By the end of this Phase the project team will be able to answer the question – Could we proceed to the Governance Approval Phase?

Links to external guidance

* [NHS digital](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) - DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems
* Ada Lovelace Institute – [Algorithmic assessment in healthcare.](https://www.adalovelaceinstitute.org/project/algorithmic-impact-assessment-healthcare/)

Supporting documents from the Toolkit

The documentation that is available to support the Scoping Phase is the [AI Verification Template](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Verification-Template-V1.0-1.docx).

The Verification Template should 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. This template should be used in conjunction with Validation template which will check if the algorithm accuracy on local data.

Stage 4: Governance Approval Phase

Purpose

This stage of conducting an AI pilot is the Initial Governance Approval Phase. This involves validation and agreement that appropriate governance is in place to proceed to Project Phase.

Scope

Governance ensures everyone follows appropriate and transparent decision-making processes and that the interests of all stakeholders are protected.  Governance group's sign off will allow progression from proposal to project.    A completed AI Project Proposal Form and AI Verification Template will provide documentation required for appropriate governance approvals.

High level steps, rational and considerations

High Level Steps for completing this Phase include:

1. Governance approval should be sought from appropriate groups.
2. The AI Project Proposal Form combined with the AI Verification Template should provide a basis for presentation to the appropriate governance bodies.
3. Risk management should continue in this phase with a Data Protection Impact Assessment (DPIA).  This will identify, assess and mitigate any actual or potential risks to privacy created by the project, expert advice from local innovation teams should be sought in competing this.

Stage checklist

✅ Governance approval from clinical lead

✅ Imaging governance group approval obtained

✅ R&D/innovation governance group approval obtained

✅ Decision made if DPIA is required

Outputs

* Clinical governance group and imaging governance group approval
* R&D/Innovation governance group approval
* Initiate DPIA

Links to external guidance

* NHS Grampian Innovation Hub - [gram.innovation-hub@nhs.scot](mailto:gram.innovation-hub@nhs.scot)
* West of Scotland Innovation Hub - [innovation@ggc.scot.nhs.uk](mailto:innovation@ggc.scot.nhs.uk)
* South East of Scotland Innovation Hub - [innovations@nhslothian.scot.nhs.uk](mailto:innovations@nhslothian.scot.nhs.uk)
* North of Scotland Innovation Hub - [tay.nospgadmin@nhs.scot](mailto:tay.nospgadmin@nhs.scot)

Stage 5: Implementation Preparation Phase

Purpose

To ensure smooth clinical deployment – key Legal, Technical and Clinical Steps need to be taken in this Phase of an AI Project.

High level steps, rational and considerations

This phase requires multidisciplinary input and needs the assistance of local IT, Security, Innovation and Clinical Experts.

1. R&D/innovation should advise on the contractual arrangements.
2. IT and the AI partner should put together an architecture overview and develop a technical readiness plan.
3. The clinical team should develop standard operating procedures, a clinical readiness plan and conduct patient engagement.
4. Unless the algorithm has been validated on local data, a formal validation is advised prior to clinical deployment.

It is important to note that these processes are complicated and resource heavy and will be greatly improved by the allocation of a project manager.

Stage checklist

✅ Written study protocol

✅ Initiate contact with patient liaison team

✅ Research Ethics Committee approval acquired

✅ Submit documents via IRAS for MHRA approval

✅ Add project to the national registry

✅ Collaboration and service level agreement in place

✅ Technical and clinical readiness plan completed

✅ Validation of the algorithm on local data

Supporting documents from the Toolkit

The documentation that is available to support the Implementation Preparation Phase, if a formal validation is required, is the [AI Validation Template](https://www.radiology.scot.nhs.uk/wp-content/uploads/2022/11/SRTP-AI-Validation-Template-V1.0.docx).

This validation is a process of determining the algorithm accuracy by testing the model with an external, real-world, local testing data set. It will assess model accuracy, safety, and bias reporting.

Actors (people involved)

* Local IT
* Security
* R&D/ Innovation Teams
* Clinical Experts

Stage 6: Clinical Deployment Phase

Purpose

Once the previous phases are complete the AI solution will be ready for clinical deployment.  This may be up to 1 year after the initial project proposal depending on how complex the solution/pre-implementation issues are.

High level steps, rational and considerations

High Level Steps for completing this Phase include:

1. One week into the clinical deployment there should be an initial progress review meeting.  This should focus on the data collection progress, service impact and general issues/risks.
2. As well as quantitative data collection, clinical deployment should afford the opportunity to collect qualitative data, use of the evaluation framework template will provide guidance for this.

Stage checklist

✅ End of week 1 stakeholder review meeting

✅ Review service performance after 4 weeks

✅ Update clinical risk log

Stage 7: Evaluation Phase

Purpose

This is the final stage of the project and involves analysing the actual performance of the AI system within the healthcare setting and resetting the clinical pathway and workflow back to the pre-project state.

High level steps, rational and considerations

1. The evaluation report gives a framework for comparing the actual performance of the AI with expected performance. It will assess the impact of the algorithm by looking at how well it integrates into existing workflows and the expected long-term acceptance by clinicians and patients
2. At the end of the trial/evaluation all stakeholders should be informed that AI systems have been removed and that workflow has returned the pre-implementation state

Stage checklist

✅ Write up evaluation report

✅ Publish results and consider publication

✅ Submission of an end of trial declaration to the MHRA and REC

✅ Disconnect and remove AI systems and return to pre-implementation workflow

✅ Perform an end of study team debrief

Links to external guidance

[Evidence standards framework (ESF) for digital health technologies | Our programmes | What we do | About | NICE](https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies)

Supporting documents from the Toolkit

The documentation that is available to support the Evaluation Phase is the AI Evaluation Template.