**Artificial Intelligence Verification Template**

*Initial Pre-project Verification of Algorithm and Company*

*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.*

This verification is a process of determining 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 the Validation template, which will ensure the algorithm accuracy is tested on local data before clinical deployment.

|  |  |
| --- | --- |
| Project Title  |  |
| Verification Date |  |
| Author |  |
| Name of manufacturer and product(s) |  |
| Website and social media links |  |
| Manufacturer location(s) |  |
| Healthcare problems solved by the product |  |
| Summary of product purpose, target population, target pathways and features |  |
| Is product in use within other NHS sites? If so, which sites? |  |
| On which independent AI platforms or marketplaces is this product available  |  |
| Available method(s) of deploymentOn-premise, off-premise NHS data centre, off-premise non-NHS data centre, edge/hybrid, private cloud, public cloud |  |
| Device certifications and classifications(e.g. CE Class IIb or UK CA) |  |
| List of standards with which the product or company complies(e.g. ISO 13485, ISO 27001, ISO 11073, ISO 14155, IEC 82304-1, BS EN ISO 14971, BS 62366, BS EN 62304) |  |
| Model type(s)Classification, regression, clustering, dimensionality reduction, ranking |  |
| Learning approach(es)Supervised, unsupervised, reinforced, semi-supervised, self-supervised, multi-instance |  |
| Manufacturer reported model performanceConfusion matrix, AUC, ROC, sensitivity, specificity, F1, recall, precision, PPV, NPV, MSE, MAE, etc **as applicable**. |  |
| Summarise evidence available for each of the following product characteristics [(NICE framework)](file:///C%3A%5CUsers%5Challm%5CDocuments%5CAI%5CCatch_up_with_JD_-_AI_Imaging_Playbook__Toolkit_%5C%28https%3A%5Cwww.nice.org.uk%5Ccorporate%5Cecd9%5Cchapter%5Coverview%29)(Indicate whether evidence is from manufacturer, independent or peer-reviewed – and whether retrospective or prospective/real-world):* Clinical effectiveness
* Performance
* Scalability
* Robustness
* Safety
* Security
* Privacy
* Fairness
* Explainability
* Value
* Usability
* Interoperability
 |  |
| Basis and process for ground truth assessment |  |
| Does independent evidence broadly support manufacturer claims? |  |
| Describe evidence of patient, public and practitioner engagement |  |
| Describe evidence of clinical and technical oversight |  |
| Manufacturer Validation Overview* Retrospective validation
* Internal vs External Validation set

Size of data set |  |
| Is the target environment similar to the training, validation and evaluation environments?Population/demography, class balance, thresholds, environmental factors, intended use, clinical pathway, etc |  |
| Describe any evidence gaps that have to be addressed prior to product evaluation and are not being addressed by your project |  |
| Describe any evidence gaps that will be addressed by your project |  |
| Comparison to other similar products and vendors |  |
| Describe any concerns with this manufacturer, product or the associated evidence, that would prevent your project from proceeding. |  |
| Comments |  |
| Recommendation |  |
| Approved by |  |