UKAS
A world of confidence

The use of AI Technologies in Accredited Conformity Assessment

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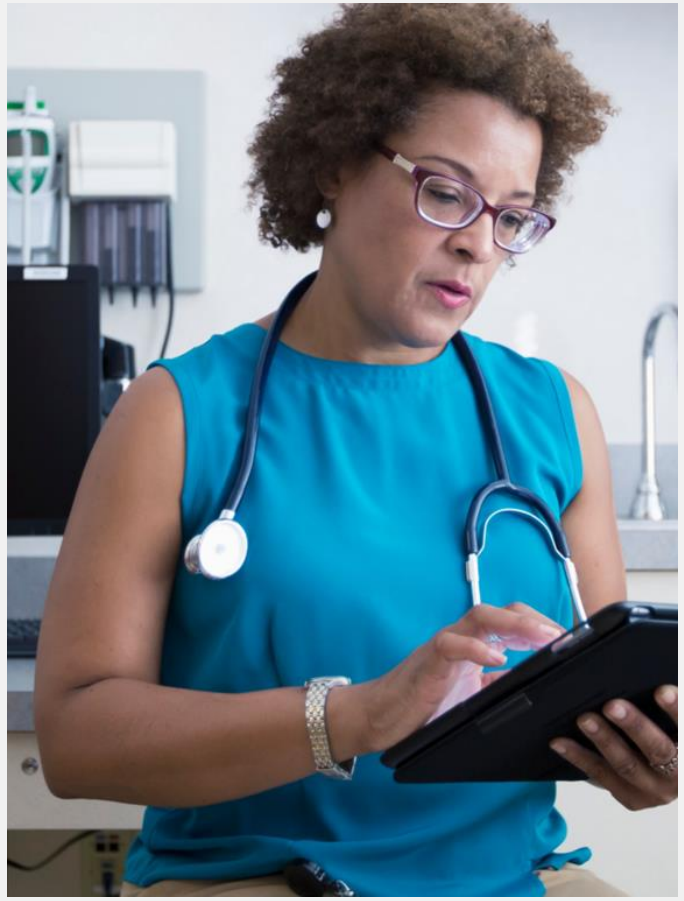
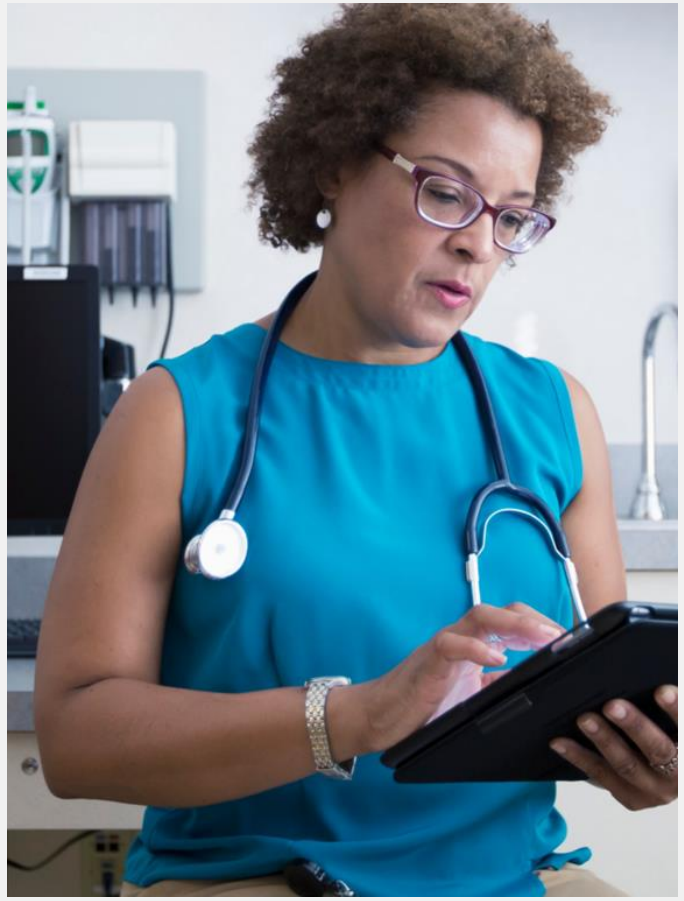
Agenda

- What is AI?
- Applications of AI technology (currently)
- Benefits of using AI
- Considerations applicable to accreditation
- Relevance to ISO 15189:2022
- Other key areas to consider for accreditation



Accreditation

- Accreditation provides independent assurance of the quality and safety of medical laboratory services.
- Accreditation drives confidence in Healthcare by underpinning the quality of results, ensuring their traceability, comparability and validity.
- Accreditation is supported/promoted by NHS Chief Scientific Officers (and equivalents), professional bodies & commissioners:
  - RCPath patient safety and quality strategy 2024-2029
  - NHS Wales Diagnostics recovery and transformation strategy
  - National strategic guidance for at Point of Need Testing – ALM, IBMS, RCPath
  - NHSE Pathology GIRFT Programme National Specialty Report



What do we mean by Artificial Intelligence?

- Algorithms & systems to digitise previously manual processes such as counting numbers of neutrophils in a single microscope field of view
  - Fixed piece of software that may be upgraded to newer versions with updates handled as for any LIMS or software upgrade with verification of changes and impact
  - These are starting to become more widespread

- True machine-learning systems which self-learn and constantly changing
  - Not aware any are currently accredited but is possible in principle, in the same way that assessment of competence is performed and how this is managed

Machine Learning (as an AI Sub-Group)

- For many tasks in Haematology and other disciplines, programming all rules and exceptions would a huge undertaking (e.g. defining rules for automated classification of blood cells)
- To aid this, ML can generate predictive models by learning from observed data without specific instructions
  - Narrow AI/ML performs a single task on an individual dataset with a predefined range and more common currently
  - Strong AI will look at multiple datasets, looking for general solutions to problems using human cognitive abilities in multiple areas
- Supervised Learning has been more common thus far in clinical models, such as labelled observations allowing a function to be learned, with evaluation of performance

Current Medical Laboratory Applications

- Traditional analysis of Cellular Pathology samples is achieved through light microscopy of stained tissue sections and cytology fluids.
- Whole slide imaging (WSI) is an existing technology that allows the digitisation of the whole slide, producing a digital image for review as an output.
- Similarly in Haematology, cell morphology remains a key tool in diagnosis of haematological malignancies such as assessment of peripheral blood (PB) and bone marrow (BM) samples
- Initially limited tasks such as counting of rbc, wbc or identification of lymphoid cell types, although systems can now classify cell types of different lineages and maturation states

Current Medical Laboratory Applications

- Various published studies presenting data around classification of blood cell types and morphological features with high sensitivity & specificity
- For example, differentiate between myelodysplastic syndrome (MDS) and aplastic anaemia using image-based algorithms for PB smears
- Also Flow Cytometry, analysing thousands of cells per second to evaluate large sets of data, able to differentiate between acute myeloid leukaemia (AML) and normal cells
  - Segregate AML patients into sub-groups of survivability
  - Similarly, for MDS to provide transformation probabilities at stages of disease progression

Benefits in medical laboratories

- Improved workflow through the laboratory, enhancing capacity
- Reducing Turn Around Times (TAT), especially those faced by Cellular Pathology departments where significant improvements have been seen and increasing implementation
- Aids decision making and patient management, especially in Haematology settings
- Supports collaborative working and ease of obtaining second opinions which improve the quality of work and mitigates issues such as shortages of resource
- Supports MDT and remote working
- Important to recognise that AI based methods are not there to replace clinicians but to aid decision making and improve workflows
- This is a key element of the NHS 10-year plan
- Certainly are now seeing expansion, with 16 Histopathology laboratories accredited for digital pathology which has doubled over the previous year

Use of AI in accredited conformity assessment

+ UKAS recognizes the value of this technology and has published a set of principles for responsible development, deployment and use of AI, with key principles identified from common themes:

  - Accountability and governance to ensure oversight & clear accountability
  - Bias and fairness to not undermine legal rights, discriminate unfairly & create unjust outcomes
  - Safety, security & robustness, with risks identified, assessed and managed continuously
  - Transparency & explainability, to ensure stakeholders understand decision making
  - Contestability & redress for all parties to challenge AI-driven decisions & outcomes that may cause harm or introduce risks

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- **Accountability and governance**

- Ensure roles and responsibilities for any AI systems are clearly assigned and disseminated, to ensure meeting standard requirements, review of and reporting on performance, ensure oversight and control with consideration of relevant risks
- Provide training and resources for development, deployment and use of AI systems
- Ensure personnel have the required competence to use AI systems, with ongoing monitoring of performance and demonstrate activities are effective
- Having access to relevant technical expertise for advice
- Clearly documented risk-based approach to identify, analyse, evaluate and manage any risks
- Awareness of threats to competence or impartiality and managing these appropriately
- Internal audit and management review to ensure sufficient oversight

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- **Bias and fairness**
- This refers to systematic errors or prejudices that can lead to incorrect outcomes
- Demonstrate that activities are undertaken impartially and take action to respond to risks arising from its implementation as identified, managing these appropriately
- AI systems should be non-discriminatory and not introduce unfair conformity assessment outcomes
- If compensating for bias in one area, care to ensure this does not create a bias elsewhere

- **Safety, security & robustness**
- Ensure confidentiality is maintained as it develops, as an ongoing process with measures in place to take actions when security breaches occur, particularly if developed in-house
- Ensure access to required data & information needed to perform activities, being wary of protection, security against tampering or loss of data, maintain integrity

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- **Transparency and explainability**
- Demonstrate validity of systems via validation/verification and confirm to specified requirements
- Consistently deliver required accuracy and remove from service when outputs are questionable, examining the effect and impact of these
- Ensure procedures are clear around validation requirements, including when changes are made
- Ensure to monitor the validity of outputs with detection of trends (e.g. statistical techniques) with data used to improve systems
- Investigation of any non-conforming work as for other areas
- Ensure publicly available information around use of AI systems, including validation & monitoring
- Addressing any complaints arising from use of AI systems, acknowledging these with complainants (e.g. receipt of complaints, notice of closure)

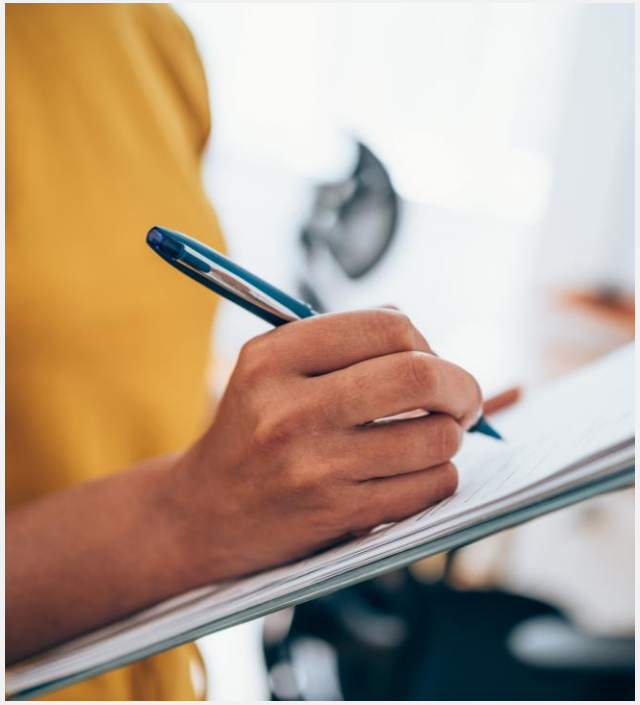
Key clauses of ISO 15189:2022 which apply

- Confidentiality
- Training/Competence and reassessment of competencies of clinicians but also technical staff processing work
- Pre-examination requirements – clear user information
- Examination phase - SOP
- Reporting including failsafe
- Equipment and method validation / verification including consideration of MU
- QA – IQC but also EQA schemes

- Planning & implementation including change control
- Patient requirements - User information including clear information on pre-exam requirements, feedback from users
- Control of records and management of information
- Risk Management
- KPI's in terms of TAT and possible quality / performance indicators
- Service Level Agreement
- Audit of the entire end to end service
- **So basically, the same as any other method**

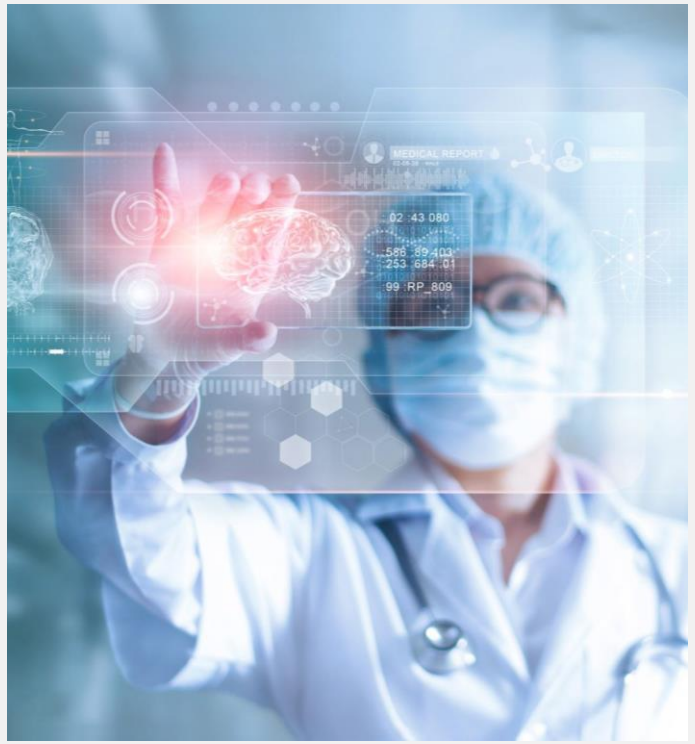
Areas to be aware of when preparing for assessment

- Refer to Best Practice guidelines (e.g. RCPath)
- Provide a detailed plan of implementation and method validation / verification as applicable.
- If more than one type of instrument is used, comparability needs to be demonstrated
- Include verification of remote reporting if this is applicable to process
- IQC & EQA participation is undertaken as is appropriate
- Records are produced, kept and maintained capturing training and validation



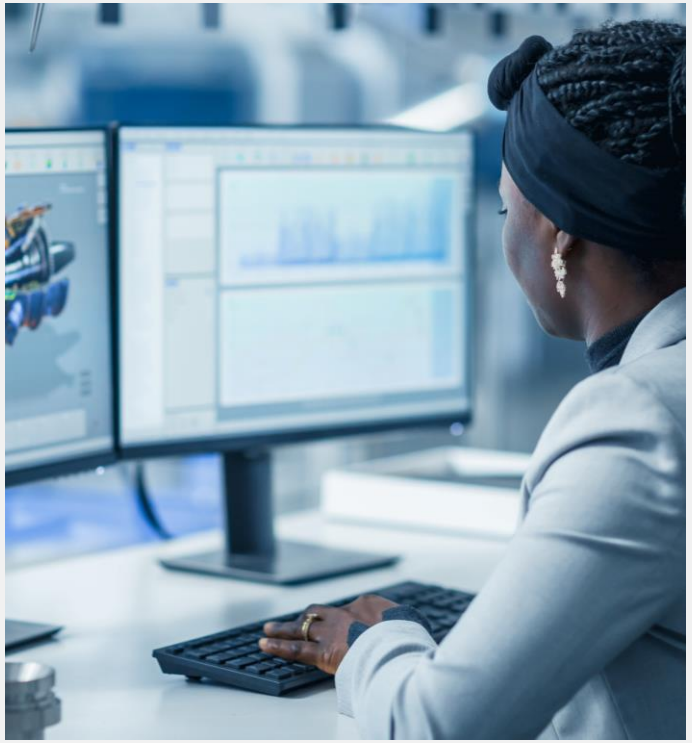
Artificial Intelligence and ISO15189:2022 accreditation

- AI technology in healthcare is assessed as a group of technologies not as a group of staff.
- Although AI technology mimics/simulates human brain neuro networks – It is not the human brain!
- UKAS, in line with the ISO 15189:2022 standard, would assess the technologies in terms of:
  - Is the technology fit for purpose?
  - What is the technology trying to achieve?
  - Is it technically valid?
  - Comparability with non-AI
  - Reproducibility
  - Robust validation data set



Considerations when applying for an Artificial Intelligence ETS

- Robust validation/verification with clinical oversight/input
- EQA participation, not just intention
- End to end IQC
- Detailed SOP
- Evidence of Stakeholder engagement
- Project planning
- Risk Management – crucial for patient safety. Pre-empt 'digital' risks such as image fidelity, algorithm bias and inter-operability problems
- Training and Competence of staff operating the AI technology



The challenge for UKAS and the opportunity for you!

Limited technical assessors who have experience in Digital Pathology and other modalities.


Any
questions?