\National Institute for Health and Care Excellence

Technology Appraisal

Artificial intelligence (AI) technologies to assist histopathology for prostate cancer diagnosis [ID6684]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: The draft remit and proposed process

Section	Number	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route Additional comments on the draft remit	1.	Sectra Imaging IT Solutions	No comment	Thank you for your comment
	2.	Aiforia Technologies Plc	No comments	Thank you for your comment
	3.	Tempus / Paige	We support this evaluation but recommend the adoption of a hierarchy of evidence that prioritizes **prospective, real-world NHS data** over retrospective, in-silico studies. While retrospective data confirms accuracy, only prospective evidence can validate the technology's impact on NHS diagnostic services. We believe it is critical to evaluate technologies based on their demonstrated ability to support services under actual clinical conditions. In this regard, we believe the evidence aiforia	Thank you for your comment. Details of how the appraisal will be approached, with a predefined methodology, will be provided as part of the external assessment groups protocol which will be published on the

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			generated around the Articulate-Pro study and similar studies should outweigh that arising from retrospective, in-silico studies.	NICE website. The planned publication date is 29th April. The NICE approach to evidence is documented in NICE process and Methods guide, Chapter 3 (PMG36, 2022). With further expansion in the University of Sheffield paper on 'Prioritising studies and outcomes for NICE HealthTech literature reviews' (DSU, 2025). Evidence most in line with the decision problem is prioritised. UK, NHS Based evidence is also prioritised to inform our assessments.
	4.	Prostate Cancer UK	Prostate Cancer UK welcomes the evaluation of Artificial Intelligence (AI) technologies to assist histopathology for prostate cancer diagnosis as we believe that there is a huge unmet need in this area given the current backlogs and workforce shortages in pathology. We also believe that the single technology appraisal route is the appropriate evaluation route for this.	Thank you for your comment.
	5.	Mindpeak GmbH	No comment	Thank you for your comment.
	6.	AIRA Matrix Private Limited	AI-based tools in digital pathology, including quality control and analytical algorithms, should be evaluated through a proportionate approach that reflects their role within the clinical workflow. Evaluation should focus on analytical and technical	Thank you for your comment. This appraisal will be focused on the diagnostic tools supporting the

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			performance, robustness across diverse datasets and laboratory conditions, usability, and impact on workflow efficiency and standardization. For non-diagnostic or adjunctive tools, the primary value lies in improving the reliability and consistency of downstream processes rather than directly influencing patient outcomes. Therefore, an appropriate evaluation route may emphasize early value assessment, technical validation, and real-world evidence generation, ensuring safe integration into clinical workflows while supporting scalable adoption.	detection of prostate cancer. We have included some of these considerations in the final scope, including: feature level accuracy in technologies and impact on different parts of the pathway including slide review times time to key milestones, reduced additional testing where available. The 'other considerations' section acknowledges the importance of optimal integration with existing workflows.
	7.	Artera Inc	As described in the NHS 10-year health plan, digital and artificial intelligence (AI) technologies will offer patients significantly more personalised care and are "among the clearest routes to secure the productivity gains that will ensure the NHS's financial sustainability". Therefore, we consider the choice of topic of 'AI for histopathology' to be a highly appropriate priority area. However, as described in more detail below, we are concerned that the remit misunderstands clinical practice in prostate cancer histopathology and imposes an artificial concept of 'histopathology for the diagnosis' of prostate cancer that does not reflect that histopathology cannot be meaningfully separated into 'diagnostic' and 'prognostic' functions, because the same pathological features that establish diagnosis also directly guide risk assessment and treatment selection. This therefore omits UKCA marked AI digital histopathology technologies that can be integrated into the existing histopathology care pathway to enhance the information already provided under standard care, without substantially altering the histopathology workload. This	Thank you for your comment This appraisal is focusing on AI technologies that can address this unmet need in the standard care pathway. Feedback from clinicians indicates that the NHS histopathologist workforce shortage and the impact this is having on histopathology turnaround time is the key unmet need that this assessment should aim to address. In order to keep the appraisal manageable in the time available, the technologies have been limited to those that are similar in intent. Those used for risk profiling would represent a different

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			represents a missed opportunity to positively impact multiple outcomes listed in the draft scope, including: • impact on clinical decision making • overall survival • time to initiate treatment • progression-free survival • adverse effects of treatment, including under- or over-treatment • health-related quality of life • cost of managing cancer, related to missed cancers or overdiagnosis Furthermore, the omitted AI digital histopathology technologies have the potential to: • ameliorate treatment delays, as improved consistency reduces the chance of requiring rework in the pathology department • address both workforce capacity constraints and time to treatment by supporting cases to be prioritised for MDT discussion versus protocolised treatment • enable more consistent and equitable care even under protocolised treatment approaches, given the known real-world variability in applying NICE guidelines for patients with low- and intermediate-risk prostate cancer.1	decision question and therefore if NICE considers these technologies, it is proposed it would be as a separate assessment. NICE recognises that risk profiling technologies for prostate cancer do propose to support shared decision making around treatment plans for prostate cancer, in particular for consistent and equitable decision making for patients. We have shared this value proposition with colleagues at NICE to consider if it would be appropriate to develop and present to the prioritisation board.
	8.	NHS England	NHS England considers the proposed evaluation route appropriate and has no substantive concerns regarding NICE undertaking a Technology Appraisal (TA) for AI technologies supporting histopathology in prostate cancer diagnosis.	Thank you for your comment.

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	9.	Ibex Medical Analytics	No comments	Thank you for your comment.
	10.	The Royal College of Pathologists Expert 1	The evaluation is very appropriate and very timely given the availability of prostate pathology AI technologies, many with regulatory clearance for diagnostic use and some centres starting to use them in clinical practice.	Thank you for your comment.
	11.	The Royal College of Pathologists Expert 2	The topic warrants evaluation	Thank you for your comment.
	12.	Cells IA Technologies. A ROVI Biotech Ltd. Company	We fully support the evaluation of this topic. Prostate cancer diagnosis can be transformed by measured adoption of AI diagnostic support in digital pathology.	Thank you for your comment.

Section	Number	Consultee/ Commentator	Comments [sic]	Action
Additional comments	13.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.

<table>
<tr><td rowspan="5">on the draft remit</td><td>14.</td><td>Aiforia Technologies Plc</td><td>No comments</td><td>Thank you for your comment.</td></tr>
<tr><td>15.</td><td>Tempus / Paige</td><td>The Faster Diagnosis Standard (FDS), which requires an 80% threshold by March 2026, highlights the critical need to evaluate technologies based on their demonstrated ability to shorten waiting times under actual clinical conditions, which Paige Prostate has shown in the Articulate-Pro study.</td><td>Thank you for your comment.

The ‘histological pathway’ section (page 4) includes reference to this 80% threshold as of March 2026.</td></tr>
<tr><td>16.</td><td>Mindpeak GmbH</td><td>We would like to add Mindpeak Prostate H&E in the list of technology for this scoping phase.
P12 in interventions, can you add Mindpeak on the list. Alos please find information for Table 1. Technologies proposed to be in scope:

<table><tr><th>Technology and Company Name</th><th>Indication for Use</th><th>Detection</th><th>Grading and Measurements</th><th>Additional Features (including PNI)</th><th>Infrastructure</th><th>Regulation</th><th>NHS Use</th></tr><tr><td>Mindpeak Prostate H&E Mindpeak</td><td>Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer</td><td>Yes</td><td>Provides automated quantification of tumor patterns and tissue ratios, along with precise measurements of total tissue and tumor lengths.</td><td>• Analyses the entire slide and assigns scores based on Gleason patterns (3, 4, 5).
• Automatically calculates ISUP score.
• Detects cribriform growth patterns.</td><td>Runs as a web service either in the cloud or on a dedicated on-premise server in the laboratory network.</td><td>CE marking not yet available</td><td>Unknown</td></tr></table></td><td>Thank you for your comment and submitting details of proposed regulation for Mindpeak GmbH. In line with NICE methods and process (PMG36, 2022), NICE supports technologies working towards regulation to be included in scope. Details on Mindpeak GmbH have been included to table 1 in the final scope.
If a technology is not appropriately regulated and available to the system before the final draft guidance is due to be published, then they will be removed from the publication.</td></tr>
<tr><td>17.</td><td>NHS England</td><td>No additional comments</td><td>Thank you for your comment.</td></tr>
<tr><td>18.</td><td>Ibex Medical Analytics</td><td>Ibex would like to understand more regarding the following:</td><td>Thank you for your comments.</td></tr>
</table>

			1. **How does the evaluation framework assess different types of AI solutions**, including: (a) Clinical and morphological features identified by the AI (e.g., an AI model that only detects cancer vs. a model that identifies and classifies prostate adenocarcinoma vs. other cancers, Gleason grading, PNI, HG-PIN, Cribriform and additional findings), (b) The accuracy of the AI solution (per clinical findings); (c) Integration capabilities with other systems within the workflow (e.g., LIS, scanners, IMS); (d) Workflow, usability, user-interface features. Are these assessed together as a whole category (e.g., for all AI solutions for breast H&E) or individually per feature/capability/solution? 2. How is **evidence categorised and weighted**, especially when comparing regulatory evidence, real-world data evidence, research-based evaluation, multi-centre evaluations, independent evaluations in clinical settings? Is there specific focus on evidence from NHS labs? 3. **How do you ensure fair comparison** when some solutions present substantially more evidence than others and offer different sets of features or capabilities? Is there any structured comparison process at all, or are solutions evaluated independently? 4. **How are accuracy and performance metrics assessed, and which features are evaluated?** For example: cancer/no cancer detection, or additional subcategories such as Gleason score and tumour length—are these assessed per feature/module? 5. **How do you evaluate different solution features and capabilities**, for example: automation vs manual solutions, workflow-integrated vs standalone tools? How are upfront	Details of how the assessment will be carried out, including consideration of these questions will be in the external assessment groups protocol which will be published on the NICE website. The planned publication date is 29th April. 1. Thank you for highlighting these components which we will consider as part of the assessment approach. We will look to capture all aspects that experts deem is important in understanding technology use and benefits. This will be considered as part of the scoping protocol and assessment using outcomes, real world evidence and implementation report. 2.NICE approach to evidence is documented in NICE process and Methods guide, Chapter 3 (PMG36, 2022). With further expansion in the University of Sheffield paper on 'Prioritising studies and outcomes for NICE HealthTech literature reviews' (DSU, 2025). Evidence most in line with the decision problem is prioritised. UK, NHS Based evidence is prioritised to inform our assessments.

			costs, capabilities, and evidence requirements incorporated into the overall cost-benefit assessment? 6. **What are the key criteria that drive your final decision**, such as clinical effectiveness, safety, cost-effectiveness, usability, and integration feasibility? Is the main focus to decrease costs, e.g., by reducing pathologist review time and unnecessary IHC tests (while maintaining diagnostic accuracy, of course)? Is it to improve the accuracy and consistency of diagnosis? Improve treatment decisions and patient outcomes?	3. Technologies are evaluated independently with evidence to support individual technologies identified and reviewed where available. 4. Please see response to point 1. Feature level accuracy has been added as an outcome to the final scope. 5. Cost approaches will be determined through the assessment informed by the scoping protocol, company evidence submissions and informed by expert advice. 6. Key criteria to inform decision making are stated in Chapter 6 of NICE process and methods PMG36 Outcomes in the scope cover a wide range of these components, including clinical effectiveness, cost effectiveness, slide review times, reduction of additional testing including IHC testing, and patient clinical outcomes including the turnaround times to diagnosis and treatment starting, impact on clinical

				decision making, adverse effects of treatment including under or over treatment and disease-free survival. 'Other considerations' section of the scope includes usability and integration feasibility. It also acknowledges that these technologies 'could help reduce variability across pathology labs and local workforce constraints, improving equity of access to timely diagnosis and management.'
	19.	The Royal College of Pathologists Expert 1	The remit should not only be about AI to 'assist histopathology for the diagnosis of prostate cancer' and the remit should be widened to include novel predictive and prognostic AI. There are AI technologies available that make these novel predictions in prostate biopsies and AI that provides such insights, for example, prediction of outcome, response to therapy or presence of particular molecular changes should be included within the remit and scope. One such example is Artera's Multimodal AI (MMAI) that has FDA and UKCA clearance for diagnostic use. This is in line with the RCPath's 2023 position statement on Digital Pathology and AI which specifies ''The College supports the use of digital pathology and AI to improve patient care. AI is a very powerful technology with the potential to improve pathology diagnosis and / or provide novel prognostic or predictive information.'' Having additional information above and beyond traditional diagnostic parameters has the potential to aid in personalised medicine decisions and help men, for	Thank you for your comment Please see response to comment 7.

			example, make better more informed decisions about whether to undergo surveillance or radical treatment. MMAI has been trained on large datasets and uses image analysis AI and clinical variables to provide a low/intermediate/high score of risk of developing distant metastasis and a risk estimate of developing prostate specific mortality. In addition, if a patient selects radiotherapy, a prediction is made as to the likely benefit (risk reduction) of adjuvant hormonal therapy (Androgen Deprivation Therapy/ADT) in development of distant metastases (biomarker negative or positive). A significant proportion of men receiving adjuvant ADT (estimated to be approximately 2/3), do not benefit and ADT could be potentially omitted from their treatment regime. I believe there are clinical trials eg PACE-B that have more evidence to publish on this topic and could alter guidance on adjuvant ADT in this setting. Prostate Cancer UK have just funded a Transformational Impact Award (£1.9million) to evaluate Artera's MMAI which has received widespread positive media coverage including in the national press. The focus is on making treatment decisions more personalised. The study is called Vanguard Path (Evaluating Novel Guidance Artificial Intelligence (AI) for Clinical Management Decision Support in Prostate Cancer Pathology). It is thus very timely and topical and novel predictive AI should be included in the remit of this technology appraisal. https://prostatecanceruk.org/about-us/news-and-views/2025/11/ai-diagnosis-and-treatment-research	
	20.	The Royal College of Pathologists Expert 2	I am not sure what regulatory approval or in process of achieving regulatory approval means in this context. It should mean at least UK CA or CE IVDR approval. In process of being awarded should not be evaluated as it is impossible to define what this means.	Thank you for your comment. In line with NICE methods and process (PMG36, 2022), technologies which are not yet available but are working towards regulatory approval may be

				included within scope of an assessment. If a technology is not appropriately regulated and available to the system by the consultation on draft guidance, then they will be removed from the publication.

Comment 2: The draft scope

Section	Number	Consultee/ Commentator	Comments [sic]	Action
Background information	21.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.
	22.	Aiforia Technologies Plc	The information is accurate and complete. Yes. From the point of view, the care pathway of Prostate Cancer is correctly described.	Thank you for your comment
	23.	Prostate Cancer UK	Prostate cancer is now the most commonly diagnosed cancer in the UK. Other than this, we believe that the background information in this draft remit is accurate and sufficient, but it could be clearer about the fact that none of these tools are intended for final decision-making without pathologist input.	Thank you for your comment. Background information (Page 1) has been updated to accurately reflect that prostate cancer is the most commonly diagnosed cancer in England (in line with Prostate Cancer UK) An additional statement added to 'The technologies' section (page 5) to clarify 'technologies are intended to support pathologists review and should not be

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				used for final decision making without pathologist oversight.'
	24.	Mindpeak GmbH	yes It's clearly described	Thank you for your comment.
	25.	AIRA Matrix Private Limited	The described care pathway is broadly appropriate and reflects current digital pathology workflows; however, it may benefit from minor refinements to ensure completeness and clarity. In particular, the pathway should explicitly distinguish between pre-analytical (slide scanning, image quality control, and algorithmic analysis), and post-analytical (pathologist review and reporting) stages.	Thank you for your comment. The 'histological pathway' section (page 3) has been updated to separate pre analytical stage and post analytic stage.
	26.	Artera Inc.	In terms of the role of histopathology in the care pathway, the background information correctly identifies core items to be reported on as a minimum when performing histopathology on prostate biopsies. However, although the draft text does acknowledge that grading is used to inform clinical decision making, the overall framing of the role of histopathology is for 'initial diagnosis' of prostate cancer. This is an incomplete description that does not adequately reflect clinical practice. In prostate cancer, histopathology cannot be meaningfully separated into 'diagnostic' and 'prognostic' functions, because the same pathological features that establish diagnosis also directly guide risk assessment and treatment selection. By imposing an artificial division to separate 'diagnostic' histopathology, the scope fails to consider the	Thank you for your comment. Please see response to comment 7

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			clinical implications of the minimum histopathology dataset also including features that provide prognostic/risk stratification information e.g. Gleason grade. Risk stratification is an essential and inseparable part of prostate biopsy histopathology, therefore it is not consistent with current clinical practice to exclude AI digital histopathology technologies that can be integrated into the current workflow to provide risk stratification information. Not only is it unreflective of clinical practice to exclude these technologies, it also represents a missed opportunity to address long-term outcomes for patients, and in particular to reduce overtreatment, which is a key concern in prostate cancer management. There is also an associated opportunity cost of needing to undertake a separate appraisal of these technologies at a later date. Taking a more holistic approach would also be consistent with NICE's general duties to encourage innovation and enhance the efficiency of healthcare services under the Health and Social Care Act 2012 when exercising its functions through the development of Technologies Appraisals. We suggest the following amendments to the draft background: <u>Unmet need</u>	

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			This section references the RCPath position statement on digital pathology and AI but omits their broader view of the potential role of AI in histopathology services: “The College supports the use of digital pathology and AI to improve patient care. AI is a very powerful technology with the potential to improve pathology diagnosis and / or provide novel prognostic or predictive information.” Therefore, we suggest that the unmet need section is updated to reflect the full view of the College as outlined in their position statement. Similarly, the section currently references the GIRFT 2025 summary of diagnostics findings and recommendations which supports innovation in AI for pathology. The GIRFT summary includes a specific focus on decision support tools and AI being developed to aid interpretation, with the recommendation to “embrace innovation in pathology, particularly in AI and improved the unmet need for tools that can aid interpretation, which should be reflected in the scope. This section appropriately highlights the Faster Diagnosis Framework and Standards and how AI innovations may help pathology departments meet these standards. However, the National Cancer Plan for England not only includes the Faster Diagnosis Standard, but also the standard that 85% of patients should start treatment within 62 days of referral.2 Therefore, the potential contribution of AI digital	

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			histopathology tools to expediting treatment decision-making should also be considered part of the unmet need that can be addressed in this appraisal. Finally, this section references the commitment in the NHS long term plan to introducing AI to increase efficient NHS services. The plan specifically references AI use to deliver personalised, precision care and treatment to identify the most effective interventions. AI risk stratification tools in histopathology have the potential to directly address this commitment, therefore we would suggest that this is specifically incorporated into this section. <u>The technologies</u> As described above, the draft scope background imposes an artificial division to separate 'diagnostic' histopathology and therefore inappropriately excludes certain AI digital histopathology technologies that can provide better risk stratification within the current standard care pathway. We suggest the following amendments to the current wording (amendments in bold font): "Technologies typically provide diagnostic overlays, measurements, **quantitative results**, and prompts for histopathologist reviews to improve accuracy and speed up **ancillary test orders and diagnostic** review times.	

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			Uses of the technologies vary driven by differences in technology features and across different pathology laboratory set ups but typically include the detection and quantification of prostate cancer (**e.g. cell counts, a score, biomarker positivity**), including grading (according to Gleason grade), measurement, identification, **and/or analysis** of clinical features (e.g. cribriform patterns), highlighting suspicious areas to assist in prioritising and reviewing the workload, measuring the tumour length and proportion of disease per core and detecting perineural invasion if present. **Histomorphologic feature evaluation to determine recurrent risk may be informative**. In some cases, prompting or ordering additional testing like immunohistochemistry (IHC) may be beneficial. The technologies may offer accurate, efficient and timely results to assist in diagnosing prostate cancer and **inform risk of patient survival to guide treatment decisions,** achieving the Faster Diagnosis Standard 28-day target **and the central cancer performance 62-day target** more consistently. Use of the technologies could also reduce inter- observer variability, **streamline and provide more actionable insights for MDT**, and improve reporting quality standards and consistency across centres, facilitating equitable access across the country.	

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			…Technologies included in the scope analyse digitised whole slide images from prostate needle core biopsies that have been stained with H&E. Technologies included in scope should, in line with **RCP minimum diagnostic datasets (2024):** • **detect prostate cancer** • **AND/OR provide information to inform prognosis and treatment decisions, including: grade the prostate cancer detected, according to Gleason grading; measure tumour length and proportion of tumour per core; generate a diagnostic score; generate a biomarker positive or negative result to guide treatment decisions** • **AND have appropriate regulatory approval or be in the process of obtaining this** • **AND be available to the NHS or be in the process of this.** <u>Treatment</u> As described above, a crucial contribution of the current standard of care histopathology for a patient with suspected prostate cancer is to inform prognosis and treatment decisions. While this is described in brief in the treatment section, it does not capture the full context of treatment decision-making	

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			in prostate cancer. Most patients are diagnosed with localised disease and many of these cancers are indolent, meaning that the potential benefits of treatment must be weighed against the potential significant harms due to treatment side-effects. Precise and, ideally, personalised risk stratification (which is informed by histopathology and can be enhanced using AI tools) is crucial to selecting the optimum management strategy to avoid both over- and undertreatment. As stated in the draft background, early diagnosis does indeed improve outcomes; however, appropriate treatment decision-making also has a major impact on both survival and quality of life. Therefore, we suggest the following amendment (in bold font): “According to NICE Guidelines (NG131), treatment decisions should consider tumour characteristics including type, size, grade, and stage as well as PSA level, Gleason score or Grade Group, and imaging findings to determine the individual's risk category and guide shared decision-making. A multidisciplinary team typically reviews each case to ensure that treatment plans reflect both clinical needs, disease severity and individual circumstances including comorbidities and preferences. Options may include active surveillance, radical prostatectomy, or radiotherapy for localised disease, and hormone therapy or	

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			chemotherapy for more advanced cancer. **Personalised risk stratification, which is informed by histopathology, is crucial to selecting the optimum management strategy to avoid the harms of either over- or undertreatment."** <u>Place of the technologies in the pathway</u> Should the scope be amended to reflect the place for digital AI histopathology tools that assist risk stratification within the diagnostic pathway, this section will need minor amendments accordingly.	
	27.	NHS England	1. The description of the prostate cancer care pathway is broadly accurate but could be strengthened by recognising that poor urinary flow and prostatic symptoms often prompt referral into the diagnostic pathway. 2. The scope states that digital pathology usage is not widespread in the NHS. This statement does not fully reflect the current position. Whilst digital pathology is not yet nationally implemented, adoption is increasing rapidly through the nationally coordinated programme supported by NHS England diagnostics funding. Current adoption data indicates:	Thank you for your comment. 1. The scope has been updated to include acknowledgement that these symptoms may require further consideration 'other symptoms that warrant further assessment include severe or persistent; poor urinary flow and lower urinary tract symptoms such as hesitancy, frequency and nocturia.'

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			• 25 of 27 pathology networks have begun digital reporting • 106 of 132 acute and specialist trusts (approximately 80%) are using digital images for primary diagnosis • 51 trusts are digitally reporting more than 50% of cases Digital pathology capability is therefore expanding quickly across England, which is highly relevant and a prerequisite prior to mobilisation of AI-supported histopathology technologies. Recognition of the ongoing national digital pathology programme would improve the accuracy of the background section.	2. Thank you for this detailed information re digital pathology nationally. This detail has been added to both the 'unmet need' section as well as the 'other considerations' section of the to update this.
	28.	Ibex Medical Analytics	Yes	Thank you for your comment
	29.	The Royal College of Pathologists Expert 2	Appropiate	Thank you for your comment
	30.	Cells IA Technologies. A ROVI Biotech Ltd. Company.	Yes. The care pathway is correctly described as we understand it.	Thank you for your comment
Population	31.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.

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	32.	Aiforia Technologies Plc	Yes	Thank you for your comment
	33.	Prostate Cancer UK	We believe that the population is defined appropriately. However, regarding whether to include patients who have previously been treated for prostate cancer: if the assessment is limited to initial diagnosis, these patients should not be included. This is because certain treatments (e.g. radiation therapy, androgen deprivation therapy [ADT], focal therapy, or chemotherapy) can alter tissue morphology and therefore samples from treated patients would not be representative of the population this technology would be used for. If the case for use is expanded (e.g., to include recurrence or progression), these patients could be included but should be evaluated separately, as diagnostic performance may differ in this population.	Thank you for your comments. Following discussion of the population at the scoping workshop, we heard that people presenting with a recurrence (after being treated and in remission) of prostate cancer may be reviewed by AI technologies for detection. It was confirmed (as stated in the comment) that samples from people previously treated (including chemotherapy, radiotherapy and androgen deprivation therapy) may have altered tissue morphology which could impact on the effectiveness of these technologies on the samples and as a result this population has been defined as a subgroup in the scope.
	34.	Mindpeak GmbH	instead of adults maybe it’s better to write men aged over 18 maybe ?	Thank you for your comment. In line with NICE writing style guide

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				(ECD1, 2016), the term adults is used to describe people over the age of 18.
	35.	AIRA Matrix Private Limited	The defined population is broadly appropriate	Thank you for your comment
	36.	Artera Inc	The population defined in the draft scope does not capture the histopathology requirements for some patients. Although NG131 does not mandate routine repeat biopsies during active surveillance for men with diagnosed low- or intermediate-risk prostate cancer, recent UK evidence indicates that repeat prostate biopsies remain part of real-world NHS practice, typically used selectively in response to PSA or MRI changes, with substantial variation between centres.1 Therefore, these patients will also require access to the technologies described in this draft scope. Here is the suggested change: “Adults with suspected **or confirmed** prostate cancer who have undergone a core needle biopsy.”	Thank you for your comment The final scope has been updated to acknowledge the surveillance groups which undergo repeat PSA level testing and may as a result go on to have prostate needle core biopsies. However The final scope remains focused on the use of AI for the initial detection of prostate cancer and so people with confirmed prostate cancer, under surveillance, would be considered out of scope for this assessment.
	37.	NHS England	No concerns with the proposed population definition.	Thank you for your comment
	38.	Ibex Medical Analytics	Yes	Thank you for your comment

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	39.	The Royal College of Pathologists Expert 2	Yes	Thank you for your comment
	40.	Cells IA Technologies. A ROVI Biotech Ltd. Company	Yes	Thank you for your comment
Sub-groups	41.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.
	42.	Aiforia Technologies Plc	No	Thank you for your comment
	43.	Tempus / Paige	We suggest a subgroup analysis based on geographic region and laboratory sub-specialization. We have evidence that shows that AI offers the greatest marginal benefit when deployed among general, non-specialist pathologists by comparison to specialist urological pathologists. Specialists already operate at or near peak diagnostic accuracy and while AI demonstrates improvements here, the biggest performance improvements are seen in the non-specialist setting, which is typical in many regional hospitals in the UK. AI therefore has the potential to narrow the performance gap, effectively standardising quality across a broader and more varied pathologist population. This has significant implications for health systems in the UK.	Thank you for your comment We have acknowledged the variation in benefits seen across different laboratories in the other considerations section The proposed reduction of the performance gap is referenced as part of the other considerations section.
	44.	Prostate Cancer UK	We believe that clinical effectiveness may depend on how well different patient groups were represented in	Thank you for your comment.

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			the data used to train the model. If certain subgroups are under-represented in the training data, there is a risk that the tool may perform less well for those patients. For example, Black men have a higher risk of developing prostate cancer and may exhibit differences in disease characteristics or patterns compared with populations that are predominantly represented in the training data. If the training data lacks patients of certain ethnicities, this could potentially affect performance in those groups. Therefore, it is important to assess whether the training data for these tools adequately represents the populations they would be used for. If the training data used was not sufficiently diverse, performance should be evaluated across different ethnic groups to ensure the tool performs consistently, even where there are no specific prior hypotheses about how performance might differ. We also believe that cost effectiveness may depend on the clinical performance of the AI tool. If performance differs across patient subgroups—for example, leading to fewer or more missed diagnoses—this may improve or reduce cost effectiveness within those groups. The number of QALYs gained may also vary according to patient characteristics such as age.	As discussed at the scoping workshop, we acknowledge the importance of understanding the datasets which have informed the algorithms. We heard from experts that there is no known variation in histological samples from different ethnicities, however this is not confirmed so the 'other considerations' section states 'the validity of AI algorithms depends on the data on which it is trained. When available, information will be reported on the representativeness of training and validation datasets for adults who have had core needle prostate cancer. If groups are not represented, the assessment will consider the potential to exacerbate or introduce health inequalities'. This consideration is also reported on in the equalities and health inequality impact assessment to consider to what extent committee may consider this.

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	45.	Mindpeak GmbH	Having no subgroups is the appropriate option.	Thank you for your comment.
	46.	AIRA Matrix Private Limited	Yes, there are subgroups within the population that may warrant separate consideration, primarily driven by variability in workflow, image characteristics, and potential impact on efficiency rather than differences in direct clinical outcomes. For example, subgroups based on specimen type (e.g., biopsy vs. resection specimens), staining protocols (e.g., H&E versus special stains or IHC), and scanner platforms or imaging settings may influence algorithm performance and therefore could be considered separately. Additionally, laboratories with high case volumes or fully digital workflows may derive greater operational and cost-effectiveness benefits due to increased scalability and reduction in manual quality control burden. Variability in site-specific practices, including tissue processing and slide preparation, may also impact the performance and utility of such technologies.	Thank you for your comment. The scope is proposed to focus on biopsies (not including resections) and use of H & E stain only. We understand infrastructure compatibility is a key consideration with significant impact on the benefits which can be seen from AI in the workflow. This is acknowledged in the final scope 'other considerations' and will be considered as part of our implementation report. We have added a statement to final scope 'other considerations' section, on page 18 to acknowledge variations in gains seen across different pathology labs for multiple reasons including; the scale of the pathology lab, sub specialities training in the lab, integration with existing digital infrastructure and use of

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				the technology as triage tool, first or second reads.
	47.	Artera Inc.	N/A	Thank you for your comment.
	48.	NHS England	No additional subgroups are proposed. However, it may be relevant to note that the incidence, risk profile, and aggressiveness of prostate cancer can vary by ethnicity. Consideration of subgroup analyses by ethnicity may therefore be appropriate when assessing clinical and cost effectiveness	Thank you for your comment. We heard from experts that there is no known variation in histological samples from different ethnicities, however it was acknowledged that this is not confirmed and remains an important consideration. The 'other considerations' section highlights the importance of understanding the data on which the AI algorithms are informed when considering the generalisability to the population. The scope states that 'Groups considered higher risk for prostate cancer, including people with a family history of prostate cancer or people of Black African or Caribbean background are encouraged to discuss with their GP from the age of 45.'

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				We have added reference in the clinical pathway section (page 2) that people with inherited genetic mutations, such as **BRCA1** or **BRCA2**, are associated with an increased risk of developing more aggressive prostate cancer. These groups will be considered as part of the assessment where data allows.
	49.	Ibex Medical Analytics	No comments related to subgroups	Thank you for your comment
	50.	The Royal College of Pathologists Expert 1	There is a risk that these technologies identify small areas of incidental low-grade cancer or areas that are labelled as atypical eg atypical small acinar proliferation that would not have been clinically significant for that man and consideration needs to be given to the cost and other implications of identifying such foci.	Thank you for your comment. Adverse effects of treatment, including overtreatment are proposed to be captured in the outcomes. Our external assessment group will consider how best to capture and incorporate such cases in the assessment.
	51.	Cells IA Technologies. A ROVI Biotech Ltd. Company	No	Thank you for your comment
Comparators	52.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.

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	53.	Aiforia Technologies Plc	There are comparators that have similar products, but they are not considered a clinical standard.	Thank you for your comment
	54.	Tempus / Paige	For the reason stated above, we suggest a subgroup analysis based on sub-specialization.	Thank you for your comment We heard that sub specialisation across labs may have an impact on the benefits seen. This is noted within the 'other considerations section in the scope'. We will look to capture this as part of the assessment report and implementation report where possible.
	55.	Prostate Cancer UK	We find the comparator to be appropriate, but it should be specified that it refers to using digital pathology without AI assistance.	Thank you for your comment. This was presented at the scoping workshop and discussion informed that the comparator remains 'Histopathologist review of prostate biopsies without the use of AI' with acknowledgement that digital pathology is a pre-requisite to the adoption of AI, that digital pathology is being more widely adopted and that it is the appropriate comparator for the economic model. However digital has not explicitly been added to the comparator to acknowledge there is currently still variation in this practice across laboratories and clinical

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				evidence in microscopy may still be informative for the assessment.
	56.	Mindpeak GmbH	Using pathologists without AI is the right gold standard.	Thank you for your comment
	57.	AIRA Matrix Private Limited	The comparators listed are broadly appropriate and reflect current standard practice within the NHS, where quality control and assessment of histopathology slides are predominantly performed through manual visual review by laboratory personnel and pathologists as part of routine workflows. This represents the primary comparator for technologies such as AIRAProstate and other AI tools. For downstream AI tools (e.g., diagnostic or prognostic algorithms), comparators may also include standard-of-care assessment by pathologists without AI assistance, and where relevant, existing validated scoring systems or clinical risk models.	Thank you for your comment
	58.	Artera Inc.	Yes, the comparator is appropriate.	Thank you for your comment
	59.	NHS England	The proposed comparators appear appropriate and reflect current NHS practice	Thank you for your comment
	60.	Ibex Medical Analytics	The comparator should be WSI reviewed digitally. Directly comparing the standard of care using a	Thank you for your comment.

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			microscope with a Digital + AI workflow may be challenging.	This was discussed as part of the scoping workshop. Centralised investment and rollout is supporting uptake of digital pathology, nationally. Published evidence from an NHS multicentre blinded crossover comparison study (Snead et al 2025), and a systematic review and meta-analysis (Azam et al 2021) supports equivalence of reporting when using digital pathology compared with light microscopy. However, clinical experts indicated that comparisons between light microscopy and AI may be useful to consider in the evidence base. The scope has been updated to reflect that both light microscopy and digital pathology can be included as comparators when capturing the clinical evidence base. Please also see response to comment 55.
	61.	The Royal College of Pathologists Expert 1	The comparator is appropriate for diagnostic assistance AI. But as per comments above, evaluation of novel prognostic and predictive AI should be in the remit and scope of this technology evaluation and an appropriate comparator included	Thank you for your comment. Please see response 7.

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			for that type of AI eg shared clinical decision making and MDT decision making without AI.	
	62.	The Royal College of Pathologists Expert 2	Yes	Thank you for your comment
	63.	Cells IA Technologies. A ROVI Biotech Ltd. Company	Yes	Thank you for your comment
Outcomes	64.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.
	65.	Aiforia Technologies Plc	The outcomes are appropriate. The outcome measures capture the most important health and system-related benefits.	Thank you for your comment
	66.	Prostate Cancer UK	We believe that the list of outcomes is appropriate and comprehensive.	Thank you for your comment
	67.	Mindpeak GmbH	All the outcomes proposed will capture the benefits of the technology.	Thank you for your comment
	68.	Qritive Pte Ltd	The proposed outcomes are appropriate. Additional considerations may include reduction in inter-observer variability, impact on pathologist workload, standardisation of reporting metrics, and pathologist confidence in diagnosis, as these may influence real-world adoption and operational impact.	Thank you for your comment. As discussed at the scoping workshop, we propose ‘concordance between AI and pathologist review’ captures inter observer variability

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	69.	AIRA Matrix Private Limited	In addition to general measures, outcomes should include analytical and clinical performance metrics, such as agreement with pathologist assessment, prognostic accuracy (e.g., ability to stratify patients by risk of disease progression or metastasis), and comparison with existing clinicopathological risk models. **Clinical utility outcomes** are also important, including the impact on treatment decision-making (e.g., changes in management strategies), alignment with multidisciplinary team (MDT) decisions, and potential to reduce overtreatment or undertreatment. Where feasible, longer-term outcomes such as progression-free survival or metastasis-free survival may be considered, although these may be supported through retrospective or validation studies. Overall, the outcomes are appropriate in principle, but ensuring inclusion of prognostic performance, clinical utility, and decision impact measures, alongside system-level benefits and risks, will provide a more comprehensive evaluation of AIRAProstate's value within the NHS	Thank you for your comment. Outcomes include: concordance between AI and pathologist review, impact on clinical decision making, adverse effects of treatment, including under or over treatment, overall survival was retained and metastasis-free, progression free and distant disease-free survival were added to the final scope.
	70.	Artera Inc.	We agree that the outcomes listed are in general appropriate. As described above, the National Cancer Plan for England includes the standard that 85% of patients	Thank you for your comment. Following the discussion of outcomes at the scoping workshop, outcomes including 'time to' data where it is

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			should start treatment within 62 days of referral.2 Therefore, the potential contribution of AI digital histopathology tools to expediting decision-making should also be considered part of the unmet need that can be addressed in this appraisal. We would suggest the following additional outcomes: Time from referral to treatment. Time commitment of NHS staff for decision making. We would also suggest that for prostate cancer, metastasis-free survival (MFS) is a highly relevant endpoint that should be added to the outcomes. The Intermediate Clinical Endpoints in Cancer of the Prostate working group have identified MFS as a valid surrogate end point for overall survival (OS) for patients with localised prostate cancer.[3,4]	available include; time to initiate treatment, referral to diagnosis, biopsy to MDT, referral to treatment, MDT to treatment. Metastasis free survival and distant disease-free survival have been added to the clinical outcomes. Overall survival has also been retained. .
	71.	NHS England	No additional outcomes suggested as stated outcomes look good and well chosen	Thank you for your comment
	72.	Ibex Medical Analytics	Yes — however, capturing the case review time field may be challenging. Departments are staffed using a standard point-based system (RCPATH)., and it will be difficult to demonstrate that staff supported by AI work 20–50% faster than those without AI. In practice, this would translate into handling 20–50% more workload with the same resources.	Thank you for your comment and highlighting the challenges at capturing these specific outcomes in practice. We appreciate these outcomes are extensive and not all data will be available in the clinical evidence review or real world evidence, in line with NICE

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			It is also difficult to assess this experimentally: time to produce report for MDT, time to MDT diagnosis. Cancer pathways are well-established, and MDTs typically involve 10–15 medical specialists, often at consultant level. Introducing a new technology makes it challenging to alter such schedules and processes. While feasible, any change is likely to be slow and gradual.	PMG 48, 2025 'Included outcomes should reflect what is important to address for the decision problem set out in the scope, rather than outcomes for which evidence is known to exist.'
	73.	Cancer Research UK	Some of the outcomes, listed either as intermediate outcomes or clinical outcomes, are not relevant to the intervention., e.g., overall survival. Grade is potentially more relevant to be included as an outcome than stage.	Thank you for your comment. This clinical outcome has been updated to state grade of cancer at detection. The outcomes around survival have been updated to include prostate specific mortality, metastasis free survival, progression free survival and distant disease-free survival. Overall survival has been retained as diagnostic accuracy could impact on survival. Our aim at scoping is to be inclusive and the list of outcomes represents those of interest to be extracted from the evidence if available.

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	74.	The Royal College of Pathologists Expert 1	As above for novel predictive and prognostic AI, impact on clinical decision making is an appropriate outcome measure. Overall survival needs to specifically look at whether mortality is prostate cancer specific mortality or due to another cause	Thank you for your comment. The impact on clinical decision making has been retained as a clinical outcome. The outcomes around survival have been updated to include prostate specific mortality, metastasis free survival and distant disease-free survival, and overall survival has been retained.
	75.	The Royal College of Pathologists Expert 2	Yes	Thank you for your comment
	76.	Cells IA Technologies. A ROVI Biotech Ltd. Company	Yes. In addition to diagnostic performance, it would be important that the scope considers several practical requirements for implementation in real-world pathology services: • Interoperability with existing digital pathology infrastructure, including compatibility with widely used slide scanners and Laboratory Information Management Systems (LIMS). • Integration into existing pathology workflows, ensuring that AI tools support rather than disrupt routine diagnostic practice. • Regulatory compliance, particularly alignment with UK regulatory frameworks and	Thank you for your comment. This was discussed in the scoping workshop and further detail has been added to the scope 'other considerations', Regulation compliance is reported in table 1 and will be reviewed throughout the appraisal. NICE supports technologies working towards regulation to be included in scope (PMG36, 2022). However, if a technology is not appropriately regulated and available to

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			international standards such as CE-IVD / IVDR where applicable. • Transparency and explainability of AI outputs, allowing pathologists to understand how algorithmic suggestions are generated. • Performance monitoring and post-deployment validation, ensuring that diagnostic performance remains consistent across institutions and patient populations. These elements are critical to ensure safe, scalable, and sustainable implementation within NHS pathology services.	the system before the final draft guidance is due to be published, then they will be removed from the publication. NICE Implementation team will provide input into this assessment to consider barriers to adoption and challenges in performance in practice and these details have been noted for this work.
Equality	77.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.
	78.	Aiforia Technologies Plc	Standardising cancer pathology ensures that every patient receives the same rigorous diagnostic precision regardless of where they seek treatment.	Thank you for your comment
	79.	Prostate Cancer UK	We consider the draft remit to be sufficient with regard to the equality aims. However, we would re-emphasise the need for proper consideration of any patient subgroups that are poorly represented in the training data used for these tools. As already noted in the draft scope, the recommendations should also consider the current variation in the adoption of digital pathology.	Thank you for your comment. In line with response to comment 48, training data is not considered a subgroup for the assessment. The adoption and implementation of digital pathology has been expanded upon in the final scope, other

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				considerations section, in response to data provided by NHS England.
	80.	Mindpeak GmbH	We believe the current wording of the draft remit and scope is appropriate and already addresses the stated aims; therefore, no changes are necessary.	Thank you for your comment
	81.	AIRA Matrix Private Limited	AI-based digital pathology tools, including AIRAProstate, rely on the quality and representativeness of training and validation datasets. There is a potential risk that under-representation of certain demographic groups(e.g., based on ethnicity or age) in development datasets could impact performance and generalisability. It would therefore be important to ensure that evidence is generated to demonstrate consistent performance across diverse patient populations, including groups protected by equality legislation. For people with disabilities, particularly those affecting vision or digital interaction, consideration should be given to user interface accessibility and usability, ensuring compatibility with assistive technologies where applicable. Thoughts: - **Performance across demographic subgroups**, including ethnicity, age, and other relevant characteristics	Thank you for your comment. With regards to the representativeness of training data, please see response to comment 48. Thank you for highlighting consideration of accessibility of these technologies. This has been added to the 'other considerations' section of the scope and highlighted in the equality and health inequality impact assessment document. Variability between different NHS settings is detailed within the 'other considerations' section in the scope. Implementation considerations and user barriers or issues will be captured as part of the implementation report alongside this appraisal.

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			- **Multi-site validation data** reflecting variability in NHS settings - **Usability and human factors evaluations**, including accessibility considerations - **Implementation considerations**, including potential disparities in access to digital pathology infrastructure	
	82.	Artera Inc.	There is considerable evidence that diagnosis and treatment of prostate cancer is inequitable, with inequalities affecting men who are older, black, and/or more socioeconomically deprived. NICE guidelines recommend radical treatment (surgery or radiotherapy) for men with high-risk or locally advanced prostate cancer.[5] However, an analysis of the National Prostate Cancer Audit (NPCA) database showed that men in these risk categories were less likely to receive radical treatment if they were older, black, or lived in a socioeconomically deprived area. Of note, the presence of comorbidities had only a small effect on the age at which patients received radical treatment, suggesting that age itself, rather than health status or life expectancy, is influencing treatment decision-making, contrary to guidelines.[6]	Thank you for your comment. We understand the value proposition that the risk prognostic technologies offer in potentially reducing inequitable care of prostate cancer. In line with response to comment 7, this point in the pathway is not being assessed as part of this appraisal.

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			In the NPCA's 2025 State of the Nation report, patients with high-risk/locally advanced prostate cancer living in the most socioeconomically deprived areas were less likely to receive radical treatment than those in the least deprived areas (75% versus 83% for men aged 60–69 years).[7] There was also a difference between ethnic groups: 68% of black men aged 60–69 years with high-risk/locally advanced prostate cancer received radical treatment compared to 82% white men of the same age and disease stage, and mortality inequalities for black patients are maintained across deprivation groups.[7,8] In addition to these findings for men with intermediate/high-risk disease, which have been shown to particularly affect certain demographics, Prostate Cancer UK have also highlighted a range of differences between current UK hospital protocols and NICE guidelines for the treatment of men with low- and intermediate-risk disease.[1] Overall, these findings suggest that there is both variability and uncertainty around treatment decision-making and potential unconscious biases that are leading to multiple inequalities in healthcare for men with prostate cancer. Digital AI histopathology technologies that provide prognostic and predictive information may mitigate these biases by providing easy-to-interpret, evidence-based risk stratification for patients with localised prostate cancer at the	

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			point of diagnosis. Providing additional, quantitative information about risks and benefits represents a debiasing strategy, which should promote analytical decision-making to reduce cognitive bias when engaging in shared decision-making with patients.[9] Therefore, by restricting the scope to include only technologies that address a narrow range of diagnostic criteria, this appraisal fails to promote equality of opportunity and misses the chance to improve equity in healthcare in England and Wales.	
	83.	NHS England	No additional comments	Thank you for your comment.
	84.	Prostate Cancer Research	Yes – the outcomes listed are appropriate in general, but they will operate unevenly across different categories of AI technologies, even when those technologies are used at the same point in the clinical pathway.	Thank you for your comment. We will look to understand these differences and use expert input to advise on application of these outcomes within the appraisal.
	85.	Ibex Medical Analytics	We did not experience any specific biases in our trials.	Thank you for your comment
	86.	The Royal College of Pathologists Expert 1	Evans et al 2024; PMID: 38600151. In this paper they describe a hierarchical model to assess the efficacy of AI software in the diagnostic imaging process (levels 1-6), which is helpful in considering the level of impact of the published literature. The 6th	Thank you for your comment. Companies will be asked to provide details on training data as part of the

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			level is societal efficacy, looking at the impact on society and the economic effect. You may wish to add these to the outcomes. The companies should supply ethnicity data when providing data on training and validation.	request for evidence, and this will be considered in line with the scope where available.
	87.	The Royal College of Pathologists Expert 2	I am not sure if minority ethnic groups have been studied in sufficient detail to know the technology translates to them. I see no reason why it should not but this disease is prevelant in those groups so it is particularly valuable to know this work has been done.	Thank you for your comment. We heard from experts that there is no known variation in histological samples from different ethnicities, however it was acknowledged that this is not confirmed and remains an important consideration. The other considerations section highlights the importance of understanding the data on which the AI algorithms are informed to better understand the generalisability to the population. 'When available, information will be reported on the representativeness of training and validation datasets for adults who have had core needle prostate cancer. If groups are not represented, the assessment will consider the potential to exacerbate or introduce health inequalities'

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				This consideration is reported on in the equalities and health inequality impact assessment to consider to what extent committee may consider this. Companies will be asked to provide details on training data as part of the request for evidence, and this will be considered in line with the scope where available.
	88.	Cells IA Technologies. A ROVI Biotech Ltd. Company	We do not believe the current scope excludes any protected groups. However, we highlight that for AI technologies to promote equality, it is essential that the evidence base (training and validation datasets) reflects the diverse demographic reality of the UK population, including ethnicity and age. We recommend that the committee monitors potential 'algorithmic bias' to ensure that diagnostic precision remains consistent across all patient groups, particularly those who may have been underrepresented in early digital pathology research. CellsIA is committed to transparency in dataset composition to mitigate these risks.	Thank you for your comment, please see response to comment 87. The 'other considerations' section of the scope also acknowledges the importance of performance monitoring and post-deployment validation to ensure diagnostic performance remains consistent across institutions and patient populations.

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Other considerations	89.	Sectra Imaging IT Solutions	No comment	Thank you for your comment.
	90.	Aiforia Technologies Plc	The product provides transparent visualization of the results and manual editing if needed, keeping pathologists in the driving seat.	Thank you for your comment individual technology functionality will be explored in more detail as part of the appraisal.
	91.	Tempus / Paige	As mentioned above, We urge NICE to prioritize **prospective evidence conducted within the NHS setting**. While retrospective validation is standard, prospective data captures the true impact on clinical decision-making and real-world workflow efficiency. Tempus/Paige has recently completed a groundbreaking prospective study in the NHS that demonstrates these tangible patient and NHS benefits (manuscript in press).	Thank you for your comment. Details of how the assessment will be carried out, including consideration of these questions will be in the external assessment groups protocol which will be published on the NICE website. The planned publication date is 29th April. NICE approach to evidence is documented in NICE process and Methods guide, Chapter 3 (PMG36, 2022). With further expansion in the University of Sheffield paper on 'Prioritising studies and outcomes for NICE HealthTech literature reviews' (DSU, 2025). Evidence most in line with the decision problem is prioritised. UK, NHS Based evidence is prioritised to inform our assessments.

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				We encourage all evidence, including manuscripts to be included in the company request for evidence submission for review by the external assessment group.
	92.	Prostate Cancer UK	We believe that this is an important topic to assess. However, we know that there are also AI technologies that can further analyse digital images of diagnostic biopsies and improve treatment decisions after diagnosis by assessing how aggressive a cancer is. This is important because localised prostate cancer can vary widely. Some cancers grow so slowly that they may never cause harm and should be managed with active surveillance rather than immediate treatment. When patients can safely follow active surveillance, they avoid or delay serious side effects such as impotence, erectile dysfunction, and incontinence. On the other hand, some localised prostate cancers are aggressive and unlikely to be cured with surgery or radiotherapy alone. These patients often need combined treatments, such as radiotherapy alongside hormone therapy. If these high-risk cancers are not correctly identified, patients may receive insufficient treatment, leading to recurrence and lower survival.	Thank you for your comment Please see response to comment 7.

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			AI tools now exist that can analyse digital images of routine prostate biopsy samples. Because they use images already produced during diagnosis, they do not add extra workload. Evidence shows that these tools can improve how cancer aggressiveness is assessed and help avoid both under- and overtreatment. We believe it is equally important that these technologies are assessed, and suggest the committee consider expanding the scope to include these AI tools that analyse digitised biopsy images to improve diagnosis and treatment decisions for men with localised prostate cancer. One example is the Artera MMAI tool, which uses AI to analyse digitised biopsy images, predicting cancer prognosis and potential effectiveness of certain treatments. Retrospective analyses of images from large, randomised trials have demonstrated that the Artera tool can identify more than 60% of men with intermediate-risk prostate cancer who would not benefit from the addition of androgen deprivation therapy (ADT) to radiotherapy. In current UK clinical practice, nearly all of these men would receive at least 6 months of ADT based on NICE guideline NG131. The Artera tool has also been evaluated in retrospective analyses for its ability to provide prognostic information on a patient's risk of adverse pathology at prostatectomy and may also have	

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			potential to support identification of men at lower risk who could be considered for active surveillance. Further work has identified uses for the tool in predicting risk of metastasis and mortality and identifying which patients would benefit most from receiving abiraterone. This tool is one example that offers additional insights beyond cancer diagnosis and grading, although similar tools may also be available. <u>Disclaimer</u> Please note that Prostate Cancer UK-funded academic research was used by Artera AI to test their tool's ability to predict men who would respond to abiraterone from their diagnostic biopsies. As a result, and in line with our standard grant IP terms, the university of the lead researcher negotiated with the company and agreed that in recognition of the value added to the underlying IP the company would make milestone payments and grant the university a small share of equity. Prostate Cancer UK receives a share of that income from the recipient university.	
	93.	Mindpeak GmbH	The use of AI in histopathology is contingent on having the necessary digital pathology infrastructure. We seek clarification on how the cost of this infrastructure will be integrated into your economic analysis. Since digitalization supports more than just	Thank you for your comment. We acknowledge that digital infrastructure is a prerequisite to digital AI technologies (page 5).

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			AI use, it shouldn't be fully attributed to the AI cost analysis.	Details of how the assessment will be carried out, including consideration of these questions will be in the external assessment groups protocol which will be published on the NICE website. The planned publication date is 29th April.
	94.	Qritive Pte Ltd	Implementation considerations such as integration with existing digital pathology systems, IT infrastructure requirements, and deployment flexibility (cloud or on-premise) may influence adoption across NHS Trusts. Variability in infrastructure readiness may impact scalability.	Thank you for your comment. We have added a statement in 'other considerations' to acknowledge the benefits seen from adoption of AI technologies will vary depending on the pathology lab set up considering the scale of the pathology lab, sub specialities training in the lab, integration with existing digital infrastructure and use of the technology as triage tool, first or second reads.' The assessment and implementation report will look to capture these aspects where possible.
	95.	AIRA Matrix Private Limited	No comments	Thank you for your comment
	96.	Artera Inc.	N/A	Thank you for your comment.
	97.	NHS England	As mentioned in the background section comments, the scope should reflect the rapid growth in digital pathology infrastructure within the NHS.	Thank you for your comment.

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			Digital histopathology has had significant central investment from NHS England through the national diagnostics and pathology programmes, and uptake is increasing across pathology networks in England. Digital infrastructure is a prerequisite for the implementation of AI technologies in histopathology, and therefore the level of digital adoption is directly relevant to implementation feasibility. The current wording in the draft scope does not fully reflect the current position: ***"Current digital pathology usage is not widespread in the NHS"*** Whilst a smaller proportion of trusts are reporting the majority of cases digitally, most pathology networks have begun digital reporting and national rollout continues. **Current position (February 2026):** • 25 of 27 pathology networks have begun digital reporting • 106 of 132 acute and specialist trusts are using digital images for primary diagnosis • 51 trusts are digitally reporting more than 50% of cases	The unmet need section has been updated to include this detail on the current adoption of digital pathology. The 'unmet need' section has been updated in line with this shared information re: current digital pathology. The 'other considerations' section has been updated to acknowledge that digital infrastructure is a prerequisite and acknowledges to some barriers to implementation which will be considered. Additional reference to the storage and infrastructure requirements were added to the data security section. As referenced in this comment and discussed in the scoping workshop, an additional statement was added to highlight that, 'Existing histopathology training programmes are on glass slide reviews and do not include review of WSI using digital pathology.

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			The rollout of AI technologies could risk reinforcing existing variation in diagnostic pathways if digital adoption is not also considered. **Key barriers to full digital adoption include:** • Training and assessment requirements still based on glass slides • Storage and infrastructure requirements for whole slide imaging • Variation in information governance arrangements across organisations **There are also strong links to national priorities, including:** • National diagnostics productivity targets • Cancer pathway improvement programmes • National plans supporting the use of AI in diagnostics • National target for 98% of histopathology tests to be reported within 10 days by March 2029 Recognition of these factors would improve the accuracy and context of the scope.	
	98.	Prostate Cancer Research	The technologies in the interventions list are a “mixed bag”. Most on the list are unimodal, image-centric tools focused on WSI-based diagnostic support and workflow (e.g. Aiforia, Ibex, Qritive, Virasoft), providing cancer detection/grading,	Thank you for your comment. Please see response to comment 7.

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			biomarker scoring and platform integration. Tempus is the outlier, operating multimodally by fusing digital pathology with clinical/molecular data to drive biomarker prediction and therapy selection. A notable omission is ArteraAI which sits in the same category as Tempus and is already in clinical evaluation in England in the NHS. Because the technologies sit in different functional categories yet are applied at the point of care with diagnosis as primary intent, they inherently influence different outcome domains, creating systematic confounding if evaluated together. If you are evaluating diagnostics, prognostic/treatment-guidance tools distort every downstream metric because they operate on different causal levers.	
	99.	Ibex Medical Analytics	**Diagnostic benefits.** The appraisal does not account for the potential diagnostic advantages of integrating AI into the clinical pathway. Establishing a current baseline may be difficult and would require audit and retrospective evaluations. Missed cancer can have substantial consequences, including lost productivity, hospitalisation, delayed treatment, misdiagnosis, reputational harm, additional testing, legal costs, and a significant burden on patients, families, and the healthcare system.	Thank you for your comment. Details of how the assessment will be carried out, including consideration of these questions will be in the external assessment groups protocol which will be published on the NICE website. The planned publication date is 29th April. NICE appraisals are conducted from an NHS and Personal Social Services perspective, and therefore productivity impacts and burdens on patients and

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				families are not explicitly captured within the outcomes. However, lived experience is considered as part of the appraisal process and discussed during committee meetings, and this qualitative evidence is an important component of decision-making. The clinical context and care pathway for the condition are also considered during committee discussions to acknowledge the wider impacts of interventions beyond the directly measured outcomes included in the appraisal.
	100.	The Royal College of Pathologists Expert 2	Perineural invasion and extra capsular invasion and distinction between PIN and invasive disease are worth considering if the technology reduces time searching for these features.	Thank you for your comment. These functions were proposed as part of the scoping workshop and acknowledged to be helpful additional features but it was agreed that they should not be minimum requirements for the technologies.
	101.	Cells IA Technologies. A ROVI Biotech Ltd. Company	The current evidence landscape is characterised by high technical proficiency but an "implementation gap" in routine practice. While retrospective validation on digitised whole-slide images has reached a high degree of maturity, we must be grounded in the fact that prospective, large-scale evidence within the unique operational pressures of the NHS remains limited.	Thank you for your comment Details of how the assessment will be carried out, including consideration of the hierarchy of evidence will be in the external assessment groups protocol which will be published on the NICE

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			In our view, the existing data—largely derived from reader-assist studies—clearly demonstrates the potential to: • Standardise outcomes: Increase diagnostic consistency, especially in grading tasks where inter-observer variability is traditionally high. • Enhance sensitivity: Improve the detection of clinically significant prostate cancer that might otherwise be overlooked in high-volume settings. • Optimise time: Measurably reduce slide review time, allowing pathologists to focus on complex cases. However, for Cells IA (as part of Rovi), the next frontier is operational validation. Future evidence must shift from "can the algorithm see the cancer?" to "how does the algorithm improve the patient pathway and laboratory resilience in a live NHS environment?	website. The planned publication date is 29th April. Please also see NICE approach to evidence documented in NICE process and Methods guide, Chapter 3 (PMG36, 2022) and DSU, 2025).
Questions for consultation	102.	Sectra Imaging IT Solutions	No comment	Thank you- no action required
	103.	Aiforia Technologies Plc	N/A	Thank you for your comment.

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	104.	Prostate Cancer UK	Questions 7 and 8 of the questions for consultation ask about the evidence on and usage of these technologies. We understand that promising performance (including high sensitivity and specificity) has been reported for these technologies, but that there is variation in the amount of published peer-reviewed evidence. In addition to the evidence identified by NICE in Medtech Innovation Briefing MIB280, we are aware that Paige Prostate has been evaluated across three NHS trusts through the ARTICULATE PRO project, but we understand that full results of this are not yet publicly available. For Ibex Prostate, we are aware of multiple validation studies largely carried out in other countries. We are aware that Paige Prostate is currently in use in the NHS through the ARTICULATE PRO project, but we are not aware of the extent of its use beyond these participating centres. Ibex Prostate is reportedly used to analyse biopsy images across health boards in Wales, and in NHS trusts in England, though the number of adopting trusts is not publicly reported. We are less familiar with the other tools being assessed through this appraisal and are unable to comment on their usage and associated evidence.	Thank you for your comment.
	105.	Mindpeak GmbH	1. Is the proposed title for this assessment appropriate? **YES**	Thank you for your comments

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			2. Is the proposed population described appropriately? **YES** 3. Is the description of the intervention appropriate? **YES** 4. Is the usage of AI technologies in the prostate cancer pathway appropriately described? **YES** 5. What level of evidence do you understand there is for the use of these technologies for initial diagnosis of prostate cancer? T**he CE-IVD level provides a strong foundation of evidence. The planned economic study is a crucial addition to this evidence base, directly addressing the need for AI tools to demonstrate their value for adoption in routine clinical practice.** 6. Do you consider that the use of AI technologies to support histopathology for prostate cancer can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? **Using standard, generic quality-of-life measurements is appropriate. Employing such measures will help establish that AI is equivalent to other IVD solutions and offers significant added value to pathologists.** 7. **Are there any other stakeholders NICE should be aware of for this topic?** YES we would like to add Mindpeak Prostate H&E	Please see response to comment 16 which confirms the addition of Mindpeak GmbH as a technology in scope of this appraisal.

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			tool in the list of Provisional Consultees company.	
	106.	Qritive Pte Ltd	AI-assisted pathology may offer benefits that are not fully captured within conventional QALY-based economic analyses. These include improved workforce efficiency, reduction in diagnostic variability, and faster turnaround times for biopsy reporting, which may help pathology services manage increasing diagnostic demand.	Thank you for your comment. We will look to capture turnaround times as part of intermediate outcomes, reduction in diagnostic variability is acknowledged in the equalities section as a potential improvement to equity of access to care. Workforce efficiencies will be captured where possible in the appraisal and implementation report. These potential benefits can also be considered qualitatively by the committee where evidence is available.
	107.	AIRA Matrix Private Limited	No comments	Thank you- no action required
	108.	Artera Inc.	**1. Is the proposed title for this assessment appropriate** We suggest amending the title to “Artificial Intelligence technologies to assist histopathology for prostate cancer” **2. Is the proposed population described appropriately? Please comment with respect to:** **a. Is it appropriate to include people who have previously been treated for prostate cancer?** Yes, this would be appropriate. Treatment for patients with recurrent or metastatic disease is highly	Thank you for your comments. Please see responses to comment 7

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			individualised and treatment decisions can be informed by AI tools used in histopathology, therefore it would be appropriate to include these patients within the scope. **b. Are there any subgroups for whom you would expect the clinical and cost effectiveness of the intervention to differ?** N/A **3. Is the description of the intervention appropriate** **a. Are there any additional considerations you think should be captured in the minimum requirements of the technologies to be included in scope?** As described above, we consider that the scope is not consistent with the role of histopathology on prostate cancer biopsies in the clinical care pathway and does not reflect the inseparability of diagnostic and prognostic/risk stratification information. We would therefore suggest amending the minimum requirements to: Technologies included in scope should, in line with RCP minimum diagnostic datasets (2024): • detect prostate cancer • AND/OR provide information to inform prognosis and treatment decisions, including: grade the prostate cancer detected, according to Gleason grading; measure tumour length and proportion of tumour per	

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			core; generate a diagnostic score; generate a biomarker positive or negative result to guide treatment decisions • AND have appropriate regulatory approval or be in the process of obtaining this • AND be available to the NHS or be in the process of this. **b. Are there any technologies which you do not feel appropriate to be in scope and why?** No. **c. Are there any technologies you feel should be added to the scope and why?** As described above, we consider that the scope is not consistent with the role of histopathology in prostate cancer diagnosis and does not reflect the inseparability of diagnostic and prognostic/risk stratification information. AI digital histopathology technologies that enhance the prognostic/risk stratification elements of the histopathology workflow should be included in the scope; for example, the ArteraAI Prostate Biopsy Assay. **4. Is the usage of AI technologies in the prostate cancer pathway appropriately described?** No, as described in more detail above, the scope does not fully reflect that histopathology on prostate cancer biopsies inseparably provides information that informs both diagnosis and prognosis/risk stratification. This is partially reflected in the understanding that Gleason grading is an important	

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			part of prostate histopathology, as it informs prognosis and treatment management. Therefore, the usage of AI digital histopathology technologies in the prostate cancer pathway should reflect this clinical reality and include technologies that also inform prognosis/risk stratification. **5. Is the comparator appropriate?** Yes **6. Are all the outcomes suitable for inclusion in the assessment? Are there any additional outcomes we should capture?** The outcomes included are suitable (although we have suggested some additional relevant outcomes above), and we would like to highlight that many of the long-term outcomes included will primarily benefit from tools that provide complete prognostic information. **7. What level of evidence do you understand there is for the use of these technologies for initial diagnosis of prostate cancer?** N/A **8. Which of these technologies do you understand are currently in use in the NHS?** Local implementation of the ArteraAI Prostate Biopsy Assay is currently being trialled in the Vanguard Path study at three UK NHS sites (Oxford University Hospitals NHS Trust, North Bristol NHS Trust, Greater Glasgow and Clyde NHS trust).	

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			9. Do you consider that the use of AI technologies to support histopathology for prostate cancer can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. As described above, there is considerable evidence that diagnosis and treatment of prostate cancer is inequitable, disadvantaging a range of groups. AI digital histopathology technologies have the potential to address these inequalities, but this is unlikely to be captured in the QALY. Prostate cancer generates a substantial societal burden that extends beyond direct healthcare costs, particularly through impacts on informal carers and wider participation in work and family life. Beyond carer impacts, prostate cancer also imposes wider societal costs through reduced productivity, early retirement, and changes in household roles. These impacts may be due to the disease itself, but are commonly due to treatment side-effects. Therefore, technologies that inform clinical decision making have the potential to reduce overtreatment and therefore ameliorate these societal burdens; however, this benefit will not be captured in the QALY.	

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			10. Are there any other stakeholders NICE should be aware of for this topic? N/A **11. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if, in addition to the equality considerations in the decision problem table, the proposed remit and scope**: • **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which AI technologies to assist histopathology for prostate cancer diagnosis could be used** • **could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology.** • **could have any adverse impact on people with a particular disability or disabilities** • **if there are any additional equality considerations, we should be aware of?**	

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			• **please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.** This is covered above.	
	109.	NHS England	**1. Is the proposed title for this assessment appropriate** Yes 2. **Is the proposed population described appropriately? Please comment with respect to:** a. **Is it appropriate to include people who have previously been treated for prostate cancer?** No - It may not be appropriate to include patients previously treated for prostate cancer, as this population may represent a different clinical pathway. b. **Are there any subgroups for whom you would expect the clinical and cost effectiveness of the intervention to differ?** Yes – May differ with ethnicity as risk and agressiveness vary with this **3**. **Is the description of the intervention appropriate** Yes, the description of the intervention is appropriate. a. **Are there any additional considerations you think should be captured** **in the minimum requirements of the technologies to be included in Scope?**	Thank you for your comments. No action required on comments; 1, 3, 4, 5, 6, 7, 8, 11 2. population. The previously treated population is discussed in response to comment 33. Groups considered higher risk for prostate cancer have been expanded upon in the scope. 9. Thank you for these outcomes which are all proposed to be captured in the updated scope outcomes. Increased capacity is proposed to be captured in the total volume of cases per session. 10.Thank you for highlighting these groups which we have reviewed for consideration. The Royal College of Pathologists,

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			No additional minimum requirements suggested. b. **Are there any technologies which you do not feel appropriate to be in scope and why?** No technologies recommended for removal. c. **Are there any technologies you feel should be added to the scope and Why?** No technologies recommended for addition to scope. **4.Is the usage of AI technologies in the prostate cancer pathway appropriately described?** Yes, the pathway description is appropriate **5**. **Is the comparator appropriate?** Yes **6**. **Are all the outcomes suitable for inclusion in the assessment?** Yes, no additonal outcomes proposed **Are there any additional outcomes we should capture**? No **7**. **What level of evidence do you understand there is for the use of these technologies for initial diagnosis of prostate cancer?** There are a variety of clinical trials published in peer-reviewed journals evaluating AI-assisted histopathology for prostate cancer diagnosis. Relevant literature can be identified through databases such as PubMed.	Institute of Biomedical Science, Royal College of Radiologists and British Association of Urological Surgeons are all already in the SH list. We have representation from NHS England including the pathology programme. We have added NPIC National pathology imaging cooperative to the stakeholder list. We will consider Digital pathology programme leads as part of our expert engagement for the appraisal.

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			8. Which of these technologies do you understand are currently in use in the NHS? Through the development of the commercial intelligence briefing and input from NHS E clinicans, there is awareness of the following providers within the NHS: • **Ibex** – Used in some NHS settings • **Paige (Galen Prostate)** – funded through the NHS AI Awards (2022) for deployment at North Bristol; Coventry & Warwick; Oxford **9. Do you consider that the use of AI technologies to support histopathology for prostate cancer can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** AI-assisted histopathology may produce system efficiency benefits not fully captured through QALYs, including: • Reduced reporting time for pathologists • Improved diagnostic turnaround times • Increased capacity for pathology services • Potential improvements in diagnostic workflow efficiency Evidence to support this could include: • Time savings per consultant pathologist • Laboratory workflow efficiency metrics • Diagnostic turnaround time reductions	

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			10. **Are there any other stakeholders NICE should be aware of for this topic?** • Royal College of Pathologists • Institute of Biomedical Science • Royal College of Radiologists • British Association of Urological Surgeons • NHS England National Pathology Programme • Pathology networks in England • Digital pathology programme leads 11. **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims.** **In particular, please tell us if, in addition to the equality considerations in the decision problem table, the proposed remit and scope:** • could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which AI technologies to assist histopathology for prostate cancer diagnosis could be used **No** • could lead to recommendations that have a different impact on people protected by the	

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			equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the echnology. **No** • could have any adverse impact on people with a particular disability or Disabilities **No** • if there are any additional equality considerations, we should be aware Of? **No** • please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. **No**	
	110.	The Royal College of Pathologists Expert 1	Technologies in use in the NHS: Paige Prostate AI in our centre. I have personal experience of using Paige Prostate AI in real time reporting of prostate biopsies. I know of other centres using Ibex. Other technology for inclusion: Artera MMAI Title may need amending to include novel predictive/prognostic AI Level of evidence available. There is a systematic review and meta-analysis (McGenity C et al 2025, PMID: 38704465). Much of the published literature involves retrospective statistical performance studies with little on real world deployment and evaluation, although there is evidence emerging. The Articulate Pro study	Many thanks for your comment.

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			evaluating Paige Prostate AI (ISRCTN91685765) in prospective NHS workflows is expected to be published soon.	
	111.	Cells IA Technologies. A ROVI Biotech Ltd. Company	8. Which of these technologies do you understand are currently in use in the NHS? Adoption across the NHS is currently heterogeneous and typically driven by local digital maturity or specific research mandates. We recognize the pioneering work of platforms like Ibex (Galen) and Paige AI, which have been evaluated in various pilot deployments and digital pathology Centres of Excellence. That said, the landscape is evolving beyond these initial pilots. The widespread deployment of digital pathology infrastructure—such as the various NHS Digital Pathology Networks—is creating a fertile ground for more modular and specialised AI assistants. At Cells IA, we observe that while these early movers have paved the way, there is a clear and growing demand for solutions that prioritize seamless LIMS integration and user-centric design to move from "pilot phase" to "routine standard of care 9. Do you consider that the use of AI technologies to support histopathology for prostate cancer can result in any potential substantial health-related benefits that are unlikely to be included in the QALY	Many thanks for your comments Re: stakeholders, RCPath and Health Tech Wales are already included as stakeholders. NHS England Stakeholder encompasses the transformation programme and NHS Digital pathology network. We have added NPIC National pathology imaging cooperative to the stakeholder list. Digital pathology academic pathology departments will be contacted for our expert engagement and or our implementation report.

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			calculation? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Yes. AI-assisted histopathology may generate several important benefits that may not be fully captured within traditional QALY-based evaluations. These include: 1. Workforce sustainability Pathology services in the UK face increasing demand alongside workforce constraints. AI tools may support pathologists by: • prioritising suspicious cases • reducing routine screening workload • improving reporting efficiency This may contribute to improved workforce sustainability, which is difficult to directly capture within standard health economic models. 2. Diagnostic consistency AI may improve inter-observer consistency, particularly in borderline or low-volume cases, potentially reducing variability in diagnosis and treatment decisions. 3. Service resilience AI-assisted workflows may support: • faster case triage	

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			• improved turnaround times • reduced diagnostic backlog These operational benefits may translate into improved patient pathways but may not be fully reflected in QALY-based outcomes. 4. Earlier treatment decisions Improved diagnostic workflow efficiency may lead to earlier initiation of treatment, which can positively affect patient outcomes and healthcare system performance. 10. Are there any other stakeholders NICE should be aware of for this topic? Yes. In addition to technology developers and clinical stakeholders, the following groups may provide valuable perspectives: • Royal College of Pathologists (RCPath) • NHS England Diagnostic Transformation Programme • NHS Digital Pathology Networks • Health Technology Wales • Digital pathology research consortia and academic pathology departments • Patient advocacy organisations focused on prostate cancer	

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			Engagement with these stakeholders may help ensure that evaluations reflect both clinical practice and patient perspectives.	
Additional comments on the draft scope	112.	Sectra Imaging IT Solutions	No comment	Thank you for your comment
	113.	Aiforia Technologies Plc	No comments	Thank you for your comment.
	114.	Prostate Cancer UK	We would also like to take this opportunity to emphasise our view that taking a slightly broader approach could lead to greater cost savings and significantly improve outcomes for men with localised prostate cancer. If the scope includes tools that analyse diagnostic biopsy tissue (as currently planned) but also provide prognostic and predictive information to help men decide on treatment, there is a real opportunity to reduce both undertreatment and overtreatment. From our experience supporting men with prostate cancer, many feel the information they receive at	Thank you for your comment Please see response to comment 7.

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			diagnosis is not sufficient to make confident decisions about their treatment. As a result, some experience treatment regret, long-term anxiety, or poorer survival outcomes due to undertreatment. We therefore recommend that this appraisal also considers whether AI tools that help guide treatment decisions immediately after diagnosis are ready to be implemented across the NHS.	
	115.	Mindpeak GmbH	No	Thank you for your comment.
	116.	Ibex Medical Analytics	We would like to make some corrections to Appendix B for the Ibex Prostate solution. 1. Regulatory Status Ibex Prostate is listed as CE-IVD, however this should be corrected to CE-IVDR. 2. Additional features: This should include detection of G4 cribriform, perineural invasion (PNI), high-grade PIN, atrophy and inflammation. 3. Grading & Measurements Update 'Automatically calculates tissue and tumour length' to *'The Ibex solution automatically identifies the tissue cores and calculates the tissue and tumour length per core. In addition it identifies the most involved*	Thank you for your comments 1. Regulatory status corrected 2. Additional features added 'Detects G4 cribriform patterns Detects high-grade PIN, atrophy and inflammation.' 3. 'Automatically identifies the tissue cores and calculates the tissue and tumour length per core. In addition, it identifies the most involved core and provides the longest length of tumour as a measurement'

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			core and provides the longest length of tumour as a measurement'.	
	117.	Cancer Research UK	We are interested in how evidence from comparator studies of different products will be weighted (relative to studies assessing single products in isolation). For example, the National Pathology Imaging Co-operative (NPIC) ENSURE-AI programme, which independently assesses commercial AI products, including in prostate cancer.	Thank you for your comment and highlighting this work for our awareness. Evidence synthesis approaches will be considered as part of the external assessment group protocol. The scoping protocol will be published on the NICE website. The planned publication date is 29th April.
	118.	The Royal College of Pathologists Expert 1	As an enthusiastic early adopter of this technology, the scoping exercise is very welcome. I have personally used diagnostic assistance AI in my reporting and can see where it could play a role in the workflow and would like to see wider uptake and use. But I do feel that we need to acknowledge that it is relatively early days in our experience of using these technologies and that what we are talking about at this stage is making best use of available pathologist time rather than replacing pathologist time with AI, standardising assessments or augmenting the information that a pathologist can provide to predict outcome – in other words information from predictive AI that is in addition to parameters such as Gleason Score. Our PPIE work has found that having a 'human in the loop' is	Many thanks for your comment. The glossary has been updated to correct this factual inaccuracy, thank you. The current scale of adoption to digital pathology has now been updated, in line with NHS England data. Other considerations section has been updated to include:

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			important to patients and we need to retain expert oversight. The emphasis of this exercise is quite heavily on cost effectiveness but this is actually a complex topic and there needs to be more emphasis on creating safe, robust and high quality services. The glossary contains incorrect information referring to breast cancer rather than prostate, this involves the core biopsy reporting categories and histological grade sections. The safety case for deployment needs to be emphasised, so that a regulatory clearance for diagnostic use is not seen as the only consideration. Labs deploying such technologies need to consider how to interface with LIMS and digital pathology systems and also whether there is an impact on UKAS accreditation (extension to scope). The safety case for deployment of Paige Prostate is outlined in Jia et al 2025, PMID: 40345136). In the ‘’other considerations’’ section, the statement ‘’Current digital pathology usage is not widespread in the NHS ‘’ should be explored in more detail with NHSE and other relevant bodies as targets have been set for digital pathology deployment and use may no longer be ‘not widespread’, but it would be useful to have some statistics in this section. In ‘’other considerations’’ the location of data storage and processing as well as being on-site or cloud based, if cloud based it is important to note if UK or	Considerations of integration with current infrastructure, data storage, security, accreditation as well as potential barriers to adoption. Detail of current training programme has been added and potential differences across histopathologists experience and subspecialisation UKAS has also been added as a named stakeholder. Cribriform has been updated in both the final scope and glossary.

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			other as this may have implications for data governance/legislation. Regarding training, it is important to consider resident doctors (histopathology trainees) and implications of training alongside AI and also requirements for training for Biomedical Scientists. There should be a recognition that human factors are important and training and validation of pathologists for AI assisted reporting should include a reference to appropriate confidence in the technology and an understanding that human observers using AI may accept, not accept or partially accept the outputs of the AI. In ''other considerations'', there needs to be a section on laboratory accreditation and any potential implications for UKAS accreditation under ISO15189(2012). In other considerations, it would be useful to briefly cover the legal position under which a pathologist or lab would be working when using AI. In the glossary, I would use the heading of ''Cribriform'' rather than ''Invasive Cribriform'' as both invasive and intraductal cribriform pattern are relevant. There needs to be a short discussion of including the percentage of pattern 4 (when present). The author of these comments declares that they are the principal investigator of the following studies:	

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			Articulate Pro, evaluating Paige Prostate AI and Vanguard Path, evaluating Artera MMAI.	
Provisional Stakeholders	119.	Sectra Imaging IT Solutions	Suggest adding Paige prostate as well	Thank you for your comment. Paige Prostate technology is included in scope with company 'Tempus' named as the owner company on the stakeholder list.
	120.	Aiforia Technologies Plc	No comments	Thank you for your comment
	121.	Mindpeak GmbH	We would like to add Mindpeak GmbH with Mindpeak Prostate H&E tool in the list of stakeholders. We have provided the Technology Appraisal Digital AI tools in histopathology for breast and prostate cancer (TA6684) Company information request Prostate Products to complement our proposal.	Thank you for your comment. Please see response to comment 16 which confirms the addition of Mindpeak GmbH as a technology in scope of this appraisal.
	122.	Artera Inc.	Artera Inc would like to continue to be considered a stakeholder due to the relevance of our technology to the histopathology care pathway in prostate cancer.	Thank you for your comment Please see response to comment 7.
	123.	NHS England	• FujiFilm • Leica • Indica • Sectra	Thank you for your comment.

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			• Siemens • Sysmex • Philips • Roche	Propose Fujifilm, Siemens, Sysmex, Phillips and Roche are added as companies which offer platforms related to the digital infrastructure for technologies in scope. Indica are already proposed to be in scope and Leica and Sectra currently listed.
	124.	Ibex Medical Analytics	We were not sure of the appropriate time to put forward suggestions for the expert reviewers. However Ibex would like to suggest the following individuals who have experience in the field of Prostate AI. [redacted]	Thank you for your comment We will consider company expert nominations as part of the request for evidence for companies in final scope.
	125.	Cancer Research UK	A minor comment – the Prostate Cancer Advisory Group and Prostate Cancer UK appear to be presented as one stakeholder. We understand this not to be the case.	Thak you for your comment Prostate Cancer UK are also listed separately under patient and carer groups. We have added a note to the

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				advisory group to acknowledge this is an affiliation.
	126.	The Royal College of Pathologists Expert 1	Should be added: UKAS British Association of Urological Pathologists (BAUP) Artera	Thank you for your comment BAUP are included in the stakeholder list UKAS have been added Artera provide a different value proposition within this pathway and do not meet the minimum criteria of technologies in scope of this appraisal. For further detail please see response to comment 7.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

Tackle Prostate Cancer