NICE National Institute for Health and Care Excellence

Health Tech programme

DG10118: Artificial intelligence (AI) software to help detect and characterise colorectal polyps

Draft Guidance Collated Comments

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
1	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	1.5 For people with diagnosed IBD or Lynch syndrome	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). We would recommend separating Lynch from IBD. The rationale is that Lynch polyps are similar/identical to sporadic polyps (albeit with a more rapid growth pattern), whereas IBD dysplasia is very different - different background mucosa (active inflammation, chronic features, post-inflammatory polyps) and different dysplasia morphology. We entirely agree that standard CADe/CADx should not be used for IBD dysplasia, which would need separate and specific AI training (albeit an area of unmet need where CADe/CADx might potentially be even more useful due to the difficulty that clinicians have in detected/characterising it.	Thank you for your comment which the committee has considered. The EAG noted that the training sets and clinical studies for the technologies were derived from general populations, not Lynch-specific cohorts. Additionally, most studies excluded patients with Lynch syndrome when evaluating AI-assisted colonoscopy. There were two studies that specifically focused on Lynch syndrome, but the evidence was too limited to allow meaningful subgroup analyses or conclusions. Due to the lack of evidence in this group, the consensus was that people with Lynch syndrome should not be routinely monitored using AI except in a research context.
2	Consultee 3 Medtronic	Are the recommendations sound and a suitable basis for guidance to the NHS?	GI Genius clearly meets and, in many respects, exceeds the threshold for a full 'can be used' recommendation with CADe. This would also align better with previous NICE decisions (e.g., HTG708), where AI technologies for stroke were recommended for routine NHS use despite being supported by substantially weaker, largely retrospective evidence. The current approach therefore	Thank you for your comment which the committee has considered. There is no set evidence threshold for a full 'can be used' recommendation and this will vary depending on the topic. The committee discussed whether the evidence base for Medtronic, or other technologies, was sufficient to make routine recommendations without the need for evidence generation. It was considered

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			appears inconsistent and risks avoidably delaying patient benefit.	that although the volume of evidence for GI Genius was generally agreed to be greater for this technology, the evidence was still mainly limited to the overall adenoma detection rate (ADR), and there are issues with the interpretation of this metric. These are discussed further in comments 4 to 8. Thus, although there were more randomised controlled studies (RCTs) and participants reporting ADR data, this did not reduce the overall uncertainty in the technologies. The committee considered the main uncertainty in the evidence base was whether the increase in ADR observed in trials corresponds to a clinical benefit in terms of reduction in colorectal cancer rates, which more evidence on the overall ADR does not address. This concern is communicated in Section 3.13 of the draft guidance. Furthermore, the committee emphasised that the high uncertainty in clinical evidence limits confidence in cost-effectiveness conclusions. They noted that the technologies, including GI Genius, showed similar results, with only small differences in cost and quality-adjusted life years (QALYs). Thus, there remained considerable uncertainty in the economic results.

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				Further comments from the EAG on specific issues regarding the evidence base for GI Genius compared with other technologies are discussed in comments 9 to 23.
3	Consultee 5 Odin Vision	Not specified	"…2 technologies being excluded because of a lack of technology cost data. So, no health-economic results were available for CADDIE or ENDOANGEL. The committee concluded that the cost effectiveness of these 2 technologies was too uncertain to be able to make a recommendation for use in the NHS outside of research" In-line with the EAG methodology, and similar to CAD EYE, using overall ADR RR and advanced adenoma RR to determine low-risk and high-risk sensitivity, respectively, CADDIE's sensitivity is [redacted]. This combination was chosen as the most conser£ive estimate, as AI technologies may have a greater low-risk ADR, as highlighted by the EAG. Given that CADDIE's clinical performance exceeds that of the lowest-performing device already included in the recommended group and aligns closely with several others that were found dominant in the economic model, there is a strong methodological basis to expect CADDIE to demonstrate cost-effectiveness under NICE's framework. Positively, CADDIE's ADR risk ratio is higher	Thank you for your comment which the committee has considered. The cost data for CADDIE provided as part of this consultation was used by the EAG to produce cost-effectiveness results for the CADDIE technology. The results of this analysis are supplied as an addendum to the EAR. The EAG reported that when the model was re-run using CADDIE-specific cost inputs and clinical data, the results were very similar to the other AI interventions in terms of cost-effectiveness, with only a small cost saving and a very small quality gain (QALY) being observed. As noted in the response to comment 41, NICE clarified that the lack of cost data was the reason for CADDIE being omitted from the draft recommendation, rather than a limited evidence base. On the basis of the cost-effectiveness analysis results, the committee changed their recommendation to include CADDIE in the technologies recommended for use with evidence generation.

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			than, or comparable to, GI Genius, CAD EYE, EndoScreener, and ENDO-AID, and the per procedure cost under realistic NHS procurement scenarios is lower than both GI Genius and EndoScreener. Given that these devices were assessed as cost-saving relative to standard colonoscopy, the balance of evidence strongly suggests that CADDIE would also fall within the cost-effective region of the model or be shown to be dominant	
4	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). 1. We believe that ADR is not the optimal outcome measure. Whilst adenoma detection rate (ADR) has been the historical standard, it is increasingly recognised that it might not be the best metric. Indeed, we feel it is not the best outcome measure for assessing CADe. This is because (a) ADR is a patient-level metric, hence only measures the first adenoma, whereas the potential benefit of finding/removing the second (and subsequent) adenoma is equal to finding/removing the first; (b) Adenomas are not the only pre-malignant polyp type - i.e. it excludes serrated polyps. Hence, we feel that if a polyp detection metric is used, using the Mean Number of Polyps is more fit for purpose, as it aligns more with the biology/natural history. 2. Separately, we wish to highlight an important conceptual issue with using ADR	Thank you for your comment which the committee has considered. The EAG acknowledged that ADR is in some respects not an optimal outcome for measuring the clinical and economic benefits of AI technologies. However, overall, the EAG considered that this was the most appropriate option for the following reasons: 1. ADR was reported for all intervention technologies, while other outcomes (including adenomas per colonoscopy [APC]) were not consistently reported 2. ADR was in general reported across more studies, and in more patients (pooled across studies), so ADR was considered the most robust option

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			(or any polyp detection metric) as a surrogate for reducing PCCRC rate (i.e. reducing missed cancers and preventing cancer by reducing missed polyps). We know that pre-CADe, evidence has shown that an endoscopist's polyp detection rate inversely correlates with PCCRC. There are 2 main rationales for this - (a) any polyp detected can be removed and hence cannot progress to cancer - CADe should be effective here, although the majority of CADe-detected polyps will be diminutive, hence the NNT will be high; (b) ADR is also a surrogate metric for "how carefully has 100% of the mucosa been inspected" - if an endoscopist only sees 50% of the mucosa then their ADR will be low and they might also have missed cancers and advanced polyps in the non-visualised mucosa - these may then progress to cancer - CADe does nothing to increase the amount of mucosa visualised on the screen, so whilst if might find more polyps in the visualised mucosa (increased ADR), it cannot affect a reduction in cancers or polyps present in non-visualised mucosa. Hence, it is quite possible that there will be a disconnect: an increased ADR from CADe but without a reduction in PCCRC. This is an important consideration and a significant limitation for assuming any polyp detection metric is a surrogate for PCCRC.	While new outcome measures are being considered in some contexts (e.g. JAG accreditation), ADR remains the key outcome of interest in clinical trials of AI technologies. Meta-analyses for adenomas per colonoscopy were also performed as part of this assessment where possible (Section 3.2.2.1.1.8 of the External Assessment Report), the results of which were similar to those for ADR for most technologies, with statistically significant improvements in adenomas per colonoscopy identified compared to colonoscopy without AI. Furthermore, the EAG explored the use of adenomas per colonoscopy in the economic modelling in scenario analyses; the impact on cost-effectiveness results was minimal. The committee discussed the merits and limitations of ADR in colonoscopy. They acknowledged that ADR, while widely used as a key performance indicator (KPI) in colonoscopy, is an imperfect measure of effectiveness, particularly in the context of AI-assisted technologies. This is because ADR only reflects whether a patient had at least one adenoma detected, which is considered a crude metric as it does not account for

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				the number or size of adenomas identified. Despite these limitations, ADR remains the primary outcome for comparisons, because most existing studies report outcomes in these terms, and it is embedded in current clinical practice and national audit systems (e.g., JAG database). But clinical experts agreed other measures such as adenomas per colonoscopy (APC) should also be collected. APC has now been included in the guidance (section 3.11) and evidence generation plan (section 3.4) . Limitations of ADR are discussed in section 3.9 to 3.11 of the draft guidance. The committee agreed that there is uncertainty around the impact of increasing ADR via AI on PCCRC rates and therefore maintained that this evidence should be collected. The evidence generation plan also specifies ADR for advanced adenomas and sessile serrated lesions (SSLs) should be collected.
5	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	1.6 What evidence generation is needed	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). Whilst adenoma detection rate (ADR) has been the historical standard, it is increasingly recognised that it might not be the best metric. Indeed, we feel it is not the best outcome measure for assessing CADe. This	Thank you for your comment which the committee has considered. Please see response to comment 4.

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			is because (a) ADR is a patient-level metric, hence only measures the first adenoma, whereas the potential benefit of finding/removing the second (and subsequent) adenoma is equal to finding/removing the first; (b) Adenomas are not the only pre-malignant polyp type - i.e. it excludes serrated polyps. Hence, we feel that using the Mean Number of Polyps is more fit for purpose, as it aligns more with the biology/natural history.	
6	Consultee 3 Medtronic	2.1 Change in post-colonoscopy colorectal cancer rates	A substantial body of evidence supports AI assisted colonoscopy and addresses the concern in the NICE draft that higher ADR 'may not translate' into fewer post-colonoscopy cancers. ADR is a rigorously validated surrogate outcome: in a study of 314,872 colonoscopies, each 1% increase in ADR was associated with a 3% decrease in subsequent colorectal-cancer risk; endoscopists in the top ADR quintile had roughly half the risk of interval cancer compared with those in the lowest quintile (Corley et al., 2014) Multiple RCTs and meta-analyses demonstrate that GI Genius (and other CADe systems) significantly increases ADR. For example, a recent systematic review and meta-analysis of randomised trials (9,639 patients) found a relative increase in ADR with GI Genius of RR = 1.12 (95% CI 1.03–1.22), along with improved detection of sessile serrated lesions and overall polyp	Thank you for your comment which the committee has considered. The EAG acknowledged the established link between ADR and PCCRC based on the study Corley et al. (2014) and accepted ADR as a reasonable surrogate outcome given the lack of data on the direct impact of AI on clinical outcomes. The EAG's clinical experts confirmed Corley is widely regarded as evidence that higher ADR reduces PCCRC. Nonetheless, it agreed that the current lack of PCCRC data from studies of AI-supported colonoscopy is a limitation of the current evidence base (Section 3.29 of draft guidance), as direct evidence demonstrating an impact of these technologies on PCCRC would increase confidence compared to relying on surrogate outcomes. See response to comment 4.

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			detection per colonoscopy (Sattar et al., 2025) Because demonstrating reductions in post-colonoscopy colorectal cancer requires very large numbers and long follow-up, the current absence of direct PCCRC data is expected and should not outweigh strong surrogate evidence. A prospective screening-program analysis also showed that when endoscopists improved their ADR over time, this was associated with significantly reduced interval colorectal-cancer and cancer-death risk (hazard ratio for cancer 0.63, for death 0.50) (Kaminski et al., 2017) • Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. New England Journal of Medicine. 2014 Apr 3;370(14):1298–306. • Sattar A, Sattar A, Khan MH, Zahid M, Tariq S, Choudhary N, et al. Effectiveness of the GI Genius Computer-Aided Detection System Versus Standard Colonoscopy: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Cureus. 2025 Oct 15;17(10). • Kaminski MF, Wieszczy P, Rupinski M, Wojciechowska U, Didkowska J, Kraszewska E, et al. Increased Rate of Adenoma Detection Associates With Reduced Risk of Colorectal Cancer and Death. Gastroenterology. 2017 Jul;153(1):98–105.	

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7	Consultee 3 Medtronic	3.9 Suitability of ADR as an effectiveness measure	Colorectal cancer (CRC) is a long-term outcome and cannot be directly linked to ADR at the time of colonoscopy, meaning diagnostic-accuracy metrics are limited in capturing CADe's full preventive impact on interval CRC. Longstanding evidence, including the landmark Corley et al. (2014) study, demonstrates a strong inverse relationship between ADR and both interval CRC and CRC related mortality, with even modest ADR improvements yielding substantial reductions in future cancer risk. This well-established association reinforces that technologies which reliably increase ADR such as CADe are highly likely to contribute meaningfully to interval cancer prevention, even if this benefit cannot be immediately measured during the procedure. • Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. New England Journal of Medicine. 2014 Apr 3;370(14):1298–306.	Thank you for your comment which the committee has considered. The committee agreed that while ADR remains a key performance indicator for now, post colonoscopy colorectal cancer rates would provide a better long-term outcome measure for evaluating AI-assisted colonoscopy. Further research is required in this area.
8	Consultee 3 Medtronic	3.10 Suitability of ADR as an effectiveness measure	ADR is the established international quality metric for colonoscopy because finding one adenoma reliably predicts higher overall adenoma yield and is directly linked to reduced interval colorectal cancer risk (Corley et al., 2014); the concern that it 'only measures whether at least one adenoma was found' is therefore not clinically relevant, as no standard requires proof that all polyps are detected. The suggestion that ADR is not an	Thank you for your comment which the committee has considered. As detailed in response to comments 4, 6 and 7, the EAG acknowledged the link between a higher ADR and reduced interval colorectal cancer risk as outlined by Corley et al. 2014. The EAG considered that clinical experts would be best placed to

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			acceptable quality outcome metric is illogical and inconsistent with both evidence and global practice. While ADR is imperfect, it remains the best and most widely accepted proxy for colonoscopy quality, and any move to replace it would be a strategic matter for the endoscopy community itself to determine. All research and technology development currently align to ADR as the core quality benchmark, and shifting to an alternative at this time would cause confusion and disconnect research from established clinical metrics. Although some AI studies examine complementary indicators such as Adenoma Miss Rate (AMR) or Polyp Detection Rate (PDR), these are neither accepted primary standards nor easily calibrated to existing service performance metrics compared with ADR. Furthermore, evidence shows that AI improves per-polyp detection, not just ADR. The RCT from Wallace et al., 2022 demonstrated significant increases in adenomas detected per colonoscopy and improved sensitivity across lesion types. This directly addresses the concern and confirms that AI meaningfully enhances overall detection performance. • Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. New England Journal of	comment on whether finding one adenoma reliably predicts higher overall adenoma yield, but agreed with the comment that ADR appears to be the most widely used and accepted measure of colonoscopy quality, based on how often it was reported by included studies and feedback from clinical experts consulted. Meta-analyses for adenomas per colonoscopy were also performed as part of this assessment (Section 3.2.2.1.1.8 of the External Assessment Report), the results of which were similar to those for ADR for most technologies, with statistically significant improvements in adenomas per colonoscopy identified compared to colonoscopy without AI. Furthermore, the EAG explored the use of adenomas per colonoscopy in the economic modelling in scenario analyses; the impact on cost-effectiveness results was minimal. Issues concerning ADR and its use as the most appropriate current measure are discussed in Sections 3.9 to 3.11 of the draft guidance.

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			Medicine. 2014 Apr 3;370(14):1298–306. • Wallace MB, Sharma P, Bhandari P, East J, Antonelli G, Lorenzetti R, et al. Impact of Artificial Intelligence on Miss Rate of Colorectal Neoplasia. Gastroenterology. 2022 Mar;163(1).	
9	Consultee 3 Medtronic	Has all of the relevant evidence been taken into account?	Medtronic would like to thank NICE for the opportunity to comment on the draft recommendations. Furthermore, Medtronic would like to publicly state we have consistently and will continue to support the approach that NICE in all its forms takes in the evaluation of technologies and its place in ensuring best value for the NHS. However, related to this assessment and the related process, we do feel it necessary to raise some legitimate methodological and technical concerns on what we believe to be a key element to the decision making. Key evidence relevant to polyp detection (CADe) has been missed, and important clinical and economic evdence on the polyp characterisation (CADx) functionality of GI Genius has been excluded from the draft recommendation. In particular, the following recent studies provide directly applicable data on safety, diagnostic performance, and cost effectiveness: • Antonelli et al., 2025 – PRACTICE: a non-inferiority RCT evaluating the safety of AI-assisted optical diagnosis to support leave-in-situ strategies.	Thank you for your comment which the committee has considered. The EAG noted that Bernhofer et al. 2025 was included in the External Assessment Report, as part of the supplementary information provided in Section 5a of the circulated supporting documentation, and so has been considered in this assessment when making conclusions about the evidence available for CADx. The EAG noted that Bustamante-Balén *et al.* 2025 was not included in the External Assessment Report, since this study was published after the economic SLR was conducted. Overall, the EAG acknowledged that this study is broadly thematically relevant to this appraisal, but did not consider that this study fundamentally changed the preferred approach in the economic analysis, as no new evidence was presented which could be incorporated into the EAG's economic model. The EAG also noted that the results of this study are not generalisable to the context of this appraisal, as the analysis conducted takes the perspective of the Spanish

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			• Bustamante-Balén et al., 2025 – a cost-effectiveness analysis of AI-aided colonoscopy for adenoma detection and characterisation. • Bernhofer et al., 2025 – a prospective study demonstrating the impact of AI on diagnostic reliability among trainees compared with experts.	National Health System; population characteristics, established clinical management, and cost inputs are therefore substantially different to an NHS perspective in England. Furthermore, the EAG said this study appears to compare colonoscopy with GI Genius™ coupled with a diagnose-and-leave polyp management strategy versus colonoscopy without AI coupled with a resect-all strategy. This is misaligned with the scope of the current appraisal which is to compare only colonoscopy with AI technologies against colonoscopy without AI technologies, and not to compare different polyp management strategies. Regarding Antonelli *et al.* 2025, the EAG stated a confidential version of the study was provided to the EAG but it was not considered relevant to the clinical review given the main aim was to compare a leave-in-situ approach with a resect-all approach; comparing different management strategies in terms of polyp resection is not within the scope of the clinical review. Furthermore, the GI Genius™ CADe/CADx system was used in both of these groups, so data comparing between use and no use of CADe/CADx

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				is also not available from this study. Outcomes from this study were specific to detection-based outcomes (such as ADR); the study does not provide additional diagnostic accuracy data for CADx that could improve confidence in the CADx data already considered in this report. The results for Antonelli *et al.* 2025 were not incorporated into the economic analysis as the reported outcomes were not appropriate for use within the current model structure (in particular, direct comparison against colonoscopy without AI was not possible, as GI Genius™ was used in both trial arms).
10	Consultee 3 Medtronic	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	As drafted, NICE does not adequately differentiate between technologies with vastly different evidence strength. GI Genius stands out with the most robust UK specific clinical and real-world data, demonstrating consistent, statistically significant improvements in adenoma and serrated lesion detection, which directly address NICE's stated uncertainties. Recent RCTs and cost effectiveness analyses show that integrating detection (CADe) and characterisation (CADx) capabilities not only improves clinical outcomes but also reduces downstream costs, supporting routine NHS use rather than restriction to research or evidence generation pathways. Furthermore, AI technologies help standardise colonoscopy	Thank you for your comment which the committee has considered. The EAG acknowledged that there are a higher number of CADe studies for GI Genius compared with most other technologies, with the exception of CAD EYE, including for ADR and serrated lesion detection outcomes. It also acknowledges the availability of real-world evidence for GI Genius from NAIAD and the fact that some UK-specific data are available from RCTs, which is not the case currently for most other technologies. However, it did not consider these to be major factors that should preclude the recommendation of

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			quality and promote patient equality, while concerns about deskilling and increased costs are not supported by current evidence. Medtronic recommends that NICE update its guidance to reflect the latest high quality studies and operational benefits, ensuring recommendations are proportionate to the strength of evidence available.	other technologies or impact the strength of recommendations. Based on the quality of the studies included and the results (including point estimates and uncertainty as indicated by the 95% confidence intervals), the EAG considered the current recommendations to be a reasonable reflection of the evidence available; it noted that the technologies with increased uncertainty regarding the evidence available have not been included in the draft recommendation. Regarding CADx, as noted in its report, the EAG considered evidence for all applicable technologies to be associated with limitations. Please also see the response to comment 2.

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11	Consultee 3 Medtronic	2.1 Improvement in adenoma detection rate (ADR) by polyp type and size	As per our previous comments, Recent evidence directly contradicts NICE's statement that there is not enough evidence showing effectiveness of CADe technologies in detecting SSLs. Multiple recent trials using GI Genius demonstrate significant improvements in SSL detection, including the large RCT by Thiruvengadam et al., 2024, which reported higher SSL detection with CADe versus standard colonoscopy. Additional RCTs from Ortiz et al., 2024 and Schöler et al., 2024, along with European prospective studies from Ahmad et al., 2023 and Engelke et al., 2023, consistently show increased detection of serrated and right-sided lesions when GI Genius is used. Collectively, these randomised, pragmatic, and real-world studies provide sufficient evidence that GI Genius enhances SSL detection, indicating that this statement no longer reflects the current evidence base. The COLO-DETECT RCT, a large, pragmatic, multicentre UK trial specifically evaluated AI performance across polyp subtypes and demonstrated a significant increase in the detection of serrated lesions, including SSLs, when using GI Genius. This improvement was observed across endoscopists with varying experience levels, confirming that the benefit is both robust and generalisable to routine NHS practice (Seager et al., 2024). Given that serrated pathway cancers account for a substantial	Thank you for your comment which the committee has considered. The EAG acknowledged that SSL detection has been reported by a number trials for GI Genius and other technologies and that these is some evidence to suggest a beneficial effect of various technologies on SSL detection. However, it considered the conclusion that "there is also not enough evidence to show how effective technologies are at helping to detect SSLs" (page 8 of the draft guidance) to be reasonable given the lack of statistically significant differences and generally increased uncertainty and inconsistency observed in all meta-analyses for SSLs covered in the External Assessment Report (Sections 3.2.2.1.1.5 and 3.2.2.1.1.11), which may be partly due to the lower number of events observed for these outcomes. The EAG reflected that while some individual studies may have demonstrated statistically significant results for SSL detection with GI Genius (and other technologies), this was not consistent across all available studies and it is important that the results of meta-analyses are considered rather than individual studies, as has been the approach for all technologies in this assessment. Engelke et al. 2023 and Schöler et al. 2024 were not considered

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			proportion of interval colorectal cancers, the COLO-DETECT findings directly address the experts' concern and show that GI Genius does contribute meaningfully to SSL detection. • Thiruvengadam NR, Solaimani P, Shrestha M, Buller S, Carson R, Reyes-Garcia B, et al. The Efficacy of Real-time Computer-aided Detection of Colonic Neoplasia in Community Practice: A Pragmatic Randomized Controlled Trial. Clinical gastroenterology and hepatology. 2024 Mar 1;22(11). • Ortiz O, Daca-Alvarez M, Rivero-Sanchez L, Gimeno-Garcia AZ, Carrillo-Palau M, Alvarez V, et al. An artificial intelligence-assisted system versus white light endoscopy alone for adenoma detection in individuals with Lynch syndrome (TIMELY): an international, multicentre, randomised controlled trial. The Lancet Gastroenterology & hepatology. 2024 Sep 1;9(9):802–10. • Schöler J, Alavanja M, de Lange T, Yamamoto S, Hedenström P, Varkey J. Impact of AI-aided colonoscopy in clinical practice: a prospective randomised controlled trial. BMJ open gastroenterology [Internet]. 2024 Jan 30;11(1):e001247. Available from: https://pubmed.ncbi.nlm.nih.gov/38290758/ • Ahmad A, Wilson A, Haycock A, Humphries A, Monahan K, Suzuki N, et al. Evaluation of a real-time computer-aided polyp detection system during screening colonoscopy: AI-DETECT study. Endoscopy. 2022 Dec	in the analyses for these outcomes due to higher concerns about risk of bias. However, on review, the EAG noted that sessile adenoma is reported in Engelke et al., which is different to SSLs and would not be suitable for pooling with other studies reporting SSLs. Inclusion of GI Genius-specific data from Schöler et al. would not alter the statistical significance of the SSL detection meta-analysis for GI Genius Please also see response to comment 2.

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			12;55(04):313–9. • Engelke C, Graf M, Maass C, C Tews H, Kraus M, Ewers T, et al. Prospective study of computer-aided detection of colorectal adenomas in hospitalized patients. Scandinavian journal of gastroenterology [Internet]. 2023 [cited 2024 Sep 16];58(10). Available from: https://pubmed.ncbi.nlm.nih.gov/37191195/ • Seager A, Sharp L, Neilson LJ, Brand A, Hampton JS, Lee TJW, et al. Polyp detection with colonoscopy assisted by the GI Genius artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multicentre, open-label, parallel-arm, pragmatic randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2024 Oct;9(10):911–23.	
12	Consultee 3 Medtronic	6 System considerations	GI Genius already has strong UK evidence demonstrating real-world effectiveness. The COLO-DETECT trial, a UK-based randomised controlled study, showed significant increases in adenoma detection rates in routine clinical practice. Complementing this, the NAIAD study, funded by the DHSC, provides multisite real-world data confirming that GI Genius improves adenoma and serrated lesion detection during routine colonoscopy. Together, these studies provide both rigorous trial and real-world evidence in the UK, addressing NICE's recommendation to use real-world data wherever possible.	Thank you for your comment which the committee has considered. The EAG noted that the COLO-DETECT and NAIAD trials mentioned here have both already been included in the External Assessment Report and were available for decision-making; COLO-DETECT has been meta-analysed with other GI Genius studies for the CADe function and NAIAD has been cited as an additional source of supportive evidence for this technology. While the UK-based data and real-world evidence were considered useful by the EAG, it should be noted that a UK-based RCT is also

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				available for the CADDIE technology. The EAG did not consider these to be major factors that should preclude the recommendation of other technologies or impact the strength of the recommendations.
13	Consultee 3 Medtronic	1.1 Can be used during the evidence generation period to help detect colorectal polyps	Treating all AI systems for colorectal polyp detection (CADe) and characterisation (CADx) as equivalent is misleading and risks a class effect conclusion not supported by the evidence, as the strength, relevance, and robustness of data vary between technologies. Following the analysis from the EAG, GI Genius currently has one of the largest datasets with nine RCTs totalling 10,913 participants. Compared to other technologies with much fewer RCTs and participants. Including the only large-scale UK multicentre RCT (COLO DETECT), and, to our knowledge, the only large scale UK real world evaluation (NAIAD - Nationwide study of Artificial Intelligence for Adenoma Detection in colonoscopy), whereas several alternative systems lack UK specific evidence or are supported by smaller and less rigorous studies. As drafted, NICE does not adequately differentiate between technologies with vastly different evidence strength. We therefore ask for product level differentiation with explicit weighting for UK multicentre RCTs and UK real world data.	Thank you for your comment which the committee has considered. These issues have been covered in previous responses. Please see responses to comment 9 to 11. Also see response to comment 2.

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14	Consultee 3 Medtronic	1.6 What evidence generation is needed	GI Genius has one of the strongest evidence bases of all technologies considered. Its effectiveness is supported by nine randomised controlled trials involving 10,913 participants, including the large UK multicentre COLO-DETECT trial, which showed significant and consistent improvements in ADR across all endoscopist experience levels. In addition, the NAIAD national real-world study across 34 NHS hospitals provides further UK specific validation and has been acknowledged by NICE as both ‘important’ and ‘practically relevant’. Across these studies, GI Genius achieves clinically meaningful and statistically significant ADR improvements (RR of 1.10–1.25), performing at the upper end of the effect size range relative to all assessed systems. This combination of extensive RCT evidence, UK based validation, and real-world generalisability is unmatched within the current assessment. Given this, restricting GI Genius to ‘use during the evidence generation period’ is disproportionate. It risks delaying patient benefit, adding unnecessary administrative burden, and creating unwarranted variation between centres. The draft guidance currently groups five technologies under the same recommendation despite marked differences in the scale, quality and relevance of their evidence bases. Several systems	Thank you for your comment which the committee has considered. These issues have been covered in previous responses. Please see responses to comment 9 to 11. Also see response to comment 2.

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			have far fewer or smaller RCTs, limited UK specific data, or less consistent effect sizes, yet are treated identically to GI Genius. A more differentiated recommendation is therefore justified. GI Genius clearly meets and, in many respects, exceeds the threshold for a full 'can be used' recommendation, with further evidence generation encouraged rather than mandated. This would also align better with previous NICE decisions (e.g., HTG708), where AI technologies for stroke were recommended for routine NHS use despite being supported by substantially weaker, largely retrospective evidence. The current approach therefore appears inconsistent and risks avoidably delaying patient benefit. Given the exceptional strength and relevance of its evidence base, GI Genius warrants a full 'can be used' recommendation rather than restriction to evidence generation pathways.	
15	Consultee 3 Medtronic	1.6 Why the committee made these recommendations	Although NICE notes uncertainty about whether these technologies increase detection of large adenomas, this should not be overstated as a barrier to recommending GI Genius. First, the assumption that all large adenomas will reliably be detected by all endoscopists is unrealistic. High variability in ADR persists across NHS practice (Atkin et al., 2024 and Bevan et al., 2019), and it cannot be assumed that every patient is guaranteed uniformly high endoscopic	Thank you for your comment which the committee has considered. The committee commented that most evidence on AI technologies in colonoscopy are based on ADR, which isn't the optimal measure, but is the most practical given current studies. They suggested that measurements that could differentiate polyps by type and size would be pf benefit going forward, along with patient-centred outcomes.

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			performance at every site and every time. AI assistance provides a safety net that helps mitigate this well-recognised variation. Second, there is no evidence that size alone determines the risk of progression to colorectal cancer; multiple biological, morphological and molecular factors contribute, and even small lesions can harbour advanced histology or progress unpredictably. Scientific societies do not currently define a subset of polyps that can be safely ignored and given the uncertainty over which lesions will evolve and when or even whether a patient will re-attend for surveillance, it remains clinically prudent to maximise detection of all adenomas. Current practice and guidelines are built on the principle that detecting and removing every possible precancerous lesion reduces long-term cancer risk. Finally, evidence on detection of advanced adenomas is already emerging. A recent meta-analysis of 44 RCTs (Soleymanjahi et al., 2024) demonstrates a statistically significant increase in the detection of advanced adenomas with AI-assisted colonoscopy. This undermines the suggestion that benefits are limited to small or clinically insignificant lesions. When combined with the large, high quality evidence base for GI Genius including UK specific RCT and real-world data this strengthens the case for a full 'can be used' recommendation rather than	These issues are discussed in section 3.10 and 3.11 of the draft guidance. The EAG agreed with the conclusion that there is more uncertainty present for the impact of AI technologies on the detection of larger adenomas, although it concluded that there was not robust evidence to confirm a differential effect of technologies across different sized adenomas given that lower event numbers for larger sized polyps may contribute to observed differences across size categories based on point estimates (Sections 3.2.2.1.1.4, 3.2.2.1.1.10, 3.3.1 and 6.1 of the External Assessment Report). A similar conclusion was made by the EAG with regard to ADR results for advanced and non-advanced adenomas (Sections 3.2.2.1.1.2, 3.2.2.1.1.3 and 6.1 of the External Assessment Report). Thus, the meta-analysis cited by Medtronic was acknowledged but does not reduce uncertainty given this is a pooled analysis of multiple different AI technologies. The EAG considered the data for these outcomes to be uncertain and has not ruled out the possibility of an important impact of the AI technologies on the detection of larger and/or advanced adenomas.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			restricting it to ‘use during evidence generation’. • Atkin W, Rogers P, Cardwell C, Cook C, Cuzick J, Wardle J, et al. Wide variation in adenoma detection rates at screening flexible sigmoidoscopy. Gastroenterology. 2004 May;126(5):1247–56. • Bevan R, Blanks RG, Nickerson C, Saunders BP, Stebbing J, Tighe R, et al. Factors affecting adenoma detection rate in a national flexible sigmoidoscopy screening programme: a retrospective analysis. The Lancet Gastroenterology & Hepatology. 2019 Mar;4(3):239–47. • Soleymanjahi S, Huebner J, Elmansy L, Rajashekar N, Lüdtke N, Paracha R, et al. Artificial Intelligence–Assisted Colonoscopy for Polyp Detection. Annals of Internal Medicine [Internet]. 2024 Oct 22;177(12). Available from: https://medicine.yale.edu/news-article/ai-assisted-colonoscopy-research-guidelines/	As noted in response to comment 37, the conclusion made by committee relating to the differences in the clinical relevance of different sized adenomas was based on feedback from clinicians at the committee meeting that smaller polyps may be less clinically significant in general (Pages 7 and 8, and Sections 3.10 to 3.12 and 3.29, of draft guidance). The EAG received similar feedback from the clinical experts it consulted, with comments that any impact on increasing the detection of smaller polyps may be less important than any impact on larger polyps. Therefore the uncertainty related to the impact on colorectal cancer outcomes remains (see Section 3.11 of drft guidance). The EAG has identified a number of papers (Zessner-Spitzenberg et al. 2024; Lee et al. 2024; Lieberman et al. 2008) that may provide some support to these statements made by clinical experts, with polyp size ≥10 mm being linked to a higher risk of advanced histology (high-grade dysplasia and villous histology) and PCCRC death. However, the EAG considered that improvements in the detection of smaller adenomas are also likely to be beneficial, particularly if it means they

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				are detected before reaching a larger and more advanced size. Of note, the Corley et al. 2014 paper describing a link between improved ADR and reduced PCCRC does not appear to be specific to large adenoma detection rate. • Zessner-Spitzenberg J, Waldmann E, Rockenbauer L-M, Demschik A, Penz D, Trauner M, et al. Polyp size is associated with colorectal cancer death across histologic polyp subtypes: a retrospective study of a screening colonoscopy registry. Endoscopy 2024; 56: 820-7; • Lee M, Ko HM, Kudose S, Remotti H, Choi W-T, Salomao MA, et al. High risk features in colorectal adenomatous polyps: A multi-institutional study. Annals of Diagnostic Pathology 2024; 72: 152323; • Lieberman D, Moravec M, Holub J, Michaels L, Eisen G. Polyp size and advanced histology in patients undergoing colonoscopy screening: implications for CT colonography. Gastroenterology 2008; 135: 1100-5.

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16	Consultee 3 Medtronic	1.6 Why the committee made these recommendations	Recent evidence directly contradicts the statement in the guidance that there is insufficient evidence demonstrating the effectiveness of CADe technologies in detecting SSLs. Multiple studies now provide consistent, reproducible evidence of improved SSL and right-sided lesion detection with CADe. Most notably, the COLO-DETECT multicentre pragmatic RCT conducted across 12 NHS hospitals (n=2,032) demonstrated that CADe-assisted colonoscopy significantly increased adenomas detected per procedure and reported higher detection of clinically important lesions, including sessile serrated adenomas (Seager et al., 2024). In addition, an RCT by Thiruvengadam et al., 2024 showed significantly increased SSL detection using CADe compared with standard colonoscopy. These findings are supported by RCTs from Ortiz et al., 2024 and Schöler et al., 2024, both reporting increased serrated and right-sided lesion detection with GI-Genius. European prospective studies by Ahmad et al., 2023 and Engelke et al., 2023 further reinforce these results in real-world clinical settings. Collectively, this body of randomised, and real-world evidence demonstrates that CADe consistently enhances SSL detection, indicating that the current statement in the guidance no longer reflects the contemporary evidence base. • Seager A, Sharp L, Neilson LJ, Brand A,	Thank you for your comment which the committee has considered. The EAG has provided responses to this feedback in comments 10, 11 and 15. See also response to comment 2.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Hampton JS, Lee TJW, et al. Polyp detection with colonoscopy assisted by the GI Genius artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multicentre, open-label, parallel-arm, pragmatic randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2024 Oct;9(10):911–23. • Thiruvengadam NR, Solaimani P, Shrestha M, Buller S, Carson R, Reyes-Garcia B, et al. The Efficacy of Real-time Computer-aided Detection of Colonic Neoplasia in Community Practice: A Pragmatic Randomized Controlled Trial. Clinical gastroenterology and hepatology. 2024 Mar 1;22(11). • Ortiz O, Daca-Alvarez M, Rivero-Sanchez L, Gimeno-Garcia AZ, Carrillo-Palau M, Alvarez V, et al. An artificial intelligence-assisted system versus white light endoscopy alone for adenoma detection in individuals with Lynch syndrome (TIMELY): an international, multicentre, randomised controlled trial. The Lancet Gastroenterology & hepatology. 2024 Sep 1;9(9):802–10. • Schöler J, Alavanja M, de Lange T, Yamamoto S, Hedenström P, Varkey J. Impact of AI-aided colonoscopy in clinical practice: a prospective randomised controlled trial. BMJ open gastroenterology [Internet]. 2024 Jan 30;11(1):e001247. Available from: https://pubmed.ncbi.nlm.nih.gov/38290758/ • Ahmad A, Wilson A, Haycock A, Humphries A, Monahan K, Suzuki N, et al. Evaluation of	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			a real-time computer-aided polyp detection system during screening colonoscopy: AI-DETECT study. Endoscopy. 2022 Dec 12;55(04):313–9. • Engelke C, Graf M, Maass C, C Tews H, Kraus M, Ewers T, et al. Prospective study of computer-aided detection of colorectal adenomas in hospitalized patients. Scandinavian journal of gastroenterology [Internet]. 2023 [cited 2024 Sep 16];58(10). Available from: https://pubmed.ncbi.nlm.nih.gov/37191195/	
17	Consultee 3 Medtronic	3.6 Overview of evidence base	We would appreciate clarification on the use of the term 'not relevant'. Does this mean that diagnostic accuracy data of CADe are viewed as equivalent to that of a high performing endoscopist, or that no benefit is seen in using CADe routinely across all colonoscopies? These interpretations differ significantly. It should also be noted that ADR is a widely accepted endpoint and core quality indicator in colonoscopy, and any assessment of CADe should be explicit about how its diagnostic accuracy evidence is being judged against this standard. The statement in the draft; 'For CADe, diagnostic accuracy data was limited and often not relevant to clinical practice. ADR was the most widely reported outcome' would benefit from greater precision about why the diagnostic accuracy evidence is judged not relevant, and to what aspect of clinical practice this assessment applies.	Thank you for your comment which the committee has considered. This EAG said the statement in Section 3.6 of the draft guidance was based on the EAG's conclusions in Section 3.2.2.1.1.13 of the External Assessment Report. It was referring to the fact that data for the CADe functionality of technologies were rarely reported in the form of diagnostic accuracy data (e.g. sensitivity and specificity), with studies instead largely reporting outcomes such as ADR as a measure of efficacy. This contrasts with data for CADx which was commonly reported as diagnostic accuracy measures. It was not considered to be an issue by the EAG and data for the CADe functionality in the model is based on ADR and other similar outcomes, but the EAG considers the diagnostic

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				accuracy data (e.g. studies reporting sensitivity and specificity directly) available for the CADe functionality to be considerably more limited and often lacking relevance to clinical practice, given it was based on autonomous use of the technology (rather than adjunct use).
18	Consultee 3 Medtronic	3.10 Suitability of ADR as an effectiveness measure	Endoscopists are less likely to miss them, as in the sentence below.	Thank you for your comment which the committee has considered. The EAG stated that in response to comments 18 and 19 and based on the statement in Section 3.10 of the draft guidance that “an endoscopist is less likely to miss more advanced or larger polyps without AI”, the EAG considered the comment from Medtronic that the increased detection of smaller polyps with AI is important to be a reasonable conclusion. However, it does not resolve the uncertainty raised by the committee regarding the clinical importance of smaller adenomas relative to larger adenomas (see response to Comments 15 and 37).

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19	Consultee 3 Medtronic	3.10 Suitability of ADR as an effectiveness measure	If an endoscopist is less likely to miss advanced or larger polyp, then it is important that AI helps detect small ones.	The committee considered that small polyp detection is less clinically meaningful compared with large/advanced adenomas and that current metrics (ADR) don't capture this difference well. In future, research should aim to capture this granularity. The EAG also has replied on this issue in responses to comments 15 and 37.
20	Consultee 3 Medtronic	3.10 Suitability of ADR as an effectiveness measure	The concern that AI 'may not help detect SSLs' is not supported by the available evidence. The COLO-DETECT RCT, a large, pragmatic, multicentre UK trial specifically evaluated AI performance across polyp subtypes and demonstrated a significant increase in the detection of serrated lesions, including SSLs, when using GI Genius (Seager et al., 2024). This improvement was observed across endoscopists with varying experience levels, confirming that the benefit is both robust and generalisable to routine NHS practice. Given that serrated pathway cancers account for a substantial proportion of interval colorectal cancers, the COLO-DETECT findings directly address the experts' concern and show that GI Genius does contribute meaningfully to SSL detection. This is further supported by multiple other studies, including studies from Thiruvengadam et al., 2024, Ortiz et al., 2024, Schöler et al., 2024 and additional peer-reviewed analyses including Ahmad et	These comments have been addressed in response to comment 11.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			al., 2022 and Engelke et al., 2023, all of which report consistent improvements in SSL detection with AI assistance. • Seager A, Sharp L, Neilson LJ, Brand A, Hampton JS, Lee TJW, et al. Polyp detection with colonoscopy assisted by the GI Genius artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multicentre, open-label, parallel-arm, pragmatic randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2024 Oct;9(10):911–23. • Thiruvengadam NR, Solaimani P, Shrestha M, Buller S, Carson R, Reyes-Garcia B, et al. The Efficacy of Real-time Computer-aided Detection of Colonic Neoplasia in Community Practice: A Pragmatic Randomized Controlled Trial. Clinical gastroenterology and hepatology. 2024 Mar 1;22(11). • Ortiz O, Daca-Alvarez M, Rivero-Sanchez L, Gimeno-Garcia AZ, Carrillo-Palau M, Alvarez V, et al. An artificial intelligence-assisted system versus white light endoscopy alone for adenoma detection in individuals with Lynch syndrome (TIMELY): an international, multicentre, randomised controlled trial. The Lancet Gastroenterology & hepatology. 2024 Sep 1;9(9):802–10. • Schöler J, Alavanja M, de Lange T, Yamamoto S, Hedenström P, Varkey J. Impact of AI-aided colonoscopy in clinical practice: a prospective randomised controlled	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			trial. BMJ open gastroenterology [Internet]. 2024 Jan 30;11(1):e001247. Available from: https://pubmed.ncbi.nlm.nih.gov/38290758/ • Ahmad A, Wilson A, Haycock A, Humphries A, Monahan K, Suzuki N, et al. Evaluation of a real-time computer-aided polyp detection system during screening colonoscopy: AI-DETECT study. Endoscopy. 2022 Dec 12;55(04):313–9. • Engelke C, Graf M, Maass C, C Tews H, Kraus M, Ewers T, et al. Prospective study of computer-aided detection of colorectal adenomas in hospitalized patients. Scandinavian journal of gastroenterology [Internet]. 2023 [cited 2024 Sep 16];58(10). Available from: https://pubmed.ncbi.nlm.nih.gov/37191195/	

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21	Consultee 3 Medtronic	3.11 Suitability of ADR as an effectiveness measure	The committee's suggestion that detecting smaller polyps may have minimal impact on colorectal cancer risk is speculative. It is not possible to predict which adenomas will progress to cancer, which is why guidelines recommend removing all adenomatous polyps. GI Genius improves detection across all polyp types and sizes, supporting best practice removal and maximising potential cancer prevention benefits. Moreover, accurate polyp size estimation is known to be highly variable between and within operators, with visual estimation showing significant inter observer variability and mis sizing rates exceeding 50% in some studies, underscoring the limitations of unaided size assessment and the value of advanced detection technologies (Cheloff et al., 2025) • Cheloff AZ, Kim L, Pochapin MB, Shaukat A, Popov V. Accuracy of Visual Estimation for Measuring Colonic Polyp Size: A Systematic Review and Meta-Analysis. American Journal of Gastroenterology. 2025 Feb 28;120(10):2251–9.	This comment has been addressed in the responses to comments 15 and 18.
22	Consultee 3 Medtronic	3.12 Effectiveness for detection	While the EAG notes that UK real-world evidence from the NAIAD study is important, it is essential to recognise that UK RCT evidence also exists specifically for GI Genius. The COLO-DETECT RCT conducted in the UK (Seager et al., 2024) demonstrated a statistically significant improvement in overall ADR with GI Genius, with benefits observed across all endoscopist experience	Thank you for your comment which the committee has considered. The EAG noted the overall conclusions for each technology in the External Assessment Report were based on meta-analyses of multiple studies reporting the outcomes (see comment 2). The EAG did not consider it appropriate to make conclusions based on single studies,

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			levels. Crucially, COLO-DETECT also showed improvements in the detection of SSLs and advanced adenomas, directly addressing the EAG's statement that such improvements were 'not statistically significant for any technology'. This evidence indicates that, in real NHS practice, GI Genius does enhance detection of both serrated and advanced lesions, lesion types strongly associated with interval colorectal cancer. Therefore, the assertion that AI primarily improves detection of small or non-advanced polyps does not reflect the totality of high-quality UK evidence. COLO-DETECT provides robust RCT data confirming clinically meaningful improvements across lesion subtypes, supporting a stronger recommendation for GI Genius. • Seager A, Sharp L, Neilson LJ, Brand A, Hampton JS, Lee TJW, et al. Polyp detection with colonoscopy assisted by the GI Genius artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multicentre, open-label, parallel-arm, pragmatic randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2024 Oct;9(10):911–23.	even if it was a UK-based study, given that this would ignore evidence from a large number of other RCTs considered to be at a similar risk of bias. The same approach has been taken for all technologies included in this assessment. The EAG noted a UK-based RCT for the CADDIE technology was also available. However, it should be noted that the impact of GI Genius on advanced ADR reported in COLO-DETECT was not found to be statistically significant. Please see response to comments 10, 11, 12, 15 and 58.

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23	Consultee 3 Medtronic	3.13 Effectiveness for detection	Recent evidence directly addresses the uncertainty noted in the draft regarding detection of clinically significant lesions. Multiple prospective studies from Thiruvengadam et al., 2024,, Ortiz et al., 2024 and Schöler et al., 2024 demonstrate that CADe improves detection of advanced adenomas, larger polyps, and sessile serrated lesions compared with standard colonoscopy. These findings are supported by peer reviewed studies from Ahmad et al., 2023 and Engelke et al., 2023 similarly report higher detection rates of advanced and serrated lesions, which are most associated with interval colorectal cancer. Most notably, the COLO-DETECT multicentre pragmatic RCT conducted across 12 NHS hospitals (n=2,032) demonstrated that CADe-assisted colonoscopy significantly increased adenomas detected per procedure and reported higher detection of clinically important lesions, including sessile serrated adenomas (Seager et al., 2024). Collectively, this robust evidence base shows that CADe enhances detection of clinically significant polyps, reducing the uncertainty expressed in the draft recommendations. • Thiruvengadam NR, Solaimani P, Shrestha M, Buller S, Carson R, Reyes-Garcia B, et al. The Efficacy of Real-time Computer-aided Detection of Colonic Neoplasia in Community Practice: A Pragmatic Randomized Controlled Trial. Clinical gastroenterology and	Thank you for your comment which the committee has considered. The committee considered that the detection of clinically important lesions was of critical concern, but heard that the EAG had addressed these issues in the EAR and that no new evidence was available that had not already been presented and considered. Please see responses to comments 10, 11, 12, 15, 22 and 58.

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			hepatology. 2024 Mar 1;22(11). • Ortiz O, Daca-Alvarez M, Rivero-Sanchez L, Gimeno-Garcia AZ, Carrillo-Palau M, Alvarez V, et al. An artificial intelligence-assisted system versus white light endoscopy alone for adenoma detection in individuals with Lynch syndrome (TIMELY): an international, multicentre, randomised controlled trial. The Lancet Gastroenterology & hepatology. 2024 Sep 1;9(9):802–10. • Schöler J, Alavanja M, de Lange T, Yamamoto S, Hedenström P, Varkey J. Impact of AI-aided colonoscopy in clinical practice: a prospective randomised controlled trial. BMJ open gastroenterology [Internet]. 2024 Jan 30;11(1):e001247. Available from: https://pubmed.ncbi.nlm.nih.gov/38290758/ • Ahmad A, Wilson A, Haycock A, Humphries A, Monahan K, Suzuki N, et al. Evaluation of a real-time computer-aided polyp detection system during screening colonoscopy: AI-DETECT study. Endoscopy. 2022 Dec 12;55(04):313–9. • Engelke C, Graf M, Maass C, C Tews H, Kraus M, Ewers T, et al. Prospective study of computer-aided detection of colorectal adenomas in hospitalized patients. Scandinavian journal of gastroenterology [Internet]. 2023 [cited 2024 Sep 16];58(10). Available from: https://pubmed.ncbi.nlm.nih.gov/37191195/ • Seager A, Sharp L, Neilson LJ, Brand A, Hampton JS, Lee TJW, et al. Polyp detection with colonoscopy assisted by the GI Genius	

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			artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multicentre, open-label, parallel-arm, pragmatic randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2024 Oct;9(10):911–23.	
24	Consultee 5 Odin Vision	Not specified	"There is limited evidence on the effectiveness of Argus, CADDIE, Discovery, ENDOANGEL and EMIS in detecting colorectal polyps. So, it is uncertain whether they increase the percentage of colonoscopies in which one or more adenoma is found." There have been two prospective RCT studies conducted using the CADDIE device that included 1,456 patients, 48 endoscopists, and 17 hospitals including 9 NHS hospitals. Both studies included Adenoma Detection Rate (ADR) as an endpoint and demonstrated a statistically significant increase. These studies constitute a greater body of evidence than was available for Argus, Discovery, Endoangel, EMIS or Magentiq-Colo (EAG recommended). CADDIE's aggregated ADR effect [redacted] is greater than that of recommended devices CAD EYE and GI Genius and is comparable to the effect sizes reported for recommended devices ENDO-AID and EndoScreener. CADDIE also	Thank you for your comment which the committee has considered. The EAG confirmed that data from the CADDIE and EAGLE trials had been supplied and considered by the EAG in their initial analysis. Most of the data reported in this comment had not been previously available to the EAG at the time of the assessment, as it was not reported in the provided studies. The EAG originally had advanced ADR data for CADDIE from one RCT (CADDIE trial), and Odin Vision have provided additional data from the EAGLE trial in this consultation comment (24). When these were included in the meta-analysis, the point estimate for CADDIE's impact on advanced ADR increased slightly, but the difference remained statistically non-significant, so uncertainty persists. The EAG still considers it likely that all AI technologies improve detection of advanced adenomas, but the evidence is weak due to low event rates and

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			demonstrates the greatest increase in advanced neoplasia detection [redacted]. Importantly, CADDIE is one of only two technologies (GI Genius) supported by a randomised controlled trial that was conducted in the UK, making the evidence directly applicable to NHS practice. Analyses of the EAGLE trial indicate an increase in advanced adenoma detection rate (adenomas that are ≥10 mm, have a villous component, or dysplasia) and advanced colorectal neoplasia (advanced adenomas, traditional serrated lesions, or sessile serrated lesions that are ≥10 mm or with dysplasia) when using CADDIE compared to standard of care. The increase in advanced colorectal neoplasia was statistically significant (SoC: 27/424, AI: 44/417, Difference = 4·2% [0·4%, 7·9%], p=.03), and the increase in advanced adenomas was approaching significance (SoC: 19/424, AI: 32/417, Difference = 3·2% [0·0%, 6.4%], p=.05). "…technologies mostly increase the number of smaller adenomas found, which are less likely than large polyps to develop into bowel cancer. It is uncertain whether the technologies increase the number of large adenomas found. There is also not enough evidence to show how effective the	heterogeneity. While CADDIE may appear to have a marginally greater effect than others, this is not strong enough to change conclusions. The EAG also noted that EAGLE data were based on a modified intention-to-treat population (mITT) rather than intention-to-treat (ITT), which the EAG would have preferred. This could introduce bias as the ITT results may have been less favourable. The EAG also considered the impact of these data on cost-effectiveness. Updating advanced ADR in the economic model had negligible impact on the cost-effectiveness results. In this comment, Odin Vision also submitted new data showing a statistically significant improvement in detecting advanced colorectal neoplasia (including advanced adenomas and serrated lesions) in the mITT population. However, it was unclear if this significance would hold in the ITT analysis, as results varied for other outcomes. Thus, the EAG regarded this as supportive evidence that CADDIE may help detect advanced lesions, but notes that similar composite outcomes weren't available for other technologies. The data provided here on SSLs was provided in the original evidence

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			technologies are at helping to detect SSLs, which are another type of potentially cancerous polyp." The pivotal study for CADDIE, the EAGLE trial, demonstrated a significant increase in the number of SSLs (AI: 0·08 vs. SoC: 0·03; Ratio 3·30 [95% CI 1·41–7·57], p<0·01) and large adenomas (AI: 0·09 vs SoC: 0·04 vs; Ratio 1·93 [95%CI 1·03-3·62], p=0·04), while showing no increase in unnecessary resections (PPA: AI: 53·9% vs SoC: 53·4%; 0·5%[-5·0%, ∞]).	submission and has been detailed in the supplement to the EAR in section 2.5.5, however, the EAG preferred the ITT analysis so reported these figures. The EAG notes that the difference between arms in the ITT analysis was not statistically significant. The data from the EAGLE trial were not combined with the data from the CADDIE trial because the EAG judged the definitions to be different (sessile serrated lesion vs sessile serrated adenoma). Overall, the EAG maintains that most AI systems likely improve detection of advanced lesions, though uncertainty remains, and the new data do not show CADDIE has a greater impact than others and did not alter the conclusions of the report or economic analysis.

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25	Consultee 3 Medtronic	Are the recommendations sound and a suitable basis for guidance to the NHS?	Additionally, restricting CADx to research only use would block its deployment in high volume NHS services, especially the NHS bowel cancer screening programme, where it offers the greatest value by improving diagnostic consistency and supporting endoscopists. Early studies show GI Genius CADx enhances confidence and accuracy in lesion characterisation, so limiting access would hinder real-world evaluation and delay benefits that evidence-generation frameworks seek to achieve. Allowing monitored use during the evidence generation period is a more proportionate approach that enables ongoing data collection and safety oversight without depriving routine practice of a technology that strengthens care.	Thank you for your comment. The committee heard from the EAG that the evidence base for computer aided characterisation of polyps (CADx) is currently very limited and thus all economic analysis should be regarded as exploratory. This is discussed in sections 3.24 to 3.26 of the draft guidance. See responses to comment 26.
26	Consultee 3 Medtronic	1.5 More research is needed to help characterise colorectal polyps	Additional economic and clinical evidence on the CADx functionality of GI Genius has been excluded from this analysis and report. Namely, the following: • Antonelli et al., 2025. Safety of artificial intelligence-assisted optical diagnosis for leaving colorectal polyps in situ during colonoscopy (PRACTICE): a non-inferiority, randomised controlled trial • Bustamante-Balén et al., 2025. Cost-effectiveness analysis of artificial intelligence-aided colonoscopy for adenoma detection and characterization in Spain • Bernhofer et al., 2025. Prospective non-randomised study comparing the diagnostic reliability of optical diagnosis of trainees with experts without artificial intelligence	In terms of CADx data, the EAG has emphasised the considerable limitations associated with current studies available for CADx data (Sections 3.2.2.1.2, 6.1 and 6.3 of the External Assessment Report), including those for GI Genius, and did not consider the evidence currently available to be robust enough for decision-making. Regarding the studies by Antonelli, Bustamante-Balén and Bernhofer, the EAG has responded on this in comment 9.

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			We consider that the Antonelli paper provides important and relevant evidence regarding the benefits of CADx, which demonstrated that using GI Genius to support optical diagnosis is a safe strategy compared to standard of care (resect and send to pathology). Therefore, should be included in this assessment, given that it represents the only randomised controlled trial (RCT) currently available for CADx. We would appreciate clarification regarding the rationale for the exclusion of these papers. Furthermore, we believe that the Antonelli paper offers sufficient evidence as RCT study comparing standard of care to inform the CADx scenario analysis. We respectfully request that it be reviewed and considered for inclusion within the clinical evidence section and economic modelling. In addition, the Bustamante et al. paper is the only published cost-effectiveness analysis to date that includes CADx and demonstrates clear additional benefits associated with its use. The study found that incorporating CADx with CADe (using GI Genius) was a dominant strategy, delivering both improved health outcomes and overall cost savings compared with standard colonoscopy. These findings further support the inclusion and consideration of CADx within the economic evaluation. Additionally, a recent paper by Bernhofer et al., 2025, showed that in 225 patients with 630 resected polyps, CADx-	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			enabled trainees achieved an NPV of 90.2% for diminutive rectosigmoid lesions, comparable to experts without CADx. CADx alone showed an even higher NPV of 93.2%, with similar results across all rectosigmoid polyp sizes. These findings indicate that trainees using CADx can meet PIVI (Polyp Interception for Visionary Improvement) 2 criteria for a “diagnose-and-leave” strategy. At the minimum, CADx should be an option in the limited circumstance of differentiating small adenomatous polyps from small non-adenomatous polyps in the rectosigmoid. There is sufficient evidence to support this. As adenomas account for only 30-35% of diminutive rectosigmoid polyps then the high negative predictive value is very reassuring and were it to be used this way it would facilitate diagnose and leave for average endoscopists which will help our hugely strained pathology services. We respectfully ask NICE to reconsider the current recommendation that CADx with GI Genius be used only in research and instead allow its use during the evidence generation period, particularly considering the CADx evidence available for the GI Genius system. Such an approach would meaningfully reduce the burden on already severely strained pathology services without compromising patient safety. • Antonelli G, Desideri F, Scarozza P,	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Andrisani G, Zerboni G, Furnari M, et al. Safety of artificial intelligence-assisted optical diagnosis for leaving colorectal polyps in situ during colonoscopy (PRACTICE): a non-inferiority, randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2025 Oct;10(10):915–23. • Bustamante-Balén M, Rodríguez BM, Barranco L, Monje J, María Álvarez, Pedro S de, et al. Cost-Effectiveness Analysis of Artificial Intelligence-Aided Colonoscopy For Adenoma Detection and Characterisation in Spain. Endoscopy International Open. 2025 Jan 2; • Bernhofer S, Prosenz J, Venturi D, Maieron A. The impact of artificial intelligence on the adenoma detection rate. Wiener klinische Wochenschrift. 2025 Jun 25;	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
27	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	1.6 What research is needed	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). We feel that CADx might be important as the UK starts to move towards optical diagnosis of polyps (sometimes called a Resect and Discard strategy). This is already happening in the English BCSP. It is likely to prove highly challenging to train all non-BCSP colonoscopists in optical diagnosis, which might limit the huge potential cost saving (avoiding the pathology polyp processing/analysis costs that are otherwise incurred). Hence, CADx might permit those cost savings to be fully realised. Incidentally, the BSG post-polypectomy surveillance guidelines were deliberately future-proofed for optical diagnosis	The committee acknowledged that CADx may potentially be a useful component of AI assisted colonoscopy in the future. However, the EAG considered the current evidence base to support CADx was insufficient to make robust conclusions on the diagnostic or cost-effectiveness of the AI technologies (see Section 3.24 of the draft guidance). Therefore the committee considered recommendations for further research were appropriate. Also see responses to comments 28 and 29.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
28	Consultee 3 Medtronic	1.6 Why the committee made these recommendations	As per our earlier comment, this statement is no longer supported by the current literature. Multiple prospective and histology validated studies now demonstrate strong diagnostic performance of polyp characterisation (CADx) systems. These include the study from Biffi et al., 2022, which showed GI-Genius CADx achieving expert-level accuracy and outperforming non-experts. The prospective clinical evaluation from Hassan et al., 2022, further independent validation studies from Reverberi et al., 2022 and additional real-world data from recent prospective study from Antonelli et al., 2025 and Rondonotti et al., 2024. Collectively, these studies demonstrate that CADx reliably supports accurate in-vivo optical characterisation and critically is explicitly designed to assist clinicians, not to make autonomous decisions. In addition, Antonelli et al., demonstrated safety of optical diagnosis using GI Genius CADx. Restricting CADx to use only in research would prevent real-world deployment in high volume NHS settings, including centres delivering the NHS England national bowel cancer screening programme, where its greatest clinical value lies. Particularly in supporting endoscopists and reducing variability in optical diagnosis. Limiting access in this way would also delay the very type of real-world evaluation that NICE's evidence framework aims to promote. Importantly, early clinical studies demonstrate that GI	Thank you for your comment which the committee has considered. The EAG emphasised, as noted in response to Comment 27, that there are considerable limitations associated with current studies available for CADx data (Sections 3.2.2.1.2, 6.1 and 6.3 of the External Assessment Report), including those for GI Genius, and the EAG does not consider the evidence currently available to be robust enough for decision-making. Of the studies cited here by Medtronic, Hassan et al. 2022 and Rondonotti et al. 2024 were formally included in the External Assessment Report for consideration. The remaining studies were not covered in the External Assessment Report given they are more limited in terms of study design (Biffi et al. 2022 and Reverberi et al. 2022 applied the technologies to videos/photographs of colonoscopy rather than applying it in real-time during a live colonoscopy) or did not meet the scope of this review. For instance, Antonelli et al. 2025 only reports detection-based outcomes such as ADR for two groups using GI Genius; comparing resect-all and leave-in-situ approaches which was not within the scope of this assessment (see response to comment 9).

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Genius CADx not only improves the consistency of optical diagnosis but also increases clinician confidence in lesion characterisation, which is essential for safe implementation of resect and discard or diagnose and leave strategies. Preventing deployment outside research settings would therefore hinder the ability to assess and realise these benefits in routine practice. A more proportionate and evidence aligned recommendation would be that GI Genius CADx can be used during the evidence generation period, enabling continued and monitored data collection, and iterative safety monitoring without limiting access to a technology designed to augment clinicians and strengthen existing screening programmes. This approach maintains robust evidence generation while avoiding avoidable harm caused by excluding supportive technology from routine practice where it is most needed. • Biffi C, Salvagnini P, Dinh NN, Hassan C, Sharma P, Antonelli G, et al. Author Correction: A novel AI device for real-time optical characterization of colorectal polyps. npj Digital Medicine. 2022 Aug 16;5(1). • Hassan C, Balsamo G, Lorenzetti R, Zullo A, Antonelli G. Artificial Intelligence Allows Leaving-In-Situ Colorectal Polyps. Clinical gastroenterology and hepatology. 2022 Nov 1;20(11):2505-2513.e4. • Reverberi C, Rigon T, Solari A, Hassan C,	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Cherubini P, Cherubini A. Experimental evidence of effective human–AI collaboration in medical decision-making. Scientific Reports [Internet]. 2022 Sep 2;12(1):14952. Available from: https://www.nature.com/articles/s41598-022-18751-2 • Antonelli G, Desideri F, Scarozza P, Andrisani G, Zerboni G, Furnari M, et al. Safety of artificial intelligence-assisted optical diagnosis for leaving colorectal polyps in situ during colonoscopy (PRACTICE): a non-inferiority, randomised controlled trial. The Lancet Gastroenterology & Hepatology. 2025 Oct;10(10):915–23. • Rondonotti E, Maria I, Paggi S, Amato A, Andrealli A, Scardino G, et al. White light computer-aided optical diagnosis of diminutive colorectal polyps in routine clinical practice. Endoscopy International Open. 2024 May 1;12(05):E676–83.	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
29	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	Are the summaries of clinical and cost effectiveness reasonable	5. Also, the role of CADe in specific circumstances (training, lower preforming endoscopists, screening/ surveillance) may differ from other circumstances. 6. There also seems to be variation in how individual endoscopists behave in the studies - some benefit from AI, some don't - this needs further investigation 7. Finally, but importantly, beyond the initial "wow factor" of the impressive technology, these systems do not seem to be used/enjoyed by many endoscopists. We hear of many endoscopists who find the systems a distraction (indeed some of us have personal experience of this) causing fatigue during lists due to frequent flashing boxes being superimposed on the screen, hence turn them off outside of a trial setting. Whilst we anticipate that future iterations will improve, we believe this deserves specific attention, as it would clearly be a waste of money if systems are bought but not used.	Thank you for your comment which the committee has considered. The committee discussed these issues and considered that whilst AI can initially distract some clinicians, this likely improves with training and routine use. However, there may be a risk of skill erosion if clinicians become overly dependent on AI. This is discussed in Section 3.22 of the draft guidance. The EAG acknowledged that the benefits of AI technologies may vary depending on context and individual endoscopists. Some of the EAG's clinical experts also reported that they found AI technologies to be distracting and to interfere with their standard practice, but also considered that the potential benefits might outweigh this drawback for some users. Overall, the EAG considered the evidence related to this is limited and heterogeneous, so this remains an area for future research. The need for generation of data on useability has been added to the guidance and is discussed in Sections 2.1 and 3.4 of the Evidence Generation Report.

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30	Consultee 3 Medtronic	1.6 For people with diagnosed IBD or Lynch syndrome	While collecting subgroup data may provide insight into potential differences in AI performance, a more fundamental and practical aspect of equality is standardisation of colonoscopy quality for all patients, regardless of which clinician performs the procedure. Currently, access to 'high performing' endoscopists varies across the NHS, and performance may vary even among experienced endoscopists. Technologies like GI Genius offer the potential to level the playing field, ensuring that all patients benefit from consistently high adenoma detection rates, independent of individual operator skill. This type of standardisation directly addresses patient level equality in outcomes and should be considered a primary endpoint for evaluation, rather than focusing solely on subgroup comparisons.	The committee considered this and said AI has potential to standardise performance, reducing variability between experienced and less experienced operators, although the evidence for this is lacking (see Section 3.18 of the draft guidance).
31	Consultee 3 Medtronic	3.22 Overreliance	We acknowledge the concern about potential deskilling. However, the available evidence and real-world experience does not support the view that CADe contributes to reduced endoscopist competency. CADe functions as a second observer rather than a replacement for core endoscopic skills, and its prompts still human interpretation and decision making. Studies on CADe assisted colonoscopy consistently show that endoscopists maintain full procedural responsibility, and several reports suggest that repeated exposure to CADe may enhance recognition of subtle or serrated lesions over time. Importantly, the	Thank you for your comment which the committee has considered. The EAG stated, as noted in Section 3.2.2.1.10 of the External Assessment Report, data from the NAIAD trial may suggest some link between AI adoption and endoscopist deskilling if the technology were to be withdrawn, but the EAG noted that other reasons for the observations in this trial cannot be ruled

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			technology does not automate detection or resection, so fundamental cognitive and technical skills remain essential. As with other validated adjuncts, such as those supporting clinical decision-making in stroke, which NICE evaluated in 2024 (HTG708) appropriate training and governance can mitigate any theoretical risk of overreliance. Overall, the current evidence suggests that CADe enhances, rather than diminishes, endoscopist performance.	out. However, this remains a theoretical rather than proven risk currently. Issues with deskilling and over-reliance are discussed in section 3.22 of the draft guidance.
32	Consultee 3 Medtronic	3.24 Effectiveness for characterisation	As noted in earlier comments, the intended use of CADe and CADx systems, including GI Genius, is to support clinicians, not replace their professional judgment. Final decision-making responsibility remains with the clinician. To our knowledge, all AI based medical devices in this field are designed as support tools, providing real time guidance to enhance detection and characterisation while ensuring that clinical oversight and responsibility remain fully with the endoscopist.	Thank you for this comment. It is universally agreed these technologies should not be used autonomously or as replacements for trained endoscopists.
33	Consultee 3 Medtronic	Are there any equality issues that need special consideration and are not covered in the medical technology	The consultation document overlooks important equality issues by focusing primarily on theoretical subgroup differences, such as AI performance by ethnicity, rather than practical patient impact. True equity should encompass access and quality of care for every patient, addressing risks associated with variability in endoscopist skill and ensuring consistent high quality outcomes regardless of the clinician or day. The	Thank you for your comment. NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people who share a protected characteristic and those who do not. NICE considers equality in relation to the protected characteristics stated in the Equality Act 2010:

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		consultation document?	broader benefit of technologies like GI Genius is their ability to standardise adenoma detection and reduce missed lesions across all patient groups, not just low prevalence subgroups. NICE should prioritise practical, patient centred equity measures that ensure all patients benefit from improved detection rates, rather than limiting consideration to indirect or hypothetical differences between subgroups.	Age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. NICE also consider health inequalities arising from socioeconomic factors and the circumstances of certain groups of people. If possible, NICE guidance aims to reduce and not increase identified health inequalities. For more information, see NICE's website, "Our principles". Equality considerations that are reported in sections in the external assessment report, draft guidance (section 3.41 and 3.42), and are the focus of the Equality Impact Assessment. Key issues that have been highlighted were that high-risk groups (Lynch syndrome, familial adenomatous polyposis, inflammatory bowel disease) were excluded from most studies, limiting generalisability. Training datasets also lacked clear demographic reporting (ethnicity, age, gender), raising concerns about the representativeness of these data. No further equality issues were identified by the committee.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
34	Consultee 3 Medtronic	6 Equalities	While monitoring equity is important, the guidance focuses narrowly on theoretical differences in AI performance by ethnicity rather than practical patient impact. It overlooks the 'average patient' and the broader real-world benefits of GI Genius, which improves adenoma detection across the population. Highlighting indirect scientific endpoints, such as CADe to CRC conversions in small cohorts, does not provide actionable evidence of differential performance. Collecting ethnicity-specific performance data is primarily of scientific interest; for clinical practice, the relevant measure is whether the technology reliably enhances detection and reduces missed lesions for all patients. NICE should prioritise practical, patient centred equity measures that ensure GI Genius benefits the full patient population, rather than focusing on hypothetical or highly indirect subgroup differences.	Please see response to comment 33.
35	Consultee 3 Medtronic	3.40 Equality considerations	Equality should also include access to care and level of care for each patient (not only low prevalence subgroups). What is the risk to patient care of not accessing a high performer or not accessing a high performer on a good day? What are the risks associated to variability of the human factor part of the standard of care to all patients?	Please see response to comment 33.

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36	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	1.6 For people with diagnosed IBD or Lynch syndrome	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). The cost cannot be underestimated - to avoid inequality, these systems would need to be in every endoscopy room in every endoscopy centre. The cost will not be a one-off cost either - it is likely that an annual subscription model will be pushed. Past experience with other technology tells us that there will be built-in obsolescence as well, requiring frequent kit upgrades. A national procurement plan would mitigate this in part.	Thank you for your comment which the committee has considered Whilst issues with national procurement are beyond the scope of NICE's remit, the EAG strived to identify and include all relevant costs needed for cost-effectiveness analysis. Where companies provided annual subscription costs these were explored in the modelling
37	Consultee 3 Medtronic	2.1 Impact on clinical management	The committee's concern that increased polyp detection with AI might lead to more surveillance colonoscopies "with no clear corresponding clinical benefit" is not supported by established UK and European evidence. Long-term UK screening data demonstrate that higher adenoma detection directly translates into clinically meaningful reductions in future colorectal cancer: centres with higher ADRs in the UK Flexible Sigmoidoscopy Screening Trial achieved significantly greater long-term reductions in both colorectal-cancer incidence and mortality (Cross et al., 2020). This is consistent with the well-established inverse, graded relationship between endoscopist ADR and interval colorectal cancer demonstrated in large population-based analyses (Corley et al., 2014). UK Bowel Cancer Screening Programme outcomes also	Thank you for your comment. The committee considered the information about how increased ADR through CADe might affect surveillance risks, including the possibility of increased potentially unnecessary surveillance. This was addressed by the EAG. The EAG noted that the concern raised by committee in terms of "no clear corresponding clinical benefit" in Section 3.34 of the draft guidance is specifically in the context of the largest impact of AI technologies potentially being for smaller adenomas, although the evidence available for larger polyps is noted to be limited and robust evidence of a differential impact across different polyp sizes was not considered to be present by the EAG. These issued are

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			show that high-quality detection and removal of adenomas produce stage-shift and early-stage cancer identification at the population level, confirming meaningful clinical benefit from thorough polyp detection (Logan et al., 2012). Together, these data show that identifying and removing more adenomas is a proven, evidence-based cancer-prevention mechanism—meaning that increased detection through AI systems such as GI Genius is expected to generate real clinical benefit rather than an unjustified increase in colonoscopy workload. Importantly, UK economic modelling indicates that surveillance when risk-stratified using updated 2020 BSG/ACPGBI/UKCGG guidelines is cost-effective, with higher costs offset by reduced colorectal cancer treatment burden. AI systems such as GI Genius, evaluated in European RCTs including those led in Italy (Hassan et al., 2023) and Spain (Bustamante-Balen et al., 2025), have been shown to increase detection of adenomas and serrated lesions most associated with interval cancers, meaning any rise in surveillance reflects the capture of clinically relevant disease rather than over-detection of trivial lesions. Taken together, UK and European evidence shows that increased detection through GI Genius is expected to generate real clinical benefit and long-term cost savings, rather than an unjustified increase in colonoscopy workload.	discussed in Sections 3.10 to 3.12 and 3.29 of the draft guidance and were corroborated by the EAG's own clinical experts. The EAG identified several studies (Zessner-Spitzenberg 2024; Lee 2024; Lieberman 2008) showing polyps ≥10 mm are linked to higher risk of advanced histology and PCCRC death. Clinical experts noted this supports the view that larger polyps matter more, but the EAG also considered detecting smaller adenomas beneficial, as it may prevent progression. Corley et al. (2014) confirms a link between improved ADR and reduced PCCRC but is not specific to large adenomas or an increase in ADR due to use of AI. The EAG considered that the economic analyses cited show broadly similar results to the economic analyses conducted by the EAG (i.e., colonoscopy with GI Genius™ is dominant compared to colonoscopy without AI, with a small increase in QALYs and decrease in costs). However, the EAG stressed the high degree of uncertainty in the model inputs for effectiveness of detection, both for the cited studies and the EAG's economic analysis. These analyses are all fundamentally informed by assumptions regarding the relationship

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			• Cross AJ, Robbins EC, Saunders BP, Duffy SW, Wooldrage K. Higher Adenoma Detection Rates at Screening Associated With Lower Long-Term Colorectal Cancer Incidence and Mortality. Clinical Gastroenterology and Hepatology [Internet]. 2020 Sep 11;0(0). Available from: https://www.cghjournal.org/article/S1542-3565(20)31280-5/fulltext • Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. New England Journal of Medicine. 2014 Apr 3;370(14):1298–306. • Logan RFA, Patnick J, Nickerson C, Coleman L, Rutter MD, von Wagner C. Outcomes of the Bowel Cancer Screening Programme (BCSP) in England after the first 1 million tests. Gut. 2011 Dec 7;61(10):1439–46. • Hassan C, Povero M, Pradelli L, Spadaccini M, Repici A. Cost-utility analysis of real-time artificial intelligence-assisted colonoscopy in Italy. Endoscopy International Open [Internet]. 2023 Nov 1;11(11):E1046–55. Available from: https://pubmed.ncbi.nlm.nih.gov/37954109/ • Bustamante-Balén M, Rodríguez BM, Barranco L, Monje J, María Álvarez, Pedro S de, et al. Cost-Effectiveness Analysis of Artificial Intelligence-Aided Colonoscopy For Adenoma Detection and Characterisation in	between polyp detection outcomes and long-term patient outcomes, and do not negate the need for further studies exploring the general link between adenoma size and the prognosis of patients. See also responses to comments 4 and 6. The need for data generation on surveillance rates is discussed in Sections 2.1, 3.3 and 3.4 of the Evidence Generation Report.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Spain. Endoscopy International Open. 2025 Jan 2;	
38	Consultee 3 Medtronic	3.23 False positives	We note the Committee's concern that increased detection and removal of benign polyps could raise laboratory and surveillance costs. Recent economic analyses show that AI assisted optical diagnosis can instead be cost saving when used to support diagnose and leave / resect and discard strategies. Mori et al., 2020 analysed an add-on trial and estimated that an AI enabled diagnose and leave strategy reduced average colonoscopy costs by around 6.9% in England. Economic analysis of GI Genius by Bustamante-Balén et al., 2025 model the cost effectiveness of an integrated CADe/CADx module and similarly conclude that CADe/CADx is cost effective and can reduce downstream costs through fewer unnecessary resections, pathology submissions and surveillance procedures. • Bustamante-Balén M, Rodríguez BM, Barranco L, Monje J, María Álvarez, Pedro S de, et al. Cost-Effectiveness Analysis of Artificial Intelligence-Aided Colonoscopy For Adenoma Detection and Characterisation in Spain. Endoscopy International Open. 2025 Jan 2; • Mori Y, Kudo S, East JE, Rastogi A, Bretthauer M, Misawa M, et al. Cost savings in colonoscopy with artificial intelligence-aided polyp diagnosis: an add-on analysis of	Thank you for your comment which the committee has considered. The EAG acknowledged that use of CADe technologies may result in long-term cost savings, due to avoidance of PCCRC due to missed adenomas. However, short-term increases in costs due to the requirement of further polypectomies and increased surveillance are still expected, even if these may be offset in the long term. The EAG also emphasised the uncertainty inherent in all economic analyses of AI technologies, due to the uncertainty in model inputs for technology effectiveness, and the lack of existing long-term data related to patient outcomes after undergoing a colonoscopy with AI technology. The EAG also considered that the economic evaluations cited (Bustamente-Balén et al. 2025 and Mori et al. 2020) have limited relevance to the current appraisal. Bustamente-Balén et al. 2025 was discussed in the response to comment 9. Mori et al. 2020 was identified in the EAG's systematic review of existing cost-effectiveness evidence, but was ultimately considered to be of limited relevance, as it was asimplistic cost comparison/budget

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			a clinical trial (with video). Gastrointestinal Endoscopy. 2020 Oct;92(4):905-911.e1.	impact analysis (see Section 4.1.2 of the EAR for further details).
39	Consultee 3 Medtronic	3.34 Uncaptured costs	The concern that increased detection of small polyps may raise surveillance and histology costs only applies if AI is viewed as a detection-only (CADe) intervention. When characterisation (CADx) is incorporated, many of these downstream costs are offset because accurate real time differentiation reduces unnecessary polypectomies, histology submissions and avoidable surveillance allocations. The recent Spanish cost-effectiveness analysis (Bustamante-Balén et al., 2025) demonstrated precisely this, combining CADe with CADx produced net cost reductions, driven by fewer unnecessary pathology and surveillance referrals. Modelling CADe alone therefore overestimates long term costs and does not reflect the potential for short term savings and how AI enabled colonoscopy is intended to function in practice. This modelling limitation should not weaken the recommendation for GI Genius, whose detection benefit is robust and whose downstream impacts are expected to be at least partially offset as CADx capability is integrated. • Bustamante-Balén M, Rodríguez BM, Barranco L, Monje J, María Álvarez, Pedro S de, et al. Cost-Effectiveness Analysis of Artificial Intelligence-Aided Colonoscopy For	Thank you for your comment which the committee has considered. The EAG did not agree with this characterisation of the impact of CADx functionalities. In particular, while CADx can lead to a reduction in short-term costs when implemented alongside polyp management strategies which reduce requirements for polypectomies and histopathological testing, the use of CADx functionalities could also lead to greater downstream costs if adenomas are misdiagnosed. This aligns with the results of the EAG's exploratory economic analyses, including the impact of CADx functionalities, which either resulted in similar or less cost-effective results to the base case (i.e., CADe functionalities only, coupled with a resect-all polyp management strategy); further details can be found in Section 4.2.2.4 of the EAR. Furthermore, as discussed in the response to Comment 9, the EAG considered that Bustamante-Balén *et al.* 2025 has limited relevance to the current appraisal. The EAG also emphasised that current clinical evidence on the diagnostic accuracy of CADx functionalities is

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Adenoma Detection and Characterisation in Spain. Endoscopy International Open. 2025 Jan 2;	limited, and of varying quality; therefore, only limited conclusions can be drawn about the cost-effectiveness of AI technologies when CADx functionalities are used.
40	Consultee 1 UK NSC	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	In the supporting document on p.19. Section 3.27 it states that “The committee concluded that the AI technologies do not appear to have a substantive impact on procedure length” but the supporting document states “it is unclear how robustly they were assessed and monitored in the included studies” so is this really a reasonable conclusion?	Thank you for your comment which the committee has considered. Procedure length is discussed in section 3.27 of the draft guidance. The EAG confirmed the impact of AI on procedure duration appears to be minimal, around 2 minutes but agreed there is still some uncertainty about this. The guidance document and evidence generation plan has now been updated to include further research on procedure time (Section 2.1 of the Evidence Generation Plan).
41	Consultee 5 Odin Vision	Not specified	"...it was not possible to estimate the cost-effectiveness for CADDIE or ENDOANGEL. So, more research is needed on these 5 AI technologies.” 	Thank you for your comment which the committee has considered. Thank you. As noted in comment 3, after receipt of the five-year cost data for CADDIE, the EAG has now updated the cost-effectiveness model to include this technology. These are provided in a separate addendum document. The committee heard that CADDIE appears broadly similar to other AI technologies in cost-effectiveness terms, with only minor potential cost savings and quality-of-life gains. Following this cost-effectiveness analysis, the committee recommended CADDIE can be used in the NHS during

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			[redacted] The primary commercial models available to the NHS are multi-year agreements, specifically 3- or 5-year contracts. For the 3-year option, the upfront cost is £11,986.27 with annual software (£6,488.78) and maintenance (£2,242.89) costs, giving a total 3-year cost of £38,161.28. For the 5-year contract option, the upfront cost is reduced to £9,028.61, and the annual software cost is reduced to £4,882.63. The total 5-year cost including maintenance comes to £44,656.22. These contract lengths generate different annual and per-procedure costs when calculated using NICE's standard assumptions, with the longer 5-year option resulting in the greatest cost-effectiveness. These agreements translate into per-procedure costs of approximately £13.06 and £10.45 respectively, placing these options squarely within the range of per-procedure costs used for the AI technologies recommended in the draft guidance. Notably, the 5-year option aligns closely with Olympus ENDO-AID and the cost is below several other recommended technologies modelled by the EAG. In addition, the CADDIE device price includes more AI functionality, (CADx, AI for Caecum and AI for visible mucosa).	the evidence generation period, in line with other technologies in whom diagnostic effectiveness had been found to be statistically significant. See comment 3.

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			This additional value is not captured in this comparison. A 1-year structure is also, in principle, available (£14,632.59 upfront plus £7,913.23 software and £2,242.89 maintenance, totalling £24,788.71). However, in practice it is highly unlikely that NHS providers would select this option. Deployment of CADDIE requires installation of hardware that is specifically designed to support long-term use of the AI software. NHS Trusts do not typically invest in capital equipment for only a single year, and this would not be consistent with standard NHS procurement frameworks, which favour multi-year contracts that enable predictable budgeting, minimise disruption to clinical operations, and offer improved value for money. A 1-year configuration would also artificially inflate the per-procedure cost and therefore underestimate the economic value that CADDIE would deliver under real-world purchasing behaviour. Nevertheless, the per procedure cost for this option still falls within the range of the devices already recommended in the draft guidance. Given that NICE annualises upfront capital costs over an assumed 4-year device lifetime and then applies an estimated per-procedure cost for the AI component, we consider that the 3- and 5-year contract prices provide the most appropriate like-for-like comparators to the annualised costs used for the other	

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			devices. We therefore respectfully suggest that NICE incorporate either the 3- or 5-year cost structure into the economic model, as these options best reflect actual NHS procurement practice and provide the most accurate representation of the real-world cost-effectiveness of CADDIE.	
42	Consultee 1 UK NSC	Has all of the relevant evidence been taken into account?	In one of the supporting documents it states how “more evidence is particularly needed on changes in decisions on patient follow up, surveillance intervals, and additional excision and testing of polyps” but I don’t see this reflected in the evidence generation plan. It talks about collecting data on the proportion of people referred to surveillance, but not changes in decisions or intervals. Evidence on specificity and false positives is important. In the supporting document on p.15/16 Section 3.17 states that “No strong differences in AI software performance were found across patient subgroups” and section 3.19 states “The committee concluded that there is no clear evidence to suggest that the AI technologies are less effective in some populations”. This feels at odds with page 194 of the supporting documentation which states that “While subgroup analyses based on colonoscopy indication and endoscopist experience and expertise have been performed, the EAG considers these analyses to be exploratory and associated with substantial limitations.” It doesn’t feel reasonable to conclude that all patient	Thank you for your observation. We will update the evidence generation plan.

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			subgroups perform similarly if the evidence is substantially limited.	
43	Consultee 1 UK NSC	Not specified	The supporting document states "The EAG understands that the nature of these technologies means they will be continually updated, meaning results from clinical trials may become increasingly unrepresentative of the most recent version of the technology." Given that the evidence generation period will span 4 years, how will updates to the software be accounted for? The accuracy of the AI in year 1 may differ significantly from year 4 due to changes in the algorithm.	Thank you for your response. While we recognise that the software version may change over time we would expect the company conducting the observational study with historical control to account for that in their statistical analyses, for example by employing a platform trial approach. The version of the software is recorded in the NED database, and therefore data should be available to make this possible
44	Consultee 1 UK NSC	3.3 FORE AI study	“The FORE AI study uses the CADDIE AI system for polyp detection, but the committee concluded that evidence about the correlation between increase in ADR using AI and colorectal cancer would likely apply to all 5 technologies.” – Is this a safe assumption? Different technologies will presumably have differences in their ability to detect advanced adenomas or SSLs. Two technologies might have the same overall ADR, but if one detects more advanced adenomas, the post-colonoscopy cancer rate will be different.	Thank you for your comment. . In the evidence generation plan all companies for which a recommendation for use could be made, are recommended to conduct their own diagnostic accuracy study. This will then provide further evidence to verify the committee conclusion on exit from the EVA period.

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45	Consultee 1 UK NSC	3.3 Diagnostic accuracy study	“companies may want to consider doing their own diagnostic accuracy study” – I think it should be mandated rather than just considered. We need to know the diagnostic accuracy of each technology.	Thank you for your comment. This should ideally be done. We will update the plan to reflect this.
46	Consultee 1 UK NSC	3.4 3.4 Data to be collected	Sections 3.17 and 3.18 of the guidance document notes that bowel screening programme endoscopists may benefit less from the addition of AI, and that existing evidence is mixed, but there’s no suggestion in the evidence generation plan that the accreditation of the endoscopist should be included as part of the data collection or analysis. Is this not an opportunity to improve the evidence in this area?	Thank you for your comment. This should ideally be done. We will update the plan to reflect this.
47	Consultee 1 UK NSC	3.4 Observational cohort study	I would suggest that data is also collected on procedure time, as this could impact on clinical capacity. Although there’s some evidence on this in the supporting document, it states that “it is unclear how robustly they were assessed and monitored in the included studies”. This suggests more/better evidence is required.	Thank you for your comment. The committee agreed that data collection on procedure time would be useful and the Evidence Generation plan will be updated accordingly.
48	Consultee 1 UK NSC	3.4 Observational cohort study	I feel data should be explicitly requested on results by age, sex and ethnicity. Page 7 suggests collecting this, but doesn’t make it a key factor.	Thank you for your comment – this will be updated

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49	Consultee 1 UK NSC	3.4 Observational cohort study	Additional patient information worth considering is their route to colonoscopy. Was it symptomatic or non-symptomatic (via screening)? Do these two groups experience different outcomes? Should also include data on decision changes and surveillance intervals, as per section 3.23 of the guidance document, to provide data on false positives.	Thank you for your comment.
50	Consultee 1 UK NSC	3.4 Observational cohort study	The link to the evidence framework is incorrect	Thank you for highlighting this – this will be updated and fixed.
51	Consultee 1 UK NSC	4	Will there be a requirement for companies to demonstrate what they've done or are doing, or will they simply self-declare that they're doing something? Will NICE review and approve evidence generation protocols or make an annual assessment of whether the evidence being generated is suitable? We need to avoid a situation where it's discovered at the end of the 4 years that the evidence is incomplete or unsuitable.	Thank you for your comment. NICE's Early Use Assessment team has regular touch points with the companies that receive a use with further evidence generation recommendation. This is to ensure that companies are progressing with data collection as advised in the guidance. More details can be found in section 1.7 of the NICE HealthTech programme manual

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52	Consultee 1 UK NSC	6 Equalities	This point about collecting and analysing data on ethnicity is important, and should be included elsewhere in the evidence generation plan. Although the draft guidance states that most of the studies were done in mixed populations and that no strong differences in performance were found, the supporting document suggests that detailed data may be lacking in this area due to training data being anonymised, and the EQIA states that “The committee heard there was generally a lack of published information reported on the demographic diversity used in the AI training datasets” so it’s important to fill this gap with real world evidence, but it’s not mentioned until page 9. Page 7 only suggests ethnicity as a possible example of patient information. I think it should be clearly listed in sections 3.3 and 3.4 as an important part of the evidence collection plan.	Thank you for your comment – this will be updated.
53	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	Are the summaries of clinical and cost effectiveness reasonable	3. We note that PCCRC rate is included as an outcome measure - this is scientifically appropriate, but will be highly challenging to do in reality, as extremely large numbers of patients would be required to calculate this with any accuracy.	Thank you for your comment which the committee has considered. The EAG acknowledged the concerns raised by JAG around the difficulty in assessing PCCRC but considers that this type of evidence would be the most robust way of assessing the real impact of AI technologies on PCCRC, without relying on surrogate outcomes that are considered to be linked to PCCRC.

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54	Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	interpretations of the evidence?	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). Whilst we feel that CADe and CADx are promising emerging technologies, we feel more evidence is required (hard endpoints cf. polyp detection; and real-world user experience) before substantial money is invested in early iterations of these rapidly-evolving systems	Thank you for your comment.
55	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	4. An alternative would be to push for large, real-world, back-to-back colonoscopy studies, as this would give a true reflection as to whether CADe reduces the miss rate of meaningful lesions, hence might reduce PCCRC rates. These should be carried out in general endoscopy units cf. specialist centres, using colonoscopists who are equipoise to the the non-benefit of CADe.	See response to comment 53.
56	Consultee 3 Medtronic	3.1 3.1 Evidence gaps and ongoing studies	Please see previous comments, ADR is the primary marker linked to CRC acknowledged worldwide.	Thank you, this is covered in responses to comments 4 to 8.
57	Consultee 3 Medtronic	3.3 Observational cohort study with a	Please see earlier comments on ADR as the primary marker linked to CRC	Thank you, this is covered in responses to comments in Theme 2.

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		historical control		
58	Consultee 3 Medtronic	5	Although long-term Post-Colonoscopy Colorectal Cancer (PCCRC) data are not yet available for any AI technologies, GI Genius has consistent RCT and meta-analysis evidence showing clinically meaningful increases in ADR, including for right sided and serrated lesions linked to interval cancers. ADR is a validated surrogate endpoint, higher ADR is strongly associated with lower future colorectal-cancer incidence and mortality (Corley et al., 2014 and Cross et al., 2022). The absence of long-term PCCRC evidence reflects the expected follow-up time required, not a lack of benefit. • Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. New England Journal of Medicine. 2014 Apr 3;370(14):1298–306. • Cross AJ, Robbins EC, Saunders BP, Duffy SW, Wooldrage K. Higher Adenoma Detection Rates at Screening Associated With Lower Long-Term Colorectal Cancer Incidence and Mortality. Clinical Gastroenterology and Hepatology [Internet]. 2020 Sep 11;0(0). Available from: https://www.cghjournal.org/article/S1542-3565(20)31280-5/fulltext	The EAG acknowledges Medtronic's comments about benefits of GI Genius on ADR, including right-sided and serrated lesions; however, it should be noted that similar results for overall ADR and right-sided/proximal ADR were observed for other technologies, and overall meta-analysis for SSLs were not statistically significant for most technologies, including GI Genius. Furthermore, the number of studies reporting right-sided ADR and SSL detection data is much reduced compared to overall ADR. Please see response to Comment 6 regarding the link between ADR and PCCRC.

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59	Consultee 2 Joint Advisory Group for Gastrointestinal Endoscopy (JAG)	Has all of the relevant evidence been taken into account?	Answering on behalf of the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). Mostly, although new studies are published almost every month.	Thank you. These will be picked up the next time the guidance is updated.
60	Consultee 3 Medtronic	1.1 Can be used during the evidence generation period to help detect colorectal polyps	The link to the evidence generation plan does not work	Thank you. This will be fixed when the guidance is published.
61	Consultee 3 Medtronic	1.6 For people with diagnosed IBD or Lynch syndrome	We fully align with NICE's position that AI technologies must only support, not replace, endoscopist review. GI Genius is designed to provide real-time assistance in identifying and characterising potential colorectal polyps, while ensuring that all clinical interpretation and decision making remain with the endoscopist.	Thank you, there is almost universal agreement on this.