



## Innovative Medical Technology Overview | April 2025

# Artificial intelligence (AI)-assisted lower gastrointestinal (GI) endoscopy

### Key messages

- Evidence suggests that the use of AI-assisted lower GI endoscopy (colonoscopy) can improve the rates of detection and missed adenomas and polyps in people referred for screening, surveillance or symptomatic colonoscopy, but may slightly lengthen withdrawal time (time from reaching the cecum until removal of the endoscopy), compared with routine colonoscopy.<sup>1-9</sup>
- Use of AI-assisted lower GI colonoscopy may increase the number of non-neoplastic lesions removed during a procedure,<sup>2</sup> but no other adverse events (AE) were reported from using AI.<sup>4, 8, 9</sup>
- An economic evaluation by Health Technology Wales (HTW) found that AI-assisted colonoscopy (computer-aided detection endoscopy) was cost-effective compared with standard colonoscopy. HTW estimated an incremental cost-effectiveness ratio (ICER) of £4,197 per quality adjusted life-year (QALY). The analysis was based on the lifetime costs and QALYs associated with the consequences of polyps being missed during standard colonoscopy that would not have been missed using computer-aided detection endoscopy. Any cost savings are likely to be realised over the long term.<sup>2</sup>
- A small focus group including staff and patients found that the benefits of AI-assisted lower GI colonoscopy were perceived as earlier identification and diagnosis of cancer, as well as reduced need for repeat procedures. Their concerns include the de-skilling of professionals, complacency and loss of human interaction.<sup>2</sup>
- Benefits of AI-assisted lower GI colonoscopy from the perspective of endoscopists include an improvement in adenoma detection rate (ADR), polyp detection rate (PDR) and quality of the procedure. Barriers to implementation include cost, accessibility and lack of guidelines.<sup>10</sup>
- The impact of AI-assisted lower GI colonoscopy on outcomes such as lower GI cancer incidence and mortality, system changes, equality and sustainability is unclear.
- The effectiveness of different AI systems is unknown.

## Definitions

**AI:** an umbrella term for a range of algorithm-based technologies that attempt to mimic human thought to solve complex tasks. In healthcare, AI can be used to spot early signs of illness and to diagnose disease.<sup>11</sup>

**Colonoscopy:** procedure in which a flexible tube with an integrated camera is used to view the rectum and colon (upper and lower).<sup>12</sup>

**Colorectal adenoma:** a type of polyp (abnormal growth) that forms on the inner lining of the rectum or colon. These are not cancer but are more likely to become cancer than other types of polyp if they are not removed.<sup>13</sup>

**Colorectal lesion:** a broad term encompassing any abnormality of the lining of the colon or rectum. This includes polyps, tumours and ulcers.

**Colorectal polyp:** small growths on the lining of the colon or rectum. Colorectal polyps are common and not usually serious but can sometimes lead to bowel cancer if not removed.<sup>14</sup>

**Computer-aided detection (CADe) and computer-aided diagnosis (CADx):** computer-aided detection and diagnosis systems aim to assist in the detection or diagnosis of diseases by providing a 'second opinion' for clinicians. CADe systems are designed to locate lesions on medical images. CADx systems can characterise lesions they find on medical images, for example distinguishing between benign and malignant tumours.<sup>15</sup>

**Flexible sigmoidoscopy:** procedure in which a flexible tube with an integrated camera is used to view the rectum and lower colon.<sup>16</sup>

**Sessile-serrated lesion (SSL):** a sub-type of polyp in the colon that is slightly flattened and has a serrated appearance.<sup>17</sup>

## The technology and its use

An endoscopy of the colon is called a colonoscopy. During a colonoscopy procedure, a flexible tube that incorporates a small camera and light are inserted into the rectum, capturing real-time video images. An endoscopist reviews these images to look for signs of pre-cancer or cancer. If any polyps or lesions are considered high-risk and cause for concern, they can be biopsied or resected during the procedure.<sup>2</sup>

AI-assisted colonoscopy incorporates diagnostic software algorithms into the procedure to support the endoscopist with deciding whether polyps and lesions should be considered high-risk. Many AI-assisted colonoscopy systems are CAdE systems that highlight areas of potential concern to the endoscopist. The endoscopist will then decide whether the area of concern should be removed or biopsied. CAdE systems may also have CAdx capabilities to characterise polyps as cancerous or not.<sup>2</sup>

### What is innovative about the technology?

In a standard colonoscopy procedure, the endoscopist visualises abnormalities using camera images transferred to a screen. AI-assisted colonoscopy offers a new tool that can flag potential abnormalities during the colonoscopy procedure. AI-assisted colonoscopy is intended to improve detection rates of pre-cancerous polyps compared with standard colonoscopy. If detection rates are improved, this may reduce incidence of colorectal cancers.<sup>18</sup>

### Regulatory information

There are AI-assisted lower GI colonoscopy systems with regulatory approval for use in Scotland. The following AI systems are currently in use in NHSScotland:

- NHS Grampian, NHS Lanarkshire, NHS Tayside: GI-Genius™ intelligent endoscopy module (Medtronic), class IIa CE marked medical device
- NHS Ayrshire & Arran: ENDO-AID CAdE™ (Olympus), class I CE marked medical device.

### Population, setting and intended use

#### Population

Public Health Scotland (PHS) published an epidemiological report on lower GI cancer as part of their work to support the AI endoscopy value case for ANIA.<sup>19</sup> We have permission to use the executive summary of their report here.

Colorectal (bowel) cancer is the fourth most common cancer in Scotland, with over 4,300 cases diagnosed each year in 2022. Scotland has a higher rate of bowel cancer than most other countries in the Western World.<sup>20</sup>

Risk factors include diet, lack of physical exercise, obesity, smoking tobacco, alcohol consumption and family history.<sup>21</sup>

Survival rates have improved over time, with almost 60% of people diagnosed with colorectal cancer surviving for at least 5 years. Survival is linked to disease stage at presentation, with better survival the earlier the disease is detected and treated. Despite improving survival rates, colorectal cancer was the second most common cause of death from cancer in Scotland in 2021.

The number of continuous inpatient stays in hospital for Scottish residents with a main diagnosis of colorectal cancer was over 14,200 stays in 2022/23; the average length of stay was just under 4 days. The total colorectal cancer burden in 2019 was ranked as the eleventh leading cause of burden of disease overall in Scotland, and the eighth leading contributor to fatal burden.<sup>19</sup>

**Setting and intended use**

There are three referral routes for colonoscopy in NHSScotland, as outlined in *Table 1*. The colonoscopy procedure is delivered in secondary care.

*Table 1: Patient subpopulations (screening, surveillance, symptomatic) eligible for colonoscopy referral in Scotland*

Patient referral route	Description
Screening	<ul style="list-style-type: none"> <li>■ Eligible people aged 50 to 74 years are invited every 2 years to complete a faecal immunochemical test (FIT) for haemoglobin, as part of the Bowel Screening Programme.<sup>22</sup></li> <li>■ A person is referred for colonoscopy if ≥80 micrograms haemoglobin per gramme of faeces is detected in their FIT sample.<sup>23</sup></li> <li>■ In 2022, 35% of colorectal cancers were diagnosed via screening in this eligible group.<sup>24</sup></li> </ul>
Surveillance	<ul style="list-style-type: none"> <li>■ People at higher risk of colorectal cancer (CRC) are followed up at specific intervals depending on initial risk identified. For example:               <ul style="list-style-type: none"> <li>○ patients who have received CRC resection should undergo a 1 year clearance colonoscopy, then a surveillance colonoscopy after 3 years</li> <li>○ identification of multiple polyps may warrant a follow-up colonoscopy in 3 years</li> <li>○ identification of a large non-pedunculated colorectal polyp may warrant a site check follow-up between 2 to 6 months, then one at 12 months and a follow-up colonoscopy 3 years later.<sup>25</sup></li> </ul> </li> </ul>

Patient referral route	Description
Symptomatic	<ul style="list-style-type: none"> <li data-bbox="416 235 1374 353">■ People who present to primary care and are experiencing new colorectal symptoms that are considered high-risk will be referred for colonoscopy.<sup>26</sup></li> <li data-bbox="416 376 1310 452">■ High-risk colorectal symptoms include bleeding, change in bowel habits, pain with weight loss and iron-deficient anaemia.<sup>26</sup></li> </ul>

## Equality considerations

Lower GI cancer includes CRC and anal cancers. Equality considerations per cancer type include age, sex, ethnicity and deprivation. AI biases (described below) should also be considered.

### CRC

Between 2017 to 2019, the following rates were observed for the United Kingdom (UK):

- incidence rates for CRC were highest for people aged 85 to 89 years<sup>27</sup>
- 44% of cases were observed in females and 56% in males<sup>27</sup>
- European age-standardised incidence rates were significantly higher in Scotland (75.1 per 100,000), compared with other UK countries (England 69.1 per 100,000; Wales 72.8 per 100,000; Northern Ireland 72.8 per 100,000).<sup>27</sup>

Between 2013 and 2017, higher European age-standardised incidence rates were observed for females across deprivation quintiles and significantly higher rates were observed for males in the most deprived quintile, compared with the least (82.4 per 100,00 compared with 90.1 per 100,000).<sup>27</sup>

### Anal cancer

Between 2017 and 2019, the following rates were observed for the UK:

- incidence rates for anal cancer were highest for people aged 80 to 89 years<sup>28</sup>
- 66% of cases were observed in females and 34% in males<sup>28</sup>
- European age-standardised incidence rates were similar across UK countries (Scotland 2.5 per 100,000; England 2.5 per 100,000; Wales 2.7 per 100,000; Northern Ireland 2.1 per 100,000)<sup>28</sup>
- age-standardised mortality rates were significantly higher in females (linked to sex differences in incidence) compared with males (0.8 per 100,000 compared with 0.6 per 100,000), and higher in Scotland (0.9 per 100,000) compared with other UK

countries (England 0.7 per 100,000; Wales 0.8 per 100,000; Northern Ireland 0.5 per 100,000).<sup>29</sup>

Between 2013 to 2017, higher European age-standardised incidence rates were observed for people in the most deprived quintile, compared with the least, for females (2.3 per 100,000 compared with 3.7 per 100,000) and males (1.3 per 100,000 compared with 2.4 per 100,000).<sup>28</sup>

For people with lower GI cancers in the UK, higher European age-standardised mortality rates were observed in the most deprived quintile, compared with the least, for females (25% higher) and males (31% higher).<sup>30</sup>

For people with lower GI cancer, we identified one study that suggested that populations categorised as white may have a higher incidence of CRC.<sup>31</sup> In this study, a lower number of outcomes were recorded for people from a range of ethnic categories and backgrounds, which may introduce bias into these findings.

We also identified a study that suggests that early onset CRC is more common in people from Asian ethnic, black ethnic, mixed and multiple ethnic groups, compared with people categorised as white, but there may be confounding factors within the sample.<sup>32</sup> For example, we have reported these terms for ethnic categories as they were used in the study, but often a variety of ethnic backgrounds, experiences and socioeconomic circumstances are contained within these broad terms. Inconsistency of the findings and limitations with the methodology limit the conclusions that can be drawn.

### **AI bias**

AI tools can develop biases in their creation and training if the data used to train the AI are not diverse and representative of the local clinical population. For example, if the AI software is trained on data that includes mostly information for one ethnic group, the AI cannot be guaranteed to work as well for people from other ethnic groups.<sup>33, 34</sup>

Automation bias may also be introduced through use of AI-assisted lower GI colonoscopy. Automation bias refers to an over reliance on the technology by clinicians, leading to complacency and reduced human detection of pathology.<sup>35-37</sup>

We did not identify any studies that described the equality impact of AI-assisted lower GI colonoscopy.

## **Summary of clinical evidence**

To inform this Innovative Medical Technology Overview (IMTO), we used and updated the health technology assessment (HTA) produced by HTW in 2024.<sup>1, 2</sup> Additional publications identified were an HTA by the Canadian Drug Agency (CDA)<sup>3</sup>, four systematic reviews<sup>5-8</sup> and two randomised controlled trials (RCTs).<sup>4, 9</sup> The available evidence focuses on CADe AI systems.

## Published evidence

### HTA

In 2024, HTW published an HTA and guidance for NHS Wales on AI-assisted colonoscopy in the detection of lower GI and pre-cancerous lesions.<sup>1, 2</sup> The HTW HTA reviewed four systematic reviews of RCTs and seven additional trials published after the reviews (total of 39 RCTs, total n=32,217) that compared AI-assisted lower GI colonoscopy with routine colonoscopy.<sup>2</sup> The HTW HTA summarised patient, system and safety outcomes from the use of AI-assisted colonoscopy (*Table 2*).

*Table 2: Patient, system and safety outcomes identified by the HTW HTA<sup>2</sup>*

Outcome	HTW HTA summary
Patient	<p>Detection:</p> <ul style="list-style-type: none"> <li>■ improvement in adenoma, polyp and SSL detection rates in AI-assisted lower GI colonoscopy group compared with the control group</li> <li>■ improvement in detection rates may vary by experience of the endoscopist, as well as the risk of adenoma but the results are exploratory and should be interpreted with caution</li> <li>■ no evidence for a difference in carcinoma detection rate between groups.</li> </ul>
System	<p>Withdrawal and procedure time:</p> <ul style="list-style-type: none"> <li>■ mixed results, but any reported differences were small.</li> </ul> <p>Technology performance:</p> <ul style="list-style-type: none"> <li>■ in studies where participants received AI-assisted, as well as standard lower GI colonoscopy (tandem studies), lower rates of missed adenomas and SSL were reported when AI-assisted lower colonoscopy was conducted first, but no differences were reported for advanced adenoma miss rate</li> <li>■ mixed results were reported for false positives and negatives (reduction and no difference)</li> <li>■ sensitivity was higher for inexperienced endoscopists during AI-assisted lower GI colonoscopy (no differences in specificity).</li> </ul>
Safety	<ul style="list-style-type: none"> <li>■ one systematic review of 14 RCTs noted that the detection and removal of non-neoplastic polyps was higher in the AI-assisted lower GI colonoscopy group compared with routine colonoscopy</li> <li>■ no other AEs were reported.</li> </ul>

HTW noted that the available evidence only focused on short-term outcomes, that the size of the effect for most outcomes was imprecise and that the following was unknown:

- the impact of AI-assisted colonoscopy systems on certain patient groups, for example people with irritable bowel disease or CRC
- the performance of AI-assisted colonoscopy systems during flexible sigmoidoscopy.

Based on the results of their HTA, HTW issued the following guidance to NHS Wales:

*'The evidence supports the routine adoption of computer-aided detection (CADe) colonoscopy for the detection of lower gastrointestinal cancer and pre-cancerous lesions.*

*Compared with standard colonoscopy, CAdE is associated with improved detection of adenomas, polyps, and sessile-serrated lesions, without considerable increases to withdrawal time.*

*Economic modelling suggests that CAdE is cost-effective compared with standard colonoscopy with an incremental cost-effectiveness ratio (ICER) of £4,197 per quality adjusted life-year (QALY) gained.*

*HTW recommends the collection of data on the real-world implementation and effectiveness of CAdE.<sup>1</sup>*

In 2024, CDA published a rapid HTA on the use of AI-assisted lower GI colonoscopy for detecting polyps, adenomas, pre-cancerous lesions and CRC.<sup>3</sup> The evidence assessed included the HTW HTA, plus three systematic reviews (37 RCTs, 12 non-randomised studies, total n=35,924) and one RCT (n=800) that were not included in the HTW HTA.

CDA reported that AI-assisted lower GI colonoscopy may improve ADR (the number of adenomas detected per procedure) as well as adenoma miss rate (AMR, number of adenomas missed), compared with routine colonoscopy without AI. The results of the studies were mixed but overall suggest that use of AI-assisted lower GI colonoscopy may increase withdrawal times (time between imaging the cecum and completing the colonoscopy procedure).

None of the included studies reported long term outcomes such as CRC incidence or mortality. The relative clinical effectiveness of different types of AI systems for colonoscopy (that is, compared with each other) is unknown.<sup>3</sup>

## Systematic reviews

We identified four systematic reviews published since the HTW HTA.<sup>5-8</sup> All four reported clinical effectiveness outcomes from studies that compared AI-assisted lower GI colonoscopy with routine colonoscopy (no AI) and included mixed populations (screening, surveillance or



symptomatic). The four systematic reviews included a total of 94 RCTs with 75,465 participants. There was overlap in the included studies across all reviews (that is, the same studies were used in multiple reviews). The available evidence focuses on AI systems that enable detection (CADE) rather than diagnosis (CADx).

### **Detection rate**

Three reviews (88 RCTs, n=73,747) reported a statistically significantly higher ADR in the AI-assisted lower GI colonoscopy group compared with routine colonoscopy<sup>5, 7, 8</sup> and two reviews (60 RCTs, n=49,886) reported a statistically significantly higher PDR in the AI-assisted lower GI colonoscopy group compared with routine colonoscopy (see *Appendix 2, Table 1* for statistics).<sup>7, 8</sup>

### **Withdrawal time**

Two reviews (72 RCTs, n=60,062) reported that the AI-assisted lower GI colonoscopy procedure resulted in a statistically significantly longer withdrawal time compared with routine colonoscopy (see *Appendix 2, Table 1* for statistics).<sup>5, 8</sup> The difference in withdrawal times was measured in seconds. It is unclear if this difference is clinically important as well as statistically significant.

### **Technology performance**

Three reviews (88 RCTs, n=73,747) reported that the AMR was statistically significantly lower in the AI-assisted lower GI colonoscopy group, compared with routine colonoscopy.<sup>5, 7, 8</sup> One review (six RCTs, n=1,718) noted that AMR and polyp miss rate (PMR) was statistically significantly lower in the AI-assisted lower GI colonoscopy group, compared with routine colonoscopy, for both screening and surveillance populations.<sup>6</sup> Two reviews (34 RCTs, n=25,579) did not identify any differences between groups for sessile-serrated lesion miss rate (SSLMR)<sup>5, 6</sup> and one review (28 RCTs, n=23,861) did not identify any differences between groups for AMR (see *Appendix 2, Table 1* for statistics).<sup>5</sup>

## **Primary research**

We identified two RCTs published since the HTW HTA and not included in the systematic reviews described above.<sup>4, 9</sup> Both RCTs (total n=2,134) reported clinical effectiveness outcomes for studies that compared AI-assisted lower GI colonoscopy with routine colonoscopy (no AI) and included a mixed population (screening, surveillance or symptomatic). One study (n=102) used the CAD EYE AI system<sup>9</sup>, while the other study (n=2,032) used the GI-Genius™ AI system.<sup>4</sup> The available evidence focuses on AI systems that enable detection (CADE) rather than diagnosis (CADx).

## Detection rate

One RCT (n=2,032) reported a statistically significantly higher ADR in the AI-assisted lower GI colonoscopy group compared with routine colonoscopy, with similar results observed in screening and symptomatic subpopulations.<sup>4</sup> Another RCT (n=102) did not identify any differences between groups.<sup>9</sup> A statistically significant increase in PDR was noted in the AI-assisted lower GI colonoscopy group compared with routine colonoscopy<sup>9</sup> as well as for sessile-serrated lesion detection rate (SSLDR)<sup>4</sup> (see *Appendix 2, Table 2* for statistics).

## Withdrawal time

Neither RCT found any differences between the study groups in the time taken to insert the endoscope or withdraw it.<sup>4,9</sup> One RCT (n=2,032) reported a statistically significantly longer mean total procedure time of one minute and 28 seconds for the AI-assisted lower GI colonoscopy group compared with routine colonoscopy, in participants without polyps (see *Appendix 2, Table 2* for statistics).<sup>4</sup>

## Ongoing studies

Four unpublished systematic reviews and 11 unpublished primary studies (two completed and nine ongoing) were identified. We did not identify any reported findings from the two completed studies. All ongoing studies are examining multiple clinical effectiveness outcomes. One of the ongoing RCTs includes three study sites in NHSScotland trialling GI-Genius™ (NHS Grampian, NHS Lanarkshire and NHS Tayside, see *Appendix 3, Tables 1 and 2*).

The National Institute for Health and Care Excellence (NICE) is due to publish guidance for the use of AI in helping to detect and characterise colorectal polyps in 2026.<sup>38</sup>

## Summary of safety evidence

We identified one HTA, one systematic review with meta-analysis and two RCTs that discussed safety outcomes associated with use of AI-assisted lower GI colonoscopy.<sup>1,4,8,9</sup> In their evidence appraisal, HTW noted that one systematic review (14 RCTs, n not reported) found that more non-neoplastic lesions were removed per colonoscopy in AI-assisted lower GI colonoscopy groups compared with routine colonoscopy groups.<sup>2</sup> No other differences in AEs were reported. The systematic review and two RCTs did not report a significant difference in AEs associated with use of AI-assisted lower GI colonoscopy.<sup>4,8,9</sup>

# Summary of economic evidence

## Technology costs

Table 3: Technology costs for colonoscopy per patient and costs associated with CADe

Description	Units	Cost	Source
Colonoscopy per patient	1	£745	NHS England (2023) day case diagnostic colonoscopy, 19+ (FE32Z) <sup>39</sup>
CADe system	1	£42,554	HTW HTA <sup>2</sup>
CADe uses per month	71	-	
CADe system life expectancy (years)	4	-	
CADe per patient	-	£12.49	

## Published data

The only economic evidence we found that was relevant to the research question was the HTW HTA. We found one additional economic evaluation published since the HTW HTA, but it was less relevant as it considered CADx in a non-UK setting.<sup>40</sup>

HTW assessed the cost-effectiveness of CADe compared with routine colonoscopy for the detection of lower GI cancer and pre-cancerous lesions, based on a review of the economic literature and a de novo cost-utility analysis.<sup>2</sup>

HTW identified six economic studies. A study from the UK perspective compared CADx to routine colonoscopy and reported that CADx was associated with lower costs than routine colonoscopy, because fewer polypectomies were required. Limitations in the study were that not all relevant costs and health outcomes were included.

The other five studies included in the HTW HTA were from non-UK settings and compared CADe to routine colonoscopy. These studies reported that CADe was either cost-effective at conventional willingness to pay thresholds or dominant (that is, cost saving and more effective) compared with standard colonoscopy.

HTW conducted a de novo economic model from the perspective of the UK NHS, considering the results of their meta-analysis, as well as the lifetime costs and QALYs associated with the consequences of missing polyps during colonoscopy. The population included in the model was people referred for a diagnostic colonoscopy for any reason.

The analysis was not conducted for clinically meaningful subgroups (that is, patients with symptoms suggestive of CRC with or without a positive FIT, or those participating in a bowel cancer screening or surveillance programme) because the studies included in the meta-analysis did not provide data on these subgroups of patients.

The analysis used a decision tree model where, following the initial routine colonoscopy or CAdE, patients were stratified according to whether: nothing was detected with either strategy; polyps were detected with either strategy; or polyps were detected only with CAdE. The number of people within the latter group depended on the difference in ADR from the HTW meta-analysis (risk ratio (RR) 1.23). The remainder of the model considered only costs and consequences in patients who would have polyps detected with CAdE, but not with the standard colonoscopy.

Patients in the model who had polyps detected only with CAdE could be found to have low-risk adenoma (LRA) or HRA. The model assumed no improvement in the detection of CRC because no studies showed improved detection of CRC with CAdE. The proportion of patients with polyps that were LRA and HRA was assumed to be equal to the prevalence of LRA and HRA in the adenoma population reweighted to exclude CRC prevalence (91% and 9%, respectively).<sup>41</sup>

Patients in the model who had a HRA detected with CAdE that would not be detected with the routine colonoscopy were assumed to avoid a 1.5 year delay to diagnosis. This was in line with assumptions in an economic evaluation that informed a previous NICE diagnostic guidance for quantitative immunochemical testing to guide CRC pathway referral in primary care (DG56).<sup>42</sup> Patients who had LRA detected only with CAdE were assumed to avoid progression to more serious disease. HTW incorporated an annual disease progression probability for LRA not progressing, or progressing to HRA or CRC, at rates estimated by the MiMiC-Bowel model.

Disease progression was modelled for the time up to invitation to bowel cancer screening (BCS) which is every 2 years in the UK in the modelled population (average age 57 years).<sup>43</sup> At BCS, a proportion of patients who had developed HRA (36%) or CRC (58%) were detected at rates derived from the BCS uptake rate (67%)<sup>44</sup>, and the proportion of advanced adenomas and CRC detected by colonoscopy (93% and 97%, respectively).<sup>42</sup> If HRA and CRC were detected at BCS, then consequences for detection without delay from the MiMiC-Bowel model were applied; cases missed at BCS were assumed to be detected following a further delay of 1.5 years.

People with LRA were modelled to continue progressing to HRA following BCS for the remainder of the model lifetime time horizon, with HRA assumed to be detected immediately.

Technology costs were included in the model (*Table 3*).

Lifetime costs and QALYs from NICE DG56 were assigned to short-term outcomes in the model (*Table 4*).<sup>42</sup> These estimates were based on unpublished data provided to HTW for the purposes of the analysis and inflated to the current price year. Delayed diagnosis of HRA led to higher long term costs but was assumed not to have an impact on health-related quality of life.

Delayed diagnosis of CRC led to lower long term costs, due to the lower cost of treatment options at later stages of disease at diagnosis, but relatively larger long term QALY loss (Table 4).

*Table 4: Long term consequences of HRA and CRC, costs and QALYs from the HTW evidence appraisal<sup>2</sup>*

Description	Cost	QALYs
Lifetime following CRC diagnosis without delay	£24,866	5.81
1.5 year delay to CRC diagnosis	-£3,525	-1.00
Lifetime following HRA diagnosis without delay	£395	10.36
1.5 year delay to HRA diagnosis	£819	-0.05

Costs were also included for polypectomy, removal of non-neoplastic lesions, initial gastroenterology consultation and gastroenterology follow-up and AEs of colonoscopy (serious bleeding and perforation). Rates of AEs did not differ between arms of the model. Costs associated with the implementation of CADe in the NHS were not included, for example the cost of training endoscopists, as these were assumed to be a small component of the per patient cost.

The results of the HTW economic model found that CADe was associated with ICER of £4,197 per QALY gained compared with routine colonoscopy. The incremental per patient pathway cost (£2.84) and QALY gain (0.0007) were small. Additional costs associated with the CADe pathway included acquiring the CADe system and removal of additional polyps and non-neoplastic lesions. The additional costs were offset by avoidance of delays to diagnosis and progression of undetected LRA.

A range of sensitivity analyses were conducted. Scenarios that resulted in an ICER greater than £20,000 per QALY were when:

- additional polyps identified by CADe were LRA only
- undetected LRA progression was only included up to the first BCS interval (2 years)
- the full cost of polypectomy was included for the removal of each non-neoplastic lesion.

Most scenarios tested in the sensitivity analyses found that CADe was the dominant strategy, that is, was less costly and more effective. Scenarios included, modelling efficacy using AMR (RR 0.46 versus 34% AMR with comparator), increasing the prevalence of HRA amongst additional polyps detected by CADe, and with lower costs of the CADe system compared to that in the base case analysis.

In threshold analysis CADe was dominant at a CADe cost below £9.35 per patient and remained cost-effective (ICER <£20,000 per QALY gained) with a CADe cost of up to £23 per patient.

The per patient cost of CADe depends on the purchase price and the number of uses per system over its lifetime.

The HTW model appears to align with Scottish clinical practice and suggested that CADe is likely to represent an efficient use of NHSScotland resources.

HTW did not present a shorter time horizon due to how costs and consequences were apportioned in the model but a scenario that limited LRA progression up to the first BCS interval resulted in an estimate of cost-effectiveness that exceeded traditional willingness to pay thresholds. This indicates that cost savings from identifying additional polyps using CADe may only accrue over the long term.

The HTW model may represent a conservative estimate of the cost-effectiveness of CADe. For instance, the analysis did not include the consequences of detecting additional SSLs with CADe, missed HRA could not develop into an interval CRC, and HRA that developed after the first BCS were discovered without delay and did not develop into an interval CRC.

The model by HTW does not provide disaggregated costs of avoided CRC or HRA, nor does it indicate when these cost savings would occur. There may be cash releasing savings included in avoidance of CRC such as the costs of pharmaceutical and surgical products. Also, the model does not estimate the number of CRC avoided beyond the first BCS interval and may underestimate the number of CRC avoided due to additionally identified HRA.

An updated economic model that provides the information necessary for the Scottish context should estimate the number of interval CRC prevented, disaggregate cost savings, identify where and when cost savings occur, their magnitude and the extent to which these are cash releasing over a time horizon relevant to decision makers. This analysis would require data for several key model parameters for a Scottish context (*Table 5*) to capture the value proposition of CADe to NHS Scotland (*Table 6*).

Table 5: Data requirements for key model parameters

Parameter
■ number of endoscopy suites performing colonoscopy in NHS Scotland
■ number of colonoscopies performed per month per endoscopy suite in NHS Scotland
■ cost of CADe software per patient in NHS Scotland
■ progression rates of SSLs
■ interval CRC by stage that are diagnosed before next BCS interval
■ CRC detected at BCS by stage
■ average annual costs of CRC by stage at detection (disaggregated)
■ bowel screening uptake rate in Scotland
■ disease specific mortality of CRC by stage at detection.

Table 6: Value proposition of CADe to NHSScotland

Value proposition components
■ A higher detection rate of lower gastrointestinal cancer and pre-cancerous lesions compared to endoscopy without AI assistance could lead to improved patient outcomes through detection of cancers at an earlier stage and a reduction in CRC rates to a level more akin to other Western countries.
■ A reduction in CRC rates could lead to lower treatment costs for the NHS. Treatment costs for CRC include costs associated with surgery, health care resource use and medication. While some surgical costs (such as costs for surgical equipment) could be cash releasing, most medicine costs would likely be cash releasing.
■ Cost savings associated with reductions in CRC rates with AI-assisted endoscopy could offset increased costs for AI software acquisition, implementation and increases in polypectomies and biopsies caused by the higher detection rate.

## Patient and staff experience

The HTW HTA discussed patient perceptions of the use of AI-assisted lower GI colonoscopy.<sup>2</sup> We identified an additional cross sectional mixed methods survey on staff perspectives.<sup>10</sup>

### Patients

In their evidence appraisal, HTW partnered with Velindre NHS Trust to run two focus groups with current and former CRC patients, their families, and carers (n=22). The purpose of the focus groups was to explore the understanding, experiences and expectations of AI in healthcare generally, as well as acceptance of its use in lower GI colonoscopy in attendees.

During discussions, people expressed concerns regarding adoption of AI-assisted colonoscopy. Concerns included the potential for de-skilling of the practitioner with an increased reliance on AI, the introduction of complacency, potential loss of human interaction and a need for reassurance with procedures being passed from clinician to AI. Following discussion of these concerns, attendees received information about the purpose of AI in colonoscopy, with information highlighting that clinicians would always make final decisions regarding care. Attendees reported that they felt reassured by this. All attendees stated that they would be happy to undergo an AI colonoscopy in the future if one was required. Benefits of using AI-assisted colonoscopy were then discussed, which included the potential for earlier identification and diagnosis of cancer, as well as reduced need for repeat procedures.<sup>2</sup>

## Endoscopy staff

A 2024 UK-based survey of 75 endoscopists highlighted benefits of using AI, including improvement in ADR, PDR, as well as quality of the procedure. Barriers identified by clinical staff included cost, accessibility and lack of guidelines. Clinical staff felt that the highest priority area of impact of AI would be in video capsule colonoscopy, with use in lower GI colonoscopy rated as the least priority area.

Clinical staff were not familiar with use of AI and no consensus was identified on the need for AI in colonoscopy. The survey authors highlighted the need for large RCTs to inform evidence-based guidelines and assessments of the costs and benefits of AI-assisted lower GI colonoscopy.<sup>10</sup>

## Conclusions

There is evidence that the use of AI-assisted lower GI colonoscopy can improve detection rates (AMR, PDR) and reduce miss rates (AMR, PMR) compared with routine colonoscopy. Use of AI-assisted lower GI colonoscopy may lead to more non-neoplastic lesions being removed per colonoscopy in AI-assisted colonoscopy groups, but no other AEs were identified in the literature.

For cost-effectiveness, HTW estimated that CADe is likely be cost-effective and is associated with an ICER of £4,197 per QALY. In some scenario analyses conducted by HTW, CADe were less costly and more effective than standard colonoscopy. Cost savings from avoiding the adverse consequences of missing polyps will only be realised over the long term.

Patients and staff in UK-based studies have identified benefits, as well as barriers to adopting AI-assisted lower GI colonoscopy, which would need to be addressed to promote buy-in for national adoption of the technology in NHSScotland. For patients, identified benefits of using AI-assisted lower GI colonoscopy included potential for earlier identification and diagnosis of cancer, as well as reduced need for repeat procedures. Identified barriers included increased reliance on AI, introduction of complacency, potential loss of human interaction and reassurance with procedures being passed from clinician to AI.



For endoscopists, benefits of using AI-assisted lower GI colonoscopy included improved detection rate and quality of the procedure. Barriers included cost, accessibility and lack of guidelines.

It is unclear how clinical effectiveness outcomes may vary by patient subpopulation (for example, screening, surveillance or symptomatic patients) or type of AI system. It is also unclear what impact AI-assisted lower GI colonoscopy could have on:

- long term outcomes such as CRC (including anal cancer) incidence and mortality
- system outcomes such as throughput and endoscopist workload
- equality outcomes
- sustainability outcomes.

Ongoing primary and secondary research will help strengthen the evidence base for clinical effectiveness and cost-effectiveness, with local evaluations likely to provide valuable insight into the impact of AI-assisted lower GI colonoscopy in Scotland.

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### Healthcare Improvement Scotland development team

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## What is an IMTO?

An Innovative Medical Technology Overview (IMTO) provides a high-level summary of health and care innovations. IMTOs include a description of the technology and its potential use in Scotland, and an overview of the evidence to help gauge the potential impact of the technology on people and health and care services.

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## Appendix 1: abbreviations

<b>ADR</b>	adenoma detection rate
<b>AE</b>	adverse event
<b>AI</b>	artificial intelligence
<b>AMR</b>	adenoma miss rate
<b>ANIA</b>	Accelerated National Innovation Adoption
<b>BCS</b>	bowel cancer screening
<b>C</b>	comparator(s)
<b>CADe</b>	computer-aided detection
<b>CADx</b>	computer-aided diagnosis
<b>CDA</b>	Canadian Drug Agency
<b>CI</b>	confidence interval
<b>CRC</b>	colorectal cancer
<b>DG</b>	diagnostic guidance
<b>FIT</b>	faecal immunochemical test for haemoglobin
<b>FN</b>	false negative
<b>FP</b>	false positive
<b>GI</b>	gastrointestinal
<b>GRADE</b>	Grading of Recommendations, Assessment, Development and Evaluation
<b>HD-WL</b>	high-definition white light
<b>HRA</b>	high-risk adenomas
<b>HTA</b>	health technology assessment
<b>HTW</b>	Health Technology Wales
<b>I</b>	intervention
<b>ICER</b>	incremental cost-effectiveness ratio
<b>IMTO</b>	innovative medical technology overview
<b>LRA</b>	low-risk adenomas
<b>NICE</b>	National Institute for Health and Social Care
<b>NHS</b>	National Health Service
<b>NPV</b>	negative predictive value

<b>P</b>	population
<b>PDR</b>	polyp detection rate
<b>PHS</b>	Public Health Scotland
<b>PMR</b>	polyp miss rate
<b>QALY</b>	quality adjusted life-years
<b>RCT</b>	randomised controlled trial
<b>RR</b>	risk ratio/relative risk
<b>SD</b>	standard deviation
<b>SSL</b>	sessile-serrated lesion
<b>SSLDR</b>	sessile-serrated lesion detection rate
<b>SSLMR</b>	sessile-serrated lesion miss rate
<b>UK</b>	United Kingdom
<b>USA</b>	United States of America



## Appendix 2: summary tables for published studies

Table 1: Summary of systematic reviews reporting patient and system outcomes that have been published since the HTW HTA.<sup>2</sup> Studies compare AI-assisted lower GI colonoscopy with routine colonoscopy (without AI) in mixed populations (screening, surveillance, or symptomatic)

Study information	Outcomes			
	Detection rate	Withdrawal time	Technology performance	Quality of the evidence
<p>Maida et al (2025)<sup>6</sup></p> <p>6 RCTs</p> <p>n=1,718</p>	Not applicable	Not applicable	<p>PMR: lower in AI-assisted colonoscopy first arm compared with routine colonoscopy first arm overall (AI group=16.3% compared with 38.1% in the control arm, RR=0.44, 95% confidence interval (CI) 0.33 to 0.60, p&lt;0.001, I<sup>2</sup>=77%) and in screening and surveillance populations (AI=17.3% compared with 36.4% in the control group, RR=0.50, 95% CI 0.37 to 0.66, p&lt;0.001, I<sup>2</sup>=67%).</p> <p>AMR: lower in AI-assisted colonoscopy first compared with routine colonoscopy first arm (AI group=15.3%</p>	<p>There was a high-risk of bias for all studies overall and in the measurement of the outcomes as assessed by the Cochrane Risk Bias 2 Tool. Bias was related to the operator not being blinded and being aware of the technology used.</p>

Study information	Outcomes			
	Detection rate	Withdrawal time	Technology performance	Quality of the evidence
			<p>compared with 34.1% in the control arm, RR=0.46, 95% CI 0.38 to 0.55, p&lt;0.001, I<sup>2</sup>=18%) overall and in screening and surveillance populations (AI=15.6% compared with 33.33% in the control group, RR=0.48, 95% CI 0.39 to 0.58, p&lt;0.001, I<sup>2</sup>=12%).</p> <p>SSLMR: no difference between groups (RR=0.44, 95% CI 0.15 to 1.28, p=0.13, I<sup>2</sup>=46%).</p>	
<p>Makar et al (2025)<sup>5</sup></p> <p>28 RCTs</p> <p>n=23,861</p>	<p>ADR: increase of 20% in the AI-assisted colonoscopy group compared with routine colonoscopy (RR=1.20, 95% CI 1.14 to 1.29, p&lt;0.01, I<sup>2</sup>=64.05% (p&lt;0.001), 22 studies included in the analysis).</p> <p>SSLDR: no difference between groups (RR=1.10, 95% CI 0.93 to</p>	<p>Longer withdrawal times observed in the AI-assisted colonoscopy group compared with routine colonoscopy by 0.15 minutes (9 seconds) (weighted mean difference=0.15, 95% CI 0.04 to 0.25, p=0.01, I<sup>2</sup>=56.42% (p&lt;0.01), 18</p>	<p>AMR: reduction of 55% in the AI-assisted colonoscopy group compared with routine colonoscopy (RR=0.45, 95% CI 0.37 to 0.54, p&lt;0.01, I<sup>2</sup>=22.44% (p=0.32), six tandem studies included in the analysis).</p> <p>SSLMR: no difference between groups (RR=0.44,</p>	<p>25 out of 28 studies demonstrated low-risk of bias as assessed by the Cochrane Risk Bias 2 Tool. Three studies demonstrated some concerns regarding bias. There was a low-risk of bias for all studies for measurement of outcomes.</p>

Study information	Outcomes			
	Detection rate	Withdrawal time	Technology performance	Quality of the evidence
	<p>1.30, <math>p=0.27</math>, <math>I^2=50.35\%</math> (<math>p=0.27</math>), 15 studies included in analysis).</p> <p>SSLDR improved by 60% in the three studies that used the ENDO-AID system (RR=1.60, 95% CI 1.21 to 2.13, <math>p=0.01</math>).</p> <p>No difference between groups were observed in studies that used GI-Genius™.</p>	studies included in the analysis).	95% CI 0.16 to 1.19, $p=0.11$ , $I^2=41.57\%$ ( $p=0.19$ ), four tandem studies included in the analysis).	
<p>Mwango et al (2024)<sup>7</sup></p> <p>16 RCTs</p> <p>n=13,685</p>	<p>ADR: Higher in AI-assisted colonoscopy group compared with routine colonoscopy (AI=40.4% compared with 31.9% in the control group, RR=1.26, 95% CI 1.19 to 1.33, <math>p&lt;0.01</math>, <math>I^2=38\%</math>, 16 studies included in the analysis).</p> <p>PDR: Higher in the AI-assisted colonoscopy group compared with routine colonoscopy (AI=52.9% compared with 40.1% in the control group, RR=1.30, 95% CI 1.16 to</p>	Not applicable	Not applicable	<p>14 out of 16 studies demonstrated low-risk of bias overall as assessed by the Cochrane Risk Bias 2 Tool. Two studies demonstrated some concerns regarding bias. There was a low-risk of bias for all studies for measurement of outcomes.</p> <p>Grading of Recommendations, Assessment, Development and Evaluation (GRADE)</p>

Study information	Outcomes			Quality of the evidence
	Detection rate	Withdrawal time	Technology performance	
	1.44, $p < 0.01$ , $I^2 = 83\%$ , 11 studies included in the analysis).			methodology was used to assess the quality of the evidence. The evidence level for the RCTs included was downgraded due to endoscopist variability, different subpopulations requiring colonoscopy and range of primary outcomes.
Soleymanjahi et al (2024) <sup>8</sup> 44 RCTs n=36,201	<p>ADR: Higher average in AI-assisted colonoscopy group compared with routine colonoscopy (AI=44.67% compared with 36.74% in the control group, RR=1.21, 95% CI 1.15 to 1.28, <math>I^2 = 76\%</math>, 39 studies included in the analysis).</p> <p>PDR: Higher average in AI-assisted colonoscopy group compared with routine colonoscopy (AI=54.01% compared with 46.53% in the control group, RR=1.21, 95% CI 1.14 to 1.27, <math>I^2 = 80\%</math>, 39 studies included in the analysis).</p>	<p>Longer total withdrawal time (minutes) in the AI-assisted colonoscopy group compared with routine colonoscopy (AI=10.33 compared with 9.68 minutes in the control group, mean difference=0.53, 95% CI 0.30 to 0.77, <math>I^2 = 93\%</math>).</p> <p>Longer inspection time in AI-assisted colonoscopy group compared with routine colonoscopy (AI=8.34 compared with</p>	AMR: lower in the AI-assisted colonoscopy group (AI=16.1% compared with 35.3% in the control group, RR=0.47, 95% CI 0.36 to 0.60, no indication for publication bias, six studies included in the analysis).	<p>All studies were rated for high concern for bias, as assessed by the Cochrane Risk Bias 2 Tool. High concern for measurement bias was also reported, due to lack of blinding for caregivers and for individuals recording outcomes.</p> <p>The certainty of the evidence varied per outcome:</p> <ul style="list-style-type: none"> <li>■ ADR=low.</li> <li>■ PDR=not reported.</li> </ul>

Outcomes				
Study information	Detection rate	Withdrawal time	Technology performance	Quality of the evidence
		7.95 minutes in the control group, mean difference=0.31, 95% CI 0.14 to 0.48, I <sup>2</sup> =95%).		<ul style="list-style-type: none"> <li>■ Withdrawal time=low.</li> <li>■ AMR=moderate.</li> </ul>

Table 2: Summary of RCTs reporting patient and system outcomes that have been published since the HTW HTA.<sup>2</sup> Studies compare AI-assisted lower GI colonoscopy (CADE) with routine colonoscopy (without AI)

Study information	Population	AI system	Outcomes	
			Detection rate	Withdrawal or procedure time
Alali et al (2025) <sup>9</sup> Kuwait	n=102 (AI n=51; Control n=51).  Mean age in years: AI=51.1 years (standard deviation (SD)=7.7); Control=54.5 (SD=8.3).  Sex: AI= 30 males (58.8%); Control= 21 males (41.2%)  Subpopulations:  Screening (AI n=48 (94.1%); Control n=48 (94.1%)).  Surveillance (AI n=3 (5.9%); Control n=3 (5.9%)).	CAD EYE (Fujifilm Co)	ADR: no difference between groups (RR=1.26, 95% CI 0.80 to 2.00, p=0.09).  PDR: increase in AI-assisted colonoscopy group (78.4%) compared with routine colonoscopy (56.8%) (RR=1.38, 95% CI 1.04 to 1.82, p=0.02).	Due to reporting problems within the paper, p values have been taken from Table 1, rather than the main body of text (the interpretation does not differ).  Procedure: Insertion time similar (322.5 seconds for AI-assisted colonoscopy and 359.9 seconds for routine colonoscopy, p=0.32).  Withdrawal: similar between groups, no difference (542.4 seconds for AI-assisted colonoscopy and 509.4 seconds for routine colonoscopy, p=0.15).
Seager et al (2024) <sup>4</sup> UK (England)	n=2,032 (AI n=1,015; Control n=1,017).	GI-Genius™	ADR: Higher rate in AI-assisted colonoscopy group compared with routine colonoscopy (adjusted odds ratio=1.47, 95% CI 1.21 to 1.78, p<0.0001). Similar results in	Procedure time: total time (measured in participants without polyps) was 1 minute 28 seconds longer in the AI-assisted colonoscopy group compared with

Study information	Population	AI system	Outcomes	
			Detection rate	Withdrawal or procedure time
	<p>Mean age years (SD, range): AI=62.5 (10.8, 19 to 87); Control=62.2 (10.8, 19 to 87).</p> <p>Sex: AI=567 male (55.9%) and 448 female (44.1%); Control=565 male (55.6%), 452 female (44.4%).</p> <p>Subpopulations:</p> <p>AI=1,015 analysed on an intention-to-treat basis (n=613 screening subpopulation, n=402 symptomatic)</p> <p>Control=1,017 analysed on an intention-to-treat basis (n=618 screening subpopulation, n=399 symptomatic).</p>		<p>screening (adjusted odds ratio=1.37, 95% CI 1.07 to 1.74, p=0.011) and symptomatic subpopulations (adjusted odds ratio=1.65, 95% CI=1.20 to 2.26, p=0.0018).</p> <p>SSLDR: higher rate in AI-assisted colonoscopy group, compared with routine colonoscopy (adjusted odds ratio=1.46, 95% CI 1.07 to 1.99, p=0.017). The difference may be driven by the higher SSLDR in screening subpopulation. No difference in SSLDR reported in the symptomatic subpopulation.</p> <p>PDR: higher in AI-assisted colonoscopy group compared with routine colonoscopy (adjusted odds ratio=1.56, 95% CI 1.29 to 1.90, p&lt;0.0001). Similar results observed in screening and symptomatic subpopulations.</p>	<p>routine colonoscopy in the overall trial population (adjusted mean difference=1.47 minutes, 95% CI 0.09 to 2.85, p= 0.037). No difference in subpopulations.</p> <p>No difference between groups in insertion time or withdrawal time.</p>

Study information	Population	AI system	Detection rate	Outcomes Withdrawal or procedure time
			CRC detection rate: no difference between groups.	



## Appendix 3: summary tables for ongoing studies

Table 1: Summary of ongoing systematic reviews (completed but not published) colonoscopies

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
<a href="#">PROSPERO 2022</a> <a href="#">CRD42022333731</a> Ecuador, Pakistan, United States of America (USA) Study end: 16/06/22	P: no specific prerequisites. I: AI-assisted colonoscopies. C: routine colonoscopies.	Primary: ADR, PDR. Secondary: withdrawal times.
<a href="#">PROSPERO 2023</a> <a href="#">CRD42023402197</a> Italy Study end: 25/12/23	P: screening or surveillance colonoscopy. I: optical diagnostic performance with assistance of CADx. C: optical diagnosis performance without assistance of CADx.	Primary: negative predictive value for adenoma optical diagnosis. Secondary: sensibility, specificity, accuracy for adenoma optical diagnosis.
<a href="#">PROSPERO 2024</a> <a href="#">CRD42024609750</a> China Study end: 03/12/24	P: diagnosis. I: use of AI in diagnosis of colorectal polyps. C: diagnosis of colorectal polyps without use of AI.	Primary: polyp detection accuracy.
<a href="#">PROSPERO 2024</a> <a href="#">CRD42024583571</a>	P: adults more than 18 years old undergoing colonoscopy in nonemergency setting.	Primary: adenoma missed rate. Secondary: ADR, withdrawal time, polyps missed rate.

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
China  Study end: 30/09/2024	I: colonoscopy with high-definition endoscopes implemented with AI systems.  C: colonoscopy with high-definition endoscopes.	

*Table 2: Summary of recently completed primary studies*

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
<a href="#">NCT05513261</a>  Spain  Target recruitment: 857  Study end: 14/05/24	P: adults aged between 40 to 79 years old, undergoing diagnostic colonoscopy or surveillance.  I: PolyDeep (functional prototype) assisted high-definition endoscopy.  C: routine colonoscopy.	Primary: ADR.  Secondary: PDR, serrated lesion detection rate, advanced lesion detection rate, withdrawal time, characterisation of the detected lesions.
<a href="#">NCT05611151</a>  USA, Germany, Italy, UK (England)  Target recruitment: 830  Study end: 10/09/24	P: adults aged between 45 to 75 years old, presenting to the endoscopy unit for colon cancer screening or surveillance colonoscopy.  I: AI-assisted colonoscopy (WISE VISION®).  C: routine colonoscopy.	Primary: adenomas per colonoscopy.

Table 3: Summary of ongoing primary studies

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
<p><a href="#">NCT05133544</a></p> <p>China (Hong Kong)</p> <p>Target recruitment: 656</p> <p>Study end: 02/24</p>	<p>P: adults aged 40 years and older undergoing outpatient colonoscopy.</p> <p>I: AI-assisted colonoscopy, Olympus ENDOCUFF VISION™ and AI colonoscopy (Olympus ENDO-AID OIP-1™).</p> <p>C: routine colonoscopy without AI or Olympus ENDOCUFF VISION™.</p>	<p>Primary: ADR.</p> <p>Secondary: PDR, sessile-serrated adenomas detection rate, sessile-serrated polyps detection rate, advanced adenoma detection rates, mean number of polyps per patient, mean number of adenoma per patients, total number of poly or adenoma per patient.</p>
<p><a href="#">NCT04441580</a></p> <p>Italy</p> <p>Target recruitment: 600</p> <p>Study end: 30/04/24</p>	<p>P: adults aged 50 to 69 years undergoing colonoscopy examination (screening).</p> <p>I: Colonoscopy using GI-Genius™ device.</p> <p>C: routine colonoscopy.</p>	<p>Primary: rate of advanced adenomas, rate of patients detected with three or more adenomas.</p> <p>Secondary: overall adenoma and poly detection rate, flat adenoma and serrated polyps and adenomas, size of lesions detected, rate of neoplasia by colonic site, post-colonoscopy surveillance, withdrawal and total procedure time, learning curve (endoscopist), patient experience, specific contribution of AI.</p>
<p><a href="#">NCT05391477</a></p> <p>Spain</p> <p>Target recruitment: 643</p> <p>Study end: 12/24</p>	<p>P: patients attending a screening colonoscopy or for post-polypectomy surveillance.</p> <p>I: GI-Genius™ AI optical diagnosis.</p> <p>C: human optical diagnosis.</p>	<p>Primary: accuracy of post-polypectomy surveillance interval assignment, negative predictive value (NPV) for adenoma in rectosigmoid polyps ≤ 5 mm.</p> <p>Secondary: diagnostic accuracy parameters of polyps ≤ 5 mm (sensitivity, specificity, positive and negative</p>

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
<p><a href="#">NCT05943288</a></p> <p>Belgium, Germany, Spain, Sweden</p> <p>Target recruitment: 820</p> <p>Study end: 31/03/25</p>	<p>P: adults 45 to 80 years old, undergoing colonoscopy for primary colorectal screening or post-polypectomy surveillance.</p> <p>I: Olympus ENDO-AID OIP-1™ endoscopy.</p> <p>C: routine endoscopy.</p>	<p>predictive value, positive likelihood ratio), cost-effectiveness, AEs, acceptability (patient).</p> <p>Primary: ADR, positive predictive value.</p> <p>Secondary: adenoma per colonoscopy, total procedure time, endoscope withdrawal time, AEs, non-neoplastic resection rate.</p>
<p><a href="#">NCT05064124</a></p> <p>UK (England)</p> <p>Target recruitment: 420</p> <p>Study end: 05/25</p>	<p>P: adults aged 18 years old and over, scheduled to undergoing a screening, surveillance or symptomatic colonoscopy.</p> <p>I: Odin Vision CADDIE™ AI-assisted polyp detection and characterisation.</p> <p>C: routine care without use of the CADDIE™ device.</p>	<p>Primary: percentage of diminutive colorectal polyps optically diagnosed correctly by endoscopists.</p> <p>Secondary: percentage diminutive rectosigmoid colorectal polyps optically diagnosed correctly, NPV, in optically diagnosing rectosigmoid diminutive adenomas, concordance, confidence of endoscopists, AE caecal intubation time and rate, experience and acceptability of the CADDIE system (patient and staff).</p>
<p><a href="#">NCT05870332</a></p> <p>UK</p> <p>Target recruitment: 4,000</p> <p>Study end: 31/05/25</p>	<p>P: adults aged 18 to 85 years old scheduled for diagnostic colonoscopy.</p> <p>I: use of GI-Genius™ module.</p> <p>C: routine care.</p>	<p>Primary: ADR.</p> <p>Secondary: adenomas per colonoscopy, polyp size and location, total procedure and withdrawal time.</p>

Study information	Population (P), Intervention (I), Comparator (C)	Outcomes
<p><a href="#">NCT06656312</a></p> <p>Taiwan</p> <p>Target recruitment: 548</p> <p>Study end: 14/09/25</p>	<p>P: adults aged 20 years and old undergoing colonoscopy.</p> <p>I: use of ASUS EndoAim™ as an assistant software to perform colonoscopy.</p> <p>C: routine colonoscopy.</p>	<p>Primary: adenoma per colonoscopy.</p>
<p><a href="#">NCT05240625</a></p> <p>Taiwan</p> <p>Target recruitment: 1,500</p> <p>Study end: 31/12/25</p>	<p>P: adults aged 40 to 80 years old, scheduled for screening or diagnostic colonoscopy for CRC or surveillance colonoscopy for post-polypectomy follow-up.</p> <p>I: aetherAI™ colonoscopy.</p> <p>C: routine colonoscopy.</p>	<p>Primary: ADR.</p> <p>Secondary: PDR, adenomas per colonoscopy, polyps per colonoscopy, non-neoplastic polypectomy rate, sessile-serrated lesions per colonoscopy, advanced adenomas per colonoscopy, withdrawal time.</p>
<p><a href="#">NCT06786793</a></p> <p>Poland</p> <p>Target recruitment: 630</p> <p>Study end: 31/12/25</p>	<p>P: adults between 50 and 65 years old, scheduled for outpatient colonoscopy.</p> <p>I: colonoscopy with support of Olympus ENDO-AID OIP-1™ system.</p> <p>C: colonoscopy without support from Olympus ENDO-AID OIP-1™ system.</p>	<p>Primary: ADR.</p> <p>Secondary: ADR between trainees and expert endoscopists, polyp morphology, cost-efficiency of AI implementation.</p>