Research Square

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Trust Me, I Might be a Medical Device: The Problem with AI Scribes

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Abstract

Background

AI-enabled digital medical scribes are increasingly promoted as a solution to documentation burden and burnout in UK primary care. Recent NHS guidance indicates that many such tools may fall within the scope of UK Medical Devices Regulations, yet there is a lack of support for clinicians to verify regulatory status or data governance claims.

Objective

To identify AI-powered health care digital scribe (ambient voice technology, AVT) products available to UK clinicians and evaluate the transparency of their regulatory, data-protection and NHS-readiness claims.

Methods

Between 1–15 November 2025 we conducted a structured web-based review using search engines, NHS innovation and procurement portals, regulatory databases (including the MHRA Public Access Registration Database), commercial catalogues and vendor materials. Products were eligible if they were marketed as healthcare AI scribes or consultation assistants that transcribe and/or summarise clinician–patient interactions. For each tool, we extracted information on features, GDPR statements, MHRA registration, claimed NHS use and access pathways.

Results

We identified 118 AI-enabled health care AVT products marketed as AI scribes. Only nine (7%) explicitly claimed Class I medical device status; of these, six could be definitively located on the MHRA register under the same or a clearly linked legal entity. An explicit GDPR or data-protection statement was present for 88 products (73%), but supporting evidence (e.g. DPIAs, UK-specific safeguards) was rarely available. In terms of market accessibility, 51 tools (42%) required direct vendor contact or a demonstration, 46 (38%) showed clear UK or NHS availability, 15 (12%) were not accessible to UK users, and access status was unclear for nine (7%).

Conclusions

There is a marked mismatch between emerging NHS expectations for AI-enabled medical scribes and the transparency of current market offerings. Clinicians may struggle to reliably verify which tools are registered medical devices, how patient data are processed, or whether NHS clinical safety standards are met. Although NHS England has since introduced a national self-certified Ambient Voice Technology (AVT) supplier registry to improve visibility of regulatory and governance compliance, this was published after completion of data collection for this study. While the registry represents an important step toward strengthening oversight, its impact will depend on supplier participation, accuracy of self-certification, and effective dissemination to clinicians and healthcare organisations.

Introduction

Recent advances in large language models (LLMs) have driven the development of AI-based digital medical scribes, systems designed to capture clinician, patient interactions and generate structured documentation for inclusion in electronic health records. Depending on the vendor, these tools provide real-time transcription, automated summarisation, SNOMED coding, and the generation of formatted consultation notes or referral letters.

The NHS Ten-Year Plan (2025) identifies artificial intelligence as a central enabler of digital transformation, explicitly referencing AI-enabled documentation assistants as a route toward a more data-driven and efficient healthcare system.

In parallel, NHS England issued guidance in April 2025 confirming that AI scribes with specific functionalities may fall within the scope of the UK Medical Devices Regulations 2002, requiring registration with the Medicines and Healthcare products Regulatory Agency (MHRA) as software medical devices. In January 2026, NHS England introduced an AI-Enabled Ambient Voice Technology (AVT) Registry hoping to improve transparency and enable suppliers to self-certify compliance with NHS standards, including DTAC and MHRA requirements.

Persistent weaknesses in oversight across digital health technologies reinforce the need for such mechanisms. Many tools currently deployed within the NHS lack robust evidence of safety, benefit, or regulatory compliance, reflecting fragmented accountability and insufficient post-market evaluation (Oskrochi et al., 2025).

Despite these policy advances, the UK market for AI scribes remains uncoordinated. Many products are marketed directly to clinicians or small practices without demonstrable alignment to UK regulatory or clinical safety standards. This study presents a structured review of AI scribe products currently available to UK clinicians. It analyses publicly available vendor information and MHRA registration data to assess the transparency of regulatory claims and the challenges clinicians face in verifying compliance.

Speech-to-text transcription tools have long been used in healthcare, but the latest generation of AI scribes marks a significant shift in capability. According to NHS England's April 2025 guidance, newer tools leveraging LLMs to summarise consultations are no longer considered passive documentation aids. Depending on their functionality, they may fall within the scope of the UK Medical Devices Regulations 2002 (NHS England, 2025b). The Medicines and Healthcare products Regulatory Agency had previously, on 3 February 2025, concluded that scribes in mental health likely fall within this remit.

The NHS 10-Year Health Plan reinforces this evolution, positioning ambient AI (AVT) and digital assistants as central to the NHS's digital-transformation strategy. Pilot evaluations cited in the plan report that AI documentation tools have reduced administrative workload by over 50%, enabling staff to focus more on patient care and improving service throughput (NHS England, 2025a).

AI tools are increasingly present in UK primary care, with around one-third of GPs already using them, yet meaningful impact is not assured. Adoption remains uneven, shaped by differing local policies in which some ICBs encourage cautious piloting while others promote more proactive use of approved systems (Kumpunen et al., 2025).

However, these innovations raise complex regulatory and ethical challenges. The MHRA defines software as a medical device as any software intended for a medical purpose, including diagnosis, treatment, or prognosis. Even if a developer does not explicitly claim medical use, a tool's interface, marketing, or deployment context can bring it within regulatory scope. Features such as automated summarisation, decision support, or clinical coding particularly when not easily verifiable by clinicians, increase the likelihood of classification as a medical device (MHRA, v1.10f).

Oskrochi et al. (2025) identified persistent deficiencies in compliance, governance, and post-market monitoring across a wide range of digital health tools currently in use. Their analysis demonstrated that many technologies are implemented without clear evidence of safety, benefit, or regulatory alignment, and that responsibility for compliance remains fragmented across multiple agencies. The authors concluded that NHS oversight mechanisms have not kept pace with the rapid evolution of digital innovation, resulting in gaps in accountability and transparency. In response to these challenges, NHS England has now introduced a self-certified AVT supplier registry, intended to act as a national reference point for organisations and clinicians seeking assurance on regulatory and governance alignment https://transform.england.nhs.uk/digitise-connect-transform/digitising-the-frontline/ambient-voice-technology-self-certified-supplier-registry/. The registry enables suppliers to declare compliance with NHS requirements, including DTAC, clinical safety standards, and (where applicable) MHRA medical device registration. While this represents an important structural intervention, the registry relies on self-certification rather than independent verification, and its effectiveness will depend on supplier participation, accuracy of declarations, and visibility to end-users. At present, there is limited evidence regarding clinician awareness of the registry or its integration into routine procurement, governance, or audit processes.

Regulatory classification carries significant implications. Products meeting the definition of a medical device must be registered with the MHRA, comply with UK Conformity Assessed (UKCA) or CE-marking requirements, and adhere to NHS clinical-safety standards (DCB0129 and DCB0160). These obligations may present barriers for smaller developers or overseas vendors unfamiliar with UK-specific regulation. The 10-Year Plan acknowledges these challenges, committing to a "faster, predictable, and risk-proportionate" regulatory framework for AI and software-as-a-medical-device, developed jointly by the MHRA and the Department for Science, Innovation and Technology (NHS England, 2025a).

Although the statutory MHRA registration fee for software devices is modest, currently £261 (rising to £300 annually in 2026), the true cost of achieving full regulatory compliance is substantial. When accounting for engineering design, risk management, regulatory documentation, clinical validation, and conformity assessment, the average development cost for a Class II medical device (including digital and software-only systems) ranges between £1.6 million and £4 million (MedTech Europe, 2024), albeit software-only devices typically occupy the lower end of this range.

There is a high turnover of small providers in the emerging digital-scribe (AVT) market. The advent of accessible LLM frameworks and open developer APIs has lowered the barrier to entry, enabling start-ups and independent developers to produce AI documentation tools with limited resources. Many of these vendors market directly to clinicians and small practices via web platforms, promoting their tools as workflow aids rather than regulated medical devices. However, the cost and complexity of full Class II certification, including quality-management systems and clinical-performance evidence, may be prohibitive for all but the largest or most established suppliers.

Professional responsibility nevertheless remains with the clinician, who must review and verify AI-generated outputs before they are entered into the patient record. Failure to identify inaccuracies could expose clinicians to liability if harm occurs, even when errors originate from the AI system (Nicholson et al., 2024). Automation bias where clinicians over-rely on plausible AI outputs has been recognised as an emerging safety concern (Abdelwanis et al., 2024). Further governance questions surround patient consent and data transparency. While some providers verbally inform patients when AI scribes are used, consent models vary. Under UK GDPR and the Data Protection Act 2018, patients have the right to understand how their data are processed, and professional guidance from the GMC and National Data Guardian emphasises the need for transparency. Although the NHS envisions a unified, digital-first health record, it is not yet standard practice to mark AI-generated documentation within patient records. This omission has implications for accountability, auditability, and trust (Mennella et al., 2024).

Methods

This study aimed to identify AI-powered digital medical scribes available to clinicians in the United Kingdom and assess the transparency of their regulatory status. The analysis focused on tools that are marketed as using AI to transcribe or summarise patient consultations and are promoted for use in healthcare settings.

Eligibility Criteria

To be included in the review, a product had to:

- Be marketed as an AI-powered digital scribe or consultation assistant in a health care setting including mental health/therapy;
- Offer transcription, summarisation, or clinical documentation support based on patient–clinician interaction;

Tools offering only basic dictation or voice recognition (e.g. standalone speech-to-text apps) were excluded unless they also included generative summarisation or structured documentation functionality.

Search Strategy

The search was conducted between 1–15 Nov 2025 using a combination of formal and informal sources to identify products available to UK clinicians. This included:

- Structured web searches (Google) using terms such as “AI scribe UK,” “digital medical scribe NHS,” “ambient documentation tool,” and “LLM scribe healthcare”;
- NHS procurement websites, innovation portals, and accelerator programme listings;
- Publicly accessible regulatory databases including the MHRA Public Access Medical Device Registration System;
- U.S healthcare technology data base - Elion;
- Company websites, marketing materials, press releases, and white papers;
- Professional discussion forums, including Reddit threads and X posts;
- LinkedIn company pages, employee posts, and industry analyst commentary.

This approach generated a list of 121 AI scribe tools potentially available to UK clinicians. These included both UK-developed and international tools, some of which are in active NHS deployment or pilot phases.

Data Extraction and Review

For each tool, data was manually extracted from public sources, including:

- Product features (e.g. transcription, summarisation, coding);
- Regulatory status (e.g. MHRA registration);
- Integration claims with UK EHR systems and NHS compliance (e.g. EMIS, SystmOne);
- Data handling practices (e.g. patient data storage, audio retention, anonymisation);
- Patient consent processes and governance indicators, if any (e.g. documentation of AI use, consent procedures, audit trails).

Where regulatory status was unclear or unverifiable via official databases, this was recorded as a key finding.

Limitations

This review has several important limitations. First, data collection was completed prior to the publication of the NHS England Ambient Voice Technology (AVT) self-certified supplier registry in January 2026. As a result, the analysis does not account for supplier participation in, or compliance declarations made through, this registry. The findings therefore represent a snapshot of the market immediately before the introduction of a national assurance mechanism and may over-estimate the current degree of opacity in regulatory signalling.

The MHRA registration database is not searchable by product function, AI capability, or clinical application, which makes it difficult to confirm whether a product is in scope or appropriately registered.

Some tools may be undergoing registration, or may self-certify as Class I devices under UK Medical Devices Regulations 2002, which does not require independent third-party assessment. As stated in MHRA guidance:

“Registration of medical devices with the MHRA... does not represent any form of accreditation, certification, approval or endorsement by the MHRA. Therefore, it is not permitted to make any claims to this effect…” (MHRA, 2023).

As such, the presence of a tool on the register should not be interpreted as confirmation of compliance with NHS safety, performance, or clinical governance expectations. Additionally, several vendors do not publish regulatory documentation or safety information on their websites, further limiting the ability to verify claims.

Results

Overview

A total of 118 AI-enabled ambient scribing (AVT) products were identified as being marketed to, or accessible by, UK clinicians. These include UK-based and international suppliers offering capabilities such as ambient voice capture, real-time transcription, generative summarisation, structured coding, and automated referral generation. Claims of regulatory compliance, NHS readiness, and data-handling transparency varied widely.

Scribe Name	MHRA Device Registration	UK Access Availability	Compliance Notes
Abridge	No	Contact required	Privacy policy legal, no direct GDPR citation
Accel eq	No	No	Some Accel privacy docs claim GDPR, check clinical context
Aesthetics 360	No	Contact required	UK sector guidance, no direct product claim
aide health	Yes (Class 1)	Contact required	NHS DCB0129/0160 clinical safety standards, GDPR data protection.
Aiva	No	Contact required	GDPR, privacy statement, EU/UK data rights
Ambience Scribe	No	Contact required	NHS-required GDPR, needs direct confirmation
Andy	No	Contact required	GDPR, HIPAA, SOC2, security audits
Anima/ Annie (UK)	Yes (class 1 claimed), could not find on pard	Yes	UK GDPR,Use in nhs reported, DPA, DTAC, DSPT, DCB0129
Augmedix (USA)	No	No	HIPAA, de-identification, US focus
Augnito (UK/IND)	Yes (class 1) (ScribeTech)	NHS dictation	UK GDPR, NHS, local hosting, security, DPA
Aura AI Scribe	No	Yes	GDPR, HIPAA, SOC2, consent
AutoMynd	No	Contact required	GDPR, HIPAA, SOC2, DPO, consent, EU hosting
Avo	No	Contact required	GDPR, HIPAA, CCPA, anonymization, audit
Avodahmed	No	Contact required	GDPR, patient consent, subject rights, industry audits
BastionGPT	No	Yes	GDPR, HIPAA, SOC2, UK/EU legal review
Bells ai	No	No	GDPR, HIPAA, SOC2, PIPEDA, UK data controls
Blueprint	No	Yes	References OpenAI's privacy; not product-level GDPR
Care cortex	No	Contact required	GDPR, HIPAA, ISO, DPO, subject rights
CarePilot	No	Contact required	GDPR, HIPAA, UK DPA, Aus Privacy Act, DPO
Chartnote	No	Contact required	GDPR, HIPAA, PIPEDA, SOC2, staff training, logging
CircleHealth AI	No	Contact required	HIPAA, Joint Commission, lacks GDPR
Clinicminds	No	Contact required	GDPR, HIPAA, PIPEDA, privacy, consent management
Commure Ambient AI	No	Contact required	GDPR, HIPAA, SOC2, end-to-end encryption
Continuous care	No	Contact required	GDPR, HIPAA, EU/UK hosting, right to be forgotten
Conveyor AI	No	Contact required	GDPR, HIPAA, SOC2, DPA/EU/UK data addendum
Corti	No	Yes	GDPR, HIPAA, ISO27001, SOC2, medical device certs
DeepCura AI (USA/CAN)	No	Contact required	GDPR, HIPAA, SOC2, DPO, ongoing audits
DeepScribe (USA)	No	Unclear	HIPAA, SOC2 only
Deliberate ai	No	Contact required	No public policy, GDPR not found
Diktamen	no	Yes	DTAC, DCB0129, DSPT, Cyber esentials, ISO 27001, ISO 9001, ISO14001
Dragon Medical One (USA)	No	NHS use claimed	Azure UK/EU hosting, ISO27001, DCB0129, NHS compliance
Eleos	No	Contact required	UK privacy, GDPR/UK GDPR, subject rights, DPO, audits
Empathia ai	No	Yes	GDPR, HIPAA, ISO27001, privacy basis
Enzohealth	No	Contact required	GDPR, HIPAA, ISO27001, SOC2
Expert Ai	No	No	GDPR for Cogito, DPO support, EU bases only for that prod.
Ezy scribe	No	No	No public GDPR documentation

Scribe Name	MHRA Device Registration	UK Access Availability	Compliance Notes
Fireflies ai	No	No	GDPR, SOC2, HIPAA, US hosting, enterprise EU option
Freed AI (USA)	No	Yes	GDPR, HIPAA, HITECH, audits, US/EU privacy
Glass health	No	Contact required	HIPAA, US-centric only
Halo scribe	No	Contact required	No public GDPR evidence
Health orbit	Yes	Yes, NHS use claimed	GDPR, UK/EU data handling, privacy framework
Heidi Health (AUS)	Yes (Class 1)	Yes, NHS use claimed	GDPR, HIPAA, NHS, ISO27001, UK hosting
Innovaccer InScribe	No	Yes	GDPR, HIPAA, SOC2, Trust Center, EU/UK
Insight aura AI scribe	No	Yes	GDPR, HIPAA, SOC2, ISO27001, UK Cyber Essentials
Iscribe	No	No (not supported)	HIPAA-only focus, no GDPR evidence
Jessica by Combine Health	No	No	HIPAA, CMS, lacking explicit GDPR
Jotpsych	No	Yes	GDPR, HIPAA, SOC2 Type 2, audit, deletion
Kiwipen (UK)	No	Yes	GDPR, ICO, Cyber Essentials, DSPT, DCB0129, DTAC
Knowtex	Yes	Yes	HIPPA, SOC 2, GDPR, iso 27001
Lexacom Scribe	Yes States class one on website unable to find on pard	Contact required	GDPR, HIPAA, ISO, UK DPA, DPO, EU/UK data controls
Lucus ai	No	Yes	GDPR, HIPAA, SOC2, UK data residency
Lyrebird Health (AUS)	Yes (Class 1)	Yes, NHS use claimed	GDPR, NHS DTAC, DCB0129, HIPAA, Australia Privacy Act
Mariana ai	No	No	HIPAA only, not GDPR for healthcare
Marvix	No	Contact required	GDPR, SOC2, EEA data, subject rights, breach notification
Mdhub	No	Yes	GDPR, HIPAA, SOC2, security audits
Mediary	No	Contact required	No privacy or public GDPR evidence, not AVT scribe
MEDILIT	No	Yes	GDPR, HIPAA, SOC2, product claim
MediSync	No	Contact required	GDPR, HIPAA, Texas regional, Elion Health confirmed
Mentalyc	No	No	GDPR, HIPAA, PHIPA, PIPEDA, rights, audit
Mircosoft DAX	Yes website states class 1 could not find on pard	Contact required	GDPR, HIPAA, HITRUST, SOC2, SCCs, EU/UK hosting
Mutuo AutoScribe (CAN)	No	Yes	GDPR, HIPAA, SOC2, PHIPA, PIPEDA, UK/EU support
Nabla Copilot (FRA/USA)	No	Yes	GDPR, HIPAA, SOC2, ISO27001, EU/US hosting
NextGen Ambient Assist	No	Contact required	GDPR, HIPAA, SOC2, Elion Health review
Nextvisit AI	No	No	Not GDPR compliant; US only, not for UK/EU (privacy stmt)
Nora note	No	Yes	GDPR, privacy, consent, UK/EU legal
Nudge	No	Yes	GDPR, minimization, data rights, consent
OmniMD AI Medical Scribe	No	Contact required	GDPR, HIPAA, CCPA, SOC2, audits, EU/UK controls
OneChart	No	Yes	No public GDPR evidence or policy
OneChart (CAN)	No	Yes	No public GDPR evidence or policy
OneLine Health	no	Contact required	GDPR, HIPAA, PIPEDA, NHS, privacy/erasure
Opus	No	Contact required	GDPR, HIPAA, SOC2, product privacy solutions

Scribe Name	MHRA Device Registration	UK Access Availability	Compliance Notes
Oracle Clinical Digital Asst.	No	Contact required	GDPR, HIPAA, SOC2, DPA, SCC, EU privacy safeguards
OrbDoc	No	Contact required	GDPR, HIPAA, SOC2, ISO27001, NHS DSPT, UK/EU
Pabau - Echo AI	No	Yes	GDPR, HIPAA, consent/audit features
PatientNotes	No	Yes	GDPR, HIPAA, UK DPA, Aus Privacy Act, audit logs
Playback health	No	Yes	GDPR, HIPAA, SOC2, explicit EU controls
Plena Health AI Scribe	No	Contact required	GDPR, HIPAA, SOC2, UK/EU privacy controls
Giiq	No	No	GDPR, staff training, privacy, subject rights
Regard	No	Contact required	HIPAA, SOC2
Reteta	No	Contact required	No public GDPR privacy policy available
Revmax	No	Contact required	GDPR, legal processing EU/UK, DPA, data rights
River Records	No	Contact required	GDPR, UK DPA, UK/EU data, subject rights
S10.AI	No	Contact required	GDPR, HIPAA, ISO, PIPEDA, EU hosting, DPA available
Sayvant	No	Contact required	GDPR, HIPAA, SOC2, audits, EU/UK subject rights
Scribble	No	Error 403 forbidden message	Privacy error, possibly inaccessible in UK
Scribe america speke	No	No	HIPAA, US-centric only
Scribeberry	No	Contact required	GDPR, HIPAA, SOC2, ISO, audits, Canadian compliance
scribematic	No	Yes	GDPR, HIPAA, ISO, CCPA, NHS guides, UK/EU privacy
ScribeMD	No	Contact required	GDPR, HIPAA, SOC2, EU/UK subject rights
ScribePT (USA)	No	Contact required	US privacy only
ScribeRyte	No	Contact required	GDPR, HIPAA, SOC2, ISO27001, privacy controls
Shine AI beam health	No	Contact required	GDPR, HIPAA, SOC2, independent audits, privacy policies
SimboAIphus	No	No	Some Symbolab legal basis, not healthcare certain
SKRIBER	No	Yes	Data protection, legal compliance
Soap suds	No	Yes	No GDPR for health context
SOAPNoteAI	No	Yes	GDPR, HIPAA, SOC2, Cyber Essentials, ISO, PIPEDA
Solventum fluency direct	no	Contact required	GDPR, HIPAA, SOC2, TX-RAMP, Cyber Essentials, ISO 27001
Speak matic	No	Unclear	No explicit GDPR found
Splose	no	Yes	GDPR, UK GDPR, ISO 27001, Health data encryption, SOC2, SSO/2FA
Sporo AI Scribe	No	Yes	GDPR, HIPAA, SOC2, UK Cyber Essentials, NHS DSPT, ISO
Suki AI (USA)	No	No	GDPR, HIPAA, anonymization, security, user consent
Sully u.s	No	Unclear	GDPR, ISO 27001, SOC2, EEA/UK compliance
Supanote AI	No	Yes	GDPR, HIPAA, PHIPA, PIPEDA, consent, audits
SwiftyNote	no	Unclear. Code never sent for log in after request	GDPR, HIPAA, AWS, privacy/security
T-Pro	No	Yes	NHS DCB0129/0160, DTAC, DSPT
Tali AI (CAN)	No	Contact required	HIPAA, SOC2, PHIPA/PIPA, lacks explicit GDPR
Tandem	Yes (Class1)	Yes NHS use	UK GDPR, NHSE, DPA, NHS toolkit, DPIA,

Scribe Name	MHRA Device Registration	UK Access Availability	Compliance Notes
			CyberEssentials
TheraPulse	No	Yes	GDPR, HIPAA, SOC2, Elion Health confirmed
Tortus (UK)	Yes (Class 1)	Yes NHS use	GDPR, CyberEssentials Plus, DTAC, DSPT, DCB0129, NHS
Triple time	No	Yes	No GDPR evidence found in public docs
Twofold Health (USA)	No	Yes	HIPAA, no public GDPR evidence
Upheal	No	Yes	GDPR, HIPAA, SOC2, PHIPA, PIPEDA, UK/EU hosting
Veradigm Ambient Scribe	No	Contact required	GDPR, HIPAA, SOC2, EU/UK compliance
Vero	No	Contact required	GDPR, ISO27001, SOC2 Type II, HIPAA, external audits
Videra Health	No	Contact required	GDPR, HIPAA, SOC2, privacy policy EU/UK
Wavo Health (CAN)	No	Yes	GDPR, HIPAA, SOC2, no audio storage, UK hosting
Zanda	No	Yes	GDPR, HIPAA, ISO, UK DPA, DPO, EU/UK data controls

Results

Regulatory verification (MHRA)

Manual verification against the Medicines and Healthcare products Regulatory Agency (MHRA) Public Access Registration Database (PARD) https://pard.mhra.gov.uk/ identified nine of 118 AI-enabled AVT products (8%) that claimed Class I medical device status. Of these nine products, six (5% of the identified AVT products) could be definitively located on PARD under the same or a clearly linked manufacturer or legal entity name at the time of review. For the remaining three products (3% of all AVT products), no corresponding PARD entry could be identified under the marketed product name. While these products may be registered under alternate legal entities or parent companies, this could not be confirmed using publicly available records.

Table 1
Publicly stated and verifiable MHRA regulatory status of AI-enabled ambient voice technology products marketed to UK clinicians (N = 118)

Regulatory status	Count	% of total
Claims MHRA Class I medical device status	9	8
Verified on MHRA PARD under same or clearly linked legal entity	6	5
Claimed Class I status but not verifiable on PARD under marketed name	3	3
No claim of MHRA Class I status	109	92

Verification was defined as a clear and defensible link between the marketed product and a registered legal entity on the MHRA Public Access Registration Database (PARD). Products not locatable under the marketed name may be registered under alternative legal or trading names.

Data protection and GDPR compliance

Of the 118 AVT products reviewed, 88 (75%) provided an explicit statement of compliance with the General Data Protection Regulation (GDPR) or UK data protection legislation on their websites or in associated documentation. Only a minority of these products linked supporting evidence, such as Data Protection Impact Assessments or references to specific UK GDPR provisions. The remaining products either provided general statements relating to privacy or security without explicit reference to GDPR or did not provide sufficient publicly available information to determine compliance.

Table 2
Publicly stated GDPR and data protection compliance among AI-enabled ambient voice technology products (N = 118)

Data protection status	Count	% of total
Explicit GDPR or UK data protection compliance statement	88	75
Generic privacy or security statements without explicit GDPR reference	23	19
No clear data protection information identified	7	6

Explicit compliance was defined as a direct reference to GDPR or UK data protection legislation in publicly available product documentation or websites.

UK access and deployment

Most AVT products demonstrated some degree of potential accessibility to the UK market, although access pathways varied considerably. Forty-nine products (42%) required direct vendor contact or a product demonstration prior to access, indicating possible UK availability but limited public transparency. Forty-three products (36%) were clearly accessible to UK users or reported active or planned deployment within UK or NHS settings. Fifteen products (13%) explicitly stated that they were not available to UK users or were not accesessible from a UK IP address, while 11 products (9%) had unclear or indeterminate access status due to insufficient or inconclusive publicly available information.

Table 3
UK access and deployment characteristics of AI-enabled ambient voice technology products (N = 118)

Access category	Count	% of total	Interpretation
Contact or demonstration required	49	42	Potential UK availability but limited public transparency
Accessible to UK users or NHS	43	36	Clear UK access or evidence of NHS use
Not accessible to UK users	15	13	Explicit geographical or market restriction
Unclear or indeterminate	11	9	Insufficient or inconclusive public information

A substantial proportion of AVT products referenced current or intended use within the NHS, commonly in the context of pilot projects, evaluations, or integrations with established clinical systems such as EMIS or SystmOne. Notably, all products that claimed MHRA Class I medical device status also reported current or planned use within NHS settings.

Several products without verifiable Class I registration displayed NHS logos or referenced NHS partnerships on their websites. While such references suggest market intent, they were not consistently supported by verifiable evidence of formal contracts or regulatory approval. In addition, a number of products appeared to be primarily aligned with international regulatory frameworks, particularly those applicable in the United States, rather than explicitly addressing UK-specific regulatory and governance requirements.

Observed Trends and Common Gaps

Brand–manufacturer discrepancies in MHRA listings can limit traceability and slow due diligence checks. In addition, cross-border data processing arrangements are often not clearly specified on supplier websites, including whether appropriate UK safeguards are in place when data are stored or processed outside the UK. Marketing assurances such as claims of being “secure” or “HIPAA compliant” are frequently presented without sufficient detail to meet NHS assurance requirements. These results reinforce the case for a central NHS mechanism such as the AVT Registry to provide verifiable evidence, reduce duplication of effort across ICBs, and support consistent, safe procurement decisions.

Discussion

This review highlights a significant gap between the regulatory expectations outlined in NHS and MHRA guidance and the transparency of AI scribe tools currently available to UK clinicians. Despite the 2025 NHS statement that high-functionality AI scribes may fall under the UK Medical Devices Regulations 2002, only a minority of tools reviewed had verifiable MHRA registration, UKCA/CE certification, or published clinical safety documentation.

For frontline clinicians, this creates uncertainty and potential professional risk. AI scribes that generate summaries, add clinical codes, or format notes for upload into patient records are not merely passive transcription tools. If a tool meets the legal definition of a medical device, clinicians using unregistered versions may bear liability in the event of harm, particularly if due diligence around regulation and safety was not exercised. Moreover, automation bias may lead clinicians to over-rely on AI-generated notes, especially under time pressure or when the output appears plausible.

Yet the appeal of AI scribes is undeniable. These tools offer benefits to clinicians and patients alike, particularly for healthcare professionals with high administrative burdens. In the context of increasingly time-constrained consultation models, tools that can reduce cognitive load and streamline note-taking hold real promise for improving care delivery (Tierney et al., 2025).

The challenge lies in the pace of development. Rapid advances in generative AI, including the integration of large language models such as GPT-4, have outstripped the capacity of existing regulatory systems to adapt. Today’s AI scribes go far beyond speech-to-text, generating structured summaries, coded entries, and even referral letters within seconds (Sollof, 2025). For clinicians, this raises the question of how they can critically evaluate and safely deploy tools whose regulatory status, audit mechanisms, and error-handling processes remain unclear.

This concern becomes especially pressing when AI scribes are embedded directly into electronic patient record (EPR) systems. Errors in transcription, summarisation, or clinical coding may be silently propagated across systems, leading to downstream risks. As more patients gain access to their health records, inaccuracies could generate confusion, complaints, or requests for correction. Misattributed diagnoses or incorrect codes could directly contribute to patient harm and may also create new burdens for data protection officers as well as compromising clinician–patient trust.

These findings also suggest that while the majority of AVT scribes have some pathway to the UK market, accessibility and verifiable compliance remain inconsistent. Nearly half of all identified tools require vendor engagement in the form of an online demonstration and discussion with a sales agent before access is granted. Fewer than ten could demonstrate confirmed medical device registration. This suggests a market still in an early stage of regulatory maturity, where international vendors are open to UK adoption but have not fully aligned with UK-specific safety, data governance, or registration standards this does not stop them trying to sell into the UK market.

Vendor engagement may, however, serve as a modest safeguard. The need to arrange a demonstration or contact a sales team introduces a degree of friction that could prevent clinicians from adopting tools without adequate due diligence or confirmation of GDPR compliance. In that sense, the "demo/contact required" model may help mitigate inappropriate or premature use. Nevertheless, discussions with several US-based vendors indicated a strong interest in selling to the UK market despite limited understanding of UK regulatory expectations. This lack of awareness could present risks for clinicians who assume these products meet local compliance standards when, in fact, they may only adhere to US frameworks such as HIPAA (Health Insurance Portability and Accountability Act).

In parallel, the NHS would benefit from a national audit framework for AI-generated documentation. Standardised approaches are needed to determine how frequently outputs should be reviewed, what constitutes an acceptable error threshold, and how the role of clinical safety officers should evolve. Without such benchmarks, quality assurance will remain fragmented and reactive.

The introduction of the NHS England AVT self-certified registry represents a potentially important inflection point in this landscape. If widely adopted and appropriately maintained, the registry could reduce duplication of due diligence across integrated care boards, support more consistent procurement decisions, and provide clinicians with a clearer route to verifying baseline compliance. However, for this potential to be realised, the registry must be visible, trusted, and actively embedded within NHS digital governance workflows. Without proactive communication, integration into existing NHS systems, or linkage to professional guidance, there is a risk that the registry remains peripheral, particularly as commercial vendors continue to market directly to clinicians outside formal procurement pathways.

Finally, while initiatives such as RADIANT (Regulatory and Innovation Network for AI Technologies) and CERSI AI (Centre of Excellence for Regulatory Science & Innovation in AI) are emerging to address the governance gap (Bray, 2025), their impact will depend on strong inter-agency coordination, visible national leadership and funding. A transparent, central register of compliant tools, such as the planned NHS AVT Registry, would provide clinicians and organisations with a trusted reference point. In the absence of such infrastructure, responsibility continues to fall on individual users to assess regulatory risk, a task that remains difficult in the current environment.

Conclusion

AI digital scribes offer considerable promise in reducing documentation burden, improving clinical workflows, and enhancing the quality of records. However, this review has shown that despite clear NHS guidance, the current regulatory landscape lacks transparency and consistency. Many tools marketed to UK clinicians do not clearly disclose their regulatory status.

The recent introduction of a national NHS self-certified AVT supplier registry is a welcome and necessary development, signalling recognition of the governance gap identified in this study. However, its late arrival relative to market growth, reliance on self-certification, and limited visibility underscore the need for continued scrutiny. To support safe, accountable adoption of AI scribes, registry participation must be coupled with clearer guidance for clinicians, improved discoverability, and alignment with audit and clinical safety processes. Without these measures, responsibility for managing regulatory risk will continue to fall on individual users, undermining both patient safety and clinician confidence in emerging AI documentation technologies.

Without such action, the NHS risks entering a period of unchecked adoption, where the benefits of AI scribes may be undermined by avoidable risks to patients, clinicians, and healthcare systems alike.

Declarations

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