accurx

Data Protection Impact Assessment (DPIA) Template:

Accurx Ambient Scribe

Introduction

This template closely follows the ICO's example of how you can record your DPIA process and outcomes. It follows the process set out in the ICO's DPIA guidance, and should be read alongside that guidance and the criteria for an acceptable DPIA set out in European guidelines on DPIAs.

Please note that under data protection law it is the responsibility of a Data Controller to consider whether to complete a DPIA. Accurx as a Data Processor cannot complete or approve a DPIA on behalf of a Data Controller. However, to support our customers in completing this task, this template provides many suggested responses for consideration.

Submitting Controller Details	
Name of Controller	
Subject/ title of DPO	
Name of controller contact/ DPO (delete as appropriate)	

accurx

DPIA Screening checklist

1. Does the proposal/ project involve processing personal data? ('Personal data' is defined as any information related to an identifiable living person which can identify that individual, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person).

☑ Yes ☐ No

Please note: if the answer to this question is no, then no further questions need to be answered and the assessment is complete. If the answer is yes, please continue.

2. Does the processing for this project include the evaluation or scoring of any of the following?
    - Profiling and predicting (especially from "aspects concerning the data subject's performance at work);
    - Economic situation;
    - Health;
    - Personal preferences or interests;
    - Reliability or behaviour;
    - Location or movements.

☐ Yes ☑ No

3. Automated decision-making with legal or similar significant effect: Processing that aims at taking decisions on data subjects producing "legal effects concerning the natural person" or which "similarly significantly affects the natural person".

☐ Yes ☑ No

accurx

4. Systematic monitoring:
   Processing used to observe, monitor or control data subject, including data collected through networks or a “systematic monitoring or publicly accessible area” i.e. CCTV.

☐ Yes ☑ No

5. Mostly sensitive data or data of a highly personal nature:
   This includes special categories of data as well as personal data relating to criminal convictions or offences.
   Special Categories of Personal Data means Personal Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation

☑ Yes ☐ No

6. Will this processing combine, compare or match data from multiple sources?

☑ Yes ☐ No

7. Data processed on a large scale:

☑ Yes ☐ No

8. The innovative use or applying new technological or organisational solutions:

☑ Yes ☐ No

9. Mostly data concerning vulnerable data subjects including children (this only applies where the entirety of the data being processed relates to this category).

☐ Yes ☑ No

10. Does the processing in itself prevent the data subjects from exercising a right (under UK Data Protection Legislation) or using a service or contract:

☐ Yes ☑ No

Please note: if you have answered 'Yes' to more than one statement above, then a DPIA must be carried by completing the upcoming sections.

Step 1: Identify the need for a DPIA

1.1 Explain broadly the purpose of the product and the type of processing it involves.

Explanatory note: provide just a short description of the purpose of the processing or product, as this will be expanded more on at 'Step 2: Describe the processing'.
You can refer to and/ link other documents, such as project proposals and demos.

The overall aim of the Accurx platform is to improve communications between healthcare staff and patients to improve outcomes and productivity. The Ambient Scribe feature specifically allows healthcare professionals to focus on listening to their patients during consultations, rather than typing or drafting documents. By reducing administrative tasks, it helps them dedicate more time to patient care and improving the overall quality of consultations.

Therefore, the Accurx Scribe feature aims to transform and enhance the quality of clinical consultations and improve care outcomes for patients. The feature enables real-time transcription of consultations, allowing clinicians to focus fully on their patients rather than dividing their attention between conversation and typing up notes. This creates a more engaged and person-centred consultation experience, which supports improved communication and better patient satisfaction.

In short, the Accurx Scribe feature does the following after it is manually started by the user:

- **Listens** to the conversation a clinician has with their patient during the consultation. The audio stream is processed in real-time during conversations and automatically deleted

as soon as the audio is transcribed by Accurx Scribe.

- **Transcribes** the conversation
- **Summarises** the transcription of the conversation
- **Generates content** based on the transcription such as clinical notes, referral and/or patient letters
- **Saves consultation notes and coding** back to the patient record

1.2 Summarise why you identified the need for a DPIA

Explanatory note: Provide the reasons on why a DPIA is required. Some examples might include:

- the product processes sensitive and/ or special category data;
- the product processes data on a large scale;
- the processing will prevent data subjects from exercising a right.

The need for a DPIA was identified due to the processing on a large scale of health data relating to patients, which is sensitive and confidential in nature, using new innovative technological solutions. Additionally, the transcribed consultations will also be matched with data from multiple sources, such as Personal Demographics Service (PDS), and/ or the Electronic Medical Record (as applicable). This is not available if using Accurx Scribe on the Mobile App.

Therefore, the DPIA is necessary to evaluate the risks to patients and their privacy associated with this type of processing and the mitigations in place to mitigate these risks, ensuring compliance with the data protection legislation.

Step 2: Describe the processing

Nature of processing

2.1 What is the source of the data?

The sources of the data are:

- the patients and the healthcare professionals themselves whose consultation is being listened to, transcribed and, afterwards, used by the healthcare professionals to generate content as they see fit; and
- the Personal Demographic Service (PDS) and/or the electronic medical systems used for fetching patient demographic information required to ensure that clinical notes are

saved to the correct patient's record. If using Accurx Scribe on the Mobile App, users cannot save a consultation to a patient's record from the app.

2.2 How will the data be collected?

The data is generated directly from patients and healthcare professionals during their consultation where Accurx Scribe is used.

Demographic data obtained from the PDS and/or electronic medical systems is obtained as part of the secure integrations that Accurx maintains with these systems.

2.3 How will the data be used?

Generated outputs are presented to healthcare professionals in the product interface to support good clinical record-keeping and to better enable them to make decisions about next actions required from patient care perspective through reviewing the generated outputs.

Healthcare professionals can generate content based on the transcription of the consultation, such as clinical notes, referral letters and patient letters. These documents are generated based on templates already defined within the product.

The product also allows healthcare professionals to save any content generated back to the patient's record.

2.4 How will the data be deleted?

The audio stream is processed in real-time during conversations and automatically deleted as soon as the audio is transcribed by Scribe. This ensures that the audio, which is highly sensitive, is not retained any longer than necessary to fulfil the necessary purpose.

Outputs generated by Scribe, such as transcriptions, clinical notes, and summaries, are retained as identifiable personal data for a period of 30 days for healthcare professional users to access.

During this 30-day period, a small number of outputs are extracted for clinical review, in line with statutory obligations relating to medical devices. The number of outputs selected for this process is derived from a statistically-robust methodology to ensure a meaningful analysis of error rates. In addition to these sampled outputs, any outputs identified by clinicians as erroneous or otherwise concerning are also included for review. Please see here for more information about how these outputs are processed for clinical safety purposes.

After this 30-day period, the majority of outputs are permanently and securely deleted. A small number, again derived from a statistically-robust methodology, are retained to support

testing of any changes to the underlying AI model's system prompt resulting from clinical review or other identified improvements. These outputs are:

- selected using a statistically-robust methodology to ensure meaningful regression testing can occur;
- minimised using Named Entity Recognition techniques to redact both structured and free-text patient data, resulting in outputs that align with the ICO's definition of "effectively anonymised" (ensuring that for this specific use case, it is no longer considered personal data); and
- support statistically-valid post-market performance monitoring, detection of rare safety-relevant errors, and compliance with ISO 14971, ISO/TR 20416, and DCB0129 obligations.

Regardless of the steps taken to minimise personal data in the outputs, they continue to be treated with the same technical and organisational measures as if they were fully identifiable, further reducing the likelihood of unintended re-identification of individuals.

Accurx have also taken into account peer-reviewed research and other published guidance relating to data minimisation and re-identification risk, such as this.

Scribe's underlying AI model is not trained or re-weighted using any patient data.

Throughout the duration of the service contract, Accurx, as a Data Processor, will comply with any data deletion instructions reasonably given by the Data Controllers. Adhering to the NHS Information Governance Standards, Accurx requires a signed confirmation from the Data Controller's Caldicott Guardian/DPO, co-signed by a senior clinical representative.

In the event of termination of the service contract, Accurx will delete or return all existing data within 90 days of the contract termination date, in line with our Data Processing Agreement (DPA).

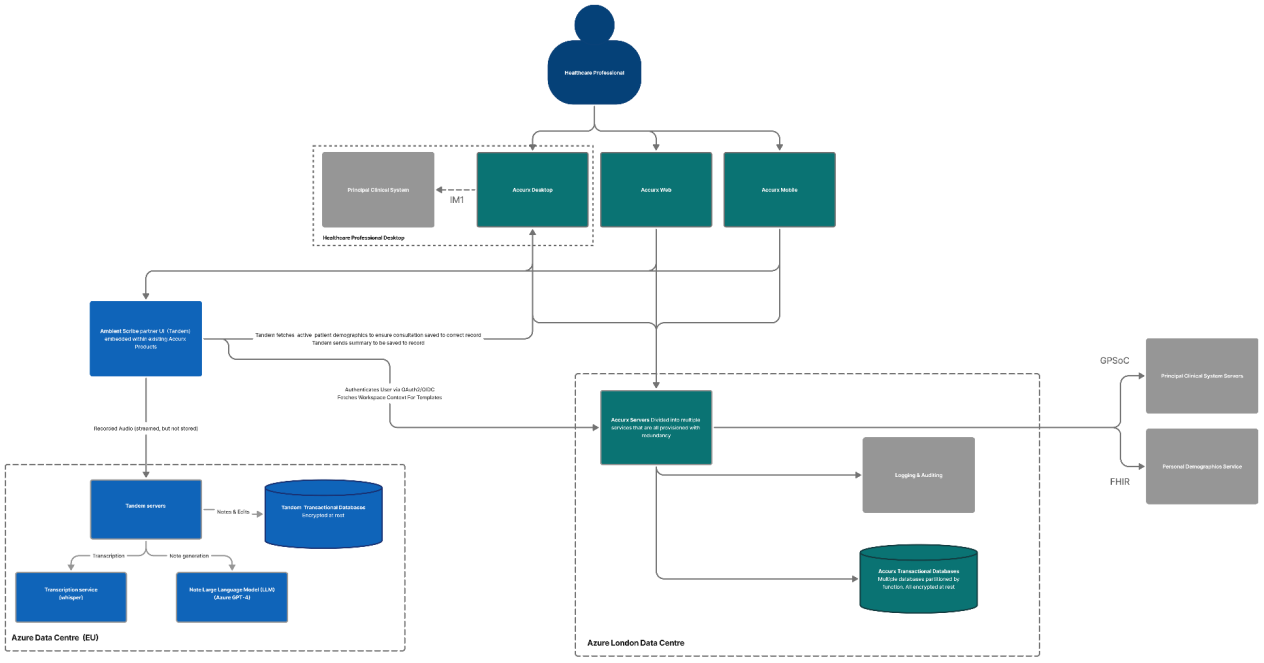
2.5 Will the data be shared with anyone?

A healthcare professional user may choose to share Scribe outputs with other healthcare professionals or the patient themselves as part of providing care.

To the extent required for the provision of the service, Accurx will only share data with the sub-processors (such as cloud service providers) involved in delivery of the Accurx software platform. All of Accurx's sub-processors are contracted with terms satisfying the requirements of UK-GDPR Article 28.

2.6 How will the data flow?

This data flow map illustrates how data flows throughout the Accurx system as part of Scribe.



Data flows are secured at a minimum with TLS1.2 encryption.

2.7 What types of processing have been identified as high risk?

Processing identified as high risk are as follows:

- Content of the transcription following a consultation with a patient which will include data relating to the health of that patient

Scope of processing

2.8 What personal data is being processed?

Explanatory note: Provide all the data fields that the product will process.

- Patient's demographic details (name, date of birth, gender)
- Patient's NHS number
- Healthcare professional's email address
- Audio stream from consultations
- Transcription of consultation

- Outputs generated (such as letters or clinical notes)

2.9 From the data fields provided, are there any special category or criminal offence data being processed?			
☑	Yes	☐	No

2.10 What are the volumes of data that are being processed?

This section to be completed by the Controller. Accurx recommends considering expected Scribe usage in conjunction with practice size or departmental throughput rates to determine this answer.

2.9 What is the frequency of processing?

Data will be generated on an ongoing basis for as long as the Data Controller uses the Accurx Scribe feature.

2.10 How long will this data be retained for?

The audio stream is processed in real-time during conversations and automatically deleted as soon as the audio is transcribed by Accurx Scribe. This ensures that the audio, which is highly sensitive, is not retained any longer than necessary to fulfil the necessary purpose.

Outputs generated by Accurx Scribe, such as transcriptions, clinical notes, and clinical documents, are retained as identifiable personal data for a period of 30 days for healthcare professional users to access.

During this 30-day period, a small number of outputs are extracted for clinical review, in line with statutory obligations relating to medical devices. The number of outputs selected for this process is derived from a statistically-robust methodology to ensure a meaningful analysis of error rates. In addition to these sampled outputs, any outputs identified by clinicians as erroneous or otherwise concerning are also included for review. Please see here for more information about how these outputs are processed for clinical safety purposes.

After this 30-day period, the majority of outputs are permanently and securely deleted. A small number, again derived from a statistically-robust methodology, are retained to support testing of any changes to the underlying AI model's system prompt resulting from clinical review or other identified improvements. These outputs are:

- selected using a statistically-robust methodology to ensure meaningful regression testing can occur;
- minimised using Named Entity Recognition techniques to redact both structured and free-text patient data, resulting in outputs that align with the ICO's definition of "effectively anonymised" (ensuring that for this specific use case, it is no longer considered personal data); and
- support statistically-valid post-market performance monitoring, detection of rare safety-relevant errors, and compliance with ISO 14971, ISO/TR 20416, and DCB0129 obligations.

Regardless of the steps taken to minimise personal data in the outputs, they continue to be treated with the same technical and organisational measures as if they were fully identifiable, further reducing the likelihood of unintended re-identification of individuals.

Accurx have also taken into account peer-reviewed research and other published guidance relating to data minimisation and re-identification risk, such as this.

Context of processing

2.11 What is the nature of the relationship with the individuals?
The relationship with individuals is that within a health and social care system, healthcare professionals are providing direct care to patients.
2.12 How much control will the individuals have over this processing activity?
This section to be completed by the Controller, with consideration of how patients will be informed of the use of Scribe and any ability for them to object to the use of Scribe. The purpose of Scribe is to improve the way consultations are carried out, which benefits both patients and healthcare professionals. Healthcare professionals using Accurx' suite of products have access to Accurx' Terms & Conditions, Data Processing Agreement, Acceptable Use Policy and additional support pages on our website setting out how the products operate and how personal data is processed. Where patients object to their personal data being processed in this manner, the Data Controller must consider how to uphold their right to object. This will likely result in the healthcare professional not using Scribe for that patient's consultation.

accurx

2.13 Would the individuals expect their data to be used in this way?

There is increasing awareness of the need and adoption of AI tools in healthcare to help deliver better outcomes for patients. The latest guidance from the UK Government recognises that the NHS should benefit from advancements in AI and digital technology to improve healthcare delivery, including reducing wait times, improving data sharing, and enhancing patient care.

Accurx is aware of the wider concerns around AI, particularly emphasised within the healthcare sector due to the sensitivity of the health data involved.

The Data Controller, i.e. the organisation for which the healthcare professionals work, must decide how best to inform patients about the use of Scribe. By transparently providing the necessary information about processing to patients, the Data Controller would likely be handling personal data in ways patients would reasonably expect.

2.14 Will any personal data relating to children aged 13 or under be processed?

Yes, the nature of the relationships with the individual is that of health and social care staff providing direct care to patients, who will inevitably sometimes be children and part of other vulnerable groups.

2.15 Are there prior concerns over this type of processing or security flaws?

There are inherent risks recognised with this type of processing, involving the use of AI technologies to transcribe and summarise clinical consultations. Key concerns identified in the wider sector include:

- **Accuracy**: AI systems may generate information that appears credible but is in fact false, misleading, or otherwise inaccurate.
- **Transparency**: There can be challenges in clearly explaining how outputs are generated in an easy to understand manner, making it difficult to understand, challenge, or explain outcomes.
- **Fairness (detrimental effects)**: There is a risk of harmful content being created by the AI system, including misinformation, hate speech, or otherwise discriminatory outputs.
- **Fairness (bias)**: There is a risk of potential biases within the AI model that could result in unequal treatment or outcomes for patients based on characteristics such as age, gender, ethnicity, or other demographic factors.
- **Automated decision-making**: There is a risk that decisions with legal or significant effects on individuals are made with the use of AI without human intervention.
- **Exposure of patient data**: AI systems may include models trained on patient data, or use it as part of continuous learning. This means patient data could be unintentionally exposed during the response to a prompt.

- **Security**: AI systems have complex supply chains which could be tampered with by a malicious actor which may result in unsafe or inaccurate model outputs.

These risks are typical of any AI-driven technology and are well-documented in regulatory and academic literature.

To address these concerns, Accurx has adopted a privacy and security by design and default approach when building Scribe. This included undertaking in-depth and thorough due diligence exercises to assess risks and impacts associated to ensure compliance with applicable law and best practice, to preserve patient safety, to uphold our obligations as a supplier to the NHS, and to maintain Accurx's reputation as a trusted healthcare systems provider.

2.16 Is this a new way of processing data?

As AI is still considered an innovative technology, and Ambient Voice Technology (AVT) has not featured in a healthcare setting for long, Scribe is still considered a new way of processing data both in purpose and nature, as explained below

- **New purpose** - the overall objective of the Accurx platform remains to improve healthcare communication with and about patients, and the specific purpose for Scribe is to provide an automated solution for recording, transcribing and summarising consultations, generating summary content based on these transcriptions to aid communication and enhance the way through which care is delivered to patients.
- **New technology** - Scribe relies on the use of cutting-edge generative AI solutions, which differs significantly from other Accurx platform features, and also from traditional consultation approaches.
- **New nature of processing** - the way Scribe collects and uses transcribed personal data is a new form of data processing, involving the use of generative AI models and markedly different to other Accurx platform features.

Taking these factors into account, the use of Scribe qualifies as a new way of processing data under the UK GDPR and Data Protection Act 2018.

2.17 What is the current state of technology in this area?

Scribe, as an Ambient Scribe tool, is gaining popularity across diverse areas of the NHS and supporting the broader digital transformation agenda. These tools are in active use in clinical settings to improve documentation and streamline workflows. While adoption is still in early stages, interest is accelerating due to increasing pressures on healthcare professionals.

This class of tools aligns closely with published NHS goals to reduce administrative burden on

clinicians, improve care quality, and modernise IT systems.

2.18 Are there any current issues of public concern that you should factor in?

In addition to the AI risks and concerns listed in section 2.15, there have been public concerns over the use of generative AI systems, such as:

- **Data Protection, Privacy and Security** - ensuring that personal data is protected due to its sensitive and confidential nature, as well as embedding privacy and security into the tool in order to maintain the confidentiality, integrity and availability of the data.
- **Consent and transparency** - ensuring that patients are informed about the use of an ambient scribe during their care, and that they can effectively exercise their right to object to such a tool being used to process their personal data.
- **Ethical use and patient trust** - ensuring that ethical concerns regarding the use of AI in healthcare are addressed, especially concerning transparency and the potential for reduced human oversight in clinical decision making. Ensuring this feature enhances, rather than replaces, human interaction is crucial for maintaining patient confidence.

To address these concerns, Accurx has adopted a privacy and security by design and default approach when building Scribe. This included undertaking in-depth and thorough due diligence exercises to assess risks and impacts associated to ensure compliance with applicable law and best practice, to preserve patient safety, to uphold our obligations as a supplier to the NHS, and to maintain Accurx's reputation as a trusted healthcare systems provider.

2.19 Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?

Accurx maintains a policy framework that aligns with information security and governance practices based on our certifications and guidelines from the following standards/bodies:

- ISO 27001:2022;
- NHS DSP Toolkit (ODS code 8JT17);
- UK National Cyber Security Centre Cyber Essentials; and
- Our management systems are externally audited at least annually and internally more frequently than annually.

In addition, Tandem Health AB as a Sub-Processor maintains its own certifications from the following standards/bodies:

- ISO27001:2022;
- ISO13485:2016;
- NHS DSP Toolkit (ODS code TAHEAB001); and
- UK National Cyber Security Centre Cyber Essentials.

accurx

Purpose of the processing

2.20 What do you want to achieve?

Scribe aims to transform and enhance the quality of clinical consultations and improve care outcomes for patients. It enables real-time transcription of consultations, allowing clinicians to focus fully on their patients rather than dividing their attention between patient conversation and note-taking. This creates a more engaged and patient-centric experience, driving improved communication and increased patient satisfaction.

From a healthcare professional's perspective, Scribe aims to reduce the administrative burden by automating the generation of consultation notes and any associated documentation.

This improves both the quality of the consultation and the efficiency of post-consultation workflows.

2.21 What are the intended effects on data subjects?

Scribe allows healthcare professionals to actively listen during appointments, rather than dividing their attention between patient conversation and note-taking. This creates a more engaged and patient-centric experience, driving improved communication and increased patient satisfaction in the following ways:

- more personal and engaged consultations;
- improved communication and understanding; and
- fostering a stronger patient-clinician relationship.

From medical studies investigating the use of Ambient Scribe tools, evidence tended to support the claim that ambient scribes enhance the clinician-patient relationship with most patients comfortable with the use of the tool and a perception of increased attention from their healthcare professional.

Healthcare professionals who have used ambient scribes have been supportive; they cite the increased capability to facilitate more personal, meaningful, and effective patient interactions whilst reducing the burden of after-hours clerical work. Early assessments of patient feedback have been positive, with some describing improved interaction with their healthcare professional.

2.22 What are the benefits of the processing for all the entities involved?

Scribe specifically allows healthcare professionals to focus on their patients during consultations rather than note-taking or drafting documents. By reducing these administrative tasks, they can dedicate more attention to patient care, improving the overall quality of consultations, driving better patient engagement, and offering time savings for clinicians.

Step 3: Consultation process

Considering how to consult with relevant stakeholders

3.1 Are the views of the impacted data subjects and/ or their representatives being sought directly in relation to this processing activity?	
☐ Yes	☐ No
3.1.a) If the answer above is 'Yes', explain how that is being achieved?	
This section to be completed by the Controller	
3.1.b) If the answer above is 'No', what is the justification for not seeking their views?	
This section to be completed by the Controller	
3.2 Who else needs to be involved within your organisation in respect of this processing activity?	
This section to be completed by the Controller	
3.3 Do you need to ask your processors to assist? If so, which ones?	
Scribe is provided by Accurx as a Data Processor, and it is powered by Tandem Health AB as a Sub-Processor. Accurx completed a thorough due diligence process before partnering with Tandem to ensure they meet Accurx' high standards for privacy, security, compliance and clinical safety. Accurx' structured, comprehensive and robust due diligence framework enabled the assessment of	

Tandem at corporate and product levels, including their:

- Information security posture, including security certifications (ISO 27001 and Cyber Essentials), internal policies, and technical controls;
- Data protection practices, including how personal data is handled, stored, accessed, and retained;
- Compliance with UK data protection laws, NHS DSPT (Data Security and Protection Toolkit), and other relevant regulatory standards;
- Company governance and accountability, including registration with regulatory bodies, contractual obligations, subprocessor arrangements, and audit readiness;
- Medical device certification (ISO13485); and
- Product-specific risks, including careful review of AI system interactions with patient information such as how audio recordings are transcribed and summarised, where data is stored and processed, who has access at every stage, and effectiveness of retention policies.

As part of the due diligence process, Accurx entered into a formal Data Processing Agreement (DPA) with Tandem as required under data protection law. This legally-binding agreement defines Tandem's responsibilities as a sub-processor and ensures that it may only act on Accurx' documented instructions on behalf of Data Controllers. The DPA sets out strict terms around confidentiality, data access, sub-processing, international transfers, security measures, and breach reporting. It provides Accurx with the right to audit and monitor Tandem's compliance on an ongoing basis. The DPA contractually ensures that personal data handled on behalf of Accurx' customers is processed lawfully and securely.

Further details can be found on Accurx's sub-processors page

3.4 Do you plan to consult information security experts, or any other experts?

During the development of Scribe, Accurx's Information Security team engaged SecureAI, a leading AI security and safety consultancy, to assist in developing a control framework for safe and secure use of generative AI both internally at Accurx and within the Accurx platform.

Step 4: Assess necessity and proportionality

4.1 What is the lawful basis for the processing set out in Article 6 of the UK GDPR?
Explanatory note: choose an option from the list below.

- ☐ 6(a) Consent
- ☐ 6(b) Contract

- [ ] 6(c) Legal obligation
- [ ] 6(d) Vital interests
- [ ] **6(e) Public task**
- [ ] 6(f) Legitimate Interests

4.2 If processing special category data, what is the condition for processing?
Explanatory note: choose an option from the list below.

- [ ] 9(a) Explicit consent
- [ ] 9(b) Employment/ Social security
- [ ] 9(c) Vital interests
- [ ] 9(d) Not-for-profit bodies
- [ ] 9(e)Made public by the data subject
- [ ] 9(f) Legal claims or judicial act
- [ ] 9(g) Reasons of substantial public interest (with a basis in law)
- [ ] **9(h) Health or social care (with a basis in law)**
- [ ] 9(i) Public health (with a basis in law)
- [ ] 9(j) Archiving, research and statistics (with a basis in law)
- [ ] Not Applicable

4.2.a) If relying on conditions (b), (h), (i) or (j), you also need to meet the associated condition in UK law, set out in Part 1 of Schedule 1 of the DPA 2018.

This section to be completed by the Controller. Accurx recommends that Data Controllers consider the applicability of the "Health and social care" condition set out in DPA2018, Schedule 1, Part 1, paragraph 2.

4.3 Does the processing of the personal data actually achieve your purpose?

This section to be completed by the Controller.

4.4 Is there another way to achieve the same outcome?

This section to be completed by the Controller.

4.5 How will you ensure data quality and data minimisation?

Data Quality and Accuracy
Scribe has several controls in place to ensure data quality and accuracy, such as:

- **Ensuring that all data is obtained from appropriate sources**: Data is recorded directly from the patients and healthcare professionals during consultations, as well as from the Electronic Medical Record and/or the Personal Demographics Service (PDS).
- **Using AI models that have been appropriately tested for accuracy**: While no AI solution guarantees 100% accuracy, Scribe uses AI models that have been demonstrated in peer-reviewed research to perform at or above the level of human transcribers.
- **Implementing robust safeguards against 'hallucinations'**: Scribe leverages advanced voice activity detection to identify and disregard audio that is too quiet or unintelligible, as silence or background noise are recognised to be a significant contributor to AI hallucination instances (where an AI model may insert words or phrases not present in the original audio).
- **Adopting a 'human-in-the-loop' approach**: Once outputs are generated using Scribe, the product displays in-product messages prompting healthcare professionals to review generated content to ensure quality and accuracy, maintaining clinical oversight and accountability. This helps to ensure that every transcription and outputs derived from it (such as letters or clinical notes) are reviewed, validated, and, where necessary, amended by the healthcare professional before being saved to a patient record or used elsewhere.
- **Continuously improving the safety, accuracy and reliability of Accurx Scribe**: As a medical device, a clinical review process is carried out over a sample of outputs generated by Scribe. This process, defined in a Clinical Review Framework agreed between Accurx and Tandem, includes clinical investigation into why edits to outputs were made, and the application of expert clinical judgment to determine whether the issue could have had any clinical safety implications.

Data Minimisation

The audio stream is processed in real-time during conversations and automatically deleted as soon as the audio is transcribed by Scribe. This ensures that the audio, which is highly sensitive, is not retained any longer than necessary to fulfil the necessary purpose.

Outputs generated by Scribe, such as transcriptions, clinical notes, and summaries, are retained as identifiable personal data for a period of 30 days for healthcare professional users to access.

During this 30-day period, a small number of outputs are extracted for clinical review, in line with statutory obligations relating to medical devices. The number of outputs selected for this process is derived from a statistically-robust methodology to ensure a meaningful analysis of error rates. In addition to these sampled outputs, any outputs identified by clinicians as erroneous or otherwise concerning are also included for review. Please see here for more information about how these outputs are processed for clinical safety purposes.

After this 30-day period, the majority of outputs are permanently and securely deleted. A small number, again derived from a statistically-robust methodology, are retained to support testing of any changes to the underlying AI model's system prompt resulting from clinical review or other identified improvements. These outputs are:

- selected using a statistically-robust methodology to ensure meaningful regression testing can occur;
- minimised using Named Entity Recognition techniques to redact both structured and free-text patient data, resulting in outputs that align with the ICO's definition of "effectively anonymised" (ensuring that for this specific use case, it is no longer considered personal data); and
- support statistically-valid post-market performance monitoring, detection of rare safety-relevant errors, and compliance with ISO 14971, ISO/TR 20416, and DCB0129 obligations.

Regardless of the steps taken to minimise personal data in the outputs, they continue to be treated with the same technical and organisational measures as if they were fully identifiable, further reducing the likelihood of unintended re-identification of individuals.

Accurx have also taken into account peer-reviewed research and other published guidance relating to data minimisation and re-identification risk, such as this.

4.6 What information will you give individuals?

This section to be completed by the Controller, with consideration of how patients will be informed of the use of Scribe.

The purpose of Scribe is to improve the way consultations are carried out, which benefits both patients and healthcare professionals.

Healthcare professionals using Accurx' suite of products have access to Accurx' Terms & Conditions, Data Processing Agreement, Acceptable Use Policy and additional support pages on our website setting out how the products operate and how personal data is processed.

4.7 How will you help to support their rights?

This section to be completed by the Controller, with consideration of how patients will be enabled to exercise their information rights relating to Scribe.

Right to be informed
The purpose of Scribe is to improve the way consultations are carried out, which benefits both

patients and healthcare professionals.

Healthcare professionals using Accurx' suite of products have access to Accurx' Terms & Conditions, Data Processing Agreement, Acceptable Use Policy and additional support pages on our website setting out how the products operate and how personal data is processed.

Right to object
Where patients object to their personal data being processed in this manner, the Data Controller must consider how to uphold their right to object. This will likely result in the healthcare professional not using Scribe for that patient's consultation.

Right of access
Accurx will promptly assist Data Controllers to comply with subject access requests. Where personal data has been heavily minimised after 30 days for regression testing purposes, the transcriptions and outputs are considered "effectively anonymised" in line with ICO guidance, no longer forming part of a relevant filing system and thus outside the scope of a reasonable and proportionate search.

Right of erasure
Accurx will promptly assist Data Controllers to comply with erasure requests

Right to not be subject to automated decision-making
This information right does not apply as Scribe does not perform automated decision-making resulting in a legal or other significant effect for an individual; it solely transcribes consultations and summarises those consultations for healthcare professional review and onward use.

Other information rights
Whilst it would be uncommon to see the rights of restriction, rectification and portability exercised in this processing context, Accurx commits to support Data Controllers in upholding individuals' rights on an ad-hoc basis should they be exercised.

4.8 What measures do you take to ensure processors comply?

This section to be completed by the Controller.

4.9 How do you safeguard any international transfers?

All personal data processed through Accurx Scribe is stored and handled exclusively within the European Union (EU). This includes all servers, databases, systems, and processes that Accurx relies on to provide the Accurx Scribe service. No patient data is transferred outside of the EU.

accurx

This intentional approach is designed to ensure full compliance with the UK-GDPR. With the UK-EU adequacy decision, personal data may lawfully flow from the UK to the EU without additional safeguards such as International Data Transfer Agreements. The UK-EU adequacy decision confirms that the EU offers a level of protection to personal data that is “essentially equivalent” to that of the UK.

accurx

Step 5 & Step 6: Identify and assess risks, and identify measures to reduce risks

Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary, as well as identifying additional measures you could take to reduce or eliminate risks identified as medium or high risk.

Product (merge cells if needed)	Risk	Likelihood of harm	Severity of harm	Overall risk	Options to reduce or eliminate risk	Effect on risk	Residual risk	Measure approved
Accurx Scribe	The transcription generated might contain inaccuracies	Rem...	Signifi...	Low	Accurx Scribe contains a range of built-in controls to help ensure the accuracy of all generated content. In addition to that, Accurx Scribe adopts a 'human-in-the-loop' approach. This means that after the transcript is generated, the healthcare professionals need to review generated outputs to verify accuracy and make any edits they require. To ensure that this human review is carried out, the product also prompts users to check that they've reviewed the information and that it is accurate before proceeding to take any actions (such as saving that transcription	Reduced	Low	Yes

accurx

					to a patient's record, sending a referral letter, patient letter, etc.)			
	The microphone does not pick up all information from the consultation	Rem...	Signifi...	Low	Recommended use of a quality microphone to capture a high quality audio stream reduces the likelihood of poor quality input audio. The product employs voice activity detection to identify and disregard audio that is too quiet or unintelligible, to reduce the likelihood that silence or background noise contribute to AI hallucination instances. The risk of poor transcription and generated output accuracy, and related treatment options, are covered above.	Reduced	Low	Yes
	The transcripts of the consultations are accessed by unauthorised parties	Rem...	Severe	Medium	All users must be logged in either via NHS SSO or through their NHS email and password to gain access to the Accurx platform, which includes Scribe. Two-factor authentication (2FA/MFA) is also mandatory at log in. Users of the Mobile	Reduced	Low	Yes

accurx

					Application (App) are required to set up a PIN or use on-device biometrics to access the App. An inactivity timeout, requiring subsequent re-authentication, further reduces the likelihood of unauthorised or malicious access to transcripts and outputs. If unauthorised access has been gained, it means that either the user's NHS SSO account was compromised or their NHS email credentials stolen. Additional controls block users of the App from taking screenshots and screen recordings of consultations on mobile. Comprehensive monitoring and alerting processes are in place to scan for unusual user behaviour such as brute forcing a user's account.			
	Sensitive patient information is leaked from language model	Rem...	Severe	Medium	Accurx has UK-GDPR Article 28 compliant contracts and agreements in place with relevant sub-processors.	Elimin...	Low	Yes

accurx

					The agreement with the language model provider has specific clauses included that mandate them not to store or further use information sent to them. The AI model that powers Scribe does not absorb, reflect or "learn" from any aspect of the conversation between patients and healthcare professionals during a consultation. Such information is: • **never** used to update, retrain or fine-tune the AI model, remaining completely separate from the development of the underlying AI technology, and • **always** kept private and confidential, with no influence on how the model behaves for others, now or in the future.			
	Tampering with Large Language Model resulting in harmful or offensive output.	Rem...	Signifi...	Low	Use of Large Language Models from a trusted supplier, with strong controls such as MFA and RBAC with regular reviews around access to any fine-tuned or custom models.	Reduced	Low	Yes

	Tampering with training or testing data could result in unwanted or unaligned model behaviour.	Rem...	Signifi...	Low	Strong access controls around training and testing datasets, with dataset versioning and change audit logs in place.	Reduced	Low	Yes
	Transcription or notes generated from the transcription saved to the wrong patient's record.	Possi...	Signifi...	Medium	Validation at point of save-to-record to ensure that the patient open in EMR is the same as the patient associated with the transcription/notes. Users using Accurx Scribe on the Mobile App, cannot save consultations to a patient's record.	Elimin...	Low	Yes

Step 7: Sign off and record outcomes

Item	Name/position/date	Notes
Measures approved by:		Integrate actions back into project plan, with date and responsibility for completion

accurx

Residual risks approved by:		If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:		DPO should advise on compliance, step 6 measures and whether processing can proceed
Summary of DPO advice:		
DPO advice accepted or overruled by:		If overruled, you must explain your reasons
Comments:		
Consultation responses reviewed by:		If your decision departs from individuals' views, you must explain your reasons

accurx

Comments:		
This DPIA will kept under review by:		The DPO should also review ongoing compliance with DPIA

accurx

Annex A - Commercial Pack for product functions

For products only - delete if not appropriate.