

ACCESS SMARTNOTES SUPPLEMENTARY TERMS AND CONDITIONS

Version: 1.1 (August 2025)

These SmartNotes Supplementary Terms and Conditions ("**SmartNotes Terms**") form part of and supplement the agreement between You and Access UK Ltd ("**Agreement**"). In the event of any conflict between these SmartNotes Terms and the Agreement, these SmartNotes Terms shall prevail to the extent of such conflict.

STATEMENT OF INTENDED PURPOSE: SmartNotes is a mobile application for healthcare professionals working within a Mental Health and Community Health settings which runs on workplace authorised iOS and Android devices and captures clinical notes and summaries during or after a consultation.

Clinician and patient speech are transmitted to an AI system located outside the UK which converts them into clinical notes and summaries that are then downloaded to the mobile application for review, editing, and approval by the clinician before being incorporated into the patient's record within the Rio Electronic Patient Record (EPR) system.

The system is intended for consultations in the English language only between a single health professional, who has been authorised to use the system, and a single patient aged 18 years or older, or where applicable the patient's adult parent, guardian or helper. The intended users, who can also add their own content, include doctors, nurses, community workers and allied professionals working in mental health, community health, hospitals, clinics and in appropriate external settings such as in the patient's home.

The AI is always 'locked' to the current version of the operating system and also extracts and downloads patient administrative information obtained from Rio EPR. The patient can access their own EPR where permitted by the purchasing institution but any changes to content must be approved by the clinician. The system can be customised by the purchasing institution to the extent permitted by SmartNotes and any customisation will be clearly flagged.

Contraindications and limitations

The system may not function within noisy environments and where the quality and/or content of audio recordings do not meet SmartNotes' internal requirements this will be flagged to the user and to Rio EPR and neither clinical notes nor summaries will be produced.

1. DEFINITIONS

In addition to the definitions in the Agreement, the following definitions apply:

"AI Content" means any output generated by SmartNotes from Audio Data.

"AI Services" means any features within SmartNotes that are powered by, use, or incorporate artificial intelligence, machine learning, or large language models.

"Audio Data" means voice recordings captured during clinical consultations.

"Clinical Documentation" means progress notes and assessment forms generated through SmartNotes.

"Healthcare Professional" means Your authorised clinical staff permitted to use SmartNotes.

"Prompts" means any inputs, queries, or instructions provided to SmartNotes' AI Services, including Audio Data and template selections

"SmartNotes" means Access Rio Smart Notes, a Class I medical device under UK MDR 2002.

"Validation Process" means mandatory clinician review and approval of all AI Content before submission.

2. MEDICAL DEVICE CLASSIFICATION AND REGULATORY COMPLIANCE

SmartNotes is a Class I medical device under UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) intended solely to assist with clinical documentation. It does NOT provide clinical decision support, diagnostic or therapeutic recommendations, monitor physiological processes, or replace clinical judgment. Technical documentation is maintained per regulatory requirements.

3. AI Technology & Limitations

3.1 Technology: SmartNotes uses Microsoft Azure OpenAI Service within Our secure environment to transcribe speech and structure documentation.

3.2 NO WARRANTY: AI SERVICES ARE PROVIDED "AS IS". WE MAKE NO WARRANTIES REGARDING ACCURACY, COMPLETENESS, OR RELIABILITY. AI CONTENT MAY CONTAIN ERRORS AND REQUIRES HUMAN VALIDATION.

3.3 Mandatory Validation: No AI Content may be used without completing the Validation Process. You acknowledge AI outputs may be inaccurate and similar outputs may be generated for other users.

4. ACCEPTABLE USE

4.1 Prohibited Uses: You shall not:

- Use SmartNotes for clinical decisions without following the Validation Process;
- Attempt to discover, extract, or reverse engineer the underlying AI models, algorithms, weights, or system components of SmartNotes;
- Use SmartNotes or any AI Content to create, train, fine-tune, or improve any other AI system or model;
- Generate harmful, illegal, or discriminatory content
- Present AI Content as human-generated or remove any indicators that content was AI-generated
- Submit requests designed to overload, test limits, or disrupt the AI Services;
- Record without required consent; or
- Use AI Services to generate, process, or distribute content that:
 - Is illegal, harmful, abusive, discriminatory, or offensive
 - Infringes any third-party intellectual property rights
 - Contains malware, viruses, or malicious code
 - Violates any applicable laws or regulations

4.2 Violations: We reserve the right to immediately terminate or suspend Your use of SmartNotes if, in our commercially reasonable opinion, we believe that You have violated any of the provisions within this Clause 4.

5. CLINICAL SAFETY AND VALIDATION REQUIREMENTS

5.1 Validation: You must ensure Healthcare Professionals complete the full Validation Process for every document, reviewing all sections and explicitly approving content before submission.

5.2 Training: All users must complete mandatory SmartNotes training covering proper use, AI limitations, and validation requirements.

5.3 Compliance: You shall comply with all applicable laws including data protection, anti-discrimination, healthcare regulations, and professional standards.

5.4 Clinical Responsibility: Healthcare Professionals retain full professional responsibility for documentation accuracy and patient care.

5.5 Patient Consent: You must obtain appropriate consent before recording consultations and follow organisational consent policies.

5.6 Risk Management: You must conduct local clinical risk assessments per DCB0160:2018 and promptly report safety incidents.

6. DATA PRIVACY AND SECURITY

6.1. No Model Training: Your customer data, Prompts, Audio Data, and AI Content are not used to train or improve the underlying AI models unless You provide explicit written consent.

6.2. Audio Data Handling:

- Audio Data is stored locally on devices during processing
- Audio Data is automatically deleted following successful submission of validated Clinical Documentation
- Maximum retention period for Audio Data is 7 days in accordance with NHS Records Management Code of Practice

6.3. Data Retention: Prompts and AI Content are retained for 30 days for security and quality purposes, after which they are automatically deleted unless longer retention is required by law.

6.4. Data Minimisation: SmartNotes processes only the minimum data necessary for clinical documentation purposes and does not retain Audio Data beyond operational requirements.

7. INTELLECTUAL PROPERTY

7.1. Your Content: You retain all rights to Your customer data, Audio Data, and Prompts. We claim no ownership rights to Your inputs to AI Services.

7.2. AI Content: Subject to Your rights in the underlying customer data, You own all AI Content generated specifically for You. However, You acknowledge that:

- Similar outputs may be generated for other users with similar prompts
- AI Content may not be unique or proprietary
- We retain rights to aggregated, anonymous insights derived from usage patterns

7.3. Feedback: Any feedback You provide about SmartNotes or AI Services may be used by Us without restriction to improve Our products and services.

8. CLINICAL RISK MANAGEMENT

8.1. Risk Awareness: You acknowledge receipt of Our Clinical Safety Case Report and Hazard Log, which identify potential clinical risks and implemented control measures.

8.2. Local Risk Assessment: You must conduct appropriate local clinical risk assessments in accordance with DCB0160:2018 standards, considering:

- a) Integration with Your existing clinical workflows;
- b) Training and competency requirements for Healthcare Professionals; and
- c) Local governance and quality assurance processes.

8.3. Incident Reporting: You must promptly report to Us any incidents involving SmartNotes that may impact patient safety or clinical care quality.

9. LIMITATION OF LIABILITY - CLINICAL USE

9.1. Clinical Decision Limitation: Our liability does not extend to clinical decisions made by Healthcare Professionals using information generated by SmartNotes, whether or not such information has been

properly validated. You acknowledge that failure to follow the mandatory Validation Process constitutes misuse of SmartNotes and You shall indemnify Us against any claims arising from such misuse.

9.2. Medical Device Liability: Our liability in connection with SmartNotes as a medical device is subject to the limitations set out in the Agreement. These limitations apply to all claims whether based on defects, patient harm, or otherwise, except to the extent that applicable law prevents such limitation.

9.3 Indemnity You shall indemnify, defend, and hold Us harmless from ALL claims, losses, damages, costs, and expenses (including reasonable legal fees) arising from or related to:

- a) Any breach of the Prohibited Use Violations in Clause 4;
- b) Any failure to complete mandatory Validation Process pursuant to Clauses 3.3 & 5.1;
- c) Any training and compliance breaches pursuant to Clauses 5.2 & 5.3;
- d) Any clinical safety matters pursuant to clauses 5.4 & 5.6;
- e) Any consent and privacy violations pursuant to clauses 5.5 & 6;
- f) Any third-party intellectual property infringement claims.

9.4 Risk Assumption: YOU assume all risks associated with AI-powered clinical documentation including transcription errors and technology failures.

10. TERM AND TERMINATION

10.1. Term: These SmartNotes Terms continue for the duration of Your SmartNotes license(s) in accordance with the Agreement.

10.2. Suspension: We may suspend or terminate Your access to AI Services immediately if You violate these SmartNotes Terms.

11. GENERAL

11.1. Updates: We may update SmartNotes and these SmartNotes Terms. Any material changes shall be notified 30 days in advance where practicable. Any mandatory safety updates may require immediate implementation.

11.2. Compliance Priority: Where compliance with medical device regulations conflicts with general commercial terms, regulatory compliance takes precedence.

11.3 Geographical Limitations: Due to its classification as a Class I medical device under UK Medical Devices Regulations 2002, SmartNotes can only be sold and used within Scotland, England and Wales.