IMAGING BEYOND LTD
GLIOMA AI SERVICE

TERMS AND CONDITIONS

Version 1.0

Dated 19th Nov 2025

This term and conditions do not replace contract.

Document Control

Version: 1.0

Owner: Imaging Beyond Ltd

Status: Approved

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Imaging Beyond Ltd may, at its sole discretion, vary these Terms upon providing the Customer with thirty (30) days' written notice. The varied Terms shall apply from the date stated in the notice.

Parties

- Supplier: Imaging Beyond Ltd (the "Company", "we", "us", "our").
- Customer: The contracting organisation identified on the Order Form (the "Organisation", "you", "your").
- Users: The Organisation's authorised personnel who access the Glioma AI Service (the "Users").

These Terms and Conditions ("Terms") govern access to and use of the Glioma AI Service (the "Service"). These Terms are incorporated into, and form part of, each Order Form executed by the parties. If there is any conflict between an Order Form and these Terms, the Order Form prevails only to the extent of the conflict.

Table of Contents (for convenience)

1. Interpretation

1.1 In these Terms, the following words and expressions have the meanings set out below. Headings are for convenience only and do not affect interpretation.

"AI Output": means any inference, score, probability, annotation, segmentation, summary, recommendation, or other output generated by the Service.

"Applicable Law": means all laws, statutes, regulations, regulatory requirements, guidance and codes of practice applicable to a party from time to time, including those relating to medical devices, patient safety, data protection, confidentiality, and information governance.

"Commencement Date": means the date specified in the Order Form on which the Service starts.

"DPA 2018": means the UK Data Protection Act 2018.

"Data Protection Legislation": means the UK GDPR, the DPA 2018, and any other applicable UK data protection or privacy laws.

"Documentation": means user guides, technical notes, safety information, and other documentation we provide in relation to the Service.

"Hybrid Report": means the report provided by the Company combining AI Output with contextual information (including limitations, required sequences, and flags) for MDT discussion.

"MDT": means a regional Neuro-Oncology Multidisciplinary Team meeting or equivalent clinical governance forum.

"Medical Device Software": means software intended by the manufacturer to be used, alone or in combination, for a medical purpose and regulated as a medical device.

"MHRA": means the Medicines and Healthcare products Regulatory Agency (UK).

"Order Form": means an ordering document signed by both parties (template in Schedule 13) specifying the selected Services, fees, term, and key commercial parameters.

"Patient Data": means information relating to an identified or identifiable patient, including imaging and associated clinical metadata.

"Service": means the Glioma AI Service and any related services described in the Order Form and these Terms, including the Schedules.

"UK GDPR": means the UK General Data Protection Regulation, as defined in the DPA 2018.

"Working Day": means any day other than a Saturday, Sunday or public holiday in England when banks in London are open for business.

1.2 References to clauses are to clauses of these Terms. References to Schedules are to the schedules attached to these Terms.

1.3 If there is any conflict between the body of these Terms and a Schedule, the body of these Terms prevails unless the Schedule expressly states otherwise.

2. Agreement, Commencement and Term

2.1 An Order Form is accepted only when signed by both parties or when we issue an invoice referencing the Order Form.

2.2 The Service commences on the Commencement Date and continues for the initial subscription term specified in the Order Form (the "Initial Term").

2.3 Unless the Order Form states otherwise, the agreement renews for successive 12-month periods (each a "Renewal Period") unless either party gives written notice of non-renewal not less than [90] days before the end of the then-current term.

2.4 Each party warrants that it has authority to enter into these Terms and that doing so does not breach any other agreement.

3. Service Description and Intended Use

3.1 The Service is Medical Device Software provided solely by Imaging Beyond Ltd.

3.2 Intended Use: The Service is intended solely for use in patients with suspected gliomas, to support MDT discussion by providing AI Output derived from MRI imaging inputs.

3.3 The Service is not intended for standalone diagnosis or for use in indications outside its approved scope.

3.4 Use outside the intended scope may lead to inaccurate inferences. The Organisation and Users are responsible for ensuring use remains within scope as defined in our MHRA registration and Documentation.

3.5 We are not responsible for inaccurate results arising from use outside the approved scope or contrary to the Documentation.

4. Clinical Governance, MDT Review and Human Oversight

4.1 All AI Output and Hybrid Reports must be reviewed and discussed in an MDT before clinical decisions are made.

4.2 AI Output is advisory only and does not replace clinical judgement. Where discrepancies occur, MDT consensus takes precedence.

4.3 The Organisation must ensure appropriate clinical governance arrangements exist, including documented pathways for review, escalation and record keeping.

4.4 Users must not rely on AI Output as the sole basis for treatment strategies, clinical trial enrolment, or patient monitoring.

4.5 The Organisation must ensure that Users have suitable training and competencies to interpret AI Output and limitations.

5. Known Limitations and Clinical Risk (False Positives / False Negatives)

5.1 False positives: The Service may generate false positive inferences. Users must communicate this risk during MDT discussion.

5.2 False negatives: The Service may generate false negative inferences. Users must communicate this risk during MDT discussion.

5.3 In the event of discordance between AI Output and MDT assessment, the MDT's decision is considered authoritative.

5.4 If the MDT disagrees with an AI inference suggesting high-grade glioma, a short-term follow-up (typically 2-3 months) may be considered, subject to clinical judgement.

5.5 The Organisation remains responsible for ensuring the overall clinical pathway is safe and appropriate, including use of additional investigations where clinically indicated.

6. Inputs, MRI Data Requirements and Data Quality

6.1 Accurate AI Output requires specific MRI sequences and minimum data quality standards as set out in Schedule 2.

6.2 Where sequences are incomplete or missing, we may indicate required sequences and/or flag increased uncertainty in the Hybrid Report.

6.3 Outputs generated from incomplete or poor-quality data carry increased risk of inaccuracy and must be treated accordingly.

6.4 The Organisation is responsible for ensuring that imaging inputs provided to the Service are lawful to share, appropriately authorised, and transferred securely.

6.5 We may reject data that does not meet the input requirements, or suspend processing until adequate inputs are provided.

7. Hybrid Report and Advisory Recommendations

7.1 Hybrid Reports may include explanatory notes, flags and advisory recommendations to support MDT discussion.

7.2 Recommendations are non-mandatory and informational. The Organisation and MDT retain full discretion whether to act on them.

7.3 We do not provide clinical care and do not assume a duty of care to any patient. Clinical duties remain with the Organisation and its clinicians.

8. Post-Market Surveillance, Feedback and Regulatory Cooperation

8.1 The Service relies on real-world feedback for post-market surveillance and continual improvement.

8.2 Where tissue resection has occurred and histopathology and/or genetic results are available, the Organisation should report the outcome back to us in a secure manner.

8.3 Feedback supports safety monitoring, performance evaluation and regulatory compliance.

8.4 The parties will cooperate in good faith with reasonable requests required for regulatory reporting, vigilance, safety investigations, or audits by competent authorities.

8.5 The Organisation must notify us promptly of any suspected serious incident, safety concern, or material performance issue relating to the Service, in accordance with Schedule 8 (Clinical Safety and Incident Reporting).

9. Account Management, Access Control and User Responsibilities

9.1 We will provide access credentials for authorised Users as specified on the Order Form.

9.2 The Organisation is responsible for ensuring only authorised Users access the Service and that credentials are not shared.

9.3 Users must comply with Schedule 1 (End User Terms) and all internal Organisation policies relevant to clinical systems and information governance.

9.4 The Organisation must notify us promptly of any suspected compromise of credentials or unauthorised access.

9.5 We may restrict or suspend access where we reasonably believe there is unauthorised use, security risk, or breach of these Terms.

10. Implementation, Training, Support and Updates

10.1 If selected on the Order Form, we will provide implementation and configuration services as described in Schedule 2.

10.2 If selected, we will provide training services as described in Schedule 3.

10.3 Support services are provided in accordance with Schedule 4, and service levels in Schedule 6.

10.4 We may issue maintenance releases and updates as described in Schedule 5. Updates may include changes required for security, safety, or regulatory compliance.

10.5 We will use reasonable endeavours to provide advance notice of scheduled maintenance.

11. Fees, Invoicing and Payment

11.1 Fees are as set out in the Order Form and are payable annually in advance unless otherwise stated.

11.2 We may invoice on or shortly after signature of the Order Form. Payment terms are 30 days from invoice date unless otherwise agreed.

11.3 Late payments may incur interest at the statutory rate under the Late Payment of Commercial Debts (Interest) Act 1998.

11.4 Fees exclude VAT (and any similar taxes), which shall be added where applicable.

11.5 If additional Users or services are added during the term, charges may be pro-rated from activation.

12. Suspension

12.1 We may suspend the Service (in whole or part) on written notice where: (a) fees are overdue; (b) we reasonably believe continued provision creates a material patient safety or security risk; or (c) the Organisation is in material breach and has not remedied it within a reasonable time.

12.2 Where practicable, we will provide advance notice of suspension and work with the Organisation to minimise clinical disruption.

12.3 Suspension does not relieve the Organisation of its payment obligations.

13. Compliance with Law and Policies

13.1 Each party will comply with Applicable Law.

13.2 The Organisation will ensure use of the Service complies with its own information governance, clinical safety and procurement policies.

13.3 The Organisation will ensure that all required patient notices, consents, approvals or other lawful bases are in place for sharing Patient Data with the Company for the Agreed Purposes.

13.4 The Organisation will keep appropriate records demonstrating compliance with these Terms and the Organisation's clinical governance obligations.

14. Data Protection and Information Governance

14.1 The parties will comply with Schedule 11 (Data Protection) and any additional data processing terms set out in the Order Form.

14.2 Where the Company processes Patient Data on behalf of the Organisation to provide the Service, the Company acts as a processor and the Organisation acts as controller (unless the Order Form states otherwise).

14.3 The Company will implement appropriate technical and organisational measures to protect Personal Data and maintain confidentiality.

14.4 Where permitted by law and agreed in writing, the Company may use de-identified and/or aggregated data for safety monitoring, quality improvement and research and development purposes, subject to Schedule 11.

14.5 Data retention and deletion are set out in Schedule 11 and Schedule 2.

15. Confidentiality

15.1 Each party shall keep the other's Confidential Information confidential and use it only for the purposes of performing or receiving the Service.

15.2 Confidential Information includes the Service, Documentation, AI models, pricing, security information, and any non-public information disclosed by either party.

15.3 Confidentiality obligations do not apply to information that is public (other than through breach), independently developed, or lawfully received from a third party.

15.4 A party may disclose Confidential Information where required by law or a competent regulator, provided it gives notice where lawful to do so.

16. Intellectual Property

16.1 All Intellectual Property Rights in the Service, Software, Documentation, AI models and related materials remain vested in the Company or its licensors.

16.2 Subject to payment of fees and compliance with these Terms, the Company grants the Organisation a non-exclusive, non-transferable, limited licence during the term to access and use the Service for its internal clinical purposes within the intended scope.

16.3 The Organisation must not: (a) copy, modify, reverse engineer or attempt to derive source code; (b) create derivative works; (c) use the Service to train other models except with our written consent; or (d) remove proprietary notices.

16.4 The Organisation retains all rights in its own data and clinical content, subject to licences granted to the Company under these Terms to deliver the Service.

17. Warranties and Disclaimers

17.1 We warrant that we will provide the Service with reasonable skill and care.

17.2 We do not warrant that the Service will be error-free or uninterrupted, or that it will achieve any specific clinical outcome.

17.3 All other warranties, conditions and terms implied by statute or common law are excluded to the fullest extent permitted by law.

17.4 The Organisation acknowledges that the Service is a decision-support tool (class I medical device) and that clinical decisions remain with clinicians and the MDT.

18. Indemnities

18.1 The Organisation shall indemnify the Company against losses arising from the Organisation's breach of these Terms, unlawful provision of data, or use outside the intended scope.

18.2 The Company shall indemnify the Organisation against third-party claims alleging that authorised use of the Service infringes Intellectual Property Rights, subject to standard exclusions (including misuse, modifications by others, and use outside scope).

18.3 Indemnity procedures (notice, control of defence, cooperation) apply as set out in Schedule 12 (Consultancy and Additional Terms) or, if not selected, by standard principles.

19. Limitation of Liability

19.1 Nothing in these Terms limits liability for death or personal injury caused by negligence, fraud, or any liability that cannot be limited by law.

19.2 Subject to clause 19.1, the Company shall not be liable for indirect or consequential losses, including loss of profit, loss of goodwill, or loss of business.

19.3 The Company shall not be liable for losses arising from: (a) use outside intended scope; (b) clinical decisions made contrary to MDT consensus; (c) misinterpretation or misuse of AI Output; (d) incomplete or poor-quality MRI data; or (e) reliance on advisory recommendations.

19.4 Subject to clause 19.1, the Company's aggregate liability in any Contract Year shall be limited to the fees paid (or payable) by the Organisation in that Contract Year, unless the Order Form specifies a different cap.

19.5 Responsibility and liability for clinical decisions, treatment and outcomes rest with the Organisation and the MDT.

20. Termination and Exit

20.1 Either party may terminate for material breach if the breach is not remedied within 30 days of written notice.

20.2 Either party may terminate immediately if the other party becomes insolvent or ceases business.

20.3 On termination: (a) access to the Service ceases; (b) outstanding fees become immediately due; (c) each party returns or destroys the other's Confidential Information where feasible; and (d) data return/deletion occurs as set out in Schedule 11.

20.4 Termination does not affect rights accrued prior to termination.

21. Audit and Records

21.1 Each party shall keep records sufficient to demonstrate compliance with these Terms for at least six (6) years (or longer where required by Applicable Law).

21.2 The Company will, on reasonable request, provide information reasonably necessary for the Organisation's clinical safety case and information governance assurance, subject to confidentiality and security constraints.

21.3 Where required by a competent authority, the parties will cooperate with inspections, audits or information requests relating to the Service.

22. Force Majeure

22.1 Neither party is liable for delay or failure to perform caused by events beyond its reasonable control, including widespread internet outages, acts of government, or cyber incidents not caused by the affected party's failure to implement reasonable safeguards.

22.2 The affected party shall notify the other and use reasonable endeavours to mitigate the impact.

23. Notices

23.1 Notices must be in writing and delivered by email or pre-paid post to the addresses in the Order Form.

23.2 Operational queries and reporting should be sent to: contact@imagingbeyond.com.

24. Assignment and Subcontracting

24.1 Neither party may assign these Terms without the other's written consent (not to be unreasonably withheld), except to an affiliate or in connection with a merger or sale of substantially all assets.

25. Variation

25.1 Any variation must be in writing and signed by authorised representatives of both parties, except that we may update operational policies where required for security, safety or regulatory compliance, provided we give reasonable notice.

26. Entire Agreement

26.1 These Terms, the Schedules and the Order Form constitute the entire agreement between the parties regarding the Service.

27. Severance

27.1 If any provision is held invalid, the remaining provisions remain in full force.

28. Waiver

28.1 A waiver is effective only if in writing. Failure to enforce a provision is not a waiver.

29. Dispute Resolution

29.1 The parties will attempt to resolve disputes promptly through escalation to senior management.

29.2 If unresolved within 14 days of escalation, either party may propose mediation under the CEDR Model Mediation Procedure.

29.3 Nothing prevents a party from seeking injunctive relief to protect Confidential Information or Intellectual Property Rights.

30. Governing Law and Jurisdiction

30.1 These Terms are governed by the laws of England and Wales.

30.2 The courts of England and Wales have exclusive jurisdiction, unless the Order Form states non-exclusive jurisdiction.

SCHEDULE 1 - END USER TERMS

These End User Terms apply to Users who access the Service through a web portal, API, or other access method provided by the Company.

1.1 By accessing the Service, the User agrees to comply with these End User Terms and the Organisation's policies.

1.2 The User must keep login credentials confidential and must not share them.

1.3 The User must use the Service only for authorised clinical purposes within the intended scope.

1.4 The User must not attempt to copy, scrape, reverse engineer, or interfere with the Service.

1.5 The User must promptly report suspected security incidents or misuse.

Acceptable Use (non-exhaustive):

- Do not upload data for non-glioma indications or for testing outside approved pathways unless expressly authorised.
- Do not use screenshots or exports containing Patient Data outside approved secure environments.
- Do not store Patient Data locally unless the Organisation's policies permit and appropriate safeguards are in place.
- Do not use the Service in emergencies where immediate action is required without appropriate human oversight.

Cookies and analytics (if applicable) will be described in the Organisation's and Company's privacy notices and as required by law.

SCHEDULE 2 - SETUP, CONFIGURATION AND MRI DATA REQUIREMENTS

This Schedule applies where implementation and/or configuration services are selected in the Order Form, and also sets out the minimum input requirements for MRI data submissions.

A. Implementation and Configuration

2.1 Project governance: Each party will appoint a project lead. The Organisation will nominate a Project Manager as the primary point of contact.

2.2 Kick-off: The parties will agree onboarding timelines, access methods, information governance approvals, and testing arrangements.

2.3 Connectivity: The parties will agree a secure mechanism for data transfer (e.g., secure portal, SFTP, VPN, or other mutually agreed method).

2.4 Configuration: We will configure organisation-level settings (sites, user roles, reporting preferences, and security parameters) as agreed.

2.5 Acceptance testing: The Organisation will participate in user acceptance testing (UAT) on representative cases prior to go-live.

2.6 Go-live: The parties will agree a go-live date and contingency arrangements.

B. MRI Sequence Requirements (minimum)

Unless otherwise agreed in writing, the Organisation should provide the following sequences for each case submission:

- T1-weighted pre-contrast
- T1-weighted post-contrast
- T2-weighted
- FLAIR
- Diffusion-weighted imaging (DWI) and derived ADC map

3D sequences for T1, and FLAIR are preferred but if they are not available, 2D sequences can also be used for Glioma AI model

Optional sequences (where available) may improve accuracy of Glioma AI model:

- Perfusion (DSC/DCE), Arterial spin labelling (ASL) and CBV maps
- Susceptibility-weighted imaging (SWI)
- MR spectroscopy, especially Multivoxel spectroscopy
- Follow-up comparative series (prior scans)

C. Data Quality and Formatting

- DICOM format preferred; NIfTI is not acceptable
- Studies must include correct orientation and complete series; corrupted or incomplete series may be rejected.
- Anonymisation: unless a lawful basis requires identifiable data, the Organisation should de-identify Patient Data prior to transfer in accordance with its policies. The pseudonymization table to re-identify the patient's information should be contracting organization. We will not hold any pseudonymization tables on our end.
- Metadata: include minimum case metadata as agreed (e.g., study date/time, site, scanner, and relevant clinical notes where permitted).

D. Submission, Rejection and Resubmission

2.20 We may reject submissions that do not meet the minimum sequence requirements or data quality thresholds.

2.21 Where rejected, we will provide a reason code (e.g., missing T1 post-contrast, corrupted series, insufficient quality, significant motion artefacts). However, in rare cases exceptions may be made purely out of good will if requested by referring physician or MDT from contracting organization (e.g. patient cannot be rescanned etc.). When such rare exceptions are made, it should be noted that Glioma AI analysis accuracy will be significantly impacted.

2.22 The Organisation may resubmit corrected data. Turnaround times restart from acceptance.

2.23 Where urgent clinical timelines apply, the Organisation must not rely on the Service and must follow standard care pathways. However, in rare cases exceptions maybe made purely out of good will.

E. Turnaround Times (indicative)

- Standard processing: Within 3 Working Days from acceptance.
- Backlog or scheduled maintenance may impact turnaround; we will communicate known delays where practicable.

SCHEDULE 3 - TRAINING

This Schedule applies where training is selected in the Order Form.

- Training for referring physicians and relevant hospital staff (e.g. MDT staff) may be provided on-site or remotely.
- Training content includes: intended use, limitations, interpretation of Hybrid Reports, workflows for MDT discussion, and incident reporting.
- The Organisation is responsible for ensuring Users attend training and maintain competencies.

SCHEDULE 4 - SUPPORT

Support is provided during Standard Support Hours unless otherwise agreed.

A. Support hours and contact

- Standard Support Hours: 08:00 to 17:00 (UK time) on Working Days.
- Support contact: contact@imagingbeyond.com (or as specified in the Order Form).

B. Severity levels

- Severity 1 (Critical): Service unavailable or severe patient safety risk; no workaround.
- Severity 2 (High): Major functionality impaired; workaround may exist.
- Severity 3 (Medium): Minor functionality issue or performance degradation.
- Severity 4 (Low): General queries, configuration changes, or enhancement requests.

C. Response and resolution targets (indicative)

- Severity 1: acknowledge within 2 hours; work continuously to restore service where feasible.
- Severity 2: acknowledge within 1 Working Day; provide workaround where feasible.
- Severity 3: acknowledge within 2 Working Days.
- Severity 4: acknowledge within 5 Working Days.

Resolution times depend on root cause, reproducibility, and required safety/regulatory validation. Non-reproducible issues may require additional information from the Organisation.

SCHEDULE 5 - UPDATING AND MAINTENANCE

5.1 We may issue maintenance releases for bug fixes, security patches, and performance improvements.

5.2 We may issue new versions where required for regulatory compliance, safety, or significant functionality changes.

5.3 We will maintain revision history and release notes suitable for clinical governance.

5.4 If an update materially changes outputs or workflow, we will provide reasonable notice and, where appropriate, updated Documentation and training materials.

SCHEDULE 6 - SERVICE LEVELS

6.1 Availability target: 90% monthly availability, excluding scheduled maintenance.

6.2 Scheduled maintenance window: typically, 00:00 to 05:00 UK time, with at least 48 hours notice where practicable.

6.3 Unscheduled maintenance may occur to address urgent security or safety issues.

6.4 Service credits (if any) are specified in the Order Form.

SCHEDULE 7 - GLIOMA AI MODULE DESCRIPTION

This Schedule describes the Service at a high level for contractual clarity. Detailed technical and clinical information is provided in the Documentation and may change through Maintenance Releases.

A. Outputs

- AI Output derived from MRI inputs to support MDT discussion in suspected glioma cases.
- Hybrid Report with: summary of inputs received, warnings for missing sequences, AI Output, and advisory notes.

B. Constraints

- The Service does not replace radiologist interpretation or MDT decision-making.
- The Service must not be used outside the intended scope or as a screening tool for the general population.

SCHEDULE 8 - CLINICAL SAFETY AND INCIDENT REPORTING

This Schedule describes safety-related communications between the parties.

8.1 The Organisation will designate a clinical safety officer or responsible clinician as the primary safety contact.

8.2 The Organisation will notify the Company promptly if it becomes aware of a suspected serious incident or near-miss involving the Service.

8.3 Notifications should include: (a) case identifier; (b) date/time; (c) description of event; (d) suspected contributing factors (e.g., missing sequences); and (e) impact or potential impact.

8.4 The Company will investigate promptly, provide interim findings where feasible, and cooperate with regulatory reporting as required.

8.5 The Company may recommend temporary mitigations (e.g., additional human review steps, suspension for specific sites) where patient safety could be impacted.

8.6 Nothing in this Schedule replaces the Organisation's duty to report patient safety incidents through its own governance and statutory reporting routes.

SCHEDULE 9 - PERFORMANCE AND SYSTEM REQUIREMENTS

- The Organisation is responsible for providing suitable network connectivity and secure clinical IT environments.
- Minimum requirements (indicative): modern browser, supported operating system, secure endpoint protection, and adequate bandwidth.
- Performance may depend on internet conditions and the Organisation's internal systems.

SCHEDULE 10 - THIRD PARTY DOCUMENTATION

Where relevant, the Company may rely on third-party standards and guidance, including (non-exhaustive):

- Relevant NHS and MHRA guidance for software as a medical device.
- UK data protection guidance, including ICO materials.
- Clinical safety standards and information governance guidance applicable to the Organisation.

SCHEDULE 11 - DATA PROTECTION

This Schedule sets out the data protection terms between the parties and is intended to support compliance with the UK GDPR and DPA 2018.

A. Roles and scope

11.1 The parties will determine and document their respective roles (controller/processor) in the Order Form or a data sharing agreement where required.

11.2 Where the Company processes Personal Data on behalf of the Organisation for the Agreed Purposes, the Organisation is the controller and the Company is the processor.

11.3 Agreed Purposes: (a) operation of the Service; (b) provision of Hybrid Reports; (c) post-market surveillance and safety monitoring; and (d) performance and security monitoring.

B. Processor obligations

- Process Personal Data only on documented instructions from the Organisation (unless required by law).
- Ensure staff are bound by confidentiality.
- Implement appropriate technical and organisational measures to ensure a level of security appropriate to risk.
- Maintain records of processing activities as required.
- Support the Organisation with data subject rights requests, DPIAs, and consultations with the ICO where reasonably required.
- Notify the Organisation without undue delay after becoming aware of a Personal Data Breach.

C. Sub-processors

11.20 The Company may appoint sub-processors (e.g., hosting providers) subject to appropriate contractual safeguards.

11.21 The Company will maintain a list of material sub-processors and provide notice of material changes where feasible.

D. International transfers

11.30 Personal Data will not be transferred outside the UK unless a lawful transfer mechanism is in place (e.g., UK adequacy regulations, IDTA, or other approved safeguards).

E. Retention and deletion

11.40 Personal Data will be retained only for as long as necessary for the Agreed Purposes and as required by Applicable Law.

11.41 On termination, the Company will delete or return Personal Data in accordance with the Organisation's instructions, unless retention is required by law.

F. Security measures (indicative)

- Access controls and least-privilege role design.
- Encryption in transit and at rest where appropriate.
- Logging and monitoring for security and audit.
- Secure development and vulnerability management.
- Backups and business continuity arrangements.

SCHEDULE 12 - CONSULTANCY AND ADDITIONAL SERVICES

If consultancy or additional services are purchased, the scope, fees and deliverables will be set out in an additional Order Form or statement of work. Unless otherwise agreed, consultancy is time-and-materials billed at agreed rates.

SCHEDULE 13 - TEMPLATE ORDER FORM

This template is for convenience and should be tailored per customer engagement.

- Supplier: Imaging Beyond Ltd, Company Number: 15712002 of 167-169 Great Portland Street, 5th Floor, London, United Kingdom, W1W 5PF

- Customer: [INSERT ORGANISATION NAME] of [INSERT ADDRESS] [INSERT COMPANY NUMBER IF APPLICABLE].

- Commencement Date: [INSERT].
- Initial Term: [INSERT].
- Renewal: [INSERT].
- Fees: [INSERT].
- Sites/Users: [INSERT].
- Selected schedules/services: [INSERT].
- Authorised signatories: [INSERT].

Signatures

For and on behalf of Imaging Beyond Ltd: _____ Date: _____

For and on behalf of the Customer: _____ Date: _____

SCHEDULE 14 CLINICAL SAFETY, REGULATORY AND INCIDENT REPORTING

14.1 This Schedule sets out the minimum clinical safety, regulatory and incident reporting obligations applicable to the use of the Glioma AI Service as a medical device software.

14.2 Clinical safety governance. The Organisation shall nominate a Clinical Safety Officer (CSO) responsible for oversight of the Organisation's local deployment, including local hazard identification, mitigation and user training.

14.3 The Company shall maintain a clinical safety management system appropriate to the MHRA registration and shall maintain records of risk management, verification and validation activities applicable to the Glioma AI Service.

14.4 Incident reporting (Organisation). The Organisation shall notify the Company without undue delay and in any event within 48 hours of becoming aware of any suspected adverse incident, near miss, or other safety issue that may reasonably be connected to the Glioma AI Service, including any case where an inference is reasonably suspected to have contributed to a delay, misdiagnosis, inappropriate escalation/de-escalation of care, or other patient safety concern.

14.5 Incident reporting (Company). The Company shall acknowledge incident reports within four Working Day and shall keep the Organisation reasonably informed of investigation progress and any field safety corrective actions, including any safety notices or urgent updates.

14.6 Regulatory notifications. Where required by law or regulator guidance, the Company shall submit relevant reports to the MHRA and/or other competent authorities. The Organisation shall provide reasonable cooperation, including anonymised case details and timelines, to support such notifications.

14.7 Recall and safety actions. The Company may suspend or withdraw access to the Service where necessary for patient safety or regulatory compliance. Where practicable, the Company will provide advance notice and an explanation.

14.8 Clinical review remains mandatory. The parties reaffirm clause 9 (Clinical Decision-Making) and clause 7 (MDT Review) of the Agreement: AI outputs are advisory and must be reviewed by appropriately trained clinicians and the MDT.

SCHEDULE 15: CHANGE CONTROL AND VALIDATION OF UPDATES

15.1 Purpose. This Schedule governs material changes to the Glioma AI Service (including model updates, workflow changes, integrations and report format changes) and defines validation and communication steps.

15.2 Change classes. Changes are categorised as (a) Minor Changes (no material impact on performance, clinical meaning, or workflow), (b) Material Changes (may affect performance, clinical meaning, workflow or regulatory status), or (c) Emergency Changes (required for safety, security or regulatory reasons).

15.3 Notice. The Company will provide at least 10 Working Days' notice for Material Changes and at least 48 hours' notice for Minor Changes where practicable. Emergency Changes may be implemented without notice if required to reduce risk.

15.4 Information provided. For each Material Change, the Company will provide a change summary, expected benefits/risks, any updated instructions for use, and (where applicable) validation evidence relevant to the change.

15.5 Organisation acceptance testing. Where the Service is integrated with the Organisation's systems, the Organisation shall provide reasonable access to a test pathway (or representative data) to allow verification that integrations continue to operate post-change. This testing does not replace clinical validation.

15.6 Reversion and mitigation. Where a Material Change results in a material operational issue attributable to the Company, the Company will use reasonable endeavours to mitigate, including rollback where feasible and clinically safe.

15.7 Documentation. The Company will maintain a change log and will make a summary available to the Organisation on request for audit and governance purposes.

SCHEDULE 16: POST-MARKET SURVEILLANCE FEEDBACK PACK

16.1 Purpose. This Schedule defines the minimum feedback data fields the Organisation shall provide to support post-market surveillance (PMS) and continuous safety monitoring.

16.2 Mandatory feedback cases. The Organisation shall provide feedback for all cases where (a) tissue resection/biopsy has occurred and histopathology and/or molecular/genetic data is available, (b) a material discordance is identified between AI output and MDT conclusion, or (c) a suspected adverse incident has occurred. (d) survival and follow up information about patients who did not undergo biopsy or surgery, if available.

16.3 Minimum dataset (to be shared securely and in accordance with Schedule 11):

(a) A unique Organisation case identifier (pseudonymised);

(b) Study date and modality (MRI);

(c) Confirmation of MRI sequence set provided (T1, T1 post-contrast, T2, FLAIR, DWI/ADC, etc.);

(d) Glioma AI inference output summary and report version identifier;

(e) MDT outcome/working diagnosis (including grade where concluded);

(f) Histopathology result and WHO grade where available;

(g) Key molecular markers where available (e.g., IDH status, 1p/19q, MGMT) as reported;

(h) Treatment path taken (e.g., surgery, chemo, radiotherapy, surveillance) in high-level terms;

(i) Any relevant follow-up imaging outcome at 2-3 months where performed;

(j) Free-text comments on discordance, artefacts, or clinical context that may have affected interpretation.

16.4 Feedback method. Unless otherwise agreed, feedback shall be provided via the Company's secure portal or encrypted transfer method agreed in writing between the parties. Feedback does not require patient’s personal detail to be shared; all feedback is anonymized.

16.5 Timing. Feedback should be provided within 30 days of availability of the relevant outcome (e.g., histopathology report issued) and, for incident-related feedback, within the timelines set out in Schedule 14.

16.6 The Company will acknowledge receipt of PMS feedback and may request clarifications where essential to safety investigation or regulatory reporting.

SCHEDULE 17: TECHNICAL AND ORGANISATIONAL MEASURES (TOMS)

This Schedule describes the minimum technical and organisational measures implemented by Imaging Beyond Ltd to protect Personal Data and patient data processed as part of the Glioma AI Managed Service. The specific controls applied in a given deployment may vary depending on the integration method agreed in the Order Form, but shall be no less protective than the baseline set out below.

1. Governance and Policies

- Information security policy suite (acceptable use, password policy, access control policy, incident response policy, change management policy).
- Appointed security lead and named data protection contact.
- Regular risk assessment and review; security objectives reviewed at least annually.
- Staff confidentiality agreements and mandatory information governance training on induction and annually thereafter.
- Documented onboarding/offboarding process for employees and contractors, including access revocation on role change/termination.

2. Access Control

- Role-based access control (RBAC) aligned to least privilege.
- Unique user IDs; no shared accounts for production systems.
- Multi-factor authentication for administrative access and remote access.
- Strong password policy, account lockout, and session timeout controls.
- Privileged access management for production support; admin access granted only for time-limited tasks where practicable.
- Periodic access recertification and audit of user permissions.

3. Encryption

- Encryption in transit using TLS 1.2+ for all web portals and APIs.
- Secure file transfer using SFTP/HTTPS with strong ciphers when agreed for DICOM transfer.
- Encryption at rest for production databases and storage volumes (industry standard algorithms).
- Key management practices including rotation and restricted access to encryption keys.

4. Network and Infrastructure Security

- Firewalls and network segmentation to isolate production systems.
- Hardened server configurations; unnecessary services disabled.
- Routine vulnerability scanning and timely remediation of critical vulnerabilities.

- Centralised logging for security-relevant events and administrative actions.
- Protection against common web threats (e.g., WAF controls where applicable).

5. Application Security

- Secure development lifecycle including code review and security testing.
- Dependency and container/image scanning where applicable.
- Separation of development, test, and production environments.
- Change control with approval and rollback procedures; emergency fixes documented post-implementation.

6. Availability, Backups, and Resilience

- Regular backups of configuration and operational data; backup integrity testing performed periodically.
- Documented disaster recovery and business continuity arrangements.
- Monitoring and alerting for system health and capacity.
- Planned maintenance windows communicated in accordance with the Service Levels Schedule.

7. Audit and Assurance

- Audit logging retained for an appropriate period (see Data Retention Schedule) and protected from unauthorised modification.
- Internal security audits and management review.
- Cooperation with the Organisation's reasonable audit requests as set out in Schedule 11.

8. Incident Management

- Documented incident response process including triage, containment, eradication, recovery, and lessons learned.
- Security incidents recorded, investigated, and reported to the Organisation as required under Schedule 11.
- Where applicable, clinical safety incidents handled in accordance with Schedule 15 (Clinical Safety and Regulatory Requirements).

9. Data Minimisation and Pseudonymisation

- Processing limited to the minimum necessary data fields for the Agreed Purposes.
- Use of pseudonymous case identifiers where feasible; direct identifiers avoided unless strictly necessary.
- Support and troubleshooting data shared using anonymised or redacted datasets where practicable.

SCHEDULE 18: SUB-PROCESSORS AND THIRD PARTIES

This Schedule sets out the framework for Imaging Beyond Ltd to engage Sub-processors to assist in delivering the Managed Service. A current list of Sub-processors (if any) and their functions should be maintained by Imaging Beyond Ltd and made available to the Organisation on request.

1. Categories of Sub-processor

- Hosting and infrastructure providers (compute, storage, networking).
- Email and ticketing providers for support communications.
- Monitoring and logging providers for availability and security monitoring.
- Secure file transfer and integration tooling providers.

2. Appointment and Controls

- Any Sub-processor shall be appointed under a written contract imposing data protection obligations no less onerous than those in Schedule 11, including confidentiality and appropriate security measures.
- Imaging Beyond Ltd remains is not liable for the performance of Sub-processors as it may sometimes be beyond control of our team (e.g. cloud provider downtime).
- The Organisation will be notified of any intended change concerning the addition or replacement of Sub-processors and may object on reasonable grounds related to data protection.

SCHEDULE 19: DATA FIELDS, METADATA, AND REPORT CONTENT

This Schedule provides a non-exhaustive list of data categories that may be processed in delivering Glioma AI. The exact fields processed will depend on the agreed workflow and integrations.

1. Patient and Case Data

- Imaging data: DICOM series for required MRI sequences (see Schedule 2).
- Case identifiers: accession number/study UID; pseudonymised case reference for service tracking.
- Optional clinical context: age band, sex, and short clinical indication (if supplied by the Organisation).
- Histopathology/genetic results for post-market surveillance feedback (where available).

2. User and Operational Data

- User details: name, professional role, organisation, professional registration number, and contact email (for audit and support).
- Operational logs: timestamps for receipt, processing, and report delivery; system health and performance logs.
- Support records: ticket history and communications relevant to service delivery.

3. Output Data in the Hybrid Report

- Inference summary (e.g., probability bands and narrative interpretation).
- Flags for data completeness and quality checks.
- Recommended actions where appropriate (advisory only).
- Versioning information: model identifier, software version, and inference timestamp.

SCHEDULE 20: CLINICAL SAFETY INCIDENT FORM (TEMPLATE)

This template may be used by the Organisation to report clinical safety concerns, adverse incidents, or near misses related to Glioma AI. The Organisation may use its own reporting form, provided it includes the minimum information below.

A. Reporter Details

- Organisation name and site.
- Reporter name, role, and contact details.
- Date/time of report submission.

B. Case Details

- Case reference / accession number (pseudonymized).
- MRI date/time and sequences provided.
- Clinical context (short summary).

C. Description of Incident

- Summary of what happened (include AI output and MDT conclusion).
- Whether patient harm occurred (yes/no/unknown).
- Immediate actions taken.
- Whether this was reported to any regulator (e.g., MHRA) and reference number if available.

D. Attachments

- Hybrid report (redacted as appropriate).
- Relevant MDT minutes extract or outcome statement (if available).
- Histopathology/genetics results (if available).

SCHEDULE 21: CHANGE REQUEST FORM (TEMPLATE)

This template may be used to request changes to configuration, integrations, or reporting outputs. This does not oblige Imaging Beyond Ltd to implement any change.

1. Request Details

- Requestor name and contact.
- Organisation and site.
- Date of request.
- Requested change description (what, why, and desired outcome).
- Priority (low/medium/high) and desired delivery timeframe.

2. Impact Assessment (to be completed by Imaging Beyond Ltd)

- Assessment of clinical safety impact (if any) and whether additional validation is required.
- Technical effort estimate and dependencies.
- Commercial impact (fees, if any).
- Proposed acceptance criteria and test plan.

SCHEDULE 22 - GLOSSARY (INFORMATIVE)

This glossary is provided for convenience and does not alter the meaning of the Agreement.

Term	Meaning
ADC	Apparent Diffusion Coefficient (derived from diffusion-weighted imaging).
DICOM	Digital Imaging and Communications in Medicine standard for medical imaging data.
FLAIR	Fluid-attenuated inversion recovery MRI sequence.
GBM	Glioblastoma, commonly used to refer to WHO grade 4 diffuse glioma.
Hybrid report	The combined output provided by the Company, typically containing AI outputs plus human review statements and limitations.
MDT	Multidisciplinary Team; in neuro-oncology typically includes radiology, neurosurgery, oncology, neuropathology and specialist nursing.
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom).
Pseudoprogression	Treatment-related imaging changes that can mimic tumour progression.

SCHEDULE 23 - SAMPLE HYBRID REPORT STRUCTURE (INFORMATIVE)

The actual layout may vary. This schedule shows an example structure to help MDT review and auditability.

- Patient identifiers (held by Organisation only) and examination identifiers
- MRI sequences received and quality checks (complete/incomplete flags)
- AI inference summary (e.g., suspected grade category; confidence bands, if provided)
- Key imaging features detected (e.g., enhancing tumour, non-enhancing tumour, necrosis/haemorrhage, oedema)
- Limitations / cautions (false positive / false negative risk statements; missing sequences; motion artefact)
- Recommendation section (advisory only): follow-up interval suggestions, consider further imaging, etc.
- MDT discussion section (completed by Organisation) and final clinical plan
- Audit trail: timestamps, version of Glioma AI, reviewer ID

SCHEDULE 24 - POST-MARKET SURVEILLANCE FEEDBACK FORM (TEMPLATE)

The Organisation should complete and send this form (or equivalent structured data) for cases where tissue resection has occurred and histopathology and/or molecular results are available.

Field	Response
Organisation name	
Hospital / Trust	
MDT date	
Study accession number (local)	
Date of MRI	
Sequences submitted	
Glioma AI inference (summary)	
MDT radiology impression (summary)	
Surgery/biopsy date	
Histopathology result (WHO grade)	
Molecular markers (e.g., IDH, 1p/19q, MGMT)	
Discrepancy noted? (Y/N)	
If discrepancy: brief narrative and any contributing factors	
Consent / lawful basis confirmation (as required by Organisation)	

SCHEDULE 25 - AUDIT LOG MINIMUM DATA FIELDS

Unless prohibited by law or the Organisation's policies, the following minimum metadata should be retained for audit and traceability. Patient identifiers should remain under the Organisation's control; the Company should retain only what is necessary to provide the service.

- Unique case reference / accession number token
- Timestamp: upload received; inference generated; hybrid report released
- Software version; model version; configuration profile
- Sequence list and completeness flags
- Quality check outcomes (e.g., motion flag, slice thickness out-of-range)
- User / reviewer identifier (Organisation and Company, as applicable)
- Any manual adjustments or annotations (with rationale)
- Support tickets linked to the case (if any)
- Post-market surveillance status: feedback requested/received