

HELIOS

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TERMS OF SERVICE, PRIVACY POLICY AND RESEARCH PARTICIPATION AGREEMENT

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CRITICAL HEALTH NOTICE — READ BEFORE USING THIS PLATFORM

EMERGENCY: HELIOS is NOT an emergency service. If you are experiencing a life-threatening situation — including severe chest pain, acute respiratory distress, loss of consciousness, severe bleeding, stroke symptoms, anaphylaxis, suicidal crisis, or any condition involving immediate risk to life — you must immediately call your local emergency number (911 in the US, 112 in the EU, 107 in Argentina, 192 in Brazil, 123 in Colombia, 911 in Mexico) and go to the nearest emergency room. Do not use this platform.

NOT A DIAGNOSTIC TOOL: HELIOS is a clinical information, record management, and care navigation platform. It is not a licensed medical practitioner. All clinical assessments presented by HELIOS are informational outputs requiring review and validation by a licensed physician before any clinical decision is made. Nothing in this platform constitutes a medical diagnosis, prescription, or treatment recommendation.

CHILDREN: This platform is not designed for users under 18 years of age. Users under 18 must have a parent or legal guardian create and manage their account. No data from users under 13 will be collected under any circumstances.

SECTION 1 — PARTIES, SCOPE, AND DEFINITIONS

1.1 Corporate Entities

This document constitutes a legally binding agreement between you ("User", "Patient", or "Research Participant") and the following corporate entities (collectively, "HELIOS", "we", "us", or "our"):

- Axxessible Technologies SL — registered in Barcelona, Spain (EU operating entity). Primary EU data controller under GDPR.
- Axxessible Tech Inc — registered in Delaware, USA (US operating entity). Primary HIPAA covered entity affiliate.
- These entities operate jointly under the brand names HELIOS, swissmed.ai, and midoctor.ai.

1.2 Platform Scope

This agreement governs your access to and use of:

- The HELIOS care-completion platform accessible at swissmed.ai, midoctor.ai, and all associated mobile applications, APIs, and integrated services.
- The HERMES clinical record reconciliation engine embedded within the HELIOS platform.
- All physician review queues, telemedicine routing, and care navigation features.
- The HELIOS clinical research participation program (separately consented in Section 12).
- All communications, notifications, and outputs generated by HELIOS systems.

1.3 Definitions

Term	Definition	Jurisdiction Relevance
AI Assessment	The structured clinical output generated by the HELIOS 107-agent consensus system prior to physician review. Not a medical diagnosis.	All jurisdictions
Clinical Navigation Output	Any information, structured summary, or care pathway recommendation produced by HELIOS for patient or physician use.	All jurisdictions
Consensus Agents	The 107 specialist-trained AI agents operating within the HELIOS orchestrator using multi-model consensus (Weighted Log Opinion Pool + Kendall's W).	All jurisdictions
De-identified Data	Patient data from which all direct and indirect identifiers have been removed per HIPAA Safe Harbor (45 CFR §164.514(b)) and GDPR Recital 26 standards.	US + EU + all LatAm
FHIR Bundle	A standardized clinical document in HL7 FHIR R4 format produced by the HERMES pipeline.	US + EU + UK
HERMES Pipeline	The 6-layer clinical record reconciliation engine processing foreign medical documents (drug resolution, lab conversion, vaccine	All jurisdictions

	normalisation, code translation, geographic risk detection, FHIR assembly).	
Medical Knowledge Graph (MKG)	The proprietary database of 121,671+ drug aliases, 76 countries, 12 government registries, and all derived clinical knowledge assets.	All jurisdictions
Physician Review Queue	The secure interface through which licensed physicians review, edit, and sign AI-generated clinical assessments before patient delivery.	All jurisdictions
Pre-Assessment Lock	The immutable, timestamped record of the AI consensus output stored before any physician interaction, required for clinical research validity.	All jurisdictions — FDA/EU MDR
Research Data	De-identified clinical data voluntarily contributed by consenting users for the HELIOS clinical validation research program.	US (FDA), EU (MDR), LatAm
Sensitive Health Data	All data relating to physical or mental health, medications, diagnoses, procedures, lab values, and genetic information.	GDPR Art. 9 / HIPAA / LatAm laws
Telemedicine Partner	Licensed physician networks and healthcare providers integrated with HELIOS to provide physician review and clinical validation services.	All jurisdictions

SECTION 2 — WHAT HELIOS IS AND IS NOT

2.1 What HELIOS Is

HELIOS is a care-completion platform providing:

- Multilingual clinical triage and symptom collection in 20+ languages using the OLDCARTS methodology.
- AI-assisted synthesis of clinical history into structured, coded medical records.
- Cross-border medical record reconciliation (drug name resolution, lab value conversion, vaccine normalisation, diagnosis code translation, geographic disease risk detection).
- Secure routing of structured clinical information to licensed physicians for review, validation, and signature.
- Patient-owned, portable, FHIR R4-compliant health records accessible across healthcare systems in multiple countries.
- Care navigation and health information to assist patients in accessing appropriate medical care.
- Environmental health monitoring (pollen, air quality, UV, weather) integrated with individual health thresholds.

2.2 What HELIOS Is Not

HELIOS is explicitly NOT:

- A licensed medical practitioner, physician, hospital, or healthcare facility.
- An emergency service or crisis intervention platform.
- A diagnostic tool — the AI Assessment is a structured clinical information output, not a diagnosis.
- A prescription service operating autonomously — all prescriptions (where offered) are issued exclusively by licensed physicians after independent clinical review.
- A substitute for in-person medical care for serious, chronic, or complex conditions.
- A mental health crisis service — users in crisis must contact emergency services immediately.

2.3 The Physician-in-the-Loop Model

All clinical outputs from HELIOS that constitute clinical assessments, diagnosis suggestions, treatment recommendations, or prescription support are subject to mandatory review by a licensed physician before delivery to the patient. This means:

1. The HELIOS AI generates a structured clinical assessment (the "Pre-Assessment") based on patient-reported information.
2. This Pre-Assessment is reviewed by a licensed physician independently — the physician reviews patient data before seeing the AI Pre-Assessment to avoid anchoring bias.
3. The physician may confirm, modify, or reject the AI Pre-Assessment.
4. Only after physician signature is any clinical output delivered to the patient.
5. All edits and reason codes from physician review are logged immutably for audit and clinical improvement purposes.

RESEARCH NOTE: The sequential disclosure model (patient data presented before AI Pre-Assessment) is required for the methodological validity of HELIOS's embedded clinical research program and FDA/EU regulatory evidence generation. This design prevents anchoring bias and ensures true independent AI-physician concordance measurement.

SECTION 3 — USER ELIGIBILITY AND ACCOUNT REGISTRATION

3.1 Eligibility

To use HELIOS you must:

- Be at least 18 years of age, OR have a parent or legal guardian create and manage your account on your behalf.
- Have legal capacity to enter into binding agreements in your jurisdiction of residence.
- Not be located in a jurisdiction where HELIOS is legally prohibited.
- Agree to provide accurate and complete information about your health history and identity.

3.2 Account Registration and Identity Verification

Registration requires: full name, date of birth, country of residence, email address, and mobile number. For prescription-related services, government ID verification may be required under applicable telemedicine regulations. You warrant that all information provided is accurate, complete, and not misleading.

3.3 Account Security

You are responsible for maintaining the confidentiality of your account credentials. HELIOS implements technical security measures including AES-256-GCM encryption at rest, TLS 1.3 in transit, and multi-factor authentication options. You must notify us immediately at security@swissmed.ai if you suspect unauthorized access.

SECTION 4 — HIPAA COMPLIANCE (UNITED STATES)

4.1 HIPAA Covered Entity Status

Axessible Tech Inc operates as a Business Associate with respect to HIPAA-covered healthcare providers integrated into the HELIOS platform. Where HELIOS functions as a health plan or healthcare clearinghouse, it may also operate as a Covered Entity. This Notice of Privacy Practices applies to all Protected Health Information (PHI) created, received, maintained, or transmitted in connection with HELIOS services.

4.2 Your HIPAA Rights (US Users)

Under HIPAA (45 CFR Parts 160 and 164), you have the right to:

- Access and receive a copy of your health information (45 CFR §164.524).
- Request amendment of your health information (45 CFR §164.526).
- Request an accounting of disclosures (45 CFR §164.528).
- Request restrictions on certain uses and disclosures (45 CFR §164.522).
- Receive confidential communications (45 CFR §164.522(b)).
- File a complaint with the HHS Office for Civil Rights (OCR) at www.hhs.gov/ocr.

4.3 Uses and Disclosures of PHI

HELIOS uses and discloses PHI for:

- Treatment: Providing clinical navigation, sharing structured health records with licensed physicians, facilitating care coordination.
- Healthcare Operations: Quality improvement, AI model performance evaluation using de-identified data, clinical audit under FDA 21 CFR Part 11.
- Payment: Processing subscription fees and insurance-related transactions.
- Required by Law: Disclosures required by federal or state law, including mandatory reporting obligations.
- Research: Only with a valid IRB-approved protocol, patient authorization, or applicable waiver. See Section 12.

4.4 Minimum Necessary Standard

HELIOS applies the minimum necessary standard to all uses and disclosures of PHI, accessing only the information reasonably necessary to accomplish the intended purpose.

4.5 Business Associate Agreements

All subprocessors handling PHI on behalf of HELIOS have executed Business Associate Agreements (BAAs) satisfying 45 CFR §164.504. Subprocessors include but are not limited to: Anthropic (AI inference), Supabase (data infrastructure), Hume AI (voice processing — HIPAA BAA executed), Twilio (communications), DocuPipe (document processing), and SendGrid (email). A current list of BAA-covered subprocessors is available at swissmed.ai/legal/baa-list.

4.6 Breach Notification

In the event of a breach of unsecured PHI, HELIOS will provide notification to affected individuals, the Secretary of HHS, and (for breaches involving more than 500 individuals in a state) prominent media outlets, in accordance with 45 CFR §§164.400-414. Notifications will be provided without unreasonable delay and within 60 days of discovery of the breach.

4.7 State Law Compliance

HELIOS complies with more stringent state privacy laws where applicable, including: California CMIA and CPRA, New York SHIELD Act, Texas THIPA, Illinois BIPA, and other applicable state health privacy statutes.

SECTION 5 — GDPR COMPLIANCE (EUROPEAN UNION AND EEA)

5.1 Data Controller Identity

For users in the European Union and European Economic Area, the data controller is: Aessible Technologies SL, registered in Barcelona, Spain (EU operating entity). Data Protection Officer contact: dpo@swissmed.ai. EU Representative for GDPR Article 27 purposes: Aessible Technologies SL, Barcelona, Spain.

5.2 Legal Bases for Processing (GDPR Article 6 and 9)

We process your personal data under the following legal bases:

Processing Activity	Legal Basis (Art. 6)	Special Category Basis (Art. 9)
Account registration and identity verification	Article 6(1)(b) — contract performance	Not applicable
Clinical triage and symptom collection	Article 6(1)(a) — explicit consent	Article 9(2)(a) — explicit consent
AI clinical assessment generation	Article 6(1)(a) — explicit consent	Article 9(2)(a) — explicit consent
Physician review and clinical validation	Article 6(1)(a) — explicit consent	Article 9(2)(h) — healthcare provision
FHIR record generation and storage	Article 6(1)(a) — explicit consent	Article 9(2)(h) — healthcare provision
Cross-border drug reconciliation (HERMES)	Article 6(1)(a) — explicit consent	Article 9(2)(h) — healthcare provision
Clinical research (de-identified)	Article 6(1)(a) — explicit consent	Article 9(2)(j) — public interest research
Environmental health monitoring	Article 6(1)(a) — explicit consent	Article 9(2)(a) — explicit consent
Safety notifications and alerts	Article 6(1)(d) — vital interests	Article 9(2)(c) — vital interests
Legal compliance and audit logs	Article 6(1)(c) — legal obligation	Article 9(2)(b) — legal obligation
EU AI Act Article 14 human oversight logs	Article 6(1)(c) — legal obligation	Article 9(2)(b) — legal obligation

5.3 Your GDPR Rights

As a data subject under GDPR, you have the following rights, exercisable by contacting dpo@swissmed.ai:

- Right of Access (Art. 15): Obtain confirmation of whether your data is processed and receive a copy.
- Right to Rectification (Art. 16): Request correction of inaccurate personal data.
- Right to Erasure (Art. 17): Request deletion of your personal data, subject to legal retention obligations.
- Right to Restrict Processing (Art. 18): Request temporary restriction of processing in certain circumstances.
- Right to Data Portability (Art. 20): Receive your data in a structured, machine-readable format (FHIR R4 IPS bundle provided on request).
- Right to Object (Art. 21): Object to processing based on legitimate interests or for direct marketing.

- Right to Withdraw Consent (Art. 7(3)): Withdraw consent at any time without affecting prior lawful processing.
- Right to Complain: Lodge a complaint with your national supervisory authority. EU supervisory authority directory: edpb.europa.eu.

5.4 Data Retention

Health data is retained for the following periods, unless earlier deletion is requested:

- Active patient records: Duration of account plus 10 years (EU medical record retention standards).
- Clinical research de-identified data: Indefinitely as part of the Medical Knowledge Graph, as de-identified data falls outside GDPR scope per Recital 26.
- Audit logs (EU AI Act and 21 CFR Part 11): Minimum 7 years, immutable, append-only.
- Session recordings and transcripts: 5 years or as required by applicable telemedicine regulations.
- Account data after deletion request: 90 days for backup systems, then permanent deletion certified.

5.5 International Data Transfers

Your personal data may be transferred to and processed in countries outside the EU/EEA. All such transfers comply with GDPR Chapter V requirements:

- Transfers to the United States: Standard Contractual Clauses (SCCs) per European Commission Decision 2021/914, supplemented by binding Technical and Organisational Measures (TOMs).
- Transfers to Switzerland: Switzerland has an EU adequacy decision. Data processed on our Exoscale Swiss infrastructure (ch-gva-2) benefits from Swiss data sovereignty.
- Transfers to other countries: SCCs or Binding Corporate Rules as appropriate.
- HELIOS primary EU data storage: AWS eu-west-3 (Paris). Swiss data storage: Exoscale SKS ch-gva-2 (Geneva). Both within EU/Swiss adequacy framework.

5.6 EU AI Act Compliance

HELIOS and HERMES are classified as high-risk AI systems under EU AI Act Annex III (healthcare AI). Full compliance obligations apply from August 2, 2027. HELIOS implements pre-compliance measures from the Effective Date of this agreement, including:

- Immutable audit logs for all AI decisions (EU AI Act Article 12).
- Human oversight mechanisms — physician review on all clinical outputs (Article 14).
- Transparency to users that they are interacting with an AI system (Article 13).
- Accuracy and robustness measures including 7 deterministic safety gates (Article 15).
- Technical documentation per Annex IV maintained and available to competent authorities.
- Post-market monitoring system feeding the HELIOS MKG improvement pipeline (Article 72).

5.7 EHDS Compliance

The European Health Data Space Regulation (EHDS) mandates cross-border health data exchange for Patient Summaries and ePrescriptions by 2029 using FHIR R4 IPS format. HELIOS natively produces FHIR R4 IPS bundles and is positioned as infrastructure-compliant with EHDS requirements from launch.

SECTION 6 — SWISS DATA PROTECTION COMPLIANCE

6.1 Swiss Federal Act on Data Protection (revFADP / nDSG)

For users accessing HELIOS through swissmed.ai or from Switzerland, the revised Swiss Federal Act on Data Protection (nDSG, effective September 1, 2023) applies. Key provisions:

- Health data is classified as "particularly sensitive personal data" under nDSG Article 5(c) and requires explicit consent.
- Data processors operating on behalf of HELIOS are bound by nDSG-compliant data processing agreements.
- Swiss professional secrecy obligations under Swiss Criminal Code Article 321 (Berufsgeheimnis) apply to all medical information processed by HELIOS in Switzerland.
- Data breach notification to the Federal Data Protection and Information Commissioner (FDPIC) within 72 hours of discovery.

6.2 Swiss Data Residency

Swiss patient data is processed and stored on Exoscale SKS infrastructure located in Geneva, Switzerland (ch-gva-2), ensuring Swiss data sovereignty. This infrastructure is separate from EU data infrastructure and does not cross Swiss borders without explicit patient consent and SCC protections.

6.3 Swissmedic

Software as a Medical Device (SaMD) functions of HELIOS deployed in Switzerland will be registered with Swissmedic as required under the Swiss Medical Devices Ordinance (MedDO) and the corresponding EU MDR/IVDR requirements, leveraging EU-Switzerland MRA frameworks upon ratification.

SECTION 7 — LATIN AMERICA PRIVACY AND REGULATORY COMPLIANCE

7.1 Argentina — Ley 25.326 and Clinical Research

For users in Argentina, the Ley de Protección de los Datos Personales (Law 25.326) and its regulatory decrees apply. HELIOS:

- Registers all databases containing Argentine user data with the Agencia de Acceso a la Información Pública (AAIP) as required.
- Obtains free, informed, and unambiguous consent (consentimiento libre, expreso e informado) for all sensitive health data processing.
- Provides Argentine users with rights of access, rectification, update, and deletion (habeas data) exercisable at legal@swissmed.ai.
- For clinical research involving Argentine users: all studies conducted in Argentina comply with Disposición ANMAT N° 6677/10 (Buenas Prácticas Clínicas) and Ley 11.179 (Código Penal) obligations regarding medical data.
- IRB equivalent: Comité de Ética en Investigación (CEI) approval obtained before any research study involving Argentine participants.
- Argentine user data for FDA submissions: collected under GCP (ICH E6) framework with CEI approval and separately documented informed consent for research participation. Consumer clinical care data collected under Law 25.326 alone is not used for FDA submissions without supplemental GCP documentation.

7.2 Colombia — Ley 1581 de 2012 and Ley 1438 de 2011

For users in Colombia:

- All personal data processing complies with Ley Estatutaria 1581 de 2012 (Habeas Data) and its regulatory decrees (Decretos 1377 de 2013, 886 de 2014).
- Health data is classified as "dato sensible" under Article 5 of Law 1581 and requires explicit authorization for collection and processing.
- Authorization for data processing (Autorización para el Tratamiento de Datos Personales) is obtained at registration and before any processing of sensitive health data.
- Privacy notices (Aviso de Privacidad) and Privacy Policies (Política de Tratamiento de Datos) are maintained in Spanish and registered with the Sistema de Registro Nacional de Bases de Datos (RNBD) of the Superintendencia de Industria y Comercio (SIC).
- Telemedicine services comply with Ley 1438 de 2011 and Resolución 2654 de 2019 (reglamentación de la telemedicina en Colombia).
- Clinical research in Colombia: INVIMA approval required for research studies; compliance with Resolución 8430 de 1993 (normas científicas, técnicas y administrativas para la investigación en salud).

7.3 Mexico — LFPDPPP and NOM-024-SSA3

For users in Mexico:

- All personal data processing complies with the Ley Federal de Protección de Datos Personales en Posesión de los Particulares (LFPDPPP) and its Reglamento.
- Health data is classified as "datos sensibles" under LFPDPPP Article 3(VI) and requires explicit written consent.
- Aviso de Privacidad is provided in Spanish before any data collection and registered with INAI.

- Users have rights of Acceso, Rectificación, Cancelación y Oposición (ARCO) exercisable at privacidad@midoctor.ai.
- Telemedicine services comply with Norma Oficial Mexicana NOM-024-SSA3-2012 (Sistemas de Información de Registro Electrónico para la Salud) and relevant COFEPRIS requirements.
- Clinical research: COFEPRIS registration required; compliance with Ley General de Salud Articles 98-103 and Reglamento de la Ley General de Salud en Materia de Investigación para la Salud.
- COFEPRIS accepts FDA, EMA, Health Canada, PMDA, ANVISA, TGA, and MFDS prior approvals under the 2025 expanded equivalency route with 30-business-day decision target.

7.4 Brazil — LGPD and ANVISA

For users in Brazil:

- All personal data processing complies with the Lei Geral de Proteção de Dados (LGPD, Lei 13.709/2018) and regulations of the Autoridade Nacional de Proteção de Dados (ANPD).
- Health data is classified as "dados sensíveis" under LGPD Article 11 and requires explicit consent (consentimento).
- Users in Brazil have rights under LGPD Article 18: confirmation, access, correction, anonymisation, portability, deletion, information about sharing, and revocation of consent.
- Brazilian Portuguese aviso de privacidade and privacy policy are maintained at midoctor.ai/privacidade.
- Telemedicine services comply with CFM Resolution 2.314/2022 and ANVISA regulatory requirements for digital health tools.
- Clinical research: ANVISA registration and CONEP (Comissão Nacional de Ética em Pesquisa) approval required; compliance with Resolução CNS 466/2012. ANVISA pathway: 12-24 months for higher-risk SaMD; HELIOS targets ANVISA registration following FDA De Novo clearance.

7.5 Other Latin American Jurisdictions

HELIOS monitors and complies with applicable privacy and health data laws in all jurisdictions where it operates, including but not limited to: Chile (Ley 19.628, Ley 20.584), Peru (Ley 29733), Uruguay (Ley 18.331), and other LatAm markets. Users in jurisdictions not specifically listed retain all rights under applicable local law. Contact legal@swissmed.ai for jurisdiction-specific inquiries.

SECTION 8 — UNITED KINGDOM COMPLIANCE

8.1 UK GDPR and DPA 2018

For users in the United Kingdom, the UK GDPR (as retained by the Data Protection Act 2018) applies. The data controller for UK users is Aaccessible Technologies SL (Barcelona), operating as an international data controller with UK data subjects. UK Representative for Article 27 UK GDPR purposes: to be designated upon UK entity incorporation (UK Ltd planned, not yet incorporated as of the Effective Date).

8.2 NHS Digital Technology Assessment Criteria (DTAC)

HELIOS is committed to meeting NHS DTAC standards before any NHS system connection or NHS patient data processing:

- Year 1 (2026): HERMES receives documents uploaded by patients or clinical staff — no direct NHS system connection.
- Year 2 (2027): EHR write-back via SMART on FHIR upon completion of DTAC assessment and NHS trust B2B agreements.
- UK data residency: NHS patient data will be processed exclusively in UK-region data infrastructure. Migration to UK-region Supabase instance will be completed before any NHS trust goes live.

8.3 MHRA and CE Mark Recognition

CE marks for HELIOS SaMD functions are recognised in the UK until June 30, 2030 (UK MHRA Medical Device Regulations). HELIOS will pursue UKCA marking via MHRA pathway in parallel with EU MDR CE marking before the 2030 deadline. All CE-marked functions of HELIOS are subject to UK mandatory incident reporting to MHRA.

SECTION 9 — DATA SECURITY ARCHITECTURE

9.1 Encryption Standards

- At rest: AES-256-GCM with envelope encryption. Per-document Data Encryption Keys (DEKs) wrapped by Key Encryption Keys (KEKs).
- In transit: TLS 1.3 with Perfect Forward Secrecy for all client-server communications. mTLS for service-to-service.
- Key management: AWS KMS for EU infrastructure; HSM-backed for Swiss infrastructure.
- Post-quantum readiness: HELIOS is monitoring NIST PQC standards (ML-KEM FIPS 203, ML-DSA FIPS 204) and will implement hybrid classical+PQC key exchange before 2030.

9.2 Access Controls

- Role-based access control (RBAC) with principle of least privilege.
- Multi-factor authentication required for all physician access.
- Immutable audit logs for all data access events (EU AI Act Art. 12, FDA 21 CFR Part 11).
- Automated anomaly detection on access patterns.

9.3 Infrastructure Security

- Primary EU: AWS eu-west-3 (Paris), Paris, France — ISO 27001, SOC 2 Type II certified.
- Swiss sovereign: Exoscale SKS ch-gva-2 (Geneva) — Swiss data sovereignty guarantee.
- Redis cache: Upstash (trusting-porpoise-29424.upstash.io) — encrypted at rest and in transit.
- No patient data stored in browser localStorage or client-side storage.
- Penetration testing: Annual third-party penetration test. Bug bounty program maintained.

9.4 Concurrency and Rate Limiting

AI inference calls are capped at 3 concurrent requests with 500ms stagger to prevent resource exhaustion and ensure clinical safety in high-load scenarios. Model fallback chain: Anthropic claude-opus-4-6 to OpenAI GPT-4o to Gemini 2.5 Flash to GPT-4o-mini (cross-provider to avoid single-provider rate limit failures).

SECTION 10 — PHYSICIAN NETWORK, CLINICAL RESPONSIBILITY, AND MALPRACTICE

10.1 Independent Physician Network

Physicians reviewing and validating HELIOS AI Assessments are independent licensed medical professionals operating through telemedicine partner networks. These physicians are not employees of Axxessible Technologies SL or Axxessible Tech Inc. They hold current medical licenses in their respective jurisdictions and carry appropriate medical malpractice insurance.

10.2 Clinical Accountability

The licensed physician who reviews and signs a clinical output is solely responsible for the clinical judgment expressed in that signed output. HELIOS provides informational tools to assist clinical decision-making; it does not substitute for physician judgment. The physician's signed assessment constitutes the clinical act; the AI Pre-Assessment is a structured informational input to that judgment.

10.3 Scope of Service and Exclusions

Physician review through HELIOS is appropriate for:

- Common acute conditions (respiratory infections, urinary tract symptoms, skin conditions, gastrointestinal complaints, allergic reactions, headaches, musculoskeletal pain).
- Medication reconciliation and prescription renewal for stable chronic conditions where initial prescription was issued by a licensed physician.
- Clinical record review, interpretation, and cross-border reconciliation.
- Care navigation for specialist referral.

Physician review through HELIOS is NOT appropriate for:

- Medical emergencies — seek emergency services immediately.
- New diagnoses of serious conditions requiring physical examination.
- Mental health crises — contact emergency services or a crisis helpline.
- Pediatric emergencies.
- Conditions requiring immediate in-person assessment.

10.4 Prescription Services

Where prescription services are offered through HELIOS:

- Prescriptions are issued exclusively by licensed physicians after independent clinical assessment.
- Initial prescriptions for new conditions require physician-patient interaction per applicable telemedicine laws.
- Prescription renewal is available only for stable chronic conditions with a documented prior prescription from a licensed physician.
- Controlled substances, injectables, and medications requiring laboratory monitoring are excluded from telehealth renewal services.
- Prescriptions comply with all applicable pharmacy regulations in the jurisdiction of dispensing.

SECTION 11 — IMMIGRATION-SENSITIVE AND VULNERABLE POPULATION PRIVACY PROTECTIONS

11.1 The Privacy Risk of Cross-Border Health Data

HELIOS serves populations including international migrants, refugees, undocumented individuals, and persons whose health data — including diagnoses, medication histories, and vaccination records — may reveal immigration status, country of origin, or politically sensitive information. HELIOS implements the most stringent privacy protections for this population.

11.2 Patient-Controlled Privacy Flags (Patent Method A7)

HELIOS implements patient-controlled privacy flags encoded as FHIR extensions and propagated through all downstream data operations. Patients may selectively restrict disclosure of:

- HIV/AIDS status and related treatment history.
- Tropical or endemic disease diagnoses that may imply country of origin.
- Vaccination records whose gaps may imply undocumented entry.
- Mental health diagnoses.
- Reproductive health information.
- Genetic information.
- Substance use disorder treatment records.

These flags propagate automatically through all FHIR bundle operations and exclude flagged data from population health analytics, research pipelines, and any disclosure not explicitly authorized by the patient.

11.3 No Disclosure to Immigration Authorities

HELIOS will not voluntarily disclose patient health information to immigration authorities, law enforcement, or government agencies relating to immigration status under any circumstances. HELIOS will resist legal compulsion for such disclosure to the maximum extent permitted by law and will provide notice to the affected patient prior to any compelled disclosure where legally permissible.

11.4 Refugee and Displaced Person Protections

For users who are refugees, asylum seekers, or internally displaced persons, HELIOS applies the highest tier of privacy protections and provides health record portability that does not depend on national identification documents. Anonymous access to health information resources is available at swissmed.ai/resources without account creation.

SECTION 12 — CLINICAL RESEARCH PARTICIPATION AND CONSENT

12.1 Nature of the Research Program

HELIOS operates an embedded clinical validation research program (the "HELIOS Validation Study"). The purpose of this study is to evaluate the accuracy and safety of AI-assisted clinical assessment compared to physician assessment, and to generate Real-World Evidence (RWE) for regulatory submissions to the FDA (De Novo pathway), EU MDR Notified Bodies, and other global regulatory authorities. Participation is entirely voluntary and separate from your clinical care.

STUDY REGISTRATION: The HELIOS Validation Study is registered at ClinicalTrials.gov before initiation of the prospective data collection phase. The registration number will be published at swissmed.ai/research. Principal Investigator: Dr. Camilo E. Gutierrez, MD, FACEP. Institutional Review Board: Northwestern Medicine IRB.

12.2 Dual Consent Model

HELIOS captures two separate consent determinations:

- Consent A — Clinical Care: Authorization for HELIOS to process your health data for clinical care purposes (mandatory to use the platform).
- Consent B — Research Participation: Voluntary authorization to contribute de-identified data to the HELIOS Validation Study (optional, may be withdrawn at any time without affecting your clinical care or account).

12.3 What Research Participation Means

If you consent to research participation (Consent B), the following occurs:

6. Your AI Pre-Assessment (the AI's clinical output before physician interaction) is captured with an immutable timestamp before the physician reviews your case.
7. Your physician's independent assessment is captured separately after their review, enabling measurement of true AI-physician concordance without anchoring bias.
8. At 30 and 90 days after your consultation, you may receive brief follow-up questions about your health outcomes (symptom resolution, any adverse events).
9. All data used for research is de-identified per HIPAA Safe Harbor (45 CFR §164.514(b)) and GDPR Recital 26 before entry into any research dataset.
10. De-identified data may be included in FDA regulatory submissions, EU MDR Clinical Evaluation Reports, peer-reviewed publications, and regulatory agency communications worldwide.
11. You will not be individually identifiable in any publication or regulatory submission.

12.4 GCP Compliance

The HELIOS Validation Study is conducted in accordance with:

- ICH E6(R2) Good Clinical Practice guidelines.
- ICH E17 General Principles for Planning and Design of Multi-Regional Clinical Trials.
- FDA 21 CFR Parts 50 and 56 (informed consent and IRB requirements).
- EU Clinical Trials Regulation (CTR 536/2014) for EU sites.
- Applicable local GCP requirements in each jurisdiction (ANMAT/CEI for Argentina, INVIMA for Colombia, COFEPRIS for Mexico, CONEP/ANVISA for Brazil).

12.5 FDA Regulatory Evidence

De-identified data collected under this research program may be used as Real-World Evidence (RWE) in support of FDA De Novo classification requests for HELIOS SaMD functions. Use of RWE in FDA submissions complies with FDA's December 2025 Guidance on Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. Retrospective analyses of pre-existing de-identified data do not require an Investigational Device Exemption (IDE) per FDA guidance.

12.6 EU MDR Clinical Evaluation

De-identified data from this research program will be included in the Clinical Evaluation Report (CER) submitted to EU Notified Bodies for HELIOS CE marking under EU MDR 2017/745. Post-Market Clinical Follow-up (PMCF) data is collected continuously through the embedded trial architecture to maintain the CER per EU MDR Article 61(11).

12.7 Latin American Regulatory Use

Research data from Latin American participants collected under jurisdiction-specific GCP frameworks (CEI/Argentina, INVIMA/Colombia, COFEPRIS/Mexico, CONEP/Brazil) may be submitted to:

- COFEPRIS (Mexico) under the expanded equivalency route (September 2025) accepting prior FDA/EMA approvals.
- INVIMA (Colombia) for SaMD registration following FDA clearance.
- ANVISA (Brazil) for registration following FDA and EU MDR clearance.
- ANMAT (Argentina) under Argentine regulatory framework.

12.8 Data Minimisation and De-identification

Research data minimisation process:

12. Patient identifier replaced by pseudonymous research_id (irreversible hash).
13. Date of birth replaced by age range (5-year bands).
14. Geographic origin replaced by WHO region code.
15. Dates of service shifted by random offset (consistent within each patient record).
16. Rare conditions suppressed where they could identify individuals.
17. Free-text fields NLP-scrubbed to remove names, locations, and identifiers.
18. De-identified dataset stored in segregated schema (helios_rwe_deidentified) inaccessible to clinical staff.

12.9 Withdrawing Research Consent

You may withdraw research participation consent (Consent B) at any time by contacting research@swissmed.ai or through your account settings. Withdrawal will not affect your clinical care or access to the HELIOS platform. Data already de-identified and incorporated into aggregate research datasets cannot be removed as individual records are no longer identifiable.

SECTION 13 — HERMES CLINICAL RECORD RECONCILIATION

13.1 What HERMES Does

HERMES (Health Exchange and Record Migration Engine System) is the proprietary clinical reconciliation engine within HELIOS. It processes uploaded foreign medical documents through six sequential layers to produce a clinician-ready output safe to act on in any healthcare system. The six layers are:

Layer	Function	Clinical Safety Output
L1 Document Ingestion	OCR extraction + 20-language clinical NLP entity extraction	Structured clinical data with OLDCARTS schema
L2 Drug Resolution	Foreign trade name to WHO INN to destination formulary (121,671 aliases, 76 countries)	Confidence-gated drug equivalents with human review for below-threshold
L3 Lab Conversion	Country + date-aware measurement standard inference (IFCC/NGSP, SI/conventional, 575 analytes)	Converted values with original values preserved and confidence annotation
L4 Vaccine Normalisation	BCG detection, 15+ name formats, IGRA substitution recommendation, 174 national schedules	FHIR ClinicalImpression with substitution recommendation
L5 Diagnostic Code Translation	CIE-10, CIM-10, CID-10, MKB-10, KCD to ICD-10-CM — uncertainty-preserving	Original code retained + best-match with confidence; mandatory review if below threshold
L6 Geographic Risk	Origin + medication intersection matrix (Strongyloides/Chagas/G6PD/NTI dose)	FHIR ServiceRequest for mandatory pre-prescribing serology

13.2 Confidence Gating and Human Review

Every HERMES output carries an explicit confidence score. Outputs below 0.80 confidence on any layer are routed to the human review queue (`hermes_human_review_queue`) and are NOT automatically delivered to the physician or patient. Narrow Therapeutic Index (NTI) drugs always route to human review regardless of confidence score.

13.3 User Responsibility for Uploaded Documents

When uploading medical documents to HERMES, you warrant that: (a) you have the right to upload and share these documents, (b) the documents accurately represent your medical history, and (c) you have obtained any necessary consent from other individuals referenced in the documents. HELIOS is not responsible for clinical errors resulting from inaccurate, incomplete, or fraudulently uploaded documents.

SECTION 14 — INTELLECTUAL PROPERTY

14.1 HELIOS IP Ownership

All intellectual property in the HELIOS platform, including but not limited to: the HERMES 6-layer pipeline architecture; the 107-agent Consensus Agents system; the Medical Knowledge Graph (MKG) with 121,671+ drug aliases; the confidence-gated drug resolution pipeline (Patent Method A1); the reporting-standard-aware lab conversion engine (A2); the vaccine history triggered substitution method (A3); the geographic-origin-treatment intersection matrix (A4); the uncertainty-preserving diagnostic code translation method (A5); the cross-national-formulary drug-drug interaction detection system (DDI-1); the immigration-status-sensitive privacy propagation method (A7); and the self-improving MKG feedback loop (MKG-1) — are the exclusive intellectual property of Axessible Technologies SL and/or Axessible Tech Inc.

14.2 Patient-Generated Data

Your personal health information remains your data. You grant HELIOS a non-exclusive, royalty-free, worldwide licence to process your data for the purposes described in this agreement. For research participants, you additionally grant HELIOS a perpetual licence to use de-identified derivatives of your data for research, regulatory, and publication purposes as described in Section 12.

SECTION 15 — DISCLAIMERS, LIMITATION OF LIABILITY, AND INDEMNIFICATION

15.1 Disclaimer of Medical Advice

DISCLAIMER: HELIOS does not provide medical advice, diagnosis, or treatment. All clinical outputs are informational and require physician review. Nothing in HELIOS substitutes for professional medical judgment. Users rely on HELIOS outputs at their own risk and should always consult a licensed healthcare provider for medical decisions.

15.2 AI Limitations

HELIOS AI systems, including the 107 Consensus Agents, may produce inaccurate, incomplete, or contextually inappropriate outputs. HELIOS implements multiple safety mechanisms (7 deterministic safety gates, Kendall's W concordance measurement, mandatory physician review) to mitigate this risk, but no AI system is infallible. Users must not rely on AI outputs alone for clinical decisions.

15.3 Limitation of Liability

To the maximum extent permitted by applicable law:

- HELIOS's total aggregate liability for any claim arising from or relating to this agreement shall not exceed the greater of: (a) the amount paid by you to HELIOS in the 12 months preceding the claim, or (b) USD 1,000.
- HELIOS shall not be liable for any indirect, incidental, special, consequential, punitive, or exemplary damages, including but not limited to damages for loss of health, personal injury, or death arising from reliance on AI outputs not reviewed by a licensed physician.
- This limitation of liability does not apply to: death or personal injury caused by HELIOS's gross negligence or wilful misconduct; fraud; or any liability that cannot be excluded under applicable law (including GDPR and EU AI Act mandatory provisions).

15.4 Indemnification

You agree to indemnify, defend, and hold harmless HELIOS and its officers, directors, employees, and agents from any claims, damages, losses, costs, and expenses (including reasonable legal fees) arising from: (a) your violation of this agreement; (b) your misuse of the HELIOS platform; (c) your provision of false or misleading health information; or (d) your violation of any third party's rights.

SECTION 16 — PAYMENT, SUBSCRIPTIONS, AND REFUND POLICY

16.1 Pricing Tiers

HELIOS offers the following service tiers:

- Free Tier: AI triage and symptom collection. No physician review. No clinical outputs.
- Clinical Tier (USD 9.90/month or USD 99/year): Full AI triage, physician review, clinical navigation outputs, health record management.
- HERMES Report: USD 29 per report (one-time, per-document cross-border reconciliation report).
- Enterprise/B2B: Custom pricing per partnership agreement.

16.2 Automatic Renewal and Cancellation

Subscriptions automatically renew unless cancelled at least 24 hours before the renewal date. Cancel at any time through account settings. Refunds are provided for unused subscription months only where required by applicable law (EU consumer rights, certain US state laws).

SECTION 17 — GOVERNING LAW AND DISPUTE RESOLUTION

17.1 Governing Law by Jurisdiction

User Location	Governing Law	Mandatory Consumer Protections
United States	Laws of Delaware, USA (without conflict of law provisions)	State consumer protection laws apply additively
European Union	Law of Spain (EU law applies mandatorily)	EU Consumer Rights Directive, GDPR, EU AI Act apply mandatorily
Switzerland	Swiss law applies	Swiss FADP, Swiss consumer law apply
United Kingdom	Law of England and Wales	UK GDPR, Consumer Rights Act 2015 apply
Argentina	Law of Argentina applies locally	Ley 24.240 consumer rights, Law 25.326 apply
Colombia	Law of Colombia applies locally	Ley 1480 de 2011, Law 1581 apply
Mexico	Law of Mexico (CDMX) applies locally	LFPDPPP, Ley Federal de Protección al Consumidor apply
Brazil	Law of Brazil (São Paulo) applies locally	CDC (Law 8.078/90), LGPD apply

17.2 Dispute Resolution

Most disputes can be resolved by contacting support@swissmed.ai. For disputes not resolved informally within 30 days:

- US users: Binding arbitration under AAA Commercial Arbitration Rules, except for small claims (under USD 10,000) which may be brought in small claims court.
- EU users: You may use the EU Online Dispute Resolution platform (ec.europa.eu/odr). Spanish courts have jurisdiction for disputes not resolved by ODR.
- Swiss users: Courts of Geneva, Switzerland.
- UK users: Courts of England and Wales.
- LatAm users: Local courts per governing law above.

CLASS ACTION WAIVER: To the extent permitted by applicable law, you waive any right to bring claims as a class action, collective action, or representative proceeding.

SECTION 18 — AI TRANSPARENCY, MODEL INFORMATION, AND PREDETERMINED CHANGE CONTROL

18.1 AI Systems in Use

HELIOS uses the following AI systems in its clinical pipeline:

- claude-opus-4-6 (Anthropic): Patient-facing chat, moderator function, HERMES clinical reasoning layers L2, L5, L6.
- claude-sonnet-4-5 (Anthropic): Specialist agents (107 Consensus Agents), safety reviewers.
- Gemini 2.5 Flash (Google): Bulk OCR pre-processing (HERMES L1), cross-model verification only.
- Hume EVI 4 mini (Hume AI): Voice interaction, emotional intelligence analysis (Face + Prosody + Language, AI-PHQ-9).
- Fallback chain: Anthropic to OpenAI GPT-4o to Gemini 2.5 Flash to GPT-4o-mini (cross-provider).

18.2 Model Update Policy (PCCP)

HELIOS operates a Predetermined Change Control Plan (PCCP) governing all changes to AI models. Model updates that: (a) change the intended clinical function, (b) materially alter performance characteristics, or (c) introduce new clinical claims require re-validation against the HELIOS clinical evidence standard before deployment. Model version and date are logged immutably per session in the clinical audit trail.

18.3 No Autonomous Clinical Decisions

HELIOS AI systems do not make autonomous clinical decisions. All clinical outputs are (a) gated through 7 deterministic safety gates, (b) presented to a licensed physician for independent review before delivery, and (c) the physician's signed assessment constitutes the clinical act. The AI provides structured information input only.

18.4 Explainability

Every HELIOS clinical output includes: the confidence score per safety gate; the consensus score (Kendall's W) across the 107 Consensus Agents; the resolution stages for any HERMES drug or lab conversion; and the reasoning chain available for physician and patient review. No black-box outputs are delivered to patients.

SECTION 19 — GENERAL PROVISIONS

19.1 Entire Agreement

This document, together with the HELIOS Privacy Addendum and any applicable jurisdiction-specific supplements, constitutes the entire agreement between you and HELIOS with respect to its subject matter and supersedes all prior agreements, representations, and understandings.

19.2 Amendments

HELIOS reserves the right to amend these Terms at any time. Material changes will be notified to active users via email and in-app notification at least 30 days before the effective date. Continued use after the effective date constitutes acceptance. For EU users, GDPR-relevant changes will be specifically flagged and consent re-obtained where required.

19.3 Severability

If any provision of this agreement is found unenforceable by a court of competent jurisdiction, that provision shall be modified to the minimum extent necessary to make it enforceable, and all other provisions shall remain in full force and effect.

19.4 Waiver

Failure to enforce any right or provision of this agreement does not constitute waiver of that right or provision.

19.5 Force Majeure

HELIOS is not liable for failures or delays caused by circumstances beyond its reasonable control, including natural disasters, pandemic, acts of government, cyberattacks on third-party infrastructure, or critical AI model provider outages — provided HELIOS has implemented the contractually required fallback chain and backup measures.

19.6 Contact Information

Purpose	Contact	Response Time
General Support	support@swissmed.ai / support@midoctor.ai	48 hours
Legal and Privacy (EU/CH)	legal@swissmed.ai	72 hours (GDPR: 30 days for formal requests)
HIPAA Privacy Officer (US)	hipaa@swissmed.ai	5 business days
Data Protection Officer	dpo@swissmed.ai	30 days per GDPR Article 12
Security Incidents	security@swissmed.ai	24 hours
Research Participation	research@swissmed.ai	5 business days
HERMES Clinical Queries	clinical@swissmed.ai	5 business days
Spanish Language (LatAm)	legal@midoctor.ai	72 hours

CONSENT ACKNOWLEDGMENT AND SIGNATURE

IMPORTANT: By creating a HELIOS account or using the HELIOS platform, you confirm that you have read, understood, and agree to these Terms of Service, Privacy Policy, and Research Participation Agreement in their entirety. If you do not agree, you must not use the platform.

CONSENT A — CLINICAL CARE (REQUIRED)

I consent to HELIOS processing my health data for clinical care purposes as described in this agreement. I understand that clinical outputs require physician validation and do not constitute medical advice.

CONSENT B — RESEARCH PARTICIPATION (OPTIONAL)

I voluntarily consent to participate in the HELIOS Validation Study. I understand that my de-identified data may be used for research, regulatory submissions (including FDA and EU MDR), and peer-reviewed publications. I understand this consent is optional, does not affect my clinical care, and may be withdrawn at any time by contacting research@swissmed.ai.

CONSENT C — CROSS-BORDER DATA TRANSFER (REQUIRED FOR INTERNATIONAL USE)

I consent to the transfer of my health information to healthcare providers, physician networks, and data processors in the countries necessary to provide the HELIOS service, subject to the protections and safeguards described in this agreement.

Signature / Digital Acceptance

Full Name: _____ Date: _____

HELIOS | swissmed.ai | midoctor.ai

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Axessible Technologies SL (Barcelona) | Axessible Tech Inc (Delaware)
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