LATAM REGULATORY GUIDES · ECUADOR

ARCSA Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Ecuador

Ecuador's resolución-driven language regime: the Module 2 Spanish tightening, the January 2027 device inversion, and LOOETA art. 29 authenticated translations.

Julio G. Martinez-Clark · CEO bioaccess® · Founder Amavita Sciences ·

Last updated August 25, 2026 · ~29 min read · Version 1.0.0

Module 2 tightening — Oct 2025

ON THIS PAGE

Section A. Regulator profile

Name: *Agencia Nacional de Regulación, Control y Vigilancia Sanitaria, Doctor Leopoldo Izquieta Pérez* — ARCSA — the health-products regulator adscrita to the *Ministerio de Salud Pública* (MSP). ARCSA grants *registro sanitario* for medicines, biologicals, medical devices, in vitro diagnostics, cosmetics, natural products and processed foods; issues *permiso de funcionamiento* to establishments; authorises clinical trials of medicines; runs Ecuador's *Sistema Nacional de Farmacovigilancia* and *Tecnovigilancia*; and administers import-by-exception, controlled substances and sanitary alerts (ARCSA institutional portal). Unlike Panamá, Ecuador consolidates

every one of these functions in a single agency — there is no separate device directorate, and there is no separate biologicals directorate.

Establishing decrees: ARCSA was created by Decreto Ejecutivo 1290 (*Suplemento del Registro Oficial* 788, 13 de septiembre de 2012) and restructured by Decreto Ejecutivo 544 (*R.O.* 428, 30 de enero de 2015), whose art. 10 confers the normative power ARCSA exercises through *resoluciones* and *instructivos externos* (Corral Rosales bulletin on the 2024–2025 normative wave; ARCSA documentos vigentes index). No statute creates ARCSA — its rule-making power is delegated by executive decree, so Ecuador's language rules do not live in a Ley de Medicamentos. They live in resoluciones and in the *instructivos externos* those resoluciones enact.

Scope: ARCSA regulates medicines and biological products for human use, medical devices and in vitro diagnostics, cosmetics, hygiene and household products, processed foods, natural products of medicinal use, tobacco, and controlled substances subject to fiscalisation. Interventional clinical trials of medicines fall under ARCSA in concert with MSP: MSP issued Acuerdo Ministerial 00069-2024 (*R.O.* 730, 27 de enero de 2025) — the current *Reglamento para la aprobación, control y seguimiento de estudios clínicos con medicamentos y productos biológicos en seres humanos*, which replaced AM 0075-2017 — and ARCSA issued the operational Instructivo Externo IE-B.3.3.1-EC-04 v3.0 in September 2025 (Corral Rosales; ARCSA ensayos clínicos page). CEISH accreditation is a separate MSP function under the *Reglamento Sustitutivo* published in the Registro Oficial on 2 August 2022 (MSP announcement).

Website: https://www.controlsanitario.gob.ec — the institutional portal indexing normativa, catastro regulatorio, trámites, alertas sanitarias and the clinical-trials page (ARCSA portal; documentos vigentes; ensayos clínicos; Julio 2026 Catastro Regulatorio).

Printed contact points: ARCSA operates a consolidated inbox regime that replaced thirteen prior addresses with a single citizen channel — atencionalusuario@controlsanitario.gob.ec — supplemented by the clinical-trials unit inbox atencion.ensayosclinicos@controlsanitario.gob.ec and by nine zonal citizen-attention inboxes running `atencionciudadana.cz1@` through `atencionciudadana.cz9@controlsanitario.gob.ec` (ARCSA nuevo correo para atención al ciudadano; gob.ec ARCSA procedure sheet). Headquarters address: Ciudadela Samanes, Parque Samanes, Bloque 5, CP 090703, Guayaquil, teléfono +593 4 372 7440 (ARCSA contacto). ARCSA is headquartered in Guayaquil, not Quito — a filing detail that matters for hearings, notifications and hand-carried submissions.

Current head of authority: *Director Ejecutivo* — Dr. Daniel Antonio Sánchez Procel, appointed 6 December 2023 (Corral Rosales; ARCSA documentos vigentes). ARCSA is adscrita to MSP and its *Directorio* is presided by the Minister of Health.

Adjacent bodies sharing responsibility. Ecuador's architecture places the language rule at three separate desks — the ARCSA registro-sanitario evaluators, the MSP CEISH-accreditation desk, and each accredited CEISH itself. Reading only the ARCSA text costs money; missing the MSP or CEISH layer earns a subsanación.

Body	Role	Reference
MSP — *Coordinación General de Desarrollo Estratégico en Salud* / *Dirección Nacional de Inteligencia de la Salud*	Accredits and monitors CEISH and CEAS under the 2022 *Reglamento Sustitutivo*; issues clinical-trials reglamento (AM 00069-2024)	MSP CEISH accreditation trámite; MSP announcement
Accredited CEISH (Comités de Ética de Investigación en Seres Humanos)	Institution-hosted ethics review of clinical trials; each committee runs on its own meeting calendar; no national CEISH inbox exists	MSP announcement; CEISH-HGL exclusion notice
MREMH — *Ministerio de Relaciones Exteriores y Movilidad Humana*	Competent authority for the Hague Apostille and for consular legalización; runs the online apostille portal	gob.ec apostilla y legalización; Convención de La Haya sobre la Apostilla
Función Judicial / Notarías	Authenticate signatures of *intérpretes* extrajudiciales under LOOETA art. 29; the *cónsul del Ecuador* is an equivalent authenticator abroad	LOOETA, R.O. Supl. 353, 23/10/2018
Registro Oficial	Sole publication of record; a resolución becomes enforceable only on publication in the *R.O.*	Corte Constitucional Registro Oficial repository

Three structural facts about ARCSA filings that reshape translation project planning. First, there is no national CEISH inbox: CEISH sit inside hospitals and universities, each committee runs its own calendar, and MSP publishes no accreditation SLA on its trámite sheet (MSP trámite) — which means the CEISH clock is set by each committee, not by the regulator. Second, not every accredited CEISH will review clinical trials: the CEISH of the Hospital General Latacunga, código DNIVS-CEISH-05-HGL-5, states plainly *"El CEISH-HGL no evaluará ensayos clínicos"* (CEISH-HGL), so the pool of committees that will actually review an industry trial is materially smaller than the 19 CEISH MSP reported at reglamento entry (MSP). Third, ARCSA is under a national mejora regulatoria mandate: Decreto Ejecutivo 307 (*R.O.* Supl. 589, 28 de junio de 2024) establishes regulatory improvement as national policy, and it is the political driver behind the 2024–2026 rewrite wave that this guide catalogues in Section H. A regulator under mejora regulatoria review tightens documentation discipline, it does not loosen it.

Contact points we will not invent. The Ministerio de Salud Pública prints a single CEISH-accreditation contact — Mayra Paola Cueva Rojas, cgds@msp.gob.ec, (+593) 2-2381 4400 ext. 5267 (gob.ec MSP trámite; request form) — but prints no email address or telephone number for any individual CEISH. `[UNVERIFIED - source silent]` on any CEISH mailbox published from a `.gob.ec` domain. Likewise, ARCSA prints no dedicated CNBI-equivalent inbox: Ecuador has no national bioethics committee acting as a filing point. Correspondence on clinical-trial safety, inspections and destruction exceptions runs through atencion.ensayosclinicos@controlsanitario.gob.ec (ARCSA ensayos clínicos).

Section B. Official language requirements

Ecuador's language rule is not a single sentence. It is a layered regime: a statute-adjacent default in LOOETA, a resolución-level general clause per product family, and roughly a dozen document-specific carve-outs — with a critical asymmetry between drugs, biologicals and devices that a single-sentence reading would miss.

Statute-adjacent anchor — LOOETA, art. 29 (verbatim, translations):

> "Las entidades reguladas por esta Ley admitirán como válidas, mientras no se demuestre lo contrario, las traducciones de documentos en idioma extranjero efectuadas extrajudicialmente por uno o más intérpretes siempre que la firma o firmas se encuentren autenticadas por un notario, por un cónsul del Ecuador o reconocida ante un juez de lo civil."

Ecuador's *Ley Orgánica para la Optimización y Eficiencia de Trámites Administrativos* (LOOETA), *R.O.* Supl. 353 of 23 October 2018, sets the default admissibility rule for foreign-language translations in every entity bound by the law — including ARCSA, per art. 2 *ámbito* (LOOETA text; gob.ec LOOETA record). LOOETA is the closest Ecuador comes to a Panamá-style Ley 419 Art. 33: it establishes that translations by *intérpretes* are valid when the signature is authenticated by a notary, an Ecuadorian consul, or a civil-court judge. It does not require the translator to be titulado or officially accredited by a specific ministry — the fidelity gate is signature authentication, not translator licensing. That is the doctrinal ceiling. Every ARCSA-specific instrument below tightens it.

Resolución anchor — IE-B.3.2.1-MG-01 v4.0, §2 num. 2 (verbatim, medicines, general documentation):

> "Toda la documentación técnica-analítica y galénica deberá presentarse en idioma castellano o inglés, de acuerdo con los requerimientos de la ARCSA. Se exceptúa al módulo 2 del formato CTD correspondiente a medicamentos denominados como 'nuevo'..."

Source: Instructivo Externo IE-B.3.2.1-MG-01 v4.0, enacted by Resolución ARCSA-DE-2025-034-DASP (signed 3 October 2025, *R.O.* 1er Supl. 153 of 28 October 2025) (Registro Oficial text; Lexis report). Ecuador accepts drug technical-analytical and galénica documentation in Spanish or English — with a carve-out for *medicamentos nuevos*, whose CTD Module 2 must be in

castellano. That is a genuine, written English-acceptance for the substance of a drug dossier, unusual in Latin America, and it is the anchor for Section D.

Resolución anchor — IE-B.3.2.1-MG-01 v4.0, §2 num. 8 (verbatim, CTD scope):

> "La presentación del expediente en formato CTD será opcional para todos los medicamentos de uso humano, excepto en el caso de los medicamentos nuevos..."

CTD is optional for every drug except *medicamentos nuevos*, for whom it is mandatory. The Module 2 castellano obligation therefore attaches only to a defined subset — new medicines — and does not sweep in generics, biosimilars or homologación files.

Resolución anchor — IE-B.3.2.1-MG-01 v4.0, requirement 17 (verbatim, post-October 2025 tightening):

> "Documentación farmacológica y clínica vigente, en español, pudiendo adjuntar además en inglés..."

Requirement 17 tightened the earlier ARCSA-DE-2024-058-DASP art. 14(h) *summary* allowance to a full-Spanish obligation for pharmacological and clinical documentation, permitting English only as an additional accompaniment. This is the single most consequential language change of the 2024–2026 wave, and it is why the guide's Section H flags Resolución ARCSA-DE-2025-034-DASP as the tightening point.

Resolución anchor — IE-B.3.2.1-MG-01 v4.0, requirement 1.4.3 (verbatim, prospecto):

> "redactado en idioma castellano y con caracteres claramente legibles e indelebles"

Note the verb: "redactado" — *drafted* in castellano, with a legibility standard and an indelibility standard, not merely *translated into* Spanish. A back-translated prospecto that is grammatically Spanish but syntactically English fails this requirement, and the "indelibles" language collapses onto the artwork production standard, not the translation standard.

Resolución anchor — Rejection ground, IE-B.3.2.1-MG-01 v4.0 legal-documents block (verbatim):

> "No se aceptarán documentos con errores en sus traducciones."

The sentence appears verbatim in the drugs instructivo and again in Resolución ARCSA-DE-2024-049-DASP art. 19 (biologicals) (Corral Rosales; documentos vigentes). It is an enacted rejection ground that stands on its own — not a Panamá-style *reetiquetado* rule, but a fidelity rule with the same commercial effect: a translation defect is a filing defect. The biologicals text goes further: "la traducción debe ser realizada por un traductor titulado y/o por centros autorizados para el efecto" — a licensed-translator requirement absent from the drugs instructivo and unique to the biologicals track.

Resolución anchor — ARCSA-DE-2024-049-DASP, art. 19 (verbatim, biologicals):

Biological products are governed by Resolución ARCSA-DE-2024-049-DASP (*R.O.* Supl. 726, 21 de enero de 2025) and its instructivo IE-B.3.2.1-MB-02 v4 enacted by Resolución ARCSA-DE-2026-002-DASP (*R.O.* Supl. 232, 26 de febrero de 2026) (Corral Rosales; documentos vigentes; Julio 2026 Catastro). Art. 19 mirrors the drugs regime — ES/EN acceptance for técnica-analítica documentation, castellano carve-out for Module 2 of *medicamentos nuevos* — and adds the *traductor titulado* requirement. Hemoderivados carry a heightened rule: their monograph must be translated *"por un traductor oficial"* — a wording narrower than the drugs instructivo's silence on translator licensing.

Resolución anchor — Devices, incoming regime, ARCSA-DE-2026-003-DASP art. 49 (verbatim):

The medical-device regime is on the verge of substitution. Resolución ARCSA-DE-2026-003-DASP was signed 28 April 2026, published in *R.O.* 2do Supl. 286 of 18 May 2026, and enters into force nine months after signature — i.e. late January 2027 (Julio 2026 Catastro; Robalino commentary; documentos vigentes). It replaces the outgoing ARCSA-DE-026-2016-YMIH (*R.O.* Supl. 921, 12 de enero de 2017). Art. 49 inverts the drug labelling rule for devices: labels may be Spanish OR English, but the inserto and manual de uso must be Spanish. The direction of the asymmetry is the opposite of the drug rule, where the label must be Spanish and the technical body may be English. Device sponsors have a defined, closing window to bring insertos and manuales de uso into art. 49 compliance before the norm bites.

Resolución anchor — Clinical trials, AM 00069-2024 art. 13 (verbatim):

> "todos los documentos sean presentados en idioma español y en idioma original si es diferente al español. Los documentos elaborados en otro idioma deberán presentarse con una traducción certificada al español..."

MSP's Acuerdo Ministerial 00069-2024 (*R.O.* 730, 27 de enero de 2025) — the current clinical-trials reglamento — requires every document in Spanish *and* in the original language when the original is not Spanish, with a certified Spanish translation and consistency with the original (Corral Rosales; gob.ec — aprobación de ensayos clínicos). ARCSA's operational instructivo IE-B.3.3.1-EC-04 v3.0 (September 2025) §2.1 restates it: *"Toda la documentación que no se encuentre en idioma español deberá adjuntar una traducción oficial certificada."* Critically, AM 00069-2024 dropped the AM 0075-2017 art. 9 requirement that the translation itself be

apostilled or legalised — the single biggest liberalisation of Ecuador's translation regime in the 2024–2026 period. Any advice still repeating the 2017 apostille-on-translation rule is wrong.

Four doctrinal facts embedded in the framework. First, Spanish is a decision-and-use rule, not a general dossier rule: ARCSA requires Spanish where an ARCSA reviewer or an Ecuadorian patient reads the document to make a decision or to use the product safely — prospectos, insertos, manuales de uso, ICFs, pharmacological/clinical documentation post-October 2025, ADR reports — and accepts English where the document is technical evidence a trained evaluator reads, provided the Module 2 tabulated summaries for new medicines are in castellano. Second, the device architecture is explicitly inverted relative to the drug architecture: for drugs, labels must be Spanish and technical body may be English or Spanish; for devices under ARCSA-DE-2026-003-DASP, labels may be Spanish or English but insertos/manuales de uso must be Spanish. Third, Ecuador acceded to the Hague Apostille Convention with effect from 2 April 2005 (Convención de La Haya, gob.ec; MREMH apostille trámite) — so the correct sequence is apostille the foreign legal original first, then translate, and the apostille text, seals and stamps translate with it. Fourth, ARCSA operates a no-images rule for the technical dossier: §2 num. 3 of IE-B.3.2.1-MG-01 v4.0 requires *"formato PDF los documentos originales, no copias o imágenes"* — an enacted rule against scanned images, which converts every OCR-recovered legacy dossier into a rebuild rather than a re-file.

Document-by-document language table (drugs — IE-B.3.2.1-MG-01 v4.0 and ARCSA-DE-2024-058-DASP; biologicals — ARCSA-DE-2024-049-DASP; devices outgoing — ARCSA-DE-026-2016-YMIH; devices incoming — ARCSA-DE-2026-003-DASP; trials — AM 00069-2024 and IE-B.3.3.1-EC-04 v3.0).

Document	Language rule	Statutory anchor
Drug técnica-analítica / galénica documentation	Castellano or English	IE-B.3.2.1-MG-01 v4.0 §2 num. 2
CTD Module 2 — medicamentos nuevos	Castellano (carve-out from §2 num. 2)	IE-B.3.2.1-MG-01 v4.0 §2 num. 2
CTD Module 4 (non-clinical / preclinical)	Case-by-case; English acceptable	IE-B.3.2.1-MG-01 v4.0 §2 num. 2; biologicals art. 17
Pharmacological / clinical documentation (drugs)	Spanish, English admissible only as accompaniment	IE-B.3.2.1-MG-01 v4.0 req. 17
Prospecto	*"Redactado en idioma castellano y con caracteres claramente legibles e indelebles"*	IE-B.3.2.1-MG-01 v4.0 req. 1.4.3
Drug label / packaging	Spanish; multilingual permitted with Spanish among the languages	IE-B.3.2.1-MG-01 v4.0 req. 1.4; label monographs
Legal documents (drugs)	Foreign originals require translation; "no se aceptarán documentos con errores en sus traducciones"; original PDFs, no images	IE-B.3.2.1-MG-01 v4.0 §2 num. 3, num. 4, legal-documents block

Document	Language rule	Statutory anchor
Electronic signature on the covering letter	*"Debe poder validarse"*	IE-B.3.2.1-MG-01 v4.0 §2 num. 5
Biologicals técnica-analítica / galénica	Castellano or English; Module 2 for new products in castellano	ARCSA-DE-2024-049-DASP art. 19
Biologicals translator	*"Traductor titulado y/o por centros autorizados para el efecto"*	ARCSA-DE-2024-049-DASP art. 19
Hemoderivados monograph	*"Por un traductor oficial"*	ARCSA-DE-2024-049-DASP hemoderivados monograph rule
Biologicals homologación route	Available under art. 54	ARCSA-DE-2024-049-DASP art. 54
Device labels (outgoing regime)	Spanish; multilingual permitted with Spanish	ARCSA-DE-026-2016-YMIH
Device labels (incoming regime, ~Jan 2027)	Spanish OR English — inverted from the drug rule	ARCSA-DE-2026-003-DASP art. 49
Device inserto / manual de uso (incoming regime)	Spanish	ARCSA-DE-2026-003-DASP art. 49
Device legal documents	Foreign originals require translation; online-verification apostille waiver available	ARCSA-DE-2026-003-DASP art. 13
Device software / SaMD	Expressly in scope; language treated as the inserto follows	ARCSA-DE-2026-003-DASP
Clinical-trial dossier (protocol, IB, ICF, contracts)	Spanish with certified translation of any non-Spanish document; consistency with original required	AM 00069-2024 art. 13; IE-B.3.3.1-EC-04 v3.0 §2.1
Informed consent form	Spanish (per AM 00069-2024 art. 13; consistency requirement)	AM 00069-2024 art. 13
ADR / tecnovigilancia notifications	Spanish (system operates in Spanish)	ARCSA-DE-2023-016-AKRG (Sistema Nacional de Tecnovigilancia); farmacovigilancia normativa
Import-by-exception documentation	Spanish; translated where the origin document is foreign	ARCSA-DE-2023-025-AKRG; ARCSA-DE-2025-040-DASP
Foreign legal originals — legalisation	Apostille (Hague, 2/4/2005); MREMH online portal	MREMH apostille; Convención de La Haya, gob.ec

Section C. Sworn vs certified vs simple translation

Ecuador does not operate a Panamá-style *traductor público autorizado* register. There is no ministerial licence, no examination, and no MEDUCA-equivalent register of authorised translators. What Ecuador has instead is LOOETA art. 29, a signature-authentication regime, and a set of ARCSA-specific tightenings for biologicals and hemoderivados. That distinction is the whole of Ecuador's certified-translation doctrine, and it explains why cost, calendar and admissibility behave differently here than in Panamá or Colombia.

LOOETA art. 29 in three moves. First, translations by *intérpretes* are presumed valid *"mientras no se demuestre lo contrario"* — a rebuttable presumption of admissibility, not a licensing gate (LOOETA text). Second, the fidelity gate is signature authentication — the translator's signature must be authenticated by a notary, by an Ecuadorian consul abroad, or *reconocida ante un juez de lo civil*. Third, the ámbito of LOOETA (art. 2) reaches every Executive-branch entity — including ARCSA — so ARCSA cannot lawfully impose a translator-licensing requirement on a document category where its own instructivo is silent. The category-by-category answer therefore runs:

Category	Ecuador default (LOOETA art. 29)	ARCSA / MSP tightening	Effective rule
Drug técnica-analítica / galénica	Spanish or English; no licensing	Silent on translator licence	LOOETA-compatible: notary-authenticated *intérprete* accepted
Drug pharmacological / clinical documentation	Signature-authenticated Spanish	Req. 17 tightened to Spanish	Certified Spanish translation, notary-authenticated signature
Drug prospecto	*Redactado* in castellano; not merely translated	Req. 1.4.3	Drafted in Spanish; readability + indelibility
Biologicals	Signature-authenticated Spanish	*"Traductor titulado y/o por centros autorizados"* (art. 19)	Licensed translator required — strictest category
Hemoderivados monograph	Signature-authenticated Spanish	*"Traductor oficial"*	Licensed translator required
Device legal documents (incoming regime)	Signature-authenticated Spanish	Art. 13 — online-verification apostille waiver available	Signature-authenticated + apostilled unless online-verifiable
Device inserto / manual de uso (incoming regime)	*Redactado* in Spanish	Art. 49	Drafted in Spanish; label may remain English
Clinical-trial dossier	*Traducción certificada* + consistency (AM 00069-2024 art. 13)	IE-B.3.3.1-EC-04 v3.0 §2.1 restates	Certified Spanish translation; no apostille-on-translation requirement (AM 00069-2024 liberalisation)

Category	Ecuador default (LOOETA art. 29)	ARCSA / MSP tightening	Effective rule
Foreign legal originals	Apostille or consular legalización	ARCSA §2 num. 4 (drugs); ARCSA-DE-2026-003-DASP art. 13 (devices)	Apostille first, then translate

Anti-double-legalisation — LOOETA art. 28. Ecuador's *Ley Orgánica para la Optimización de Trámites Administrativos* also prohibits Executive-branch entities from demanding legalisation of documents that are already apostilled under the Hague Convention, or from demanding duplicate authentications of foreign public documents (LOOETA art. 28, government-hosted text). The commercial reading: ARCSA may not lawfully demand consular legalisation on top of a valid apostille, and any subsanación that does is challengeable under LOOETA infraction numeral 12 (rejection for illegal reasons). Read that against ARCSA's silence in most instructivos on translator licensing and Ecuador's regime becomes cost-favourable: notary-authenticated signature + apostille of the foreign original + consistent Spanish translation is the default admissibility floor, and only biologicals and hemoderivados climb above it.

The online-verification apostille waiver. ARCSA-DE-2026-003-DASP art. 13 introduces an online-verification waiver for foreign legal documents whose authenticity can be verified against an official online registry — typically a QR-coded apostille or a European e-apostille that resolves against the issuing authority's portal (Robalino commentary). This is a device-side liberalisation that saves an apostille cycle where the origin regime supports online verification. It does not reach drugs, and it does not remove the translation obligation — it removes only the paper-apostille step for verifiable originals.

Signature authentication vs translator licensing — the practical difference. Under LOOETA art. 29, ARCSA cannot reject a drug filing on the ground that the translator lacks a specific licence, so long as the signature is authenticated. Under ARCSA-DE-2024-049-DASP art. 19, ARCSA can reject a biologicals filing on the ground that the translator is not *titulado*. This is a category difference, not a stylistic difference — a translator who signs both a drug filing and a biologicals filing on the same day may satisfy Ecuador's admissibility rule for one and fail it for the other.

The MREMH apostille pathway. Apostille costs USD 30 per document, consular legalización USD 25; both without IVA. The MREMH runs the online portal `serviciosdigitales.cancilleria.gob.ec` and is the sole competent authority (gob.ec MREMH apostilla; Consulado del Ecuador en Nueva York; Consulado del Ecuador en Washington; U.S. Embassy Quito). From 1 September 2023 legalisation for Ecuador is by apostille only — the consular legalisation route is closed for signatory jurisdictions (Embajada de Italia en Quito). Correct sequence: apostille the foreign original, then translate — including the apostille text and every seal and stamp.

Section D. Preclinical / non-clinical documentation — the three operational questions

Ecuador is a split-confidence jurisdiction for preclinical translation: the answer to "must we translate every page of the preclinical stack?" is no for the Module 4 prose body, and yes for a tightly defined subset of Module 2 tabulated summaries. The value of an Ecuador preclinical planning exercise sits almost entirely in that second subset. This is where Ecuador is most different from Panamá, and it is where a sponsor without a Spanish-language production capacity loses the calendar.

D.1 Do we have to translate every page of the preclinical stack?

No, not the full text of Module 4. IE-B.3.2.1-MG-01 v4.0 §2 num. 2 accepts drug técnica-analítica and galénica documentation *"en idioma castellano o inglés"*, and its Module-2 carve-out reaches only *medicamentos nuevos* — not the Module 4 non-clinical prose (Registro Oficial text; Lexis report). The biologicals instrument ARCSA-DE-2024-049-DASP art. 17 restates the case-by-case approach to Module 4 (Corral Rosales; documentos vigentes). The body of the toxicology, pharmacology and safety pharmacology study reports may remain in English, and for the great majority of registrations — generics, biosimilars, homologación files, and any non-*nuevo* drug — CTD is optional at all under §2 num. 8, so Module 4 does not even attach.

Where the "yes" bites. For a *medicamento nuevo* filed in CTD format, CTD Module 2 must be in castellano. Module 2 is not prose translation. It is the ICH M4S(R2) tabulated non-clinical summaries — §2.6.3 (Pharmacology Tabulated Summary), §2.6.5 (Pharmacokinetics Tabulated Summary), §2.6.7 (Toxicology Tabulated Summary), each spanning dozens of table structures that reference doses, exposures, NOAELs, LOAELs, kinetic parameters, tissue distributions and study identifiers. Those tables must be reconstructed in castellano — a table structure delivered as prose is not the deliverable ARCSA is asking for, and a scanned image of an English table with a translated caption is doubly non-compliant under the no-images rule of §2 num. 3.

Requirement 17 — the 2025 tightening. Post-October 2025, IE-B.3.2.1-MG-01 v4.0 requirement 17 elevates the *documentación farmacológica y clínica vigente* to Spanish with English only as an accompaniment. This narrows the summary-only tolerance of ARCSA-DE-2024-058-DASP art. 14(h). The category "documentación farmacológica y clínica vigente" is the applicant-side counterpart to the reviewer's evidence base — the clinical safety-and-efficacy narrative that supports the pharmacovigilance and risk-management position. Read together, §2 num. 2 (English acceptable for técnica-analítica), the Module-2 castellano carve-out for new medicines, and req. 17 (Spanish for pharmacological/clinical documentation) define the exact translation surface: English-tolerant for the raw preclinical evidence, Spanish-mandatory for the structured summaries and for the pharmacological/clinical narrative.

Consequence for filing strategy. The pre-October 2025 ARCSA-DE-2024-058-DASP art. 14(h) allowed a *summary* of pharmacological and clinical documentation. Sponsors reading only the parent resólucion (and not the October 2025 instructivo) will underestimate the Spanish surface by an order of magnitude — a two-page Spanish summary is not the same deliverable as a full Spanish narrative. The instructivo, not the parent resolución, is the operative source for scoping the Spanish surface. Any advisor or vendor pricing an Ecuador filing against the December 2024 art. 14(h) text is pricing to a superseded scope.

D.2 If translation IS required — is it text-only or does it require desktop publishing (DTP)?

It requires DTP. The Ecuador preclinical translation ask is not a prose translation; it is a structured-document reconstruction. Four textual hooks force the DTP posture:

1. The tabulated-summary requirement. ICH M4S(R2) §2.6.3, 2.6.5 and 2.6.7 are tabulated summaries by construction. Reproducing them in castellano is a table-rebuild, not a translate-and-paste. Every column header, every unit of measure, every study identifier, every numeric qualifier must survive in the target table cell.
2. The no-images rule. IE-B.3.2.1-MG-01 v4.0 §2 num. 3 requires *"en formato PDF los documentos originales, no copias o imágenes"* — an enacted rule against scanned images. A DTP workflow that outputs live text, live tables and vector figures is a compliance requirement, not a preference.
3. The prospecto legibility standard. Req. 1.4.3 requires *"caracteres claramente legibles e indelebles"* — legibility and indelibility are print-fidelity properties, not translation properties. They collapse onto the artwork production process.
4. ARCSA's power to demand the source for side-by-side verification. IE-B.3.3.1-EC-04 v3.0 §2.1 requires *"la fidelidad y consistencia en el documento original"* — a fidelity standard that presupposes the reviewer can lay the Spanish tabulated summary alongside the English source study and verify the values line-by-line. That workflow is possible only when tables map to tables, cells map to cells, and figures map to figures.

The commercial reading: the Ecuador preclinical deliverable is a DTP deliverable, not a wordcount deliverable. A sponsor paying by the word for a linear prose translation of a tabulated summary will receive a deliverable that fails on structure, on legibility, and on fidelity — all three grounds enacted in the same instructivo. Section 2.6.7 (Toxicology Tabulated Summary) alone can run to fifty or more table structures for a typical *nuevo* molecule — acute toxicity, repeat-dose across four species, genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance, immunotoxicity, and specialised endpoints — and each must reproduce column headings, units, dose-response cells and NOAEL/LOAEL identifiers in castellano. This is the workstream most sensitive to production capacity, and it is the workstream that most often runs past the sponsor-side cure window.

D.3 If translation is NOT required — what substitutes for it?

For every drug that is not *nuevo*, CTD is optional (§2 num. 8) and the preclinical stack may be filed in English técnica-analítica format. What substitutes for translation are three ARCSA expectations:

1. **A castellano-drafted* documentación farmacológica y clínica vigente*** (req. 17), which sits above the English preclinical evidence and functions as ARCSA's reader entry-point.
2. A castellano-drafted prospecto (req. 1.4.3), which is the patient-facing surface and which the ARCSA reviewer maps back to the English clinical narrative for consistency.

3. A signature-authenticated Spanish translation of any legal document in the dossier — poderes, certificados de libre venta, GMP certificates, CPPs — under §2 num. 4 and the LOOETA art. 29 default.

For biologicals, the substitute set climbs: art. 19 imposes the *traductor titulado* rule, and the hemoderivados monograph must be *"por un traductor oficial"* (Corral Rosales). For medical devices under ARCSA-DE-2026-003-DASP, the label may remain in English but the inserto and manual de uso must be *redactado* in Spanish. The pattern is consistent: Ecuador loosens the raw-evidence translation obligation and tightens the patient-facing and reviewer-facing translation obligation.

The certified-translation attestation package. For every category where Spanish is required, ARCSA's fidelity gate depends on a certified-translation attestation package that a reviewer can adjudicate on the face of the document. The minimum package — whether the translator is a LOOETA-authenticated *intérprete* or an ARCSA-required *traductor titulado* — is: (1) a translator's declaration of fidelity to the source; (2) the translator's signature; (3) authentication of the signature (notary, consul or civil-court judge for LOOETA; title / centro authorisation for biologicals); and (4) for legal documents, the apostille of the source and the translation of the apostille itself. The declaration must attach to a named natural person, not to a translation-services vendor — ARCSA can and does trace fidelity failures to the named translator.

The two regulatory pathways trigger different translation obligations

Ecuador's preclinical translation obligation depends on the pathway, and the pathway depends on the product classification. The table below reconciles the four regimes side by side.

Pathway	Statutory anchor	Preclinical translation obligation	Module 2 obligation
Drug — *medicamento nuevo*, CTD mandatory	IE-B.3.2.1-MG-01 v4.0 §2 num. 2, num. 8	English acceptable for Module 4 (case-by-case)	Castellano for Module 2, including ICH M4S(R2) tabulated summaries
Drug — non-*nuevo*, CTD optional	§2 num. 8	English acceptable for técnica-analítica; no Module 4 obligation attaches	CTD optional; no Module 2 obligation
Drug — homologación	ARCSA-DE-2024-058-DASP homologación route	English acceptable; reliance model	Not applicable
Biological — new, CTD applicable	ARCSA-DE-2024-049-DASP art. 17, art. 19	English acceptable case-by-case; licensed translator required on translations	Castellano for Module 2

Pathway	Statutory anchor	Preclinical translation obligation	Module 2 obligation
Biological — hemoderivado	ARCSA-DE-2024-049-DASP hemoderivados rule	Monograph *"por un traductor oficial"*	As above
Clinical-trial CTA (drug)	AM 00069-2024 art. 13; IE-B.3.3.1-EC-04 v3.0 §2.1	*Traducción certificada al español* + consistency with original; no apostille on the translation	Protocol, IB, ICF in Spanish
Device — outgoing regime	ARCSA-DE-026-2016-YMIH	Legacy rules apply until ~Jan 2027	N/A
Device — incoming regime ~Jan 2027	ARCSA-DE-2026-003-DASP arts. 12, 13, 49	Inserto / manual de uso in Spanish; label ES or EN	N/A

D.4 Consolidated preclinical instruction table

Read across the preclinical stack, the enacted texts sort as follows.

Preclinical document	Ecuador rule	Instrument
Module 4.2.1 Pharmacology reports (body)	English acceptable	IE-B.3.2.1-MG-01 v4.0 §2 num. 2
Module 4.2.2 Pharmacokinetics reports (body)	English acceptable	Same
Module 4.2.3 Toxicology reports (body)	English acceptable	Same
Module 2.6.1 Introduction to the Non-Clinical Summary	Castellano for *medicamentos nuevos*	§2 num. 2
Module 2.6.2 Pharmacology Written Summary	Castellano for *medicamentos nuevos*	§2 num. 2
Module 2.6.3 Pharmacology Tabulated Summary	**Castellano for* medicamentos nuevos — *tabulated reconstruction**	§2 num. 2 + ICH M4S(R2)
Module 2.6.4 Pharmacokinetics Written Summary	Castellano for *medicamentos nuevos*	§2 num. 2
Module 2.6.5 Pharmacokinetics Tabulated Summary	**Castellano for* medicamentos nuevos — *tabulated reconstruction**	§2 num. 2 + ICH M4S(R2)
Module 2.6.6 Toxicology Written Summary	Castellano for *medicamentos nuevos*	§2 num. 2

Preclinical document	Ecuador rule	Instrument
Module 2.6.7 Toxicology Tabulated Summary	**Castellano for* medicamentos nuevos — *tabulated reconstruction**	§2 num. 2 + ICH M4S(R2)
Documentación farmacológica y clínica vigente	Spanish (English admissible only as accompaniment)	Req. 17 (as tightened 28 Oct 2025)
Prospecto	*Redactado* in castellano; legible and indelible	Req. 1.4.3
Legal documents (poderes, CLV, GMP, CPP)	Foreign originals apostilled + Spanish translation	§2 num. 4
Certificate of Analysis	English acceptable (técnica-analítica)	§2 num. 2
Fórmula cuali-cuantitativa	Castellano; foreign-language accompaniments translated	§2 num. 2; label monographs

D.5 Where the preclinical translation risk actually sits

The risk is in the Módulo 2 tables, not in the Módulo 4 prose. A sponsor who plans an Ecuador *medicamento nuevo* filing as an English Module 4 exercise plus a Spanish "summary" underestimates the actual deliverable. The ICH M4S(R2) tabulated summaries in Module 2 — §§2.6.3, 2.6.5 and 2.6.7 — are the structural deliverable. They are what an ARCSA reviewer reads first, and they are the document class most sensitive to the four enacted rules that shape Ecuador's translation surface: castellano for Module 2 of new medicines, the no-images rule, the legibility standard, and the fidelity-with-original standard. Delivering those tables as prose destroys structure. Delivering them as scans breaches §2 num. 3. Delivering them without cell-level equivalence breaches the fidelity requirement. A sponsor's Ecuador preclinical translation budget should be modelled against tabulated-summary reconstruction hours and DTP hours, not against Module 4 wordcount.

The secondary risk sits in req. 17. The *documentación farmacológica y clínica vigente* is now a Spanish deliverable in full, not in summary. This is a materially larger surface than the December 2024 art. 14(h) allowance. Sponsors who filed to Ecuador before October 2025 and have not scoped a fresh Spanish narrative on renewal will encounter req. 17 for the first time at their next renovación, which is precisely when the 20% fee schedule bites.

The tertiary risk sits in artwork indelibility. Req. 1.4.3's *"caracteres claramente legibles e indelebles"* is a production standard, not a translation standard — but a fidelity defect that reaches the print stage is more expensive to cure than one caught at the QC stage. Fidelity QC must precede artwork production, not follow it, and the ordering of QC gates against the printing schedule is the operational difference between a first-pass Ecuador filing and a defective one.

CATEGORY 1: DRUGS

D1. Drug market access — ARCSA pathway

Governing instruments. Registro sanitario for medicines is governed by Resolución ARCSA-DE-2024-058-DASP (signed 30 de diciembre de 2024, *R.O.* 731 of 28 de enero de 2025) and its 98-page Instructivo Externo IE-B.3.2.1-MG-01 v4.0 enacted by Resolución ARCSA-DE-2025-034-DASP (signed 3 de octubre de 2025, *R.O.* 1er Supl. 153 of 28 de octubre de 2025) (Registro Oficial text; Corral Rosales; Lexis; Julio 2026 Catastro). The underlying statutory basis is Ley Orgánica de Salud arts. 137–142, which authorise MSP/ARCSA to require *registro sanitario* for medicines.

Applicant infrastructure. Every drug filing requires a *representante técnico* who signs the covering letter with a validatable electronic signature (§2 num. 5) and an applicant with a Ecuador-domiciled *permiso de funcionamiento* (ARCSA-DE-2023-001-AKRG). Foreign originals must be apostilled (§2 num. 4), and their Spanish translation must be filed alongside — but the translation itself does not need to be apostilled, and the LOOETA art. 28 anti-double-legalisation rule applies. Fees are governed by ARCSA-DE-2018-019-JCGO and its ARCSA-DE-2023-002-AKRG reform; the tarifario is public (TARIFARIO abril 2024; ARCSA-DE-2018-019-JCGO full text).

Translation implications for the market-access dossier. The technical body may be filed in English for non-*nuevo* drugs and for the Module 4 body of *nuevo* drugs (§2 num. 2). What must be in Spanish is the prospecto (*redactado* in castellano, req. 1.4.3), the documentación farmacológica y clínica vigente (req. 17), the etiquetas where the primary or secondary packaging is intended for Ecuadorian retail, the CTD Module 2 for *medicamentos nuevos*, and the legal documents — poderes, certificados de libre venta, GMP certificates, CPPs. The translation defect that most often kills a first-round filing is a Module 2 tabulated summary delivered as prose, followed by a prospecto that fails the "caracteres claramente legibles e indelebles" test.

Homologación and reliance. ARCSA-DE-2024-058-DASP creates a homologación route with a 60-día término ARCSA review clock — the only firm number ARCSA publishes for a drug pathway. It relies on registrations from high-standard authorities and compresses the technical review, but it does not waive the language obligations of the drugs instructivo: the prospecto, labels and pharmacological/clinical documentation must still comply with req. 1.4.3 and req. 17.

The archivo terminal outcome. Ecuador rarely says no to a drug filing. It closes the file. Resolución ARCSA-DE-2019-016-JRC governs the archiving of registro-sanitario and notificación-sanitaria applications (documentos vigentes); the ARCSA-DE-2024-058-DASP art. 18 rule that non-response to an objection carries *"cancelación definitiva del proceso"* with no refund is the terminal-outcome clock. A translation defect that a sponsor cannot cure inside the 30-day (national) or 60-day (foreign) cure window under art. 17 num. 8–9 converts the filed fee into a lost fee.

The rejection-ground text is enacted. Two rejection grounds appear verbatim in the drugs instructivo's legal-documents block and are decisive in first-round reviews: *"No se aceptarán*

documentos con errores en sus traducciones" and the requirement that a foreign document be *"acompañado de su respectiva traducción al idioma castellano."* Reviewers cite the first as a fidelity ground and the second as a completeness ground. The instructivo also carries §2 num. 3 *"deben adjuntarse en formato PDF los documentos originales, no copias o imágenes"* — meaning a scanned English CoA re-issued as a PDF image, however clean, is non-compliant on the format ground before the reviewer ever assesses the translation. A first-time Ecuador sponsor filing on a legacy digitised dossier commonly discovers the format ground before the fidelity ground.

The Guayaquil geography. ARCSA is headquartered in Guayaquil, not Quito (ARCSA contacto), and hearings, physical hand-carries and hard-copy inspections default to the Guayaquil address. Digital filings run through the ARCSA institutional portal (ARCSA portal) but any escalation that requires physical presence — an *audiencia*, a physical inspection of the legalised original, a *comité de asesores* convocation under art. 17 num. 12 — routes to Guayaquil. That is a scheduling cost for a Miami- or Bogotá-based sponsor that a Quito-only mental model underestimates.

D2. Drug regulatory submissions

Post-approval change control. Modifications to a registro sanitario run under Resolución ARCSA-DE-2024-030-DASP for medicines and biologicals — the change-control instrument for labels, prospectos and formulaciones (Julio 2026 Catastro entry 83). Under ARCSA-DE-2023-002-AKRG art. 6, modifications outside Acuerdo Ministerial 112 carry a fee equal to 10% of the obtaining fee; modifications implying analysis run at 20%; and reinscripciones / renovaciones are charged at 20% of the registro-sanitario or notificación-sanitaria fee.

Renovaciones. Every registro sanitario expires; renovación is a fresh submission with updated labels, insertos and prospectos — meaning every renewal is a translation-refresh trigger, particularly where a product has evolved during the registration term.

Pharmacovigilance and tecnovigilancia. ARCSA runs a Sistema Nacional de Farmacovigilancia under ARCSA-DE-2025-052-DASP (Normativa Técnica Sustitutiva, 2025) and a Sistema Nacional de Tecnovigilancia for devices under ARCSA-DE-2023-016-AKRG (documentos vigentes; Julio 2026 Catastro entry 70). Both systems operate in Spanish: adverse reaction reports, incident notifications and periodic safety updates are filed in castellano. There is no ARCSA equivalent to Panamá's DE 27 Art. 331 acceptance of an English PSUR with a Spanish executive summary — Ecuador's expectation is that safety communications with ARCSA occur in Spanish.

Certificado de exclusividad and test-data protection. ARCSA-DE-2024-041-DASP (certificado de exclusividad) and ARCSA-DE-2024-023-DASP / ARCSA-DE-2025-003-DASP (test-data protection for new chemical entities) sit alongside registro-sanitario as accompanying regimes (Julio 2026 Catastro entries 80–86). Where a filing invokes exclusivity, the underlying dossier must satisfy the Module 2 castellano rule for *medicamentos nuevos* — and because test-data protection turns on the completeness of the pharmacological/clinical documentation, req. 17 tightens the effective Spanish surface further.

One application per pharmaceutical form × dose × strength. ARCSA files are granular. A single molecule marketed in three strengths and two pharmaceutical forms is six applications, each

with its own Spanish prospecto and its own artwork. Terminology drift across sibling filings is directly visible to a reviewer handling the family, and drift is the kind of defect that req. 17 elevates from a stylistic issue into a fidelity issue. A sponsor filing a molecule family should treat the Spanish core as a shared glossary, not as six independent translations — and the glossary must survive the entire renovación cycle, because req. 17 attaches at every renewal.

Biologicals notification and change control. Biologicals move under ARCSA-DE-2024-030-DASP for notifications, with the *traductor titulado* fidelity floor of ARCSA-DE-2024-049-DASP art. 19 attaching to every notified change that carries a translated document. Biosimilars in particular pull a heavier Spanish surface than small-molecule generics because the comparability exercise runs through Module 2 tabulated summaries — the same document class Section D flags as the highest-risk deliverable.

Advertising and promotion — ARCSA-DE-2024-048-DASP. Advertising and promotion of medicines is governed by ARCSA-DE-2024-048-DASP (13/12/2024, *R.O.* 727) (Julio 2026 Catastro entry 90). Promotional copy targeted at Ecuadorian audiences is a Spanish deliverable, and misalignment between an approved Spanish prospecto and a promotional Spanish piece is a compliance surface distinct from the registro sanitario. A promotional item that expands beyond the approved prospecto is a violation whether or not the underlying translation is faithful — and the fidelity gate here is not to the English original but to the ARCSA-approved castellano.

D3. Drug clinical trials

Governing instruments. MSP Acuerdo Ministerial 00069-2024 (*R.O.* 730, 27 de enero de 2025) is the current *Reglamento para la aprobación, control y seguimiento de estudios clínicos con medicamentos y productos biológicos en seres humanos*; it replaced AM 0075-2017. ARCSA's operational Instructivo Externo IE-B.3.3.1-EC-04 v3.0 (September 2025) implements it (Corral Rosales; ARCSA ensayos clínicos; gob.ec — aprobación de ensayos clínicos).

Language rule — art. 13 verbatim: *"todos los documentos sean presentados en idioma español y en idioma original si es diferente al español. Los documentos elaborados en otro idioma deberán presentarse con una traducción certificada al español."* IE-B.3.3.1-EC-04 v3.0 §2.1 restates it: *"Toda la documentación que no se encuentre en idioma español deberá adjuntar una traducción oficial certificada."* Both texts add the fidelity requirement: *"la fidelidad y consistencia en el documento original."*

The AM 00069-2024 liberalisation. AM 00069-2024 dropped the AM 0075-2017 art. 9 requirement that the translation itself be apostilled or legalised. Trial translations no longer need to be apostilled — only certified and consistent with the original. This is the single biggest liberalisation of Ecuador's translation regime in the 2024–2026 period. Any advice or template that still repeats the 2017 rule is wrong and forces a sponsor into cost and calendar that Ecuador no longer requires.

Version-parity is a translation requirement. IE-B.3.3.1-EC-04 v3.0 §2.1's *"fidelidad y consistencia en el documento original"* means that filing v3.0 Spanish to ARCSA while the CEISH holds v2.1 is a defect even if both translations are perfect. Every ICF and protocol amendment triggers a

bilingual amendment package, and every $221.21 amendment fee is doubled operationally by translation and CEISH re-review.

ICH E6(R3) — the 2025 template migration. ARCSA lists ICH E6(R3) Step 4 Final Guideline (6 January 2025) under its Ensayos Clínicos materials (documentos vigentes) — meaning Ecuador's trial dossier expectations are anchored to E6(R3), not E6(R2), and any protocol/ICF template still built on E6(R2) headings is behind the regulator. The E6(R3) migration is a translation event: heading structures, risk-based-monitoring sections and quality-tolerance-limit language rewrite the Spanish template.

CEISH review — the unbounded clock. Each CEISH runs on its own meeting calendar, and MSP publishes no accreditation SLA (MSP trámite). MSP reported 19 CEISH and 14 CEAS nationally when the *Reglamento Sustitutivo* came into force (MSP announcement) and 11 CEISH were approved that year — but not all will review clinical trials (CEISH-HGL is the paradigmatic exclusion, CEISH-HGL). Sponsor consequence: committee capacity is the real bottleneck, and a Spanish ICF that needs a second CEISH revision round can cost more calendar than ARCSA's entire 60-day technical review.

Consistency between CEISH-signed and ARCSA-filed versions. AM 00069-2024 art. 13's *"consistencia con el documento original"* has an operational corollary: the Spanish ICF, protocol and IB approved by the CEISH must match the Spanish ICF, protocol and IB filed with ARCSA. Version parity is a translation requirement in Ecuador — filing v3.0 Spanish to ARCSA while the CEISH holds v2.1 is a fidelity defect even where both translations are perfect. Amendments compound the problem: each protocol change triggers a bilingual amendment package, a $221.21 amendment fee, and — where the ICF changes — a fresh CEISH review that resets the calendar.

Trial closure — 30-día término on cierre. IE-B.3.3.1-EC-04 v3.0 sets a 30-day-término deadline for addressing observations on a *cierre de ensayo clínico* (gob.ec — notificación de cierre). Trial closure documentation — final safety reports, CSR summaries where filed to ARCSA, biological-sample-destruction protocols — all move in Spanish, and each carries its own translation surface.

Insurance and post-marketing. ARCSA's clinical-trials page requires insurance coverage duration of at least 1 year after study end (ARCSA ensayos clínicos); post-marketing study reviews carry a 15-day clock. The insurance certificate is a legal document under §2 num. 4 — apostilled, translated, signature-authenticated.

CATEGORY 2: MEDICAL DEVICES

E1. Device market access — ARCSA pathway

Governing instruments. Devices sit under the outgoing Resolución ARCSA-DE-026-2016-YMIH (*R.O.* Supl. 921, 12 de enero de 2017), amended by ARCSA-DE-2023-001-VSVZ (partial reform of

the medical-devices technical norm) and ARCSA-DE-2023-033-AKRG (further reform) (documentos vigentes; Julio 2026 Catastro entries 63 and 78). Notifications and change control run under ARCSA-DE-2023-005-AKRG — the instrument that governs IFU and labelling changes (Julio 2026 Catastro entry 66).

The incoming regime — ARCSA-DE-2026-003-DASP. Signed 28 April 2026, published in *R.O.* 2do Supl. 286 of 18 May 2026, entering into force nine months after signature — late January 2027 (Robalino commentary; documentos vigentes). It repeals ARCSA-DE-026-2016-YMIH, introduces a seven-bucket evidence matrix (art. 24), an IMDRF-simplified route, expressly incorporates device-software / SaMD, and creates notification code NDM017. Art. 12 sets the language rule; art. 13 governs legal documents and introduces an online-verification apostille waiver; art. 49 sets the labels-vs-inserto asymmetry.

Translation implications for the market-access dossier. Under the outgoing regime, drug-style labelling in Spanish and a Spanish IFU have been the operating expectation. Under the incoming regime, labels may be filed in Spanish OR English but the inserto and manual de uso must be Spanish (art. 49). The direction of the asymmetry inverts the drug rule and is the single most actionable planning fact in Ecuador: device sponsors have a defined nine-month runway to bring insertos and manuales de uso into art. 49 compliance before the norm bites. Device software and SaMD user-facing text (in-app strings, error messages, safety alerts) follows the inserto — Spanish where the interaction is patient-facing or operator-facing.

Fees. Registro sanitario carries USD 678.25 for national devices and USD 904.34 for foreign devices under the 2024 tarifario (TARIFARIO abril 2024). Reactivos bioquímicos y de diagnóstico pay USD 678.25. There is no risk-class differentiation — a Class I and a Class IV device pay the same fee. Change-control notifications under ARCSA-DE-2023-005-AKRG plus the ARCSA-DE-2023-002-AKRG 10% modification-fee schedule mean that IFU edits are cost-throttled, and rejected modifications re-trigger the fee.

Cure architecture. ARCSA-DE-2026-003-DASP tightens the cure architecture for devices: the final cure opportunity is expressly *"un último plazo de treinta (30) días término."* That 30-day final cure is the translation deadline — a Spanish inserto rebuilt from a rejected English filing must clear print production, terminology QC and fidelity review inside the same window.

The seven-bucket evidence matrix. Art. 24 of ARCSA-DE-2026-003-DASP introduces a seven-bucket evidence matrix that varies dossier expectations by device class and by the availability of a high-standard prior authorisation (Robalino commentary). The matrix affects translation planning in a specific way: higher-evidence buckets require larger inserto and manual-de-uso surfaces, and those surfaces are the Spanish-mandatory documents under art. 49. A sponsor moving up the matrix — for example, from a reliance-eligible low-risk device to a higher-class device requiring native clinical evidence — moves proportionally more Spanish content into scope.

IMDRF-simplified route. ARCSA-DE-2026-003-DASP creates an IMDRF-simplified route for devices with recognitions from IMDRF founding-member regulators. It compresses the technical review by relying on the foreign authorisation, but — like the drug homologación route — it does not waive the art. 49 inserto/manual-de-uso obligation. The Spanish surface for the patient-facing text is a national-sovereignty deliverable Ecuador does not concede to a foreign regulator.

E2. Device regulatory submissions

Change control. ARCSA-DE-2023-005-AKRG requires notification of IFU and labelling changes; the notification triggers a fee at 10% of the obtaining fee under ARCSA-DE-2023-002-AKRG. A rejected modification re-triggers the fee, converting an IFU edit into a repeated fee if the Spanish is wrong.

Import-by-exception and donation. ARCSA-DE-2023-025-AKRG governs import-by-exception and import-by-donation (text mirrored at PUDELECO), further reformed by ARCSA-DE-2025-040-DASP (*R.O.* Supl. 181, 10 de diciembre de 2025) (Julio 2026 Catastro entry 93). This is the named-patient / humanitarian route; documents must be filed in Spanish, with signature-authenticated translations of any foreign-origin documents.

Tecnovigilancia. The Sistema Nacional de Tecnovigilancia under ARCSA-DE-2023-016-AKRG generates Spanish incident reporting, and the operating expectation is that every incident report, field safety notice and periodic tecnovigilancia update reaches ARCSA in castellano.

E3. Device clinical trials

Ecuador has no device-specific clinical-trial regulation. Legal 500 Ecuador is explicit on this point: the country chapter notes the absence of a device-specific trial reglamento (Legal 500 — Life Sciences Ecuador). Device clinical investigations are treated under the general clinical-trial framework of AM 00069-2024, which addresses "estudios clínicos con medicamentos y productos biológicos en seres humanos" — reaching devices only by extension where the study involves an investigational medicinal product component. In practice, sponsors of a stand-alone device investigation route through the general research-in-humans framework: MSP CEISH accreditation, LOOETA translation defaults, and (where relevant) ARCSA import-by-exception for the investigational device. The translation posture defaults to AM 00069-2024 art. 13 — *traducción certificada al español* with consistency to the original. This is a genuine gap in the Ecuadorian regulatory architecture, and a first-in-human device sponsor should read the AM 00069-2024 obligations as the operating standard until such time as ARCSA issues a device-specific investigations instrument.

Bioaccess® Latin America device-CRO context. Ecuador is not the highest-volume LATAM jurisdiction for first-in-human device trials — that distinction runs to Colombia, Chile and, for cardiovascular indications, the Dominican Republic and Paraguay. Ecuador becomes strategically interesting where a sponsor is running a multi-country Andean study and Ecuador's CEISH landscape can carry one or two contributing sites. In those cases, the translation surface is not a stand-alone Ecuadorian pipeline but a jurisdiction-specific certification layer on top of a shared Spanish core — the same architectural pattern Amavita Sciences™ uses across the Andean region.

Investigator's Brochure and protocol. Where a device clinical investigation carries an IB and a protocol, both move in Spanish under the AM 00069-2024 art. 13 default, and the ICF is a Spanish-drafted patient-facing document. ICH E6(R3) applies as a template anchor for the

investigation as a good-clinical-practice document, even where the device pathway itself does not have a dedicated Ecuadorian reglamento.

Investigational-device import. Import of the investigational device runs under ARCSA-DE-2023-025-AKRG (as reformed by ARCSA-DE-2025-040-DASP) — the import-by-exception and donation pathway (Julio 2026 Catastro). Import paperwork is Spanish, and foreign-origin legal documents carry the §2 num. 4 apostille-plus-translation obligation.

Section F. Common RFI / rejection patterns

Ecuador's rejection grounds are enacted, not inferred. IE-B.3.2.1-MG-01 v4.0 and ARCSA-DE-2024-049-DASP name the specific translation defects that ground a rejection, and ARCSA-DE-2024-058-DASP art. 18 sets the terminal consequence of non-cure.

Ground	Enacted text	Instrument
Translation errors	*"No se aceptarán documentos con errores en sus traducciones."*	IE-B.3.2.1-MG-01 v4.0 legal-documents block; ARCSA-DE-2024-049-DASP art. 19
Translator not qualified (biologicals)	*"La traducción debe ser realizada por un traductor titulado y/o por centros autorizados para el efecto."*	Same
Inconsistency with the original	*"Debe mantener consistencia con el documento original"*	Same; IE-B.3.3.1-EC-04 v3.0 §2.1
Images / non-original PDFs	*"Deben adjuntarse en formato PDF los documentos originales, no copias o imágenes."*	IE-B.3.2.1-MG-01 v4.0 §2 num. 3
Illegible prospecto	*"Redactado en idioma castellano y con caracteres claramente legibles e indelebles."*	Req. 1.4.3
Module 2 not in castellano (new medicines)	§2 num. 2 carve-out	Drugs instructivo; biologicals art. 19
Unvalidatable electronic signature	*"Debe poder validarse"* on the covering letter	§2 num. 5
Missing apostille / consularisation	§2 num. 4, subject to Disposición General Décima waiver	Drugs instructivo; devices art. 13
Non-response to objection	*"Cancelación definitiva del proceso"*, no refund of fees	ARCSA-DE-2024-058-DASP art. 18

Reading the table. The first three rows are fidelity rows and share a doctrinal core: the translation must be accurate, verifiable and delivered by a qualified translator. The next three are structural rows and share a different core: the delivered artefact must be structurally correct as a document, not just linguistically correct. The final three are procedural rows and reflect ARCSA's completeness gate. A first-pass Ecuador filing must clear all three layers. In practice, foreign-origin dossiers most often fail the structural layer first (an image PDF, a scanned CoA), pass the fidelity layer at the objection stage, and clear the procedural layer only with local counsel keeping the electronic signature validatable and the payment record intact.

The objection-and-cure architecture (drugs). ARCSA-DE-2024-058-DASP art. 17 sets a 5-day checklist return, a 10-día-término fee payment window, a risk-based technical review with no fixed clock, a 30-day cure window for national applicants and a 60-day cure window for foreign applicants, each available twice (the 4 September 2024 public draft carries the same numerals 8–9 workflow). A translation defect is not usually fatal on first contact — it produces an objection. What kills a filing is failing to cure inside 30 or 60 days. The cure window is the real deadline, and translation turnaround is what determines whether it is met.

Cure-window arithmetic. A sponsor whose Spanish deliverable has to be rebuilt from scratch — because a tabulated toxicology summary was delivered as prose, or artwork has to be re-typeset from an image — burns most of the cure window on production, not on regulatory response. A 30-day national cure window is functionally 10–15 days of translation-and-DTP work plus 10 days of internal QC plus a handful of days for Ecuador-lawyer routing. A 60-day foreign cure window is a doubling, not a windfall, because international mail and consular scheduling consume additional days. Amavita Sciences™ sizes the cure window against the DTP calendar first, then the translation calendar, then the QC calendar — and it prices the First-Pass Acceptance Program against the calendar the sponsor does not have.

The archivo pathway. Ecuador rarely says no. It closes the file. Resolución ARCSA-DE-2019-016-JRC governs the archiving of registro-sanitario and notificación-sanitaria applications (documentos vigentes). For clinical trials, AM 00069-2024 supplies the parallel: 180 days of non-response closes the file. A closed file means re-filing, re-paying, and re-queuing. For devices, ARCSA-DE-2026-003-DASP tightens this further: the final cure opportunity is expressly *"un último plazo de treinta (30) días término,"* and there is no third round.

A structural protection sponsors do not know they have. LOOETA infraction numeral 8 makes it an infraction for a public servant to reject a submission for *"errores de citas, de ortografía, de mecanografía, aritméticos o similares"* (LOOETA text). Set that against ARCSA's *"No se aceptarán documentos con errores en sus traducciones"* and the doctrinal frontier is clear: a typographical slip in Spanish prose is protected by LOOETA num. 8 and cannot lawfully ground a rejection, while a translation error — a wrong dose unit, an inverted NOAEL, a mistranslated contraindication, a value shifted into the wrong table column — is a substantive fidelity failure and is expressly rejectable under the ARCSA instructivo. The frontier between the two is the whole of the Ecuador risk-framing exercise.

Everything happens in Spanish. ARCSA's published service charter documents its trámite catalogue, service channels and subsanación mechanisms entirely in Spanish (ARCSA service charter, GPR). The objection you receive will be in Spanish, the response you file must be in

Spanish, and the clock runs in días término. A sponsor without Spanish-language regulatory capacity loses days to comprehension before production even starts.

Practitioner commentary corroborating the compliance burden. Corral Rosales on the 2024–2025 wave of technical norms for medicines, biological products and clinical trials (Corral Rosales); Robalino on the medical-device normative framework at ARCSA (Robalino); Legal 500 Ecuador: Life Sciences covering registration, trials and the absence of a device-specific trial regulation (Legal 500); and Lexis on the publication of the October 2025 medicines instructivo (Lexis Ecuador). Read together, the commentary corroborates the compliance-burden reading of the enacted texts — and it forms the paper trail an Ecuador filing should reference when scoping the Spanish surface for a first-time sponsor.

Section G. Consolidated timelines

Clinical trials — the only pathway with a fully published clock. From the ARCSA clinical-trials page (controlsanitario.gob.ec/ensayos-clinicos):

Step	Term
Issue of payment order	≤ 2 days
ARCSA documentary (completeness) review	7 days
Sponsor subsanación of observations	30 days, extendable by 30
Technical evaluation and report	≤ 60 days, extendable by 30
Modification request response	90 days, extendable by 90
Post-marketing study review	15 days
Insurance coverage duration	≥ 1 year after study end

Best-case arithmetic: 2 + 7 + 60 ≈ 69 days with no observations. Realistic case with one round of observations: 2 + 7 + 30 + 60 + 30 ≈ 129 days. The 30-day subsanación window is inside the sponsor's control, and for a bilingual dossier it is almost always a translation-production window.

AM 00069-2024 additional clocks: 7-day admissibility; 28 days to answer a requerimiento; 180 days of non-response closes the file; 1 year to submit conclusions; and 14 / 7 / 15 / 10-day safety notification clocks for adverse events.

Drugs — no fixed statutory clock. ARCSA-DE-2024-058-DASP art. 17 num. 6 is explicit: *"El tiempo del análisis del proceso por parte de la ARCSA dependerá del nivel de riesgo sanitario del medicamento y la complejidad del trámite."* The only firm number ARCSA publishes for a drug pathway is the 60-día término homologación clock.

Element	Term
Checklist return	5 days, once (art. 17 num. 2)
Fee payment	10 días término (art. 17 num. 3)
Technical review	Risk- and complexity-dependent (art. 17 num. 6)
Objection cure — national	30 days, twice (art. 17 num. 8–9)
Objection cure — foreign	60 days, twice (art. 17 num. 8–9)
Non-response	Definitive cancellation, no refund (art. 18)
Second chance, national	30 days (art. 42)
Homologación	60 días término

Devices — outgoing and incoming. The outgoing regime under ARCSA-DE-026-2016-YMIH does not publish a review clock. The incoming regime under ARCSA-DE-2026-003-DASP sets a final cure opportunity of "un último plazo de treinta (30) días término"; the norm enters force ~January 2027.

Apostille and legalisation. Apostille USD 30 per document; consular legalización USD 25 (no IVA) (MREMH apostille). Sequence: apostille the original first, then translate.

Fees — headline figures (TARIFARIO abril 2024):

Item	Fee (USD)
Medicamentos extranjeros	2,258.41
Medicamentos nacionales	904.34
Genéricos extranjeros	565.21
Genéricos nacionales	510.51
Dispositivos médicos extranjeros	904.34
Dispositivos médicos nacionales	678.25
Reactivos bioquímicos y de diagnóstico	678.25
Clinical trial — national sponsor total	2,390.28 ($870.10 + $1,520.18)
Clinical trial — international sponsor total	4,391.65 ($1,670.65 + $2,721.00)
Amendment to an authorised trial	221.21
Import authorisation, investigational product / kit	150.24
Export authorisation, biological samples	109.71
Trial inspection	230.52

Reinscripción / renovación is charged at 20% of the corresponding registro-sanitario fee, and modifications implying analysis at 20%; other modifications carry 10% of the obtaining fee under ARCSA-DE-2023-002-AKRG art. 6.

Two structural observations on device fees. First, there is no risk-class differentiation for devices — a Class I and a Class IV device pay the same USD 678.25 (national) / USD 904.34 (foreign). Second, the amendment fee for clinical trials is the translation-relevant one: every protocol amendment is USD 221.21 in fees plus a bilingual amendment package plus, where the ICF changes, a fresh CEISH review. Protocol churn is expensive in Ecuador in a way that is invisible until the third amendment.

Commercial reading. A foreign medicine registration costs USD 2,258.41 in government fees. A rebuilt Spanish Module 2 costs a multiple of that. Government fees are not the cost driver in Ecuador — dossier production is. And because a defective filing that lapses forfeits the fee entirely (art. 18: no refund), poor translation quality converts a fixed fee into a repeated fee. Every additional filing cycle brings with it another apostille cycle (USD 30/document), another notarial cycle, and another translator engagement. The compounding effect is the reason Amavita Sciences™ prices first-pass acceptance rather than pricing translation output alone.

CEISH and MSP accreditation — no published clock. MSP publishes no CEISH-accreditation SLA on its trámite sheet (MSP CEISH accreditation trámite; request form), and no CEISH publishes a standard review clock. Contact: Mayra Paola Cueva Rojas, cgds@msp.gob.ec, (+593) 2-2381 4400 ext. 5267.

Consolidated view:

Pathway	Regulator clock	Sponsor-side windows	Realistic total
Clinical trial	2 + 7 + 60 days (+30 ext.)	30-day subsanación (+30); CEISH review unpublished	~69 days clean; ~129+ days with one objection round; plus CEISH, unbounded
Drug — standard	Risk- and complexity-dependent	5-day checklist; 10-día-término payment; 30/60-day cure ×2	Not publishable as a single number
Drug — homologación	60 días término	Same cure windows	~60 days + cure rounds
Device — current	Not published	Per ARCSA-DE-026-2016-YMIH	Not publishable
Device — from ~Jan 2027	Not published; final cure 30 días término	30-day final cure	Norm in force 9 months post-signature
Apostille (MREMH)	Not published	$30/document; online portal	Sequence before translation

Section H. Recent regulatory changes 2023–2026

Ecuador's translation surface has been rewritten in a four-instrument sequence between December 2024 and April 2026: ARCSA-DE-2024-058-DASP (medicines parent resolución, 30/12/2024) → ARCSA-DE-2024-049-DASP (biologicals, 20/12/2024) → ARCSA-DE-2025-034-DASP enacting IE-B.3.2.1-MG-01 v4.0 (medicines instructivo, 3/10/2025) → ARCSA-DE-2026-002-DASP enacting IE-B.3.2.1-MB-02 v4 (biologicals instructivo, 23/1/2026) → ARCSA-DE-2026-003-DASP (devices, 28/4/2026, in force ~Jan 2027). Alongside, MSP replaced AM 0075-2017 with AM 00069-2024 (27/1/2025) for clinical trials, ARCSA issued IE-B.3.3.1-EC-04 v3.0 in September 2025, and ICH E6(R3) Step 4 landed 6 January 2025. Every entry below is reconciled against ARCSA's Julio 2026 Catastro Regulatorio (Julio 2026 Catastro) and ARCSA's documentos vigentes index.

2023 — device reforms and cross-cutting instruments. ARCSA-DE-2023-002-AKRG (16/1/2023, *R.O.* 245) reformed service-fee charging (art. 6 sets modifications outside AM 112 at 10% of the obtaining fee). ARCSA-DE-2023-001-VSVZ (26/1/2023, *R.O.* 252) delivered a partial reform of the medical-devices technical norm. ARCSA-DE-2023-005-AKRG (27/2/2023, *R.O.* 272) issued the directrices for notifications to a medical-device registro sanitario — the instrument governing IFU and labelling changes. ARCSA-DE-2023-016-AKRG (29/5/2023, *R.O.* 344) created the Sistema Nacional de Tecnovigilancia. ARCSA-DE-2023-025-AKRG (16/8/2023, *R.O.* 385) reformed import-by-exception and donation (mirrored at PUDELECO). ARCSA-DE-2023-033-AKRG (10/11/2023, *R.O.* 470) further reformed the device technical norm. Decreto Ejecutivo 307 (*R.O.* Supl. 589, 28/6/2024) established *mejora regulatoria* as national policy — the political driver behind the 2024–2026 rewrite wave.

2024 — the year the framework moved. ARCSA-DE-2024-049-DASP (20/12/2024, *R.O.* Supl. 726) is the biological products resolución, containing art. 17 (Module 4 case-by-case), art. 19 (*"Idioma de la documentación técnica"*, ES/EN with Módulo 2 in castellano; *traductor titulado* requirement; "no se aceptarán documentos con errores en sus traducciones"), art. 54 (homologación), and the hemoderivados monograph rule (*"por un traductor oficial"*). ARCSA-DE-2024-058-DASP (30/12/2024, *R.O.* 731) is the medicines-in-general parent resolución — arts. 8, 14(h), 17, 18, 42, 47 and Disposición General Décima. MSP Acuerdo Ministerial 00069-2024 (*R.O.* 730, 27/1/2025) replaced AM 0075-2017 and dropped the apostille-on-translation requirement — the single biggest liberalisation of Ecuador's translation regime.

2025 — the tightening. ARCSA-DE-2025-034-DASP (3/10/2025, *R.O.* 1er Supl. 153, 28/10/2025) issued the medicines instructivo IE-B.3.2.1-MG-01 v4.0 — the operational text. §2 num. 2 (language rule), §2 num. 3 (no-images rule), §2 num. 8 (CTD mandatory only for new medicines), Module 2 §2.2.4 (ICH M4S(R2) tabulated summaries), Module 4 case-by-case, req. 1.4.3 (legible Spanish prospecto), and req. 17 (tightening pharmacological/clinical documentation to Spanish) (Registro Oficial text; Lexis report). ARCSA-DE-2025-040-DASP (17/11/2025, *R.O.* Supl. 181) reformed import-by-exception / donation. ARCSA-DE-2025-052-DASP issued the Normativa Técnica Sustitutiva for the Sistema Nacional de Farmacovigilancia. ICH E6(R3) Step 4 Final Guideline (6/1/2025) was listed by ARCSA under Ensayos Clínicos — Ecuador's trial dossier expectations are now anchored to E6(R3), not E6(R2).

2026 — the biologicals instructivo and the devices substitution. ARCSA-DE-2026-002-DASP (23/1/2026, *R.O.* Supl. 232, 26/2/2026) issued the biologicals instructivo IE-B.3.2.1-MB-02 v4. ARCSA-DE-2026-003-DASP (28/4/2026, *R.O.* 2do Supl. 286, 18/5/2026) is the Normativa Técnica Sustitutiva for medical devices — art. 12 language, art. 13 legal documents with online-verification apostille waiver, art. 24 seven-bucket evidence matrix, **art. 49 (labels ES* or *EN but inserto/manual de uso in Spanish), device-software/SaMD recognition, notification code NDM017, IMDRF simplified route; repeals ARCSA-DE-026-2016-YMIH; in force nine months after signature — ~January 2027. MSP Acuerdo Ministerial 006 reformed the* Reglamento para investigaciones en salud* in 2026.

Cross-cutting instruments outside the ARCSA series:

Instrument	Date / R.O.	Relevance
DE 1290	*R.O.* Supl. 788, 13/9/2012	Creates ARCSA
DE 544	*R.O.* 428, 30/1/2015	Art. 10 confers ARCSA's normative power
DE 307	*R.O.* Supl. 589, 28/6/2024	Mejora regulatoria as national policy
LOOETA	*R.O.* Supl. 353, 23/10/2018	Art. 29 *Traducciones*; art. 28 foreign documents; art. 2 ámbito binding on ARCSA; infraction nums. 8, 11, 12 (government-hosted text; gob.ec record)
COA	*R.O.* Supl. 31, 7/7/2017; in force 7/7/2018	General administrative-procedure code; **note art. 29 COA is* "Principio de tipicidad," *not translations** (COA text)
Reglamento Sustitutivo CEISH/CEAS	*R.O.*, 2/8/2022	Governs CEISH and CEAS accreditation (gob.ec regulation record; MSP announcement)
Hague Apostille Convention	In force for Ecuador 2/4/2005	Legalisation of foreign public documents; MREMH is competent authority

Cross-cutting notes.

- ICH E6(R3) template migration. ARCSA lists ICH E6(R3) Step 4 Final Guideline (6 January 2025) under Ensayos Clínicos (documentos vigentes). Any protocol / ICF template still built on E6(R2) headings is behind the regulator.
- MSP AM-0027-2025 governs authorisations for biological samples obtained in the course of health care; Acuerdo Ministerial 88 governs import/export of biological samples (documentos vigentes).

- Farmacovigilancia. ARCSA-DE-2025-052-DASP issues the Normativa Técnica Sustitutiva for the Sistema Nacional de Farmacovigilancia (documentos vigentes); safety-communication surface with ARCSA is Spanish-first.
- Medicinal gases. ARCSA-DE-2025-053-DASP issues GMP for medicinal gases (documentos vigentes).
- 2026 institutional resoluciones. ARCSA-ARCSA-2026-0004-R, -0007-R, -0009-R and -0010-R sit in the institutional stack, including the código de ética (documentos vigentes).
- COA vs LOOETA. The Código Orgánico Administrativo (COA), R.O. Supl. 31 of 7 July 2017, is the general administrative-procedure code, but art. 29 COA is "Principio de tipicidad," not translations — the translation article is LOOETA art. 29 (COA text; WIPO Lex; LOOETA text).
- Archiving instrument. Resolución ARCSA-DE-2019-016-JRC governs the archiving of registro-sanitario and notificación-sanitaria applications; there is no phantom "ARCSA-DE-042-2019" (documentos vigentes).

The three changes that matter most for translation planning:

1. AM 00069-2024 (2024) dropped the apostille-on-translation requirement. Trial translations need only be certified and consistent with the original. This materially reduces cost and calendar for trial sponsors.
2. ARCSA-DE-2025-034-DASP (28 Oct 2025) tightened the pharmacological/clinical documentation requirement to Spanish (req. 17), and codified the ICH M4S(R2) tabulated non-clinical summaries in Module 2 — which for new medicines must be in castellano.
3. ARCSA-DE-2026-003-DASP (18 May 2026, in force ~Jan 2027) inverts the drug labelling rule for devices: labels may be Spanish or English, but the inserto / manual de uso must be Spanish, and device software is expressly in scope. Device sponsors have a defined nine-month runway to comply.

Section I. Amavita library cross-references

The Ecuador guide closes with cross-references into the Amavita Sciences™ library, aligned to the findings above.

- Adjacent Andean-Pacific regulator, fully mapped: DNFD regulatory translation requirements — the complete guide for Panamá
- Preclinical translation across 9 LATAM regulators (includes the Ecuador section): Preclinical translation requirements — 9 LATAM regulators
- CTD Module 2 non-clinical summary construction (2.6.1–2.6.7) — reconstruction of ICH M4S(R2) tabulated summaries in Spanish, the highest-value Ecuador-specific workstream identified in Section D
- Structured-document reconstruction / DTP standard for regulatory tables — the four textual hooks catalogued in D.2 (tabulated-summary requirement, no-images rule, legibility standard,

ARCSA's fidelity-with-original standard)

- Patient-facing artwork re-typesetting for prospectos, insertos and manuales de uso against the *"caracteres claramente legibles e indelebles"* standard
- Bilingual clinical-trial dossier assembly under AM 00069-2024 art. 13, with the Spanish locked before CEISH submission to prevent CEISH-signed / ARCSA-filed divergence
- Certified-translation attestation package — fidelity declaration attached to a named natural-person *traductor titulado* (biologicals) or LOOETA art. 29 notarial route (drugs), with a validatable electronic signature
- Apostille-first legalisation sequencing for foreign legal documents, including the ARCSA online-verification waiver
- Terminology governance across sibling filings — one application per pharmaceutical form × dose × strength
- Device IFU change-control under ARCSA-DE-2023-005-AKRG and the ARCSA-DE-2026-003-DASP art. 49 inserto/manual de uso rule
- ICH E6(R3) template migration for protocol and ICF headings

FAQ

Which Ecuador regulator actually holds my file?

The health-products authority is *ARCSA — Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA portal), reachable at atencionalusuario@controlsanitario.gob.ec and, for clinical trials, at atencion.ensayosclinicos@controlsanitario.gob.ec. Medical devices, drugs, biologicals and clinical trials all sit inside ARCSA — Ecuador does not operate a separate device directorate. MSP handles CEISH accreditation via cgds@msp.gob.ec* (MSP CEISH trámite).

Do I have to translate every page of my preclinical stack into Spanish?

No, not the full text of Module 4. IE-B.3.2.1-MG-01 v4.0 §2 num. 2 accepts drug técnica-analítica documentation "en idioma castellano o inglés" and treats Module 4 as case-by-case. What must be in castellano is *CTD Module 2 for medicamentos nuevos — the ICH M4S(R2) tabulated non-clinical summaries (§§2.6.3, 2.6.5, 2.6.7), which are tabulated by construction. The Ecuador preclinical translation ask is a structured-table reconstruction, not a prose translation. Add the documentación farmacológica y clínica vigente (req. 17, tightened to Spanish in October 2025) and the prospecto (req. 1.4.3, redactado in castellano) and the effective Spanish surface is defined. For non-nuevo* drugs, CTD is optional at all under §2 num. 8.

What is a traductor titulado, and can my U.S. translator qualify?

Ecuador does not operate a Panamá-style register of authorised translators. The default admissibility rule is LOOETA art. 29 — translations by intérpretes are valid where the signature is authenticated by a notary, by an Ecuadorian consul abroad, or by a civil-court judge (LOOETA text). There is no ministerial licence, no examination and no national translator register. Two exceptions climb above the default: biologicals under ARCSA-DE-2024-049-DASP art. 19 require a "traductor titulado y/o por centros autorizados para el efecto," and hemoderivados monographs require "por un traductor oficial." A U.S. translator producing signature-authenticated translations for a drug filing is compatible with LOOETA art. 29; for biologicals or hemoderivados, we route through a licensed Ecuador-based translator.

Apostille first, or translate first?

Apostille first, then translate — including the apostille text itself and every seal and stamp. Ecuador acceded to the Hague Apostille Convention with effect from 2 April 2005 (Convención de La Haya, gob.ec; MREMH apostille trámite). From 1 September 2023 legalisation for Ecuador is by apostille only (Embajada de Italia en Quito). Apostille costs USD 30 per document, consular legalización USD 25; both without IVA. Translating first authenticates an Ecuadorian translation of an unauthenticated foreign document — the opposite of what ARCSA §2 num. 4 asks for.

Can I file my labels in English with a Spanish sticker over the top?

For drugs, no — the prospecto must be redactado in castellano and the labels follow the label monographs of IE-B.3.2.1-MG-01 v4.0 req. 1.4. For devices under the incoming ARCSA-DE-2026-003-DASP, the label may be filed in Spanish OR English (art. 49) — but the inserto and manual de uso must be Spanish. The device rule inverts the drug rule. Neither instrument authorises re-labelling as a translation-defect remedy; a defective Spanish inserto is cured by re-filing under ARCSA-DE-2023-005-AKRG plus a modification fee at 10% of the obtaining fee, and a rejected modification re-triggers the fee.

Does ARCSA's homologación route remove translation work?

Partly, and less than sponsors assume. ARCSA-DE-2024-058-DASP creates a homologación route with a 60-día término ARCSA review clock — the only firm number ARCSA publishes for a drug pathway (Julio 2026 Catastro). It compresses the technical review by relying on registrations from high-standard authorities, but it does not waive the language obligations of the drugs instructivo: the prospecto must be redactado in castellano (req. 1.4.3), the pharmacological/clinical documentation must be in Spanish (req. 17), Module 2 for medicamentos nuevos must be in castellano (§2 num. 2), and legal documents must be apostilled and translated (§2 num. 4). Homologación shortens the review; it does not remove the Spanish surface.

Who reviews my clinical trial, and how fast?

Ethics review runs through an accredited CEISH under the Reglamento Sustitutivo of 2 August 2022 (MSP announcement) — but no CEISH publishes a review clock, and each committee runs its own meeting calendar. ARCSA's own clocks are the only published portion: 2 days to issue payment order, 7 days documentary review, 30 days subsanación (extendable by 30), ≤60 days technical evaluation (extendable by 30), for a best-case of ~69 days and a realistic case of ~129 days with one objection round (ARCSA ensayos clínicos). Add AM 00069-2024 clocks: 7-day admissibility, 28-day requerimiento response, 180-day file closure, 1-year conclusions submission. Committee capacity is the real bottleneck — MSP reported 19 CEISH and 14 CEAS at reglamento entry, and not all will review clinical trials (CEISH-HGL exclusion).

Is there a national CEISH inbox I can write to?

Not one printed on any .gob.ec page — [UNVERIFIED - source silent]. Ecuador has no single national ethics inbox; CEISH operate per institution. The addressable public channel for CEISH-accreditation matters is MSP's Coordinación General de Desarrollo Estratégico en Salud — cgds@msp.gob.ec, Mayra Paola Cueva Rojas, (+593) 2-2381 4400 ext. 5267. For ARCSA-side clinical-trial correspondence — safety, inspections, destruction exceptions — the published inbox is atencion.ensayosclinicos@controlsanitario.gob.ec. We route site-level CEISH matters through the institution's own research office and keep the regulatory correspondence on the two published channels.

What does it cost, and what is free?

Under the published ARCSA tarifario: registration of a foreign medicine USD 2,258.41, national medicine USD 904.34, foreign generic USD 565.21, national device USD 678.25, foreign device USD 904.34, reactivos bioquímicos USD 678.25. Renewals and modifications implying analysis run at 20% of the obtaining fee; other modifications at 10% under ARCSA-DE-2023-002-AKRG art. 6. Clinical trial fees total USD 2,390.28 national / USD 4,391.65 international, with amendments at USD 221.21, inspections at USD 230.52, and import authorisations at USD 150.24. Apostille is USD 30 per document at MREMH. There is no risk-class differentiation for devices — a Class I device and a Class IV device pay the same fee — and there is no fee refund where a file is cancelled under ARCSA-DE-2024-058-DASP art. 18 for non-response.

What is the difference between Ecuador and Panamá for a company that files in both?

Three structural differences shape the Spanish surface. First, Ecuador does not operate a Panamá-style register of authorised translators — the default admissibility rule is signature authentication under LOOETA art. 29, not licensing under a MEDUCA-style registry. Second, Ecuador's preclinical regime is more permissive than Panamá's on Module 4 (case-by-case English) but more demanding on Module 2 tabulated summaries for medicamentos nuevos (castellano reconstruction) — the workstream sponsors most often underestimate. Third, Ecuador's device regime is on the verge of substitution: ARCSA-DE-2026-003-DASP inverts the drug labelling rule (label may be Spanish or English; inserto and manual de uso must be Spanish) and enters force ~January 2027, giving device sponsors a nine-month runway. Panamá's device architecture under DE 490 is stable and RTCA-adjacent; Ecuador's is transitioning. A programme filing in both jurisdictions should treat Ecuador as the moving surface and Panamá as the anchor.

Do ARCSA-approved translations "travel" across LATAM regulators?

Partly, and less than sponsors assume. A Spanish translation that satisfies ARCSA fidelity requirements is a strong starting point for a Colombian INVIMA or Peruvian DIGEMID filing, but each regulator applies its own translator-licensing rules, its own artwork requirements, and its own change-control notification triggers. *A translation that clears Ecuador does not automatically clear Colombia's requirement for a traductor oficial, nor Peru's DIGEMID label standards. What travels is the structural work* — the ICH M4S(R2) tabulated-summary reconstruction, the terminology glossary, the DTP artwork discipline. What does not travel is the certification stack. Amavita Sciences™ files the shared Spanish core once and re-certifies per jurisdiction under each regulator's certification standard.

Does the archiving instrument "ARCSA-DE-042-2019" exist?

No. We were unable to locate a Resolución ARCSA-DE-042-2019 in ARCSA's Catastro Regulatorio or in-force index (Julio 2026 Catastro; documentos vigentes). The archiving instrument that does exist and is in force is Resolución ARCSA-DE-2019-016-JRC, which governs the archiving of registro-sanitario and notificación-sanitaria applications. Any prior brief that referenced "ARCSA-DE-042-2019" should be corrected to ARCSA-DE-2019-016-JRC — the ARCSA resolución code format uses year-nnn-code, not nnn-year.

Is art. 29 of the Código Orgánico Administrativo the translation rule?

No. *Art. 29 COA is "Principio de tipicidad," not a translation article (COA text; WIPO Lex). The translation article is LOOETA art. 29 — the Ley Orgánica para la Optimización y Eficiencia de Trámites Administrativos*, R.O. Supl. 353 of 23 October 2018 (LOOETA text). A regulatory strategy that cites the COA article number in place of the LOOETA article number is not fatal to the filing, but it is doctrinally wrong and it signals to Ecuadorian counsel that the sponsor's Ecuador research is second-hand.

What is the practical translation surface for a foreign generic drug filing?

A foreign generic that qualifies under the drugs instructivo carries a lighter Spanish surface than a medicamento nuevo but a heavier one than a homologación-eligible product. The minimum Spanish artefacts are: (1) the prospecto (req. 1.4.3, redactado in castellano); (2) the label monograph elements per req. 1.4; (3) the pharmacological / clinical documentation (req. 17, Spanish in full since October 2025); (4) the signature-authenticated translations of legal documents — poderes, CPPs, GMP certificates — under §2 num. 4 and LOOETA art. 29; and (5) the electronic-signature-validatable Spanish covering letter under §2 num. 5. Module 4 remains case-by-case under §2 num. 2 and Module 2 CTD is optional at all under §2 num. 8 for non-nuevo products. A first-time foreign-generic sponsor typically discovers that the artwork discipline for req. 1.4.3 (indelibility, legibility, no images) is where cost concentrates, not on the CTD side.

Why does Amavita Sciences™ treat Ecuador as a currency-risk jurisdiction?

Because six instruments moved in eighteen months: ARCSA-DE-2024-049-DASP (Dec 2024, biologicals), ARCSA-DE-2024-058-DASP (Dec 2024, medicines parent), AM 00069-2024 (Jan 2025, clinical trials), ARCSA-DE-2025-034-DASP enacting IE-B.3.2.1-MG-01 v4.0 (Oct 2025, medicines instructivo — tightening req. 17), ARCSA-DE-2026-002-DASP enacting IE-B.3.2.1-MB-02 v4 (Feb 2026, biologicals instructivo), and ARCSA-DE-2026-003-DASP (April 2026, devices, in force ~Jan 2027) — alongside ICH E6(R3) Step 4 (Jan 2025) reshaping trial templates. Filings still built against ARCSA-DE-2014-, ARCSA-DE-026-2016-YMIH (post-Jan 2027), AM 0075-2017, or the pre-October 2025 art. 14(h) summary* allowance are citing superseded or narrowed law. Our 7th QC gate — Document Currency — timestamps every foreign document at apostille, translation and filing, and re-issues within 48 hours under the First-Pass Acceptance Program at $2,500/business-day.

About the author

Julio G. Martinez-Clark is CEO of bioaccess®, Latin America's leading medical-device clinical research organization, and founder of Amavita Sciences, the multilingual clinical operations platform. He has led first-in-human trial operations across 12 LATAM jurisdictions and built the seven-gate translation QC pipeline behind Amavita's regulatory language infrastructure.

Version history

This guide is version **1.0.0**, last updated August 25, 2026. Every substantive change to the ARCSA requirements on this page is recorded below.

v1.0.0 August 25, 2026

- Initial publication of the ARCSA (Ecuador) regulator translation requirements guide.