LATAM REGULATORY GUIDES · COSTA RICA

CONIS Regulatory Translation Requirements: The Complete Guide for Clinical, Drug, and Device Filings in Costa Rica

The three-authority map (CONIS, DRPIRS, CCSS), the Ley 8142 sworn-translation blanket rule, and the version-drift trap after a folio set is cut.

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Last updated August 25, 2026 · ~30 min read · Version 1.0.0

Sworn folio-set regime

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Section A. The regulatory authorities and where translation intersects each of them

Costa Rica does not run its clinical-research and product-registration regime through a single authority. Three separate bodies decide whether Spanish-language paperwork is sufficient, and a sponsor that maps the country to one of them will file to the wrong desk.

A.1 The three-authority table

Authority	Statutory basis	Scope	Contact of record
CONIS — Consejo Nacional de Investigación en Salud	Ley 9234, art. 34; Decreto 39061-S	National biomedical-research registry, CEC accreditation, protocol registration	conis@misalud.go.cr; investigadores.utib@misalud.go.cr; (506) 4003-5113 / 5115; Edificio Norte, Primer Piso, Calle 16 Av. 6 y 8, San José. Site: conis.ministeriodesalud.go.cr
DRPIRS — Dirección de Regulación de Productos de Interés Sanitario	Decreto 44972-S; Circular MS-DRPIS-2790-2025	Sanitary registration of drugs, biologicals, devices, cosmetics, food supplements, chemical products, and natural products	drpirs.correspondencia@misalud.go.cr; drpirs.atencioncliente@misalud.go.cr. Director: Dr. Ignacio Calderón (Carlos Ignacio Calderón Arroyo)
CCSS / CENDEISSS / AISSS — Centro Nacional de Desarrollo Estratégico e Información en Salud y Seguridad Social	CCSS Reglamento de Investigación Biomédica (10-03-2021)	Governs any biomedical research conducted inside Caja hospitals and clinics — a stricter regime layered on top of CONIS	coinccss@ccss.sa.cr; bioetica@ccss.sa.cr; 2519-3044

Read the table as three overlapping perimeters, not three separate silos. A sponsor running an interventional device trial at a Caja hospital passes through all three: CONIS registers the study nationally, DRPIRS handles any product-registration touchpoint, and CCSS's CEC and AISSS layer must clear the institutional and contractual side. Each authority applies the country's translation rules with a slightly different accent, and the strictest reading wins.

A.2 The Ley 9234 anchor — and what it does not say

Ley N.° 9234 (2014) — Ley Reguladora de Investigación Biomédica is the statutory ceiling for the clinical-research side (published text). It creates CONIS (art. 34), it defines participant-facing language duties in articles 13, 27(d), and 30(c) — informed consent must be understandable to the participant in language and cultural context — and it delegates the operative dossier-language rules to secondary regulation. Ley 9234 does not contain a dossier-translation clause. The dossier-language framework lives at the regulation layer, not at the statute layer. Any Costa Rica-specific translation obligation a sponsor is asked to satisfy will trace back to one of three secondary instruments — Ley 8142 on official translations, Decreto 39061-S on clinical trials, or the RTCA/RTCR product-registration texts — not to Ley 9234 itself.

Sanctions, on the other hand, live in the statute. Article 72 authorises administrative fines of up to 30 percent of the study value; article 73 authorises multiples of the *salario base*, up to 300

base salaries; articles 78 through 85 define criminal exposure ranging from three to eight years of imprisonment for the most serious conduct; and article 80 authorises debarment for five to ten years (Ley 9234, published text). These are not the ordinary consequences of a translation defect, but they are the ceiling under which the whole regime operates and they explain the enforcement posture the sponsor will encounter at CONIS and at CCSS.

A.3 Adjacent bodies and public communications the guide relies on

Two adjacent public documents shape everything below:

- CENDEISSS-AB-0096-2022 — a CCSS Asesoría de Bioética memorandum transcribing the operative CONIS enforcement position on translation. This is the source of the single most quotable sanction line in the Costa Rican regime, discussed in Section F.
- CENDEISSS-AB-0115-2024 — a 2024 CENDEISSS reminder to Caja units, restating the biomedical-research procedure. Its role here is to confirm that the 2022 posture is still operative.

A.4 Contacts we won't invent

We have named the addresses and phone numbers that are stated on primary sources or in official circulars. Where the Ministry maintains a page but the page did not render at the time of writing — most consequentially the list of appointed traductores oficiales at rree.go.cr — we say so, and we recommend confirming translator appointments against the Ministry's Dirección Jurídica directly before commissioning work. We have not filled that gap with names we could not verify.

Section B. The official-language requirements — the three-layer architecture

Costa Rica's language regime is a three-layer stack. Each layer is set at a different altitude, and each answers a different question. Reading them together is what the guide does; reading them separately is what generates the RFIs.

B.1 Layer 1 — the blanket sworn-translation rule (Ley 8142, art. 3)

Ley N.° 8142, Ley de Traducciones e Interpretaciones Oficiales, article 3, states plainly that any document issued in a language other than Spanish and intended to produce legal effects in Costa Rica must be translated by an oficial translator appointed by the Ministry of Foreign Affairs (Ley 8142 as published on TSE). This is the *blanket rule*. It covers everything from a corporate power of attorney to a CPP to an apostille certificate.

The important consequence. Absent a more specific instrument that carves out a different rule, a foreign-language document filed with any Costa Rican authority for a regulatory purpose defaults to a traducción oficial. Sponsors used to jurisdictions with a "certified translator" tier need to internalise this: Costa Rica has no such tier for regulatory filings. The only category the state recognises is *traductor oficial* — a person appointed by executive agreement, with a seal, a *cédula*, and a stated language pair.

B.2 Layer 2 — the clinical-trial dossier language rule (Decreto 39061-S, art. 44)

Decreto Ejecutivo N.° 39061-S, the *Reglamento para las Investigaciones Biomédicas*, converts Ley 9234 into an operative filing regime. Article 44 lists the documents required in a clinical-trial dossier for CONIS and imposes the language rule document by document. The four sworn or Spanish clauses that matter most:

- 44(b) — the protocol, in original language and *traducción oficial al español*, dated and versioned.
- 44(c) — the monografía o manual del investigador (Investigator's Brochure), in original language and *traducción oficial al español*, dated and versioned.
- 44(d) — the informed consent form, in Spanish, in plain and comprehensible language, dated and versioned. Not required to be sworn — comprehensibility (Ley 9234 arts. 13 and 27(d)) is the operative standard here.
- 44(f) — the case report form, in English or Spanish. This is the only explicit English permission on the interventional track, and it exists because CRFs travel through the sponsor's global data-management stack.
- 44(s) — the investigational product label, in Spanish (Decreto 39061-S).

Article 44 has been reformed once by Decreto 39533-S. Article 46 governs the observational track. The wording of art. 46(b) requires the protocol *en español* but does not restate "traducción oficial." Read against Ley 8142 art. 3, the safer reading is that a foreign-language observational protocol still needs sworn translation to produce legal effects, but the observational track drops the sworn requirement for participant-facing materials in some CEC readings. Where an observational protocol is filed to a CCSS CEC, the CCSS reglamento imports the stricter interventional standard through form AP-I (CENDEISSS CEC page) — the observational relief evaporates.

B.3 Layer 3 — the product-registration language rules (RTCA drugs, RTCR devices)

Drugs. Costa Rica applies the Central American technical regulation RTCA 11.03.59:18, adopted domestically by Decreto 43259-COMEX-S-MEIC in force 3 January 2022 (RTCA 11.03.59:18 on SIECA). The operative numerals for language:

- 6.4 — every official or legal document must be in Spanish or accompanied by a translation issued per the national law of the state of origin. In Costa Rica, that anchors back to Ley 8142.

- 6.6 — foreign official or legal documents must be legalised. Since 14 December 2011, that means apostille (see C.5).
- 6.5 — corrections on certifications may be made only by the issuing body. The translator is not a corrector.
- 6.3 — official documents carry their stated validity; where none is stated, two years from issuance.
- 6.7 — cross-reference to original current documents already in the regulator's archive is allowed with identification of the earlier filing and a simple photocopy — a cost-saver we discuss in D.3.
- 6.13 — once artwork is approved, the Spanish text is frozen as approved.
- 7.11.1 NOTA 1 — safety and efficacy studies are accepted in electronic format where the regulator has free access to the information.
- 9.1.5 / 9.2.4 NOTA 1 — a declaración jurada of non-marketing permits a draft Spanish artwork at renewal.
- 11.4 — documentation that is *incompleta, incorrecta o no vigente* is an express ground of rejection.
- 12.7 — grounds of cancellation.

The parallel national rules under Decreto 28466-S (drug registration, in force since 2000) survive in points not superseded by the RTCA: article 27.2.11 requires the third-party manufacturing contract to be *debidamente legalizado y traducido, cuando aplique*; article 27.2.13 requires the Spanish label texts; article 37 permits simultaneous multilingual labelling only if the information is the same; article 32 sets the 30-business-day evaluation clock (Decreto 28466-S).

Devices. Devices are governed by RTCR 505:2022, enacted by Decreto Ejecutivo N.° 43902-S, in force 10 September 2023 (MEIC Reglatec entry for RTCR 505:2022; EY tax alert on RTCR 505:2022). Its operative language propositions:

- Device labels must be in Spanish.
- An etiqueta complementaria is permitted to translate mandatory information and to add mandatory information not included from origin, never to modify or correct origin information.
- Inserts and manuals must be in Spanish.
- Software and mobile applications for medical use are in scope — UI strings, on-screen instructions, help documentation and electronic IFUs are inside the Spanish perimeter.
- Post-registration changes travel a 22-day notification track for defined change types.

B.4 The document-by-document language table

Document	Rule	Anchor
Interventional protocol	Original + traducción oficial, dated and versioned	39061-S art. 44(b)

Document	Rule	Anchor
Investigator's Brochure	Original + traducción oficial, dated and versioned	39061-S art. 44(c)
Informed consent	Spanish, comprehensible, dated/versioned — sworn not required	39061-S art. 44(d); Ley 9234 arts. 13, 27(d)
Assent (minors)	Spanish	39061-S art. 44(e)
Case report form	English or Spanish	39061-S art. 44(f)
Participant materials, diaries, questionnaires	Spanish	39061-S art. 44(g)
IND/IDE, FDA/EMA approval letter	Foreign official document → traducción oficial	39061-S art. 44(h); Ley 8142 art. 3
Device FDA/EMA classification	Traducción oficial	39061-S art. 44(i)
GMP + sterility certification (sterile devices)	Apostille + traducción oficial	39061-S art. 44(r); RTCA 6.6
Investigational product label	Spanish	39061-S art. 44(s)
Contracts, MTAs, any instrument with legal effect	Traducción oficial — CONIS will not register without it	CENDEISSS-AB-0096-2022 transcribing Oficio CONIS-421-2021; Ley 8142 art. 3
CCSS: foreign corporate documents	Original apostillado + traducción oficial where non-Spanish	CCSS Reglamento art. 29(c)(1)
CCSS: powers of attorney	Original apostillado, Spanish or with traducción oficial	CCSS Reglamento art. 29(c)(2)
Drug dossier: CPP, CFS, GMP, POA, manufacturing contract	Spanish or accompanied by translation per origin law; apostilled	RTCA 6.4 and 6.6
Third-party manufacturing contract (national)	*Debidamente legalizado y traducido, cuando aplique*	Decreto 28466-S art. 27.2.11
Drug artwork	Spanish; multilingual only if same information	Decreto 28466-S arts. 27.2.13, 37
Draft artwork at renewal (not-yet-marketed product)	Spanish + declaración jurada of non-marketing	RTCA 9.1.5 / 9.2.4 NOTA 1
Preclinical/clinical conclusive reports (reliance route)	Same in form and substance as approved by RRA — see Section D	Decreto 39433-S art. 3(a)
Safety/efficacy studies (RTCA route)	Electronic filing permitted with free regulator access	RTCA 7.11.1 NOTA 1

Document	Rule	Anchor
Device label	Manufacturer's original in Spanish; *etiqueta complementaria* for translation only	Registro EMB, Ministerio de Salud
Device inserts and manuals	Spanish	Same source

Where two layers speak to the same document, the strictest reading wins.

Section C. Sworn vs certified vs simple — Costa Rica has only one tier that counts

C.1 There is no "certified" tier

In several Latin-American jurisdictions the practitioner encounters a "certified translation" tier as a middle ground between sworn work and freely commissioned rendering. Costa Rica does not operate that tier for regulatory filings. The only tier the state recognises for documents intended to produce legal effects is traducción oficial, executed by a person appointed under Ley 8142 by *acuerdo ejecutivo* of the Ministerio de Relaciones Exteriores y Culto (Ley 8142). A "certified" translation issued by a commercial vendor with a company stamp is, for CONIS or DRPIRS purposes, a *simple* translation. It has no more standing than an in-house rendering.

C.2 Who qualifies as a traductor oficial

Appointment. Under Ley 8142 art. 5 the Ministry's *Dirección Jurídica* is the appointing office. Appointments are made by *acuerdo ejecutivo*. The Ministry's public function page for translators is the Dirección Jurídica / Traductores Oficiales page.

Substantive gate — Ley 8142 art. 6. The candidate must be of legal age; a Costa Rican national or a foreign national with legal residence; command Spanish and the other language(s) fully; demonstrate at least five years of continuous, verifiable professional experience in each language; pass an examination authorized by the Ministry of Foreign Affairs; and have no criminal or disqualifying record (Ley 8142).

Capacity implication. A five-year experience gate combined with a Ministry examination and individual executive-agreement appointment produces a small, finite, named national pool of official translators per language pair. Costa Rica is not a market where a sponsor can spin up incremental sworn-translation capacity on demand for a large dossier under deadline pressure. Sworn-translation capacity must be reserved in advance, and the guide treats official-translator availability as a schedule risk equivalent to any other critical-path resource.

Registry and public list. Under Decreto 30167-RE art. 21, the *Asesoría Jurídica* maintains the registry, publishes the list on the Ministry's website, and sends a copy to the *Poder Judicial* every six months (Reglamento a la Ley 8142). Article 12 establishes the public character of the registry. [UNVERIFIED — Primary list unavailable as of August 2026] The public page did not render at the time of this writing. Verify translator appointment against the Ministry's Dirección Jurídica directly before commissioning work.

Discipline — Ley 8142 arts. 9 to 14 and 17. Suspensions of one month for negligence, six months to one year for recurrence, and up to ten years of suspension for wilful adulteration of a document. Article 18 records sanctions in a public *prontuario* (Ley 8142). This is the reason a Costa Rican official translator will faithfully reproduce a defect rather than smooth it over. It aligns with — and reinforces — RTCA numeral 6.5 (only the issuing body corrects its document) and the RTCR 505:2022 prohibition on using the complementary label to correct origin information. Defects are fixed upstream at the source. Never in the translation layer.

C.3 The physical form of a Costa Rican sworn translation

All from Decreto 30167-RE, the Reglamento a la Ley 8142 (full text):

- Article 14 — letter-size paper, maximum 30 lines per page, translator signs the left margin of every folio.
- Article 15 — mandatory opening header naming the translator, the acuerdo ejecutivo, the Gaceta publication, and the document being translated.
- Article 16 — consecutive folio numbers; blank spaces filled with dashes; body closes with "Última Línea."
- Article 17 — closing legend with date, language pair, folio count; signature on the right; timbres on the left, cancelled by the translator's seal; a timbre on each folio.
- Article 18 — the seal contains full name, *cédula*, acuerdo ejecutivo number, language pair, and the words "Costa Rica."
- Article 19 — abbreviations and numerals are prohibited unless they appear in the original.
- Article 20 — illegible source content is disclosed inside the translation.

Five operational consequences the guide treats as first-order planning inputs:

1. A sworn translation is a physical artifact. Wet signature per folio, stamps per folio, seal cancellation. It cannot be produced as a PDF export. It must be printed, signed, stamped, and physically delivered or scanned as an artifact.
2. The 30-lines-per-page ceiling inflates page count. A dense English protocol page can expand to several folios. Sponsors budgeting sworn translation on source-page count will under-budget. Budget on target folio count at 30 lines per page.
3. Article 19's prohibition on abbreviations not in the source collides with clinical writing. AE, SAE, PK, ITT, mg/kg, q.d. — a Costa Rican sworn translation reproduces those that appear and cannot introduce those that do not. The output reads differently from a commercially localised

protocol and must not be "cleaned up" downstream, because that breaks the legal instrument.

4. Article 20 turns source-scan quality into a disclosure event. A poor scan of an apostilled certificate produces an illegibility statement inside the sworn translation. Source scan quality is a regulatory variable, not an administrative one.
5. The Última Línea and consecutive folio numbering make the sworn translation an unsplittable, unmodifiable unit. Any amendment requires a fresh sworn translation of the affected instrument, with a new date and folio count. This is the single largest driver of translation spend across a multi-amendment trial.

C.4 The allocation table — sworn / Spanish-original / English-permitted

Consolidated from the rules above:

Document	Requirement	Anchor
Interventional protocol	Traducción oficial	39061-S art. 44(b)
Investigator's Brochure	Traducción oficial	39061-S art. 44(c)
Informed consent	Spanish, plain, dated/versioned — not sworn	39061-S art. 44(d)
Case report form	English or Spanish	39061-S art. 44(f)
Investigational product label	Spanish	39061-S art. 44(s)
Contracts, MTAs, legal instruments	Traducción oficial — CONIS will not register otherwise	Oficio CONIS-421-2021, transcribed in CENDEISSS-AB-0096-2022
CCSS foreign corporate docs	Apostillado + traducción oficial (if non-Spanish)	CCSS Reglamento art. 29(c)(1)
Observational protocol (CONIS)	Spanish; no "traducción oficial" clause	39061-S art. 46(b)
Observational protocol (CCSS CEC)	Original + traducción oficial, form AP-I	CENDEISSS CEC page
Drug: CPP, CFS, GMP, POA	Spanish or accompanied by translation; apostilled	RTCA 6.4 and 6.6
Reliance-route conclusive reports	*Mismos en forma y fondo* — do not translate	Decreto 39433-S art. 3(a)
Safety/efficacy studies (RTCA)	Electronic accepted with free regulator access	RTCA 7.11.1 NOTA 1
Device label	Spanish original from manufacturer; *etiqueta complementaria* for translation	Registro EMB

C.5 Apostille and Convenio de La Haya — sequencing

Costa Rica is a Hague Apostille Convention party. Accession was approved by Ley N.° 8923 of 22 February 2011, entering into force for Costa Rica on 14 December 2011 (HCCH country profile for Costa Rica). The competent authority is the Ministerio de Relaciones Exteriores y Culto, Departamento de Autenticaciones.

A note on legacy wording. Decreto 28466-S (2000) refers to the free-sale certificate as "debidamente consularizado" (Decreto 28466-S). Since 14 December 2011, for public documents originating in a Convention party, the apostille replaces consular legalization — but the older "consularizado" language survives in Costa Rican regulation and in some reviewer habits. [UNVERIFIED whether the legacy "consularizado" clause has been formally superseded in Decreto 28466-S text.] A sponsor may still receive an RFI phrased in consularization terms where an apostille is the correct instrument.

C.5.1 THE SEQUENCING RULE

The order of operations is the most common expensive mistake:

1. Issue the source document in the country of origin.
2. Apostille it in the country of origin. The apostille certifies the foreign official's signature on the foreign-language document. It must be affixed before translation, because the apostille itself is part of the document to be translated — it bears text.
3. **Sworn-translate the document* together with its apostille *in Costa Rica.** Under Decreto 30167-RE art. 15 the translator's header names the document translated, and art. 17 states the folio count — the apostille content sits inside the folio set.
4. File the apostilled original plus the sworn translation together. CCSS Reglamento art. 29(c) states it explicitly: "Documentos originales apostillados y con traducción oficial en los casos que esté redactado en un idioma diferente al español" (CCSS Reglamento). The conjunction is *and*, not *or*.

Failure mode 1. Sponsor translates first, then apostilles. Result: apostille attached to a translation, certifying a Costa Rican translator's signature — meaningless. Dossier returned. Rebuild costs a full apostille cycle plus a fresh sworn translation, typically several weeks.

Failure mode 2, subtler. Document apostilled correctly, then sworn-translated, but only the underlying document is translated and the apostille is left untranslated. Under Ley 8142 art. 3 the apostille is itself a foreign-language instrument intended to produce legal effects. Translate the apostille with the document, in the same folio set.

Currency clock interaction. RTCA numeral 6.3 gives official documents the validity stated by the issuing authority, and two years from issuance where none is stated. The apostille-then-translate-then-file chain consumes weeks. The currency clock runs on the underlying certificate's issue date, not on the filing date. A CPP issued 22 months before filing, correctly apostilled and sworn-

translated, can still be rejected under numeral 6.3 and numeral 11.4. Build the chain backwards from the filing date and treat certificate issue dates as perishable inventory.

This is why Amavita Sciences™ operates a 7th QC gate — Document Currency. Our first six gates match the industry standard: source completeness, terminology, tabular integrity, ICF comprehensibility, format compliance, and cross-reference. Our seventh gate reads every certificate's issue date against the filing date and against the RTCA 6.3 clock, and flags anything within 90 days of the two-year cliff. In Costa Rica specifically, this gate has saved more filings than any other single control we run.

Outbound leg. Ley 8142 art. 4 and Decreto 30167-RE art. 13 govern authentication for foreign use (Ley 8142; Decreto 30167-RE). Where a Costa Rican site's CEC approval, CONIS registration certificate or investigator credentials must travel to a sponsor's home regulator or to an FDA inspection file, the outbound leg is a separate authentication chain and a separate cost that sponsors routinely omit from country budgets.

Section D. Preclinical / non-clinical documentation

D.1 Is full-text translation of the entire preclinical CTD (Module 4) required?

No — and Costa Rica gives an unusually clear regulatory basis for saying so. The answer differs by pathway, and both pathways stop well short of full Module 4 translation.

D.1.A THE MARKET-ACCESS PATHWAY (DRUG REGISTRATION)

**What the regulation demands is a* conclusive report*, not a module. RTCA 11.03.59:18, numeral 7.11.1(a), requires under* Estudios de Seguridad y Eficacia*:

> *"Informes concluyentes de los resultados de los estudios pre clínicos"*

and at 7.11.1(b) the conclusive clinical reports of Phase I, II and III studies (RTCA 11.03.59:18).

The unit of submission is the conclusion, not the corpus. Not the individual study reports, not the raw toxicology tabulations, not the GLP audit trails, not the full Module 4 as filed with FDA or EMA.

The same numeral then removes the paper burden. RTCA 11.03.59:18, numeral 7.11.1, NOTA 1:

> *"Estos estudios se aceptarán en formato electrónico, siempre y cuando la Autoridad Reguladora tenga acceso libremente a la información."*

Safety and efficacy studies are accepted electronically, conditioned only on the regulator having free access. There is no clause requiring these studies to be sworn-translated. Compare numeral 6.4, which attaches its Spanish-or-translation rule to *todo documento oficial o legal*. A preclinical study report is a scientific document, not an official or legal one. The instruments carrying the translation and legalization burden are the CPP, GMP certificate, free-sale certificate, powers of attorney, manufacturing contracts, and sworn declarations. The science does not.

Definitional confirmation. Decreto 39433-S defines, at inciso (g), the *informe concluyente del estudio preclínico* as *"Una descripción escrita de un ensayo/estudio de cualquier medicamento realizado in vitro o en animales de experimentación, en los que los datos preclínicos están integrados en un solo informe..."* (Decreto 39433-S). "Integrados en un solo informe" — Costa Rican law defines the preclinical deliverable as a *single integrated document*. That is a definitional, not merely practical, rejection of a translate-everything posture.

D.1.B THE CLINICAL-TRIAL PATHWAY (CONIS / CEC)

Here Costa Rica is stricter than most of the region in one specific place and no others.

Article 44 of Decreto 39061-S requires* traducción oficial *of exactly two documents: the protocol at 44(b) and the monografía o manual del investigador at 44(c) (Decreto 39061-S).

The IB is the preclinical carrier — and Costa Rica requires it sworn. This is the sharpest divergence from the other countries in this series. The IB contains the integrated non-clinical summary in narrative and tabular form. Costa Rica does not ask for Module 4. It asks for the document that summarises Module 4, and it asks for it as a sworn translation.

The practical consequence is that Costa Rica's preclinical translation burden is concentrated, not diffuse. A sponsor does not translate thousands of pages of toxicology. It sworn-translates one document — but that document is long (commonly 100 to 250 pages), technically dense, updated at least annually, and subject to the 30-lines-per-page folio rule of Decreto 30167-RE art. 14, which inflates it further. This is the single largest identifiable line item in a Costa Rican trial-startup translation budget.

Article 44(h) and 44(i) — a copy of the IND/IDE or the FDA/EMA approval letter, and for devices the FDA or EMA classification — are foreign official documents with legal effect and fall under Ley 8142 art. 3 sworn translation, even though article 44 does not restate the language rule for them.

D.2 Scope of the "DTP" — what preclinical content actually has to be delivered

Costa Rica does not use the term DTP. The functional equivalent resolves differently on each pathway.

Market-access pathway:

1. The informe concluyente — integrated into a single report (RTCA num. 7.11.1(a); Decreto 39433-S definition (g)).
2. Filed electronically, provided the regulator has free access (RTCA num. 7.11.1 NOTA 1).
3. Language: no sworn-translation clause attaches. Scientific, not official/legal.
4. Where the reliance route of Decreto 39433-S is used, the report must be identical in form and substance to the RRA-approved version — see D.3.
5. Currency: numeral 7.11 caps clinical study reports at 10 years old, or the applicant must justify the age.

Clinical-trial pathway:

1. Investigator's Brochure — original + traducción oficial, dated and versioned (art. 44(c)).
2. Protocol — carries the preclinical rationale in its background and dose-justification sections, original + traducción oficial, dated and versioned (art. 44(b)).
3. IND/IDE or FDA/EMA approval letter (art. 44(h)); for devices, the FDA/EMA classification (art. 44(i)).
4. GMP + sterility certification for sterile devices (art. 44(r)).
5. Nothing in article 44 requires individual non-clinical study reports.

Version-control discipline. Both 44(b) and 44(c) require *con fecha y versión*. Combined with Decreto 30167-RE art. 17's requirement that the sworn translation state its own date and folio count, this produces a three-way version binding: source document version ↔ sworn translation date and folios ↔ CEC submission record. Any IB update or protocol amendment breaks all three and requires a fresh sworn translation. Costa Rica's version-discipline requirement is stricter than its translation-volume requirement.

D.3 What substitutes for full-text translation — four mechanisms

SUBSTITUTION 1 — REFERENCE-AUTHORITY RELIANCE UNDER DECRETO 39433-S (THE PRIMARY MECHANISM)

Instrument. Decreto Ejecutivo N.° 39433-S of 9 November 2015, reformed by Decreto 40084 of 3 October 2016 and by Decreto 44251 of 16 October 2023 (full text).

Article 1 (as reformed): enables the Ministry of Health to recognize the *informes concluyentes* of clinical and preclinical safety and efficacy studies, bioequivalence studies, and biosimilarity studies evaluated and approved by Reference Regulatory Authorities, as evidence for drug sanitary registration.

Article 2 (as reformed by Decreto 44251) lists the authorities: AG (Liechtenstein), EMA and EU national competent authorities, FDA, Health Canada, IMA (Iceland), MHRA, NOMA (Norway), PMDA (Japan), Swissmedic, TGA, plus Regional Reference Authorities: ANMAT, ANVISA, CECMED, COFEPRIS, INVIMA, ISP.

Article 2's exclusion criteria are where language reappears — surprisingly. An authority is excluded if its transparency criteria fail, including at a)1: *"Información en idioma español o con convertidor o traducción a idioma inglés"* (Decreto 39433-S). Costa Rica's own regulation accepts information in Spanish or in English translation for assessing a foreign authority's transparency. The Ministry is on record, in a decree, treating English as workable for scientific-assessment material. That is a citable interpretive anchor for the position that scientific evidence in the registration dossier is not subject to a sworn-Spanish requirement.

Article 2 bis (added by Decreto 44251): the *Listado de Autoridades Reguladoras de Referencia* is published by *resolución administrativa* in *La Gaceta* and on the Ministry's website, reviewed annually, and inclusion/exclusion requests resolved within 30 días naturales. Currency warning: the operative list is the current administrative resolution, not the decree text. Verify the resolution in force before advising.

Article 3(a) is the single most important sentence in Costa Rica's Section D. The conclusive clinical and preclinical reports must be "los mismos en forma y fondo" as those evaluated and approved by the RRA, demonstrated either by a document issued by that authority or by a *Declaración Jurada* per Anexo A, signed by the product holder or its legal representative.

The "forma y fondo" requirement is, in effect, a prohibition on translating the report. If the report must be identical in form and substance to the document the FDA or EMA approved, then a Spanish sworn translation is *by construction* not the same document in form. The mechanism therefore works the opposite way from what sponsors assume:

> The report is submitted as approved — in its original language — and the Spanish-language legal bridge is the sworn declaration, not a translation.

The Declaración Jurada per Anexo A is a short Spanish instrument executed by the holder or legal representative. It is the Costa Rican functional equivalent of a translation certificate, and it is the substitute artifact a sponsor produces instead of a thousand-page sworn translation.

Article 3(b) routes bioequivalence reports through Decreto 32470-S art. 12(1); article 3(c) routes biologicals and biosimilars through Decreto 37006-S (RTCR 440:2010).

SUBSTITUTION 2 — ELECTRONIC FILING WITH FREE REGULATOR ACCESS

RTCA num. 7.11.1 NOTA 1. Available independently of the reliance route.

SUBSTITUTION 3 — CROSS-REFERENCE TO DOCUMENTS ALREADY IN THE REGULATOR'S ARCHIVE

RTCA num. 6.7. For a sponsor with a portfolio in Costa Rica, this converts a repeat sworn-translation cost into a photocopy. It requires disciplined internal record-keeping of filing references.

SUBSTITUTION 4 — SWORN DECLARATIONS REPLACING DOCUMENTS

Costa Rica uses the *declaración jurada* as a substitute in at least four places:

- Decreto 39433-S Anexo A — attests the conclusive reports are identical in form and substance to those approved abroad.
- RTCA num. 9.1.5 / 9.2.4 NOTA 1 — attests the product has not been marketed, permitting Spanish draft artwork instead of as-marketed labelling.
- Decreto 39061-S art. 44(tt) — a non-notarial sworn declaration regarding the OIC/OAC.
- CCSS Reglamento art. 30 — sworn declarations on the source of funds under Ley 8204.

Why the pattern matters. Costa Rica is comparatively willing to accept a Spanish sworn declaration by a responsible person in place of a translated foreign document. That is the country's characteristic risk-allocation choice: it shifts liability onto the declarant — with perjury exposure — rather than demanding a translated paper trail. A sponsor's Costa Rica strategy should be built around identifying every point where a declaration can lawfully substitute for a translation, and executing those declarations with genuine internal verification, because the liability is real.

D.4 Consolidated preclinical instruction table

Deliverable	Pathway	Language / form required	Substitution available	Citation
Integrated preclinical conclusive report	Drug registration	*Informe concluyente*, single integrated report; electronic accepted; no sworn-translation clause	RRA reliance + Anexo A; archive cross-reference	RTCA 7.11.1(a) and NOTA 1; Decreto 39433-S

Deliverable	Pathway	Language / form required	Substitution available	Citation
Clinical conclusive reports (Ph I/II/III)	Drug registration	*Informes concluyentes*; ≤10 years old or justified; electronic accepted	Same	RTCA 7.11.1(b) and 7.11
Full Module 4 / individual study reports	Drug registration	Not required	n/a — the requirement is the integrated conclusive report	RTCA 7.11.1(a); Decreto 39433-S def. (g)
Investigator's Brochure	Clinical trial	Original + traducción oficial, con fecha y versión	None. Hard requirement.	39061-S art. 44(c)
Protocol	Clinical trial	Original + traducción oficial, con fecha y versión	None on interventional	39061-S art. 44(b)
Observational protocol (CONIS)	Clinical trial	Spanish; no "traducción oficial"	Lighter track	39061-S art. 46(b)
Observational protocol (CCSS CEC)	Clinical trial	Original + traducción oficial (form AP-I)	None — CCSS imports stricter standard	CENDEISSS CEC page
IND/IDE, FDA/EMA approval letter	Clinical trial	Foreign official document → sworn translation	None	39061-S art. 44(h); Ley 8142 art. 3
Device FDA/EMA classification	Clinical trial	Sworn translation	None	39061-S art. 44(i)
GMP + sterility (sterile devices)	Clinical trial	Sworn translation + apostille	None	39061-S art. 44(r); RTCA 6.6
Bioequivalence reports	Drug registration	Per Decreto 32470-S art. 12(1)	Reliance available	Decreto 39433-S art. 3(b)
Biologicals / biosimilars evidence	Drug registration	Per Decreto 37006-S / RTCR 440:2010	Reliance available	Decreto 39433-S art. 3(c)
Device technical & medical specifications	Device registration	Spanish; inserts and manuals in Spanish; *etiqueta complementaria* for label translation	Origin-document-unavailability letter	Registro EMB; EY alert

D.5 Where the submission risk actually sits

Not in the volume of preclinical translation. In five places.

Risk 1 — The IB sworn translation is the critical path, and it recurs. The only large document Costa Rica unambiguously requires as *traducción oficial*. Long, technical, annually updated, and each update requires a fresh sworn translation because Decreto 30167-RE arts. 16 to 17 make the translation an indivisible, dated, folio-counted instrument. Model IB versions, not trials.

Risk 2 — Official-translator capacity is a finite national resource. Ley 8142 art. 6 sets a five-year experience-plus-examination bar; appointment is individual by executive agreement; each appointee owes 20 free pages per semester to the state (Decreto 30167-RE art. 33). There is no surge capacity. Reserve translator capacity in advance and treat it as a critical-path resource.

Risk 3 — The apostille-before-translation sequence, and the apostille's own text. Detailed in C.5. Two failure modes, both send the dossier back for a full re-cycle.

Risk 4 — Document currency, running against a slow chain. RTCA numeral 6.3 makes undated certificates expire two years from issuance; numeral 11.4 makes documentation that is *incompleta, incorrecta o no vigente* an express cause of rejection; numeral 6.5 forbids corrections on certifications except by the issuing body. The apostille-plus-sworn-translation chain consumes weeks. The currency clock and the preparation clock run against each other, and this is where dossiers quietly die.

Risk 5 — The "forma y fondo" trap. A sponsor that helpfully translates its preclinical conclusive report into Spanish and files the translation may fail Decreto 39433-S article 3(a) on its own terms, because the filed document is no longer identical in form to what the RRA approved. Under the reliance route, do not translate the report. File it as approved and execute the Anexo A declaración jurada. Getting this backwards converts a cheap declaration into an expensive translation *and* creates a compliance defect.

A sixth, forward-looking risk. The Ministry has had a reform of Decreto 39061-S articles 44(b), 44(c), 44(l) and 44(z) in SICOPRE consultation since November 2025 (Informe Final de Gestión, Dra. Marín Mena). Incisos (b) and (c) are precisely the two sworn-translation clauses. **Any guide statement about the IB and protocol translation requirement must carry a dated "as of" qualifier and a monitoring instruction pointing at SICOPRE and* La Gaceta.*

Category 1 — Drugs and biological products

D1. Market access via DRPIRS

The Direction that receives drug sanitary registration filings — formerly DRPIS — was renamed DRPIRS (Dirección de Regulación de Productos de Interés Sanitario) effective 28 October 2025, by Circular MS-DRPIS-2790-2025 (circular text). The reform to the *Reglamento Orgánico del Ministerio de Salud* was published as Decreto 44972-S, signed on 3 March 2025 (draft text at Imprenta Nacional).

The new organic structure creates three operating units inside DRPIRS: Registro y Autorizaciones de Comercialización, Normalización, and Vigilancia y Control. The Director is Dr. Ignacio Calderón (Carlos Ignacio Calderón Arroyo).

What this means for a sponsor. Filings mid-2025 and later use the DRPIRS name. Older correspondence continues to reference DRPIS. Circulars, procedure guides and forms are being reissued gradually; if you receive a form or a circular that still references DRPIS, that alone is not a defect and does not require re-filing. Cite Circular MS-DRPIS-2790-2025 in a cover letter where useful.

D2. Drug dossier submissions and language

The operative content-and-language rules for drug submissions are RTCA 11.03.59:18 (regional) and Decreto 28466-S (national), consolidated in B.3 and C.4 above. Two application points bear repeating for the market-access track:

- The scientific package — informes concluyentes for preclinical, phases I/II/III clinical, bioequivalence and biosimilarity — is not on the sworn-translation table. It is on the electronic-filing-with-free-access track (RTCA 7.11.1 NOTA 1) and, where applicable, on the RRA-reliance track (Decreto 39433-S) with Anexo A as the Spanish legal bridge.
- The official-and-legal package — CPP, CFS, GMP, POA, manufacturing contract, sworn declarations, artwork — is on the sworn-translation-plus-apostille track, with the currency clock of RTCA 6.3 running against every certificate.

Registration validity is 5 years (RTCA 11.03.59:18).

D3. Drug clinical trials — the CONIS + CEC + CCSS overlay

For a drug clinical trial, the CONIS registration under Decreto 39061-S sits on top of any product-registration touchpoint with DRPIRS. Where an investigational product is not yet nationally registered — the normal case — the trial dossier lives at CONIS and the CEC, with CCSS's AISSS layer added for any Caja site. Documents to prepare in sworn form for a drug trial:

- Protocol (44(b)).
- Investigator's Brochure (44(c)).
- IND/FDA approval letter (44(h)).

- GMP + sterility certification if the product is sterile (44(r)).
- Contracts, MTAs, powers of attorney with legal effect (Oficio CONIS-421-2021, per CENDEISSS-AB-0096-2022; Ley 8142 art. 3).

Circular MS-DRPIS-UR-972-2023 applied the *medical-need* route under RTCA numeral 7.11.5(b) to specific product categories (circular text). Sponsors relying on this route should cite it in the cover letter.

Category 2 — Medical devices

E1. The device regime is national, not regional

For drugs, Costa Rica applies a Central American regional technical regulation. For devices there is no RTCA. Devices are governed by RTCR 505:2022, a purely national instrument enacted by Decreto Ejecutivo N.° 43902-S (MEIC Reglatec — "Nacional").

Three consequences. First, a sponsor cannot leverage a Guatemalan or Honduran RTCA filing into Costa Rica for devices — there is no mutual-recognition annex. Second, the device language rules are set unilaterally by Costa Rica and can change without regional negotiation. Third, the Costa Rican term of art is "equipo y material biomédico" (EMB), not "dispositivo médico" — searching for "medical device" terminology in Costa Rican sources will miss the operative documents.

Key dates. Signed 30 November 2022; published in *La Gaceta* No. 44, Alcance 38, 9 March 2023; in force 10 September 2023 (MEIC Reglatec).

Scope. Biomedical equipment and materials, their accessories, and software and mobile applications for medical use (same source). SaMD is inside the Spanish-language perimeter.

E2. Classification, exemption, and the translation obligation

Costa Rica classifies EMB by risk. Class 1 devices do not require sanitary registration, under Decreto Ejecutivo N.° 41387-S. The Ministry's labelling guide states that Class 1 EMB may state on the label that the product is exempt from registration.

Do not over-read the exemption. All EMB, regardless of class, must comply with the labelling requirements. The registration file disappears; the translation obligation does not. A Class 1 device sold in Costa Rica still needs a Spanish label and Spanish inserts and manuals.

RTCR 505:2022 modified the classification parameters relative to the prior regime (EY alert), so a device's Costa Rican class should be re-derived under the current text.

E3. Device labelling and translation — consolidated

From the Ministry's own EMB registration requirements (Registro EMB):

Rule	Statement
Origin	Label must be the manufacturer's original
Language	Label must be in Spanish
Translation vehicle	Etiqueta complementaria for translation and to add mandatory information
Prohibition	Complementary label may not modify or correct origin information
Inserts and manuals	Spanish

Operationalising the* etiqueta complementaria *correctly. Treat it as a bounded, auditable artifact with three permitted content classes:

- Spanish rendering of mandatory origin-label content.
- Mandatory Costa Rican content absent from the origin label (registration number, local representative details, exemption statement for Class 1).
- Nothing else.

Forbidden: any change to, correction of, softening of, or reconciliation of origin-label information.

Governance recommendation. Build a two-column reconciliation record for every device: origin-label field → complementary-label rendering, with a mandatory disposition field of *translated* / *added-as-mandatory* / *escalated-to-holder*. Any field otherwise dispositioned "corrected" must be escalated to the registration holder for amendment of the origin label. This record is the artifact that demonstrates compliance if the *Unidad de Vigilancia y Control* asks.

High-consequence translation fields. From the *Especificaciones Técnicas y Médicas* — items 6 (single-use/reusable), 7 and 8 (sterilization method and pre-use sterilization), 10 (conditions of use and maintenance), 11 (storage and transport) — are not documentation formalities. They are use-safety instructions. A single-use device mislabelled as reusable, a sterilization method mistranslated, or a storage-temperature range rendered with a unit error is a patient-safety event. These fields require independent verification, distinct from general document review. Item 12 pulls safety data sheets into scope for IVD reagents and cleaning/sterilization solutions.

E4. Post-registration changes — the 22-day notification track

RTCR 505:2022 reduced to 22 days the evaluation window for post-registration changes filed as notifications (EY alert):

- Changes to the design of the labelling.
- Cancellation of a code.
- Change or expansion of local distributors.
- Change of holder address without change of origin.

[UNVERIFIED — Initial device registration evaluation clock under RTCR 505:2022 not retrievable from primary sources.] Confirm before advising on end-to-end timelines.

E5. Device clinical trials

Interventional device trials in Costa Rica follow the same Decreto 39061-S regime as drug trials — protocol and IB sworn (arts. 44(b) and 44(c)), FDA/EMA classification sworn (art. 44(i)), GMP + sterility certification sworn where relevant (art. 44(r)). Where the site is a Caja hospital, the CCSS Reglamento layer applies additionally.

Section F. Common RFI and rejection patterns

Eleven patterns we have seen most frequently across CONIS, DRPIRS and CCSS reviews:

Pattern 1 — The CONIS translation enforcement quote. *Oficio CONIS-421-2021*, transcribed in CENDEISSS-AB-0096-2022, states: *"en caso de no cumplir con lo anterior, no se procederá a la inscripción del mismo ante el CONIS."* The clause reaches protocols, MTAs and contracts. This is the single most quotable enforcement statement in the Costa Rican regime.

Pattern 2 — Translate-first, apostille-after. Detailed in C.5.

Pattern 3 — Apostilled but apostille left untranslated. Detailed in C.5.

Pattern 4 — Currency expiry. Certificates within their two-year window at signing but expired at filing. RTCA 6.3 and 11.4.

Pattern 5 — Reliance-route report translated. The sponsor helpfully translates the RRA-approved conclusive report and files the translation, failing Decreto 39433-S art. 3(a) *forma y fondo*.

Pattern 6 — Missing Anexo A declaración jurada. Reliance route invoked but the Spanish legal bridge omitted.

Pattern 7 — Etiqueta complementaria used to correct origin. RTCR 505:2022 prohibition.

Pattern 8 — IB version drift. New IB version circulated to sites without a fresh sworn translation, breaking the art. 44(c) *fecha y versión* binding.

Pattern 9 — Consularizado language. Reviewer asks for consularization where an apostille is correct and sufficient (Ley 8923 in force since 14 December 2011).

Pattern 10 — Legacy DRPIS references. Filings between October 2025 and mid-2026 that still reference DRPIS. Not a defect; a stylistic RFI. Cite Circular MS-DRPIS-2790-2025 in the cover letter.

Pattern 11 — Observational protocol assumed lighter at a CCSS site. Article 46 of Decreto 39061-S has no *traducción oficial* clause for the observational protocol, but a CCSS CEC imports the stricter interventional standard through form AP-I.

Section G. Consolidated timelines

G.1 Drug registration

- Normal track: 30 business days (Decreto 28466-S art. 32).
- Reliance route: 99 business days (Decreto 39433-S art. 4).
- Post-registration variations with clinical impact: 44 business days.
- Registration validity: 5 years.

G.2 Devices

- Post-registration notification track: 22 days (EY alert).
- Regulation entry into force: 10 September 2023 (six-month transition from 9 March 2023 publication).

G.3 CONIS / CEC

- CEC pronouncement: 1 calendar month (Decreto 39061-S art. 42).
- CEC accreditation: 30 días naturales.
- SAE reporting: 24 hours.
- CEC archive retention: 15 años.

G.4 CCSS

- Expedited review: 15 días naturales.
- Full committee: 30 días naturales.

- AISSS contract review: 10 días hábiles.
- Study start: 8 days after CONIS registration (CCSS Reglamento).

G.5 Critical path

The translation-driven items on the critical path are: IB sworn translation (widest span), apostille of foreign certificates (multi-week, controlled at origin), protocol sworn translation and each amendment thereto (recurs), and traductor oficial capacity (finite national pool). None of the four is compressible in the two weeks before submission. All four are compressible in the twelve weeks before submission with disciplined scheduling.

Section H. Recent regulatory changes 2023 to 2026

H.1 2023

- Decreto 44251 (16 October 2023) — reforms Decreto 39433-S art. 2 and 2 bis: RRA list criteria, annual review, 30-día resolution window for inclusion/exclusion requests (Decreto 39433-S consolidated).
- RTCR 505:2022 in force 10 September 2023 — device regime; SaMD in scope; 22-day notification track (EY alert).
- Circular MS-DRPIS-UR-972-2023 — application of RTCA numeral 7.11.5(b) medical-need route (circular).

H.2 2024

- CENDEISSS-AB-0115-2024 — CCSS reminder reaffirming the 2022 biomedical-research posture (memorandum).

H.3 2025

- Decreto 44972-S (signed 3 March 2025) — reform of the *Reglamento Orgánico del Ministerio de Salud*; new DRPIRS structure (draft text).
- Circular MS-DRPIS-2790-2025 (28 October 2025) — announces the DRPIS → DRPIRS rename, effective 28 October 2025 (circular).
- SICOPRE consultation opened November 2025 — reform of Decreto 39061-S articles 44(b), 44(c), 44(l) and 44(z) (the two sworn-translation clauses among them) (Informe Final de Gestión).

- *[UNVERIFIED — full text of MS-DM-4164-2025 on* Admisibilidad *is confirmed by index but not retrievable.]*
- PAHO recognition (23 December 2025) of Costa Rica's regulatory system consolidation (PAHO notice).

H.4 2026

- SICOPRE reform of Decreto 39061-S art. 44 — pending publication as of mid-2026. Any guide statement about the IB and protocol sworn-translation clauses carries an "as of August 2026" qualifier and a monitoring instruction pointing at SICOPRE and *La Gaceta*.

H.5 Change table

Date	Instrument	What changed	Where in this guide
16 Oct 2023	Decreto 44251	RRA framework annual review	D.3 Substitution 1
10 Sep 2023	RTCR 505:2022 in force	Device regime; SaMD; 22-day track	E1–E4
3 Mar 2025	Decreto 44972-S	DRPIRS organic reform	D1
28 Oct 2025	Circular MS-DRPIS-2790-2025	DRPIS → DRPIRS rename	A.1, D1, Pattern 10
Nov 2025 → open	SICOPRE consultation	Reform of 39061-S art. 44(b)(c)(l)(z)	D.5, H.4
23 Dec 2025	PAHO consolidation notice	External confirmation	H.3

Section I. Amavita Sciences™ library cross-references

The following resources sit in the Amavita library and support the propositions above:

- The seven-gate QC framework — source completeness, terminology, tabular integrity, ICF comprehensibility, format compliance, cross-reference, document currency. The seventh gate is the one that most reliably prevents Costa Rican rejection under RTCA 6.3 and 11.4.
- The apostille-and-sworn-translation sequence checklist — issue → apostille at origin → sworn-translate the document *with* its apostille → file both together.
- **The two-column* etiqueta complementaria *reconciliation record — origin-label field → complementary-label rendering → disposition (*translated / added-as-mandatory / escalated-

to-holder*).

- The IB version register — one row per IB version, one column per country, one cell per sworn translation status. Costa Rica is the country that most often forces a fresh row.
- The Anexo A declaración jurada template — Costa Rica-specific; executed by the holder or legal representative; the substitute artifact for a translated conclusive report on the reliance route.
- The Panamá guide — the parallel jurisdiction; the shared architectural template with a very different substantive posture on preclinical translation.

FAQ

Do we have to translate the full preclinical CTD (Module 4) for a Costa Rican drug registration?

No. RTCA 11.03.59:18 numeral 7.11.1(a) requires the informe concluyente of the preclinical studies, not the module. NOTA 1 accepts these studies electronically where the regulator has free access. Decreto 39433-S at definition (g) confirms the deliverable is a single integrated report.

Do we translate the FDA-approved preclinical report before filing under the reliance route?

No. Under Decreto 39433-S art. 3(a), the report must be mismos en forma y fondo as the RRA-approved version. Translating it makes it not the same document in form. File it as approved, in its original language, and execute the Anexo A declaración jurada as the Spanish legal bridge.

What exactly does Costa Rica require in sworn form for a clinical trial?

Two hard requirements: protocol (Decreto 39061-S art. 44(b)) and Investigator's Brochure (art. 44(c)), both original language plus traducción oficial, dated and versioned. The IND/IDE approval letter (44(h)), device FDA/EMA classification (44(i)), and GMP/sterility certification for sterile devices (44(r)) are foreign official documents that pull sworn translation through Ley 8142 art. 3.

Is the informed consent a sworn translation?

No. Art. 44(d) requires Spanish, plain, comprehensible, dated and versioned. Ley 9234 arts. 13 and 27(d) supply the comprehensibility standard. It is not a traducción oficial.

Can we use a certified translation instead of a sworn one?

No. Costa Rica does not recognise a "certified" tier for regulatory filings. The only recognised tier is traducción oficial by an appointed traductor oficial under Ley 8142.

Do we apostille before or after translating?

Apostille first, translate second. Then translate the document together with its apostille certificate in the same folio set. CCSS Reglamento art. 29(c) states it: "Documentos originales apostillados y con traducción oficial en los casos que esté redactado en un idioma diferente al español."

Can the etiqueta complementaria fix errors on the origin device label?

No. RTCR 505:2022 explicitly forbids using the complementary label to modify or correct information from origin. Defects must be fixed by the manufacturer amending the origin label. There is no in-country workaround.

Are software and mobile applications for medical use in scope for translation?

Yes. RTCR 505:2022 pulls SaMD and mobile apps for medical use inside the Spanish-language perimeter. UI strings, on-screen instructions, help documentation and electronic IFUs are translation deliverables.

Our IB just got a new version. Do we need a new sworn translation?

Yes. Article 44(c) requires con fecha y versión, and Decreto 30167-RE arts. 16 to 17 make the sworn translation an indivisible, dated, folio-counted instrument. You cannot swap a page. A fresh sworn translation is required for the affected instrument.

The Ministry renamed DRPIS to DRPIRS. Do we refile?

No. Filings referencing the old DRPIS name between the effective date of Circular MS-DRPIS-2790-2025 (28 October 2025) and the gradual reissuance of forms are not defective. Cite the circular in the cover letter if a reviewer raises the point.

How current does a CPP have to be at filing?

RTCA numeral 6.3 gives the stated validity, or two years from issuance if none is stated. Numeral 11.4 makes a no vigente certificate a rejection ground. Build the chain backwards from the filing date and treat certificate issue dates as perishable inventory. This is what our seventh QC gate — Document Currency — enforces.

About the author

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Version history

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

v1.0.0 August 25, 2026

- Initial publication of the CONIS (Costa Rica) regulator translation requirements guide.