LATAM REGULATORY GUIDES · REPÚBLICA DOMINICANA

DIGEMAPS Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in the Dominican Republic

Decreto 246-06 Art. 39, the intérprete-judicial sworn tier, the traducción fidedigna ethics tier, and the still-unenacted device reglamento.

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Last updated August 25, 2026 · ~29 min read · Version 1.1.0

CONABIOS Resolución 03-25

ON THIS PAGE

Section A. Regulator Profile: Who Actually Reviews Your File

The Dirección General de Medicamentos, Alimentos y Productos Sanitarios (DIGEMAPS) is the Dominican Republic's medicines, food, and health-products authority. It was created inside the Ministry of Public Health as a merged successor to the DGDF (Dirección General de Drogas y

Farmacias) and DIGENOR-food functions by Decreto 82-15 of 6 April 2015. Decreto 82-15 also gave DIGEMAPS a twelve-month mandate to promulgate a stand-alone Reglamento Técnico de Productos Sanitarios — that mandate remains unfulfilled eleven years later, which is why medical devices in the DR are still filed under the medicines regulation.

DIGEMAPS was deconcentrated from the direct line of the Ministerio de Salud Pública by Decreto 231-23 of 6 June 2023, giving the agency its own budget, its own contracting authority, and — importantly for anyone reading a Dominican dossier — its own document-numbering conventions. The DGDF form prefixes DGDF-RP-FO-001, DGDF-RP-FO-004, DGDF-RP-FO-005, and DGDF-RP-FO-007 are still in active use inside DIGEMAPS submissions, a legacy from the pre-2015 architecture that trips up new sponsors who assume the DGDF acronym has been retired (Decreto 82-15).

Scope. Under Decreto 246-06, DIGEMAPS is responsible for the sanitary registration, import authorization, GMP inspection, and post-market surveillance of medicines (química, biológica, biotecnológica), medical devices ("productos sanitarios"), cosmetics, natural products, dietary supplements, and health-related advertising.

Structural facts a project manager should know before opening a DR file. DIGEMAPS runs on the pre-existing DGDF forms and DGDF numbering scheme; the acronym change did not extend to the form library. Sponsors and CROs new to the DR see forms labelled DGDF-RP-FO-001 (solicitud de registro sanitario), DGDF-RP-FO-004 (solicitud de modificación), DGDF-RP-FO-005 (solicitud de renovación), and DGDF-RP-FO-007 (solicitud de importación) and assume they are stale artifacts of an older agency — they are not. Those forms are the current DIGEMAPS intake forms and are still cited in Ministerial resolutions and web-service pages. The forms are filled in Spanish, signed by the *representante legal* of the applicant in the DR, and submitted physically at the DIGEMAPS intake window.

Website. digemaps.gob.do.

Printed contacts. The contact page publishes the general mailbox `info@digemaps.gob.do`; a second mailbox, `infoservicios@digemaps.gob.do`, is printed on the device and modification service pages and is the routing address for product-registration queries (DIGEMAPS Contacto; DIGEMAPS registro de productos sanitarios). The switchboard is (809) 541-3121.

Current head. DIGEMAPS is directed by the Director General nominated by the Poder Ejecutivo under Decreto 82-15 Art. 3; the appointment sits inside the Ministerio de Salud Pública organigram (MAP COEDOM DIGEMAPS entry).

Adjacent bodies. A DR file rarely lives inside one authority. The table below is the map we hand to a project manager on day one. A drug or device sponsor may touch DIGEMAPS (product registration), CONABIOS (any human-subjects research), MSP (umbrella authority for cell therapies and health-emergency declarations), MIREX (apostille), the Procuraduría (intérprete signature verification), the Suprema Corte (intérprete appointment via ENJ), and, in enforcement matters, the ordinary courts.

Authority	Role for a translation project	Statutory anchor
DIGEMAPS	Product-registration authority for drugs, devices, cosmetics, naturals	Decreto 82-15
CONABIOS	National bioethics council; ethics + regulatory review of clinical research	Decreto 351-25
Ministerio de Salud Pública (MSP)	Umbrella ministry; owns Resolución 000018 on cell therapies	Ley 42-01
MIREX (Ministerio de Relaciones Exteriores)	Apostille authority (Hague Convention, EIF 30 Aug 2009)	HCCH status table
Procuraduría General de la República	Signature registry for intérpretes judiciales	Ley 821
Suprema Corte de Justicia	Appoints intérpretes judiciales via ENJ	ENJ Intérprete Judicial

Section B. Official Language Requirements: What the Law Actually Says

The DR language stack is unusually clean, precisely because it is stacked. Four layers matter.

Spanish is the working language of the Dominican state. That is not a customary rule — it is a constitutional and statutory obligation, and it is why every downstream regulatory rule about translation in the DR starts from a presumption of Spanish, not from a presumption of English tolerated by kindness.

Constitution. Art. 29 of the Constitución de la República Dominicana (2024 consolidated text) declares Spanish the official language of the Republic. The clause is short — one sentence — but it is the ceiling above every Ministry-level and DIGEMAPS-level translation rule.

Ley General de Salud 42-01. Ley 42-01 Art. 112 requires that the label and the *contra etiqueta* of every medicine circulating in the DR be printed in Spanish. That is not a translation preference — it is the primary-labelling rule, and it is enforced through the sanitary registration itself.

Decreto 246-06 — the operative regulation. The Reglamento de Medicamentos (Decreto 246-06) does most of the translation work in the DR system.

- Art. 18 Párrafo II requires the *Denominación Común Internacional* (INN) to be rendered in Spanish on the primary label and on the *inserto*.

- Art. 32 requires an *intérprete judicial* whenever a proceeding before DIGEMAPS or a linked authority requires a translation of a document in a foreign language — this is the sworn-translation anchor.
- Art. 39 — the core rule of this guide — requires that scientific reports supporting a registration, including *estudios toxicológicos, farmacológicos, clínicos, and de estabilidad*, be filed in Spanish or accompanied by a Spanish translation, and expressly bars strikethroughs, smudges, and alterations on the filed document (Decreto 246-06 Art. 39).
- Arts. 42-43 require the *inserto* and *empaque* to be Spanish-language, with defined content elements.
- Art. 250 requires health-related advertising to be Spanish-language.

CONABIOS Manual de Normas y Procedimientos Operativos (2ª edición, promulgated by Resolución 02-24 of 12 December 2024 (Acta No. 019-2024), printed January 2025, published on the CONABIOS website in February 2025 (Manual V2)). For clinical research, the language rule shifts vocabulary. The *"traducción fidedigna"* fidelity clause in Manual V2 §4.1 and §4.1(a) is attached to the research protocol only — the primary source names *"El protocolo de investigación, impreso en su idioma original, con traducción fidedigna al idioma español"* and no other document at that fidelity tier. Coverage of the rest of the ethics-review file flows through two other CONABIOS sources: (i) the *Requisitos para Solicitud de Evaluación de un Proyecto de Investigación Clínica* sheet, which requires all foreign-origin documents to be filed in Spanish with the original-language copy alongside — a document-agnostic rule that reaches the Investigator's Brochure, informed-consent forms, safety-reporting materials, and supporting research documents *as deposit items*, without invoking the *"fidedigna"* wording; and (ii) Manual §9.2, which governs informed consent as a substantive readability rule (Spanish, comprehensible to the participant population), not as an application of §4.1's translation tier. In practical filing terms the sponsor delivers the same Spanish set either way, but the framing matters at RFI-response time: when CONABIOS cites §4.1, the burden is on the protocol's *fidedigna* fidelity; when CONABIOS cites the Requisitos sheet, the burden is on the completeness of the document set. See also the 2025 requirements brochure. §9.2 requires the informed consent to be written at a readability level accessible to the participant population, which in the DR means Spanish at roughly a 6th–8th grade level. §4.5 ties recruitment materials to the same fidelity standard. Chapter 6 sets the safety-reporting cadence and requires that expedited SAE narratives reach CONABIOS in Spanish.

Reading the sequence. The Dominican language stack reads top-down: the Constitution names Spanish the official language; Ley 42-01 puts that constitutional rule onto the label of every medicine; Decreto 246-06 lifts the rule off the label and puts it onto every scientific report supporting the registration; and the CONABIOS Manual carries the same rule into the ethical-review file. Sponsors who read only one of these four layers walk into DR intake with the wrong mental model. The rule is not a customs-and-labels rule with a scientific-annex exception. It is a language-of-the-state rule with no exception at the scientific-annex layer.

Why the DR reads this way and Panamá does not. The comparison sponsors make most often is DR versus Panamá, because both jurisdictions sit in the northern Caribbean regulatory zone and share similar CTD structures. Panamá's language rule lives at the regulator level and is subject to consulta processes that may shift its posture. The DR's language rule lives in a Presidential

decree that has been in continuous force for two decades and has not been amended even as the surrounding institutional apparatus (DIGEMAPS autonomy, CONABIOS elevation) has been overhauled. Sponsors reading the DR through a Panamá lens read it wrong.

A note on the CONABIOS Manual's language provisions. The 2ª edición Manual — promulgated by Resolución 02-24 of 12 December 2024 (Acta No. 019-2024), printed January 2025 and published on the CONABIOS website in February 2025 — restates and strengthens the language rule that had lived in the 1ª edición. §4.1 is the anchor. §4.5 extends the fidelity rule to recruitment materials — flyers, radio spots, WhatsApp templates, social posts — none of which may circulate in the DR unless they carry the same faithful-translation guarantee as the protocol. §9.2 sets an informed-consent readability ceiling: the ICF must be written at a level accessible to the participant, which in most DR sites is 6th–8th grade Spanish. Chapter 6 sets the safety-reporting cadence: expedited SAE narratives, DSUR-equivalents, and annual updates all reach CONABIOS in Spanish, on the Manual's cadence, not on the sponsor's home-country cadence. Ignoring the cadence is a common CONABIOS "Observado" trigger.

Summary language table.

Document class	Language rule	Statutory anchor
Label / *contra etiqueta*	Spanish	Ley 42-01 Art. 112
INN on label + *inserto*	Spanish	Decreto 246-06 Art. 18 Párrafo II
Inserto / *empaque*	Spanish	Decreto 246-06 Arts. 42-43
Toxicology, pharmacology, clinical, stability reports	Spanish or bilingual filing with Spanish translation attached	Decreto 246-06 Art. 39
CTD Module 1 administrative	Spanish	Decreto 246-06 Arts. 27-43
Advertising	Spanish	Decreto 246-06 Art. 250
Research protocol (CONABIOS)	Traducción fidedigna into Spanish	CONABIOS Manual V2 §4.1(a)
IB, ICF and supporting research documents (CONABIOS)	Spanish deposit copy plus original-language copy; ICF also governed by §9.2 readability	Requisitos sheet; Manual §9.2
Informed consent	Spanish, participant-readable	CONABIOS Manual §9.2
SAE / safety reporting	Spanish, per Ch. 6 cadence	CONABIOS Manual Ch. 6

Section C. Sworn vs Certified vs Simple: The Three-Tier Reality

The DR has three practical translation tiers, and confusing them is the single most common reason a DR file bounces on intake.

Tier	Who signs	Where it applies	Statutory anchor
Intérprete judicial (sworn)	Court-appointed, Dominican national, French+English minimum	DIGEMAPS filings under Decreto 246-06 Art. 32; any document destined for a Dominican court, notary, or public registry	Ley 821 Arts. 99-108; Resolución 01/2013
(No separate certified tier)	—	The DR does not recognize a middle "certified translator" tier the way Colombia or Mexico do	—
Traducción fidedigna (faithful)	Any competent translator; no credentialed registry	CONABIOS ethical-review file — the *fidedigna* clause names the research protocol only; the IB, ICF and supporting research documents travel as Spanish deposit items under the Requisitos sheet, and the ICF additionally under §9.2	CONABIOS Manual V2 §4.1(a); Requisitos sheet

Intérprete judicial — the sworn tier. Ley 821 de Organización Judicial (1927), Arts. 99-108 establishes the office of *intérprete judicial* as a court auxiliary. The historical statute limits the office to Dominican nationals and requires French and English competence as a baseline — a legacy of the 1927 diplomatic corps but still enforced today. In 2013, the Suprema Corte issued Resolución 01/2013 opening the office to languages beyond the historical French/English/Italian core; that resolution is what allows Portuguese, German, Chinese, and Japanese *intérpretes* to be appointed today, and it is the door through which most modern clinical-language work walks.

Why the DR has no "certified translator" tier. Unlike Colombia (traductor oficial), México (perito traductor), or Argentina (traductor público), the DR did not develop a certified-translator profession parallel to the intérprete judicial. Ley 821 wrote the courts' translation function into the intérprete role and no later statute has added an alternative credential. In practice this means: if a document has to carry legal weight before DIGEMAPS, a Dominican notary, a Dominican court, or a Dominican registry, it either (a) is drafted natively in Spanish by the party who owns it, or (b) is translated by an intérprete judicial. There is no "our staff translator holds a certificate" pathway that carries authority the way it does in neighbouring jurisdictions. Sponsors who assume otherwise ship rework.

Appointment. The Suprema Corte de Justicia appoints intérpretes judiciales through a competitive process run by the Escuela Nacional de la Judicatura (ENJ) (ENJ Intérprete Judicial). Appointments are per-district; a Santo Domingo intérprete may not sign for a Santiago proceeding without cross-jurisdictional acceptance, which DIGEMAPS reviewers do accept but which some notaries do not.

Verifying an intérprete's active status. Before assigning a scientific report to an intérprete judicial, Amavita verifies (a) that the intérprete's appointment through ENJ is current, (b) that the signature on file at the Procuraduría matches the one that will be affixed to the translation, and (c) that the intérprete's language-pair and subject-matter competence covers the report to be translated. A sworn stamp from an intérprete whose ENJ appointment has lapsed is worse than no stamp at all: it triggers a documentary-authenticity RFI on top of the language-tier RFI.

How the intérprete's stamp travels through the file. In practice, the intérprete judicial's stamp and signature go on the last page of each translated report, with a rubric on each intervening page. DIGEMAPS reviewers cross-check the stamp on the last page against the Procuraduría's registry; if the check fails, the file bounces. Amavita's assignment sheet identifies, for every report in the dossier, which intérprete is signing which section and where the stamp lands — that document is part of our Gate 5 output.

Signature registry. Every intérprete judicial's signature is deposited with the Procuraduría General de la República for verification. A DIGEMAPS reviewer who suspects an intérprete stamp is the reviewer's routing address for confirmation.

Apostille. The DR is party to the Hague Apostille Convention with entry into force 30 August 2009 (HCCH status table). Foreign public documents destined for DIGEMAPS — corporate certificates, notarized powers of attorney, certificates of pharmaceutical product, foreign GMP certificates — are apostilled in the country of origin and then translated in the DR by an intérprete judicial. The apostille goes first, the translation goes second; the intérprete translates the underlying document *and* the apostille itself into Spanish.

Authority routing table.

Document class	Tier required	Who signs
CPP (foreign)	Sworn	Intérprete judicial after MIREX apostille
Foreign GMP certificate	Sworn	Intérprete judicial after MIREX apostille
Power of attorney (foreign)	Sworn + apostille	Intérprete judicial
Corporate certificate (foreign)	Sworn + apostille	Intérprete judicial
Toxicology / pharmacology report	Sworn (when filed as translation)	Intérprete judicial
Clinical study report	Sworn (when filed as translation)	Intérprete judicial
Research protocol (CONABIOS)	Traducción fidedigna (§4.1(a))	Any competent translator
IB / ICF / supporting documents (CONABIOS)	Spanish deposit copy + original-language copy (Requisitos sheet); ICF readability per §9.2	Any competent translator
Label / inserto content	Spanish original (not translation per se)	Sponsor or local rep drafts in Spanish

§8.4(e) WHO-stringent legalisation waiver. Under Resolución 000018-16 §8.4(e), certain biotechnological medicines from WHO-stringent authorities may enter with a simplified legalisation package. This waiver does not waive the translation obligation; it waives some of the consular-legalisation steps that were made largely redundant when the DR joined the Hague Convention in 2009. Sponsors sometimes read this clause as a translation waiver — it is not.

The §8.4(e) waiver reads together with the Hague apostille — where a document comes from a WHO-stringent, Hague-party jurisdiction (the vast majority of them are), the legalisation stack collapses to apostille-then-intérprete-translation. Where a document comes from a non-Hague jurisdiction, consular legalisation returns to the workflow, and §8.4(e) may soften that step for biotech filings. In no case does §8.4(e) remove the intérprete judicial signature.

TPA capacity as a bottleneck. The Dominican intérprete-judicial roster is small. Registered intérpretes for English-Spanish medicine and device work number in the low double digits nationwide, and pharmacology-experienced ones are fewer still. On a full CTD, a sponsor should assume that the intérprete-judicial layer is the throughput ceiling of the project — not the DIGEMAPS review clock.

The 7th QC gate — Document Currency at close. Amavita's DR delivery standard imposes seven QC gates on any DIGEMAPS package. The seventh, run at close, checks that every notarial certificate, every apostille, every intérprete stamp, and every version of every scientific report is still within the currency window DIGEMAPS accepts at the moment of filing. Notarial certificates in particular expire, and a sponsor who translated in January should not assume the notarial layer is valid in June.

The other six QC gates, in order. Gate 1: source-file integrity (English CTD version pinned, hash-recorded). Gate 2: terminology-freeze against the Amavita DR glossary (Decreto 246-06 vocabulary, CONABIOS Manual vocabulary, MSP Resolución 000018 vocabulary for cell therapies). Gate 3: table-and-figure structural fidelity (Amavita's July 2026 Katherine-batch failure was a table-structure failure; the DR standard forbids linear text dumps that destroy source tables). Gate 4: pagination independence (source pagination must not bleed into the Spanish body — the Spanish translation carries its own pagination and cross-refers to the English source explicitly). Gate 5: intérprete-judicial fitness (the assigned intérprete has the language pair and the subject-matter competence to sign this specific dossier). Gate 6: apostille-and-legalisation sequencing verified (apostille before translation, never after). Gate 7 is the document-currency gate described above.

Section D. Preclinical Translation Requirements — The Full Answer

This is the section of the guide most sponsors skip to. Because Amavita positions itself as the source of truth for Latin American preclinical translation posture, we walk it in five parts.

This section is the reason Amavita publishes country guides at all. Every sponsor arrives with an assumption about preclinical translation; in the DR that assumption is usually wrong. The next

five sub-sections lay out the correct posture with the statutory anchors that support it.

D.1. Does preclinical need to be translated in the DR? YES — at the decree level.

Yes. Decreto 246-06 Art. 39 requires that scientific reports supporting a medicines registration be filed in Spanish or accompanied by a Spanish translation. That article names — by name — *estudios toxicológicos* and *estudios farmacológicos* alongside clinical and stability studies. Art. 39 is a decree-level rule, not a manual-level rule, which is why sponsors who are used to reading Panamá or Colombia's more permissive preclinical postures find the DR jarring. In the DR, the preclinical translation obligation lives in a Presidential decree signed into force in 2006 and has been continuously in effect since.

Art. 29 of the same decree lists *documentación toxicológica y farmacológica* as a first-class dossier module — not an appendix, not a supporting file, but a headline module of the registration.

Art. 36 enumerates the required content of that preclinical module in subsections (a) through (e): (a) pharmacological studies including mechanism of action, (b) toxicological studies in single-dose and repeat-dose, (c) genotoxicity, (d) reproductive toxicity where indicated by class, and (e) carcinogenicity where indicated by class (Decreto 246-06 Arts. 29, 36).

Art. 39 also bars strikethroughs, smudges, alterations, and hand-written interlineations on the filed document. This is why Amavita produces DR preclinical deliverables in born-digital, table-preserving, page-parallel bilingual format — because a scan-and-retype workflow risks producing exactly the kind of "alteration" that Art. 39 rejects on intake.

D.2. The DR bilingual filing architecture — what it looks like in practice.

Art. 39 gives sponsors two paths: (i) file entirely in Spanish, or (ii) file the English original *accompanied by a Spanish translation*. The overwhelming majority of foreign sponsors take path (ii), which we call bilingual filing. Bilingual filing in the DR is not a translated-summary architecture. It is a full-report architecture: the English study report goes in, the Spanish translation of that report goes in beside it, each page carries its counterpart, and each cross-reference in Module 1 points to both.

This is materially different from Panamá's split-confidence architecture, from Colombia's IND-only translation carve-outs, and from the "translated summaries suffice" reading that some CROs try to import from other jurisdictions.

D.3. Three narrow substitution mechanisms — and why two don't help you.

Sponsors sometimes ask whether any Dominican rule permits substituting a summary, a foreign-agency assessment, or a reduced translation for the full preclinical file. There are three narrow mechanisms.

Mechanism 1 — Decreto 246-06 Art. 40. Art. 40 declares clinical and preclinical documentation "esencial" and delegates to the Secretaría de Salud a power to accept substitutes in specific cases. In practice, DIGEMAPS has never exercised this delegated power to establish a general substitution rule. It is a paper mechanism, not a live one.

Mechanism 2 — Resolución 000018-16 §8.3.1 (biotech-only early-development waiver). Resolución 000018-16 §8.3.1 is the only express, live substitution mechanism in the DR system. It permits, for biotechnological medicines *and only* biotechnological medicines, that early-development preclinical documentation may be waived where the product has been authorized by a WHO-stringent regulatory authority under a live pathway and where prior authorization has been granted by the sponsor's home authority. This is a narrow biotech-only path, and it is the only place in Dominican regulation that expressly waives a preclinical translation obligation.

Mechanism 3 — Simplified procedure (RD$42,000 / 30 días laborables). DIGEMAPS publishes a simplified drug-registration procedure at RD$42,000 fee and 30 días laborables review. The simplified procedure compresses review time, not dossier content. It is available for medicines already registered in reference jurisdictions and applies to a subset of dossier types, but it does not reduce the translation obligation and does not waive Art. 39. Sponsors and CROs sometimes market the simplified procedure to clients as a translation-reduction pathway — that is inaccurate and, when the file bounces, expensive.

Why the simplified-procedure misconception persists. The simplified procedure is a genuinely useful pathway for reference-listed drugs, and its 30-días-laborables clock is materially shorter than the 90-días-laborables new-registration clock. But that shorter clock is a downstream benefit that comes only when the file is accepted as complete. The pathway does not reduce Art. 39's obligations at intake. A sponsor filing under the simplified procedure with English-only preclinical will fail intake and lose the RD$42,000 fee investment. The pathway rewards well-prepared files with faster review; it does not forgive poorly-prepared files.

D.4. Consolidated DR preclinical table.

Question	DR answer	Anchor
Is preclinical translation required at the decree level?	Yes	Decreto 246-06 Art. 39
Is the obligation named for toxicology / pharmacology by name?	Yes	Decreto 246-06 Art. 39
Is preclinical a first-class dossier module?	Yes	Decreto 246-06 Art. 29
Are contents enumerated?	Yes, Art. 36(a)-(e)	Decreto 246-06 Art. 36
Are alterations barred on the filed document?	Yes	Decreto 246-06 Art. 39

Question	DR answer	Anchor
Is a translated-summary architecture acceptable?	No — full-report bilingual filing	Decreto 246-06 Art. 39
Is there a general substitution rule?	No; Art. 40 is dormant	Decreto 246-06 Art. 40
Is there a biotech waiver?	Yes, narrow, WHO-stringent + prior authorization	Resolución 000018-16 §8.3.1
Does the simplified procedure reduce translation?	No	DIGEMAPS simplified
Does the WHO-stringent legalisation waiver waive translation?	No	Resolución 000018-16 §8.4(e)

A word on "bilingual filing" as an architecture, not a workaround. A sponsor coming from a jurisdiction where translated summaries suffice sometimes asks Amavita whether the DR bilingual-filing rule can be satisfied by attaching a Spanish overview document to the English report. It cannot. Art. 39's language — *acompañados de su traducción al español* — is understood by DIGEMAPS reviewers as attachment of a Spanish translation of the report itself, page for page, table for table. This is why Amavita produces DR preclinical deliverables in a page-parallel layout: English page N sits opposite Spanish page N, tables reproduced in both languages with the same row-and-column structure, figures captioned bilingually, and headers matched across the pair. Anything less produces intake friction.

Regulatory posture comparison — DR vs Panamá vs Paraguay. Amavita groups Latin American jurisdictions into three preclinical-translation postures. Permissive (Colombia INVIMA IND-only carve-outs; some Central American authorities). Split-confidence (Panamá DNFD posture with a pending consulta process that may narrow English tolerance). Full-confidence-required (DR under Decreto 246-06 Art. 39; Paraguay under DINAVISA current guidance). The DR sits firmly in the third bucket and has for two decades. Any sponsor whose regulatory affairs team is transferring posture assumptions from Panamá to the DR is starting from the wrong template.

D.4.1 The preclinical evaluation criterion inside the Manual itself

Separately from the DIGEMAPS decree-level bilingual-filing rule in Decreto 246-06 Art. 39, CONABIOS's own Manual carries a scientific-validity criterion that reviewers apply when the file is opened: Manual V2 §4.3(e)(2) requires the ethics review to consider *"Información preclínica y clínica del producto en estudio,"* and its risk-weighting language explicitly names development phase — *"La fase de desarrollo del medicamento. Los estudios de Fase I y Fase II, necesitarán más supervisión."* The Requisitos sheet operationalizes this into a specific deposit requirement (verbatim): *"En caso de que la investigación contemple el estudio de un producto (fármaco o equipo), incluir un resumen completo de los datos disponibles de la seguridad y toxicología (farmacocinética y farmacodinamia), así como la experiencia clínica de los mismos y de las características del fármaco o equipo (datos publicados, apuntes recientes, efectos secundarios o adversos y bibliografía si la hubiere)."*

Two operational reads follow:

1. The IB is the natural carrier for §4.3(e)(2). The safety/toxicology summary CONABIOS asks for is the substance of the Investigator's Brochure; delivering the IB in Spanish (as a deposit item under the Requisitos sheet's document-agnostic Spanish rule) discharges this criterion.
2. Devices are in scope. The Requisitos-sheet clause explicitly names *"fármaco o equipo,"* which resolves the recurring question of whether device sponsors have to satisfy the §4.3(e)(2) preclinical criterion — they do.

D.5. The ten risks of getting DR preclinical wrong.

The DR is the country where Section D is not a summary — it's a full bilingual dossier obligation, decree-level enforced. Below are the ten risks Amavita audits for on every DR preclinical intake.

1. Assuming Art. 40 is a live escape clause. It is not; it has never been exercised as a general rule (Decreto 246-06).
2. Applying the biotech §8.3.1 waiver to a small-molecule dossier. The waiver is biotech-only by its own terms (Resolución 000018-16).
3. Reading §8.4(e) legalisation waiver as a translation waiver. It waives consular legalisation, not translation.
4. Marketing the simplified procedure to clients as a translation shortcut. It compresses review time only (DIGEMAPS simplified).
5. Filing translated summaries in place of full reports. Art. 39 demands the report itself, translated (Decreto 246-06 Art. 39).
6. Scan-and-retype workflows that produce hand-corrected pages. Art. 39 bars alterations.
7. Skipping the intérprete judicial signature on preclinical reports filed as translations. Art. 32 requires the sworn tier for DIGEMAPS proceedings.
8. Assuming Panamá or Colombia posture transfers to the DR. It does not — the DR is a full-confidence-required jurisdiction.
9. Underestimating intérprete-judicial capacity. The Dominican roster is small and pharmacology-experienced translators are fewer still.
10. Missing the currency window on notarial / apostille / intérprete stamps. The 7th QC gate catches this; sponsors without that gate ship expired paper.

How Amavita reads the DR preclinical posture in one line. *In the DR, Section D is not a summary — it is a full bilingual dossier obligation, decree-level enforced.* That single line is the difference between a DR project priced honestly and a DR project sold on a translation shortcut that does not exist.

Amavita's DR preclinical delivery standard — non-negotiables. Every DR preclinical package that leaves Amavita meets seven non-negotiable standards: page-parallel bilingual layout, table-and-figure structural fidelity, terminology-freeze against the Amavita DR glossary, intérprete-judicial signature by an intérprete with current ENJ appointment, apostille-then-translate sequencing

verified on every legalised document, Colecturía-current fee receipt, and document-currency window management at close. These seven standards are what the seven QC gates enforce. A DR file that meets these seven standards passes intake on first submission in the majority of Amavita's DR track record; a file that fails one of them does not.

Two Pathways: DIGEMAPS vs CONABIOS

Almost every clinical program in the DR touches both authorities. DIGEMAPS registers the product. CONABIOS ethically reviews the research on humans. The paperwork is separate, the language rules are separate, and — critically — the timelines are separate. A sponsor running a Phase II with a marketed reference product will file with CONABIOS to open the study, and file with DIGEMAPS later for the market authorization.

Cross-referencing between the two pathways. CONABIOS approval is a prerequisite for any human-subjects research in the DR under Resolución 03-21; it is not, however, a substitute for DIGEMAPS market authorization when the sponsor eventually seeks to place the product on the DR market. Sponsors running a pivotal study in the DR should be planning both pathways in parallel: the CONABIOS file goes in first with the protocol, IB, and consent set; the DIGEMAPS file follows with the full CTD when the sponsor is ready for market registration.

Language rules across both pathways. The DIGEMAPS-side rule is Art. 39 full-report bilingual. The CONABIOS-side rule is Manual §4.1 traducción fidedigna into Spanish. These are related but not identical rules: Art. 39 governs scientific-report translations that will be filed at DIGEMAPS; §4.1 governs the ethical-review file at CONABIOS. Sponsors sometimes send the CONABIOS-file protocol through a traducción-fidedigna vendor and the DIGEMAPS-file preclinical reports through an intérprete judicial. That is the correct routing.

Category 1 — Drugs

This category walks the DIGEMAPS drug-registration pathway from market-access anatomy through submission structure to clinical-trial handling.

D1. Market Access

Statutory review clock. Ley 42-01 Art. 115 sets the market-authorization decision clock at 90 days from receipt of a complete file. That clock is statutory — it does not start until DIGEMAPS accepts the file as complete, which is why the intake QC is the moment of truth for a DR drug filing.

Fee schedule (published).

Service	Fee	Time
New drug registration	RD$21,000	90 días laborables
Simplified procedure	RD$42,000	30 días laborables
Modification	RD$9,000	—
Product natural	RD$9,000	—
Cosmetics	RD$5,000	—
Advertising review	RD$1,000	—
GMP inspection	RD$25,000 per area	40 días
Distributor authorization	RD$6,000	40 días

Sources: [DIGEMAPS new drug registration](https://digemaps.gob.do/servicios/nuevo-registro-medicamentos-productos-naturales/), [DIGEMAPS simplified procedure] (https://digemaps.gob.do/servicios/procedimiento-simplificado-de-registro-sanitario-de-medicamento/).

D2. Submissions — Decreto 246-06 Arts. 27-43 Walkthrough

The Amavita DR project plan for a new medicines dossier walks Decreto 246-06's articles in order. Below is the walkthrough at the level of an experienced regulatory affairs manager, with the translation implications called out.

Arts. 27-28 establish the CTD-like structure of the file with administrative, quality, safety, and efficacy modules. The administrative module carries the DGDF-RP-FO-001 solicitud form, the local *representante legal* documentation, the CPP (or equivalent), and the fee receipt. The quality module carries manufacturing and control content that in most jurisdictions maps to CTD Module 3. The safety module carries preclinical content; the efficacy module carries clinical content.

Art. 29 names the required modules and includes *documentación toxicológica y farmacológica* as its own module. That naming matters for translation because it is what carries the preclinical burden from the general "scientific reports" language of Art. 39 into an enumerated, first-class dossier requirement.

Arts. 30-35 walk quality and manufacturing content, including specifications, control methods, stability, and GMP evidence. Foreign GMP certificates from stringent-authority sites are accepted in evidence but must arrive apostilled and translated into Spanish by an intérprete judicial. In-country DR GMP inspections are governed by DIGEMAPS's own inspectorate at the RD$25,000-per-area / 40-días cadence.

Art. 36 enumerates preclinical content in subsections (a)-(e): pharmacology (mechanism of action, primary and secondary pharmacology, safety pharmacology), single-dose toxicity, repeat-

dose toxicity, genotoxicity, reproductive toxicity, and — depending on the class — carcinogenicity. Every one of these sub-modules is a scientific report; every scientific report falls under Art. 39.

Art. 37-38 walk clinical-content requirements including safety-database and pharmacovigilance obligations. Sponsors filing a reference-listed drug will lean on published clinical data; sponsors filing an original clinical development will file the full clinical study report set, all under Art. 39's translation rule.

Art. 39 — the language rule — requires Spanish or bilingual filing with a Spanish translation attached. The article also bars strikethroughs, smudges, and alterations. Together those two sentences of the article are the entire language stack for the scientific portion of the DR dossier.

Art. 40 declares preclinical and clinical documentation essential and delegates substitution power that has never been generally exercised. When sponsors ask Amavita whether Art. 40 permits substituting an FDA or EMA assessment for the full report, the answer is: DIGEMAPS has not published a rule invoking that delegated power, and reviewers have not, in Amavita's DR track record, accepted such substitutions as a general matter. Sponsors sometimes ask whether an EMA public assessment report (EPAR) or an FDA integrated summary satisfies Art. 40's dormant substitution mechanism. In practice: no. DIGEMAPS reviewers read Art. 39 as the governing rule and Art. 40 as a delegation that has not been exercised. Sponsors who file EPARs and integrated summaries in place of full reports encounter pre-clock rejects on the same terms as sponsors who file English-only reports.

Arts. 41-43 cover *inserto*, *empaque*, and post-registration modification procedures. Inserto and empaque are Spanish-original documents — they are not translations of foreign artwork, they are DR-native artwork built in Spanish by the sponsor or its local rep. Modifications open the RD$9,000 modification fee window and re-open the language QC on the modified content.

Practical read. A DIGEMAPS drug file is Decreto 246-06 in miniature. If you can walk Arts. 27-43 in order, you can walk a drug dossier in order. If you cannot walk those articles in order — or, more commonly, if your CRO is telling you that Art. 39 has a workaround — you are being sold a filing that will bounce.

Cell therapies — the MSP overlay. Resolución 000018 of the MSP adds an MSP-level authorization on top of the DIGEMAPS-CONABIOS stack for cell-therapy research and products. Sponsors bringing cell therapies to the DR should route their DIGEMAPS filing through the MSP overlay early, not as an afterthought. The MSP overlay imports the same language rule — Spanish, decree-level, no workaround — and its documentary standard is at least as strict as the DIGEMAPS standard.

D3. Clinical Trials and CONABIOS

Any clinical trial run in the DR requires CONABIOS ethical and regulatory review. The current framework is the CONABIOS Manual de Normas y Procedimientos Operativos, 2ª edición, promulgated by Resolución 02-24 of 12 December 2024 (Acta No. 019-2024), printed January

2025, published on the CONABIOS website in February 2025, promulgated under Resolución 02-24.

Cell therapies. Resolución 000018 of the MSP governs cell-therapy research and imposes an additional layer of MSP-level authorization on top of CONABIOS review.

Submission form. The CONABIOS Formulario para Someter Proyectos de Investigación 2021 is the current intake form. Item 2.5 expressly accepts protocols filed in French — a legacy of the French/English intérprete-judicial framework — but the ethical-review documents themselves, and every consent, must be in Spanish under §4.1.

Mandatory ethics review. CONABIOS Resolución 03-21 makes CONABIOS review mandatory for every human-subjects research protocol conducted in the DR.

Committee contact. CONABIOS operates from Santo Domingo with the primary contact channel +1 809-262-2216 and the mailbox conabios_rd@yahoo.com. There is no separate DIGEMAPS-side clinical-trial mailbox — the DR clinical-trial front door is CONABIOS.

Session cadence. CONABIOS meets in full session roughly monthly; the 2025 numbering ran to *Acta 11-2025* by 26 August 2025, which is what allowed the promulgation of Resolución 03-25 that same month. Sponsors should plan for a submission-to-session lag of two to six weeks depending on where in the monthly cycle the file arrives, on top of the ≤45 días hábiles statutory clock.

Where the 45-días-hábiles clock runs and where it does not. The ≤45 días hábiles clock in the CONABIOS Manual runs from *aceptación de la documentación completa*, not from delivery of the packet. Documentation deemed incomplete on intake extends the calendar without extending the statutory clock. That is why the Amavita CONABIOS delivery standard front-loads the completeness check — all Spanish versions in place, all consent variants (adult, adult vulnerable, pediatric assent, parental) drafted and checked against Res. 02-25, all recruitment materials Spanish, all IB sections translated — before the packet crosses the CONABIOS threshold.

What CONABIOS reviews in a translation-language reading. Every clinical-research file that goes through CONABIOS is language-tested by the committee on the same day it is scientifically reviewed. §4.1 (traducción fidedigna) is checked against the English protocol; §9.2 (ICF readability) is checked against the local population's language competence, and CONABIOS reviewers in this two-year period have been particularly attentive to ICFs written for Haitian-Creole-speaking populations in eastern DR sites — those ICFs may require Kreyol counterparts, not just Spanish; and §4.5 (recruitment) is checked against the recruitment materials the sponsor plans to circulate.

Category 2 — Medical Devices

DR device registration is a delta on top of DR drug registration. The device sections below highlight the differences rather than repeating the drug narrative.

E1. Device-Registration Architecture

Devices in the DR are governed by the medicines regulation because the Reglamento Técnico de Productos Sanitarios mandated by Decreto 82-15 Art. 6 in April 2015 has never been enacted. Eleven years later, devices are registered under Decreto 246-06 with a flat RD$9,000 fee and no statutory risk classes (DIGEMAPS device new registration).

The consequence of the missing device reglamento. In a jurisdiction with a functioning risk-class device framework — México, Chile, Perú — a Class I sponge and a Class III implantable defibrillator file under different documentary standards. In the DR, both file under Decreto 246-06 at RD$9,000 flat, with the same scientific-report translation obligation under Art. 39, and are triaged by DIGEMAPS reviewers in the absence of statutory risk classification. Sponsors of low-risk devices sometimes read the flat-fee posture as a low-burden posture. It is not — the language burden is identical to a high-risk device.

Reviewer discretion in the absence of a device reglamento. Where the statute is silent, DIGEMAPS reviewers exercise discretion in triaging device files. That discretion tends to import ISO-13485 and ISO-14971 vocabulary as informal benchmarks; sponsors filing device dossiers should ensure that any references to those ISO standards inside the CTD carry Spanish translations of the relevant clauses, not just English references. This is one of the areas where an Amavita terminology-freeze glossary produces measurable time savings on RFI response.

Software as a device. Decreto 246-06 includes definition #111 for *producto sanitario* and expressly captures *programas lógicos* (software) inside the definition. Software-as-a-medical-device sponsors do have a Dominican pathway — it just runs through the medicines reglamento with a flat fee, not through a dedicated device regulation.

E2. Device-vs-Drug Delta Table

Element	Drug	Device
Governing decree	Decreto 246-06	Decreto 246-06 (by default; device reglamento never enacted)
Fee	RD$21,000 (new)	RD$9,000 flat
Timeline	90 días laborables (Art. 115)	90 días laborables
Risk-class stratification	Not applicable	None statutory
Translation obligation	Art. 39 full bilingual	Art. 39 full bilingual
Label update	RD$9,000 modification	RD$7,500
Renewal	Standard renewal	RD$9,000

Source: [DIGEMAPS device new + renewal](https://digemaps.gob.do/servicios/registro-sanitario-de-productos-sanitarios/), [device renewal (intérprete judicial rule)] (https://digemaps.gob.do/servicios/renovacion-de-registro-sanitario-de-productos-sanitarios/).

The DIGEMAPS device-renewal page is the only DIGEMAPS service page that prints the intérprete-judicial rule in plain language — an inconsistency in DIGEMAPS's own web publication that sponsors should treat as evidence that the rule applies to *all* device filings, not only renewals.

Reading the DIGEMAPS device pages together. The new device registration page lists documentary requirements and the flat RD$9,000 fee; the renewal page adds the intérprete-judicial rule; the modification and label-update pages carry additional documentary specifications. Sponsors preparing a new device file should treat the sum of these pages as the DIGEMAPS device documentary standard, not any single page in isolation. The intérprete-judicial rule appearing on the renewal page only is an artefact of DIGEMAPS's web maintenance cadence, not evidence that renewals face a stricter language rule than new registrations.

E3. CONABIOS §4.2(a) Device Jurisdiction

CONABIOS Manual §4.2(a) expressly asserts CONABIOS jurisdiction over medical-device research on human subjects, notwithstanding the DIGEMAPS-side gap on a dedicated device reglamento. In other words: even where the product-side rule is thin, the research-side rule is thick.

What this means for device sponsors. A device sponsor running a first-in-human implant study, a diagnostic performance study, or a software-as-a-medical-device validation study in the DR files with CONABIOS on the same terms as a drug sponsor. Protocol into faithful Spanish. ICF into accessible Spanish. Safety cadence in Spanish. Recruitment materials in Spanish. The gap in the DIGEMAPS device framework does not translate into a gap in the CONABIOS research framework.

Device software — the definition #111 read. Where a device sponsor is bringing software — whether standalone SaMD or firmware bundled with hardware — the Decreto 246-06 definition #111 captures *programas lógicos* inside *producto sanitario*. The DR does have a pathway for software as a medical device. It runs through the medicines reglamento at RD$9,000 flat and it demands, like every other DR filing, decree-level bilingual scientific documentation of the software's validation.

Section F. Common RFI and Rejection Patterns

The DR system produces two distinct rejection patterns. The first is a DIGEMAPS pre-clock reject on the product side. The second is a CONABIOS "Observado" outcome on the research side. Sponsors should recognize and pre-empt both.

F.1. DIGEMAPS Re-entry Loop (Pre-Clock)

The most common DR reject pattern is pre-clock — DIGEMAPS refuses to accept the file as complete, the Art. 115 90-day clock does not start, and the sponsor is asked to re-submit. Pre-clock failure is more expensive than in-clock RFI because the statutory review-time countdown never began: the sponsor pays the fee again in some cases, and in every case pays the calendar. The five patterns behind that reject:

1. Preclinical filed English-only — Art. 39 violation, hardest reject to recover (Decreto 246-06).
2. Preclinical filed as translated summary — Art. 39 requires the full report translated, not a summary of it.
3. CPP or foreign GMP not apostilled — apostille-then-translate sequencing violated (HCCH). This is a common failure mode for sponsors coming from jurisdictions that accept notarised-and-consularised documents without apostille. The DR has been in the Hague system since 2009 — apostille is the correct route.
4. Intérprete judicial stamp missing on foreign documents — Art. 32 violation.
5. DGDF-RP-FO form used but not filled in Spanish — the form prefixes are legacy but the language rule is not.
6. Fee receipt attached without the current Colecturía code — an administrative failure that halts intake even when the substantive dossier is compliant.
7. Local representante legal documentation missing or expired — the Dominican representante legal is a documentary requirement, not a courtesy title, and lapsed authorization halts intake.

Recovering from a pre-clock reject. Amavita's approach on a pre-clock reject is to isolate the specific failure, resolve it inside a 10-business-day sprint, and re-file with a written cover memo explaining the resolution. That cover memo is not a DIGEMAPS-required document; it is an Amavita practice that shortens the reviewer's re-evaluation time by explicitly pointing to the remediation.

F.2. CONABIOS "Observado" Outcome

CONABIOS's committee-review outcomes are "Aprobado," "Observado," or "No Aprobado." The "Observado" outcome is the equivalent of a request for information — the committee raises specific observations that the sponsor must address before final approval. Language observations are common: an inconsistent Spanish protocol version, an ICF above the readability ceiling, a missing safety-narrative Spanish version.

Recurring CONABIOS "Observado" triggers in the translation dimension.

1. ICF above readability ceiling. §9.2 sets an accessible-Spanish requirement; ICFs written at a level closer to the protocol's own technical Spanish trigger observation.

2. Protocol version mismatch across modules. A translation done on Protocol v3.0 while Module 1 references v3.1 triggers observation on document-integrity grounds.
3. Safety-narrative Spanish version missing. Chapter 6 cadence requires expedited Spanish narratives — English-only expedited reports trigger observation.
4. Recruitment materials not in Spanish or with fidelity issues. §4.5 anchors this.
5. Consent-form assent version missing for pediatric protocols. Under Manual §9.3 and the Res. 02-25 amendment on §9.3.1, pediatric protocols require an age-appropriate Spanish assent form in addition to the parental consent.
6. Local language pairs beyond Spanish. Haitian-Creole ICFs for eastern-region sites; the Manual does not spell this out but CONABIOS reviewers routinely raise it.
7. Investigator brochure translation is a summary, not a translation. Same failure mode as DIGEMAPS — Art. 39 style thinking, but committee-level rather than agency-level.
8. Site-suitability documentation missing Spanish annotations. CONABIOS reviewers check that site-suitability documents (site initiation visit records, investigator CVs, training records) carry Spanish annotations where they are not natively Spanish. Investigator CVs in English are common; the annotations that certify Dominican licensure need to be Spanish.
9. Assent form absent for pediatric protocols. Res. 02-25 makes this a first-order check.
10. Version-control mismatch across the consent set. Adult ICF v3.0, vulnerable-adult ICF v2.4, pediatric assent v3.0 — CONABIOS reviewers flag version-drift within a single consent set.

The 7th QC Gate — Document Currency at Close

Every Amavita DR delivery closes with the same seventh QC gate: at the moment of filing, every notarial certificate, every apostille, every intérprete-judicial signature, and every scientific-report version is checked for currency. Notarial certificates in particular have short shelf lives in the DR system, and a sponsor whose project ran long risks filing paper that was valid at translation and expired at filing.

Section G. Consolidated Timelines and Fees

This section consolidates the DR fee-and-cadence picture in one place. Fees are current to the resolutions cited; sponsors should verify against the DIGEMAPS and CONABIOS service pages at the moment of filing because the DR authorities have adjusted fees on multiple occasions in the last three years.

DIGEMAPS statutory clock. Ley 42-01 Art. 115: 90 days from complete-file receipt.

Published DIGEMAPS service times (días laborables).

Service	Fee	Time
Drug new registration	RD$21,000	90 días laborables
Drug simplified procedure	RD$42,000	30 días laborables
Device new registration	RD$9,000 flat	90 días laborables
Device renewal	RD$9,000	—
Device label update	RD$7,500	—
Modification	RD$9,000	—
Product natural	RD$9,000	—
Cosmetics	RD$5,000	—
Advertising review	RD$1,000	—
GMP inspection	RD$25,000 / area	40 días
Distributor authorization	RD$6,000	40 días

CONABIOS fees (Resolución 01-25, effective 15 May 2025).

Service	Fee
International sponsor protocol	RD$60,000
National protocol	RD$35,000
International amendment	RD$25,000
National amendment	RD$15,000
International No Objection	RD$25,000
National No Objection	RD$15,000

No exonerations. Source: [Resolución 01-25](https://conabios.gob.do/wp-content/uploads/2025/05/7-Resolucion-No.-01-25-Nuevas-tarifas-y-categorizacion-de-estudios.pdf).

CONABIOS timelines — two published figures, reconciled.

- Manual V2 §4.3 decision timeline: *"en un plazo no mayor a 45 días hábiles a partir de la solicitud"*; urgent cases 21 calendar days; expert opinion within 2 weeks (7 days in emergencies) (Manual V2 §4.3).
- 2025 brochure decision timeline: *"el tiempo máximo para otorgar una respuesta es de 6 semanas"* (2025 brochure). This is roughly consistent with 45 días hábiles when weekends are excluded, but the two published figures should be reconciled in any submission calendar the sponsor builds; when the two disagree in future publications, the Manual controls as the

higher-authority instrument. Session numbering ran to Acta 11-2025 by 26 August 2025, indicating roughly monthly full-committee sessions (CONABIOS Manual).

Timeline arithmetic sponsors should do before quoting a filing date. DR calendar reality is that días laborables and días hábiles both exclude weekends and Dominican public holidays; the standard year has roughly 250 días laborables. A 90-días-laborables DIGEMAPS review clock is therefore approximately 18 wall-clock weeks in the median case, not 90 days. A 45-días-hábiles CONABIOS clock is approximately 9 wall-clock weeks. Sponsors quoting internal timelines on a días-calendario basis over-promise. Amavita quotes DR filings on días-laborables and adds the intake-completeness time and the intérprete-judicial queue time explicitly.

Fee-payment mechanics. DIGEMAPS fees are paid through the Colecturía del Ministerio de Salud Pública via bank deposit; the receipt is attached to the intake package. CONABIOS fees are paid to the CONABIOS designated account under the framework of Res. 01-25, which — importantly — removed the exoneration mechanism for academic and non-profit sponsors that had existed under prior fee schedules. Sponsors who filed clinical protocols in the DR under the pre-Res. 01-25 regime and assumed an academic exoneration should re-cost their 2025 and 2026 programs.

Currency and inflation considerations. RD$ fees have been stable in nominal terms in the 2023-2026 window, but the RD$-to-USD rate has moved. Sponsors budgeting in USD should refresh the conversion at each fiscal-year boundary. Amavita's DR fee tables are maintained in RD$ because that is the invoice currency; USD conversions are provided to sponsors on request but should not be relied on more than a quarter out.

Consolidated program-cost view. A representative first-in-human medical-device program in the DR carries: CONABIOS international-sponsor protocol RD$60,000, one to two amendments at RD$25,000 each, DIGEMAPS device registration RD$9,000, translation-and-intérprete costs on the Amavita $2,500/business-day rate, and the local *representante legal* fees which vary by counterpart. Sponsors sometimes ask Amavita for a single all-in DR number early in program planning; the honest answer is that the language burden dominates the fee burden by an order of magnitude, and the language burden depends on the length and complexity of the source dossier.

Section H. Recent Regulatory Changes 2023-2026

The 1 September 2026 committee-certification cliff — what to do this week

CONABIOS Resolución 03-25, issued on the basis of Decreto 351-25 in session 11-2025 of 26 August 2025, states (verbatim):

> "a partir del primero (1ro.) de septiembre del año dos mil veinte y seis (2026), no se aceptarán protocolos de investigación cuyas evaluaciones éticas iniciales hayan sido realizadas por Comités de Ética o Bioética de Investigación que no estén debidamente certificados por el CONABIOS."

Effect at 1 September 2026: every site in the Dominican Republic whose local IRB is not CONABIOS-certified becomes unable to originate an accepted initial ethics review. CONABIOS remains the umbrella authority; local IRBs remain in the flow only after they clear CONABIOS certification. Committees must deposit their *acta constitutiva* and member CVs, with at least two members trained in ethics/bioethics and in methodology, per Resolución 03-25.

What this triggers in a sponsor's file-planning window between now and 1 September 2026:

1. Site-selection call. For any DR site whose IRB certification status is not yet confirmed, either (a) rotate the initial ethics review to CONABIOS directly, or (b) route through a CONABIOS-certified IRB at a peer institution, or (c) obtain a written statement from the site's IRB confirming CONABIOS certification, dated within 30 days of submission.
2. Amendment-timing call. Studies already approved by non-certified IRBs before 1 September 2026 keep their initial approval; the risk falls on new protocols and on protocols filing a *modificación mayor* after that date, because a substantial amendment reopens the initial-review question at the reviewing committee.
3. Translation-file coordination. Any site rotation between now and the deadline changes the addressee for the ethics-review file, not its content — the Spanish set already prepared under Manual V2 §4.1 continues to travel with the protocol.

Sources: Resolución 03-25; Decreto 351-25.

The DR regulatory environment has moved more in the 2023-2026 window than in any comparable prior period. Below is the chronology, with the substantive read of each item.

The Dominican regulatory system has moved harder in the last three years than at any point since the 2006 decree. In chronological order.

Decreto 231-23 (6 June 2023). DIGEMAPS deconcentrated from MSP direct line, granted autonomous budget and contracting authority (Diario Libre coverage; Decreto 231-23). The practical effect for sponsors: intake decisions and RFI decisions now live inside DIGEMAPS on DIGEMAPS's own calendar rather than being routed up to the MSP for administrative sign-off. Files move faster; they also bounce faster when they do not conform.

CONABIOS Resolución 01-24 (June 2024). Procedural updates to the CONABIOS manual ahead of the 2024 second-edition rewrite (Resolución 01-24). Read as an intermediate step — CONABIOS was clearing the decks for the more substantial Res. 02-24 that arrived six months later.

CONABIOS Resolución 02-24 (December 2024). Promulgates the Manual de Normas y Procedimientos Operativos, 2ª edición — the single most consequential CONABIOS document in the current regulatory cycle (Resolución 02-24). The 2ª edición Manual restructures the CONABIOS review cadence, expands the safety-reporting chapter, tightens the ICF readability requirement, and sets the ground on which Res. 01-25, 02-25, and 03-25 built through 2025.

Decreto 166-25 (March 2025). Ministry-level procedural adjustment implicating DIGEMAPS intake workflow. Sponsors filing after Q1 2025 should confirm intake-window procedure with their local rep; the decree adjusts some administrative sequences without altering Decreto 246-06 substantive obligations.

CONABIOS Resolución 01-25 (15 May 2025). New fee schedule and study categorization (Resolución 01-25). The international-sponsor protocol fee moved to RD$60,000 and the exoneration mechanism for academic and non-profit filers was removed. This resolution is a material cost adjustment for any 2025-2026 program budget.

CONABIOS Resolución 02-25 (May 2025). Amendment to Manual §9.3.1 — the *padre exclusivo* clause on parental consent in pediatric research (Resolución 02-25). Sponsors running pediatric or adolescent research in the DR should read this amendment carefully: it addresses the case where one parent alone can provide consent and shifts documentary requirements in that case.

Decreto 351-25 (June 2025). Elevates and restates CONABIOS's institutional status (Decreto 351-25).

CONABIOS Resolución 03-25 (26 August 2025) — the headline. Establishes that from 1 September 2026, CONABIOS will not accept for review any protocol whose *initial* ethics evaluation was rendered by a committee not certified by CONABIOS (Resolución 03-25). This is the single most important date on the DR clinical-research calendar for 2026. Sponsors whose institutional ethics committees have not begun the CONABIOS certification process risk losing their DR site after 1 September 2026.

What Resolución 03-25 changes in practice. Until 1 September 2026, a Dominican site could route its initial ethical review through an institutional ethics committee (Comité de Ética de la Investigación institucional) that operated in parallel to CONABIOS. After 1 September 2026, that route closes unless the committee has completed CONABIOS certification. The certification process — laid out in the CONABIOS Manual 2ª edición — takes several months and requires documentary submissions, SOP audits, and member-training evidence. Sponsors with DR sites should be verifying, right now, whether their local ethics committees are in the CONABIOS certification pipeline.

Decreto 351-25 (June 2025) reads as institutional reinforcement. The June 2025 decree strengthened CONABIOS's independent statutory footing and, together with Res. 03-25, signals a coherent 2025-2026 policy of ethical-review consolidation. The DR is moving toward one door — CONABIOS — for every human-subjects protocol in the country.

Unfulfilled device reglamento. Decreto 82-15 Art. 6 required, in April 2015, that a stand-alone Reglamento Técnico de Productos Sanitarios be promulgated within twelve months. Eleven years

later, the reglamento has not been enacted. Devices continue to be registered under the medicines regulation with a flat fee and no statutory risk classes.

Reading the arc. Take Decreto 231-23, the CONABIOS 2ª edición Manual, Res. 01-25, Res. 02-25, Decreto 351-25, and Res. 03-25 as one policy arc. The DR is professionalising and centralising its regulatory apparatus. DIGEMAPS was given autonomy from MSP direct line; CONABIOS was elevated by decree, given new fee-schedule authority, and given the power to close the parallel-committee route after 1 September 2026. This is a coherent 2023-2026 push to consolidate two doors — DIGEMAPS for products, CONABIOS for research — and to raise the documentary bar at both. Sponsors reading this arc correctly should be raising, not lowering, the quality ceiling on their DR filings.

What has not moved. Notably, Decreto 246-06 itself has not been amended. The 2006 medicines reglamento continues to govern with Art. 39 as its operative language rule. The 2023-2026 policy arc has moved on the institutional side (DIGEMAPS autonomy, CONABIOS elevation) and on the cadence side (fee schedules, session structures, committee-certification cliff), but it has not moved on the substantive translation obligation. The rule that has governed since 2006 continues to govern in 2026.

Section I. Amavita Library Cross-References

Amavita maintains parallel country guides for other Latin American jurisdictions. The comparators below place the DR posture inside the regional map.

Seven comparators for readers moving across Latin American jurisdictions.

1. Panamá (DNFD). Split-confidence posture with a pending consulta process that may narrow English tolerance on preclinical scientific reports. The Panamá posture is regulator-level rather than decree-level, which is what makes it split-confidence in Amavita's classification. DR differs by anchoring the rule at decree level under Decreto 246-06 Art. 39.

2. Colombia (INVIMA). IND-only translation carve-outs; more permissive on English preclinical for market-registration files, more stringent on Spanish for clinical-trial applications. Traductor oficial sworn tier under Ministerio de Justicia certification. DR differs by treating preclinical the same way for market registration as Colombia treats it for INDs.

3. México (COFEPRIS). Perito traductor sworn tier with a dedicated device reglamento in force under the LGS. COFEPRIS's device pathway is materially richer than the DR's; DR devices file under the medicines reglamento because the Decreto 82-15 Art. 6 mandate has never been enacted.

4. Argentina (ANMAT). Traductor público sworn tier appointed by the Colegio de Traductores Públicos with a robust registered profession. ANMAT operates a separate device framework. DR differs on both counts: single Ley 821 intérprete judicial tier only, and no device framework.

5. Chile (ISP). Traductor oficial tier via the Ministerio de Relaciones Exteriores. ISP has published risk-class device rules distinct from medicines. DR posture is closer to a full-bilingual jurisdiction with no such device carve-out.

6. Perú (DIGEMID). Perito judicial sworn tier appointed by the Poder Judicial. DIGEMID has a distinct device framework and clearer risk-class rules than DR devices.

7. Paraguay (DINAVISA). Closest posture to DR: full-confidence-required preclinical translation. Amavita groups DR and Paraguay together as the two Latin American jurisdictions where scientific reports must be Spanish or bilingual across the board.

How to use the comparators. Sponsors filing in the DR after filing in one of these six other jurisdictions should not carry the other jurisdiction's translation posture into the DR project. The DR is its own thing. The Colombia posture will produce a DR pre-clock reject; the Panamá posture will produce a DR pre-clock reject; the México posture will produce a DR pre-clock reject on the device side because México's risk-class shortcuts do not exist in the DR. Only Paraguay's posture transfers cleanly, and Amavita's Paraguay guide handles that comparison in more depth.

Amavita's regional posture map, in one sentence per country, is what sponsors use to sequence their Latin American filings. Sponsors filing in only one country in a given cycle should ignore the map; sponsors filing in three or more should read it before setting the sequence.

A note on the Amavita library. The library is organised country by country, with the DR at the anchor. Sponsors who read the DR guide and then want to compare postures on Panamá, Colombia, or Paraguay should ask Amavita for the parallel guides; the guides share the same section structure so cross-referencing is straightforward.

Regional-filing sequencing recommendation. Sponsors planning a multi-country regional filing across the DR and the six comparator jurisdictions above should sequence the DR filing early rather than late. The DR's full-confidence-required posture forces the sponsor to produce a decree-compliant preclinical translation that then serves as a strong content baseline for filings in the more permissive jurisdictions. Filing Colombia first and DR second wastes translation work; filing DR first and then rolling forward wastes very little.

About the Author

Julio G. Martinez-Clark is the CEO of bioaccess®, a Latin American clinical-research operations firm, and the founder of Amavita Sciences™, the clinical-language and regulatory-translation arm serving Latin American filings for medicines, biologics, and medical devices. He has led Latin American clinical operations for over two decades and has personally supervised regulatory-translation deliverables into every major Latin American jurisdiction, including the Dominican Republic under Decreto 246-06.

Julio's work in the Dominican Republic dates to the pre-2015 DGDF era and covers the deconcentration transition under Decreto 231-23, the emergence of the CONABIOS 2ª edición Manual under Resolución 02-24, and the 2025 fee-and-cadence realignment across CONABIOS resolutions 01-25, 02-25, and 03-25. Amavita Sciences™ was founded to codify the delivery standards that Julio developed running DR, Panamá, Paraguay, and Colombia programs at bioaccess®: page-parallel bilingual layouts, seven-gate QC, intérprete-judicial-queue-first sequencing, and terminology-freeze glossaries.

bioaccess® remains the clinical-operations sister brand and runs first-in-human, feasibility, and pivotal studies across Latin America. Amavita Sciences™ runs the language and regulatory documentation layer for those studies and for outside sponsors. The two brands share a delivery philosophy: nothing goes out that a decree-level reviewer would push back on.

Editorial stance of this guide. This guide is written to be the DR guide Amavita would want to read if it were a sponsor starting from scratch. It is not a marketing document dressed as a guide. Every statutory citation is verifiable at the URLs printed; every fee and every timeline traces to a DIGEMAPS or CONABIOS published source or a resolution promulgated by the responsible authority. Where Amavita has an opinion — for example, on the risk of taking the simplified procedure as a translation shortcut — we say so and mark it as opinion rather than statute. The guide will be updated when Decreto 246-06 is amended, when the Reglamento Técnico de Productos Sanitarios is finally enacted, when the CONABIOS 1 September 2026 cliff arrives, or when any other DR authority publishes a change that materially affects the translation workflow. Sponsors who reference this guide inside their own SOPs should timestamp their reference; regulatory guides age fast in the DR right now.

Dominican Republic submission on your calendar?

If your next DR filing crosses the 1 September 2026 CONABIOS certification cliff, or if your CTD includes toxicology and pharmacology reports that would fall under Decreto 246-06 Art. 39, Amavita Sciences™ can start a pilot on your dossier this week. Our First-Pass Acceptance Program is a fixed-fee delivery, priced at $2,500 per business-day, that produces a decree-compliant, intérprete-judicial-signable bilingual dossier engineered against every one of the seven QC gates described in Section C.

The Dominican Republic is not the country to test whether a translated summary will pass. Decreto 246-06 Art. 39 has been continuously in force since 2006. The 1 September 2026 CONABIOS cliff is 12 months out. Sponsors who begin the intérprete-judicial and CONABIOS-certification legwork now file on time. Sponsors who begin in Q2 2026 do not.

Two operational takeaways. First, if your DR site's ethics committee has not begun the CONABIOS certification process, that work starts today, not next quarter. The certification process takes months and Res. 03-25 does not grandfather protocols whose initial review predates certification. Second, if your dossier includes toxicology or pharmacology reports and your CRO is telling you

those reports can be filed in English or as summaries, ask for the statutory citation. There is not one that supports that posture. Art. 39 is the rule.

Start a pilot with Amavita Sciences™.

How the pilot runs. We take one preclinical study report from your dossier — typically the 90-day repeat-dose toxicity or the 26-week chronic — and translate it end-to-end into DR-decree-compliant page-parallel bilingual format, walk it through seven QC gates, and stage it for intérprete-judicial signature. The pilot output ships in ten business days. You see, on your actual document, what a decree-compliant DR deliverable looks like, what our terminology-freeze glossary produces, how the page-parallel layout preserves table structure, and where your source file has hidden gaps that would have driven a pre-clock reject.

Why we price on business-days and not on words. The DR obligation is not a translation-price problem. It is a delivery-standard problem. Amavita's $2,500/business-day pricing includes the seven-gate QC, the terminology-freeze against the DR glossary, the intérprete-judicial coordination, the page-parallel formatting, and the currency-window management at close. Word-rate pricing collapses under the weight of the delivery standard; business-day pricing aligns your budget with the actual output you need.

Sponsors we serve on DR. First-in-human device sponsors staging a CONABIOS submission for a 2026 site. Small-molecule sponsors filing DIGEMAPS market authorization under Decreto 246-06. Biotech sponsors testing the Res. 000018-16 §8.3.1 waiver eligibility. CROs whose DR partner has flagged translation quality as a bottleneck. Academic ethics committees in the CONABIOS-certification pipeline ahead of 1 September 2026.

One conversation before you file. Even if you do not run a pilot with Amavita, run the one-conversation-before-you-file check with someone who knows the DR system. Ask them to confirm, on paper: (1) Art. 39 governs your preclinical dossier, (2) the intérprete-judicial tier is the only one that clears DIGEMAPS scientific-report filings, (3) the CONABIOS 1 September 2026 cliff applies to your DR sites' ethics-committee posture, and (4) your fee-and-cadence budget matches Res. 01-25. If the person you ask cannot answer those four questions in one sentence each, they are not the person who should be advising you on your DR filing. Amavita answers those four questions on every intake call.

Closing note. The DR sits inside a two-year policy arc that has moved harder than any comparable period since Decreto 246-06 was promulgated in 2006. That arc is coherent: DIGEMAPS given autonomy, CONABIOS elevated by decree and given fee-schedule authority, ethical review consolidated under a certification framework by September 2026. Sponsors reading the arc correctly should be pricing DR filings up, not down. The translation obligation has not softened; the enforcement apparatus has hardened. Amavita's positioning as the DR translation-and-regulatory-language specialist is a bet that sponsors who do the work now, at a delivery standard that matches Decreto 246-06 Art. 39, will file on time and clear intake on first submission. Sponsors who do not do that work now will file late and clear intake on the second or third attempt. The gap between the two outcomes is measured in months of program time. Amavita's job is to close that gap on your behalf.

Contact. To open a DR pilot conversation, reach Amavita Sciences™ through the bioaccess® channel at jmclark@amavitasciences.com. Include your target filing month, your dossier size in pages, and the specific preclinical reports you plan to file. We reply inside one business day with a scoped pilot proposal on the $2,500/business-day First-Pass Acceptance Program.

Guide version. This guide reflects the DR regulatory environment as of the fourth quarter of 2026, including Resolución 03-25 and its 1 September 2026 committee-certification cliff. Future amendments to Decreto 246-06, enactment of the Reglamento Técnico de Productos Sanitarios, or new CONABIOS resolutions will trigger a guide update. Sponsors who want to be notified of guide updates should tell Amavita at intake.

One last read on the DR. Two decades of continuous Decreto 246-06 practice, ten years of unfulfilled device reglamento, one year to the CONABIOS committee-certification cliff. That is the DR in three sentences. Sponsors who take those three sentences seriously build DR filings that clear intake on first attempt. Sponsors who do not take those three sentences seriously build DR filings that do not. The choice is not Amavita's to make; it is yours.

Amavita Sciences™. bioaccess®. Decree-compliant clinical language for Latin America.

— End of guide —

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 **1.1.0**, last updated August 25, 2026. Every substantive change to the DIGEMAPS requirements on this page is recorded below.

v1.1.0 August 25, 2026

- Corrected the scope of the traducción fidedigna clause: Manual V2 §4.1/§4.1(a) attaches to the research protocol only; IB, ICF and supporting documents travel under the Requisitos sheet and Manual §9.2.
- Fixed the Manual V2 edition date (Resolución 02-24 of 12 December 2024, Acta No. 019-2024, printed January 2025).
- Added a Section H action panel for the 1 September 2026 committee-certification cliff, the §4.3(e)(2) preclinical criterion as D.4.1, and a reconciliation of the two published CONABIOS decision timelines.

v1.0.0 August 25, 2026

- Initial publication of the DIGEMAPS (República Dominicana) regulator translation requirements guide.