Ecuador · Spanish · ARCSA

ARCSA Document Checklist for Clinical Trials in Ecuador

A pre-submission checklist covering the required forms, translations, and workflow steps for ARCSA clinical trial and marketing authorization dossiers. Use this to scope a pilot or QC a package before filing.

1. Required forms and administrative documents

- Solicitud de autorización de estudio clínico (ARCSA application form), signed by the local sponsor representative.
- Power of attorney (poder) naming the local regulatory representative — apostilled if issued abroad.
- Sponsor authorization letter and CV of the coordinating investigator.
- CEISH approval letter from an accredited ethics committee (Comité de Ética de Investigación en Seres Humanos).
- Insurance certificate covering trial subjects in Ecuador with local coverage confirmation.
- Good Manufacturing Practice (GMP) certificate and Certificate of Pharmaceutical Product (CPP) for the investigational product.
- Proof of ARCSA fee payment (comprobante de pago).

2. Translations required in Ecuadorian Spanish

- Clinical trial protocol and any amendments.
- Investigator's Brochure (IB) with all appendices and safety updates.
- Informed Consent Form (ICF) and any assent forms, adapted to Ecuadorian reading level and site details.
- Patient-facing materials: diaries, questionnaires, recruitment ads, visit cards.
- Safety narratives, SAE reports, and DSUR summaries.
- Product labeling, Instructions for Use (IFU), and packaging inserts.
- Case Report Form (CRF) headers and any subject-facing CRF sections.

3. Certification and legalization

- Legal instruments (POA, contracts, sponsor declarations) translated by an official translator recognized in Ecuador.
- Foreign public documents apostilled under the Hague Convention; consular legalization only when the origin country is not a Hague party.

- Technical documents prepared by qualified medical translators and reviewed by clinicians familiar with Ecuadorian regulatory usage.
- Translator certification statement attached to each translated legal document.

4. Submission workflow

- Confirm local sponsor and regulatory representative are registered with ARCSA.
- Obtain CEISH approval before submitting to ARCSA — ARCSA will not open review without it.
- Compile the dossier in the ARCSA-required order with a table of contents in Spanish.
- Submit through the ARCSA electronic portal (VUE) with paginated PDFs and matching filenames.
- Track observaciones and respond within the ARCSA-defined window; keep a versioned translation log.
- Notify ARCSA of protocol amendments, SUSARs, and annual safety reports in Spanish on the required timelines.

5. Common failure modes to QC before filing

- Inconsistent INN usage across protocol, ICF, IB, and labeling.
- Dosing, units, or abbreviations rendered literally from English instead of Ecuadorian prescribing usage.
- ICF written above the expected reading level or leaving English placeholders in site/contact fields.
- Missing appendix translations (questionnaires, sample diaries, IFU).
- Apostille attached to the source document but not to its Spanish translation.

Ready to scope your ARCSA pilot? Visit amavitasciences.com/start-your-latam-pilot — timeline in 2 business days.