COMPARISON OF CANADIAN CTA & U.S.

IND SUBMISSION REQUIREMENTS

CLINICAL TRIAL APPLICATION (CTA)	INVESTIGATIONAL NEW DRUG APPLICATION (IND)
Principle New CTA fi led for each trial	**Principle** One IND fi led per product, unless new indications or different route of administration
Review Time 30-day default review for most trials (7-day for Comparative BA and healthy volunteers) • Clarifaxes – respond within 2 calendar days • NSN – Not Satisfactory Notice • NOL – No Objection Letter • CTSI form submitted for each investigator/site	**Review Time** 30-day default review for initial IND filing • Information requests • Clinical Hold • Safe to proceed letter for initial IND (usually) • New investigators submitted as Protocol Amendment
CTA Format Common Technical Document (CTD) submitted as paper copy (including Word and/or pdf fi les on CD)	**IND Format** Old Format "Parts 1 to 10" or CTD (paper or electronic copy)
CTA Content • Module 1: Forms, Protocol, PSEAT-CTA or submission rationale, Investigator's Brochure (IB), Informed Consent Forms (ICF) • Module 2: Quality Overall Summary (QOS; NCE use templates) • Module 3: Quality documents for biologic • Canadian signature on forms	**IND Content** • Parts 1 to 10 or CTD Modules 1 -5 (forms, Protocol, IB, CMC, all pharm/tox and clinical reports must be submitted) • If draft nonclinical reports submitted, final audited reports should be available within 120d • U.S. Agent signature (requires physical location in US)
New Protocol Any new Protocol requires filing of new CTA	**New Protocol** New protocols (Phase I, II or III) added to IND as Protocol Amendment
CTA Amendments (CTA-A) • Protocol Changes (e.g., inc/exc criteria, safety or risk, duration) • New CMC (Quality) that may aff ect drug quality or safety • Requires 30-day review period	**Protocol Amendment** • New protocol, Protocol changes, New investigator • Administrative changes may not need submission • Can be initiated after submission to FDA and IRB approval
CTA Notifications (CTA-N) • Minor changes to protocol or CMC, study closure • Notify within 15 days of change	**Information Amendment** • CMC, nonclinical or clinical information • Everything else
Annual Report NOT required. Instead submit IB update annually, as a CTA-N. Pharmacology/Toxicology and Clinical information is only contained in the IB	**Annual Report** Required
Labeling Both French and English required "Investigational Drug: To Be Used By Qualifi ed Investigators Only" and "Drogue de recherche: Réservée uniquement à l'usage de chercheurs compétents".	**Labeling** "Caution: New Drug-Limited by Federal (or United States) law to investigational use."
Lot Release Required for Biologics submit "Fax-Back Form" for each lot	**Lot Release** Not required
Record Retention 25 years	**Record Retention** 2 years post-market approval or 2 years after FDA notified

FOR MORE INFORMATION

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