

# REGULATORY PATHWAYS BY REGION

## Comparative Table



ALTASCIENCES

Altasciences' regulatory experts partner with drug developers from the earliest stages of drug development planning to ensure a clear, efficient path toward clinical trials and beyond. Through strategic regulatory pathway assessments, gap analyses, and tailored development plans, our team identifies the most appropriate route while proactively addressing potential risks and requirements.

To support informed decision-making across regions, **this infographic provides a comparative overview of key health authorities**, highlighting their respective ethics and regulatory submission processes for early-phase clinical trials. By aligning requirements side by side, it offers a clear snapshot of similarities, differences, and critical considerations involved in navigating global regulatory pathways.

	EUROPE	UNITED KINGDOM	UNITED STATES	CANADA	AUSTRALIA
<b>Submission Process</b>	Single harmonized CTA per trial submitted via the EU Clinical Trial Information System (CTIS) portal with regulatory and ethics reviews.	Single CTA per trial submitted to the MHRA and REC via the Integrated Research Application System (IRAS) portal with regulatory and ethics reviews.	Complete IND filed to FDA per product development program, submitted via the ESG.  Separate ethics submission to site or private IRB; submissions can be done in parallel.	CTA per trial to Health Canada via email or ESG.  Separate ethics submission to private REB; submissions can be done in parallel.	CTN scheme: upon determination of eligibility with HREC, CTN is submitted to HREC and TGA is notified.  CTA Scheme (mandatory for Class 4 Biologics): TGA review of preclinical and CMC data, and HREC review of the clinical trial protocol.
<b>Regulatory Submission Fees</b>	Yes	Yes	No	No	Yes
<b>Review Time</b>	<ul style="list-style-type: none"> <li>60 calendar days</li> <li>75 days with validation issues</li> <li>106 days with validation issues and RFI</li> <li>50+ days for advanced/gene therapy programs</li> <li>RFI: responses within 12 days</li> </ul>	<ul style="list-style-type: none"> <li>47 calendar days for initial outcome and information requests issued</li> <li>up to additional 90 calendar days for xenogenic cell therapy products</li> <li>Information requests: response within 60 calendar days (sponsor driven)</li> </ul>	<p>IND:</p> <ul style="list-style-type: none"> <li>30 calendar days</li> <li>Information requests: response within 2-5 calendar days</li> </ul> <p>IRB:</p> <ul style="list-style-type: none"> <li>5 business days (meeting every working day)</li> </ul>	<p>CTA:</p> <ul style="list-style-type: none"> <li>30 calendar days</li> <li>RFIs: response within 2 calendar days</li> </ul> <p>REB:</p> <ul style="list-style-type: none"> <li>5 business days (meeting 3 times a week)</li> </ul>	<p>HREC:</p> <ul style="list-style-type: none"> <li>-30-60 calendar days with clock stop(s) upon issuance of information request</li> </ul> <p>TGA:</p> <ul style="list-style-type: none"> <li>-35-50 days in parallel or sequential to HREC</li> </ul>
<b>Review Decision</b>	<ul style="list-style-type: none"> <li>Authorized</li> <li>Authorized subject to conditions</li> <li>Refused</li> </ul>	<ul style="list-style-type: none"> <li>Accepted</li> <li>Accepted, subject to conditions</li> <li>Grounds for non-acceptance</li> </ul>	<ul style="list-style-type: none"> <li>Safe to proceed letter for initial IND</li> <li>Clinical hold (undefined period, depends on response to information requests)</li> </ul>	<ul style="list-style-type: none"> <li>NOL (No Objection Letter)</li> <li>Withdrawal without prejudice</li> <li>NSN (Non-Satisfactory Notice)</li> </ul>	<ul style="list-style-type: none"> <li>Approved</li> <li>Approved, with conditions</li> <li>Deferred</li> <li>Not approved</li> </ul>
<b>Submission Content</b>	<p>Part 1: Cover letter, application form, protocol, IB, GMP compliance statement, IMPD, scientific advice and pediatric plan, labels, proof of payment.</p> <p>Part 2: Recruitment materials, ICFs and consent process, suitability of facilities, insurance, site contract.</p>	<p>Part 1: Cover letter, application form, protocol, IB, GMP compliance statement, manufacturer's authorization, IMPD, scientific advice and pediatric plan, labels, proof of payment.</p> <p>Part 2: Recruitment materials, ICFs and consent process, suitability of facilities,</p>	<p>IND in eCTD format:</p> <ul style="list-style-type: none"> <li>Module 1 administrative documents</li> <li>Module 2 nonclinical summaries, clinical</li> <li>Module 3 CMC sections</li> <li>Module 4 nonclinical reports</li> <li>Module 5 protocol, ICFs, investigator qualification and statement</li> </ul> <p>Ethics: Protocol, IB, ICFs, recruitment materials</p>	<p>CTA: Cover letter, application forms, protocol, IB, ICFs, quality overall summary (QOS) or IMPD.</p> <p>Ethics: Protocol, IB, ICFs, recruitment materials.</p>	<p>CTN scheme: Cover letter, application forms, protocol, IB, ICFs, recruitment materials, safety monitoring plan, ethics approval letter.</p> <p>CTA Scheme: Cover letter, application forms, protocol, IB, ICFs, recruitment materials, safety monitoring plan, CMC data, nonclinical data, ethics approval letter.</p>
<b>Annual Report</b>	DSUR	DSUR	FDA: DSUR or IND Annual Report Ethics: Not required	Health Canada: Not required Ethics: Not required	CTN scheme: HREC progress report CTA Scheme: DSUR, HREC progress report

*\*IND (Investigational New Drug), CTA (Clinical Trial Application), IRB (Institutional Review Board), IB (Investigator's Brochure), ICF (Informed Consent Form), RFI (Request for Information), MHRA (Medicines and Healthcare products Regulatory Agency), REC (Research Ethics Committee), REB (Research Ethics Board), CTN (Clinical Trial Notification), HREC (Human Research Ethics Committee), TGA (Therapeutics Goods Administration), CMC (Chemistry, Manufacturing, and Controls), eCTD (Electronic Common Technical Document), ESG (Electronic Submission Gateway), IMPD (Investigational Medicinal Product Dossier), DSUR (Development Safety Update Report).*

## Not sure which regulatory pathway is right for your program?

Whether you're preparing your first submission or optimizing your global regulatory strategy, our experts are here to help. Reach out to discuss how we can guide you toward the right regulatory pathway.

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