

REGULATORY COMPARISONS OF IND AND CTA SUBMISSIONS



Submission Principles

EUROPE

Single harmonized CTA per trial submitted via the EU Clinical Trial Information System (CTIS) portal with regulatory and ethics reviews.

UNITED KINGDOM

Single CTA per trial submitted to the MHRA and REC via the Integrated Research Application System (IRAS) portal with regulatory and ethics reviews.

UNITED STATES

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.

CANADA

CTA per trial to Health Canada via email or ESG.
Separate ethics submission to private REB; submissions can be done in parallel.

AUSTRALIA

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.

REGULATORY COMPARISONS OF IND AND CTA SUBMISSIONS



Timelines for Full Application Review

EUROPE

60 days to as many as **106 days**, if information requests;
110 to 156 days for advanced/gene therapy products

UK

47 days to as many as **107 days**, if information requests;
up to **137 days** for xenogenic cell therapy products

AUS

30 to 60 days with clock stops,
if information requests

U.S.A.

30 days

CANADA

30 days