Similarities and Differences Between the CTA and IND

Deciding to submit a Clinical Trial Authorisation (CTA) or Investigational New Drug Application (IND) is a significant milestone in developing a new drug, biologic, or vaccine. Suppose the goal of a development program is to initiate clinical trials within European member states, the United Kingdom, or North America. In that case, strategic consideration to how, when, and whether to submit a CTA or IND is critically important.

Consider the purpose, content, and procedural similarities and differences between the CTA and IND.

THE PURPOSE OF CTA AND IND

Clinical Trial Authorisation (CTA)

for EU & UK

The CTA provides part of the pathway by which new medicinal products can obtain a Marketing Authorisation Application (MAA) from a regulatory agency and become available for use as a new treatment in patients.

Investigational New Drug Application (IND)

for US FDA

Legal Purpose

An IND is the mechanism to allow investigational drug to be transported across state lines.

Practical Purpose

The primary purpose of an IND is to allow initiation of clinical testing within the United States, with a passive approval process.

THE CONTENTS OF THE CTA VS. IND

CTA			Common Technical Document (CTD)	IND		
Cover letter, CT application & form (EudraCT)	IB / replacement document	IMP Labelling (Annex 13) (536/2014 Annex VI)*	**M1** Administrative information	IND cover letter & forms (1571 & 3674)	Investigator's Brochure (IB)	IMP Labelling (21 CFR 201.56 and 201.57)
			M2 Summaries	All relevant summaries needed		
IMPD (Full or Simplified)		GMP-related documents	**M3** Quality	Full 3.2.S and 3.2.P		
			M4 Non-clinical Study Reports	Non-clinical reports {SEND datasets}		
Study protocol		Site-specific documents	**M5** Clinical Study Reports	Study protocol	Clinical Study Reports (if complete)	Form 1572
£ € Fees Translation Services		• CESP, Eudralink or local portal • EMA Clinical Trials Information System (CTIS)	**Additional information**	$ No Fees		Submitted eCTD

PROCEDURAL COMPARISON OF CTA VS. IND

	CLINICAL TRIAL AUTHORISATION (CTA)	INVESTIGATIONAL NEW DRUG APPLICATION (IND)
How is the CTA or IND approved?	CTA is either approved or rejected (grounds for non-acceptance).	INDs are cleared (30-day review period).
Summary of content	CTA consists of concise summary documentation. List of Core Documents Required for the Initial Trial Application: 1. Clinical trial application cover letter 2. Clinical trial application form 3. Study protocol 4. Investigator's Brochure (IB) 5. GMP-related documents 6. Investigational Medicinal Product Dossier (IMPD) 7. Drug labels 8. Evaluation fees	IND includes summaries and individual reports. List of Core Documents Required for the IND: 1. Cover Letter 2. Forms (1571; 3674) 3. Investigator's Brochure (IB) 4. General Investigational Plan 5. Investigational Drug Label 6. Module 2: Summaries 7. Module 3: DS and DP Sections 8. Module 4: Non-clinical study reports and SEND datasets 9. Module 5: Protocol, 1572, CV for Investigator(s)
How are amendments handled?	• Substantial amendments must be submitted for "approval." • Non-substantial amendments can be submitted as a notification or submitted with a subsequent substantial amendment.	• INDs are "amended" throughout their lifecycle. • If FDA has concerns, the IND can be put on clinical hold (Partial or Full), until concerns are addressed.
Meetings with regulatory agency	Pre-submission meetings can be requested.	Pre-IND meeting for drugs & biologics with FDA are optional. (Veristat highly recommends them.)
Fees for submission	Fees may apply to each meeting and CTA submission.	No cost to submit meeting request, IND or amendments.
How is each submitted?	In accordance with The Clinical Trial Directive 2001/20/EC, CTA submission are conducted per local member state requirements. Centralised EU Portal: It is intended that the CTIS* will "go live" on 31 January 2022. UK Portal: For the UK as of 1 January 2021, CTAs are submitted via the MHRA Submission portal.	FDA requires electronic submission via their Electronic Submissions Gateway (ESG).

*The Clinical Trial Regulation (EU) No. 536/2014 was adopted and entered into force in April 2014. However, the timing of its application depends on confirmation of full functionality of the Clinical Trials Information System (CTIS). The CTIS will contain the centralised EU portal and database for clinical trials foreseen by this Regulation. This new CTIS system will harmonise electronic submission and assessment process for clinical trials conducted in multiple Member States.

Meet Veristat – Getting It Right, the First Time

We understand that the stakes are high and submitting your CTA and/or IND might be the next critical milestone in your clinical development program. To give you an advantage, Veristat has assembled a team of scientific-minded experts that is adept at preparing for and writing your CTA or IND.

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