IND PROCEDURES
Regulatory Assistance

The US law requires that a drug be the subject of an approved marketing application before it is transported across state lines, e.g. to clinical investigators. The IND is the way for the sponsor to get this exemption from the FDA. So, before a new drug in a preclinical development status can be used for clinical studies, an IND has to be submitted.

IND Lifecycle summary

Steps	Regulatory Activity		Description	Regulatory timings
IND Application	1. PRE-IND MEETING		This is an opportunity for sponsors/ investigators to **gain valuable feedback on the data necessary** to warrant IND submission.	Scheduled Meeting Date: 1 - 4 months from receipt of request
	2. IND SUBMISSION		The **FDA** has an opportunity to **review the IND for safety** to assure that research subjects will not be subjected to unreasonable risk. FDA reviewers may request information during the review period and the Sponsor is expected to respond quickly with answers.	30 days FDA review
	3. REVIEW OUTCOMES	ACTIVE	**Some review divisions** may issue a "safe to proceed letter". Otherwise, "no news is good news".	0 days
		CLINICAL HOLD	- **Full Clinical Hold:** A delay or suspension of all clinical studies under an IND. - **Partial Clinical Hold:** A delay or suspension of only part of the clinical studies under an IND.	30 days FDA revision after receipt of the response letter addressing the clinical hold deficiencies
Once the IND is active:				
IND Maintenance Activities	AMENDMENTS		- **Protocol Amendments:** new protocols, changes in protocol or new investigators. - **Information Amendments:** new toxicology, chemistry (CMC) or other technical information or discontinuance of a clinical investigation.	Submission within 30 days
	SAFETY REPORTING		Serious and unexpected **adverse reactions must be reported.**	Submission no later than 7-15 days
	ANNUAL REPORTING		Report of the **progress of the investigation.** The annual report can be satisfied by submission of a DSUR.	Submission within 60 days of the 1-year anniversary of IND effective date

ASPHALION
Knowledge from experience

Regulatory Services

We can support you throughout the whole lifecycle of the IND procedure in a variety of activities:

- eCTD publishing of initial submissions
- eCTD publishing of maintenance activities:
  - Protocol Amendments
  - Information Amendments
  - Annual Reports
  - IND Safety reports
- Document formatting following FDA specifications
- Personalized templates
- eCTD Submission trough FDA Electronic Submissions Gateway (ESG)

EXTEDO
eRegulatory Affairs

Regulatory Solutions for US FDA INDs

- eCTDmanager: eCTD compilation and publishing for all US FDA submissions, including INDs.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.
- SafetyEasy: It handles the reporting and management of all serious and non-serious adverse events, including DSUR documentation.

For further information, please contact:
ectd@asphalion.com | info@extedo.com