

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. | 30 days FDA revision after receipt of the response letter addressing the clinical hold deficiencies. |
| | | | - Partial Clinical Hold: A delay or suspension of only part of the clinical studies under an IND. | |
| | 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 daysed. | |
| | 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 | |



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 through FDA Electronic Submissions Gateway (ESG)



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.