

Multiple documents are examined by the regulatory authority prior to granting approval for clinical study or marketing. These documents are evidence that the product development was undertaken in compliance to regulatory guidelines that ensure the safety and quality of the formulation for sale in the specific marketing country.

For initial approval, sponsors are required to prepare huge multiple dossiers for regulatory submission which involves a lot of co-ordination with the participating sites. Once these initial study approval dossiers are submitted, the Indian regulatory authority (DCGI) gives their feedback in the form of Approved, Rejected or Additional Data Required.

**To help sponsors get quick approvals MED DEVICES provides the following services:**

- Interaction with regulatory agencies
- Direct interaction with FDA / DCGI with efficient communication saves crucial time for the project Knowledge of current regulations and understanding of regulatory environment ensures smooth and efficient drug development process
- DCGI approvals for clinical trials
- Review and preparation of efficacy and safety data from preclinical/animal / clinical studies for presentation to DCGI Faster approvals of clinical trial protocol from DCGI
- IND / Drug registration.
- In parallel to these regulatory submissions, EC submissions are carried out at various sites. With the help of experienced, full time clinical research coordinators we help the investigators with all the ethical committee submissions, documentation and safety reporting following strict timelines.
- Master File Maintenance
- Review of Site's Essential Documents

