

## **Submission of Clinical Trial Documents for IHEC Approval**

- **Protocol**
- **Investigator's brochure**
- **Informed Consent Form**
- **Patient Information Sheet**
- **Case Report Form**
- **Clinical Trial Agreement**
- **DCGI approval letter**
- **CTRI registration details**
- **Certificate of insurance**
- **Investigator's CV**
- **Investigator's undertaking document**