# US Drug Approval Process

BRIJIX Medical Consulting

**Discovery** → **Preclinical** → **IND** (30 days) → **Phase I** → **Phase II** → **Phase III** → **Data Analysis NDA prep.** → **NDA** → **Marketing & Post-Marketing**

Medical Expert Meeting

Clinical Strategy Confirmation

pre-IND Meeting (within 60 days of request)

- Substance Characterization
  - Mutagenicity
  - Toxicology
- Manufacturing
  - Quality
  - Stability
- Clinical Planning
  - Protocol
  - Sites and investigators (FDA 1572)
  - IRBs, consent forms

meeting minutes

IND filing FDA 1571

eCTD format

Adverse event reporting

Warning letters
Clinical hold

Safety reports (FDA 3500A, 7 or 15 days)
Protocol amendments (30 d review)
Information amendments

End-of-Phase-II Meeting (60 d request)

- Provide Proof of Concept (efficacy)
- Discuss Phase III design
  - indications
  - dosing
  - safety
  - manufacturing

DB lock

Pre-NDA Meeting (60 d request)

NDA submission FDA 356h

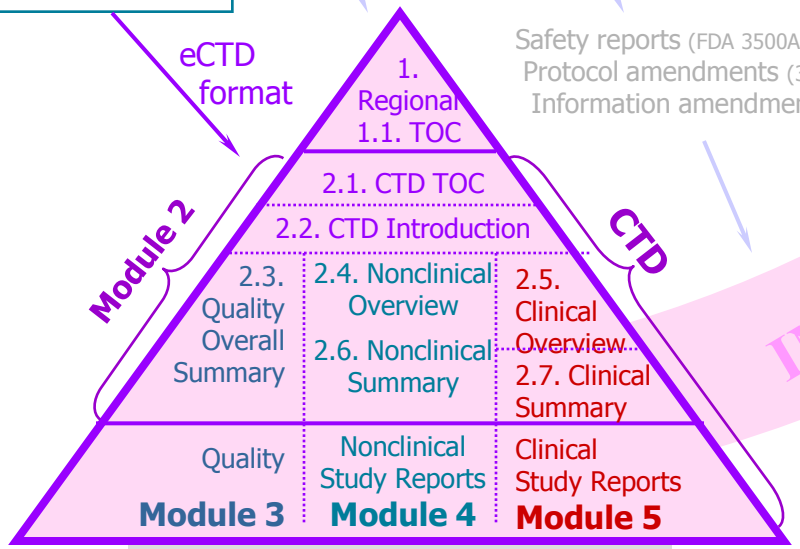
1. FDA accept: 60 d
2. FDA formal review
3. Questions & Answers
4. FDA decision:
   - approval
   - approvable
   - nonapprovable

Adverse Drug Experience reporting:
- Serious/unexpected: 15 d
- Quarterly for 3 years
- Annual reports

Market Placement:
- Reimbursement (CPT code)
- Sales/Marketing
- Partnering/licensing

Annual Reports:
- Individual study information
- Summary information (clinical & nonclin.)
- Investigational plan for coming year
- Changes to Investigator brochure, protocol
- Report of foreign marketing developments

IND Maintenance




PDF on XML backbone