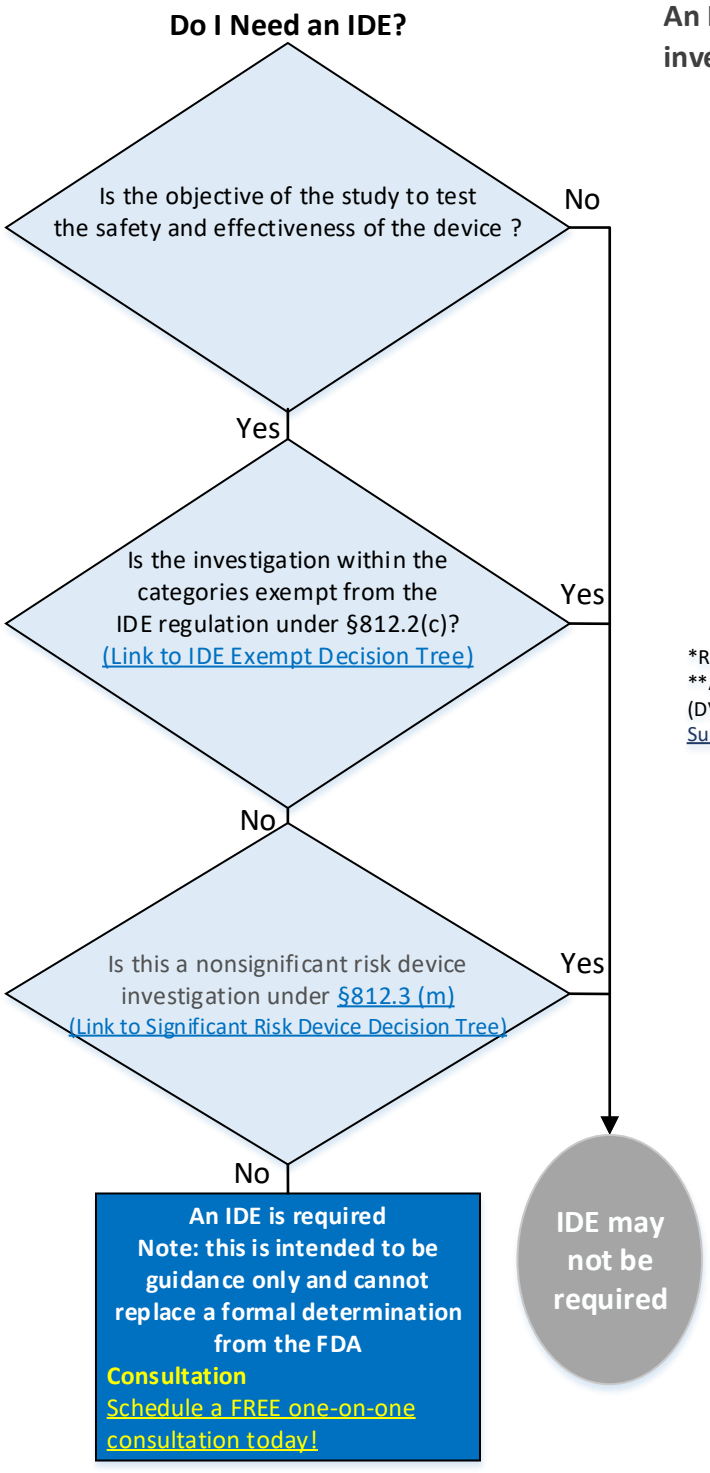
Investigational Device Exemption (IDE) Application Quick Guidance

Do I Need an IDE?



An Investigational Device Exemption (IDE) is a regulatory submission to the FDA that that permits an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Product	Regulatory Oversight Body	Regulatory Pathways	Way to Submit
Device Exempt from IDE	IRB	IRB Approval	
Significant Risk (SR) Device Not Exempt from IDE	FDA and IRB	IDE and IRB Approval Required	Send eCopy** & Cover Letter to CDRH/CBER
Non-Significant Risk(NSR) Device Not Exempt from IDE	IRB	Abbreviated IDE* & IRB Approval Required	

*Refer to Abbreviated IDE Requirements

**An electronic copy (eCopy) is an electronic version of a medical device submission created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive. For details on the eCopy program, including the technical standards for eCopies, refer to the eCopy Program for Medical Device Submission guidance and eCopy Program for Medical Device Submissions

At a GLANCE

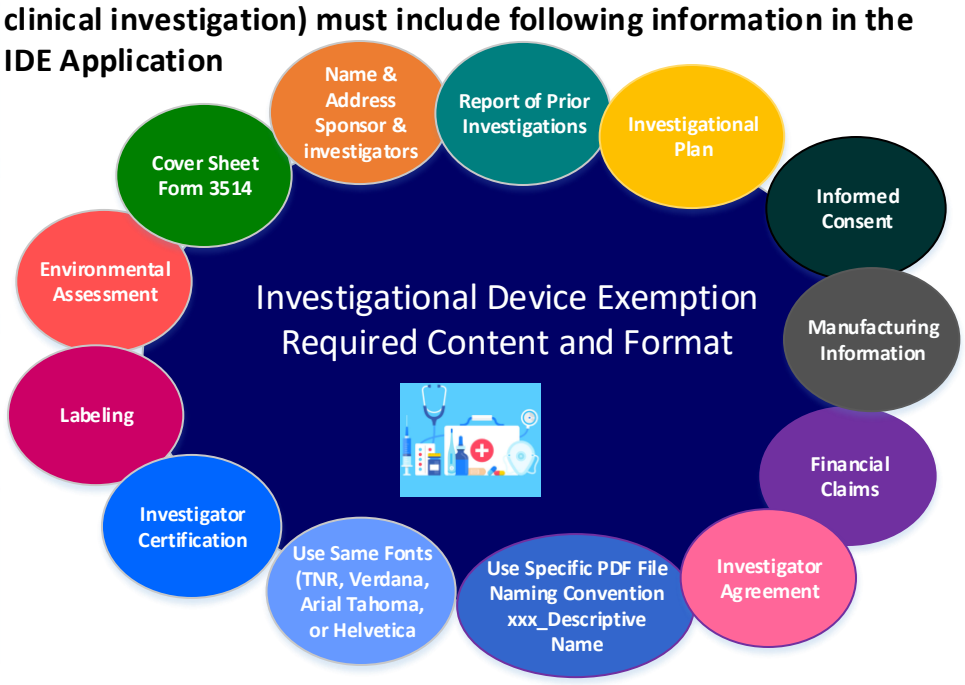
NSR device studies do not need IDE
IRB serves as FDA's surrogate for review and approval

FDA Review Phase
30 days for Response

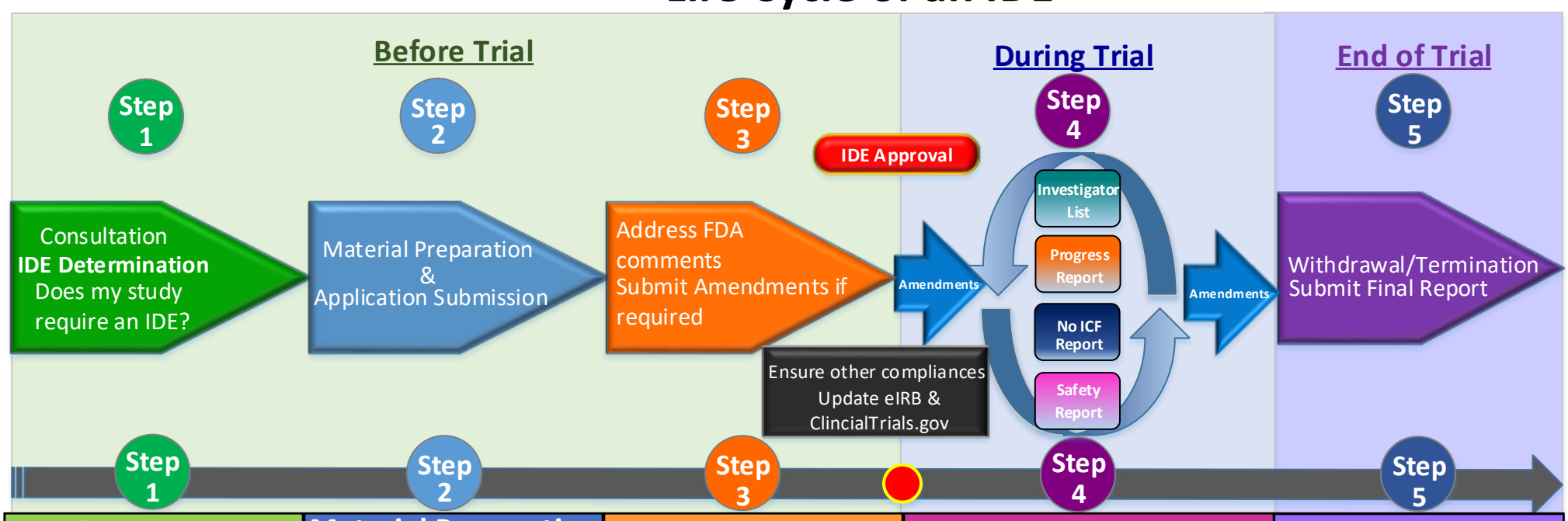
Sponsor will be notified the date FDA receives original application

Possible Responses
Approved
Approved with condition
Staged approval
Disapproved

Sponsor-investigator (an individual who initiate and conducts a clinical investigation) must include following information in the IDE Application



Life Cycle of an IDE



Book one-on-one Consultation

Assigned SI-Support staff help with:

1. Determination of regulatory pathway based on the product classification
   - IDE Exempt Device
   - Significant Device (IDE)
   - Non-Significant Device (Abbreviated IDE)
2. Determination of the Document Control Center (DCC) (CDRH vs CBER)
3. IDE application preparation by providing Templates
   IDE Submission Guidance
4. Preparation of other parallel requirements
   - IRB submission
   - ClincialTrials.gov registration

Material Preparation & Submission

1. Prepare IDE contents using
   - Initial application template
   - Cover Letter template
2. Once completed, contact SI office for review
3. SI staff prepares IDE applications in eCopy using a free eSubmitter-eCopies tool on FDA's website
4. SI staff determines if an eCopy on the CD, DVD, or flash drive meets the technical standards using the free eCopy Validation Module
5. Investigator choses the eCopy media (CD, DVD, or flash drive), then save
6. Investigator attaches a paper copy of signed cover letter to eCopy in CD, DVD or flash drive and send the package to CDER or CBER DCC

FDA Process eCopy

1. DCC staff notifies sponsors the date FDA receives the original application and assigns IDE number
2. DCC staff loads eCopy into the official repository eCopy hold notification (by letter, email, and/or fax) will be sent if an eCopy fails the loading process
3. Respond to DCC staff with
   - Cover letter with a signature
   - Replacement eCopy (full submission # and identify as "replacement eCopy")

FDA Review IDE

Address FDA comments, submit protocol amendment if required
Within 30 Calendar days: FDA will issue
- IDE Approval
- IDE Approval with Conditions
- Staged Approval (with and without Conditions)
- IDE Disapproval

Maintenance

Once IDE is approved, update IDE status in IRB study & ClincialTrials.gov record accordingly

Submit below required IDE reports

IDE Report	Timeline
Protocol Amendment	5 working days
Progress Report	At least yearly
Investigator List	Every 6 months If required
Unanticipated Adverse Effect	10 working days
Failure to Obtain ICF	5 working days
Recall & Device Deposition	30 working days
Determination	5 working days
Investigational Plan	5 working days or pre-approval
IRB Approval	5 working days
Final Report	30 working days

Closing IDE

Withdraw IDE
-If the IDE is not approved
-IDE is approved but no subjects enrolled

Terminate IDE
- IDE is approved, subjects are enrolled, but study is terminated
-FDA may terminate a study, with or without the agreement of the investigator

Submit Final Report within 30 working days of termination/ completion of the study
-When all subjects have reached the end of follow-up