



**FACET**  
LIFE SCIENCES

# POINTS TO CONSIDER WHEN PREPARING FOR AN FDA MEETING

The probability of a “green light” from FDA for your IND is higher if you hold a pre-IND meeting.

If a pre-IND meeting is desired, request the meeting according to Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (December 2017) for drug products

Consider the desired format of your pre-IND meeting with FDA (Call, face-to-face, teleconference/video conference or written response only [WRO]). There are pros and cons for each type.

Prepare and submit the background package according to above guidance. It's best to have a draft of the background package prior to submitting your meeting request.

In your background package, compile and clearly articulate any questions you have.

- Keep questions concise
- Seek concurrence
- Provide background for each question

For the best outcomes, be prepared! Conduct rehearsals prior to the meeting.

- Review questions and FDA preliminary comments with attendees
- Decide which responses require clarification or follow up and assign a lead speaker for each item to be discussed
- Have all attendees take notes during the FDA meeting
- Be sure to submit the Sponsor's meeting summary to FDA within 48 hours of the meeting

DON'T FORGET, FACET IS HERE TO HELP YOU GET TO  
AND THROUGH THE FDA!

[WWW.FACETLIFESCIENCES.COM](http://WWW.FACETLIFESCIENCES.COM)

