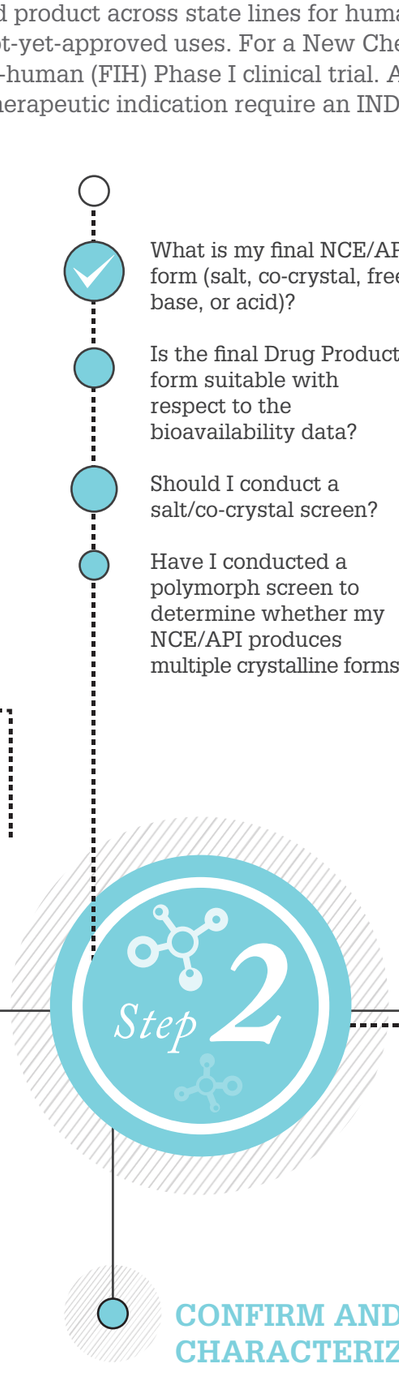
Five Steps You Won't Want to Miss When **Filing an IND**

The US Food and Drug Administration (FDA) requires drug makers to submit an Investigational New Drug (IND) application when shipping an unapproved product across state lines for human clinical trials, as well as for approved products being studied for not-yet-approved uses. For a New Chemical Entity (NCE), filing an IND is the first step towards a first-in-human (FIH) Phase I clinical trial. Active Pharmaceutical Ingredients (APIs) targeting a new therapeutic indication require an IND filing as well.

CLICK THE STEP BUTTONS TO LEARN MORE ABOUT THESE FIVE PIVOTAL STEPS.

CONFIRM CMC ASPECTS AND CLINICAL PROTOCOL AT A PRE-IND MEETING

- Is my regulatory strategy suitable for the target indication?
- Do I have enough GMP steps in my manufacturing process?
- What impurities do I need to identify and characterize?
- Will my clinical protocol meet target objectives?



CONFIRM AND CHARACTERIZE NCE/API CHEMICAL STRUCTURE

- What is my final NCE/API form (salt, co-crystal, free base, or acid)?
- Is the final Drug Product form suitable with respect to the bioavailability data?
- Should I conduct a salt/co-crystal screen?
- Have I conducted a polymorph screen to determine whether my NCE/API produces multiple crystalline forms?

DEVELOP FIT FOR PURPOSE/PHASE APPROPRIATE ANALYTICAL METHODS

- What are my acceptable limits to assure identity, strength, quality, and purity?
- Have I qualified my final test methods?
- Is my NCE/API stable during toxicology and clinical studies?
- Am I using stability indicating method(s) to monitor results during my stability studies?

IDENTIFY FINAL DRUG PRODUCT FORM

- Do I know and can I reproduce my bioavailability data?
- Is the final Drug Product form suitable with respect to the bioavailability data?
- Is particle size of the NCE/API a concern with regards to formulating the Drug Product?
- Should I micronize my NCE/API or consider spray drying or another formulation technique?

MAINTAIN THE IND THROUGHOUT CLINICAL DEVELOPMENT

- Is my process optimized and scalable? Is the final form controlled?
- Have I performed subsequent polymorph screen(s)?
- Has the impurity profile been adequately defined?
- Have I validated my analytical methods?