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Primer
Investigational New Drug (IND) approval is the first step towards being able to begin your clinical trials. Getting here required hard work and a great Pre-IND Meeting strategy. The sooner you can begin your clinical trials, the sooner your product will be on the market, and in order to prevent any hiccups in this process, your final IND

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Drug (IND) Application | FDA

The IND is the means through which you obtain this exemption from the FDA. Most folks prepare and submit IND applications to initiate clinical investigations of a new drug or biologic, but an IND application is also required for a change to an existing approved drug or biologic. This includes new

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indications, significant labeling changes, dosage forms and scheduling, routes of administration, or patient populations (e.g., pediatric, gender).

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FDA Subject:

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The regulation specifies that the CMC section of an IND should describe the composition, manufacture, and control of the drug substance and the drug product.

Uncertainty about how much information needs to be filed with FDA, and when it needs

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to be submitted, can lead to confusion, delays in the development and the clinical trial approval ...

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