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Investigational New Drug Applications (IND)  
The initial IND is a regulatory submission

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that allows a drug company to proceed to the clinical research phase. These applications can easily exceed 10,000 pages and include a variety of multidisciplinary information, including a wide range of non-clinical study reports, manufacturing information, and administrative reports.

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IND Submissions: A Primer was written by  
Meredith Brown-Tuttle, RAC, a regulatory  
consultant whose background incorporates all  
aspects of drug, device and biologics  
development including, clinical research,  
data management, medical writing, and  
regulatory affairs. She served for six years

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IND Submissions: A Primer is the only comprehensive IND manual of its kind. This 600-page, spiral-bound, hardcover book is easy to use, providing step-by-step instructions on how to plan, write, and submit regulatory documents. Each chapter (62 in total) is divided by easy-to-read tabs.

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A Primer is a step by step guide that covers a wide range of topics for IND submissions, starting from style guides, submission planning to publishing. IND submission process starts with a pre IND meeting with the FDA. The writing and compilation of various sections of the IND follows. There is also a section on writing amendments to an IND.

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

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Get to know the investigational new drug application (IND). This includes the types, laws and regulations, and emergency use of INDs.

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A regulatory submission for a healthcare

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product includes any documentation or information submitted to a regulatory agency for review, for notification or in response to a request for additional information related to a healthcare product. The format can be paper or electronic, or both. The amount of information involved and its required complexity can vary significantly.

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Regulatory submissions for healthcare products: A primer follows there is also a section on writing amendments to an ind ind submissions a primer

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An Investigational New Drug (IND) sponsored by a corporate entity is considered as a 'Commercial IND.' Center for Drug Evaluation and Research (CDER) has the authorization to designate IND as commercial if it finds the

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intent to commercialize the drug in future.  
In the United States, INDs must be registered  
with the Food and Drug Administration (FDA).  
As part of the implementation of FDA ...