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IND is a regulatory submission 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,

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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

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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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How To Ace Your FDA IND Submission (And How To Rebound If ...

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