

**Successful Investigational New Drug Preparation without Reinventing the Wheel.**

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**Public Summary:**

The biotech industry is the usual venue of new drug development, with costs estimated between \$500 million and \$2 billion per drug developed (Adams and Brantner, 2006). Occasionally, members of an academic medical community may choose to develop a new drug within their own institution because they are focused on an orphan disease and/or their new therapy may lack a successful financial model. The Dermatology Department at Stanford University School of Medicine has focused on creating a successful treatment for epidermolysis bullosa since 1988. Support for this process has come from philanthropy (<http://www.ebkids.org>) as well as federal and state funding. During this process, we have learned that most academic medical centers do not prepare faculty for the challenges of developing new drugs. The focus of this Editorial and the Supplementary Material online is to review the process for beginning a clinical trial for a new drug product in the United States. Major goals include Investigational New Drug (IND) approval and completion of multiple clinical trials, with a final goal of New Drug Application (NDA) approval, allowing the drug to be prescribed, sold, and marketed within the United States (FDA, 2010a, 2010b).

**Scientific Abstract:**

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