



Pharmaceutical Industry Collaborations

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CALGB Group Meeting, June 2005

Overview

- Central Office role in industry relations
 - INDs
 - Supply of study drugs
 - Distribution of study drugs
 - Release of information to industry
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Central Office Role

- Communications with industry go through the Central Office.
 - Such communications include:
 - Determination of the need for an IND
 - Agreements to provide drug
 - Contracts to provide funding
 - Development of a mechanism for drug distribution
 - Provision of information to industry
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When Do We Need an IND?

(FDA Guidance, September 2003)

- For any investigational agent, for which the NCI does not hold an IND
 - For commercial agents being used for an unapproved indication and supplied by industry if one or both of the following are true:
 - study is being conducted with the intention of registration for a new indication
 - dose, regimen, or population under study is such that risks are expected to be significantly increased
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Notes About CALGB INDs

- For our purposes, an IND involves cross-referencing the IND of the manufacturer.
 - The IND holder (i.e. sponsor) is CALGB.
 - The “responsible person” is the Group Chairman.
 - INDs do not cover the (unapproved) use of the drug outside of the U.S.
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Clinical Trial Application (CTA)

- The CTA is the “Canadian version” of the IND; it is required for any drug used outside of the approved indication(s) in Canada.
 - NCIC CTG files the CTA for CTSU trials they have endorsed (i.e. those for which 10% of total accrual is expected to come from Canadian sites).
 - Canadian sites must register through NCIC CTG.
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Provision of Study Drugs

- Pharmaceutical companies may (directly) provide drug for use in a particular study
 - CALGB holds the IND
 - IND exempt
 - Provision of commercially available drug when 3rd party payers are unlikely to reimburse or when there is no 3rd party coverage
 - Study drug is provided pursuant to a letter of agreement between the company and CALGB
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Distribution of Study Drugs

- Currently, the CALGB has no distribution mechanism of its own.
 - The NCI usually doesn't distribute drugs for which it does not hold an IND.
 - The pharmaceutical company providing a drug will generally be expected to distribute the drug to institutions.
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Release of Information to Industry

- Regulatory information and adverse event reports may be provided as described in the letter of agreement and protocol.
 - Requests for information about accrual, drug supply, etc. should be directed to the Central Office.
 - Progress reports from the CALGB Agenda Books are provided to industry.
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Release of Information to Industry

- Release of efficacy data on phase III studies is under the control of the DSMB.
 - All data (on any phase study) should be released by the Statistical Center. Study chairs should not provide information from forms or flow sheets.
 - Requests for data from previously completed trials (e.g. to support an NDA) require new negotiations with the Central Office and the Statistical Center.
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