



Investigator-Initiated Industry-Sponsored Research Funding

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Bayh-Dole Act

- Sponsored by Senators Birch Bayh of Indiana and Bob Dole of Kansas; was enacted by the United States Congress on December 12, 1980.
- Allows for the transfer of exclusive control over many government funded inventions to US universities and businesses operating with federal contracts for the purpose of further development and commercialization.
- Augmented technology transfer from its investigational origins to applications by the industrial sector
- Facilitated growing collaborations between industry and academic institutions

Biotechnology and Pharmaceutical Companies

- Are interested in all aspects of basic to applied research
- Translational research and clinical projects receive the largest portion of corporate investments
- Support comes in the form of donations, collaborative contracts, and competitive grant awards

Types of Research Eligible for Support by Biotech/Pharmaceutical Industry

■ Academic Non-Human Studies

- Material Requests - often provided free
- Compound Transfer Forms

■ Translational Research

- *In vitro* or animal studies that require funding
- Companies may issue requests for applications (RFAs) in areas of particular interest. RFAs appear on their web site and are advertised in leading scientific journals.

Types of Research Eligible for Support by Biotech/Pharmaceutical Industry

- Clinical studies of approved and unapproved uses, involving approved or unapproved drugs
- Observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease
- Independent research on disease states, including novel diagnostic screening tools (biomarkers) and surveys

Industry will Not Support

- General educational & training activities
- Ongoing clinical / routine programs
- Start-up funds to establish new research programs or expand existing programs
- Purchase of capital equipment not related to the project or that would generate revenue
- Construction
- Hiring of staff not dedicated to the study

Identifying Industry Funding Sources

- Personal Liaison
- Regional Medical Representatives
- Web sites
 - Therapy Area
 - Pharmaceutical Company
 - Professional Organizations

Intellectual Property Considerations

- Work with Tech Transfer to protect IP
 - Thoroughly review “terms of agreement” and contractual details
 - Policies regarding publication
 - Conflict of interest
 - Future obligations

Submission Process

■ Concept

- Sufficient information to determine interest in full proposal
- Including requirements, synopsis, objectives

■ Full

- Detailed budget
- Synopsis, rationale, endpoints
- Statistical methods
- Investigator and Institutional expertise
- Publication plans

Review Process

- Internal review committee
 - Scientific, medical merit
 - Availability of resources
 - Research priorities
- Budget and Overhead Costs
 - Know what the company will not compensate
 - Identify costs excluded from overhead

Requirements for IIR Collaboration

- IRB/Ethics Committee approval
- Regulatory Response Documentation (IND)
- Fully executed IIR agreement
- Final study protocol

Investigator IND

- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- If a pharmaceutical company will be supplying the drug, but will not itself be submitting the IND, the company is not the sponsor.

IND is Not Needed When:

- Product is approved by FDA and being used according to the approved labeling
- Investigation is not intended to be reported to FDA or support any significant labeling or advertising change
- Investigation does not involve a change in route or dosage that changes the risk to the population
- Investigation is conducted in compliance with IRB and Informed Consent regulations
- Cancer Studies of new combinations, new schedules or new routes of administration are exempt if there is sufficient clinical experience described in the literature to determine that the treatment is safe

Study Conduct

- PI is responsible for compliance with all ICH GCP guidelines, applicable local rules and regulations
- Study Registration on clinicaltrials.gov
- Safety Reports

Safety Reporting Requirements

- Report any Serious Adverse Event to industry sponsor (as well as FDA) within 24 hours
- Reporting period – first administration of drug to 28 days following last dose
- PI responsible for all IRB, FDA reporting obligations

Study Closure

- Contract requires submission of final results
- Company review of any publication
- Certification that all safety reporting was completed

Things to consider

- Company is more likely to support projects that will potentially be of value to them – Think: Biomarkers
- Company expects good business practice as well as good science and high standard of clinical practice
- Potential for long-term, mutually beneficial relationship