



Post-Marketing Research Policy

A. OVERVIEW

This policy applies to the United States and covers post-marketing research agreements with customers (including both entities and individuals) and grants to customers, for research performed other than in support of or for the purpose of seeking regulatory approvals. These agreements must be designed to meet a legitimate business or scientific need and may only be entered into in compliance with this policy and the related procedures.

B. DEFINITION

“Customer” includes any healthcare provider and any other person or entity in the position to purchase, prescribe, recommend or arrange for the purchase, sale or formulary placement of Company products, including, but not limited to, physicians and physician groups, hospitals, and pharmacists, as well as any individual employed by such entities in a position to recommend or arrange for the purchase, prescription, or ability to recommend, influence, or arrange for the purchase, sale or formulary placement of pharmaceutical products.

C. LEGITIMATE BUSINESS NEED

For purposes of this policy, a legitimate business/scientific need is a need, defined and documented in advance, for information designed to further scientific advances in which the Company currently has business interest or may have such business interests in the future, including research relating to the use of existing Company products. Securing orders, formulary position or purchases, or encouraging the use of Company products through obtaining access to customers through a research agreement is not a legitimate business need.

D. EVALUATION OF PROPOSED RESEARCH

Any request for a research agreement must be accompanied by a documented, detailed protocol and budget concerning the activities to be undertaken. The following factors must be considered in evaluating any proposed research agreement:

1. **Qualified Investigator** – The proposal must be submitted by, or proposed to be assigned to, an Investigator who is qualified by education and/or experience to carry out the proposed research.
2. **Quality of Research Proposed** – The proposal should be evaluated as to: (a) the scientific merit of the proposal (including the extent to which the proposal advances scientific knowledge); (b) the relevance to areas of interest to the Company; (c) the likelihood to produce useful information not otherwise available; and (d) the scope of the proposed study to assure that its scope does not exceed that needed to produce meaningful results.
3. **Adequacy of Reporting** – The proposal must provide for adequate reporting, including, at a minimum, the submission of annual progress reports, and the

preparation of a written report upon the conclusion of the study. The Company will comply, or arrange for compliance, with FDA's post-marketing study reporting requirements set forth in Section 21 CFR 314.81(b)(2)(viii).

4. **Conformance with Regulatory Requirements** – The proposal, protocol and research support must conform to all applicable FDA and other regulatory requirements, including the Health Insurance Portability and Accountability Act (“HIPPA”) and all adverse event reporting requirements established within the FDA's safety reporting regulations. The research proposal must analyze whether an investigational new drug application is required under FDA regulations, Section 21 CFR 312.2(b).
5. **Alternative Sources** – Because any fee for service arrangement with customers may raise questions under the healthcare fraud statutes that regulate the industry, the availability of such services from a non-customer must be evaluated before a research agreement with a customer is proposed. In addition, prior to proposing to enter into a research agreement that will involve customers, the availability of such information from existing sources must also be evaluated.

E. SUBMISSION OF PROTOCOL

Where support is requested by a physician, the proposal and protocol must be prepared by the physician who intends to act as the principal investigator for the research. Company personnel should not prepare such proposals. No commitments regarding funding may be approved by any Company sales personnel.

F. PAYMENT FOR SERVICES

1. Payment for services must be fair market value compensation linked to the services to be provided.
 - i. In determining fair market value of a proposed fee for a research agreement: (a) the amount must compare favorably with rates paid to non-customers for comparable services, or with rates generally recognized in the industry as fair market value; or (b) the proposed payment must be within a fair market value range as determined by an independent expert in providing fair market value appraisals for research services.
 - ii. The following are not appropriate in determining fair market value: (a) the added value of obtaining the research services from a customer; (b) the purchases expected to be made for by the customer; or (c) whether the customer, or others under his or her direction or control, has influenced or could influence a formulary or procurement schedule decision with respect to products.
2. Payments made under a Research Agreement will be made only if an approved Agreement has been executed and is in compliance with the following:

- i. Payment will only be made where a completed form certifying that the work required for such payment has been performed and is submitted to the Finance Department.
- ii. The Finance Department will issue a payment only by check or wire transfer to the official name and address or account of the party identified in the Agreement. Each check will reference the Agreement under which it is issued.
- iii. Research Agreements must be evidenced by a written agreement that has been approved by the Legal Department.