

General Information:

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Contracting Office Address: Food and Drug Administration, Tara Hobson,
Contract Specialist

Description: Atrial Fibrillation Ablation Registry Study

This is a Request for Information (RFI) to identify the capabilities of the marketplace of all interested parties.

This request is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the Food and Drug Administration (FDA) for any future solicitation. No official solicitation exists; therefore, please do not request a copy of a solicitation. If in the future an official solicitation is released, there is no guarantee that sources responding to this will be included on the source list. Telephone inquiries will not be accepted.

The FDA makes no implied or in fact contract by issuing this RFI. Acknowledgement of receipt of responses will not be made, nor will respondents be notified of the FDA's view of the information received. Do not send any material that requires a non-disclosure agreement or that may be business sensitive. Responses received that include a non-disclosure agreement or identify information that is business sensitive will not be accepted. Responses to this notice will not be returned.

According to FAR Part 10, Market Research, the results of the market research will be used to:

- i) Determine if sources capable of satisfying the agency's requirements exist;
- (ii) Determine if commercial items or, to the extent commercial items suitable to meet the agency's needs are not available, nondevelopmental items are available that—
 - (A) Meet the agency's requirements;
 - (B) Could be modified to meet the agency's requirements; or
 - (C) Could meet the agency's requirements if those requirements were modified to a reasonable extent;
- (iii) Determine the extent to which commercial items or nondevelopmental items could be incorporated at the component level;

- (iv) Determine the practices of firms engaged in producing, distributing, and supporting commercial items, such as type of contract, terms for warranties, buyer financing, maintenance and packaging, and marking;
- (v) Ensure maximum practicable use of recovered materials and promote energy conservation and efficiency; and
- (vi) Determine whether bundling is necessary and justified.
- (vii) Assess the availability of electronic and information technology that meets all or part of the applicable accessibility standards issued by the Architectural and Transportation Barriers Compliance Board at 36 CFR Part 1194.

The extent of market research will vary, depending on such factors as urgency, estimated dollar value, complexity, and past experience. The contracting officer may use market research conducted within 18 months before the award of any task or delivery order if the information is still current, accurate, and relevant. Market research involves obtaining information specific to the item being acquired and should include—

- (i) Whether the Government's needs can be met by—
 - (A) Items of a type customarily available in the commercial marketplace;
 - (B) Items of a type customarily available in the commercial marketplace with modifications; or
 - (C) Items used exclusively for governmental purposes;
- (ii) Customary practices regarding customizing, modifying or tailoring of items to meet customer needs and associated costs;
- (iii) Customary practices, including warranty, buyer financing, discounts, contract type considering the nature and risk associated with the requirement, etc., under which commercial sales of the products or services are made;
- (iv) The requirements of any laws and regulations unique to the item being acquired;
- (v) The availability of items that contain recovered materials and items that are energy efficient;
- (vi) The distribution and support capabilities of potential suppliers, including alternative arrangements and cost estimates; and
- (vii) Size and status of potential sources.

Mission and Objectives:

The FDA anticipates a need to continue the development of an Atrial Fibrillation Ablation Registry. The contractor shall furnish the necessary personnel, material, services, facilities, and otherwise do all things necessary for or incident to creating registries that will be able to assess the prevalence, demographics, management, and outcomes of patients who receive the identified medial devices. In addition the registries

should be able to evaluate the safety and effectiveness of ablation devices in a real-world setting and evaluate the risk of adverse events and device performance in patient subgroups.

RFI Instructions:

Please complete **Part A**, Specification Questionnaire, describing your company's capabilities; **Part B**, Size of Business, and **Part C**, Estimated Dollar Value Range.

Responses shall be:

- identified with the RFI number ;
- no more than ten (10) pages in length;
- not submit marketing materials;
- submitted to the email as indicated above.

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Part A. Technical Capability, Qualifications, and Experience Questionnaire

Specification Questionnaire:

Do you have the expertise in developing national registries on procedures and devices used to treat cardiovascular diseases?

Do you have the experience and personnel needed to develop a database framework and database reporting system?

Do you have the infrastructure needed to develop and test data collection forms?

Do you have the expertise to critically evaluate methods used to collect follow-up information, such as the use of electronic medical records or probabilistic matching?

Do you have the experience organizing and maintaining working groups comprised of a broad array multidisciplinary stakeholders?

Part B. Size of Business

State whether your company is a large business, small business (and also state your under socioeconomic status), College/University, or a non-profit organization.

Part C. Estimated Dollar Value Range

Based on the government's mission, objectives, and scope of work, what dollar value range would you determine to be the most accurate rough estimate.

Under \$150,000.00

Over \$150,000.00 and Under \$500,000.00

Over \$500,000.00 and Under \$1,000,000.00