



International Pharmaceutical Aerosol Consortium on Regulation and Science

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Request for Proposals: “Recruitment for IPAC-RS IFU Usability Assessment”

I. Overview

The Instructions-for-Use (IFU) Subgroup of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) has developed a standardized IFU for a pressurized metered dose inhaler (pMDI), and would like to test its clarity and comprehensiveness in a formative Human Factors Assessment (the “**Assessment**”). To aid with recruitment for this Assessment, IPAC-RS is inviting proposals from organizations experienced in managing recruitment for Human Factors studies.

II. Details of the Assessment

- Participants will be asked to simulate use of a pressurized metered dose inhaler (pMDI).
- Participants will be asked to inhale through a pMDI device which will contain a placebo (Note: these devices will not contain any therapeutic active ingredient). An appropriate ethics review will be conducted (as arranged by IPAC-RS representatives) in advance of the Assessment. There may also be an attending Health Care Provider (HCP), to be arranged by the recruiting organization.
- The Assessment participants will each attend an individual session lasting 45 minutes.
- The Assessment will be conducted in London, UK.
- The Assessment will take place over three days in a standard market research facility, to be arranged by the recruiting organization.
- FocusVision may be needed.
- IPAC-RS estimates the Assessment will take place in February 2018.

III. Requirements for the Recruiting Organization

- 1) The recruiting organization should be knowledgeable about, and shall comply with, all applicable laws and regulations. As the Assessment will be conducted in the UK, it must be conducted in line with the BHIA regulations.
- 2) The recruiting organization shall arrange, liaise with, and pay for, a standard market research facility (the “Facility”), where the Assessment will be conducted.
 - a) FocusVision must be provided at the Facility.
 - b) The Facility must be capable of accommodating up to 10 Attendees, including a designated Observer, in the back room. Observer and Attendees will be provided by IPAC-RS.
 - c) An additional small side room at the Facility for consultations may be also required to accommodate the attending HCP.
- 3) The recruiting organization shall arrange for, and compensate, an attending Health Care Provider. IPAC-RS shall be consulted in selecting an appropriate HCP.
- 4) The recruiting organization shall manage recruitment of participants.
- 5) The recruiting organization shall recruit 20 participants (to ensure at least 16 interviews are completed, accounting for cancellations and no-shows).
- 6) The recruiting organization shall compensate the participating subjects for their time (a single 45-minute interview per participant).

IV. Participant Requirements

In line with the protocol developed by the IPAC-RS IFU Subgroup, the following participants are required for the Assessment:

- Healthy adult volunteers who have no or limited experience of using an inhaler. During screening interviews, the details of the subjects’ prior experience with inhalers shall be elucidated.
- The participants in the Assessment should be representative of intended users, therefore there should be a range of educational attainment broadly representative of the UK adult population, a range of ages (18-60 years old) and there should be a gender balance (minimum 40% of each gender).

V. Proposal Evaluation and Selection

IPAC-RS will evaluate all received proposals based on the presented qualifications and proposed costs. IPAC-RS plans to select an organization to recruit subjects for the Assessment no later than **November 20, 2017**.

VI. How to Submit a Proposal

If your organization is qualified and interested, please send a complete proposal to [svetlana.lyapustina\[at\]dbr.com](mailto:svetlana.lyapustina[at]dbr.com) by **October 16, 2017**. Any questions during the preparation of proposal should be emailed to the same address. The proposal should include:

- Description of the organization's expertise in human-subject recruitment and competences relevant to the required tasks.
- Complete listing of anticipated costs and expenses.
- Contact information.

IPAC-RS is not responsible for any costs or expenses incurred by the organizations in responding to this RFP.

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