

# Validation Study Proposals

Describes the steps necessary to propose a validation study.

Progress of a biomarker to a validation study is a critical step in the development of a biomarker and is, therefore, a critical part of EDRN. Due to the importance of the step and the fact that funding needs are likely to be large, the application process has some additional requirements to those of Associate Members.

Applicants are encouraged to submit their validation study proposal to the relevant collaborative group and seek their concurrence before the EC reviews their proposal. The differences are described below:

## 1. Pre-proposal:

A pre-proposal/letter-of-intent, limited to 3 pages, must be submitted to the appropriate Collaborative Group Chair or directly to the EC. Validation Studies are collaborative, therefore, the pre-proposal must name the EDRN sites which will be included as part of the collaboration. A Biomarker Reference Lab and the Data Management and Coordinating Center must be consulted for all Validation Studies. A Clinical Epidemiology and Validation Center should be included as needed.

The Collaborative Group Chair will disseminate the pre-proposal amongst Collaborative Group members for discussion and recommendation. Applications submitted directly to the EC may be reviewed by the EC or referred to the appropriate Collaborative Group for review. If approved by the EC, the submitting investigator will be asked to complete a full proposal as described below and submit it to the NCI EDRN Program Office.

## 2. Proposal:

Once the pre-proposal is approved by the EC, the investigator contacts a Biomarker Reference Lab, Data Management and Coordinating Center, and/or Clinical Epidemiology and Validation Centers, as appropriate for collaboration, and develops a full proposal with them. The full proposal should be prepared as described in Section 6.2.3 with the exception that it should not exceed 10 pages rather than 3 pages. A detailed background and rationale are not necessary but presentation of preliminary data is required.

Full proposals are submitted to the NCI EDRN Program Office. The full proposal is evaluated by EC or appointed ad hoc committee and external reviewers (non-EDRN members). The remaining steps for the Validation Study review process are the same as steps 3 & 4 in Section 6.2.6.