Submission Form for Responses to NIH Guide Notice NOT-CA-07-019 entitled "Request for Information (RFI): Development of Assays/In Vitro Devices for Use in Clinical Oncology"

How to Submit a Response:

Please complete the contact and response sections of the form. You do not have to complete the file online, or in one step. You can save your work on your local disk and submit it when it is complete. Submit your response to the NCI by clicking the "Reply by Email" button. Do not submit your response more than one time.

Responses will be accepted until 12 midnight EDT on July 25, 2007.
All information provided will be processed and analyzed with strict anonymity.

Inquiries

Inquiries concerning the Notice may be directed to:

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jessupj@mail.nih.gov

Technical questions regarding the completion and submission of the form may be directed to:

Dave Segal
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
301-846-5128
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Please provide contact information. However, this is optional and not essential for submission of this form.

First Name:
Middle:
Last:
Phone:
email:

Institution:
Address:
City:
State:
Zip Code:

Type of Institution:
- ◯ Academic
- ◯ Small Business
- ◯ Other (specify below)

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Submission Form for Responses to NOT-CA-07-019 (continued)

Section 1 - To better understand the assistance you need, please describe the background information regarding the specific purpose(s) and details of your assay or in vitro device as well as problems encountered during its development:

1-A: What clinical decision is the assay designed to inform? *(check all that apply)*

- ☐ Eligibility for trial/treatment
- ☐ Stratification of risk of recurrence or disease progression
- ☐ Guiding treatment
- ☐ Prognosis
- ☐ Predicting tumor response to therapy
- ☐ Predicting adverse response in patient to therapy
- ☐ Other *(please comment below)*:

1-B: What patient population is targeted *(e.g., disease site, stage, treatment, etc.)*?

1-C: What type of molecular species will the assay measure?

Please specify what the assay will measure *(e.g., miRNA, gene expression profiling, SNPs, aCGH, etc)*:

- ☐ RNA
- ☐ DNA
- ☐ Protein
- ☐ Other *(please comment below)*:

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Section 1 - Continued

1-D: Does the assay measure one or more markers or their ratio? ◯ Single ◯ Multiple ◯ Ratio of Markers

1-E: What type of technology does the assay use? *(check all that apply)*

- ☐ ELISA
- ☐ IHC
- ☐ ISH
- ☐ RT-PCR
- ☐ PCR
- ☐ DNA Microarray
- ☐ SNP Microarray
- ☐ CGH
- ☐ MS or other proteomic strategy
- ☐ Other *(please comment below)*:

1-F: If the assay is multiplex, what technology platform is used?

please comment below:

1-G: What stage of development has the assay/in vitro device attained with level of evidence supported by preliminary data (e.g, publications)?

- ◯ Level I - tested for association with clinical endpoint in a prospective Phase III trial
- ◯ Level II - shown to be associated with a clinical endpoint in at least one meta-analysis or more than 1 Level III analysis
- ◯ Level III - associated with clinical endpoint in a retrospective series of more than 100 patients in a multivariate analysis
- ◯ Level IV - associated with clinical endpoint in a retrospective series of less than 100 patients or a univariate analysis

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Section 1 - Continued

1-H: What stage of technical or analytical validation has the assay/in vitro device attained?

- ◯ Research use only
- ◯ Clinical use in a CLIA certified laboratory
- ◯ Commercial kit

Please add any other comments about technical or analytical validation for this assay/in vitro device:

1-I: Specific challenges and barriers encountered to date?

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Submission Form for Responses to NOT-CA-07-019 (continued)

Section 2 - Please describe types of assistance needed to accelerate/facilitate assay/device development.

2-A: Tissue and Fluid Resources

Please identify and describe clinical annotation and uniform treatment requirements below (*Please check all that apply)*:

Clinical Annotation:

- ☐ Path Report
- ☐ Surgical Procedure
- ☐ TNM
- ☐ Other Pathlogic Factors
- ☐ Treatment
- ☐ Site Specific Markers (e.g., ER, PR, CEA, PSA)
- ☐ Outcome
- ☐ Uniform Treatment Required (as in a clinical trial)

2-B: Technical expertise *(Please check all that apply)*:

- ☐ assay optimization
- ☐ reagent preparation
- ☐ platform modification

You may add optional comments below:

2-C: Statistical expertise *(e.g., sample size, method of analysis, variables to include)*: ◯ Yes ◉ No

You may add optional comments below:

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Section 2 - Continued

2-D: Study design expertise *(e.g., consultation about how to design a trial to study marker)*: ◯ Yes ◉ No

(You may add optional comments below)

2-E: Clinical expertise *(e.g. for consultation on clinical endpoints, patient recruitment, and other needs*): ◯ Yes ◉ No

(You may add optional comments below)

2-F: General Comments regarding types of assistance that would accelerate your assay/device development efforts:

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Submission Form for Responses to NOT-CA-07-019 (continued)

Section 3 - Services and/or resources that you feel are most critical, i.e., that would allow you to proceed more efficiently to and through successful development *(check all that apply)*

- ☐ Tissue Resources
- ☐ Technical Advice
- ☐ Statistical Advice
- ☐ Study Design Advice
- ☐ Clinical Advice
- ☐ Other *(please comment below)*:

Section 4 - The route/formal steps by which you intend to bring your assay into clinical practice:

- ☐ further evaluation in retrospective/correlative clinical studies
- ☐ definitive clinical trial
- ☐ offer to perform the test at your own institution as a CLIA-certified reference laboratory
- ☐ application to the FDA for marketing approval
- ☐ license or sell to a partner for commercial development
- ☐ Other *(please comment below)*:

Section 5 - Other comments relevant to CDP that are not specifically addressed in these questions (optional).

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