Clinical Assay Development Program

• Not a grants program or funding mechanism: provides services
• Services are provided by laboratories at NCI-Frederick or by Clinical Assay Development Network (8 CLIA-certified laboratories)
• Services are provided to efficiently develop diagnostic tests that address clinical needs, including co-development of targeted agents and predictive markers

→ **Goal:** Move promising assays from research bench to CLIA-lab setting and into clinical trials
Clinical Assay Development Network

- Contracts (Basic Ordering Agreement – BOA)
- Later stage assay optimization and validation
- CLIA certified labs: Expertise in one or more traditional assay platforms:
  - IHC
  - ELISA
  - ISH
  - qRT-PCR
  - qPCR
  - DNA sequencing
Application Deadlines

- Application Deadlines for 2013:
  - February 15, 2013
  - June 15, 2013
  - October 15, 2013

http://cadp.cancer.gov
Clinical Assay Development Program: Process

1. Application Submitted
2. Special Emphasis Panel
3. Internal Review
4. Senior Advisory Committee

- Application Submitted: Outside experts
- Special Emphasis Panel: Gov’t experts
- Internal Review: Submitter, Project Management Staff, CDP, CADNs & SAIC-F Staff
- Senior Advisory Committee: Project Team
- Obtain Resources: SOW/RFP sent to CADN
- Project Team: SEG Review, Task Order Issued, MTAs, Specimens/OHSRP
- START: National Cancer Institute
SEP Evaluation

• Scientific Merit
  – Hypothesis sound; clinical utility

• Feasibility
  – Performance characteristics in context of intended clinical use

• Impact/Clinical Need
  – Novel insight; adds significantly to current clinical practice

• Path to Clinical Implementation
Success rate

- 7 review cycles
- 1-7 applications/cycle
- 0-2 applications/cycle accepted
- 6 current projects in CADP
## Examples

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Project</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>Agios Pharmaceuticals, Inc</td>
<td>Oncometabolite and DNA sequencing assay to support early clinical trials</td>
<td>Completed</td>
</tr>
<tr>
<td>Insight Genetics</td>
<td>Novel PCR assay CDx</td>
<td>In progress</td>
</tr>
<tr>
<td>Cvergenx</td>
<td>Novel signature for radiation sensitivity</td>
<td>In progress</td>
</tr>
<tr>
<td>Fox Chase Cancer Center</td>
<td>IHC assay to predict drug sensitivity</td>
<td>In progress</td>
</tr>
<tr>
<td>NCI CCR</td>
<td>Novel assay to predict drug response</td>
<td>In progress</td>
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</tbody>
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