

Clinical Assay Development Program

<http://cadp.cancer.gov>

Cancer Diagnosis Program
DCTD, NCI, NIH

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

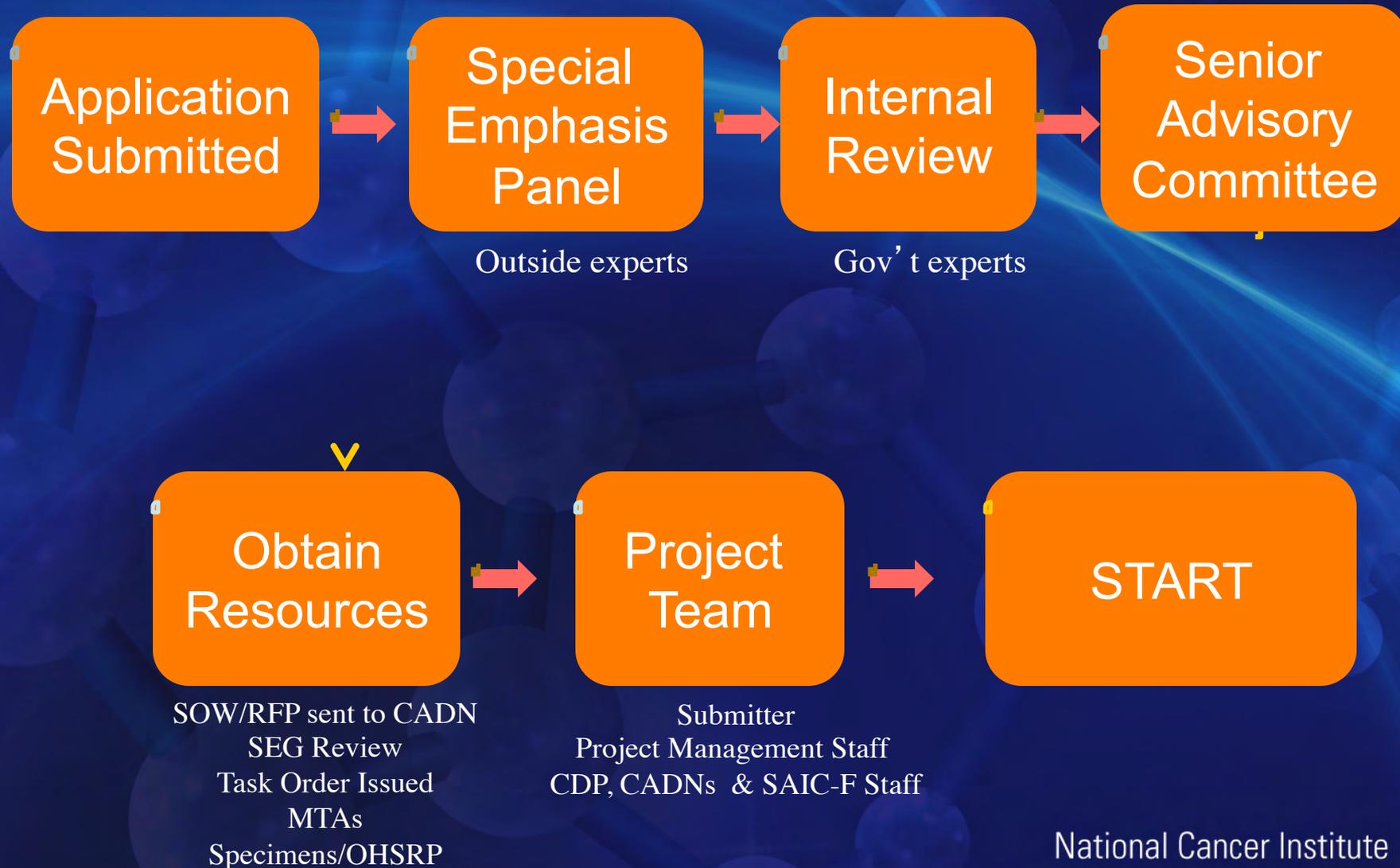
- Contracts (Basic Ordering Agreement – BOA)
- Later stage assay optimization and validation
- CLIA certified labs: Expertise in one or more traditional assay platforms:
 - IHC
 - ELISA
 - ISH
 - qRT-PCR
 - qPCR
 - DNA sequencing

Application Deadlines

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

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Clinical Assay Development Program: Process



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
- 30%
- 30%
- 30%
- 10%

Success rate

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

Examples

| Applicant | Project | Status |
|----------------------------|--|-------------|
| Agios Pharmaceuticals, Inc | Oncometabolite and DNA sequencing assay to support early clinical trials | Completed |
| Insight Genetics | Novel PCR assay CDx | In progress |
| Cvergenx | Novel signature for radiation sensitivity | In progress |
| Fox Chase Cancer Center | IHC assay to predict drug sensitivity | In progress |
| NCI CCR | Novel assay to predict drug response | In progress |



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