

**Redesign of the Early Experimental  
Therapeutics Program: NCI Early Phase  
Therapeutics Network**

**NCI-Clinical Trials and Translational  
Research Advisory Committee**

**Percy Ivy, MD**

**Associate Chief, Investigational Drug Branch  
Cancer Therapy Evaluation Program**

# Challenges for an Early Phase Therapeutics Network

## – *Accrual*

- Newer agents may be very active in tumors with a mutation(s)
- However, smaller patient populations with the mutation marker must be identified
- Studies will require multi-site/multi-disciplinary participation if biomarker driven
- A sizable/flexible program that can rapidly adapt to accrual needs is required
- Develop resources that address scientific and IRB review

## – *Biomarkers*

- Validated assays in qualified labs

## – *Translation*

- Understand MOA and mechanism of resistance
- POC and POM, molecular characterization
- Technology expertise

# **DCTD/CTEP Goals for an Early Phase Therapeutics Network**

- ***Optimize Integration* of Experimental Therapeutics with NCI/DCTD-funded Assets/Programs**
  - **Development of interdisciplinary teams**
  - **Promote collaboration between preclinical and clinical investigators**
- ***Molecular characterization* of patient tumors to enable evaluation of POM, POC, combinations, resistance**
  - **Resources for collection (with biopsies), tumor banking, and analysis**

# NCI Experimental Therapeutics Program (NExT)

**AGENTS**

**Special Emphasis Panel (SEP)**

..... prioritizes agents for NCI development

External

**NCI Review, Analysis and Funding Allocation**

Internal

..... membership: DCTD, DTP, CTEP / IDB, CCR

NCI

**Cancer Therapy Evaluation Program (CTEP)**

..... development plan, agreements / CRADA

External

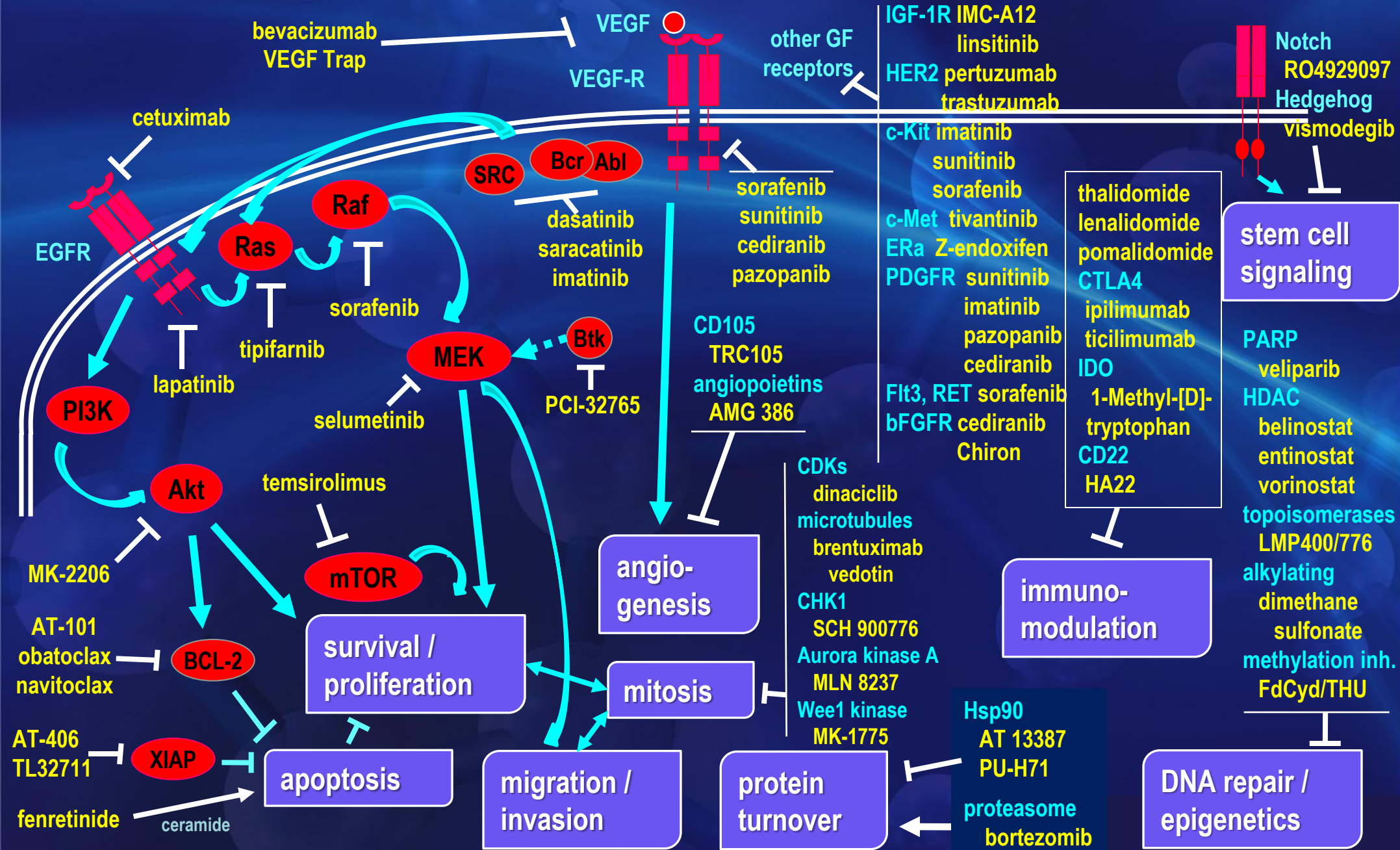
**Investigational Drug Steering Committee (IDSC)**

**U01 / N01 sites**

..... LOI solicitation

**Clinical Trials**

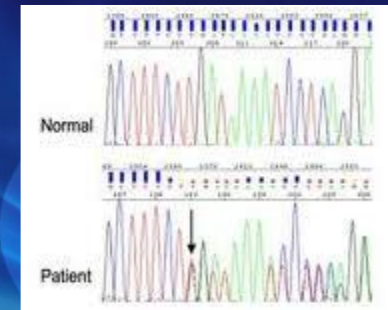
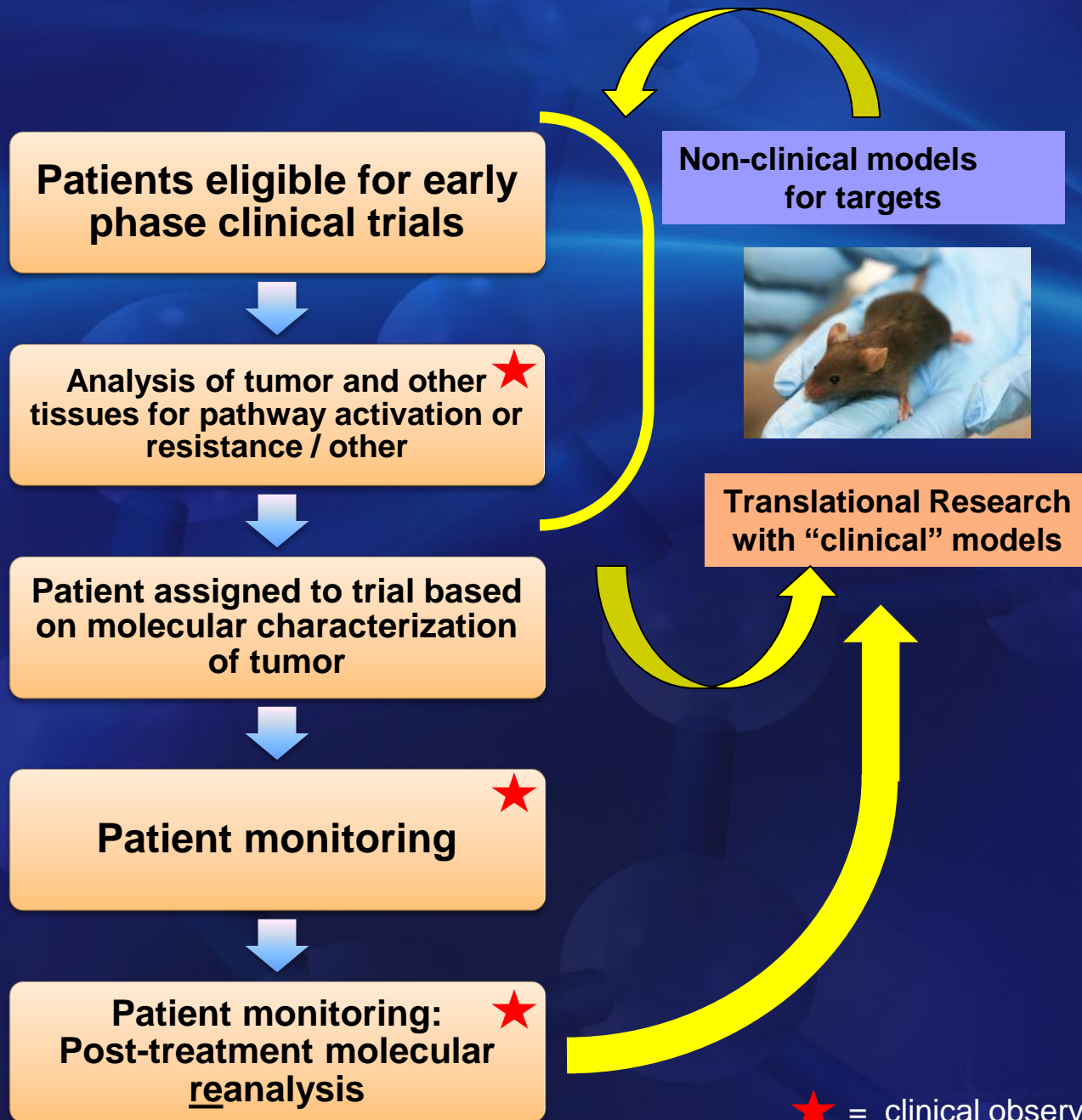
# High Priority Targets and Agents



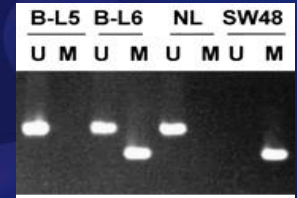
# How is the System Evolving?

- ***Team Science*** focused approach
- ***Molecular profiling*** of patient tumors from early experimental therapeutics clinical trials
- ***Enhanced collaboration***, both within NCI/DCTD (PD Lab, CRADA collaboration, CDP, CIP, RRP) and with other NCI-sponsored programs, including SPORES, Centers, mouse models consortia, grantees (P01s)

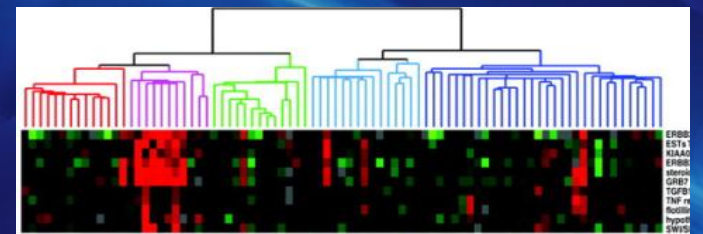
# Translational Clinical Research: Bedside to Bench and Back



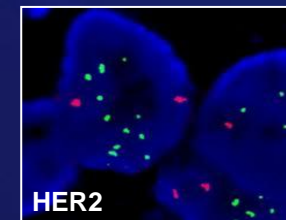
• Sequencing



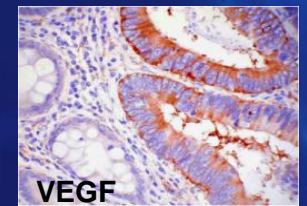
• Methylation status



• Expression arrays



• FISH



• IHC

★ = clinical observation

# NCI Early Phase Therapeutics Network

## Team Science:

### Investigational Agent Specific

- **Clinical Scientists**

- Early Trials – Clinical Trials Network (ET-CTN) Investigators
- NCI/DCTD

- **Translational Scientists**

- SPOREs
- P01s/Imaging Networks
- NCI/DCTD

- **Cancer Biology Scientists**

- NCI/DCB



# Summary for Discussion

- Redesigned ET-CTN should learn from every clinical trial performed
- Each patient's tumor should be molecularly characterized to inform current and future drug development
- ET-CTN focus should be primarily on defining POM, POC, target engagement, comprehensive multi-phase tumor evaluation
- NCI funds many translational and cancer biological grants and Designated Cancer Centers that should be leveraged in in this effort
- NCI's early drug development effort should be scientifically-focused and complement the pharmaceutical industry whose primary goal is drug approval

***What is the most effective way to integrate/implement our collaborative strategy?***



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