NCI Division of Cancer Treatment and Diagnosis:

An Overview of Resources Available for Extramural Scientists

Dr. Jason Cristofaro
Intellectual Property Advisor
National Cancer Institute
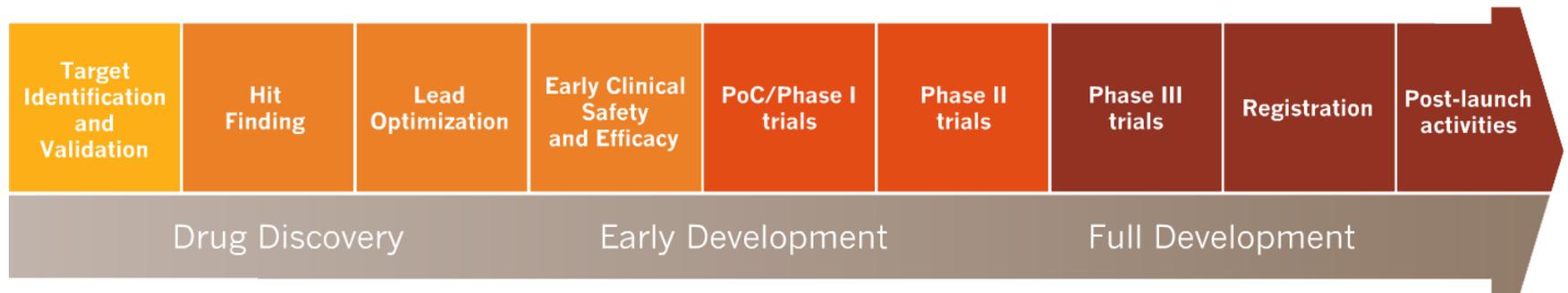National Institutes of Health

NExT Pipeline:

Rapid Access to Intervention Development (RAID)

Drug Development Group (DDG)

IND-supporting clinical studies

Early clinical studies through NCI-sponsored clinical trial(s)

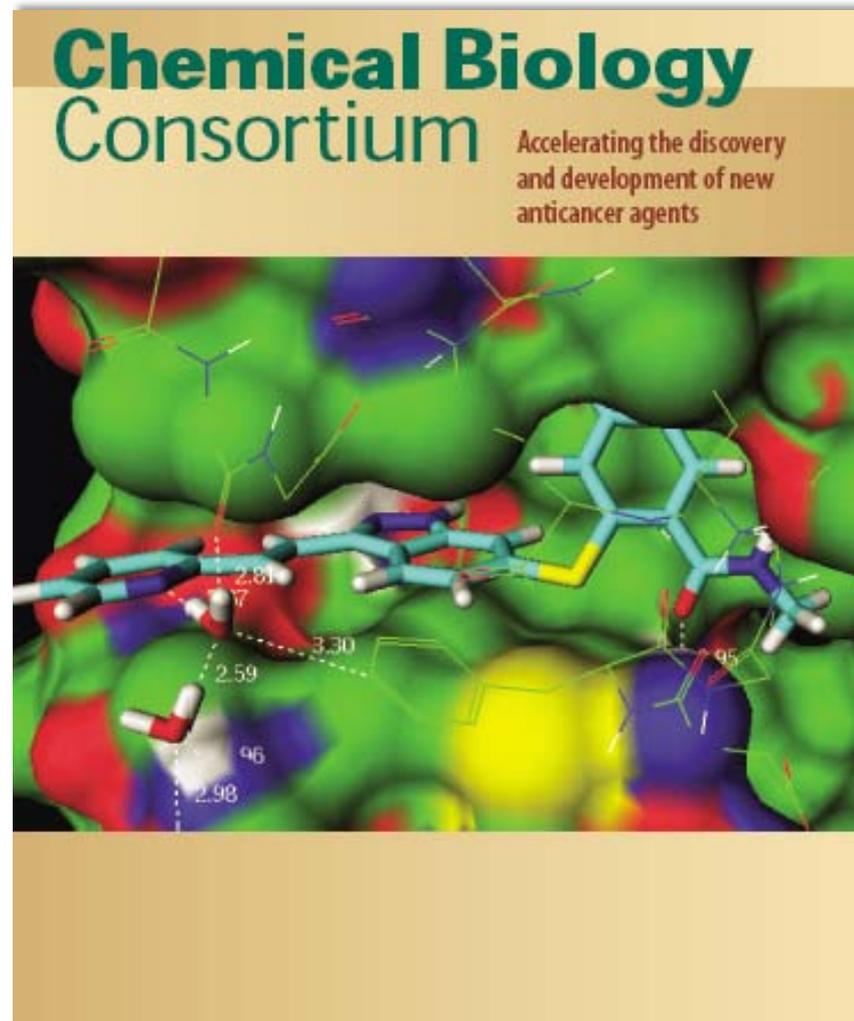| Target Identification and Validation	Hit Finding	Lead Optimization	Early Clinical Safety and Efficacy	PoC/Phase I trials	Phase II trials	Phase III trials	Registration	Post-launch activities
Drug Discovery			Early Development			Full Development		

Chemical Biology Consortium
target discovery through **clinical candidate**

Mission: provide resources and to develop treatments for cancer therapy and deteciton.

Adapted from Novartis Oncology

Overview of NExT Development Functions

- Directs R & D contracts to prioritize drug discovery and development (active role).

  - NCI-held IND: Drug Development Group (DDG).

  - Investigator-held IND: RAID, DCIDE.

- Contract Activities:

  - Discovery: screening, informatics, repositories, R*A*N*D.

  - Development: formulation, *in vivo* testing, bulk synthesis, pharmacology, toxicology

- Access to External Cooperative group clinical trial resources

- DTP also manages grants pertinent to drug discovery, biochemical pharmacology (passive role).

The Chemical Biological Consortium:
A New NCI Initiative

Adapted from Pfizer Oncology

Developmental Therapeutics Program

❖ Provide access to DCTD pre-clinical contract research resources to academic/small business community (Managed by DCTD Staff)

❖ <u>Examples of DTP "RAID-like" tasks</u>:
  ★ acquire/formulate bulk drug
  ★ produce biologicals
  ★ test efficacy of agent in animals
  ★ pharmacology/toxicology studies

❖ Natural Products Branch – Natural Products Repository

❖ Screening activities/Repositories

RAID

❖ Provide access to DCTD pre-clinical contract research resources to academic/small business community (Managed by DCTD Staff)

❖ Allow studies to occur under investigator or academic center sponsorship instead of NCI

❖ Examples of RAID tasks:
  ✦ acquire/formulate bulk drug
  ✦ produce biologicals
  ✦ test efficacy of agent in animals
  ✦ pharmacology/toxicology studies

❖ Bridge the gap between a LEAD DISCOVERY and a DRUG

❖ Traditional focus is on Academic researchers

Clinical Trial Evaluation Program

❖ Provide access to extramural cooperative group clinical trial resources

❖ Provides regulatory support for investigator-held and NCI held IND filings.

❖ Phase 1, Phase 2 and Phase 3 clinical trials all supported

❖ Generally requires a CRADA and an understanding of the IP option to collaborator.

❖ Traditional focus is on large pharma, but willing to provide assistance for smaller companies seeking resources for clinical trials.

Cancer Imaging Program (CIP)

- Imaging probes under current CIP IND
  - Assist PIs with regulatory issues
  - Facilitate access to some probes
  - PET Drugs: FLT, FMISO, FES, NaF
- Imaging probes under RDRC or other IND
- Extramural investigators – DCIDE Program
- ICBIO: Confidential forum for PIs with NCI/FDA/CMS
- http://imaging.cancer.gov/

CANCER IMAGING PROGRAM

NExT Request for Proposal

Extramural scientists may apply for NCI Resources via the NExT Pipeline

https://dctd.cancer.gov/nextapp or
https://dctd.cancer.gov/nextregistration