

Towards a Federal Workforce in Hematology and Oncology



Reinventing the Federal Oncology Workforce:

Goal: Create Multilateral Benefit in a Joint Program to Recruit Combined FDA and NCI/CCR Clinical Investigators

- FDA gains an academic oncologist with disease-specific expertise who is actively involved and understands critical nuances of the field
- NCI gains a clinical investigator and leader who understands regulatory considerations in drug development
- The oncologic community gains a regulator/academic who will provide a leadership voice to help design trials with regulatory endpoints in mind.

A Joint Program Recruiting Clinical Investigators

for combined FDA/CCR Positions

- Combined recruiting effort by:
 - FDA Center for Drug Evaluation and Research (CDER)/ Office of Hematology and Oncology Products (OHOP)
 - NCI-Center for Cancer Research (CCR)
- 3 FDA/CCR Investigator positions
- Joint appointment at NCI and FDA; FDA employee
- Time divided between clinical and regulatory duties



Investigators will serve in two capacities:

Associate Office Director for Clinical Research (FDA)

Principal Investigator (NCI)

- At FDA: become an expert in regulatory processes focusing on a specific disease type, from IND to NDA and post-marketing; develop a pivotal role in guiding industry and academia in their approach to drug development.
- At NCI: collaborate with existing clinical teams for the development and execution of clinical trials, enrollment and treatment of patients, analysis and publication of data; serve as a sounding board for clinical trial design.

FDA/CCR Investigators: What We Seek

- Mid-Career Clinical Investigator with clinical trial experience
 - 5 – 10 years post fellowship
 - American Board of Internal Medicine Subspecialty Board Certified
- Expertise in a particular disease area in hematology/oncology
- Academic level: Associate Professor/Professor
- Prioritizes maintaining an active clinical research career
- Interested in developing regulatory expertise in oncology, with an opportunity to influence academic and industry approaches to drug development

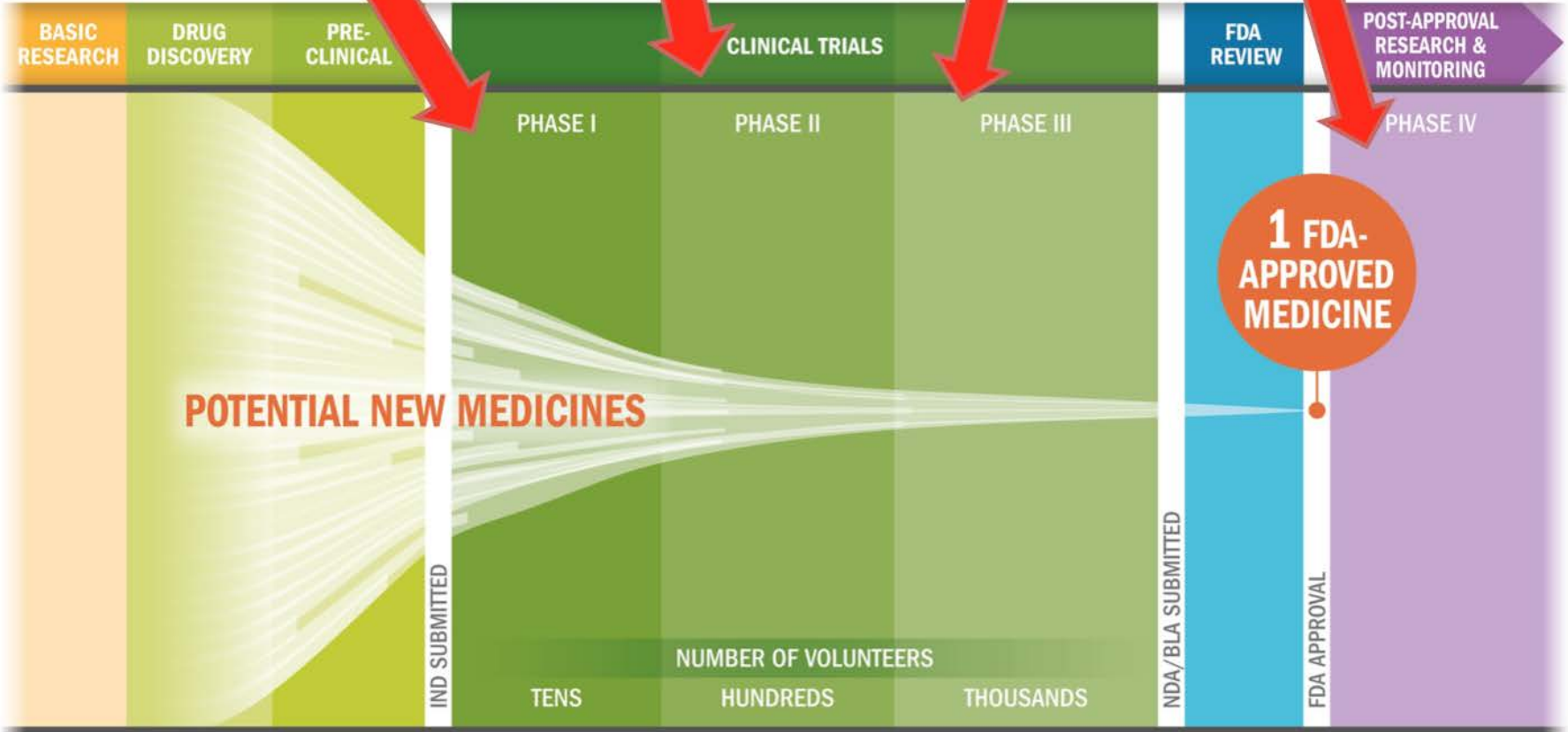
Clinical Regulatory Pathway: Then

Safe dose

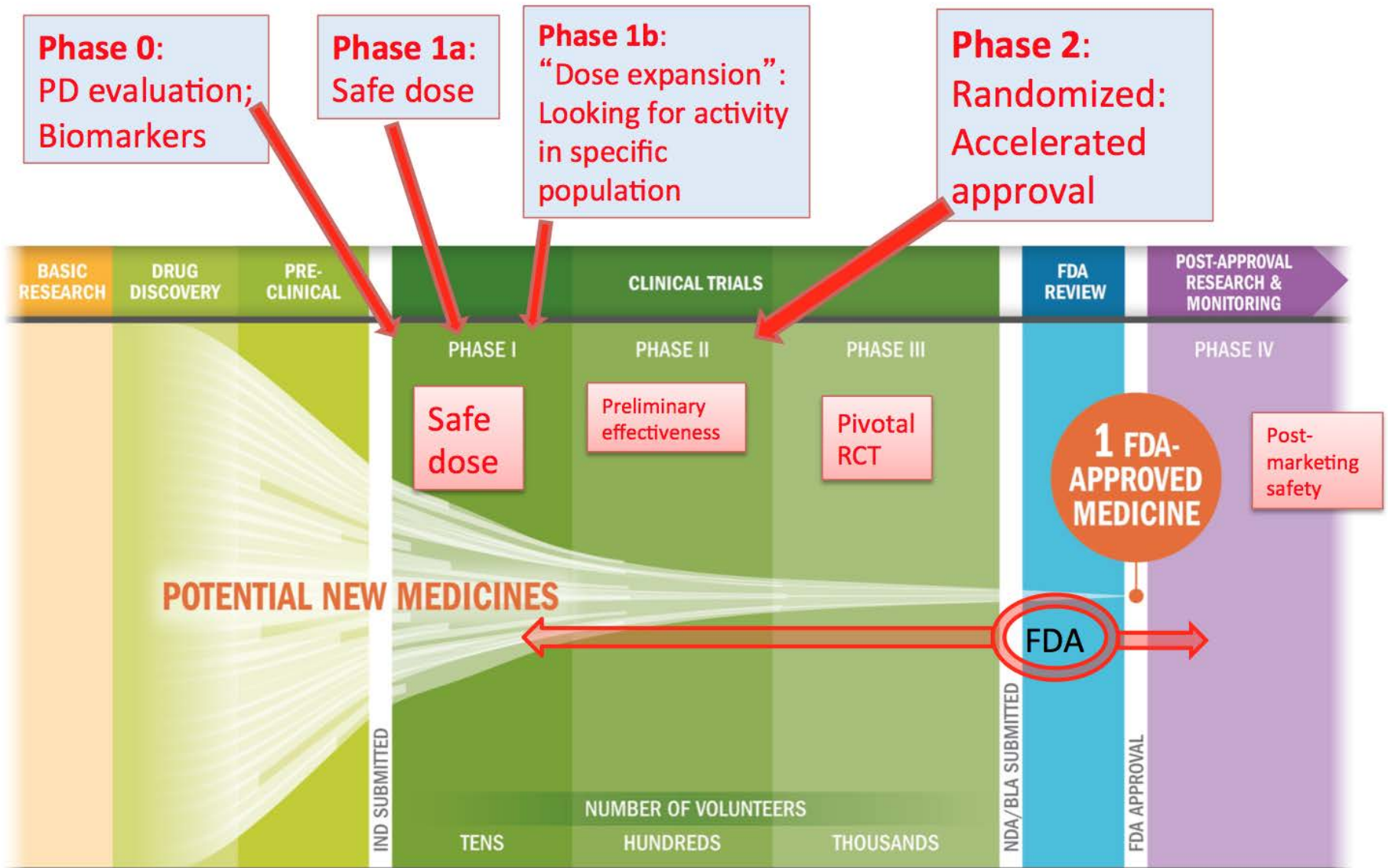
Preliminary effectiveness

Pivotal RCT

Post-marketing safety



Clinical Regulatory Pathway: Now

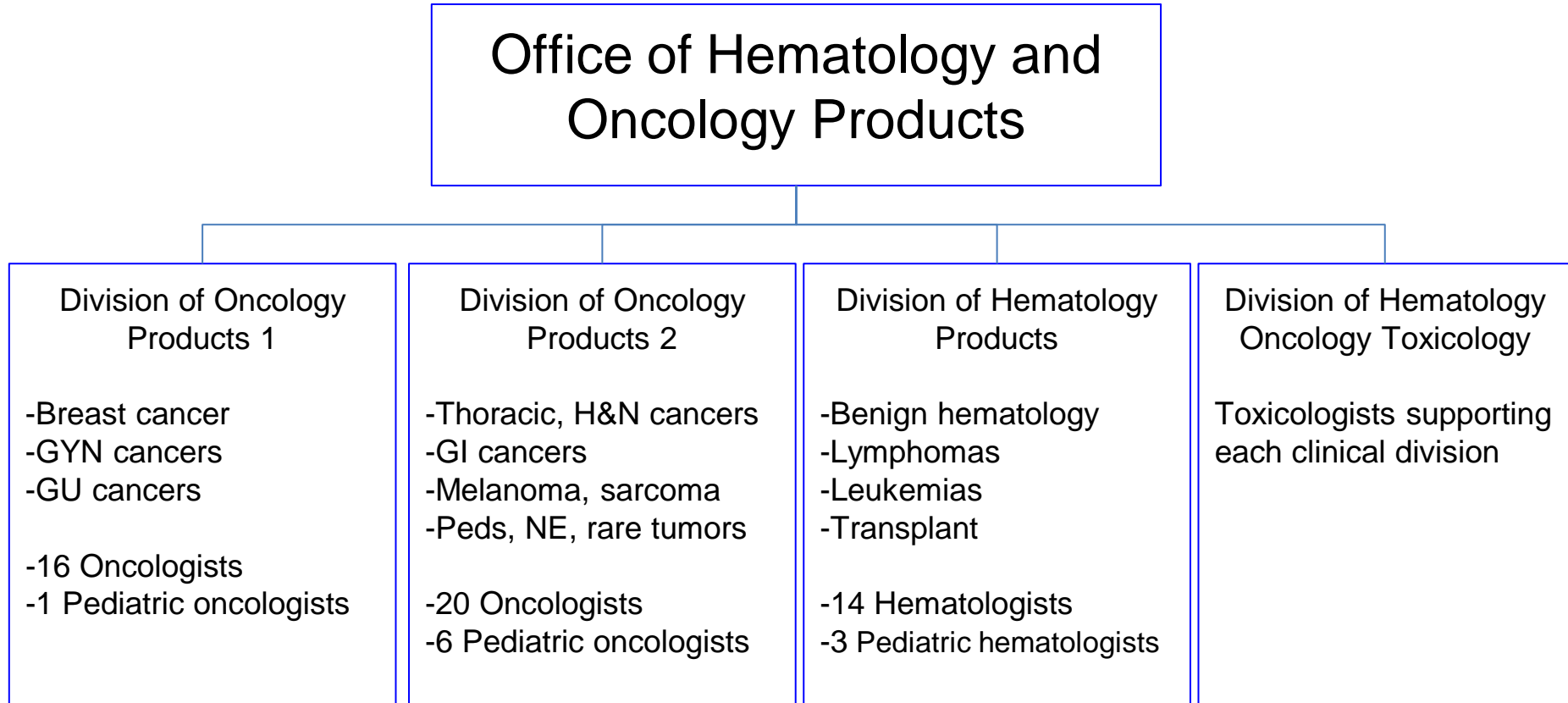


Office of Hematology and Oncology Products, FDA

- Located in Silver Spring Maryland
- Almost 200 employees including medical and pediatric hematologists/oncologists and other physicians, nurse practitioners, pharmacologists, toxicologists and support staff.
- Work very closely with other centers, divisions and offices with an array of scientists including biostatistics, chemists, physicists, and others throughout the FDA

Reorganized in 2011 into disease-specific divisions, modeled after academic setting
→ to provide more nuanced support for clinical trial design and drug development

Reorganization was instrumental in creating a new drug development environment





Associate Director,
Clinical Research, OHOP, FDA



- Regulatory training within the context of a multidisciplinary disease-specific regulatory team
- Develop expertise in the application of federal drug regulations in a specific therapeutic area
- Oversee a portfolio of drug and biologic products at all phases of development
- Lead meetings with industry and academic sponsors, providing regulatory and trial design advice



Associate Director, Clinical Research, OHOP, FDA



- Lead meetings with industry and academic sponsors, providing regulatory and trial design advice
- Represent FDA to external stakeholders, including academia, industry, and patient advocacy organizations at national and international meetings
- Opportunity to conduct and publish regulatory science, leveraging exclusive data and computing resources available at FDA
- Must recuse themselves from regulating products used in trials

Principal Investigator at the NCI's Center for Cancer Research (CCR)

- Investigators will collaborate with a team & clinic in the CCR
- Investigators will develop and submit clinical trials – within framework of clinical branch agenda and patient population
- Scientific review of clinical trials will follow CCR SOP
- An estimated 2 - 4 actively accruing clinical trials per PI
- Investigator will participate in teaching
- Clinical activities fully funded
- Conduct investigator-initiated, industry, & cooperative group studies



Clinical Oncology Branches in the CCR

1. Genitourinary Malignancy Branch
2. Thoracic and GI Oncology Branch
3. Developmental Therapeutics Branch
4. Women's Malignancies Branch
5. Lymphoid Malignancies Branch
6. Dermatology Branch
7. Experimental Transplantation and Immunology Branch
8. HIV and AIDS Malignancy Branch
9. Vaccine Branch
10. Radiation Oncology Branch
11. Pediatric Oncology Branch
12. Urologic Oncology Branch
13. Endocrine Oncology Branch
14. Surgery Branch
15. Neuro-Oncology Branch



Center for Cancer Research: Unmatched Protocol Support

- Center for Cancer Research has centralized much of the clinical trial infrastructure
- Protocol Support Office: Services at all stages of protocol lifecycle
 - Help with drafting LOIs and Protocols
 - Support for Scientific Review process
 - Drafting and submission of IND's
 - FDA submission
 - IRB submissions
- Tech Transfer: An office for agreements with industry partners; submission of patent applications
- Research Nursing: Highly skilled research nurses well versed in Good Clinical Practice
- Clinical Care: Medical Oncology fellows in clinic; nurse practitioners in clinic and in hospital
- Core Facilities: Intramural laboratories specializing in assays of biologic endpoints
- Basic Science: Intramural basic science laboratories eager to collaborate
- Data Management: Centralized data management provides highly skilled data managers to support data entry and downloads, and continuing review and other regulatory submissions

A Vision for the FDA/NCI Collaboration:

- FDA/CCR Clinical Investigator a leader in the whole academic community
- Some leadership roles these investigators could play at **FDA**:
- Bring disease-specific expertise to the FDA
 - Awareness of finer issues in each particular disease
 - Interaction with cooperative groups
 - Outreach with advocacy groups
- Push unmet clinical needs at the FDA, e.g.
 - CNS metastases
 - Fertility and other survivor issues
 - Integrate real-world data
 - Liaise with NCI and FDA on mission-critical programs, e.g. NCI-MATCH
- Advance efforts to modernize clinical trial design to align with the clinical community
 - Data collection standards

A Vision for the FDA/NCI Collaboration:

- FDA/CCR Clinical Investigator a leader in the whole academic community
- Some leadership roles these investigators could play at **NCI**:
- This person could help design trials that establish and use new regulatory endpoints:
 - Alternatives to the gold standard, overall survival
 - Alternatives to the current surrogates, PFS, ORR
 - e.g. Kinetic analyses
 - Alternatives to the current dose-finding schema,
 - e.g. Continuous Reassessment Model
 - Challenge or expand currently accepted inclusion criteria
 - Highlight regulatory considerations in individual trials
- Continue academic activities
 - Education of fellows
 - Serve on editorial boards
 - Serve as attending staff in the NIH Clinical Center

Logistics and Application

- FDA will serve as chair of search committee; CCR will participate in search and selection
- During recruitment, each candidate will identify a clinical branch with mutual interest; meet and discuss areas of mutual interest with CCR Branch Chief
- Questions? Contact: NCI: Dr. Susan Bates 301-496-5941, FDA: Dr. Sanjeeve Bala 240-402-4975

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