



Society for Immunotherapy of Cancer

Meet-the-Expert Webinar: Careers In Government

Monday, December 7, 2020
2:00-3:00 p.m. ET

Webinar Agenda

2:00-2:10 p.m. ET Overview: Welcome and Introductions

2:10-2:25 p.m. ET Presentation – Jennifer Gao, MD

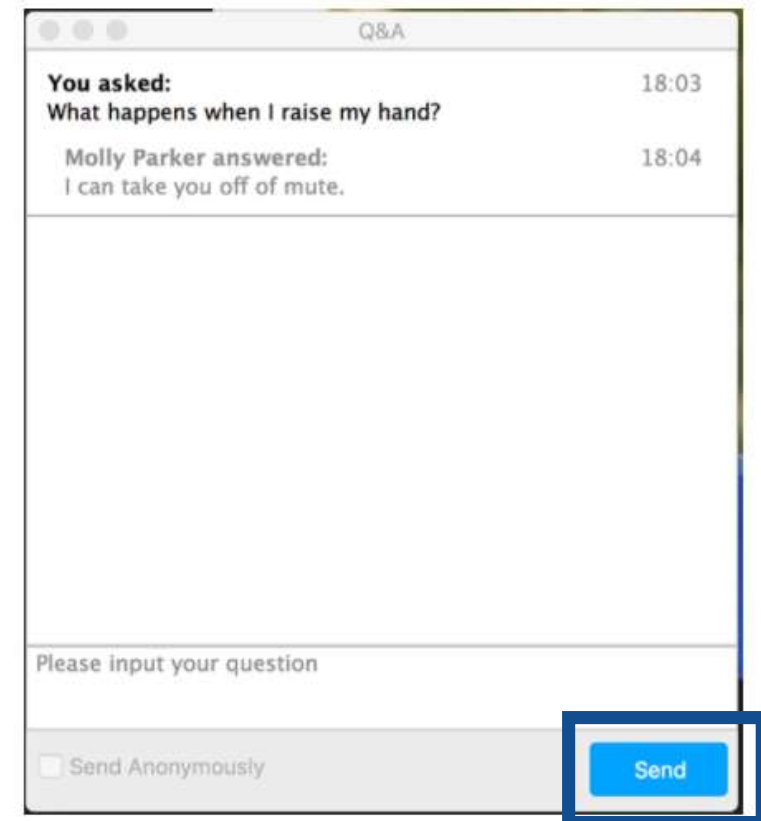
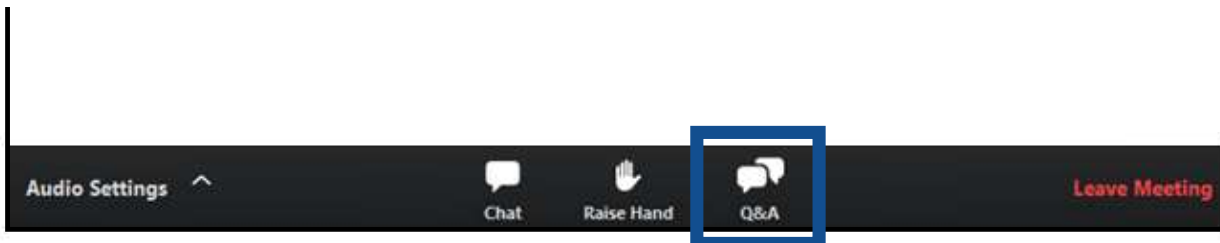
2:25-2:40 p.m. ET Presentation – Kathryn Lurain, MD, MPH

2:40-2:55 p.m. ET Question and Answer Session

2:55-3:00 p.m. ET Closing Remarks

How to Submit Questions

- Click the “Q&A” icon located on at the bottom of your Zoom control panel
- Type your question in the Q&A box, then click “Send”
- Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)



Webinar Faculty



Chris Langsdorf –
Thermo Fisher Scientific



Jennifer Gao, MD – *Food
and Drug Administration*



Kathryn Lurain, MD, MPH
– *National Cancer Institute*

Oncology 2025

A Vision For the Future

Jennifer J. Gao, MD
Associate Director for Education
Oncology Center of Excellence

December 7, 2020

FDA Mission

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

Drug and biologics must be proven safe and effective to FDA's satisfaction before companies can market them in interstate commerce.

FDA **does not** take into account cost or payment issues.

FDA **does not** regulate “practice of medicine”.

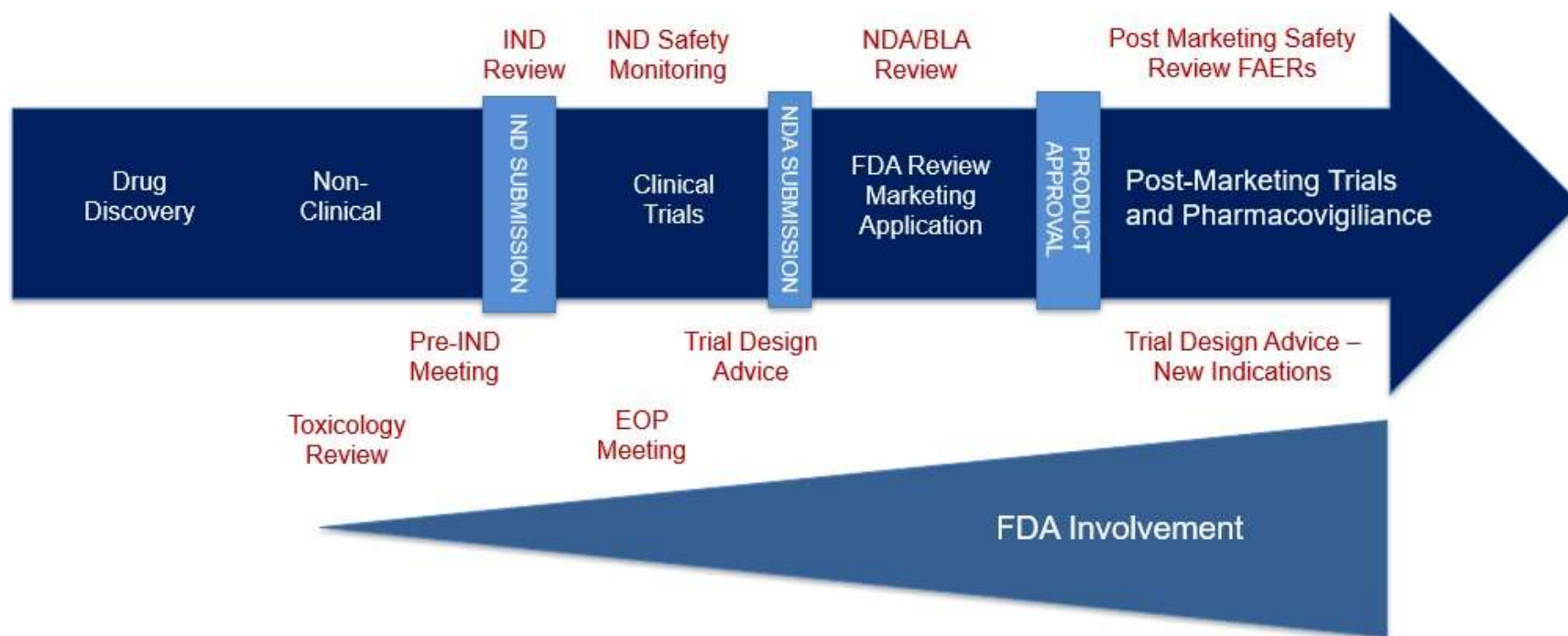
Oncology Center of Excellence



Office of Oncologic Diseases: Clinical Divisions



Drug Development Lifecycle

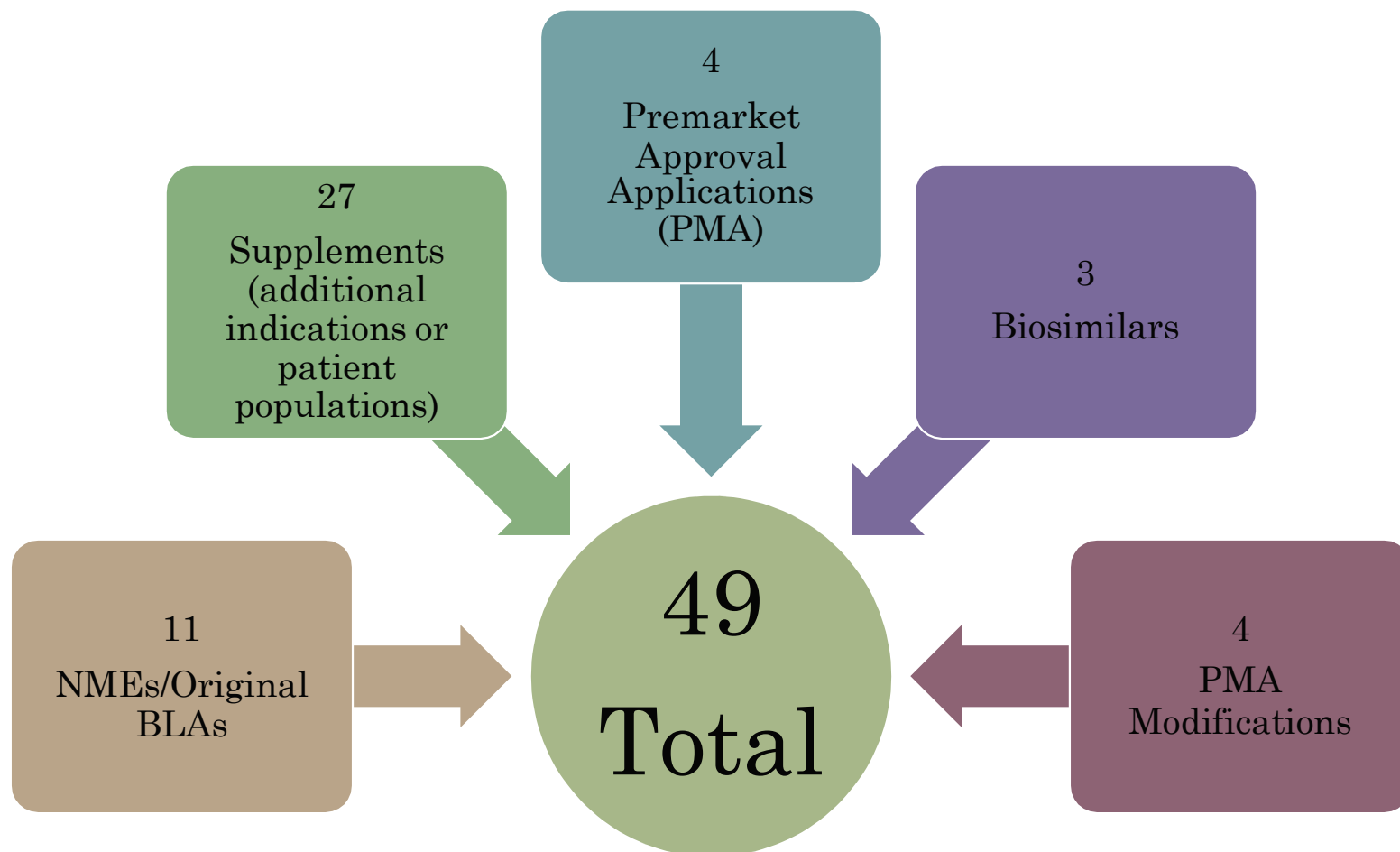


IND: Investigational New Drug Application, **NDA:** New Drug Application, **BLA:** Biologic Licensing Application, **FAERs:** FDA Adverse Event Reporting System



Striking the Balance

2019 Oncology Approvals



OCE Projects



PROJEC1 SOCRATES

Interagency Oncology Task Force Fellowship

- Eligibility: apply through the NCI IOTF program
- Duration: 1-2 years
- Clinical track: up to 2 fellows per year



Project Renewal



FDA mission: promote and protect public health



Project Renewal: accurate and up-to-date information to inform prescribing decisions

Establish
repeatable,
objective,
scientific
process

Engage and
collaborate
with
oncology
community

Educate on
regulatory
policy &
product
label

FDA takes first action under new international collaboration with Australia and Canada designed to provide a framework for concurrent review of cancer therapies



Project Orbis

- Global collaboration
- Launched Oct 2004
- September 17, 2019: first action under Project Orbis with TGA (Australia) and HC (Canada)
- Utilization of RTOR and AAid programs

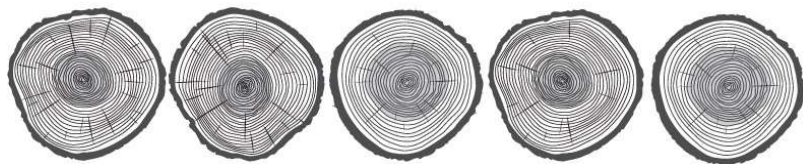
Project Community



Project Silver

Improving the evidence base for treating older adults with cancer

- Regulatory policy
- Advocacy and outreach
- Global engagement
- Research and publications



FDA analyses of survival in older adults with metastatic non-small cell lung cancer in controlled trials of PD-1/PD-L1 blocking antibodies

Shanthi Marur¹, Harpreet Singh^{1,*}, Pallavi Mishra-Kalyani¹, Erin Larkins, Patricia Keegan, Rajeshwari Sridhara, Gideon M. Blumenthal, Richard Pazdur

U.S. Food and Drug Administration, White Oak, MD, USA



original reports

Outcomes of Older Women With Hormone Receptor–Positive, Human Epidermal Growth Factor Receptor–Negative Metastatic Breast Cancer Treated With a CDK4/6 Inhibitor and an Aromatase Inhibitor: An FDA Pooled Analysis

Lynn J. Howie, MD¹; Harpreet Singh, MD¹; Erik Bloomquist, PhD¹; Suparna Wedam, MD¹; Laleh Amiri-Kordestani, MD¹; Shenghui Tang, PhD¹; Rajeshwari Sridhara, PhD¹; Jacqueline Sanchez, MA¹; Tatiana M. Prowell, MD¹; Paul G. Kluetz, MD¹; Belinda L. King-Kallimanis, PhD¹; Jennifer J. Gao, MD¹; Amna Ibrahim, MD¹; Kirsten B. Goldberg, MA¹; Marc Theoret, MD¹; Richard Pazdur, MD¹; and Julia A. Beaver, MD¹

Perspectives

Enrollment of older adults on oncology trials: An FDA perspective☆

Harpreet Singh ^{*}, Julia A. Beaver, Geoffrey Kim, Richard Pazdur

Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD, United States

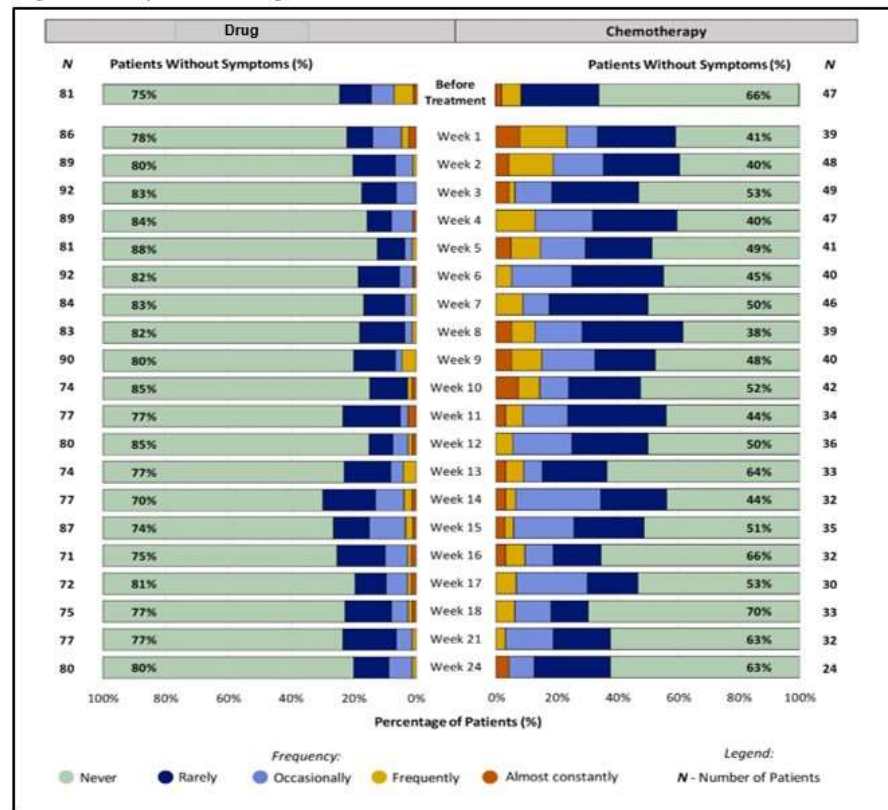
Project Patient Voice

- Pilot
- Publicly available website
- Describes patient reported, longitudinal, symptomatic adverse events
- Data collected from cancer clinical trials for approved drugs
- Sponsors voluntarily provide existing PRO data (I.e. submitted with NDA/BLA) for consideration

All Patients Who Completed the Questionnaire Described Their Experience of NAUSEA During the First 24 Weeks of Treatment:

Figure 1 shows the proportion of patients reporting the frequency of NAUSEA at each time point. For example, at week 2, 20% of patients taking drug reported nausea (ranging from rarely to almost constantly). The range of patients who reported having any amount of nausea during the first 24 weeks while taking drug was between 12% - 30%.

Figure 1. Patient-Reported Nausea During the First 24 Weeks on Treatment



Project Equity

- Develop policy/guidance
- Increase enrollment in oncology clinical trials
 - Generate evidence throughout life cycle of drug (i.e., pre- and post-approval)
- Foster internal and external research & policy collaborations
- Integrate diverse perspectives in regulatory activities
- Integrate across all OCE programs



Project Facilitate

Assisting healthcare providers with requests for access to investigational oncology products

DO YOU NEED HELP SUBMITTING A SINGLE PATIENT IND EXPANDED ACCESS (EA) REQUEST (ALSO KNOWN AS COMPASSIONATE USE) FOR A PATIENT WITH CANCER?

...FDA's Oncology Center of Excellence (OCE) can help:

- Locate IRB resources
- Find an EA contact for a drug/biotech company
- Complete Form FDA 3926



Phone: (240) 402-0004

Email: OncProjectFacilitate@fda.hhs.gov

www.fda.gov/oce

Patients: Talk to your healthcare provider to discuss whether expanded access is an appropriate option.

Academics and Publications

CCR Perspectives in Regulatory Science and Policy

FDA's Approach to Regulating Biosimilars

Steven J. Lemery¹, M. Stacey Ricci², Patricia Keegan¹, Amy E. McKee¹, and Richard Pazdur¹

CLINICAL
RESEARCH

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CCR Drug Updates
U.S. Food and Drug Administration Approval Summary: Atezolizumab for Non-Small Cell Lung Cancer

Chana Weinstock, Sean Khozin, Daniel Suzman, Lijun Zhang, Shenghui Tang, Sakar Wahby, Kirsten B.

CDK4/6 inhibitor treatment for patients with hormone receptor-positive, HER2-negative, advanced or metastatic breast cancer: a US Food and Drug Administration pooled analysis

Jennifer J Gao*, Joyce Cheng*, Erik Bloomquist, Jacquelyn Sanchez, Suparna B Wedam, Harpreet Si, Rajeshwari Sridhara, Kirsten B Goldberg, Marc R Theoret, Paul G Kluetz, Gideon M Blumenthal, R

Perspective
Residual Disease after Neoadjuvant Therapy — Developing Drugs for High-Risk Early Breast Cancer

Tatiana M. Prowell, M.D., Julia A. Beaver, M.D., and Richard Pazdur, M.D.



The NEW ENGLAND
JOURNAL of MEDICINE

The
Oncologist®

FDA Approval Summary: Mylotarg for Treatment of Patients with Relapsed or Refractory CD33-Positive Acute Myeloid Leukemia

KELLY J. NORSEWORTHY, CHIA-WEN KO, JEE EUN LEE, JIANG LIU, CHRISTY S. JOHN, DONNA PRZEPIORKA, ANN T. FARRELL, RICHARD PAZDUR
Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, Maryland, USA
Disclosures of potential conflicts of interest may be found at the end of this article.
Key Words. Acute myeloid leukemia; Mylotarg • U.S. Food and Drug Administration approval

Regulatory Issues: FDA

Clinical Review & Education

Special Communication

Patient-Reported Outcomes in Cancer Drug Development and US Regulatory Review
Perspectives From Industry, the Food and Drug Administration, and the Patient

Ethan Basch, MD, MSc; Cindy Geoghegan, BA; Stephen Joel Coors, PhD; Ari Granasakthy, MSc, MBA; Ashley F. Slagle, PhD; Elektra J. Papadopoulos, MD, MPH; Paul G. Kluetz, MD



One Pill.
One Life.
One Career.

One pill can transform a life.

One life can transform many.

One career can transform that pill,
that life, that many.

Transformative Careers. FDA Oncology.

Further information regarding careers at FDA Oncology:
futureofhemeonc@fda.hhs.gov



Careers at the National Cancer Institute

Why I love working at the Disneyland of Clinical Research

Kathryn Lurain, MD, MPH

Assistant Research Physician

HIV and AIDS Malignancy Branch

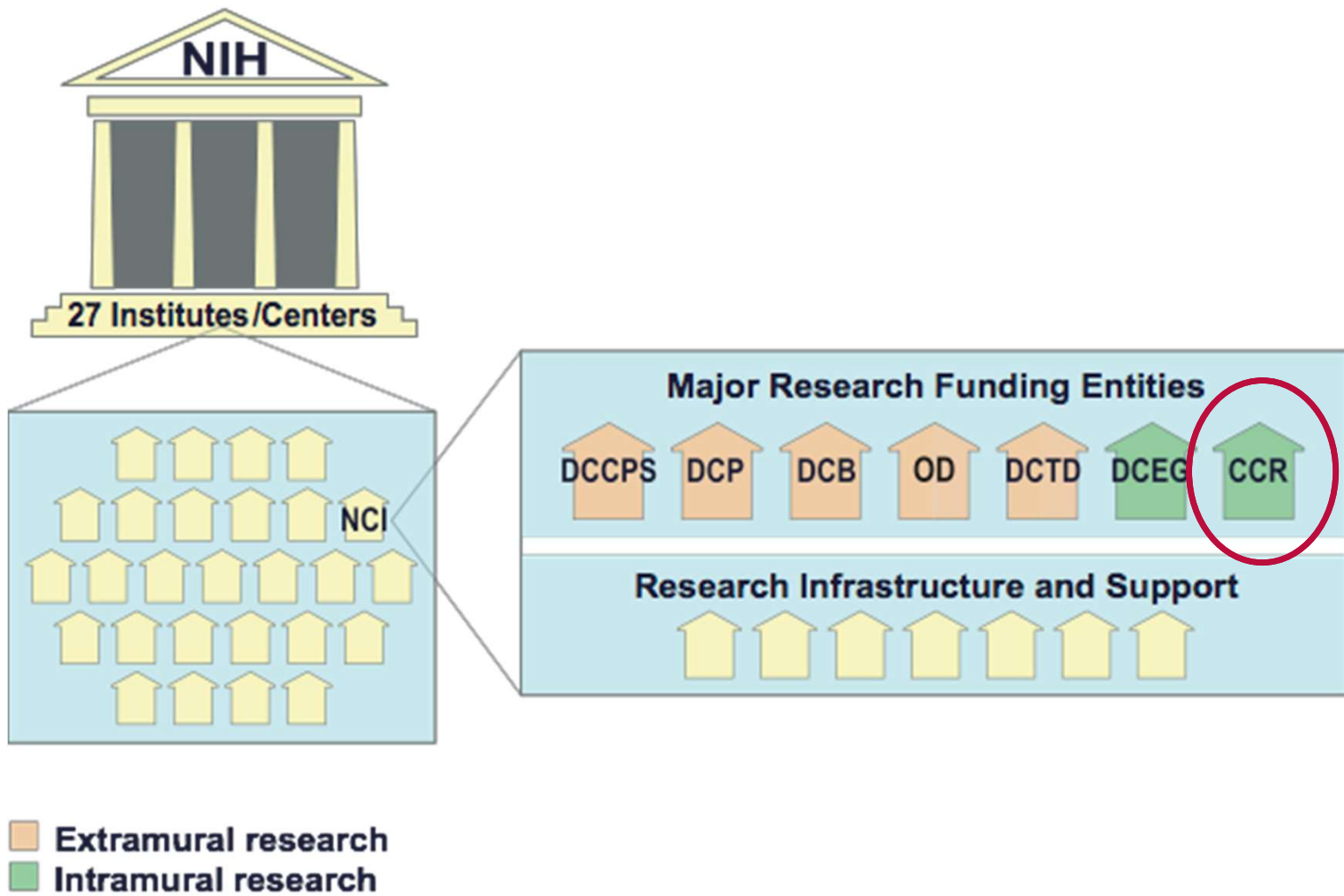
The NIH Bethesda Campus



President Roosevelt on October 31, 1940

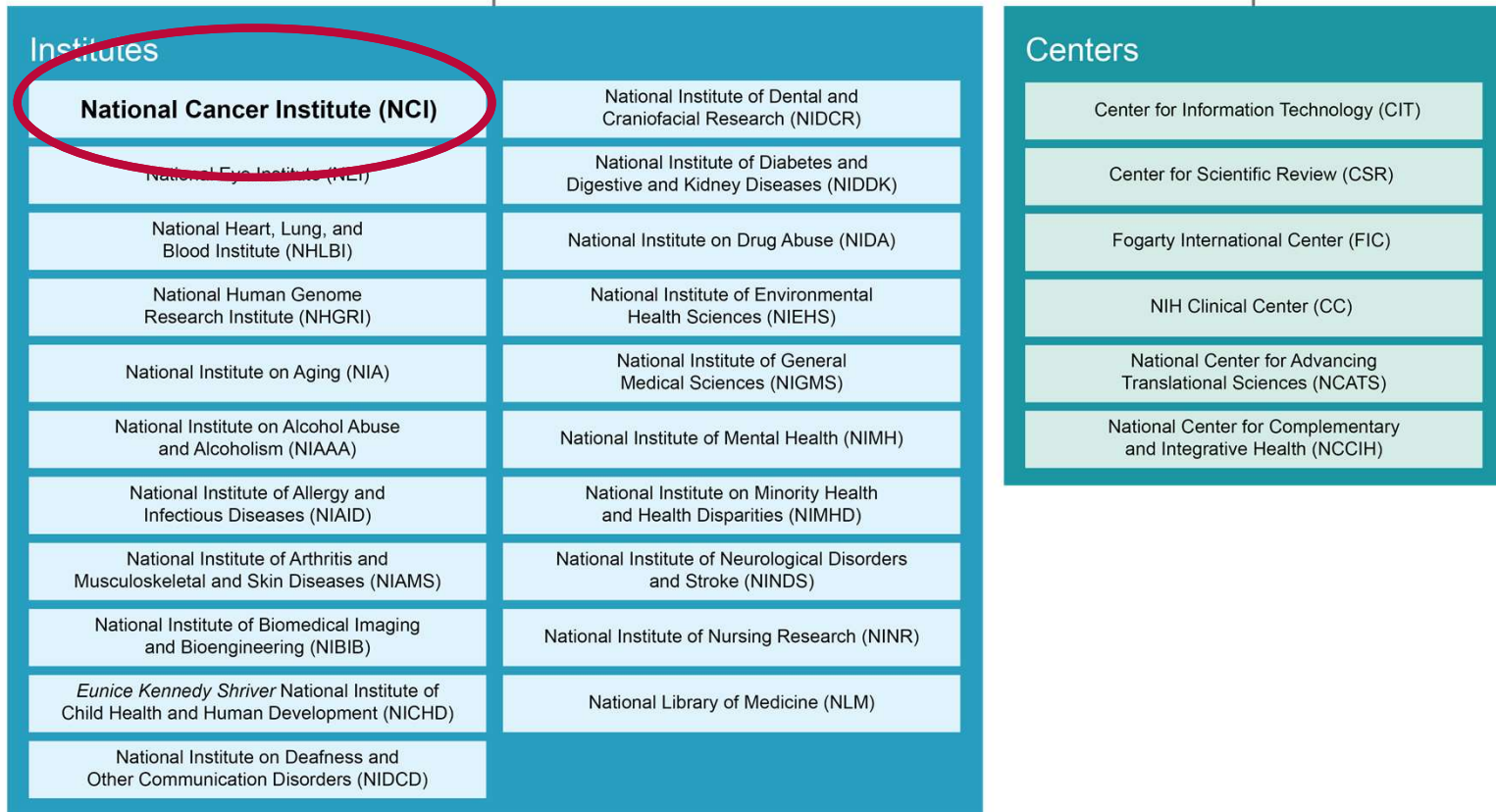




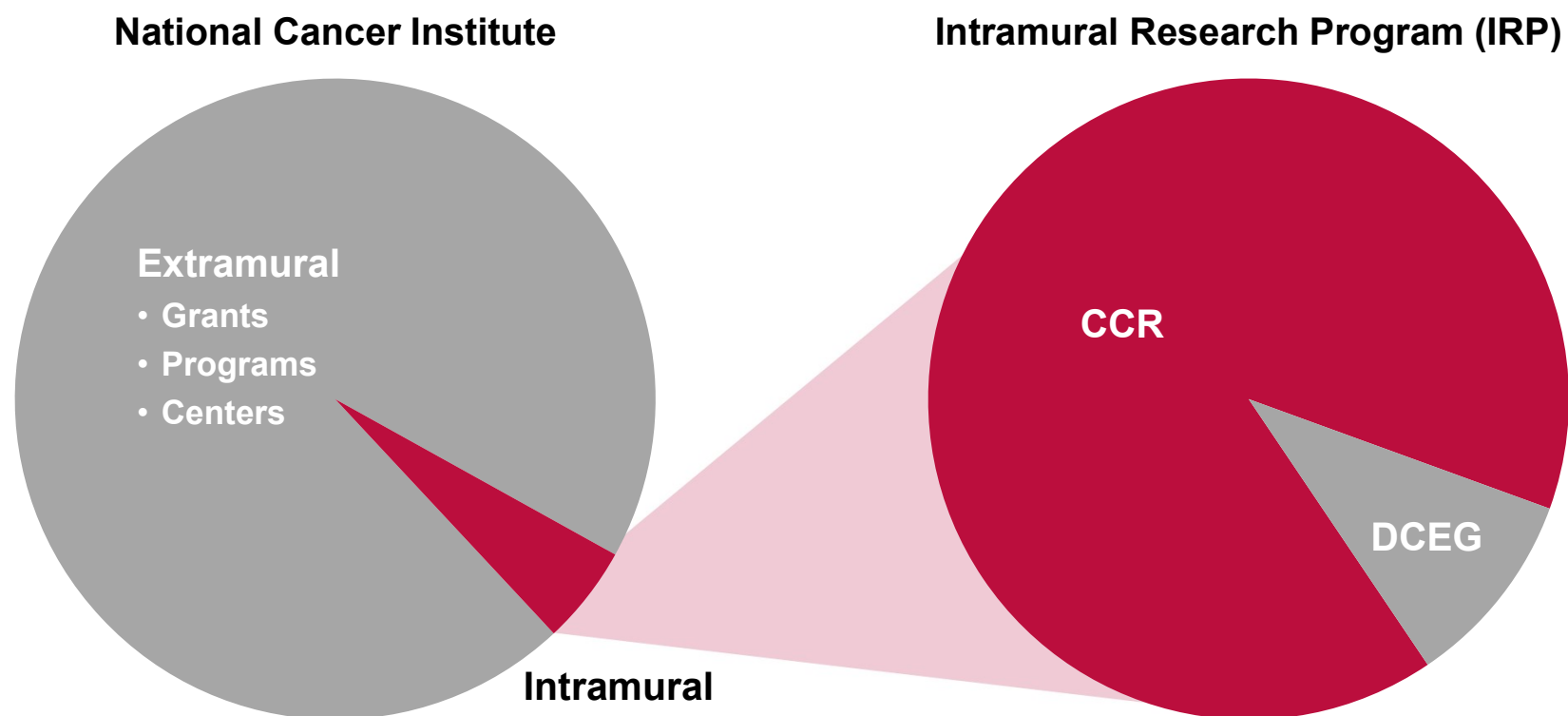




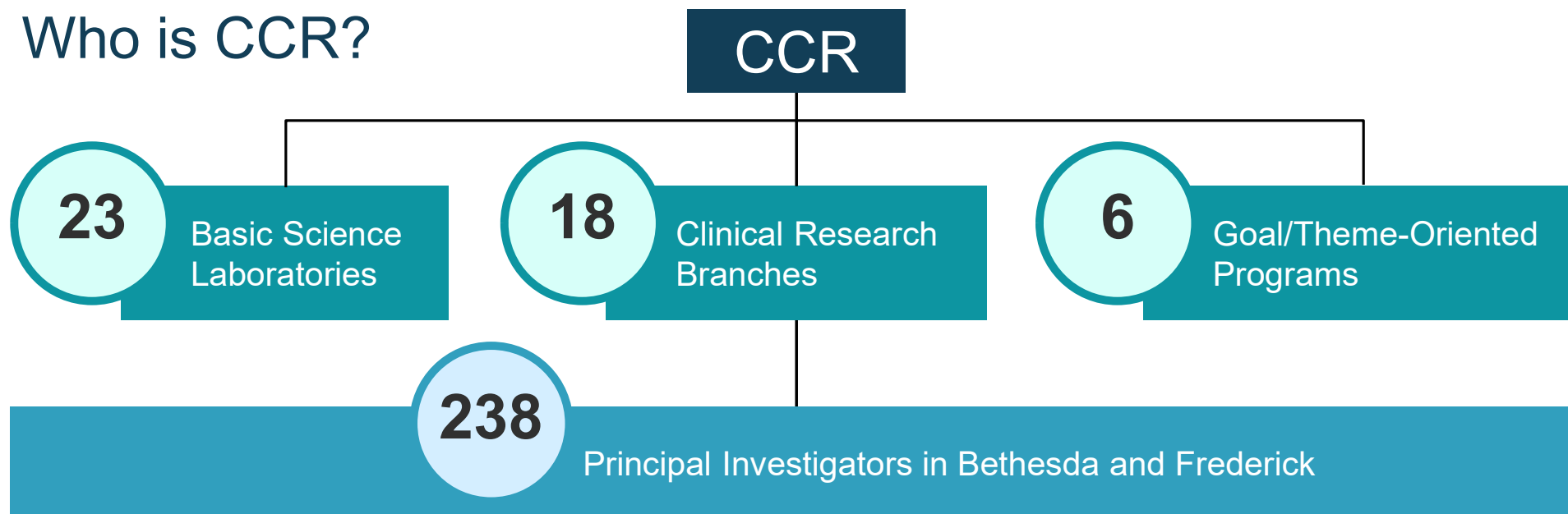
NIH Office of the Director (OD)



The NCI Intramural Research Program



Who is CCR?



~300 staff scientists/staff clinicians

~500 technical lab staff

~900 postdoctoral/clinical fellows

~250 postbaccalaureate/predoctoral students

~500 summer students

Our **MISSION**

To improve the lives of cancer patients by solving **important, challenging and neglected problems** in cancer research, prevention and patient care

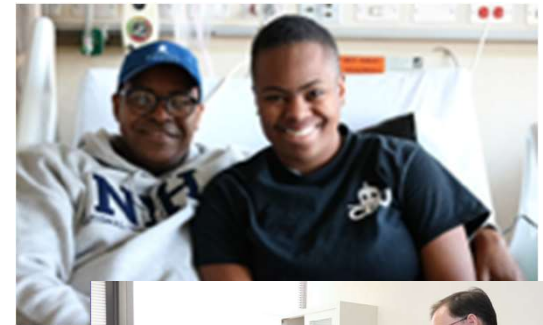
Our **VISION**

To create the **cancer medicines of tomorrow**

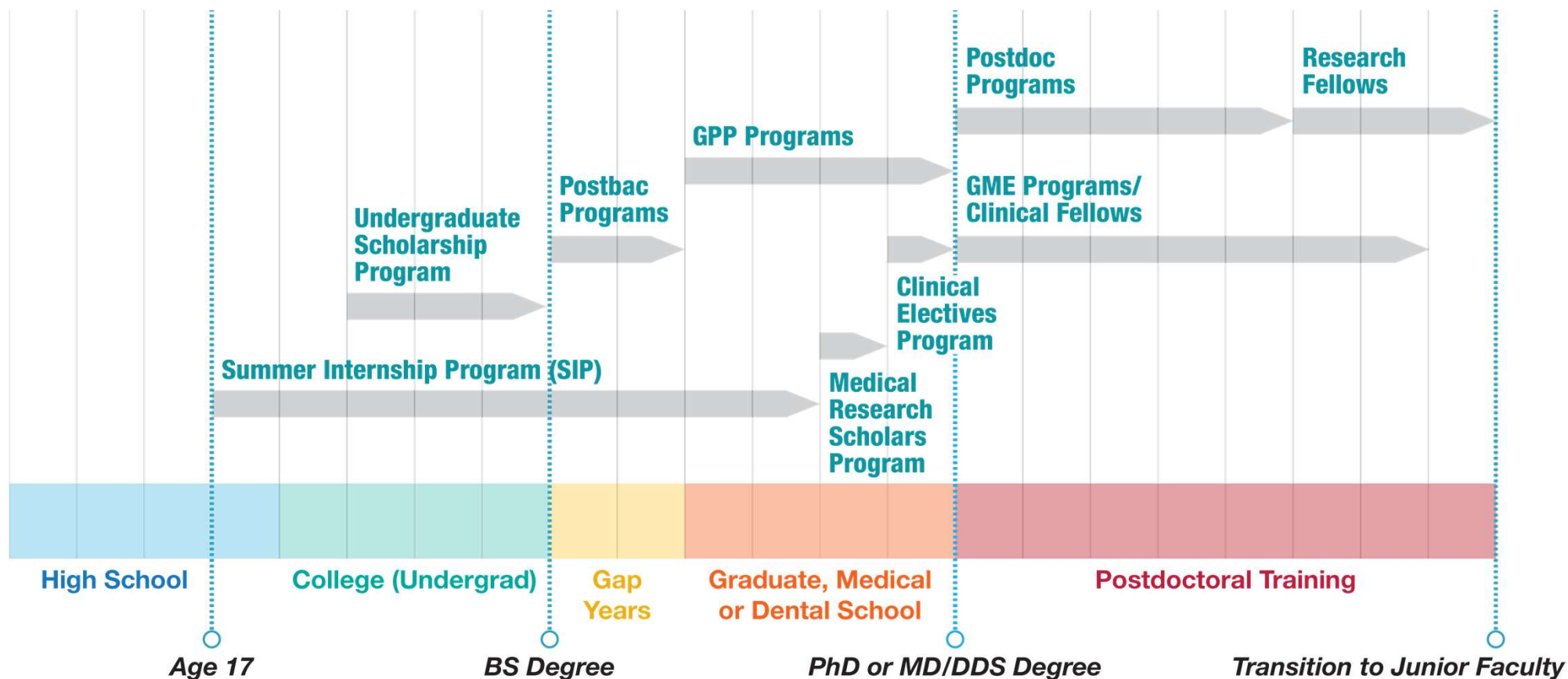


The NCI Intramural Clinical Research Program

- NIH is the largest clinical research center in the world
- The NIH clinical center is not a regular hospital
 - *Dedicated to patient-intensive clinical research and developing new approaches for prevention, diagnosis and treatment of cancer*
- Opportunity for **bench-to-bedside** and **bedside-to-bench research**
- Clinical training for next generations of scientists



CCR Training for Young Clinicians & Scientists at Many Levels



NIH Hematology-Oncology Fellowship Graduates 2020



Examples of Groundbreaking CCR Research

- ➡ Combination chemotherapy
- ➡ Anti-retroviral therapies
- ➡ Discovery of TGF β
- ➡ HPV vaccine development
- Early gene therapy
- Pioneering immunotherapy
- Development of immunotoxins
- ➡ Molecular classification of lymphoma and renal cancer
- Epigenetics and chromatin biology
- Basic Immunology
- Imaging technology (SKY, UroNav)
- Laser capture microdissection
- Discovery and use of KGF (Kepivance)

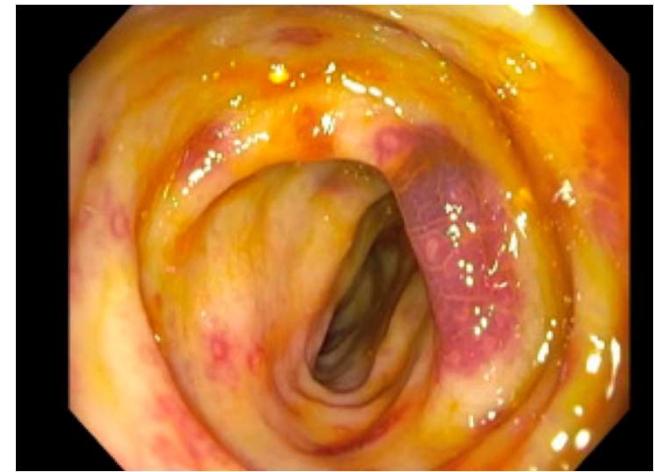


CCR Drug Approvals

Status	Drug Name	Drug Type	Target	Investigator/s	Approval Date
Approved for marketing	Avelumab	Anti PD-L1 Antibody	Merkel Cell Carcinoma	Gulley/Schlom	March 2017
Approved for marketing	Yescarta	CD19 CAR T	B-Cell Lymphoma	Kochenderfer/Rosenberg	October 2017
Approved for marketing	Lumoxiti	Anti CD22-toxin	Hairy Cell Leukemia	Pastan/Kreitman	September 2018
Approved for marketing	Selumetinib	MEK inhibitor	NF1	Widemann/Gross	April 2020
Approved for marketing	Pomalidomide	Immunomodulator	Kaposi Sarcoma	Yarchoan	May 2020

Breakthrough Therapy	LN-145	TIL therapy	Advanced cervical cancer	Surgery Branch	May 2019
Breakthrough Therapy	CD22	CD22 CAR T	B-cell Acute Lymphoblastic Leukemia	Shah	August 2019
Breakthrough Therapy	MK-6482	Hypoxia-inducible factor-2 alpha inhibitor	von Hippel-Lindau disease-associated renal cell carcinoma	Linehan/Srinivasan	July 2020
Orphan Drug	Zotiraciclib	Kinase inhibitor	Glioma	Wu	December 2019

The story of pomalidomide in Kaposi sarcoma

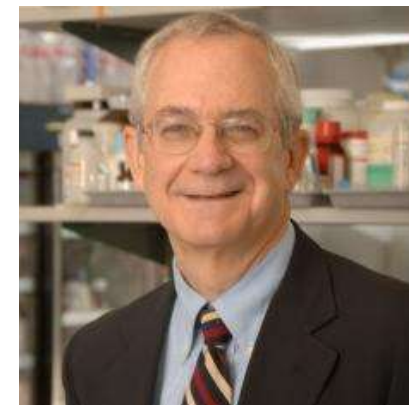


The story of pomalidomide in Kaposi sarcoma

Journal of Clinical Oncology 2000 Jul;18(13):2593-602

Activity of Thalidomide in AIDS-Related Kaposi's Sarcoma

By Richard F. Little, Kathleen M. Wyvill, James M. Pluda, Lauri Welles, Vickie Marshall, William D. Figg, Fonda M. Newcomb, Giovanna Tosato, Ellen Feigal, Seth M. Steinberg, Denise Whitby, James J. Goedert, and Robert Yarchoan



Blood (2011) 118 (11): 2970–2975

Pomalidomide plus low-dose dexamethasone in myeloma refractory to both bortezomib and lenalidomide: comparison of 2 dosing strategies in dual-refractory disease

Martha Q. Lacy,¹ Jacob B. Allred,² Morie A. Gertz,¹ Suzanne R. Hayman,¹ Kristen Detweiler Short,¹ Francis Buadi,¹ Angela Dispenzieri,¹ Shaji Kumar,¹ Philip R. Greipp,¹ John A. Lust,¹ Stephen J. Russell,¹ David Dingli,¹ Steven Zeldenrust,¹ Rafael Fonseca,³ P. Leif Bergsagel,³ Vivek Roy,⁴ A. Keith Stewart,³ Kristina Laumann,² Sumithra J. Mandrekar,² Craig Reeder,³ S. Vincent Rajkumar,¹ and Joseph R. Mikhael³

The story of pomalidomide in Kaposi sarcoma

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ClinicalTrials.gov

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Trial record 1 of 1 for: NCT01495598

Previous Study | [Return to List](#) | Next Study

Pomalidomide for Kaposi Sarcoma in People With or Without HIV

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Sponsor:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
National Institutes of Health Clinical Center (CC) (National Cancer Institute (NCI))

ClinicalTrials.gov Identifier: NCT01495598

Recruitment Status: Active, not recruiting
First Posted: December 20, 2011
Last Update Posted: October 8, 2020



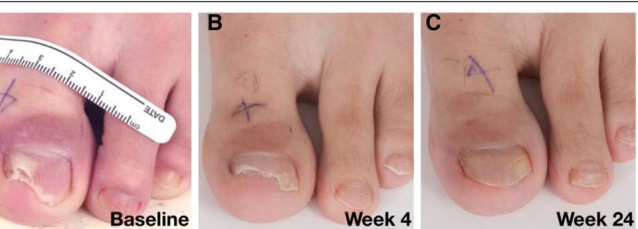
VOLUME 34 · NUMBER 34 · DECEMBER 1, 2016

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Pomalidomide for Symptomatic Kaposi's Sarcoma in People With and Without HIV Infection: A Phase I/II Study

Mark N. Polizzotto, Thomas S. Uldrick, Kathleen M. Wyvill, Karen Aleman, Cody J. Peer, Margaret Bevans, Irini Sereti, Frank Maldarelli, Denise Whitby, Vickie Marshall, Priscila H. Goncalves, Vikram Khetani, William D. Figg, Seth M. Steinberg, Jerome B. Zeldis, and Robert Yarchoan



The story of pomalidomide in Kaposi sarcoma

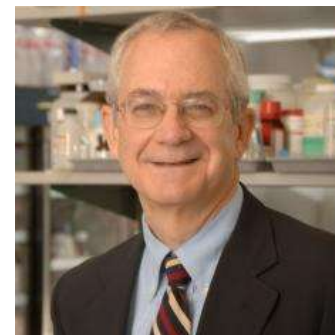
www.impactjournals.com/oncotarget/

Oncotarget, 2017, Vol. 8, (No. 31), pp: 50342-50358

Priority Research Paper

Restoration of immune surface molecules in Kaposi sarcoma-associated herpes virus infected cells by lenalidomide and pomalidomide

David A. Davis^{1,*}, Suraj Mishra^{1,*}, Holda A. Anagho¹, Ashley I. Aisabor¹, Prabha Shrestha¹, Victoria Wang¹, Yuki Takamatsu¹, Kenji Maeda¹, Hiroaki Mitsuya¹, Jerome B. Zeldis² and Robert Yarchoan¹



ONCOIMMUNOLOGY

2019, VOL. 8, NO. 2, e1546544 (16 pages)

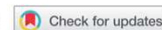
<https://doi.org/10.1080/2162402X.2018.1546544>



Taylor & Francis
Taylor & Francis Group

ORIGINAL RESEARCH

OPEN ACCESS



Pomalidomide increases immune surface marker expression and immune recognition of oncovirus-infected cells

David A. Davis^{a*}, Prabha Shrestha^{a*}, Ashley I. Aisabor^a, Alexandra Stream^a, Veronica Galli^b, Cynthia A. Pise-Masison^b, Takanobu Tagawa^a, Joseph M. Ziegelbauer^a, Genoveffa Franchini^b, and Robert Yarchoan^b



The story of pomalidomide in Kaposi sarcoma

Pomalidomide combined with chemotherapy...



[Journal of Clinical Oncology](#) > [List of Issues](#) > [Volume 38, Issue 15 suppl](#) >

SARCOMA

A phase I trial of pomalidomide in combination with liposomal doxorubicin in patients with Kaposi sarcoma with or without other KSHV-associated diseases.

[Ramya Ramaswami](#), [Kathryn Anne Lurain](#), [Anaida Widell](#), [Priscila Hermont Goncalves](#), [Irene Ekwede](#), [William Douglas Figg](#), [Cody J. Peer](#), [Ralph Mangusan](#), [Jomy George](#), [Seth M. Steinberg](#), [Vikram Khetani](#), [Denise Whitby](#), [Thomas S. Uldrick](#), [Robert Yarchoan](#)

Novel combination immunotherapy approaches...

NCI Protocol #: 10363
Local Protocol #: pending
ClinicalTrials.gov Identifier: TBD

TITLE: A Phase I Study of pomalidomide and nivolumab in patients with virus-associated malignancies with or without HIV

Coordinating Center: NCICCR / NCI Center for Cancer Research

Principal Investigator: Kathryn Lurain, MD, MPH
HIV and AIDS Malignancy Branch
National Cancer Institute

Immunomodulatory agents for new virus-driven cancers...

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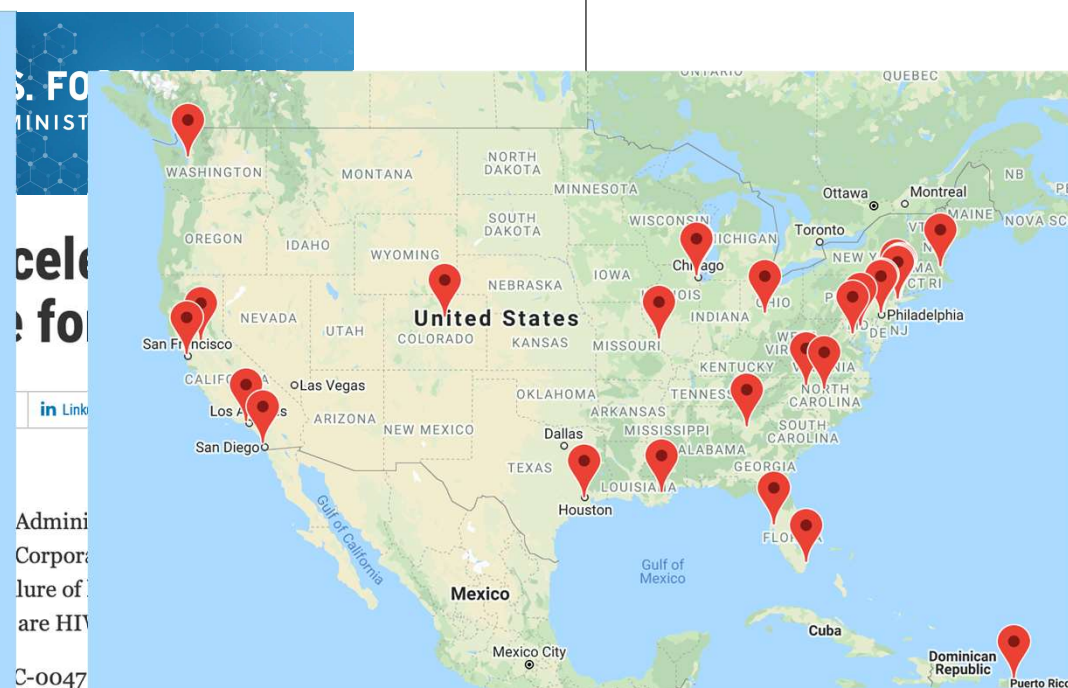
Trial record 1 of 1 for: NCT02911142

[Previous Study](#) | [Return to List](#) | [Next Study](#)

Lenalidomide Combined With Modified DA-EPOCH and Rituximab (EPOCH-R2) in Primary Effusion Lymphoma or KSHV-associated Large Cell Lymphoma

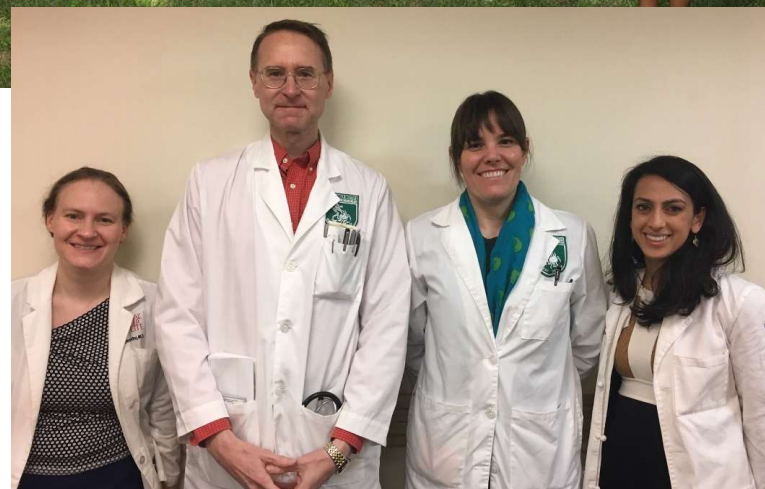
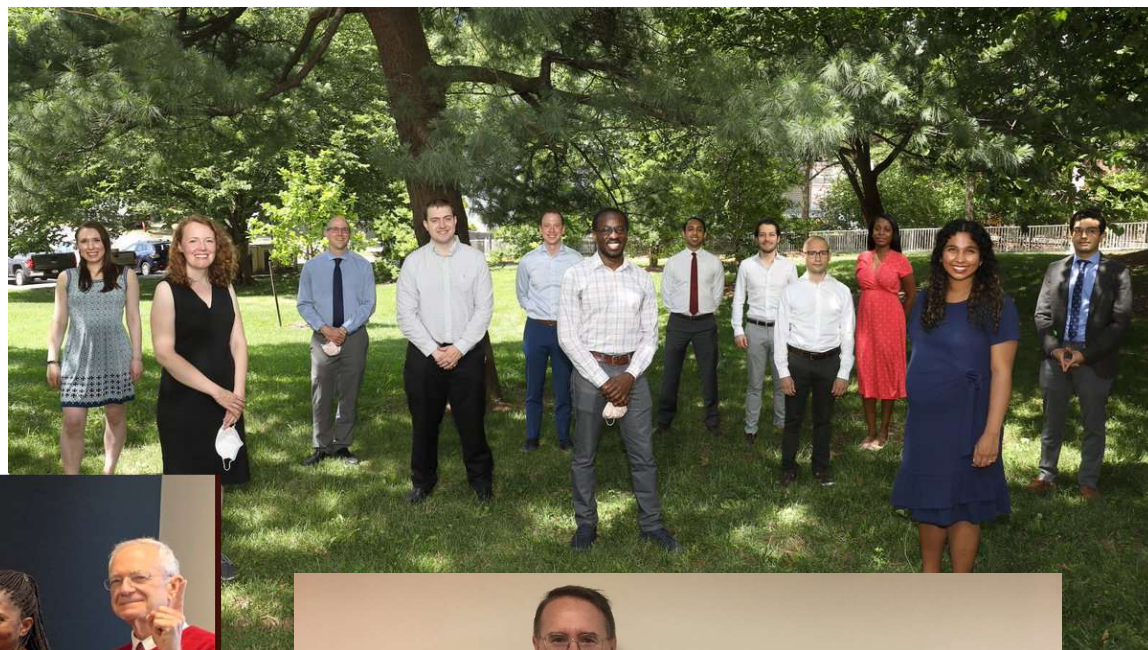
ClinicalTrials.gov Identifier: NCT02911142

The story of pomalidomide in Kaposi sarcoma



Administrative
Corporate
Structure of
are HIV
C-0047
stitute. Twenty-eight patients (18 HIV-positive, 10
idomide orally once daily on days 1 through 21 of
ssion or unacceptable toxicity. All HIV-positive
etroviral therapy.

The NCI Intramural Research Program



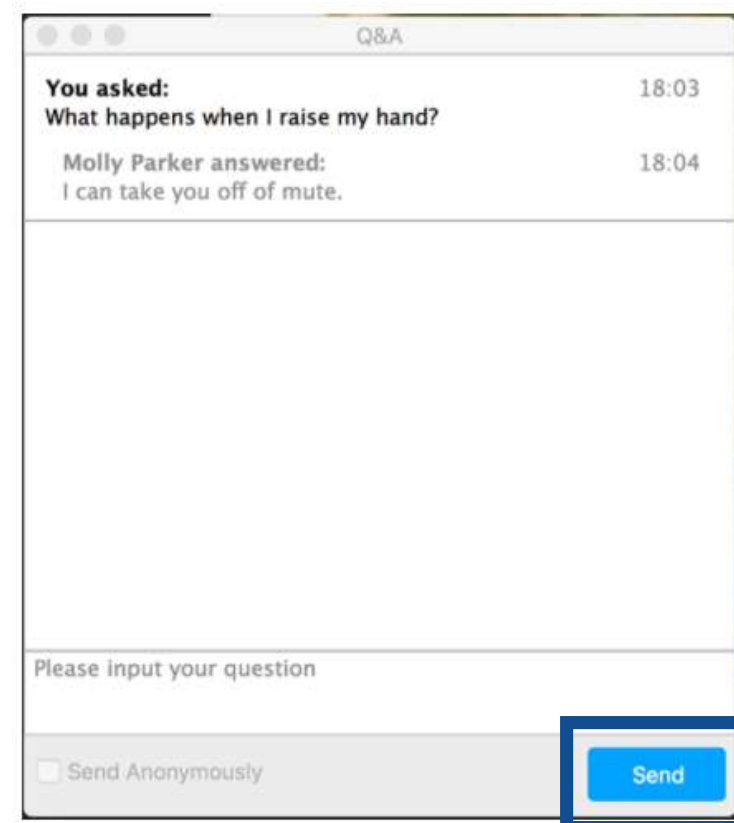
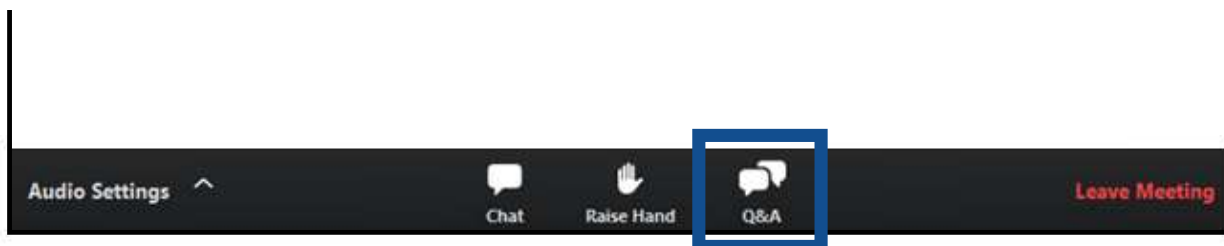


NATIONAL CANCER INSTITUTE
Center for Cancer Research

ccr.cancer.gov

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Society for Immunotherapy of Cancer

Cancer Immunotherapy Winter School

Feb. 22–24, 2021 • Virtual Program

The Society for Immunotherapy of Cancer (SITC) Cancer Immunotherapy Winter School is a comprehensive cancer immunotherapy education program, led by experts in the field. Participants will improve their understanding of the core principles of tumor immunology and cancer immunotherapy and examine developing areas in the field.

Attendees are able to tailor their learning experience as the program offers both clinical- and research-focused tracks. In addition to deepening their understanding of integral facets of the field of cancer immunotherapy, attendees will expand their professional network, developing new relationships with faculty and other thought leaders in this intimate setting.

Register for the Virtual Program at:

<https://www.sitcancer.org/education/winter-school>



Society for Immunotherapy of Cancer



sitcancer.org/careerconnections

Career Connections Online Job Board

The Career Connections Online Job Board gives job seekers the key information on talent seekers and the job openings they need to make the next step in their career, including:

- Search jobs by location
- Set personal notifications and preferences
- Learn more about talent seekers
- Directly apply for open positions

Questions/Comments: connectED@sitcancer.org