

# NCI Center for Cancer Research

*Patient Safety at the CC – Right Path*

*William Dahut, M.D., Clinical Director*



Presentation to the Clinical Center  
Research Hospital Board  
October 19, 2018

## Our Vision

CCR is the world's leading catalyst for tomorrow's cancer research and patient treatments.

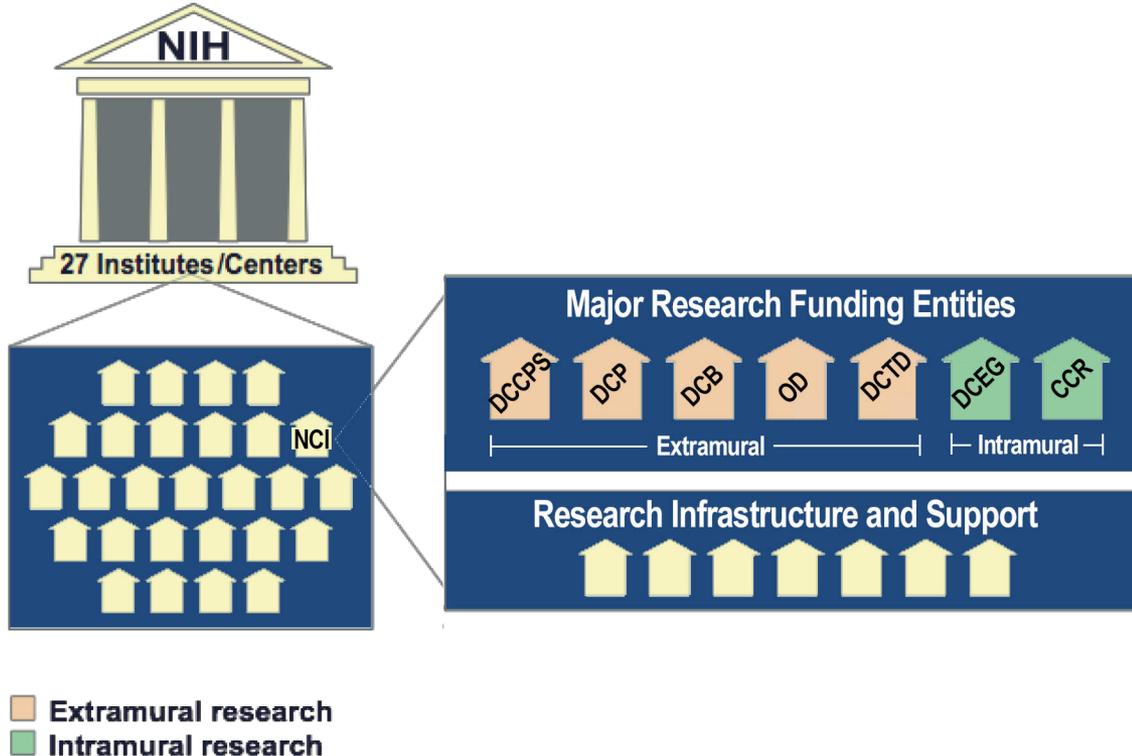
“...our goal is not to practice today's medicine, but to create the medicine of tomorrow.”

Steve Rosenberg on CBS

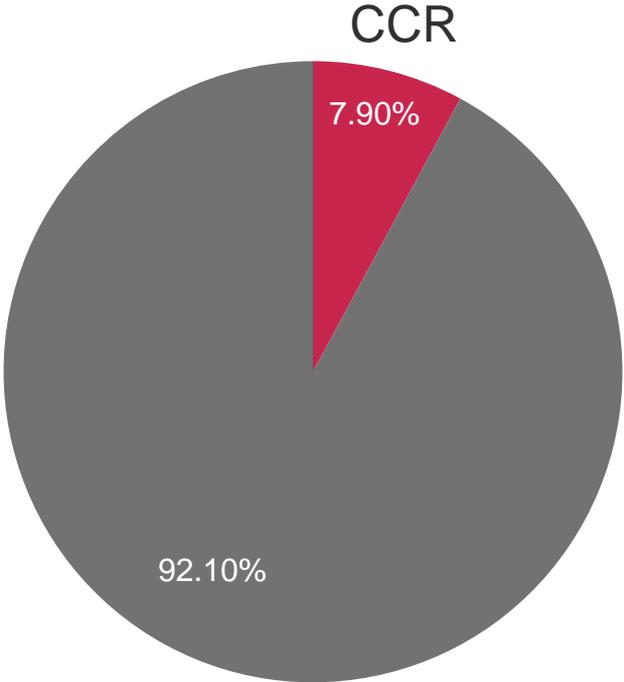
## Our Mission

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

# CCR is a part of the Intramural Research Program (IRP) at NIH



# NCI Budget



# NCI Clinical Center Usage

## Adjusted Patient Days\* by IC

Institute	FY 2017	FY 2017 % Total
NCCIH	133	0.17%
NCI	26,558	34.48%
NEI	1,832	2.38%
NHGRI	2,324	3.02%
NHLBI	8,956	11.63%
NIA	1	0.00%
NIAAA	3,426	4.45%
NIAID	12,014	15.60%
NIAMS	1,607	2.09%
NICHD	3,615	4.69%
NIDCD	14	0.02%
NIDCR	774	1.01%
NIDDK	4,419	5.74%
NIEHS	116	0.15%
NIMH	6,477	8.41%
NINDS	4,636	6.02%
NINR	115	0.15%
<b>Total</b>	<b>77,017</b>	<b>100.00%</b>

\*Adjusted Patient Days = Inpatient Days + (OP Visits x 0.4)

## % Financial Consumption\* by IC

Institute	FY 2017 % Total
NCCIH	0.08%
NCI	36.20%
NEI	1.31%
NHGRI	2.91%
NHLBI	14.76%
NIA	0.01%
NIAAA	2.73%
NIAID	17.47%
NIAMS	2.14%
NIBIB	0.08%
NICHD	4.38%
NIDA	0.01%
NIDCD	0.03%
NIDCR	0.60%
NIDDK	6.02%
NIEHS	0.19%
NIMH	5.61%
NINDS	5.38%
NINR	0.10%
<b>Total</b>	<b>100.00%</b>

\*NIH CC Calculated Financial Consumption %

# The NCI Center for Cancer Research in numbers

**235** Principal Investigators, **58** Tenure Track Investigators

Total Staff of **~2,900**, **~900** Post-docs and Clinical Fellows

**2** campuses, Bethesda (**164** PIs, basic and clinical), Frederick (**65** PIs, basic)

**23** Labs and **18** Branches

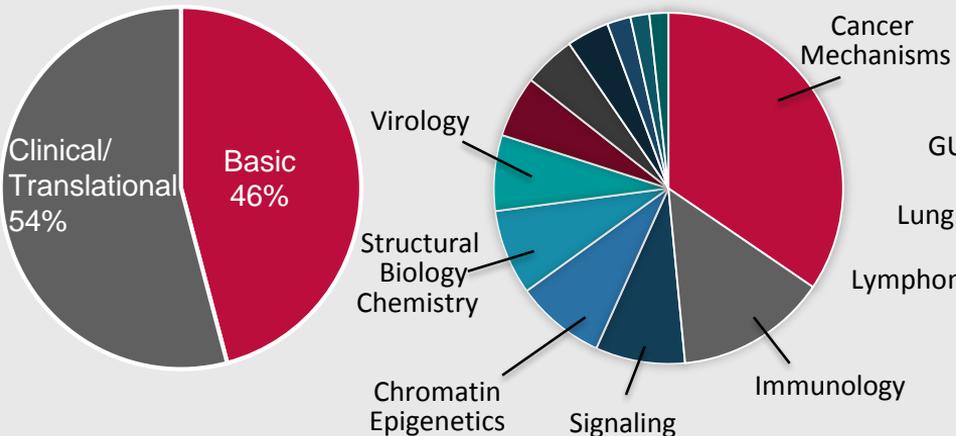
Publish **~2,500** papers per year

**~60** new patents per year; **~\$70M** patent/licensing royalty generated for NCI

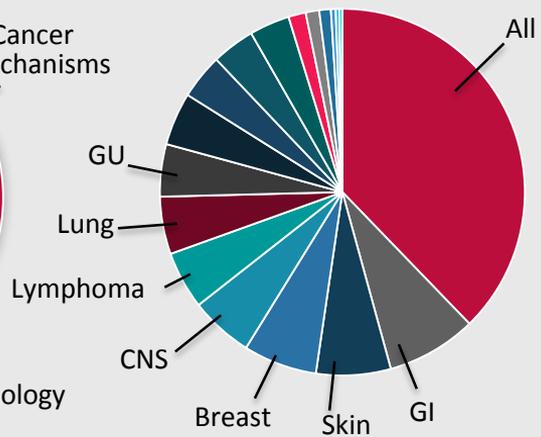
**251** open clinical trials

# The CCR Scientific Portfolio

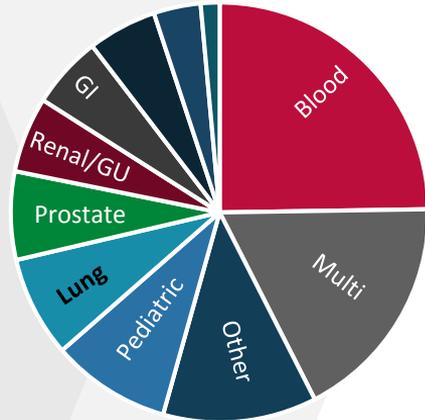
## Research topics



## Research by cancer sites

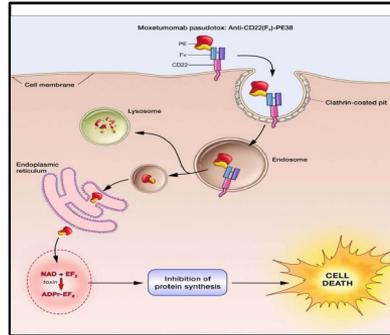


## Trials by cancer sites



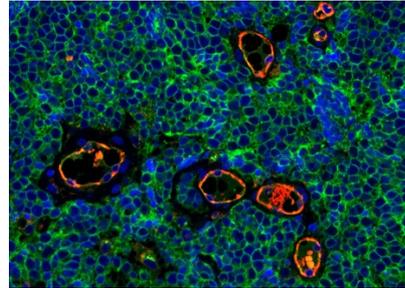
# Moxetumomab Approved by FDA for Hairy Cell Leukemia

Moxetumomab was originally discovered by Ira Pastan, M.D., and colleagues in NCI's [Center for Cancer Research \(CCR\)](#), and later licensed to MedImmune/AstraZeneca for clinical development.



## CCR plays key role in first FDA-approved drug for treatment of Merkel cell carcinoma

Avelumab, marketed as Bavencio, is the first FDA-approved treatment for MCC. Trials based at the Center for Cancer Research (CCR)...were instrumental in streamlining avelumab's approval.



## FDA grants orphan drug status to selumetinib for neurofibromatosis type 1 (NF1) treatment

Brigitte Widemann, M.D., Chief of the Pediatric Oncology Branch, and her colleagues started a phase I clinical trial to test selumetinib in NF1 patients with plexiform neurofibromas... The team found that in the majority of patients, tumors shrank by 20-50 percent when they were given selumetinib.



# Rosenberg, NCI-supported researchers to receive 2018 Albany Prize

Steven A. Rosenberg, M.D., Ph.D., Chief of the Center for Cancer Research (CCR) at the National Cancer Institute (NCI), has been named a recipient of the 2018 Albany Medical Center Prize in Medicine and Biomedical Research for his leading role in the development of immunotherapy to treat cancer. Dr. Rosenberg will share the honor with fellow immunotherapy researchers James P. Allison, Ph.D., and Carl H. June, M.D.

NCI Press Release  
August 2018

IN THE LAB  
After 30 years, an immunotherapy to rival CAR-T finally nears the clinic



Surgical Oncologist Dr. Steven Rosenberg Receives the 2018 Jacobson Innovation Award of the American College of Surgeons

International award recognizes cancer researcher's role in developing effective immunotherapies and gene therapies for patients with advanced cancers



By JONATHAN LAPOOK CBS NEWS June 4, 2018, 6:39 PM

**Groundbreaking treatment saves life of woman with late-stage breast cancer**

STAT+

# CCR's Douglas Lowy and John Schiller receive the 2017 Lasker~DeBakey Clinical Medical Research Award

... for their groundbreaking research leading to the development of human papillomavirus (HPV) vaccines. The Lasker Awards are widely regarded as the country's most prestigious biomedical research prizes and have recognized outstanding basic and clinical medical research since 1945.



# Safety following the NIH Red Team Report

The addition of three full-time hospitalists

- Contracted with Hopkins/Suburban to hire a pool of hospitalists
- Provides coverage 2/3 inpatient services for the Medical Oncology Service (solid tumor and HIV/Lymphoma service) and the Urologic Oncology service
- Replaced five advanced practitioners, starting in July 2017

Total number of patients seen during FY18		# of admissions	Requirement for admission/hospitalization
	928	61	Work-up
		516	Treatment
		4	Pharmacokinetics
		347	Adverse Event

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: Sign out/transitions in care

- Primary team members: Christopher Pleyer, Rahul Lakhotia, MOS hospitalist service (Vikas Kapoor and Dan Johnson)
  - Faculty: Marijo Bilusic and James Gulley
  - Participants: All fellows, all hematology/oncology consult attendings, faculty who attend on in-patient services
- Issue: Transitions of care can lead to medical errors and adverse events.
- Plan: Sign-out process and hand-outs vary significantly between multiple teams and services. To address this suggestions from teams were taken and used to plan implementation of changes to improve effectiveness.
  - a) Training about transitions of care was provided to all fellows.
  - b) Electronic sign-out tool (tab) was updated and is now incorporated in the CRIS for all inpatient rotations
  - c) A new program called I-PASS is to be implemented across the Clinical Center and all fellowship programs at NIH; pilot project already started (allergy and immunology and infectious disease) in November 2017
  - d) In person sit down

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: OP12 Clinic Flow

- Primary Team members: Lekha Mikkilineni, Kathryn Lurain, Charalampos Floudas
  - Clinical Center contributors: Ekene Monyei, Linda Tondreau and OP12 charge nurses
  - Participants: includes all fellows (all rotate through this clinic)
  - Faculty: Marijo Bilusic and James Gulley
- Issue: OP12 clinic is inefficient and poorly coordinated causing poor patient flow and decreased fellow satisfaction
- Plan: Patients spend a lot of time waiting for nursing evaluation and later waiting for attending physicians; the team will obtain data on wait times
  - a) 14 day patient flow study (May 2017- June 2017)
  - b) Patient satisfaction survey
- Outcome:
  - Data from the flow study and patient survey were obtained, weekly adjustments and follow-ups made, discussed further in fellow meetings
  - Dr. Bilusic and Dr. Mikkilineni worked together to continuously analyze data, which was presented to the Chief of the Medical Oncology Service
  - A Patient Care Coordinator was to be hired to support this activity; further PDSA will focus on impact of the PCC

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: Documentation/Notes/New Patient Records

- Primary Team Member: Jason Redman
  - Clinical Center Contributor: David Herion
  - Faculty: Marijo Bilusic and Ravi Madan
- Issue: Current documentation and quality of notes needs improvement
- Plan: Working closely with NIH Clinical Center leadership and Information Technology administrators to provide fellow feedback aimed at facilitating improvements to electronic medical record formats.
  - a) Notes: Standardize sign out format, home screen layout, progress notes and ordering screens. These have been implemented with positive feedback from fellows across the program.
  - b) New Patient Records: Initiated a program to streamline transfer of new patients' medical records from referral teams to clinicians performing new patient 'screening visits' at the NCI. Fellows will have access to a database of outside medical records. Access to this user-friendly platform will add efficiency to the record review process. This project is in progress.

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: SOP for OP12 clinic admissions

- Primary Team Members: Scott Norberg, Charalampos Floudas, MOS hospitalist service
  - Clinical Center Contributor: David Herion
  - Faculty: Marijo Bilusic
- Issue: An SOP for OP12 admissions is lacking, fellows and nurses have noted that several recent admissions which were planned have been missed by various team members or night cover personnel.
- Plan: We have been working with the OP12 nursing staff, inpatient hospitalist team and inpatient nursing staff to determine what they need for an effective hand-off between the outpatient clinic and the inpatient unit.
  - We have also drafted a SOP that will standardize the process throughout the Institute. This project has expanded to include our electronic medical records and developing ways to create an electronic admission order that streamlines the current process.
- Outcome: Currently studying the effects of the new SOP

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: Sepsis algorithm

- Primary Team Members: Laura Lee (Clinical Center), Christopher Pleyer
- Issue: Cancer patients are immunocompromised and sepsis should be treated within 1 hour.
- Plan: Commonly used antibiotics should be premixed and readily available.
  - a) Commonly used/needed antibiotics now available in OMNICELL machines on floors on the 3rd floor in order to facilitate rapid antibiotic administration. Compliance with antibiotic administration <60 minutes for febrile neutropenia appears to be improving (data waiting to mature).
  - b) Pending a response from the patient safety team on developing a SOP and order sets.
- Plan: The fellowship program previously created a series of plasticized pocket note cards with different antibiotic regimens for management of neutropenic fever, including cases that are serious enough to meet sepsis criteria, and also conducted a series of management conferences on sepsis that may occur in patients who are not neutropenic.
  - Responses from patient safety team and SOP development will be integrated with prior efforts to determine whether new placards, additional management conferences and continued efforts towards having pre-mixed antibiotics readily available are necessary.

# Safety following the NIH Red Team Report

## Fellow Led QI/QA Project: Clin-FelCom

- Primary Team Members: Christopher Pleyer, Peter DeMaria
  - Clinical Center Contributor: Robert Lembo
- The Committee is working with the MEC and GMEC office on several quality improvement and patient safety projects:
  - Improving access of radiology services during non-business hours
  - Creation of a more standardized and streamlined process for admitting patients to the NIH Clinical Center, involving working with the office of patient safety and clinical quality improvement

# Safety following the NIH Red Team Report

## Completed Project: CRIS oncology tab

- Background: Oncology-related information was scattered throughout the CRIS system making it difficult to efficiently and accurately obtain specifics surrounding the care of cancer patients.
- Safety measure: A CRIS oncology tab was developed to provide accurate and concise patient-specific information related to the prescribing, dispensing, and administration of chemotherapy and investigational oncology agents.
- Primary team members: Dr. Jharana (Tina) Patel (DCRI), Dr. David Herion (DCRI), Dr. Barry Goldspiel (CC Pharmacy), Dr. James Gulley (NCI), Dr. Lisa Cordes (NCI/OD)

# Safety following the NIH Red Team Report

## Completed Project: Authorized prescribers

- Background: All practitioners at NIH had access to order sets containing investigational agents which could lead to inappropriate prescribing practices.
- Safety measure: Developed and implemented a process to ensure only necessary providers have access to CRIS order sets for NCI investigational agents. Orders therefore cannot be entered without requiring a co-signature from a physician PI/Al on that specific NCI trial.
- Primary team members: Oncology Clinical Pharmacy Specialists (CC Pharmacy), Dr. Barry Goldspiel (CC Pharmacy), Dr. Jharana (Tina) Patel (DCRI), Dr. Vicki Skahill (DCRI), Dr. James Gulley (NCI), Dr. Lisa Cordes (NCI/OD)

# Safety following the NIH Red Team Report

## Completed Project: Patient-centric workflow

- Background: Clinical Center Pharmacy and nursing staff expressed concern regarding timing of Genitourinary Malignancies Branch (GMB) orders for administration in the 3SE-S Day Hospital.
- Safety measure: To improve patient flow and minimize demand on nursing and pharmacy staff, the GMB team modified our approach to clinic scheduling to ensure patients receiving treatment in the day hospital were seen earlier in the day and screens/consultations were later in the day. An 8:15 a.m. patient appointment slot was also added.
- Primary team members: NCI GMB team, CC OP12 Nursing Staff, Linda Tondreau (CC Nursing), Dr. James Gulley (NCI), Dr. Fatima Karzai (NCI)

# Safety following the NIH Red Team Report

## Ongoing Project: Co-signature project

- Background: Current policies do not require the co-signature of an attending physician/PI/AI for anticancer agents or investigational agents prior to order verification or administration.
- Safety measure (completed): To ensure investigational and chemotherapeutic agents are properly reviewed by a trained individual, the GMB team successfully piloted a manual process requiring the appropriate co-signature prior to order verification.
- Safety measure (future): Expand on the success of the GMB co-signature pilot to include an automated process in CRIS for all of Adult Medical Oncology.
- Primary team members: NCI GMB team, Dr. Jharana (Tina) Patel (DCRI), Dr. Rosa Nadal (NHLBI), Dr. James Gulley (NCI), Dr. Lisa Cordes (NCI/OD)

# Safety following the NIH Red Team Report

## Future Project: Chemotherapy competency program

- Background: Standard of practice at outside cancer centers require practitioners who are involved with the prescribing of anticancer agents undergo a comprehensive training program specific to this area. The NIH currently does not offer such a program.
- Safety measure: Develop a chemotherapy competency program for NCI fellows and incoming NPs/PAs. This program would involve educational components and hands-on training for prescribing anticancer agents.
- Primary team members: Dr. Marijo Bilusic (NCI), Dr. James Gulley (NCI), Dr. Lisa Cordes (NCI/OD), others TBD

# Safety following the NIH Red Team Report

## Future: Standard of care project

- Background: Unlike investigational agents, CRIS order templates for standard of care chemotherapy regimens have not been developed at the NIH.
- Safety measure: Develop standardized order sets for commonly used anticancer regimens in an effort to reduce the potential for medication errors, integrate evidence-based supportive care recommendations, and comply with established standards surrounding chemotherapy prescribing and administration.
- Primary team members: Dr. Rosa Nadal (NHLBI), Dr. Cecilia Monge Bonilla (NCI), Dr. Marijo Bilusic (NCI), Leslie Smith (CC Nursing), Dr. Jharana (Tina) Patel (DCRI), Dr. James Gulley (NCI), Dr. Lisa Cordes (NCI/OD), others TBD

# Prostate Cancer Multidisciplinary Clinic

10-year anniversary  
2008 to 2018

## **Radiation Oncology Branch**

Dr. Lindsay Rowe, PCMC Medical  
Director  
Dr. Deborah Citrin  
ROB residents  
Tess Cooley-Zgela, RN  
Kelli Brown  
Clinical Center nurses: Amy  
Wilkins, Elizabeth Heneghan,  
Dawn Berth

## **Urologic Oncology Branch**

Dr. Peter Pinto  
Dr. Vladmir Valera  
UOB Senior Fellows

## **Department of Pathology**

Dr. Maria Merino  
Pathology residents

## **Molecular Imaging Program**

Dr. Peter Choyke  
Dr. Baris Turkbey  
Radiology residents

## **Medical Oncology**

Dr. William Dahut  
Dr. David VanderWeele  
Dr. Fatima Karzai  
Dr. James Gulley  
Dr. Ravi Madan  
Dr. Howard Parnes  
Guinevere Chun, RN, PCMC Case  
Manager  
Anna Couvillon, NP, PCMC Team  
Lead  
Amy Hankin, PA  
Nikki Williams, NP  
GMB Fellows

## **Clinical Center Department of Interventional Radiology**

Dr. Brad Wood  
Vickey Anderson, NP

# When his PSA score spiked, prostate surgery loomed, but NIH offered another way

Marilyn Fenichel  
The Washington Post  
February 25, 2013

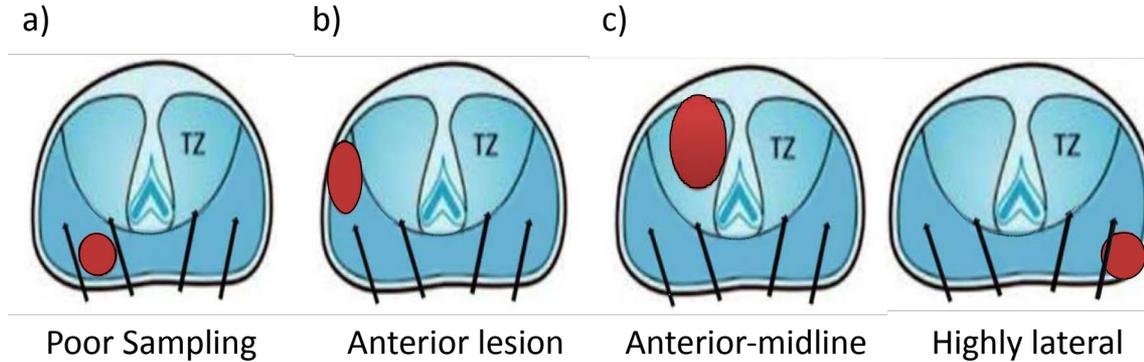
## ‘A breakthrough in imaging’

For almost a decade, research oncologists and medical engineers have been developing and refining a system using an advanced MRI device to take images of all 12 cores of the tiny prostate gland. This method “is a breakthrough in imaging for prostate cancer, analogous to the introduction of mammography for breast cancer,” said **Peter A. Pinto**, head of the prostate cancer section of NCI’s urologic oncology branch.



# Needed: image guided biopsy

## Over diagnosis with



“Why is the prostate the only organ in the body that is biopsied blind?” Peter Pinto, M.D. (2003)

Courtesy: Caroline Moore UCL

# Multi-parametric Prostate MRI



3 Tesla MRI



Endorectal  
coil

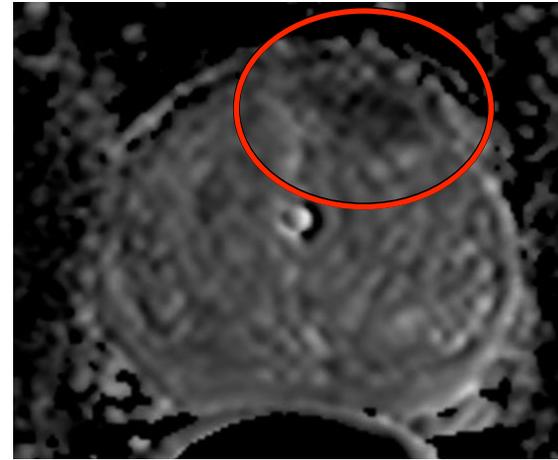
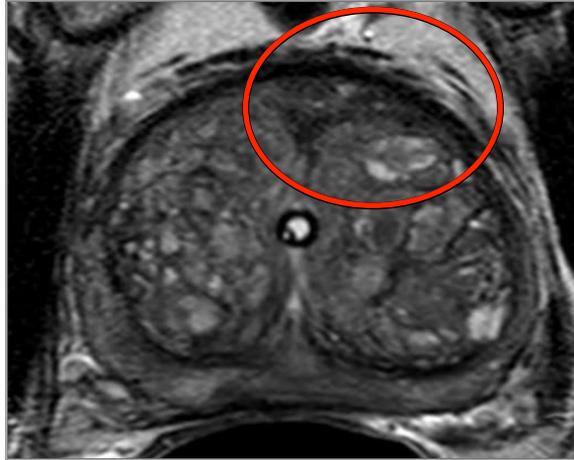


16-channel  
cardiac coil

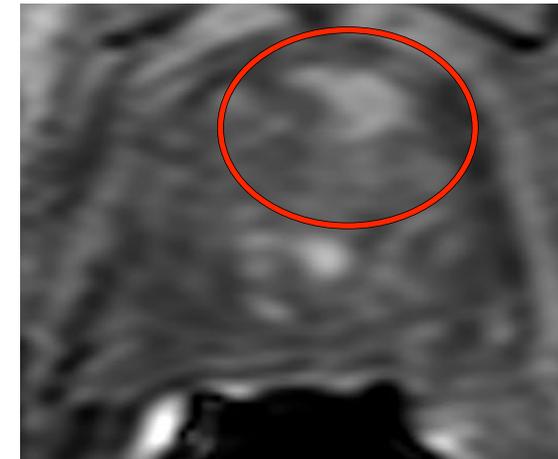
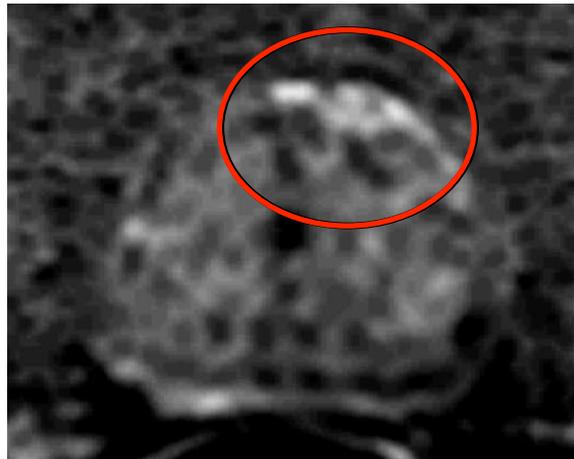


Baris Turkbey, M.D.

# 66-year-old man, PSA=7.33ng/dl, 2 prior negative TRUS guided biopsy

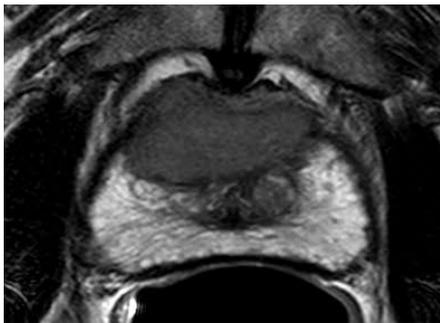


Left mid anterior  
TZ-1.8cm

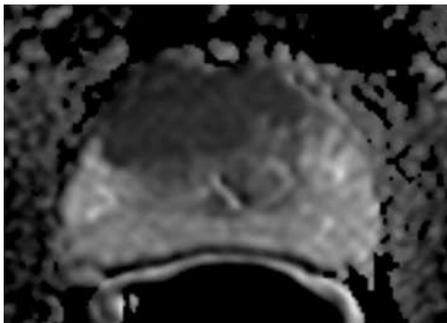


Gleason 3+4 (60% core involvement)

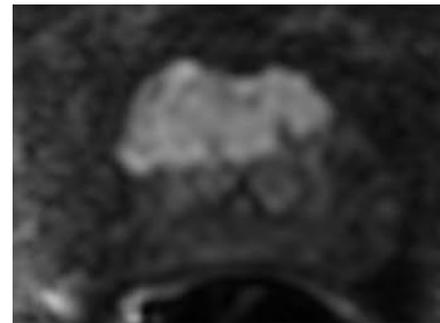
# 72-year old man with a serum PSA=38.6ng/dl with 3 prior TRUS guided biopsies



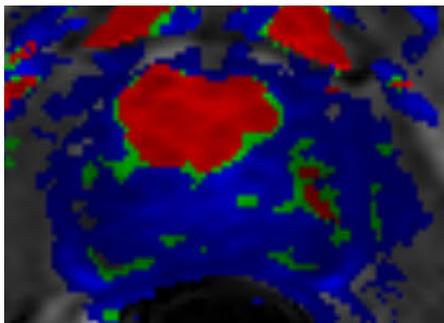
T2W MRI



ADC map



B=2000 DWI



DCE MRI permeability map

Color encoded contrast enhancement

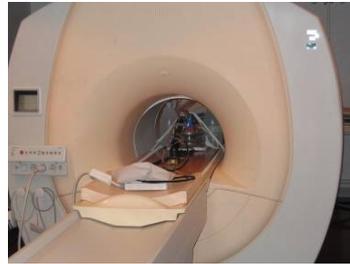


Brad Wood, M.D.

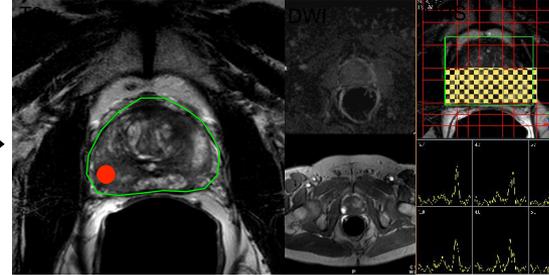
18F-DCFBC PET study localizes the anterior TZ lesion

# Prostate Fusion-targeted biopsy workflow

Prior to  
MRI Suite



MRI acquisition with ERC

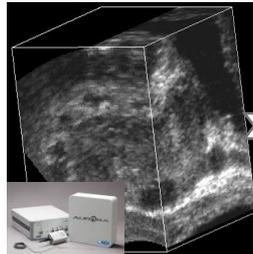


Prostate segmentation and target identification

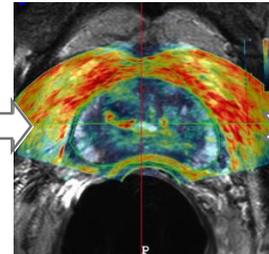


Day of  
procedure

Pre-procedure

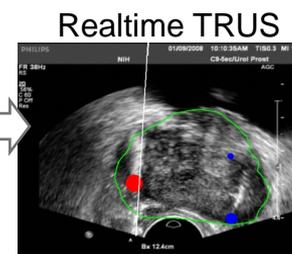


3D TRUS  
acquisition



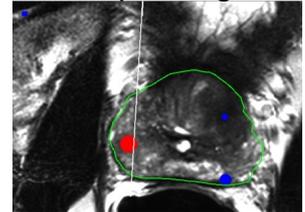
MRI - 3D TRUS  
registration

Intra-procedure

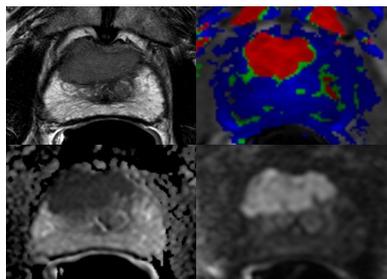


Targeted biopsy with  
realtime TRUS/MRI fusion

Corresponding MRI



# The Development of Prostate Imaging and Image Guided Biopsy 2000-2016



Multiparametric MRI 2000's



In gantry biopsy 2003-6



MRI-TRUS-GPS-2006



Clinical MR-TRUS Fusion 2008

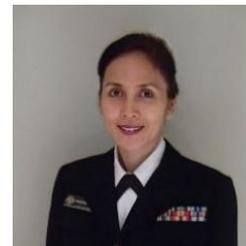
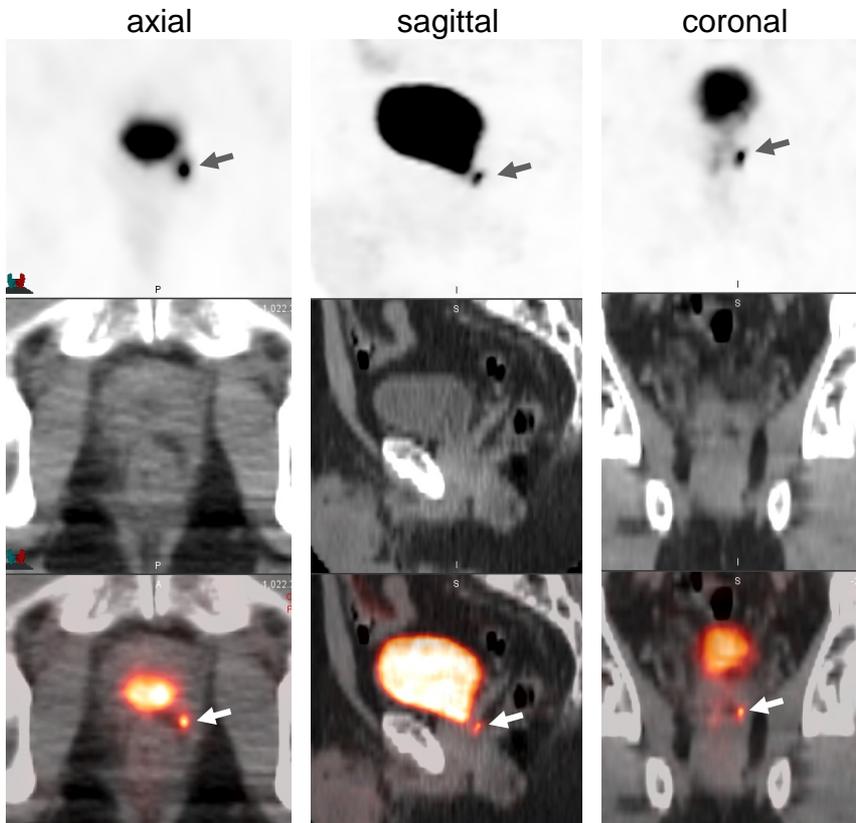


Commercial MR-TRUS fusion  
Devices 2013



Worldwide Image  
Guided Bx (IGB) 2018

# Local Recurrence: DCFPyl PET/CT



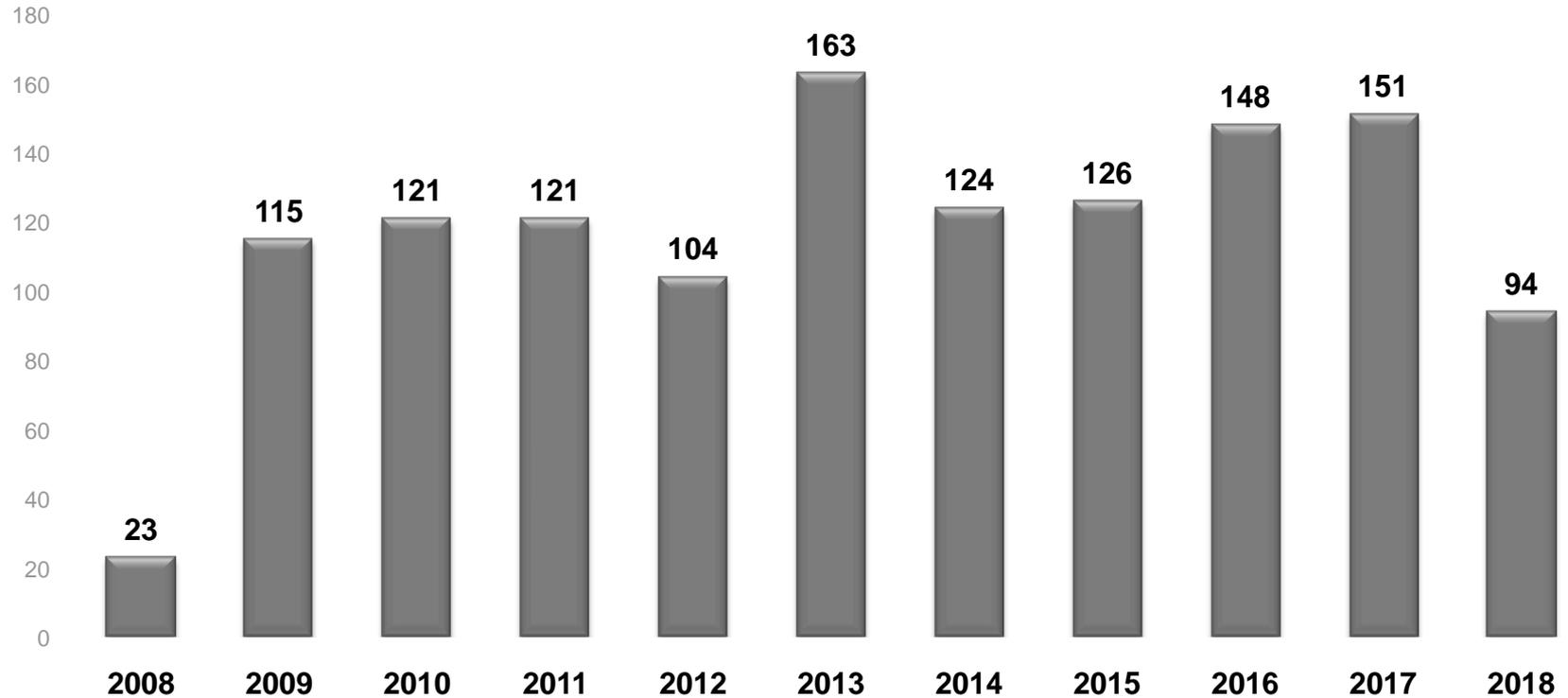
Liza Lindenberg



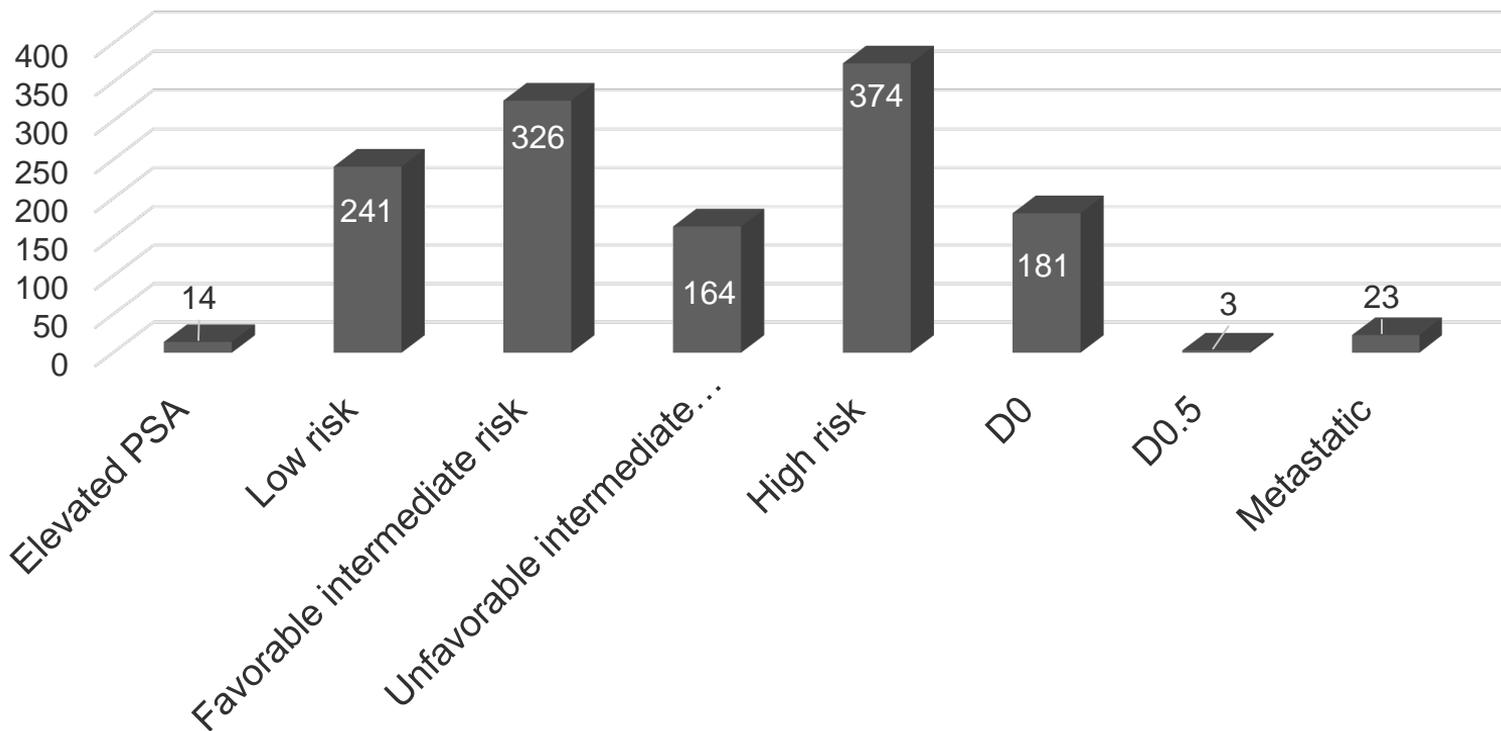
Esther Mena

Status post-prostatectomy (2007) Recent PSA (10/02/17) = 1.29 ng/mL.

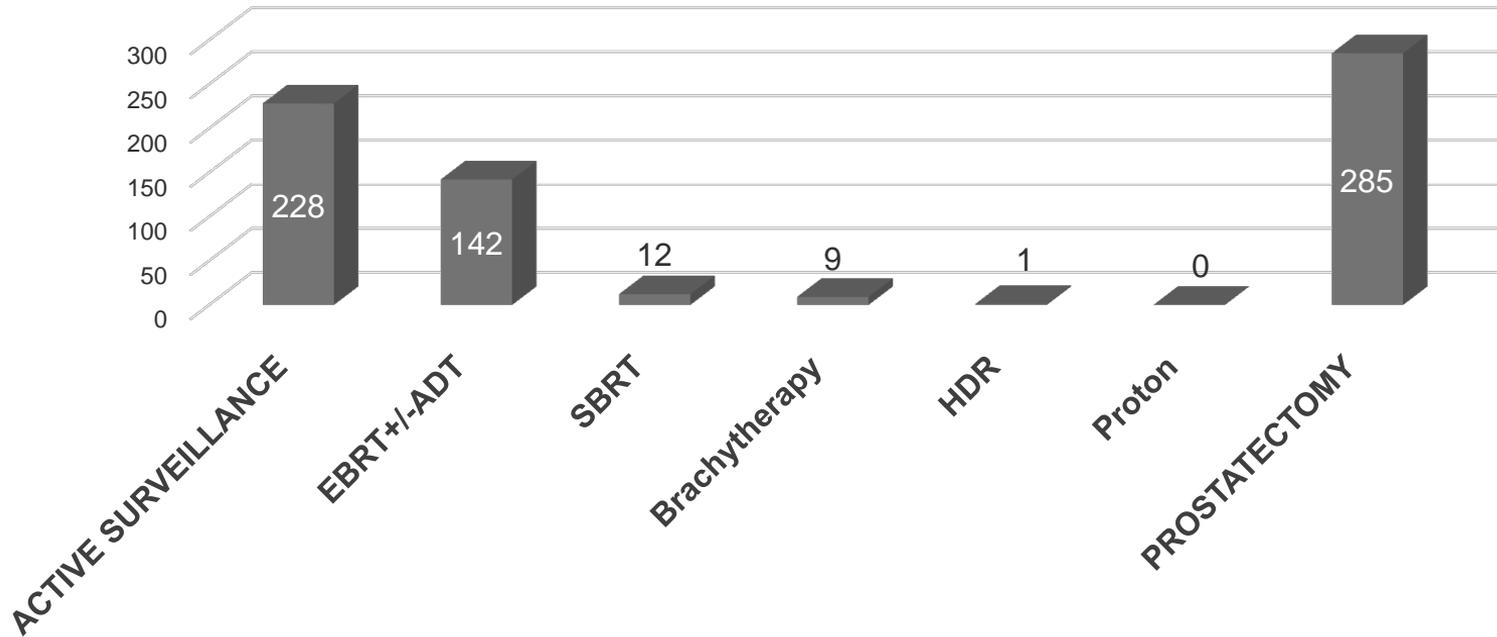
# Overall patient visits = 1290



# NCCN Risk Group (2008 to 2018)



# Treatment Decision - Newly Diagnosed (2008 to 2018)



# Treatment Decision – Post-Definitive Therapy (2008 to 2018)



# The Right Path

- As the largest user of the Clinical Center, NCI has a responsibility to lead the charge, affirming patient safety as our top priority. Our focus has resulted in, and continues to address:
  - Process improvement
    - Transition of care, documentation, patient flow, order sets
  - Education and training at all levels
    - Clin Fel-Com, clinical trials orientation
  - Transparency from leadership
    - All Hands, Clinical Directors, Staff Clinicians meetings
  - Collaboration across disciplines and organizations
    - Co-sponsored improvement projects



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**Center for Cancer Research**

[ccr.cancer.gov](http://ccr.cancer.gov)