ICLIO National Conference

Expanding Access to Immunotherapy in the Community Setting

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9.30.16
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Association of Community Cancer Centers

accc-iclio.org

Only 5% of cancer patients will ever go on a clinical trial

85% of these patients get treatment in the Community

Objectives

Understand the difficulties of providing innovative cancer therapies in a rural health system

Explore the utility of virtual tumor boards to facilitate access to novel therapies and trials

Determine the impact of virtual tumor boards on immunotherapy access in the community

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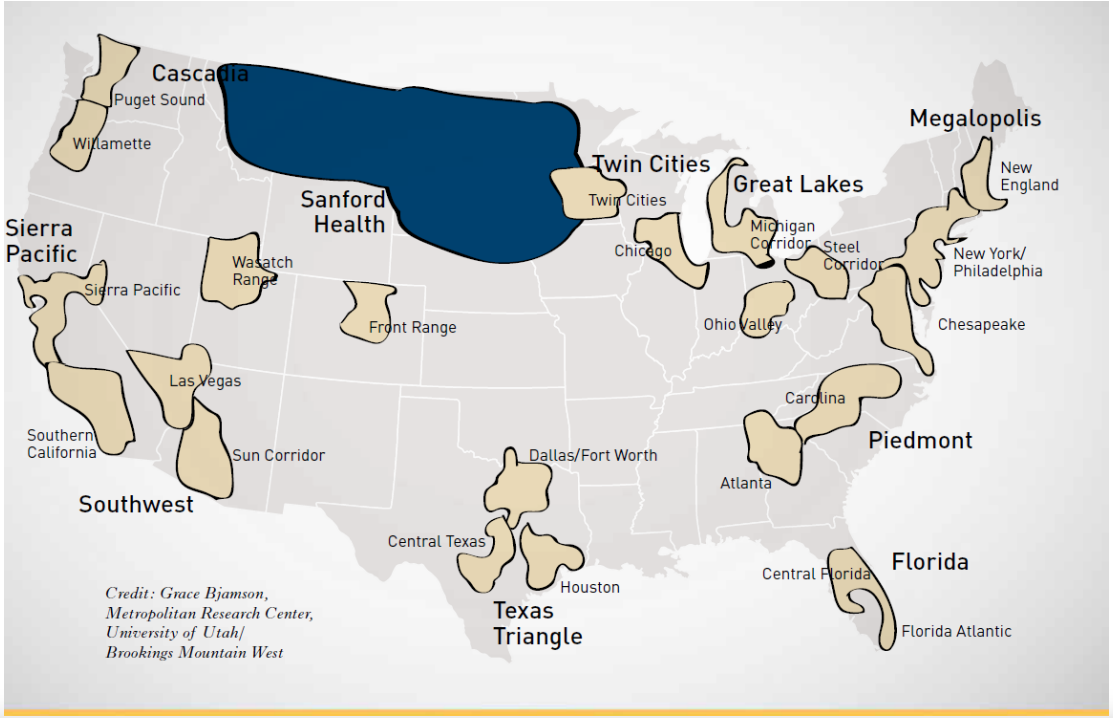
Sanford Health

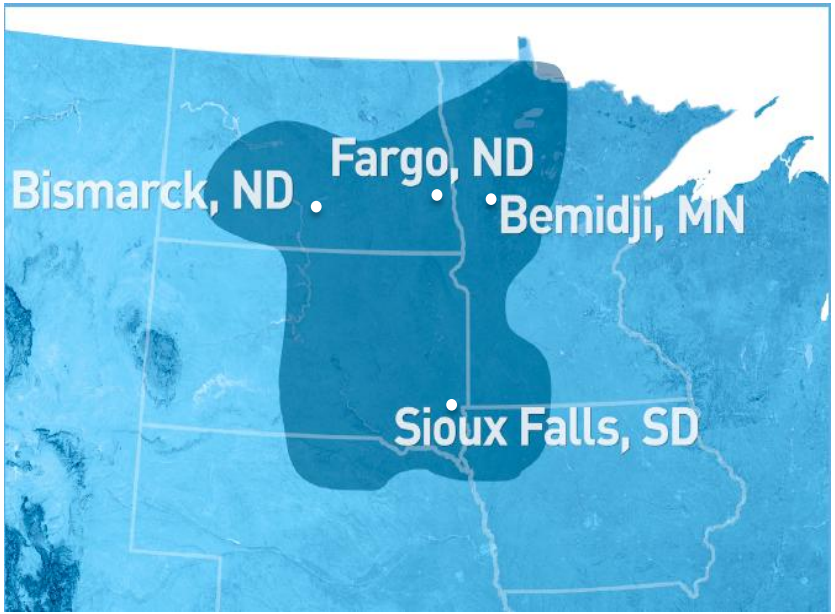


Cancer Program

- >200,000 mile catchment area
- 43 hospitals and nearly 250 clinics in nine states
- 4500+ analytical cancer cases annually

NCI Community Oncology Research Program (NCORP)

- NCI supported clinical trials
- 2013- 494 enrollments
- Basic and translational research program
- Sanford BioBank



Changes in Cancer Care

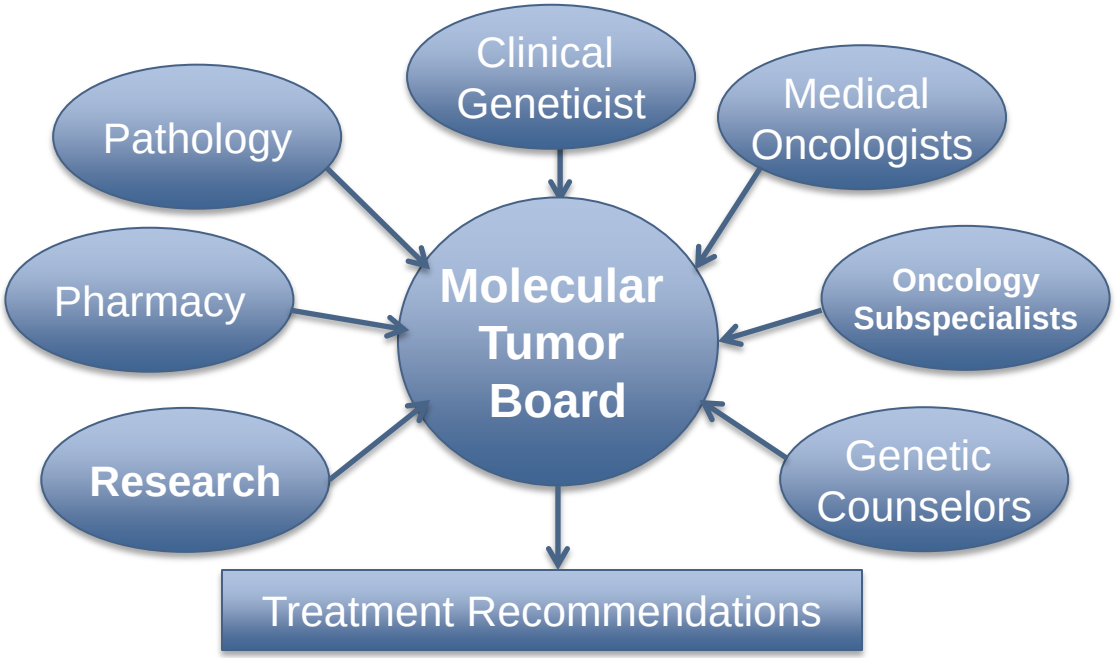
- Shift towards precision medicine trials
- Immunotherapy emerging as a treatment option
- More specialized treatments – more challenging for rural cancer centers

Confronting These Challenges

- Develop infrastructure to improve specialized testing (i.e. NGS, PD-L1 testing)
- Educate clinicians on novel biomarkers and treatment options
- Determine clinical trial needs for patient population
- If trials not available - drug access

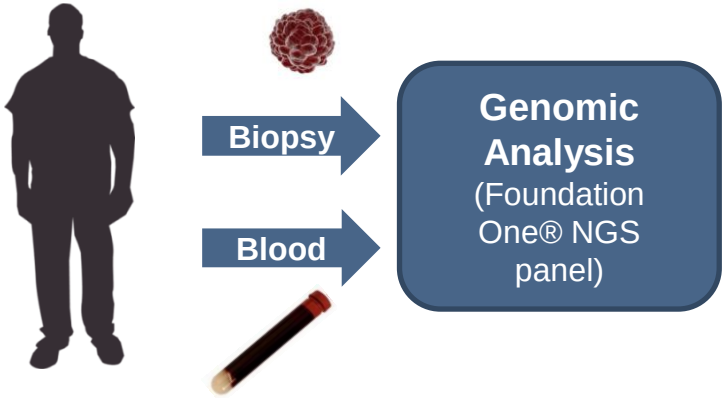
Multi-disciplinary Tumor Board

The Community Oncology Molecular Tumor Board



- Developed in 2014
- Facilitate molecular testing and trial matching
- Weekly videoconferenced tumor board
  - Rural cancer centers
  - Basic researchers
  - Special guest experts
- Documented in EMR

Sanford GEMMA Study (NCT02416518)



Primary Goal:
Identify Genomic Matched Treatments for Advanced Cancer Patients with Limited Options

	Sanford (n = 109)	Cleveland Clinic (n = 250)	MD Anderson (n= 2000)
Treatable Target	**90.8%**	63%	39%
Genomic Matched Treatment	**39.4%**	10%	41%
Genomic Matched Clinical Trial	**16.2%**	3%	11%

Unexpected importance of immunotherapy

Powell SF, et al. J Clin Oncol 34, 2016 (suppl; abstr e18036)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

PD-1 Blockade in Tumors with Mismatch-Repair Deficiency

D.T. Le, J.N. Uram, H. Wang, B.R. Bartlett, H. Kemberling, A.D. Eyring, A.D. Skora, B.S. Luber, N.S. Azad, D. Laheru, B. Biedrzycki, R.C. Donehower, A. Zaheer, G.A. Fisher, T.S. Crocenzi, J.J. Lee, S.M. Duffy, R.M. Goldberg, A. de la Chapelle, M. Koshiji, F. Bhaijee, T. Huebner, R.H. Hruban, L.D. Wood, N. Cuka, D.M. Pardoll, N. Papadopoulos, K.W. Kinzler, S. Zhou, T.C. Cornish, J.M. Taube, R.A. Anders, J.R. Eshleman, B. Vogelstein, and L.A. Diaz, Jr.

N Engl J Med 2015; 372:2509-2520, June 25, 2015

Table 2. Objective Responses According to RECIST Criteria.

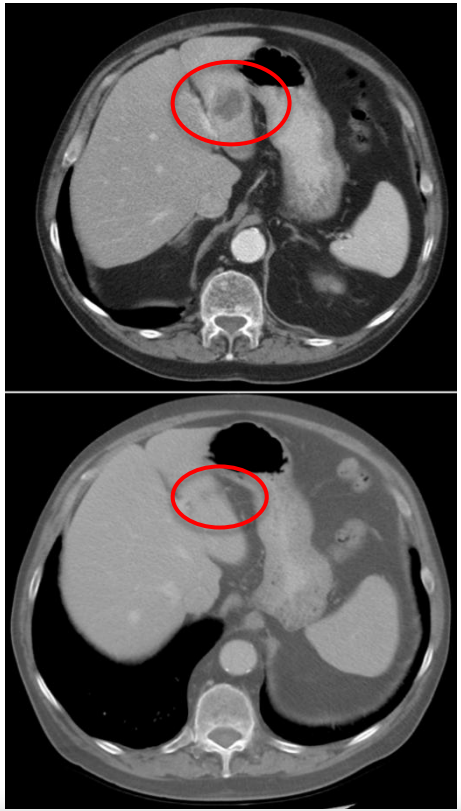
Type of Response	Mismatch Repair–Deficient Colorectal Cancer (N=10)	Mismatch Repair–Proficient Colorectal Cancer (N=18)	Mismatch Repair–Deficient Noncolorectal Cancer (N=7)
Complete response — no. (%)	0	0	1 (14)*
Partial response — no. (%)	4 (40)	0	4 (57)†
Stable disease at week 12 — no. (%)	5 (50)	2 (11)	0
Progressive disease — no. (%)	1 (10)	11 (61)	2 (29)
Could not be evaluated — no. (%)‡	0	5 (28)	0
Objective response rate (95% CI) — %	40 (12–74)	0 (0–19)	71 (29–96)

Ampullary or cholangiocarcinoma	4 (44)
Endometrial	2 (22)
Small bowel	2 (22)
Gastric	1 (11)

Microsatellite Instability (MSI)

Novel biomarker for immunotherapy

Metastatic lung adenocarcinoma



Progressed on all standard therapies

Nivolumab (Opdivo)

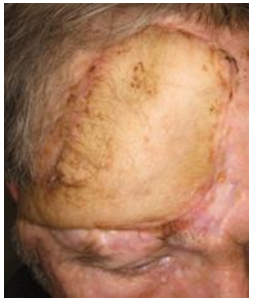
>75% reduction in tumor burden

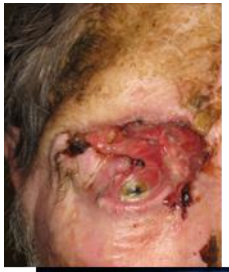
TUMOR TYPE: LUNG ADENOCARCINOMA

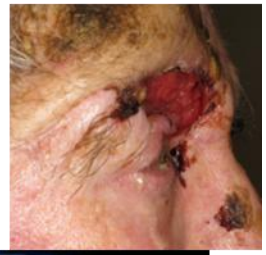
Genomic Alterations Identified†

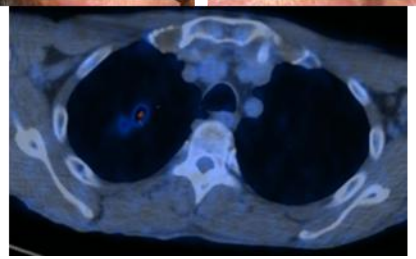
BRCA1 G401*
CDK4 amplification – equivocal‡
PTEN L57S
INPP4B splice site 2135+2_2135+2delT
MYC amplification
TP53 I254F
ARID1A S610fs*9
DAXX M369fs*1
FAT1 K316*
LRP1B splice site 10531+1G>C, W1962*
MAGI2 Y893*
MSH2 splice site 2210+1G>T
SPTA1 G822*

Metastatic Cutaneous Squamous Carcinoma



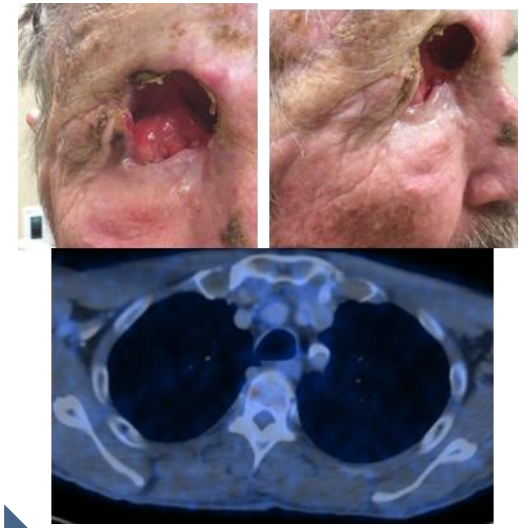






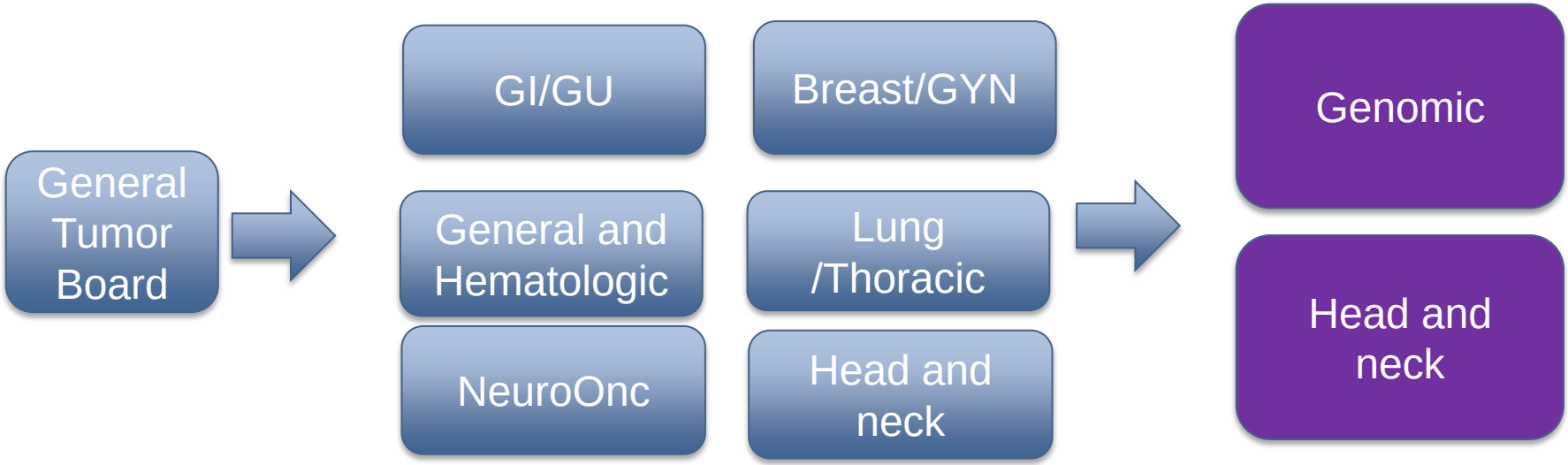
Genomic Alterations Identified†

MLH1 R100*
PDGFRA P589S
CDKN2A p16INK4a W110* and p14ARF G125R
TP53 R342*, S362fs*8
ARID2 I436fs*4
ASXL1 G645fs*58
BLM N515fs*16
CHD4 P30fs*172
NOTCH1 C1207*
SMARCA4 M272fs*31
SPTA1 splice site 4981-2A>C



Immunotherapy - *Pembrolizumab*

Tumor Board Evolution

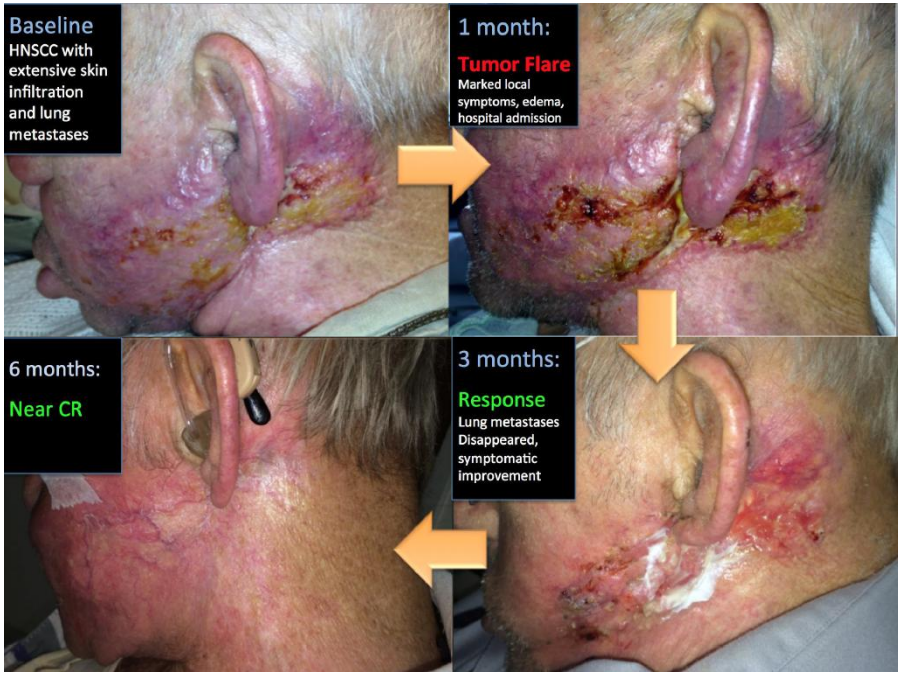


Single Institution General

Single Institution Specialized

Multi-institutional "Virtual"

Head and Neck Cancer and Immunotherapy

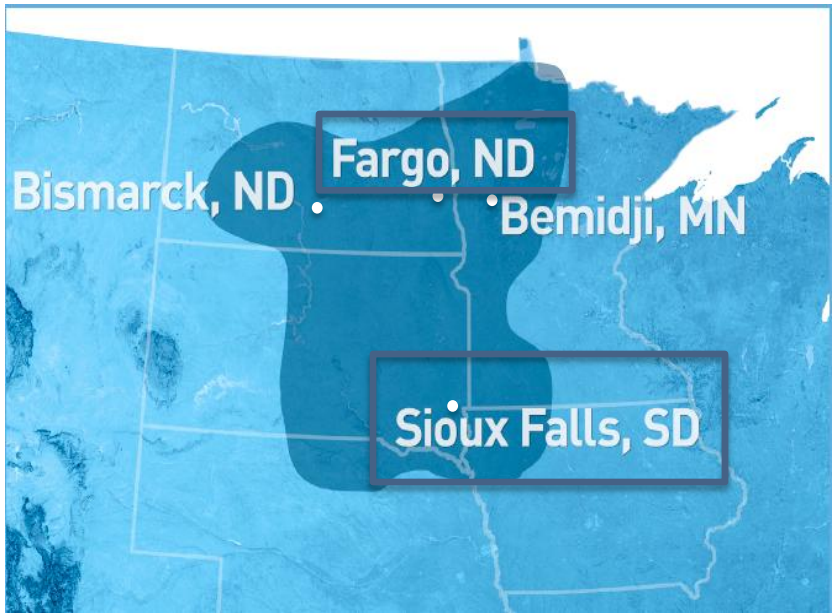


Seiwert TY, et al. J Clin Oncol 33, 2015 (suppl; abstr LBA6008)

- PD-1:PD-L1 inhibitors emerging treatment option
- 2015 - Access limited to clinical trials
- Most in early phase testing

Reformatting our H&N Tumor Board

- Communication and coordination between sites
- Identify clinical trial gaps
- Role of immunotherapy in our population



Birth of an Immunotherapy Trials Program

Head and Neck (Squamous Cell Carcinoma)	Keynote 055
	Keynote 048
	CheckMate 358
	Echo 204
Melanoma	EA6134 (NCI)
	EA6141 (NCI)
	Echo 204
Cervical	CheckMate 358
Breast	Keynote 119
Merkel Cell Skin Cancer	CheckMate 358
Non-Hodgkin Lymphomas	Echo 204
Ovarian	Echo 204
Sarcomas	Alliance A091401

Lung (Non-Small Cell Carcinoma)	Keynote 021
	ATLANTIC Trial
	Keynote 189
	Echo 204
	Checkmate 370
	Lung-MAP (NCI)
	NCI ALCHEMIST (NCI)
Gastric, GE junction, Esophageal	Keynote 059
	Keynote 180
	Keynote 181
Colon	Echo 204
	Keynote 177
Prostate	Keynote 199

Industry and Government Partnerships

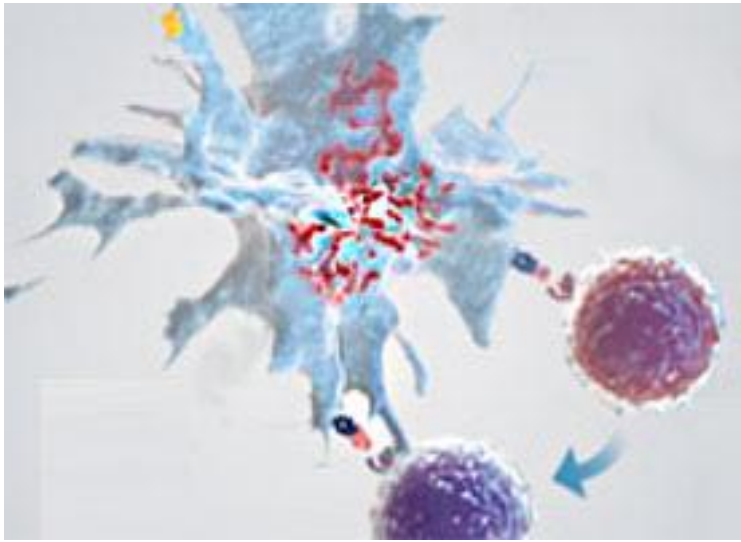
Investigator-Initiated Immunotherapy Research

- Phase IB Pembrolizumab with Chemoradiotherapy (CRT) for head and neck cancer

- COMPASS - Community Oncology use of Molecular Profiling to Personalize the Approach to Specialized cancer treatment at Sanford

Future Investigator-Initiated Studies

Therapeutic Cancer Vaccines

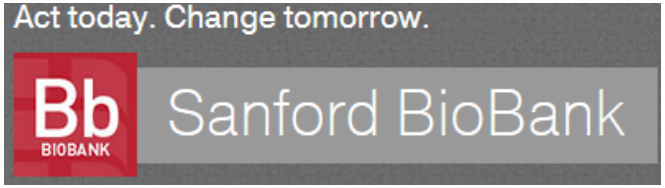


Oncolytic Viruses

Translational Research

- Immunotherapy biomarker research
- Novel immunotherapy drug development
- NIH-funded program
  - $11.7 million Centers of Biomedical Resarch Excellence (CoBRE) award

SANFORD RESEARCH



Program Mission

- **Expand access** to promising new cancer therapies through **clinical trials**
- **Improve the precision** of these novel therapies through **genomic and molecular testing**
- Lead in providing **innovative cancer care** in the **community**
- **Develop** cancer therapies that will help **transform cancer care**

Summary

- Unique challenges in accessing novel therapies in rural communities
- Virtual tumor boards can facilitate provider education, clinical trial matching, and improve patient access
- Developing our virtual tumor boards has grown immunotherapy trials program

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