Clinical Trials at WVUCI

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Presentation Focus:

- Personalized Medicine and Clinical Trials
- Clinical Trials in the Mission of WVUCI

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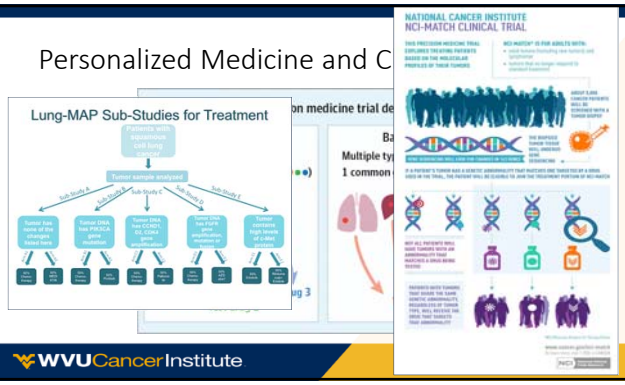
Personalized Medicine and C



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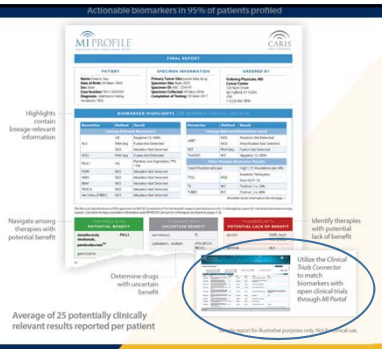
Identifying Clinical Trials with Personalized Medicine:



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Personalized Medicine Trials at WVUCI:

Disease Team	Precision Trial Classification	Protocol No.	Title	Status	Total Accruals:
Multiple	Basket	EAY131	Molecular Analysis for Therapy Choice (MATCH)	OPEN TO ACCRUAL	15
Multiple	Targeted	4010-01-001	A Phase I Dose Escalation and Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Advanced Solid Tumors.	OPEN TO ACCRUAL	0
Lung	Umbrella	A151216	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)	OPEN TO ACCRUAL	16
Lung	Targeted ALCHEMIST	A081105	Randomized Study of Erlotinib vs Observation in patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant NSCLC	OPEN TO ACCRUAL	1
Lung	Targeted ALCHEMIST	E4512	A Phase III Double-Blind Trial of Stratified Adjuvant Therapy for Stage IB Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the ALK Fusion Protein	OPEN TO ACCRUAL	0
Lung	Targeted ALCHEMIST	EA5142	Adjuvant Nivolumab in Resected Lung Cancers (ANVIL): A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in NSCLC	OPEN TO ACCRUAL	6
Lung	Umbrella	S1400	Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer. (LUNG-MAP)	OPEN TO ACCRUAL	15
Breast	Targeted	BIG411	A randomized, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in operable HER2-positive primary breast cancer	STUDY CLOSED	1
Breast	Targeted	MK3475-119	A Randomized Open-Label Phase III Study of Single Agent Pembrolizumab versus Single Agent Chemotherapy per Physicians Choice for mTNBC (KEYNOTE-119)	STUDY CLOSED	1
GI	Targeted	A021502	Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Stage III Colon Cancer and Deficient DNA Mismatch Repair	OPEN TO ACCRUAL	0
GI	Targeted	E1208	A Phase III Randomized, Double-Blind Trial of Chemoembolization with or without Sorafenib in Unresectable HCC with and without Vascular Invasion	STUDY CLOSED	1
GI	Targeted	NRG-GI004	A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer	OPEN TO ACCRUAL	0
Head and Neck	Targeted	E1311	A Randomized, Placebo Controlled Phase II Trial of Afatinib (BIBW2992) as Adjuvant Therapy Following Chemoradiation in Patients with Head and Neck SCC	STUDY CLOSED	1
Hem Malignancy	Targeted	AP24534-12-301	A Phase 3 Randomized, Open-Label Study of Ponatinib versus Imatinib in Adults with Newly Diagnosed CML	STUDY CLOSED	2
Hem Malignancy	Targeted	ARRAY-520-216	Randomized, Open-label, Phase 2 Study of Carfilzomib With or Without ARRY-520 (KSP Inhibitor) in Advanced MM	STUDY CLOSED	2
Hem Malignancy	Targeted	CALGB50904	A Randomized Phase II Trial of Ofatumumab and Bendamustine versus Dexamethasone, Bortezomib and Bendamustine in Patients with Untreated Follicular Lymphoma	STUDY CLOSED	1
Hem Malignancy	Targeted	CAMN107AUS37	A Phase II Randomized, Multicenter Study of Treatment-Free Remission In CML-CP Patients who Achieve and Sustain MR4.5 After Switching to Nilotinib	STUDY CLOSED	1
Hem Malignancy (non-BMT)	Targeted	CLBHS89D2308	Randomized, Double-Blind, Placebo Controlled Phase III Study of Panobinostat in Combination with Bortezomib and Dexamethasone in Relapsed Multiple Myeloma	STUDY CLOSED	2
Hem Malignancy			Phase III, Randomized, Open-Label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Relapsed or		

WVUCI's Mission: Reduce the Impact of Cancer on West Virginians & Appalachia

- Provide state of the art **clinical care** to patients and their loved ones
- Dedicate ourselves to **research, education, and service**
- Commit ourselves to address **health disparities**

Our Values

Quality
Innovation
Teamwork
Service
Accountability

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How do we increase clinical trial success?

Clinician Support

Colleague Awareness

Patient Education & Awareness

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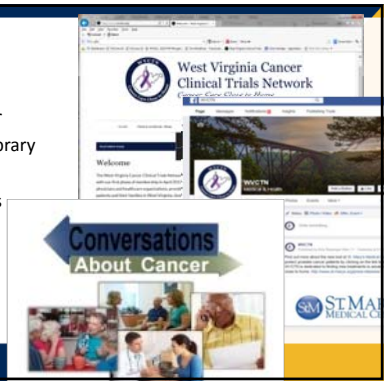
Patient Education:

- Conversations About Cancer
  MOH show with WV Library
- Train the Trainer
- Survivorship Support groups
- 1:1 Education
- Waiting Room materials
- WVCTN Website
- Social Media



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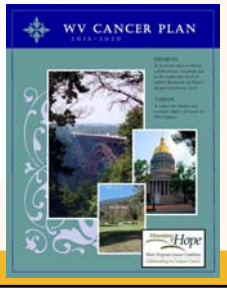
State-wide Awareness and Partnership:

Mountains of Hope
West Virginia Cancer Coalition
Collaborating to Conquer Cancer

NASW
National Association of Social Workers
WEST VIRGINIA CHAPTER

WEST VIRGINIA ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR WEST VIRGINIA



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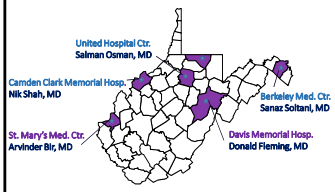
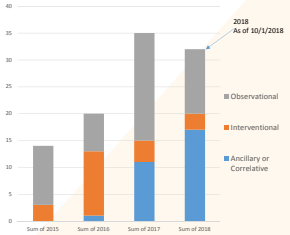
Partnership Opportunities: Affiliate Networks

2015 through YTD





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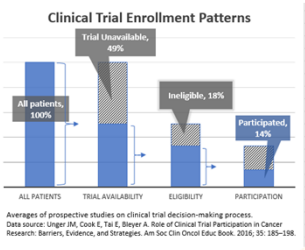
Identifying Barriers in Cancer Clinical Trials:



Nearly 1 in 5 publicly funded cancer studies are unable to recruit enough subjects which results in early closure and a waste in time/resources with no conclusive answers.

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ASCO-Friends of Cancer Research Broadening Criteria Project

- The purpose of eligibility criteria are to protect the safety of participants. Having highly restrictive eligibility criteria creates barriers, slow accrual and limit understand of the intervention's benefit-risk profile.
- Growth in the molecularly targeted treatments creates a need to revise the common criteria.
  - With targeted drugs already decreasing the patient pool then we need to ensure other criteria is safely expanded for patients to qualify

Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement
Edward S. Kim, Suanna S. Bruinooge, Samantha Roberts, Gwynn Ison, Nancy U. Lin, Lia Gore, Thomas S. Uldrick, Stuart M. Lichtman, Nancy Roach, Julia A. Beaver, Rajeshwari Sridhara, Paul J. Hesketh, Andrea M. Denicoff, Elizabeth Garrett-Mayer, Eric Rubin, Pratik Multani, Tatiana M. Prowell, Caroline Schenkel, Marina Kozak, Jeff Allen, Ellen Sigal, and Richard L. Schilsky
Journal of Clinical Oncology 2017 35:33, 3737-3744

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ASCO-Friends of Cancer Research Broadening Criteria Project

The Old Standard:

- No prior treated or stable brain metastases.
- Excluding HIV/AIDS status even if on stable
- Minimum age requirements (over the age of 18)
- Organ Dysfunction
- Prior and concurrent malignancies

Suggested Updates:

- Allow treated and/or stable brain mets with no progression for at least 4 weeks. Evaluate if active brain mets could be allowed on safety and response.
- Focus on current CD4 and T-cell counts and AIDS defining conditions and consider ART a con med
- Include pediatric cohorts in phase I trials and expand later phase trials to age 12 or older.
- Renal function based on CrCl over Creatinine if not renally excreted and institutional normal on liver function. Evaluate use of EF values if no known cardiac risks.
- Liberalize prior/concurrent malignancy if does not interfere with the safety or efficacy assessment of the study regimen.

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Benefits and Risks of Expanded Criteria:

Table 2. Benefits and Risks of Expanded Eligibility Criteria

Benefit and Risk	Patients and Physicians	Sponsors and Investigators
Benefits	Earlier access to investigational agents and expanded trial and treatment options More complete safety data, which can inform clinical use and enable safe delivery if investigational agent becomes commercially available Availability of efficacy and safety data can inform weighing of commercially available treatment options across a broader array of patients and increase confidence in therapy selection Earlier identification of drugs that may not be efficacious in a particular patient population or that may cause more harm than good	Ability to generalize to real-world patients and potentially reduce postmarketing requirements Faster accrual; more patients may be eligible at each site, which may reduce the overall number of sites needed to successfully complete accrual Identification of potential safety issues during clinical trials may facilitate early development of mitigation strategies, enabling broader uptake after approval Efficacy in traditionally understudied population could potentially result in expanded marketing claims and provide a differentiating factor between drugs of same class
Risks	Limited data from small cohorts may not be adequate for clinical decision making Patients who are inherently sicker may have higher risk of experiencing an adverse event as a result of the drug or disease Additional procedures for increased safety monitoring in some situations may incur additional costs to patients and/or the study Additional resources may be required to ensure clinical and research staff are capable of managing the additional patients on study	More variability in outcomes: may require larger sample sizes and inferences may not be as precise Potential safety concerns: may require separate cohorts or analysis plans and early stopping rules for excess toxicity May complicate attribution of adverse events; consider randomization and data from other drugs in class Increased costs associated with additional cohorts, statistical requirements, additional testing, or special expertise to manage specific patient needs

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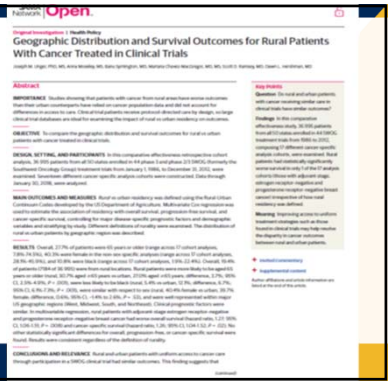
Rural Health Disparities in Cancer Patients:

Prior studies have all shown inferior survival for rural patients with cancer.

Comparison of just under 37,000 patients from 44 SWOG treatment trials in 17 different disease cohorts. Allowed ease of comparison with uniform staging, treatment and protocol directed follow-up.

FINDINGS: Rural patients had a statistically significant worse survival in only 1 of the 17 cohorts.

CONCLUSION: Improving access to uniform treatment strategies such as those found in clinical trials may help resolve the disparity in cancer outcomes between rural and urban patients.


Network Open

Geographic Distribution and Survival Outcomes for Rural Patients With Cancer Treated in Clinical Trials

Abstract

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Help us move the Needle:

- Be an Advocate!
  - Offer assistance in searching online or contact WVCTN to help search for clinical trials applicable to their disease.
  - If eligibility is a barrier talk with research team about reasoning behind the safety restrictions and amend when possible.
- Be a Partner!
  - A patient may enroll on a trial at another location and ask you to aid in collecting clinical testing such as vitals, lab work, off treatment week physicals and side effect management. It is important to have open and clear communications between your practice and the research team.
- Join the Fight!
  - Contact WVUCI to see how you can add clinical research in your clinical practice

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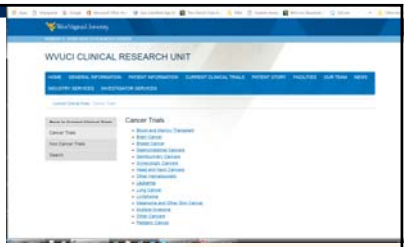
Thank you


WVUCI CLINICAL RESEARCH UNIT

Cancer Trials

https://www.hsc.wvu.edu/ctru/current-clinical-trials/cancer-trials/

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