


We are called to make a healthy difference in people's lives.

Rural Oncology Care: Making it Work and Establishing Clinical Trials Networks


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Essentia Health Cancer Center
Duluth, MN
October 27, 2023



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Disclosures

I have no disclosures.

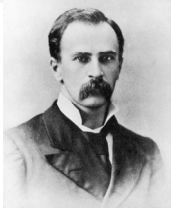


My stance

- A patient never inconveniences a doctor.
 - Sir William Osler, MD (1849-1919)
- "... for the secret of the care of the patient is in caring for the patient."
 - Francis Peabody, MD (1881-1927)
 - JAMA (1927) 88:877-882




Francis Peabody, MD



Sir William Osler, MD

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Essentia Health Overview



Essentia Health

Our Mission


We are called to make a healthy difference in people's lives.




Our Values

- Quality
- Hospitality
- Respect
- Joy
- Justice
- Stewardship
- Teamwork

Benedictine heritage



Mother Scholastica Kerst and Sister Alexia Kerst founded St. Mary's Hospital in Duluth in 1888

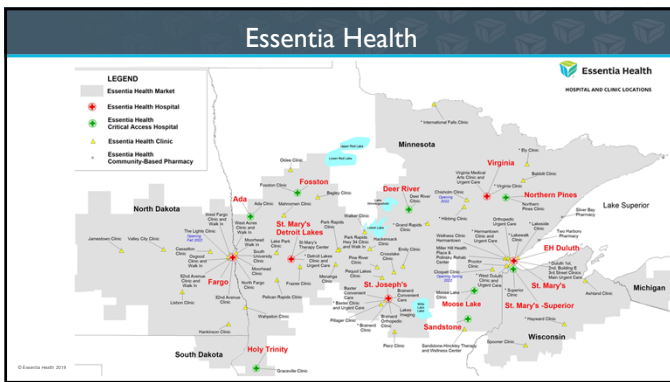


St. Mary's Hospital, Oct. 1925

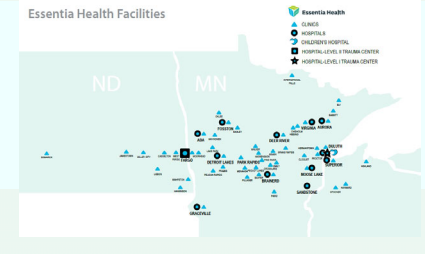
We are a secular organization with several faith-based entities

Essentia's history

Many organizations joined as one

Essentia Health at a glance



Essentia Health Facilities






- 15,000 colleagues
- 14 hospitals
- 78 clinics
- 6 long-term care facilities
- 6 assisted living & independent care facilities
- 7 ambulance services
- 1 research institute




Geography Fun Facts

- Estimated Square Mile Coverage
- East Market 31,258
 - Without Brainerd 25,000
- West Market 23,915
- Total Sq Miles 55,173
- West Virginia 24,034

Essentia by the numbers

	FY22 (year ended 6/30/2022)
 Unique Patients	603,938
 Total encounters	1,759,385
 Patient days	201,107
 Surgeries	43,114
 ED visits	159,920



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Quality recognition



2022 CMS Hospital Quality ratings:
 St. Mary's Medical Center (Duluth) – **5 STARS**
 Essentia Health-Duluth – **5 STARS**
 Essentia Health-Fargo – **5 STARS**
 St. Joseph's Medical Center (Brainerd) – **4 STARS**
 St. Mary's Hospital (Detroit Lakes) – **4 STARS**



St. Mary's Medical Center
Voted "Best Medical Facility" in Duluth News Tribune



Essentia Health-Fargo
voted "Best Medical Facility" in Fargo Forum



St. Joseph's Medical Center
named Top 100 Rural & Community Hospital

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Demographics

Eastern North Dakota/Northwestern Minnesota

- Median age: **38.4**
- Median household income: **\$58,404**
- Education
 - No high school diploma: 7%
 - High school graduates (or GED): 28%
 - Some college, no degree: 23%
 - Associate degree: 13%
 - Bachelor degree and above: 29%

Northeastern Minnesota/Northwestern Wisconsin

- Median age: **43.6**
- Median household income: **\$48,919**
- Education
 - No high school diploma: 7%
 - High school graduates (or GED): 33%
 - Some college, no degree: 24%
 - Associate degree: 12%
 - Bachelor degree and above: 24%

Central Minnesota/Brainerd Lakes Area

- Median age: **44.9**
- Median household income: **\$51,617**
- Education
 - No high school diploma: 8%
 - High school graduates (or GED): 34%
 - Some college, no degree: 25%
 - Associate degree: 12%
 - Bachelor degree and above: 21%

From 2018 presentation

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Integrated care, close to home



- Rural and mid-urban integrated care system
- Deep commitment to safety, quality and patient experience
- Support coordinated acute care, chronic disease management and preventive medicine
- Create healthier communities for those we are privileged to serve

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Essentia Health Cancer Center

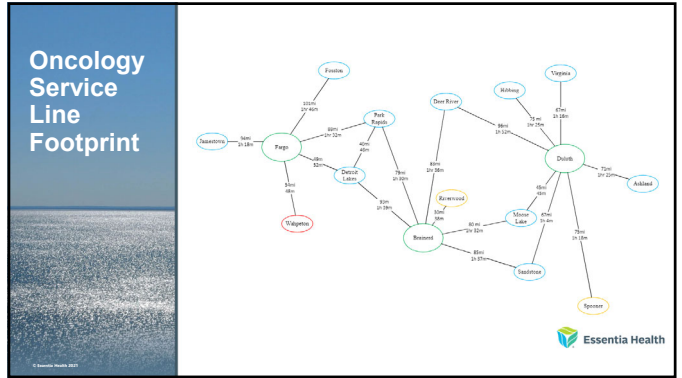
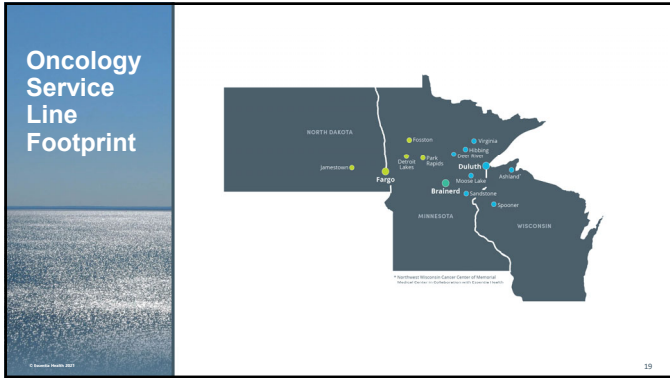
- Oncology/Hematology
 - 12 physicians
 - 9 APCs
- Pediatric hem/onc
 - 3 physicians
- Rad onc
 - 6 physicians
- Surgical subspecialties
 - Breast and melanoma surgery
 - Colorectal surgery
 - Hepatobiliary/pancreas and foregut surgery
 - Thoracic surgery
 - Genitourinary surgery
 - Gynecologic surgery
 - Head and Neck surgery
 - Neurosurgery crani-epinal
 - Orthopedic oncology surgery
 - Interventional Radiology
- Cardio-oncology
 - Palliative care and hospice
 - Dedicated inpatient 30-bed service
 - Basically, everything but transplant and cellular therapies.

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Essentia Health Cancer Center Volumes

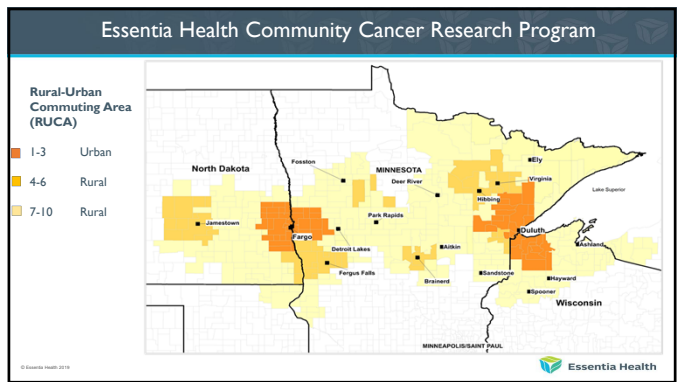
- Approximately 3500 new analytic cancer cases annually
- Approximately 45,000 cancer center clinical encounters annually
- Approximately 44,000 infusion center visits annually

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History of Cancer Research at Essentia Health

- 1977 – Founding member of NCCTG - Duluth Clinic
- 1983 – NCI support awarded – CCOP
- 2006 – Pediatric clinical trials initiated – COG, partnership with U of M
- 2010 – Essentia Central (Brainerd) initiates program
- 2011 – Essentia West (Fargo) initiates program
- 2014 – NCI support awarded – NCORP
- 2017 – EHCCRP – Duluth, Hibbing, Virginia, Ashland, Brainerd, Fargo, Fergus Falls, Aitken
- 2017 – MNCCTN Expands access to multiple small clinics
- 2019 – NCORP renewed



Essentia Health Community Cancer Research Program

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Approximately 60-80 ongoing clinical trials!

- NCORP/NCTN
- COG
- MNCCTN
- Industry
- Investigator initiated
- Foundation

EHCCRP Trial Enrollments

- 2020: 838
- 2019: 630
- 2018: 501

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Masonic Cancer Center Minnesota Cancer Clinical Trials Network

Partners and Locations

Providing Access Across Minnesota

MNCCTN is led by the Masonic Cancer Center, University of Minnesota and brings together healthcare organizations across the state. Together, we aim to improve cancer outcomes for all Minnesotans.

As of 2023, 23 site locations offer cancer clinical trials, with additional sites across the state to be added in the coming years.

Clinical trials originate from Minnesota's two NCI Designated Comprehensive Cancer Centers, the Masonic Cancer Center and Mayo Clinic Cancer Center, along with the Hormel Institute in Austin.

How do we decide which studies to open?

- What is the science?
 - We emphasize NCTN trials via the Alliance and pharma studies via the AFT
- Do we see these patients?
- What are the infrastructure needs?
 - Patient travel
 - Pathology
 - Radiology
 - Radiation oncology
- What are the numbers?
 - Desire at least break-even

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EHCCRP - Maximizing Trial Accessibility

```

    graph LR
      A[Rural Cancer Patient] --> B{Does a clinical trial exist?}
      B --> C{Is the clinical trial accessible?}
      C --> D{Is the patient eligible for trial?}
      D --> E{Is the trial presented to the patient?}
      E --> F{Is the trial accepted by the patient?}
      G[Available Trial Sites] --> C
      H[Provider Engagement] --> E
      I[Patient Specific Factors] --> F
    
```

- Trial options close to home/infrastructure
- Rural friendly study procedures
- Involve local care teams
- Minimize disparities

Adapted from: Traylor and Saitel. *Curr Pediatr Rep.* 2020; 2:127-145.

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Neuro-Oncology Infrastructure

Map showing various cancer centers and their infrastructure, including:

- Essentia Health Jamieson Clinic
- Essentia Health South University Clinic
- Sanford Brain and Spine Center
- Sanford Roger Maris Cancer Center
- Sanford Jan Lambeth Cancer Center
- Essentia Health Grand Rapids Clinic
- Essentia Health Park Rapids Clinic
- Essentia Health St. Joseph's Cancer Center
- Essentia Health Sandstone Clinic
- Essentia Health Spooner Clinic
- Essentia Health Virginia Clinic
- St. Mary's Medical Center
- St. Luke's Regional Cancer Center
- St. Luke's Hospital
- Northwest Wisconsin Cancer Center
- Merropolitan Medical Center
- Essentia Health Grand Rapids Clinic
- Essentia Health Park Rapids Clinic
- Essentia Health St. Joseph's Cancer Center
- Essentia Health Sandstone Clinic
- Essentia Health Spooner Clinic
- Essentia Health Virginia Clinic
- St. Mary's Medical Center
- St. Luke's Regional Cancer Center
- St. Luke's Hospital
- Northwest Wisconsin Cancer Center
- Merropolitan Medical Center

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Clinical trials in rural areas

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Rural Health Subcommittee of Community Oncology

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

NCI National Clinical Trials Network

NCI Community Oncology Research Program

Daniel A. Nikcevich, MD, PhD
Essential Health Cancer Center
Duluth, MN

Nicole L. Stout, DPT, CLT-LANA
West Virginia University Cancer Institute
Morgantown, WV

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Goals of the Rural Health Care Working Group

Support operations that increase patient and hospital access to cancer clinical trials.

Identified barriers to oncology clinical trial enrollment:

1. Institutional commitment. Infrastructure and resources not available to open clinical trials.
2. Practice commitment.
3. Tank of gas.
4. If top three addressed, then my main barrier is access to early phase studies or novel therapeutics.

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NCI National Clinical Trials Network

NCI Community Oncology Research Program

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RHWG Survey of Alliance Membership

- Survey developed to describe rural participation in clinical trials and sent in April 2021
- Better understand impact of COVID-19 pandemic on participation
- Definition rural: US Department of Agriculture based on county of the clinical site
- Responses n=36

Commonly Cited reasons rural patients decline participation

Reason	% respondents (n=33)
Weather concerns	~2
Lack of understand about clinical trials	~3
Direct travel expenses	~5
Number of visits required	~10
Too much burden placed on family members	~12
Concern about the agents being tested	~15
Time and distance to travel is too much	~35

Key drivers to rural clinical trial participation in your practice

Driver	% respondents (n=31)
Model of outreach and community engagement	~48
Infrastructure resources	~35
Common EMR and IRB	~8

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Rural Friendly Clinical Trial Design

Facilitators to Trial Availability

Decentralized/Hybrid Study Procedures and Design


- Central IRB
- Remote consenting
- Telemedicine
- Central imaging review
- Remote trial site monitoring
- Local administration-standard therapy
- Budget for travel support- gas cards, transport services
- Audit committee: no increased protocol deviations

Study Type	2019 (%)	2020 (%)
% of Rural Pts to All Studies	~18	~22
% Rural Pts to CTEP Studies	~20	~22
% Rural Pts to DCP	~15	~22

D. Nikcevic and N. Stout, Co-Chairs, Alliance Rural Health Support Committee

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Success stories: Deer River experience



WELCOME TO
DEER RIVER
GATEWAY TO THE CHIPPEWA

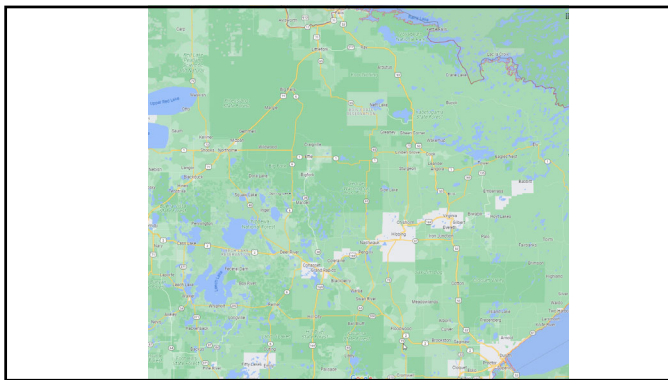
• Deer River, population 909
• Essentia Health CAH, clinic, and nursing home

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Patient story

- 66 yo female from Effie, MN (Pop 123)

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Patient story


- 66 yo female from Effie, MN (Pop 123)
- Symptomatic with bulky lymphadenopathy
 - Excisional lymph node biopsy reveals mantle cell lymphoma
- Receives care in Deer River, MN (Pop 909)
- NCORP site
- Enrolled to EA4181

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Care Team:

- Dr. Nikkevich, MD/PhD hematology/oncology
- Jessica Lahti, PA hematology/oncology- (transitioned to new position)
- Mary Wilch, RN - infusion / regional oncology supervisor
- Angela Williams, RN - infusion
- Valerie White, RN - infusion
- Dakota Flohaug, RN - infusion
- Shirley Mattfield - huc - hematology/oncology
- Lori Reigel, LPN - hematology/oncology


 Nikkevich, Daniel A.	 Williams, Angela K.
 Lahti, Jessica M.	 White, Valerie
 Mattfield, Shirley	 Flohaug, Dakota
 Reigel, Lori	 Wilch, Mary

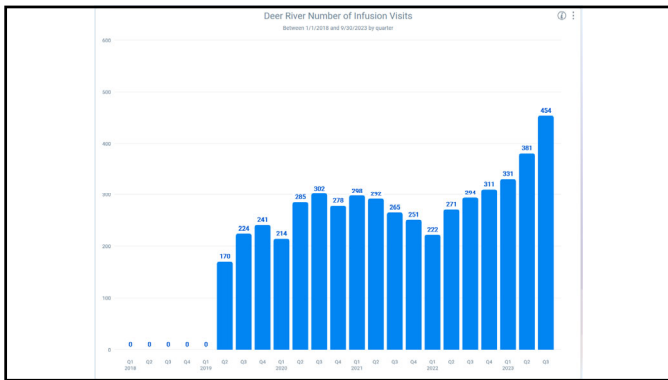
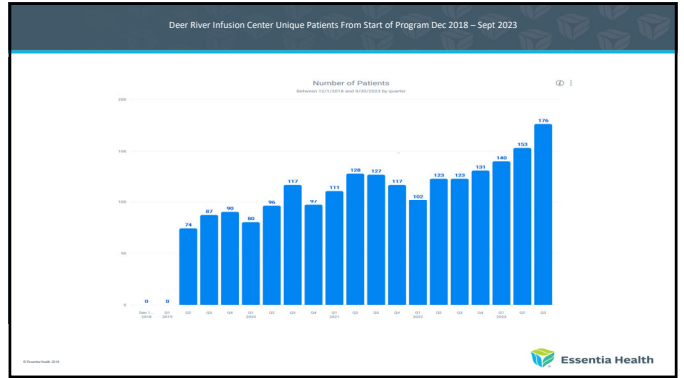
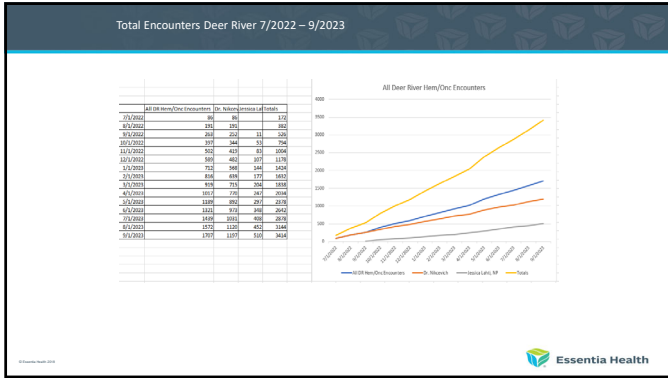
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Deer River Scope of Services:

Scope of Services:

- Deer River
 - Infusion Therapy
 - Clinical Trials
 - Lung Cancer Screening
 - Mammography
 - Imaging Services
 - CT, MRI, U/S
 - Surgery (limited biopsies and IV access)

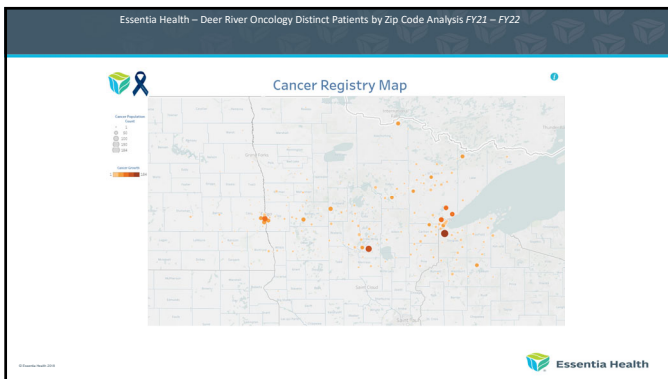
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Deer River Oncology Clinical Trials

DR opened: 6/29/2018
 1st patient enrolled 6/26/2019
 DR is 3rd for enrollment (DLH #1 and Virginia #2) out of 22 sites/affiliates
 We have accrued 30 patients to clinical trials.
 Clinical trial accrual in breast cancer, lung cancer, colon cancer, lymphoma, and symptom control studies




Deer River successes

- Virtually 100% organic growth
- Key driver to financial viability of local medical campus
- \$Multi-million annual margin

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What are the key elements of success?



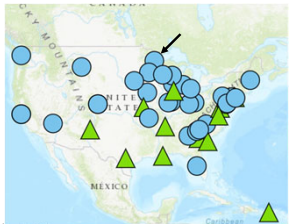
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Key Elements to success

- Cancer center culture of curiosity
- Recognition of clinical trials as a standard of care
- Practice model that supports a rural presence
- Essentia Health Cancer Center practice is hub-and-spoke
 - Everyone does outreach
 - Local presence
 - Virtual visits helpful, but do not replace the bedside

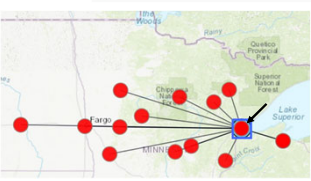
Facilitators to Trial Availability

Community clinical trial networks - NCI NCORP




NIH NATIONAL CANCER INSTITUTE Community Oncology Research Program (NCORP)

- Community Sites (32)
- ▲ Minority Community Sites (14)
- Affiliates / Sub-affiliates Sites (1012)



<https://ncorp.cancer.gov/findsite/map.html>



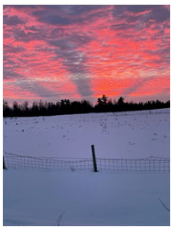

Key Elements to success

- An integrated clinical environment
 - Either owned or affiliated.
- Common EMR
- Local IRB supports the CIRB
- Administrative and executive leadership support
- Scientific support
- Essentia Institute of Rural Health

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Critical Importance of Community Clinical Trial Enrollment

- Equity
- Ensure diverse study populations – Rural/Native American/Elderly
- Maximize enrollment
- “NCCN believes that the best management of any patient with cancer is in a clinical trial.”

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Challenges to rural oncology care and clinical trials

- Physician engagement
- Physician/APC/nurse recruitment
 - Challenges to recruit to rural sites
 - Challenges to recruit to hub-and-spoke

Challenges to rural oncology care and clinical trials

- Administrative and leadership support
- Local medical and administrative culture does not value research and clinical investigation
- Financials
- Stability of local clinical practice
- Community engagement and trust

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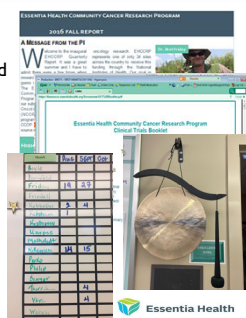
Physician engagement



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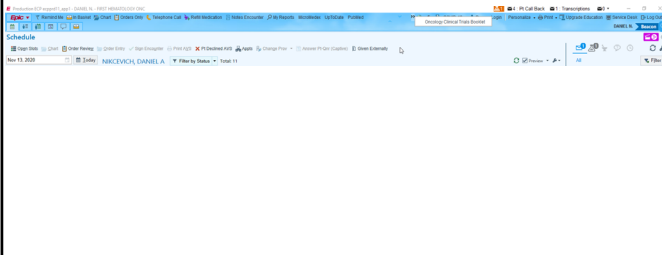
Rural Provider Engagement – Maximizing Local Enrollment

- NBTS Survey – Physician importance¹
- Organizational and Physician factors associated with engagement²
 - 1) Adequate research staff/infrastructure
 - 2) Provider Education
 - 3) Direct research involvement- NCORP
- Research navigation – local, NBTS, ABTA



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Window



Essentia Health Community Cancer Research Program Clinical Trials Booklet

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Updated October 29, 2023

Breast Protocols

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Adjuvant

- NISABP BR003: A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple Negative Breast Cancer (TNBC)
- SWOG S1418 Phase III trial to evaluate efficacy and safety of MK-3475 (Pembrolizumab) as adjuvant therapy for TNBC with >= 1 cm residual invasive cancer or positive lymph nodes after neo-adjuvant chemo
- Alliance A011502 A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial

Advanced/Metastatic

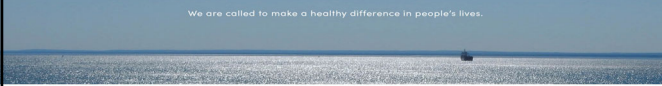
- NRG BR004 A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/ Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer
- ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH) All Solid Tumors

Cancer Control


- Alliance A221505 PHASE III RANDOMIZED TRIAL OF HYPOFRACTIONATED POST MASTECTOMY RADIATION WITH BREAST RECONSTRUCTION
- Alliance A011401: 'BWEL' Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment Of Overweight and Obese Women with Early Breast Cancer
- ICARE2: Integrated Cancer Repository for Cancer Research

Protocol	Treatment	Eligibility	Special Notations	Site Availability
Breast Adjuvant Alliance A011502 A Randomized Phase III Double-Blinded Placebo-Controlled Trial of Aspirin as Adjuvant Therapy for HER2-Negative Breast Cancer: The ABC Trial Companion Study: Alliance A011191 Evaluation of mammographic breast density effect of Aspirin	Randomization: ASA/placebo one 300 mg tablet daily x 5 years Registration: Collect baseline mammogram from time closest to 1 year and then 2 years on therapy on A011502 Collect mammogram from time closest to 1 year and then 2 years on therapy on A011502	Inclusion: <ul style="list-style-type: none"> Women / men >18 and <70 years of age ECOG 0-1 IF ER and PR negative, tumor must be node positive or >2 cm and node negative. Patients must be registered within 18 months of diagnosis. pN1mic is eligible. IF ER and/or PR positive, tumor must be node positive and within 10 years of diagnosis. pN1mic is eligible. Last dose of chemotherapy or radiation therapy must be at least 30 days prior to study registration Exclusion: <ul style="list-style-type: none"> Hx of stroke Hx atrial fb and MI Regular NSAID/aspirin use Eligibility for companion study: <ul style="list-style-type: none"> Currently enrolled in A011502 Hormone receptor negative Baseline breast density measurement (1 of the following: <25% density, scattered areas of fibroglandular density or breast composition category b, c, or d per BI-RADS) Baseline digital screening mammogram Contralateral unaffected breast in place. Prior biopsy on the unaffected breast are eligible. 	Open: 3-2017 Co-Enroll A011401 (BIVEL) Aspirin/Placebo provided by study Research Team Paige Soehnardt Karin Bohline	Open: <ul style="list-style-type: none"> Duluth Brainerd Fargo Fergus Falls Outreach Sites- Please contact study team. Go to Staff Contact List

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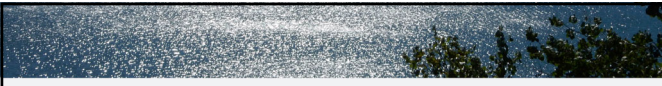


Local community engagement and trust




Local community engagement and trust

- Talks with medical staff and nursing staff
- Talks with local groups
 - Schools
 - Civic groups
 - Support groups
- Annual meeting with local hospital board



Community engagement and trust

- Gas cards
 - Travel. Travel. Travel.
- Local fundraisers
 - Deer River Foundation gas cards
 - International Falls gas cards
- Lodging, meals, wigs



FULL RESULTS

Open 2 Stroke
 Melody Wald - New Market, MN
 Arctic Cat Thunder Cat 130mph

Open 4 Stroke
 Tyce Jackson - Int'l Falls, MN
 Arctic Cat XF 119mph

1000 2 Stroke
 Melody Wald - New Market, MN
 Arctic Cat ZRT 109mph

1000 4 Stroke
 Lane Jackson - Int'l Falls, MN
 Arctic Cat High Country 114mph

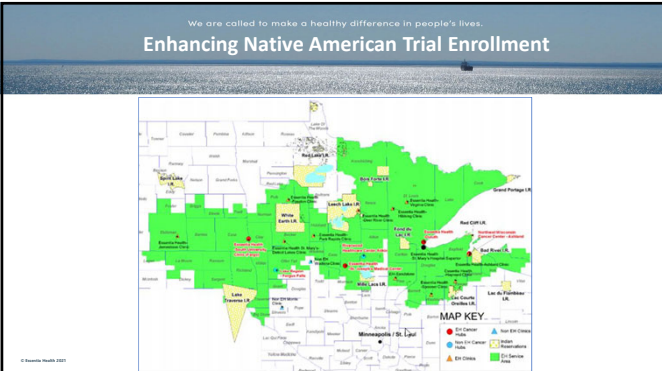
800cc
 Melody Wald - New Market, M
 Ski Doo Mach Z 108mph

700cc
 Mark Lofgren - Fargo, ND
 Arctic Cat Crossfire 91mph

600cc
 Gabe Krebs - Fairbault, MN
 Polaris XCR 86mph

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Enhancing Native American Trial Enrollment




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AICAF/EHCCRP Collaboration

Goals:


1. To develop a sustainable transparent working relationship between the Essentia Health Community Cancer Research Program and American Indian Communities that includes knowledge and effort from both entities.
2. To provide applicable community based clinical cancer research, which is to improve over all American Indian Community health and longevity.
3. To create a safe and caring environment where participants feel safe to partake in clinical cancer research. This clinical research engagement would provide opportunities in cancer screening, prevention, treatments, registry, and education.
4. To implement a holistic approach to clinical cancer research that includes prevention, screening, treatment, and education from both American Indian traditional practices and Essentia Health practices.



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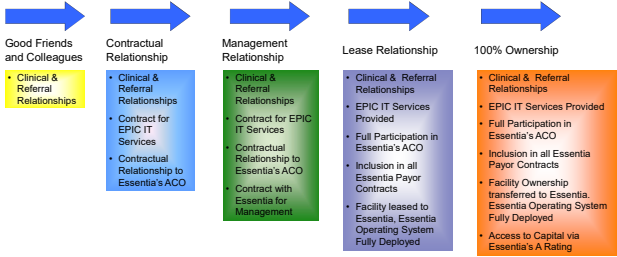
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Why should we do this work? What is the clinical rationale? What is the business case?



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Essentia Health Affiliation Models



- Good Friends and Colleagues**
 - Clinical & Referral Relationships
- Contractual Relationship**
 - Clinical & Referral Relationships
 - Contract for EPIC IT Services
 - Contractual Relationship to Essentia's ACO
- Management Relationship**
 - Clinical & Referral Relationships
 - Contract for EPIC IT Services
 - Contractual Relationship to Essentia's ACO
 - Contract with Essentia for Management
- Lease Relationship**
 - Clinical & Referral Relationships
 - EPIC IT Services Provided
 - Full Participation in Essentia's ACO
 - Inclusion in all Essentia Payor Contracts
 - Facility leased to Essentia, Essentia Operating System Fully Deployed
- 100% Ownership**
 - Clinical & Referral Relationships
 - EPIC IT Services Provided
 - Full Participation in Essentia's ACO
 - Inclusion in all Essentia Payor Contracts
 - Facility Ownership transferred to Essentia, Essentia Operating System Fully Deployed
 - Access to Capital via Essentia's A Rating

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Clinical Enterprise Viability

		Mission	
		+	-
Margin/ROI	+	Viable	Possibly viable
	-	Possibly viable	Non-viable

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Other business considerations

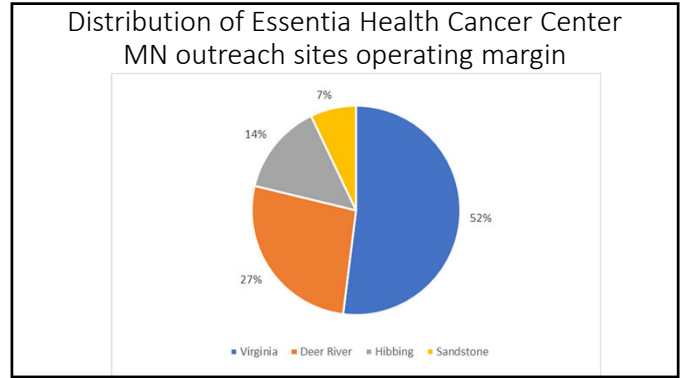
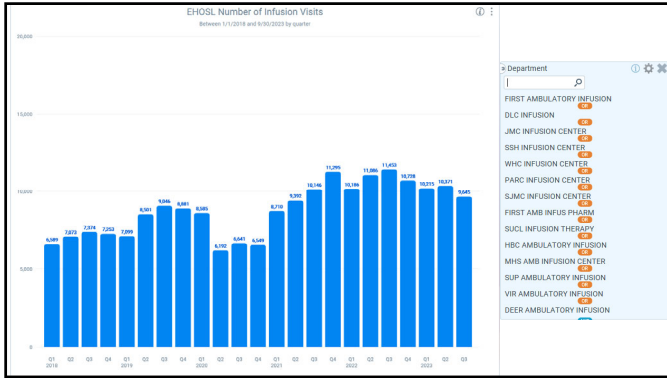
- Payer mix
- CAH reimbursement
- Sole community provider reimbursement
- PPS reimbursement
- 340b chemotherapy reimbursement
- Strategic and market share growth

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Other business considerations

- Downstream
 - Surgery
 - Pathology/laboratory
 - Radiology
 - Radiation oncology

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How does this relate to West Virginia?

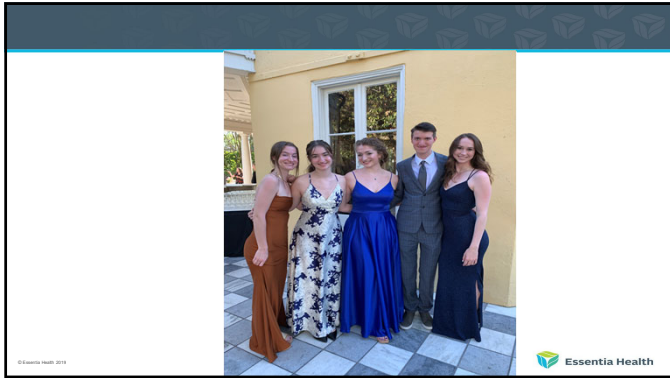
WVU Cancer Institute 2022 Annual Report by WVU Medicine Marketing &am... - Flipsnack

Back to the patient story...

- 66 yo female from Effie, MN (Pop 123)
- Symptomatic with bulky lymphadenopathy
 - Excisional lymph node biopsy reveals mantle cell lymphoma
- Receives care in Deer River, MN (Pop 909)
- NCORP site
- Enrolled to EA4181
- **Obtained CR**
- **Living her retirement dream in Effie.**

Conclusions


- On-site regular presence is key to grow the practice ss in rural oncology care
 - Practice model and culture
 - Physician and executive leadership support
- Rural clinical trial enrollment is critical – An extremely important **Standard of Care**
- Foster local trial availability – NCORP and MNCCTN
- Support rural oncology patients, their local healthcare facilities, and their communities
- The business case exists for rural oncology care, and has equal importance to the clinical science



We are called to make a healthy difference in people's lives.

Thank you!

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