Clinical Trial Basics

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Community Cancer Care and Prevention

MONTANA CANCER CONSORTIUM

Fighting Cancer through Research

NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

What Are Cancer Clinical Trials?

- Research studies involving people
- Try to answer scientific questions and find better ways to prevent, screen, diagnose, or treat cancer

Why Are Clinical Trials Important?

- Cancer affects all of us
- Each year in the U.S.A:
  - More than half a million people are expected to die of cancer — more than 1,500 people a day
  - 1 of 4 deaths is from cancer
  - More than 1 million new cancer cases are expected to be diagnosed

Why Are Clinical Trials Important?

- Clinical trials translate results of basic scientific research into better ways to prevent, diagnose, or treat cancer
- The more people that take part, the faster we can:
  - Answer critical research questions
  - Find better treatments
  - Find ways to prevent cancer

What Are Better Treatments?

- Better outcomes
  - More cures
  - Longer survival
  - Less side effects
  - Less time
  - Less expensive
  - Higher quality of life

Types of Clinical Trials

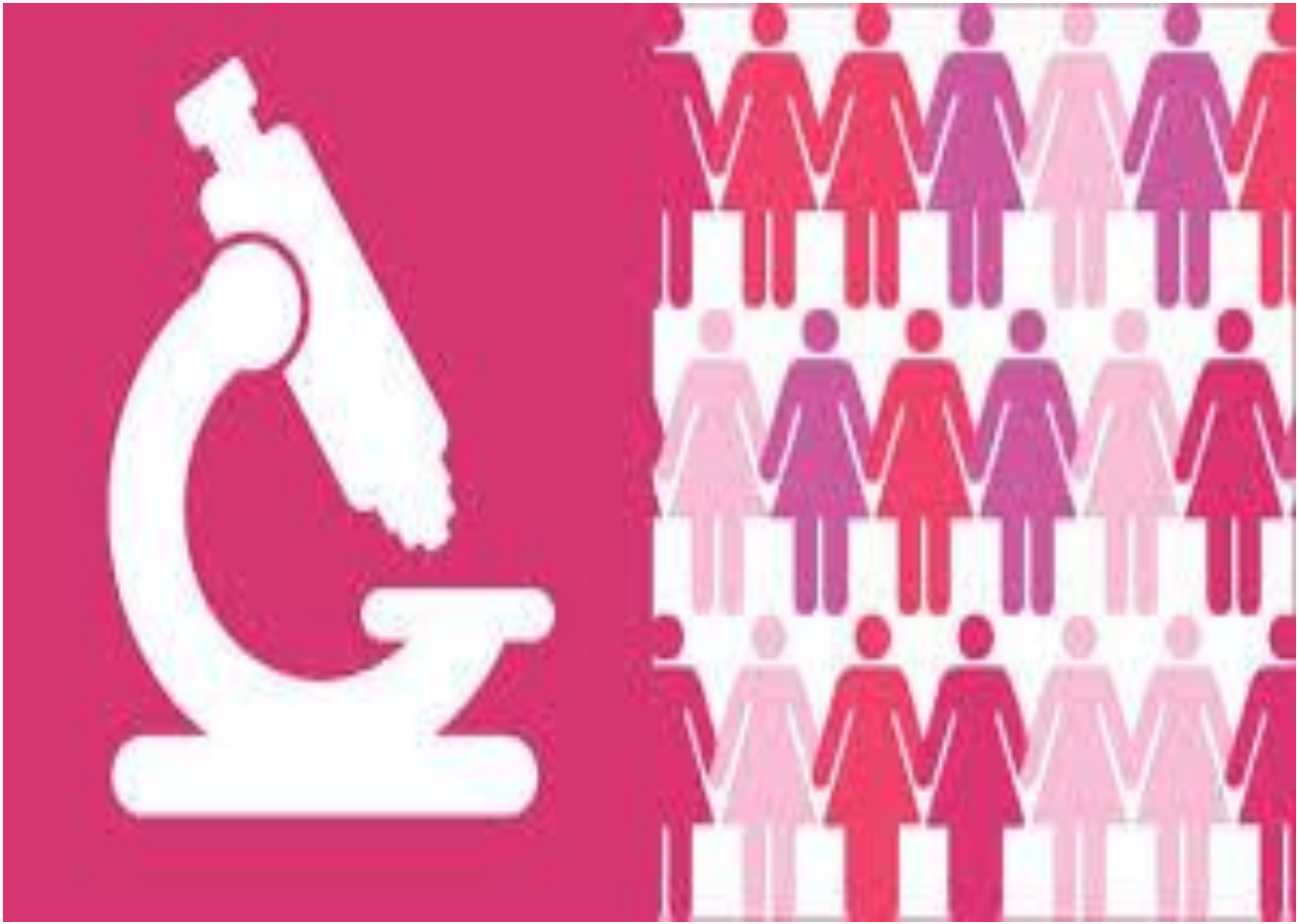
- Treatment
- Prevention
- Screening and Early Detection
- Diagnostic
- Genetics
- Quality of Life/Supportive Care

Clinical Trial Phases

- Basic Science
- Pre-Clinical Testing (Animal Models)
- Phase I Trials
- Phase II Trials
- Phase III Trials
- Phase IV Trials

Basic Science

- Generate a hypothesis
- Experiments may involve test tube studies



Preclinical Testing

- Test in an appropriate animal model
- Looking for efficacy and toxicity

Phase I Trials

- How does the agent affect the human body?
- How should treatment be given?
- What dosage is safe?
- 15-30 participants

Phase II Trials

- Does the agent or intervention have an effect on the cancer?
- Less than 100 participants

Phase III Trials

- Is the new agent or intervention (or new use of a treatment) better than the standard?
- Participants have an equal chance to be assigned to one of two or more groups
- 100 to thousands of participants

Phase IV Trials

- Usually takes place after drug is approved
- Used to further evaluate long-term safety and effectiveness of new treatment
- Hundreds to thousands of participants

Clinical Trial Protocol

- A recipe or blueprint
- Strict scientific guidelines:
  - Purpose of study
  - How many people will participate
  - Who is eligible to participate
  - How the study will be carried out
  - What information will be gathered about participants
  - Endpoints

Benefits of Participation

- Patients will receive, at a minimum, the best standard treatment
- If the new treatment or intervention is proven to work, patients may be among the first to benefit
- Patients have a chance to help others and improve cancer care

Risks of Participation

- New treatments or interventions under study are not always better than, or even as good as, standard care
- Even if a new treatment has benefits, it may not work for every patient
- Health insurance and managed care providers do not always cover clinical trials

How Are Patients' Rights Protected?

- Office for Human Research Protections (OHRP)
- FDA Regulations
- Informed consent
- Scientific review
- Institutional review boards (IRBs)
- Data safety and monitoring boards

Improving Cancer Prevention, Detection, and Treatment

Once proven safe and effective in a clinical trial, an intervention may become the new standard of care

Who Sponsors Clinical Trials?

- Physicians
- Medical Institutions
- Foundations
- Volunteer Groups
- Pharmaceutical Companies
- Government Agencies-(NCI)

National Cancer Institute (NCI)

The NCI sponsors a large number of clinical trials and has a number of programs designed to make clinical trials widely available.

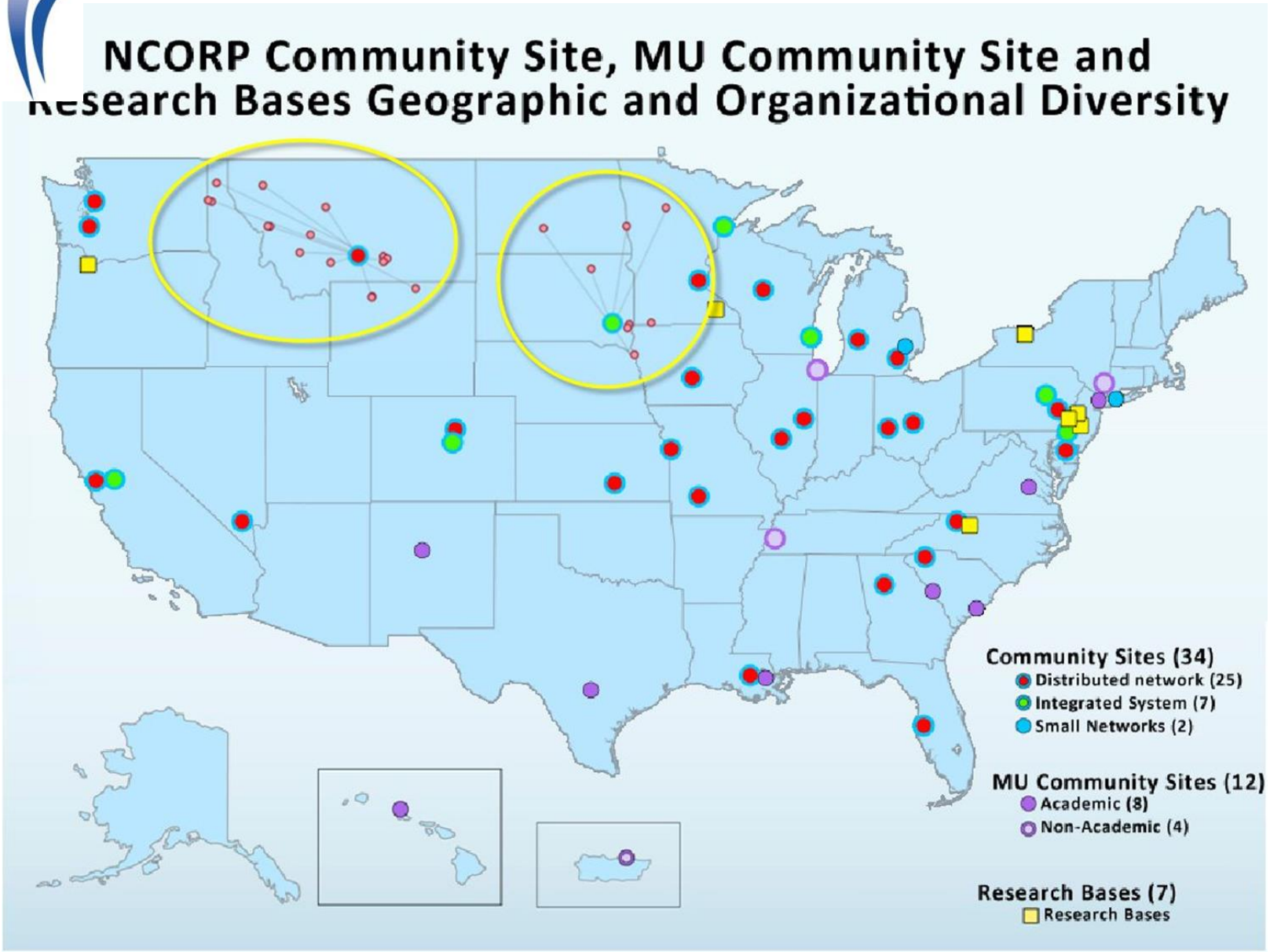
NCORP

The NCI Community Oncology Research Program (NCORP) is a national NCI-supported network that brings cancer prevention clinical trials and cancer care delivery research (CCDR) to people in their communities.

NCORP Activities

- designs and conducts cancer prevention, supportive care and symptom management, screening, and surveillance clinical trials;
- designs and supports health-related quality of life studies for patients on treatment trials;
- designs and conducts cancer care delivery research (CCDR) studies;
- participates in treatment and imaging clinical trials conducted by the NCI National Clinical Trials Network (NCTN); and
- integrates health disparities research questions into NCORP studies.
- natural history and mechanisms of cancer and its treatment-related symptoms and toxicities;
- post-treatment surveillance (such as tumor markers of recurrence, and optimal screening modalities);
- under- and over-diagnosis of cancer; and
- management of pre-cancerous lesions.

NCORP Disbursement



Montana Cancer Consortium
Montana NCORP

The Montana Cancer Consortium (MCC) is an independent nonprofit organization whose mission is to bring “state-of-the-art” cancer treatment to Montana, northern Wyoming, and northern Idaho through National Cancer Institute (NCI) sponsored clinical research.

- Central office in Billings, MT
  - Assist members with the entire research process
- Members include
  - Cancer centers in service area
  - Medical oncologists, radiation oncologists, GYN oncologists, and surgeons

MCC History

- Founded in 1995
- Received CCOP Funding 1996-2014
- Awarded competitive 5 year NCORP grant in 2014
- Reapplication for NCORP grant in 2018

MCC Clinical Trials

- Wide variety of clinical trials available
  - Average ~100 active trials

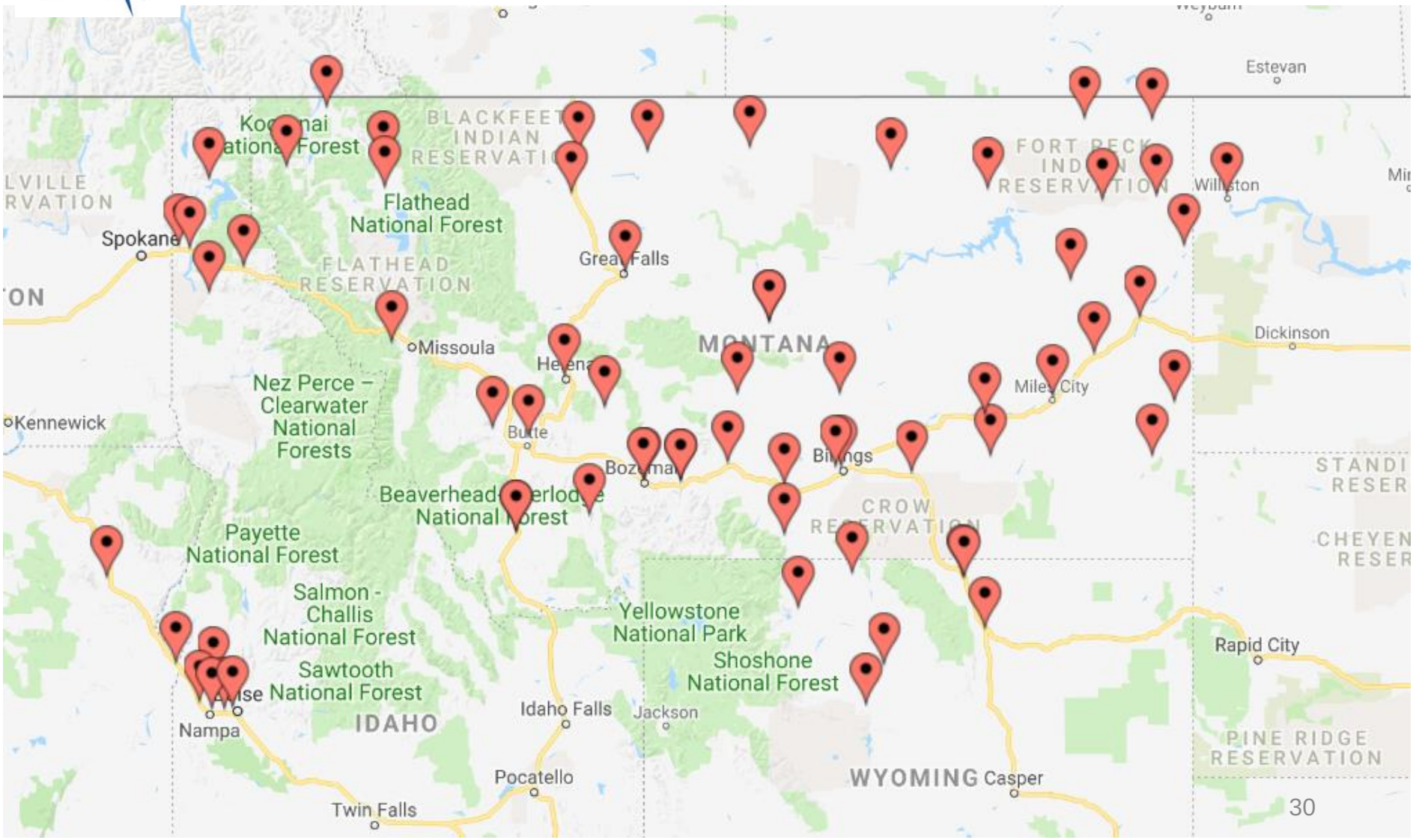
- Currently restricted to adults but include all disease sites
  - Treatment
  - Prevention
  - Screening and early detection
  - Diagnostic, quality of life and supportive care
  - Care delivery

MCC Affiliate Sites

10 Component Sites

- Benefis Healthcare, Great Falls, MT
- Billings Clinic, Billings, MT
- Bozeman Health, Bozeman, MT
- Community Hospital of Anaconda, Anaconda, MT
- Community Medical Center, Missoula, MT
- Great Falls Clinic, Great Falls, MT
- Kalispell Regional Medical Center, Kalispell, MT
- Kootenai Health, Coeur d'Alene, ID
- Saint Alphonsus-Boise, ID
- Welch Cancer Center, Sheridan, WY

MCC Affiliate Sites Serve 57 Additional Outreach Sites



Only 3 percent of U.S. adults with cancer participate in clinical trials

Patient Participation in Clinical Trials

- In the United States, approximately 40% of cancer patients are potential eligible candidates to participate in a clinical trial at the time of their diagnosis
- Only 10% of potentially eligible patients are made aware of clinical trials and offered the option to receive their treatment as a participant
- Only 3% of patients actually participate in a clinical trial

Numerous Barriers

- Patient related
- Physician related
- Scientific
- Financial

Patient Related Barriers

- Don’t know about clinical trials
- Don’t have access to trials
- May be afraid or suspicious of research
- Fear that quality of life will be reduced
- Fear of receiving a placebo in place of actual treatment
- Belief that standard therapy is better
- Cultural
- Financial

Patient Related Barriers

- Many are misperceptions
  - Education needed to overcome these misperceptions

Clinical Trial Participants are NOT Guinea Pigs

Physician Participation in Clinical Trials

- Nationally, only 1 in 8 oncologists (13%) are involved in clinical trials

- Montana Cancer Consortium Accrual (2018)

- MCC has more than 100 ongoing clinical trials. MCC physicians have entered more than **4000** patients to treatment, cancer control, and prevention clinical trials. MCC physician members includes nearly every medical oncologist and board certified radiation oncologist in the state of Montana and northern Wyoming and northern Idaho.

Physician Related Barriers

- Lack awareness of appropriate clinical trials
- Be unwilling to “lose control” of a person’s care
- Believe that standard therapy is best
- Be concerned that clinical trials add administrative burdens
- Direct and indirect added costs

Physician Related Barriers

- Increase awareness
- Institution support
  - Research staff
  - Time dedicated to research activities

Scientific Barriers

- Bottleneck in the scientific process of developing new treatments
- Process of review of research is onerous
- Education of local cancer care specialists
- Financial

Scientific Barriers

- Local, national, and international cooperation needed
- Centralize review processes
- Increase education

Financial Barriers

- Finances are a barrier for all facets of cancer care
- Patient travel
- Physician time
- Insurance denials

Financial Barriers

- Institution support
- Expansion of satellite treatment locations
- Diversified research program
  - Combination of federally and industry funded trials
- State and Federal legislation
  - Montana SB55
  - Health Care Reform

Why Providers Participate in Clinical Trials

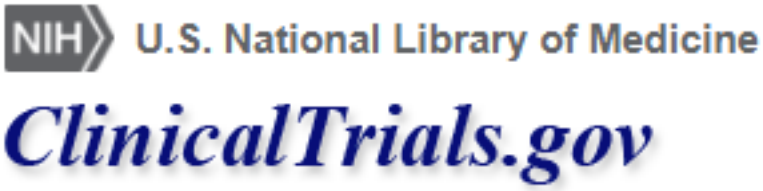
- Professional commitment to provide patients with the best possible care

Increase Participation in Clinical Trials

- If 10% participated, studies could be completed in one year, instead of the three-five years that studies currently require

Internet Websites

www.mtcancer.org



QUESTIONS?