Clinical Research in Central Oregon

What's Available to You, to Our Community, and Why

Tim Beard, MD
Bend Memorial Clinic (BMC)

Archie Bleyer, MD
St. Charles Health System (SCHS)

Objectives

1) Understand why clinical research is crucial to Central Oregon
2) Realize the breadth of clinical trials open to entry at our healthcare facilities
3) Discover what the IRB is and how it helps assure that our clinical trials are optimal
4) Anticipate our Clinical Research Center

Brings Cutting-Edge Healthcare* to Central Oregon Sooner

Extraordinary Care close to Home
The “Latest and Greatest”

Examples
1) Ortho/Neuro/Surgical Devices
2) Cancer Chemotherapies: Carboplatin, Bevacizumab, …
3) Anti-thrombosis Treatments
4) Alvimopam

Alymopam

- Research to standard of care exemplified
- Phase 3 trials at BMC and SCMC
- Results
- Methylaltrexone?

Brings Cutting-Edge Healthcare to Central Oregon Sooner

Alymopam

- P&T committee
- Our study
- 3 groups of patients
- $4000 per patient hospital savings
BRINGS CUTTING-EDGE HEALTHCARE TO CENTRAL OREGON SOONER

A BETTER WARFARIN (COUMADIN)?

- Factor Xa Inhibitors

OTHER EXAMPLES

- Sentinel lymph node surgery
- Colectomy
- Spiral CT for coronary and lung imaging
- Respiratory support for premature infants
- Thoracoscopic ablation for atrial fibrillation
- Oral therapy for pulmonary hypertension

Progress vs. Safety in Clinical Trials

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*Personal and Societal

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Raise Benefit & Safety Simultaneously

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Community Practice

and Raising the Fulcrum
Levels of Review of NCI-Sponsored Clinical Trials

- Concept
- Protocol
- Accruals
- Results

Medical Specialties Input and Support of Cancer Clinical Trials

- Cardiology
- Gastroenterology
- Neurology
- Rheumatology
- Pulmonology
- Ophthalmology
- Psychiatry

494 hospitals with 174,062 patients with non–ST-segment Acute Coronary Syndrome

- 123 Hospitals 4.9 (3.5-9.7) % on Trial
- 145 Hospitals 0 Entries
- 226 Hospitals 1.0 (0.5-1.4) % on Trial

Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials

- In-hospital mortality (%)
  - Low
  - Intermediate
  - High

Also, Adherence to AHA guidelines correlated with clinical trial activity
Cost of Treating Cancer Patients in Clinical Trials

- Cost of Treating Cancer Patients in Clinical Trials Just Slightly Higher*
- Clinical Trials Appear Not to Drive Up Cost of Treatment**
- 99% of the time, the extra costs are paid by the sponsor (federal, industrial, ly sources, not the patient


Objectives

1) Understand why clinical research is crucial to Central Oregon
2) Realize the breadth of clinical trials open to entry at our healthcare facilities

and how I and my patients can participate

For our community ...

- Prestige as major medical center
- Patient Retention
- Patient Recruitment
- Healthcare Reform Competitiveness
- Grant Competitiveness
- Philanthropy
- Key Collaborations

Specialties Conducting Clinical Research in Central Oregon during Past Decade

- Oncology
- Cardiology
- Orthopedic Surgery
- Neurosurgery
- Neonatology
- Surgery
- Neurology
- Psychology
- Nephrology
- Infectious Disease
- Immunology
- Sleep Disorders
- Pulmonology
- Trauma
- Sports Medicine
- Rheumatology
- Patient Monitoring Equip.
- Pediatrics/Adol. Med.
- Acupuncture
- Other Integrative Med.
- Patient Satisfaction
- Rural Health

Breadth of Clinical Trials Open in Central Oregon

- Sponsored
  - National Institutes of Health (NIH)
  - National Cancer Institute (NCI)
  - National Heart, Lung and Blood Institute
- Universities (OHSU, Portland State)
- Private/Corporate Enterprises
  - Pharmaceutical Industry
  - Medical (Human) Device Industry
  - Other Healthcare Systems (e.g. US Oncology)
- Investigator-Initiated (N = 4)
- IRB Approved
  - SCHS IRB
  - Western IRB

Central Oregon Clinical Trials

- SCHS Trials April 2009 - March 2010
  - 11 healthcare organizations
  - 921 Central Oregonians currently on trials
  - 180 Patients entered past year
  - 42 trials open for new subjects
  - 25 trials closed to entry, in follow-up
- BMC Trials
  - 31 trials open for new subjects
  - 133 Central Oregonians currently on trials
  - 89 Patients entered past year
- Total Number of Patients on Trials: 1,054
CENTRAL OREGON INVESTIGATORS

- What it takes
- Time
- Ancillary help
- Certified Physician Investigator
- Meetings

TYPES OF STUDIES

- Phase I
- Phase II
- Phase III
- Phase IV

RISK EVALUATION MANAGEMENT STRATEGY (REMS)

- What is it
- Is this research?

CLINICAL TRIAL ENVIRONMENT

- How to do it?
- What do you need?
- Facility
- Collaboration

Our Researchers and Their Research

**Oncology**
- Robert Boone, MD
  - STAR
  - ASSURE
  - TAILORx
  - IBCSG 24-02
  - MA 27
  - JMA 17
  - S0226
  - ...
  - ...
  - ...
  - ...
- Michel Boileau, MD
  - SELECT
- Bill Martin, MD
  - E5202
- Linyee Chang, MD
  - AXXENT
- Russ Omizo, MD
  - PRIMA
- Steve Kornfeld, MD
  - S0925
  - ...

**Heart**
- Bruce McClellan, MD
  - AFIB
  - COMM AFIB
  - OASIS
  - LUNAR
  - ...
- Michael Widmer, MD
  - ASCEND
  - LGVX
  - LGVY
  - RED-HF
- Chris Hatelstad, MD
  - TACT2
- John Blizzard, MD
  - MEND CABG
- Tim Hanlon, MD
  - EXCEED
- Gavin Noble, MD
  - ARISTOTLE
- James Laughlin, MD
  - VITAL
- Jason Wollmuth, MD
  - SATURN
<table>
<thead>
<tr>
<th>Researchers and Their Research</th>
<th>Orthopedic Surgery / Physical Therapy</th>
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<tbody>
<tr>
<td>Knute Buehler, MD</td>
<td>Cara Walther, MD</td>
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<tr>
<td>CECT</td>
<td>KNEEBOUND</td>
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<tr>
<td>EXETER</td>
<td>Viviane Ugalde, MD</td>
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<td>James Verheyden, MD</td>
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<tr>
<td>ASCENSION MCP, PIP</td>
<td>Brett Gingold, MD</td>
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<td>Scott Jacobsen, MD</td>
<td>OP1 Implant</td>
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<tr>
<td>Michael Coe, MD</td>
<td>Kathleen Moore, MD</td>
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<td>David Stewart, MD</td>
<td>OP1 Putty</td>
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<td>Anthony Hinz, MD</td>
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<td>Robert Thomas, MD</td>
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<th>Researchers and Their Research</th>
<th>Neurosurgery</th>
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<tr>
<td>Raymond Tien, MD, PhD</td>
<td>Brad Ward, MD</td>
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<tr>
<td>SAPHIRE</td>
<td>COAST</td>
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<td>NEUROFORM</td>
<td>KAVIAR</td>
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<td>Mark Belza, MD</td>
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<th>Bend Memorial Clinic</th>
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<tr>
<td>Tim Beard, MD</td>
<td>Bill Schmidt, MD</td>
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<td>Pozen</td>
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<td>Acolor cystectomy</td>
<td>Eclipse</td>
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<td>BRI DVT</td>
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<td>Pozen Endo</td>
<td>Clovis Pancreaticb</td>
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<tr>
<td>Mary Carroll, MD</td>
<td>Ted Braich, MD</td>
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<td>Takeda SYR 322</td>
<td>ACORN</td>
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<td>Trial Net DM</td>
<td>Karen Oppenheimer, MD</td>
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<td>Lilly GBDA</td>
<td>Daichi Engage</td>
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<td>Lilly IOQC</td>
<td>Rob Matthews, MD</td>
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<tr>
<td>Mike Feldman, MD</td>
<td>Greg Borstad, MD</td>
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<td>Mitsubishi KRM</td>
<td>Takeda Gout, MD</td>
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<td>Luitpold anemia</td>
<td>Lilly BCDO</td>
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<td>Matt Lasala, MD</td>
<td>Abbott RA</td>
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<td>Genentech Stage</td>
<td>Gavin Noble, MD</td>
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<td>Roche Emerge 6</td>
<td>Borealis</td>
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<td>Genentech Sundial</td>
<td>Aspect</td>
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<td>Roche Emerge 8</td>
<td>Rich Koch, MD</td>
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<td>BRI COPD</td>
<td>Lilly Taby</td>
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<tr>
<td>Adam Williams, MD</td>
<td>Mike Harris, MD</td>
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<td>Forest COPD</td>
<td>ICON/BMS</td>
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<tr>
<td>Stephen Archer, MD</td>
<td>Darren Kowalski, MD</td>
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<td>BOLD</td>
<td>LAPCOLON</td>
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<td>Timothy Beard, MD</td>
<td>Francis McCabe, MD</td>
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<td>WELCH ALLYN</td>
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<td>MINTX Colec</td>
<td>Jon Lutz, MD</td>
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<td>Susan Gorman, MD</td>
<td>WESTNILE</td>
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<td>MWEndometrial Ablation</td>
<td>Brain O’Hollaren, MD</td>
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<td>Linda Leffel, MD</td>
<td>ALVIMOPAM</td>
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<td>Breast implant</td>
<td>Richard Koch, MD</td>
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<td>David Dedrick, MD</td>
<td>LEGACY</td>
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<td>Restless Legs</td>
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<td>Lyle Fagnon, MD</td>
<td>Terry Chianello, PhD</td>
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<tr>
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<td>Noura Sall, MS, CCRC</td>
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<tr>
<td>Timothy Beard, MD</td>
<td>Andrea Andrus, CCRC, RDCS</td>
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<td>Susan Gorman, MD</td>
<td>Aimee Soles, CRA</td>
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<td>Linda Leffel, MD</td>
<td>Cardiovascular Services, SCHS</td>
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<td>David Dedrick, MD</td>
<td>Meredith Dawson, CCRC</td>
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<td>Lyle Fagnon, MD</td>
<td>The Center for Orthopedic and</td>
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<td>Neurosurgical Care and Research</td>
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<td>Megan Boone, CRA</td>
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<td>Kristi Sterry, CCRP</td>
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<td>Cancer Center, SCHS</td>
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Research Coordinators
(continued)

- Karla Lichter, MS, CCRC
- Pamela Gogenola, CCRC
- Joanne Smith, CCRC
- Christine Reed, BS, CCRC
- Aaron Pratt, BS, CRC
- Jennifer McCormick, MA, CRC
- Molly Johnson
- Danielle Quinlin
- Anne Bergin
- Joanne Smith
  Bend Memorial Clinic

Research Coordinators
(continued)

- Monica Wickham
  Advanced Specialty Care
- Sara McCarthy
  NW Endocrinology

Research Coordinators
Ex Officio

- Karen Doolan, RN, NP, CRA
- Teddy Richardson, RN, CRA
  Heart Institute of the Cascades
- Deb Rogers, RN, NP, CRA
  The Center for Orthopedic and Neurosurgery Care and Research
- Janice McDaniel, CCRP
  SCHS Cancer Center

Objectives

1) Understand why clinical research is crucial to Central Oregon
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History and Ethics

- Nuremburg Code (WWII)
- Wichita Jury Case (1953)
- Milgram “Obedience to Authority”
- Declaration of Helsinki (1964)
- PHS Tuskegee Syphilis (1932-1971)
- Humphrey “Tea Room Trade” (1970)
- Zimbardo “Simulated Prison” (1973)
- Belmont Report (1979)

SCHS Institutional Review Board (IRB)

Legally mandated to assure that
1) The conduct of all research activities involving humans or specimens from humans within the SCHS is in compliance with
   - International (ICH)
   - Federal (DHHS, FDA, etc.)
     - State
       - 45CFR46
       - 21CFR50
       - 21CFR56
   - Local

Respect for Persons
Beneficence
Justice
The rights and welfare of our people willing to participate in clinical research are protected.

The risks, discomforts and inconveniences of the research is justified relative to potential individual and societal benefit.

All subjects are fully informed and freely consent.

All human subject research and research proposals at SCHS is reviewed and approved.

IRB includes scientists and community members.

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- IRB includes scientists and community members.

**SCHS IRB**

- Founded: 1988
- Studies approved: 330+ since 1994
- Prior Chairs:
  - Michel Boileau, MD
  - Bruce Brundage, MD
  - Derek Gillespie, PharmD
  - Mary Jane Kuhar, MD
  - Robert Boone, MD
  - Steve Meyer, MD
  - Allen Merritt, MD

**Other Prior Members**

- Keith Harless, MD
- Cherie McKenzie, RN
- Christopher Clark, MD
- Rose Dusen-Speck, LPT
- Barton Clements, EdD
- Dave Vial, PharmD
- Cherri McKenzie, RN
- Dorothy Barrow, RN
- James Harley, JD
- Rick Martin, BS
- Ellen Eisman, PhD
- Alan Burke, MSW
- John Rask, MD
- Bryce Yerman, MD
- Craig Miller, MD
- Darius Azin, MD

**SCHS IRB 2011**

Total Members = 8

**SCHS Members**

- Archie Bleyer, MD, Chair
- Bill Danaher, Spiritual Care
- Robert Cutter, PharmD, Pharmacy

**SCHS IRB 2011**

Community Members:

- Katie Richards, MD, Chair Alternate Emergency Medicine
- James Ritzenthaler, MD, Internist, Director, Volunteers in Medicine
- David Lyon, PhD, Vice President, Physical and Biological Sciences, Bend Research Inc.
- Adam Carroll, PhD, Bend Research Inc.
- Michael Gibson, BS, Patient Advocate
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Promotes Critical Thinking and Jobs!
- Attracts high quality physicians who demand a cutting-edge professional environment while desiring Central Oregon quality of life
- Adds new $ to Central Oregon economy
  - New healthcare technology companies
  - Venture capital (Bend Angel Fund $1.2m)
  - New jobs
  - New facilities (Juniper Ridge)

Thoughts for the Future
- Enhanced recruitment
- All research sites work together
- Central database of research
- Central Oregon Clinical Research Center (COCRC)

Central Oregon Clinical Research
Website launch pending

Clinical Research Associate Forum
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Review
1) Why clinical research here is crucial
2) Breadth of our clinical trials
3) Why and how of our IRB
4) Central Oregon Clinical Research Center

ableyer@stcharleshealthcare.org   541-706-6998
theard@bmctotalcare.com .......... 541-317-4310