2016 Pacific Northwest Annual Workshop on Methods in Radiation Oncology Clinical Trials

Collaborative Life Science Building • OHSU Portland, Oregon

May 5-7, 2016

Course Director:
Charles Thomas Jr., MD
Professor and Chair OHSU Radiation Medicine

Course Co-Directors:
Mohamed Khan, MD, PhD
Associate Professor University of British Columbia
Ramesh Rengan, MD, PhD
Medical Director SCCA Proton Therapy

Course Coordinator:
Bridgett Sparkman
Executive Specialist
Target Audience
Radiation Oncology Physicians, Residents, fellows and Junior Faculty

OBJECTIVES
Following this CME course, participants should be able to demonstrate the following:

- Define primary & secondary trial aims and appropriate endpoints to measure in radiotherapy clinical trials.
- Define Phase 0, I, II, III, and other clinical trial designs for radiotherapy clinical trials
- Understand the basic clinical trial biostatistics
- Learn best practices for image-guidance driven clinical trials
- Understand how to incorporate immune-based endpoints in radiotherapy clinical trial design
- Understand how to incorporate QOLife endpoints in radiotherapy clinical trial design
- Understand the role of clinical informatics in radiotherapy clinical trial design
- Learn best practices in particle therapy-based clinical trial design

Accreditation
Oregon Health & Science University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit
OHSU School of Medicine, Division of CME, designates this live activity for a maximum of 11.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
# 2016 Pacific Northwest Annual Workshop on Methods in Radiation Oncology Clinical Trials

## Thursday May 5, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:30 pm</td>
<td>Registration</td>
<td></td>
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<tr>
<td>7:00 pm - 8:00 pm</td>
<td>Welcome, Course Overview and Pre-Test</td>
<td>Charles Thomas, MD, Ramesh Rengan, MD, PhD, Mohammed Khan, MD, PhD</td>
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</tbody>
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## Friday May 6, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am</td>
<td>Registration/Continental Breakfast</td>
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<tr>
<td>8:00 am</td>
<td>Responsibilities of the PI</td>
<td>Charles R. Thomas, MD</td>
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<tr>
<td>8:20 am</td>
<td>Primer on Biostatistics for Clinical Trials</td>
<td>James Moon</td>
</tr>
<tr>
<td>9:00 am</td>
<td>Phase I-II Radiotherapy-based Clinical Trials: Design and Endpoints</td>
<td>Ramesh Rengan, MD, PhD</td>
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<tr>
<td>9:45 am</td>
<td>Break Image-guided Radiotherapy Clinical Trial Design</td>
<td>Dave Fuller, MD, PhD</td>
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<tr>
<td>10:20 am</td>
<td>Coffee Break &amp; Poster Review of Clinical Trials</td>
<td></td>
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<tr>
<td>11:00 am</td>
<td>Imaging Endpoints in Clinical Trials: RESIST, PERCIST, &amp; Beyond</td>
<td>Elena Korngold, MD</td>
</tr>
<tr>
<td>11:30 am</td>
<td>Design of Parallel Pathology &amp; Imaging Endpoints in Radiotherapy-based Clinical Trials</td>
<td>Krisitna Young, MD, PhD</td>
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<tr>
<td>12 Noon</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>1:00 pm</td>
<td>Discussion of Concept Sheets</td>
<td>Open Discussion</td>
</tr>
<tr>
<td>1:45 pm</td>
<td>Incorporation of Novel Translational Research Endpoints in Clinical Trials</td>
<td>Mohammed Khan, MD, PhD</td>
</tr>
<tr>
<td>2:10 pm</td>
<td>Immune-Based Endpoints in Radiotherapy –Based Clinical Trials</td>
<td>Marka Crittiden, MD, Michael Gough, PhD</td>
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<tr>
<td>2:45 pm</td>
<td>Normal Tissue Considerations in Design of Radiotherapy Trial Design</td>
<td>Charles Thomas, MD</td>
</tr>
<tr>
<td>3:20 pm</td>
<td>Radiosensitivity &amp; Radioresistance Prediction Tools in Trials</td>
<td>Javier Torres-Roca, MD</td>
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<tr>
<td>4:00 pm</td>
<td>Panel #1</td>
<td></td>
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<tr>
<td>5:00 pm</td>
<td>Adjourn</td>
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## Saturday May 7, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
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</thead>
<tbody>
<tr>
<td>7:45 am</td>
<td>Continental Breakfast</td>
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<tr>
<td>8:25 am</td>
<td>Clinical Informatics in Radiotherapy Trial Design</td>
<td>Dave Fuller, MD, PhD</td>
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<tr>
<td>9:05 am</td>
<td>Particle Therapy-Based Clinical Trial Design</td>
<td>Ramesh Rengan, MD, PhD</td>
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<tr>
<td>9:45 am</td>
<td>QOLife Endpoints in Clinical Trial Design</td>
<td>Lilie Lin, MD</td>
</tr>
<tr>
<td>10:25 am</td>
<td>Mathematical Modeling in Design of Radiotherapy Time-Dose-Fractionation</td>
<td>Andrew Trister, MD, PhD</td>
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<tr>
<td>11:05 am</td>
<td>Role of the Research Associate in Radiotherapy Clinical Trials</td>
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<tr>
<td>11:30 am</td>
<td>Lunch</td>
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<tr>
<td>12:30 pm</td>
<td>Breakout Sessions (Disease Oriented)</td>
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SATURDAY, May 7, 2016 (CONT’D)

Breakout Session 1  Breast Radiotherapy Clinical Trial Designs  Charlotte Kubicky, MD, PhD
Breakout Session 2  Gyn Onc Radiotherapy Clinical Trial Design  Nina Mayr, MD
Breakout Session 3  GU Radiotherapy Clinical Trial Design  Timur Mitin, MD, PhD
Breakout Session 4  GI Radiotherapy Clinical Trial Design  Charles Thomas, MD
Breakout Session 5  Soft-Tissue & Bone Tumor Clinical Trial Design  Arthur Hung, MD
Breakout Session 6  Pediatric Oncology Clinical Trial Design  Archie Bleyer, MD, FRCP
Breakout Session 7  Lung Radiotherapy Clinical Trial Design  Ramesh Rengan, MD, PhD
Breakout Session 8  Head and Neck Clinical Trial Design  Dave Fuller, MD, PhD
Breakout Session 9  Palliative Radiotherapy Clinical Trial Design  Sophia Bornstein, MD, PhD
Breakout Session 10 CNS Radiotherapy Clinical Trial Design  Jerry Jaboin, MD

1:30 pm  Panel #2
2:00pm  Post-Test & Adjourn

Airport Shuttles

GENERAL INFORMATION
Advanced registration closes one (7) business day prior to start of course.

HOW TO ENROLL
Tuition:  $400  Practicing Physicians
        $350  Residents/Fellows
Payment can be made by Visa, MasterCard, or check.

REGISTER VIA:
Online:  www.ohsu.edu/som/cme

General Contact Information:
E-Mail:  cme@ohsu.edu
Phone:  503-494-8700
Fax:  503-494-0392
Address:
Continuing Medical Education, L-602
Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, OR 97239

Course Coordinator:
Bridgett Sparkman
sparkmab@ohsu.edu
503-494-1998

CONFERENCE LOCATION
The Collaborative Life Sciences Building & Skoures Tower brings together Oregon Health & Science University, Oregon State University and Portland State University in one location to benefit all of Oregon. The $295 million building is the first on this scale to combine the resources of multiple universities to offer the best possible science education and research opportunities for students. The facility strengthens partnerships between the universities while expanding their teaching facilities, class sizes and research activities.

Residence Inn Riverplace in Downtown Portland, OR is located near Tom McCall Waterfront Park and within walking distance to Portland’s city center. The Residence Inn Portland Downtown is an extended stay hotel providing spacious suites with all the comforts of home. Guests can enjoy walking along the Willamette River, taking the Portland Streetcar to visit many downtown Portland attractions or viewing the city via the Portland Aerial Tram. Located in South Waterfront near downtown Portland, our extended stay hotel is minutes from Oregon Health Sciences University (OHSU) and also the Oregon Convention Center. Start your day with a complimentary hot breakfast buffet.
To make your reservation please call 1-503-552-9500
COURSE DIRECTORS
Charles R. Thomas, Jr., MD
Professor and Chair
Department of Radiation Medicine
OHSU Knight Cancer Institute

Ramesh Rengan, MD, PhD
Course Co-Director
Medical Director
Seattle Cancer Care Alliance
Proton Therapy

Mohmed Khan, MD, PhD
Course Co-Director
Leader of Radiation Oncology
British Columbia Cancer Agency
Associate Professor
University of British Columbia

VISITING FACULTY
Archie Bleyer, MD
Adjunct Faculty
Clinical Research Professor
Department of Radiation Medicine
OHSU Knight Cancer Institute

Clifton David Fuller, M.D., Ph.D
Assistant Professor
Department of Radiation Oncology
The University of Texas MD Anderson Cancer Center

Charlotte Kubicky, MD, PhD
Associate Professor
Department of Radiation Oncology
OHSU Knight Cancer Institute

COURSE FACULTY (CONT'D)
Arthur Y. Hung, MD
Assistant Professor
Medical Student Clerkship
Medicine
OHSU Knight Cancer Institute

Javier F. Torres-Roca, MD
Associate Member
Research and Clinical Trials
Moffitt Cancer Center

Elena Korngold
Associate Professor
Department of Diagnostic Radiology
Oregon Health and Science University

Marka Crittiden, MD, PhD
Physician-Scientist
The Oregon Clinic
Radiation Oncology

Michael Gough, PhD
Scientist
Earles A. Chiles Research Institute

Kristina Young, MD, PhD
Department of Radiation Oncology
The Oregon Clinic

James Moon
Biostatistician
Fred Hutchinson Cancer Research Center

Lill L. Lin, MD
Assistant Professor
Department of Radiation Oncology
Hospital of the University of Pennsylvania

Sophia Bornstein, MD, PhD
Physician-Scientist
Department of Radiation Oncology
OHSU Knight Cancer Institute

Alex Guimaraes, MD, PhD
Associate Professor
Section Head of Abdominal Imaging
Diagnostic Radiology
OHSU

Timur Mitin, MD
Assistant Professor
Department of Radiation Medicine
OHSU Knight Cancer Institute
Medical Director
Tuality OHSU Cancer Center

Andrew Trister, MD, PhD
Postdoctoral Fellow
Sage Bionetworks
Resident Physician

Nina A. Mayr, MD
Professor and Chair
Department of Radiation Oncology
University of Washington
School of Medicine

John Minger
Senior Research Assistant
Department of Radiation Oncology
OHSU Knight Cancer Institute

Jerry Jaboin, MD, PhD
Assistant Professor
Department of Radiation Medicine
Washington University

Directions:
Start at the Residence Inn Portland Downtown/RiverPlace
1. Head west on SW River Pkwy toward SW Moody Ave (112 ft)
2. Turn Left onto SW Moody Ave (0.3 mi)
   Destination will be on your left
   Collaborative Life Sciences Bldg & Skourtes Tower,
   2730 SW Moody Ave