Patient Reported Outcomes: Upping the game for PRO methods and design in clinical trials

Date: Thursday, July 18, 2019
Start and End Time: 1-5pm Eastern Time

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss case studies of NRG clinical trials using patient reported outcome (PRO) designs
2. Discuss how to improve and standardize PROs for clinical trials
3. Apply standards and procedures required to improve PRO designs and statistical methods

1:00 - 1:05pm: Welcome and Introductions – Deborah Watkins Bruner, RN, PhD, FAAN (Co-PI, NRG NCORP, Senior Vice President for Research, Emory University)

1:05 - 1:15pm: How to improve PRO designs that inform future trials or implementation research– Deborah Watkins Bruner, RN, PhD, FAAN

1:15 - 1:20pm: Q&A

1:20-1:40pm: Improving statistical methods to meet the goals – James Dignam, PhD (SDMC Executive Director, NRG Oncology; Professor, Biostatistics, The University of Chicago)

1:40 - 1:45pm: Q&A

1:50 - 2:35pm: Case Study 1 – RTOG 0415: A Phase III Randomized Study of Hypofractionated 3DCRT/IMRT versus Conventionally Fractionated 3DCRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer

- 1:50 - 2:05 pm: Introduction to PRO study design in RTOG 0415 – Stephanie Pugh, PhD (NCORP Deputy Director, Statistics, NRG Oncology)
- 2:05 - 2:25pm: Analyzing longitudinal PRO data using effect sizes – Don Hedeker, PhD (Professor, Biostatistics, The University of Chicago)
- 2:25 – 2:35pm Q&A

2:35 - 2:50pm: BREAK

2:50 - 3:45pm: Case Study 2 Introduction– RTOG 1203: A Randomized Phase III Study of Standard vs. IMRT Pelvic Radiation for Post-Operative Treatment of Endometrial and Cervical Cancer (TIME-C)

- 2:50 - 3:05pm: Introduction to PRO study design in RTOG 1203 – Karen Gil, PhD (Professor, Obstetrics and Gynecology, Summa Health System; NRG Oncology Cervix/Vulva Cancer Subcommittee member)
- 3:05 - 3:35pm: PRO-CTCAE/moonshot and Standardizing QOL analysis – KEYNOTE SPEAKER Amylou Dueck, PhD (Associate Professor, Biostatistics, Mayo Clinic, AZ)
- 3:35 - 3:45pm: Q&A

3:45 – 4:15pm: Panel Discussion NCORP PIs
Panel Moderator: Benjamin Movsas, MD, co-Chair NRG Patient Centered Outcome Research Committee (PCOR), Chair, Radiation Oncology, Henry Ford Hospital, Detroit

Discussion of templates and guidance in design and analysis

- Kathryn Weaver, PhD, MPH, Associate Professor, Wake Forest University; CCDR Lead, Wake Forest NCORP Research Base – Do PRO guidance cover the use in CCDR adequately.
- Electra Paskett, PhD, Professor, The Ohio State University; Deputy Director, Alliance NCORP Research Base – Are the use of PROs adequately addressing issues in health disparities?

- Karen Mustian, PhD, MPH, Professor, University of Rochester – Observations from symptom management trials – would more templates or guidance improve design?
- Lynne Wagner, PhD, Professor, Wake Forest University; Co-PI, ECOG-ACRIN NCORP Research Base – Use of PROs to understand treatment tolerability and signify risk for early discontinuation

4:15 - 4:30pm: Q&A
4:30 – 4:45pm: Conclusion & Action Items – Deborah Watkins Bruner, RN, PhD, FAAN