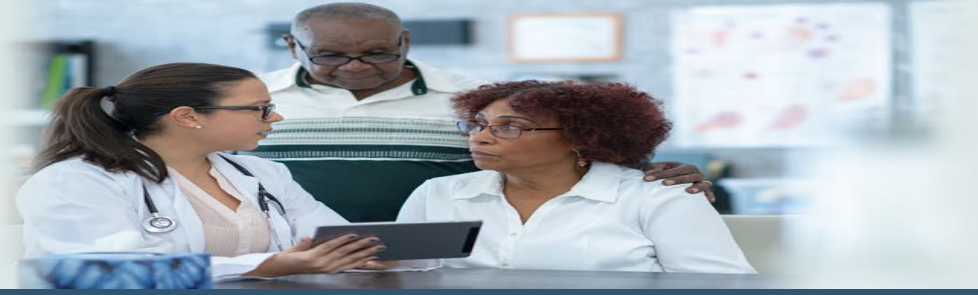


SESSION 6

Advancing Progress in Person-Centered Clinical Cancer Research

Co-Moderators

Gwen Darien, Patient Advocate Foundation
Lawrence Shulman, University of Pennsylvania

Panelists

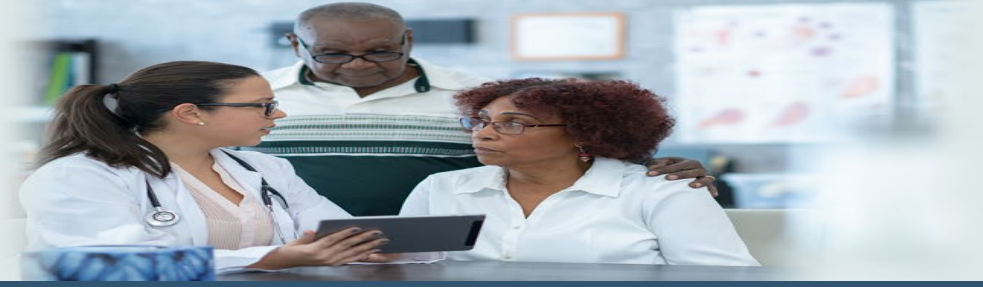
Session 1: Gwen Darien and Randy Jones
Session 2: Larry Shulman and S. Gail Eckhardt
Session 3: Roy Herbst and Robert Winn
Session 4: Rich Schilsky and Cleo Ryals
Session 5: Shivaani Kummar and Larissa Nekhlyudov

Session 1 & Keynote

Integrating Person-Centeredness into Clinical Cancer Research

KEY OBSERVATIONS IDENTIFIED BY SESSION SPEAKERS

- Everyone wins when clinical cancer research is person-centered.
- Navigation increases clinical research participation.
- Navigating the clinical trial process, the eligibility criteria, and the associated financial and insurance considerations is overly complex for patients.
- Patient-clinician relationship is key to advancing person-centered research.
- Family caregivers are influential in clinical research participation, and they need to be recognized as key players at every stage of the process.

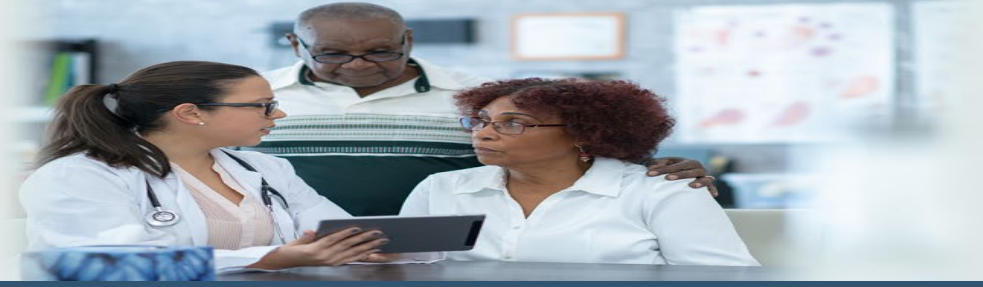


Session 1 & Keynote

Integrating Person-Centeredness into Clinical Cancer Research

OPPORTUNITIES TO ADVANCE PROGRESS

- Consider rural populations, older populations, the evolution of healthcare delivery, artificial intelligence and its evolution, the advent of social media and other forms of technology.
- Effectively align incentives in clinical cancer research with the value of patients.
- Train and fund individuals in communities to serve as clinical trial navigators to increase trust in the process.
- Engage patients as partners and create bidirectional learning opportunities for clinical cancer researchers and patients.
- Address the financial toxicity considerations for patients in clinical research participation.
- Leverage technology effectively to connect patients to clinical cancer research.

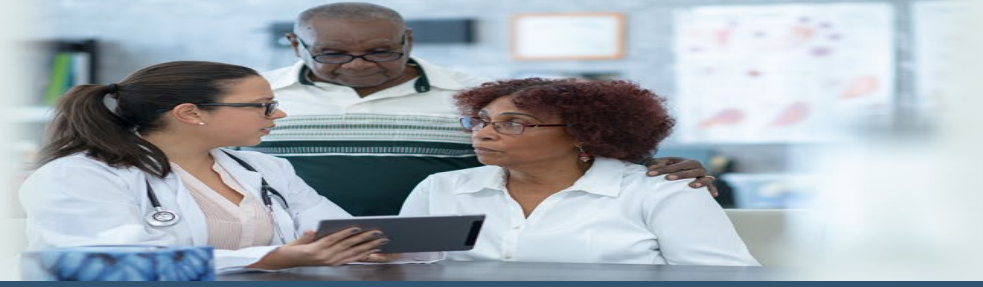


Session 2

Designing and Operationalizing Person-Centered Clinical Cancer Research

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Clinical investigators under-detect and under-report symptoms/toxicities on therapeutic trials; this is being addressed with PRO-CTCAE although use in early clinical trials has not been fully operationalized
- Measurement of clinical outcomes should be inclusive of what matters most to persons with cancer; this can be implemented using tools like PROMIS®
- Equity includes community access to trials, including early phase/Phase I; this has been hampered by many factors including transportation/logistical barriers
- Rural and under-resourced parts of the country are clinical research deserts; there is no one-size-fits all solution, no one group that can fully remediate this problem
- Most persons with cancer reside is communities where oncology care is provided; how can we bridge the gap between practice sites and industry?

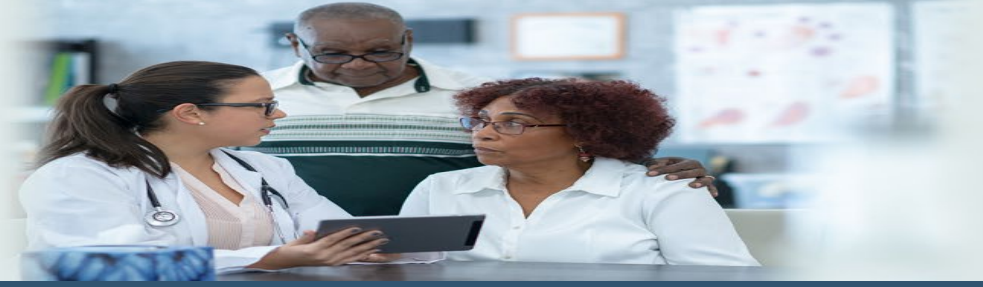


Session 2

Designing and Operationalizing Person-Centered Clinical Cancer Research

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Patient-centered toxicity reporting methods such as PRO-CTCAE need to be better applied to early-phase trials, regularly incorporated into FDA guidance, and supported by industry
- It is critical that researchers continue to design endpoints for trials that adequately capture person-centered priorities; FDA's Patient-focused Drug Development Guidance can facilitate this, but is it being fully deployed?
- The Hybrid Decentralized Model represents one approach to ensuring community access to early phase studies but will require customization and enhanced resources to be viable across diverse communities
- Solutions to providing access to clinical research in rural and under-resourced areas will require innovative approaches, tools, and multi-faceted and PP partnerships to be successful
- Large clinical trial networks like SCRI are developing innovative approaches to increase clinical trial availability at community sites, are there learnings that can be applied in less resourced environments?



Session 3

Building the Evidence Base for Person-Centered Clinical Cancer Research

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

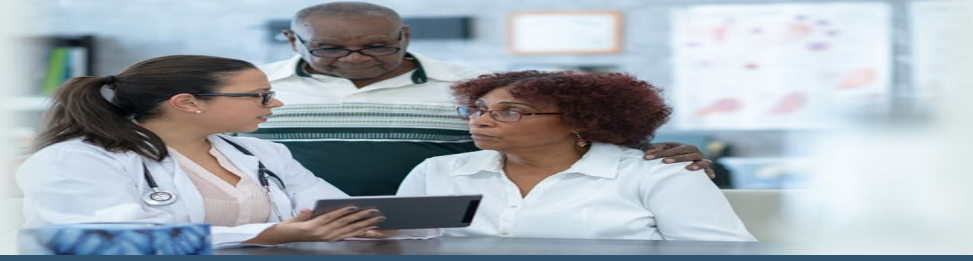
- Improved clinical research diversity has the potential to increase recruitment and retention rates, build trust, and enable local clinicians to administer clinical trials.
- Complex clinical trials increase barriers to enrollment.
- Pragmatic trials are designed to reflect the real-world population by employing simplified study procedures, making clinical research more equitable and inclusive.
- Team science and interdisciplinary approaches are key to advancing person-centered clinical cancer research.
- EORTC Quality of Life Group measurement strategy continues to evolve, preserving many of the benefits of static measures while increasing the accessibility and coverage of PRO measures, with the view to amplify patients' voices.

Session 3

Building the Evidence Base for Person-Centered Clinical Cancer Research

OPPORTUNITIES TO ADVANCE PROGRESS

- Bring clinical trials to the point of care and engage patients in all stages of the clinical research process.
- Determine meaningful interpretations and thresholds for PROs.
- Treat PROs as any other relevant clinical endpoint.
- Create opportunities for clinical cancer research to reflect the complexity of cancer treatment and the individuality of patients' experiences.
- Apply components of pragmatic trial designs in clinical cancer research.
- Reach out to regulatory agencies for advice early in the clinical research process.

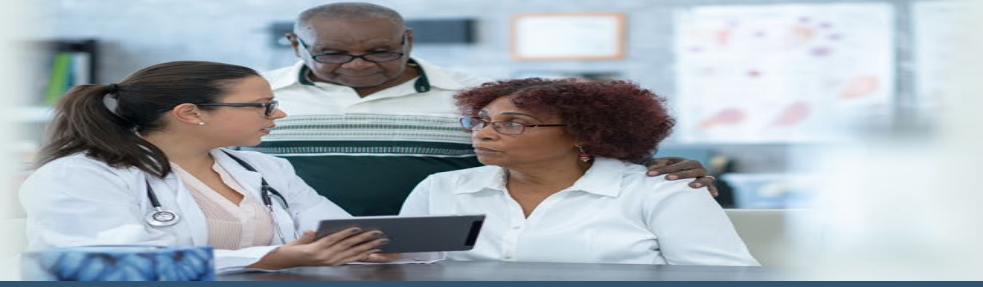


Session 4

Regulatory and Structural Considerations in the Design of Person-Centered Clinical Cancer Research

KEY OBSERVATIONS IDENTIFIED BY SESSION SPEAKERS

- Patients don't want more treatment; they want better treatment.
- The great progress that has been made in the treatment of cancer is, in part, the result of partnerships between the pharmaceutical industry and public entities.
- Patient engagement and interests may be prioritized differently in industry vs public sponsored trials
- Publicly sponsored trials provide an important infrastructure to address questions important to patients through CER studies. Adding pragmatic elements to trials can speed enrollment and improve access.
- PROs and patient experience can complement standard efficacy and safety measures when pre-specified as part of prospective trial procedures.
- Early phase trials provide opportunities to explore optimal dose and scheduling questions, adherence and patient preferences.
- Sponsors should consider their goals in collecting PROs and ensure data collection is fit for purpose.



Session 4

Regulatory and Structural Considerations in the Design of Person-Centered Clinical Cancer Research

OPPORTUNITIES TO ADVANCE PROGRESS

- Reduce patient burden through the use of pragmatic trial designs and procedures that are feasible and not overly complex.
- Reach out to regulatory agencies for advice on patient-centric trial designs early in the product development process.
- PRO objectives should be well understood; instruments should be fit-for-purpose and endpoints should be well-defined to support intended use.
- Progressively liberalize eligibility criteria during product development to facilitate dose optimization.
- Incentivize NCTN groups to “return to their roots” and design trials that answer questions important to patients.
- Leverage artificial intelligence tools to reduce patient and site burden in clinical trials.
- Engage and align incentives across key stakeholders, including payors, regulators, pharma, and patients.

Session 5

Reporting Findings from Clinical Cancer Research Back to Participants

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Key issue 1: Lack of consistent practice to report results back to participants
  - What results-clinically actionable ; exploratory research? Summary? Individual data? Who should share? Who is responsible? Who tracks the documentation? Time frame?
- Key issue 2: Not all participants would want the results? Opt in/opt out in consent documents
- Key issue 3: Lacking the skills to effectively communicate to study participants and populations- social media, journals

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Session 5

Reporting Findings from Clinical Cancer Research Back to Participants

OPPORTUNITIES TO ADVANCE PROGRESS

- Requirement for lay language summary that would need to be shared with participants and documented. Record participant wishes using opt-in/opt out language in consent form
- Opportunities for sponsors, investigators, journals, regulatory bodies
- Collaboration between investigator and advocacy organizations, communication specialists
- Leverage new technologies, social media and other communication channels for people to access
- Rethink the process for presenting and publishing results
- Training

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