SESSION 6

Opportunities to Advance Progress in Public-Private Partnerships for Clinical Cancer Research

CO-MODERATORS

Roy Herbst, Yale University
Richard L. Schilsky, University of Chicago

PANELISTS

Session 1: Roy Herbst and Richard L. Schilsky
Session 2: Edith Perez and Heidi Smith
Session 3: Gideon Blumenthal and Esther Krofah
Session 4: Otis W. Brawley *(participating virtually)* and Kristen Rosati
Session 5: Neal Meropol and Lawrence Shulman

SESSION 1

Rationale and Objectives for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS

- Leverage partner resources to accomplish the scientific goals that would not be possible by either party alone
- Recognize the impact of globalization on clinical cancer research
- Generate knowledge for public use, and be fair, transparent, and inclusive
- Trust, clear understanding of shared/divergent interests, goals, and priorities are essential
- Agreed upon approaches to IP rights and data sharing
- Speed, flexibility, communication
- Leadership, governance, accountability
- Project management is key
- Use public-private partnerships to de-risk trials
- Ensure data quality that is fit for purpose
- Improve trial access and diversity

SESSION 1

Rationale and Objectives for Public-Private Partnerships

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Contracting, contracting, contracting
- Speed, speed, speed
- Culture change/control/flexibility
- Accountability and leadership
- Sharing data/IP/revenue
- Save the clinical investigator
- Policy change may be less important than flexibility in policy implementation
- Create PPPs of lawyers!
- Clarify roles/expectations from the start
- Increase the use of master agreements for contracting
- Incentivize health systems to accelerate contracting/trial launch
- Expand patient engagement in the governance of PPPs
- Increase salary support and protected time for clinical investigators
- Path to promotion for participants in team science

SESSION 2

Exemplars of Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS

- Dr. Herbst discussed LungMAP - Project management and building a team to move things forward is key; allowing flexibility of design – adaptability in a pragmatic design; importance of pre-screening and keepign the patient at the center of what we do.
- Dr. Meyer and Dr. Gopalakrishna gave us a walk-through PALLAS and posed the question to all of us how do we move the needle faster and shared lessons learned emphasizing the need to require biospecimen collection as well as the decision-making and alignment up front also the potential positive impact on sharing the burden of CPP impact.
- Dr. Reckamp walked us through the possibilities and importance of making 'Bold Bets' of the Pragmatica-Lung Trial and leaning into the discomfort to reduce the burden staff and HCPs
- We heard from Dr. Singh from the FDA perspective and again the importance of people and partnerships with the intent to move forward in the service of patients; the concept of also public –private- private – and working together for the greater good; Science and innovation has no clock – but patients are waiting.
- Drs. Adams, Dancey, Golfinopoulos, Mooney and Nichols took us through the complexity across the systems from US, Canada, EU and the importance of alignment on the goals, the concept of giving up some 'control' , avoiding complexity, engaging the right people who are committed to these partnerships and carrying them through

SESSION 2

Exemplars of Public-Private Partnerships

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Are there barriers to decentralized clinical trials, and how do we remove them?
- Is there something we can influence regarding drug shipment across borders (e.g. does NCI – NCTN have a best practice?)
- Concomitant medications and adverse effect reporting: do we need to inform policy or create a framework so that industry understands that depending on the lifecycle there may be different pathways for reporting?
- Real-world evidence/data – is there a way we can use to increase representation; are there attributes for data quality that are a must-have vs nice-to-haves?
- Importance of coordination with patient advocacy, societies, etc. is there a playbook or guidelines, rules of engagement/best practices?
- Set the clinical scientific questions to be answered. What study, who will lead from each partner? Set governance guidelines reflecting the goals of each party, be flexible on design based on potential changes in standard of care, active ongoing meetings with transparent and frequent communication.
- Timing is everything, speed and quality, efficiency

SESSION 3

Regulatory and Policy Considerations

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS

- Significant policy changes such as the Inflation Reduction Act, Bayle Dole, March In, FTC oversight of mergers and acquisitions may have unintended consequences in private sector capital flowing to biotechs
- Unused human biospecimen collected as part of studies
- Engagement of participants through the study design process including return of results to participants
- Organizational culture, leadership, governance, data collection and harmonization, contract negotiation, long times to activation, restrictive eligibility criteria, control, ownership of IP across multiple partnering organizations and with regulators
- Difficult for early career investigators to participate in the development process with industry
- Government agency mission/role is defined by regulation or legislation; innovative mechanisms may be poorly served by existing infrastructure, staffing, and processes
- Corporate structure that the final word is the attorneys' without a broader picture; turnover of senior leadership within industry and leads to rework and lack of standardization; inability to leverage prior structures and agreements

SESSION 3

Regulatory and Policy Considerations

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Public-private partnerships can be leveraged beyond traditional clinical trials to biomarker qualification and validation studies (e.g. ctMoniTR Project)
- Recognize the role of not-for-profit foundations to successfully run disease specific platform studies including in rare diseases (Foundations offer more agile funding support)
- Develop public-private partnership training programs that enable academic clinical investigators to participate in the bench-to-bedside process of early drug development; provide access to mentorship outside home institution, leadership training
- Encourage stakeholders to engage early and often and work with the agency to problem solve and identify opportunities for successful clinical trial partnerships
- NCI Clinical Trials Innovation Unit could provide a means of testing innovative collaborations, interventions, biomarkers, procedures, and designs
- Recognize complementary assets, gains, and risks of each stakeholder and where the interests of each do not overlap
- Integrate community, patient, and public engagement in studies to address mistrust in science and misinformation

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 1: Misaligned academic incentives

Potential solutions:

- **Funder requirements**
  - **Mandatory and clear requirements with oversight**
  - **Costs of data sharing provided**
- **Journal expectations**
- **Investigator credit for data sharing**
  - **Valued as a promotion criterion**
  - **Valued as a contribution to grant and other funding applications**
  - **Evidence-based incentive: open data badge**
  - **Attribution for creation- -DOI of dataset**

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 1: Misaligned academic incentives

Potential solutions continued:

- **Institutional support**
  - **Enable FAIR data sharing**
  - **Infrastructure support**
  - **Planning for data sharing at beginning of research project**
  - **Transparency with participants regarding use of 1) clinical data, (2) excess clinical biospecimens, (3) clinical research data, and (4) research biospecimens**
  - **IT redesign**
  - **Consequences for misuse**

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 2: Lack of standards for data sharing (which hampers journal and funder expectations for data sharing and sponsor sharing of clinical trial data)

Potential solutions:

- **Implement data standardization and rich metadata, including data dictionaries for data sharing to be findable, accessible, interoperable, and reusable**
- **Public-private partnerships with appropriate data expertise to align datasets to enable cross-trial patient-level meta-analysis**

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 3: Need for greater patient/participant/community engagement and education

Potential solutions:

- **Fresh articulation of the value proposition to engage people in sharing their data**
- **Involve patients and patient advocacy organizations in contributing to and advancing research**
- **Better communications with patients/participants about value of research**
- **Outreach to community -- explanation of the value proposition in different populations**
- **National public educational agenda to illuminate the value of data reuse**

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 4: Need for greater protection of individual privacy and against community harm

Potential solutions:

- **Federal law prohibiting re-identification of individuals from de-identified data sets (with carefully crafted exceptions)**
- **Development of policies and/or a governance structure to effect real consequences and enforcement for data misuse**
- **Objective third-party evaluation (a public-private advisory board?) for sharing non-consented sensitive datasets**
- **Application to vet appropriate secondary use of datasets**

SESSION 4

Enhancing Data Sharing for Public-Private Partnerships

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS– AND OPPORTUNITIES TO ADVANCE PROGRESS

Issue 5: Complexity of laws governing data sharing

Solutions:

- **Early education and engagement of institutional legal counsel**
- **Feedback to lawmakers about the value of secondary research and need for consistency across the country**

SESSION 5

Embedding Clinical Cancer Research in Health Care Delivery

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS AND PANELISTS

- Many patients in the U.S. and globally have not had access to high-quality cancer care and have not benefitted from the advances made in cancer treatment in recent years
- Improving access to clinical studies is a public health imperative, particularly for patients in historically marginalized and underrepresented communities, including rural settings
- Existing community-based consortia provide proof-of-concept for successful conduct of clinical research in local communities
- Direct support for patient education and engagement can contribute to high-quality care and research access
- Partnership can include multiple parties, including the private sector, non-profit funding organizations, and clinical networks
- New technologies and operational models can enable research that is embedded within health care delivery workflows

SESSION 5

Embedding Clinical Cancer Research in Health Care Delivery

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Recognize Public-Private Partnerships as an opportunity to achieve shared patient-centric goals
- Seek precompetitive opportunities to share cost and benefits
- Develop regulatory policies that facilitate clinical research in community settings
- Embrace pragmatic design and operational elements
- Ensure adequate public and private sector funding to support consortium capabilities, suitability for partnership
- Private sector and health care delivery systems should work together to develop and test innovative models and interventions to improve access to high-quality care and treatments
- Streamline trial logistics and invest in the workforce, including navigation, to provide return on investment for health care centers, aid in engagement, and improve outcomes