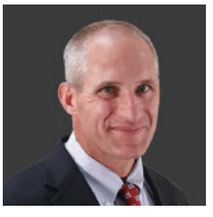
CLINICAL RESEARCH AS A CARE OPTION

APRIL 29-30, 2019 SHERATON IMPERIAL HOTEL RALEIGH-DURHAM, NC

INTEGRATING CLINICAL CARE AND CLINICAL RESEARCH. THE FUTURE OF HEALTH CARE OPTIONS.

Co-Chairs



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CEO
WILMINGTON HEALTH

SARAH LARSON
Director of Global Clinical Operations
BIOGEN

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DAY ONE - MONDAY, APRIL 29, 2019

8:00 am
Registration and Morning Coffee/Tea

8:30 am
Co-Chairs' Opening Remarks
State of the Movement: What are the Sustaining Facets to Integrate Clinical Research as a Care Option (CRAACO) and Identify Treatment Gaps for Patients
CRAACO co-chairs open the program addressing:

- Health systems and pharma share the common goal of serving patients and want a future of more care options.
- Pharma wants to advance new therapies
- Challenges include:
  - Access and healthcare disparity
  - Inequities in research
  - Broader community engagement

Jeff James
CEO, **Wilmington Health**

Sarah Larson
Director of Global Clinical Operations, **Biogen** and *Cancer Veteran*

8:45 am
Understanding the Goals of Care vs Research

- Goals for care vs goals for research
- Oversight and governance
- Is there an ethical burden of breaking down the line between research and care?
- What is the hesitation behind embracing the blurring of this boundary?
- In areas like precision medicine, this is already blurring, how to manage?
- Hurdles stopping large companies from thinking about this– Is it practical? Ethical?

Murray Abramson, MD, MPH
VP, Global Clinical Operations, **Biogen**

Greg Burke, MD, MSc
Chief Science Officer, Senior Associate Dean for Research, **Wake Forest School of Medicine**

9:10 am
New Models of Clinical Research

- Why CRAACO is beneficial in a broad way beyond individual academic centers
- Where does CRAACO sit in the broader contextualized world?

Irfan Khan, MD
CEO and Founder, **TrialScout**

Joseph Kim, MBA
Senior Advisor, Patient Experience and Design Innovation Design Hub Foundations, **Eli Lilly & Company**

Craig Lipset, MBA
Head of Clinical Innovation, **Pfizer, Inc**

Kelly McKee
Head, Patient Recruitment, Rare Diseases, **Vertex Pharmaceuticals**

9:30 am
Surgeon's Perspective on Integrating Clinical Care and Clinical Research
Dr Laura Esserman, the architect behind the I-SPY 2 TRIAL™ has achieved remarkable progress with this clinical trial in improving the outcomes of early stage, breast cancer for patients who are at high risk for early recurrence. I-SPY 2 is also impacting far beyond breast cancer by increasing efficiencies that promise to accelerate the development and delivery of more effective therapies for other cancer types and a range of other diseases. This would not be possible with out the integration of care and research. In this keynote session, hear this surgeon's view on the future of integrating care and research.
Laura Esserman, MD, MBA
Director, UCSF Carol Franc Buck Breast Cancer Center; Alfred A. de Lorimier Endowed Chair in General Surgery; Professor of Surgery and Radiology, **UCSF**

10:00 am
How Sanford Health Systems Integrated Clinical Care and Clinical Research - Going from 3% of Patients in Clinical Trials to 10% in 8 years: Case Study

- Creating a system for all providers to work seamlessly
- Educational programs and continual training across all areas of care and specialties for trial offerings
- Identifying gaps in trial availability
- Attracting providers who are interested in clinical research for their patients
- NCORP site

Sharon Hunt
VP Cancer Services, **Sanford Health Systems**

10:30 am
Morning Networking Break

11:15 am
Pfizer's Collaborative Approach with a Healthcare System to Integrate Clinical Research into Clinical Care
Craig Lipset, MBA
Head of Clinical Innovation, R&D, **Pfizer**

Aimee Quirk
CEO of Innovation, **Ochsner Health System**

11:45 am

How to Integrate Industry Sponsored Clinical Trials Into Your System to Give Patients the Best Options

- How to build your programs
- How to become and integrated care & research organization
- How to integrate clinical research into your care system
- Case study: University of Buffalo-Roswell Park and TrialScout's strategic partnership

Irfan Khan, MD
CEO and Founder, **TrialScout**

12:05 pm

Addressing Barriers Health Systems Face in Integrating Clinical Care and Clinical Research

- Financial barriers – Speaking to administration's bottom line
- Historical barriers – Who are the key stakeholders that need to be converted into believers of the CRAACO movement?
- Logistical issues – How can we make study startup a more streamlined process?
- Culture change – Onboarding an outside group nested into an existing infrastructure
- Does adding the offering of clinical trials disrupt the ability of the physicians in the clinics to have appropriate patient flow?
- How do you offer patients the options of clinical research?
- Insight from the front line of physicians seeing patients

Greg Burke, MD, MSc
Chief Science Officer, Senior Associate Dean for Research, **Wake Forest School of Medicine**

1:00 pm

Lunch & Networking

2:00 pm

What Disadvantages Do Patients Face in Understanding a Clinical Trial

- Strategies and ideas to reduce the burden to patients
- Understanding of clinical care with their physician?
- Communication, consent and data sharing

Moderated by:
Cindy Geoghegan
Cancer Veteran, Patient Advocate

Panelists:
Allison Greiner
Patient Advocate

Sarah Larson
Director of Global Clinical Operations, **Biogen** and *Cancer Veteran*

Kelly Piacsek
VP Patient Centered Research, **Aurora Research Institute**

2:30 pm

Patient Data Management

It is better for patients at large to share data and with personalized medicine, we must share data. It is not an n-of-one every time you see the patient, however, it is crucial that we achieve the following:

- De-identify patient data
- Educate patients on the safety and privacy of the sharing of the data
- The de-identified data is secure
- A clear understanding of this on the consent form
- What IT capabilities are available to handle this?

Moderated by:
Sarah Larson
Director of Global Clinical Operations, **Biogen** and *Cancer Veteran*

3:00 pm

How Can Patient Advocacy Play a Role in Connecting Clinical Care and Clinical Research?

- How can patient advocacy groups better educate their patients and caregivers on the advantages of participating in clinical research
- How can patient advocacy help demystify the clinical research process?
- What is the patient advocacy perspective on integrating clinical care and clinical research?
- How does patient advocacy work with health systems and pharma? What are the commonalities and obstacles to bridging this gap?

Albert A Rizzo, MD, FACP, FCCP
Senior Medical Advisor, **American Lung Association**

Lilly Stairs
Patient Advocate

3:20 pm

Effectively Democratizing Access to Clinical Trials for All
Making clinical research a care option is the ultimate opening of access to clinical trials.

- How are underrepresented groups affected, whether by race, ethnicity, socioeconomic lines, by access to clinical research
- Where are these movements to open access to clinical trials happening?
- How can we educate underserved communities about clinical research?
- Why do they often have access difficulties?
- Does offering these care options enhance access in a broad sense
- Is it helping or hindering trial recruitment and does that correlate with demographic factors already involved in disproportionate recruitment?
- How do we tap into the goldmine of diversity in patients?
- How do we overcome the issues of trust?
- How do we overcome the issues of reimbursement?

Jonathan Jackson, PhD
Director, CARE Research Center, **Massachusetts General Hospital**

3:45 pm

Afternoon Networking Break

4:15 pm
At the Starting Stages: Creating Infrastructure to Provide Outstanding Clinical Research

- Having providers understand what's in it for them
- How do we keep a repository so we can all learn from the experiences we require?
- How to create the infrastructure? Where to start?
- How do we understand how a physicians' involvement in clinical care translates into revenue for the healthcare system?

John H Stewart, IV, MD, MBA, FACS
Physician Executive for Oncology Services, University of Illinois Health and Associate Director for Clinical Sciences, **University of Illinois Cancer Center**

4:45 pm
The Tools Needed to Implement Processes of Budgeting, Protocol, Coordination in Day-to-Day Operations
Members of the Trial Innovation Network discuss the strategies that are being implemented in their individual institutions in order to provide better clinical services to their providers and communities.

- Putting infrastructure in place
- Leveraging expertise of people who run networks and coordinating centers to design successful studies
- Creating pre-negotiated contracts
- Operating with clinical data research networks to improve efficiencies

Bree Burks
Senior Director, **Vanderbilt Institute for Clinical and Translational Research**

Jamie Roberts, MPH, MA, CCRP
Director, Clinical Research Networks, **Duke Clinical Translational Science Institute (CTSI)**

5:10 pm
Building an Interoperable Data Network to make Patients the Brokers of Their Own Data
Patients being able to control the use of their own data will become an important part of the definition of patient centricity, but it is going to take more than effective EMRs to make patients the true brokers of their own data. The Center for Medical Interoperability (CMI) is a neutral authority that is in the process of building critical national infrastructure that will streamline the sharing of digital healthcare data at all levels of care.

- What future capabilities will healthcare demand from its supporting technology?
- Why don't we have ability to exchange/share/automate information among technologies (ex. EMRs, medical devices, software applications, databases, etc.)?
- How have other industries achieved interoperability and data liquidity among technologies? Examples from finance, airlines, cable/ telecommunications industries
- How does the absence of a standardized platform-based infrastructure impede innovation and contribute to the continual fragmentation of healthcare?
- Is there a better way to design and structure our technical underpinnings so as to deliver benefits to all stakeholders? Is this scalable?
- What does it mean to build the digital system around the person?

Meredith Karney
VP, Health Economics and Value, **Center for Medical Interoperability**

5:30 pm
Networking Reception

DAY TWO - TUESDAY, APRIL 30, 2019

8:15 am
Morning Coffee/Tea

8:45 am
Co-Chairs' Opening Remarks
Jeff James
CEO, **Wilmington Health**

Sarah Larson
Director of Global Clinical Operations, **Biogen** and *Cancer Veteran*

9:00 am
Building an Infrastructure for the Integration of Care and Clinical Research with Consortia from Philadelphia, El Paso, and Chicago
These consortia representing three geographic regions are taking steps to normalize clinical research within their respective health systems. They will discuss the aspirations, barriers, and processes of implementing these initiatives, including:

- Interoperability of information systems
- Availability for manpower
- Practitioners having and making the time for research

Joshua J Jacobs, MD
Head of Research, **Rush University Medical Center**

Emma Schwartz, MPH
President, **Medical Center of the Americas Foundation**

David Whellan, MD, MHS, FACC, FAHA, FHFSA
Senior Associate Provost Clinical Research, COO, **Thomas Jefferson University, PIER Consortium**

9:50 am
How to Offer More Options to Patients without the Administrative Burden- Making Clinical Research the Rule, Not the Exception

- How do we do a better job of site specific startup besides population specific startup?
- How do you implement relatively quickly?
- What are the strategies and opportunities from a regulatory perspective?
- Dealing with the challenges of safety standards and protocols, which are critical and arguably primitive
- Guidance on managing the reality of overhead costs and timelines, which can make the process highly selective

Kelly Piacsek
VP Patient Centered Research, **Aurora Research Institute**

Denise Snyder
Associate Dean for Clinical Research, **Duke University School of Medicine**

10:10 am
Morning Networking Break

10:45 am
Case Study: How Wilmington Health is Streamlining the Processes behind the Integration of Clinical Care and Research to Reduce the Burden to Patients and Investigators

- Going from a fragmented patient journey to a streamlined one
- How to take the patient experience to "just making it another visit type"
- How to take study protocols and make them more native to EMR
- General best practices for streamlining the process for patients and investigators
- What it took to actively normalize the flows and processes of clinical research

Jeff James
CEO, **Wilmington Health**

11:05 am
Virtual Trials: Reducing the Burden of Clinical Research to Create More Effective Care Options, but How?

- How are virtual trials, telemedicine, and remote monitoring affecting the integration of clinical research into clinical care?
- Where is the overlap within the community and what are the implications?
- How to get started and what to expect and challenges?
- Next steps
- Thoughts on the future of virtual trials in healthcare?

Moderated by:
Craig Lipset, MBA
Head of Clinical Innovation, **Pfizer, Inc**

Panelist:
Michelle Longmire, MD
Co-founder and CEO, **Medable**

11:30 am
Innovator's Showcase

12:00 pm
Lunch

1:00 pm
Changing the Way You Think About Clinical Research: Developing Competency Standards for PIs

- How are these standards established?
- What are we doing to propagate the use of them?
- Helping career development and training
- Pushing to get stakeholder buy-in for these competencies through the Workforce Innovation Steering Committee

Jim Kremidas
Executive Director, **ACRP**

John H Stewart, IV, MD, MBA, FACS
Physician Executive for Oncology Services, University of Illinois Health and Associate Director for Clinical Sciences, **University of Illinois Cancer Center**

1:20 pm
Working through Payer Realities
Payor representation will join Jeff to have a frank discussion on:

- Understanding financial risk
- Infrastructure needed
- Value based systems and the effect on payment
- Expanded access
- Formularies and coverage

Moderated by:
Jeff James
CEO, **Wilmington Health**

Panelist:
Neil Shah, PharmD
Specialty Pharmacist, **Blue Cross Blue Shield North Carolina**

1:45 pm
The Need for an Internal Advocate: How Can Clinical Research Professionals bring CRAACO into Clinical Operations?
In this session, participants will receive an insider's view of how being an advocate within pharma for patients and sites can benefit clinical trial awareness, participation, and experiences.
Kelly McKee
Head, Patient Recruitment, Rare Diseases, **Vertex Pharmaceuticals**

2:00 pm
What can Pharma do to Make it Easier for Health Systems to Collaborate for the Integration of Clinical Care and Clinical Research to Give Patients Best Options?

- How does pharma work with a healthcare system so that they can get patients into treatment before the disease progresses and expand the program in an ethical, supportive, sustainable way?
- If pharma and health systems cannot make this integration possible in a place where there is such a need for it, where will it happen?

Moderated by:
Ülo Palm, MD, PhD
SVP, Global Drug Development Operations, **Allergan**

2:30 pm
Group Activity Call to Action: What are the Hurdles to Ensuring CRAACO is Sustainable, Effective, and Achieving Intentional Goals
Mary Hennings
former VP, Market Planning Innovation and Implementation, BCBS Massachusetts, **Mary N. Hennings, Consulting LLC**

Joseph Ternullo, JD, MPH
Vice Chair, Immediate Past President, **Society for Participatory Medicine**

3:15 pm
Conference Concludes