Enhancing the Incorporation of Patient Perspectives in Clinical Trials
Reminders:

- Restrooms: Outside meeting room-Men to the right and Women to the left as you are looking at the stage
- Please turn phones on vibrate or silent
- Please do not personal hotspot as this can interfere with the AV equipment
- This event is being broadcast live- participants will be muted throughout the event
Docket Information

A docket is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. We encourage you to submit your written comments to the docket by May 20, 2019: https://www.federalregister.gov/d/2019-01826 or go to www.regulations.gov and search for docket number 2019-1826.
Donna Cryer, Global Liver Institute
Session I: Enhancing Awareness & Access
Session I: Enhancing Awareness & Access

Moderator: Pamela Tenaerts, Executive Director, CTTI

Patient Perspectives:

Donna Appell, Hermansky-Pudlak Syndrome Network

Steven Hall, Cystic Fibrosis Patient Advocate

Jamil Rivers, Breast Cancer Patient Advocate
Session I Case Examples

- **Ronnie Tepp**, Principal Investigator of the All of Us Research Program
- **Nancy Roach**, Founder of Fight Colorectal Cancer
Reaching, Educating and Engaging Diverse Communities: *All of Us* Research Program Case Study

Ronnie Tepp, Principal, HCM Strategists
Disclaimer
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Mission:
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment and care for all of us
Coincident with advancing the science of medicine is a changing culture of medical practice and medical research that engages individuals as active partners—not just as patients or research subjects.

We believe the combination of a highly engaged population and rich biological, health, behavioral, and environmental data will usher in a new and more effective era of American healthcare.

-- Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH, September 17, 2015
All of Us Mission and Objectives

Nurture relationships with one million or more participant partners, from all walks of life, for decades.

Our mission
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.

Deliver the largest, richest biomedical dataset ever that is easy, safe, and free to access.

Catalyze a robust ecosystem of researchers and funders hungry to use and support it.
All of Us Research Program Core Values

1. Participation is open to all.
2. Participants reflect the rich diversity of the U.S.
3. Participants are partners.
4. Trust will be earned through transparency.
5. Participants will have access to their information.
6. Data will be accessed broadly for research purposes.
7. Security and privacy will be of highest importance.
8. The program will be a catalyst for positive change in research.
A Transformational Approach to Diversity

demographics

health status

geography

data types
HCM’s framework: The Participant Engagement Journey

- Start at point of relevance
- ‘Inside out’ strategy
- Digital/non-digital tools and experiences
- Multiple touchpoints
The Value of Participating in *All of Us*

- **An opportunity to learn** some of your own health indicators and get your own data
- **An opportunity to fight disease** and improve the health of future generations
- **The opportunity to ensure that your community is included** in the studies that may lead to new understanding and new treatments
- **The opportunity to be part of a movement** to make our health care more precise, more personal, and more effective
Value is Different for Each Community and Person

- Help improve the health of your children, grandchildren, and future generations
- Ensure that your local community is included
- Learn about your own health
- Choose to access your data
- Learn about additional research opportunities
Right Messenger + Right Tool = Strong Value Statement

- Materials are passive
- People are engaging
- Provide trusted messengers with a variety of tools and they are able to localize a national program to resonate with the target audience
Community & Provider Gateway Initiative (CPGI)

- Network of trusted community messengers who can engage communities in an authentic and impactful way.

- Focused on education and awareness of All of Us within their communities.
CPGI Network (as of February 2019)
Snapshot of activities (August 2018-February 2019)
Generating activity around National launch: May 2018
Since 2016, our team has cultivated relationships with community and provider organizations to garner support for the program at launch and beyond to help increase awareness of All of Us and the importance of participating in research in communities across UBR populations.

Types of organizations include:

- Patient/Disease/Research Advocacy
- Community-based
- Minority serving
- Faith-based
- Provider trade associations
- Professional Societies
Activities in Support of Launch  *(Non-CPGI, Non-funded, May – July 2018)*

71 Community and Provider organizations completed an activity at launch in support of *All of Us*.

- **Social Media**: 39
- **Email distribution**: 16
- **Blog/website/other**: 5
- **Webinar**: 1
- **In-person activity/meeting presence**: 8
- **Champions Program**: 26

*some organizations engaged in more than one activity*
Key takeaways:

- Don’t be confined by traditional stakeholders
- Think creatively about partnerships
- Use a variety of engagement models
- Give your partners space to define value
March 18, 2019

Enhancing Awareness and Access

Nancy Roach, Fight Colorectal Cancer
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Tom Marsilje, PhD aka Dr. Tom
Stage IV

Colon cancer has spread to other parts of the body:

- Distant lymph nodes
- Lung
- Liver
- Abdominal wall
- Ovary
- Colon

Metastatic cancer
Cancer cells in the lymph system
Cancer cells in the blood
Primary cancer
Promise of Immunotherapy ....

How the Promise of Immunotherapy Is Transforming Oncology

Wall Street Journal, December 4 2014
Search terms:
- Metastatic CRC
- Recruiting
- Not yet recruiting

270 trials total

What about phase 1 trials for solid tumors?
“As a patient, I had no interest in participating in a trial which had both the highest risk of failure as well as limited long-term benefit, even if the experimental therapy worked as designed. I knew that I may only have one shot at a trial, so I wanted to choose that trial wisely and make that potentially single shot count the most!” — Dr. Tom Marsilje
What does that mean?

- **MSS tumors**: Majority of patients (>95%) who have micro-satellite stable tumors (MSS)

- **No trials in China**: at that point, 4-5 years ago, Tom had concerns about listing trials that most people probably wouldn’t be able to access
What does that mean?

- **Highest “potential” chance of benefit:** Chance for a durable response, even if it’s a small chance. Immunotherapy trials* are characterized as highest “potential.”

- **Lowest “potential” chance of trial failure:** Trials can fail due to either safety or lack of efficacy. CRC trials that have advanced to Phase 2 or Phase 3* are characterized as lowest “potential” for failure.

- * means parameters will evolve as science evolves
Hacking for Good: Improving Access to Clinical Trials

By Ben Holtzman  Engineering & Product
http://trialfinder.fightcrc.org/
Curation Process

- Level 1 Curation
  - Research advocate team
    - Is this for stage 4 MSS CRC patients?
    - Is it immunology or phase 2 / phase 3 trial?
    - We now accept trials from China
  - In, Out, or Maybe
Curation process

- Level 2 curation
  - Super advocates with scientific background and scientist support
    - Generally decide questions around potential impact or complex eligibility criteria
  - In or Out, with comments
Impact of curation

Search terms:
- Metastatic CRC
- Recruiting
- Not yet recruiting

375 trials total vs 270 in CT.gov
Utilization since May 2017

- Over 14,000 users have utilized the tools, amounting to nearly 26,000 unique searches.
- Aside from the United States, the countries with patients using the tool the most are the United Kingdom and China.
- Users spend over two and a half minutes per session and navigate between two and three pages each session.
Tom Marsilje, 1972-2017

I DON'T ALWAYS GO TO INFINITY

BUT WHEN I DO I GO BEYOND
Thank you to ...

- Maia Walker, the wizard behind the curtain
- FightCRC research advocates who curate
- Flatiron who programmed
- Erika Hanson Brown, the Mayor of Colontown
- Reece Garcia, the FightCRC staff person who juggles (and all the FightCRC staff who believed and helped)
Questions?

- Nancy.Roach@FightColorectalCancer.org
Session I Panel Discussion

- **Donna Appell**, Hermansky-Pudlak Syndrome Network
- **Steven Hall**, Cystic Fibrosis Patient Advocate
- **Jamil Rivers**, Breast Cancer Patient Advocate
- **Ronnie Tepp**, Principal Investigator of the All of Us Research Program
- **Nancy Roach**, Founder of Fight Colorectal Cancer

- **Richardae Araojo**, Associate Commissioner for Minority Health Director, Office of Minority Health, FDA
- **Luther T. Clark**, Deputy Chief Patient Officer and Global Director, Scientific Medical and Patient Perspective, Office of the Chief Patient Officer, Merck
- **Fabian Sandoval**, CEO & Research Director Emerson Clinical Research Institute
- **Pamela Tenaerts**, Executive Director, CTTI (moderator)
Lunch Break

Session will resume promptly at 12:20 p.m.
Session II: Design & Conduct of Patient-Centric Trials
Session II: Design & Conduct of Patient-Centric Trials

Moderator: Pat Furlong, Parent Project Muscular Dystrophy

Patient Perspectives:

Melissa Beasley, Eosinophilic Esophagitis Patient Advocate
Len Schwartz, Parkinson's Foundation
Theresa Strong, Foundation for Prader-Willi Research
Session II Case Examples

- **Mary Elmer**, Director of the Patient, Caregiver and Consumer Experience, Merck. Member, TransCelerate BioPharma

- **Joseph Kim**, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly
March 18th, 2019

Patient Protocol Engagement Toolkit and the Study Participant Feedback Questionnaire
Mary Elmer, TransCelerate BioPharma Patient Experience Initiative
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TransCelerate:

A Not-for-Profit Entity Created to Foster Collaboration

Our Shared Vision:
To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.
TransCelerate’s Initiatives deliver practical solutions to overcome inefficiencies in research & development

**OUR MISSION:**
Collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines

### HARMONIZE PROCESS AND SHARE INFORMATION
- Clinical Data Standards
- Common Protocol Template
- Common Statistical Analysis Plan Template
- Comparator Network
- DataCelerate™
- eSource
- Digital Data Flow
- Placebo Standard of Care
- Toxicology Data Sharing
- Common Clinical SAE*
- Modernization of Statistical Analysis*

### IMPROVE THE PATIENT AND SITE EXPERIENCE
- Clinical Research Access and Information Exchange
  - Common Registry Data Packet
- Clinical Research Awareness
- eConsent
- eLabels
- Investigator Registry
- Patient Experience
- Patient Technology
- Site Qualification and Training
- Shared Investigator Platform

### ENHANCE SPONSOR EFFICIENCIES & DRUG SAFETY
- Advancing Safety Analytics
- Clinical Data Transparency
- Data Monitoring Committee
- Intelligent Automation Opportunities in Pharmacovigilance
- Interpretation of Guidance and Regulations*
- Protocol Deviations
- Quality Management System
- Risk-Based Monitoring
- Value of Safety Information Data Sources

* New Work approved by TransCelerate Board for 2019
Patient Experience Initiative Roadmap

2016
- Assess literature & conduct Patient interviews

2017
- Development of toolkits (P-PET & SPFQ)

Q1 – Q2 2018
- Obtain patient advisor and member company stakeholder feedback and continue toolkit development

Q3 – Q4 2018
- Finalize toolkits and start Member Company pilot testing

Q3 2019
- Update toolkits based on learnings from the pilot and release for public use
TransCelerate Patient Experience Initiative

- This initiative seeks to develop patient engagement tools will contribute to an improved partnership between sponsors and patients in clinical studies.

Patient Protocol Engagement Toolkit

- **P-PET**: Target Product Profile, Clinical Development Plan, Protocol Concept, Protocol Optimization
- Design clinical studies with patient input

Study Participant Feedback Questionnaire Toolkit

- **SPFQ**: Protocol Execution, Data Analysis, Data Dissemination, Post Study
- Gather patient feedback during clinical studies
How TransCelerate is Developing the Patient Experience Toolkits

**Research Phase**
- **SECONDARY RESEARCH**
  - Search, summarize, analyze, & categorize 110+ related publications, articles, and conferences
- **PRIMARY RESEARCH**
  - Conduct Patient Advisory Board for initial feedback
  - Patient focus groups to understand universal study elements from patient perspective

**Development Phase**
- **ToolkitFocused RESEARCH**
  - Conduct Patient Advisory Board for P-PET input
  - Conduct site focus group for patient clinical study experience-specific input
  - Conduct 1:1 concept elicitation interviews with patients
  - Prioritize study elements by leveraging the Common Protocol Template (CPT) and develop questions, visual aids, guidance for sponsors

**Testing the Toolkits**
- Test P-PET questions with patient advisors
- Test P-PET with mock study team (proof of concept)

**Launch Phase**
- Launch P-PET Version 1 for public use
- Toolkit maintenance activities

**Research Phase**
- Launch P-PET Version 1 for public use
- Toolkit maintenance activities

**In Progress**
Study Participant Feedback Questionnaire (SPFQ) Toolkit

Socialization Deck

Implementation User Guide

SPFQ (Beginning, Middle, End)

Section A: Your experience before you started the study (to be completed within 1 month of study enrolment)

Thank you for your participation. Your experiences in this trial are important to us and we would like to hear about them. Your answers will help us improve future trials. There are no right or wrong answers, and it will take approximately 35 minutes to complete. Your answers will be kept anonymous and will not impact your participation in this trial.

Please select one response for each item.

A1: I understand the treatment process in this trial (for example: when and how to take or use a treatment).

A2: The information given to me before joining the trial was something I needed to know.

A3: The information given to me before joining the trial was something I wanted to know.

A4: The information given to me before joining the trial was something that I still have questions about.

Implementation User Guide for Wave 1 Pilot Testing

Table of Contents

1. SPFQ Toolkit Implementation User Guide - Wave 1 Pilot - testing the implementation materials
2. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
3. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
4. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
5. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
6. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
7. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials
8. SPFQ Toolkit - Implementation User Guide - Wave 1 Pilot - testing the implementation materials

CTTI
Thank You For Your Input!

Patient Advisor

Site Advocacy Group (SAG)

Patient Advisory Boards (PAB)
For more information on the TransCelerate Patient Technology Initiative, visit us:
https://www.transceleratebiopharmainc.com/initiatives/patient-experience/

For more information about TransCelerate, visit us:
www.TransCelerateBioPharmaInc.com

Watch our “About Us” Video

Sign up for our Newsletter, Accelerate to Innovate
Design of Patient Centric Trials
Case Examples: CoDESIGN - Eli Lilly and Company
Joseph Kim, Sr. Advisor Patient Experience and Design Innovation
Design Hub Foundations
Disclaimer

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PURPOSE: Ensure Lilly’s Clinical Programs and Trials are designed to provide exceptional experiences for patients & research professionals.

MISSION: Utilize the CoDESIGN experience to understand and appreciate the needs of individual Clinical Programs and Trials by ensuring trial designs are:

- Thoughtfully supportive of the patient
- Implemented effectively by sites
- Differentiated against the market by payers
- Meet the safety and efficacy thresholds set by regulatory bodies
Case Study 1 - Endpoints

- **Endpoints**
  - **Problem:**
    - While FDA approved end points might be focused on evidentiary disease progression/modification, measurement of symptomatic relief can be strongly desired.
  - **Outcome:**
    - Patients help us to include these as endpoints based on their feedback.
Case Study 2 - Procedures

- Timing/Volume of Procedures
  - Problem:
    - Study team was unsure of number of procedures or the timing between them
    - Were they out of sync with the practical realities of the health care system or patient lives?
  - Outcome:
    - Through patient and site collaboration, Lilly is often able to uncover these scenarios and have redesigned the schedule of procedures as a result.
Case Study 3 - Invasiveness

- Invasive Procedures
  - Problem:
    - Invasive procedure proposed in an immunocompromised patient
  - Outcome:
    - Patients informed us that this was a non-starter. Protocol changed procedure to “optional.”
Case Study 4 – Drug appearance

- **Drug Appearance**
  - **Problem:**
    - Multiple pills involved and they all share a similar look
  - **Outcome:**
    - Patients helped to create solutions to help make sense of the different pills and any associated activities
Case Study 5 – IRB perspectives

- IRB perspectives
  - **Problem:**
    - Digital health wearable desired as a solution to help patients participate successfully
    - Historically, not viewed favorably by IRBs
  - **Outcome:**
    - Lilly collected strong site and patient feedback on better ways to support patients with digital health wearable
Questions
Session II Panel Discussion

- **Melissa Beasley**, Eosinophilic Esophagitis Patient Advocate
- **Len Schwartz**, Parkinson's Foundation
- **Theresa Strong**, Foundation for Prader-Willi Research
- **Mary Elmer**, Director of the Patient, Caregiver and Consumer Experience, Merck. Member, TransCelerate BioPharma
- **Joseph Kim**, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly
- **Susan McCune**, Director, Office of Pediatric Therapeutics in the Office of the Commissioner Office of Pediatric Therapeutics, FDA
- **Karlin Schroeder**, Senior Director of Community Engagement, Parkinson's Foundation
- **Pat Furlong**, Parent Project Muscular Dystrophy (moderator)
Afternoon Break

Session will resume promptly at 2:20 p.m.
Session III: Post-Trial Communication & Engagement
Session III: Post-Trial Communication & Engagement

Moderator: Bray Patrick-Lake, Duke Clinical Research Institute

Patient Perspectives:
  Carly Medosch, Chronic Illness Patient Advocate
  Linnea Olson, Lung Cancer Patient Advocate
Session III Case Examples

- **David Leventhal**, Senior Director, Clinical Innovation, Global Product Development Division, Pfizer
- **Jessica Scott**, Head of R&D Patient Engagement, Takeda
Return of Results
Aggregate and Individual

Jessica Scott, MD, JD
Head of R&D Patient Engagement, Takeda

David Leventhal
Senior Director
Clinical Innovation, Pfizer

March 18, 2019
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Session III: Post-Trial Communication & Engagement

1. Evolving landscape
   • Overcoming challenges and progressing solutions
   • Working as part of multi-stakeholder consortia
   • Seeking to progress change internally and externally

2. Plain Language Summaries

3. Individual Return of Results
Takeda, Pfizer and others have been partnering over the past five years with various organizations including:

- Harvard Multi-Regional Clinical Trial Center
- TransCelerate BioPharma
- Health Research Authority Task Force on European Union Clinical Trial Regulation
- Layperson Summary Guidance
- Patient Data Access Initiative
- Supporting individual Public-Private Partnerships
Plain Language Summaries
Plain Language Summaries

- Make results accessible to study participants and general audience
- Aggregate results of a single trial written in plain language
- Explain technical terms and complex concepts in simple language
Plain language summaries

EU Clinical Trials Regulation 536/2014 (Article 37) (EU CT Regulation)

New EU database once it becomes available

Annex V ten elements that must be addressed in the lay summaries

Consistency in the way trial results are presented will be helpful

Effective from 2020
Working Collaboratively

- Harvard MRCT*
  - MRCT Return of Results Guidance Document, Version 3.1, December, 2017
  - Return of Aggregate Results to Participants Toolkit Version 3.1

- TransCelerate BioPharma Inc**
  - Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results EU CTR Task Force and formal Guidance
  - Layperson Summaries of Clinical Trials: An Implementation Guide

Draft Plain Language Summary Guidance Document Submitted to FDA, September 2017

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Remaining barriers/challenges

- Sponsors need to develop summaries and method of distribution
- Pre-publication concerns—no clear position from journals
- Need for clear FDA guidance
- Role of Independent Review Board (IRB)
- Potential to be seen as promotional

"84% of Investigator/Physicians agree aggregate results should be shared with patients → 44% have never shared with study participants”

Harvard MRCT Survey
"I don't think it is just an opportunity - I think it is an obligation - an unmet obligation that pharma disseminate updates on the drug and on your trial."

Patient, US
Understanding the landscape

TransCelerate Survey: Patient Perspective*
Over 3,000 patients surveyed across 36 countries - 2017

- 66% say
  "Knowing that my health and treatment record will be shared with me after my participation in the trial (e.g. my personal results)"

- 83% say The majority of patients want their lab/test results

- 68% say want to know whether they received study drug or placebo

Regulatory changes
EU Clinical Trials Regulation 536/2014 (Article 37) (EU CT Regulation)

Key legislative considerations
HIPAA, CLIA, GDPR,
California Privacy legislation

*Accessed on March 15, 2019 at:
Return of individual results to participants

Consensus Study Report*
A landmark in the individual return of results space providing recommendations for the US, July 2018

*Accessed on March 15, 2019 at:
http://nationalacademies.org/hmd/Reports/2018/returning-individual-research-results-to-participants.aspx
Understanding the value of accessing Clinical Trial Data / Results

- Inform ongoing treatment
- Decrease expenses / risk of repeated tests
- Improved trust
- May improve clinical trials efficiency
- Portability of data
Gaining clarity on Individual Return of Results – what & when

- Harvard MRCT*
  - Return of Individual Results to Participants Recommendations Document Version 1.2 (Guidance), November 2017
  - MRCT Return of Individual Results to Participants Toolkit Version 1.2 (Toolkit), December 2017

Data types recommended for return, at a minimum, are highlighted in yellow

- **A: Urgent Results & Urgent Incidental Findings**
  - Participant Screened
  - Pt On Trial
  - Pt Last Visit

- **B: Routine Results & Non-Urgent Incidental Findings**
  - End Trial

- **C: End of study Individual Results**
  - Study Group Assignment
  - 1° Endpoints
  - 2° Endpoints
  - Safety endpoints

- **D: Exploratory Results**
  - Includes exploratory endpoints
  - During or after close of study
  - May lead to future research

- **E: Aggregate Results**
  - 1° Endpoint
  - 2° Endpoints
  - Summary of Conclusions

*Accessed on March 15, 2019 at https://mrctcenter.org/resources/?project=return-of-individual-results
Working with PDAI:

A collaboration of research sponsors dedicated to the return of individual research results.

To enable trial participants to access their data in a responsible manner that is standardized across pharmaceutical companies.
PDAI - Working to solve the follow-up challenges facing patients, sites and investigators

**Patients**

Patients surfaced the following pain points regarding post-trial follow-up:

- A desire for **trial results** communicated promptly upon completion of the trial
  - Personal
  - Aggregate
- A desire to know which **trial arm** (experimental vs. standard of care/placebo)
- A greater sense of **closure** and **appreciation** from trial team reflected in clinical trial follow up

**Primary Investigators & Nurse Coordinators**

Investigators and coordinators mirror patients in the patient request for trial results, however, the following barriers arise:

- Primary investigators and nurse coordinators **often do not know trial results themselves** until they are published
- Trial results, between writing and peer review, **are published a significant amount of time after trial completion**
- Patients often ask what trial arm they were on, however **the study team is often not informed during or after the study**

“Trial results are published and released to the public typically over 1 year after trial completion. At this point, most patients have moved on; Oftentimes we do not know or ever find out trial arm of specific patients.”

– Coordinator, US
<table>
<thead>
<tr>
<th>Patients are in control</th>
<th>Responsibly share information</th>
<th>Not just data, information</th>
<th>Singular intention</th>
<th>Seamless sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect patient privacy and autonomy by ensuring patients only receive the data they wish to</td>
<td>Return data in a timely manner and withhold only the information needed to maintain trial integrity and comply with regulations</td>
<td>Provide context so patients can understand their data</td>
<td>Create a consistently positive patient experience that remains adaptable to each sponsor’s unique context</td>
<td>Minimize burden on sites, investigators and patients</td>
</tr>
</tbody>
</table>
Innovative Medicines Initiative (IMI)  
Health Outcomes Observatories

Benefits to Patients:

Collect standardized Patient Generated Data and PROs

Value-Based Healthcare

Improved Patient Care & Outcomes

New platform to empower patients to contribute their outcomes data in a standardized way via digital tools to create transparency of health outcomes for Patients, HTAs and HCPs.

Project Partners:
Takeda
AbbVie
Novartis
Pfizer
Sanofi
Lilly
Future focus: Evolving landscape toward Individual Return of Results

- Need for regulatory harmonization
- Address conflict of laws
- Consistency in IRB approach
- Change organizational culture internally & externally
- Develop vendor capabilities
- Further understand patient perspectives
- Conduct pilot studies
- Share learnings and best practices
Session III Panel Discussion

- **Carly Medosch**, Chronic Illness Patient Advocate
- **Linnea Olson**, Lung Cancer Patient Advocate
- **David Leventhal**, Senior Director, Clinical Innovation, Global Product Development Division, Pfizer
- **Jessica Scott**, Head of R&D Patient Engagement, Takeda
- **Suzanne Schrandt**, Director of Patient Engagement, Arthritis Foundation
- **Michelle Tarver**, Director of the Patient Science and Engagement Program, Center for Devices and Radiological Health, FDA
- **Bray Patrick-Lake**, Duke Clinical Research Institute (moderator)
Recapping Key Themes & Looking Forward
Recapping Key Themes & Looking Forward

Panelists:

- **Michael Kurilla**, Director, Division of Clinical Innovation, National Center for Advancing Translational Sciences, NIH
- **Craig Lipset**, Head of Clinical Innovation, Global Product Development, Pfizer
- **John Wilbanks**, Chief Commons Officer, Sage Bionetworks
- **Peter Saltonstall**, President and CEO, National Organization for Rare Disorders
- **Pamela Tenaerts**, Executive Director, CTTI
- **Theresa Mullin**, Associate Director for Strategic Initiatives, Center for Drug Evaluation and Research, FDA
- **Donna Cryer**, Global Liver Institute (moderator)
Thank you for joining us.