Town Hall
Working Together to Address Challenges in Conducting Clinical Trials

Speakers
Joanne Dourado, BSN, MBA
Site Engagement Director - United States
Eli Lilly and Company
Peg Ford
Co-Founder/Immediate Past President
Ovarian Cancer Alliance of San Diego
Suparna Wedam, MD
Medical Officer
US Food and Drug Administration
David Waterhouse, MD, MPH
Co-Chair, Department of Oncology Hematology Care, Inc.
Oncology Hematology Care, Inc.

Introduction
David Waterhouse, MD, MPH
Chair, ASCO Research Community Forum
Oncology Hematology Care, Inc.

Rules of Engagement
Cancer is the Enemy
Not Each Other
Site Leadership Perspective

David Waterhouse, MD, MPH
Chair, ASCO Research Community Forum
Oncology Hematology Care, Inc.

Lead from the back
—and let others believe they are in front.

— Nelson Mandela
A Patient Perspective
Peg Ford
Ovarian Cancer Alliance of San Diego

We call on patients to:
1. Speak up about their concerns, questions and what’s important to them
2. Recognize that they have a right to be equal participants in their care
3. Seek and use high-quality information

We call on clinicians, researchers, editors, journalists, and others to:
1. Provide accurate information about options and the uncertainties, benefits and harms of treatment in line with best practice for risk communication
2. Ensure that the information they provide is clear, evidence-based, and up-to-date and that conflicts of interest are declared

Patients Need:
1. Study design reflects real-life management of disease
2. Patients’ preferences, values and perspectives (community) are taken into consideration in study design
3. Potential Risks and Benefits
4. Patient-reported Outcomes (PROs): Simple, Ease to access, Direct from patient without interruption through others;
5. Consent Form: Short; all information in layperson’s language (aim of study; possibility of adverse effects, random assignment with possibility could be assigned to placebo; option of withdrawing if they desire) time to process;
6. Access: Social-economic, racial and ethnic participation and availability of sites
7. Support: emotional, mental, stress
8. Financial (financial toxicity) employment concerns, costs, transportation
9. Family considerations: spouse/significant other, children, parents
10. Results: Informing patients of results; results are forward progress; patients’ experience end points: PFS/OS
11. The Right Drug at the Right Time for the Right Patient at the Right Dose!

‘Nothing About Me Without Me’
"Patient-centered medicine cannot be practiced without patients actively participating in their own health care choices and in the research that informs such decisions."

Industry Sponsor Perspective:
What can industry do to improve the process of clinical trials?
Joanne Dourado, BSN, MBA
Eli Lilly and Company

Areas of Problems, Delays and Frustrations

- Execution Issues
  - Delay in IRB approval
  - Start-up activities
  - training
  - documentation
  - Safety reporting & safety reviews
  - Standard of care changes during enrollment period
  - inability to perform timely monitoring of data
- Enrollment Issues
  - Inadvertent enrollment
  - Not meeting enrollment expectations
- Quality Issues
  - Inadvertent enrollment
  - Poor data entry
  - Inaccurate & insufficient documentation
  - Not following trial specific procedures

How Can Industry/Lilly Improve Trial Conduct?

- Simplify Study Materials
- Protocol
- Informed Consent Form (ICF)
- Study tools
- Training materials
- Enable One Portal for Study Communication
- One time entry of information
- Enable real time communication of changes
- Utilized across multiple sponsors to reduce multiple entries
- Site Patient Input to Trial Design & Feasibility
- Better trial from the start with key stakeholder input
- Enables operational improvement of trial execution
FDA Perspective

Suparna Wedam, MD
US Food and Drug Administration

Disclosures

I have no financial relationships to disclose

No references to non-FDA approved uses of drugs/products in this presentation

FDA Office of Hematology and Oncology Products
Oncology Center of Excellence

Who Are We?
• Medical, Pediatric and Radiation Oncologists
• Toxicologists
• Clinical Pharmacologists
• Biostatisticians
• Pharmacists
• Oncology Advanced Practice Providers
• Regulatory Project Managers

What do we do?
• Review clinical trials to evaluate new therapies
• Ensure patient safety
• Ensure that trials work for patients

Broadening Eligibility Criteria

• Collaboration with ASCO and Friends of Cancer Research
• First Round
  – Brain Mets
  – Organ Dysfunction
  – Patients with HIV
  – Pediatric population
• Second Round
  – Washout Periods and Concomitant Medications
  – Prior Therapies
  – Test Intervals and Lab Reference Ranges
  – Performance Status

Involving the Patient

• Patient Reported Outcomes (PROs)
• Patient Focused Drug Development
• Project Patient Voice
  – Pilot project to communicate PRO data from commercial trials that quantify longitudinal symptomatic side effect data on a public facing FDA website
• Opportunities for FDA Patient Engagement

U.S. Food & Drug Administration Project Facilitate

Assisting healthcare providers with requests for access to investigational oncology products

DO YOU NEED HELP SUBMITTING A SINGLE PATIENT IND EXPANDED ACCESS (EA) REQUEST (ALSO KNOWN AS COMPASSIONATE USE) FOR A PATIENT WITH CANCER?

FDA’s Oncology Center of Excellence (OCE) can help:
  • Locate IRB resources
  • Find an EA contact for a drug/biotech company
  • Complete Form FDA 3926

Phone: (240) 402-0004
Email: OncProjectFacilitate@fda.hhs.gov

Patients: Talk to your healthcare provider to discuss whether expanded access is an appropriate option.
Oncology Center of Excellence (OCE) Projects

- **Project Community**
  - Extend cancer awareness and education of cancer drug development beyond the immediate
    Washington, DC metropolitan area
- **Project Orbis**
  - Facilitate collaboration with international regulatory agencies
- **Project Point/Counterpoint**
  - Combine FDA and Company Oncology Drug Advisory Committee (ODAC) briefing document
- **Project Renaissance**
  - Explore and define FDA’s role in drug repurposing for rare cancers with an unmet need
- **Project Renewal**
  - Update the safety and efficacy information for oncology product labeling
- **Project Socrates**
  - Initiative focusing on oncology education within the OCE. Includes partnering with organizations such as ASCO, ASH, etc.
- **Project Switch**
  - Explore the use of external control arms derived from legacy clinical trial datasets submitted to the FDA

**Discussion**
Facilitated by David Waterhouse, MD, MPH

**Closing Remarks**
David Waterhouse, MD, MPH
Chair, ASCO Research Community Forum
Oncology Hematology Care, Inc.