ACRP 2017 MEETING & EXPO

SEATTLE, WASHINGTON — APRIL 28 – MAY 2

INNOVATION. IMPLEMENTATION COLLABORATION.

See the future of clinical research at the ACRP Meeting & Expo. Learn from the influencers, innovators, and regulators driving change in clinical trial operations. You and your team will gain practical strategies to manage change, streamline operations, and minimize risk. Position yourself for success at the premier education and networking event for clinical research professionals.

YOUR CHANCE TO MEET DIRECTLY WITH OFFICIALS FROM THE U.S. FOOD AND DRUG ADMINISTRATION

U.S. FDA officials will be at ACRP 2017 to take your questions during an exclusive 'FDA Office Hours' forum, while presenting several educational sessions designed to provide you with clarity on agency expectations related to CDER BIMO compliance and enforcement, electronic records, eSource data, eConsent, and more.

FDA Sessions Include:

- **Signature Series: A Conversation with the FDA**
- **Electronic Records, eSource Data, and eConsent: Clinical Investigations and Regulatory Expectations**
- **FDA Office Hours**
- **CDER BIMO Compliance and Enforcement: What You Need to Know!**

Doug Burrow
Acting Director, FDA Office of Scientific Investigations

Douglas Pham
Acting Director, FDA Division of Enforcement and Postmarking Safety

Jan Hewett
Regulatory Counsel (Policy), FDA Office of Scientific Investigations

Sean Kassim
Director, FDA Office of Integrity and Surveillance

SIGNATURE SERIES SESSION: INNOVATING CLINICAL TRIALS WITH MOBILE TECHNOLOGY

Learn effective solutions for integrating mobile technologies into your clinical trials from representatives of the Clinical Trials Transformation Initiative.

Linda Coleman
Director, Human Research Protection Program, Yale University

Philip Coran
Sr. Director, Quality & Regulatory Affairs, Medidata Solutions

Matt Kirchoff
Clinical Research Operations Manager, International Research Pharmacy Operations, NIH/NIAID

Virginia Nido
Global Head, Industry Collaborations, Roche, Genentech

SIGNATURE SERIES SESSION: THE STATE OF THE INDUSTRY

Learn how process, technology, and workforce innovation are shaping the current and future state of clinical research from experts across the field.

Elisa Cascade
President, Data Solutions, DrugDev

Kenneth A. Getz
Director and Associate Professor, Tufts University

Terri Hinkley
Workforce Innovation Officer, ACRP

Jim Kremidas
Executive Director, ACRP

Leanne Madre
Director of Strategy, Clinical Trials Transformation Initiative

WHAT'S NEW FOR ACRP 2017?

- More Advanced-Level Content for Experienced Professionals
- Educational Sessions for a Broader Spectrum of Professionals
- Greater Emphasis on Practical Application to Improve Trial Operations
- "Master Series" Sessions Helping Put Theories into Practice
- Educational Content Aligned with Core Competencies for Clinical Research Professionals

WHAT'S IN IT FOR YOU?

- 100+ Educational Sessions Uniquely Tailored to Professionals Conducting Clinical Trials
- Networking Opportunities for Peer-to-Peer Exchange and Engagement
- Ability to Earn Continuing Education Units
- On-Demand Access to All ACRP 2017 Sessions through the Online Conference Library for 2 Years

WHO'S ATTENDING?

- 2,000+ Clinical Research Professionals, Including Trial Coordinators, Monitors, Investigators, Project and Site Managers, Patient Recruiters, and More
- 100+ Expert Speakers from Sponsors, CROs, Sites, Regulatory Agencies, and More
- 100+ Exhibiting Companies and Organizations

GET APPROVAL TO ATTEND

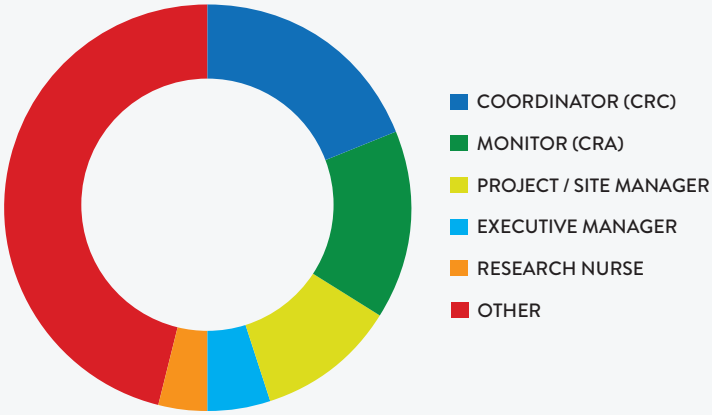
Use our attendee ROI toolkit to gain employer support for your trip to ACRP 2017. Show the return on investment you and your organization will enjoy.

REGISTER

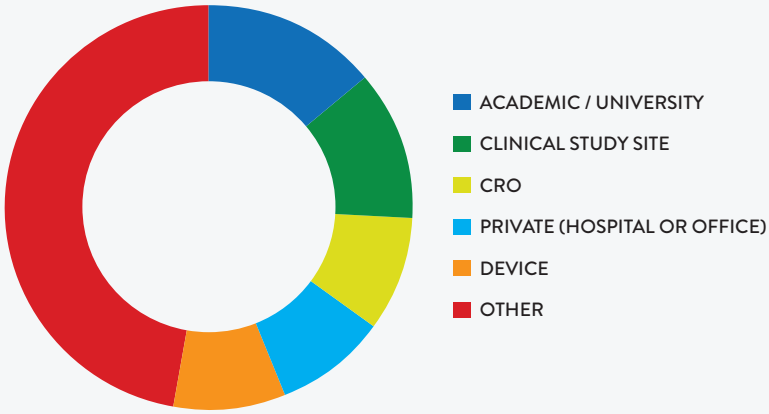
Visit conference.acrpnet.org for more information.

WHO ATTENDS THE ACRP MEETING & EXPO

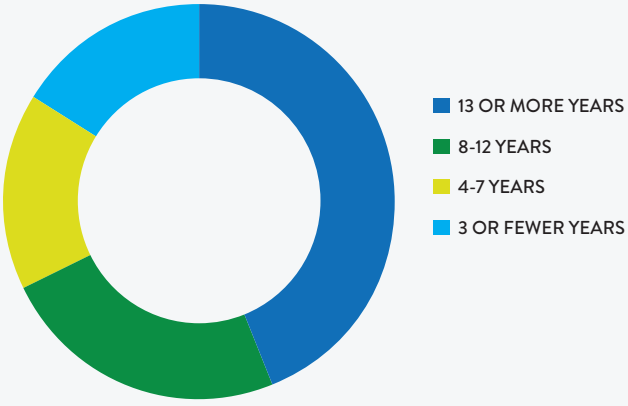
ATTENDEES BY JOB ROLE



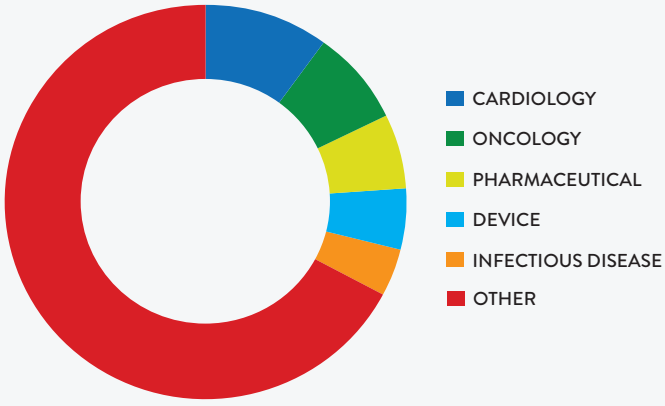
ATTENDEES BY ORGANIZATION TYPE



ATTENDEES BY YEARS OF EXPERIENCE



ATTENDEES BY SPECIALTY AREA



SIGNATURE SERIES SPEAKER

When the Physician Becomes the Patient

Keith Eaton M.D., Ph.D

Hear the inspiring story of Dr. Keith Eaton, a medical oncologist who in 2012 was diagnosed with leukemia and given a less than 5% chance of survival. Dr. Eaton went through multiple rounds of chemotherapy before receiving CAR T-Cell therapy, which reduced his cancer to undetectable levels. He subsequently underwent a stem cell transplant and returned to a healthy life as an active clinical investigator. His amazing survival story offers rare insight into clinical trials from both the researcher and subject perspectives.

NEW FOR 2017! MASTER SERIES SESSIONS

This new session format provides a deeper learning experience by allowing attendees to put theory into practical application. Each Master Series session is split into two parts: the first dedicated to concepts and theory, and the second dedicated to practical application in clinical trial operations.

The ICH GCP E6 R2 Revisions: Impact on the PI and the Site

This "master series" session will review the changes and clinical research practices impacted by the new requirements that serve both as the starting point for an organization's gap analysis, and the subsequent re-design of work practices for compliance with the new ICH GCP E6 R2.

Going Paperless: A Smart Way to Increase Site Efficiency and Save Resources

This 2-part "master series" session will help you develop site-specific solutions for moving to paperless operations. Learn to effectively manage digital medical records, IRB submissions, communications, and more in this interactive, hands-on session.

Ethical Challenges in Pediatric Research

Join an expert panel to examine regulations protecting children involved in clinical trials. Attendees will then engage in a series of interactive pediatric research case studies to help identify, discuss, and resolve various regulatory and ethical issues related to pediatric clinical trials.

Clinical Research Finance & Billing: Are You Leaving Money on the Table?

Learn how to create sound research finance and billing audit plans. This interactive session will help attendees identify lost revenue opportunities and non-compliant billing to Medicare and other insurance providers, common errors in billing and financial operations, and ways to avoid expensive claim submission errors and claims re-work.

REGISTER

Visit conference.acrpnet.org for more information.

The Quality Risk Management Plan: The Key to a Quality Trial
Learn about Quality Risk Management Plans and how they can address organization needs across various areas, including IP, safety, data, risk, and regulatory and project management. Position studies for quality execution and audit readiness by participating in exercises related to potential risks encountered in clinical trials and methodologies for mitigation and documentation.

Current CRU Issues in Planning and Executing Phase 1 Trials
Explore issues affecting clinical researchers at the site and sponsor level in Phase 1 trials, including evaluation of protocols for feasibility, telemetry, TQT studies, FIH trials, and cost-saving measures for sponsors and audits. Attendees will engage in interactive exercises, including reviewing draft proposals, to gain insight into how to interpret and address abnormal findings.

Mastering the Art of Writing Monitoring Reports
Learn what makes for a good monitoring report and take away tips for making sure reports are well-documented, clear, and succinct. Attendees will write mock monitoring reports based on scenarios to hone monitoring report-writing skills.

Dramatization of the Informed Consent Process: Good Theater or Bad?
Explore the informed consent through speaker-led dramatizations of real-world informed consent procedures. Attendees will participate in discussions about the strengths and weaknesses of each dramatized informed consent procedure, while learning the most important aspects of the informed consent process.

SIGNATURE SERIES SPEAKER

Living with Eyes Wide Open
Isaac Lidsky

A child actor turned successful entrepreneur, Isaac Lidsky may have the most eclectic resume in business. He graduated from Harvard College at 19 and from Harvard Law School; served as a Supreme Court law Clerk; was a Justice Department litigator; founded a tech startup; turned a failing construction subcontractor into a highly profitable construction services company; and founded Hope for Vision, a nonprofit that funds the development of treatments and cures for blinding diseases. His book, “Eyes Wide Open” was named one of the Washington Post’s top 10 leadership books to read in 2017.

SCHEDULE AT A GLANCE

FRIDAY, APRIL 28

8:00am – 12:00pm (Half-Day Workshops)
- Practicing Good Science Through Ethical Study Design
- Hands Across the Water: A Comparison of Clinical Trials in the EU and U.S.

1:00 – 5:00pm (Half-Day Workshops)
- Unlocking the Value of Ethics Using Educational Games
- Fine-tune Your Vulnerability Radar: Protecting the Vulnerable

8:00am – 5:00pm (Full Day Sessions)
- Let's Get Clinical! The Clinical Research Boot Camp
- Clinical Research Project Management: Essential Tools and Communication Strategies
- ACRP Certification Exam Prep Course
- Tools to Help Clinical Sites Optimize Performance and Maintain GCP Compliance
- GCP Auditing: Apply Your New Skills at Work

SATURDAY, APRIL 29

8:15 – 9:30am (Signature Series Session)
- A Conversation with the FDA

9:50 – 10:50am (Sessions)
- Effective Communication Strategies to Drive Program Success
- New Ways to Engage, Align and Retain Your Employees
- Mastering Your Response to the Dreaded FDA Form 483
- The Seismic Shift in the Monitoring Paradigm: From Quality Control to Quality Assurance
- U.S.-based IRBs vs. European and Latin American Ethics Committees
- Wearables and Big Data: The New Gold Standard for Clinical Trials

11:05am – 12:05pm (Signature Series Session)
- When the Physician Becomes the Patient: The Inspiring Story of Dr. Keith Eaton

12:00 – 3:00pm (Lunch, Expo Hall Open, Poster Sessions)

12:15 – 1:45pm (Expo Hall) Exhibitor Presentations

12:30 – 2:00pm (Expo Hall)
- FDA Office Hours

2:30 – 3:30pm (Sessions)
- eConsent: Preparing for Paperless Consent
- Making Business Intelligence the Cornerstone of Your Study Improvement Process
- Master Series Program, Part I — The ICH GCP E6 R2 Revisions: Impact on the PI and Site
- The Shared Investigator Platform: Revolutionizing Communication Between Sites and Sponsors
- How to Create, Structure and Implement a Mentoring Program Within Your Clinical Research Organization or Practice
- Coming in 2018! Get Ready for the New EU Medical Device Regulation
- Master Series Program, Part I — Going Paperless: A Smart Way to Increase Site Efficiency and Save Resources

3:45 – 4:45pm (Sessions)
- Lessons Learned: Preparing for a Successful FDA Advisory Committee Meeting
- Master Series Program, Part II — Going Paperless: A Smart Way to Increase Site Efficiency and Save Resources
- Data Managers: The Frontline Defense of Trial Risk Management
- An Auditor's View of Compliance Challenges in Research-naïve Locations
- Master Series Program, Part II — The ICH GCP E6 R2 Revisions: Impact on the PI and Site

SUNDAY, APRIL 30

8:15 – 9:30am (Signature Series Session)
- The State of the Industry

9:50 – 10:50am (Sessions)
- Core Competencies in Clinical Research: An Analysis of International Differences in Perceptions and Relevance
- Breaches in Research Integrity: Maintaining the Public's Trust and Confidence
- Investigator Attrition: Strategies to Turn the Tide
- Safety Reporting on Investigator-initiated Sponsored Research: It's Everyone's Job
- Layperson Summaries: Should the U.S. Follow the EU Regulation?
- Regulatory Affairs Committee: 2016 Year-End Review and Looking Ahead

11:05am – 12:05pm (Signature Series Session)
- Living with Eyes Wide Open – Speaker Isaac Lidsky

12:00 – 3:00pm (Lunch, Expo Hall Open, Poster Sessions)

12:15 – 1:45pm (Expo Hall) Exhibitor Presentations

12:30 – 2:00pm (Expo Hall)
- FDA Office Hours

2:30 – 3:30pm (Sessions)
- Forging a New Path to Professionalism: GCP vs. Core Competency-based Training
- Clinical Evaluations of Safety and Risk
- Master Series Program, Part I — Ethical Challenges in Pediatric Research
- Bring Your Own Device: Is It Right for Your Clinical Research Enterprise?
- Attaining the Perfect Balance: Objective Protocol Feasibility Scoring
- Master Series Program, Part I -- Clinical Research Finance & Billing: Are You Leaving Money on the Table?
- Electronic Records, eSource Data, and eConsent: Clinical Investigations and Regulatory Expectations

3:45 – 4:45pm (Sessions)
- Evidence-based Analysis: The Path to Exceptional Clinical Research

- The Science of Site Management: Using Metrics to Guide Decisions
- Master Series Program, Part II -- Ethical Challenges in Pediatric Research
- Master Series Program, Part II -- Clinical Research Finance & Billing: Are You Leaving Money on the Table?
- Maximizing the ROI of Your Clinical Trial Management System
- Melding Consumer Big Data with Medical Big Data: The Regulatory and Ethical Implications
- Insights on Effective Communication and Outreach Among Patients and Advocacy Groups

MONDAY, MAY 1

8:30 – 9:30am (Sessions)
- A Novel Approach: Using an Online Patient Community to Develop a PRO Instrument
- The 2016 Medical Device Directive: What It Means to You
- Beyond Audit Survival: The Busy Clinical Research Professional's Guide to Audit Preparation
- Master Series Program, Part I — The Quality Risk Management Plan: The Key to a Quality Trial
- Trends, Strategies and Tools for Achieving Informed Consent
- Phage Therapy: The Answer to Antibiotic Resistance?
- Harmonized Core Competencies for Monitors: A New Framework for Measuring Performance

9:45 – 10:45am (Sessions)
- CDER BIMO Compliance and Enforcement: What You Need to Know!
- Electronic Records, eSource Data, and eConsent: Clinical Investigations and Regulatory Expectations
- Putting Patient-Centric Principles into Practice
- Master Series Program, Part II — The Quality Risk Management Plan: The Key to a Quality Trial
- What's That You Say? When Research Subjects Struggle to Hear
- Build a Better Site Budget to Ensure Trial Success
- Capturing High-value Metrics that Drive Clinical Research Performance

11:00am – 12:00pm (Signature Series Session)
- Innovating Clinical Trials with Mobile Technology

12:00 – 3:00pm (Lunch, Expo Hall Open, Poster Sessions)

12:15 – 1:45pm (Expo Hall)Exhibitor Presentations

2:30 – 3:30pm (Sessions)
- Key Considerations in Building Your Site's Quality Improvement Program
- 2017 Update: U.S. Healthcare Regulatory Changes and Their Impact on Clinical Research
- Master Series Program, Part I — Current CRU Issues in Planning and Executing Phase 1 Trials
- Master Series Program, Part I -- Mastering the Art of Writing Monitoring Reports
- Critical Issues in the Clinical Trials System
- Blowing the Whistle: A 2017 Update on Fraud, Waste and Abuse in Clinical Research
- Master Series Program, Part I — Dramatization of the Informed Consent Process: Good Theater or Bad?

3:45 – 4:45pm (Sessions)
- The Social Media Blueprint: Tips for New Patient Advocacy & Recruitment
- Battle of the Clinical Trial Agreements: Sites vs. Sponsors
- Master Series Program, Part II — Dramatization of the Informed Consent Process: Good Theater or Bad?
- Master Series Program, Part II — Current CRU Issues in Planning and Executing Phase 1 Trials
- A Quick Guide to Managing and Monitoring IVD Studies
- Lead and Succeed in Your Clinical Research Team
- Master Series Program, Part II – Mastering the Art of Writing Monitoring Reports

TUESDAY, MAY 2

8:30 – 9:30am (Sessions)
- The Power and Reach of Social Media in Clinical Trials
- Revitalizing a Workforce: Aligning Job Classifications with Competencies
- Medical Cannabis: A Substitute for Prescription Opioid Use?

9:45 – 10:45am (Sessions)
- Obtaining Consent in Acute Settings
- Lessons Learned: Moving to Regulatory and Source eBinders
- The Evolving Clinical Research Enterprise: What Recent Legal and Regulatory Changes Mean to You

11:00am – 12:00pm (Sessions)
- Optimize Workflow and Resource Allocation Using LEAN-R
- Returning Research Test Results: Know Your Ethical and Legal Obligations

NETWORKING EVENTS

FRIDAY, APRIL 28

1:00 – 5:00pm – Seattle Tours (additional registration fees apply)
5:00 – 6:00pm – Attendee Orientation
5:30 – 7:00pm – Volunteer Reception (invitation only)

SATURDAY, APRIL 29

6:30 – 8:15am – CISCRP Medical Heroes 5k Run & Walk
12:15 – 2:30pm – ACRP Chapter Leader Luncheon (invitation only)
4:45 – 6:00pm – Exhibit Hall Opening Celebration
7:00 – 9:00pm – Certification Milestone Recognition Ceremony (invitation only)

SUNDAY, APRIL 30

5:00 – 6:00pm – ACRP/Academy Business Meeting
6:30 - 8:00pm – Meeting & Expo Speakers Reception (invitation only)

MONDAY, MAY 1

5:00 – 6:30pm – ACRP Movie Night: Trial by Fire and Q&A with Producer Charles Mattocks

JOIN US IN THE EXPO HALL

Explore the latest products and service offerings in the clinical research enterprise in the ACRP 2017 Expo Hall. More than 100 industry-leading companies and organizations will be showcasing innovative products, services, and solutions, including:

- Clinical Trial Management Systems
- CRO Services
- Electronic Data Capture Systems
- IRB Services
- Patient Recruitment Services
- Site Services & Selection
- Training & Education
- Translation Services
- And More

EXPO HALL HOURS

Saturday, April 29
12:00-3:00pm & 4:45-6:30pm
Sunday, April 30
12:00-3:00pm
Monday
12:00-3:00pm

REGISTER

Visit conference.acrpnet.org for more information.

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To become an Exhibitor or Sponsor, contact Tammy Workman at tworkman@acrpnet.org.