6th Annual

VIRTUAL EVENT

Endpoint Adjudication

DECEMBER 2-3, 2020
Delivered as a 100% Virtual Event
in EDT Time Zone

ACHIEVE A ROBUST ENDPOINT ADJUDICATION STRATEGY AND ACCELERATE REGULATORY APPROVAL TIMELINES

Limit Study Variability. Streamline Data Collection. Ensure Efficient CEC Review.

Join an expert speaker line-up for the latest advice for effectively managing clinical trial endpoint adjudication, and connect with your peers virtually to exchange experience.

PROGRAM CHAIRS AND ADVISORY BOARD:

Co-Chair:
CLAUDE PETIT, PH.D.,
VP Biometrics and Data Management,
Boehringer Ingelheim

Co-Chair:
KIM BROWN,
Department Manager, C5Research
Cleveland Clinic

ADVISORS:

ERNEST SPITZER, M.D.,
Department of Cardiology, Thoraxcenter, Erasmus University Medical Center, Rotterdam, The Netherlands and Director of Clinical Endpoint Adjudication and Data Monitoring,
Cardialysis

FEATURED SPEAKERS:

SYLVIE BARTUS, PH.D.,
Director, Safety,
Global Clinical Affairs,
Edwards Lifesciences

JAMES JANUZZI, M.D.,
FACC, FESC, Hutter Family Professor of Medicine, Harvard Medical School, Cardiologist, Massachusetts General Hospital, and Senior Medical Director,
Baim Institute for Clinical Research

PIERLUIGI TRICOCI,
M.D., Executive Director, Cardiovascular and Metabolic Therapeutics Area,
CSL Behring

informaconnect.com/endpoint-adjudication

Brought to you by informa connect

6th Annual

VIRTUAL EVENT

Endpoint Adjudication

Collaborate with Industry Thought-Leaders on the Following Topics:

- Panel Discussion on Complex Cases that Generated a Lot of Discussion and Involvement from the Steering Committee
- Adjudication for International Trials
- Case Study Comparison: EXCEL Trial - What went wrong? Lessons Learned and Best Practices for Future Trials
- Adjudication Case Studies for Different Disease States
- The Dream Scenario for Building an Adjudicator Committee

Endpoint Adjudication convenes leading clinical experts to discuss the latest insights, current trends and most critical elements in managing the complex process. This event is paramount to achieving better outcomes. Don't miss this opportunity to participate in the industry's leading event dedicated to your professional community!

Who Should Attend:

You will benefit from attending this event if you are working at a pharmaceutical company, biotech, medical device company or academic research institute with involvement in the following areas:

- Adjudication
- Biostatistics
- CEC Committee's and Review
- Clinical Affairs
- Clinical Operations
- Clinical Project Management
- Data Management
- Medical Affairs
- Pharmacovigilance
- Protocol Management
- Safety

DAY 1: WEDNESDAY, DECEMBER 2ND

Throughout the Conference there will be live keynote sessions, on-demand sessions and an opportunity for live Q+A with our speakers. The agenda below provides our recommended viewing order, but any sessions marked with ** will be available on demand. All times listed are EDT time zone.

10:25 am **Chairperson's Opening Remarks ****

Claude Petit, Ph.D., VP Biometrics and Data Management, **Boehringer Ingelheim**

10:30 am **Stakeholder Panel: Complex Cases that Generated Hefty Discussion/Involvement of Steering Committee ****

Moderator: Kim Brown, RN, Department Manager, C5Research, **Cleveland Clinic**

Confirmed Panelists:
James Januzzi, MD, FACC, FESC, Hutter Family Professor of Medicine, Harvard Medical School, Cardiologist, Massachusetts General Hospital, and Senior Medical Director, **Baim Institute for Clinical Research**
Sylvie Bartus, Ph.D., Director, Safety, Global Clinical Affairs, **Edwards Lifesciences**
Pierluigi Tricoci, MD, Executive Director, Cardiovascular and Metabolic Therapeutic Area, **CSL Behring**

- What to do when there is a lot of discussion/involvement from Committee's
- Overall problem solving for complex cases and definitions or insufficient definitions.
- When is it appropriate to have interaction with sponsor and/or steering committee?
- Documentation of agreements – Where do you write down if the committee decided or another – do you include in visible documents or not.

11:00 am - Take a Break and Visit the Virtual Exhibit Hall

11:20 am **Panel Discussion: Best Practices and Lessons Learned to Better Harmonize Adjudication Processes in Clinical Trials and Collaborate Across Stakeholders**

Panelists:
Claude Petit, Ph.D., VP Biometrics and Data Management, **Boehringer Ingelheim**

James Januzzi, MD, FACC, FESC, Hutter Family Professor of Medicine, Harvard Medical School, Cardiologist, Massachusetts General Hospital, and Senior Medical Director, **Baim Institute for Clinical Research**

- Challenges to building standards and definitions? How can we combat these?
- How do you trigger events and document triggering processes?
- How do you manage/align interaction between committee's? (CEC's with DSMB's, Steering, Safety)
- How do you handle large volume of events needing adjudication?
- Specifics for non-cardiovascular adjudication?
- How do you efficiently and securely transfer around confidential information?
- The best adjudication flows and approaches ie. 3 or 5 members, when to use remote vs. Face to face meetings.
- Source document collection in different geographies.

11:50 am **Case Study Comparison: EXCEL Trial - What went wrong? Lessons Learned and Best Practices for Future Trials**

Ori Ben-Yehuda, M.D., FACC, Executive Director, Clinical Trials Center, **Cardiovascular Research Foundation**

12:10 - Grab Some Lunch then Come Back to Join in Networking Activities, Watch Product Showcases, and Connect with Your Key Product and Service Providers in the Virtual Exhibit Hall!

1:15 pm **GCP Aspects of Oversight for Adjudication Panels**

Terry Katz, Director, Head of Global Data management and Statistics, **Merck Animal Health**

1:35 pm **Using AI to Screen Medical Images for COVID-19 Infection that Could Confound Interstitial Lung Disease Studies**

Dan Gebow, Chief Innovation Officer, **Bioclinica**

1:55 pm Live Speaker Q&A and Networking

DAY 2: THURSDAY, DECEMBER 3RD

10:25am **Chairperson's Opening Remarks**
Kimberly Brown, RN, Department Manager, C5Research, **Cleveland Clinic**

10:30 am **Plenary Panel – Adjudication for International Trials: What are the Reasonable Expectations of Standards?**
Moderator: Ernest Spitzer, M.D., Department of Cardiology, Thoraxcenter, Erasmus University Medical Center, Rotterdam, The Netherlands and Director of Clinical Endpoint Adjudication and Data Monitoring, **Cardialysis**

Donald E. Cutlip, Vice Chair, Department of Medicine, Beth Israel Deaconess Medical Center and Chief Medical Officer, **Baim Institute for Clinical Research**

- How do local practices impact adjudication?
- How to efficiently get source documents needed for adjudication?
- What do you do when a patient is admitted to a hospital that isn't the trial site hospital?
- How do you define the source documents needed for adjudication?
- What strategies do you follow in order to get complete adjudication dossiers?
- What processes or checklists can be put together and provided to teams to alleviate some of the barriers for international trials?
- European GDPR – how to understand and address this in international trials.
- Is translation still a financial burden; what needs to be translated and what doesn't?

11:00 am - Take a Break and Visit the Virtual Exhibit Hall

11:45 am - Networking Lunch

11:20 am **Case Studies: Highlighting the Differences Between Specific Cause of Death vs. Undetermined**
Claes Held, FESC, FACC, Professor in Cardiology, **Uppsala Clinical Research Center**

11:40 am **Case Study for Adjudication for Different Disease States**

12:10 pm - Grab Some Lunch then Come Back to Join in Networking Activities, Watch Product Showcases, and Connect with Your Key Product and Service Providers in the Virtual Exhibit Hall!

1:15 pm **Adjudicating Causality for Device Studies**
Ernest Spitzer, M.D., Department of Cardiology, Thoraxcenter, Erasmus University Medical Center, Rotterdam, The Netherlands and Director of Clinical Endpoint Adjudication and Data Monitoring, **Cardialysis**

1:35 pm **Panel: The Dream Scenario for Building an Adjudicator Committee**
Panelists:
Sylvie Bartus, Ph.D., Director, Safety, Global Clinical Affairs, **Edwards Lifesciences**
Pierluigi Tricoci, MD, Executive Director, Cardiovascular and Metabolic Therapeutic Area, **CSL Behring**

- How to do it right the first time and duplicate the process
- Lessons learned/best practices
- Technology needs?
- Communication needs?
- Stakeholders involved from the start?
- Contract strategies (with adjudicators, stakeholders etc.)

2:05 pm Live Speaker Q&A and Networking

4 WAYS TO REGISTER

CALL:
888-670-8200 (U.S. Toll-free) **or**
+1 941-554-3500 (International)

EMAIL:
register@informaconnect.com

ONLINE:
informaconnect.com/endpoint-adjudication

SEND A TEAM AND SAVE
To take advantage of group booking discounts, please contact Matt Douglas :
Email: Matthew.Douglas@informa.com | Tel: +1 339 298 2144
Please note that group discounts cannot be redeemed online

REGISTER EARLY TO SAVE UP TO $100!

REGISTER NOW