

BEST CLINICAL & REGULATORY **PRACTICES** Conference

EFS Study Conduct, FDA Review, and Inspectional Readiness

Preliminary Program

The Jacobs Institute

Buffalo, New York

OCT 26-27
2026



- ✓ FDA Regulatory Perspectives and Submission Pathways
- ✓ Moving from Early Feasibility to Pivotal Marketing Studies
- ✓ Global Perspectives, Neuro Trials

- ✓ Preparing Clinical Sites for an FDA Inspection
- ✓ Running FDA Mock Audits
- ✓ Early Feasibility Study Start Up Goals & Costs

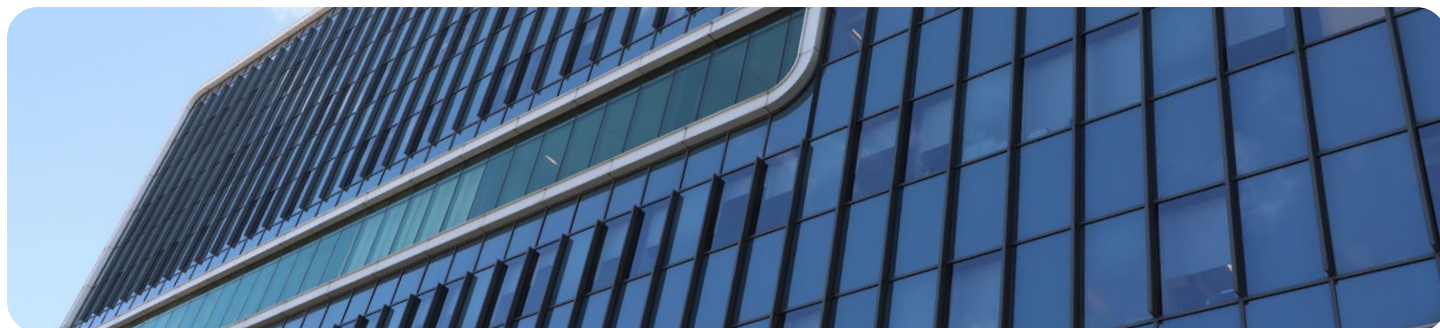
Conference **SCHEDULE**

Sunday, October 25	Pre-Conference Social Mixer
5:00 - 7:00 PM	Informal gathering at Bacchus Wine Bar, 56 W Chippewa St, Buffalo, NY 14202 Hosted by The Jacobs Institute, Office of Regulatory Services
Monday, October 26	Day 1 Medical Device Investigations and Regulatory Review
7:30 - 8:00 AM	Registration & Complimentary Breakfast
8:00 - 8:05 AM	Conference Welcome Address Adnan Siddiqui, MD, PhD <i>CEO & CMO The Jacobs Institute</i>
8:05 - 8:35 AM	US Perspective on Medical Device Clinical Investigations Michelle Tarver, MD, PhD <i>Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration</i>
8:35 - 9:00 AM	Q & A with Dr. Michelle Tarver
9:00 - 9:30 AM	Academic Pursuits in Conducting Clinical Trials – New Frontiers in Neurosurgery Elad Levy, MD <i>Chairman, University at Buffalo Department of Neurosurgery University at Buffalo</i>
9:30 - 10:00 AM	Human Subjects Protections – Latest Updates from the Office of NIH TBD <i>Office for Human Research Protections, U.S. Department of Health and Human Services</i>
10:00 - 10:30 AM	Break
10:30 - 11:00 AM	Human Subject Protections & Institutional Review Boards – Best Practices Amber Whaley <i>Western IRB Chair Lead, Western IRB</i>
11:00 - 11:30 AM	The Updated Outlook from the MDIC Consortium on US EFS Studies Robert (Chip) Hance, MBA <i>CEO, Regatta</i>
11:30 - 12:00 PM	Panel Discussion
12:00 - 1:30 PM	Complimentary Lunch
1:30 - 2:00 PM	The Early Feasibility Study – Growing EFS Studies in the US Andrew Farb, MD <i>(Invited)</i> <i>CMO, Office of Cardiovascular Devices, Office of Product Evaluation and Quality Center for Devices and Radiological Health, U.S. FDA</i>
2:00 - 2:30 PM	Conducting the Study and Partnerships with Hospitals and Clinical Centers Joyce Markiewicz <i>(Invited)</i> <i>President and CEO, Catholic Health Hospitals, Buffalo, New York</i>
2:30 - 3:00 PM	Statistical Perspectives & Considerations George Chu <i>(Invited)</i> <i>Sr. Director, Global Biostatistics, Edwards Lifesciences</i>
3:00 - 3:30 PM	An International Perspective on Device Development - Regulatory Considerations from other Countries and Regions Yoshiki Arakawa, MD, PhD <i>Kyoto University Graduate School of Medicine, Kyoto University Hospital</i>
3:30 - 4:00 PM	Panel Discussion
	End of General Session
5:00 - 7:00 PM	Reception Vue Rooftop Lounge, 210 Franklin Street, Buffalo, NY 14202

**Program and Faculty subject to change.*

Conference **SCHEDULE**

Tuesday, October 27	Day 2	Clinical Trial Execution and Oversight
7:30 - 8:00 AM	Registration & Complimentary Breakfast	
8:00 - 8:30 AM	FDA Perspectives – Clinical Trial Studies, Study Conduct, & Audit Preparedness Xiaolin (Lin) Zheng, PhD <i>(Invited)</i> <i>Acting Director, Office of Neurological and Physical Medicine Devices, Office of Product Evaluation and Quality U.S. FDA</i>	
8:30 - 10:00 AM	New Technology Innovation Session 1	
10:00 - 10:15 AM	Break	
10:15 - 12:00 PM	New Technology Innovation Session 2	
12:00 - 1:00 PM	Complimentary Lunch	
1:00 - 1:30 PM	Discussion & Objectives from a Device Manufacturer – Medtronic Sudha Iyer <i>Vice President, Clinical Research and Medical Science, Medtronic</i>	
1:30 - 2:00 PM	Transitioning from EFS to a Pivotal Study, Best Practices TBD <i>Cerevasc (Invited)</i>	
2:00 - 2:30 PM	A Regulatory Perspective on Audit Readiness: Viewpoint of an FDA Investigator Phil Pontikos <i>Former FDA Investigator & BIMO Director FDA Partners</i>	
2:30 - 3:00 PM	Prepping for a Clinical Site Audit – A Perspective from a Clinical Coordinator Jen Gay, CCRP <i>Project Manager, Vastrax</i>	
3:00 - 3:15 PM	Viewpoint on Regulatory & Quality – Building the EFS Ecosystem in Buffalo Carlos Peña, PhD, MS <i>Chief Regulatory Officer, Office of Regulatory Services & Chief Quality Officer, Office of Quality Services, The Jacobs Institute</i>	
3:15 - 3:45 PM	Investment in Neurological Clinical Trials - an NIH Perspective Clinton Wright, MD <i>Director, Division of Clinical Research, National Institute of Neurological Disorders and Stroke</i>	
3:45 - 4:15 PM	A CMS Primer on Reimbursement Considerations After the Study Shari Ling, MD <i>(Invited)</i> <i>TBD, Center for Clinical Standards & Quality Centers for Medicare and Medicaid Services</i>	
4:15 - 4:45 PM	Global Outlook on Working Across Regulatory Boundaries – Best Practices TBD <i>TBD</i>	
4:45 PM	Closing Adnan Siddiqui, MD, PhD <i>CEO & CMO The Jacobs Institute</i>	



**Program and Faculty subject to change.*

Hotel & Travel **INFORMATION**

AIRPORTS

The Jacobs Institute and recommended hotel options are located approximately 10 miles from Buffalo Niagara International Airport (BUF), or 98 miles from Toronto Pearson International Airport (YYZ).

Toronto Pearson is approximately a 2-hour drive from Buffalo and requires crossing an international border. Attendees should ensure they have appropriate travel documentation and allow extra time for border processing.

TRANSPORTATION

Uber and Lyft are both available in the Buffalo area. For taxicab service from the airport, follow the signage outside of the baggage claim area to the taxi area.

Black Car Service

A Touch of Class Limousine
(716) 957-4192

Buffalo Black Car Service
(716) 818-2828

Taxi Cab Service

Buffalo Airport Taxi
(716) 633-8294

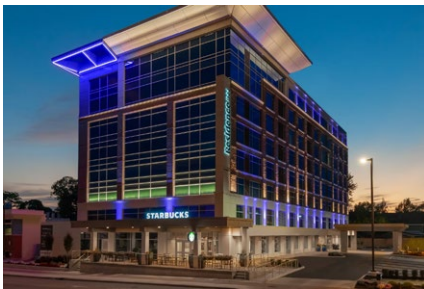
Buffalo-Niagara Airport Taxi
(716) 333-1119

HOTELS

PREFERRED HOTEL

Residence Inn Buffalo Downtown

620 Delaware Avenue
Buffalo, NY 14202
(716) 247-5252



Located in the Allentown district of Downtown Buffalo, the Residence Inn is minutes from the Buffalo Niagara Medical Campus and offers free onsite parking as well as an attached Starbucks.

Jl Corporate
Rate Available!
Scan QR to book



The Westin

250 Delaware Avenue
Buffalo, NY 14202
(716) 854-9000



Invoke rest and beauty at The Westin Buffalo, a hotel perfect for escaping the ordinary. Relax in their artful guest rooms with complimentary Wi-Fi, LCD TVs, ergonomic workstations and signature beds.

The Curtiss Hotel

210 Franklin Street
Buffalo, NY 14202
(716) 954-4900



This premier 5-star boutique hotel set within the historic 1913 Harlow C. Curtiss building. It features 68 luxury rooms, a revolving restaurant, a rooftop lounge (VUE), and unique year-round indoor/outdoor, heated urban hot springs.

CONFERENCE LOCATION

The BEST Clinical and Regulatory Practices Conference will be held in Room 5019 on the 5th floor of the Gates Vascular Institute.

Address: 875 Ellicott Street, Buffalo, NY 14203

Location Note: Conveniently located on the 5th floor, directly across the hall from the Jacobs Institute.

CONFERENCE PARKING

Ample parking is available for a daily fee at the Ellicott Street Ramp, located directly across from the Gates Vascular Institute at 854 Ellicott Street.

RECEPTION INFORMATION

PRE-CONFERENCE SOCIAL MIXER

Bacchus Wine Bar

56 W. Chippewa Street
Buffalo, NY 14202

Sunday, October 25th
5:00 - 7:00 PM

Business casual or smart casual



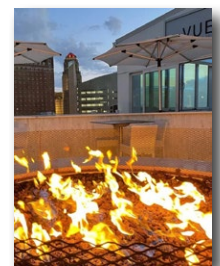
OPENING RECEPTION

Vue Rooftop Lounge

210 Franklin Street
Buffalo, NY 14202

Monday, October 26th
5:00 - 7:00 PM

Upscale casual



Visitor **INFORMATION**

Buffalo's story is one of a remarkable comeback, trading its industrial past for a vibrant future shaped by a redeveloped waterfront, lively neighborhoods, and a booming craft beer scene. Fueled by more than \$1 billion in new investment, the city is bursting with fresh energy and an endless list of things to explore. If you appreciate world-class design, you can't miss the chance to tour seven different Frank Lloyd Wright structures scattered throughout the area. Art lovers will find their inspiration at the stunning, newly expanded AKG Art Museum, while history buffs can step back in time at the very spot where Theodore Roosevelt was sworn in as President. For a more laid-back vibe, you can soak up the local atmosphere at Canalside's boardwalk or the colorful hubs of Larkin Square. And, of course, no visit is complete without a quick trip to see the awe-inspiring power of Niagara Falls, an absolute must-see that's just a short drive away.

MUST SEE ATTRACTIONS

Frank Lloyd Wright's Martin House

125 Jewett Pkwy
Buffalo, NY 14214
<https://martinhouse.org/>



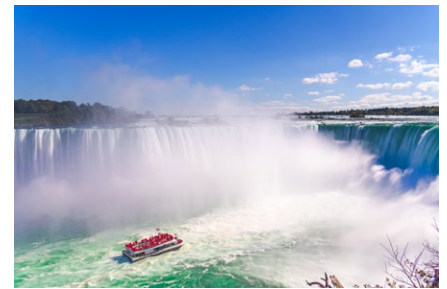
Buffalo AKG Art Museum

1285 Elmwood Ave,
Buffalo, NY 14222
<https://buffaloakg.org/>



Niagara Falls State Park

332 Prospect St,
Niagara Falls, NY 14303
<https://www.niagarafallsstatepark.com/>



DINING & MIXERS

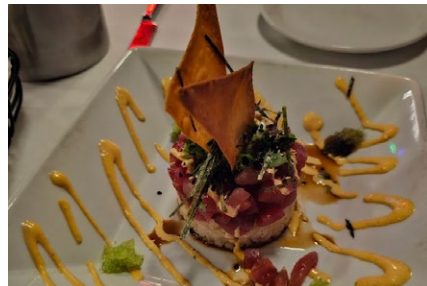
Webster's Bistro & Bar

102 Webster St.
North Tonawanda, NY 14120
<https://webstersbistro.com/>



The Left Bank

511 Rhode Island St.
Buffalo, NY 14213
<https://www.leftbankrestaurant.com/>



Quenelle

341 Franklin St.
Buffalo, NY 14202
<https://www.quenellebuffalo.com/>



VISITOR BUREAU

Buffalo provides authentic and unexpected experiences for those looking to explore beyond the expected. The region's revitalized waterfront and meticulously restored architecture are complemented by a thriving arts scene and a genuine culinary renaissance. From its vibrant, walkable neighborhoods to a wide array of outdoor activities and deep historic charm, the city has transformed into a not-to-be-missed treasure for any visitor. There's something to do for everyone. Ideas can be found at the region's official tourism agency, Visit Buffalo.

VISIT
Buffalo

