

BEST Clinical & Regulatory PRACTICES Conference

EFS Study Conduct, FDA Review, and Inspectional Readiness

At The Jacobs Institute, Inc. • 875 Ellicott Avenue • 5th Floor • Buffalo, New York

October 20-22, 2024

THE JACOBS INSTITUTE, INC.

Buffalo, N.Y.

Come Innovate with Us

Preliminary Program

OPTIONAL BONUS SESSION – LIVE CASE BROADCAST ON DAY 2



Learn about early feasibility studies
& explore Western New York!

REGISTER TODAY AT [JIMEETINGS.ORG](https://www.jimeetings.org)





Welcome to Buffalo, New York and the BEST Clinical and Regulatory Practices Conference!

We are delighted to host you at the Jacobs Institute (JI), an Innovation Center nestled in the heart of downtown Buffalo whose concept was realized by Dr. Nick Hopkins. The JI's mission is to accelerate the development of next-generation technologies in vascular and neurologic medicine through collisions of physicians, engineers, entrepreneurs, and industry in a NOT-FOR-PROFIT environment.

Our conference goal is to discuss neurosurgical and vascular medical device studies and best practices for getting a medical device clinical investigation off the ground. We have put together a nationwide conference that brings together some of the brightest experts in clinical trial design, execution, and auditing of studies, with folks from government (FDA, NIH), Industry, and academia coming to share their experience and best practices.

Our primary goal is to help foster the discussion on neurological and vascular research and clinical phases of medical device studies, the intersection between NIH and FDA, and what we believe to be an uptick in EFS studies in the US. We have also invited NIH staff to discuss human subjects research and FDA management to provide their review and inspectional guidance on the readiness for trials to be submitted for market authorization. Other topics include sample size calculations and analysis plans, trial design considerations, and transitioning from EFS to pivotal studies.

Our dual registration options for onsite and virtual viewing allows for both domestic and international engagement that is key in promoting a novel dialogue and exchange around clinical, regulatory, and medical device innovation.

We are appreciative of your participation and engagement in this conference.

And get ready to explore Buffalo and the Jacobs Institute.

Carlos Pefia, PhD
CRO CQO

Adnan Siddiqui, MD, PhD
CEO & CMO

Pamela Marcucci
VP, Programs





MEETING PURPOSE

Targeting clinical, academic, and regulatory audiences from different backgrounds, the JI's **BEST Clinical & Regulatory Practices Conference** will provide attendees with the tools that they need to conduct ethical clinical trials that produce credible clinical data and ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices, including novel devices that are being studied in a clinical trial.



**University at Buffalo's
Clinical and Translational
Research Center**

The Jacobs Institute, Inc.

**Kaleida Health's
Gates Vascular Institute**

The Jacobs Institute, Inc. (JI) is a non-profit organization whose mission is to accelerate the development of next-generation technologies in vascular medicine through collisions of physicians, engineers, entrepreneurs, and industry. The JI's vision is to improve the treatment of vascular disease in Western New York and the world, while fostering local economic development and honoring the memory of Lawrence D. Jacobs, MD. Capitalizing on relationships with medical professionals across the globe and in our own building, the **Jl's Idea to Reality Center (i2R)** is an independently operated one-of-a-kind medical device innovation center with a strong emphasis on high quality medical technology design, clinical feedback at every stage of development, and research, regulatory, and entrepreneurial expertise all under one roof.

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Sunday, October 20	Pre-Conference Social Mixer
5:00-7:00 P.M.	OPENING RECEPTION AT BACCHUS WINE BAR Hosted by The Jacobs Institute, Inc., Office of Regulatory Services



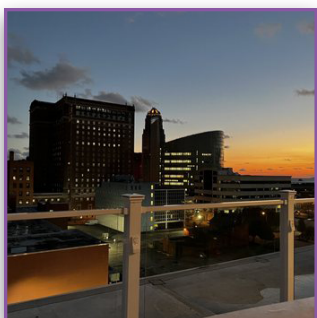
Bacchus Wine Bar

is located in the historic CALUMET BUILDING in the heart of Buffalo's entertainment district.

• 56 West Chippewa Street • Buffalo

Monday, October 21	Day 1
7:30-8:30 A.M.	REGISTRATION & COMPLIMENTARY BREAKFAST
8:00-8:05 A.M.	CONFERENCE WELCOME ADDRESS Carlos Peña, PhD Chief Regulatory Officer & Chief Quality Officer, The Jacobs Institute, Inc.
8:05-8:30 A.M.	ACADEMIC PURSUITS IN CONDUCTING CLINICAL TRIALS - FROM THE PI BOARD ROOM Elad Levy, MD Chairman, University at Buffalo Department of Neurosurgery
8:30-9:00 A.M.	HUMAN SUBJECTS PROTECTIONS Adnan Siddiqui, MD, PhD Chief Executive Officer & Chief Medical Officer, The Jacobs Institute, Inc.
9:00-9:30 A.M.	INVESTMENT IN NEUROLOGICAL CLINICAL TRIALS - AN NIH PERSPECTIVE Nick Langhals, PhD Director, National Institute of Neurological Disorders and Stroke
9:30-10:00 A.M.	A NEW CHAPTER ON CLINICAL INVESTIGATIONS IN THE US - FOCUS ON NEURO Tom Oxley, MD (Remote) Chief Executive Officer, Synchron
10:00-10:30 A.M.	COFFEE BREAK

Monday, October 21		Day 1	
10:30-11:00 A.M.	HUMAN SUBJECT PROTECTIONS & INSTITUTIONAL REVIEW BOARDS - BEST PRACTICES Zach Chakan IRB Administrator, University at Buffalo Institutional Review Board, Office of Research Compliance		
11:00-11:30 A.M.	A REVIEW OF FINDINGS FROM THE MDIC CONSORTIUM ON US EFS STUDIES Chip Hance, PhD CEO, Regatta		
11:30 A.M.-12:00 P.M.	PANEL DISCUSSION All Speakers Open Mic (Moderator-TBA)		
12:00-1:30 P.M.	COMPLIMENTARY LUNCH IN THE ATRIUM		
1:30-2:00 P.M.	THE EARLY FEASIBILITY STUDY - AN FDA PERSPECTIVE Andrew Farb, MD (Remote) Chief Medical Officer, Office of Cardiovascular Devices (OHT2), Office of Product Evaluation and Quality, Center for Devices and Radiological Health, U.S. Food and Drug Administration		
2:00-2:30 P.M.	ANATOMY OF PIVOTAL STUDY Christina Brennan, MD Senior Vice President, Clinical Research, Northwell		
2:30-3:00 P.M.	STATISTICAL CONSIDERATIONS Douglas Landsittel, PhD Chair of Biostatistics, University at Buffalo		
3:00-3:30 P.M.	TRANSITIONING TO A PIVOTAL STUDY - BEST PRACTICES Ansaar T. Rai, MD (Remote) Professor and Chair, Department of Neuroradiology, West Virginia University		
3:30-4:00 P.M.	PANEL DISCUSSION All Speakers Open Mic (Moderator-TBA)		
End		Day 1	
5:00-7:00 P.M.	RECEPTION AT VUE ROOFTOP LOUNGE -OPEN BAR!!!		



Vue Rooftop Lounge

AT CURTISS HOTEL offers breathtaking panoramic views of downtown Buffalo, Lake Erie, and the Canadian shoreline.

- 210 Franklin Street • Buffalo

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Tuesday, October 22	Day 2
7:30-8:30 A.M.	REGISTRATION & COMPLIMENTARY BREAKFAST
8:00-8:30 A.M.	INTRODUCTIONS TO DAY 2 - A REGULATORY PERSPECTIVE ON SITE READINESS: VIEWPOINT OF AN FDA INVESTIGATOR Michael Marcarelli, PhD (Remote) <i>BIMO, U.S. Food and Drug Administration (Retired)</i>
8:30-9:00 A.M.	DISCUSSION & OBJECTIVES FROM THE DEVICE MANUFACTURER Bruce Van Deman <i>Sr. Director, Global Clinical Research, Medtronic</i>
9:00-9:30 A.M.	FDA PERSPECTIVES - CLINICAL TRIAL STUDIES, STUDY CONDUCT, & AUDIT PREPAREDNESS Xiaolin (Lin) Zheng, PhD (Remote) <i>Director, Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices, Office of Product Evaluation and Quality. U.S. Food and Drug Administration</i>
9:30-10:00 A.M.	INSPECTIONAL BEST PRACTICES - A DEVICE MANUFACTURERS SCORE CARD Amy Smith <i>VP Global Regulatory Affairs, Microvention</i>
10:00-10:30 A.M.	PREPARING FOR A SITE INSPECTION Jennifer Gay <i>Clinical Trial Coordinator, UB Neurosurgery</i>
10:30-10:45 A.M.	PANEL DISCUSSION All Speakers Open Mic (Moderator-TBA)
10:45-11:00 A.M.	COFFEE BREAK
11:00-11:30 A.M.	LESSONS LEARNED WORKING WITH THE FDA - BEST PRACTICES Fred Khosravi <i>CEO, Imperative Care</i>

Tuesday, October 22		Day 2	
11:30 A.M.-12:00 P.M.	STUDY MONITORING - A CLINICAL RESEARCH ORGANIZATION VIEWPOINT Ryan Bouchard President & CEO, Vastrax, Inc.		
12:00-12:30 P.M.	CONDUCTING AN FDA AUDIT Kevin Lawson, Partner Chief Executive Officer, KSL Diagnostics		
12:30-1:00 P.M.	GLOBAL PERSPECTIVES AND MEDICAL AFFAIRS Patrick A. Brouwer, MD, MSC Senior Medical Director, Head of Worldwide Medical Affairs, Cerenovus		
1:00-1:05 P.M.	CLOSING		
2:30-5:00 P.M.	BONUS SESSION - OPTIONAL LIVE CASE BROADCASTS Neurovascular Cases in Buffalo, NY		
End		Day 2	



Register today at
JIMEETINGS.ORG

In person registration - \$900
Virtual registration - \$550
Please register early

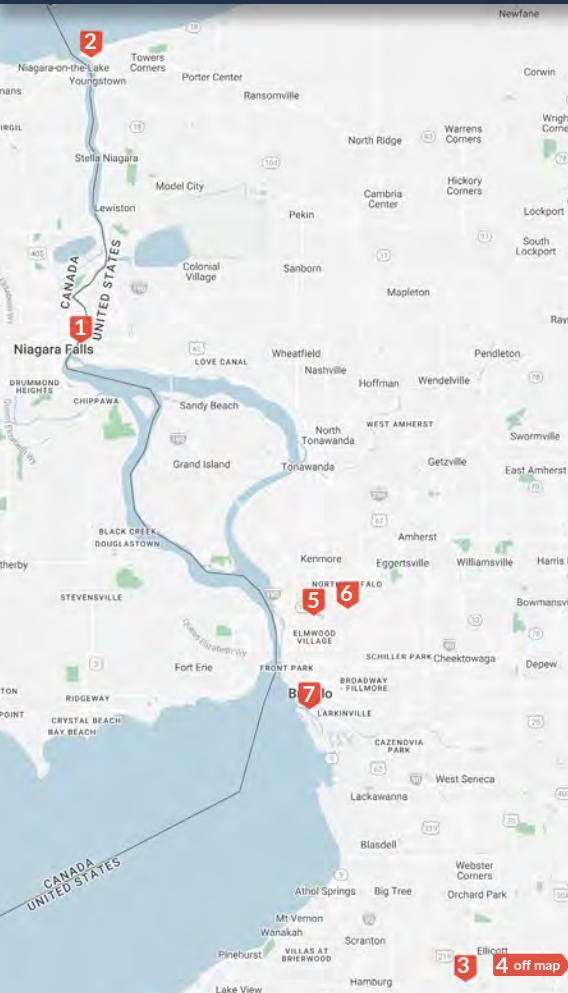
The Jacobs Institute, Inc. would like to thank our partners and speakers whose contributions make this conference possible.

 Buffalo General Medical Center
 Gates Vascular Institute
A Kaleida Health Facility

 JACOBS INSTITUTE MEETING SERVICES

 Kaleida Health

 Jacobs School of Medicine and Biomedical Sciences
University at Buffalo



Make it a weekend

to remember with your family.

Visit Western New York attractions such as Niagara Falls (1) and Fort Niagara (2). Hike in fall foliage at Chestnut Ridge Park (3) or Letchworth State Park (4). Explore the newly renovated Buffalo AKG Art Museum (5) and restored Frank Lloyd Wright's Martin House Complex (6). Walk along the water at Canalside (7) and investigate its attractions including the Ralph C. Wilson, Jr. Children's Museum and the Buffalo Heritage Carousel.



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Buffalo, N.Y.

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AIRPORT, TRANSPORTATION & HOTEL INFO



AIRPORTS

Buffalo Niagara International Airport (BUF)
4200 Genesee Street, Buffalo, NY 14225

Toronto Pearson International Airport (YYZ)
Large international airport in Toronto, ON (Canada)
~ 1.5 - 2 hour drive to/from Buffalo



TRANSPORTATION

Uber & Lyft are available in Buffalo
Rental cars are available in the airport

TAXI SERVICE

[Buffalo Airport Taxi](#)
(716) 633-8294

[Buffalo Niagara Airport Taxi](#)
(716) 333-1119

BLACK CAR SERVICE

[A Touch of Class Limousine](#)
(716) 957-4192

[Buffalo Black Car Service](#)
(716) 818-2828



PREFERRED HOTEL

[Residence Inn Buffalo Downtown](#)
Close to GVI/ JI
620 Delaware Avenue, Buffalo

Click the following to receive the JI corporate rate:

**RESIDENCE INN BUFFALO
DOWNTOWN
(JI Rate)** 

OTHER HOTEL OPTIONS

[The Westin](#)
250 Delaware Avenue, Buffalo

[Buffalo Marriott at LECOM HARBORCENTER](#)
95 Main St. Buffalo

[Hyatt Regency Buffalo](#)
2 Fountain Plaza, Buffalo

BOUTIQUE HOTELS

[Mansion on Delaware](#)
414 Delaware Avenue, Buffalo

[Curtiss Hotel](#)
210 Franklin Street, Buffalo



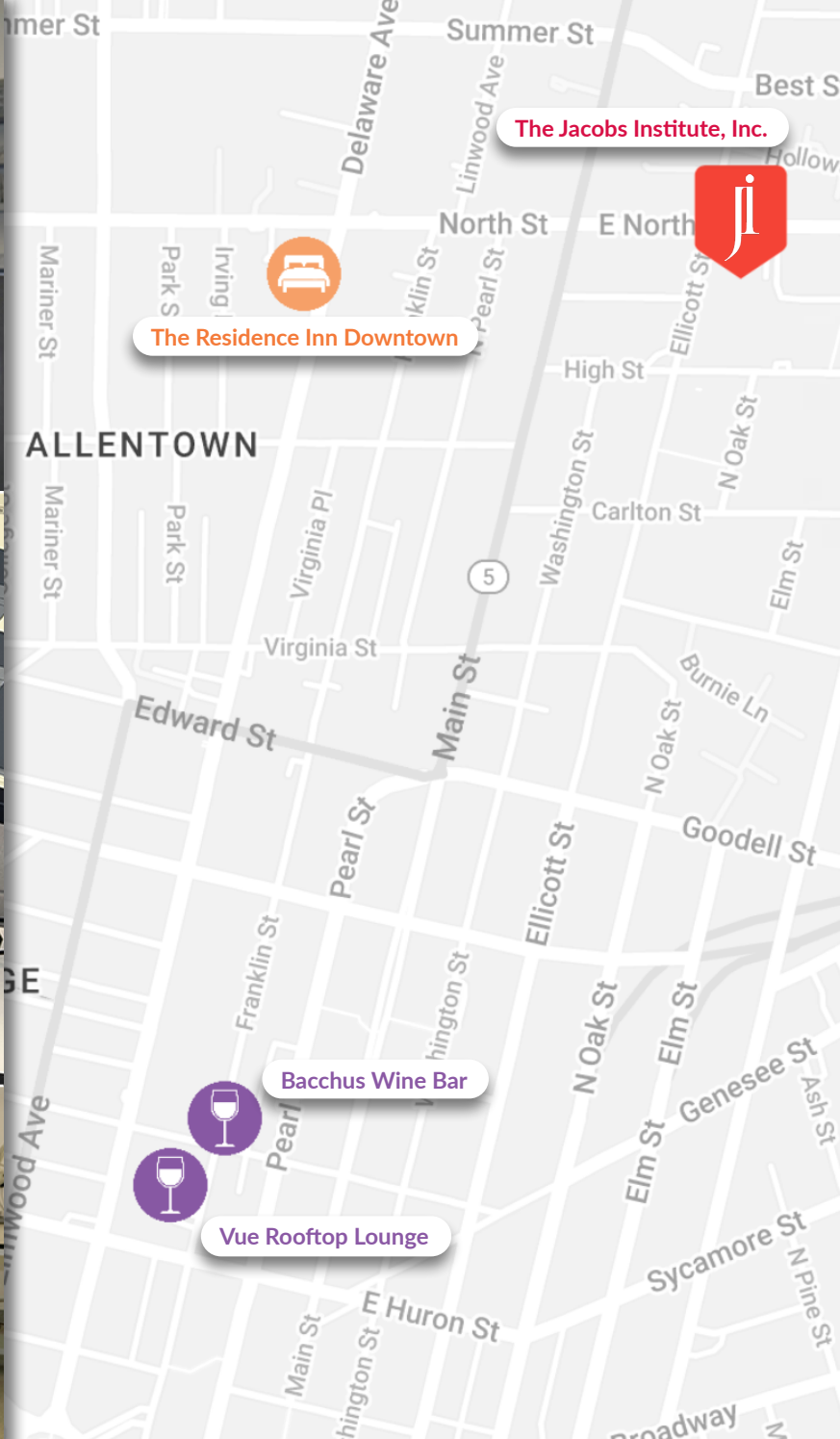
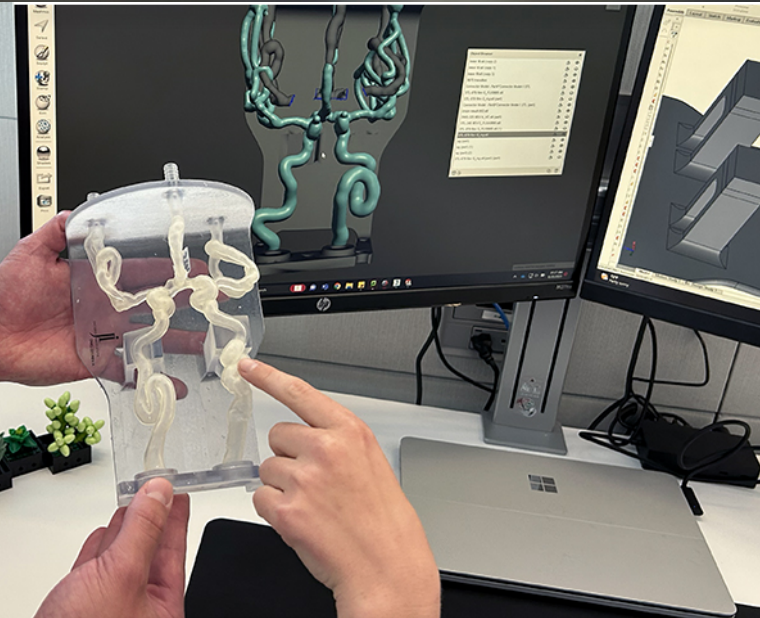
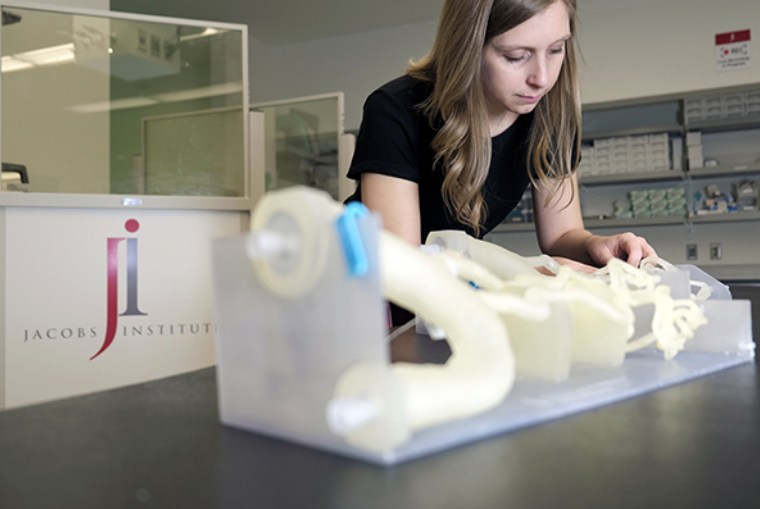
HAVE QUESTIONS?

Please contact The Jacobs Institute, Inc.:

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pmarcucci@jacobsinstitute.org





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