

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

<b>Day One - Sunday, July 25, 2021</b>			
<b>Presentation Time</b>	<b>Running Time</b>	<b>Title</b>	<b>Speaker</b>
11:00 AM ET	10 min	Welcome and Opening Remarks	
		Carolyn J.M. Best, PhD Director of Research American Urological Association	Steven Kaplan, MD Chair of Research, American Urological Association Icahn School of Medicine at Mount Sinai
		Steven Grambow, PhD Director, Duke Clinical Research Training Program Vice Chair of Education and Assistant Professor Department of Biostatistics and Bioinformatics Duke University Medical Center	Charles D. Scales Jr., MD, MSHS Associate Professor of Surgery Associate Professor in Population Health Sciences Principal Investigator, Urinary Stone Disease Research Network (USDRN) Department of Urology, Duke University Medical Center
11:10 AM ET	20 min	The Urology Clinical Trials Landscape	Claus Roerhborn, MD University of Texas Southwestern
11:30 AM ET	5 min	Session One: Clinical Trial Design - Moderator's Introduction	David Jarrard, MD (Session Moderator) University of Wisconsin-Madison
11:35 AM ET	30 min	Developing the Study Question for a Randomized Trial	Ian M. Thompson, Jr., MD Professor Emeritus, University of Texas CHRISTUS Santa Rosa Health System Texas Urology Group
12:05 PM ET	10 min	Discussion, Q&A	<i>Moderator: David Jarrard, MD</i>
12:15 PM ET	30 min	Identifying a Study Population for a Clinical Trial	Hunter Wessells, MD, FACS Professor and Nelson Chair in Urology School of Medicine University of Washington
12:45 PM ET	10 min	Discussion, Q&A	<i>Moderator: David Jarrard, MD</i>

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

12:55 PM ET	15 min	Break	
1:10 PM ET	30 min	Critical Elements of RCT Design	John T. Wei, MD, MS David A. Bloom Professor of Urology Medical Director, Brighton Center for Specialty Care Division Head, Andrology General and Community Urology University of Michigan
1:40 PM ET	10 min	Discussion, Q&A	<i>Moderator: David Jarrard, MD</i>
1:50 PM ET	30 min	Elements of Trial Design: Endpoint Selection and Assessment; Surrogate Endpoints	Tian Zhang, MD, MHS Associate Professor of Medicine Division of Medical Oncology, Department of Medicine Duke Cancer Institute Duke University
2:20 PM ET	10 min	Discussion, Q&A	<i>Moderator: David Jarrard, MD</i>
2:30 PM ET	30 min	Subgroup Analysis for a Randomized Trial	Seth P. Lerner, MD, FACS Professor, Scott Department of Urology Beth and Dave Swalm Chair in Urologic Oncology Vice-Chair for Faculty Affairs Baylor College of Medicine Medical Center
3:00 PM ET	10 min	Discussion, Q&A	<i>Moderator: David Jarrard, MD</i>
3:10 PM ET	5 min	Introduce Goals and Instructions for Breakout Sessions	Charles D. Scales Jr., MD, MSHS
3:15 PM ET	15 min	Break and Transition to Breakout Groups	
3:30 PM ET	60 min	Breakout Session One: Identifying Key Questions in Clinical Research	Small Group Meetings with Mentors, as follows:
		Mentors:	Mentees:
		STEVE GRAMBOW	ROSALYN ADAM

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

		PHILIPP DAHM	BORIS GERSHMAN KYLE ROSE
		SARAH PSUTKA	PATRICK HENSLEY IBARDO ZAMBRANO
		CHUCK SCALES	NAVEEN KACHROO KYMORA SCOTLAND
		TIAN ZHANG	DANIEL SHAPIRO REZA NABAVIZADEH
		SETH LERNER	JOHAR RAZA SYED MATTHEW HO
		STEVE KAPLAN	RAJAT JAIN
		ANGELA SMITH	NANNETTE PEREZ
		VIRAJ MASTER	RAJU CHELLURI
		MIKE FABRIZIO	DEVIN PATEL
		IAN THOMPSON	ED MESSING
		MARK LITWIN	PAUL GELLHAUS
4:30 PM ET	10 min	Transition to General Session	
4:40 PM ET	20 min	Closing Discussion, Q&A, What to Expect for Tomorrow	Steven Grambow, PhD
5:00 PM ET		Adjourn for the Day	

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

<b>Day Two - Monday, July 26, 2021</b>			
<b>Presentation Time</b>	<b>Running Time</b>	<b>Title</b>	<b>Speaker</b>
11:00 AM ET	10 min	Opening Remarks, Recap from Previous Day, and Goal Setting	Charles D. Scales Jr., MD, MSHS Associate Professor of Surgery Associate Professor in Population Health Sciences Principal Investigator, Urinary Stone Disease Research Network (USDRN) Department of Urology, Duke University Medical Center
11:10 AM ET	5 min	Session Two: Clinical Trial Biostatistics – Moderator’s Introduction	Steven Grambow, PhD Director, Duke Clinical Research Training Program Vice Chair of Education and Assistant Professor Department of Biostatistics and Bioinformatics Duke University Medical Center
11:15 AM ET	30 min	Hypothesis Testing Framework	Charles D. Scales Jr., MD, MSHS
11:45 AM ET	10 min	Discussion, Q&A	<i>Moderator: Steven Grambow, PhD</i>
11:55 AM ET	30 min	Sample Size/Power Considerations – Impact on Trial Design	Steven Grambow, PhD
12:25 PM ET	10 min	Discussion, Q&A	<i>Moderator: Steven Grambow, PhD</i>
12:35 PM ET	30 min	Reporting Effect Size and Precision in Clinical Research	Emily C. Zabor, DrPH Assistant Staff Biostatistician Department of Quantitative Health Sciences Taussig Cancer Institute, The Cleveland Clinic Assistant Professor of Medicine Cleveland Clinic Lerner College of Medicine Case Western Reserve University
1:05 PM ET	10 min	Discussion, Q&A	<i>Moderator: Steven Grambow, PhD</i>
1:15 PM ET	25 min	Break	

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

1:40 PM ET	5 min	Session Three: Clinical Trial Reporting – Moderator’s Introduction	Henry Lai, MD (Session Moderator) Professor of Surgery (Urology) and Anesthesiology Director of Research Division of Urologic Surgery Washington University School of Medicine
1:45 PM ET	30 min	How to Design a Trial So That it Doesn’t Fail: Practical Considerations You Won’t Find in the Textbooks	Andrew Vickers, PhD Attending Research Methodologist Memorial Sloan Kettering Cancer Center
2:15 PM ET	10 min	Discussion, Q&A	<i>Moderator: Henry Lai, MD</i>
2:25 PM ET	30 min	Guidelines for Reporting Medical Research: Choosing Your Checklist	Sarah P. Psutka, MD, MS Associate Professor, Department of Urology University of Washington Seattle Cancer Care Alliance
2:55 PM ET	10 min	Q&A/Discussion	<i>Moderator: Henry Lai, MD</i>
3:05 PM ET	20 min	Break	
3:25 PM ET	5 min	Introduction of Keynote Speaker	Charles D. Scales Jr., MD, MSHS
3:30 PM ET	50 min	Keynote: Ethics in the Design and Conduct of Clinical Research	Jeremy Sugarman, MD, MPH, MA Harvey M. Meyerhoff Professor of Bioethics and Medicine Berman Institute of Bioethics and School of Medicine Johns Hopkins University
4:20 PM ET	20 min	Q&A/Discussion	<i>Moderator: Charles D. Scales Jr., MD, MSHS</i>
4:40 PM ET	5 min	Introduction and Instructions for Breakout Sessions	Charles D. Scales Jr., MD, MSHS
4:45 PM ET	20 min	Break and Transition to Breakout Groups	
5:05 PM ET	60 min	Breakout Session Two: Mentor/Mentee Meetings	Small Group Meetings with Mentors, as follows:
		Mentors:	Mentees:
		STEVE GRAMBOW	ROSALYN ADAM
		PHILIPP DAHM	BORIS GERSHMAN KYLE ROSE

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

		SARAH PSUTKA	PATRICK HENSLEY IBARDO ZAMBRANO
		CHUCK SCALES	NAVEEN KACHROO KYMORA SCOTLAND
		TIAN ZHANG	DANIEL SHAPIRO REZA NABAVIZADEH
		SETH LERNER	JOHAR RAZA SYED MATTHEW HO
		STEVE KAPLAN	RAJAT JAIN
		ANGELA SMITH	NANNETTE PEREZ
		VIRAJ MASTER	RAJU CHELLURI
		MIKE FABRIZIO	DEVIN PATEL
		IAN THOMPSON	ED MESSING
		MARK LITWIN	PAUL GELLHAUS
6:05 PM ET	20 min	Break and Transition to General Session	
6:25 PM ET	5 min	Session Four: Advanced Topics in Clinical Trials - Moderator's Introduction	Ralph V. Clayman, MD (Session Moderator) Distinguished Professor / Endowed Chair in Endourology Dean Emeritus Department of Urology University of California, Irvine
6:30 PM ET	20 in	Mobile Technologies, EDC in Clinical Trials	Gregory E. Tasian, MD, MSc, MSCE Attending Urologist, Children's Hospital of Philadelphia Associate Professor of Urology in Surgery Associate Professor of Epidemiology in Biostatistics and Epidemiology Perelman School of Medicine, University of Pennsylvania
6:50 PM ET	10 min	Discussion, Q&A	<i>Moderator: Ralph V. Clayman, MD</i>
7:00 PM ET	5 min	Closing Discussion, Q&A, What to Expect for Tomorrow	Charles D. Scales Jr., MD, MSHS
7:05 PM ET		Adjourn for the Day	

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

<b>Day Three – Tuesday, July 27, 2021</b>			
<b>Presentation Time</b>	<b>Running Time</b>	<b>Title</b>	<b>Speaker</b>
11:00 AM ET	10 min	Opening Remarks, Recap from Previous Day, and Goal Setting	Steven Grambow, PhD
11:10 AM ET	5 min	Session Five: Strategies for Success in Urological Clinical Research – Part One – Moderator’s Introduction	Willie Underwood, III, MD, FACS, MPH, MSc (Session Moderator) Buffalo Center for Health Equity
11:15 AM ET	20 min	Pragmatic/Adaptive Trials	Matthew Roe, MD, MHS Chief Medical Officer Verana Health
11:35 AM ET	10 min	Discussion, Q&A	<i>Moderator: Willie Underwood, III, MD, FACS, MPH, MSc</i>
11:45 AM ET	20 min	Participant/Stakeholder Engagement in Clinical Research	Angela Smith, MD, MS Associate Professor of Urology Director of Urologic Oncology Lineberger Comprehensive Cancer Center University of North Carolina  John Gore, MD, MS Professor of Urology University of Washington Seattle Cancer Care Alliance
12:05 PM ET	10 min	Discussion, Q&A	<i>Moderator: Willie Underwood, III, MD, FACS, MPH, MSc</i>
12:15 PM ET	20 min	Patient Reported Outcomes in Clinical Trials	Mark S. Litwin, MD, MPH Chair, Department of Urology Professor of Urology, Health Policy & Management, and Nursing University of California Los Angeles
12:35 PM ET	10 min	Discussion, Q&A	<i>Moderator: Willie Underwood, III, MD, FACS, MPH, MSc</i>

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

12:45 PM ET	20 min	Building the Clinical Research Team	Willie Underwood, III, MD, FACS, MPH, MSc Buffalo Center for Health Equity
1:05 PM ET	10 min	Discussion, Q&A	<i>Moderator: Willie Underwood, III, MD, FACS, MPH, MSc</i>
1:15 PM ET	15 min	Break	
1:30 PM ET	5 min	Session Six: Strategies for Success in Urological Clinical Research – Part Two – Moderator’s Introduction	John Gore, MD, MS (Session Moderator) Professor of Urology University of Washington Seattle Cancer Care Alliance
1:35 PM	20 min	Establishing a Research Program in the Community Setting and Opportunities for Collaboration	Raoul S. Concepcion, MD, FACS Chief Science Officer U.S. Urology Partners
1:55 PM ET	20 min	Building a Research Program in Clinical Trials Research <i>(to include funding)</i>	Viraj Master, MD, PhD Winship Cancer Institute  Michael D. Fabrizio, MD, FACS Urology of Virginia
2:15 PM ET	15 min	Discussion, Q&A	<i>Moderator: John Gore, MD, MS</i>
2:30 PM ET	20 min	Effective Use of Patient Registries for Clinical Research <i>(This talk is not accredited for CME)</i>	Matthew Roe, MD, MHS Chief Medical Officer Verana Health
2:50 PM ET	10 min	Discussion, Q&A	<i>Moderator: John Gore, MD, MS</i>
3:00 PM ET	15 min	Break	
3:15 PM ET	15 min	GCP and Regulatory Considerations (How to Stay out of Clinical Trial Jail) <i>(pre-recorded presentation)</i>	Scott E. Eggener, MD Bruce and Beth White Family Professor of Surgery and Radiology Vice Chair, Section of Urology Director, High Risk and Advanced Prostate Cancer Clinic The University of Chicago Medical Center



**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
 July 25-27, 2021

3:30 PM ET	20 min	Translating Trial Results to Guidelines and Clinical Practice	Philipp Dahm, MD, MHSC Professor Residency Program Director Vice Chair of Education Department of Urology University of Minnesota
3:50 PM ET	10 min	Discussion, Q&A	<i>Moderator: John Gore, MD, MS</i>
4:00 PM ET	5 min	Introduction and Instructions for Breakout Sessions	Charles D. Scales Jr., MD, MSHS
4:05 PM ET	15 min	Break and Transition to Breakout Groups	
4:20 PM ET	60 min	Breakout Session Three: Next Steps & Where Do I Go From Here?	Small Group Meetings with Mentors
		Mentors:	Mentees:
		STEVE GRAMBOW	ROSALYN ADAM
		PHILIPP DAHM	BORIS GERSHMAN KYLE ROSE
		SARAH PSUTKA	PATRICK HENSLEY IBARDO ZAMBRANO
		CHUCK SCALES	NAVEEN KACHROO KYMORA SCOTLAND
		TIAN ZHANG	DANIEL SHAPIRO REZA NABAVIZADEH
		SETH LERNER	JOHAR RAZA SYED MATTHEW HO
		STEVE KAPLAN	RAJAT JAIN
		ANGELA SMITH	NANNETTE PEREZ
		VIRAJ MASTER	RAJU CHELLURI
		MIKE FABRIZIO	DEVIN PATEL
		IAN THOMPSON	ED MESSING
		MARK LITWIN	PAUL GELLHAUS

**Methods in Clinical Urology Research (MCURe) Workshop**  
**A live virtual workshop, presented by the AUA Office of Research**  
July 25-27, 2021

5:20 PM ET	5 min	Transition Back to General Session	
5:25 PM ET	5 min	Closing Remarks and Discussion	Charles D. Scales Jr., MD, MSHS Steven Grambow, PhD Carolyn J.M. Best, PhD
5:30 PM ET		Adjourn Meeting	