

List of Prior NCRAF Meeting Presentations

Date	Speaker	Speaker Affiliation	Topic
2024-03-26	RJ Wirth and Rikki M. Vinton	Psychometric Group	Measuring What Matters to Patients
2024-02-29	Merrie Mosedale	UCB	Review of Key FDA (CDER) Activities
2024-02-15	Kirsten Messmer	AgencyIQ	New Year, New EU Pharmaceutical L
2023-11-09	12 speakers/topics	various	2023 ROUNDTABLE DINNER
2023-10-26	Cheng Li and Shauna Swanson	Stemline Therapeutics	Applying Human Factors Engineering
2023-09	Moderator: Demetrius Pappas (Synchrogen) (Moderator: Saad Samir (AbSyn) (Sethe D		
(Joint presentation with AMWA)			
2023-05-30 through 2023-09-26	multiple	multiple	NCRAF 2023 Pharma/Biologics Wo
2023-06-01	Linda Bowen	Seagen	2023 SPRING SYMPOSIUM_ Opport
2023-04-25	Amanda Parrish & Nicole Evers	Duke University	Algorithm-Based Clinical Decision Sup
2023-03-23	Rachel Capone	Syner-G Biopharma Group	An Overview of FDA Orphan Drug De
2023-02-16	Kirsten Messmer	AgencyIQ	The EU Clinical Trials Regulation Imp
2022-11-16	9 speakers/topics	various	2022 ROUNDTABLE DINNER
2022-06-07 through 2022-09-27	multiple	multiple	NCRAF 2022 Pharma/Biologics Wo
2022-04-28	J. Kaitlin Morrison	UNC-Lineberger	Regulatory and Clinical Development
2022-03-31	Lauren Seabrook	Enzyvant	Regulatory Affairs - Ag vs. Biotech; W
2022-02-24	Amritha Kidiyoor	Impact Pharmaceutical Services	What's in a Name? Proprietary Namin
2021-10-10	NCRAF members	all	Family Day at NC Museum of Life and
2021-06-01 through 2021-09-28	multiple	multiple	NCRAF 2021 Pharma/Biologics Wo
2021-05-20	Edit Muhari-Stark	Biocryst Pharmaceuticals	Regulatory Strategies in Global Pedia
2021-04-22	Alex Gaffney, Kirsten Messmer, AgencyIQ, Angelo	AgencyIQ	FDA and the pandemic: What's next, a
2021-03-18	David Jensen	Duke University	Limiting the Clinical Trial to What you

2021-02-18	Birgitta Hedin	Chiesi Group	Global Regulatory Strategies
2020-12-03	Maria Oyaski	Bavarian Nordic	COVID Vaccine Development
2020-10-18	NCRAF members	all	Outdoor Picnic / Get-together
2020-09-17	Jim DiBiasi	3D Communications	The Art of Effectively Managing Virtual
2020-06-02 through 2020-09-29	multiple	multiple	NCRAF 2020 Pharma/Biologics Work
2020-05-21	Edie Williams, Connie Edie Williams and Cwik Business Development	Edie Williams and Cwik Business Development	Developing High Performance Teams
2020-03-19	Clare Matti	NCRAF	BREXIT – What to Expect for Medical
2020-02-13	Will Lee	Cato	IND Submission Lessons Learned
2020-01-16	Carrie-Lynn Langlais	Bacteriophage & Drug Development	Limited Population Pathway for Antibacterial
2019-12-13	Sathya Ganesan	G1 Therapeutics	Developing a Draft Package Insert
2019-11-07	12 speakers/topics	various	2019 ROUNDTABLE DINNER
2019-10-17	David Shoemaker	Rho	US Legislation and Resulting Regulatory
2019-09-19	Steven Castillo	Inpernum Pharma Consulting	Transitioning to a Career in Pharma F
2019-06-04 through 2019-09-24	multiple	multiple	NCRAF 2019 RAC(US) Workshop S
2019-05-09	Kristen Buck	Optum	2019 SPRING SYMPOSIUM_Acceler
2019-04-18	Susan Watts	Syneos Health	Update on Pediatrics: US, Europe, Ja
2019-03-21	Pete Etchells	Regulatory Affairs Professional Society	The RAC Sector-Based RAC Exams
2019-02-21	Kirsten Messmer	PPD	CRISPR Babies - Scientific Progress
2018-12-13	Denise Sturdy	Duke Clinical Research Institute	GDPR: What We (Think) We Know S
2018-11-15	Moderator:Ernie Hood Emily Huddle (Gilead)	Panelists: Wanda Wiley (Novella Clinical); Steve Gray (Duke Clinical Research Institute) The Fast Track: Careers in Regulatory Science	
2018-11-08	14 speakers/topics	various	2018 ROUNDTABLE DINNER
2018-09-20	Dani Minnick and Scott Burian	HRB	Bench to Clinic: Preparing for a Succ
2018-06-05 through 2018-09-25	multiple	multiple	NCRAF 2018 RAC(US) Workshop S

2018-05-16	Ben Yerxa	Foundation Fighting Blindness	2018 SPRING SYMPOSIUM_The Will
2018-04-26	Moderator: Ed Field (Pacifi	Ed Field (Pacifi	Business Strategies and Regulatory
2018-03-22	Michelle Thompson	FDA Quality and Regulatory	Food Safety Decision-Making
2018-02-22	Tammy Carrea	Baebies	Navigating a Panel Review -
FDA Advisory Committee Approval of a De Novo Medical Device			
2018-01-18	Yuan Xu	Focus 42	Change Control Best Practice Decidin
2017-12-14	Eileen Fein and Allison May	3D Communications	RAPS Webinar: PDUFA VI (Patient V
2017-11-09	14 speakers/topics	various	2017 ROUNDTABLE DINNER
2017-10-19	Kelly Roney, Brant Hamel, Matt Medlin, Lakshmi	Verka Raghavan	RAPS Regulatory Convergence Round
2017-09-21	Charity Schuller, Sheila Pappas	PPD, Catapult, Quintiles	Starting Your Regulatory Affairs Caree
2017-06-06 through 2017-09-26	multiple	multiple	NCRAF 2017 RAC(US) Workshop S
2017-05-17	Robert Califf	Former FDA Commissioner	Spring Symposium_A Sit-down Tal
2017-04-20	Catherine Carlisle	QAC Communications	FDA Advisory Committees 101: The E
2017-03-16	Kirsten Messmer and Charity Schuller	PPD	Demystifying US Biosimilars
2017-02-16	Paul Vick and Denise Sisk	Siemens Health and DCRI	21st Century Cures Act - the ambition
2017-02	Clare Matti, Denise Sisk, et al	Multiple	NCRAF 2017 RAC(EU) Workshop S
2016-11-09	13 speakers/topics	various	2016 ROUNDTABLE DINNER
2016-10	Bob Rohde, Susan Sisk		Out-of-(CSR)-Body Experiences-Tips
2016-09	Suneela Thatte	Quintiles India	Regulatory Turnaround makes India a
2016-06-07 through 2016-09-27	multiple	multiple	NCRAF 2016 RAC(US) Workshop S
2016-05	Carla Balch	NantCare and NantCRO	Spring Symposium_A Regulatory C
2016-04	Susan Bostian	Duncklee & Dunham	Environmental Regulations for Destru
2016-03-10	Jane Horvath	3D Communications	Truth & Consequences: Pricing, Patie
2016-02-18	Kirsten Messmer and Charity Schuller	PPD	"Regulatory Intelligence" - Building Str

2016-02-23	Stefan Burde	BSI Healthcare	EU IVD regulation – current status and
2016-01	Clare Matti, Denise Stupp, et al		NCRAF 2016 RAC(EU) Workshop S
2016-01-28	Rebecca Carson Rogers	Schulman IRB	"Orphan Devices" - Humanitarian Use
2015-12-09	eCTD group	various	Holiday Lunch
2015-11-12	16 speakers/topics	various	2015 ROUNDTABLE DINNER
2015-10-15	Jay Campbell	North Carolina Board of Pharmacy	Regulation of Pharmacy Compounding
2015-10-14	Bob Rohde, Evan Richardson, and Martin Wileman		eCTD group meeting_ Preparing for a
2015-09-17	Mike Hinckle	K&L Gates LLP	Expanded Access - Tough Choices and
2015-09-09	eCTD group	Open panel discussion	ECTD Meeting-Stump the Chumps
2015-06-11	David Shoemaker	Rho	Spring Symposium_Regulatory Devel
2015-06-02 through 2015-09-29	multiple		NCRAF 2015 RAC(US) Workshop S
2015-04-16	BJ Witkin	Impact Pharmaceutical Services	Electronic Publishing for Paper People
(Things your publisher wishes she could tell you)			
2015-03	Clare Matti, Denise Stupp, et al		NCRAF 2015 RAC(Canada) Worksh
2015-03-19	Mike Benecky	GSK	Regulation of Companion Diagnostic T
2015-02-11	Bob Rohde, Evan Richardson, BJ Witkin, and eCTD group		CTD group PDF Toolbox Comparison
2015-01-15	Erin O'Reilly	Duke Translational Medicine Institute	Mobile Apps for Medical Devices
2015-01	Clare Matti, Denise Stupp, et al		NCRAF 2015 RAC(EU) Workshop S
2014-11-13	15 speakers/topics	various	2014 ROUNDTABLE DINNER
2014-11-12	Martin Wileman	BioCryst	eCTD Group_Feedback from conferen
2014-10-16	Kamali Chance	Quintiles	Development of Biosimilars in the US
2014-10-08	Kelly Hibbard and Evan Richardson		eCTD Group_SPL (structured product
2014-09-23	Julie Omohundro	--	Networking Lunch_Globalization of Re
2014-09-18	Amanda Parrish and Duke O'Reilly	Duke Translational Medicine Institute, Duke University	Discussion with CDERS about Pre-Ma

2014-06-03 through 2014-09-30	multiple	multiple	NCRAF 2014 RAC(US) Workshop Series
2014-05-01	Robert Califf	Duke Translational Medicine Institute	SPRING SYMPOSIUM_Disrupting the Pipeline
2014-04-17	Susan Watts	GSK	PREA Compliance, Pediatric Study Plans
2014-03-20	Dana Minnick, Anita Woodring, and David Hume	Food and Drug Administration	Pre-IND Drug Development
2014-03-12	Kathy Elks and Don Alexander	Alapac Pharma and Carlyle/ECTD	ECTD Group_Results of the ECTD Program
2014-02-16	Drusilla Scott	Cempra Pharmaceuticals	Follow the Yellow Brick Road - Special Topics
2014-01-17	Larry Hoffman	LMH Associates	The Pre-IND Program: 12 Steps to a successful IND
2014-01	Clare Matti, Denise Shultz, et al	multiple	NCRAF 2014 RAC(EU) Workshop Series
2013-11-21	Linda Karolak	--	Networking Lunch
2013-11-14	11 speakers/topics	various	2013 ROUNDTABLE DINNER
2013-10-22	Laurin Mancour	Athenium Consulting	Networking Lunch_Career Development
2013-10-17	Alison St. John	US Department of Defense	GLP and GMP in the Field of Biodefense
2013-09-19	Lisa Olson	PAREXEL	Electronic Records are Not My Responsibility
2013-09-17	David Jensen	Duke Clinical Research Institute	Networking Lunch_Regulatory Aspects
2013-08-28	Mary K D'Rozario	CRP Link	Networking Lunch_Regulatory Issues
2013-06-27	April Mayberry		Networking Lunch_Regulatory Affairs
2013-06-04 through 2013-09-17	multiple	multiple	NCRAF 2013 RAC(US) Workshop Series
2013-05-09	Brett Week	FDA-Atlanta District	SPRING SYMPOSIUM_Stories from the Field
2013-04-25	Bob Rhode		Networking Lunch_ IND/eCTD Issues
2013-04-18	Ken Edds	Kenneth Edds Associates	What to Expect during an FDA Audit
2013-03-28	NCRAF members	___	Networking Lunch_
2013-03	Clare Matti, Denise Shultz, et al	multiple	NCRAF 2013 RAC(Canada) Workshop Series
2013-03-21	Tamara Pinkett	Quintiles	A Statistician's Perspective of Traditional vs. Adaptive Clinical Trials

2013-02-21	Linda Charles and Maria Oyaski	Small-company experience on DSURs and approach for late stage	
2013-02-19	Wanda Wiley	___	Networking Lunch_Information Sheet
2013-01-23	Clare Matti and Alex McCormick	MCP	Networking Lunch_Preparing for the F
2012-12-13	Robb Giddings	___	Networking Lunch_Deriving Maximum
2012-11-08	11 speakers/topics	various	2012 ROUNDTABLE DINNER
2012-10-04	Jason Rock	Global Submit	Regulated Product Submissions (RPS
2012-09-13	RAPS Webinar	__	Strategies for your Career: Finding Y
2012-09-13	Laurin Mancour	__	Networking Lunch_Career Developme
2012-09-12	Linda Charles and Maria Oyaski	___	eCTD Group_DSUR's (Developmenta
2012-08-28	April Mayberry	__	Networking Lunch_Regulatory Curren
2012-06-21	Lisa Sanders	__	Networking Lunch_A Moderated Disc
2012-05-03	Pierre Leveau and Debra B. D	European Directorate for the Quality of Medicines & Health C	SPRING SYMPOSIUM - Solidarity
2012-04-19	Drusilla Scott	Cempra Pharmaceuticals	What's New in Orphan Drugs
2012-04-18	Lisa Olsen	__	Networking Lunch_Part 11 – Why you
2012-03-20	April Mayberry	__	Networking Lunch_”To Say or Not to S
2012-03-14	David Shoemaker	Rho	PDUFA V: Possibilities and Practical I
2012-02-16	Amy Kniefel	AptivSolutons	eCTD Friendly Module 3: Consideratio
2012-01-25	Neil Armstrong	MeddiQuest	Recasting EU Medical Device Directiv
2011-11-xx	12 speakers/topics	various	2011 ROUNDTABLE DINNER