List of Prior NCRAF Meeting Presentations

Date	Speaker(s)	Speaker Affiliation	Topic
2025-05-29	**Rob Califf (former FDA commissioner)**	**Duke University**	**Spring Symposium _ Regulatory Science and Regulatory Affairs in Unc**
2025-04-24	Allison Kalloo	Allison Kalloo LLC	From Patient to P
2025-03-20	Stephanie Byrd	Syner-G Biopharma Group	Bridging Science and Compliance: Th
2025-02-27	Stefan Burde	TÜV SÜD	Lab Developed Tests - US and EU Pe
2025-01-23	Kirsten Messmer	KM Intel LLC	What's Happening in Europe in 2025?
2024-11-14	11 speakers/topics	**various**	**2024 ROUNDTABLE DINNER**
2024-10-17	Joshua Taylor and Sheila Plant	[illegible]	Importance of Development Plans and
2024-09-12 (Joint presentation with AMWA)		Moderators: Abigail Agoglia (Whitsell Innovations) and Julie DiFiore [illegible] Panelists: [illegible]	
2024-05-20	**Susan Neadle**	**Combination Products Consulting Services LLC**	**Spring Symposium _ Regulatory St**
2024-04-24	Carmen Amador	The LaSalle Group	Lessons Learned: Effective Inspection
2024-03-26	RJ Wirth and Rikki Mangan	Vector 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	Alcami and Stemline Therapeutics	Applying Human Factors Engineering
2023-09 (Joint presentation with AMWA)	Moderator: Demetrius Carter (Syner-G)	Panelists: Kim Jochman [illegible] (Merck), [illegible] (AbbVie) [illegible]	Crafting Case Studies: The Synergy between [illegible]
2023-05-30 through 2023-09-26	**multiple**	**multiple**	**NCRAF 2023 Pharma/Biologics Wor**
2023-06-01	**Linda Bowen**	**Seagen**	**2023 SPRING SYMPOSIUM_ Oppor**
2023-04-25	Amanda Parrish & Nicole Economou	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 Messner, Legacy D'Angelo	POLITICO	FDA and the pandemic: What's next,
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 Virtua
2020-06-02 through 2020-09-29	**multiple**	**multiple**	**NCRAF 2020 Pharma/Biologics Wo**
2020-05-21	Edie Williams, Connie Cwik	Cwik Williams and Cwik Business Consultants	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 Consultants	Limited Population Pathway for Antiba
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 Regulat
2019-09-19	Steven Castillo	Inpernum Pharma Consulting	Transitioning to a Career in Pharma R

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 Professionals 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	Panelists: Wanda Wiley (Novella Clinical); Steve Gray (Duke Car… Emily Huddle (Gilead)	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	Rho	Bench to Clinic: Preparing for a Succe…
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 Wi…**
2018-04-26	Moderator: Ed Field (BioLabs NC)	Panelists: Susan Nichols (Falcon Therapeutics) and Richard Smith…	Business Strategies & Regulatory…
2018-03-22	Michelle Thompson	FDA Quality and Regulatory Consultants	Risk-Based 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 M[illegible]	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 Venkataraman		RAPS Regulatory Convergence Roun…
2017-09-21	Charity Schuller, Sheila Plant, [illegible]	PPD, Catalent, QuintilesIMS	Starting Your Regulatory Affairs Care…
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 Leonard	3D 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 Stuckey	Duke Health and DCRI	21st Century Cures Act - the ambition
2017-02	**Clare Matti, Denise Stuckey, 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 St
2016-02-23	Stefan Burde	BSI Healthcare	EU IVD regulation – current status an
2016-01	**Clare Matti, Denise Stuckey, et al**	**multiple**	**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 Compoundin
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 ar
2015-09-09	eCTD group	Open panel discussion	ECTD Meeting-Stump the Chumps
2015-06-11	**David Shoemaker**	**Rho**	**Spring Symposium_Regulatory Dec**
2015-06-02 through 2015-09-29	**multiple**	**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 Stuckey, et al**	**multiple**	**NCRAF 2015 RAC(Canada) Worksh**

2015-03-19	Mike Benecky	GSK	Regulation of Companion Diagnostic T
2015-02-11	Bob Rohde, Evan Ri	[illegible]	[illegible] PDF Toolbox Compariso
2015-01-15	Erin O'Reilly	Duke Translational Medicine	[illegible] Devices
2015-01	**Clare Matti, Denise**	**[illegible] 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 confere
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	[illegible] ational Medicine	[illegible] about Pre-Ma
2014-06-03 through 2014-09-30	**multiple**	**multiple**	**NCRAF 2014 RAC(US) Workshop S**
2014-05-01	**Robert Califf**	**Duke Translational Medici**	**[illegible] UM_Disrupting th**
2014-04-17	Susan Watts	GSK	PREA Compliance, Pediatric Study Pl
2014-03-20	Dana Minnick, Anita	[illegible]	[illegible] ND Drug Development
2014-03-12	Kathy Elks and Don	[illegible] harma and Carlyle	[illegible] Group_Results of the ECTD Pr
2014-02-16	Drusilla Scott	Cempra Pharmaceuticals	Follow the Yellow Brick Road - Specia
2014-01-17	Larry Hoffman	LMH Associates	The Pre-IND Program: 12 Steps to a s
2014-01	**Clare Matti, Denise**	**[illegible] et al**	**NCRAF 2014 RAC(EU) Workshop S**
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 Developme
2013-10-17	Alison St. John	US Department of Defense	GLP and GMP in the Field of Biodefen
2013-09-19	Lisa Olson	PAREXEL	Electronic Records are Not My Respo

2013-09-17	David Jensen	Duke Clinical Research Institute	Networking Lunch_Regulatory Aspect
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 S**
2013-05-09	**Brett Week**	**FDA-Atlanta District**	**SPRING SYMPOSIUM_Stories from**
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 Sturdy, et al**	**multiple**	**NCRAF 2013 RAC(Canada) Worksh**
2013-03-21	Tamara Pinkett	Quintiles	A Statistician's Perspective of Traditio
2013-02-21	Linda Charles and Maria Oyaski	Grifols_small-company experience	Update on DSURs and approach for l
2013-02-19	Wanda Wiley	__	Networking Lunch_Information Sheet
2013-01-23	Clare Matti and Alex McCormick	DCRI	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 Discu
2012-05-03	**Pierre Leveau and D**	**European Directorate for the Quality of Medicines & HealthCa**	**SPRING SYMPOSIUM_Biologics**
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 E
2012-02-16	Amy Kniefel	AptivSolutons	eCTD Friendly Module 3: Considerati
2012-01-25	Neil Armstrong	MeddiQuest	Recasting EU Medical Device Directiv
2011-11-xx	12 speakers/topics	**various**	**2011 ROUNDTABLE DINNER**
2011-10-xx	Henrietta Ukwu	PPD Inc.	Evolution and Transformation of the re