BREAK-OUT SESSIONS

To foster conversation, participants will go to different virtual rooms after brief presentations for small-group live discussion.

To access these break-out rooms, Webex instructions are emailed separately to individual break-out groups. After the break-out sessions, participants rejoin the main session for report-outs.

Join main session

Meeting number (access code): 612-666-793
Meeting password: CVresearch20

1st Break-out session: 10:35am – 11:20am Eastern Time
2nd Break-out session: 12:15pm –1:00pm Eastern Time

Group Assignments

Last Name	First Name	Session 1	Session 2
Allen	Larry	3	1
Bhatt	Deepak	4	1
Bohula May	Erin	3	2
Butler	Javed	4	1
Carson	Peter	3	1
Casale	Paul	1	4
Douglas	Pamela	3	3
Farb	Andrew	6	2
Felker	Michael	3	2
Foody	JoAnne	6	3
Fry	Ed	1	4
Gluckman	Ty	1	2
Henderson	Jeff	2	1
Hessen	Margaret	5	1
Hochman	Judith	6	1
Itchhaporia	Dipti	4	1
Januzzi	Jim	5	1
Khan	Naeem	6	3
Kosiborod	Mikhail	2	n/a
Krumholz	Harlan	4	4
Maddox	Tom	2	3
Masoudi	Fred	5	2
Last Name	**First Name**	**Session 1**	**Session 2**
McCarthy	Cian	5	3
Mensah	George	2	4
Narula	Jagat	5	3
O'Connor	Christopher	6	n/a
Patrick-Lake	Bray	2	2
Poppas	Athena	5	3
Reisman	Lonny	1	3
Rumsfeld	John	5	1
Seltzer	Jonathan	3	2
Shah	Monica	2	3
Singh	Jag	1	2
Solomon	Scott	6	3
Stecker	Eric	3	3
Stockbridge	Norman	4	2
Turco	Justine	5	n/a
Vaduganathan	Muthu	4	4
Walsh	Mary Norine	2	4
Wang	Tracy	3	2
Wasfy	Jason	1	4
Zuckerman	Bram	4	1

DISCUSSION QUESTIONS

Session 1: The Immediate Impact of COVID-19 on Cardiovascular Research: Supporting the Research Community During a Pandemic

Start time: 10:35 a.m.
End time: 11:20 a.m.

Group 1: Leveraging telehealth for patient enrollment and follow-up visits.

Lead moderator: *Jag Singh*
Group members: *Ty Gluckman, Paul Casale, Ed Fry, Lonny Reisman, Jason Wasfy*
ACC Staff: Amanda Ladden-Stirling (astirling@acc.org)

Discussion Questions:

What electronic data sources can be used to identify patients for enrollment?

In what ways can consenting, longitudinal follow up and adverse event reporting be done virtually? What platforms are needed? Are there any unique differences from the virtual/telehealth platforms being used for clinical care?

How might laboratory testing be done remotely (e.g., home-based laboratory testing)? What about other testing/evaluation (e.g., 6-minute walk)?

What's needed to accelerate greater collection of patient reported outcomes (PROs)?

Group 2: Current challenges posed by COVID-19 and potential solutions for patient recruitment and retention, site start-up, etc.?

Lead moderator: *Monica Shah*
Group members: *Tom Maddox, Joseph Allen, Jeff Henderson, Mikhail Kosiborod, George Mensah, Bray Patrick-Lake, Mary Norine Walsh*
ACC Staff: Sahisna Bhatia (sbhatia@acc.org)

Discussion Questions:

How are you currently handling patient enrollment at your institution? What are your biggest challenges? What have you instituted to overcome some of these barriers?

How has your institution managed FTE support for research and allocating staff to support protocols?

Have your patient retention rates been impacted due to COVID-19? If so, how? What are some things that can prevent high dropout rates?

What can be done to alleviate patients' safety concerns?

How should studies account for interruptions in the supply chain due to limited inventory of investigational products?

Group 3: Lasting impact on data: Effects on endpoints and outcome interpretation.

Lead moderator: *Michael Felker*
Group members: *Eric Stecker, Larry Allen, Erin Bohula May, Peter Carson, Pamela Douglas, Jonathan Seltzer, Tracy Wang*
ACC Staff: Shira Klapper (sklapper@acc.org)

Discussion Questions:

As additional testing kits and methods become available, is the mandatory screening for COVID-19 or the presence of the virus in enrolled patients desirable?

Should patients who report testing positive for COVID-19 be removed from ongoing studies, especially where the study drug/device may make it more difficult to treat? Why or why not?

How might events occurring during the pandemic influence interpretation of outcomes during the course of clinical trials? For example, how to interpret all-cause mortality endpoint if a trial is conducted in setting of high burden of COVID-19?

Should endpoints occurring in clinical trials during the COVID pandemic be reviewed or re-reviewed to identify un-recognized or un-reported COVID19? For example, how to interpret all-cause mortality endpoint if a trial is conducted in setting of high burden of COVID-19?

Group 4: Effects on clinical trials' FDA regulations.

Lead moderator: *Bram Zuckerman*
Group members: *Harlan Krumholz, Deepak Bhatt, Javed Butler, Dipti Itchhaporia, Norman Stockbridge, Muthu Vaduganathan*
ACC Staff: Ashleigh Covington (acovington@acc.org)

Discussion Questions:

What might be COVID-19's downstream effects on approvals of new drugs and devices?

How might inclusion/exclusion criteria and other aspects of study protocols be amended/accounted for in COVID-19 positive patients?

Given the temporal shift at the moment, what kind of analysis could be permitted, that may only be good now, to stay on as we move forward?

Group 5: COVID-19 and maintaining the rigors of peer review in a crisis.

Lead moderator: *Jagat Narula*
Group members: *Jim Januzzi, Margaret Hessen, Fred Masoudi, Cian McCarthy, Athena Poppas, John Rumsfeld, Justine Turco*
ACC Staff: Severa Chavez (schavez@acc.org)

Discussion Questions:

How can we balance the need for timely information, but maintain rigorous scientific principles in research publication?

Should there be a CONSORT-like criteria list for these sorts of publications?

Group 6: Delays in the launch of new products to market.

Lead moderator: *JoAnne Foody*
Group members: *Judith Hochman, Chris O'Connor, Naeem Khan, Andrew Farb, Scott Solomon*
ACC Staff: Amy Dearborn (adearborn@acc.org)

Discussion Questions:

What are the short-term impacts of delays in new product launches?

What are the longer-term impacts of delays in new product launches?

How do we avoid delays in the future due to resurgences of COVID-19 or future pandemics?

Session 2: The Intersection of CV Disease and COVID-19: Paving the Way for Future Clinical Research Opportunities

Start time: 12:15 p.m.
End time: 1:00 p.m.

Group 1: What are the range of questions we should be asking? How important are they? Ranked in order of easy, medium, hard.

Lead moderator: *John Rumsfeld*
Group members: *Jim Januzzi, Larry Allen, Deepak Bhatt, Javed Butler, Peter Carson, Jeff Henderson, Margaret Hessen, Judith Hochman, Dipti Itchhaporia, Bram Zuckerman*
ACC Staff: Severa Chavez (schavez@acc.org)

Discussion Questions:

Has the COVID-19 pandemic changed the way you think about clinical evidence?
- Regulatory approval
- Observational research
- Clinical trials

What are the largest challenges and opportunities for clinical trials in the COVID era?

How can ACC (and other professional organizations) lead - and optimally support - clinical research in the COVID era?

What are the key questions we should be addressing in clinical research?
- COVID-related questions
- CV-related questions in the COVID era

Group 2: How to collect data - Is the case report form obsolete? What do we need to know and how might we answer the questions a different way?

Lead moderator: *Fred Masoudi*
Group members: *Ty Gluckman, Erin Bohula May, Andrew Farb, Michael Felker, Bray Patrick-Lake, Jonathan Seltzer, Jag Singh, Norman Stockbridge, Tracy Wang*
ACC Staff: Sahisna Bhatia (sbhatia@acc.org)

Discussion Questions:

How can you supplement the inevitable “holes” in EHR data capture?

Can patients contribute to real-world data collection? What role do PROs play in future research?

How to deal with COVID19 testing and coding limitations in research?

Group 3: Process for how we get closer to real-time knowledge generation. Innovative Strategies for rapid cycle research.

Lead moderator: *Tom Maddox*
Group members: *Eric Stecker, Pamela Douglas, JoAnne Foody, Naeem Khan, Cian McCarthy, Jagat Narula, Athena Poppas, Lonny Reisman, Monica Shah, Scott Solomon*
ACC Staff: Shira Klapper (sklapper@acc.org)

Discussion Questions:

How do we leverage real-world data to support observational and experimental designs?

What is the role of the common data model as it relates to future research around the intersection of COVID-19 and CV disease?

What is the role of multi-center data registries in supporting real-time knowledge generation?

What should our data sharing policies entail to best serve societal, institutional, patient and investigator interests?

How do we accelerate the research results to balance speed with appropriate rigor?

Group 4: Process for how we get closer to real-time knowledge generation. Innovative Strategies for rapid cycle research.

Lead moderator: *Harlan Krumholz*
Group members: *Paul Casale, Ed Fry, George Mensah, Muthu Vaduganathan, Mary Norine Walsh, Jason Wasfy*
ACC Staff: Ashleigh Covington (acovington@acc.org)

Discussion Questions:

How do we leverage real-world data to support observational and experimental designs?

What is the role of the common data model as it relates to future research around the intersection of COVID-19 and CV disease?

What is the role of multi-center data registries in supporting real-time knowledge generation?

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