

**HF Collaboratory: Devices and Drugs Working Group Call Q2
August 3, 2020**

Members Present

Devices:

William Abraham (Chair, Ohio State University)
Robert Kazmierski (FDA Co-Chair) (FDA/CMS)
Amrut Ambardekar (U. of Co)
Mona Fiuzat (Duke)
Liz Galle (CVRx)
Al Gianchetti (Xylocor)
Richard Jacob (Patient)
Christopher O'Connor (Inova)
Meir Shinnar (FDA)
Randall Starling (Cleveland Clinic, FDA)
Bram Zuckerman (FDA)

Drugs

Scott Solomon (Brigham and Women's, Chair)
Ellis Unger (FDA, Co-Chair)
Ankeet Bhatt (Brigham and Women's)
Javed Butler (University of Mississippi)
Michael Felker (Duke)
Marv Konstam (Tufts)
Steven Simonson (Windtree)
Norman Stockbridge (FDA)
John Teerlink (UCSF)
Brandon Walsh (Arena)

Staff

Heather Applegate

Unable to participate

Peter Carson (VAMC DC)
JoAnn Lindenfeld (Vanderbilt)
Mitch Pspotka (Inova)
Joseph Rogers (Duke)
Dan Schaber (Medtronic)
Emily Zeitler (Dartmouth)
Martina Brueckmann (Boehringer-Ingelheim)
Graziella Collu (AstraZeneca)
Mary DeSouza (BMS)
Marty Lefkowitz (Novartis)
Joerg Koglin (Merck)
Lothar Roessig (Bayer)

1. Manuscripts

Bill Abraham gave a summary of publications that have been published/will be published:

- Editor's Page: Heart Failure Collaboratory Statement on Clinical Trials on the Landscape of COVID-19 (May 2020 – JACC: HF)
- Editor's Page: Heart Failure Collaboratory Statement on HF Remote Monitoring in the Landscape of COVID 19 and Social Distancing (August 2020 – JACC: HF)
- HF-ARC (2.0) Scientific Expert Panel: Conduct of Clinical Trials in the Era of COVID-19 (decision letter to revise for co-publication in JACC/EHJ)
- HF-ARC (1.0) Standardized Definitions for Heart Failure (decision letter to revise, transferred from JACC/EHJ for co-publication in JACC:HF/EJHF)

Action Items

- Mitch to revise and resubmit ARC manuscripts
- All publications are posted to website: www.hfcollaboratory.com

2. COVID 19 Data Collection CRF

Scott Solomon, Orly and Ankeet developed a 5-page case report form module that focuses on symptoms and other behavioral variables to learn how the pandemic is affecting trials. Calls have been held with industry to broadly discuss the form and methods of data collection in current trials.

The COVID 19 CRF sub-group is now holding more focused one-on-one calls with sponsors to discuss formal engagement.

The group also had discussions with Medidata. Medidata has developed a direct to patient platform that would be easily interchangeable. Medidata said they would be willing to expand to include some of HFC's CRF elements. They would also be willing to make it available free of charge to those using their system, and could make it available to those not using their system. (Currently approximately 50 – 75% of trials use Medidata.)

Ankeet has developed a spreadsheet of all active HF trials – over 250.

Initial concerns were that the form would be burdensome and have a lack of engagement. Patients have reported that the form is an important contribution and can be completed in 10 minutes. It is likely that industry and other sponsors will likely need this info at the conclusion of their trials.

Central IRB: Liz Galle made the suggestion of approaching WIRB for a central IRB. Incorporating the CRF would be easier if there was central IRB approval in place. There is currently no mandate for centralized IRB, but it is definitely quicker. Work should be done to expand the willingness of sites to move to a centralized IRB and advocate for efficiencies. However, many sites require institutional IRB approval even when central IRB has approved. This is an important topic for the HFC to focus on.

Action Items

- Continue 1:1 calls with trial sponsors for incorporating COVID data collection
- Continue discussion with Medidata and options for operationalizing data capture
- COVID CRF available for anyone interested in using it (contact Ankeet/Scott S)
- Will post CRF to website when published
- Discussion at future think tank: elaborate on the issue of centralizing IRBs

3. Meetings

1. Interpreting and Implementing New Clinical Trials Data: March 6 meeting

Manuscript: Ankeet reported the manuscript is in final stages of draft; plans to have by end of week.

2. Statistical Approaches for HF Drug and Device Development: COVID Considerations and Beyond: Friday, Sept. 11 (Zoom)

Scott and Janet Wittes to lead. Scott walked the group through the agenda (attached).

The opening session will be followed by case examples of several trials. Next, talks about adaptive design. The suggestion was made for adaptive trials in COVID world – platform idea of studying multiple interventions at once and adapting to most promising. Oncology examples may also be helpful.

There will be continued discussion for Bayesian borrowing from the 2019 meeting.

Action Items:

- March 6 meeting manuscript to be finalized and submitted (Ankeet)
- Suggestions for speakers to share real examples of adaptive design (ARCA as option; Hussein Al-Khalidi, Ph.D. from Duke was DSMB statistician; others?)
- Invite Cyrus Mehta, Barry group as options
- Update agenda: Afternoon session add a talk on “implementation in regulatory trials” – Heather to send around invited statistical panel including FDA statisticians

3. Fall HFC Working Group/Think Tank Meeting – Thursday, Sept. 10 (Zoom - will move time to 4-6pm ET)

The agenda was reviewed (attached). Bill discussed the Clinical Virtual Trials Session. LOFT would be a good example. This was set up as traditional trial, then done completely remotely without bring patients into clinic.

Bill also mentioned an FDA app for remote electronic consenting of patients. He provided the below:

As mentioned on our call, the FDA has made the COVID MyStudies App available for FDA regulated trials conducted during the COVID-19 public health emergency. The COVID MyStudies App is available in the Apple App and Google Play stores as a platform enabling investigators to obtain informed consent securely from patients when face-to-face contact is not possible or practical due to COVID-19 public health measures to control the virus. There is no cost associated with use of the COVID MyStudies App during the COVID-19 public health emergency. The COVID MyStudies App is 21 CFR Part 11 compliant. For more information, investigators and study sponsors interested in using the app should see <https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app>.

Action Items:

- Update time to 4-6pm ET (Heather)
- Update agenda for virtual trials presentation: Bill Abraham and invite George Sopko (NIH)
- Include discussion of FDA app for consent
- Other suggestions?

4. HFC Website

Mona reviewed the new website (ww.hfcollaboratory.com) and highlighted some of the features.

Action Items:

- Look at website and provide any feedback

5. Lean CRF Modules

We previously began the process of developing Lean CRF modules, but diverted to COVID focused discussions and projects. Several people completed their assigned tasks so we have a starting point. The group agreed this is still of interest.

Action Items:

- Following September WG/TT meeting, will re-engage on developing modules.

6. Other – additional topics:

Patients' Understanding of Healthcare Research

With current climate, patients need to better understand the healthcare research eco system. What are ways that patients can better appreciate what clinical research is in 21 century?

Group pointed to HFSA efforts: HFSA initiated patient members with goal to educate HF patients and HFSA website has patient-focused center on trials.

Rob Califf has two good articles – one in JAMA and one in JACC – reflecting on current situation and potential silver lining. These include ideas for practical things we can do to education patients??

Action Items:

- Continue to work on these efforts (Research Networks group has started patient engagement efforts)
- Connections with AHA (Mariell can help)
- Follow -up with HFSA on patient initiatives (John T, Mona, Randy)