Conducting clinical trials from home: The implementation of a remote work model in CARE

Krystal Capers, MPH , Valerie Banner-Goodspeed, MPH, Maximilian Schaefer, MD

[1]Department of Anesthesia, Critical Care & Pain Medicine, Beth Israel Deaconess Medical Center, Boston, MA

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

CARE Center For Anesthesia Research Excellence BIDMC

Background

- ❑ The Center for Anesthesia Research Excellence (CARE) was established in October 2014 to facilitate all aspects of clinical research within the Department of Anesthesia, Critical Care and Pain Medicine, with an emphasis on in-hospital, 'boots on the ground' assistance for researchers.
- ❑ CARE participates in various research domains including:
  - ✓ Interventional trials
  - ✓ Physiologic studies
  - ✓ Epidemiologic studies
  - ✓ Education research
  - ✓ Simulation research
  - ✓ Quality Improvement research
  - ✓ Outcomes research
- ❑ CARE research is also represented in various divisions including Critical Care, Cardiothoracic Anesthesia, Pain Medicine, Obstetric Anesthesia, General Anesthesia, and Education / Quality Improvement.
- ❑ On March 11,2020 CARE implemented an effective remote work model due to the COVID-19 pandemic, and was able to carry out 11 COVID research studies.

Meet the Team

Front Row (left to right): Trishna Sadhwani, Melisa Joseph, Valerie Banner-Goodspeed (Program Manager), Maximilian Schaefer (Program Director), Krystal Capers, Aiman Suleiman **Back Row** (Left to Right): Andrew Toksoz-Exley, André De Souza Licht, Evynne Gartner, Danny Le, Ariana Saroufim, Lauren Kelly, Najla Beydoun, Peter Santer, Felix Linhardt, Tim Tartler, Omid Azimaraghi
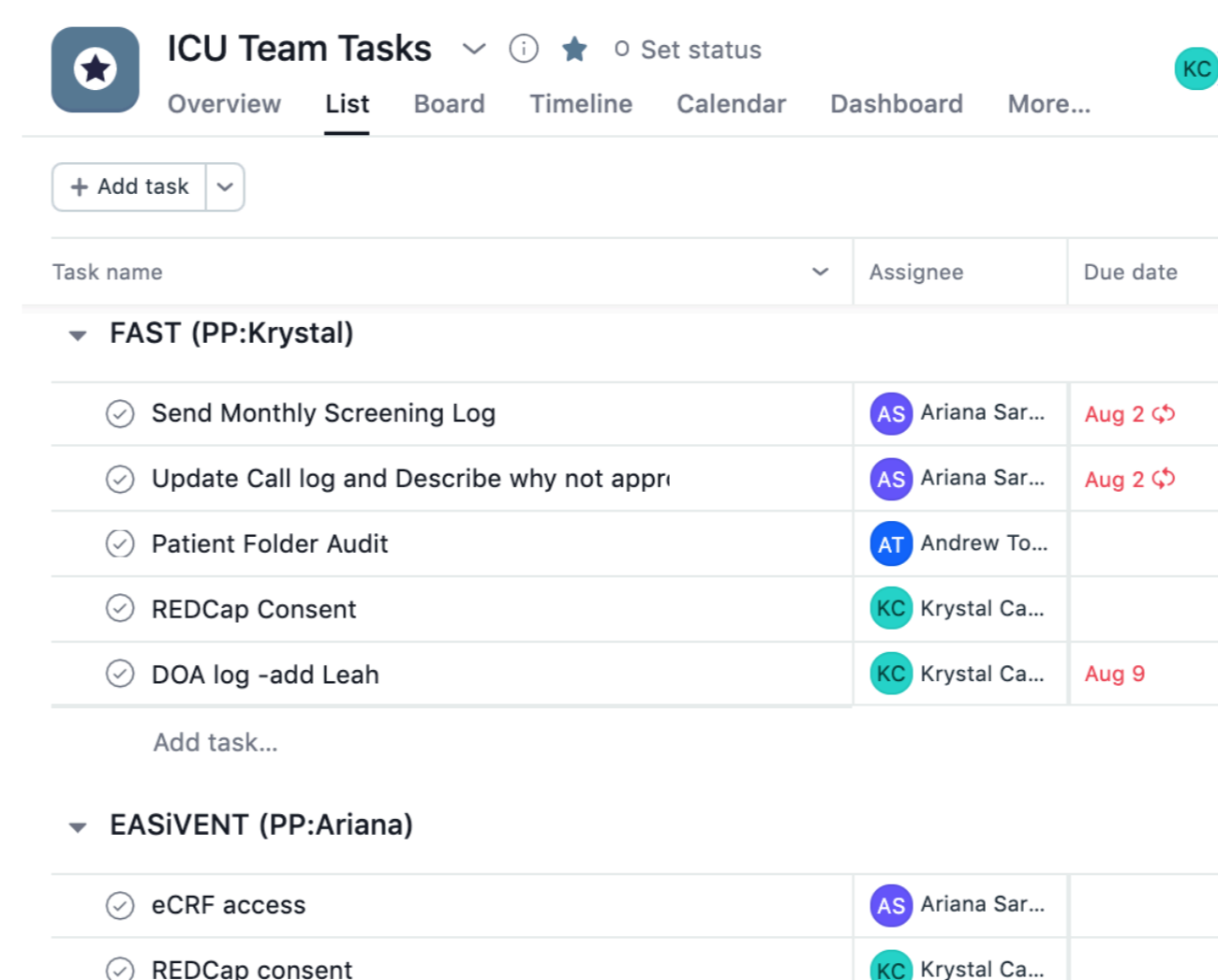
Acknowledgements

Methods

- ❑ Communication was vital while we worked remotely. Our team utilized various group chats (mobile devices), worked simultaneously on shared documents (google drive), and attended weekly team meetings (zoom).
- ❑ We utilized a number of new web applications to communicate within our teams and to keep our tasks on track, relying particularly on Smartsheet and Asana.

Asana

- • Asana is a desktop and mobile app that was designed to help teams organize, track, and manage their work**.**
- • Each research study had an associated list of tasks that were assigned to members of the team.
- • Team members were able to mark action items as complete and team managers were notified in real time.
- • Asana also has a chat function that can be utilized to communicate within the team for each individual task that has been assigned.
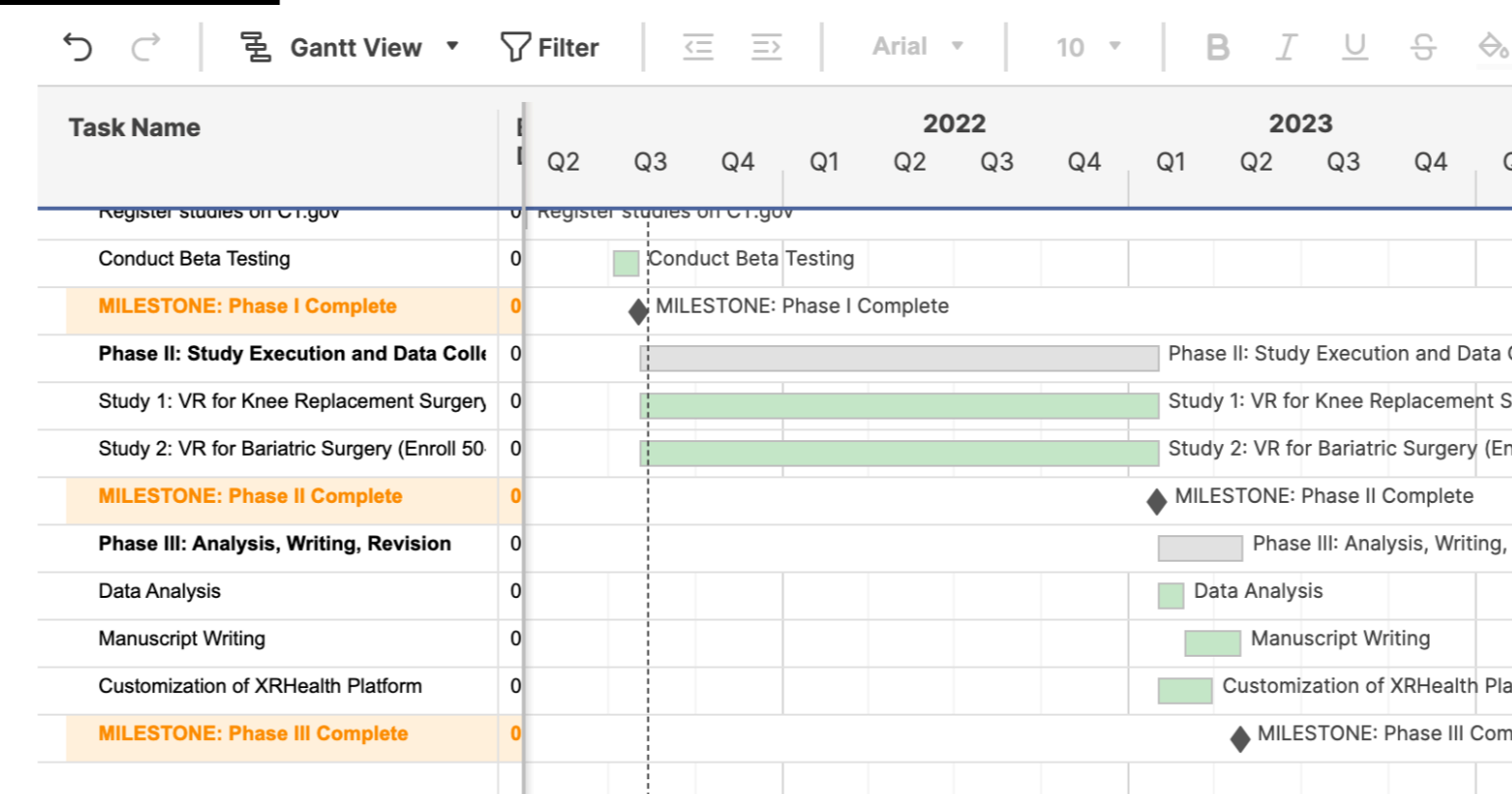

Zoom

- • Zoom was the primary video teleconferencing program used for our remote work model implementation.
- • Our research team members were accustomed to working alongside each other, but the video feature allowed us to see each other from our respective locations.
- • The screen share function was utilized to show our meeting agendas, and also to navigate study documents and applications together.

Smartsheet

- • Smartsheet is a web-based project management program.
- • It can be used to assign tasks, track project progress, manage calendars, and share documents
- • We utilized Smartsheet primarily for onboarding new team members and for project start up tasks.
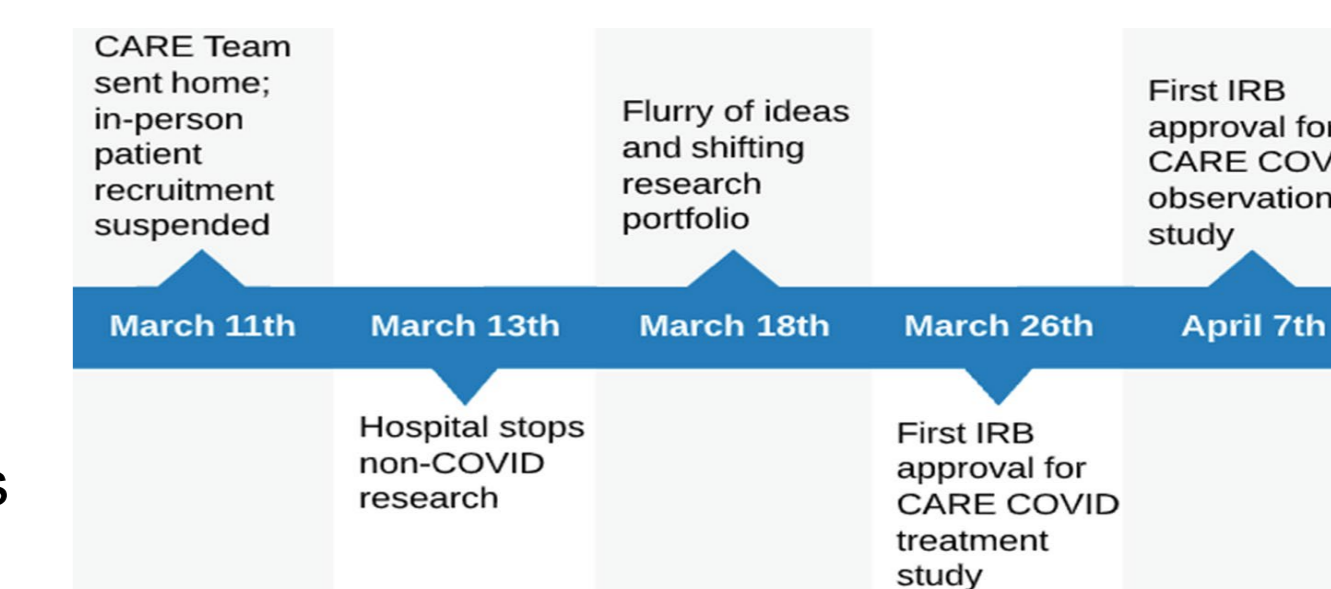

Challenges

4 out of 4 of our research assistants transitioned to Professional School.	We utilized zoom for side-by-side team training and shadowing as we onboarded our new team members.
We had a flurry of new proposals for COVID research when non-COVID research was suspended.	The team assisted our regulatory specialist with drafting IRB proposals. We utilized a google drive to assist each other.
Most of our trials required consent from our participants.	We shifted from consenting in person to consenting remotely. We utilized various resources such as REDCap, Google Voice, and Doximity.
Our clinical trials require an on-site presence to assist with various tasks such as data collection and consenting.	Our study physicians, research pharmacists, and respiratory therapist played a large role in helping us enroll in our clinical trials.

Results

- ❑ We were successfully able to enroll patients into 11 clinical trials and observational studies while operating in this remote work model, including:

  - ❑ 7 Interventional Trials
    - ❑ 3 COVID drug trials
    - ❑ 1 non-COVID drug trial
    - ❑ 3 device trials
  - ❑ 4 Observational Trials
    - ❑ 3 Epidemiological Studies
    - ❑ 1 Survey Based Study

March 11th	March 13th	March 18th	March 26th	April 7th
CARE Team sent home; in-person patient recruitment suspended		Flurry of ideas and shifting research portfolio		First IRB approval for CARE COVID observational study
	Hospital stops non-COVID research		First IRB approval for CARE COVID treatment study	

- ❑ The rapid conversion to fully remote with solid communication strategies allowed us to have 3 of the first 5 IRB applications for COVID-specific human subject research protocols at BIDMC.

Conclusion

- ❑ Strong communication and technology solutions allowed us to remotely support departmental research throughout the pandemic.
- ❑ Demonstrable productivity and continued high work quality enabled us to remain fully staffed, with no team members placed on furlough or redeployed.
- ❑ While our team has returned on site, we have adapted this remote work model with flex remote days and continued electronic project management support.