Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Challenges for Researchers During the Pandemic

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10:45 - 11:30 AM EST
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Challenges for Researchers During the Pandemic

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2021 DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research

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Federico M Asch MD
Cardiovascular Core Laboratories and Cardiac Imaging
MedStar Health Research Institute
Scope of my Lab’s Research Work

- Core Services
- Investigator-Initiated
Specific Challenges Due to the Pandemic

• Team Work disruption, well-being

• Patient enrollment challenges,

• Dynamics of our research sponsors
How were you able to get your research back up and running

• Old projects

• New Opportunities
What lessons did you learn?

• Risk Assessment Evaluation

• Prepare in advance

• Identify unique opportunities and shift of goals or plans
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Sharon Dowell, MBBS
Associate Professor of Internal Medicine
Howard University
Clinical trials
Observational studies
Clinical registry
Address Disparities
Diversity in Research
Access to Medications
Access to Providers
Improve Self-Efficacy
Specific Challenges Due to the Pandemic

Patients had limited broadband access

- Recruitment
- Consent
- Study Procedures
- Follow-up
Research Rebound

TTT, HURAEDs, Clinical trials

New questions about health equity and telemedicine in RA
Lessons Learned

• If we have critical momentum, we can influence change
• For low-risk studies, virtual consent is an option
• Not everything can be done virtually
• Disparities in Telehealth/tele-research exist
• The importance of collaboration and a diverse team
• There is always a question that needs an answer
Thank You

HU Rheumatology Research Team
Gail Kerr (MD)
Mercedes Quinones (MD)
Tara Jamshidi (MD)
Micayla Wilson (RC)
Haja Kamara (RC)
Dermatology Collaboration with Ginette Okoye (MD)
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Jill P Smith, MD
Professor of Medicine
Georgetown University &
DC Veterans Affairs Medical Center
Challenges with Clinical Research Work

- Bench to Bedside translation clinical trials:
  - Phase 1 clinical trial is subjects with nonalcoholic steatohepatitis NASH (NCT04152473)- Enrollment started January 2020
  - The patients eligible for this clinical trial with metabolic syndrome & obesity were the same population at high risk for COVID
  - The IRB protocol was approved at 2 sites (Georgetown & the VA hospital)- but research at the VAMC closed completely during COVID
  - Getting subjects to come to the hospital for screening & consenting & participation in the trial was difficult
Solutions for Clinical Research

- Submitted an IRB protocol modification to be able to consent subjects by telephone
- Established an account with LabCorp to draw routine lab tests and to perform Biometrics so subjects could visit a LabCorp close to their home and not have to risk coming to the hospital.
- Obtained approval to FedEx investigational medication to subjects’ homes
- Obtained approval from the VAMC to recruit subjects from the VA and treat them at the CRU at Georgetown University.
- Cost: In order to cover the extra cost of PPE for staff, LabCorp account etc: I submitted an application for PA-18-591: Administrative Supplements to Existing NIH Grants and Cooperative Agreements- it was funded
Challenges with Bench Research due to Pandemic

Laboratory research: Molecular Biology, animal preclinical studies, Graduate student thesis projects.

- Projects were delayed due to some Core facilities like Histology being closed.
- Had to develop & submit a plan for the times and numbers staff would be in lab.
- Weekly COVID tests were required and daily COVID building access done
- Difficulty teaching grad students laboratory skills when the laboratory was closed and there was social distancing.
Solutions for Continuation of Bench Research

• Spent time writing new grants and manuscripts
• Revised animal projects and treatment dosing schedules to have less time in the facility
• Lab meetings were changed to virtual ZOOM weekly meetings
• Some animal colonies were not maintained – other investigators had to euthanize animals
What lessons did you learn?

**PROS**

• Patients like telephone consenting for research studies

• Patients enjoyed the flexibility and safety of having bloodwork done at a small lab close to home rather than risk coming to the hospital

**CONS**

• For teaching students / residents, face to face learning and hands-on research cannot be replaced with virtual learning