

THE FUTURE OF CLINICAL RESEARCH AT UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS: INNOVATIONS AND LESSONS LEARNED DURING COVID

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ELAM Sponsor: Dean John J Reilly

ELAM Mentors: Drs. Thomas Flaig and Alison Lakin, Vice Chancellor of Research and Associate Vice Chancellor of Regulatory Compliance

- CU-AMC >\$600M in research grants
- > 4,000 multi-disciplinary clinical research protocols
- Federal Cancer Center, CTSA, DRC, NORC
- University of Colorado Hospital, Children’s Hospital Colorado, VAMC
- Complexity and investigator burden conducting research across institutions

COVID -19 suspended almost all clinical research: new space and research restart authorization processes had to be developed in real time

1. OVERSIGHT



- Existing: Each Center/Institute/Hospital had independent processes and leadership teams
- COVID: The VCR and AVR of Regulatory Compliance assembled committees comprised of key decision-makers from each unit
 - Weekly meetings, joint decision making and policy documentation/ processes , e.g. categorization of protocols based on risk/benefit
 - Members were conduits of information to and from all units
 - Cohesive strategic planning

- Future: How to maintain and sustain stakeholder engagement?

2. COMMUNICATION



- Existing: Meetings with Dean, VCs to align over time
- COVID: New websites, cross referral, coordinated communications
 - Consistency of information across sites
 - New, clear formats developed

- Future: Continue alignment and reliance on oversight committee for coordination

- Existing: Each unit had additional review and approval procedures, beyond Human Subjects Research Portal
- COVID: Each unit individually approved study visits via email, complying with CU-AMC and hospital policies and procedures
 - Common REDCap portal for all research restart approvals
 - Based on Children’s system, leveraged expertise across institutions
 - Real time data and tracking for CU-AMC and hospitals
- Future: Project Manager employed by VCR, redesign Human Subjects Research Portal

3. STREAMLINING



4. COLLABORATION



- Existing: Resources spread across CU-AMC units and hospitals
- COVID: Pivot clinical research resources to allow hospitals to focus on clinical care
 - Redeploy research space and nursing time to hospital for sick line screening, COVID testing and vaccination
 - Research unit space for clinical care and EUA mAb infusions
 - Transfer CReST to VCR office to build comprehensive services
- Future: How to maintain enhanced relationships and work at the speed of COVID?

Work Products: PA. Flume, EF Berbari, L Viera, R Hess, J Higgins, J Armstrong, L Rice, L True, R Shaker, JB Buse. RA Panettieri Jr. (2021) [Managing the risks and benefits of clinical research in response to a pandemic. JCTS, 5\(1\), E105](#); Second, senior author manuscript currently under review.

- This work kept the clinical research enterprise nimble and prepared for all waves of COVID and current and future rapid research funding applications
- Future: Discussing Department of Pediatrics Vice Chair for Research; successful redesign and implementation of Human Subjects Research Portal