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

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• 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

3. STREAMLINING
• 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

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?


• 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