CONDUCTING A COVID-19 VACCINE TRIAL USING CTSA RESOURCES: LESSONS LEARNED

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ABOUT THE VACCINE STUDY

AZD1222 is being developed for the prevention of COVID-19. AZD1222 is a recombinant replication-defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein, commonly known as the “Oxford vaccine” or as “ChAdOx.” We describe a “scale up” approach utilizing CTSA resources to conduct a multisite clinical trial testing a COVID vaccine in the midst of a pandemic incorporating at risk populations.

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SPECIFIC AIM

Assess the safety, efficacy, and immunogenicity of AZD1222, a non-replicating ChAdOx1 vector vaccine, for the prevention of COVID-19 in adults ≥ 18 years of age.

PRIMARY OBJECTIVES

1. Estimate the efficacy of 2 IM doses of AZD1222 compared to placebo for the prevention of COVID-19.
2. Assess the safety and tolerability of 2 IM doses of AZD1222 compared to placebo.
3. Assess the reactogenicity of 2 IM doses of AZD1222 compared to placebo.

https://coronaviruspreventionnetwork.org/

FRONTIERS: KU CTSI PLAN

• Enroll 1,250 participants
• Partner with Children’s Mercy Kansas City’s established vaccine center
• 9 Distinct Enrolling Sites under One CTSA:
  • Rainbow CTSU (main KUMC campus)
  • Fairway CTSU (suburban KUMC campus)
  • Wichita CTU (rural campus)*
  • KC Care (urban FQHC serving downtown Kansas City)
  • Swope Health (FQHC serving African-Americans)
  • TMC Lakewood (extended care facility)*
  • Tabernacle Bible Church (rural)*
  • Dold Foods (Meat packing plant)*

  *Use of mobile van at 5 sites

LOCAL AND REGIONAL COMMUNITY ENGAGEMENT

• Partnered with JUNTOS Center for Advancing Latino Health and the NBC Community Development Corporation for the engagement of Latinx and African-American communities, respectively
• Use of non-traditional spaces
  • Barbershops/beauty salons
  • Grocery stores (“tienditas”)
  • Hotels/Restaurants

LESSONS LEARNED

• Staff Training: considerable amounts of advanced training; multiple walk throughs with dummy participants; additional complexity with multiple vendors; ongoing retraining at each site
• Data Capture: 8 websites for participant-level data capture; one staff dedicated solely to managing data entry
• Labor Intensive at Site-Level: dedicated study supervisor serving as point of contact at each site; scheduling is challenging; consenting is time intensive
• Engaging Community, especially rural sites, is challenging but absolute necessary to do early in planning
• Utilized combined outreach models to target populations
• Communication and broad engagement is key to success
  • Engage community partners early in the development process
  • Engage academic partners and push back CRO when missing the target
• Utilize CTSA infrastructure for: contracts; IRB/regulatory; Clinical Trials Units; community outreach

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