Bringing HIV Study Protocols to Life

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The National Institute of Allergy and Infectious Diseases (NIAID) supports four research networks as part of its HIV clinical research enterprise. The networks are made up of more than 100 clinical research sites, each with local experts, robust research infrastructure and well-trained cross-functional staff who maintain standardized procedures and quality controls aligned with their network.

The HIV clinical trials network sites have made tremendous contributions to the National Institute of Health's scientific priorities by offering direct access to and consultation with populations most affected by HIV globally and by delivering high-quality clinical research with strong connections to trusted community outreach platforms. Their approach to community engagement anchors clinical research sites beyond the scope of any individual study and, when possible, aligns scientific questions and study protocols based on local context.

Since the start of the 2020 research network grant cycle, HIV clinical research sites have enrolled about 93,000 participants across 78 clinical trials in 25 countries. The networks were able to quickly pivot to support NIAID's emerging infectious disease priority areas, including COVID-19 and mpox. Of the 93,000 participants since 2020, about 78,000 were enrolled into COVID-19 clinical trials sponsored by NIAID's Division of AIDS.

Clinical trial sites currently operate with a hub-and-spoke model, with each hub providing centralized support to their linked clinical research sites. This model leverages shared resources where possible and practical and ensures robust oversight to promote high-quality clinical trial operations. Hubs provide infrastructure and services, including laboratory, pharmacy, regulatory, data management and training to support execution of NIAID-sponsored clinical research.

Future networks will need to maintain core strengths of current models while expanding capacity in areas vital to further scientific progress. These include operations that inform pandemic responses and extending our reach within communities impacted by HIV, including populations historically underrepresented in clinical research. Additionally, there may be opportunities for

clinical research sites and other partners to conduct implementation science research based on their capacity and access to relevant populations in the context of specific scientific questions.

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