PPD's Remote Monitoring Strategies Deliver Quality, Continuity and Minimize Trial Disruptions at HIV/AIDS Network Sites During Height of Pandemic

PPD's Expertise and Experience

PPD has a solid relationship with all network sites:

- 25+ year history working with PACTG/IMPAACT, ACTG, HVTN, HPTN, MTN, and non-network sites
- PPD CRAs are trained in HIV/infectious disease/pediatric treatment and prevention protocols globally
- Our regional footprint in Africa, Asia, and the Americas reduce costs and ensures in-country, operational expertise
- We offer in-country regulatory expertise in NA, LA, EMEA, and APAC regions to support country-specific remote monitoring requirements, including pediatric age-based regulations in all four regions
- Our clinical expertise spans multiple EDC systems for data capture and monitoring needs, including Veeva Site Vault, Medidata, NIAID CRMS, REDCap, and others.

MONITORING CHALLENGES

- COVID made on-site monitoring nearly impossible, thus all had to quickly pivot to remote source data verification (SDV)
- Regulatory requirements differ by country and by patient population (pediatrics vs. adult), which required a customized monitoring approach
- Clinical EDC systems differed by protocol – Veeva Site Vault, Medidata, NCRMS, REDCap, and others
- Preparing for remote monitoring visits was labor intensive and very time consuming for the site staff
- Site timeline challenges and other delays in a select number of network sites that were monitored by another Sponsor-selected CRO who had limited experience in remote monitoring and lacked the depth of site relationships that PPD has
- Other CROs did not have the internal processes set up nor regulatory and ethics approvals in place to seamlessly switch between remote, on-site, and hybrid monitoring strategies for the fluid COVID-19 situation

In Q1 2020, PPD clinical and regulatory teams worked with 300+ sites to successfully pivot to remote monitoring for 64 global protocols

PPD STRATEGIES

- **Resource ramp up** – re-prioritization of resources across active protocols, with some monitors working cross-region, to supplement local teams from across the globe
- **Re-prioritization** of workload within a visit, and utilizing effective planning beforehand, including notifying the staff of the order of work for the upcoming visit, ensuring that they had all of the required documents uploaded in time for the visit and in respect for their limited time
- **Leveraging PPD's strong site relationships** to drive remote, on-site, and hybrid monitoring preparation and execution throughout the fluid COVID-19 situation
- Team **experience and ability to adopt** to the use of a complex system, using 2+ systems per site to perform source and CRF review