

Remote monitoring

Supporting database freezes more than two years sooner than planned for two HIV prevention trials network PrEP studies

Background

Despite the COVID-19 pandemic causing major biopharma industry disruptions, our remote monitoring strategies supported the acceleration of FDA drug approval during the height of the pandemic. Our team supported an accelerated FDA approval of a new long-acting injectable HIV PrEP drug by two years, even though clinical sites, and site resources, were operating at a disadvantage during the height of the pandemic. This case report reviews the success of HPTN 083 (cisgender men) and HPTN 084 (HIV-uninfected women), which enrolled a combined 7,000+ patients across approximately 60 global sites (NA, LA, EMEA, APAC).

Challenges

High-effective data read out by the drug safety monitoring board (DSMB) resulted in the decision to stop the studies early and advance to open label use:

- **HPTN 083:** March 2023–Nov 2020
- **HPTN 084:** Jan 2023–April 2021
- Data needed to be cleaned within a 6-month period, resulting in the review of 1,200+ participants on HPTN 083 and 900+ participants on HPTN 084

Our remote monitoring team strategies allowed us to review 1,400+ charts remotely in 6-months and handle 800+ data queries.

Solution

With the benefit of our capacity management systems and practices, we were better equipped to handle the uncertainties of COVID-19:

- Additional monitoring resources were re-prioritized and allocated to both studies from less active studies to support remote source data verification (SDV) needs
- 1,400+ charts were reviewed remotely in a 6-month period across both studies
- 800+ data queries were addressed, many in 10 business days prior to database freeze

We implemented remote SDV strategy in 30 days at 40+ locations to overcome COVID-19 site visit restrictions.

Results

Our seamless work with the data center ensured that quality data was being received and queries were managed in an expedient fashion. The two HIV PrEP studies met their accelerated data lock target dates and FDA approval of the new long-acting PrEP drug was approved in 2021.

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