Case study

Clinical trials

Our experience accelerates startup, delivers 3x faster and more patients on NIAID/DAIDS-ACTG COVID-19 ACTIV-2 outpatient platform trial

Background

The PPD™ clinical research business of Thermo Fisher Scientific's extensive feasibility and preferred site networks accelerated the startup of the NIAID/DAIDS-ACTG COVID-19 ACTIV-2 platform trial, despite the challenges and uncertainties that existed at the height of the COVID-19 pandemic. The COVID-19 outpatient treatment master protocol enrolled 4,000+ patients (>1,600 Ph II + >2,400 Ph III) across 8 IPs provided by 7 different companies over an 18-month period, including a placebo arm later replaced with an active comparator arm.

400,000 global sites considered via our database assessment, 7,000 sites contacted, resulting in 1,000 sites interested, 447 sites qualified, and 263 sites activated in 22 counties

Startup and enrollment challenges

Feasibility and site selection:

- Finding new sites with the ability to support IP handling with varying routes of administration
- Finding sites with dedicated areas to see COVID-positive patients
- Selecting sites meeting government requirements/qualification needs
- Varying protocol requirements which led to the largest feasibility we have never performed

Adapting to the COVID-19 landscape:

- Epidemiology changes – fluctuations in patient population potential based on virus evolution and vaccine roll-out
- Limited IP – limitation on regional recruitment in specific phases for certain IPs, due to IP provider restrictions, IP availability, and country approved devices to be utilized in administration of IP
- New lab requirements – local lab attestation needed for COVID-19 testing at non-US sites
- Equipment limitations – e.g., laminar flow hoods, due to pandemic supply chain issues
- Frequently changing platform design – changing strategy due to the data safety monitoring that stopped some IPs and progressed others, thus sites had to adapt to multiple amendments and protocol design change

Strategy

- Seamless startup team approach
- Closely coordinated with DAIDS to make swift and data-driven decisions on site selection needs
- Included 24 of our top performing sites, 9 AES sites, and 6 TransCelerate sites, resulting in expedited startup through master CDAs & pre-established site relationships
- Support recruitment goals by utilizing 38 ACTG sites with positive DAIDS' network experience and contracts to expedite study reviews and decisions to facilitate activation
- All other sites chosen via extensive/targeted feasibility; these

sites are performing well on the trial

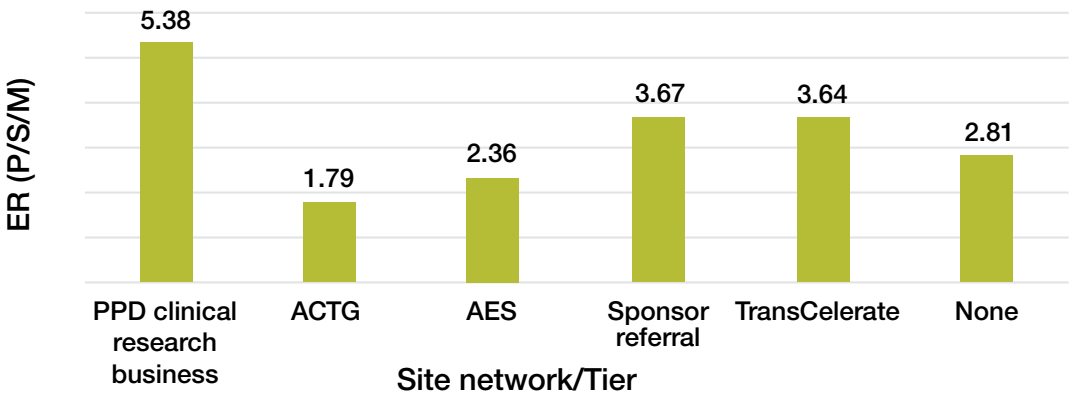
- Our internal data innovation team developed custom dashboards to track trial performance, giving the team the ability to oversee the critical startup activities and enrollment performance across all sites.green light for screening

Results

The study successfully completed five SAD (plus extension) and three MAD cohorts on time. Transparency and trust from the client allowed our team to successfully manage the complex study.

Site network results

Select network sites were activated in approximately **105 days** based on master CDAs and contract templates already in place, enrolling more patients **1.5X to 3X** faster than other site networks.



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