A Data Driven Approach to Coordinate Challenging Smallpox Vaccine Logistics

The Specific Situation

- A randomized, double-blind, placebo-controlled Phase III smallpox vaccine immunogenicity and safety study needed to enroll 4,000 healthy subjects across 34 sites in the US, for a trial lasting up to nine months.

- The Sponsor selected Chiltern to perform full services, including coordination of the Data Monitoring Committee.

- The study design required separate masked and unmasked personnel and study procedures and an atypical resourcing strategy given the uneven enrollment rates.
A Customized Solution

- Deploy a customized Collaborative Technologies solution to facilitate strict masked and unmasked data control based on project-specific roles and responsibilities. This included adapting the Chiltern SAFE eTMF for unblinded and blinded document management, setting up the endpoint IRT for medication distribution and notifications and establishing secure areas for coordinating and communicating directly with the Data Monitoring Committee (DMC).

- Use customized EDC reporting to calculate real-time source document verification status. Compare actual monitoring time required from prior visits to forecast optimal timing and duration of subsequent visits based on data available to monitor.

- Ramp up and down CRA resourcing at exactly the right times based on predicted monitoring. Add co-monitors to supplement efforts at high volume sites and for maintaining masked / unmasked tasks.

- Develop and deliver site-specific recruitment plans prior to site initiation to ensure investigators and coordinators buy-in to recruitment objectives. Send monthly enrollment status notifications to generate competition among sites and hold sites accountable for their performance.

The Positive Outcomes

*Focusing from the outset on the resources necessary for successful enrollment and monitoring led to creation of a flexible and extremely effective staffing model. Similarly, understanding the technological implications of combining blinded and unblinded activities enabled Chiltern to implement a data infrastructure that was both secure and accessible.*

- Enrollment was completed 2 months ahead of schedule.

- Proactive process development and site outreach boosted site engagement.

- Accurate forecasting of the number and length of monitoring visits allowed CRA resources to be adjusted in real-time throughout the trial.

- Chiltern has been selected for 2 subsequent projects, and the Sponsor continues to approach Chiltern for repeat business.