

## **The Truth of the Matter Blog Series**

### **Vaccines and Infectious Diseases**

#### **When Time Is of the Essence, It's Essential to Pick a CRO with the Right Experience**

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Imagine there is a sudden outbreak of a novel disease with no known vaccine or treatment. Or, although a tested vaccine is available, there is not enough supply to effectively counteract the swift spread of the disease.

Sadly, we can imagine those scenarios only too well as we have seen both in recent years with the COVID-19 pandemic and outbreaks of other infectious diseases, such as mpox (formerly known as monkeypox).

When an outbreak occurs, urgent action and joint efforts with a trusted and experienced partner is imperative to act quickly and efficiently.

The Emmes Group has contributed to the response of major health crises since the 1980s. Through these experiences, our team has developed rapid response capabilities that allow us to take action urgently and decisively during emergent pandemic situations.

When time is of the essence, our team implements innovative approaches to expedite study startup. Some recent examples include our involvement with vaccine studies led by government and biopharma companies.

A recent open-label, Phase II study of a vaccine for mpox was initiated to investigate if a smaller dose from the limited supply of vaccine would be as effective as the traditional dose. For this study, we shortened the startup timeline without compromising quality or patient safety in any of the steps. The Emmes team utilized our established library of forms with a rolling approach to draft and complete as needed – rather than waiting to deliver any forms until all were complete. Taking this approach, we were able to review the protocol and Informed Consent Form (ICF) in one day and finalize the electronic Case Report Forms (eCRF) specifications in less than 10 days. Two days later, we deployed Advantage eClinical, the industry's first fully unified eClinical platform, with the randomization module and critical safety eCRFs. We continued releasing the remaining eCRFs on a rolling basis throughout the startup period.

By streamlining and innovating processes while pursuing multiple workstreams in tandem, Emmes was able to prepare the study to go live just 12 days after protocol finalization. Following this expedited startup process, enrollment for the first stage of the two-phase study was completed in approximately one month.

When an outbreak of an infectious disease occurs, it may become prevalent in a new demographic group or geographic area. For example, instances of a disease that had primarily been seen in adult populations may suddenly increase among adolescents. These scenarios also require urgent responses. With our wealth of vaccine trial experience and biostatistics expertise, we provide statistical considerations and trial design recommendations to help sponsors select and reach the endpoints needed for these shifts in study populations. In a recent trial, we developed customized demographic reports that were updated three to four times daily to ensure the trial stayed on track with the demographic goals of the sponsor.

Using a combination of established tools and processes and a proactive approach to customization and innovation, the Emmes team works with speed and flexibility to meet sponsor needs and timelines for vaccine trials.

Through our individual roles in data and project management for the Emmes Group, we are proud to stand shoulder-to-shoulder with sponsors, clinicians, patients, and healthy volunteers in these critical situations – all working urgently with a common purpose: to make the world a healthier place for us all.

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To learn more about the Emmes Group's vaccines and infectious disease experience and capabilities, please visit us online at <https://www.emmes.com/vaccines-and-infectious-diseases>.