

Capabilities in Vaccine Studies

Vaccine Expertise

Health Decisions has conducted clinical trials of prophylactic and therapeutic vaccines for a variety of indications, including influenza, cytomegalovirus and human immunodeficiency virus. The methods that Health Decisions has developed for such studies are ideal for early phase studies of many types of prophylactic vaccines, including:

- Cytomegalovirus
- Hepatitis A, B and C
- Herpes Zoster
- HIV
- HPV
- Influenza, inc TIV, H1N1
- Meningococcal Meningitis
- Pneumococcus
- Rotavirus
- Streptococcus
- Varicella

Health Decisions offers compelling advantages to sponsors of vaccine studies. Although reducing time to market is important in all therapeutic areas, vaccine studies present their own unique timeline challenges. Deadlines are often determined by seasonality or the spread of disease. Furthermore, it is difficult to compress timelines in both the early and late stages of vaccine development and production. Health Decisions has optimized many of the time-critical operational processes in clinical testing of vaccines, especially in early phases.

Advantages in Vaccine Trials

- Real-time access to reactogenicity data
- Ability to ensure rapid data availability and processing and ensure timely response by DSMB/SMC
- Access to sites and subjects through our network of proven enrollers, enabling us to meet challenging enrollment deadlines
- Proven techniques for rapid study startup, including CRF setup, database development and site selection
- Timely site and study performance metrics to ensure that investigative sites submit data promptly, follow study procedures closely and meet schedules
- The option to use electronic source documents, greatly reducing monitoring and source-data verification costs and accelerating site closeout and database lock

Data-Driven Insight and Expertise

Whether advising on overall development strategy, program planning and study design, or planning individual trials and ensuring optimal trial management and execution, Health Decisions' senior professionals use their extensive development expertise, experience, and advanced data-driven analytics to provide insights that improve planning and execution of every Health Decisions study. Health Decisions' systems and processes provide streaming data and role-specific information that enable earlier, better decisions at all levels of trial management and execution throughout the life-cycle of each study.

Case Study: Prophylactic H1N1 Influenza Vaccine

Rapidly Evaluating the Safety, Reactogenicity and Immunogenicity of a Novel H1N1 Influenza Vaccine Candidate

Study Compound: Novel H5N1 influenza vaccine

Phase: 2

Active Sites: 2, U.S.

Patients Enrolled: 80

Patient Population: Healthy adults 19 – 49 years old

Study Design: Evaluate the safety, reactogenicity and immunogenicity of X given in the same arm with the standard influenza vaccine in healthy adults

Challenges Faced:

- Ensure rapid enrollment to meet demanding timelines – the study had to be completed before the impending expiration of the standard influenza vaccine that was administered with the test vaccine.
- Complete evaluation of safety, reactogenicity and immunogenicity in time to allow high-volume manufacturing in the event of favorable results
- Provide same-day access to safety and reactogenicity data to identify any issues rapidly and prevent enrollment and dosing delays
- Minimize monitoring costs to remain within the sponsor’s budget constraints while also ensuring high data quality
- Tightly manage operations based on real-time metrics to prevent operational glitches that might lead to delays.

Risk Management and Mitigation: Health Decisions utilized innovative data-capture technology to provide same-day access to safety and reactogenicity data and electronic source documents. Rapid access to such data enabled completion of enrollment in three weeks. In addition, electronic source documents enabled substantial use of remote monitoring, thus limiting monitoring costs. The use of electronic source documents also reduced the need for manual data entry and data transcription from paper source documents, increasing data accuracy and reducing the need for source data verification. The sponsor was able to evaluate the novel vaccine rapidly. Safety and reactogenicity results were favorable.

The CRO of Choice for Forward-Looking Biopharma and Medical-Device Companies

Health Decisions is the CRO of choice for forward-looking biopharma and medical-device companies and a driving force in the modernization of clinical development. Health Decisions uses data-driven insight and agility to deliver clinical development success, reduce timelines and risk and increase quality and returns for biopharma and device companies worldwide. For 25 years and in more than 300 clinical trials involving tens of thousands of patients in many therapeutic areas, Health Decisions has improved the efficiency of clinical development through innovative methodology, processes and technology. Health Decisions’ clinical-development services have enabled biopharma and device companies to bring new products to market faster and at lower cost, thus providing the public with earlier access to improved treatments and diagnostics at more affordable prices. Health Decisions received the 2014 ACRP Award for Innovation in Clinical Research and was a 2013 CIO 100 Award Honoree for delivering true business value through its innovative Agile Risk-Based Monitoring+ technology. Health Decisions is headquartered in Durham, NC and operates on five continents.



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