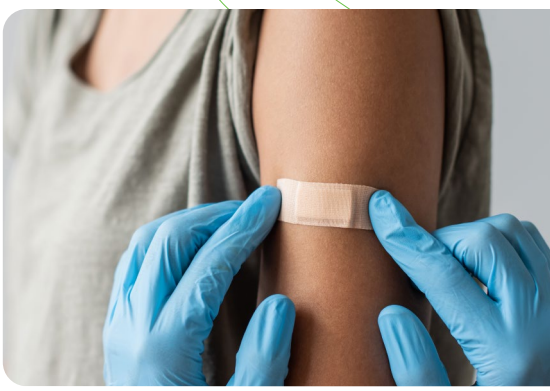
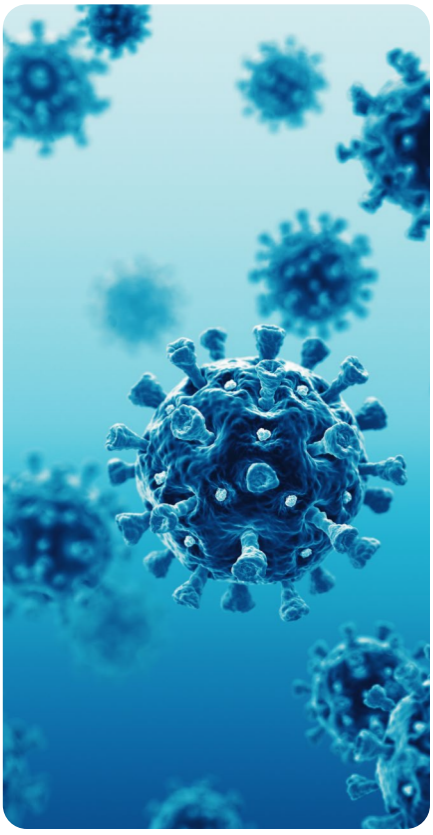
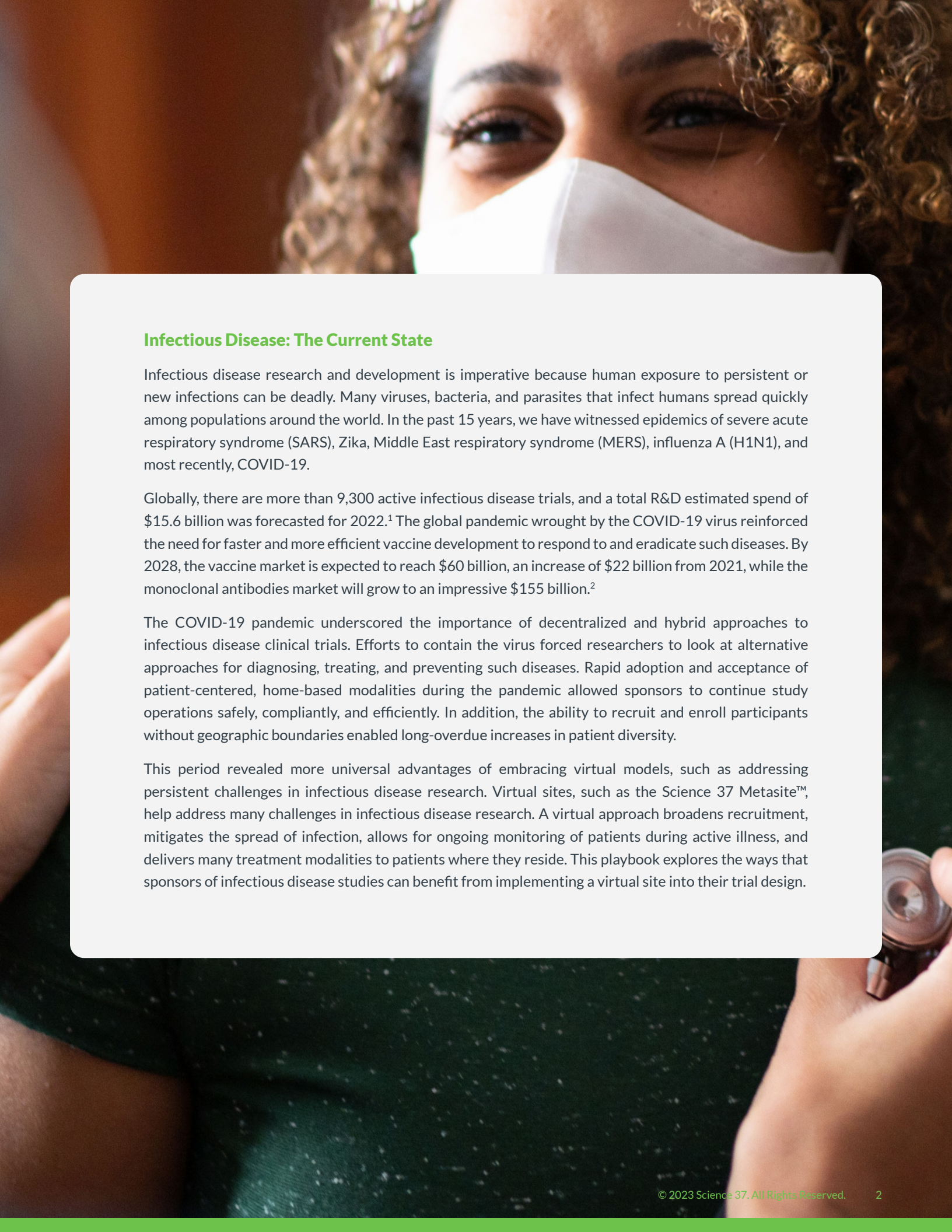
Science37

THE INFECTIOUS DISEASE CLINICAL TRIAL PLAYBOOK

How to Operationalize Infectious Disease Trials with a Virtual Site.







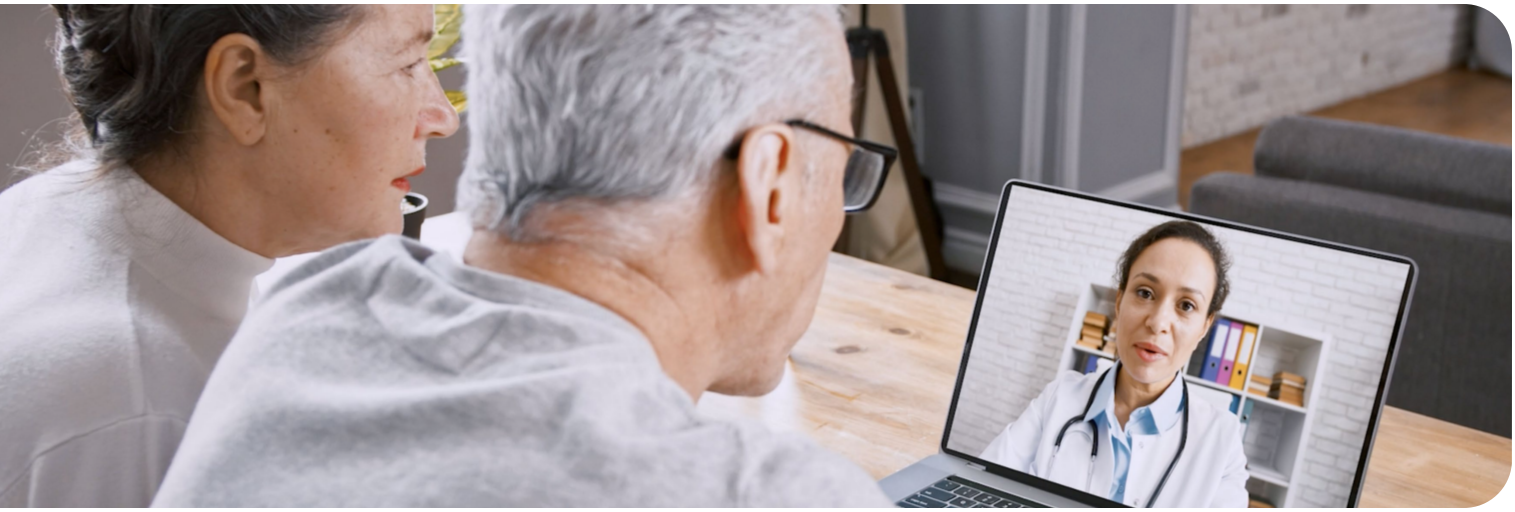
Infectious Disease: The Current State

Infectious disease research and development is imperative because human exposure to persistent or new infections can be deadly. Many viruses, bacteria, and parasites that infect humans spread quickly among populations around the world. In the past 15 years, we have witnessed epidemics of severe acute respiratory syndrome (SARS), Zika, Middle East respiratory syndrome (MERS), influenza A (H1N1), and most recently, COVID-19.

Globally, there are more than 9,300 active infectious disease trials, and a total R&D estimated spend of $15.6 billion was forecasted for 2022.[1] The global pandemic wrought by the COVID-19 virus reinforced the need for faster and more efficient vaccine development to respond to and eradicate such diseases. By 2028, the vaccine market is expected to reach $60 billion, an increase of $22 billion from 2021, while the monoclonal antibodies market will grow to an impressive $155 billion.[2]

The COVID-19 pandemic underscored the importance of decentralized and hybrid approaches to infectious disease clinical trials. Efforts to contain the virus forced researchers to look at alternative approaches for diagnosing, treating, and preventing such diseases. Rapid adoption and acceptance of patient-centered, home-based modalities during the pandemic allowed sponsors to continue study operations safely, compliantly, and efficiently. In addition, the ability to recruit and enroll participants without geographic boundaries enabled long-overdue increases in patient diversity.

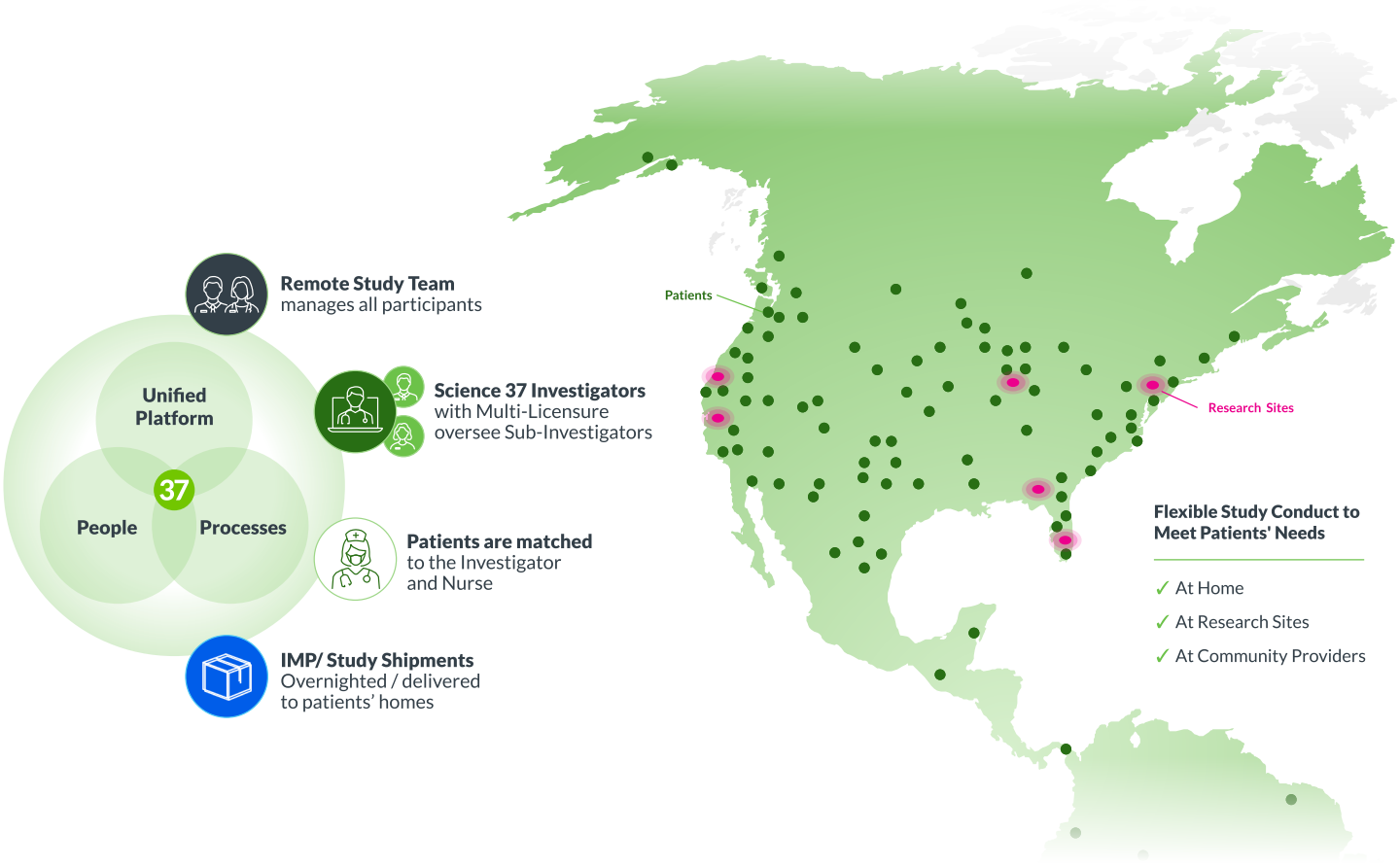
This period revealed more universal advantages of embracing virtual models, such as addressing persistent challenges in infectious disease research. Virtual sites, such as the Science 37 Metasite™, help address many challenges in infectious disease research. A virtual approach broadens recruitment, mitigates the spread of infection, allows for ongoing monitoring of patients during active illness, and delivers many treatment modalities to patients where they reside. This playbook explores the ways that sponsors of infectious disease studies can benefit from implementing a virtual site into their trial design.



Opportunities with Virtual Sites

Sponsors can add a virtual site to an existing trial or deploy it as a stand-alone site. Unlike onboarding traditional brick-and-mortar sites, a virtual site can be launched quickly and integrated seamlessly so patients and providers can access clinical trials — regardless of geographic location.

Virtual sites, such as the Science 37 Metasite™ offer a patient-centered approach that applies decentralized tools across the clinical trial journey, allowing patients to be recruited from anywhere and seen in the comfort of their own homes or at a nearby clinic. To reduce patient burden, clinical trial protocols are being designed to leverage telemedicine, mobile nursing, direct-to-patient shipping, and direct-from-patient biospecimen collection.



The Metasite Powers Infectious Disease Trials Like Never Before

Access Patients Beyond Site Geography

The average patient lives two hours from a traditional site, which limits participation. With a virtual site, a sponsor can reach any patient. A virtual site reduces geographic, financial, and other barriers to participation. This improves equity across all racial, ethnic, and socio-economic populations.

Enable Omnichannel Recruitment

A multi-prong recruitment strategy allows sponsors to screen, enroll, and retain a larger, more diverse population than traditional sites can offer. Depending on the study protocol, Science 37 helps sponsors recruit participants through a global network of outreach providers that includes patient advocacy groups, testing centers, and retail pharmacy partners. The ability to access such broad sources of participants is important when stratified, targeted sub-populations are required, such as for preventative studies.

Collaborate with a Premier Medical Affairs Team

The medical affairs team consists of physicians with a broad range of therapeutic expertise. Internists, neurologists, dermatologists, pulmonologists, and oncologists are available to collaborate on complex trials in most clinical indications. In addition, Science 37 has relationships with key thought leaders around the globe to support clinical trial execution.

Mitigate the Risk of Spread

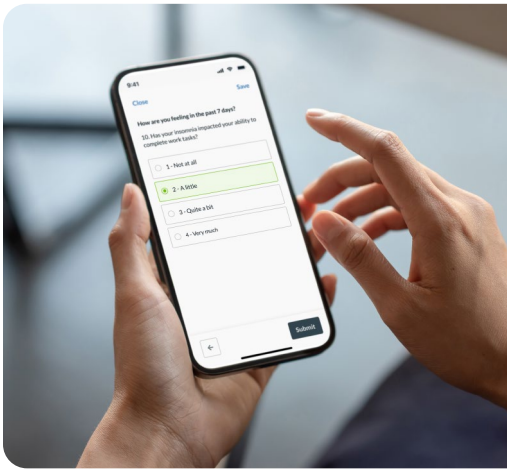
Patients can participate in trials from their homes—mitigating the type of exposure that can occur at a brick-and-mortar site and reducing the spread of the infectious disease. After carefully evaluating safety protocols and potential risk factors, sponsors can provide investigational medicinal products and rescue medications for self-administration.

Monitor Patient Safely

To mitigate the potential risks of trial medications, telemedicine and mobile healthcare networks preform remote management and patient monitoring. Physicians, mobile nurses, and research coordinators are trained in the study protocol to identify and respond to adverse treatment reactions. Telemedicine investigators are supported by the team while performing adverse assessment grading, attributing toxicity, and adjusting doses. Studies utilize electronic patient-reported outcomes and data from sensors and wearable devices to track new and worsening symptoms. Further, at-home patient administration kits typically include rescue medication to address acute reactions.

Collect Endpoint Data from Anywhere

Vital sign capture and patient self-reporting can occur from anywhere, with data accessed continuously through evidence collected by eCOA/eDiaries, eSource, connected devices, or in-clinic technology. By leveraging remote data collection, travel and site visits are reduced —improving the experience for infectious disease patients who may suffer from therapy-related side effects. Participants can reach community providers through the Science 37 platform, enabling near-instantaneous responses to their concerns. The model greatly enhances sponsors' ability to detect and evaluate adverse events.



Deliver Flexible Treatment Options

Infectious disease studies often require administration of biologic agents per protocol. Science 37 has extensive experience in delivering both vaccines and antibodies directly to a participant's home by maintaining cold chain combined with the monitoring of IP that requires these considerations. Whether administering treatment in a participant's home or at a defined local facility, a strict chain of custody of all medication and intensive supervision of all study activity is ensured.

ACCELERATE AND IMPROVE CLINICAL RESEARCH

Science 37 has enabled:

3-4 MONTHS Faster Trial Startup

96%+ Patient Retention

3x Patient Diversity

The Metasite Addresses Complexities in Vaccine/ Infectious Diseases Prevention Studies

Precision Delivery: Temperature-Controlled IMP

Pharmacy manuals are reviewed to understand the transportation requirements of IMP, with Science 37 adapting the direct-to-patient journey accordingly. Specially designed packaging, precise chain of custody methods, and continuous temperature monitoring ensure that IMP is delivered to the home untampered and ready for administration.

Seamless Coordination: Harmonizing Multiple Schedules

Protocols dictate how IMP is prepared and administered. Science 37 provides either a one-or two-nurse solution to dosing, depending on IMP requirements. If it requires blinded preparation or administration, one nurse prepares the IMP in a secure fashion and the second nurse administers the IMP in a blinded fashion. If the IMP is sent to the home already prepared and blinded, or if the IMP is given in an open-label fashion, only one nurse is deployed to the home. Based on the pharmacy manual and protocol, Science 37 orchestrates the scheduling of the nurse(s), the investigator, the coordinator, and the participant for a well-prepared and seamless visit.

Unwavering Safety: Protecting Participants Post-Injection

As safety is our number one priority, post-dosing monitoring is done with the nurse at the participant's side, while the investigator observes through telemedicine in real-time. Should an adverse event occur, Science 37 nurses are equipped with medication appropriate for reactions—Epipens, Solumedrol, Benadryl, and Albuterol. Rescue medications are adjusted based on IMP requirements.

Faster, More Inclusive, and Patient-Friendly Clinical Research

The Science 37 Metasite improves access, lowers patient burden, and streamlines treatment delivery and administration. It provides virtual trial capabilities across the spectrum of infectious disease studies, including immunization, pre-and post-exposure, prophylaxis, and therapy. Increasingly, sponsors are witnessing accelerated and more efficient clinical trials.

Recruit patients from anywhere via digital outreach and provider partners

Enroll and retain a representative population to increase success rate of prophylaxis research

Connect the right treatments with affected patients to mitigate or treat the impact of infectious diseases

Pre-exposure **Post-exposure**

Reach a broader patient cohort while studying immunization effectiveness

Support long-term follow-up of vaccine effectiveness through a unified experience

Administer treatments safely and conveniently with direct-to-patient approach

CASE STUDY

The Science 37 Metasite in Action: Accelerating Enrollment for an Infectious Disease Trial.

A biopharma company was conducting a phase II randomized controlled trial for an infectious disease. The protocol required the participation of high-risk comorbidity patients ages 65+ or 18+ that tested positive with symptom onset within a short timeframe. In addition, the sponsor cited concerns with the oversaturation of competing studies, participant unwillingness to travel to a site because of illness, and the risk of infection control. The sponsor also wanted a diverse and representative population for the study.

Science 37 was able to implement this study and address all of the sponsor's concerns. Science37 delivered a Metasite with broad recruitment through digital outreach and involvement with our community-based provider network. Supplies and IMP were shipped directly to the patients and biospecimen collection was done in the home under the supervision of our telemedicine team. Our decentralized approach facilitated robust recruitment and rapid enrollment. We delivered a solution that enabled sick patients to be treated at home and that delivered high-quality data from a diverse population of participants.

✓ **Virtual Telemedicine Investigators** ✓ **In-Person & Virtual Participation** ✓ **Unified Platform**

The Results

- 450+ participants screened
- >86% enrollment
- 94% retention rate
- 13 community provider locations

Science 37 enrolled more than 86% of all study participants through the Metasite (with 12 brick and mortar sites delivering 14%).

This accelerated approach resulted in a more than 3-year reduction of the clinical trial timeline.

Let's Talk

Accelerate your clinical research with the Science 37 Metasite.

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Dr. Weinstein graduated with honors from the University of Pennsylvania in 1983 & received her medical degree from the New York University School of Medicine in 1987. In 1990, she became a diplomat of the American Board of Internal Medicine. She practiced internal medicine in Palm Beach County for 16 years and was recognized as #39 on the Top Internists by *Town and Country* magazine in 2000. She is an active member of the Academy of Clinical Research Professionals, The American Medical Women's Association. The American College of Physicians and The National Association of Professional Women recently awarded Dr. Weinstein "Woman of the Year" for her contribution to the field of medical research.

Sources

[1] *Vaccines Market Size, Trends, and Forecast to 2028.* Retrieved October 27, 2022, from https://www.coherentmarketinsights.com

[2] *The Future of Monoclonal Antibodies Market Economy Size Expected a Growth of USD 155.2 Billion by 2028; According to Vantage Market Research.* Retrieved October 27, 2022, from https://www.globenewswire.com/en/news-release/2022/06/28/2470166/0/en/The-Future-of-Monoclonal-Antibodies-Market-Economy-Size-Expected-a-Growth-of-USD-155-2-Billion-by-2028-According-to-Vantage-Market-Research.html#:~:text=The%20Monoclonal%20Antibodies%20market%20was,2028%3B%20based%20on%20primary%20research

About Science 37

Science 37 Holdings, Inc.'s (Nasdaq: SNCE) mission is to accelerate clinical research by enabling universal trial access for patients. Through our Metasite™ we reach an expanded patient population beyond the traditional site and deliver the recruiting power of up to 20 sites in one with greater patient diversity. Patients gain the flexibility to participate from the comfort of their own home, at their local community provider, or at a traditional site when needed. Our Metasite is powered by a proprietary technology platform with in-house medical and operational experts that drive uniform study orchestration, enabling greater compliance and high-quality data. To learn more, visit www.science37.com, or email science37@science37.com.

