

Category

Best Digital Health Solution

General Information**Company Name ***

Science37

Number of employees *

1-10

Turnover and/or Funding

N/A

words remaining :

500

Product/Solution Name *

The Science 37 Metasite™

Corporate Name ***Date of Approval ***

2022-12-31

Indications *

Atopic Dermatitis

Acne Vulgaris

Psoriasis

Pemphigus Vulgaris

Rosacea

Herpes Labialis

Netherton Syndrome

Lupus erythematosus

Major Depressive Disorder

Postpartum Depression

Post-Traumatic Stress Disorder (pharmacological and psychotherapy tx)

Schizophrenia

Bipolar Disorder

Impulse control disorders

Alzheimer's Disease and MCI

MS Biomarker

Pediatric RLS

Late-Onset Tay Sach's
Phase I/II Homocysteinuria (Will be starting Phase III Homocysteinuria)
Phase III Phenylketonuria
Parkinson's Disease
Restless Leg Syndrome
Huntington's Disease
Seizure
Migraine
MS Biomarker
Pediatric RLS
Late-Onset Tay Sach's
Phase I/II Homocysteinuria (Will be starting Phase III Homocysteinuria)
Phase III Phenylketonuria
Parkinson's Disease
Restless Leg Syndrome
Huntington's Disease
Seizure
Migraine
Refractory Chronic Cough
CRSwNP + Asthma
Pulmonary / Respiratory Complications in Patients with NMD
COPD
COVID-19 Treatment
COVID-19 Prevention
RSV prevention
Clostridium Difficile
Vaccine Development
Precision oncology trials
Population health and early detection studies
Long term follow up for Cell/Gene therapy
Expanded access protocols
Atherosclerosis
Hyperlipidemia
Hypertension
Coronary artery disease (CAD)
Familial hypercholesterolemia
Atrial fibrillation
Rare (i.e. Ehlers-Danlos Syndrome)
Late Onset Tay-Sachs and Sandhoff disease (III)
Cholestatic pruritus due to primary biliary cholangitis (III)
Vascular Ehler-Danlos Syndrome (III)
Congenital Adrenal Hyperplasia (pre-screening for gene therapy)
Homocystinuria (natural history, I/II, III)
Pemphigus Vulgaris (IIIb)
Congenital Sucrase-Isomaltase Deficiency (VI)
Phenylketonuria (III)

words remaining :

309

Therapeutic Areas *

Respiratory

Cardiology

Rare Disease

CNS (Psychiatry and Neurology)

Dermatology

Endocrinology

Oncology

Infectious Disease

words remaining :

487

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Therapeutic Area Expertise.pdf](#)

Background information and need for drug / device**(please be as specific as possible in your description; limit 500 words)**

Imagine being a patient in a clinical research study, who must travel 67+ miles each way to access potentially life-saving treatments.

The Science 37 Metasite, solves the patient access dilemma, through a virtual site that allows patients to access clinical trials, regardless of location. It combines the necessary technology (eConsent, eCOA, Telemedicine, and Connected Devices/Wearables) as part of a unified platform, with mobile healthcare, telemedicine investigators, and community clinics needed to reach patients where they are. This combination allows patients to be enrolled and seen in the comfort of their own homes rather than co-located to a traditional site enabling the end-to-end clinical trial.

Using the Metasite, patients can perform most of the functions needed in a clinical trial from an app that can be downloaded onto their personal devices. From the app, patients can easily enroll in a study, schedule telemedicine appointments with investigators, and input valuable patient data (eCOA/ePRO).

A mobile healthcare team and/or community-based clinics can also be integrated where vitals or other services are involved. Medical professionals travel to a patient's home to perform services, while community-based clinics support study procedures such as diagnostic imaging, which cannot be performed in a patient's home. The Science 37 Metasite uses one Form 1572 and one IRB submission for all 50 U.S. States.

The Science 37 Metasite transforms clinical research by meeting patients where they are, providing convenience and flexibility. It delivers personalized care, with acute attention to detail, while accessing a patient population that mirrors census, with broad demographic, gender, and racial representation-leading to a more diverse and inclusive participant base to meet regulatory guidelines.

The Metasite is transforming research across therapeutic areas. In oncology, the Metasite has enabled:

- Remote clinical research for precision medicine studies delivering access to disadvantaged communities. Science 37 recently launched a hybrid trial with an oral targeted agent, looking for a rare tumor population -which was able to enroll patients across the United States.
- In early detection trials, we are improving access to patients that otherwise would not have been able to reach traditional research sites, improving the diversity of trial participants.
- In a hybrid breast cancer study, we reduced patient burden tremendously, providing treatments at home every 3 weeks. With early breast cancer patients receiving up to 18 cycles over the course of 12.5 months, bringing the treatment to the patient, significantly reduced patient burden, improving retention. The magnitude of this trial is summed up perfectly in what the Medical Director stated "All clinical trials are special but this one is above and beyond anything I have seen in my oncology career." A patient in this trial said " I was vulnerable to infection, so being able to get top-notch oncology care without having to drive to the clinic meant the world to me."

Some other recent innovation that Science 37 has delivered with the Metasite, includes:

- The launch of our first trial using remote, in-home spirometry for a top pharma company's asthma trial. Our team coordinated training of mobile nurses to ensure the quality of data resulting from the remote spirometry was of the highest standards.
- The operationalization of 60-hour, at-home infusions for a postpartum depression study. The magnitude of this study in terms of reducing patient burden (for new mothers) in itself is groundbreaking.
- The decentralized arm of a pivotal Phase III atrial fibrillation trial for a top pharma company.

The Metasite delivers:

- Patient recruitment and retention rates that surpass industry standards. In one study the entire enrollment goal was met within 10 days of study launch, significantly impacting study timelines. In other studies, the Metasite has delivered patient retention rates upward of 90%, and in one instance a 100% retention rate.
- Mobile nursing visits with the highest standards. In a recent breast cancer trial, we delivered more than 2,000 home nursing visits-without a single missed visit!
- Support of studies of all sizes. In one study we collected 25,000 medical records, but we have also helped studies in need of rescue delivering just a few hard-to-find patients that make the biggest difference.

The possibilities with a Metasite are endless, and Science 37 is helping the industry advance by creating a model that not only accelerates research but puts patient needs first.

words remaining :

-210

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [S37_Metasite_Brochure_2023_Mar3.pdf](#)

History of the development of the solution/product *

(please be as specific as possible in your description; 500 words)

Science 37 launched in 2014, as the pioneer in Decentralized Clinical Research. Through the Metasite, Science 37 is reaching a level beyond DCT technology, by bringing trial conduct into patient homes.

words remaining :

469

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Science 37 Dermatology Playbook.pdf](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

The Science 37 Metasite is dramatically improving clinical trial access and equity, by eliminating a key barrier to participation which is travel and distance. By bringing trials to the patient's home, and leveraging mobile nurses and telemedicine investigators, sponsors are seeing recruitment, enrollment, and retention rates that far surpass industry standards. We are seeing startup times of under 12 weeks, which accelerates research for all parties involved. We are delivering a proven virtual site model that works for everyone. The Metasite represents a significant step forward in addressing the challenges facing the clinical research field, and its potential impact on the future of healthcare cannot be overstated.

words remaining :

393

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [How Science 37 Accelerated Enrollment for a Diagnostic Oncology Trial.pdf](#)

Please provide appropriate references (PubMed, Abstract, Website) *

Below are some medical publications that feature some of our work and studies, in addition to posters presented at medical conferences.

<https://ascopubs.org/doi/full/10.1200/JCO.22.00358>

<https://dcricri.org/ipersonal-launch/>

https://www.science37.com/sites/default/files/2022-11/S37_MADRS_Poster_Web.pdf

<https://www.science37.com/sites/default/files/2022->

06/S37_ASCP_Poster_ChrisReist_3000x2000px%20(1).pdf

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [InDepth Experience.pdf](#)