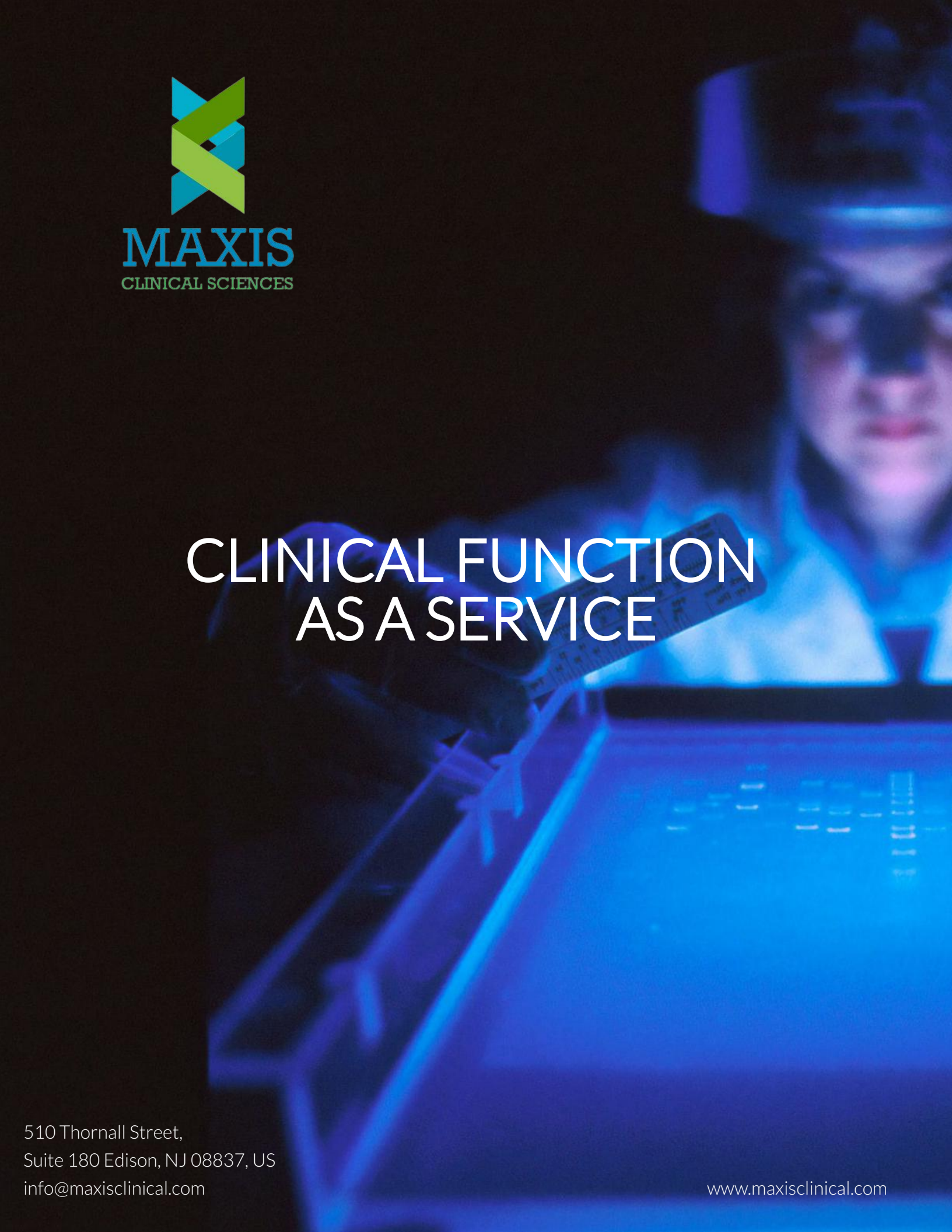


MAXIS
CLINICAL SCIENCES

CLINICAL FUNCTION AS A SERVICE

510 Thornall Street,
Suite 180 Edison, NJ 08837, US
info@maxisclinical.com

www.maxisclinical.com

BACKGROUND

For the past 2 decades, Maxis Clinical has followed a paradigm of providing life sciences and healthcare sponsors with comprehensive clinical development outsourcing services. We are prepared to assist the industry in any way necessary, including through our digital transformation services, app development services, data management, hybrid outsourcing models, clinical staffing, and functional staffing services. As a leader in clinical development outsourcing, we are now as excited as ever to take the reins of the process and ensure the success of our clients. That said, through a holistic, collaborative approach and innovative thinking, we continue to offer our services within Biopharmaceutical, Pharmaceutical, Biotech, CRO, Diagnostic, and Medical Device domains.

We know from experience and industry trends that the outsourcing strategy produces superior outcomes. Increasing time to market, enhancing the quality of the services, and achieving cost effective solutions are key reasons to outsource. Your project's quality, performance, and time-to-market will all be better if you decide to outsource, so we've put all of our resources into offering a wide range of our clinical and digital services. Our talented people and systems provide our Sponsors with unmatched value and experience in clinical development, digital services, and more. Your unique challenges will never be exactly the same as anyone else's, which is why it's crucial that you align yourself with an expert partner that knows what you're facing and can help you address them. In conclusion, we can confirm that our service, Clinical Function as a Service, is here to stay and is the optimum solution to address our Sponsors' business and strategic objectives. We know what you need, and that is exactly what we will deliver.

INSIGHTS

Traditionally, life sciences or healthcare organizations employ internal staff to perform responsibilities such as monitoring, managing projects, developing research protocols, and conducting studies or trials. Alternately, such companies may choose to outsource the entirety of their clinical study developments. Examples of outsourcing models include hiring consultants to lead a clinical study's development, hiring a CRO or CMO to run a specific trial, or having a dedicated PbR (patient-based research) department handle all product development and clinical studies.

Our Clinical Function as a Service model allows for the demarcation of core and non-core competencies within an organization, allowing for the selection of service providers with expertise in each area, such as RWD/RWE Solutions, Clinical Data Integration and Aggregation, Staffing Solutions, AI Model Training, Digital Health App Development Services and so on.

This model eliminates the burden of employment and frequently minimizes day-to-day management needs but provides strategic direction and direct integration within your business's functions.

Many life sciences and clinical research organizations have demonstrated the efficacy of outsourcing models, which are now widely recognized as the industry standard. Companies are becoming aware of the necessity to return to the fundamentals of clinical development.

Utilizing outsourcing services to manage a project or a team will help achieve this objective. In addition, this model offers advantages such as higher productivity, worker flexibility, and cost savings. With proper diligence in selecting an outsourcing partner, businesses can boost the productivity of their development teams by using full-service outsourcing and reaping the aforementioned benefits.

MAXIS
CLINICAL SCIENCES

EXPERTISE

Dedicated teams for clinical development with a solid therapeutic basis for optimal performance, full flexibility and transperancy in delivering productivity at all times. Staffed more than 3000 talents for Clinical studies and demonstrated 30% reduction cost savings

Clinical Data management services to develop, manage and maintain regulatory compliance with all data sources. With right knowledge and expertise in helping deliver on-time study lock with full-cycle data quality management, processing, and standardization

Global specialists with local expertise and support throughout the development process with services spanning across clinical data management, regulatory and biostats programming and exploratory analytics

Centralised monitoring technology platform that provides a holistic, credible, quality-driven, and cost-efficient method to track and diligently manage different aspects of clinical trials, ultimately allowing you to achieve high data quality in a cost-effective manner to fulfil your study objectives.

Necessary tools and technology to drive down the total cost of delivery and bring efficiency, as well as transparency, to the benefit of clinical trial sponsors. Collaborated with 30+ global clients till date.

MAXIS
CLINICAL SCIENCES

BENEFITS

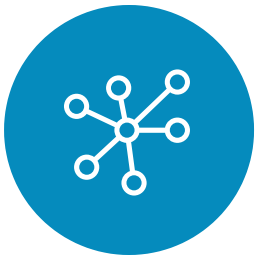
Proven clinical domain expertise and experience working with high quality standards, world class practices and a high degree of professionalism.

Improve the company's growth possibilities and put it in a position of market leadership by providing services to clients in record time.

Account managers who are experts in their field and committed to meeting your company's unique demands over time.

Staffing implementation strategies that boost adoption and return on investment from projects to expedite time to market and keep costs down.

Effective & transparent process that guides businesses through ethical and legal decisions.



Global SOPs -
GCP-ICH and 21 CFR Part 11 Regulatory Compliant is the core of our quality system

MAXIS
CLINICAL SCIENCES

CATEGORIES

Accelerate the process of your clinical development projects with our services that deliver a flexible combination of functional expertise, resource management, and technology-based solutions to address the need of healthcare and life sciences global reforms.

Clinical Development

- Central Monitoring
- Project Management
- Clinical Data Management
- CDISC Standardization
- Pharmacovigilance
- Medical Monitoring
- Drug Safety Monitoring
- Regulatory Operations
- Medical Affairs
- Translational Medicine
- Pharmacovigilance

Data Centric

- Real-world Data Analytics
- Clinical Data Integration and Aggregation
- AI model training
- SaMD compliant Digital Health App Development
- Pharmacokinetics
- Statistical programming
- Biostatistics
- Medical writing

Regulatory

- Clinical and regulatory strategy
- Medical Information processing
- Case processing and reporting
- Authorization application
- Regulatory maintenance and administration

MAXIS
CLINICAL SCIENCES

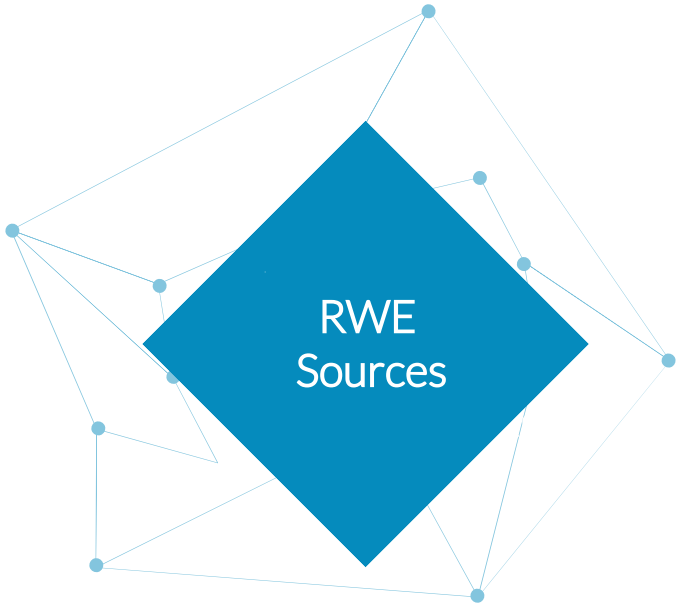
RWD & RWE

What is Real World Data (RWD)?

When it comes to healthcare, the term "Real-World Data" (RWD) refers to information related to patients' health and the delivery of care that is frequently collected from a variety of sources.

What is Real World Evidence (RWE)?

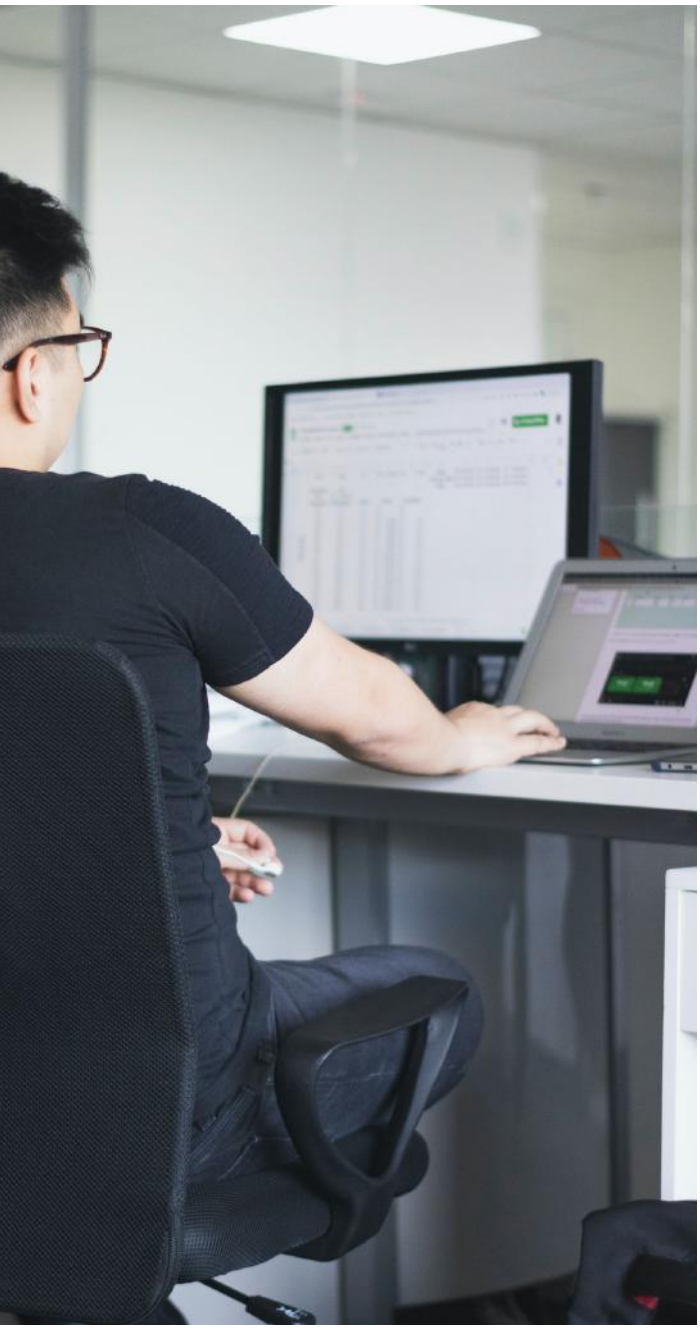
Clinical data about the use and potential advantages or dangers of a medical product gathered via study of RWD is known as Real-World Evidence (RWE).



- Electronic medical and health records
- Billing and claims processes
- Product and disease databases
- Patient-generated or biospecimen data
- Evidence collected from non-traditional medical sources

MAXIS
CLINICAL SCIENCES

REAL WORLD DATA ANALYTICS SOLUTIONS

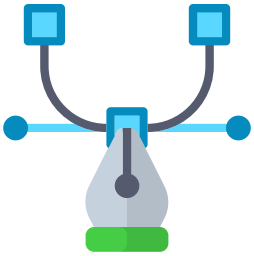


Maxis Clinical's real-world data experts team collaborates closely with industry stakeholders to create customized solutions to support their RWD and RWE efforts across the full drug development spectrum. Real-world data methods and analytics from Maxis Clinical can be used to:

- Perform post-marketing obligations, post-approval safety studies, and/or post-marketing requirements
- Support new regulatory efforts
- Support labeling extension
- Meet Pediatric data requirements
- Perform information-linking research
- Build detailed patient journeys
- Develop clinical procedures and protocols
- Evaluate site inclusion or exclusion criteria and feasibility
- Evaluate safety and effectiveness of therapies in usual practice and comparative effectiveness
- Use PRO measures to evaluate patient receptivity to therapy.
- Evaluate under-represented and/or specific patient populations
- Support a variety of RWE-related initiatives

MAXIS
CLINICAL SCIENCES

REAL WORLD DATA ANALYTICS SOLUTIONS



Our Real-World Data Analytics Offerings Include, But Are Not Limited To, The These Methods For Helping Clients Locate Data That May Be Used To Tackle Problems They've Run Into During The Entire Drug Development Process

- Consulting for Business and Strategic Planning
- Efficient Study Design for Genomics and Translational Medicine
- Clinical Trial Study Design Optimization
- Recruiting Subjects and Assessing Study Locations
- Prescription Drug Monitoring and Patient Safety
- Market Access and Evidence Generation in the Real World

SaMD APP DEVELOPMENT

"Innovative software app for the future of Medical Devices"

Historically, medical devices served a specific function, while modern ones serve numerous functions. They are a component of a fast developing and interdependent ecosystem for healthcare technology.

Thanks to technology improvements, devices have become smaller and more portable, and a new category known as Software as a Medical Device (SaMD) has transformed computers into comprehensive patient care networks. Whether only utilised in a clinical setting or made available to patients at home, partner software for medical devices can assist physicians and patients in better understanding best practises, analysing data, and incorporating device functionality into larger care plans and patient health goals.

Maxis Clinical's extensive experience in related fields ensures the efficacy and usefulness of the SaMD devices. Our expert team is well-versed in developing SaMD and HIPAA or GDPR compliant app for both patients and healthcare professionals to facilitate the usage of medical devices.

SaMD APP DEVELOPMENT

Maxis Clinical transforms healthcare delivery with the cutting-edge, clinically validated & regulatory compliant ready app development services

Our healthcare app development services bring new techniques of disruption for preventive, interpretive, and vigilant healthcare, streamlining existing administrative processes while increasing efficiency and reducing costs. We develop your app to be the catalyst for the next big thing in the healthcare industry

Our expertise in Healthcare App Development

Digital Health Apps

Digital Health Record

Mobile Prescription

Process Management

Medical Insurance Claim

Digital Health Information Exchange

Lab Management

Software Integration

Lifestyle Tracking

Patient Treatment Portal

CLINICAL DATA – INTEGRATION & AGGREGATION SOLUTIONS

Challenges

The healthcare industry, clinical research, and patient-owned medical devices all produce massive amounts of data at an astonishing rate. However, much of this data is held in isolated silos by separate hospital administration systems that don't talk to one another. Useful insights can be gleaned from medical data by any healthcare facility with the correct software and tools. But you need to integrate and aggregate your material correctly before you can analyze it and draw conclusions.

Solutions

Maxis Clinical's data custodianship solutions aim to aggregate data continuously and automatically from all the disparate sources in real time, so that the integrated data can be leveraged to drive actionable data-driven insights across the study, and to speed up data management processes to get to analysis-ready data more quickly. For our clients, we have built cutting-edge systems and procedures for integrating and aggregating healthcare data assets.

We handle the challenging issues involved in developing robust resources that guarantee achievement. The unique capacity to aggregate rich, relevant data that we have developed over the past two decades is crucial to our aim of producing real-time, actionable insights.

At the patient level, we merge information from an EHR's data repository with claims data that has been adjudicated and other useful data sources. With this method, healthcare organizations and value-based care can benefit from a constantly refreshed data asset.

AI MODEL TRAINING

AI models deployed in the clinical setting or for healthcare must be trained using clinical training data. The correct training data can improve AI models and healthcare outcomes in ways that other data sources cannot when used appropriately. For example, when trying to determine if a tumor is malignant or benign, it is important that the training data include examples of all possible forms of cancer.

Without the clinical training data, it is not possible to train an AI model, which is primarily accomplished through supervised machine learning.

There are many different sources of data available, and each source can be leveraged for use in training AI models to learn and improve their predictive capabilities. Access to high-quality and accurate data sets is the first step towards building a successful AI product.

AI MODEL TRAINING SERVICES

Clinical training data and real-world data can be gathered from a number of sources, including longitudinal data, case study data, self-reported and picture based reports, billing information, healthcare visit patterns, and third parties. Our AI and ML experts' team can train the following AI models for text prediction (NLP), for Question Answering Systems, for Machine translation, for Data Scraping, gathering insights from the data and more:

- Medical Imaging Pattern Recognition and Signal Analysis
- Tests and reports for CT scan, X-Ray, and MRI.
- Skin care and Image Evaluation
- Remote patient monitoring and healthcare
- Clinical Trials and Development
- Disease management system
- Rapid identification of severe diseases such as Cancer
- Drug Development and Related Methods

CUSTOMER REVIEWS

VP,
Medical Affairs

Japanese Pharma Company

Maxis Clinical has always been a good partner to us and has been attentive to our MSP account requests and have a tactful approach to submitting well-qualified candidates in a timely manner. Working with Maxis Clinical has been a pleasure, they have a strong client focus and truly understand the goals and objectives of an MSP. The team goes beyond to ensure they deliver a high level of service.

CEO

Large Biotech Company

They constantly endeavor to exceed expectations by custom-tailoring their candidate searches based on our requirements thus, ensuring delivery of spot-on candidates within the promised timeframe.

CUSTOMER REVIEWS

Head,
Clinical Data Management

Oncology Biotech Company

Managing our clinical programs and accelerating our innovation requires access to the highest quality clinical data and related information with efficient analytical tools at all times. With Maxis Clinical Data Integration and Aggregation Solutions, we were able to easily achieve that across the portfolio of studies, improving data quality and decision speed.

COO

Digital Health Company

When it came to creating a health app for our venture, Maxis Clinical not only lived up to our expectations, but surpassed them. They have a knack for conveying information clearly and effectively, and they are always thinking of innovative ways to add value. They are not only reliable in terms of completing projects on time and under budget, but they have also earned the status of go-to experts on a number of pressing matters.

Get in touch!

MAXIS
CLINICAL SCIENCES

www.maxisclinical.com

510 Thornall Street, Suite 180 Edison, NJ 08837

(732) 889-2444

info@maxisclinical.com