

# Product FAQ

For more information, please visit: [www.litmushealth.com](http://www.litmushealth.com)

## What is Litmus Health?

We are a clinical data science platform focused on health-related quality of life. We help researchers running clinical trials better understand patients' behavior and environment by validating data at the point of experience from wearables, smart devices, and home sensors.

Our platform leverages machine learning and big data analytics. Aligning time series, building models, and looking for correlations are a few of the activities we support.

By effectively capturing and analyzing patient-generated data that are all around us, we help sponsors and CROs make better go and no-go decisions based on better, earlier patient data.

## What products and services does Litmus offer?

The Litmus platform can be used to study any disease or therapeutic area to help researchers understand their patients' health-related quality of life.

Our modifiable platform enables investigators and their sponsors to build custom trials tailored to their specific research needs. The Litmus platform supports multiple data sources that describe patients' behavior and environment. We also draw from a library of validated surveys, or we can integrate with an instrument of your choice. We are device agnostic.

The platform is used by patients via our proprietary app and is accessible to investigators and their sponsors through any modern web-browser.

Litmus also offers 24/7 customer support services and is engaged at every stage of the trial.

## Who are Litmus' customers? How is Litmus being used today?

At the outset, we're primarily targeting researchers and clinical trials focused on complex chronic inflammatory diseases like systemic lupus erythematosus, multiple sclerosis, and rheumatoid arthritis. This is where, right now, we see the greatest benefit of integrating electronic technology.

For one, many of these diseases are multifactorial, caused by a combination of lifestyle, behavioral, and genetic factors. Figuring out the impact that one factor has on a disease state over another is imperative, and something for which the Litmus platform is uniquely suited. Second, they require careful quality of life considerations that Litmus helps to measure and quantify.

## **What do you mean by health-related quality of life? Why does this matter?**

We think health-related quality of life should be the ultimate endpoint. The pharma industry has traditionally focused on longevity, developing treatments that extend our lives. Today, we're seeing a shift to treatments that measure a patient's quality of life alongside longevity. A focus on quality of life promises to improve patients' lives and improve the pharma business model. In fact, more and more drugs are being approved based on these factors. We are focused on helping investigators and their sponsors bring better drugs to market, faster.

We've written a guest post that explains our take on the importance of using health-related quality of life as an endpoint in pharma. Find it [here](#).

## **How does the product actually work?**

The Litmus Platform has four major components. They work in tandem:

The first is data ingestion. We collect patient behavior and environment from over 200 smart devices, wearables, and home sensors.

Our data science platform allows researchers to easily run sophisticated algorithms on their data. Aligning time series, building models, and looking for correlations are a few of the activities we support. Many customers also use our platform to augment data with outside information. For example, an asthma researcher might combine real-time freely-available pollution information with patient GPS information to model the relationship between air quality and asthma control.

We provide investigators and their sponsors with an interactive dashboard that allows them to monitor study progress and see high-level population insights. Users can drill down to see how individual de-identified patients are faring on each trial.

Fourth and finally, Litmus offers both Android and iOS patient trial companion apps, through which patients connect third party devices and answer validated survey questions at regular intervals or when triggered by behaviors identified in the study's design.

## **Are there specific disease states that are ideally-suited for Litmus?**

We have been working hard on building our platform to study inflammatory diseases, but we also want to support a wide array of conditions. Therefore, our platform is designed to be scalable and extensible to any condition or disease state. From Crohn's disease and ulcerative colitis, we are planning to expand to asthma and diabetes and then to other diseases, including cancer.

## **Wait, so you're an app?**

The Litmus Trial Companion app is a component of the entire system – patients are able to input their data through an app on their smart phones. The app is the “connector” that allows patients to connect to their wearable device. It also provides a platform to distribute surveys and other questions. Finally, the app facilitates the collection of GPS data from the phone.

## **Is your patient-facing app available on iOS and Android?**

Yes

## **What software do I need to use Litmus?**

You don't need any special software. Everything is hosted and device agnostic. Investigators and their sponsors can however download their raw Litmus research data anytime and import it into another tool or platform.

## **What data do you actually collect? How do I upload my data to Litmus?**

The data Litmus collects depends on the study design and sensors available to the devices used. Common data types collected will include survey responses, GPS, heart rate, step counts, and sleep monitoring data, plus many more, including specialized data such as glucose monitoring with the right devices, or air quality using non-wearable devices.

Data can be collected through your smartphone, direct from devices, or through partner systems. Devices only need to be connected to the Litmus platform, and data collection is automated. However, data collected from partners do require that you upload your device data to their systems following their specific guidelines.

## **With what wearables do you connect?**

Our platform is device-agnostic, so we can connect with any wearable on the market.

## **I want to use surveys too. Can you integrate those?**

Yes, you can integrate surveys by either manually entering the information or facilitating a survey through our app for the patient to take at predetermined intervals.

## **What do you mean by “adding value” to the data?**

Pharma companies and their research counterparts have been playing with smart devices, wearables, and home sensors in small studies for the last 18 months. What characterizes these early efforts is a very basic data infrastructure that pipes information from each hardware into a database, usually an electronic data capture system.

Moving data from one place to another is step one in a much more complex pipeline, assuming one intends to use these data for decision making.

The basic ETL (extract, transform, load) operation that the Litmus platform performs is a significant value to any organization working with data, but that's only the beginning. With that work complete, the Litmus platform allows researchers to run simple machine learning packages on their own with little or no prior experience needed. Augmenting data with orthogonal information is a common activity, as are things like aligning time series, performing interpolation, and looking for correlations.

Every other platform that specializes in remote patient monitoring and / or biotelemetry leaves off at the point at which data are put in researchers hands. For Litmus, collection is just the prologue.

## **You've talked about modeling device errors, what does that mean and how does it work?**

One of the real and perceived shortcomings of new devices from makers like Garmin, Fitbit, Jawbone, Withings and even Google is the notion that data from each unit will be too variable to trust.

This is particularly problematic for any researcher or sponsor who intends to use these data as part of an FDA submission.

Litmus' most important R+D project this year is the modeling of errors, or MOE for short. This is also an area in which we have developed considerable IP.

Basically, each device's variance isn't a problem, if we can normalize for it within an acceptably small margin of error. Put another way, we know the devices aren't perfect, but we do know the expected distribution of data, and we can adjust for errors accordingly.

MOE is work that Litmus can apply across the board with all of our customers. We've started with the most commonly used research devices, but our work will continue, since new entrants seem to launch every month. We think that MOE is one of the most significant contributions we can make to modern clinical research, as it enables the inclusion of data that would otherwise be left behind. With so many people out there with smart devices, wearables, and home sensors, MOE promises to bring researchers petabytes of information previously off limits.

## **How do I, as a researcher, see that data? Do I need a team of data scientists?**

Litmus delivers data in a way that is easily digestible for any investigator or sponsor, accessible on any modern web browser. The platform allows researchers to run simple machine learning packages on their own with little or no prior experience needed.

The Litmus dashboard displays data that indicate each study's progress and shows population trends at-a-glance. Researchers can drill down to view individual participants' data. Data scientists are optional and not required.

Data sets can also be securely downloaded and analyzed using your preferred data analysis program or tool.

## **How does the product account for patient privacy and security of data?**

Litmus conforms to HIPAA guidelines and Litmus data are collected and stored in compliance with 21 CFR Part 11 standards. If you're not familiar with these designations, think of HIPAA as being primarily about the privacy and protection of patients and patient information, while 21 CFR Part 11 determines what the FDA considers to be valid electronic data.

Neither, you should know, is it a checkbox that can be completed at any single moment in time. Rather, each requires culture of privacy, security, and careful recordkeeping. In order to be successfully auditable, Litmus has had to reorganize our people, policies, procedures and technology in a way that most startups find too arduous.

Luckily, Sam and James on our team were brought up in this environment both academically and professionally. They don't know any other way. Besides these official designations, it is worth point out the following three attributes.

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**IRB-Certified:** The Litmus Health Platform has undergone rigorous review by the University of Chicago IRB and has been approved for data collection. The close attention paid to security and privacy standards means that clinical data on subjects never leaves the University of Chicago. Rather, the research team maintains the associations between research subjects and their anonymous identifiers used by Litmus. Even though Litmus keeps all data stored according to rigorous standards, the data itself contain no protected health information. These layers of privacy and security protection are a foundational piece of Litmus' platform.

**Certificates of Confidentiality:** Whenever possible, Litmus partners with researchers who have obtained federal Certificates of Confidentiality. These certificates offer an important protection for the privacy of research study participants by protecting identifiable research information from forced disclosure (e.g., through a subpoena or court order). The certificates allow investigators and others with access to research records to refuse to disclose information that could identify research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, State, or local level.

**Chief Privacy Officer:** As a licensed physician and head of an internal research institute at the University of Chicago, Sam is particularly qualified for his role as Chief Privacy Officer. He is very experienced with de-identifying data sets and adjudicating disclosures of sensitive information so that participants are protected and research is not impeded. At Litmus, he ensures that our workforce is trained to the highest standards and perpetuates a culture of diligence. He will also weigh in on partnerships, to make sure that anyone we work with has the same commitment to privacy.

## How are the data backed up?

All data are redundantly backed-up on servers at Google's data centers, and encrypted at rest and in transit. Data and back-ups are encrypted to keep the data safe even in the event of a security flaw, and data are stored as multiple distributed copies that will survive hardware failures, fires, or other damage to a data center.

## What happens to the data after the trial is over?

When the trial is over a customer has three non-exclusive options:

1. Download the entirety of their data.
2. They can instruct us to keep that data in our data science warehouse, to which they already have a secure login.
3. Or they can continue to interact with that same warehouse via the API Litmus provides.

Litmus does not keep, store, or have access to customer patient data, except for anonymized or aggregated information used to train our algorithms and improve our platform.

## What does the on-boarding process look like? How do I get started? How long does it take?

Litmus needs to see your protocol in order to understand our scope of work. If you do not yet have a protocol, we are happy to help consult on its design.

Litmus can typically be up and running for customers in 4 weeks or less.

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Sometimes customers need us to integrate with a novel device or data stream, in which case production may take a few weeks longer.

Once we have a protocol in hand, Litmus simply proposes a scope of work, a price, and professional services if needed.

Once a negotiation is complete, contracting can quickly begin.

### **What product support is provided during the trial?**

The Litmus customer success team is involved at every stage of a trial and is never more than a phone call away. We take each engagement very seriously.

Each trial is assigned to a dedicated success partner, and when necessary, Litmus can also forward-deploy a sales engineer to your site.

For subjects, the first line of help is our comprehensive mobile support library, which handles most common problems. Litmus also staffs a 24/7 patient support number for urgent needs.

In some cases a patient's issue may pertain to third-party device instead of the Litmus software. We have made arrangements with each of our device partners to support customer trials with hand-off procedures unique to each.

### **How much does it cost?**

Platform pricing starts at \$250K plus annual fees per enrollment, discounted as volume increases. We take on non-commercial academic work on a case-by-case basis.

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