

Executive Summary

The answers we need are all around us¹. Litmus is a clinical data science platform focused on health-related quality of life.

We use real life data collected at the point of experience from wearables, smart devices, and home sensors to guide management and to inform endpoints. We help our customers describe the full value of their work in observational studies, therapeutic trials, and post-market research.

From small observational studies to large scale registries, we help researchers unlock fundamentally new insights from patient data.

For early stage trialists, the decision to go from phase 2 to phase 3 is an expensive one, and several hundred million dollars usually hang in the balance. Moreover, peak sales only last as long as the patent clock allows. Continuously measuring outcomes in multiple dimensions leads to faster, more efficient pipelines.

For post-market researchers, we can help evidence marketing claims and support price by evidencing new dimensions of benefit.

The Litmus platform supports more than 200 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 and disease agnostic.

Once data are collected, Litmus uses machine learning to align time series data, interpolate, integrate multiple orthogonal data sources, and look for correlations between behavior, environment and patient outcomes. We can also model device errors² on a per-device basis. We don't just route data, we augment and interpret it.

Data are delivered to partners in different ways, depending on your workflow. We can provide a raw CSV, a secure login to our analytics data warehouse, a hosted Python notebook, or a RESTful API. In the near future, we will also provide a suite of modules that allow researchers to run sophisticated machine learning packages on the raw data with the click of a button.

The Litmus Study Hub dashboard displays data that indicate each study's progress and shows population trends at-a-glance. Researchers can drill down to monitor individual participants' data.

The Litmus trial companion mobile app is available for iOS and Android phones. It serves as a clearinghouse for device data, which it gathers and sends back to the platform. The app also handles survey responses, which can be collected at regular intervals or triggered by external events.

Our work with Takeda Pharmaceuticals is a great example of Litmus in action. Dr. David Rubin is studying 500 enrollees over three years patients at the University of Chicago's Digestive Diseases Center³. We're gathering data from smartphones and Fitbits to better understand the relationship between sleep, activity and flares in Crohn's and Colitis patients. Our ultimate research goal is to use the models to accurately predict outcomes.

We currently seek additional partners in any therapeutic area. Litmus can be fully deployed in as little as four weeks.

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 under our Litmus Free program.

Litmus is HIPAA and 21-CFR Part 11 compliant. The data we collect are ready for submission in CDISC's CDASH format, as mandated by the FDA⁴.

We'd love to hear from you early in your process to show you Litmus firsthand. We are happy to consult as needed on protocols and overall trial design.

If you agree with us that that quality of life is the ultimate endpoint⁵, please send us a note: hello@litmushealth.com

Litmus Health. Real life data.

¹ http://www.pharmatimes.com/magazine/2016/september/track_record

² <https://techcrunch.com/2016/08/18/what-the-fitbit-lawsuit-means-for-clinical-researchers>

³ <https://sciencelife.uchospitals.edu/2016/05/17/tracking-real-time-data-to-personalize-treatment-for-ibd/>

⁴ <https://www.cdisc.org/FDA-Final-Binding-Guidance-on-Standards>

⁵ <http://social.eyeforpharma.com/clinical/quality-life-ultimate-endpoint>