

A Ripple Science case study



Medical Laboratory team from Detroit-based

BIOTECH ADOPTS RIPPLE TO BUILD A GLOBAL REGISTRY

Functional Fluidics, a venture backed biotech company in Detroit, is building a global registry of sickle cell patient biomarker data to work with the Pharma industry on accelerating drug discovery.

According to Jennell White Ph.D, Director of Scientific Research and Regulatory Affairs at Functional Fluidics, "It was difficult to recruit patients from clinics at the time of COVID, but having the ability to engage with potential participants remotely, through email, and tracking them in Ripple made it possible. We also used Ripple to communicate with the labs feeding patients to the study."

Jennell was recruiting for multiple sickle cell studies in which participants were required to make a single visit to provide blood samples at one of several remote sites. With Ripple, Jennell and her team were able to rely on technology to streamline the screening and consent workflows at the sites

Ripple's eConsent was key to maintaining compliance in our COVID study. Before I would find missed signatures and initials on forms and had to recontact patients, but Ripple won't let you proceed without completing all the required signatures."

- Jennell White PhD.,

Director of Scientific Research and Regulatory Affairs

Problem:

Functional Fluidics wanted to build a global registry of sickle cell patient biomarker data to work with the Pharma industry on drug discovery.

Solution:

Ripple provided a 21 CFR Part 11 compliant solution that checks all the boxes required by Pharma study sponsors.

Benefits:

- Build a database and workflows that are 21 CFR Part 11 compliant
- Screen and consent patients remotely via secure technology
- Protect PII/PHI and de-identify data when needed
- Avoid missing signatures and decrease paper consent pains
- Streamline, automate andmonitor communications with patients and sites
- Instantly view and screen new participants from remote sites
- Quickly stand up new studies and accelerate time to first patient enrolled



When the pandemic hit, Functional Fluidics relied on Ripple to quickly stand up new workflows that accommodated COVID-19 restrictions for in-person visits. Ripple allowed the team to directly communicate with patients throughout the process without the need for additional in-person visits. By communicating through Ripple's HIPAA-compliant system, the team was able to protect patient privacy and de-identify data as appropriate.

Ripple also enabled Functional Fluidics to manage all communication with remote study sites and better track study sample collection, transportation, and analysis in real-time.

What stands out is Ripple's training. Our customer experience was and is great in large part because we have access to our customer success manager's calendar for training and support."

- Jennell White PhD., Director of Scientific Research and Regulatory Affairs

Looking to the future, Functional Fluidics plans to leverage its global sickle cell biomarker database to work with the pharma industry on drug discovery. Jennell noted that, "having Pharma customers, we need to make sure that from the start our data is secure and checks all the boxes required to pass a 21 CFR Part 11 pharma security audit."