

# Launching a Phase 3 Pivotal Trial in a Pandemic with the Medidata Rave Clinical Cloud <sup>70</sup>

## The Challenge: Adapting to Pandemic Restrictions

TissueTech was set to launch a Phase 3 pivotal trial for the treatment of severe diabetic foot ulcers in March 2020—just as governments began lockdowns to combat the spread of COVID-19. “Up to 50% of patients with this condition face VbejiVi^dc VcY \*"nZVg bdgiVa^in gViZh! hd h^c^ÐXVcian YZaVn^c\ ijZ ig^Va IVh dji of the question,” says Tommy Lee, Vice President for Clinical Operations.

The original study plan called for in-person clinic visits and 100% on-site source YdXjbZci kZg^ÐXVi^dc H9K Ãcd adc\Zg edhh^WaZ Yjg^c\ ijZ eVcYZb^X WZXVjhZ of safety concerns for a vulnerable patient population, travel restrictions, and limited site access. “We needed creative solutions to minimize adverse impacts from the pandemic on patient enrollment, retention and safety, clinical trial integrity, and data quality,” says Lee.

## The Solution: The Medidata Rave Clinical Cloud

After reviewing FDA guidance on the conduct of clinical trials during the COVID-19 public health emergency, TissueTech reached out to Medidata. “We’ve been collaborating with Medidata for years and we wanted their guidance on how to quickly pivot to remote trials ,” L

## Virtual Patient Visits

Patients were given the option to meet with clinicians via a telehealth application, eliminating skipped visits due to safety concerns or restricted site hours. Before the visit, patients took photos of the foot ulcer using a mobile device that also measures wound area and depth. "Images are automatically uploaded to Rave Imaging and then saved straight into Rave EDC, giving us sites to comply with FDA 21 CFR Part 11.

## Remote Site Visits and Targeted Monitoring

The original Phase 3 trial plan called for monitoring visits every 4-6 weeks and critical issues that could affect participant safety and the credibility of results.

With one URL and one login, monitors working from home could access all Medidata applications, conveniently uploading and downloading documents via a web browser. "We've found that remote monitoring with Rave TSDV makes us