Launching a Phase 3 Pivotal Trial in a Pandemic with the Medidata Clinical Cloud

The Challenge: Adapting to Pandemic Restrictions

BioTissue (formerly 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 amputation and 5-year mortality rates, so signi□cantly delaying the trial was out of the question,” says Tommy Lee, former Vice President for Clinical Operations.

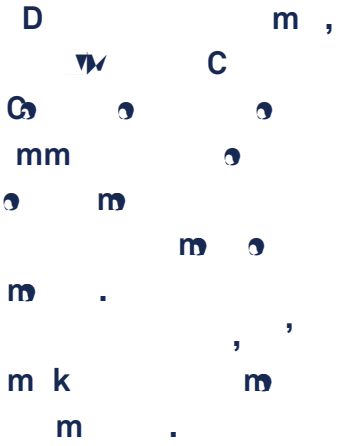
The original study plan called for in-person clinic visits and 100% on-site source document veri□cation (SDV)—no longer possible during the pandemic because of safety concerns for a vulnerable patient population, travel restrictions, and limited site access. “We needed creative solutions to minimize adverse impacts from the pandemic on patient enrollment, retention and safety, clinical trial integrity, and data quality,” says Lee.

The Solution: Medidata Clinical Cloud

After reviewing FDA guidance on the conduct of clinical trials during the COVID-19 public health emergency, BioTissue 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,” Lee says.

Medidata’s team of experts advised BioTissue on using the Medidata Clinical Cloud™ to virtualize patient visits, remotely capture and review medical images, and shift to remote monitoring. “For ef□ciency, we wanted to minimize the number of technology vendors we used for our clinical trial process,” Lee says. “Medidata helped us achieve our goal by providing a single, integrated platform for the full trial continuum—from startup to □nal report.”

Before the pandemic, BioTissue used Rave EDC, CTMS, RTSM, eTMF, and eCOA. To pivot to remote trials, Medidata recommended adding Imaging, TSDV, and Remote Source Review. Working with a single vendor helped BioTissue launch the trial in July 2020, just three months after the pandemic derailed the original plan.



Tommy Lee, former Vice President for Clinical Operations, BioTech

- Launched pivotal Phase 3 trial during COVID-19 pandemic
- Protected patient safety with remote visits
- Increased trial ef□ciency and effectiveness with TSDV (Total Source Data Veri□cation)
- Avoided additional burden for sites by using a cloud-based platform with a single log-in
- Enabled study monitors to remotely review source documents, avoiding site visits

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 oversight,” Lee says. Rave Imaging automatically strips personally identi□able information (PII) and personal health information (PHI), lowering the burden for 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 100% source data veri□cation (SDV). To adapt to pandemic restrictions, BioTissue shifted to remote monitoring and targeted SDV (TSDV), focusing on review of critical issues that could affect participant safety and the credibility of results.

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