

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 significantly 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 verification (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 efficiency, 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 final 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.

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Tommy Lee, former Vice President for Clinical Operations, BioTech

Value

- Launched pivotal Phase 3 trial during COVID-19 pandemic
- Protected patient safety with remote visits
- Increased trial efficiency and effectiveness with TSDV (Total Source Data Verification)
- 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 identifiable 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 verification (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.

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 more efficient because we don't have to wait weeks for the next site visit to collect documents or conduct SDV," Lee says. "As a result, we're reviewing data more frequently and more robustly than we could with on-site monitoring."

Enduring Benefits After the Pandemic

BioTissue plans to incorporate the new processes in future trials, even after pandemic restrictions ease. Patients in upcoming spinal bifida and osteoarthritis studies, for example, will be able to request telehealth visits under certain conditions, an option the company expects will improve patient recruitment and retention. Future studies will likely also include remote monitoring, enabling study monitors to review data in between scheduled on-site visits.

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About BioTissue

Founded in 1997, BioTissue is a pioneer in the clinical application of human placental tissues. More than 680,000 patients have been treated with BioTissue's products and its scientific and clinical advancements have been documented in over 380 peer-revised publications.