Case Study

TissueTech enlisted eKare technology in late-phase research of a biologic candidate to treat complex Wagner Grade 3 and 4 diabetic foot ulcers incorporating Medidata integration and remote monitoring.

Customer Profile

TissueTech, Inc. is a scientific and market leader in regenerative medicine and an emerging biotechnology company. Since its inception, clinicians have performed more than 500,000 human implants of the company's products under the regulatory classification of human cell and tissue products (HCT/Ps). TissueTech's mission is to develop and commercialize regenerative therapies derived from human birth tissue for patients with serious unmet clinical needs.

Setting Up for Success

One of TissueTech's primary principles is leveraging technology to ensure compliance with all regulatory guidelines and improve the quality, standardization, reproducibility, and efficiency in conducting clinical trials. Embarking on two Investigational New Drug Phase 3 clinical trials as part of their Biologics Licensing Application process to treat Grade 3-4 complex diabetic foot ulcers, TissueTech enlisted eKare's inSight® technology to ensure regulatory standards to collect important wound data necessary to study the safety and efficacy of TissueTech's biotherapeutic product TTAX01.

For TissueTech, inSight streamlines accessible, accurate, and reproducible wound data collection from all users, regardless of whether a patient is taking photos of their wound from home or having them taken by a healthcare provider in a clinical setting. "The ability for us to monitor the status of the patient's wound in real-time while obtaining accurate measurements to track a wound's progress at the participating investigator sites is of paramount importance during the conduct of a clinical trial," explains Nick McCoy, VP of Clinical Operations at Tissue Tech. Moreover, TissueTech utilizes eKare's powerful tool to provide guidance and support quickly when questions arise about trial protocol.

> *We are confident through working with eKare and the U.S. Food and Drug Administration that the eKare device and solution meets these stringent requirements and helps improve how we document and capture these critical endpoints for our wound trials.*
>
> - **Nick McCoy**
> Vice President of Clinical Operations at Tissue Tech

COVID-19 Rapid Response

The COVID-19 pandemic has been a catalyst for change. Almost every aspect of clinical trials has been informed by the recent U.S. Food and Drug Administration (FDA) guidance issued in March 2020 due to the pandemic. The TissueTech study team made the difficult decision to halt the first of two of the Phase 3 trials planned to initiate in March. Responding quickly, the team implemented eKare's remote patient monitoring tools enabling trial participants the ability to complete certain trial visits via Telehealth at home, minimizing their risk of exposure to the virus, and allowing clinicians and the study team to monitor patient progress remotely. "inSight has allowed us to quickly adapt to this new operating environment and more fully leverage the capability to implement remote-based monitoring solutions to ensure data quality and compliance with Good Clinical Practice requirements and alignment with recent FDA guidance," explains McCoy.

CHALLENGE

- The need for accurate, reproducible wound data
- Meeting standards for clinical trial acceptance
- Clinical Trial delays due to Covid-19
- EDC integration to streamline data collection

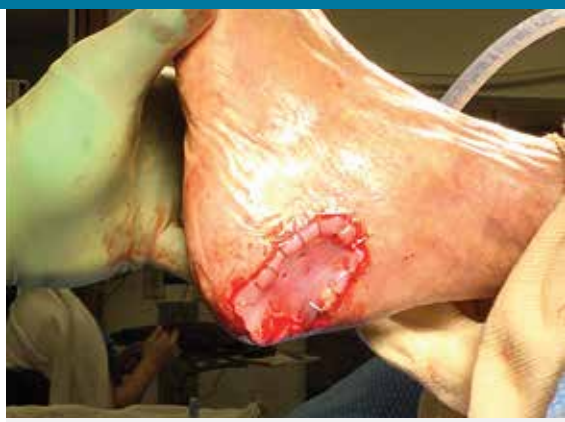
SOLUTIONS

- inSight imaging for accurate wound data
- Remote patient monitoring to enable virtual engagements
- Seamless EDC integration with Medidata® to maximize data integrity and efficiency

A Longstanding Partnership

A key factor in the success of the partnership is the ability to integrate the eKare inSight system with Medidata's RAVE Electronica Data Capture (EDC) system, TissueTech's primary EDC vendor. After working closely with the Medidata team during study start-up, study data integrates seamlessly in and out of the system in real-time, eliminating concerns about data timeliness and accuracy as it moves between systems. "We have continuously shared a very collaborative and successful partnership with the eKare team," says McCoy. "They have been more than willing to help support rapid deployment, implementation, and training across our clinical programs while demonstrating a desire to continue to improve and enhance their current offerings to meet our specific needs."

eKare and TissueTech attribute their successful partnership to their common values including the importance of technology, the accuracy of data, and the continued drive for innovation to improve patients' quality of life. "TissueTech is a true pioneer. We are honored to have partnered with them over the years. I look forward to what the future holds," says Dr. Kyle Wu, Chief Medical Officer of eKare.



INSIGHT BENEFITS

Sponsor

Standardization, Quality, Validation, Inter-operability

Clinical Investigator

Ease of use, accuracy of wound image and measurements

Patient

Ability to see wound healing progression visually

To learn more, visit **www.ekare.ai**