Case Study



A new standard to streamline wound measurement and management for patient-centered care.



Client Profile

Professional Education and Research Institute (PERI) is a premier clinical research organization (CRO) based out of Roanoke, VA. The group specializes in phase I-IV clinical trials and has conducted specialty research in the wound care space since 2005 across diverse indications, including diabetic foot ulcers, venous leg ulcers, peripheral neuropathy and peripheral vascular disease. The PERI team includes a group of highly experienced Clinical Trial Managers, Clinical Research Associates and Regulatory specialists who are committed to advancing research and improving patient outcomes.



Wound healing is a complex process that requires routine assessment and monitoring of a variety of variables, including wound surface area, tissue type and exudate level. While wound area is a good predictor of healing outcomes, there is no well-defined gold standard for assessment of chronic wounds.

Assessments practices can vary greatly from site to site. The ruler method is still frequently used. Some sites have adopted acetate tracing or digital planimetry, which requires calculation of squares within the wound border.

These assessments method are cumbersome and prone to error. In clinical research, where accuracy and precision are paramount in assessing primary outcomes of an intervention, there is a need for a reliable and validation solution. When PERI turned to eKare (Fairfax, VA), they were looking for a best-in-class solution that meets the highest standards for data quality and integrity. The team recognized the limitation of 2-dimensional length by width measurements. Most wounds seen in clinical practice are irregularly shaped and linear measurements can overestimate the wound area by up to 44%.1 Moreover, manual measurements have a low degree of agreement and consistency between examiners. This posed a unique challenge for multicenter clinical studies.

PERI needed a robust solution that would enable high quality digital wound assessment, wound documentation and remote monitoring of data. The eKare team worked closely with PERI's project management team to offer a personalized solution.

66 eKare has standardized and streamlined wound measurements across all sites. The simple and intuitive system has helped make the office visit more efficient.

The eKare platform was efficiently implemented within timeline and budget. It streamlined and standardized wound measurements across all sites.

eKare's secure cloud platform allows wound images and documentation to be reviewed and monitored in real-time from anywhere, adding significant value for the data management team and sponsors. Onsite monitoring alone comprises up to 30% of the total clinical trial cost.2 The shift to remote monitoring improved data quality, increased efficiency and reduce the overall cost associated with 100% onsite source verification.

eKare's inSight[®] 3D allows PERI team to generate essential clinical information including:

- automated, non-contact wound measurement (area, depth, volume)
- high quality digital wound imaging

- wound history and progress
- wound assessment and treatment plan
- clinical dashboard



At the onset of the pandemic when most clinical research activity had stalled, PERI was able to move at full speed without any disruption to research and monitoring activity. eKare responded quickly with a patient app that utilizes the latest cutting-edge innovations in artificial intelligence. It allows patients to capture wound images at home without the need for reference or calibration markers. The wound area is delineated automatically and available for clinical review in real-time. Moreover, eKare's telehealth app is seamlessly integrated with inSight[®], which allows quick access to record during a teleconsultation.

eKare's platform has offered maximum configurability, allowing PERI to tailor solution to specific protocol requirement. Additionally, established pre-built integration with major EDCs significantly reduces time, development efforts and cost associated with study start. The integration is build with latest Fast healthcare Interoperability Resource (FHIR) standards to ensure safe access to data that feeds directly into the provider workflow. All together, eKare has standardize wound assessment, data collection, management and analysis, allowing Peri to achieve greater efficiency.

Access controls

Streamlines sharing and prevents unauthorized access to patient information

Audit trails

Activity is time stamped and recorded to ensure data integrity and accountability

Reporting

Patient and study level trends, including quality, safety and protocol compliance issues can be easily tracked and reviewed.



1. Goldman RJ, Salcido R. More than one way to measure a wound: an overview of tools and techniques. Adv Skin Wound Care. 2002;15(5):236 43

2. U.S. Department of Health & Human Services. Examination of clinical trial costs and barriers for drug development and site monitoring. https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development/463-data-and-site-monitoring

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