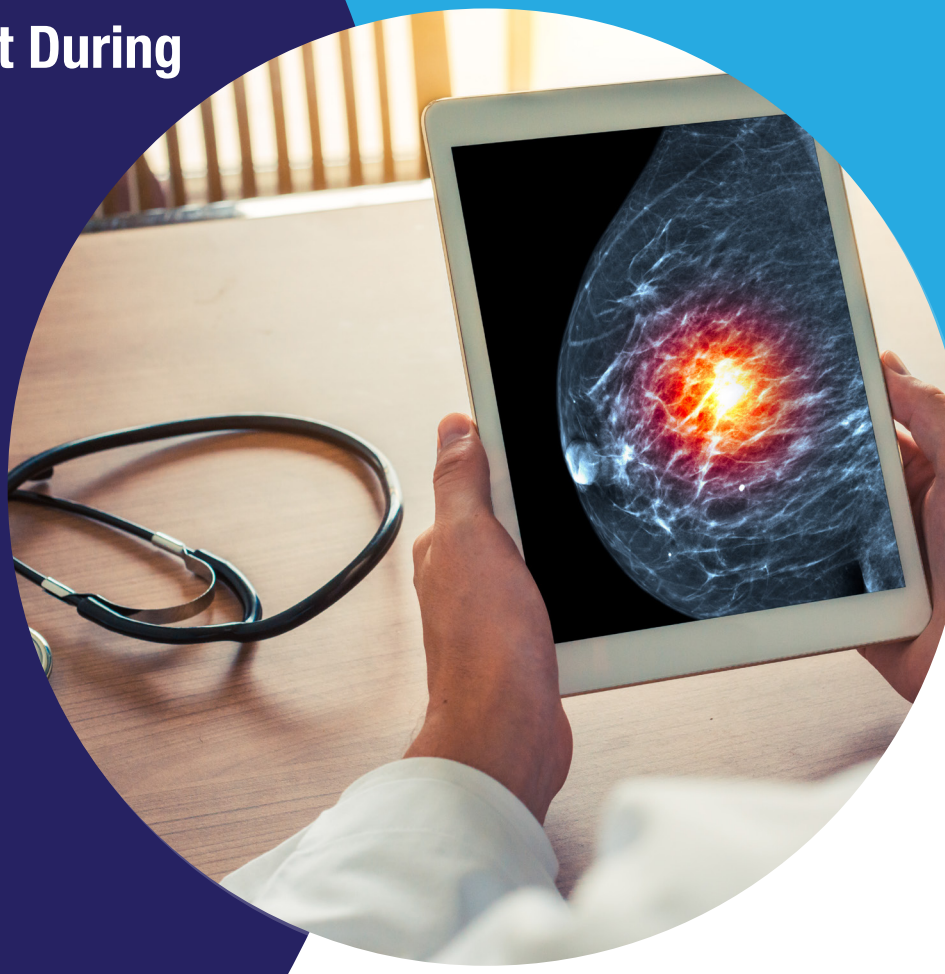
CASE STUDY

Virtual Expanded Access Program Providing Breast Cancer Patients Early Access to Treatment During the COVID-19 Pandemic

Evidera's team of researchers offers innovative methods and approaches to mitigate the risk to patient safety during the COVID-19 pandemic



170+

Decentralized study approaches engineered since 2019

Experience across all digital and virtual study models

Key Takeaways

Evidera designed a virtual study solution allowing oncology patients to safely receive access to an investigational product at home during the COVID-19 pandemic

Digital study platform went live and the first site was activated within 6 weeks

First study patient was screened within 8 weeks

Background

During the COVID-19 pandemic, a large pharmaceutical client required an alternative solution to on-site visits for an early access program. The solution had to be rapidly deployed to speed access to an investigational treatment for breast cancer patients. This was critically important due to their vulnerable health status and risk factors related to COVID-19.

Approach

In planning for the study, the client was receptive to incorporating novel approaches and quickly fostered a deep collaboration with the Evidera team to achieve study objectives as quickly as possible. Evidera's dedicated study innovation team was positioned to help move the study forward quickly and worked with the client's teams to drive rapid internal decisions.

To best ensure patient safety during the pandemic, Evidera partnered with Science37 to develop an integrated study solution that would support patients virtually. Evidera experts applied their virtual study expertise to inform a collaborative study engineering process, protocol, and informed consent form (ICF) development and review. Science37 provided virtual metasite services allowing study coordinators and mobile nurses to facilitate in-home patient visits, data collection, direct-to-patient clinical supplies, and study drug administration. A single Science37 platform was implemented to digitally enable a variety of study activities including:

- eConsent
- eSource
- Electronic data capture (EDC)
- Electronic patient-reported outcomes (ePRO)
- Video telemedicine

Results

- Digital study platform went live and the first site was activated within 6 weeks
- First study patient was screened within 8 weeks
- Virtual approach mitigated risk to patient safety during the COVID-19 pandemic and enabled early patient access to treatment

Impact

- Continuity of care was provided to vulnerable breast cancer patients during the COVID-19 pandemic by providing rapid access to their treatment
- Patients were able to receive treatments as safely as possible through virtual approach and well-planned risk mitigation strategy

Virtual study expertise informs collaborative study engineering, protocol, and ICF development and review

Science 37 platform digitally enables with eConsent, eSource, EDC, ePRO, and video telemedicine

Committed sponsor, virtual study site, and safety management team with a focus on **expedited site activation and patient-centered solutions**

Our team of experts works to create bespoke digital and virtual solutions that position the patient at the center of studies, resulting in reduced burden for both patients and sites. By leveraging our relationships with leading technology partners, our deep experience with virtual and digital studies, and our dedicated team, we can deploy the right solutions to fit your peri- and post-approval study needs.

Email info@evidera.com to learn more about our digital and virtual solutions