

CLARINESS

CASE STUDIES

Cardiovascular conditions

Case study highlights:

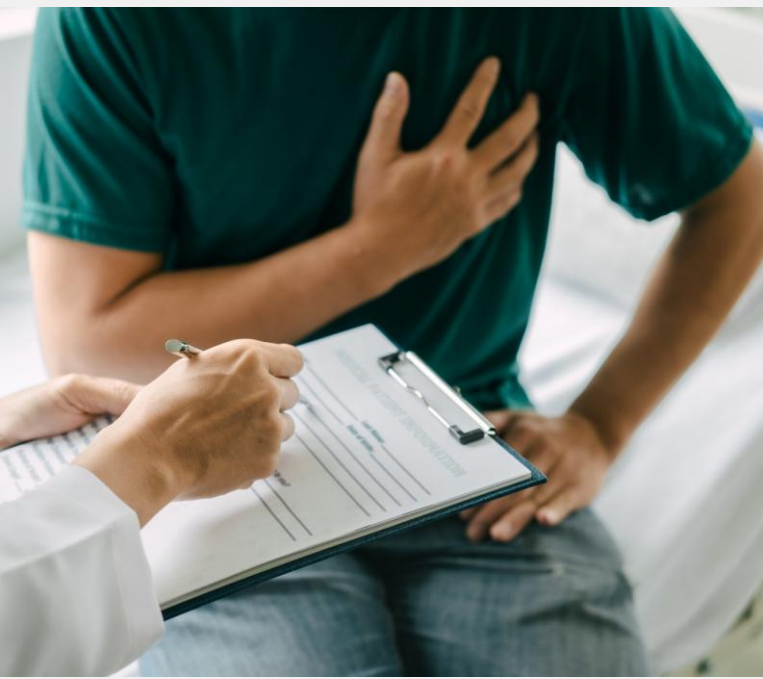
- ✓ Achieved a 97% increase in site productivity through ClinLife®
- ✓ Randomizations delivered using just 1/3 of the budget in China
- ✓ Successfully found & contacted 58% of LTFU patients for Phase III study
- ✓ Cost was 50% less for screened & randomized patients
- ✓ Exceeded number of planned referrals by 12%
- ✓ 100 referrals a week delivered for a rare population subset



CASE STUDY

CARDIOVASCULAR DISEASE

We achieved a 97% increase in site productivity through ClinLife®



Overview:

We successfully enhanced patient recruitment for a Phase III cardiovascular and type 2 diabetes study with the following challenges and scope:

- > Target enrollment of 27,000 patients across 30 countries and >640 sites in APAC, EE, LATAM, NA, WE and ZA
- > Originally planned for 15 months, with significant delays when we recused the US sites 8 months into the project, replacing the previous US vendors

Our approach:

- > Leveraged search engine marketing, banner advertising on relevant websites, and social media platforms to reach the target patient population
- > 2-level patient pre-qualification process including online and phone-based pre-screening, and scheduling of screening visit appointments with pre-qualified patients for trial sites
- > Site support activities, including site helpdesk to streamline operation and optimize site resources

Our results:



5

Months saved of recruitment time



37%

Contribution of randomized patients from Clariness supported sites



2K+

Randomized patients

CASE STUDY

CARDIOVASCULAR DISEASE

Randomizations delivered using just 1/3 of the budget in China



Overview & challenges:

- > Patient recruitment for an international sponsor's cardiovascular outcomes study in China
- > The sponsor's screen fail rate (SFR) was between 80-95% due to the complexity of the study, leading to low enrollment
- > China's stringent regulatory restrictions with online advertising required strategic, but measurable, offline recruitment, via a network of trusted healthcare providers

Our approach:

- > We leveraged our network of 20 local and trusted affiliates to engage patient communities
- > We worked directly with healthcare providers and their patients, to enhance identification efforts and built trust
- > Patients referred via healthcare providers ensured a higher quality of referral, reducing SFR by 55%, allowing us to deliver more randomizations than planned, using just 1/3 of the budget

Our results:

✓ **15%**

Referral to consent rate
of offline patients

✓ **55%**

Reduction in screen fail
rate (40% vs 90%)

✓ **-66%**

Budget used to deliver target
randomizations

CASE STUDY

CARDIOVASCULAR DISEASE

Successfully found & contacted 58% of LTFU patients for Phase III study



Overview:

- > Our client saw a high number of patients being reported as lost-to-follow-up (LTFU), jeopardizing FDA submission
- > We were contracted to ascertain and document vital statuses of patients that sites report to be LTFU or withdrew their informed consent (WC), which was possible per Informed Consent Form (ICF)
- > Conducted legal and ethical outreach tailored to each patient and country
- > We ran a 5-month recruitment campaign across 34 sites in 16 countries

Our approach:

- > Secured contractual agreements with sites to access patient information
- > Utilized public records, country-specific white pages, Google and Facebook for patients who could not be reached using known contact information
- > Used local language call scripts and email templates for optimal patient engagement
- > Collected endpoint data and updated patient contact information using a pre-defined script

Our results:



70%

of approached investigators opted in and signed contracts to use Clariness LTFU service



58%

of patients reported as LTFU were successful located and contacted



63%

of all LTFU and WC cases were successfully closed

CASE STUDY

CARDIOVASCULAR DISEASE

**Cost was 50% less
for screened &
randomized patients**



Overview:

- > Our client came to us to rescue a behind-plan patient recruitment for a Phase III cardiovascular study program supporting 2 protocols:
- 1. One closed enrollment prior to Clariness' project start
- 2. The other protocol had more difficult I/E criteria and multiple sites decided not to continue with the study
- > Patients were unaware of their LDL-C value – resulting in high screen failure rate
- > We ran a 2-month recruitment campaign across 188 sites in 7 countries

Our approach:

- > Multi-national online awareness campaign employing optimized, country-specific mixes of outreach tactics
- > Implemented a 2-level patient pre-qualification process including online and phone-based pre-screening
- > Provided site support activities, including site helpdesk, optimize site resource efficiency

Our results:



4,190

ClinLife® patients referred to sites



50%

reduction in cost for screened and randomized patients



2 months

ahead of schedule, the study enrollment target was met

CASE STUDY

CARDIOVASCULAR DISEASE

Exceeded number of planned referrals by 12%



Overview:

- > We conducted an online patient recruitment for a Phase III cardiovascular study
- > The study enrollment phase was originally scheduled for 12 months; however, due to the impact of COVID-19, it was shortened to 5 months
- > The initial plan included 18 countries and over 300 sites but was reduced to 250 sites across 16 countries

Our approach:

- > We implemented a 2-level patient pre-qualification process, including online and phone-based pre-screening
- > Site newsletters celebrated and shared progress of high performing sites
- > In-person site visits (pre-COVID-19) by Site Engagement Managers in certain countries helped boost campaign confidence and helped us better understand site-specific requirements

Our results:

✓ **12%**

More than planned referrals with 12% less countries participating and 92% of media budget spent

✓ **21%**

contribution of randomized patients at supported sites during the time that our campaign was active

✓ **8,185**

ClinLife® patients referred to sites

CASE STUDY

HYPERTRIGLYCERIDEMIA

**100 referrals a week
delivered for a rare
population subset**



Overview:

- > Short-term digital recruitment for Phase III study in the Czech Republic, South Africa, and the UK, to dramatically boost referrals
- > Strict I/E criteria requiring:
 - Very high levels of triglycerides
 - Prior cardiovascular events
 - The usage of statins

Our approach:

- > We generated traffic of 250,000 patients to ensure volumes would match the expectedly high digital screener fail rate
- > Our Enrollment Success Team screened the deeper level requirements, ultimately screening out over 16,000 patients
- > Our Site Success Managers then worked with sites to manage referrals and generate high patient satisfaction

Our results:

✓ **737**

Pre-screened
referrals generated

✓ **95%**

Site opt-in rate due to
demand for more referrals

✓ **100%**

Patient satisfaction from
exit surveys

CLARINESS



Get in touch

Learn how we can support and scale
your cardiovascular studies

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About Clariness

At Clariness, we accelerate patient recruitment for clinical trials, to bring new medicines and treatments to patients faster. With 20 years of experience in digital recruitment, we know how to connect you to the right patients, under budget and ahead of schedule.

We have supported 1,200+ clinical trials across all major indications.

Our extensive experience and medical knowledge in a multitude of therapeutic areas has proven to significantly improve patient enrollment and retention rates, which is why we have been entrusted with patient recruitment studies for 13/15 leading pharmaceutical companies, across 7,000+ research centers worldwide.



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