

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, countryspecific 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 behindplan patient recruitment for a Phase III cardiovascular study program supporting 2 protocols:
- 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 prequalification process including online and phone-based pre-screening
- Provided site support activities, including site helpdesk, optimize site resource efficiency

Our results:



4,190



50%



 ${ootnotesize {rac{1}{2}}}$ 2 months

ClinLife® patients referred to sites

reduction in cost for screened and randomized patients

ahead of schedule, the study enrollment target was met

CASE STUDY

CARDIOVASCULAR DISEASE

Exceeded number of planned referrals by 12%



- 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 prequalification 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%



8,185

ClinLife® patients referred to sites



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



Get in touch

Learn how we can support and scale your Type 2 Diabetes study

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