AutoCruitment

CARDIOVASCULAR CLINICAL TRIAL PATIENT RECRUITMENT

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INTRODUCTION

Patient Recruitment for Cardiovascular Clinical Trials: **Understanding Patient Perspectives**

Cardiovascular disease is estimated to affect more than 520 million individuals worldwide. In the next 12 months, over 90 Cardiovascular clinical trials will begin, and there are more than 1,000 that are already recruiting participants.

Clinical research plays a crucial part in understanding and approving treatment options for conditions across the therapeutic area. The patient profile is variable based on age, gender, ethnicity, genetics, lifestyle factors, medical history, environmental factors, and psychological factors.

There are five indications that that make up close to half of the planned trial starts and 35% of the trials already recruiting patients: coronary artery disease, heart failure, arrhythmia, stroke, and hypertension. This therapeutic area brief provides a look at the patient profile for each of the five conditions and highlights why Direct-to-Patient advertising is an ideal approach for recruiting patients for clinical research in these conditions.

PATIENT PROFILE: *CORONARY ARTERY DISEASE*

Coronary Artery Disease (CAD) predominantly affects older adults, becoming more prevalent after age 40 and increasing significantly with advancing age, particularly beyond 65. While men are generally at higher risk for CAD, the gender disparity lessens after women reach menopause. Additionally, individuals of South Asian descent experience higher rates of CAD compared to other ethnicities. Lower socioeconomic status is also commonly linked to an elevated risk of CAD.

Medical History: Genetics and other cardiovascular conditions
A history of cardiovascular conditions, like hypertension and hyperlipidemia, are strongly associated with CAD, as are diabetes and previous cardiovascular events. The common trait amongst the risk factors is the increased workload on the heart and atherosclerosis. Obesity is also a risk factor as it is a significant driver of other cardiovascular risk factors. Family history also increases CAD risk, suggesting that there is a genetic component to the condition.

Lifestyle Factors: Smoking and diet
Several modifiable factors increase the likelihood of developing CAD: Smoking, which increases atherosclerosis and clotting tendencies, diet, physical inactivity, and excessive alcohol consumption.

Psychosocial Factors: Stress, Mental Health, Social Support
Stress is a significant contributor to CAD, likely because stress triggers a variety of physiological responses like increased heart rate and blood pressure. Similarly, anxiety triggers the same response in the body and is another contributing factor. Depression is common in this population, and can lead to increased risk of complications, decreased quality of life, and poor medication adherence. With strong social support networks and increased medical literacy, individuals with CAD can experience improvements by decreasing stress and increasing adherence to treatment protocols.

Environmental Factors: Pollution, Diet, and Geography
Developed countries experience higher rates of CAD, largely due to lifestyle factors such as diet, smoking, and lack of physical activity. Urbanization, including air and noise pollution, also contributes to the increased risk of developing CAD.

PATIENT PROFILE: *HEART FAILURE*

Heart Failure (HF) affects both men and women, although some types are more common in women, and its prevalence increases with age. Compared to other ethnic groups, African Americans are at a higher risk which is primarily due to higher rates of other cardiovascular and cardiovascular-impacting diseases: hypertension, diabetes, and obesity.

Medical History: Cardiovascular conditions and events
Patients with heart failure often have a history of other cardiovascular diseases, such as coronary artery disease, hypertension, and myocardial infarction. Additionally, it's possible that they have experienced other cardiovascular events, like heart attack or stroke, which can lead to heart muscle damage.

Lifestyle Factors: Diet, activity
A poor diet, one that is high in sodium and saturated fats, can exacerbate HF symptoms, as can a less active lifestyle. Regular physical activity is important for heart function and overall well-being, and the lack of activity can increase the risk of heart failure.

Psychosocial Factors: Quality of life, mental health
Depression and anxiety are common in heart failure patients and can impact treatment adherence and outcomes. To add to that, heart failure can affect quality of life, leading to social isolation and emotional distress.

Environmental Factors: Pollution, Climate
Exposure to air pollution and environmental toxins may worsen heart failure symptoms and outcomes, and extreme weather conditions and fluctuations also have an impact. The impact of both pollution and climate is worse for those with already compromised cardiovascular function.

PATIENT PROFILE: *HYPERTENSION*

Hypertension affects more than a billion people worldwide, and men and women are equally impacted. Hypertension's prevalence increases with age, primarily due to atrial stiffness and other age-related factors. African Americans have higher rates of hypertension compared to Caucasians and Hispanics, much of this due to genetics and socioeconomic factors.

Medical History: Chronic conditions, previous cardiovascular events
Patients with hypertension often have a history of cardiovascular events such as heart attacks or strokes, and according to studies published in the American Heart Journal, individuals with hypertension are at increased risk for cardiovascular morbidity and mortality. Hypertension commonly coexists with other chronic conditions such as diabetes mellitus, hyperlipidemia, and obesity, which further increase cardiovascular risk.

Lifestyle Factors: Diet, activity
A poor diet, one that is low in fruits and vegetables and high in sodium and saturated fats can exacerbate HF symptoms, as can a less active lifestyle. Regular physical activity is important for heart function and overall well-being, and the lack of activity can increase the risk of Hypertension.

Psychosocial Factors: Stress, psychological well being
Persistent stress may lead to high blood pressure by interfering with its regulation, while poor mental health and depression are also associated with a higher risk of developing hypertension.

Environmental Factors: Urbanization, pollution
Hypertension is more prevalent in urban settings due to sedentary lifestyles and high stress levels. Furthermore, urban dwellers are often exposed to air pollution, which is another factor that can increase the risk of hypertension.

PATIENT PROFILE: *ARRHYTHMIAS, ATRIAL FIBRILLATION (AF)*

The most common form of **arrhythmia, Atrial Fibrillation**, is estimated to affect over 37 million people world wide, and men and women are equally affected. Previous studies have reported a lower AF prevalence among racial and ethnic minorities. While arrhythmias can affect people of all ages, they are more frequently observed in older adults because of aging-related changes in the heart.

Medical History: Cardiovascular conditions, previous arrhythmias
There are often underlying conditions at play in patients with arrhythmias – coronary artery disease, heart failure, or previous heart attacks. Additionally, these individuals often have a history of chronic or recurrent arrhythmias.

Lifestyle Factors: Diet, physical activity
While regular exercise is generally beneficial, intense physical activity could be a trigger for arrhythmias in some individuals. Excessive caffeine or alcohol consumption are also possible triggers.

Psychosocial Factors: Stress, well-being
Emotional stress or anxiety can trigger arrhythmias in susceptible individuals, and other psychological factors, like depression, may influence the severity and treatment outcomes.

Environmental Factors: Toxins, climate, temperature
Exposure to certain environmental pollutants or toxins seem to play a role in the development of arrhythmias, although direct causation is not well-established. Additionally, extreme weather conditions can affect heart function and potentially induce arrhythmias in susceptible individuals.

PATIENT PROFILE
STROKE

Stroke predominantly affects older adults, especially those over 65 years. While men have historically had higher stroke rates than women, this gap has been closing recently. Certain racial and ethnic groups, including African Americans, Hispanics, and American Indians, face a higher risk compared to Caucasians, often due to prevalent risk factors like hypertension, diabetes, and obesity.

Medical History: Cardiovascular conditions.
Hypertension is both the leading cause of stroke and the most controllable factor. Conditions like diabetes and high cholesterol contribute to atherosclerosis, which is another stroke risk factor. Individuals with a history of transient ischemic attacks or previous strokes are more susceptible to future strokes, with conditions like atrial fibrillation further elevating the risk.

Lifestyle Factors: Smoking, diet, obesity, physical activity
Several lifestyle factors significantly increase the risk of stroke. Smoking and tobacco use are major contributors, as they damage blood vessels and promote clot formation. Physical inactivity and an unhealthy diet can lead to being overweight, further elevating stroke risk. Excessive alcohol consumption also plays a role by raising blood pressure and increasing the prevalence of atrial fibrillation.

Psychosocial Factors: Stress, mental health
Chronic stress and poor mental health can negatively impact cardiovascular health, making strokes more likely.

Environmental Factors: Air pollution, climate change
Recent evidence suggests that exposure, both short-term and long-term, can increase the risk of stroke. Alternatively, exposure to greenspace has been linked to less severe stroke and lower post-stroke mortality.

STANDARD DIAGNOSTIC & TREATMENT PATH

Individuals seeking care for almost all cardiovascular conditions, with the exception of stroke, will begin with their Primary Care Physician (PCP). The PCP will typically refer them to a Cardiologist who will order diagnostic tests, although some PCPs will proactively order diagnostic tests before the referral.

From there, the patient might see a Surgeon or Interventional Cardiologist and then begin their treatment regimen. Treatment will range from medication and/or surgical intervention to lifestyle changes for CAD, Hypertension, Heart Failure, and Arrhythmia, and there are similarities across the conditions. Typical lifestyle modifications will include diet, exercise, cessation of smoking, reducing alcohol consumption, and stress management.

The reasons these patients might seek a different treatment pathway are similar across the conditions. Access to new treatments, lower or no cost ongoing monitoring and care, and the potential for better outcomes, especially in chronic conditions.

In individuals with strokes, the diagnostic and treatment paths are different, due to the urgent nature of diagnosis and treatment. Treatment often follows a three-step process: Acute Treatment, Rehabilitation, and Long-Term Management. A patient might look for clinical research as a care option to support rehabilitation and long term care outcomes, especially if their recovery is not progressing as expected or desired.

PATIENT HESITANCY & CONCERNS

There are billions of individuals worldwide who suffer from any number of cardiovascular conditions, with differing degrees of severity. While most individuals will seek treatment (when they have access to appropriate medical care) for cardiovascular conditions, there is understandable hesitation in seeking care outside of their current treatment pathways. There are three key factors that might keep patients with cardiovascular conditions from seeking care outside of their current treatment pathway:

- Active relationship with their provider and their symptoms and the impact of their disease are well managed
- Suspected financial burden that comes from clinical trial participation – travel costs and time away from work are most frequently cited by patients
- Challenge in managing co-existing conditions that are not holistically addressed by the trial
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Patients also express fears and hesitation towards participating in clinical research in general:

- Safety: With approved, effective treatments available, it could feel unsafe to participate
- Patient Burden: Financial and time commitments deter patients from engaging in clinical research (whether real or perceived)
- Education: There are misconceptions about clinical research, from the time required to the safety of participation, patients often lack understanding about the research process
- Impact on Treatment: If their symptoms are well-managed, a patient is unlikely to seek out a new treatment

THERAPEUTIC ADVANCEMENTS

Depending on the therapeutic area, different types of treatment or routes of administration have been the ‘gold standard’; however, clinical research and drug development are designed to improve and constantly push that gold standard forward. In January 2024, the American Heart Association named the top advances in disease research across several indications.

HYPERTENSION

Angiotensinogen, a protein secreted by the liver, is believed to play a key role in increasing blood pressure.

A new study tested a drug that decreased angiotensinogen production and showed promising results in a Phase 1 study.

STROKE

Thrombectomy, a minimally invasive procedure to remove a blood clot from the blocked artery in the brain that caused the stroke, is the standard treatment for midsized strokes.

Until recently, individuals who experienced more severe strokes have not benefitted from this procedure. New studies in Asia, Europe, and the US indicate that even those with the most severe strokes can have improved outcomes with Thrombectomy.

CORONARY ARTERY DISEASE

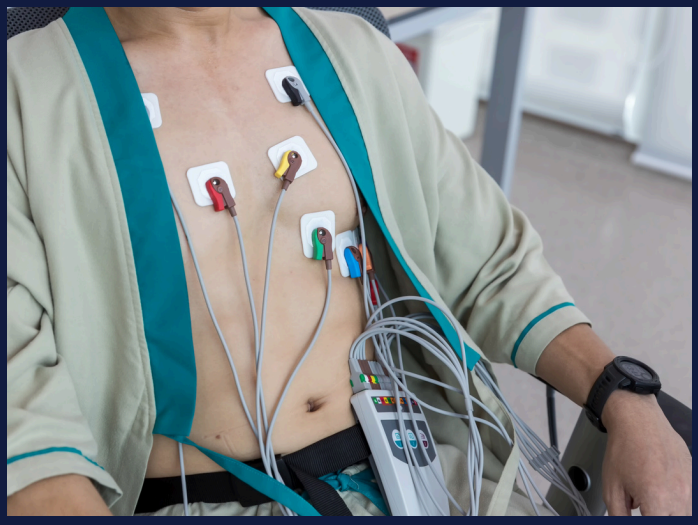
Percutaneous coronary intervention (PCI) is a non-surgical procedure used to insert a stent into heart blood vessels that have become blocked or narrowed due to plaque buildup along the artery walls, but stent placement can be challenging based on location of the buildup.

Improved image guidance enables more precise, tailored placement of stents, therefore improving patient outcomes.

THERAPEUTIC ADVANCEMENTS

ARRHYTHMIA/ATRIAL FIBRILLATION + STROKE

Patients are often treated with Direct Acting Oral Anticoagulants at different intervals depending on severity of the stroke, but new research suggests that sooner might be better, especially when it comes to decreasing the risk of recurrent strokes.



CARDIOVASCULAR DISEASE + OBESITY

Glucose lowering drugs (GLP1s) have been prescribed for weight management in individuals with Type 2 Diabetes.

There's growing evidence that shows cardioprotective benefits, regardless of how well the Diabetes is being managed.

CARDIOVASCULAR, KIDNEY, AND METABOLIC (CKM)

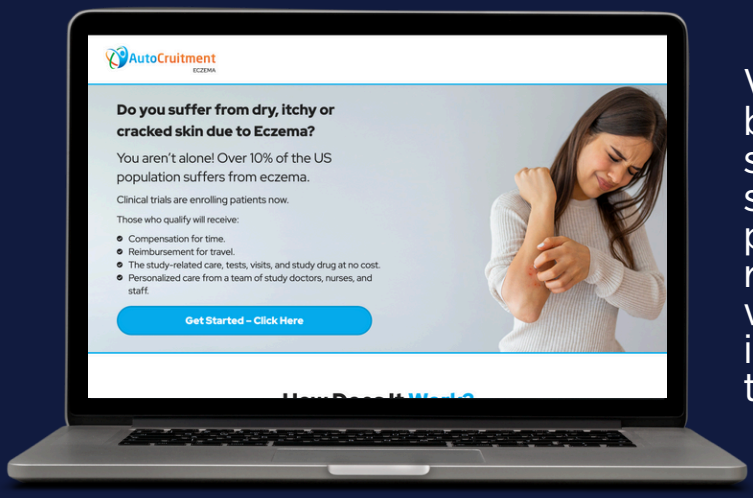
There is a common thread between obesity, chronic kidney disease, diabetes, and cardiovascular disease, and new research is looking at the link and long-term risks associated with poor CKM health.

A risk calculator was released in 2023, and there is an increased focus on the treatment of CKM syndrome – those with cardiovascular disease and those at risk of developing it.

UNLOCKING ACCESS TO INDIVIDUALS WITH CARDIOVASCULAR CONDITIONS

Finding potential Cardiovascular clinical trial participants can be challenging, but Direct-to-Patient Advertising as a recruitment approach is powerful in this population.

The conditions reviewed in this brief have been searched, on average, 642,000 times per month for the last year. The search volume for some of the most common symptoms such as chest pain, palpitations, shortness of breath, swelling, weakness, and wheezing, have a average monthly search volume of over 800,000. Potential patients are often turning first to online sources for information and education about their diagnosed or suspected condition as well as side effect management for their existing treatment.



With that activity, an online profile begins to evolve, and by using sophisticated targeting and screening algorithms, Sponsors can put information about clinical research directly in front of people who are already seeking information outside of the traditional physician-led approach.

Direct-to-patient recruitment builds awareness and empowers patients (or their caregivers) to seek best-fit solutions for the condition.

PATIENT MOTIVATION

Whether or not someone has received a formal diagnosis, their search for information about symptoms or conditions implies a desire for a solution. If they're presented with a clinical trial as a treatment option and take steps to determine their eligibility, the patient is likely to be more engaged and proactive at the start.

Traditional recruitment methods focus on data mining to find potential matches but often overlook the individual's interest or motivation.

Direct-to-patient recruitment, however, reaches those actively seeking solutions, placing research opportunities directly in their path.

THERAPEUTIC AREA SNAPSHOT

AutoCruitment has recently completed 7 Cardiovascular Studies

Average increase in enrollment rate: 127%

Average time saved: 5.6 months

Total Randomizations Contributed: 383

AUTOCRUITMENT METHODOLOGY

Targeted Direct-to-Patient Recruitment

- Diverse recruitment channels
- Web-based technology platform
- Proprietary algorithms to hyper-target and identify the right patients

Enhanced Qualification Services

- Sophisticated online screener, customized to protocol
- Second-line clinical phone screening
- AI-powered EMR Capture & Intelligence

Dedicated Engagement Support

- Patient advocates provide support throughout recruitment and enrollment
- Research site support to reduce the patient recruitment/enrollment burden

ABOUT AUTOCRUITMENT

AutoCruitment unlocks access to the 90% of patients who cannot be found through traditional recruitment methodology alone. By targeting and engaging directly with patients, they're at the center of their recruitment journey.

AutoCruitment is the leading direct-to-patient recruitment company, and we help life sciences companies find the right patients for their trials, at exactly the right time.

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