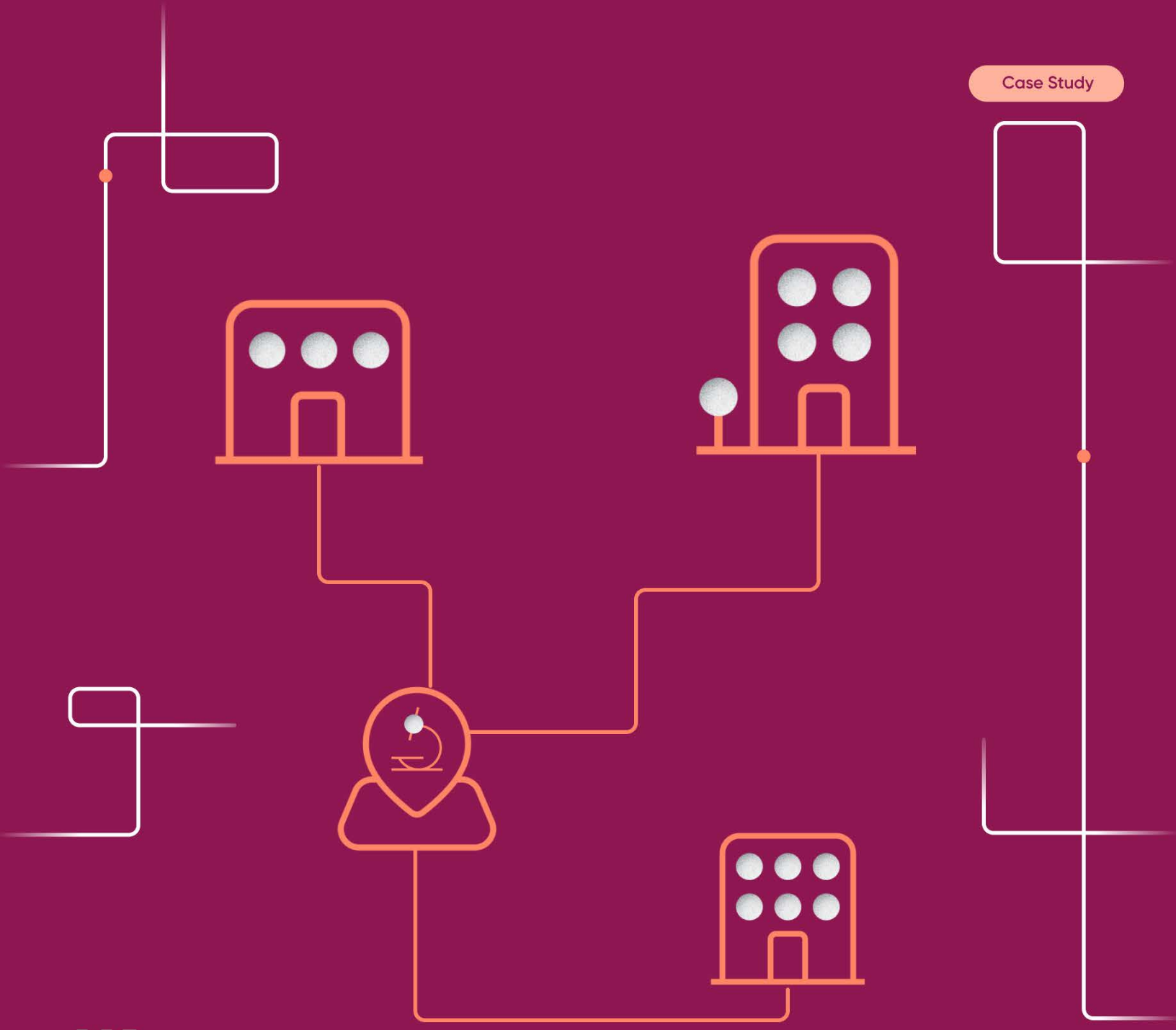
Case Study



H1

Site Feasibility or Success? Setting Up a Clinical Trial in Different Medical Therapies in a New Market

CASE STUDY

Site Feasibility or Success? Setting Up a Clinical Trial in Different Medical Therapies in a New Market

Assessing new label expansion trial sites: data at the indication level

A global life sciences company was looking to create a phase III clinical trial in a new country, market and therapeutic area for a drug label expansion. Since it was a new and unfamiliar therapeutic area, the company couldn't rely on its existing and go-to key opinion leaders (KOLs) and healthcare providers (HCPs) knowledge to guide their site selection and feasibility process effectively.

The Problem

The feasibility team was struggling to efficiently identify and analyze vast amounts of data from disparate sources to develop an aligned target list of sites and doctors that will pass the feasibility team's high standards.

The Ask

The company asked H1 to help find net new investigators and rising stars as well as principal investigators (PI) and sites who fit the needs of the trial across the globe. The company asked H1 to support its efforts to efficiently accelerate label expansion in a novel disease area by finding appropriate potential investigators and trial sites that would drive confidence in the study's positive outcome for the company.

The Approach

First, H1 aligned with the client to understand their strategic goals and which PI attributes would best match their feasibility strategy. Second, we tapped into Trial Landscape, our clinical trial knowledgebase product. With Trial Landscape we were able to derive a tech-first, data driven approach to understand investigator and trial site experience, investigator subject matter experts, and clinical trial historical performance data.

As a clinical trial management system (CTMS) network partner of H1, the company leveraged H1's Trial Landscape solution to quickly drill into sites and doctors with relevant trial experience over the last 5 years. They were able to layer on trial performance data at the site level to ensure that each identified target site had a history of effectively executing trials that met the same criteria of its client's upcoming study.

Methodology:

Step 1:

Analyze H1 data and insights to surface relevant sites based on trial experience, trial performance data, and academic expertise:

- Clinical trial performance data tied to relevant indication
- Phase 3 clinical trial experience
- Performing trials within the last 5 years
- Relevant publications tied to the indication
- Locations that matched those of interest from the Client

Step 2:

Sites were tiered based on how many parameters matched the client's strategic criteria.

Step 3:

Sites in the highest tiers were further broken down to identify and analyze the performance of PIs. Historical trial performance and relevant trial experience was validated.

Step 4:

PIs were tiered within an indication to help the sponsor take a more targeted approach.

The Results

Key insights delivered by H1 included: trial sites that recruited and executed like-trials in a timely fashion, and most importantly, retained existing patients on studies that had already run.

Once sites with historical performance data were identified, H1 analyzed the performance of principal investigators on those trials in the selected country, to understand their individual and historical performance on other trials.

With this carefully curated data, H1 was able to identify **56 net-new principal investigators** who were a strategic match for the client's trials.

Connecting the world with the right doctors

H1 is the connecting force for global HCP, clinical, scientific and research information. The H1 Connect platform democratizes access to HCP knowledge and groundbreaking insights for life sciences, academic medical institutions, health systems, and payors. H1 Connect fuels a robust product that helps customers discover and engage industry experts, drive equitable research, access groundbreaking science, and accelerate commercial success with the most robust and accurate healthcare professional data.

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