CACI | Roche

How Roche diversified international clinical trials through demographic & health variable data

Background

Running & recruiting for clinical trials to gain regulatory approval of new medications

For international pharmaceutical and diagnostics company, Roche, a core function of the organisation is the running of clinical trials for regulatory approval of new medications. In particular, the Insights and Analytics team is involved in supporting late-stage trials by identifying the most appropriate hospital locations and clinical trial patients for these trials across countries to enable the most effective recruitment process.

The process of confirming that these medications work requires substantial evidence for the team to gather and present to regulatory agencies to approve or reject them. The process of recruiting patients for clinical trials is therefore a fundamental aspect of the approval proceedings and can often be a challenging and extensive undertaking.

In addition to this, there has been an increasing drive across the sector to ensure appropriate diversity in clinical trials, driven by regulatory bodies in the US, UK and Europe. To do this effectively would require data, consultancy and an innovative approach that could supply the team with granular information, which is why CACI stood out to help Roche achieve this goal.

Challenge

Skewed clinical trial populations, evolving regulations & data hurdles

- **Historically, clinical trial populations have often differed from the populations that use the medications, resulting in clinical trial patients being predominantly Caucasian and coming from more affluent socioeconomic backgrounds.** It is therefore imperative for Roche, along with the wider sector, to find a new and innovative way to recruit more diverse populations and ensure their medications will be suitable for all demographic backgrounds (and all genetic variances).

- **Regulations are evolving and regulatory agencies are driving a new view on diversity and inclusion in clinical trials.** Ensuring that these trials are representative of the population is therefore becoming increasingly mandated, prompting Roche to reassess their clinical trial strategy and population representation.

- **Lack of data availability, legal barriers, data collection and protection and privacy issues are all common hurdles in clinical trials, especially in Europe.** With increasing data regulations and cultural variances between different countries on data privacy, the accessibility of the data points required has huge variances globally. This substantial variation between countries and the lack of granular data caused Roche's Insights and Analytics team to struggle to find the necessary information to target the best suited clinical trial patients.

Solution

Leveraging demographic & health variable data to bolster clinical trials in five European markets

By working with CACI, Roche's Insights and Analytics team has used a combination of demographic and health variable data within CACI's analytical and mapping tool, InSite, to determine locations that would best suit the recruitment of more diverse populations for clinical trials in five European markets.

With diversifying clinical trials being the team's goal, the key variables they needed to understand included ethnicity, deprivation, education attainment, economic status, rural versus urban, smoking, pollution and other disease risk factors. CACI developed bespoke models for these variables by combining key demographics such as age, income and gender with survey data on a country-by-country basis to generate models at a postcode level for each of the required countries.

These variables and demographic data were delivered within a bespoke InSite system to bolster the Insights and Analytics team's data interrogation, create maps to better understand locations and combine results with other third-party data. The bespoke model data sources also helped the team understand where this range of factors is present in each local demographic's population.

Roche is using this data in combination with their own medical information to build an internal tool, Sitescape, which is used company-wide to generate a view of potential hospital locations to host clinical trials while maximising population reach. This enables CACI's population data to be overlaid and visualised on a map, highlighting the diversity of various populations, the number of people living in proximity of local hospitals and other key demographic factors. It also enabled the team's hotspotting of hospitals to identify the best opportunities for recruiting specific clinical trial patients, understand the interaction between the medical and population requirements and showcase Roche's innate efforts to diversify their clinical trial population samples.

Results

Enhanced data-driven decision-making for optimised clinical trials

While still in its early days, Roche's Insights and Analytics team has already tremendously benefitted from CACI's bespoke model and expertise, delivering the model to the team and providing training on how to use it. The team has since been able to use data-driven decision-making to tackle any clinical trial strategisation obstacles versus relying on assumption.

Having previously worked with CACI on smaller, UK-focused projects, the ability to now take this bespoke model to scale so that it can be accessed across other countries has augmented Roche's diversity strategy, with the team particularly pleased by CACI's quick data generation and innovation in terms of modelled data from survey data sources.

> **Now, for the first time, we have data that [the team] can see and help their decision-making,"** Jonathan Wharton, Portfolio Analytics Manager at Roche, explained. **"I think it's particularly useful that we have it on a region-by-region basis, because being able to visualise this on a map is something that the team really appreciates**

Working directly with CACI's data scientists has created trust and maintained the Insights and Analytics team's oversight of the data verification and modelling process, which has led to positive interactions and enhanced verification capabilities. The Insights and Analytics team has also been able to communicate how the model works to the wider organisation, which has significantly bolstered the adoption process.

> **The innovative approach with CACI was taking all that demographic data collected across Europe, tagging it with running surveys, and modelling it based on... geographic locations of different populations,"** Jonathan concluded. **"That allowed us to come up with some numbers in those various locations, which was something we couldn't find anywhere else.**

What's next?

Clinical trial expansion & broadened demographic variances

Roche's Insights and Analytics team continues to plan their next strategy and expects to further expand their clinical trials based on the outcomes of this initial project. The many different variables created through this project have also encouraged the team to explore additional demographic variances that can enhance future clinical trials. These potential variances can also help the team explore how they can access patients with disabilities or who live in areas of social deprivation to further diversify their trials.

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