Case Study

Managing Worldwide Population Growth

Problem Identification

Submission with a very short turnaround on non-standard data with an unclear scope of work.

Family planning is essential for women's health, for securing personal autonomy, and, in essence, the health and wellbeing of community. It is estimated that 222 million women (WHO study) in developing countries do not have access to contraception, though they may want to use it. In an innovative approach, our client, a major pharmaceutical company, and a medical technology manufacturer combined their resources, along with support from The Bill & Melinda Gates Foundation and other public/private institutions, to develop a low dose formulation of a very popular long acting injectable contraceptive. Each of these subcutaneous injectables provides 3 months of contraceptive protection for women living in areas of the world that are hard to access.

A high priority study was to be conducted for submission on this formulation. This data was collected in a non-standard way with multiple data integrity issues and in a very short time period, 75 days.

In order to complete this submission within a very short timeframe on non-standard data with integrity issues and an unclear scope of work, our client required a partner who has a flexible resourcing model and could work as an extension of their team.

Once work authorization was approved it was determined that this submission would need both statistical as well as programming support. In order to complete this submission EG Life Sciences assembled a team of programmers and a statistician that was experienced in working on submissions with non-standard source data. An initial proposal was drafted on methods of handling data issues taking into account various scenarios with the intention of utilizing the maximum amount of available data in a meaningful way.

Once approved by our client's subject matter experts, the EG Life Sciences team was provided with the non-standard data in Excel files that contained integrity issues and missing values. The team was tasked with the creation of safety reports to be derived from this data for submission. Our team coordinated with the client to create a possible list of tables that could be produced for this submission.

A total of 30 tables, along with 15 raw dataset and 5 derived dataset, were created from the Excel spreadsheet and was thoroughly validated for integrity. As a result of this work, submission was made on time.

This submission was approved in The European Union and multiple FP2020 focus countries. As a part of our client's commitment towards women's health in developing countries, an agreement was signed on November 2014 to expand access to its injectable contraceptive for women in poorer countries at an affordable cost in conjunction with The Bill & Melinda Gates Foundation and Children's Investment Fund Foundation (CIFF).

Nature and Scope of Challenge

- Data with integrity issues
- Little to no guidance from client team
- High priority submission with very tight timelines

Problem Resolution

- Team of programmers and a statistician that are experienced in working on submissions with non-standard source data
- Plan was created on handling missing data and approved by client
- Flexible resourcing model

Value Proposition

Flexible resourcing model and submissions experience with short turnaround times. Ability to use maximum amount of available data in a meaningful way if data has problem resolution.

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