



IVRS/IWRS

Introduction

In 1977 this customer was created as a "virtual" pharmaceutical company without any internal discovery organization or manufacturing facilities. The company's corporate structure and business model have always been unique. The corporate culture can best be described as flexible and versatile. The company's early decision to look outside for new compounds helped to shape its business model. Today the company continues to search the world for in-licensing opportunities, focusing its efforts on rapid, high-quality drug development, and marketing and sales in North America.

The customer asked Bilcare to provide an Interactive Voice Response System (IVRS) for a Phase III gastroenterology study. The scope included Enrollment and Randomization and collected data for the associated Patient Diary.

Challenge

The challenge for Bilcare was to develop an IVRS for a relatively large Phase III study that would handle 109,931 calls including:

- + 70,964 incoming calls from patients
- + 11,417 incoming calls from investigators
- + 10,052 outbound patient reminder calls
- + 17,498 faxes

Outcome

Bilcare collected data on 3,543 patients of which:

- + 2,827 were enrolled and randomized
- + 667 were enrolled but discontinued
- + 59 screened but were never enrolled

Over the 128 day period, the system had 100% uptime.

At its peak the system was processing 20 or more concurrent calls for several hours each day.

It would take at least 20 people working around the clock to process the same number of calls. Assuming a standard minimum wage of \$8.00 per hour (for a knowledge worker) the project would have cost the company at least \$491,520 in wages.

Benefits

- + Improved study metrics and visibility of study milestones
- + Improved data integrity and compliance for patient diary data
- + Cycle time reductions on study initiation
- + Cost savings on total study expenses
- + Error free randomization
- + Secure emergency unblinding
- + Tracking of drug distribution
- + Expedient management of limited drug supply

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