QLT Inc.,

A Case Study…
Vancouver-based Biotech Firm, QLT Inc.,
Partners with Global Vision Technologies, Inc.,
to Implement Two Online Patient Registry Systems.

Introduction:
Vancouver, Canada - QLT Inc. is a global biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies. Their research and development efforts are focused on pharmaceutical products in the fields of ophthalmology and dermatology.

Visudyne® (verteporfin) was the first therapeutic treatment approved worldwide for certain forms of wet age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 55. Visudyne is commercially available in more than 75 countries for the treatment of predominantly classic subfoveal choroidal neovascularization (CNV) and in a number of countries for occult subfoveal CNV caused by AMD.

The Challenge:
Recently however, alternative treatments for wet AMD with different modes of action have been approved or used. Although Visudyne still played a role in treatment of wet AMD... the newer, alternative treatments had taken a more predominant role.

Preliminary studies and case series supported Visudyne's use in combination with other wet AMD targeted therapies.

In order to gain a better scientific understanding of Visudyne use in combination with these other therapies QLT began to investigate real-world treatment regimens and outcomes associated with Visudyne therapy in combination with anti-VEGF antibody therapy, through the use of the an online data capture system.

The Journey:
In early 2006, the objectives were formalized.

- To establish a "core" group of investigators who would take a lead on using Visudyne in combination with one or more additional therapies (an Anti-VEGF and potentially a steroid).
- Provide training to retrospectively collect data on patients receiving Visudyne in combination could be potentially collected in a secure, database... possibly web-based.
- In time – would be able to show preliminary indications that would suggest the combination therapy was effective and look to publish the new clinical and scientific data as soon as it was collected and analyzed.
- And establish a methodology or system to collect the data so that they could provide scientific and clinical rationale for publication.

It was at that time that Global Vision Technologies (GVT) was asked to discuss a potential relationship to help with the collection of the data. QLT came to know GVT through an established relationship they had with Novartis Pharmaceuticals and GVT's expertise and proven technology for secure, rapid and custom software development, clinical case note modules, case management and clinical data collection solutions.

The Solution:
Due to the large volume of scattered anecdotal evidence for combination therapy a need for a central, easily accessible database for the collection of combination data was necessary. QLT contracted with GVT to develop a custom, comprehensive, web-based patient registry solution that specifically addressed their needs.

The ultimate goal of the project would be to generate a large, aggregate dataset to lessen the "combination data void" while providing insight into combination therapy safety data and emerging trends in VA outcomes from existing data.

GVT's subject matter expertise that included design and functionality, site recruitment / communication, training and management, as well as navigation logic provided the perfect foundation for their new data collection initiatives and registry program.

During the design phase, one thing was for certain however robust the system was, the fact remained that it also needed to be easy to use and navigate with real time customer service support during data entry especially for the investigators, study coordinators and data entry personnel. Any impediments to the technical side of the data collection process could spell problems down the road for the team both from a customer motivation perspective and from a data analysis perspective.

ClinicalPURSUIT is GVT's patient registry solution, built on a proprietary, secure, HIPAA & Part 11 compliant workflow engine. The platform was designed to easily accommodate customizations, business rules and workflow logic, error-trapping and sequential QA formatting. In addition, the platform provided for the necessary auditing, time stamp and electronic signature capture validations and tracking, essential to any clinical data capture endeavor.

The system allowed QLT the flexibility to add or remove data capture fields as the system and data capture methodologies changed... without putting the integrity of the data at risk.

In addition, because of the simple, point and click design... every effort was made to streamline the data entry process by providing system users with a single path of entry to follow... which would make for a pleasurable, expedient and trouble-free data entry experience for the coordinators.

The Registry program and discussions were initiated in July 2006 and 30 days later in August 2006, the new system and website was launched. The goal was to enroll 1000 patients, treated with a specific combination therapy and monitor the patient outcomes over the course of two years.

As more and more data was collected and newer treatment regimens were investigated, a decision was made to form a second study. In April 2007, a second Registry was launched, specifically to collect data and track patients treated with a

"The greatest benefit that we receive from using Global Vision Technologies' patient registry program is the ability to analyze our treatment results objectively on an ongoing basis and to compare these results with a larger pool of patient data from other practices... without the time-consuming process of retrospective chart review.

The data analysis tools intrinsic to ClinicalPURSUIT are invaluable. Using this system, we have been able to present our practice data to other members of the medical center and ophthalmic community in a timely fashion with limited added effort and preparation.

The members at GVT are effective team builders.

Rather than present a pre-packaged product, they offer a flexible solution that can be molded to the specific application and user group."

Dr. Paul Griggs, M.D.
Retina Specialist

Virginia Mason University, Seattle, WA

unique treatment regimen. The goal of the second registry was similar to the first Registry, and sought to enroll 1000 patients and monitor outcomes over a period of 12 months.

The Results

In a combined effort with the QLT management team and in order to meet the patient enrollment goal of 1000 patients... GVT helped to manage and expedite the data collection process & train study centers with the online data entry screens. The goal of 1000 patients was met within 6 months of the website's launch.

As with any successful data collection and analysis effort, there is a need to run streamlined reports so that the analysis process can be fast and accurate. Queries need to be run and open communication needs to be ongoing with the investigators to ensure the integrity and quality of the data and any questions posed are answered. GVT's custom reporting tools helped QLT define and build specific reports that "sped up" the reporting, data dump and analysis time frames.

Starting in late 2006, the results of the data collection and analysis efforts of both registries were presented as both poster and podium presentations world-wide. A manuscript of the first registry is currently underway and is expected to be published in 2008.

The Registry Program included the following:

- Registry #1: 79 investigators from USA and Canada, including a Canadian data subset
- Registry #2: 65 investigators from USA and Canada

Throughout the two-year program, the system was never down or inaccessible and was available 24X7; the feedback from the investigator and data entry team was very positive.

But, the ability to rapidly collect the dataset, in a secure, web-based solution and to then present that data at over 20 or so venues was the greatest achievement of the Registry program.

There is no question that in order to understand treatment trends that warrant further exploration– data needs to be collected rapidly, securely – and with a team-building methodology and approach, so that the program has the greatest chance of success and the most important outcomes are easily identified.