REMEDY INFORMATICS

CASE STUDY

ACCELERATING BLOOD DISORDER RESEARCH WITH THE INVESTIGATE™ INTEGRATED RESEARCH MANAGEMENT SYSTEM

CUSTOMER PROFILE

ORGANIZATION

The Zimmerman Program for the Molecular and Clinical Biology of VWD at the BloodCenter of Wisconsin's Blood Research Institute

RESEARCH/CLINICAL FOCUS

Developing a scientific and clinical understanding of von Willebrand disease (VWD), a bleeding disorder that occurs in about one in every 100–1,000 people.

NEED

A single system for managing an NIH-funded research project spanning globally distributed research sites and disparate data sources, such as patient registries, sample data, biorepositories, lab test results, and clinical findings.

SOLUTION

Investigate™, an Integrated Research Management System that connects clinical, laboratory, and biobanking data types and streamlines the capture, querying, and reporting of complex, multicenter research activities so that researchers can rapidly correlate results and act on findings.

INVESTIGATE™ ENABLES THE BRI TO

• Support collaborative research across all participating sites by providing a single, secure source of all project work.
• Simplify administration and maintenance of project data through a web-based system that has completely eliminated manual updates and the need to maintain duplicate database copies at project sites.
•Track patients, specimens, lab test results, and clinical findings in real-time.
•Conduct longitudinal studies and use accumulated data to find previously unrecognized patterns that provide insights into VWD or suggest new research studies.

THE CHALLENGE

Few institutions would turn down the chance to lead a multicenter, international research effort. In addition to prestige, however, a coordinating center also gains the responsibility for ensuring that research runs smoothly and that all participants have access to the data they need to advance the project. Since 2005, the Blood Research Institute (BRI) of BloodCenter of Wisconsin has served as the coordinating center for a global study of von Willebrand Disease, the most common hereditary coagulation disorder in humans. The TS Zimmerman Program for the Molecular and Clinical Biology of VWD is an NIH program project grant encompassing research at the BRI, the Medical College of Wisconsin, Queen's University in Canada, and the University of Sheffield in the United Kingdom. The program collects patient samples at treatment centers in Atlanta, Detroit, Houston, Iowa City, Indianapolis, Milwaukee, New Orleans, and Pittsburgh as well as 22 secondary centers throughout the U.S.

As the coordinating center for the TS Zimmerman Program, the BRI is responsible for managing and centralizing all research data associated with the project. Until recently, a Microsoft Access database was sufficient to the task. But as the project grew to encompass data on over 3,000 patients and families, BRI realized it had outgrown its legacy system. There were several capabilities that BRI needed:

- Web accessible data access. With the legacy system, data from participating centers had to be sent electronically to Wisconsin and manually uploaded into the local database. In addition, each individual site had to maintain its own copy of the master database. A web-based, common repository would enable all participating researchers to upload data and gain access to project work—wherever it was conducted—in near real-time.

- Integrated, consolidated data access. The legacy system required differently structured data, such as patient data and sample data, to be stored separately. This required researchers to conduct separate, multiple searches to gather together information for reports or analyses. BRI needed a system that would enable researchers to intelligently query multiple data sources regardless of data type in order to conduct longitudinal studies for patients over time or mine data to uncover interesting patterns or trends.

- Room to grow. BRI had many ideas for projects to run in the grant's renewal, which would require new study procedures and collecting

different types of data. Any system BRI implemented would need to provide a robust framework that was also flexible enough to accommodate the diverse needs of very different research labs.

"The administrative and operational overhead associated with this type of long-term, observation study makes things very complex for a coordinating center," said Erik Bergman, Manager, Clinical Research Systems at BRI. "We needed a system that would help us quickly bring new sites on-board and that would be intuitive and easy to use. This would help us administer the study, ensure enrollment was tracking consistent to the plan, and provide dashboards and reports to measure progress and push back information to sites to help them see how they are doing."

THE SOLUTION

In 2010, BRI implemented Investigate™, the first and only integrated research management system to integrate disparate data types and provide powerful query tools to offer a single, holistic, systems view of basic, translational, clinical, and outcomes research. Investigate combines the best features of biobank management, study management, LIMS, ELN, and clinical registry software into an intuitive, web-based system that provides persistent, secure data storage; a single, unified user interface for entering and analyzing data; and intuitive, non-SQL query tools for visualizing and analyzing disparate data types. A built-in, extensible ontology engine helps Investigate harmonize all data entering the system, map related concepts, and match semantically identical terms to provide necessary structure along with the freedom to augment the system to conduct logical and informed research.

Investigate's cloud-based implementation is particularly useful to multisite, collaborative research such as the BRI-VWD program. "With multiple sites across the country that need to enroll patients, register samples, and send samples to the coordinating center for testing, we had to get away from keeping multiple copies of databases at each site and provide access to a single system," said Bergman.

> "From my perspective, a once time-consuming process now is something that just happens. Before, creating a report meant pulling data from different databases with one-at-a-time searches. It was truly like searching for a needle in a haystack. It's been great playing with Investigate's query builder, creating new reports, and placing various conditions on the data to analyze it in different ways."
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> **- Pam Christopherson, Sr. Research Coordinator**

Investigate has relieved Pam Christopherson, senior research coordinator at BRI, from the tedious task of receiving data from participating sites and uploading it into the master database. With Investigate, sites upload data themselves from a central, secure login. "From my perspective, a once time-consuming process now is something that just happens," said Christopherson.

BRI also appreciated the ability to intelligently query all collected data through Investigate's uniquely intuitive Venn-diagram guided query tools. "Before, creating a report meant pulling data from different databases with one-at-a-time searches," said Christopherson. "It was truly like searching for a needle in a haystack. It's been great playing with Investigate's query builder, creating new reports, and placing various conditions on the data to analyze it in different ways."

> "Things are happening in real time. Data is entered, samples are studied faster, we get results sooner, and we can instantly compile a report to see what samples we have, what testing needs to be done, and where there are gaps in our processes. We have a better overall flow, better management, and better control of our project." **- Pam Christopherson, Sr. Research Coordinator**

RESULTS AND BENEFITS

The ability to rapidly and intelligently query the data has already had an impact on studies conducted under the grant. For instance, one form of VWD, Type 1C, was initially discovered and reported by BRI. Patients with Type 1C produce a variant form of von Willebrand Factor (VWF) and therefore do not respond to desmopressin, a hormone that promotes the release of VWF and is therefore the typical therapy for Type I VWD. "We have enough enrolled patients that we were able to pull out the data to prove this correlation, and it ensures that patients are tested for Type 1C so that they can get the right treatment," said Christopherson.

The ability to analyze the accumulated data and determine potential patterns in the data will factor prominently in the grant renewal according to Bergman. The program's primary findings in the first five years have questioned the fidelity of VWD diagnoses. "We see patients without a defined mutation that have an aspect of VWD, such as low levels of bleeding," said Christopherson. "And sometimes two family members have the same mutation, but only one is symptomatic. With Investigate, we can segment specific populations out, look for potential correlations, and then create a study with a slightly different configuration from the parent study to test the hypothesis."

Such follow-on work is further enabled because Investigate has streamlined data management and maintenance. "Things are happening in real time," said Christopherson. "Data is entered, samples are studied faster, we get results sooner, and we can instantly compile a report to see what samples we have, what testing needs to be done, and where there are gaps in our processes. We have a better overall flow, better management, and better control of our project."

The BRI team is confident that Investigate will be able to support the program as it moves into the renewal phase. "We are a small (relatively speaking) organization compared to some large, academic research centers, but the needs of the researchers involved in this type of project are relatively complex and very different from one another," said Bergman. "Investigate offers a robust framework and native ability for us to extend the system to capture new information as our research requires."

About Remedy Informatics, Inc.

Remedy is the leading provider of clinical registries and research informatics products. Built on the powerful Mosaic™ Platform, Remedy products enable researchers to accelerate translational medicine discoveries from bench to bedside. Remedy's mission is to tangibly, measurably and permanently improve the effectiveness of Life Science and Healthcare Research around the world.

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