Case Study

Successfully Managing Disease-Specific Registries with eClinical Technology

MedNet Solutions Supports Industry-Academia Collaborative Registry; Facilitates Quick Attainment of Enrollment Goals and Generation of Multiple Publications

Research Challenge

T-Cell Lymphoma represents a rate heterogeneous group of diseases that accounts for 10-15 percent of all non-Hodgkin's Lymphomas (NHLs) in the Western world. Peripheral T-Cell Lymphomas (PTCLs), responsible for the majority of T-Cell NHLs in adult patients, are often aggressive and therefore require aggressive treatment. Traditionally, patients with newly diagnosed PTCL have been managed with chemotherapy regimens designed for aggressive B-Cell NHL, yet they generally have a poorer response to therapy and shorter survival rates compared to patients with aggressive B-Cell Lymphomas.

Data on treatment outcomes have been derived primarily from retrospective reviews, and there were no well-established standards of care overall. How patients are managed in the context of daily clinical practice, both on and off trials, was also previously unclear. Specifically, there was a lack of information regarding the factors affecting treatment decisions and whether there were differences in treatment by clinical practice setting.

Registry Objectives

Given the absences of treatment data for newly diagnosed PTCLs, the COMPLETE Registry was established in 2010 as a 75-site observational study intended to provides insight into PTCL practices patterns and outcomes in the United States. The specific objectives were:

Primary Objective:

- Describe, in detail, patterns of care for patients with PTCL by treatment setting, independent of any specific intervention

Secondary Objective:

- Document outcomes, overall and by treatment regimen
- Identify factors influencing treatment decisions
- Determine incidence and severity of selected toxicities
- Identify supportive care received for managing selected toxicities

The Utilization of eClinical Technology in Facilitating Data Collection

Given that resources for observational Registries are typically limited - from both a site personnel and cost perspective - it was essential to partner with an eClinical/Electronic Data Capture (EDC) company that would help facilitate high-quality, cost effective and efficient data collection and management.

The Registry Sponsor, Spectrum Pharmaceuticals, following a thorough evaluation of various technology vendors, ultimately selected MedNet Solutions' eClinical platform as the ideal solutions to streamline data-driven Registry activities.

MedNet was chosen as the Registry's partner of choice based on the following key criteria:

- Previous positive site experience with the MedNet platform for large observational studies
- A single, unified system
- Solution affordability
- Easily navigable user interface
- Robust dashboards and reporting tools, available 24/7

Upon Registry kickoff, MedNet's internal project management team quickly ramped up with the creation, testing and validation of study-specific functionality, workflows and associated processes. By month seven, 70+ sites were confirmed; by year four, the Registry hit its target of enrolling 500 subjects.

iMedNet™ eClinical

Delivering Results

"We have been extremely pleased with the way COMPLETE Registry has been conducted and the outcomes realized to date.

Critical to the Registry's success was the utilization of MedNet Solutions' eClinical platfrom in addition to the organization's dedicated and responsive project management team.

The MedNet platform has allowed us to provide an important leadership roles within the PTCL medical community through sharing of much-needed information with those dedicated to the treatment of this rare disease."

- Mark Acosta, PharmD

Sr. Director of Strategice Education and Resources

Spectrum Pharmaceuticals

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Critical eClinical Functionality Leading to Success

Significant to the success of the COMPLETE Registry were the following MedNet eClinical Technology capabilities:

Ease of Data Collection

The highly intuitive nature of the MedNet platform allowed Registry users across multiple study sites to easily navigate t he system and effortlessly input data. The incorporation of real-time edit checks also permitted personnel to benefit from immediate feedback during data entry, and important step in decreasing the number of downstream queries.

Role-Specific To-Do Lists

Given the lack of on-site monitoring and oversight due to the observation nature of the Registry, to-do lists were a critical stem pin keeping the study on track and successfully capturing and managing high-quality data. This capability delineated role-specific responsibilities and incorporated assurances that specific items were completed and/or reviewed with appropriate sign-off.

Specific to the COMPLETE Registry, to-do lists were created for Research Coordinators (RCs) to identify data to be entered and queries to be addressed. For principal Investigators (PIs), to-do lists focused on completed CRFs that required review and sign-off.

Patient Record Grid

The patient record grid was an important tool for sites to understand where each patient was in the Registry at any particular time and what items were due for each subject.

Triggered Forms

This capability, based on per-determined patient windows and events, triggered forms and to-do list items for timely completion. This allowed sties to easily keep track of subjects and stay current with data entry requirements, which was of particular importance given the extended follow-up intervals.

Reporting Tools

MedNet's robust, yet easy-to-use reporting capabilities allowed users to create ad hoc reports and download data in multiple formats (i.e. Excel, SAS, etc.). Reporting of high-quality, real-time data was of paramount importance in not only facilitating ongoing publication of data, but also in identification of best practices and lessons learned. Reporting tools also armed the COMPLETE Registry steering committee with the data needed to better understand what sites may be falling behind and why, and provided the opportunity to re-engage with sites based on observed best practices.

Further, the data generated via MedNet's reporting capabilities was a critical step in allowing the Registry biostatistician to provide analytic reports that have supported multiple abstracts and manuscripts. These abstracts included much-needed information on PTCL treatment patterns, the factors affecting treatment decision and the outcomes of patients.

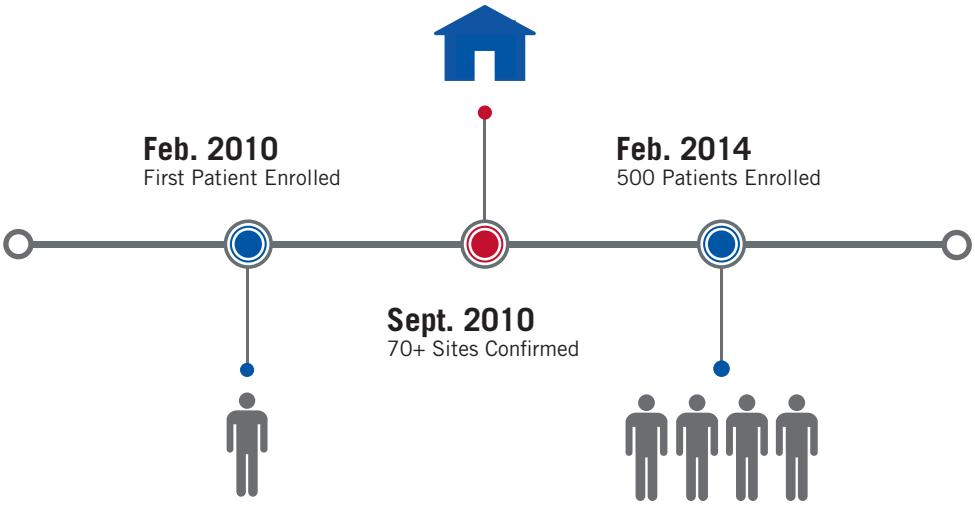
Results

With MedNet's eClinical technology at the forefront, Spectrum Pharmaceuticals has been able to achieve numerous goals related to the COMPLETE Registry to date.

Enrollment Goals Achieved

Of particular significance was the role of MedNet's staff in quickly getting the Registry configured, providing critical functionality that allowed study personnel to achieve planned enrollment goals.

COMPETE Registry Timeline (2010 - 2014)



MedNet Solutions

About MedNet

MedNet Solutions is a leading healthcare technology company specializing in electronic data solutions designed for the global life sciences community. MedNet's proven, flexible and easy-to-use cloud-based eClinical systems dramatically improve the efficiency of clinical studies and registries of all types and sizes. Beyond simply electronic data capture (EDC), MedNet's solutions deliver the tools and dashboards required to expertly manage all aspects of clinical research. Since 2001, pharmaceutical, medical device, biotechnology and Contract Research Organizations (CROs) around the world have trusted MedNet to consistently deliver the technology innovation, experience and reliability they need for success. For more information, please visit www.mednetstudy.com.

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Numerous Publications Created

Additionally, with the MedNet eClinical platform's robust reporting capabilities, the COMPLETE Registry was able to publicly present initial study data within 16 months of the first patient enrolled date. Thus far, 11 abstracts* have been presented at major medical meeting and two manuscripts are currently under evaluation by peer-reviewed medical journals.

Conclusion: Advancing Patient Care

Significant advancements in patient care for those with PTCL have resulted from the utilization of the MedNet eClinical platform. Through MedNet-generated data, the COMPLETE Registry has been able to provide those with PTCL medical community a better understanding of patterns of care, various interventions and how treatment settings factor into care decisions. This has been an important step in allowing medical professionals to deal upon the most recently available information to help achieve better patient care and outcomes.

Given the success of the COMPLETE Registry to date, the study is expected to continue for the foreseeable future to help provide additional research information leading to enhanced treatments for PTCL.

*COMPLETE Registry Abstracts to Date

1. 11-CML 2011: Foss FM, Et Al. Comprehensive Oncology Measures for Peripheral T-Cell Lymphoma Treatment (COMPLETE), a New International Treatment Registry.
2. TCF 2012: Foss FM, et al. Comprehensive Oncology Measures for Peripheral T-Cell Lymphoma Treatment (COMPLETE), First Report of Supportive Care Information.
3. ASH 2012: Foss FM, et al. Comprehensive Oncology Measures for Peripheral T-Cell Lymphomas Treatments (COMPLETE): First Detailed Report of Primary Treatment.
4. ASH 2012: Hsi ED, et al. Biomarker Quality Assurance (QA) Findings from the Comprehensive Oncology Measures for Peripheral T-Cell Lymphoma Treatment (COMPLETE) Registry.
5. TCF 2013: Foss FM, et al. Comprehensive Oncology Measures for Peripheral T-Cell Lymphoma Treatment (COMPLETE): Early Data on Transplantation.
6. ASH 2013: Carson KR, et al. Analysis of Peripheral T-Cell Lymphoma (PTCL) Subtype by Race adn Geography using the Comprehensive Oncology Measures for Peripheral T-Cell Lymphoma Treatment (COMPLETE) Dataset.
7. TCF 2014: Foss FM, et al. Management of T-Cell Lymphoma (PTCL) Diagnostic Work-Up in the United states Using the COMPLETE Dataset.
8. TCF 2014: Foss FM, et al. Analysis of Peripheral T-Cell Lymphoma: What Registries Tell Us.
9. ASH 2014:Pinter Brown LC, et al. Patient Characteristics and Initial Treatment Patterns in US for Most Common Subtypes of PTCL.
10. TCF 2015: Shustov AR, et al. Baseline Characteristics, Treatment and Outcomes of patients with CD30+PTCL.
11. 13-ICML 2015: Nabhan C, et al. Patterns of Care and Treatment Characteristics of Patients >70 Years of Age with PTCL.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing and commercializing drug products, with a primary focus in Hematology and Oncology. Spectrum currently markets six hematology/oncology drugs, and expects and FDA decision on another during in the second half of 2016. Additionally, Spectrum's pipeline includes two drugs targeting blockbuster markets in advanced stages of clinical development have generated a robust, diversified and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

RESULTS

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