Building Product Clinical Stories Based on Real World Evidence – An "SME" CASE STUDY

SME Health Systems

Complex Disease States Require RWE Data to Optimize Outcomes

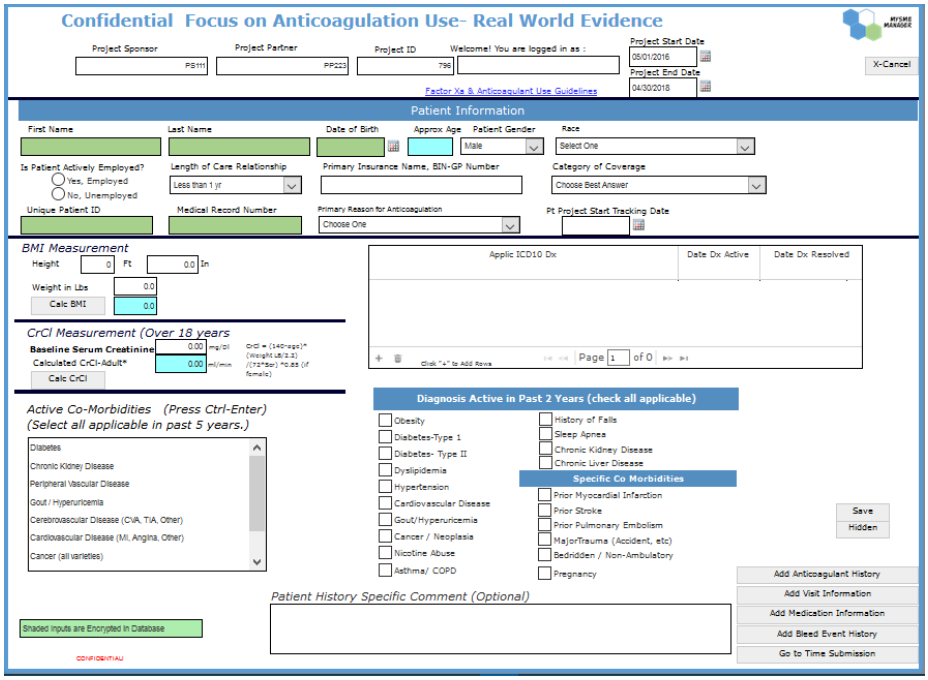
The promises of Real World Evidence (RWE) to support more rational medical decision making will remain elusive without practical ways to tap the many contributing data sets that lead to accurate, evidence-based conclusions. RWE is gathered directly from medical practice systems and claims utilization data – by definition, outside of clinical trials.

This Case Study describes a collaborative pilot project between a manufacturer and its targeted health systems and provider entities that aims to foster better understanding of treatment options, decision making processes and outcomes. This project details the use of anticoagulants in a specific disease subcategory.

> "Robust RWE will not only tap increasing volumes of data, but weave together different sources of data, such as clinical data, genomic data and socioeconomic data, to yield a better picture of individual patient characteristics and improve medicine's ability to treat individual patient needs. [1] "

Project Snapshot – Anticoagulation Treatment Options

Methodology: Each unique project undergoes the same basic process before it can be proposed to and implemented by any number of project partners who may independently elect to participate.



1. **Project Definition Phase**. SME Health Systems resources work directly with the manufacturer and its team of consultants and managers to define the needed flexible data container for this project. At this phase the data fields sought and the flow of collection are mutually agreed.

2. **Form Design Phase.** The forms are designed for data collection, and modified based on feedback from the sponsor.

3. **Form Testing Phase.** The forms are tested for flow and data output for future analysis.

4. **Project Launch Phase.** The forms are ready and project partners can accept the project and begin to collect data, as agreed.

5. **Project Proposal & Acceptance.** After an introductory discussion around mutual interest, the project is proposed by the manufacturer as a Project Sponsor and is voluntarily accepted by the hospital system or provider as a Project Partner. The parties share a standard Master Service Agreement and Project Agreement, using MySME Manager™.

6. **Anticoagulation Project Work Underway:** The data is gathered by the Project Partner into the designated forms which tracks patients (with anonymized, encrypted identities) with a need for anticoagulation based on a defined list of diagnoses in their Electronic Medical Records (EMR) systems. This partner has 500 patients in its population that meet the criteria; of those 500, 46 patients meet the criteria for specific follow-up.

The project activities and associated data (with encryption of identified patients) are gathered by a small team of QA nurses assigned to the project. At the end of each month, any activities related to these patients (including a short compliance phone survey administered every two months) that have been gathered are saved to an invoice which is generated and sent to the Sponsor, along with the minimal agreed dataset. The fees collected for the project help the provider to offset project and organizational costs.

How Parties Benefit from Project Enablement

SME Health Systems Offers

- A technical framework and help desk (MySME™ Manager) to enable documentation, data, and billing processes between manufacturers (Sponsors) and various healthcare providers, payers or hospitals (Partners) for mutually agreed finite projects.
- Flexible data collection containers that hold the requisite RWE & project data
- An invoice process for each project, in accordance with the mutually agreed Fair Market Value (FMV) terms and conditions. The invoice is generated by the Partner and submitted to the Sponsor, along with the agreed data.
- Assistance with solicitation and support of Project Partners (hospitals, payers, providers or specialty pharmacies)
- SME Health Systems gathers administrative fees from the Sponsor

Manufacturer Needs Addressed

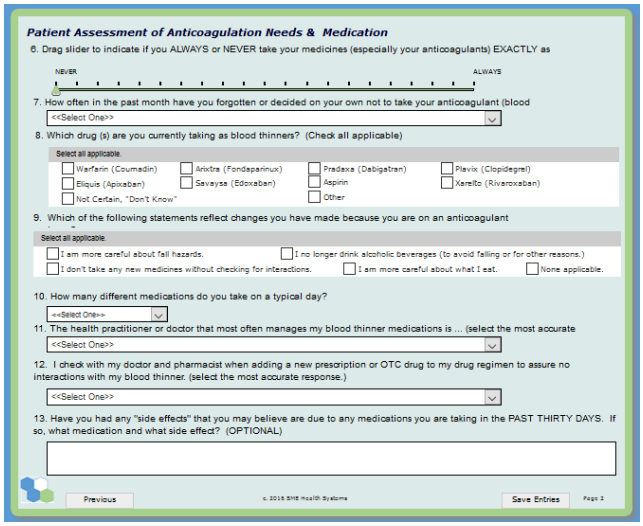
- A means to gather data in HIPAA compliant and consistent way across any number of Partners contributing toward homogeneous RWE data.
- A means to develop meaningful local provider relationships to support Safety & Medical Effectiveness projects and dialogue.

Provider Needs Addressed

- A legitimate means to engage with manufacturers for the tracking of "Safety & Medical Effectiveness" of treatment options.
- A means to cover costs for efforts not directly tied to patient care, especially those associated with tracking quality metrics and reports.
- HIPAA compliant data procedures

Project Bi-Monthly Meeting: The parties hold a Project Meeting on a scheduled bi-monthly basis (and otherwise by phone or as necessary) at the Partner's site to track progress and discuss any concerns identified.

Pilot Result Anticipated While results are still in the early phases, both sides are looking forward to an analysis focused on results objectively gathered to be reviewed over the course of 2017. Each side has a heightened understanding of the therapeutics and clinical issues that are part of the project goals.



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