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Technology Considerations to Enable the Risk-Based Monitoring Methodology

Shelly Barnes, BS¹, Nareen Katta, MS, MBA², Neil Sanford, MS³, Thomas Staigers, BS⁴, and Thomas Verish, MS⁵

Abstract
TransCelerate BioPharma Inc developed a methodology based on the notion that shifting monitoring processes from an excessive concentration on source data verification to comprehensive risk-driven monitoring will increase efficiencies and enhance patient safety and data integrity while maintaining adherence to good clinical practice regulations. This philosophical shift in monitoring processes employs the addition of centralized and off-site mechanisms to monitor important trial parameters holistically, and it uses adaptive on-site monitoring to further support site processes, subject safety, and data quality. The main tenet is to use available data to monitor, assess, and mitigate the overall risk associated with clinical trials. Having the right technology is critical to collect and aggregate data, provide analytical capabilities, and track issues to demonstrate that a thorough quality management framework is in place. This paper lays out the high-level considerations when designing and building an integrated technology solution that will aid in scaling the methodology across an organization’s portfolio.

Keywords
risk-based monitoring, TransCelerate, technology, solution, requirements

Introduction
Successful implementation of risk-based monitoring (RBM) is largely dependent on 3 critical factors: people, process, and technology. The TransCelerate BioPharma Inc RBM methodology position paper¹ describes a framework that articulates the process considerations for RBM. Tools were also developed to support the approach and enable implementation of RBM processes within a sponsor’s organization. Such tools are targeted at both people and processes, and revisions have been and will be made as experience with the RBM methodology increases. These tools speak to people aspects, such as change management, training, and stakeholder communications.

With respect to technology, simple data capture and presentation were initially thought to be sufficient; namely, identification of the risk indicators, capture and comparison of the data to thresholds, and presentation were considered the basics of any system (Figure 1).

Although basic to describe, the challenges in producing such a model as described in Figure 1 are numerous. These challenges include the following:

- Many organizations have data located in multiple databases with no standardization or organization of data across the applicable functional areas.
- Numerous functional groups within an organization require access or visibility to the data at different levels.
- Organizations vary across several key factors, such as therapeutic area focus, standard operating procedures, and other associated organizational risks.
- The risk indicators carry different weighting, depending on several factors, and therefore algorithms for aggregated data have to be constructed to meet these needs.

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The frequency of system refresh and the understanding of what is considered sufficient or "real time" can be difficult to define. Last, preferences may differ for how data are visually presented. Determination of how to present data (ie, visualizations), the amount of information that can be displayed on a screen, the level of detail needed, and the adequacy of actions that individuals must take to address and resolve identified issues must be considered in the context of an organization’s standard operating procedures and good clinical practice guidelines.

There are recognized benefits to incorporating the other components of the TransCelerate methodology into any novel technology solution to holistically enable RBM. Inclusion of tools to enable risk assessment—such as the risk assessment categorization tool, identification of critical data and processes, and creation of monitoring and quality management plans that manage identified risks—has clear benefits in this process. Coupling all of these with the ability to track the noted issues to resolution and consequently feed information back into risk identification is what will enable fully integrated implementation of the RBM methodology.

In alignment with the RBM methodology, the incorporation and use of predictive analytics is relevant. Predictive analytics offer a new dimension with respect to data quality and the ability to identify trends, patterns, and outliers in trial and site performance. Therefore, future technology solutions need to combine clinical trial data sources and operational systems (eg, clinical trial management systems [CTMSs]) to supply the necessary data for predictive analytics.

As TransCelerate companies have implemented the RBM methodology and piloted the tools associated with the TransCelerate position paper, the desirability of a seamlessly integrated technology solution has been identified. The availability of such a solution would be foundational in allowing an organization to fully implement the RBM methodology to scale. In this paper, the intent is to provide an initial description of the capabilities that any such technology solution should possess and communicate them both to vendors creating potential solutions and to sponsors that will be adopting and using these solutions.

**Table 1.** Definition of terms.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manifest file</td>
<td>A file that contains a list of all supporting files that are encapsulated in a .zip file in addition to having important metadata that can be utilized for search purposes.</td>
</tr>
<tr>
<td>Issue</td>
<td>An identified observation during the execution of a clinical trial with potential to affect patient safety or data quality, which should be tracked through resolution and documented.</td>
</tr>
<tr>
<td>Risk</td>
<td>A potential issue identified during the risk assessment, which may arise during the execution of a clinical trial for which there should be risk indicators and thresholds in place for continual monitoring and a mitigation plan in place for resolution upon identification.</td>
</tr>
</tbody>
</table>

- The frequency of system refresh and the understanding of what is considered sufficient or “real time” can be difficult to define.
- Last, preferences may differ for how data are visually presented. Determination of how to present data (ie, visualizations), the amount of information that can be displayed on a screen, the level of detail needed, and the adequacy of actions that individuals must take to address and resolve identified issues must be considered in the context of an organization’s standard operating procedures and good clinical practice guidelines.
Methodology

A landscape assessment was conducted to assess the current state of technology available for conducting the various components of the RBM methodology. A gap analysis was performed to generate a more robust list of capabilities most desirable in a future state solution. These include capabilities around data aggregation/integration, analytics and visualizations, and issues/action management. This output provides the next level of requirements definition to enable construction of an enterprise technology solution.

Results

End User Requirements

Ten technology providers presented their systems and were interviewed by TransCelerate. From these interviews and demonstrations in combination with industry experience, a set of model system criteria emerged and is presented here.

The following end user criteria were identified for inclusion in a technology solution and categorized into 2 major areas:

- Overall use
- Reporting and visualization requirements

Overall Use

The ideal technology solution for RBM should be able to

- Identify trends, patterns, and outliers to gauge performance at the program, protocol, country, and/or site level
- Integrate all appropriate components of the TransCelerate RBM methodology and data sources for analysis
- Track issue management, including identification, escalation, and resolution at the program, protocol, country, and/or site level
- Proactively produce alerts when risk indicator values meet predetermined thresholds
- Recommend mitigation actions based on the TransCelerate RBM methodology position paper,1 including but not limited to
  - Trial performance in both absolute and relative terms
  - Current number of threshold exceptions at each site
  - Overall trial risk profile
  - Data/processes critical to trial execution, patient safety, and data integrity
- Allow for intuitive navigation
- Provide user-friendly administration screens to administer risk indicators and the rules associated with them
- Focus quality management and site-monitoring activities to areas of higher risk
- Calculate and display simple and easy-to-understand performance scores at any level (eg, across program, protocol, site)
- Include appropriate global training or support, including web, phone, and in-tool help
- Capture monitor feedback from site interactions
- Include user interface to manage access and security at multiple levels throughout the structure to enable secure, role-based access to data; sign-on and authentication should be tied to the sponsors, or, in the future, the system may incorporate single sign-on capabilities, should that functionality become prevalent in the industry.
- Include an audit trail to capture all transactions as desired by sponsor and mandated by regulators
- Enable the continual review and analysis of risk indicators, clinical and operational data, and performance metrics at various levels with a configurable data refresh rate for decision making
- Allow for risks to be identified, assessed, and then pushed into the appropriate documentation (eg, the monitoring plan)
- Allow for documentation solutions to embed the documents, such as the risk assessment output (eg, the risk assessment categorization tool)
- Store output from the risk assessment (eg, risk assessment categorization tool) in a centralized location (eg, the integrated quality risk management plan) at the sponsor.
- Remain adaptable as experience with RBM grows and sponsors learn more about what works and adds value

Reporting and Visualization Requirements

The ideal technology solution to enable RBM should be able to

- Provide drill-down capability to review and analyze source data
- Produce graphical/visual representations of analyses
- Filter on subsets within various analysis representations
- Allow for generation of text-, CSV-, or PDF-based reports
- Allow for dynamic redefinition and modifications to new risk indicators, thresholds, and alerts
- Possess customizable risk indicator algorithms as needed for each unique protocol
- Work seamlessly with third-party systems if trials are externally sourced
• Provide functionality to send and receive relevant information, such as alerts and recommended actions to monitors
• Possess templates for core visualizations and analytics
• Allow for reusability of a core or standard set of analytics across trials
• Allow for creation of trial-specific visualizations and analytics
• Allow for accesses/licenses to third parties involved

Data Sourcing, Aggregation, and Integration Layer

Data Sourcing
To maximize the data-sourcing model for any technology solution, system independence is ideal as it pertains to source systems. Many technical solutions have limitations and accept data from only a handful of source systems. Development of a solution based on assessment of the format of a data transfer rather than its compatibility with a certain database will allow a sponsor’s data transfer process to be much more flexible in handling data aggregation. When data are transferred, one of the key components is maintenance of an intact data lineage. To achieve this, each transfer of data should contain a manifest file (Appendix Figure A1).

The manifest file (Table 1) serves 3 primary and important functions:

• A manifest file contains reference metadata that will enable the data warehouse to route the data to the correct location while keeping the warehouse hierarchy.
• A manifest file contains information that can be used to validate data transfers against a data standards catalog and version of that catalog.
• The contextual metadata located within the manifest will provide an easy method for users to search for trial data in the future and help facilitate seamless aggregation for data across a program and, in turn, will allow a sponsor to look at clinical or operational data trends throughout the life of a program.

Another important aspect of the data-sourcing and aggregation process includes data validation. Without having a single data standard across all data providers, conducting a data quality validation can be difficult. However, it is still possible to perform some degree of data validation.

• It would be preferable for the data warehouse (or database) to have the ability to access a copy of the standard (eg, Clinical Data Interchange Standards Consortium) that the sponsor plans to use.
  ○ This would allow the sponsor to quickly scan the data transfer and validate that it meets structural specifications, thus increasing the quality of each transfer of clinical data.
• In addition to the structural validation, it would be beneficial to conduct a secondary-tier validation on the format of the data that are transferred.
  ○ This level of review will make sure that the sponsor’s data provider is transferring the exact same data for every transfer. If one transfer deviates (eg, data variable is dropped), the validation check will send an error notification and reject the file.

Once the data have successfully passed the quality checks mentioned above, location and storage begin to play a pivotal role for identification of how data aggregation occurs. One way to easily relate the data is to store data in a hierarchical format by starting at the highest level of data categories, such as the program level (Appendix Figure A2). This can be achieved in several ways:

• The ability to use metadata to automatically create a “folder-like” location for the data.
  ○ Allows all study data associated with that metadata to be automatically sorted there
• Aggregating data by the data category (eg, clinical vs operational).
• Collating studies within the same program within the same folder structure.
• The ability to aggregate similar data sets from disparate sources in a similar location; for example, adverse event data from multiple contract research organizations will end up in an adverse event view within the data warehouse.
• Access to viewing the same type of data (eg, adverse event) across multiple studies within a program.
  ○ Allows a sponsor to compare trial data throughout the life cycle of a clinical trial program.

As noted above, the first example is more around structured (raw and formatted) clinical/operational data. Unstructured data are another important category of clinical data that has a vast array of best practices associated with it:

• The solution should be able to store and search this information.
• There should be an ability to develop a taxonomy backbone, which would be editable by the sponsor.
  ○ Developing a taxonomy backbone will allow the sponsor to categorize key metadata for the unstructured data to be accessible.
• There should be an ability to identify standardized data fields within the unstructured content.
There should be a validation check within the data warehouse that rejects any unstructured content at the document level that does not have mandatory fields filled in.

- Developing this standardized nomenclature can help to eliminate a repository of “lost” documents.

**Key Considerations**

Below are a few complexities to be managed when sourcing the data to drive the RBM methodology:

- Data reside in several clinical systems.
- Data reside at and with multiple vendors, organizations, and stakeholders.
- Different technology solutions exist that drive the same process (eg, multiple electronic data capture [EDC] solutions).
- Different operating models across the industry may have the source systems reside within the company’s firewall, hosted by the application service provider or supported by a contract research organization.
- The systems can be a blend of off-the-shelf and custom-developed applications.
- There is an absence of systems for certain data (eg, Excel trackers).

Given these complexities, the technology framework to enable RBM should have the following capabilities to support different operating models across the industry:

- A source system–agnostic data model that supports the risk indicators as outlined in the TransCelerate position paper.¹
- A data load engine that allows for staging of source data from multiple sources, including internal sources and external sources, such as Centre of Medicines Research. The engine should support multiple options, such as database connections, web services, flat files, and so on.
- A mapping engine, such as extract, transform, load (ETL), which allows the source data to be mapped to an internal data warehouse that supports RBM.
- Framework to load unstructured data in combination with structured data.
- Framework to segregate areas for exploration and standard reporting.
- The framework should allow for both incremental and cumulative data. This applies to the data sourcing as well as the RBM data model.
- The framework should allow for creation of data snapshots to support the traceability of decisions made during the course of the trial.
- System should send alerts to the appropriate users (eg, failed steps in the data flow process, successful completion of data sync).
- Define and store accessible metadata.
- Data transfers must be validated against a data standards catalog.
- Includes data integrity checks and sends error message and rejects the transfer if it fails integrity checks.

**Data Integration Layer**

A common and historical solution for integrating the disparate data sources and populating the data aggregation layer (Figure 1) involves the development of point-to-point integration solutions to capture the needed data from the source systems. The technology utilized is typically some form of ETL method or direct database connectivity for staging the data in a data warehouse for aggregation. In either scenario, the information is captured on a scheduled basis, meaning that there is a delay in identification of the events and execution of appropriate actions to resolve the events.

A more sophisticated way to integrate the data would be based on the service-oriented architecture (SOA) methods. By implementing an SOA, the required data and events can be exposed as a service from the source systems. These services are triggered immediately as the event occurs, making the information available to the technology solution on a real-time basis. The use of services also increases the system landscape flexibility.

However, based on the key considerations and complexities outlined previously, certain data sources might not be SOA ready. A hybrid solution with the ETL and SOA environment would be a reasonable starting point for many companies. Upon appropriate modernization of the source systems, the long-term strategy for a technology solution should include a desire to achieve a complete SOA-based design for data integration. The SOA design decouples the source systems with the RBM framework and provides the flexibility and agility of maintaining the clinical roadmap without affecting the investment in RBM.

**Algorithm Development**

An RBM program is highly reliant on the set of data selected to be analyzed and the calculated algorithms executed on those data. The parameters of a clinical study are based on the expected outcomes of each protocol. The needs of a protocol vary based on criteria such as the therapeutic area, phase of the study, geographic proximity, as well as the number of sites and patients. This diversity means that a set of predetermined calculations for determining the risk indicator results will not be equally effective. These algorithms will require the ability to
be customized on an individual study basis to enable central monitoring capabilities through calculated risk indicators to be used across all monitoring roles and responsibilities. Application characteristics needed to achieve this include the following:

- **End user–facing characteristics**
  - User-friendly interface (eg, wizard based)
  - Configurable application of algorithms at user-defined levels of study (eg, study, region, country, on-site monitoring vendor, site)
  - Sponsor and program/project level library of algorithms
  - User-defined weights and thresholds, whether static or dynamic, applied to overall algorithm
  - User-defined probability (of occurrence) and impact of risk
  - Tiered application of user defined variables (weights, probability, etc)

- **Calculation administration**
  - Parameterized input values supporting various study types
  - Visual alerts
  - Proactive notifications based on user-defined level of risk
  - Fully auditable with role-based access permission for modification

**End User–Facing Characteristics**

The primary users of an RBM application are the clinical study sponsor staff, quality assurance, or an independent centralized data review team. Their primary role is to demonstrate oversight at multiple levels of the study. Any system design for this use should have a user-friendly interface that allows the primary users the ability to define, view, and amend associated risk indicators and their associated calculations. For example, the use of a “wizard” to walk the user through the steps necessary to set up (calculations) and associate risk indicators with a target study employing RBM is a critical requirement. Ongoing and regular monitoring/viewing of the applicability or value that a risk indicator has on a study may lead to maintenance of these indicators. The application should also make use of a nontechnical wizard or an equally simple data entry screen to allow for necessary maintenance.

While having a user-friendly interface is key to creating and maintaining risk indicators for studies, equally important is the application’s ability to proactively or passively notify key stakeholders of the elevated risks based on the setup/maintenance performed above.

Proactive notification for distribution to target study team users as a method of highlighting elevated risk is as necessary as visual alerts, which are discussed in the Calculations Administration section below. Such timely notification alerts the study team to a potential issue and provides the team the time to effectively act to resolve/mitigate the elevated risk. The frequency of these communications should be configurable to maximize effectiveness of notification. The distribution of the notifications must be selectable for the appropriate level of clinical role to receive the notification (eg, clinical manager, field monitor, central monitor, general user), as each type of notification may not be pertinent to all clinical staff. Notifications could be sent as e-mails, for example, with a proper escalation path to supervisors and managers. The notification message could state that “For Study <study #>, Site <study #>: the Site Risk Score has elevated the level to HIGH RISK” and contain the full risk indicator details, sent to the proper list of study staff.

**Examples of front end–configurable items:**
- Study risk parameters
- Add/remove specific risk indicators at various study levels
- Risk indicator scoring weights/thresholds to further refine risk level
- Role-based application of weights and thresholds at the various study levels
- Capability of top-down application of weights/thresholds to lower study levels
- Alert distribution and frequency at various study levels
- Ability to simulate scenarios with different parameters and perform ad hoc calculations

**Calculation Administration**

On the back end of the system, the risk indicator computational rules drive the calculation’s layer through its process. The more aspects of the risk indicator rules that can be parameterized, the more types of study types and scenarios can benefit from a risk-based program. Elements of the algorithms, such as weights and thresholds, should not be hard coded into the computational layer. These elements should also not be global but rather tiered capable at the program level, study level, country level, and even perhaps down to the site level.

The data sources for use in the computational rules may also vary. For example, multiple CTMSs may be used for different study phases.

**Examples of risk indicators calculable parameterized items include**

- Source data input definition for each risk indicator
- Risk indicator scoring ranges to define risk level
- Embedded calculation variables (nondata source; eg, percentages)
- Date- and time-based values
Maintaining an audit trail of parameterized values, who makes them, and when is important for overall management and trending of applied risk indicators. These values should not be stored as a single array but include the history of all changes. The history should be saved in such a way that allows the user to scroll through not only the historical list of values but also the combination of values that were previously combined in use.

Visual alert capability needs to be included to provide quick and intuitive identification of high risks. Visual alerts should be applicable on every study level selected for risk identification by the user. The display of the alerts should be within the user’s dashboard screen.

Alerts should also be available to other applications through the support of a service. The application should generate a service within an SOA environment. This will allow an organization to take advantage of the alerts generated through the RBM process in other applications within their clinical systems landscape, such as CTMSs, data capture systems, and business process management systems.

**Predictive Analytics**

Although the TransCelerate RBM methodology is heavily based on tracking risk indicators and taking appropriate actions, predictive analytic capabilities can further amplify impact of the methodology. For example, mining the historical operational data of a particular investigator site can help predict that site’s performance on a new trial. These predictive risk indicators can be used as the baseline risk indicators and later be adapted to the site’s performance on the current trial. A second illustration of the value that predictive analytics can offer includes determination of the frequency of on-site monitoring visits. Based on several parameters—such as subject visit schedule, study drug dispensation schedule, previous site performance, and so on—the sponsor would be able to predict the workload for the monitor during the site visit, aiding in the planning and preparation for the trip. These predictive analytics can also be applied to a subset of the data. As experience is gained with the identification and application of risk indicators and as abundant data are gathered to reflect not only the reported risk but the effectiveness of the mitigating activities, the ability to support building and testing predictive models and then running them against large volumes of data should provide opportunities to further reduce risk for future studies.

**Guiding Principles**

The following should be guiding principles in the development of the issue management systems:

- Ensures proactive risk management tracking and management of all aspects of risk-based monitoring (e.g., central monitoring, source data review [SDR], source data verification [SDV])
- Provides a single source for all trial roles involved with risk/issues management (Table 1)
- Allows team members to take a more proactive approach to managing risk by tracking the risks of their trial, including site-, country-, and protocol-level risks/issues
- Integrates with the aggregation platform set forth in this document
- Drives global consistency in processes, tools, and nomenclature for tracking issues
- Reduces the time and manual effort involved in managing risk (e.g., automate targeted changes in monitoring [SDR/SDV] in the EDC system with direct change)

**Workflow**

The system requires the capability of creating automatically generated events as well as manually generated events when an action is required. While each type of event is generated by different means, the associated automated workflow and routing of the events should be standard.

To drive the workflows, standard roles need to be identified for use in the issue management system. Ideally, the roles can be
pulled from the sponsor’s CTMS system, but some roles may not be captured, so alternate means of entering roles and workflows (eg, manual entry or spreadsheet upload) would be required.

**Automatic Events**

An automatic event would occur when a risk is outside the prescribed threshold. When this occurs, an event will be triggered in the issue management system, and an issue will be automatically generated. An alert would then be sent to the person identified to review and take action, as necessary.

**Manual Events**

Ideally, all risks would be identified through an automatic process, but there are situations where manual entry of the event in the system, along with the associated metadata, is required. This could include issues identified by monitors during a site visit or through remote monitoring, by clinical review during medical monitoring, by a data manager during data cleaning, and so on. The user would then manually enter the event in the system, along with the associated metadata (project, protocol, risk indicator exceeded, etc). An alert would then be sent to the person identified to review and take action, as necessary.

**Process After Event Is Generated**

Once the event has been entered into the system, the individual would then review the data and determine if action is required. That action will be determined by the sponsor based on its quality plan, but it could include a broader review of data, a site visit, or no action at all. While a standard workflow per event type should be established, each user should have the ability to route to additional people, as needed.

One of the key actions that might be triggered is an adjustment to the SDV/SDR strategy. Based on a site’s risk, the amount of clinical data that need to be source data verified and reviewed would need to be adjusted on an ongoing basis. The technology team recognizes that certain EDC platforms are more flexible in adjusting the SDV/SDR requirements, while some EDC solutions are relatively inflexible. This challenge can be mitigated if the clinical data can be pooled into the RBM framework and SDV/SDR requirements are managed and adjusted within the RBM framework instead of directly in the EDC system. This would even allow for configuration of certain algorithms and workflows based on the site’s risk scores that can help drive the SDV/SDR rates within the RBM framework.

**Metadata**

Metadata should be pulled from the sponsors systems, when available. If data are to be manually captured, drop-down lists of standard items should be available. The sponsor should have the ability to add data items to the drop-down lists, but this access should be restricted to an administrative function. Capturing the metadata consistently will allow the sponsors to produce reports looking for trends not only at the trial level but at an organizational level for all phases of the portfolio.

**Discussion**

**Flexible Adaptation**

As highlighted throughout this document, there are numerous challenges with varying complexity for creating an end-to-end technology solution to enable RBM. In addition, organizations may have different operating models and technology landscapes that can add further complexity. Hence, the technology framework must have a flexible yet robust infrastructure and allow for gradual adaptation, both for number of trials and therapeutic areas and for the number of risk indicators. This should include flexibility in adding weightings and ratings to variables used to formulate risk indicators, as well as flexibility around editing risk indicator calculations. The framework should be able to adapt and evolve with the regulations as the industry gains experience implementing RBM. A hosted option could be a consideration for organizations trying to reduce the internal IT footprint. A key design consideration would be to decouple the source systems from the RBM framework to enable agility for organizations to switch technologies (eg, EDC, CTMS) without disrupting the trial operations.

**Technology Solution Success Measures**

It should be emphasized that a technology solution alone will not guarantee successful implementation of RBM in an organization. There are other considerations around people and process that must be accounted for as well. With that said, assessment of impact that a technology solution has on clinical operations should still be performed but may be influenced by these interdependent variables. The following list contains proposed measures that would aid in determining the level of impact that any technology solution that enables RBM has on an organization.

- Time to convert entire portfolio to RBM
- Number of supporting systems retired
- Costs to maintain technologies that support clinical research
- Time to embed the technology solution in existing organizational processes and platforms
Conclusion

The TransCelerate RBM position paper\textsuperscript{1} provides a methodology for organizations to consider when implementing RBM. It is heavily based on regulatory guidance documents that outline the processes for companies that execute clinical trials. Companies should consider embedding these processes into the organization to mitigate the risks identified during protocol development. The manner in which a company implements the methodology will depend on the needs of their business. Combining the right processes with the appropriate technologies is essential to scale the methodology across the clinical portfolio. These technologies should provide flexibility of implementation and utility, in the form of ease of integration (eg, SOA), configurability to limit customized/one-off implementations, and a highly intuitive user interface that guides end users through complex indicator calculations.

As information technology companies build the next generation of data collection systems (EDC, eSource, PRO technologies, CTMS, etc), it is highly desirable that they do so with this methodology in mind. A simple example is that most systems now have the ability to track SDV conducted by a monitor, whether at the site or remotely. If errors are identified during the review, monitors should have the ability to track those items in the issues management system. Over time, other considerations will have to evolve to align with this ideal design of a technology solution, including the ability for systems to isolate critical data for review.

An issue management system was identified as a preferred attribute as stated above, but this is specific to meeting the needs of the RBM methodology. Future solutions should consider the potential to have an integrated quality management tool that not only tracks those risks but also ties in audit findings, corrective and preventive action documents, and so on, as part of the vision. This would lead to the increased ability to demonstrate that risks are appropriately managed and used to design better trials.

While this article intends to provide guidance on the end user and system attributes for a technology to enable RBM, it also intends to facilitate the future thinking on how to improve overall risk management activities through improved processes and technologies.

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Reference

Appendix

Please note that the definitions provided below are applicable to clinical data only.

- **DataProvider**: Defined as the group or organization that is transferring data to sponsor’s system.
- **StudyID**: Defined as the trial or program for which the data transfer contains data.
- **DataType**: Defined as the type of data that is provided to the sponsor.
- **UniqueID**: Defined as the Unique ID (ie, time stamp) for when the data transfer was sent to the sponsor database.

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**Figure A1.** Example for a file-sourcing model for structured data.

```xml
<DataProvider>_<StudyID>_<DataType>_<UniqueID>.zip
  · Data Set A.xpt
  · Data Set B.xpt
  · Data Set C.xpt
  · Manifest.xml
```

**Figure A2.** Data storage in a hierarchal format.