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Dear members,

I’m very honoured to be your Chair of SCDM in 2019. It’s exciting to be a part of such a great volunteer organization that globally and so well represents a discipline that you are passionate about. I want to thank all the volunteers who work many hours on behalf of the Society - your efforts are what makes the Society the great professional organization that it is. We wouldn’t be a Society without you, your expertise and your commitment! I also wanted to thank Shannon Labout, the past chair, for her leadership last year in advancing the Society in the areas of education, regional expansion and innovation. From a personal perspective, I’d like to thank her also for all of her guidance and encouragement. I would like to thank Jaime Baldner, past chair 2018, for her leadership and great enthusiasm - she will be missed on the Board!

We also have new Board members joining, Maria Craze, Mayank Anand, and Rick Ittenbach, the Board is comprised of very talented individuals from all aspects of the data management discipline and we are very lucky to have them at the helm of SCDM! And a special thank you to our newly created SCDM Advisory Board. The SCDM Advisory Board is made up of a who’s who in our discipline and has already provided the Board great advice on where they see the discipline evolving to and how SCDM can be the organization to lead the change. And finally, thanks also to our colleagues at MCI who are the engine to keep the Society moving forward in daily activities as well help us with long term strategic planning. The old adage that ‘it takes a village’ rings true here!

You may have noticed that our logo is a little different. A “25” has been added as we are celebrating our 25th silver anniversary this year! As you often do when hitting a special milestone, we took this opportunity as a Board to reflect on where the society started, the progress we’ve made and where we want to be in the next 25 years and beyond - our vision.

We’ve had many successes and achievements over the past 25 years. From very humble beginnings of being founded in 1994 by 11 data management leaders with encouragement by the FDA to a growing and vibrant society with over 2200 members from 49 countries, 4 global offices and 7 conferences last year across the world (India, China, Europe and the US)! We have also recently moved our Japan Exploratory Committee to a full-fledged Steering Committee. Our educational offerings are the hallmark of the society. For example, we authored the global go-to Good Clinical Data Management Practices (GCDMP) guidance and host on-line courses and webinars.
We’ve also established certification to recognize the Clinical Data Management professional (CCDM) since 2004. Leading in providing white papers on hot topics, the Innovation Committee has published papers on eSource and mobile Health (mHealth). Additionally, SCDM launched the eSource Implementation Consortium last year, bringing together academia, pharma and technology vendors to use emerging techniques and standards to facilitate dataflow from Electronic Health Record systems (EHRs) to clinical data management systems or warehouses. These achievements and many more are all thanks to the dedication of our great volunteers!

To lead and provide direction for the Society for the next 25 plus years, the Board has created a new bold vision and mission for the Society!

**SCDM Vision (our aspirational view of the Society):** Leading innovative clinical data science to advance global health research and development

Our new vision is action oriented in leading the future of our profession to advance and ensure its key place in global health research. We are building on the core of clinical data management today as THE custodians of the clinical data, that will always be at the heart of all we do and will never change, but also proactively preparing for and leading in the future in an expanding world of data management- clinical data science- where the data sources are more diversified and larger in number and size and where technology year on year plays an increasingly integral part of our daily lives as clinical data managers. How will we proactively prepare for and lead in the future?

**SCDM Mission (what we do):** Connect and inspire professionals managing global health data with global education, certification and advocacy

The mission focuses on concrete actions of what we will do: global education, certification and advocacy as our drivers to lead and advance global health research. And how we will do it: by connecting and inspiring data management professionals.

Our goals for 2019 are focused on our mission of education, certification and advocacy. As a top priority, we are investing in revising chapters and writing new chapters for the GCDMP. We will be providing more opportunities to learn and share your knowledge through conferences and forums, active committees and taskforces such as the Innovation Committee and the eSource Implementation Consortium, and more on-line courses and webinars on fundamentals and fresh new topics through state of the art educational platforms. A new certification exam is offered with the flexibility of taking it on-line. And thought leader advocacy through active participation in forums on SCDM’s behalf and providing you a new community platform to collaborate with each other to share best practices and for committees and taskforces to work together more easily and reach their goals quicker.

We hope you are energized by our 2019 goals! **Now** is the perfect time to.... join a Committee, lead a Taskforce, attend a conference, forum or single day event, run for the Board, share your knowledge for a GCDMP chapter, teach an on-line course, present a webinar— to get involved with your Society, to help your career, to give back to others and have some fun along the way! ![clic here to go to the volunteer page](#)

I look forward to serving you as the 2019 Chair of SCDM. Please contact me ([linda.king@astellas.com](mailto:linda.king@astellas.com)) or our Executive Director Triphine Dusabimana ([triphine.dusabimana@mci-group.com](mailto:triphine.dusabimana@mci-group.com)) if you’d like to find out more about volunteer opportunities, the Society’s new vision and mission or would like to share your ideas and thoughts on our future. Be on the lookout for more about our new vision and mission this year!

See you in Baltimore in September!

Kindest regards,

Linda King
SCDM Board Chair, 2019
Letter from the Editor

Dear readers,

I am pleased to present you with the first edition of Data Basics for 2019. As most of Europe and North America have moved forward in time with daylight saving time, our first articles are an indication that our discipline too is once again moving into new territories through the leverage of high technology.

In the lead article, Steve Shevel alludes to some of the potential benefits of the application of artificial intelligence (AI) to the biopharma industry. However, he advises us to ensure our organizations are well prepared to accept and integrate this technology in order to get those benefits.

Another promising technology is visualization, and Debu Moni Baruah’s detailed case study provides an example of how to use it efficiently.

We must not forget, however, that the patient’s welfare is the reason why clinical research exists. The next 2 articles address current initiatives to try and get data from the patient in his/her natural environment, using “real life” data to produce “real life” treatments.

Gretchen Friedberger & Alexandra Botezatu propose their “Principles and Best Practices for Managing eCOA Data”. They highlight some benefits and the key phases in implementing Electronic Clinical Outcome Assessments (eCOA) solutions.

Nicole Rodriges, for her part, discusses the concepts of Real World Evidence and Real World Data, as well as their impact on our world as clinical data managers.

We conclude this issue with a case study from Vincent Miller and his colleagues, who created a data management system and share with us the key success factors they’ve identified in the process.

I hope you’ll enjoy this Spring “bouquet” of articles and I’m looking forward to reading your contributions to Data Basics in our next editions.

Nadia

Catch up with your learning in 2019! You might have missed some great opportunities. Check out our course and webinar schedules, and their updates on the SCDM website. For more information and to register, please see the website here.
Almost everywhere you turn today, or any conference you attend, you are likely to encounter someone talking about Artificial Intelligence (AI) and the associated proclamation of how AI’s implementation is going to be disruptive to almost every aspect of business. There are countless articles being written, talks being given, and startups emerging, all leveraging AI as a game changer and sometimes overselling it as a panacea.

The biopharma industry, typically a slow adopter of new technology, has moved rather quickly to grasp the potential of AI, albeit not its application yet, in bringing new drugs to market, and like other industries is enthused at the numerous opportunities that AI affords in completely automating what were once manual tasks. There is of course the regular chorus of caution against the use of artificial intelligence, with many good and salient arguments about why we should be careful in how we adopt and apply AI.

One of the most recent arguments I heard on exercising caution presented the premise of "benefit" and how that premise is vastly different in humans as opposed to machines. The argument, in short, was that humans do tasks in order to gain some benefit which can take any number of forms – monetary, charity, goodwill, benevolence, personal growth, etc. While on the other hand, machines will never possess a conscience that will dictate to them a diverse reasoning for why they are doing a particular task and for what purpose. Instead, the argument claims, a machine’s primary focus will be to advance its own directive without emotion or thought of others. This may very well have some veracity to it, but like it or not, the argument will not stop the advance of AI in the biopharma or other industries.

So, the next question then becomes: how do organizations deal with AI once they begin to advance its application? I believe this is the particular area that requires a more direct and specific focus. The potential benefits of applying AI to our industry are irrefutable. If you can get machines to predict outcomes more effectively, analyze data more holistically, and pinpoint potential roadblocks to success more accurately, then all of those outcomes in the end add significant benefit to bringing new treatments to market for people who desperately need them.

But, are your organizations prepared for the integration of AI into your existing processes and structures? The answer is, probably not. Most of the attention to date has been focused on the application of AI towards a specific problem and how to solve that problem, but very little has been applied to how to integrate AI into company structures, cultures and processes. There is a wonderful TED talk on this very issue by Matt Beane [professor at University of California at Santa Barbaral], where he points out the devastating impact that a one-dimensional implementation of AI can have to the next generation of human knowledge and capability. I recommend you take 9 minutes out of your day and listen to the talk, because it is very poignant and thought-provoking. Matt’s conclusions are equally applicable to the rush to implement AI at biopharma companies without taking the time to plan ahead and prepare organizations to accept it. How will companies adapt when AI is leveraged to identify and target specific geographic areas for subject and site recruitment? How will governance structures change if AI is successful in predicting and analyzing safety projections and how will this impact PV departments and DSMBs? How will organization’s procedures and support structures adapt to an AI solution that automates a large portion of monitoring or protocol development? As this technology matures there is little doubt that efficiencies will be gained in a number of areas, but at what cost to the human, cultural and emotional intelligence segments of your organizations?

There is an analogous example and good case study to draw from, in biopharma’s strong shift to outsourcing in clinical research which continues to accelerate inexorably. The shift started when executives at biopharma companies, with the advice of consultants, decided that because of the fluidity of clinical trials they should look at reducing their fixed costs [in-house resources] in favor of variable costs [outsourced resources]. The financials all made a lot of sense; therefore, in a relatively short time the resource models were drastically overhauled and the few people that were retained at the biopharma companies were shifted almost overnight from a role of a contributor...
to a role of overseer often with little more than a few days of training to help them along. The result of this quick shift in role and organizational expertise culminated in relationships with CROs and other vendors plagued with friction and assignments of blame. In addition, it had the unintended consequence of resulting in a perceptible decay of operational knowledge and expertise at the biopharma companies themselves, as those skills were no longer practiced or fostered. Equally unfortunate is that the projected savings, in both costs and efficiencies, have not materialized in a meaningful way, as evidenced by some recent studies conducted by Tufts Center for the Study of Drug Development (CSDD)\textsuperscript{1}.

So, as we embark upon the exciting and inspirational path of AI and all that it can offer to the clinical research world, it would behoove us all to direct just a portion of our focus away from the technology itself and towards the organizations seeking to benefit. Preparing organizations and people to accept a technology that promises to be far more disruptive than anything we have encountered before, may be the difference between a rapid successful adoption versus a path strewn with impediments and tribulation. ■

REFERENCES:


2) Getz, Kenneth A. (Dec 1, 2018) "Insights into Outsourcing Practices and Oversight Effectiveness." Applied Clinical Trials, 27(12)
ABSTRACT

One of the basic tenets underpinning visualization is that it does more with less. With the increasing complexity of clinical trials and the ever-increasing data burden, efficient decision making without analytics and visualization appears to be unrealistic. But, with the myriad of visualization strategies and solutions available, it is easy to expose the end users to visual burden which retards decision making. Many factors such as level of visual literacy of end user, complexity of visualization, relevance, approach of setting visual hierarchy etc., may impact the success and acceptability of visualization. In this paper, some simple and doable concepts such as a design thinking model of visualization, a visual communication method, a new model of visual hierarchy, and end user’s visual preference are discussed.

DOING MORE WITH LESS

When any timeline approaches, especially database lock (DBL), there is generally an intense pressure to speed data cleaning while restraining costs and/or staying within the budget. Given the burden of this duality, clinical data managers (CDM) are expected to make smarter decisions on intelligence derived from data - at a faster pace. A successful data visualization case study was discussed in the Fall Edition of 2017 in which the scope of analytics and data visualization in clinical data management via a clean patient tracker was discussed at length. The main emphasis of the case study was a guided data cleaning approach with a clean patient tracker in which clinical data managers could visualize the volume and type of dirty data sliced at site, patient or form level, and anticipate the required velocity of data cleaning and achievability of milestones. The approach proved to have potential to expedite data cleaning and positively impacted DBLs of two large studies.

Along with study health review, leadership teams also invest a considerable amount of time to keep track of “how things are going” mostly via meetings in which operational and project management metrics are also discussed. Use of visualization does expedite decision making during these meetings but with the disparate data load, it is very easy to expose the end users or decision makers to visual burden. In this article an evolved, easy to follow and sustainable strategy of developing user-friendly visualizations are discussed.

VISUAL BURDEN

Quantitative visualization [e.g. open queries per month] of periodic reports pulled at different time points can be woefully inadequate at helping stakeholders to spot risk factors and bottlenecks that can disrupt cycle times and budgets. This is mainly because of the inefficient ways in which data is captured, stored, analysed and visualized. Reliance on conservative methods such as paper, shared file in different drives, which lacks much-needed project and risk management functionality, adds more burden to the end user and most of the time it is up to the level of experience of the reviewing individual to distil insights while reconciling the information visualized. On top of that, identified issues demand further analysis to figure out the “why” and “how” questions. This generally requires time-consuming meetings and many email exchanges between stakeholders. These shortcomings are particularly acute during DBL, a phase that is widely regarded as demanding, stressful, sometimes resource intensive and in need of better operational approaches. To improve operations, stakeholders can embrace solutions with automated workflows that guide team members at various levels through the many steps involved and provide alerts for tasks needing attention. Complexity and volume of the visual representations, relevance [target audience] and arrangement of visual hierarchy are a few more important factors that contribute to visual burden.
ROADMAP TO VISUALIZATION THAT WORKS

Before hunting for insights, clinical data managers must have a clear idea of what is actionable. Approaches that travel down the rabbit hole of data exploration will lose time and waste resources unless they can set parameters on what, why and how they want to visualize.

To develop visualizations that are accepted and appreciated by end users one should -

• explore data visualization solutions through Human Centred Design (HCD),
• establish a time saving Visual Communication Plan,
• ensure to consider the Pre-Attentive Attributes of Visualizations,
• follow an appropriate design of Visual Hierarchy – F pattern, Arrow Head Model

DEVELOPING USER-FRIENDLY DATA VISUALIZATION USING HUMAN CENTRED DESIGN (HCD):

HCD starts with empathy, a deep human focus, in order to gain insights which may reveal new and unexplored course of actions to develop preferred visualization suitable for different stakeholders. Visualizations developed based on general assumptions and common sense are prone to fall into the trap of visualization knowledge gap (e.g. how to read a chart) between developers and end users which contributes to unacceptability of visualization. The six phases of HCD help in sealing such gaps and developing user-friendly visualizations.

Table 1: Phases of HCD

<table>
<thead>
<tr>
<th>Phases</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
<td>Observing the end-user, finding opportunities - identifying patterns of behaviour, pain points, and steps where users have a difficult time doing something.</td>
</tr>
<tr>
<td>Ideation</td>
<td>Come up with as many ideas as possible (stay focused on the requirements of the end users).</td>
</tr>
<tr>
<td>Rapid prototyping</td>
<td>Develop simple prototypes, test them with the end-users.</td>
</tr>
<tr>
<td>User feedback</td>
<td>Get input from your end-users on the prototypes.</td>
</tr>
<tr>
<td>Iteration</td>
<td>Use the feedback received to fuel the changes to the design.</td>
</tr>
<tr>
<td>Implementation</td>
<td>Implement.</td>
</tr>
</tbody>
</table>

Adoption of HCD has several other perks which include improved user experience, reduced training and support cost due to early connect and familiarization during rapid prototyping phase, reduced discomfort and stress (especially applicable for new or less experienced end users) and most importantly it’s contribution towards sustainability.

SAVE TIME WITH A VISUAL COMMUNICATION PLAN

When it comes to visualization, there is no one size fits all approach that works. Merely converting data from tables into charts does not solve the purpose and seldom assists in speeding up decision making. Also, randomly arranging different charts into one place does not make an efficient dashboard. However, it is possible to save time and resources by following few simple tips. A doable framework is listed in table 2.
**Table 2: Visual Communication**

<table>
<thead>
<tr>
<th>Phases</th>
<th>Description</th>
<th>Points to consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set questionnaires</td>
<td>- List questions to get visual answers.</td>
<td>No programming or visualization planning should be done. The goal here is to list what needs to be visualized.</td>
</tr>
<tr>
<td></td>
<td>- List Key Performance Indicators (KPIs) to use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Have brainstorming sessions with experts and stakeholders</td>
<td></td>
</tr>
<tr>
<td>Visual Discovery</td>
<td>- Find visual answers (types of charts, graphs or infographics, etc.)</td>
<td>No programming, visualization applications should be used. Use pen, paper, whiteboards, etc. It takes a lot lesser time to draft the visualization design on a whiteboard or paper than in any application.</td>
</tr>
<tr>
<td></td>
<td>- Plan and design visualization and hierarchy.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Programming, business intelligence tools, testing, analysis.</td>
<td>Consider Pre-Attentive Attributes of Visualizations</td>
</tr>
<tr>
<td>Daily data visualization</td>
<td>- Final version</td>
<td>Simple, low volume, should speak for itself.</td>
</tr>
<tr>
<td></td>
<td>- Suitable for formal presentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Should be able to update easily</td>
<td></td>
</tr>
</tbody>
</table>

To understand overall project health, a data manager may have to track and analyse over hundreds of project parameters within the scope of CDM. In such situations one can either visualize only the key performance indicators or develop an indicator type visualization system where project health is displayed using RAG status (Green = project is on track, Amber = some issues, being managed, needs to be closely monitored, Red = serious issues, milestones/timelines being missed, recovery plan required) or develop a hybrid using both approaches. For periodic project health review meetings, such approaches tend to help more as it is less labour intensive to programmatically derive RAG status from standard sources. A very economic approach of achieving a hybrid model is displayed in Image 1. To programmatically derive overall RAG, all source (input) reports are added with a status column, with a standard “yes/no” type of answer. Anything completely manual should be pushed to the Sandwich Model bucket so that the same can be used as an input for RAG. This design is extremely easy to adopt and can even be executed using simple spreadsheet functions. While RAG tells “how” things are going on, one can further drill down exploring “why” something is happening using charts and graphs linked to the RAGs.

**Image 1:** Whiteboard draft of a hybrid RAG enabled project health tracking system

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Doing More with Less for Faster DBL: A Data Visualization Case Study (How not to fail in data visualization) Continued from page 8
VISUALIZATIONS TEND TO FAIL WITHOUT THE PRE-ATTENTIVE ATTRIBUTES

For failsafe visualizations it’s essential that all the visuals (charts, graphs, infographics, etc.) in Daily Data Visualization phase pass the “Pre-Attentive Test”.

Image 2: Examples of Pre-Attentive Attributes of visualization

Visual attributes such as colour, form, spatial positioning and movement are immediately taken in and processed by the perceptual ability of vision, even before the complex cognitive process of the human mind come into play. In simple words - one should be able to comprehend the visualization effortlessly. For example, when it comes to colour, lesser is always better. Adding more colours (especially more than 7 colours) makes the visualization difficult to understand. Dashboard designers follow the 5 seconds rule – this is the amount of time it should take to find the relevant information as one scans the dashboard. It’s true that different types of data demand different types of visualization. However, understanding the visual preference of end users always helps the developer select the best possible type of visualization or add sufficient amount of information about how to read them.

VISUAL PREFERENCE OF END-USERS

The author conducted an online survey in November 2018 to understand the visual preferences of data managers. 77 clinical data management individual contributors and 11 senior leaders responded to the survey and expressed their visual preference. Most of the leaders (67%) expressed their preference towards only RAG whereas few (33%) wanted to see the parameters constituting RAG along with it. Majority (78%) of them were inclined towards filtering and drill - down options where it is possible to see all, and be able to filter to a sponsor, or a therapeutic area or a specific study. 100% of them voted to visualize the study, operational and project management metrics together. When asked to rank their favourite charts, Column Charts received highest rank, followed by Pie Chart, Bar Chart and Line Chart. Area Charts and Scatter Charts have received lowest ranking. Similar trend of visual preference was observed from the individual contributors as well. However, few of them were not sure about RAG and the concept of viewing study, operational and project management metrics together.

VISUAL HIERARCHY – F - PATTERN, ARROW HEAD MODEL

Arranging visual information effectively is highly essential to pass the 5 second test. F - pattern is a popular choice where the most important visualizations are positioned in the upper left corner. From there a hierarchy of support data related to the main visualization is created. The supporting charts on the bottom usually provide context and background data. These can be positioned in a logical sequence to scan quickly. However, F- pattern is applicable for end users who are habituated to read from left to right. In a global business environment, data managers interact...
with stakeholders of different cultures. Arrow head model enriches the concept of F - pattern of visual hierarchy by adding direction and modulating the volume of information displayed. For example, if a hybrid model of visualization needs to be adopted to track project health, then RAG (minimal information that denotes how things are going on) should be positioned in the left top corner of the page. The charts displaying the key KPIs (provides information on why something is happening) may find their place towards the bottom of the F. If the page is a web based one and login is required, then right top portion is generally ideal for the same.

**Image 3: F - pattern**

**AN END USER’S REACTION TO VISUALIZATION**

Sneha Cheriyanath is a young clinical data manager who is responsible for query management, reconciliations, listing reviews and the like. She was never a fan of charts and graphs. However, when she was introduced to visualizations that provided valuable insights into her assigned study (e.g., pending items requiring priority attention, the number of data points needing cleaning to achieve timelines), she felt empowered. She was able to overcome the typical “work allocation and delivery” model and start supporting the study independently. Sneha knew that she should look at the dashboard, locate what’s holding the clean status back for the patients and prioritize on the sites with upcoming scheduled monitoring visits.

**CONCLUSION**

Visualizations should present a quick and easy way to get the answers the user needs to make the right decisions. More data doesn’t mean more insights. We have more data than we know what to do with, which means that opportunities to create charts are endless. While developing a visualization, it is tempting to include a lot of data points, make it very fancy, and ignore the requirements of the end users. Visualizations should be developed as tools to support decision-making, not just as a laundry list of KPIs. HCD, an easy to follow visual communication plan and efficient way to establish visual hierarchy helps data managers to develop simple yet effective visualizations with minimal efforts that helps the entire team (from individual contributor to leadership) to make quick and independent decisions required at their level and be ever ready for difficult milestones such as database locks.
REFERENCE

3. IDEO’s human centered design process: How to make things people love, 2018; https://www.usertesting.com
7. Baruah Debu. DIY (Do It Yourself) – Make a Data Sandwich to Save Time (A Case Study), Data Basics, Volume 24, 2018; Issue 2.
ABSTRACT

With the quality of data captured throughout a trial playing a crucial role for the success or failure of a study, clinical data management (CDM) is a key element of any clinical research program. CDM is the process of collecting, cleaning, and managing subject data in compliance with regulatory standards, with the aim of generating high-quality, reliable, statistically sound data. Clean and consistent data is the ultimate goal and Electronic Clinical Outcome Assessments (eCOA) solutions can deliver this. For data managers, eCOA technology makes it quicker and simpler to collect and transfer clinical data according to the precise requirements of a study protocol, resulting in improved transparency, better quality data, and increased patient recruitment and site compliance. eCOA technology also provides better quality and defensible data by adhering to the ALCOA principles, defined by US FDA guidance as Attributable, Legible, Contemporaneous, Original and Accurate data. ALCOA relates to paper as well as electronic data and is used by the regulated industries as a framework for ensuring data integrity; it is key to Good Documentation Practice (GDP). eCOA technology also provides a complete audit trail through accurate time and date stamps, hence reducing risk when it comes to regulatory submission.

This article will highlight some of the benefits of eCOA vs. paper COA and outline key data management phases for successful eCOA implementation. It will also offer data managers some principles and best practices for managing eCOA data.

ECOA FOR CLINICAL DATA MANAGERS

eCOA utilizes technology such as smartphones, tablets, personal computers, and mobile apps to allow patients, clinicians, and caregivers to directly report clinical outcomes. eCOA produces highly accurate data that allows for a better understanding of the patient experience in clinical trials and ultimately helps simplify the path to regulatory approval.

During a study lifecycle, data managers deal with data from many sources such as MRI scans, EDC, lab data, as well as eCOA – all of which are equally important. Ultimately, data managers want to collect clean data from these sources, smoothly integrate and deliver it in the correct format to the statisticians, and lock their study database(s) quickly, to generate the highest quality data possible to ensure regulatory approval. Procedures to do this include Case Report Form (CRF) designing, CRF annotation, database designing, data entry, data validation, discrepancy management, medical coding, data extraction and database locking. However, a recent survey of clinical data management professionals shows that the time required to design and release clinical study databases is having a negative impact on conducting and completing trials. According to the 2017 eClinical Landscape Study from Tufts Center for the Study of Drug Development, it takes companies an average of 68 days to build and release a clinical study database.

To overcome this challenge, it is crucial that data managers understand the latest technology being used within clinical research, including eCOA, and how this technology can be utilized to collect the most robust, clean, complete, defensible data to support clinical trials. A clinical outcome assessment (COA) measures a patient’s symptoms, as well as their mental state, or effects of a disease/condition on a patient. Some are unobservable concepts, such as pain intensity, moods, feeling and eating habits.
Principles and Best Practices for Managing eCOA Data

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There are four types of clinical outcome assessments (COAs) which are used to provide evidence of a treatment benefit:

1. Patient-Reported Outcomes (PROs)
2. Clinician-Reported Outcomes (ClinROs)
3. Observer-Reported Outcomes (ObsROs)
4. Performance Reported Outcomes (PerfOs)

**BENEFITS OF ECOA VS. PAPER COA**

From improving the capture, transparency and quality of clinical trial data to increasing patient and site compliance, eCOA solutions offer obvious advantages over paper-based methods. As a result, it is fast becoming the first-choice method when it comes to capturing clinical outcome assessment data, whether directly from patients, clinicians or observers.

For data managers, eCOA improves the quality, reliability and integrity of data sets. At the point of data entry, built-in logic and real-time edit checks prevent incomplete and inconsistent data entries. Additionally, scores can be automatically calculated, and response options can be standardized. Unlike paper-based COA, eCOA solutions provide a real-time view of data captured.

eCOA solutions allow for integration with medical devices and can utilize additional meaningful data, such as peak expiratory flow (PEF) values in asthma studies via a spirometer, or blood glucose levels in a diabetes trial via a glucometer. As well as integration with medical devices, eCOA solutions also allow for computer adaptive testing, integration with additional sensors and potential data points, e.g., data endoscopic scores, ensuring data managers get a complete picture of the patient’s status.

Another area for discussion is the recall period for a PRO instrument such as an eDiary. Is the participant able to validly recall the information requested within the time period specified? Questionnaires with short recall periods or items that ask patients to describe their current or recent state are preferable. If the detailed recall of experience over time is necessary, the instrument should incorporate appropriate methods and techniques for enhancing the validity and reliability of retrospectively reported data and make use of a diary for data collection. With eDiaries this time scale is set in hours. This recall period is to ensure the device creates accurate data by not allowing too much time to pass between inputs of data, otherwise this concludes with data not being accurate.

eCOA also could reduce the number of queries generated if data verification is integrated into the electronic forms with edit and logic checks. However, it is important for data managers to know that the eSource data collected via the eCOA system is unlike any other transcribed eCRF data and therefore should not be queried and cleaned in the same manner. Sponsor/CRO review and query of the source data should be planned and kept at a minimum, for example, subject identifiers or seeking clarification on data points that may point to safety issues.

eCOA offers numerous benefits for data managers when it comes to locking the data. This includes allowing data managers to view data at any time – they can simply pick a data range and request an extract or a full data export for interim data analysis, whenever they need it. eCOA also provides data managers with options to analyze the data in many ways and get exactly what they need from it – a task which would either not be possible or take considerable time with paper-based analysis. Finally, eCOA also prevents any additional data entry once the database is locked, compared to paper-based processes: the data can then easily be exported.

Integration and reconciliation with other clinical data sources can occur more quickly than with paper-based COA. eCOA also meets the ALCOA principles to ensure confidence in data captured. When combined, these benefits lead to overall better-quality data and more accurate, higher compliance rates compared with traditional paper-based data capture.
BEST PRACTICES FOR ECOA DATA MANAGEMENT

There are several ways in which data managers can ensure best practice when it comes to managing data, including active data management, data cleaning and data changes, as well as how to effectively monitor with eCOA.

1. Active data management
Throughout the duration of the trial, proactive management of data is essential to ensure data quality, completeness, correctness, consistency, and integrity. How active data management is carried out should be tailored to each trial, focusing on specific study characteristics (risks, design, etc.) and the final use of the data (endpoints, analysis, etc). After eCOA data has been captured from a patient’s device and transferred to the study database, it can be managed through a web portal as well as exported to, and integrated with, other systems in real-time. Data managers can run data reconciliation checks with the data from other vendors (e.g., EDC) to add further value. In addition, sponsors are likely to be utilizing data management visualization tools, which can also be integrated with eCOA data to gain further insights.

2. Data monitoring
To effectively monitor data, the data manager needs to have an in-depth understanding of the design of the project, including what is being measured and critical variables based on the protocol, all of which should be defined in the data management plan. Next, a comprehensive set of reports, as well as the capability to update them and create new ones, is essential for efficient data management. Typical reports for monitoring data include compliance reports, visit schedule, subject administrative information and external data reconciliation, but it is also important that reporting is tailored for each trial to address the specific needs for the project. Due to the complex nature of eCOA data, proper data monitoring can allow the data management team to proactively identify issues that could potentially impact signal detection within the broader data set.

KEY DATA MANAGEMENT PHASES FOR SUCCESSFUL ECOA IMPLEMENTATION

Data management is an ongoing process. At the outset of any project an initial meeting is needed to discuss the protocol design, overall activity and data architecture, and operational considerations. During the set-up phase, the end-to-end data flow should be reviewed to ensure optimal set up and design to proactively prevent issues at study conduct stage. The design should take into consideration how the data will be used and accommodate an effective way to handle and prevent issues. This serves as a basis for defining and planning how the data will be managed and how issues will be addressed. For data managers, important phases include:

1. Planning and Set Up of eCOA:
   • How questionnaires will be presented to the patient, clinician or observer
   • The data structure and how data relationships affect other parts of the database
   • The rules and definitions (edit checks – automated system queries coming up when discrepant data is being entered) around the data that is being collected and how that will translate as a deliverable for the end customer
   • Determining if there is a need to reconcile with external data sources. If so, this needs to be specified and tested during set up

2. Data Management Plan for Study Conduct:
   • Data Maintenance Processes
   • Data Clarification Forms (DCF) and data change processes
   • eCOA Data flow (inclusive of third-party data incorporation if applicable)
   • Definitions – for example, what does ‘non-compliance’ mean in this project?
3. Database Lock (select data / analyze in multiple ways)
   - Ability to pick a data range and request an extract or a full data export at any time for interim data analysis and / or database lock.
   - Prevent any additional data entry once the database is locked

4. Data Export:
   - Raw Data Files – export data at any time
   - Real-Time Integration – eCOA allows access to the data in real-time
   - Data Extraction Tool – match the sponsor’s database format
   - Data Archiving for sites and sponsor

Due to its advantages over paper-based methods, eCOA adoption within clinical trials is continuing to rise. However, study teams must ensure they follow best practice guidelines from the start of each project to reap the benefits this technology can offer and have a positive impact on conducting and completing trials, both for data managers and the patient.

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ABOUT CRF BRACKET
CRF Bracket was formed in 2018 by the merger of CRF Health and Bracket to provide life science companies with patient-centric technology solutions that advance clinical research and transform the patient experience. The company’s solutions include electronic clinical outcome assessments (eCOAs), eConsent, patient engagement, interactive response technology (IRT), clinical supply forecasting and management, and endpoint quality services that combine advanced analytics and therapeutic area-specific scientific consulting. CRF Bracket’s applications are trusted by pharmaceutical companies of all sizes, including all of the top 20 pharma’s, as well as CROs, biotech’s, and academic institutions on over 4,000 global clinical trials. For nearly 20 years, CRF Bracket has been committed to helping life science companies bring life-changing therapies to patients and communities around the world. To learn more visit www.crfhealth.com and www.bracketglobal.com.

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Welcome to a new world order where “Data” is the new currency and its value is realized not in how “big” data is, but in value we can derive from it. As the phrase goes “The devil is in the details”, we must be able to analyze trends and make effective clinical and business decisions from the vast amounts of clinical and healthcare data generated every minute of every day. Traditionally, health and medical records have been collected in silos – with hospitals, insurance companies, wellness centers, pharma and medical device companies conducting clinical research, collecting and processing data fit for its purpose, although the patient must provide it multiple times in multiple locations. Over the past two years, the FDA has released guidance documents that establish the importance of breaking down the silos, and hence utilizing “Real Word Evidence” to support statistically validated evidence generated from clinical trials for drugs and devices. This initiative was a result of the 21st Century Care act, that emphasizes on using technological advances to meet the urgency in developing safe and effective medical products.

From FDA.gov, the definitions of Real-World Data and Real-World Evidence are as follows:

**WHAT ARE RWD AND WHERE DO THEY COME FROM?**

“Real world data are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources”. Examples of RWD include data derived from electronic health records (EHRs), claims and billing data, data from product and disease registries, patient-generated data including in home-use settings, and data gathered from other sources that can inform on health status, such as mobile devices.

**WHAT IS RWE?**

“Real world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD”. 1

Drug and device makers have acknowledged the importance of this collaborative use of data to look beyond the traditional gold standard for product development, i.e. randomized controlled trials. This has led to methods for generating and using RWE to support regulatory decision and hence a greater need for adoption of technologies that aid in collection and integration of these data sources.

**POTENTIAL BENEFITS OF RWD / RWE IN REGULATORY DECISION MAKING**

- Enables evidence development in settings where traditional RCTs are impractical to conduct (e.g. rare diseases, etc.)
- Fills important evidentiary gaps that are not typically addressed with traditional RCTs (e.g. real-world uses of products in patients with multiple comorbidities, long-term outcomes, etc.)
- May allow sponsors to generate evidence in support of an efficacy claim that is potentially more useful to payers and patients
- May significantly reduce time and cost of evidence development for some regulatory decisions [?]

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Real World Evidence: Impact on Clinical Data

By Nicole Rodrigues
Access to the large amounts of electronic clinical data being generated and collected today can be used to identify safety signals and support risk-benefit analyses when data quality is ensured, and advanced analytics are applied. Real-world evidence in the future will be able to support regulatory decision making across the pre- and post-market continuum. To make that vision a reality, we must develop systems to ensure that data quality is appropriate and sufficient for regulatory decision making, that data flows seamlessly between systems. [1]

REAL WORLD EVIDENCE FOR SAFETY AND EFFICACY IN DRUGS AND DEVICES?

The combination of trusted observational methods and replication have allowed sponsors and FDA to make safety-related decisions and label revisions based on RWD and RWE but making broader use of such approaches for efficacy-related label changes or other types of clinical questions around effectiveness will take additional standards and methods development. [1]

Randomized Clinical trials (RCTs) have been considered the gold-standard for determining safety and efficacy of any therapy. The baseline characteristics, risk profiles, and treatment patterns of the patients recruited in RCTs may differ largely from those receiving treatment in routine clinical practice. Real-life data gathered using broader inclusion criteria and fewer exclusion criteria would therefore help to bridge the gap between RCTs and daily clinical practice. [4]

For example, RWD could be leveraged to increase the efficiency of RCTs through faster EHR-enabled identification and recruitment of study participants, or to increase retention by using physician appointments as opportunities to collect data throughout the study. [1]

FDA relies only upon valid scientific evidence to determine whether there is a reasonable assurance that a device is safe and effective. However, it is possible that RWE can meet this threshold under conditions where the underlying RWD were accurately and reliably captured at clinically relevant time intervals throughout the device lifecycle. RWD collected using a randomized exposure assignment within a registry can provide a sufficient number of patients for powered subgroup analyses, which could be used to expand the device's indications for use. [1]

FDA hence, is planning to increase the use of RWE to support regulatory decision making and in order to accomplish this, CDRH (Center for Devices and Radiological Health) is planning to develop a nationwide evaluation system called NEST (National Evaluation System for health Technology) and develop a framework for the incorporation of real-world evidence into regulatory decision making.
During its development life-cycle, a new oncology therapeutic faces multiple go/no-go decision points. Limited resources mean some good drugs are never fully explored. By clarifying real-world unmet needs, RWE may help optimize decisions during predevelopment and guide clinical development strategies. During clinical development, RWE may also inform clinical trial design and conduct about specific populations. Understanding prevalence patterns for potential trial candidates (e.g., rare cancers progressing on chemotherapy) may facilitate patient enrollment. [5]

UNDERSTANDING EHRS AS DATA SOURCE FOR REAL WORLD EVIDENCE AND ITS IMPACT ON DATA COLLECTION

EHRs may enable clinical investigators and study personnel to have access to many types of data (e.g., clinical notes, physician orders, radiology, laboratory, and pharmacy records) that can be combined, aggregated, and analyzed. EHRs may have the potential to provide clinical investigators and study personnel access to real-time data for review and can facilitate post-trial follow-up on patients to assess long-term safety and effectiveness of medical products. [6]

Hence, the FDA guidance helps us understand that the way ahead is to enable the different systems to talk to each other by interoperability. Interoperable systems may simplify data collection for a clinical investigation by enabling clinical investigators and study personnel to capture source data at the patient’s point-of-care visit. Interoperable systems may also reduce errors in data transcription, allowing for the improvement in data accuracy and the quality and efficiency of the data collected in clinical investigations. FDA encourages sponsors and health care organizations to work with EHR and EDC system vendors to further advance the interoperability and integration of these systems. [6]

IMPACT AND OPPORTUNITIES FOR DATA MANAGEMENT

Having understood the role of Real-world data to support regulatory decisions on safety and effectiveness of the therapy, one must assess the collection, processing and quality of this data to reliably provide this real-world evidence. The variety of data sources in RWE and the potential lack of a controlled data collection environment may impact the overall quality of the data, however with technological advances and by defining new, improved and robust data processing practices, we can look forward to leveraging these real-world data sources further than it is currently in practice.

Data Collection and Standardization

There are practical challenges like the complex and diverse clinical data standards used by the health care and clinical research communities, which may hinder the exchange of information between different electronic systems. [3] The data sources for real world data may or may not adhere to standard data collection techniques. However, in the clinical trial industry, case report forms are designed to be CDISC compliant. Hence any data source that needs to integrate with CRFs would need to be mapped accordingly. In addition, a thorough assessment would need to be performed to ensure that the data elements extracted fulfill the requirements for study endpoint analysis.

System validation

Sponsors should ensure that the interoperability of EHR and EDC systems (e.g., involving the automated electronic transmission of relevant EHR data to the EDC system) functions in the manner intended in a consistent and repeatable fashion and that the data are transmitted accurately, consistently, and completely. Additionally, sponsors should ensure that software updates to the sponsor’s EDC systems do not affect the integrity and security of EHR data transmitted to the sponsor’s EDC systems. [4]

Data Validation

Using real world data sources poses challenges like missing and incomplete data, inconsistency in use of terminologies, inconsistency in collecting data elements. The variability in healthcare data collection hence requires robust data validation practices.
FDA encourages exchange of structured data (e.g., demographics, vital signs, laboratory data) between EHR and EDC systems so that data may be entered once at the point-of-care and used many times without manual re-entry or manual source data verification. Sponsors should ensure that the structured data elements obtained from the EHR correspond with the protocol-defined data collection plan (e.g., time and method of measurement). [6]

CONCLUSION

Interoperability of various data systems and hence the integration of data from these would change the way we do clinical data management today. We may have to wear a few more hats and juggle with few more tasks, as real-world evidence paves its way into traditional clinical trials. A better understanding of data standards, healthcare data source compatibility, and statistical significance of data elements to meet clinical trial endpoints are just some of the new aspects that clinical data managers would need to add to their existing myriad tasks. We could also foresee our roles to evolve into more than just Clinical but as Healthcare Data Managers.

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RUNNING RACES TO SUPPORT HER SISTER’S DIAGNOSIS  
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ABSTRACT

The Virtual Exercise Rehabilitation In-home Therapy: A Randomized Study (VERITAS) found that patients who received virtual physical therapy after total knee arthroplasty had significantly lower post-acute health care costs and rehospitalizations compared with those receiving traditional physical therapy. Effectiveness and safety were similar. This article examines lessons learned during VERITAS implementation from the perspectives of patients, providers, and the study team. Key success factors are identified, including creation of a clinical data management system that was agile, efficient and flexible for the user, the patient and the coordinating center.

The Virtual Exercise Rehabilitation In-home Therapy: A Randomized Study (VERITAS) was the first large-scale randomized controlled clinical trial that compares virtual physical therapy with traditional physical therapy. Conducted independently by the Duke Clinical Research Institute, the study found that patients who received virtual physical therapy after total knee arthroplasty had significantly lower post-acute health care costs and rehospitalizations, with similar effectiveness and safety versus traditional physical therapy.

During the trial, 306 patients undergoing total knee arthroplasty across four different clinical sites were randomly assigned to take part in either 1) a virtual physical therapy program with an avatar coach, in-home 3-D biometrics and tele-rehabilitation, or 2) usual physical therapy care at home or in an outpatient clinic. A total of 287 patients completed the trial, with 143 patients receiving virtual physical therapy and 144 receiving usual care.

Patients undergoing usual care had higher total costs of care in the 12-weeks after surgery and fewer hospital readmissions than those with virtual physical therapy. Patients receiving virtual physical therapy had no differences in six- and 12-week functional status, pain, or overall health.

The results of the study – which used Reflexion Health’s FDA-cleared Virtual Exercise Rehabilitation Assistant, VERA™, with clinician oversight – were presented at the American Association of Hip and Knee Surgeons Annual Meeting (November 2-4, 2018).

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3 Richard C. Mather, III, "Virtual physical therapy had lower health care costs, similar outcomes vs usual care", American Association of Hip and Knee Surgeons Annual Meeting, Nov. 1-4, 2018, https://www.healio.com/orthopedics/knee/news/online/%7Bf13680a36-8ae4-4d37-872c-0401ac8ed1ad%7D/virtual-physical-therapy-had-lower-health-care-costs-similar-outcomes-vs-usual-care
A patient flow chart for the VERITAS study is shown in Figure 1.

**Figure 1.** VERITAS patient flow chart

DATA FLOW MANAGEMENT

Data management processes were set up for remote data gathering from the VERA system and patient monitoring. An electronic randomization database allowed the four sites to correctly enroll and randomize all patients after obtaining informed consent. Once randomized, study participants were assigned a universal identifier (UID) for tracking the various elements of participation across databases.

Site coordinators entered electronic case report form (ECRF) information into a web-based data capture platform. Relevant information was transferred into the follow-up database to support patient follow-up interviews and monitoring of study timelines. For virtual rehab patients, data from the web-based platform was passed to the remote monitoring database to trigger VERA installation in the patients’ homes.

DATABASE CHART/ARCHETYPE

A centralized monitoring framework was created for all participant data regardless of randomization assignment (Figure 2). Sites completed an electronic randomization form, baseline data collection form, post-surgery discharge form, and six-week follow-up form for all participants. Sites were given password-protected, role-based access to the web-based data capture system to complete these electronic forms.

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Data from the web-based platform were exported nightly to Oracle databases for staging, and from there to the project tracking database for patient monitoring, follow-up completion, and storage. The tracking database served as a landing pad for participant data, enabling scheduling, intake/export, storage, and follow-up. To increase quality control, each system generated scheduled and ad hoc data quality reports (DQR). Efforts to prioritize essential data and core processes centered around identifying areas of overlap, commonalities and ways to reduce effort and increase efficiency.

The study design took advantage of advances in artificial intelligence and machine learning. In designing the data management systems, extensive input was obtained from providers on the elements that were most important to patient care, the structure and composition of data, who should have access to the collected data, and which users were the primary beneficiaries of the system.

Figure 2: VERITAS centralized data monitoring framework
KEY LEARNINGS

Having technology and systems in place is not always sufficient. Spending time to train and reassure individual participants – particularly within the provider community – is also essential.

From the user perspective, the onboarding process in the virtual therapy arm was highly successful, with the sponsor providing a specialized team to install the technology at the patient’s home. This was followed by a video chat session with one of two physical therapists, during which clinical baseline data were collected within the virtual therapy system, giving an indication of the patient’s current level of mobility and flexibility. A personalized workout regimen was created for each patient, with the ability for patients to set personal goals. Patients were instructed to follow this regimen at home, and the virtual system tracked and recorded the exercise sessions. The physical therapists remotely monitored patient progress via a clinician dashboard, which included automated daily or weekly reports, and alerts if any deviations occurred. These same automated reports, through email logic, were used to provide feedback and doctors’ notes to additional physical therapists or the patient’s surgeon as needed.

The team anticipated that multiple sessions with the physical therapist would be required to support patients, and a toll-free number was set up that could transcribe messages into email format. In fact, most patients required only one video session with a physical therapist, and most follow-up visits were initiated by the therapists. Patients ranged in age from just over 40-85 years, and all were able to overcome any ‘technology gap’ and successfully participate in the study. However, a few patients preferred not to use the remote system, electing in-person consultations instead. This was specific to individual patients and did not reflect any uniform issues with implementation.

For those assigned to usual care, follow-up and interaction with a physical therapist was based on the care plan created at hospital discharge. This group was monitored according to standard local practice, with phone calls or emails between patients, coordinators and surgeons, and routine physical therapy sessions as needed, either in a clinic or home-health provider setting.

Patient feedback in the virtual therapy arm was extremely positive, with appreciation for the convenience of being able to exercise at home rather than drive to the clinic, and with requests by patients who were planning a second knee replacement to re-enter the virtual therapy arm of the study.

From the physical therapist perspective on using the system, it took time to gain full confidence in the use of remotely captured data for patient care. Challenges existed in visualizing how the system would work and whether it truly could provide sufficient data and patient access to manage care from a remote location. Experience with the system was required to build confidence in the reports, and to be sure that patients were ready for discharge from their therapy programs when they had not been seen in person. For the physical therapists, there was a learning curve involved in fully understanding what electronic information on performance and participation needed to be visualized to ensure appropriate patient care. Over time, the therapists became confident that they could care for patients safely and effectively by identifying the key data variables, the location of those variables, and creating a structured process for review and analysis.

From the physical therapists’ viewpoint, the initial reaction to the pilot study protocol was to be ‘open but skeptical,’ with questions about the potential for errors, and doubts about whether patients in the remote monitoring arm would do as well as those receiving traditional physical therapy.

At the outset, it was evident that a plan was needed for the post-operative exercise regimen, but it was unclear how scheduling, tracking and ongoing study management could be integrated with the physical therapists’ existing clinical work and caseload. There were also initial questions from both physical therapists and physicians about the potential accuracy of measurements of the patients’ ranges of motion. The study found that although there were some differences, remote measurements proved adequate to determine whether or not patients were improving.

The VERA platform used in the VERITAS study did not take the place of the physical therapist, but rather enabled the flow of communication and monitoring between the therapist and the patient without the limitations of scheduled clinic time and location. Video contact allowed the physical therapist and patient to form a relationship, sometimes providing for a more relaxed interaction than is possible within the time constraints of the clinic.
While there were occasional technical issues requiring back-up email or phone calls, the remote monitoring approach was successful overall. The approach was particularly useful for patients who found it difficult to attend the clinic in person. The physical therapists also appreciated the flexibility of working remotely, viewing this as a breakthrough in their profession.

**From the study team perspective**, remote access to physical therapy appears very promising for the many patients who travel long distances to receive care. Challenges with technology were expected among this older population, but these were fewer than anticipated. Typically, the ease of contact with the physical therapist provided an extra layer of reassurance, enabling patients to receive feedback and request more support if needed. As a result, the system harnessed the best combination of personal support plus technology, innovation and engagement.

For the study team, navigating the technology and study tools posed challenges that were inherent to a study of new technology conducted as part of clinical practice. There were initial issues in incorporating data and information from remote consultations into daily workflows. The information flow was refined after the study started, with patient data sent to providers to inform in-clinic patient encounters and treatment decisions, and to the coordinating center to be analyzed for the study. Platforms that allow integration of this type of tool to track and monitor the patient are promising for the future of healthcare, and steps are already being taken with real-time data capture – which has great potential for clinical as well as research applications.

Questions remain on how best to integrate the virtual therapy system into routine practice, where this technology would likely be one of a suite of virtual programs. The largest hurdles will be implementation and scalability on the health system level to support a larger and potentially underserved groups of patients, especially those for whom issues such as distance, transportation, and cost limit access to healthcare. It remains important to deliver the right care to the right patient, and this technology can be flexible in meeting varying patient needs.

**SUCCESS FACTORS**

The creation of a clinical data management system that was agile, efficient and flexible for the user, the patient and the coordinating center was a key success factor. Other features that were essential to the success of this project are listed in Panel 1.

**Panel 1:** Key success factors in data management for the VERITAS study

- Security around networks
  - Authorization
  - Universal Identifiers
- The type of data being collected and the type of data needed for feedback
  - Presentation of actionable data
  - Real time data feed
  - Downstream scheduling
- Frequency of data capture
- Algorithms utilizing structured databases
  - Rules engine
  - Automation of data flow and reporting
- Data transmission pathways
  - One-way vs. bi-directional data feeds
- Reporting and visual analytics
  - Dashboards
  - Automated summary reports

**CONCLUSION**

Overall, the study’s design for information data capture and management met the needs of the patients, therapists and the study team. Challenges remain for broader implementation and scalability, but these challenges are inherent to any organization that seeks to implement new workflows and technologies. Once overcome, this platform has promise in other areas of healthcare, such as medication management and physician scheduling.
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Vincent Miller, MMCI, is Informatics Project Leader at the DCRI. Vincent has 19 + years of research experience in areas including mobile health, participant engagement and data source integrations. He specializes in identifying research and business objectives paired with informatics solutions for clinical research data management, and translational or clinical research projects. He has worked with new technologies in eConsent, integrations, application development, devices and remote data acquisition. He focuses on actively designing more efficient and effective data management support for projects.

Laura Webb, CCRP, is Clinical Trials Project Leader at the Duke Clinical Research Institute (DCRI). Laura has worked at the DCRI for more than 24 years in data management, clinical trials coordination and outcomes research management. She has led multiple outcomes research studies and statistical coordinating centers in a variety of therapeutic areas, including cardiology, stroke and orthopedics. She has a keen interest in the development and use of mobile and e-health devices in research, and has managed multiple projects involving design, development and/or utilization of these technology platforms. Laura served as the project leader for the VERITAS study.

Bryan T. Hoch, PT, is a physical therapist at Duke University Hospital. He began as a computer programmer, returning to school and obtaining a Doctorate of Physical therapy from Duke University in 2013. He obtained his Orthopaedic Specialty License (OCS) in 2016 and has enjoyed engaging with patients primarily with orthopaedic needs, including back and neck pain, joint replacements and some vestibular rehabilitation.

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Janet Prvu Bettge, ScD, is an Associate Professor in Orthopedics and Nursing and Co-director of the Duke Clinical and Translational Science Institute’s Accelerator Core. She is trained in rehabilitation and health services research and leads research that builds capacity for wide-scale implementation of evidence-based care to improve health outcomes, healthcare quality and health policy.

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