VERISTAT

Considerations for Enhancing Clinical Trial Efficiency

Through Thoughtful Clinical Trial Database Design

Nothing is more important in clinical development than collecting clean clinical trial data, especially if you plan to use that data for your marketing application(s), but similarly important if you are just using the data to make go/no-go decisions.

As you begin your clinical trial database design and build journey, you should start by asking yourself the following three strategic questions that will help you make informed decisions throughout this process:

Who are your stakeholders?

What is important to them?

What are your short-term goals?

What will impact these? (Number of sites, end users, duration of study, etc.)

What are your long-term goals?

Will you submit this data to the regulatory agencies? Should the data be collected in the most SDTM-compliant way?

If you don't consider these questions, you may end up repeating work later, therefore it's very worthwhile taking the time to address these considerations before you design your clinical trial database.

THE STAKEHOLDERS

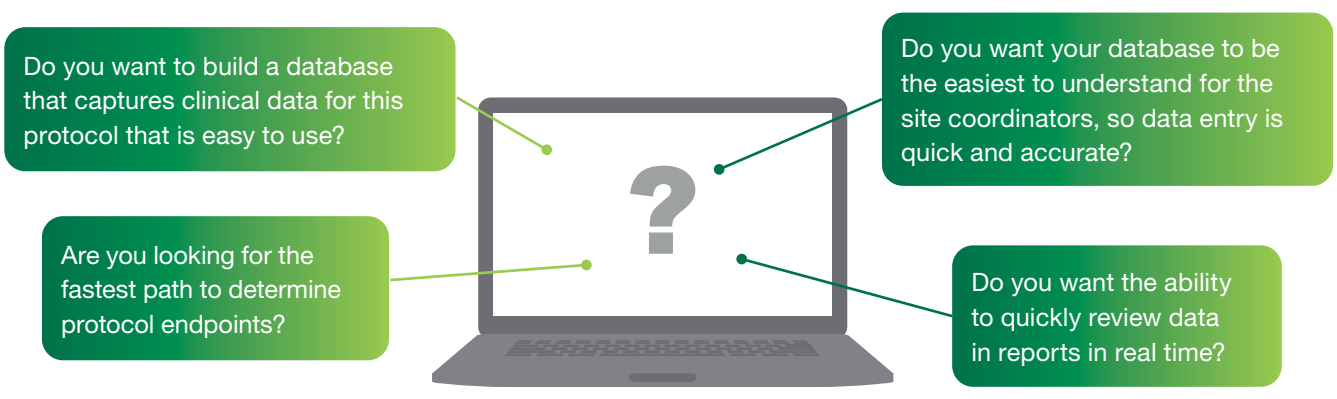
Immediate stakeholders are the database end-users:

Stakeholder	What's important to them
Site/Study Coordinators (SCs) Principal Investigators (PIs)	• Are the forms easy to fill out? • Do I know what information to enter, where and in what format? • Am I only entering information in one eCRF or am I spending time entering the same data over and over again in different eCRFs? • Are coded lists too lengthy with extra, unnecessary choices?
Clinical Research Associates (CRAs)	• How intuitive is it to mark data Source Document Verified? • How easy is query resolution? • Do the sites require extra or constant training/re-training?
Data Managers	• Will the data collected enable us to determine if the product is safe/effective? • Are we spending too much time chasing queries?
Read-Only Roles	• Can I easily extract this data? • What reports are available to me to quickly analyze this data?

Other stakeholders downstream will convert/migrate the data for marketing applications, and/or use the data to analyze the study endpoints:

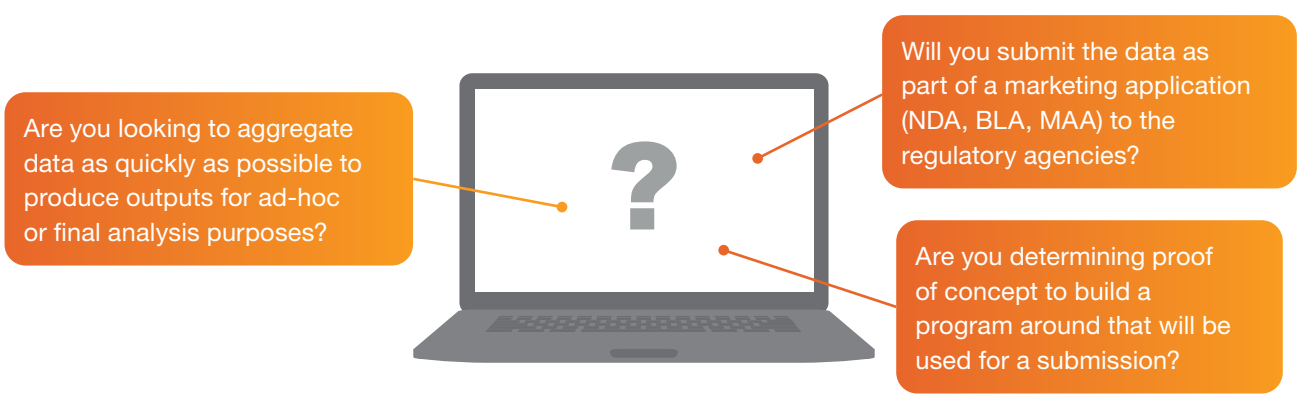
Biostatisticians	ADaM and SDTM Programmers	Medical Writers
• Does the database capture data appropriated to assess the safety and or efficacy endpoints for this study? • Will the data meet SDTM conventions?		

SHORT-TERM GOALS



In these examples, the key considerations for your database design/build may be **speed or price** of database build, or the **database "usability" for clinical stakeholders** such as the clinical sites.

LONG-TERM GOALS



In these examples, the key considerations for your database build/design would focus on **SDTM compliance, accuracy, turnaround time, and/or overall price.**

REAL-WORLD EXAMPLES

Since every product development situation is unique, there is no one easy or right answer that fits everyone's needs. Below are a few real-world examples of how Veristat addressed all the stakeholder needs and program goals in very different ways:

- Sponsor knows that the data they are asking us to collect will never be used in a regulatory submission. They are only conducting the study for proof-of-concept; therefore, we help them decide that 100% SDTM compliance isn't a top priority. We proceed to build the database to be user-friendly way, allowing the sponsor to analyze the results quickly and access data in real time.
- Sponsor knows that this trial data will be used as part of a marketing application and therefore wants to apply as many SDTM principles to the eCRFs as possible, to minimize the time spent later on migration efforts. They know the eCRFs will not be site- and user-friendly, but since this is a single center study, the sponsor is willing to invest significant time in training site personnel on the nuances of the forms.
- Sponsor did not focus on SDTM compliance when they built their study databases, and now needs to spend significant time, money, and effort to migrate the data for a marketing application. The migration efforts were not accounted for in the submission timelines nor in budgets. This was the last study needed in a marketing application submission to the regulatory agencies. The migration timelines delayed the final timeline for submission. And, this means a lot of extra stress and effort for the medical writers waiting on the final data outputs. In hindsight, the sponsor wishes they had known to think about SDTM compliance when they started their studies.

FINAL RECOMMENDATIONS FOR SUCCESS

Speak with all your stakeholders before you embark on your database build journey.

Weigh the pros and cons of satisfying each stakeholder's needs against your overall short- and long-term goals.

Identify the "quick wins" – places where you can easily satisfy the needs of one stakeholder without much effort.

Seek advice from experts who can help you see the big picture.

CONTACT VERISTAT

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