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A Guide for Establishing and Governing Data Collection Standards

Companies that leverage internal data collection standards can increase efficiency, speed execution, and improve data quality. But establishing standards is hard and maintaining them is even harder. How should you get started? And how do you ensure compliance with standards across your organisation?

Many data management teams report that their standards initiatives have stalled or failed because executives aren't bought-in, standards are over-proliferated, or they are stuffed with exploratory variables. In this guide, leaders across pharmaceuticals, biotechnology, generics, and medtech will learn best practices to build and maintain an effective clinical data collection standards program while driving team adherence.

The guide also provides recommendations on defining specification and variable tables and when it is appropriate to develop internal standards versus using existing widely accepted standards. Best practices are drawn from real-world experiences and case studies to provide leaders with actionable insights and advice for defining their approach to data collection standards.

Establishing Standards for Long-term Success

Beginning your journey toward data collection standards1 requires two essential resources: a team willing to drive the development and improvement over time of proposed templates or standards; and executive buy-in to get started on the right foot and ensure speedy approvals once completed. In addition, internal alignment is critical to the success of your standards, so involve downstream teams such as programming and statistics to incorporate their needs and requirements early on. Here are some tips to get started.

Involve all stakeholders with a 'horse in the race.' Involve representatives from each group to ensure alignment across biostatistics, clinical, medical, and data management. Each group will have competing interests and therefore should be represented in decision-making meetings, especially when discussing compromises and trade-offs.

Identify the right people. When nominating people across each area, consider their natural tendencies and inner motivations. Look for individuals with an inclination to organise and classify. These projects are usually added on top of the person's day job, so look for the unique team members who think data standards are both cool and crucial to success.

Categorise decisions as you go. If your organisation doesn't have standards in place, the most pragmatic way to get started is to codify decisions as you go and build a library of standards over time. Capture critical choices, the reasons for each decision, and usage guidance within a simple standards manual and FAQ guide. Selecting a few case report forms (CRF), auditable records designed to capture patient information to fulfil the goals of a clinical trial, is a great way to set a baseline.

Tap your partners for learnings. Your data and technology providers can be valuable partners in creating data collection standards. They might have existing standards for you to springboard off, which already include lessons from multiple clients. Vendors may also have visibility across studies in your organisation and can identify commonalities to help formulate your standards.

Defining Data Standards

When it comes to data collection, identifying your endpoints and objectives is key. What data is necessary to feed your analysis? Standards should only collect what's required to support your study objectives. Exploratory data could be helpful but diverts resources from critical areas and places an additional burden on patients and sites. Take these first steps to start defining your data standards.

Don't reinvent the wheel. You should leverage industry standards such as CDISC's Clinical Data Acquisition Standards Harmonization (CDASH) as a foundation. Years of industry collaboration have contributed to their design and using them will help ensure traceability and mapping to end deliverables such as SDTM variable names.

Make area-specific forms as needed. Every therapeutic area often has distinct data collection requirements and will need standardised forms. When possible, make area-specific forms additive to your corporate standards rather than a variation. Introducing variations can be a slippery slope toward version proliferation and a breakdown of control.

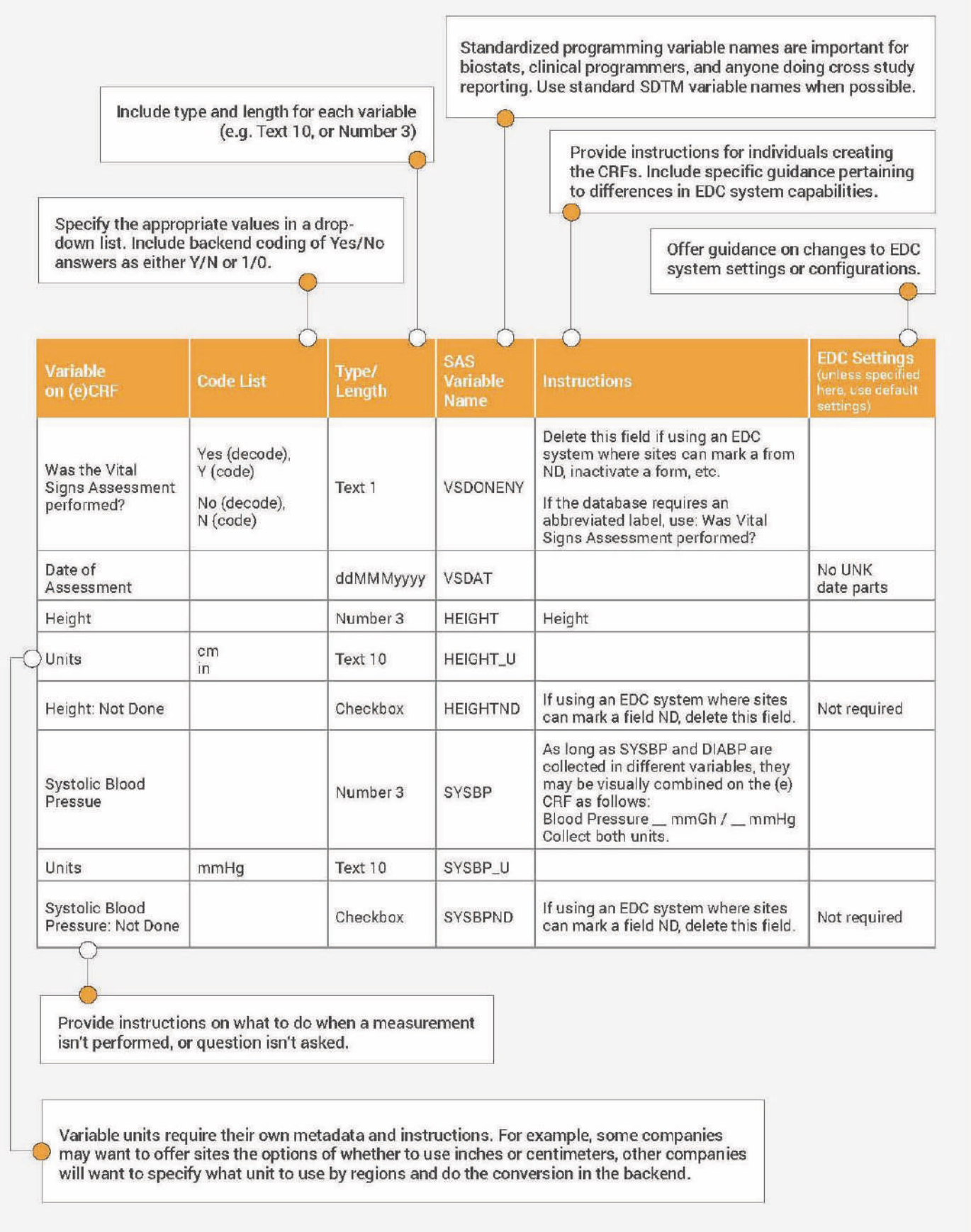
Keep fields lean. Placing an item in your standard requires every study going forward to collect that data. Packing CRF standards with exploratory fields will significantly increase costs for data collection, cleaning, and monitoring. Each field also places additional burden on the patient, and patient burden is something we must all seek to reduce.

Provide "suggested templates" as an add-on. Official standards should be infrequently changed and rigorously enforced. To increase your efficiency and consistency and allow some flexibility, offer unofficial templates that function as starting points and can be readily changed.

Keep it real. Define standards that capture reality. Limiting your CRFs to collect only what you want to occur, or excluding options that would capture unwanted outcomes, will result in dirty data and avoidable queries as research sites attempt to document activities accurately.

Align with site's source documents. Investigator sites may already capture some data. Designing CRFs to fit the site's source documents, thus ordering your fields to match the site's natural procedural order, streamlines data entry.

Go beyond CRFs. Standardise the supporting documentation such as the CRF completion guides, test cases, and mappings to transformation programs. When a study reuses collection instruments, programmers can leverage the programs that transform the data to SDTM. The time savings generated by reusing supporting documents and downstream programs are critical to making the financial case for standards and securing executive-level buy-in.



Variable on (e)CRF	Code List	Type/ Length	SAS Variable Name	Instructions	EDC Settings (unless specified here, use default settings)
Was the Vital Signs Assessment performed?	Yes (decode), Y (code) No (decode), N (code)	Text 1	VSDONENY	Delete this field if using an EDC system where sites can mark a from ND, inactivate a form, etc. If the database requires an abbreviated label, use: Was Vital Signs Assessment performed?	
Date of Assessment		ddMMMyyyy	VSDAT		No UNK date parts
Height		Number 3	HEIGHT	Height	
Units	cm in	Text 10	HEIGHT_U		
Height: Not Done		Checkbox	HEIGHTND	If using an EDC system where sites can mark a field ND, delete this field.	Not required
Systolic Blood Pressue		Number 3	SYSBP	As long as SYSBP and DIABP are collected in different variables, they may be visually combined on the (e) CRF as follows: Blood Pressure __ mmGh / __ mmHg Collect both units.	
Units	mmHg	Text 10	SYSBP_U		
Systolic Blood Pressure: Not Done		Checkbox	SYSBPND	If using an EDC system where sites can mark a field ND, delete this field.	Not required

Figure 1: Sample Specification and Variable Table

Defining CRF Standards in Practice

These best practices for establishing and maintaining data management standards are ideal for companies that have run at least five clinical trials. Why? At that point, companies can capitalise on the efficiencies of standardising. If you aren't ready yet, assess whether your company has the necessary level of maturity to begin working on internal standards. Factors such as staff willingness to change and the ability to enforce standards will be vital in making decisions.

Once you are ready, identify the core forms that are most consistent protocol to protocol. Examples include demographics, vital signs, and medical history. The objective is to standardise common forms where you are collecting the same data. Start small and with basic forms to avoid overwhelming your resources. As you gain experience and success with the common forms, you will be well-positioned to extend into therapeutic specific forms such as oncology and orthopaedics.

As you start defining your CRF standards, track and manage versions at the individual form level and form grouping. For example, version 12.0 of a therapeutic area standard may include version 4.0 of the serious adverse event form for that therapeutic area. The superset of CRF specs can also include standards for default EDC settings, subject numbering guidelines, abbreviations, and other standardised conventions.

Please see Figure 1 as an example of one company's specification and the variable table used to provide instructions, variable names, code list values, and more for each data element and unit on its form.

Setting up Governance, Deviations, and Practices for Updates

A practical standards program includes a formal deviation process whereby individuals can ask for permission to vary from the standards for a study. Provide clear guidelines on submission for deviations that do not include email since it lacks the tracking and workflows necessary for effective management. The governance committee must approve any deviation from a standard, and the expected answer to requests should be a "no." Typically, only deviations that are necessary for analysis should be approved. Follow these three steps to create a formal structure.

Build company-wide commitment with executive committee support. The executive committee provides oversight and approves new standards and changes. Building a strong, cross-functional executive committee is crucial to maintaining corporate buy-in. Without executive-level alignment, you will see unauthorised changes, deviations will become common, and standards will fail to deliver expected benefits.

Manage deviations and change requests through a governance committee(s). A manager-level governance committee should do most of the standards work across three main functions: approving/denying deviation requests, developing new standards, and reviewing existing standards periodically to evaluate whether updates are needed. The governance committee needs direct access to other teams, such as biostats programming, to ensure they fully understand the impact of the deviation before making a decision.

Committee decisions should be documented and shared with downstream study stakeholders and vendors. When working with a vendor, it's important that your standards are provided upfront so that they understand what to look for. Separate committees or sub-committees may be required for different therapeutic areas to ensure sufficient domain experience, agility, and scale.

Capture standard updates. Making updates to standards is an infrequent but important part of a healthy standards program. Proactively improve them by including those standards with recurring deviation requests. This is where tracking deviation requests and approved deviations can help drive informed decisions and maintain confidence in the quality and relevance of standards across the organisation.

Cultivating Adoption and Use

Many standards initiatives don't deliver efficiencies because deviation requests were too readily approved, or study teams proceeded independently without regard for the process. Fostering adoption of the standards across your organisation is crucial to the initiative's success, so ensure everyone involved in a study understands the value of data collection standards. To do this right, prioritise change management with these three tools.

FAQ docs. Develop an FAQ or similar policy document that outlines what types of changes are acceptable and not allowed. Documenting what is not permitted, along with the supporting rationale, will decrease the burden of redundant requests on governance committees.

Onboarding and training. New employees start jobs with existing perspectives, approaches, and habits. Training on data collection standards should be mandatory for every new employee hired within the data management and biostats organisation to ensure alignment and consistency.

The course should include the standards, the organisation's philosophy on standards, the areas required to use standards, the importance of adhering to standards, and the negative impact on costs and speed that deviations can have on a study. Set expectations that standards have been established for a reason, that pre-approved deviations or variations of a standard need to be documented, and that requests to diverge from standards will be declined except for exceptional circumstances.

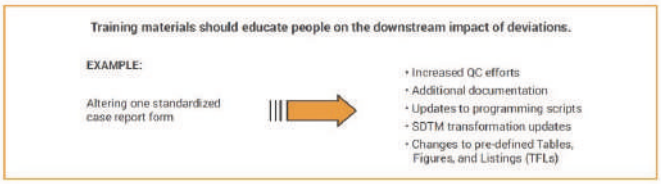


Figure 2: The impact of deviations

Consistency and execution. Leverage your data management team to perform spot quality control checks. Have them review and double-check the CRFs, data exchange specs, and other documents for new studies to ensure the standards are being followed. Library reports in some electronic data capture (EDC) systems also provide usage and deviation metrics and insights, making it easier to identify what is working and what is not.

Collaborating with Technology Providers

Technology partners are a critical part of implementing any successful standards program. Sponsors own the adoption and utilisation of standards by their teams, but vendors often implement standards and use them when configuring systems or case report forms. Maximise partner relationships by adopting these three strategies.

Tap into technology partner expertise. Vendors know their own systems end-to-end and provide valuable insights and advice on the optimal means to accomplish your goals. Don't be afraid to ask for advice.

Enlist vendors to help enforce standards. Equip vendors with your standards to verify approval from the governance committee when they see a deviation. A good partner will collaborate and support this.

Provide a point of contact. Give vendors a point of contact for communicating requests to deviate from standards. Having a single place to go for questions or conflicts prevents delays and helps keep the process moving forward.

A good time to re-evaluate your standards is when your company explores new strategies and technologies for data management. Bringing in a new system can introduce innovative capabilities and more efficient ways of working and collaborating across teams. Don't miss out on efficiency gains because your standards tie you to old systems and outdated processes.

Ensuring Success

It is essential to understand where things can go wrong. Recognising shortcomings can prevent issues down the road and drive maximum value out of data collection standards. Here are five tips for driving long-term success.

Experience matters. Start discussing data standards after completing numerous studies. By waiting to gain experience executing trials, you can identify the most common forms and the best starting point.

Recruit a seasoned team of champions. For a successful implementation, leverage both internal and external resources. Your internal data management resource should have at least five years of experience in the medical field. Partner with a technology provider with proven, purpose-built solutions for clinical studies and first-hand experience working with companies of your size.

Don't try to boil the ocean. Once you secure buy-in's from key stakeholders throughout your organisation, start small. Pick the forms best suited to building a foundation. While these vary from company to company, consider starting with forms from the CDASH CRF library. CDISC provides a library of CRFs designed as a baseline for companies to take and modify according to their own needs.

Maximise the review board's authority. Deviations should only be approved under unique circumstances and thorough review. A strong committee also can pick up what needs to be changed to improve standards. Repeated deviation requests provide insights into how a standard may not meet requirements.

Evolve the thinking. Reviewing standards for relevance and impact will ensure alignment with company requirements and long-term value. This process should also include comparing internal standards with evolving industry regulations. During this review, look at your upcoming trials and consider adding new standards that can accelerate CRF development. If there are common deviation requests, this is an excellent time to ask if the standard is too limited and make appropriate changes.

Standards Enable Speed and Effectiveness

A standards program can deliver significant improvements for clinical teams if established with solid principles and governance right from the start. Standards enable faster builds in EDC systems and higher quality data entry at sites. With alignment around the data that should be captured for every study, companies get complete reporting, more efficient cleaning, and transformations, and simplified data sharing and analysis across sources and studies.

This can transform clinical data teams, helping them move faster and more efficiently. If they can work with greater speed and precision, patients will get access to life-changing medicines faster. That is the ultimate goal, after all.

REFERENCES

1. The term "standard" has different meanings in different organisations. For the purpose of this article we consider it the documents, data, and processes established by the organisation to serve as a model or formal guideline.

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Ami Dudzinski Mehr, vice president, Vault CDMS MedTech, Veeva Systems, has over 20 years of professional services experience and has devoted her career to implementing EDC and IRT/IVRS software for clinical trials. Ami is currently part of the Vault CDMS leadership team, responsible for strategy in the MedTech space. Earlier in her career, Ami was responsible for trial build and enablement delivery at Oracle and Phase Forward.

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