CDISC AND EDC: SHAKING HANDS

Both CDISC and EDC have offered process efficiency to the industry with the goal of reducing time to market and limiting the cost of new drugs. The EDC vendors have contributed to this efficient process by bringing in the tools that make the complete clinical trial more transparent to all of the parties involved. Increased data visibility not only allows faster query resolution, but also enables project managers to respond quickly to any trend in the trial (such as inaccurate completion of case report form (CRF) pages) which, in the end, leads to a faster database lock. CDISC has contributed to trial efficiency by offering a number of standards that are all vendor-neutral and platform-independent. These standards allow the FDA to run their review-tools on the submitted data, leading to far fewer questions about the data structure and therefore shorter review cycles with faster approval. In addition, data standards simplify the transfer between providers (Lab, ECG, IVRS) and receivers (data management and statistics teams), while the trial is ongoing.

CDISC and EDC have offered real benefits to the clinical research industry over the past decade, but there has never been a true ‘link’ between them until recently. Clinical Data Acquisition Standards Harmonization (CDASH) is a new standard in the CDISC portfolio that integrates the SDTM requirements into the CRF. The SDTM model has always been the CDISC standard receiving the most attention and EDC has been working for years on improving data acquisition. CDASH is therefore the missing link between CDISC-SDTM and EDC.

CDASH: NOW WHAT?

The CDASH team released the CDASH v1.0 specifications in October 2008. These specifications include 16 domains that are all therapeutic area agnostic. More extensive CDASH specifications and a CDASH User Guide are expected to be published in the first quarter of 2010. CDASH is, at the moment, still a work in progress. However, the work that has been done by the CDASH team is already providing a number of benefits.

Efficient Data Acquisition and Data Monitoring at the Sites
Sites have always been asked to complete non-standard CRFs while patients are performing daily assessments, and CRFs are expected to be completed on time and accurately by the site. Hindering this, the variety of CRF questions and layouts is almost unlimited. Replacing non-standard CRFs by the 16 CDASH CRFs has already significantly improved the situation at the site.
Greater Standardisation in SDTM Datasets

The SDTM model is widely accepted as ‘the’ submission standard for clinical trials. The reality is that companies around the world are all implementing slightly different variants of the SDTM standard. This spectrum of implementations originates from the diversity of CRFs that exists today. Non-standard CRFs are capturing similar information in different terminology for the same data across companies. It can even be the case that similar information is captured in different SDTM domains because of the non-standard CRFs. The current 16 CDASH CRFs are associated with standard SDTM mappings and standard CDISC controlled terminology, which is already reducing the spectrum of SDTM implementations that exists today.

Faster Go-Live of EDC Trials

The eCRF design tools that are on the market today come with a number of time-saving features, such as extensive library capabilities and collaboration functionalities that allow multiple eCRF designers to work on the same trial at the same time. EDC applications can have an earlier go-live date because:

- The eCRF design time is shortened as CDASH eCRF forms can be pulled out of the EDC library as and when they are needed
- The CDASH forms can be created in the library with edit checks. These edit checks are available in the new trial as soon as the eCRF form has been added. This functionality reduces the current development time for edit checks programming significantly
- CDASH eCRF forms with associated edit checks that are selected from a validated library guarantee shorter user acceptance testing cycles for EDC trials

The CDISC Operational Data Model (ODM) standard even allows the transfer of CDASH EDC-library forms from one tool to another. As a consequence, a company is never limited to a single EDC application when using a CDASH EDC-library.

EDC-CDASH-CDISC: END-TO-END

The ultimate goal for all clinical trials is to evaluate the safety and efficacy of the investigational medication and to prepare for registration afterwards. This process has always been subject to business pressure that is trying to move the product to market faster, while at the same time spending less money. It is therefore very important to take advantage of all business benefits that are provided by EDC vendors, the CDASH data acquisition standard, and the CDISC models that are used when submitting data. A streamlined EDC-CDASH-CDISC end-to-end implementation guarantees the highest quality in the shortest time for the full life cycle of the trial. Streamlining the complete process flow is really the key to ensuring that the benefits of each standard ripple through to the next standard in the process flow, as illustrated in Figure 1:

- Standard CDASH CRFs can be transformed to standard SDTM datasets using standard extract transform load (ETL) code
- Standard CDASH CRFs are easier to complete and therefore generate fewer data queries. Furthermore, EDC applications are able to fire data queries as soon as the data is entered. This leads to an earlier database lock date
- Statistical analysis can be performed at a much faster rate on a locked SDTM database that is compliant with the CDASH-SDTM mapping and that makes use of CDISC controlled terminology. As a consequence, the safety and efficacy results will be available sooner. Furthermore, the creation of the ADaM datasets on top of fully compliant SDTM datasets will be much smoother and validation can be done more efficiently

These EDC-CDASH-CDISC integration benefits and the generally accepted benefits of EDC and CDISC help to ensure that clinical trials can be completed on time, on budget and in scope.

CONCLUSION

The library capabilities of current eCRF design tools already allow the industry to implement the current CDASH standard, while still leaving all options open for the implementation of therapeutic area specific domains when released by the CDASH team in the future. From an eCRF application design point of view, the cost savings of using standard eCRF forms are obvious. Furthermore, the positive impact of CDASH on SDTM cannot be underestimated. The existence of the ODM standard even allows the uploading of CDASH CRF pages from one design tool to another with no re-work at all. In time, CDASH, with standard controlled terminology, will be the foundation of a turnkey EDC-CDISC solution.