CROs: Stuck in a Rut?

Dave Smith at SAS UK asks why the uptake of CDISC mapping solutions has been slow in contract research organisations

The implementation of Clinical Data Interchange Standards Consortium (CDISC) standards is proceeding at various rates across the pharmaceutical industry, and there seem to be nearly as many approaches as there are organisations. This article will discuss one of the practical aspects of implementation, namely the mapping of source data structures to study data tabulation model (SDTM) and analysis dataset model (ADaM) standards, and examine why some contract research organisations (CROs) have been slow to invest in technical solutions to expedite this process.

According to a study conducted by CDISC, Tufts and Gartner, the lack of standards implementation is costing, on average, an estimated $9 million per trial in direct costs, and reducing the potential to shorten the time taken for clinical trials by 60 per cent (1). Of most interest to CROs is the second figure; a great deal of the direct costs to a CRO’s bottom line is taken up with the expensive process of converting source data to CDISC SDTM and ADaM standards.

This process generally involves a complex restructuring of data in a way that must be transparent and validated; a reasonably sized Phase III study can take around six months to convert if done through the traditional hand-cranked code method. This would be a validated process, but the provenance of each item of data is not immediately clear, and clarity around derived items is something the FDA is particularly keen to ensure.

MARKET OPPORTUNITIES

For CROs, there are two main opportunities that technology can bring to this process. The first is a reduction in direct costs. The amount of resources needed to convert data to SDTM and ADaM can be reduced by around 50 per cent, making the process more efficient and scalable, producing a higher quality end product. The second is an increase in business by exploiting the market opportunity associated with a faster, higher quality service for sponsors. It is also worth stating that there is a significantly reduced business risk to be achieved by applying technological controls to the conversion process.

FAILURE TO ADOPT: POSSIBLE REASONS

There are many possible reasons why companies have been slow to adopt technology in this area, and some of these are generic to all innovations in the CRO sector, such as the industry’s innate conservatism and the fact that CROs are often too busy with their day-to-day activities to give time to process improvement.

The Inconsistent Uptake of CDISC Standards

While all pharmaceutical companies are at least considering their CDISC implementation strategies, by no means have they all actually submitted data in SDTM format, and fewer still have integrated CDISC standards into their processes as a method of increasing their trial throughput. That said, most sponsors require study data to be delivered in SDTM format at the end of a trial, and CROs have
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To respond to this requirement. There is always an element of the chicken and egg in CRO technology adoption: unless the pharmaceutical companies demand something, the CROs will not move; however, unless they have a demonstrable capability, they will not win the business. Allied to this issue is the inconsistency of standards implementation by the sponsor companies, with many adopting variations of SDTM as part of their process. This makes CROs doubt that they will be able to automate the process – however, providing that their solution is scalable and flexible, this need not be the case.

This uncertainty has led to CDISC projects being given to the people most likely to need to change, such as data managers and clinical programmers. Without concerted leadership at higher management levels, these groups are unlikely to fully support change; they will typically either attempt to write solutions themselves or to undermine the change process to ensure that the change does not happen. Naturally, there are exceptions; those who are happy to act as change agents within their organisations need to be nurtured and directed appropriately. Clinical programmers should also be reminded that their greatest value is in their clinical data understanding, without which their role could easily be commoditised.

**Competition from ‘Home-Grown’ Solutions**

There has been some confusion in the marketplace about what is really required from a solution, and this is partly a by-product of the appearance of a number of small niche vendors, each having a particular strength and attempting to position that strength as the key capability in the market. The desire of clinical programmers to produce home-grown solutions has added to this confusion. At face value, a solution built around an organisation’s needs to include a complete set of metadata items through the process. The investment worthwhile, the solution needs to include a complete set of transformations, be fully scalable across the enterprise and give full traceability of metadata items through the process.

**Delivery Mechanisms**

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**Rising Prices of Contracts**

Perhaps the most compelling reason for inertia among CROs is that the extended processing time needed to create SDTM and AdAm structures has been priced into the contracts. If the sponsor is willing to pay the CRO to take six months to convert a study to SDTM, why should they change? Of course, this is not a sustainable position; as sponsor companies begin to implement the technology enabled CDISC standards, they will quickly realise that their CRO partners could do better, and will apply price pressure to ensure that they are getting sufficient value.

**CONCLUSION**

It has been relatively straightforward to produce a list of excuses for inaction among CROs, but for each reason there is a compelling counter-argument, and the need for change is evident. The most likely scenario is that those that move first will gain the biggest advantages, and this is already perhaps evident in the numbers reported in the top five publicly quoted CROs; the level of detail needed to prove this theory is not publicly available, so it must remain conjecture. Suffice to say that the fastest growth in that cohort is seen in one of the earliest adopters of technology to enable CDISC standards.

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**Reference**

1. CDISC, Tufts and Gartner Study  