

# Dianthus Medical Limited

*Collective inspiration*

CDISC standards:  
streamlining the clinical data flow



Managing data from clinical trials is an extremely complex undertaking. Data must be captured, cleaned, stored and analysed before they can be of value. The Clinical Data Interchange Standards Consortium (CDISC, <http://www.cdisc.org>) is a global, non-profit organisation which has done great work in defining standards for all the various stages of managing and analysing clinical data. We have found that using the CDISC standards has made the way we work with data far more efficient, and in this issue of our quarterly newsletter we want to explain a little about how the standards work and the benefits of adopting them.

*If you want to know more about CDISC standards, or if you would like us to arrange a free internal seminar at your organisation on this subject, please email us at [research@dianthus.co.uk](mailto:research@dianthus.co.uk) or call +44 20 8545 6830.*

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## CDISC standards: streamlining the clinical data flow

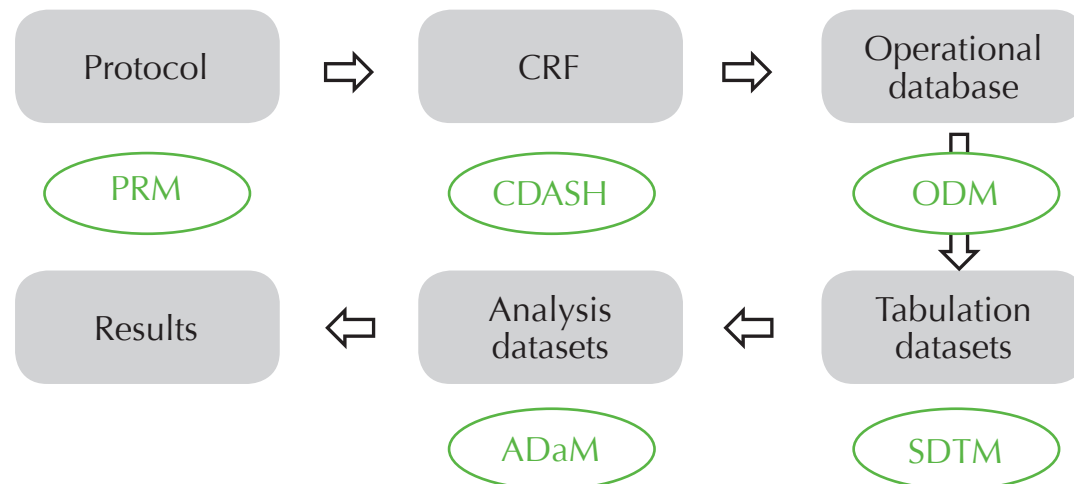
CDISC standards are designed to encompass the entire data flow in a clinical trial, from initial collection to results of analyses. An overview of how the standards fit into the process is shown in the diagram below.

The first part of any clinical trial is developing the protocol. The CDISC Protocol Representation Model (PRM) is an exciting new way of thinking about protocols. Although this standard is new, we are working towards implementing it at Dianthus. We wrote much more about this development in our Q3 2010 newsletter (please let us know if you want a copy).

The Clinical Data Acquisition Standards Harmonisation (CDASH) standard applies to the way data are captured in clinical trials on case report forms (CRFs). The standard is equally applicable to paper or electronic CRFs. By standardising the CRF design process, it can provide great time savings in developing CRFs. Also, when CRFs are standardised, designing clinical databases and converting the data to a format suitable for analysis is also more efficient.

Data in clinical trials are managed in an operational database, the purpose of which is to allow data to be entered, quality checked, and queried, so that the final product is a clean dataset ready for analysis. The

### Overview of CDISC standards



Operational Data Model (ODM) is an XML-based standard which allows the output of operational databases to be standardised. This data from the operational database can be imported into statistical analysis programs using the same code in each study, saving further time.

The Study Data Tabulation Model (SDTM) defines a standard format for storing data from clinical trials. The standard is very well thought out so that it maintains a standard dataset structure, while being flexible enough to capture data from studies with a wide range of different designs and outcome measures. Again, standardisation can result in great time savings in the way the data are processed. If data are in the same format in every clinical trial, then many statistical programs can be reused, saving time and money. Moreover, if data from multiple trials need to be combined for meta-analysis, the standard dataset structure makes this a trivial task. It is also worth noting that when trials are submitted to the FDA, raw data are expected to be submitted in SDTM format.

The Analysis Dataset Model (ADaM) defines a structure for datasets used for analysis. It has similar advantages to the SDTM in allowing re-usable statistical programs and the efficiencies that result. In addition, ADaM allows data analyses to be easily replicable and traceable. One of the general principles of ADaM datasets is that they should be “analysis ready”, in other words that statistical output can be produced by a single statistical procedure, with no data manipulation steps required. All the data manipulation necessary for statistical analysis is done at the point that the ADaM datasets are produced. This makes quality checking of outputs easier, reducing the chance of errors in analysis.

At Dianthus, we have been embracing the CDISC standards, and have been impressed with the increase in efficiency that we have noticed. Statistical analysis of clinical trials is now a far less time-consuming process than before we were using standardised datasets.

# Dianthus

## Medical Limited

Dianthus Medical is an innovative company providing state-of-the-art analytical solutions for the general pharmaceutical industry and organisations working in the biomedical sector. Your medical writing, statistical consultancy and data analysis needs are met with right-first-time consistency to the highest ethical standards.

The pharmaceutical and biomedical industries will experience unprecedented challenges from 2010 to 2013. Clinical trials will become fast-paced, taking place throughout the globe and require even greater control and management. Our free quarterly snapshot bulletins containing comment and research findings permit you to share the latest news and professional opinions on clinical trial processes.

From a business perspective the need is continued growth, increasing shareholder value and reducing time to market for your products.

***Dianthus prides itself on its ability to accelerate many processes used in the delivery of trials and it does this by applying its powerful knowledge-base and leading-edge expertise in protocols which are the foundation of our core disciplines.***

For all your clinical data management, statistical consultancy, analytical and medical writing needs, Dianthus has wide-ranging intellectual property assets that deliver tangible results and good value for money.

Our team of experts have visionary skills and are trained scientists. To discuss this report and take advantage of our well-proven and trusted services, please contact us at [research@dianthus.co.uk](mailto:research@dianthus.co.uk).

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For further information on our quality control procedures and to receive our free quarterly research, news, and comment, Medical Directors and other professionals should register with Dianthus by sending an email to: [research@dianthus.co.uk](mailto:research@dianthus.co.uk) or calling our offices.

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