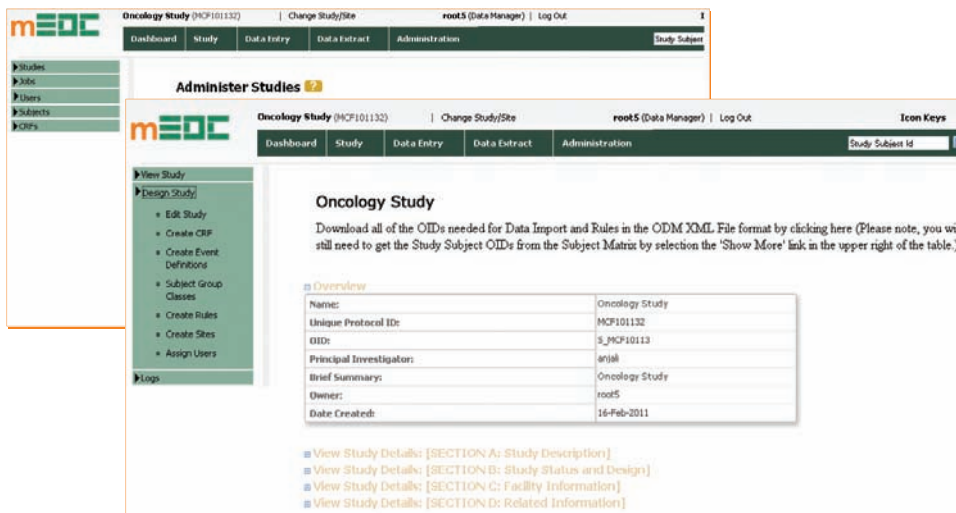


DATASHEET

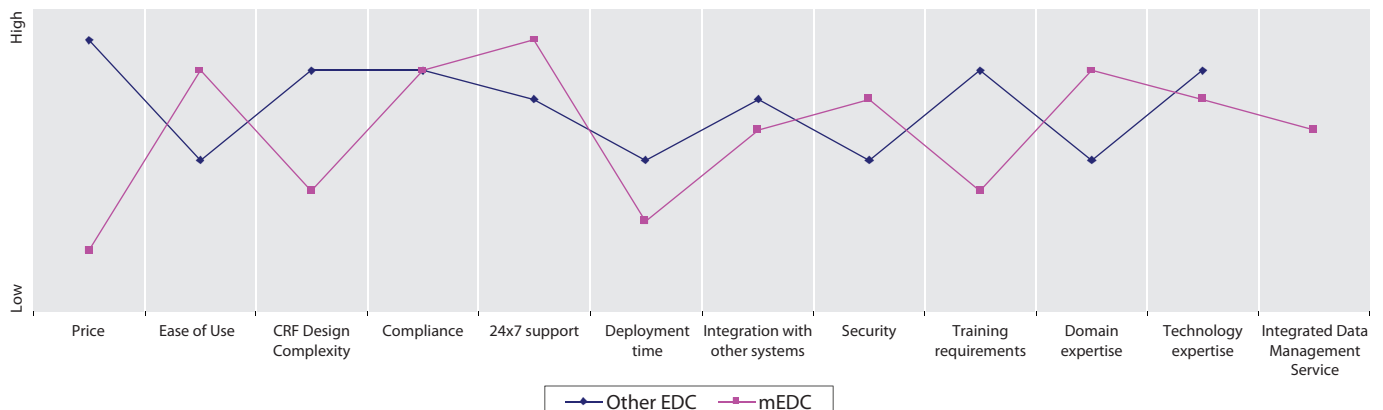
mEDC is a web based electronic data capture and clinical data management system designed to support both electronic and paper based studies, of all clinical trial phases from phase I to Late Phase/ Post-Market Surveillance studies during the drug development process. DDi has a successful track record in conducting various clinical trials using mEDC. Having established a unique EDC and CDM Center of Excellence, DDi offers its customers a cost-effective integrated suite of e-clinical solutions and data management services.

Key Features

- Core CDMS functionalities: Study design & Set-up, Edit checks, Discrepancy management, Database lock and Archival
- Single/ Multi-site management
- Graphical representation of subject wise data entry status
- Complete audit trail and auto medical coding
- Fully compliant with FDA 21 CFR Part 11, GAMP 5 and ICH-GCP guidelines
- Supports univariate and multivariate edit checks
- Supports hybrid studies (both paper CRF and eCRF)
- Single/ Double data entry
- Intuitive role-based views and displays
- Data exports to SAS, CDISC, Excel formats
- English and Japanese language support



Value Differentiation



## Key Benefits

**Create eCRF forms with ease without programming:** mEDC offers a unique interface for stakeholders to easily design and create complex CRF forms within the mEDC system. mEDC supports English and Japanese language and allows re-use of the CRFs for multiple events and studies.

**Highly configurable and adaptable:** mEDC is very flexible and adaptable to various processes and standards. It has been designed to accommodate the best practices in clinical trials, and can be easily customized for any specific study phase or therapeutic area.

**Run adaptive trials and implement protocol amendments quickly:** Sponsors can now deploy all mid-study amendments without compromising study database integrity. mEDC manages multiple CRF editions and seamlessly migrate existing data into new forms and visit structures.

**Rich, intuitive user interface:** mEDC provides easy navigation of the system and is very user friendly. The rich graphical interface with robust features ensures high acceptance by the stakeholders.

**Increased data accuracy and reduced cleaning time:** With sophisticated edit check programming and auto medical coding feature, mEDC substantially reduces the data cleaning time and increases the data accuracy level. It allows for hassle free query resolution and real time study monitoring with graphical representation of subject wise data entry status and ad-hoc reports.

**On-demand ad-hoc reporting and data extraction:** Clinical dataset files can be extracted on-demand in mEDC, and can be exported to standard formats like SAS, CDISC, CSV, XML and Excel. Clinical data reports can be automatically generated, even after studies are amended, based on the specific security access rules defined in the study.

**Quick Implementation:** Based on the client's existing IT infrastructure and study needs; mEDC can be easily and rapidly deployed either as an on-demand/ Hosted solution or as an on-premise system with complete validation. DDi has capability to provide both dedicated and shared hosting environment with 24/7 technical support.

**Seamless integration with third-party systems:** Clinical data from mEDC can be easily shared with other clinical systems like IWRS, IVRS, CTMS, ePRO and drug safety systems. It provides seamless integration with DDi's mClinical product suite.

**Integrated data management services:** Unlike other EDC vendors, DDi has in-house capability to provide complete data management services along with mEDC, leveraging its EDC and CDM Center of Excellence.

**Lower total cost of ownership:** mEDC product is very easy to install and set-up, and requires little programming/ technical knowledge. With flexible deployment options and support services, mEDC is available at a very low cost which truly reduces the client's total cost of ownership.



- ▶ Easy eCRF creation
- ▶ Reusable CRFs
- ▶ Multi-lingual
- ▶ Highly configurable
- ▶ CRF Versioning
- ▶ Quick amendments
- ▶ Simple and Easy-to-use
- ▶ Faster deployment
- ▶ Better decision making
- ▶ Increased data accuracy
- ▶ Reduced cleaning time
- ▶ On-demand ad-hoc reports
- ▶ Seamless integration with third-party systems
- ▶ Integrated data management services
- ▶ Cost effective

For a demo or further information, contact [DDi@makrocare.com](mailto:DDi@makrocare.com)

