

Electronic Data Capture **Features**

SETUP

- Uses intuitive web style interface for Remote Data Entry (RDE)
- Visual interface can be customized on a per-study basis
- Set up your own studies
- Create CRF screen libraries
- Support for line speeds as low as 56K
- Integrates directly with standard Clindex CTMS/CDMS
- Easy installation with minimal site setup configuration

ACCESSIBILITY

- CRFs simultaneously accessible from both RDE and Clindex CDMS
- Control your own data
- Control which users can access, sign and modify CRFs
- Sites can access CTMS information
- Sites can update specific CTMS information
- Site user activities limited by role
- Support for hybrid studies (i.e., combined use of paper and RDE)
- Allows restricted access for Core Labs etc.

DATA QUALITY MANAGEMENT

- Electronic CRF data can be uploaded as part of main CRF
- Data query tracking for both site and sponsor review
- On-screen highlighting of data queries/annotations/modifications
- Investigator can review and print signed CRFs as Adobe files (PDF)
- Automatic linking of CRF and field level modifications to data queries
- Automatic field validation as data is entered
- Investigator can sign CRF from study coordinator's session, using separate signature password.
- Soft and hard validations
- Floating hints to guide site personnel during data entry
- Cross-CRF computed fields and validations
- Automatically skip fields on condition
- Directly links to Clindex product inventory system
- Supports complex cross form edits
- Allows both sponsor and site CRF locking
- Optional automatic patient ID assignment
- Supports multi-arm and stratified randomizations
- Full 21 CFR Part 11 Electronic Signature/Electronic Records validation

TRIAL MANAGEMENT

- Document sharing between site and sponsor
- Documents (e.g., Investigator's curriculum vitae) can be uploaded by site users into system
- Customizable alerts to notify site users of specific issues
- Report list available to investigator is customizable
- Visit manager tracks which CRFs are due
- Task list tells sites which CRFs need to be collected, entered and signed
- Share study news in main study screen
- Monitor and send messages to site RDE users
- Sponsor can share news with site RDE users