VDC™
VIRTUAL DATA CAPTURE™

Data Sheet

The following is a description of ClinCapture's Virtual Data Capture™ (VDC™) product line. The product line consists of multiple modules.

electronic Clinical Outcomes Assessment - eCOA

ClinCapture **Virtual Data Capture™ (VDC™)** Offers the following eCOA modules:
ePRO – electronic Patient Reported Outcomes
eCRO – electronic Clinician Reported Outcomes
eORO – electronic Observer Reported Outcomes

ePRO

ePRO or "electronic Patient Reported Outcomes" are surveys, which are part of **Virtual Data Capture™ (VDC™)** eCOA, and are administered to clinical subjects remotely to collect study-specific data in accordance with the study protocol. Surveys are easily built and customizable within the **Virtual Data Capture™ (VDC™)** environment. **Virtual Data Capture™ (VDC™)** ePRO surveys are conducted remotely via email. Clinical Research Coordinators enter data into the application to trigger the ePRO survey. The clinical subject receives a link to the ePRO survey in their email. This provides a secure way of collecting data because only the subject has access to their password protected email account. Once the subject has completed the survey, the data is recorded within the application. Site personnel can receive and email once the subject has completed the ePRO survey. **Virtual Data Capture™ (VDC™)** ePRO allows flexibility in clinical trials because surveys can be completed outside of the research site.

eCRO

eCRO or "electronic Clinician Reported Outcomes" are surveys, which are part of **Virtual Data Capture™ (VDC™)** eCOA, and are administered to clinicians remotely to collect study-specific data in accordance with the study protocol. Surveys are easily built and totally customizable within the application environment. ClinCapture **Virtual Data Capture™ (VDC™)** eCRO surveys are conducted remotely via email. Clinical Research Coordinators enter data into the application to trigger the eCRO survey. The clinician receives a link to the eCRO survey in their email. This provides a secure way of collecting data because only the clinician has access to their password-protected email account. Once the clinician has completed the survey, the data is recorded in real-time within the application. **Virtual Data Capture™ (VDC™)** eCRO allows flexibility in clinical trials because surveys can be completed outside of the research site.

eORO

eORO or "electronic Observer Reported Outcomes" are surveys, which are part of **Virtual Data Capture™ (VDC™)** eCOA, and are administered to observers remotely to collect study-specific data in accordance with the study protocol. Surveys are easily built and totally customizable within the application environment. ClinCapture **Virtual Data Capture™ (VDC™)** eORO surveys are conducted remotely via email. Clinical Research Coordinators enter data into the application to trigger the eORO survey. The observer receives a link to the eORO survey in their email. This provides a secure way of collecting data because only the observer has access to their password-protected email account. Once the observer has completed the survey, the data is recorded in real-time within the application. **Virtual Data Capture™ (VDC™)** eORO allows flexibility in clinical trials because surveys can be completed outside of the research site.

eConsent

eConsent or "electronic informed consent" is a remote way to collect informed consent from a potential subject for a clinical trial. **Virtual Data Capture™ (VDC™)** allows for a smooth and compliant informed consent process. ClinCapture **Virtual Data Capture™ (VDC™)** eConsent also allows flexibility for different languages for each consent form. eConsents are sent to the clinical subject via email. This eliminates the need for the subject to be in the office to be consent for a trial. eConsents are easily built and implemented within the application environment. Clinical Research Coordinators enter data into the application to trigger the eConsent form. The clinical subject receives a link to the ePRO in their email. This provides a secure way of collecting informed consent because only the subject has access to their password-protected email account. Once the subject has completed the survey, the data is recorded within the application. Upon completion of the eConsent, site personnel will receive an email notification regarding completion of the eConsent. The site personnel will review the data and electronically sign the consent. Upon signature of the site personnel, a copy of the executed informed consent form will be sent to the site and distributed to the subject. The provider can easily access the eConsent form signed by the subject within the application environment using their **Virtual Data Capture™ (VDC™)** log-in credentials. Subject data is organized by subject identifier within the subject matrix within the system. eConsents are managed by the site personnel delegated to obtaining informed consent for the study protocol. Any site-level user (Principal Investigator or Clinical Research Coordinator) has the ability to send, sign, manage, and view the eConsent before and after signature.

eSource

ClinCapture **Virtual Data Capture™ (VDC™)** eSource eliminates the need for paper while collecting data onsite or remotely. Data is entered directly into the system by the provider during subject study visits. This saves valuable time at the research site by reducing the time spent entering clinical data. Electronic source is a valuable research tool that reduces transcription errors as well as provides real-time access to data for review, per the FDA guidance. **Virtual Data Capture™ (VDC™)** eSource maintains data integrity by providing a full audit log for all data entered into the system. Each site user has unique login credentials for **Virtual Data Capture™ (VDC™)**. Each data point entered is recorded with time, date, and data originator on the audit log.