



t+ Clinical – CDISC Data Export

What is CDISC?

CDISC (Clinical Data Interchange Standards Consortium) define a number of standard data formats. Any enterprise wishing to interoperate with other enterprises can use the standards to achieve this goal.

Objective

To allow other enterprises to import Study (or Trial) data collected by t+ Clinical on behalf of the Sponsor.

Operation

At any point during the lifetime of a Study the data for the Study can be exported (i.e. the exported data is a snapshot of the current state of the Study) – the timings of these snapshots are defined in the Study protocol by the enterprise operating the Study.

The result of the export is an XML file which conforms to the CDISC ODM V1.2 standard; any system which supports data import from this standard may then import the data.

The actual file may be delivered to the requesting enterprise by any means including use of the secure t+ Client Portal.

Further Information

CDISC Website:

<http://www.cdisc.org>

CDISC ODM V1.2 XML Schema:

<http://www.cdisc.org/schema/ODM1-2-0.xsd>

CDISC ODM V1.2 Specification:

<http://www.cdisc.org/models/odm/v1.2/ODM1-2-0.html>



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