

psiODM is a flexible tool for producing CDISC ODM-compliant XML export files directly from an Oracle Clinical database.

psiODM provides users the ability to create CDISC ODM-compliant XML exports of their metadata and clinical data, directly from an Oracle Clinical database. Taking advantage of the fixed nature of the Oracle Clinical data model, it is possible to immediately produce XML extracts without the need for any initial configuration. Users can also easily modify the default mappings between the OC data model and ODM structures if required.

ODM files provide an organization many possibilities for making better use of the data held within their Oracle Clinical database. For example:

- Sponsors can use ODM files to provide a machine readable copy of their standards to CROs.
- CROs can provide regular feeds of clinical data to their sponsors.
- All users can produce vendor and platform independent archives of their clinical data that include a full transactional history.

Future proof your clinical data

CDISC ODM is an open, vendor neutral, platform independent format for transporting and archiving clinical data. As such it provides a "future-proof" solution for archiving your clinical data. psiODM provides the mechanism to move the following data to ODM files:

- Metadata
- Clinical data
- Audit trail
- Laboratory normal ranges
- Investigator comments
- Investigator details
- Discrepancies and their history

Key Features

- User definable mappings from Oracle Clinical to ODM
- Results stored within a secure XML-enabled database
- Produces both "snapshot" and "transactional" files
- Export files containing a study's full transactional history
- Multiple source Oracle Clinical databases
- Files available through windows explorer

“ For companies looking to archive all Oracle Clinical studies and data as they transition to other technologies psiODM provides exactly what is required.

”

Tim Billington
Chief Sales Officer

psiODM

Fileid	Description	Filetype	Granularity	Priorfileid	Odmver
10018	TB 001 - Full Archive	Transactional	All		1.3.1
10019	TB 002 - MetaData	Transactional	MetaData		1.3.1
10027	TB 002 - Data	Transactional	AllClinicalData	10019	1.3.1
10028	RB 001 - MetaData	Transactional	MetaData		
10029	RB 001 - Site 1	Transactional	SingleSite		
10030	RB 001 - Site 2	Transactional	SingleSite		


```

<?xml version="1.0" encoding="ISO-8859-1" ?>
- <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:ds="http://www.w3.org/2000/09/xmldsig#" CreationDateTime="2005-04-06T10:30:00" Description="XML File" >
- <Study OID="4022">
- <GlobalVariables>
  <StudyName>TB_002</StudyName>
  <StudyDescription>Headache</StudyDescription>
  <ProtocolName>TB_002</ProtocolName>
</GlobalVariables>
- <MetaDataVersion OID="1" Name="TB_002" Description="Live Version of TB_002">
  <Protocol>

```

For more information

To learn more about pharmasol services or software solutions, please contact info@pharmasol.de or visit www.pharmasol.de

© Copyright pharma solutions international

GmbH 2015

pharma solutions international GmbH

Lothringer Dell 27

67659 Kaiserslautern

Germany

Produced in Germany, March 2015

Other company, product or service names may be trademarks, or service marks of others.

References in this publication to pharmasol products, programs or services do not imply that pharmasol intends to make these available in all countries in which pharmasol operates. Any reference to a pharmasol product, program or service is not intended to imply that only pharmasol's product, program or service may be used. Any functionally equivalent product, program or service may be used instead.

All customer examples cited represent how some customers have used pharmasol products and the results they may have achieved. Actual environmental costs and performance characteristics will vary depending on individual customer configurations and conditions.

This publication is for general guidance only.

Photographs may show design models.