

“Using pharmaSOL's generic dictionary updater we no longer need to rely on costly, external help to update all of our TMS dictionaries. The predictive impact reports allow us to determine the update impact before we carry out the update and afterwards our coders can quickly act on the listed actions. Its simply a small but very useful little tool.”

Peter Lipczak, Vice President IT, Cyncron A/S

psiDict – a generic TMS dictionary updater

Dictionary Updates made easy

Dictionary Updates have traditionally been very technical, complex tasks requiring the creation of SQL load and update scripts.

Building up internal knowledge to support dictionary updates is difficult, especially due to the relatively low frequency these skills are required and refreshed. Buying in external help, on the other hand, is very expensive.

psiDict is a generic TMS Dictionary Updater that eliminates the complexity of dictionary updates and allows TMS end users to carry out dictionary updates themselves. An intuitive GUI guides the users through the process of updating a dictionary.

Because it works independently of the TMS dictionary structure psiDict can update any strong dictionary defined in TMS. Dictionaries such as MedDRA, WHODrug, HARTS, COSTART or any custom strong dictionary you may have set up in TMS are suitable for updating using psiDict, all using the same GUI and the same process.

Secure and Safe

psiDict works only on the staging Pre-Dictionary tables in TMS. It does not update any productive data directly.

Working from the new version of the dictionary, psiDict prepares all dictionary updates in the Pre-dictionary tables, which are then validated by the standard TMS activation process before it is moved to the productive tables.

Convenient

psiDict can automatically create and activate a virtual dictionary allowing you to retain your previous dictionary version. The application automatically ensures that virtual dictionaries are taken at the appropriate point in time preventing any potential data loss.

Predictive

Even before the update process is initiated it is possible to view a predictive impact analysis of the update. The impact report will list any coded terms that will be declassified because

- the term used for coding will be deleted
- a better automatch will become available
- a company term used for coding is replaced by an external term

This predictive impact analysis will facilitate the coders to identify and recode recreated omissions.

| Dictionary Name | Domain | Declass. Reason | Project | Date | Status | Error | Doc. No. |
|--------------------------|----------|-----------------|----------|---------|--------|-------|----------|
| ALAB | MEDICINE | TERM DELETED | MYTERM01 | MY TERM | + | NOGET | NOGET |
| ANTHRAZYCLIN SULFONAMIDE | MEDICINE | NEW AC SOURCE | MYTERM01 | MY TERM | + | NOGET | NOGET |
| ANTHRAZYCLIN | MEDICINE | NEW AC SOURCE | MYTERM01 | MY TERM | + | NOGET | NOGET |
| ANTHRAZYCLIN | MEDICINE | TERM DELETED | MYTERM01 | MY TERM | + | NOGET | NOGET |

Dictionary Updates and Beyond

Additional Features

In addition to updating dictionaries psiDict allows you to

- load externally created codes (VTAs)
- load verbatim terms (VTs) into any TMS domain for coding and subsequent extraction to an ASCII file

Both the load of VTAs and VTs is enabled from comma delimited ASCII files. This enables CROs to efficiently code verbatim terms for sponsors or allows sponsors to load VTAs created by CROs.

Unlimited Possibilities for Limited Budgets

Why psiDict?

- You need a simple and efficient dictionary update process?
- You want to maintain multiple dictionaries with one single update process and user interface?
- You want to load all the version updates from the dictionary vendors but can't keep up?
- You require a predictive impact analysis of the forthcoming dictionary update?
- You don't want to have to create and validate custom programming for each dictionary?
- You want to rely on a proven application with a strong customer base?

psiDict is a generic, simple to use, TMS dictionary structure independent, updating tool that will allow you to keep up to date with all dictionary updates.

In fact psiDict is so simple to use it enables TMS end-users to carry out TMS dictionary updates rather than Administrators with enhanced SQL skills.

psiDict has a strong customer base of 10+ clients including major pharmaceutical companies as well as small and medium sized CROs.

Why pharmaSOL?

Since 1999, pharmaSOL has been helping major pharma companies all around the world to streamline their internal and external business processes, implement and customize their OLS (Oracle Clinical, TMS, RDC, AERS) software.

Each of our employees has more than 10 years of experience with Oracles Life Science Suite and is a proven industry expert.

Experience

- Only provider of an Oracle Accelerate approved rapid implementation approach for Oracles life Science Suite
- Service provider to the Life Science industry for more than 8 years
- Experienced consultants, ex-Oracle consultants
- A proven track record of more than 100 successful projects

Service oriented, project focused

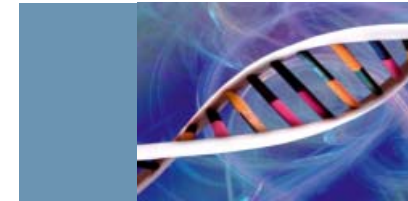
- We understand the needs of our customers
- We get them up and running quickly
- We help them to maintain a validated and efficient system

A broad range of value added services to ensure the lowest total cost of ownership

- Hosting facilities
- Support contracts
- eLearning solutions
- experts contracting
- Applications
 - psiLearn – a complete eLearning suite tailored for OLS
 - psiLab – normalized lab support in OC
 - suppsi.com – a flexible support ticketing system
 - psiDict – a generic TMS dictionary updater
 - psiScan – an Oracle Clinical Workflow and Scan enhancement enabling split screen data entry
 - psiComply – well tested Oracle Life Sciences Validation Suite based on GAMP 5.

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Innovative Solutions

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