

Upgrading to DataFax 3.7 Birds of a Feather Session

Attendees: Beth Pavlicberry, Protein Design Labs, Inc.
* Andres Busette, V.A. Medical Center
Rose Gonsalves, ALZA
Vikas Gulati, ICON Clinical Research
Pascal Groenen, Factory-CRO Medical Services
* Brad Harris, Pharmacyclics, Inc.
Pongthep Miankaew, Mahidol University
Kerry Murmello, ICON Clinical Research
* Darryl Pahl, DF/NET Research, Inc.
David Powers, Genaera Corporation
Carol Richardson, Ross Products Division, Abbott Labs
* Gustav Sporon-Fiedler, H. Lundbeck
Wayne Taylor, Clinical DataFax Systems, Inc.
Irene Toropin, Genaera Corporation
Huiming Tu, Premier Research Group plc
Valerie Warburton, Protein Design Labs, Inc.
* Kim Woodhouse, Univ of CA, San Francisco

* Attendees from companies that have upgraded to version 3.7.00x. Mahidol University is running v3.5; all other sites are running v3.6.

Purpose: To discuss successes and challenges in upgrading to DataFax version 3.7.00x

Summary:

New items in 3.7: Cycles must be used in the visit map. Screening visits automatically become cycle 0. There can be an end cycle for logs. Optional visits may require creation of a cycle. Studies that do not use cycles may require changes to the visit map. DFunexpected.drf has been added to record the arrival of any unexpected data records.

Data does not change when updating to 3.7. Some companies found data inconsistencies that required clean up during the upgrade.

There were no issues with 3.7 releases; CDSI will submit bug reports to them if there are problems.

Installation: v3.7 must be installed, then each patch loaded individually, in order.

When upgrading to a new server, a company could choose to install v3.7, perform the validation on the new server, then validate the data migration.

Upgrading archived studies: The group does not recommend upgrading archived studies because of resources needed to upgrade and maintain the study, plus the requirement to restore it if there is a disaster. Archived studies are accessible via PDFs and SAS data sets.

Group wisdom:

- Read all upgrade documentation carefully and note which features are no longer available.
- Review visit maps for each study before upgrading.
- Allow enough time and resources for both the physical upgrade and validation testing and documentation.
- Draft upgrade requirements so that validation documents will trace back to specific requirements.
- Do not test/validate features you will not use.

- Archived studies may not continue to be viewable in future releases, so think carefully about whether to upgrade them.
- Develop an SOP for archived studies that will not be upgraded.

V3.7.004: Items currently listed as in development on the website will most likely be included in this release. 3.7.004 estimated available June 2005. Some companies are choosing to wait for version 3.7.004 before upgrading

V3.7.004 Requests:

- Add sort order to change list
- Add new features to the ATK, especially regulatory features