Title: Database Archiving
Description and Work Instruction

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WORKFLOW

For project close-out it is necessary to archive individual projects as well as complete customers selectively and to remove from a secuTrial®-installation after this. As intermediate steps an reversible inactivation, which leaves the data within the database without putting load on the server's memory, and a database-closure, where data in the database can still be viewed and analysed.

The workflow covers the following steps:

1. Project close-out(optional, individually for setup and productive)

2. Project scheme / customer inactivation

3. Project scheme / customer archiving (not possible within the first 24 hours after inactivation)

4. Project scheme / customer deletion (only if there is a valid archive available)

The actions in the context of archiving (inactivation / activation / archiving / deletion) can be triggered by additional buttons on the edit page of the customer or scheme. Actions need to be confirmed on an intermediate page by re-entering customer administrator username and password. Additionally there will be a further confirmation - in case of deletion even two further confirmations - whether the respective action shall be carried out.

The inactivation / activation occur immediately. Archiving and deletion are started and then performed in background processes, since depending on the amount of data these can take a longer time. After completion of the action you can be notified by e-mail. In the e-mail any eventually occurring problems will be listed, e.g. undeletable files. The result of the action (content of the email) is also shown in the archival history of the linked validity indication.

An archive is valid if, after completion of the archiving, the modules were started once again (e.g. at night) and if the project schema / the client was not reactivated after creation of the archive.

PROJECT CLOSE-OUT

The project close-out is optional and is separated in the respective customer admin tool for the setup- and productive-instance. Thus a lock is placed on the relevant project data.

This status is in the customer admin tool viewed or considered for the archiving workflow.

INACTIVATION / ACTIVATION

It is no longer possible to login into inactivated customer projects. The data model for the customer and all customer-generated schemes are no longer generated on the next restart of the applications (except for creating the archive). Therefore no more database connections established with the corresponding DB schemes are established. The data remains otherwise unchanged in the database.

No data models and database connections are established for inactivated schemes at the next reboot. Data is no longer accessible except for the expandable view in the AdminTool and FormBuilder (see below). Inactivation acts both in setup and in the productive part of the database.

Note: When working in the AdminTool it is important to note that there are project-independent data associated with the project that can still be edited. These are the roles (in this case a warning is displayed) and also the general patient status.

By activation, the inactivation can be abolished completely. All data will be accessible after the next reboot, the setup-area for reactivated projects of active customers even after the next login.

ARCHIVE CREATION

Being permanently inactivated for at least 24 hours a database schema (customer project) can be exported from the database as an archive, the original data will remain in the database and the file system. The archiving takes place on the server in a background process. The customer administrator can be notified by e-mail about the success of archiving. The archive is in a subfolder of the new "archive" directory on the server, named after the customer and schema code and a time stamp stored (see Deployment). For permanent protection this subfolder has to be copied to CD, DVD or tape by the system administrator and to transfer to the data owner. In case of deletion, the corresponding archive directories have to be deleted manually by the system administrator also.

Important: The permanent backup cannot be controlled by secuTrial® and is in the responsibility of the system administrator!

ARCHIVE CONTENT

An archive contains all project- or customer-specific database content and all the general data of the current secuTrial® installation. It contains SQL scripts to reinstall the secuTrial® installation with the archived data version, CSV files and patient records for all archived centers. Moreover all referenced resources (e.g. logos, download documents, exports on-hold, patient-images) are archived.

In particular:

- Database content ("data"):

- all patient medical data (content project-scheme)

- Schema archive all data directly associated with the subscriber management of the project,

- Customer-archive: complete participants management

  - export data in CSV-format (one file per database table), SQL (including re-init script) and HTML (= patient records per center)

- Resources:

  - all the project / customer-related files in the file system (such as statistics, download documents, logos, patient image file)

- Documentation:

  - database documentation of all schemes

  - documentation-dossiers of all project versions

  - configuration files of the installation

- Readme.txt:

  - Description of the archived system (version numbers, character set, customer / schemas)

  - Help to re-install

  - A list of all files contained

Note: By archiving the data on the server will be duplicated. Thus the capacity limits of the server can be achieved in case of extensive database content and particularly for the large volume of patient images! Do contact the system administrator before archiving!

ARCHIVE RE-INSTALLATION

For a subsequent view into the data the SQL scripts contained in the archive can be used to re-install the schema / customer project. Therefore a completely empty database instance is necessary. It is not possible to import multiple archives in the same or in an existing Secutrial® database!

After importing the database a corresponding Secutrial® version must be setup and resources contained in the archive copied back to the configured directories.

It should be made sure that the character set of the new server ("file.encoding") match with the old system, otherwise e-signatures contained in the data are invalid.

The Readme-file within the archive contains a brief instruction.

DELETE

For a schema or a customer project to be deleted, a corresponding valid archive has to be created. A successfully created archive will be valid until the next reboot of the CustomerAdminTool (the delay is necessary because of internal processing procedures). If a schema or a customer project is activated again after creation of an archive, all previously created archives are out of date and are classified as invalid, but they remain unchanged on the server. To delete again the entire workflow (inactivation, storage) has to be repeated.

During deletion individual resources, e.g. orphaned patient images may not be deleted. This will be logged in the action-result (= mail) and must be manually deleted either via CustomerAdminTool or by the server administrator.

RESTRICTIONS ON PROJECT SCHEMA ARCHIVING AND DELETION

In contrast to the treatment of an entire customer there are some but few limitations in the selective archiving and deletion of administrative data from individual project schedules. Thus, even after the inactivation of a project scheme, some project-related data, such as role-rights and general patient status can still be edited and changed.

Messages linked to the project can only be collected for archiving, if there are only recipients within the corresponding project. On deletion all messages remain unconsidered.

Filtering in the AdminTool archive logs for subprojects is not possible. Therefore, this table is not archived or deleted in a single subproject scheme. If this data is necessary, a customer-archive must be created.

PREVENT REBOOT DURING ARCHIVING

While archiving or deletion is performed in the background, it is not possible to restart from the background page of the CustomerAdminTool. A corresponding message will be displayed behind the time-entry window,

Conversely, the creation of an archive or to perform a deletion is not possible if a restart is requested or the next restart requested from within the FormBuilder (release version action) is triggered in less than 2 hours. Again a corresponding message text will be displayed.

ARCHIVING HISTORY AUDIT TRAIL

All actions within the archive are listed in the CustomerAdminTool under the menu item "history."

Here are listed:

- Date of Action
- Archiving Action
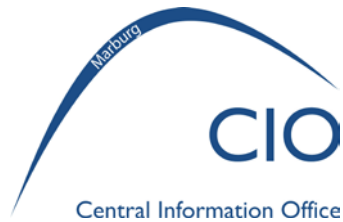
- For archives: timestamp of the archive

- User who triggered the action

- Customer

- Project / Scheme (if set)

- Validity (linked to action results if set)

- Status icon (see handling)

Even after you delete the project schemes or customer projects all previous actions to remain logged in the history. Such historical actions are grayed out.

The list can be filtered by:

- Current / recent

- Action

- Customer

- Project

FURTHER REFERENCES

secuTrial® Manual: Customer Admin Tool (PDF document)