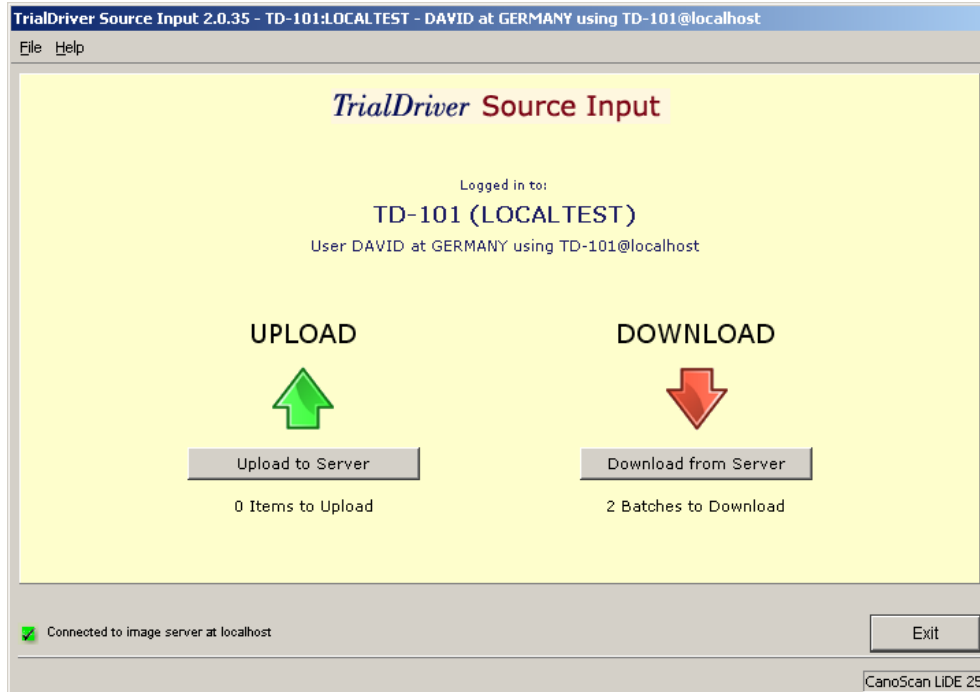


TrialDriver Scanning Client – TDSCAN

Uploading and Downloading Source Documents

Introduction

A small and easy-to-use program (TDSCAN), suitable for installation in the field at CRO offices, study sponsor sites, Phase I clinics etc, is used to acquire the source documents for a clinical trial. It integrates scanning software for the acquisition of paper based images with secure data transmission capabilities to transfer the input material to the clinical database server, which may be located anywhere on the internet. TDSCAN accepts data as TIF images (single- or multipaged) and/or PDF files.



The TDSCAN program provides at once two key functions: Firstly it acts as an Image Transfer Agent for the managed transfer of batches of electronic source documents. Secondly it acts as the portal through which source documents are input into the TrialDriver Data Management System

Data batches are transferred through a database server which implements a secure access policy. Users log in to the system by selecting a study and providing a username/password pair

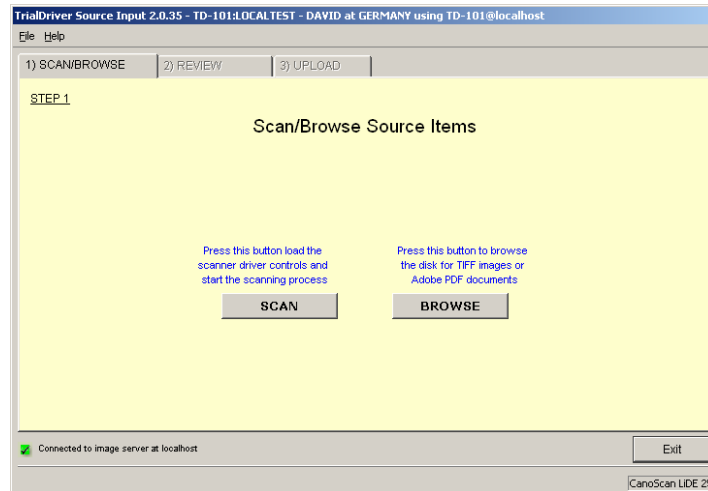
The screenshot above shows the introductory screen after successfully logging in to the *tdscan* program. Two buttons allow the user to select either “upload” or “download” mode. Beneath the buttons are noted if there is any new material to be up- or downloaded for the current user location

A note on user locations

Part of a user profile is his or her “location” - this is generally a company name and not necessarily a physical location. Several users can share the same location. Batches are presented for download based on location so that if one user has downloaded a batch, it will not be presented to a different user at that same location. For this reason it is good practice to designate a single PC as a download machine, which multiple users can log into and out of and in this way prevent study data from being stored on disparate machines

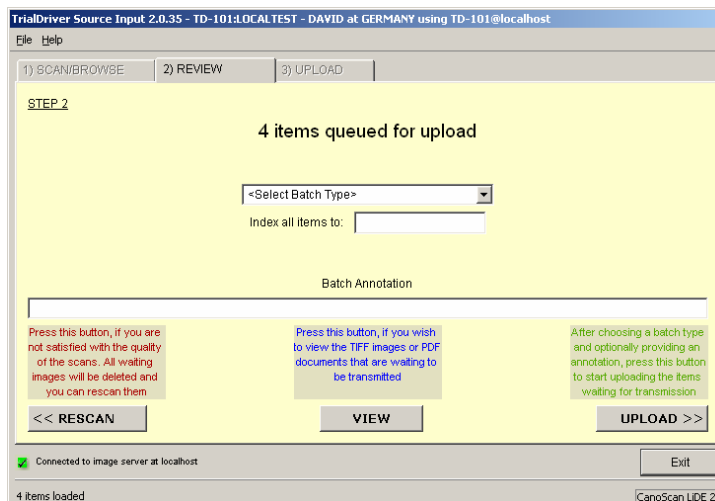
Uploading Source Material

After selecting the *upload* option on the startup screen, the user is presented with a choice of whether to scan images or browse for files of TIF or PDF type.



- Choosing the **SCAN** option will start a dialog specific to the installed scanner at the site - each scanner manufacturer supplies their own driver software. Operate the scanner controls so that B/W TIF files are produced with a 300 dpi resolution. Only TIF files saved with the industry standard CCITT Group 4 compression scheme, or files not compressed at all, are supported.
- Choosing the **BROWSE** option will display a file selection dialog allowing the selection of TIF or PDF files, which may not however be mixed in a single batch. The same restrictions on TIF file types as above apply here.

Once either of the above dialogs close, the program moves to the next screen, allowing the user to preview the batch material and optionally annotate or index it.



This screen displays the number of items in the batch. A drop-down list of batch types lets the user describe the contents of the batch - if no description is applicable then choose the MIXED batch type. Optionally the user can elect to provide a batch annotation and/or a subject ID, to which all the material in the batch will be indexed. If the subject ID consists of multiple parts (discrete SITEID and SUBJID values, for instance), then join the component parts with a slash, e.g. 03/2145

The user can preview the contents of the batch prior to uploading it (click the VIEW button). If for any reason the batch is unsatisfactory, then click the RESCAN button to scrap the current batch and return to the previous screen.

Finally, click the UPLOAD button to initiate the upload process, during which time a progress status is displayed and the user interface is disabled.

Once the upload completes, a summary of the upload process is displayed. This summary information should be transcribed into the scanning log for the study. After closing the summary box, the user interface buttons are enabled allowing the user to either upload more material or exit the application.

Scanning Log Entry for Study TD-101

Please enter the following information into the Scanning Log for this study

Batch ID	# Items	Batchtype	Timestamp	Username	Machine-ID	Status
000024	4	CRFPAGE	2008-01-21 10:30	DAVID	PASCAL	COMPLETE
Subject unspecified		Batch Annotation				

Error conditions which can occur during upload

During the upload of source material, two error conditions can occur:

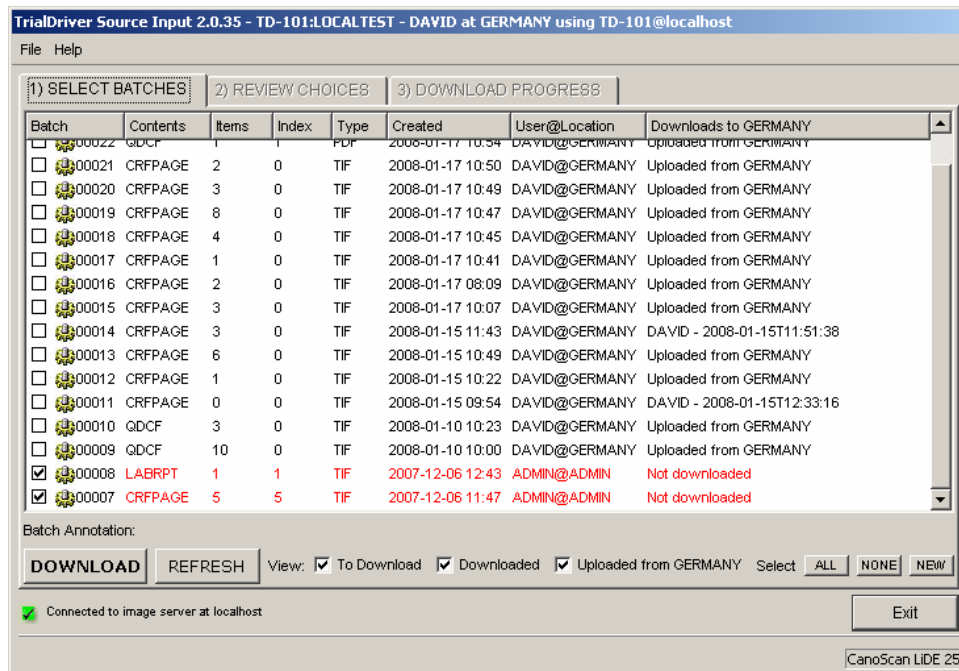
- The connection to the internet is lost
- The scanning application is terminated by an external cause (e.g. power failure)

In both cases, nothing is lost. Scanned material is stored on the local PC and is only removed from the storage directory once it has been successfully entered into the TrialDriver database. In the both cases, the scanning application will recover from the condition and once connectivity is restored or the application restarted, it will automatically offer to upload the rest of the interrupted batch. In the case of a program crash or similar (second case above), the interrupted batch will be released from its loading status after a one hour timeout period

Downloading Document Batches

After selecting the *download* option on the startup screen, the user is presented with a list of batches available for download. Downloading batches of images is a three step process:

- Select batches for download
- Review storage location for the downloaded material
- Start the download.

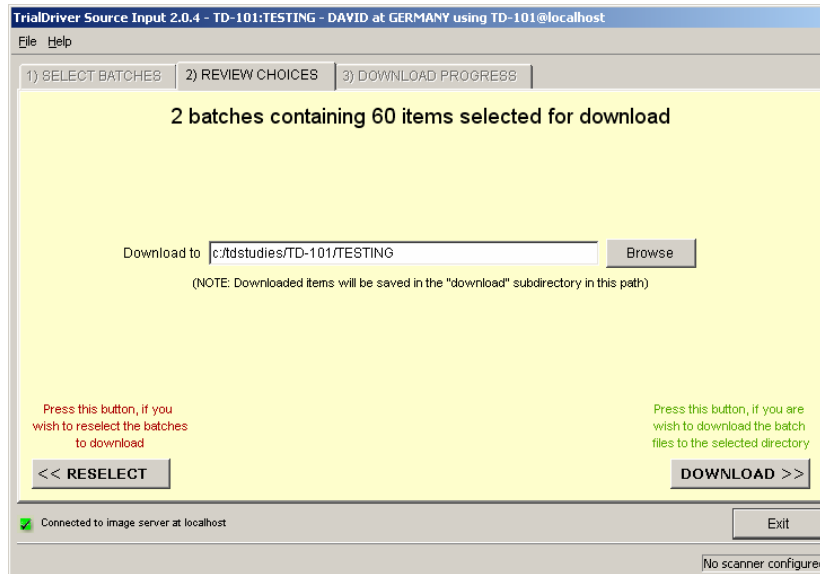


After choosing the *download* option on the initial screen, the user is presented with a list of batches available for download (screenshot above). By default, the user is presented with batches which have never been downloaded to his/her location and these are preselected for downloading.

The batch list displays information about the batches such as its' unique ID number, the nominal content type of the batch, the number of items in the batch, the number of items which have been optionally indexed to subject in the TrialDriver system, the file type of the batch (TIF or PDF), the date of creation and the originator and some batch tracking information pertaining to the current user location

Located beneath the batch list is a row of buttons and switches which lets the user refresh or modify the displayed batches. By default only "new" batches are shown but the user can elect to see also batches which have previously been downloaded or even those which were uploaded from the current location. Any batch can be selected for download, and batches may be downloaded multiple times to a given location if necessary.

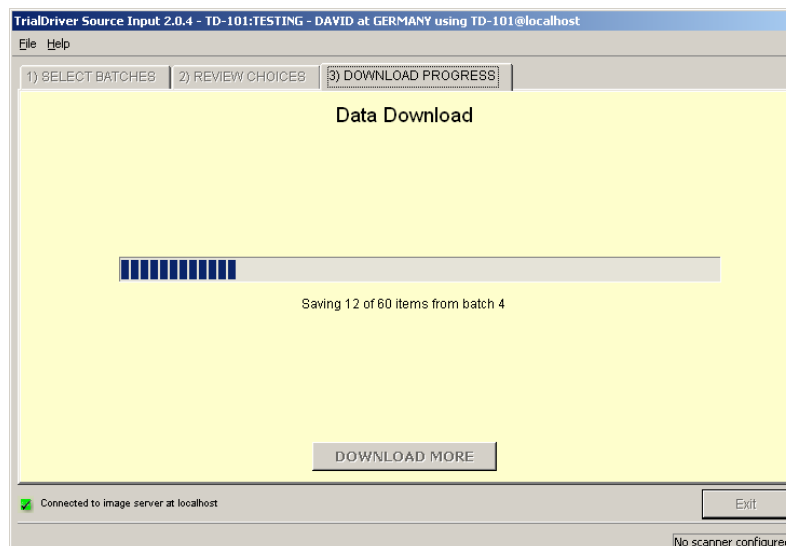
Batches are selected for download by toggling the check marks to the left of the batch ID numbers in the batch list. Once the batch selection has been made, the user can click the **DOWNLOAD** button at bottom left to move on to the next step.



This screen summarizes the choices made and displays a location in which the files will be saved on the local machine. The directory location is automatically calculated according to the settings made for the currently loaded study, but can be overridden if desired, by clicking the **BROWSE** button.

Please note that the files will actually be saved in a path which is subordinate to the directory path displayed in the box - namely in a subdirectory named “*download*” and then in a subdirectory named according to the batch ID number.

By clicking the **RESELECT** button the user is taken back to the previous screen, otherwise click the **DOWNLOAD** button to start the actual process.



The last screen simply shows a progress bar indicating the download progress. While it is running it cannot be interrupted unless the internet link goes down. So far as the tracking system is concerned, a batch is either downloaded completely or not at all.

When the process is finished batches will have been saved to the location specified - see below for a discussion of the files which comprise a downloaded batch. On-screen buttons now give the user the option of selecting further batches for download or exiting the application.

File contents of downloaded batches

Batch contents are stored in a directory named `BATCHnnnnn`, where *nnnnn* is the five-digit sequential batch number. It contains three types of file

- The original scanned images or documents which comprise the batch. Images are saved as individual TIF files. These files are named `BATCHnnnnn_mmm.tif` or `.pdf`, where *mmm* is the sequential number of the file within the batch
- A PDF (named `BATCHnnnnn.pdf`) which contains the batch images in a reduced resolution, which is suitable for printing control documents
- A machine-readable “Batch Index” file (named `BATCHnnnnn.idx`) which lists the components of the batch. This file is suitable for controlling the flow of data into a downstream process.
- The batch index file may list document indexing information, if this step has been performed in the TrialDriver system - otherwise it simply lists basic file-related information

Scanning Guidelines.

TrialDriver scanning is very flexible and, with the exception that images must be scanned as black and white TIF images at 300 dpi, there are no other hard and fast rules about how source material has to be scanned. However, in the interests of rapid indexing of the scanned material, there are some recommendations:

Prior to scanning the material

- Make sure you are logged in to the correct study!
- Make sure you have a scanning log. If necessary, print copies of the scan log page included in this document.
- Where feasible, scan pages in batches which each belong to a single patient. A good size for a scanning batch is about 20-50 pages. If there are fewer pages per patient than this, then combine patient pages into a single batch.
- Sort the pages in ascending order.

After scanning the pages, but before uploading:

- Confirm that the item count (ie number of pages) displayed on screen matches your expectations.
- Use the batch viewer to briefly check the quality of the images
- From the dropdown list, choose the category of material which best describes the scanned batch. If no category appears appropriate, choose “Untyped”
- If all the pages of a scanned batch belong to a single patient, enter the patient number into the edit box provided.
 - If the study has a single number as the patient ID, enter that number
 - If the study splits the patient ID into separate site and patient numbers, enter these two components separated by a slash, e.g. “03/901”
- If the pages belong to multiple patients, *leave the patient number edit box blank*
- Enter an optional description of the batch in the “Batch Annotation” edit box.

After uploading the batch

- Transcribe the batch information displayed on screen into the written scanning log.

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Batch ID	# Items	Batchtype	Timestamp	Username	Machine-ID	Status
Subject ID		Annotation				

Batch ID	# Items	Batchtype	Timestamp	Username	Machine-ID	Status
Subject ID		Annotation				

Batch ID	# Items	Batchtype	Timestamp	Username	Machine-ID	Status
Subject ID		Annotation				

Batch ID	# Items	Batchtype	Timestamp	Username	Machine-ID	Status
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