

PORTAL USER GUIDE

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LOGIN



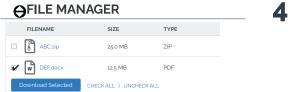


PAGE

DOWNLOAD

Click and download selected files for review and for local translations





UPLOAD FILES

Upload files in English and/or local language for layout. Name your file following the naming conventions*





SELECT STUDY

Select from your list of studies



REVIEW **EDITED FILES**

PROJECTS/STUDIES

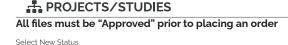
Once Moonlight Imaging has formatted your files in local language, you will be able to review the files and add comments if the document needs changes. To submit changes and corrections click to open the file in Adobe Acrobat (PDF), make comments, save and upload. Or add your comments in the comments area in portal.

When you upload your edited file follow the naming conventions": & add "_comments" at the end of file string After Edit should be posted using this string:

\$

Study Number_Country Code_Language_Doc Description_Version Date_comments.pdf

APPROVE FILES



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ORDER MATERIALS



✓ Approved

8 & 9

TRACK your shipments

PROJECTS/STUDIES

TRACKING NUMBER 100000000000 2

10

*NAMING **CONVENTION**

for Portal **Documents**



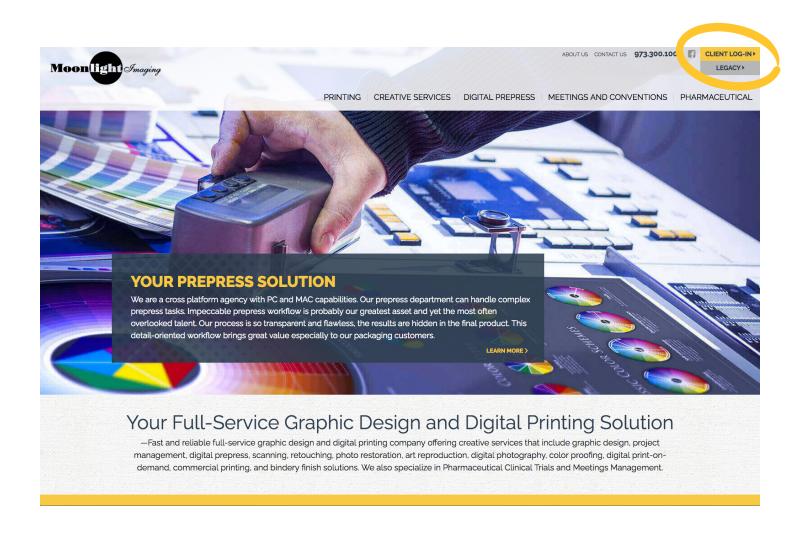
NAMING CONVENTION for Translation **Uploads





GETTING STARTED

- When a study is initiated GTOS will provide the Moonlight Imaging Web Administrator (portal@moonlightimaging.com) a list of names and emails for the study team.
- Moonlight will issue User Names and Passwords which will be sent to their individual email address.

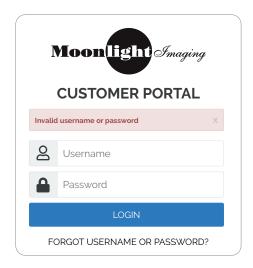


LOG IN

Login requires a username and password. These are assigned by Moonlight Imaging Portal Administrator.

- Users can use the "Forgot Username
 Or Password" to have the system email
 their username and a link to reset their
 password. The reset password links are
 only valid for one hour after being issued.
- If user enters invalid passwords more than three times this will trigger a risk and will lock the account for 5 minutes. User will be able to retry to input the password after that 5 minutes has elapsed.
- When a user signs in for the first time, they will be presented with the portal's Terms of Use and be required to accept before entering.
 They will not see the message again.
- Agree will close the terms window, record the user has accepted the terms and show the home screen.

 Disagree and logout will log the user out and return them to the login screen.

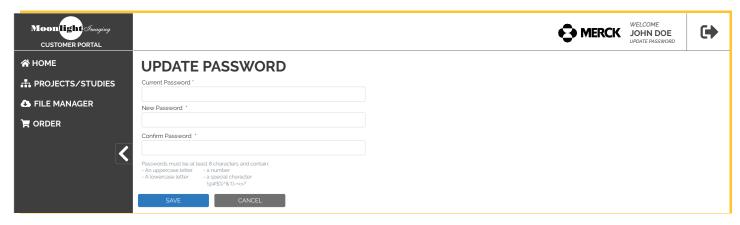




Update Password

The user can update their password.

- You are not able to update your name or email address, only Portal Admin can modify this information.
- Passwords must be at least 8 characters long and contain: a lowercase letter, an uppercase letter, a number and a special character: !@#\$%^&*()-+<>?

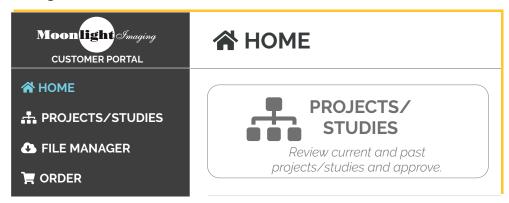


SELECT STUDY



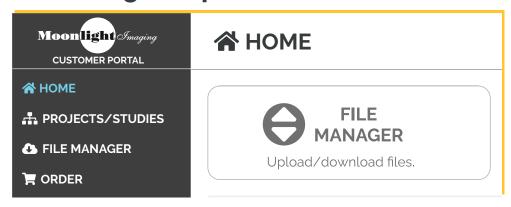
Home page includes icons and a brief description of each customer portal area the user has access to:

Projects/Studies

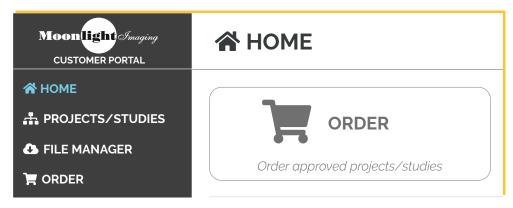


To select a study go to Projects/Studies. Here you will see a list of the studies that you are associated with and this is where you can review and download study documents.

File Manager - Upload and Download Files



Order



DOWNLOAD FILES - STEP 1

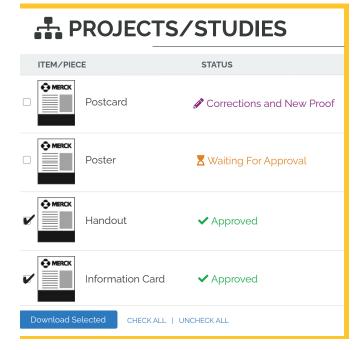
Download documents FOR REVIEW

GTO goes into the **Project/Studies** to pull down the ENG documents to review

- All assigned users can download documents for review.
- The default status of the document for review is Waiting for Approval.
 The status of each item includes a unique color for each status. Please see page 5 for a detailed description.
- Click the checkboxes next to items and download a zipped file of all selected files.
- Once reviewed, the GTOS should approve the document so it can be used by the COM to move on with the translation phase.



Review current and past projects/studies and approve.





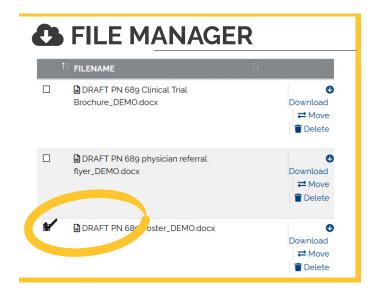
Download documents FOR TRANSLATIONS

Once the ENG version of the document is **available** the EXUS COMs associated with the study will receive an email auto notification that Word files are ready to download for translation.

COM then goes into the **File Manager** to pull down the ENG **Approved** Word documents to translate.

- Select the study for which you would like to download the documents.
- The status of the documents will appear as Approved.
- Click the checkboxes next to items and download a zipped file of all selected files





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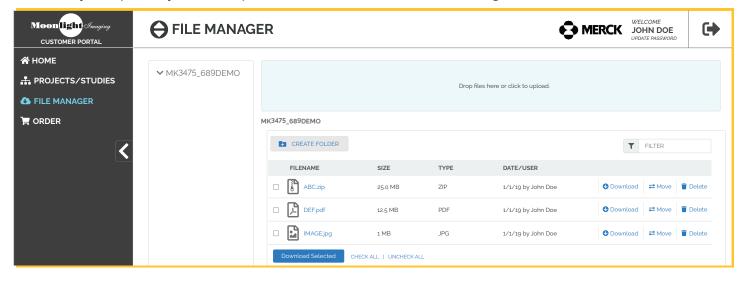
UPLOAD FILES - STEP 2

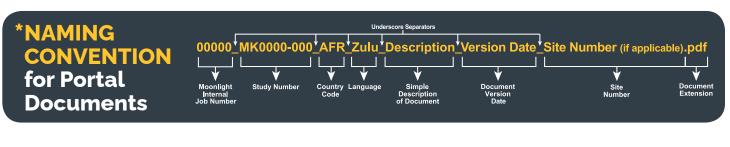
Upload locally translated documents

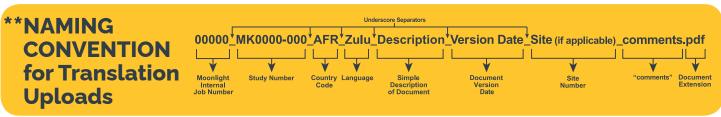
When in-country translations are completed the COM uploads the file in **File Manager** area so that Moonlight Imaging can create the language document layouts.

This can be done for support after translation and before EC submission (if needed) or after EC approval before distribution to sites.

- Go to File Manager and you will only see projects/studies you are assigned to.
- Select the study for which you would like to upload the documents.
- To upload the files, either drag and drop your files into the box or click to browse and select individual files.
- When you upload your files, please follow the standard naming convention** followed below







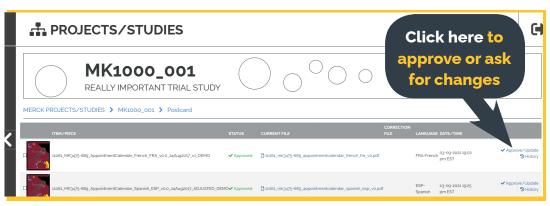
REVIEW EDITED FILES - STEP 3

Once the translated document layouts are complete they will be posted in **Projects/Studies** and an email notification will be sent to the COM. A thumbnail of the current file is displayed on the **Projects/Studies** section.

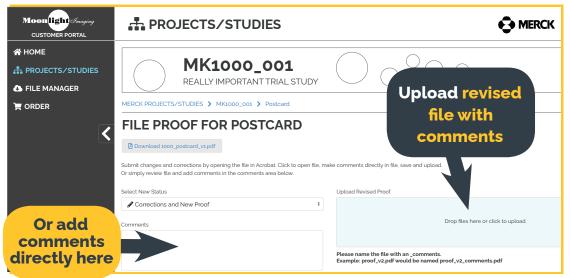
- Go to Projects/Studies and select the study for which you would like to review the documents.
- Olick on the file name to view the formatted document in local language.



 Once the document is reviewed, select
 Approved or ask for changes by changing the document status to either Approved with Corrections or Corrections and New Proof (see different status descriptions on page 5).



 If changes are needed, you can either upload a revised file with comments describing the changes needed, or add the instructions directly on the Comments box.



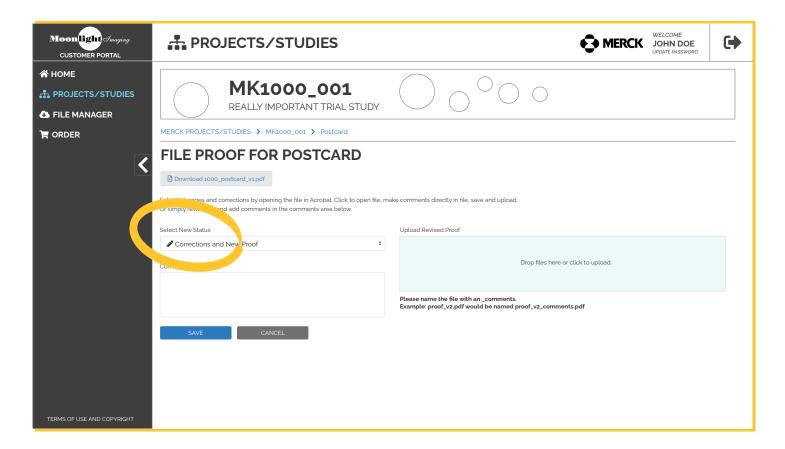
File Name Tip: Remember when uploading edits – to name your edited file following the naming conventions* and add "_comments" at the end of file string.



APPROVAL FILES - STEP 4

All US and EXUS document files must be **Approved** before placing an order.

- Once the document is ready for approval, go to Projects/Studies and select the study for which you would like to approve.
- Select the file, change to "Approved" on the "Select New Status" pick-list and click Save.
- Only the COM assigned as the approval person can "Select New Status" for their study documents.
- The updated document will save to the item History.



Approved - Document is Final Approved

Approved with Corrections - Document needs minor edit but is Approved

Corrections and New Proof - Corrections Needed a New Proof is generated for Review

Hold - Document currently placed on Hold

Cancel - Document no longer needed

Waiting for Approval - Document pending review and approval

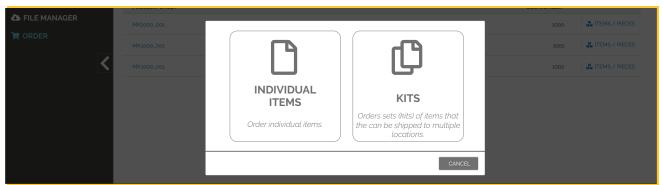
ORDER MATERIALS

- To place an order, the COM goes to the Home Page of the study and clicks on the Order icon or can access ordering on the menu bar.
- Select the appropriate study. Click on Order Items to proceed.

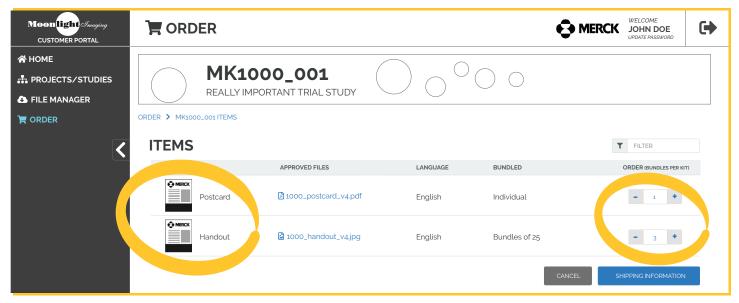


Ordering Icon

The icon allows users to select if they want to order individual items (for one site) or kits (for several sites).



 Select items for the order and quantities and click shipping information. Then proceed to shipping by clicking on shipping button.

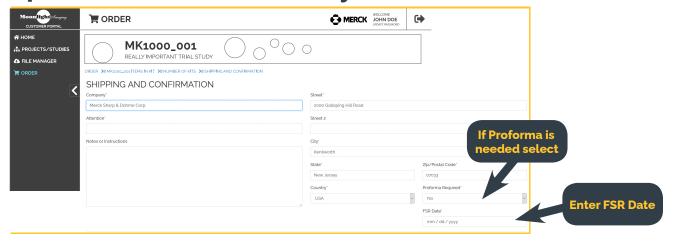


SHIPPING



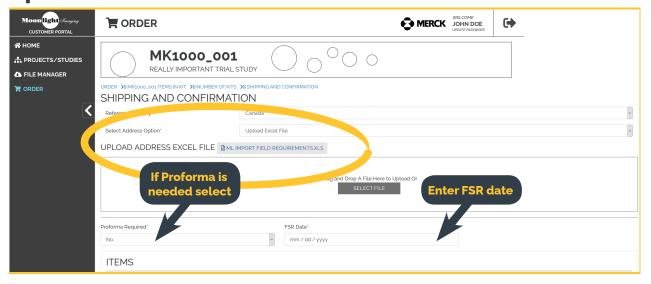
- When shipping individual items you will have to input shipping information manually.
 - Input shipping information manually
 - Complete if Proforma invoice is needed
 - Complete your Latest Estimate Country First Site Ready Date

Upload Manual Address Entry



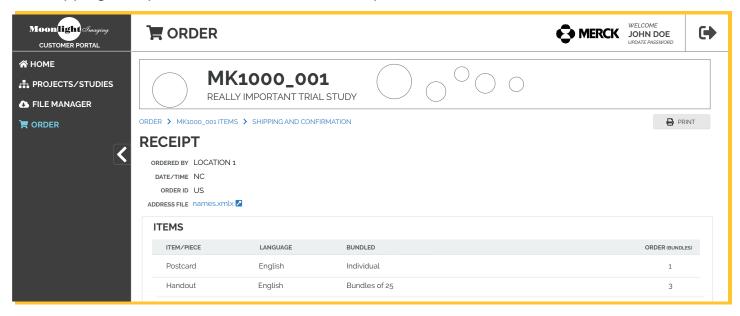
- When shipping by <u>Kits</u>, you have the option to:
 - Input shipping information manually
 - Upload your own Address Excel File
 - Update the original Address Excel File for the study provided by GTOS, which will appear loaded in the portal
- Please Download the original Address Excel for the study, Edit the file to remove the sites that you do not want to receive materials and Upload the edited file back into the Portal.
 - Complete if Proforma invoice is needed
 - Complete your Latest Estimate Country First Site Ready Date

Upload Address Excel File

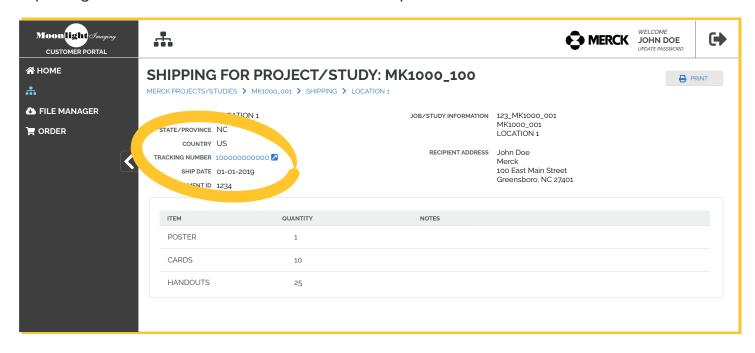


TRACK YOUR SHIPMENTS

• A shipping receipt will show after the user has placed an order.



The following day after our shipping export, shipping receipt can be printed – go to the
 Project/Study Page and click on View Shipping Details and the shipping information for that package will include the track number for the shipment.





For any questions related to the use of Moonlight Portal, please contact the Moonlight Imaging Portal Administrator at portal@moonlightimaging.com

Only the assigned COM per country will be able to access the study documents. Please remember that if there is any change on the team (i.e. COM changes), portal@moonlightimaging.com should be notified.

Full name and email address of the new team member should be provided so he/she can gain access to work with the study documents.

