

# **USER'S MANUAL**

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Release No.	Date	Revision Description
Rev. 0	12/10/22	User's Manual Created
Rev. 1	03/01/23	Added additional software's update information



#### INTRODUCTION

Valitracks is a cloud-based linguistic validation software that streamlines the validation process, making it easy for users to manage the entire process online from any device and location. With Valitracks, all parties involved in the validation process can stay informed about the progress, interact with the process, and discuss any issues that arise, ensuring transparency and collaboration. Valitracks is designed with a user-friendly interface that is intuitive and easy to navigate. This makes it accessible to users with varying levels of technical expertise. Whether you're a researcher, a clinician, or a project manager, the platform offers a range of features to meet your needs. The software is designed to improve the efficiency and accuracy of the validation process, allowing you to focus on other aspects of your work. This guide manual has been created to help users understand the features and functions of Valitracks, and how to use them effectively. By following the guide, you will be able to make the most of this powerful software and ensure the success of your validation process.

This manual contains the various profile entities in <u>Valitracks</u>, please choose your own profile/subscription and proceed to the table of contents in the next page to read the relevant section in the manual.

• Translator/Reviewer, Patient's Profile, Clinician's profile, Interviewer's Profile, Basic-Linguistic Validation, Advanced linguistic Validation, In Vivo Testing.

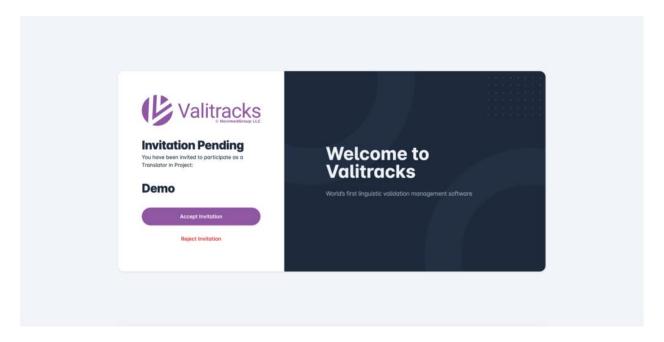
# **User's Manual - TABLE OF CONTENTS**

# **Table of Contents**

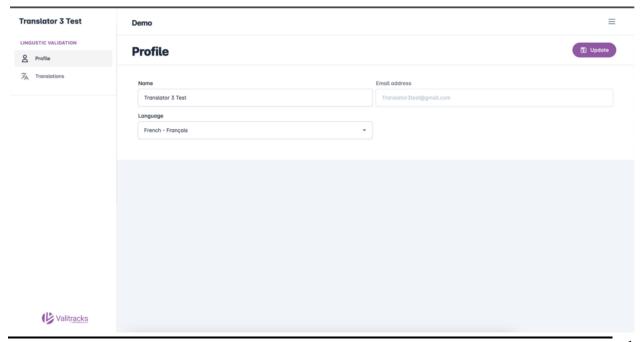
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## 1.0 TRANSLATOR/REVIEWER

Watch our video guide here.



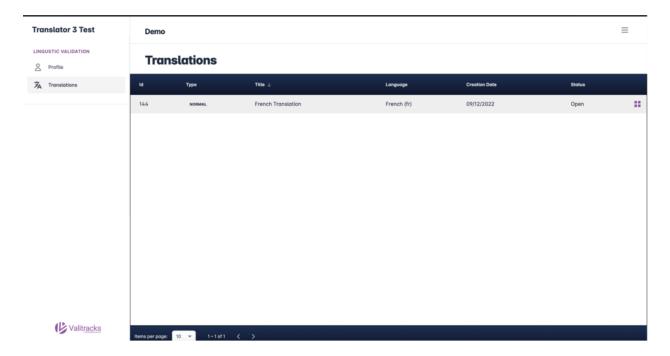
Edit Profile: Press on Profile to edit your details.



#### **Access Translations:**

Access the tasks that have been assigned to you. Any task that has been assigned to you will appear in the translations

List after pressing on it.



Near each translation press on the purple squares to access the translation dashboard.

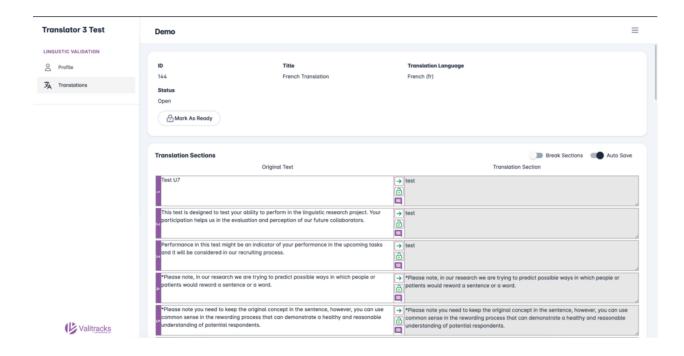
**For Translation**: Insert the translation in the right column.

On the right side up you can find the autosave and break sections icons.

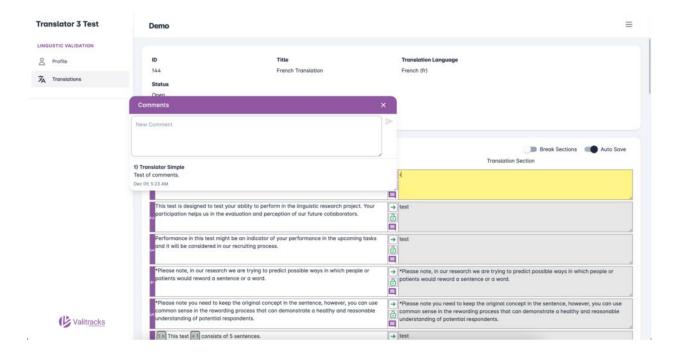
The autosave is automatically working to save all of your edits.

In case you want to break the sections in order to control the tags enable the break section option.

This might be useful for the right to left languages.



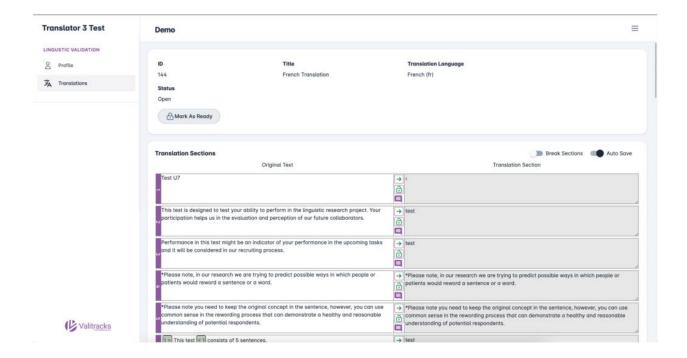
**For comments/Proofreading tasks/review tasks**: Press on the purple note box near each section and add your comments/read the comments for the section.



In case you are done editing a section and you want to lock it you can press on the green lock near each section.

The Green arrow copies the whole content from the left to the Right column.

When you finish translating you can lock the whole document by pressing the mark as ready on the top left side of the page.



## 2.0 PATIENT'S PROFILE

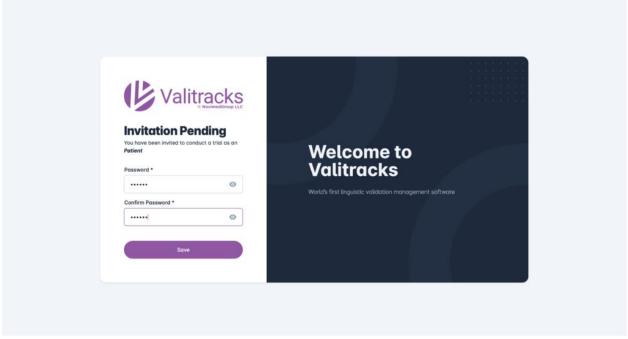
## Watch our video guide here.

Welcome to Valitracks, our patient platform is dedicated to assessing your personal understanding and experience of our clinical instruments. Your participation is appreciated and is a large contribution to clinical research and questionnaire standardization.

You will receive an invitation email or message with a link. Please accept the invitation and create your password.



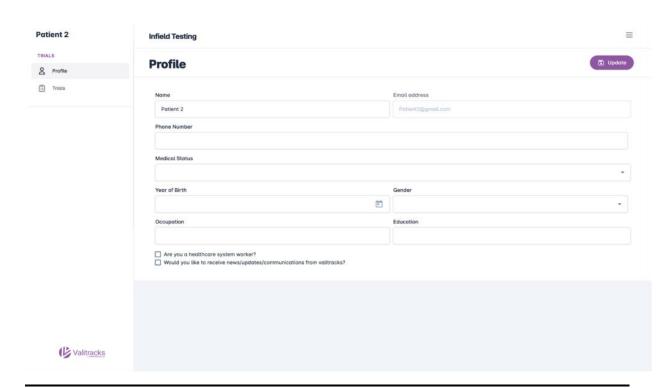
Add your password and retype it.



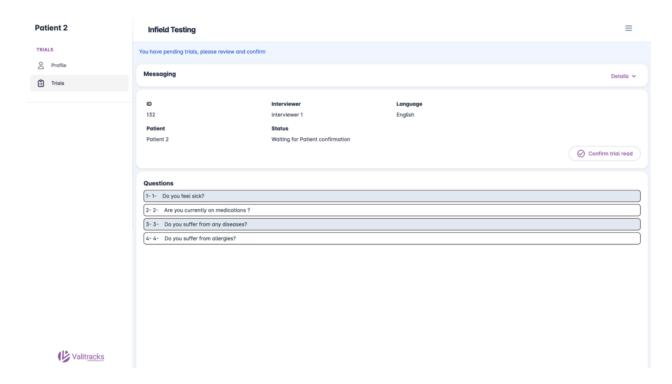
When you access the system for the first time, check your details in the profile tab and edit/add your missing details as you wish.



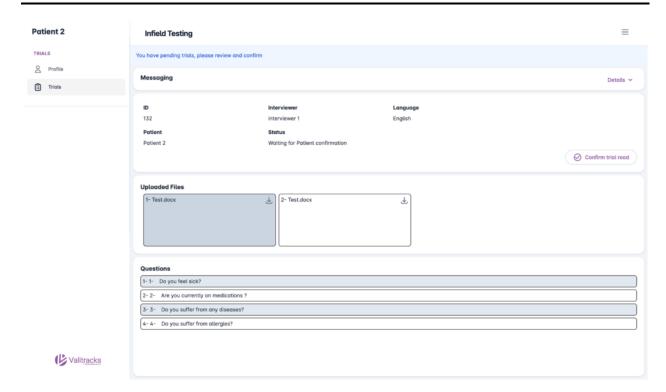
Access your profile.



Please go to the trials tab, and check the trials that have been assigned to you as well as any files that are attached to them.



After reading the instructions for the trial you can see the trial details and the questionnaire, after you read the questionnaire you can confirm the trial read. You can also see the messaging tab and contact your interviewer if you have any questions before the trial, furthermore, you can find some instructions there.



Download the files below the "Uploaded files" tab.

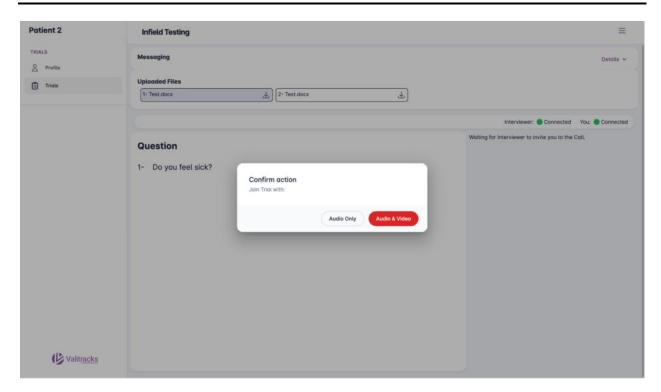
#### **Start of trial**

At the time of the trial please log in to your trials tab, in case the trial is delayed or you have any issues, you can use the messaging tab to contact your

Interviewer and set up a call.

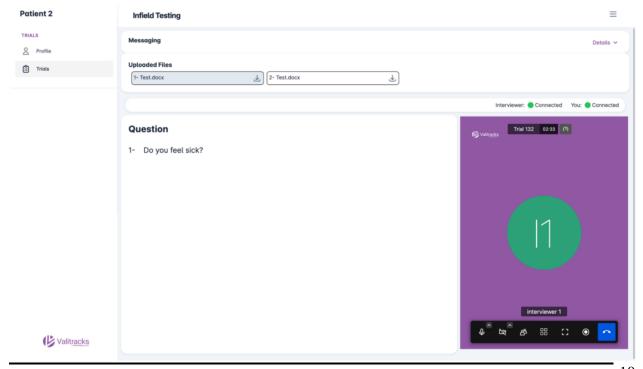
Use the Valitracks help tab in case you have any technical issues and chat with our team.

Join the call audio or audio and video.



You can find the question section in Infront of you while the interviewer is asking you questions about the specific section.

The interviewer might ask to record the call.

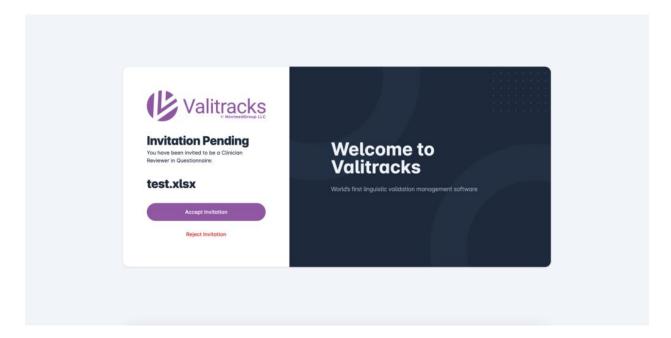


#### 3.0 CLINICIAN'S PROFILE

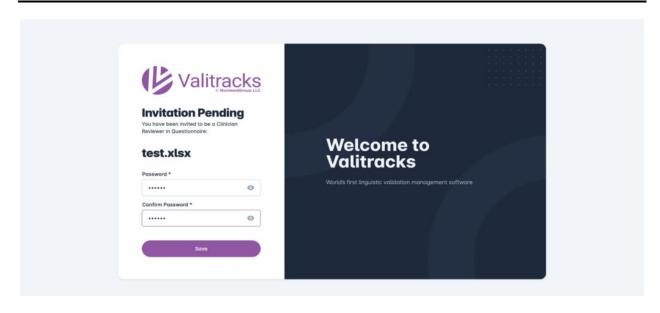
Watch our video guide here.

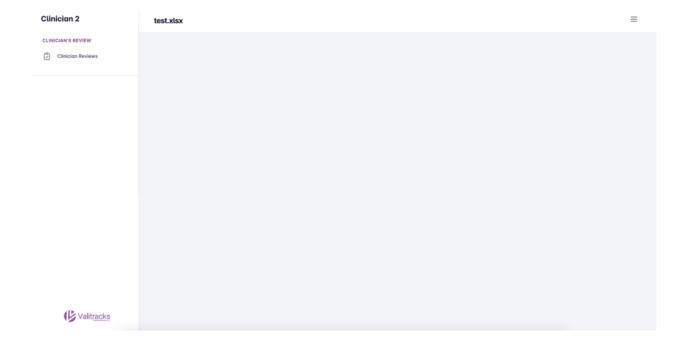
Welcome to Valitracks, our clinician's platform is dedicated to assessing your personal understanding and experience of our instruments. Your participation is appreciated and is a large contribution to clinical research and questionnaire standardization.

You will receive an invitation email or message with a link. Please accept the invitation and create your password.

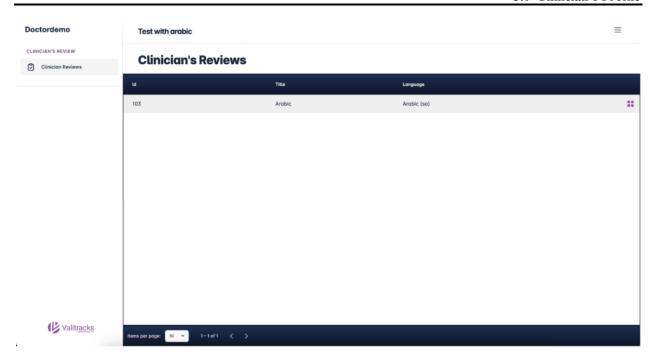


When you access the system for the first time, check your details in the profile tab and edit/ add your missing details as you wish.



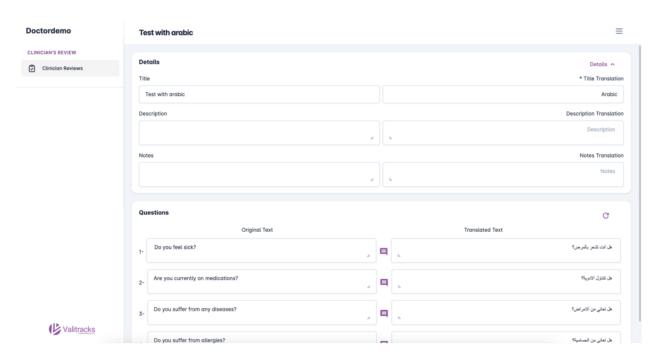


Please go to the trials tab, and check the trials that have been assigned to you as well as any files that are attached to them.



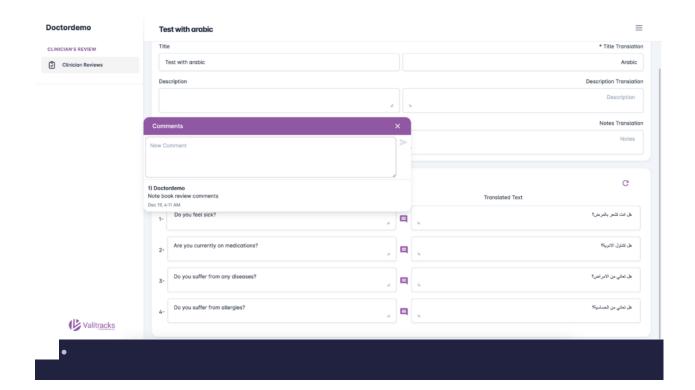
Please click on the squares on the right-side panel of the project. Click on the Details tab to see the full details of the study and if any instructions are there for you.

#### P



Add your review results to the purple notebook for each section which appears in the middle between the source and the target languages of each section.

You can see the comments of the project manager and other parties to your review in the same notebook.



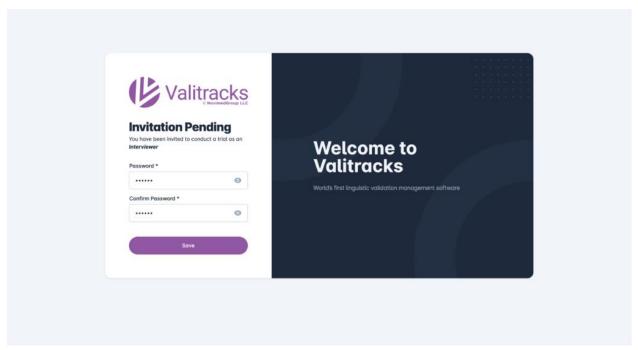
## 4.0 INTERVIEWER'S PROFILE

## Watch our video guide here.

Welcome to Valitracks, our interviewer's platform enables you to manage all of your cognitive debriefings.

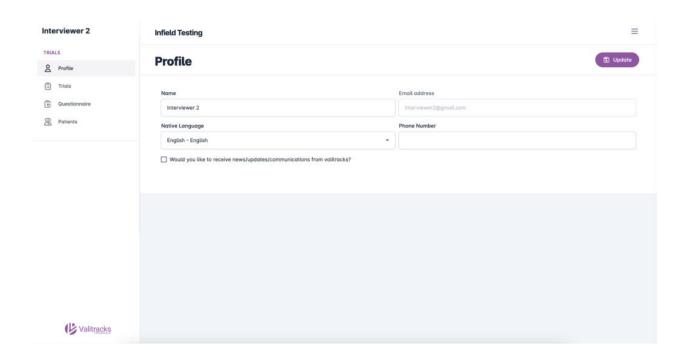
You will receive an invitation email or message with a link. Please accept the invitation and create your password.



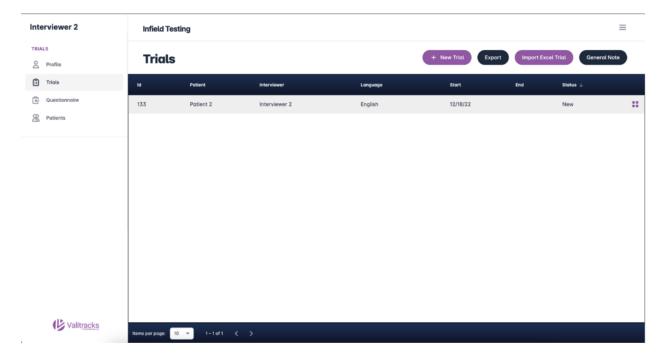


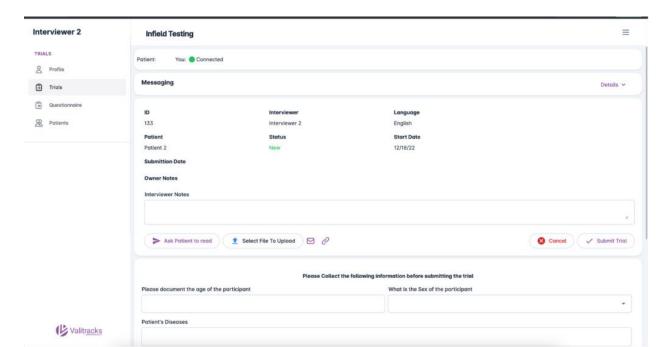
When you access the system for the first time, check your details in the profile tab and edit/add your missing details as you wish.





Please go to the trials tab, and check the trials that have been assigned to you as well as any files that are attached to them.





Press on the squares to access the trials dashboard

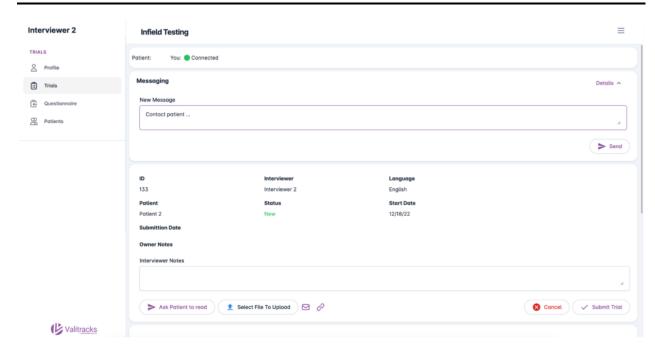
Press ask the patient to read to share the questionnaire with the patient.

In case you want to upload any file use the select file to upload.

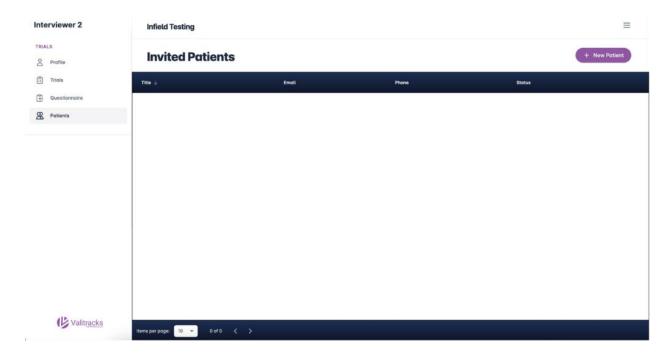
In case you upload the file, the file is automatically shared with the project manager however you need to open the lock sign to share it with the patient as well.

In case you have performed the recording and meeting offline, you can upload the file as an mp3.

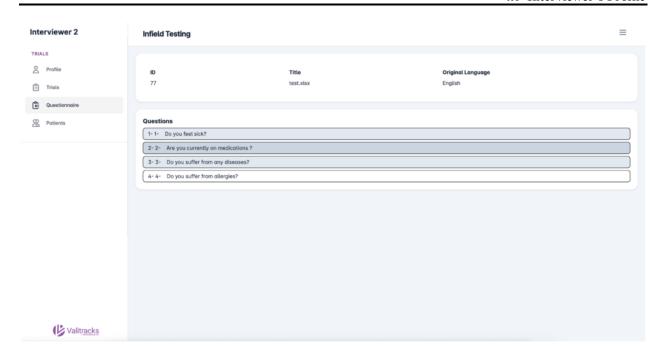
You can also see the messaging tab and contact the patient there.



In case you have patients that you recruited on your own you can add them using the patient tab.



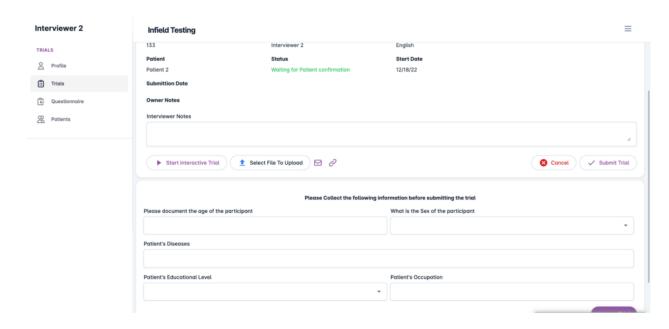
See the full questionnaire using the questionnaire tab



#### Start trial

Go to the trials tab and fill up the details on your patient before the interview starts or after (sex, education, occupation, etc), this information are needed to

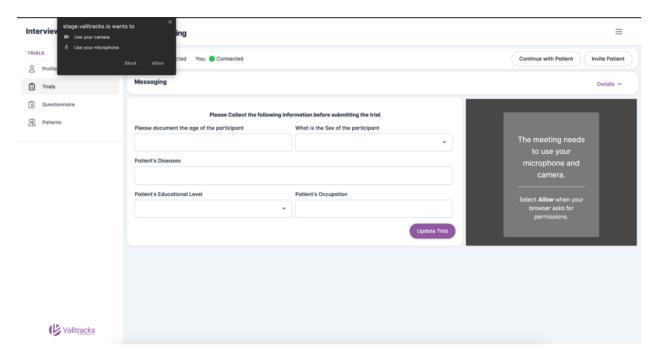
generate an automatic summary report.



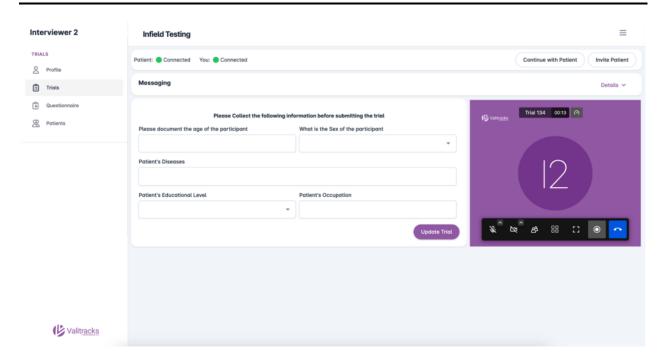
Start the interactive trial when you see on the top of the screen that the patient has logged in and the light near them is green.



- 1-Press on Strat interactive trial
- 2- Press on invite patient to start the call.
- 3- Allow microphone and cam.

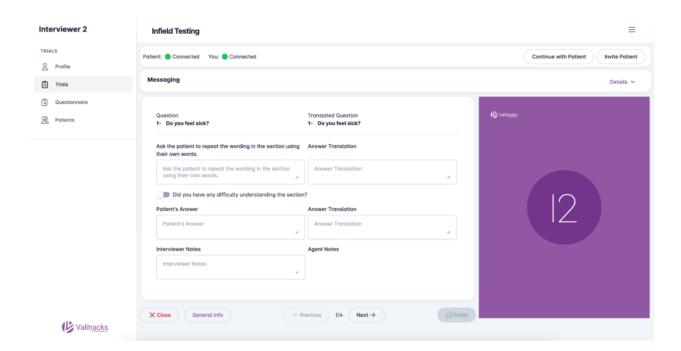


Record the conversation after acquiring the consent of the patient by clicking on the white circle near the phone's icon.

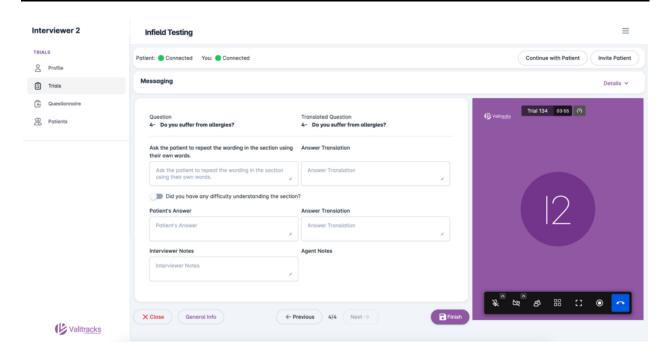


Edit the summary of the interview while interviewing or after finishing the interview.

Move between questions using the next and previous tabs.

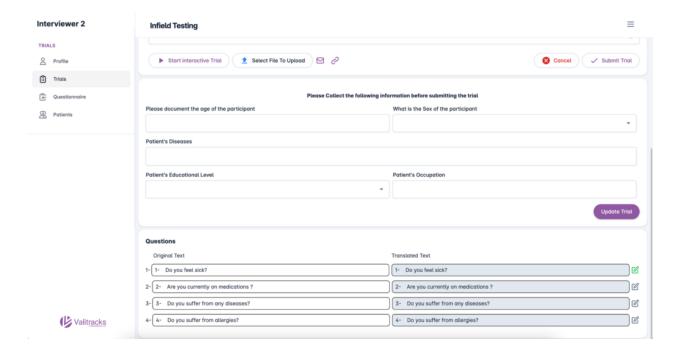


Close the call using the phone icon.

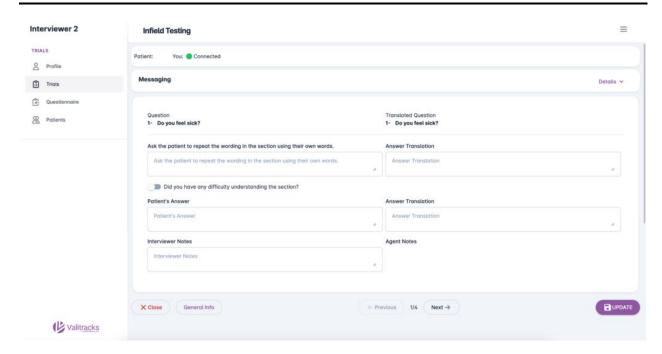


After filling all tabs press on the finish tab.

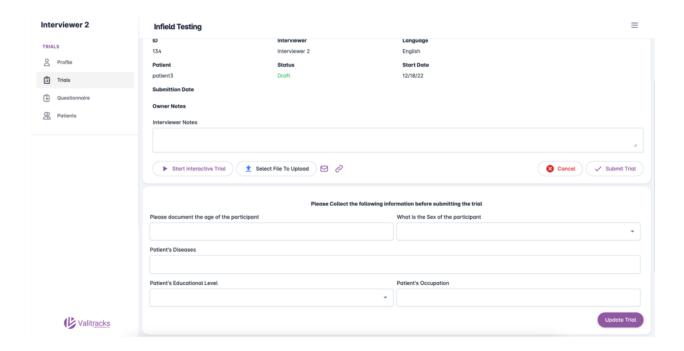
Fill in the summary after the call was finished or check the results and edit them using the trials tab.



Click on the pencil icon near each section to access the summary and edit it. Also, you can see agent's notes from the project manager.



Use submit trial when you are ready to.



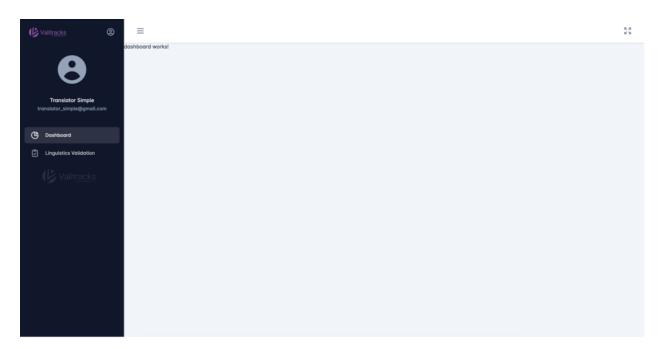
## 5.0 BASIC - LINGUISTIC VALIDATION

### Watch our video guide here.

#### **Translation- Linguistic Validation Basic**

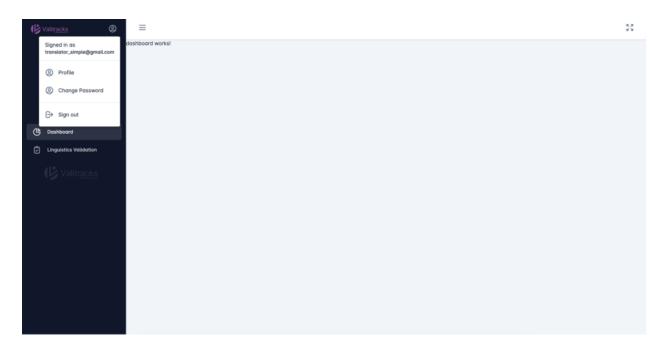
With the Basic Linguistic Validation subscription, you will have access to a variety of tools that are essential for the medical translation process. This subscription includes a CAT (computer-aided translation) tool, which allows you to translate text quickly and efficiently. It also includes a documentation tool, which can help you keep track of important information related to your translations. In addition, the Basic Linguistic Validation subscription comes with a discussion tool, which allows you to collaborate with other members of your team and discuss important issues related to your translations. This tool can be a valuable resource for ensuring that your translations are accurate and consistent. With this subscription, you will also be able to assign roles to different members of your team, including translators and reviewers. This can help you manage the translation process and ensure that it is completed efficiently and effectively. Overall, the Basic Linguistic Validation subscription provides all of the tools and resources you need to perform and manage the medical translation process.

#### Login Page-

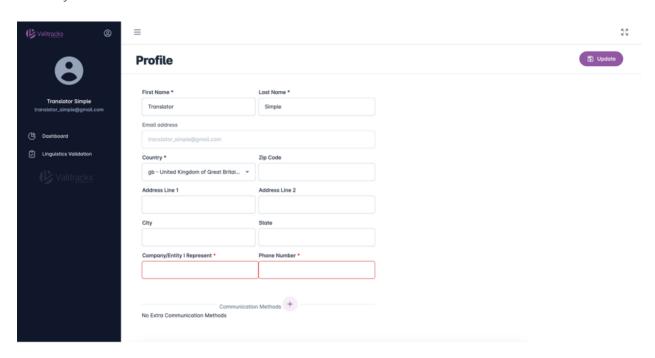


#### Profile -

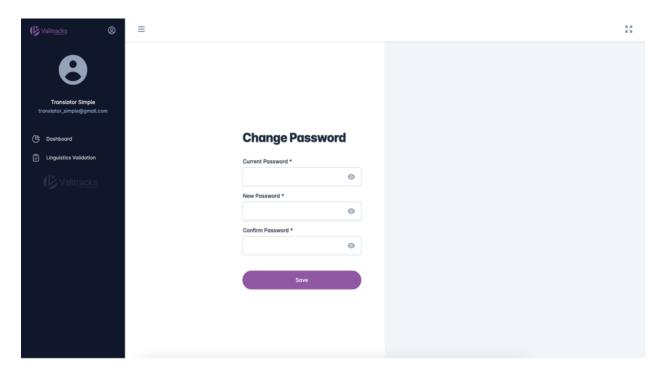
Access your profile and change the password and details by pressing on the top left side of the screen.



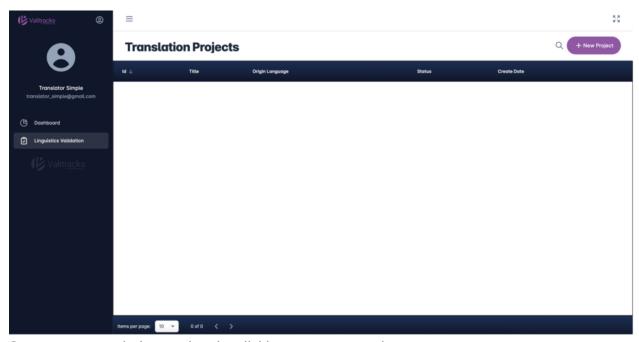
Edit any data here.



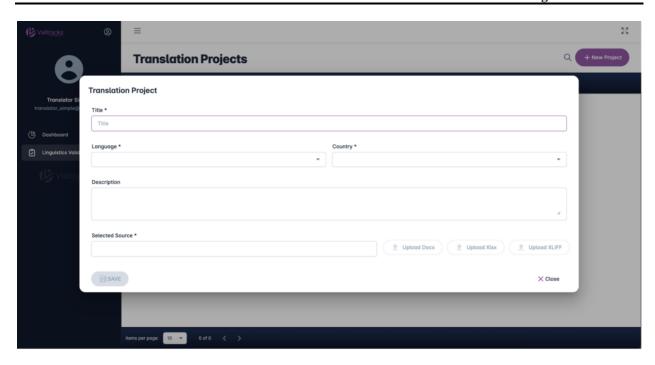
## Change Password Screen



Access Translation by clicking on the linguistic validation tab.

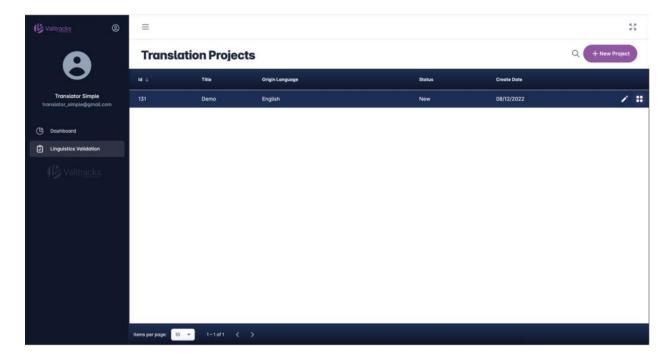


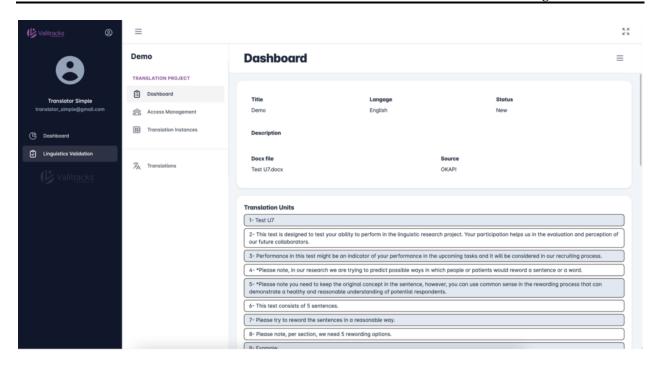
Start a new translation project by clicking on a new project.



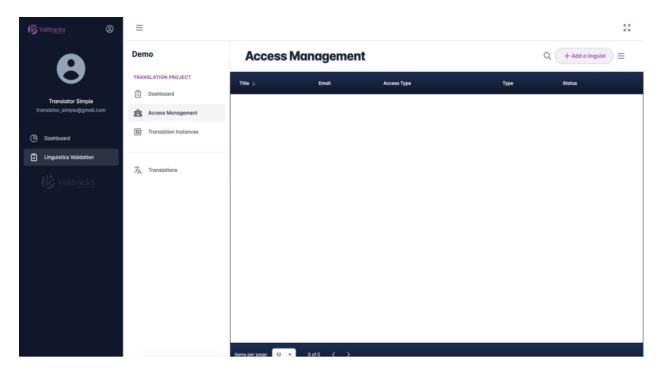
Fill in the relevant fields and upload the file.

After you uploaded the file press on the purple squares on the right side to access the project's dashboard

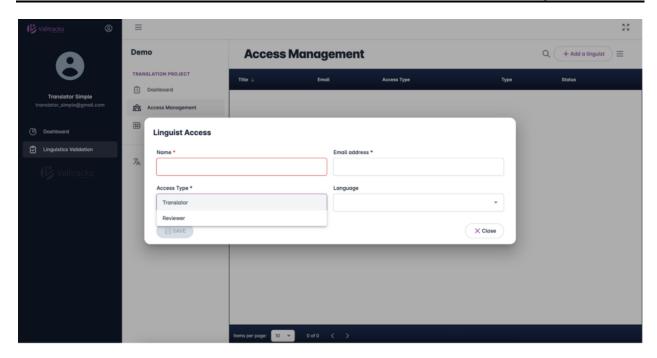




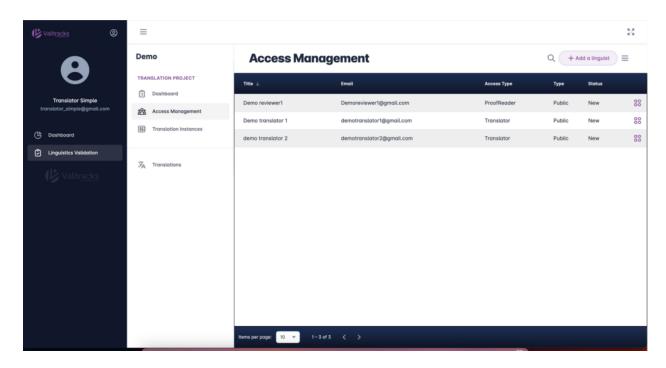
Click on access management and add linguistic experts to your team. Click on add a linguist on the top right side.



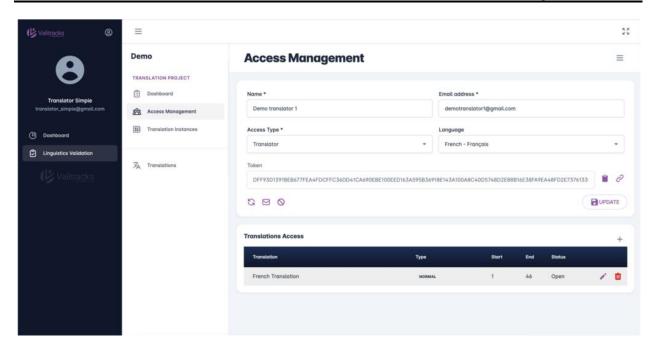
Choose a type of linguist (translator/reviewer) and fill in the details.



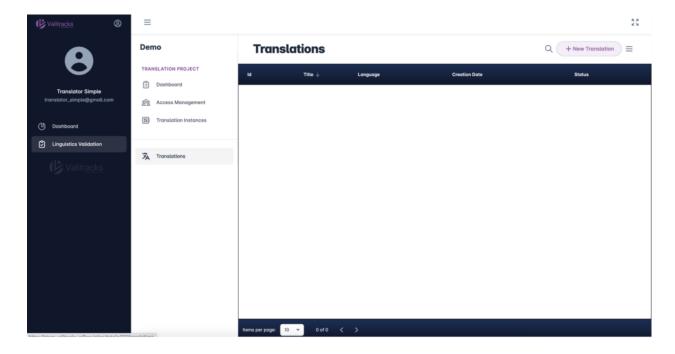
Add as many translators and reviewers as you need.

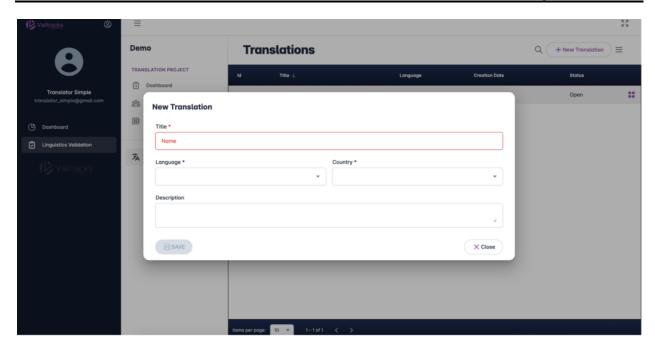


The system automatically sends an invitation email to the translator/reviewer you added to your system, however, you can also copy an invitation link to the system by going to the access management tab>>>> press on the profile (squares near the profile)>>>> copy the token of the translator's profile and share it with them.

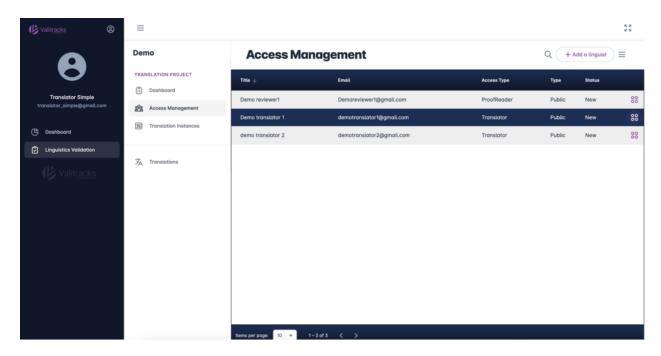


Create a translation task by going to the translation tab and creating the translation you need.

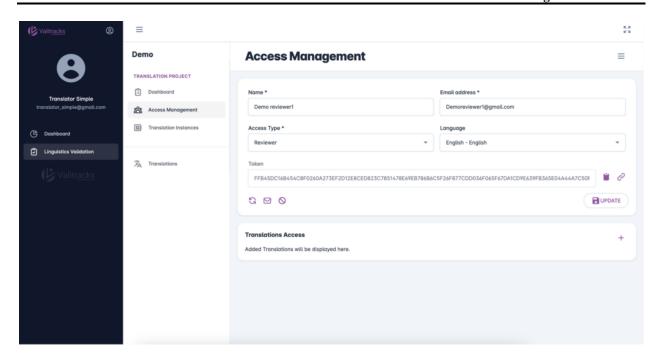




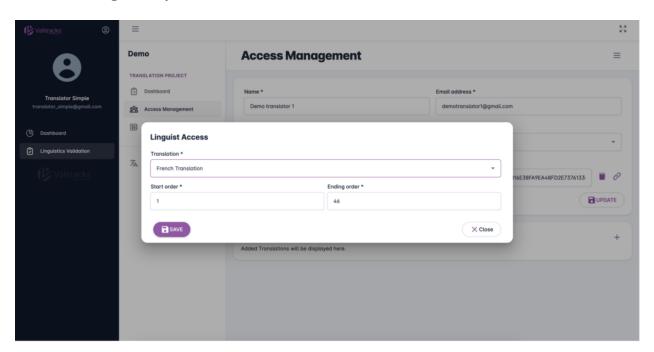
Control the translation by allocating translation instances to each translator. Press on each translator/reviewer's squares to allocate a task to him.



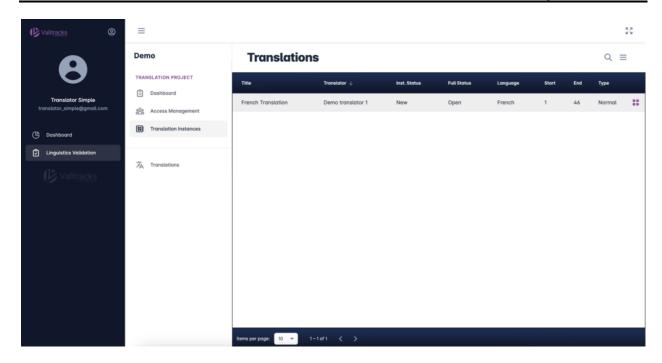
Press on the + sign to add and allocate a translation to the translator.



Control the segments you allocate to each translator

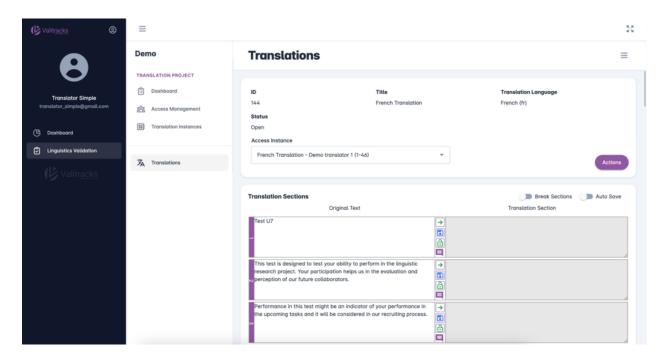


In the translation instances tab, you can find all the tasks for the translation you created



To follow up on each translation go within translation instances to the squares icon and enter the specific dashboard of the translation

## **Translation Dashboard**



In the translation dashboard, you can find the source text on the left and the translation text on the write.

The Green arrow automatically copies the text from the left side to the right side.

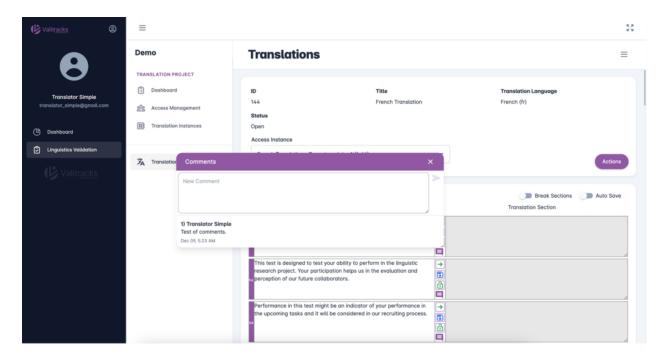
When pressing on autosave you will be auto-saving any edit to the translation, alternatively, you can save each segment separately by using the save icon.

The Green lock icon locks the segment for any edit and reopens it as well.

The purple Icon is a discussion icon for the segment, any discussion between you and the translator and reviewer will be performed there.

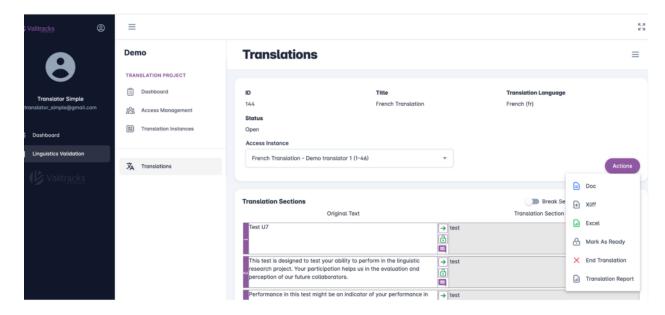
You can add your comments as you wish.

The break section button makes sure that all tags (XIIFF) are separated, this could be useful in right-to-left languages (Arabic/Hebrew).



In the actions button you can access a few functionalities:

- 1. Generate a post-translation doc document
- 2. Generate a post-translation Xliff document
- 3. Generate a post-translation excel document
- 4. Mark the translation as ready.
- 5. End translation.
- 6. Generate a translation report including all translation versions, changes, dates and hours of changes, and the whole feed of discussion on the segments.



## 6.0 ADVANCED – LINGUISTIC VALIDATION

## Watch our video guide here.

This subscription includes is called an advanced linguistic validation subscription. It includes full access to our basic linguistic validation subscription (CAT tool, Documentation system, live commenting, XLIFF, and doc file generation) additionally to building your customized linguistic validation process. You can choose to build your validation process in the way you want by adding the number of forward translations you need and assigning them to the different team members. Creating a reconciled version (merged version dashboard) and assigning it to the members you choose and then creating the back translation section and assigning it to the professional you choose. Finally, the system will create for you a final version option providing you access to the reconciled version, comments, and discussion from the back translation. This will speed up your final version creation.

## **Manage your Profile:**

## Login Page-

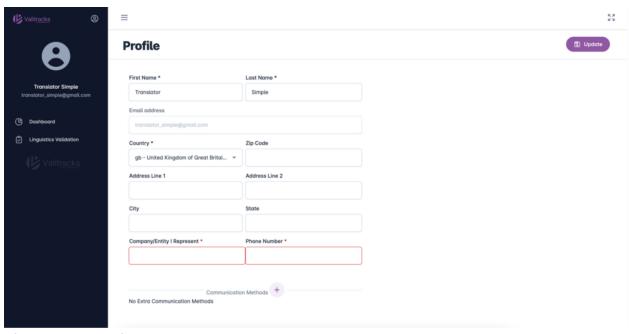


# Profile -

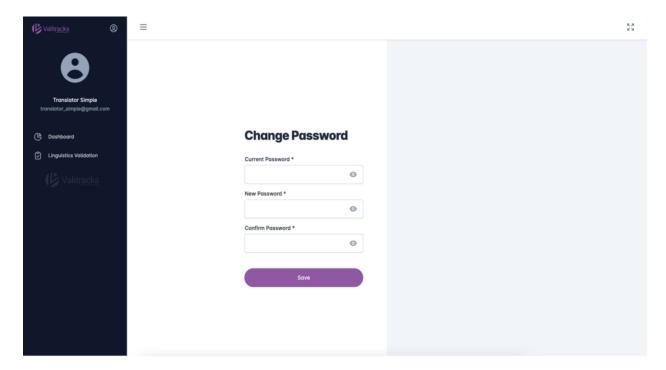
Access your profile and change the password and details by pressing on the top left side of the screen.



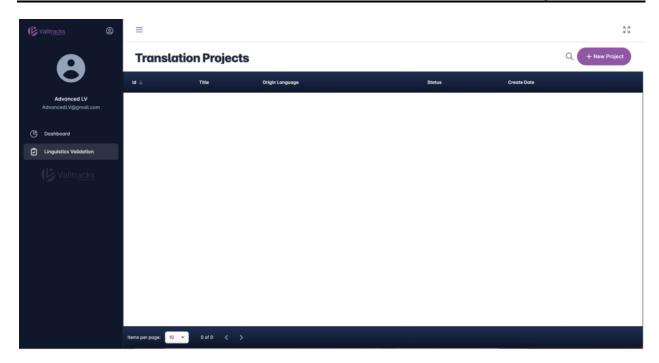
Edit any data here.



Change Password Screen

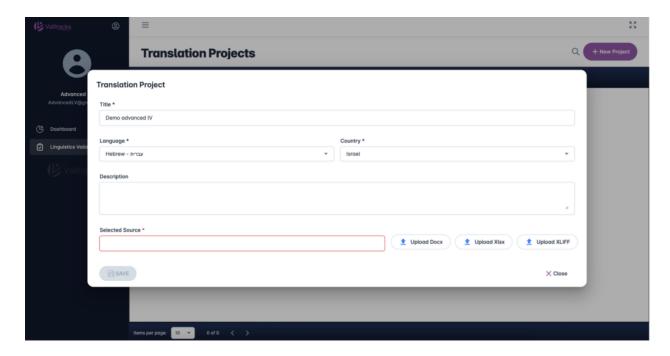


**Customize your Process:** 

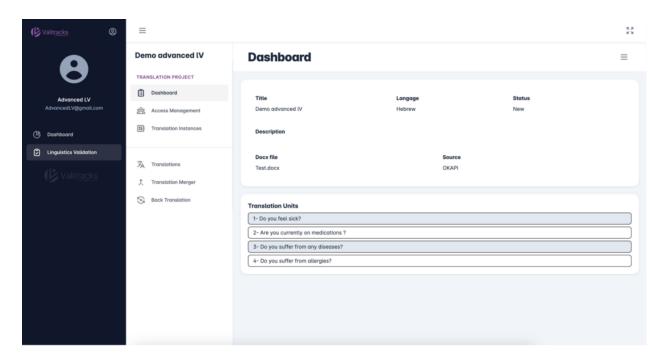


Open your new project by pressing on the new project window in purple (top-right side).

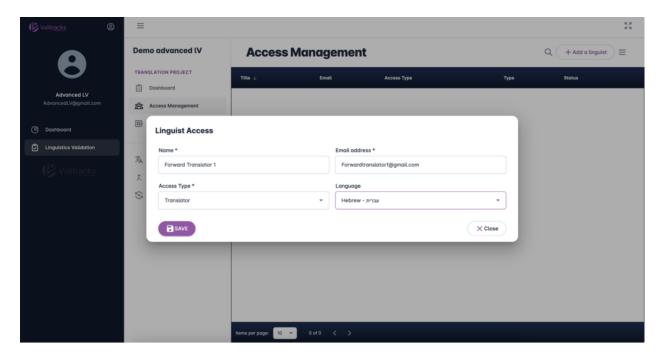
Create your project and upload the file you would like to process ( XLIFF, Docx, or Xlsx).



After uploading your file, the system will automatically take you to the dashboard of the project:



Click on access management and add linguistic experts to your team. Click on add a linguist on the top right side.

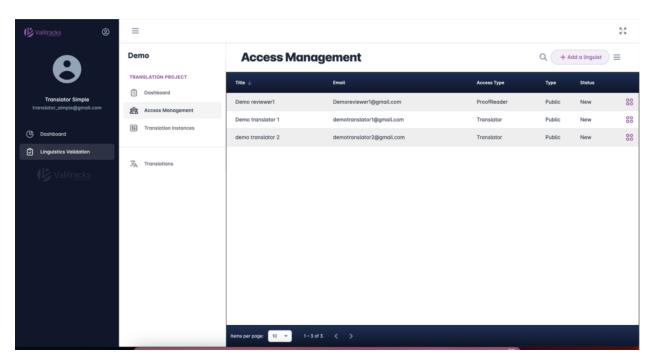


Demo
Access Management

Translator Simple
Translator

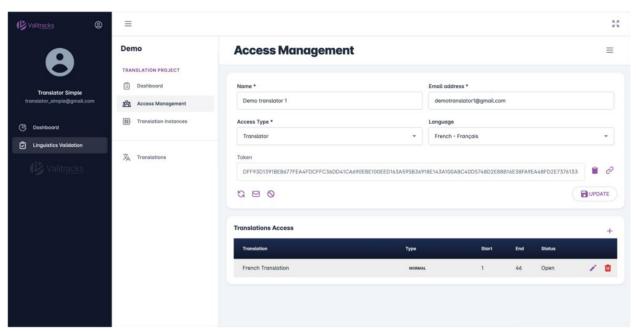
Choose a type of linguist (translator/reviewer) and fill in the details.

Add as many translators and reviewers as you need

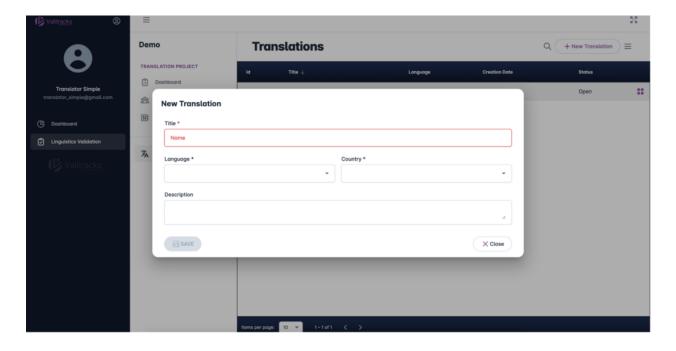


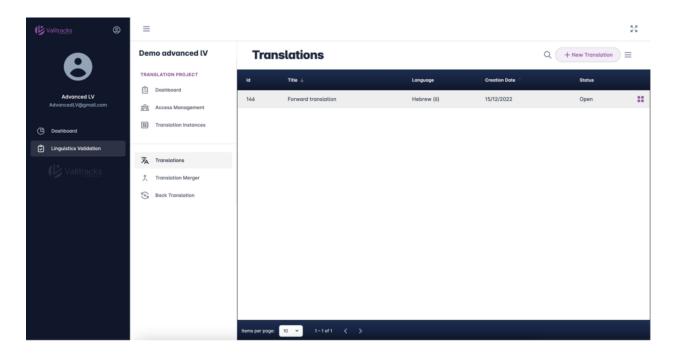
The system automatically sends an invitation email to the translator/reviewer you added to your system, however, you can also copy an invitation link to the system by going to the

access management tab>>>> press on the profile (squares near the profile)>>>> copy the token of the translator's profile and share it with them.

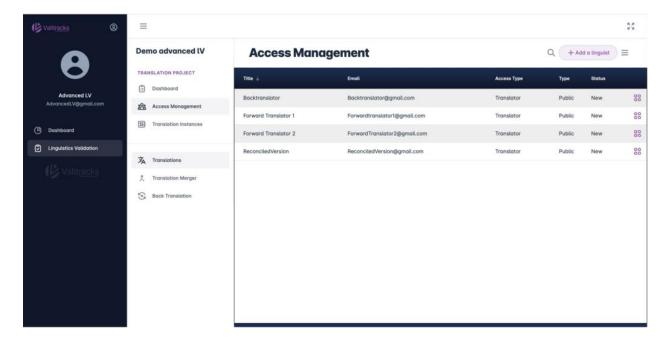


Create a translation task by going to the translation tab and creating the translation you need. Add as many translations as you need.

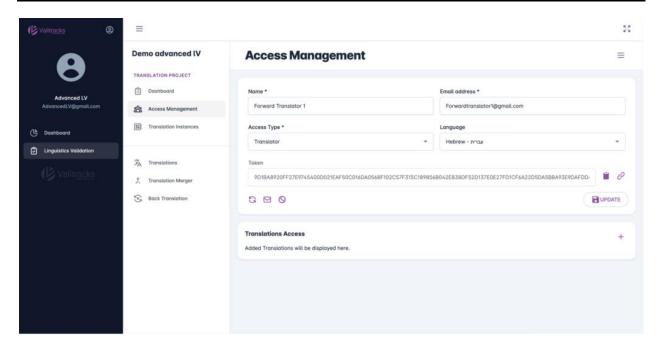




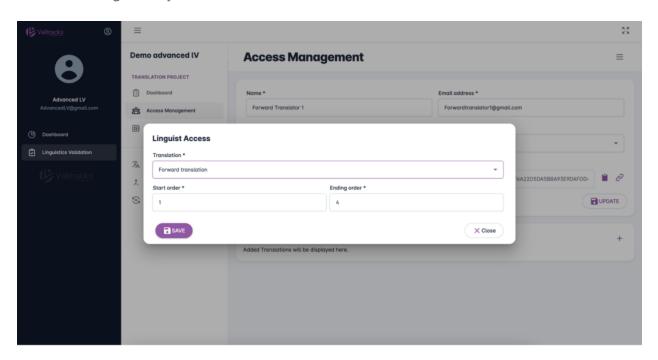
Control the translation by allocating translation instances to each translator. Press on each translator/reviewer's squares to allocate a task to him.



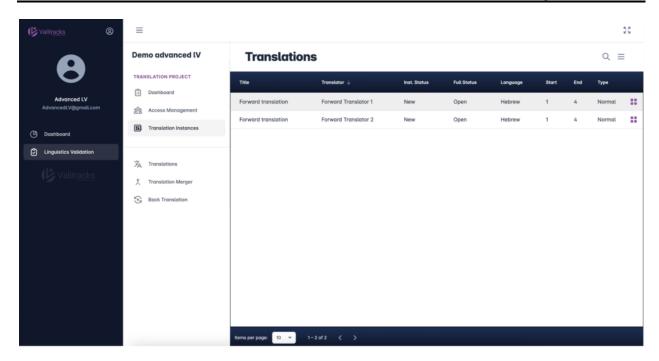
Press on the + sign to add allocate a translation to the translator.



Control the segments you allocate to each translator

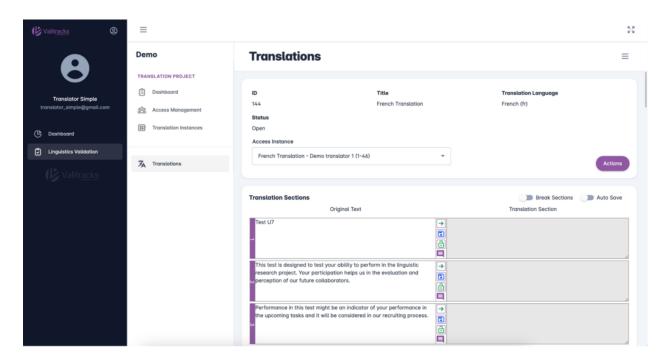


In the translation instances tab, you can find all the tasks for the translation you created



To follow up on each translation go within translation instances to the squares icon and enter the specific dashboard of the translation

## **Translation Dashboard**



In the translation dashboard, you can find the source text on the left and the translation text on the write.

The Green arrow automatically copies the text from the left side to the right side.

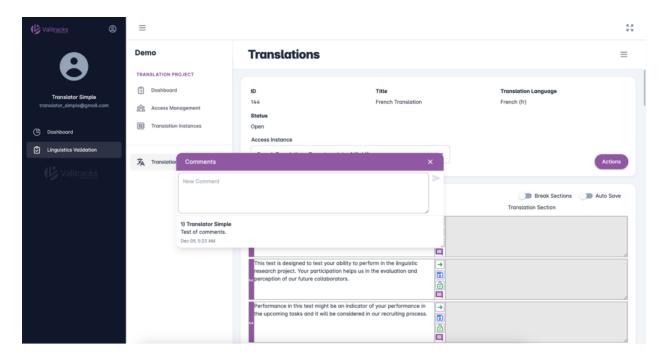
When pressing on autosave you will be auto-saving any edit to the translation, alternatively, you can save each segment separately by using the save icon.

The Green lock icon locks the segment for any edit and reopens it as well.

The purple Icon is a discussion icon for the segment, any discussion between you and the translator and reviewer will be performed there.

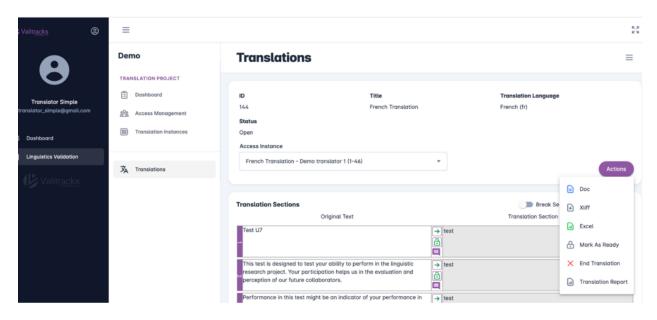
You can add your comments as you wish.

The break section button makes sure that all tags (XIIFF) are separated, this could be useful in right-to-left languages (Arabic/Hebrew).



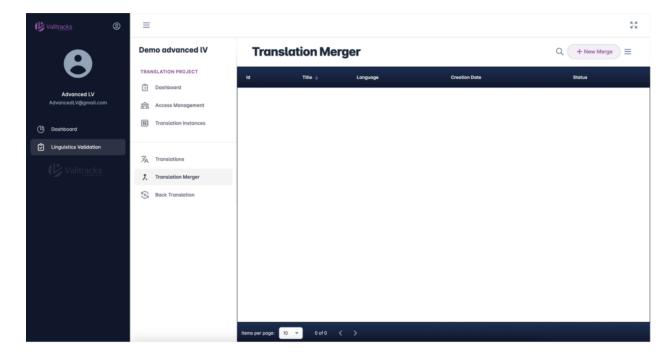
In the actions button you can access a few functionalities:

- 1. Generate a post-translation doc document
- 2. Generate a post-translation Xiff document
- 3. Generate a post-translation excel document
- 4. Mark the translation as ready.
- 5. End translation.
- 6. Generate a translation report including all translation versions, changes, dates and hours of changes, and the whole feed of discussion on the segments.

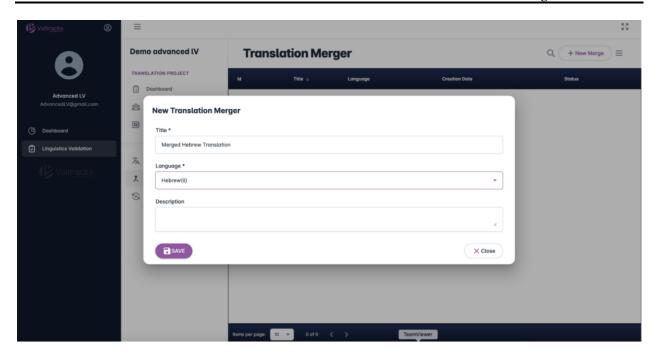


## **Reconciled Merged Version:**

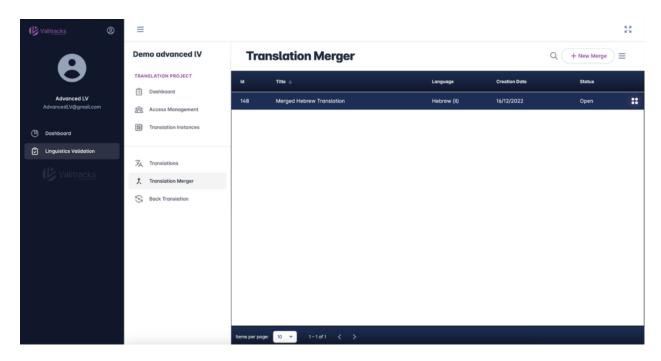
To be able to use this functionality make sure you created a separate translation for each translator. After you have assigned your forward translation versions to your various translators, go to the translation merger tab.



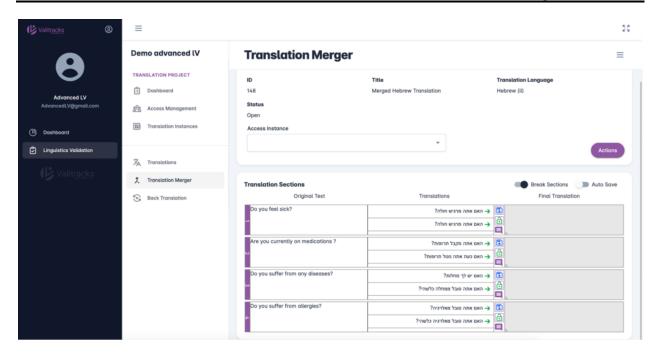
Click on add new merge on the right top of the page:



To access the dashboard press on the purple squares near the merged translation

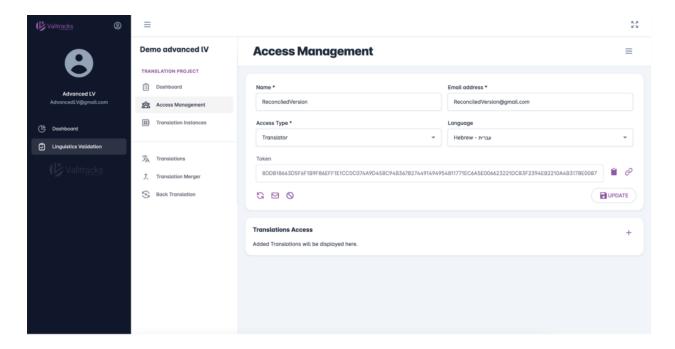


The system automatically couples the existing translations in the suggested language.

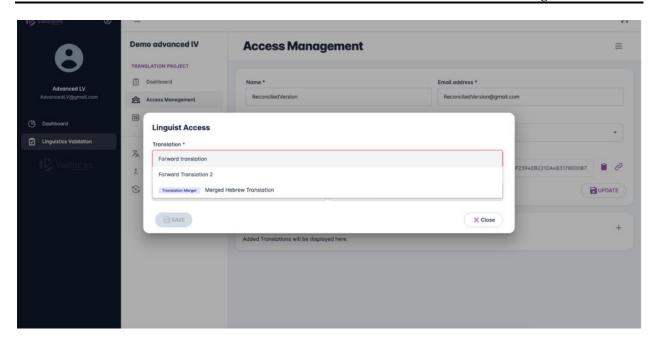


Translator will be able to choose between the existing versions and create the reconciled version in the right column.

Use Access management to assign the Merged/reconciled version creation to the relevant translator.

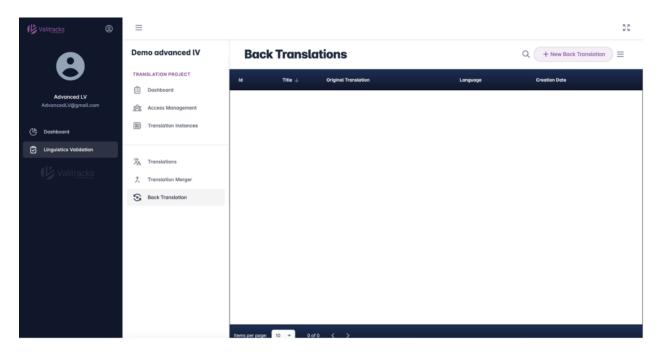


Choose the Merged translation Version that you created to assign it to the Translator.

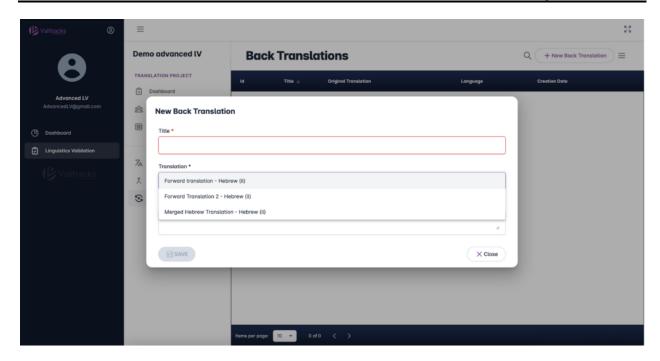


#### **Back Translation:**

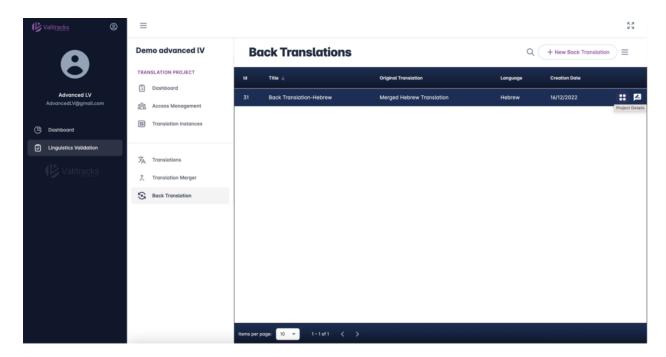
Create a new Back translation task by using the left-side menu. Press on the top right side, purple " +New Back Translation" Icon.

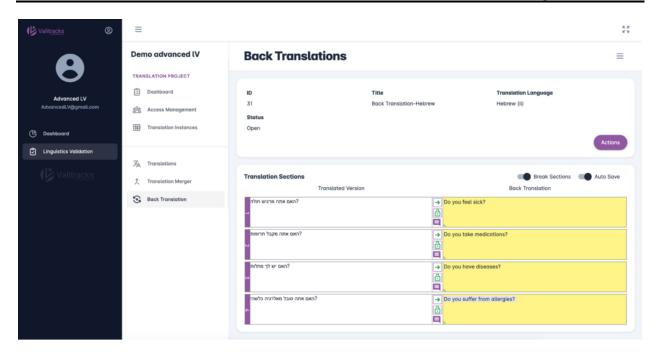


Choose the translation version that you would like to back-translate (usually the reconciled version- Merged translation).



Press on the Purple squares to access the back translation dashboard.



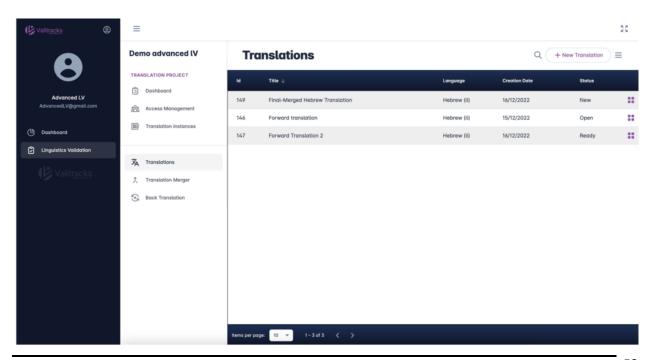


Use the purple note sign to document the discussion on the back translation.

#### **Final Translation:**

When you create the back translation the system automatically creates a final version task from the previously created "Merged Translation/Reconciled version"

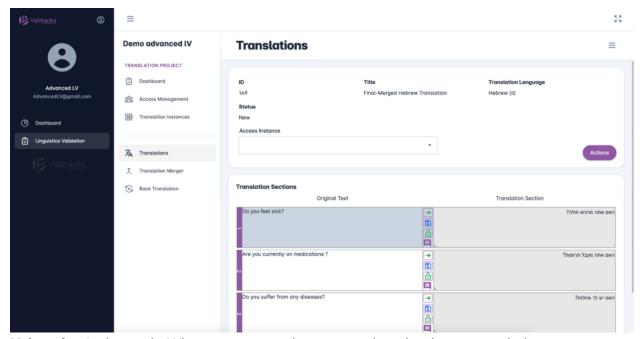
Access Final Translation from the "Translations" Dashboard.



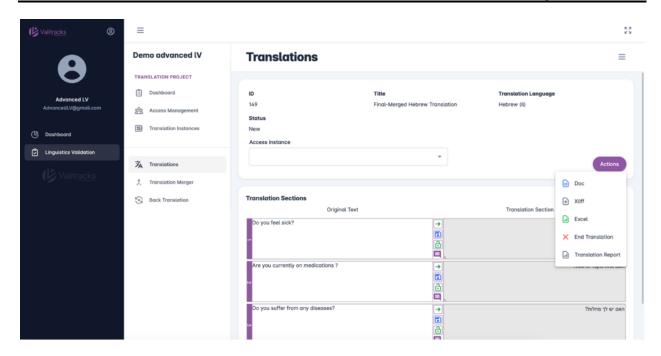
 $\label{lem:continuous} \mbox{Valitracks } \mbox{ 1.0 - User's Manual . Novimed Group } \mbox{@2022-2023. All rights reserved.}$ 

Access the final translation by clicking on the Purple squares.

The system automatically imports here the previously performed merged translation with the comments and the discussion from the back translation. This way the translator can understand what happened in the back translation and apply the needed changes according to the discussion that happened there. A further discussion with the project manager can be conducted here to reach the final version of the translation.



**Using the** Actions tab: When you are ready, you can download your translation report, export the file in your proffered version and end the translation.



#### 7.0 IN VIVO TESTING

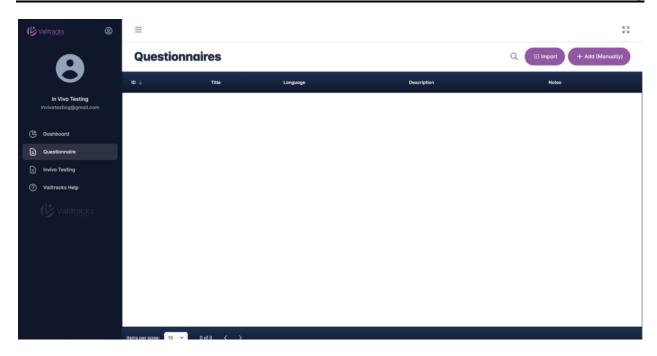
## Watch our video guide here.

A "In vivo testing subscription" is a service that provides a digitalized comprehensive linguistic validation process for conducting real-time testing of language-based materials, such as patient-reported outcomes (PROs) or quality of life (QoL) measures. The subscription includes a variety of features and tools to facilitate the linguistic validation process, such as Virtual Cognitive debriefing. Digital Clinician's review, Video conference platform: This online service allows the linguistic validation team to conduct remote interviews and meetings with participants or reviewers via videoconference. Interview documentation: This involves recording and transcribing interviews or focus groups to create a written record of the feedback and insights gathered during the linguistic validation process. Automatic report generation: The software automatically generates reports or summaries of the linguistic validation process based on the data collected, including feedback from participants and reviewers. Overall, an "In vivo testing subscription" is a comprehensive service that provides the tools and support needed to conduct a thorough linguistic validation process for language-based materials.

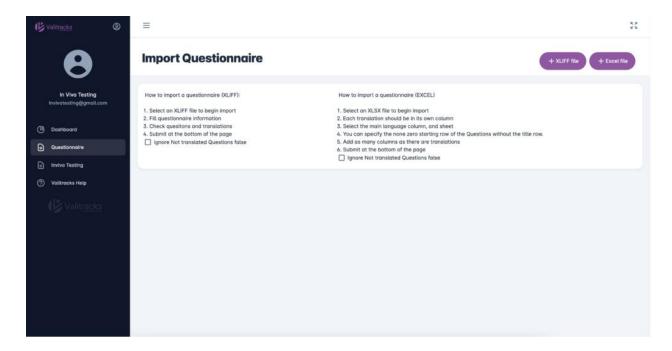
## **In-Vivo Testing Section**

This section is for the next step of linguistic validation, which includes live testing of the instrument. After the post-translated instrument/questionnaire was created you can import it to the platform as follows:

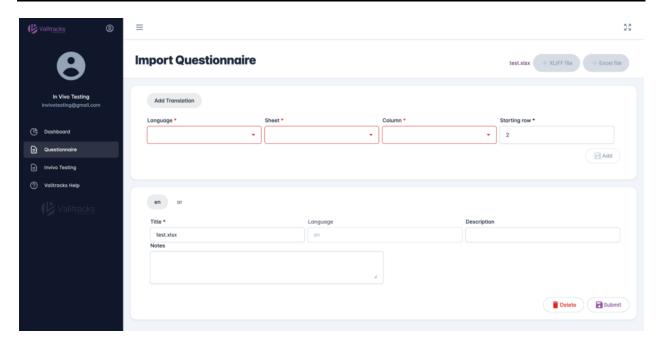
1. Import the questionnaire using, the questionnaire tab.



Press on Import if you have a version of a questionnaire that you would like to import.



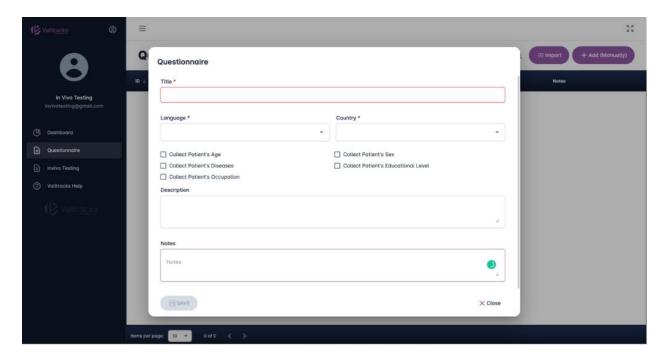
After you automatically imported the files allocate the relevant columns to each language to create separate versions of the instrument within the system.



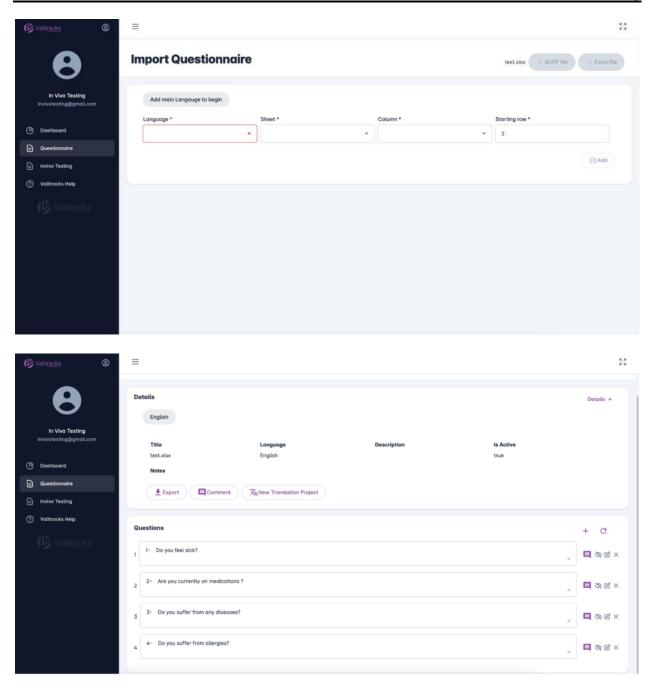
Press submit to proceed.

reserved.

Press on add manually if you would like to manually create the questionnaire.



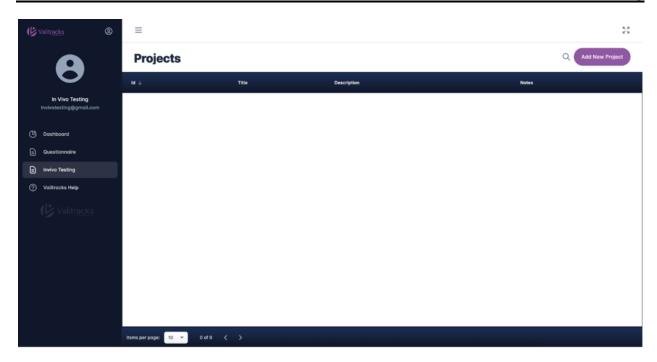
Using the automatic import function you can import a built-in Excel file or Xliff file, while using excel edit the relevant columns and rows as well as sheets that include the questionnaire.



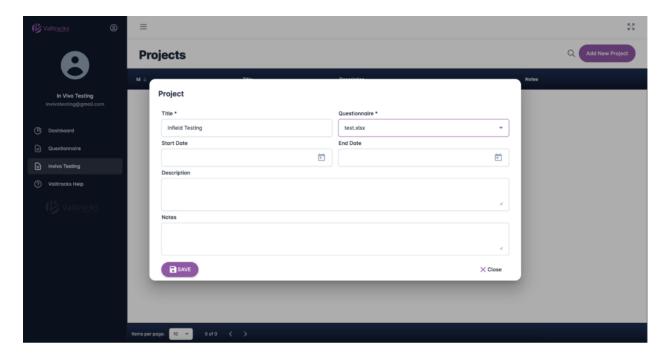
After the questionnaire was created/imported into the system go to the Invivo testing tab.

# 1. Invivo testing

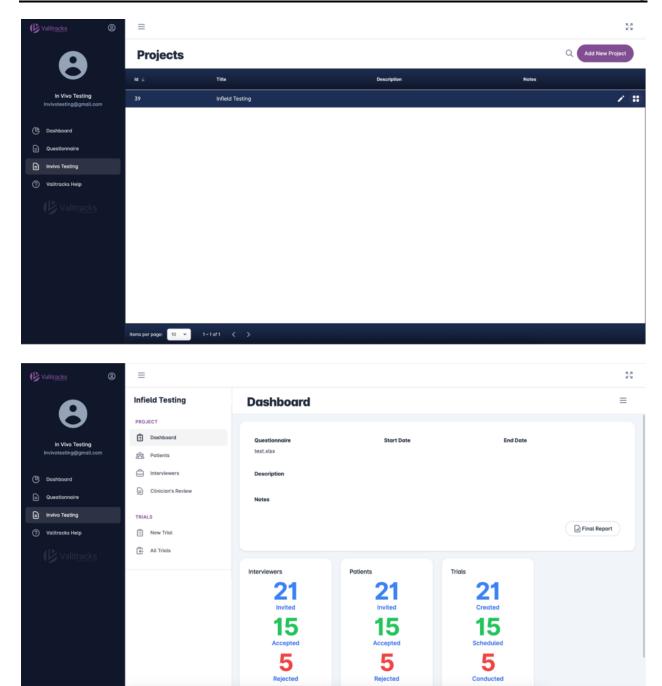
Add a new project by clicking on the purple tab on the top right side of the page.



Fill in your project's details, and dates, and pick a questionnaire from the list.



After adding the project to the dashboard you can access the in vivo testing project's dashboard by pressing on the purple squares near the project's title.

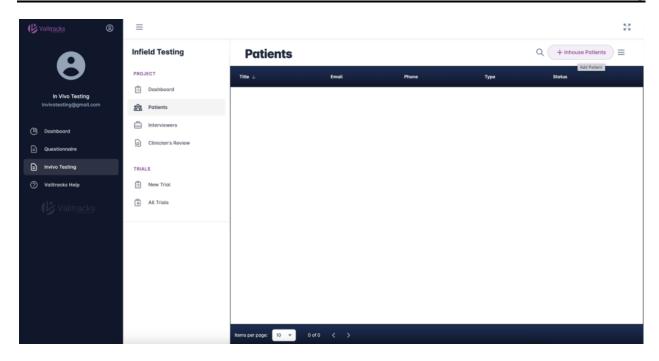


# 3-Cognitive debriefing interviews-

Start your cognitive debriefing interview project by adding patients and interviewers to create your trial.

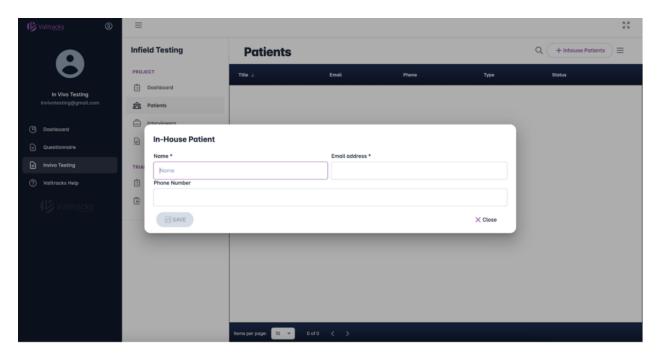
A-Patients – Press on the patient's icon in the dashboard.

Press on the in-house patient's to add your recruited patients' profiles.

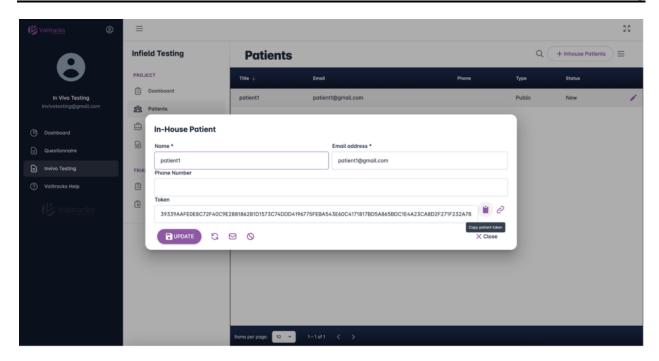


Add your patient's details to create your patient's profile.

This way add as many patient profiles as you need for your trial.

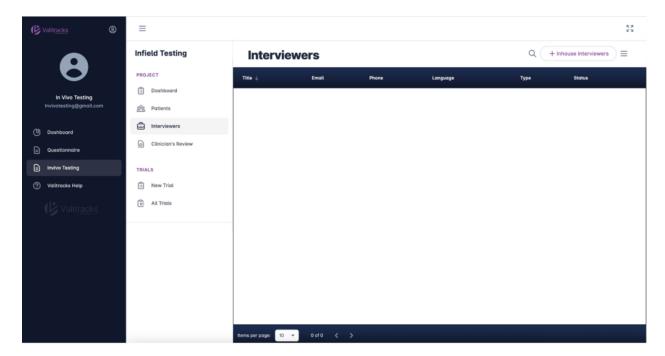


System will be sending an automatic invite email to the patient to invite them to the system. You can also send the invite token using any messaging platform you want by copying the token. To do so, click on the pencil icon on near the project title to get the token.



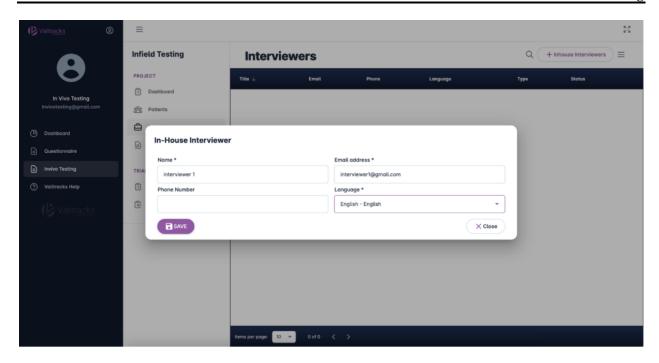
## B-Interviewer – Press on the Interviewer's icon in the dashboard.

Press on in-house Interviewer to add your recruited Interviewer's profiles.

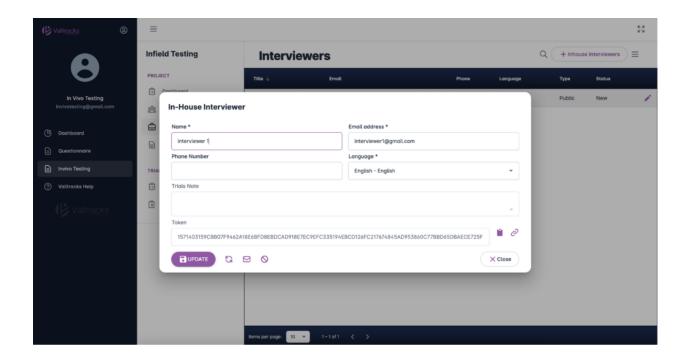


Add your Interviewer's details to create your Interviewer's profile.

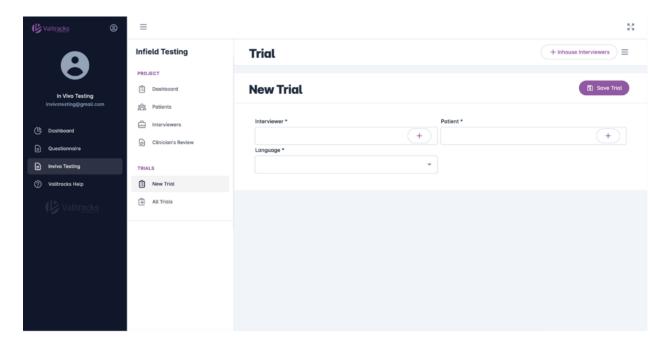
This way add as many Interviewer profiles as you need for your trial.



The system will be sending an automatic invite email to the Interviewer to invite them to the system. You can also send the invite token using any messaging platform you want by copying the token. To do so, click on the pencil icon near the project title to get the token.

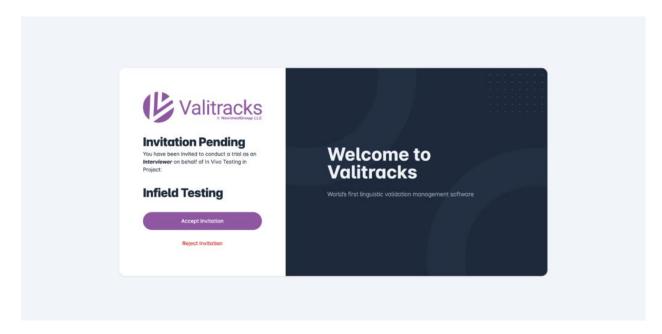


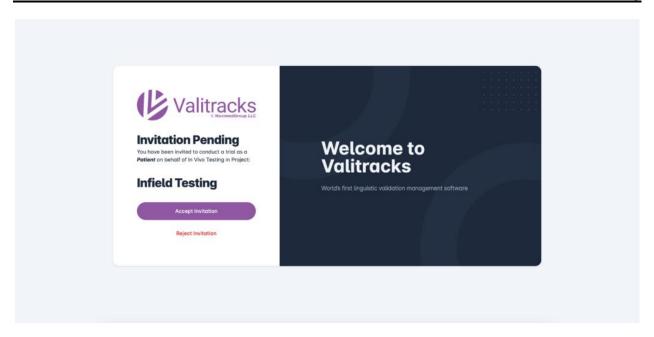
#### C-Create a trial- Press on a new trial



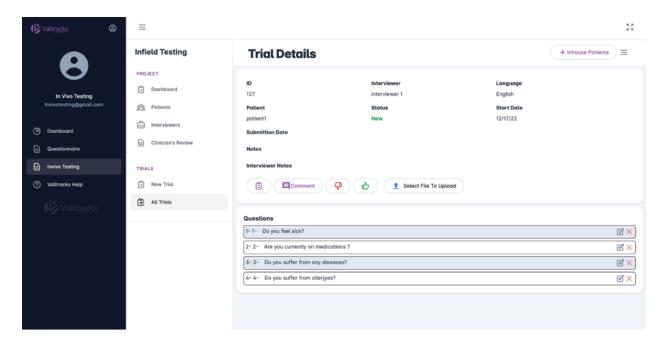
Meet between the relevant interviewer and the patient to create a trial, and add the relevant language of the interview.

This is possible only after the patient and the interviewer have accepted the invite to the system. You can do it for them if you do use the token for their profiles to be able to speed up the process.





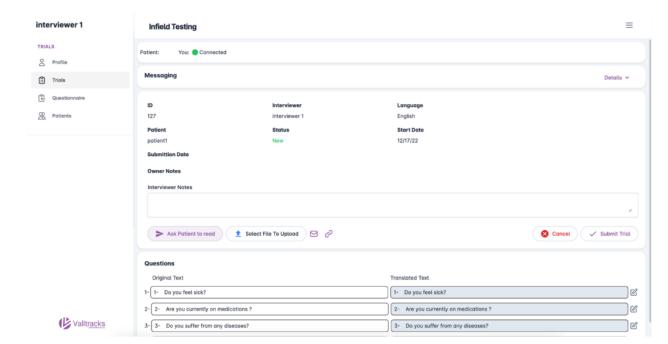
By going to all trials you can find all the trials that you created.



At this stage, the progress of the trial is in the hands of the interviewer as they need to progress with the trial depending on the agreement on the meeting time with the patient.

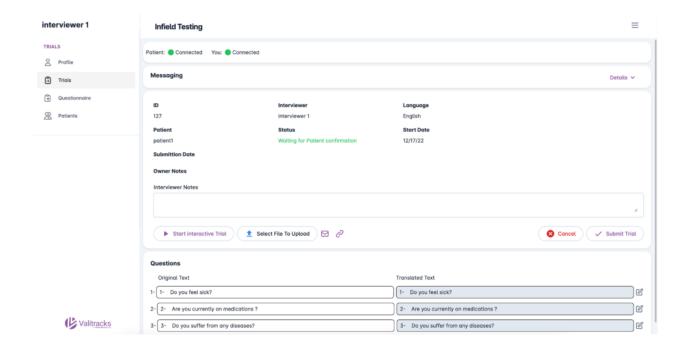
## Interviewer's dashboard interview progress:

Press on ask the patient to read to share the questionnaire with the patient before your interview. If you have any files to share with the patient like informed consent or



For any additional data, you can as a file and upload it (using select file to upload).

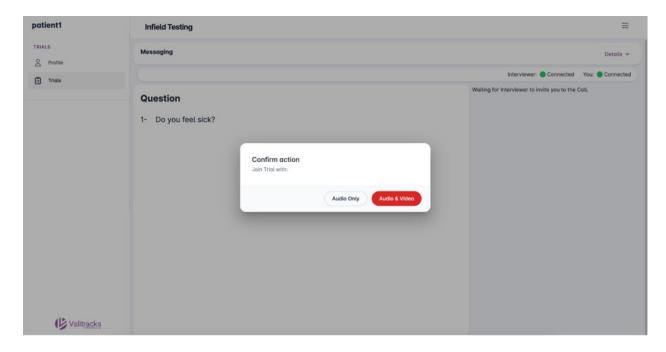
Start an interactive live interview with the patient by pressing on start interactive interview from the dashboard, when the interview is ready.



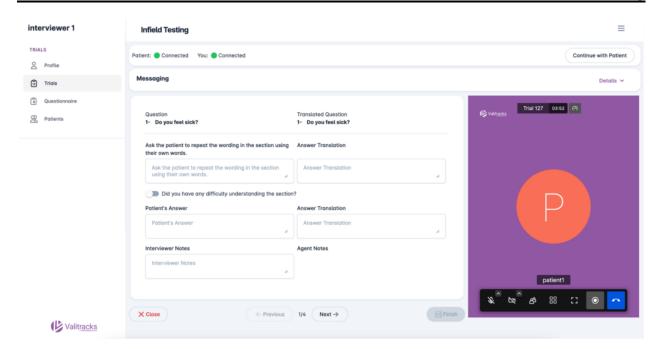
After clicking on Strat interactive trial the interactive trial dashboard is created. Enable microphone and cam (if needed in the popup window).

After doing so, press on **invite patient** to send the patient interview connection request.

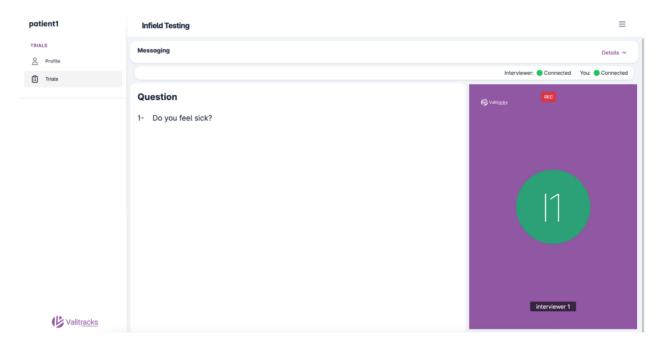
The patient has to accept the interview request and choose audio only or audio and video call.



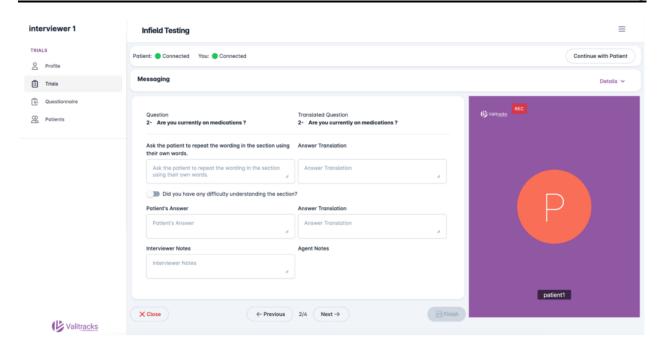
Using the interviewer dashboard ask the patient's consent to record the call and click on the white circle near the phone icon within the call.



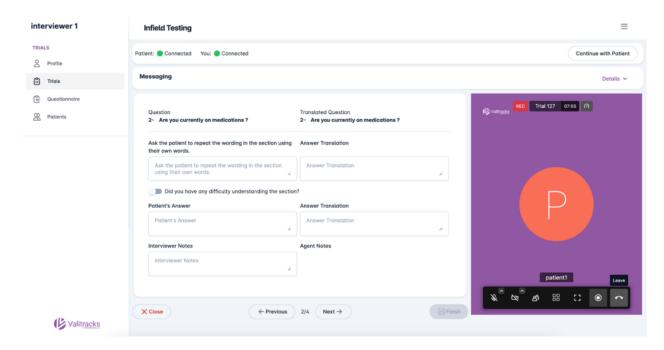
# Patient's interview interactive platform



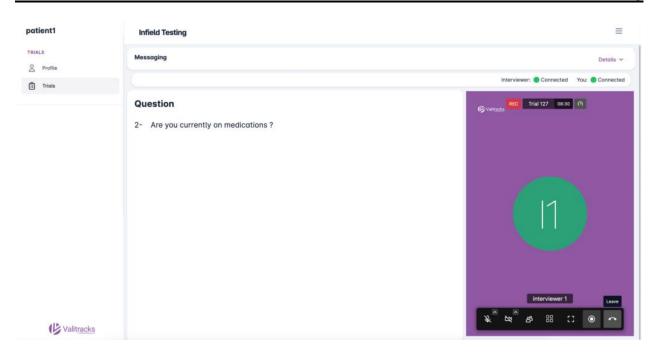
Press on the next icon to pass from one question to the next one.



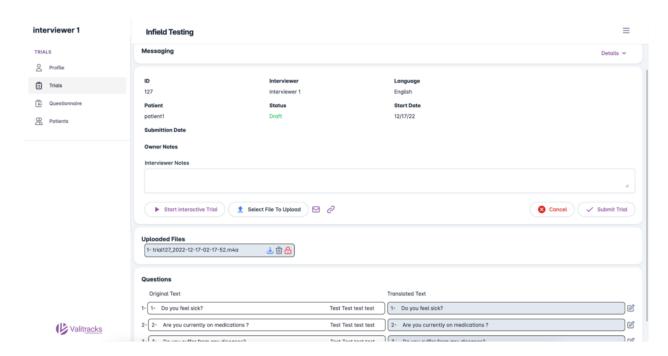
Close the call by pressing the call icon



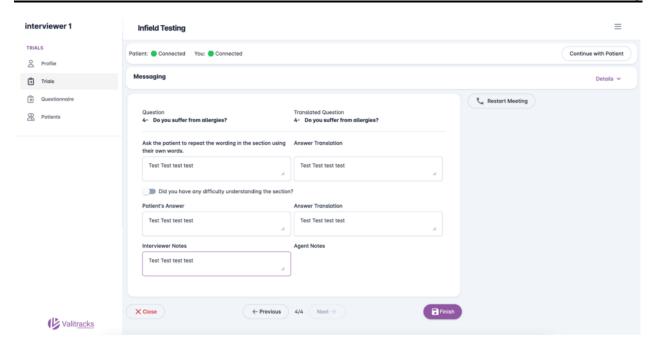
Close the call by pressing the call icon



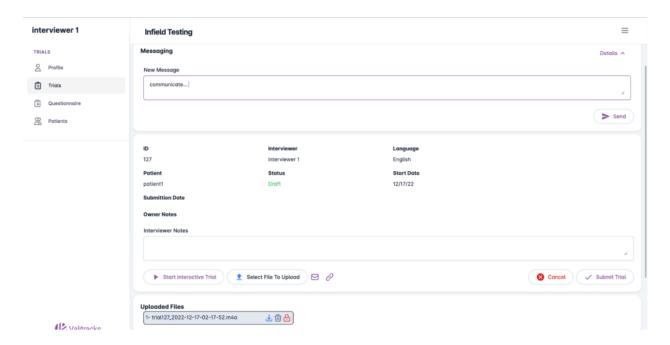
Go to trials on the dashboard to be able to download the call recording that might help you fill the summary report.



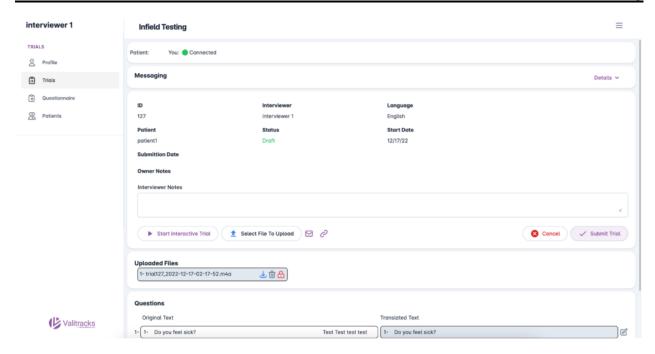
After filling out the summary report press on the finish to be able to finalize the interview.



If there is any issue to communicate with the patient you can use messaging system that will go directly to the patient.



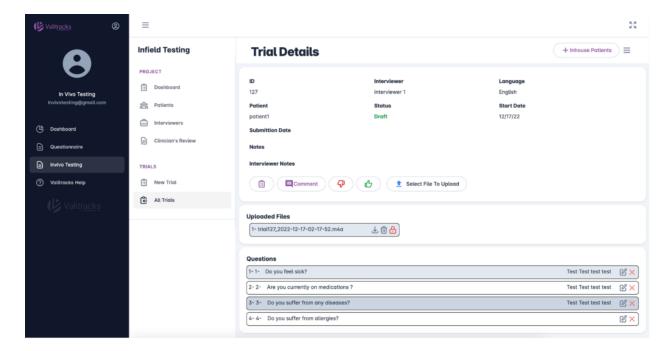
When you finish the summary of the interview **submit trial** so that your project manager can generate a follow-up stage or finalize the trial and generate a final document.

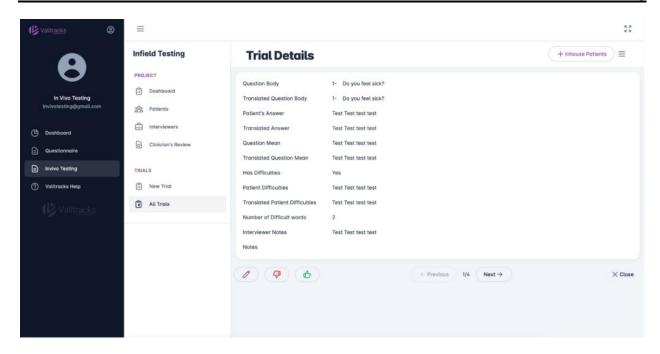


Trial follow-up as a project manager

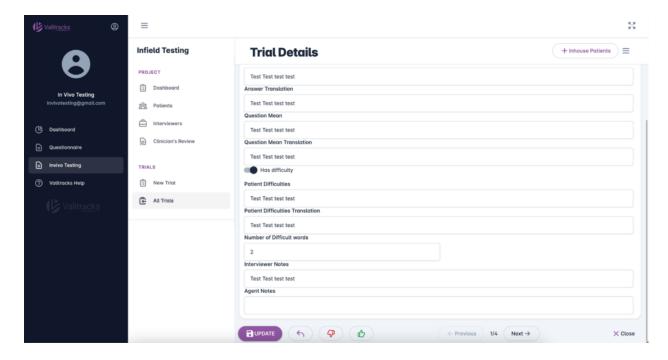
Access your dashboard as a project manager go to all trials and press on the pencil sign to see the summary of the interviewer for each section.

Find any study files and recordings in the uploaded files section.

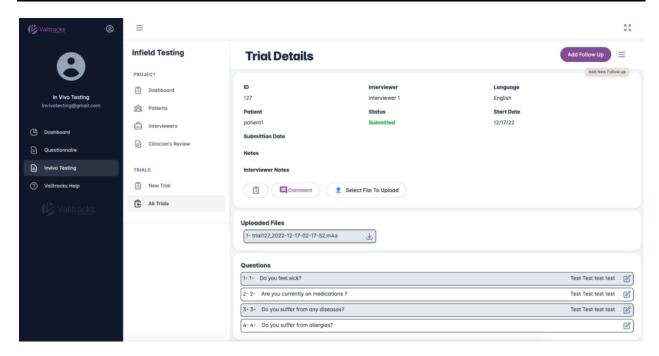




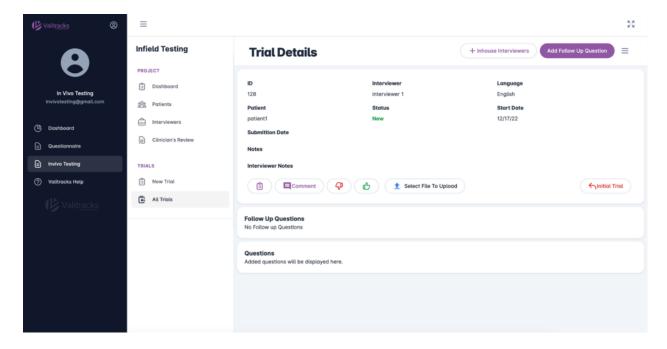
If you want to add any comment as a project manager press again on the pencil icon and add your comments in the "agent notes" section.



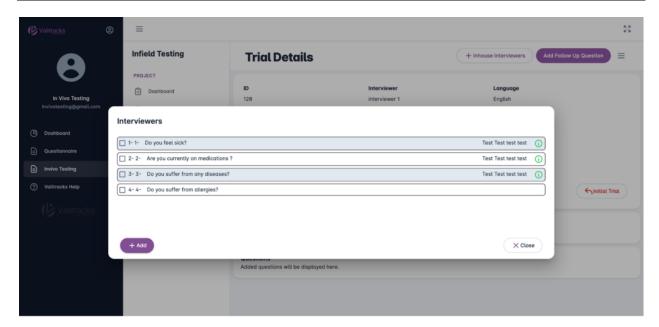
After you checked the summary, if you want the interviewer to follow up on some sections, click on the purple add follow up button on the top right side of the page.



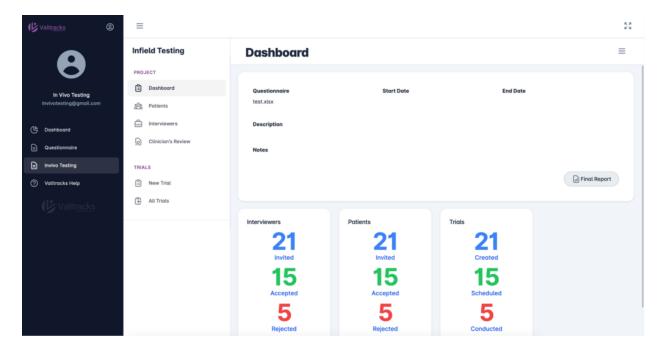
Press on add follow-up question to choose from.



Choose the questions that you would like to retest on the patient. Or add more questions, using the add button.



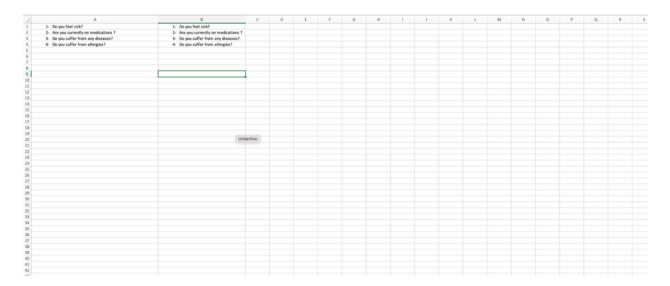
Create a summary report, go to in vivo testing, and access the trial dashboard by clicking on the squares. On the right side, you can find "final report", click on it and download the final report.



## 4-Clinician's review:

Please make sure you import at least 2 language documents (original and one translation at least).

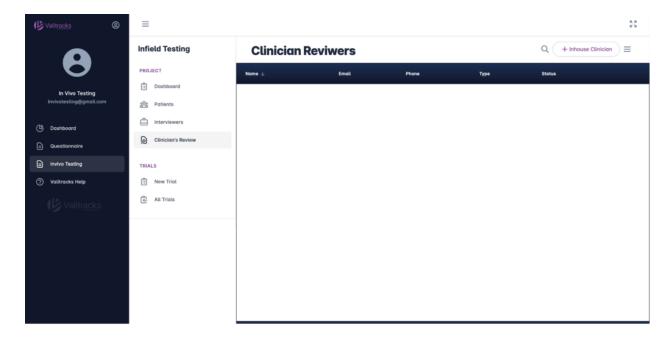
In case you want to test the original file, create a duplicated column, one for the original language and one for the tested language ( if its both the same language just duplicates it in the other column See the example in the picture):



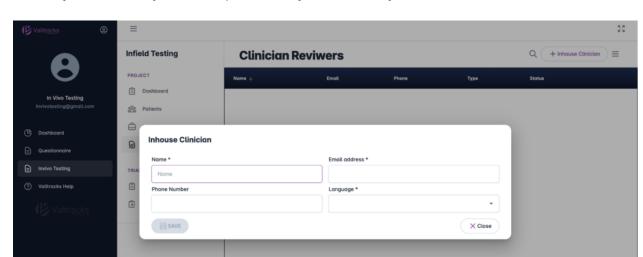
After you imported the translation.

Press on the Clinician's icon in the dashboard.

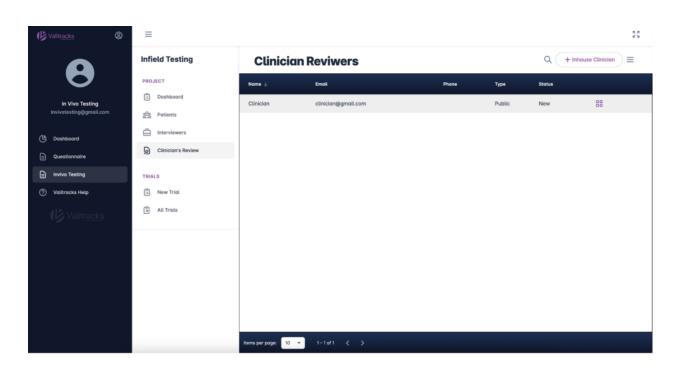
Press on in-house Clinician to add your recruited Clinician's profiles.



Add your Clinician's details to create your Interviewer's profile.

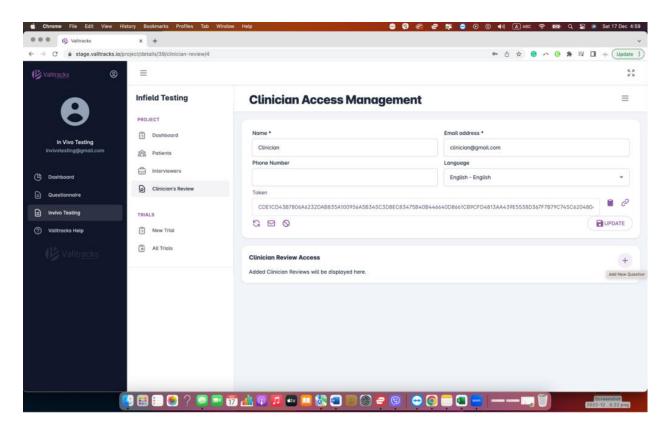


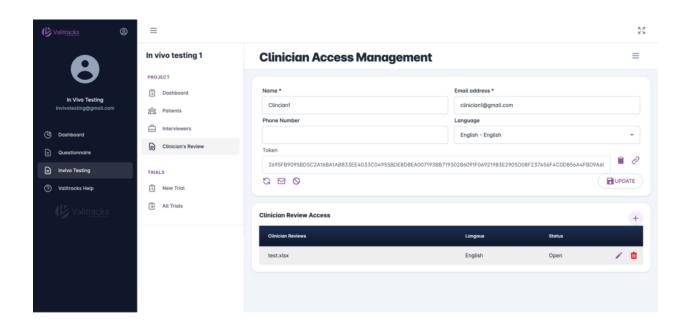
This way add as many Clinician profiles as you need for your trial.



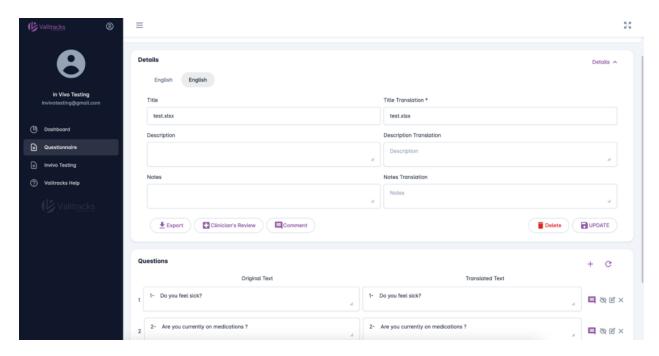
The system will be sending an automatic invite email to the Clinician to invite them to the system. You can also send the invite token using any messaging platform you want by copying the token. To do so, click on the squares icon on near the project title to get the token.

Allocate the translation for the review using clinician access management using the "+" at button to add the file and allocate it to the clinician.

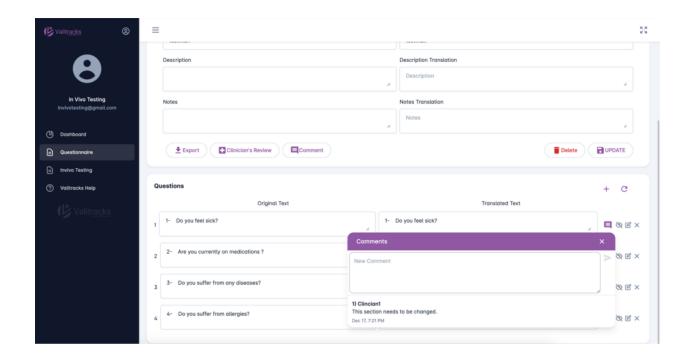




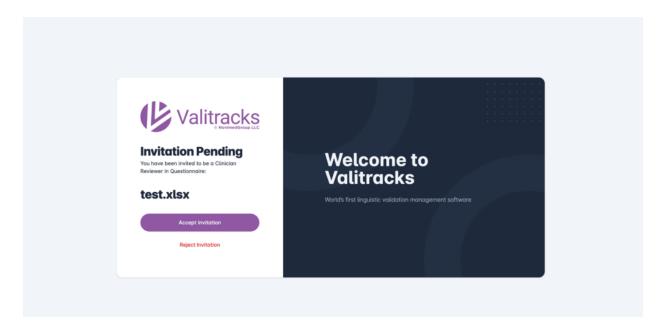
To access the clinician review comments go to the questionnaire tab and press on the translation version that you want to see the clinician's comments on.



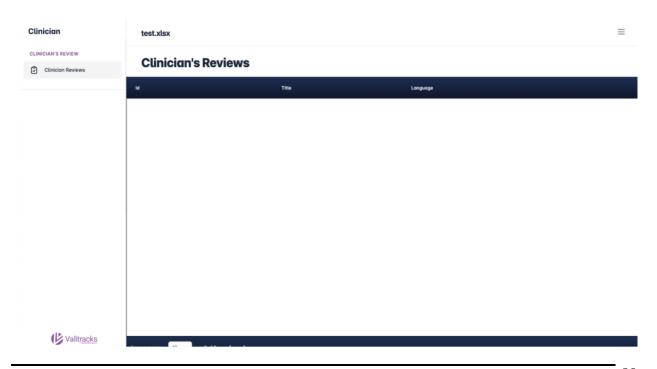
Press on the purple notebook to see the clinician's comments and to comment on them.

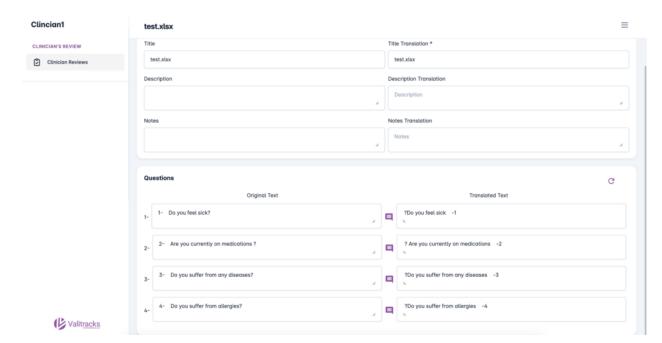


## Clinician's Dashboard



## Clinician's review dashboard





To access the review press on the purple squares:

Press on the purple notes and add your comments to each section.

