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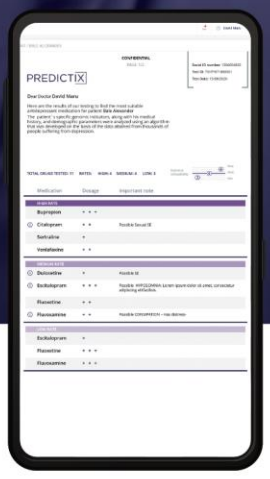
AI Personalized Medicine



PREDICTIX

Physician User Manual

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PLEASE READ THIS USER MANUAL BEFORE USING THIS PRODUCT

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1. Product Overview

1.1 What is PREDICTIX

PREDICTIX is a stand-alone software product that is intended to support a clinician decision in choosing the most suitable treatment for an individual patient suffering from a psychiatric disorder.

For the Patient, the system consists of a web-based consent form, a questionnaire, and in cases where the patient chooses to, a CE approved DNA collection kit to collect a saliva sample.

Depending on the project settings, the Patients can be invited by their Healthcare professional to fill out questions from the Predictix questionnaire. In cases where a genetic test is performed, the patients will be able to deliver a saliva sample, using the DNA sample collection kit provided, to the processing lab indicated on the envelope (either through the physician or by themselves).

For the physician, the system consists of web-based login and query forms, which allow the physician to log in into the system and to access patients' Report Forms when they are available.
Physicians may also have permissions to generate a new analysis test for a patient, by filling the patient personal information and questionnaire.

Behind the scenes, PREDICTIX performs a series of complex calculations, using the details of a patient DNA analysis together with clinical, behavioral and demographic information, utilizing a powerful scientific algorithm designed using data from thousands of patients.

PREDICTIX calculates the likely effectiveness of a range of antidepressant medications. Equipped with this information, the physician can make a more informed decision about the right treatment for their patient.

For the laboratory, the system consists of a web-based validation and upload form, which allows the lab to access a patient's DNA file, validate the data, and upload the test results.

For the manager, the system consists of a web-based login, which allow the manager to create a new analysis test, by filling the patient personal information and questionnaire, uploading the matching lab genetic file (in cases where a genetic test is performed), reviewing ongoing and completed jobs that are in the system with each job status and the ability to manually reset the job and send the final report to the physician.

For the administrator, the system consists of web-based forms to define and manage accounts, projects and system parameters.

1.2 Intended Use and Indications for Use

PREDICTIX is a stand-alone software intended to support a clinician in choosing the most suitable treatments/s for an individual patient diagnosed with a psychiatric disorder. The software uses patients' data as input for the analysis which may include one or more of the following inputs: clinical, demographic, behavioral, genetic.

1.3 Important information

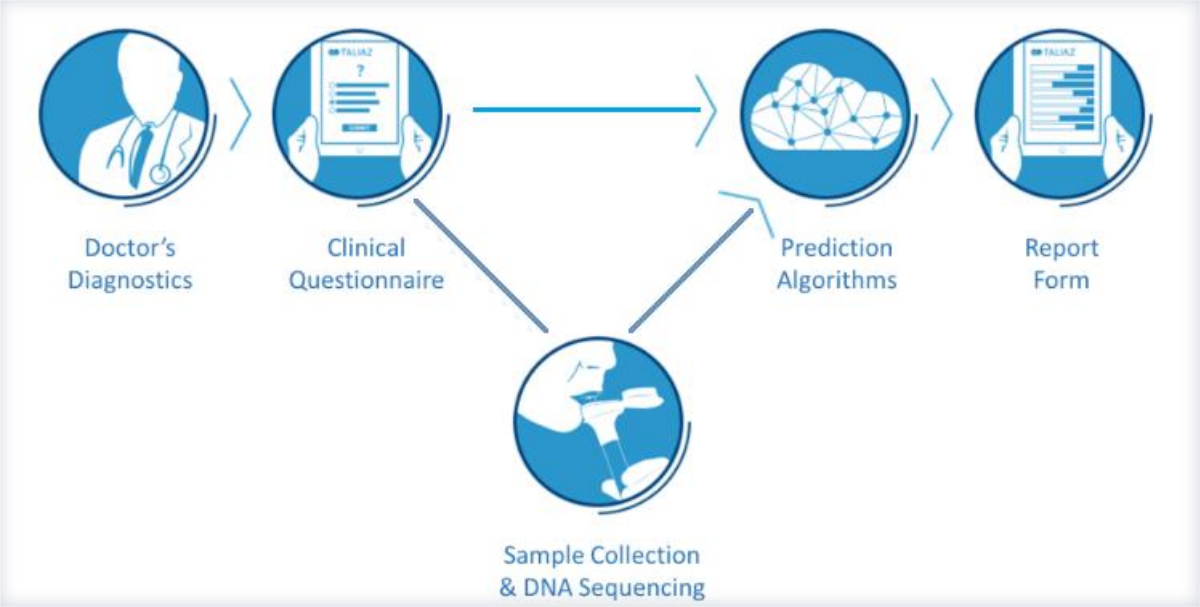
- PREDICTIX is not intended to replace direct communication with healthcare professionals.
- Data provided by the system should only be used by healthcare professionals who will need to consider all other clinical findings assessments and exams to come to a treatment decision.
- Patients should talk to their prescribing physician immediately if there are any concerns or if their condition changes.

1.4 Glossary and Abbreviations

Analysis Test	The process of collecting the patient's data and running the PREDICTIX algorithm to generate the report.
DNA Sample	A small amount of saliva or buccal swab collected by the patient in the Collection Kit
Lab	Medical laboratory that will analyze the patient's DNA sample and upload a specific genetic report to the PREDICTIX system
Report Form	Customized list of medications to support the physician's decision about treatment for the patient, based on PREDICTIX big data algorithms and a patient's clinical, demographic, behavioural and/or genetic information.
Patient	Person diagnosed with a psychiatric disorder, receiving consultation and treatment by their doctor.
Physician	A Physician or other healthcare professional that receives the results of the Report Form.
Questionnaire	Detailed list of questions and answers provided by the patient, used in the calculation of suggested medications.
Project	A set of configurations (Medical institutions, roles, flows) that will be applied for all users that are assigned to the project. Each project can hold a different set of configurations that will be managed by the PREDICTIX Admin. Each project will be assigned with its relevant users that has a common ground.
PREDICTIX Designated link	The PREDICTIX system URL that is available upon request from the system administrator and /or Taliaz. A custom URL may be used in different installations.

2. How the PREDICTIX System Works

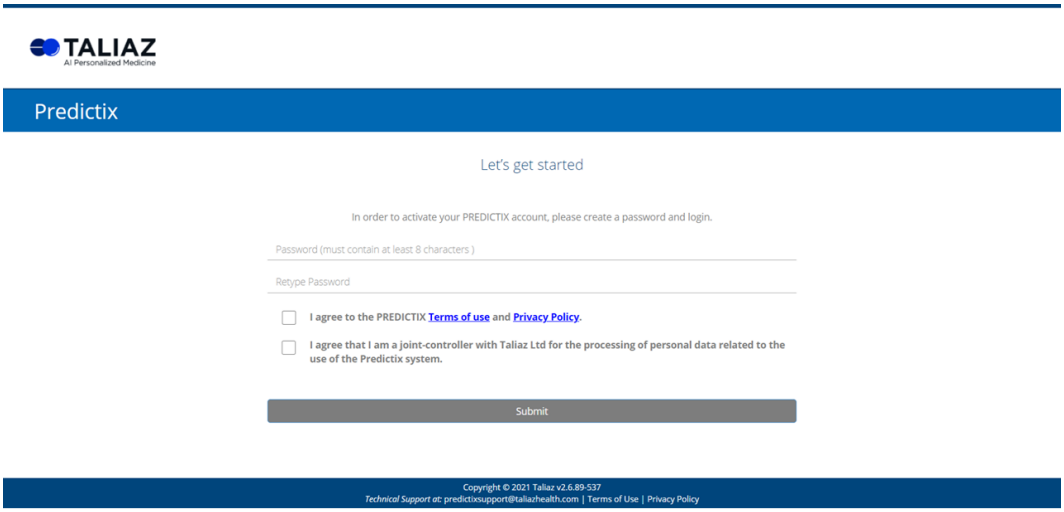
The diagram below shows how the various components of the PREDICTIX System work together to allow the patient and physician to receive a Report Form.



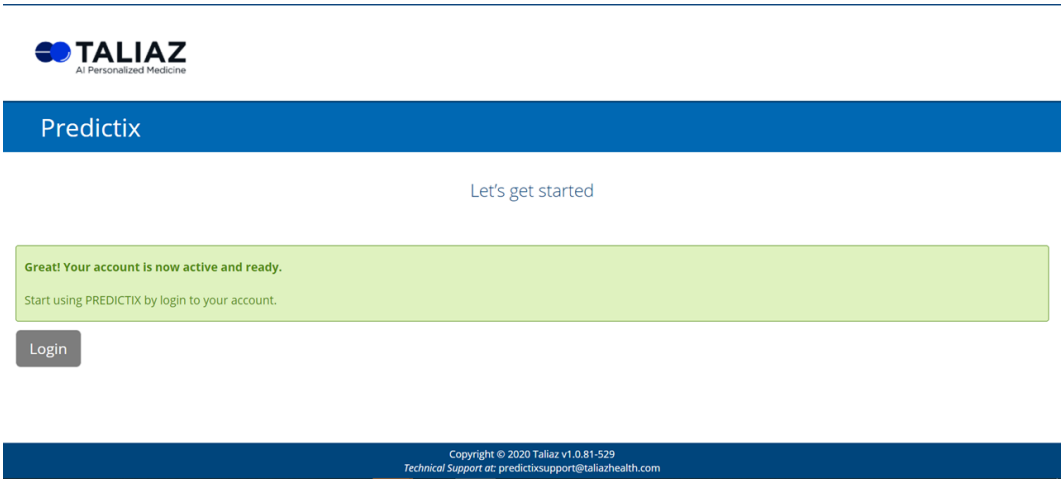
3. Creating your PREDICTIX account

A Taliaz Admin will create your account on the PREDICTIX system, once your account is created, you will receive an email invitation to complete the account creation process. The email contains a link that will redirect you to the PREDICTIX system, where you will be able to create your own personal password.

Once a password has been created, and you have agreed to the 'Terms of use' and the 'privacy policy', click the 'submit' button.



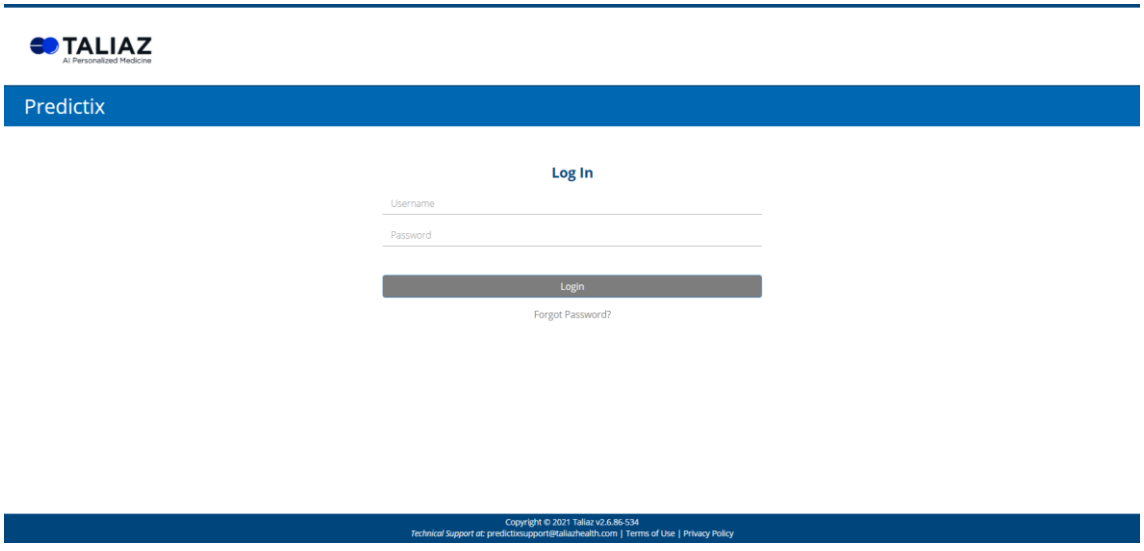
ACCOUNT ACTIVATION SCREEN



A success message will be displayed and your account will be ready for use. Press the Login button

You will be redirected to the Login screen.

For your convenience, it is recommended to add the Login page to your web-browser's 'favorites' / 'bookmarks'. Below are instructions for adding a bookmark your web-browser:
Google Chrome
Microsoft Edge



LOGIN SCREEN

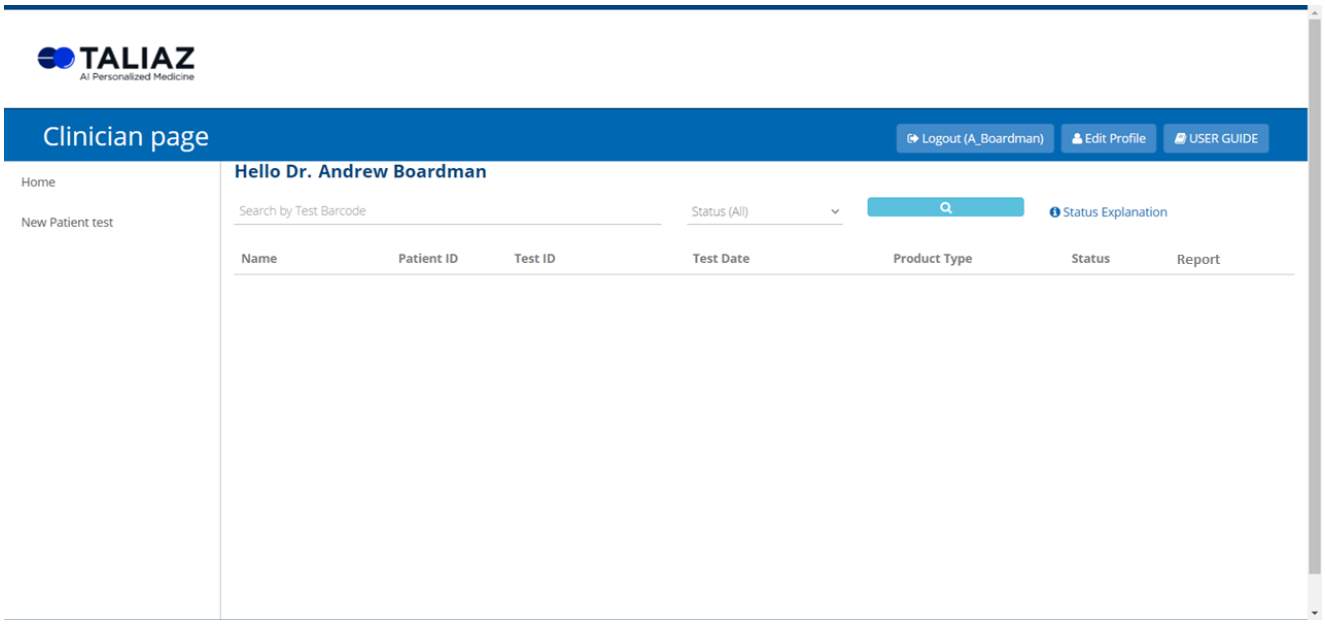
Enter your username and password and Press **Login**.

4. Clinician Interface (Not in Clinical Trial Environment)

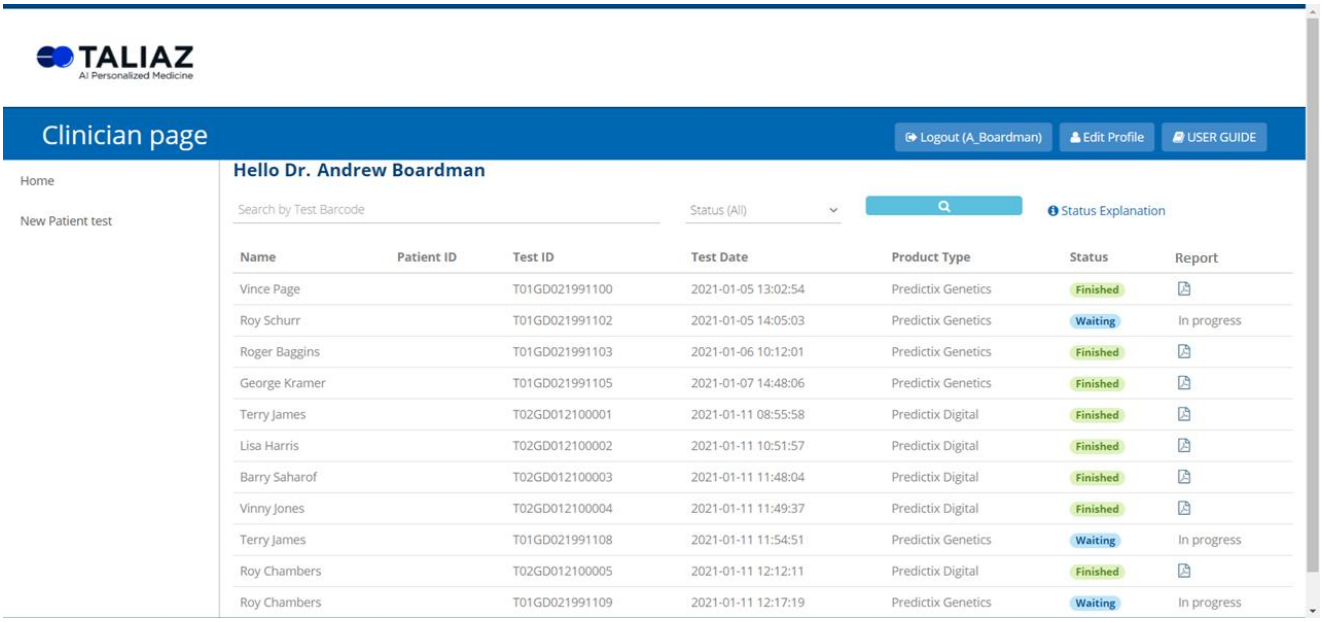
***For Clinical Trial Environment please refer to section 5**

4.1 Patient Test List – View Ongoing Tests, Completed Tests and Final Reports

The Patient Test List screen shows ongoing tests, and completed tests together with their Final Reports. You can search and filter reports by the Test ID or by the status of the analysis test.



INITIAL PATIENT TEST LIST SCREEN



PATIENT TEST LIST SCREEN AFTER PATIENT TESTS HAVE BEEN PERFORMED

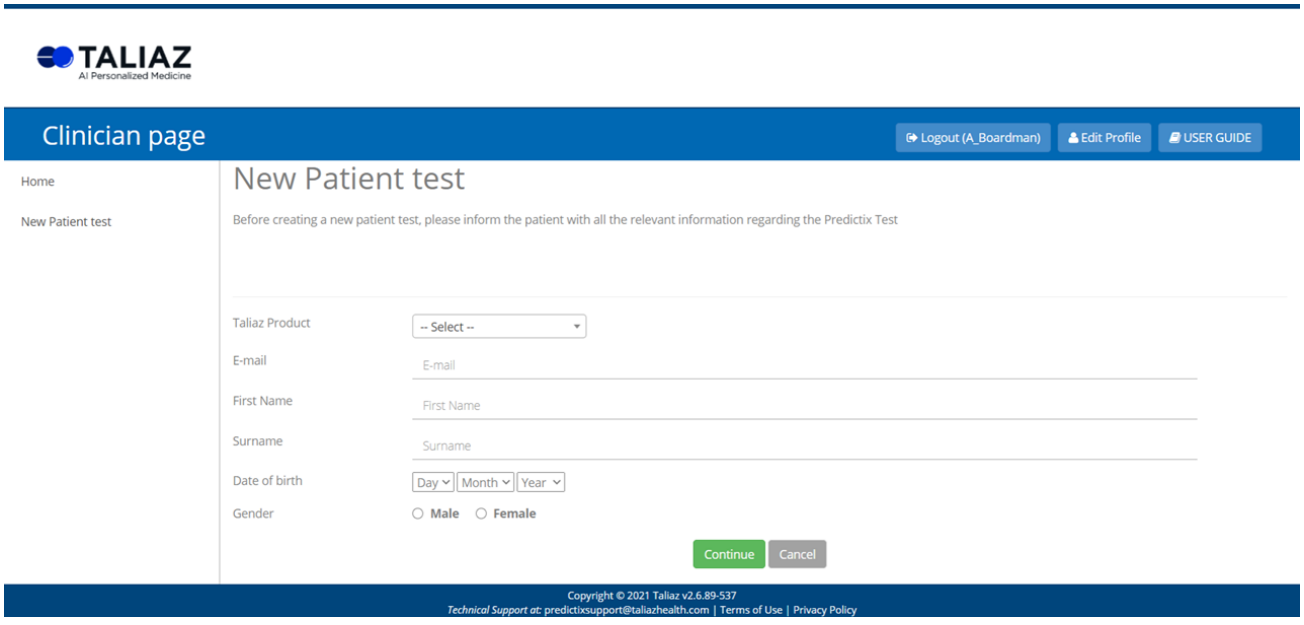
4.2 Creating a New Patient Test

In order to generate a Test for a patient, click on 'New Patient Test' on the left sidebar menu:

LEFT MENU

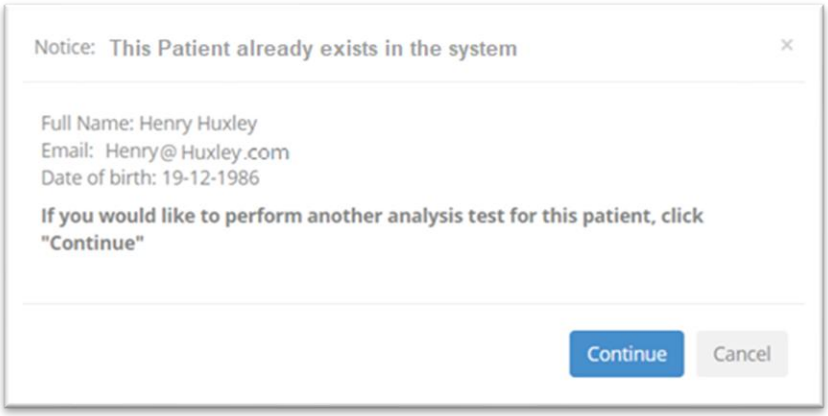
You will be redirected to the New Patient Test screen.

1. Select the relevant **Predictix Test type** (i.e., Predictix Digital Antidepressant) which you would like to perform.
2. Insert the patient's Email address, first name, last name, date of birth, and gender.

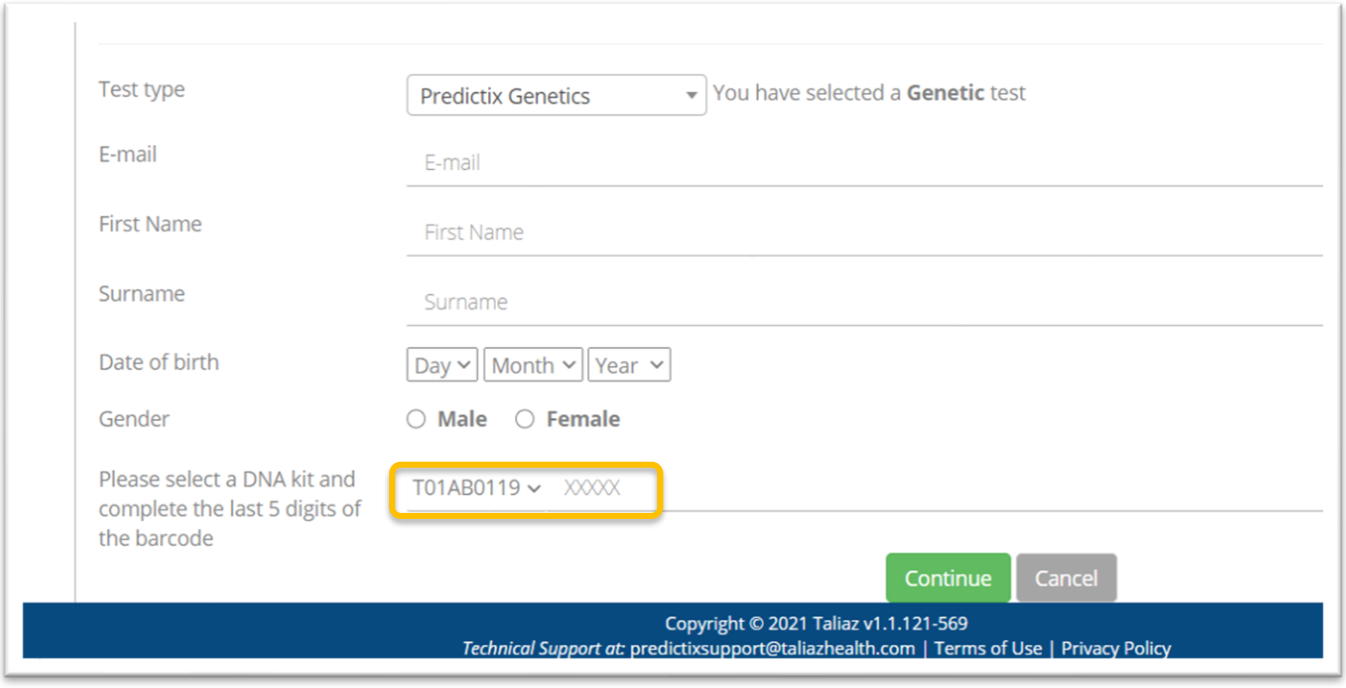


NEW PATIENT TEST

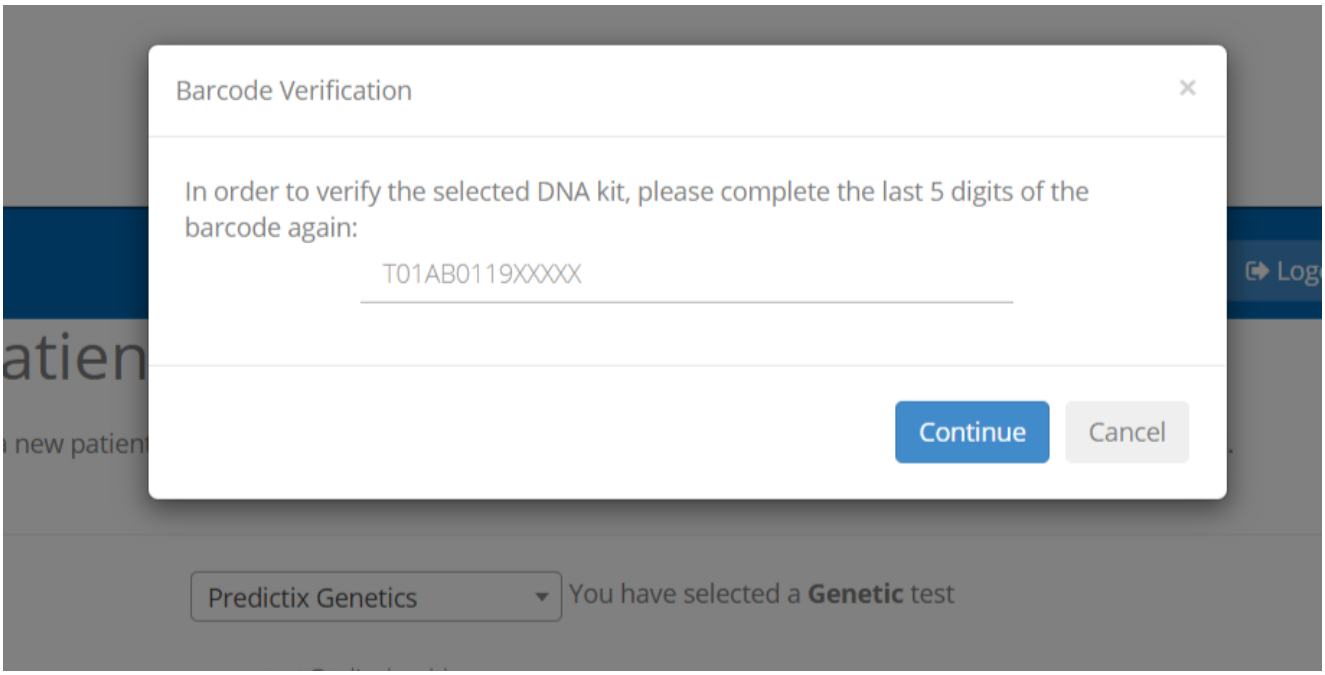
- The system will indicate if the patient's Email address already exists in the system, and also whether the patient has been registered to the Predictix system with another Healthcare professional:



- In case a Genetic Test is selected, you will be asked to select a DNA kit and insert the last five digits of the barcode:

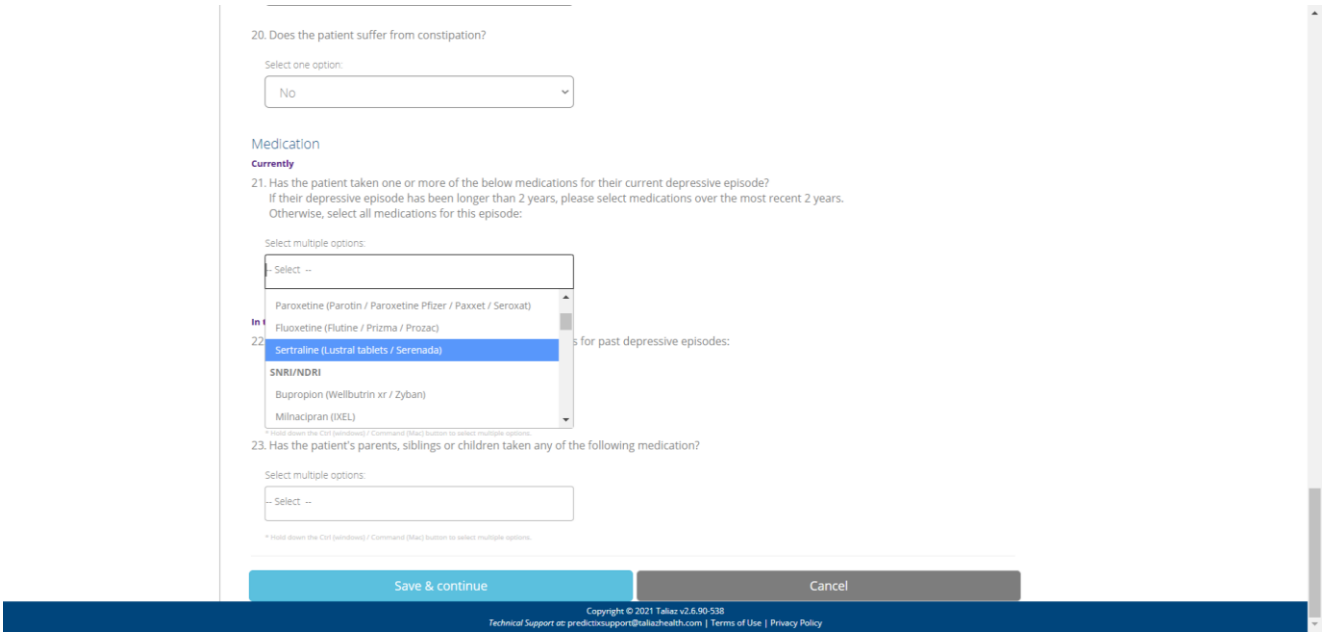


DNA KIT SELECTION AND BARCODE COMPLETION

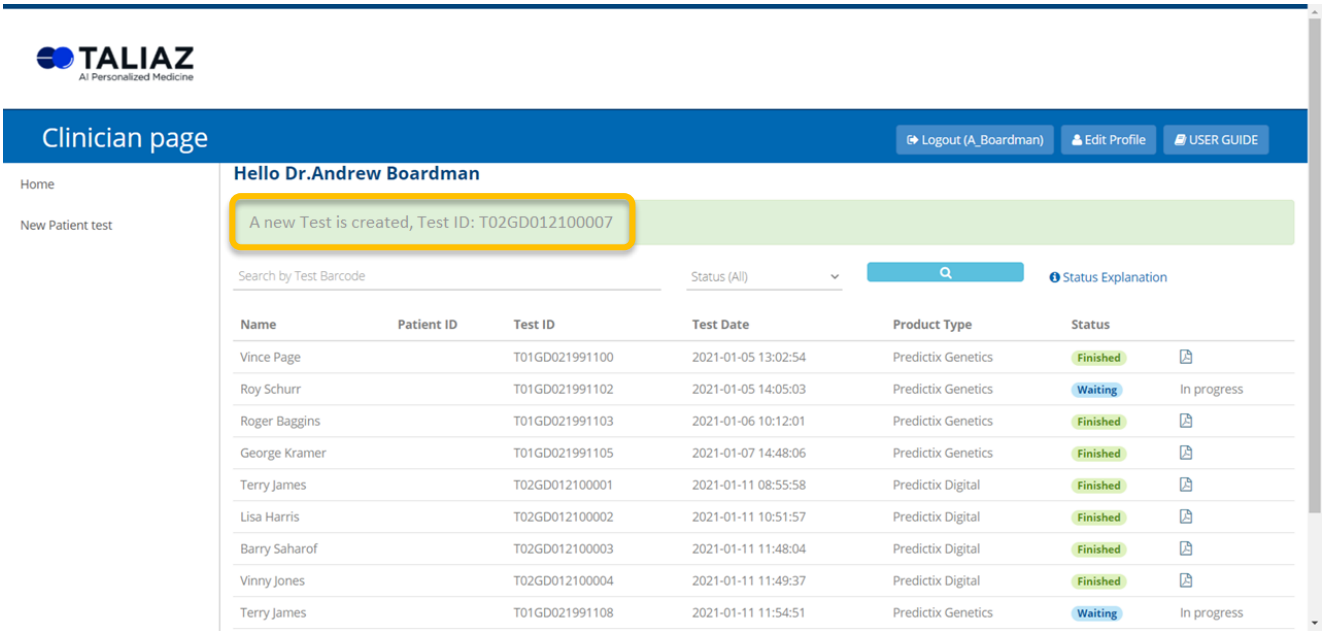


DNA BARCODE VERIFICATION

3. Click the Continue button at the bottom of the New Patient Test page.
4. Go through the patient consent together with the patient.
    - *An Email containing the consents, the terms of use, and the privacy policy will be sent to the patient.*
5. Answer the **Predictix Questionnaire** together with the patient, review the answers, and press **Submit**.



You will be redirected to the main Clinical Page.



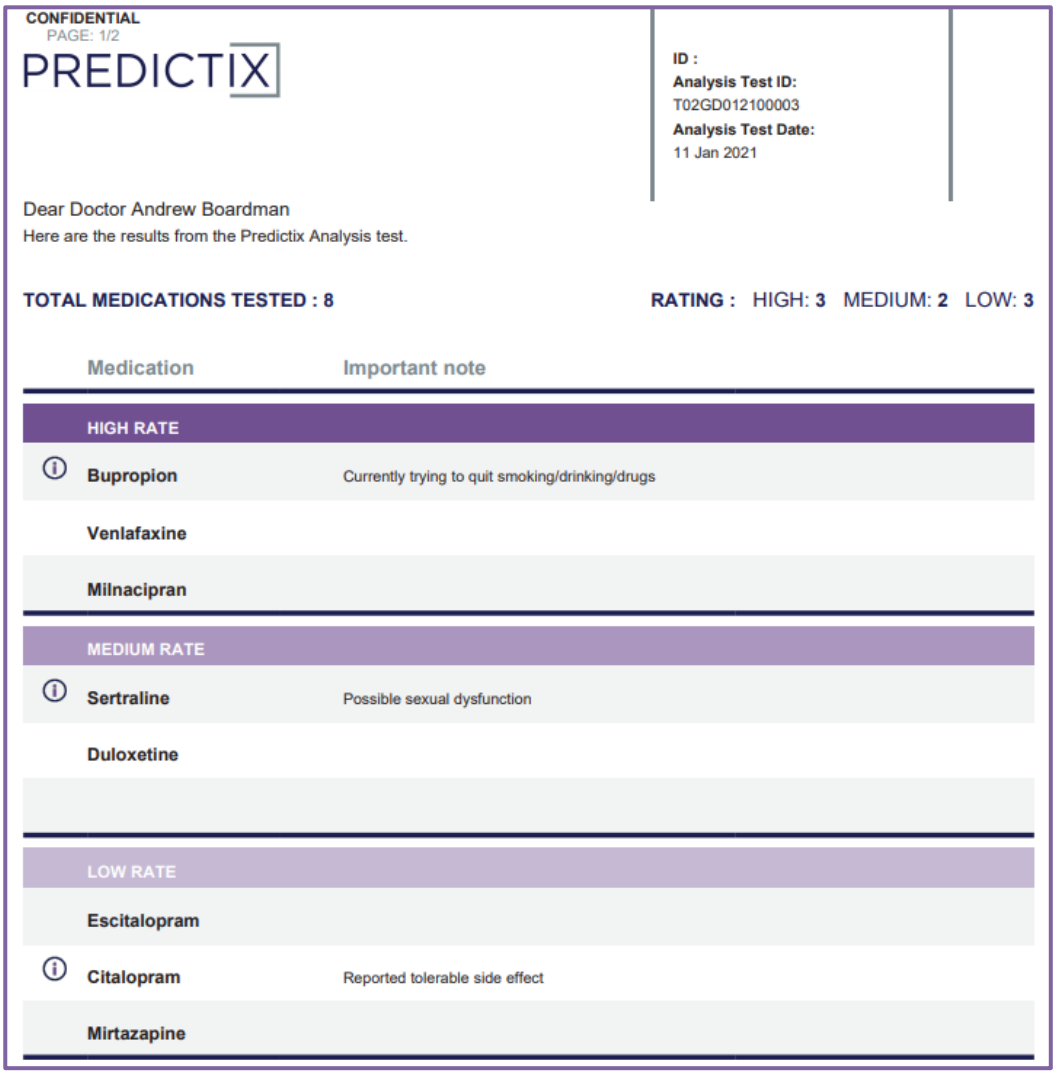
Please validate that the barcode of the DNA kit matches the Test ID.

** In case a second Genetics Test is generated for a patient, the system will not request a DNA sample. The Predictix Platform will use the existing DNA analysis for the patient, and a seperate Test ID and report will be generated.*

- After collecting the DNA sample from the patient, you will be able to send the sample back to the Laboratory.
- The Laboratory will process the DNA sample, and upload the analysis results to the PREDICTIX system.
- Once both the questionnaire and the lab results are in the system, the PREDICTIX Algorithm will run and generate the final report.

Once the report is ready, you will receive a notification by Email.

Press on the pdf icon to view the Report Form. A sample Report Form is shown below (Design may change in different versions and tests).



CONFIDENTIAL
PAGE: 1/2

PREDICTIX

ID :
Analysis Test ID:
T02GD012100003
Analysis Test Date:
11 Jan 2021

Dear Doctor Andrew Boardman
Here are the results from the Predictix Analysis test.

TOTAL MEDICATIONS TESTED : 8

RATING : HIGH: **3** MEDIUM: **2** LOW: **3**

	Medication	Important note
	HIGH RATE	
ⓘ	**Bupropion**	Currently trying to quit smoking/drinking/drugs
	Venlafaxine	
	Milnacipran	
	MEDIUM RATE	
ⓘ	**Sertraline**	Possible sexual dysfunction
	Duloxetine	
	LOW RATE	
	Escitalopram	
ⓘ	**Citalopram**	Reported tolerable side effect
	Mirtazapine	

REPORT FORM – SAMPLE DESIGN (PREDICTIX DIGITAL ANTIDEPRESSANT)

CONFIDENTIAL
PAGE: 1/2

PREDICTIX

ID :
Analysis Test ID:
T01GD021991100
Analysis Test Date:
05 Jan 2021

Dear Doctor Andrew Boardman
Here are the results from the Predictix Analysis test.

TOTAL MEDICATIONS TESTED: 11 **RATING:** HIGH: **3** MEDIUM: **4** LOW: **4**

	Medication	Dosage Optimization	Important note
	HIGH RATE		
	Venlafaxine	+++	
	Duloxetine	++	
ⓘ	**Escitalopram**	++	**Possible sexual dysfunction**
	MEDIUM RATE		
ⓘ	**Sertraline**	+	**Reported tolerable side effect**
ⓘ	**Bupropion**	++	**Currently trying to quit smoking/drinking/drugs**
	Milnacipran	++	
	Mirtazapine	++	
	LOW RATE		
	Citalopram	++	
	Fluoxetine	+++	
	Fluvoxamine	+++	
	Paroxetine	+++	

REPORT FORM – SAMPLE DESIGN (PREDICTIX GENETICS ANTIDEPRESSANT)

CONFIDENTIAL
PAGE: 2/2

PREDICTIX

ID :
Analysis Test ID:
T01GD021991103
Analysis Test Date:
06 Jan 2021

High Rate: High likelihood for compatibility, to be prescribed/used subject to an advice of a qualified physician
Medium Rate: Medium likelihood for compatibility, to be prescribed/used with caution subject to an advice of a qualified physician
Low Rate: Low likelihood for compatibility, to be prescribed and/or used only under strict instructions and monitoring by a qualified physician

Dosage + : Consider reduction of standard dose as appears in the Medication Guide, and titrate to maximum tolerated dose
Dosage + + : Consider administrating standard recommended dosage as appears in the Medication Guide
Dosage + + + : Consider increase and titration up to maximal allowed dose as appears in the Medication Guide

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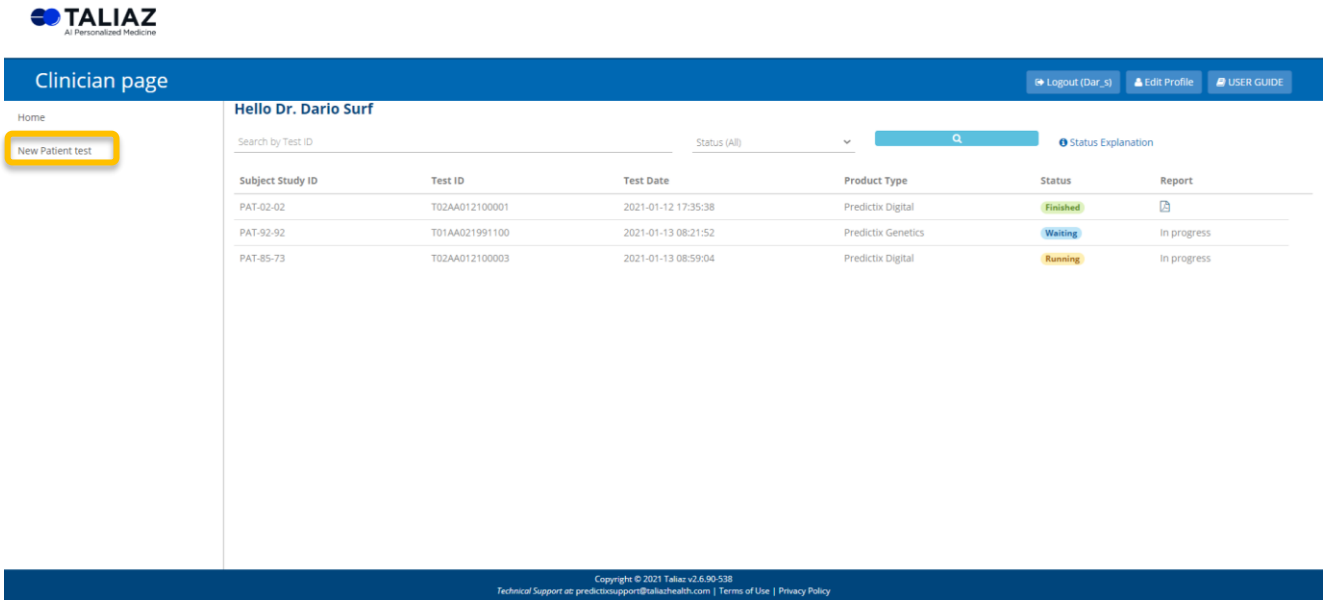
REPORT FORM DISCLAIMER AND ADDITIONAL INFORMATION

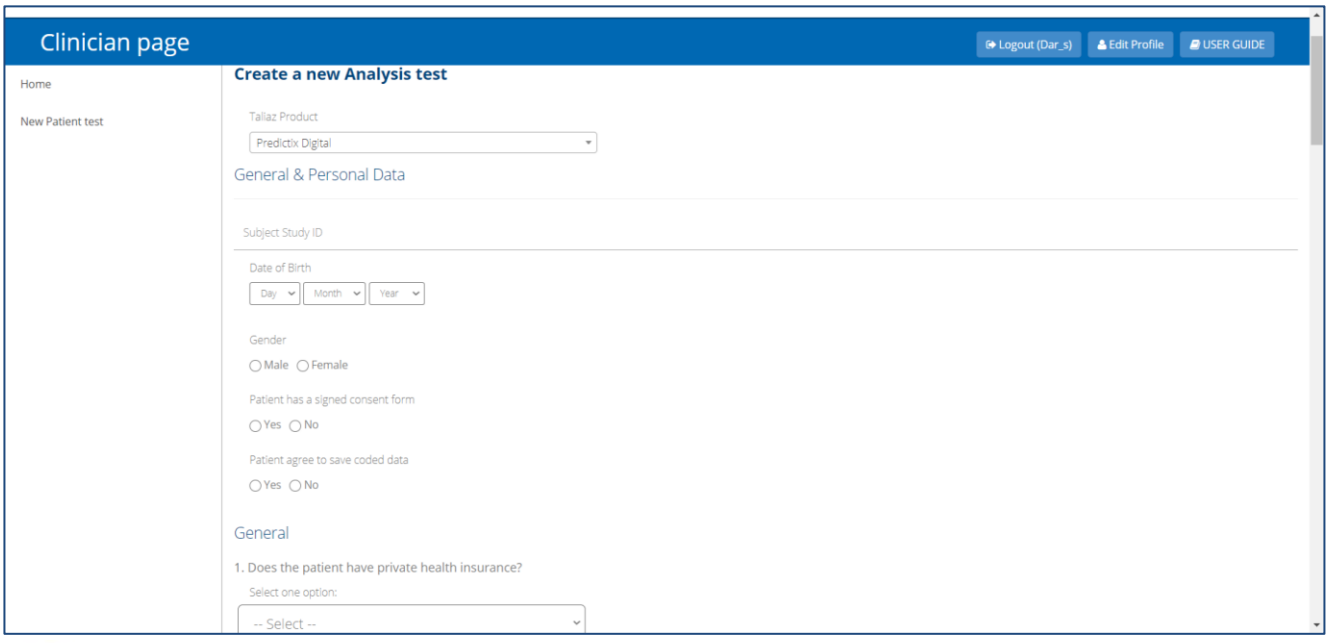
5. Clinical Trial Project

For projects that are set as a 'Clinical trial' project, the physician will have the patient sign the paper copy of the Informed consent. The Physician will then fill in the PREDICTIX questionnaire from the web interface, manually insert the Analysis test barcode and the study subject id (The patient information will be pseudo anonymized on the system and there will not be any identification data stored from the questionnaire). Once the questionnaire is completed, the Physician will be asked to re type and verify the Analysis test barcode. Once confirmed, the new Analysis test will be created. The PREDICTIX Algorithm will run and generate the final report. When the report is ready a notification will be sent to the physician.



PATIENT TEST LIST SCREEN IN CLINICAL TRIAL PROJECT

Click on 'New Patient Test' in the navigation menu and the PREDICTIX Questionnaire will show.



1. Select the relevant **Predictix Test type** (i.e., Predictix Digital Antidepressant) which you would like to perform.

2. Enter all of the patient information.
The patient data is pseudo-anonymized, and no identifying information is requested.

3. Enter the PREDICTIX barcode / Analysis Test ID (for Genetic Test only)

4. Enter the study subject ID, which matches the conversion table you have locally.

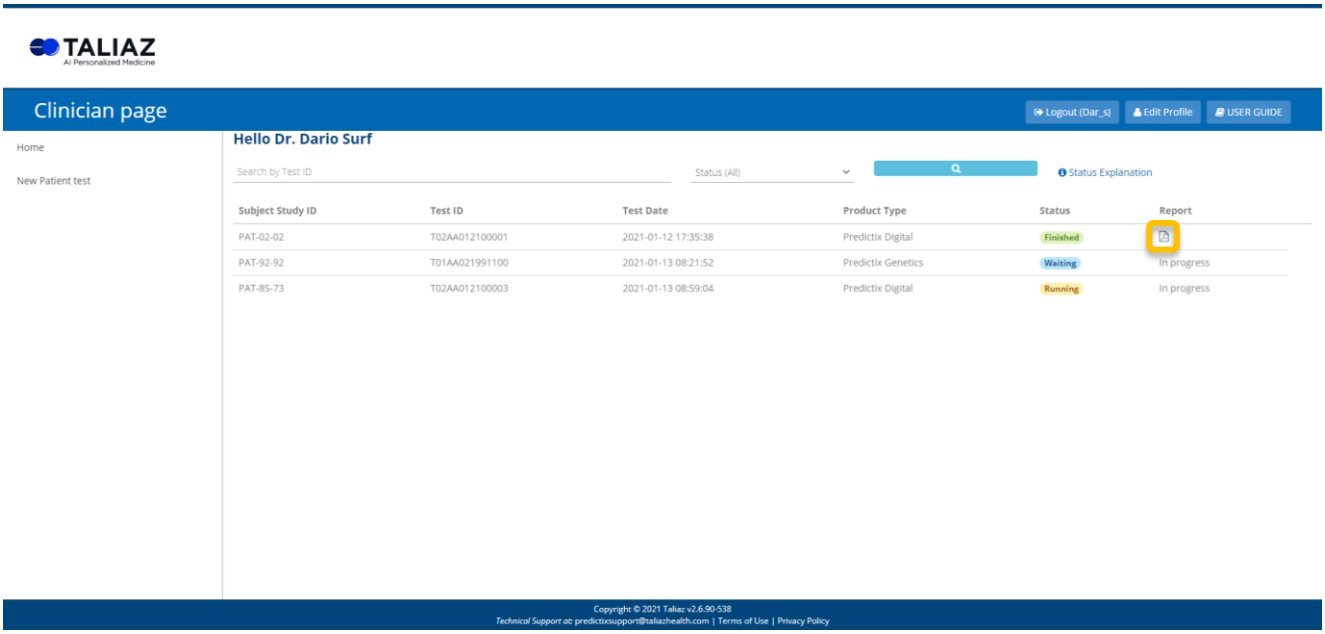
5. Complete the questionnaire together with the patient and click 'Continue'.

A popup window will open asking you to re-enter the last 5 digits of the PREDICTIX barcode / patient ID.

Review the Questionnaire with the populated data, make sure all the data entered is correct, and click the 'Submit' button.

Once the report is ready, you will receive a notification by Email.

Press on the pdf icon in the test list page to view the Report Form.



6. Troubleshooting

In any case of trouble handling the device or unknown issues, contact us at:

Tel: +972-(0) 3-6505595 or via mail support@taliazhealth.com
Working hours 09:00 – 17:00. Outside of working hours please leave a message or send an e-mail.