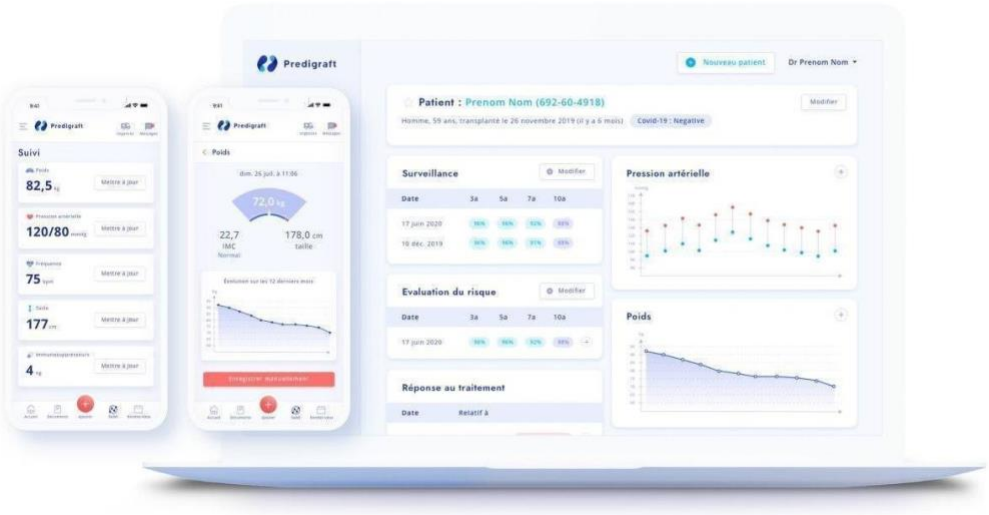
Predigraf
t v.1.14
User
Manual

Healthcare Professional



Please read this entire manual carefully before using Predigraft software, a class IIa medical device.

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This manual complies with **EU** Medical Device **Regulation 2017/745.**

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1. About this manual

This manual is an integral part of the Predigraft software. It details the presentation of the application, its configuration, and its use.

The electronic version of this manual is available online at www.cibiltech.com. If required, a printed version can be provided upon request at the following address: contact@cibiltech.com.

Note: The screenshots shown in this user manual are examples only, they are not exhaustive and may differ slightly from the views available in the user interface.

Intended Audience: This manual is intended for healthcare professionals.

2. Security Information

Only healthcare personnel who have read these instructions in full are authorized to use Predigraft. For correct and safe use and for all maintenance interventions, it is essential that personnel follow standard safety procedures.

2.1. Primary risks related to the use of Predigraft

The main risks identified are related to the input of data that can result in:

- **An overestimation of the patient's current or expected state of health:**

When an input is erroneous (i.e. falsely reassuring) and an alert is not sent to the healthcare professional, the chances of graft survival are higher than expected.

- **An underestimation of current or expected health status:**

When an input is erroneous (i.e. falsely critical) and an alert is sent to the healthcare professional, the probabilities of graft survival are lower than expected.

Note: Predigraft is a decision support tool. The clinical assessment of health status by the health professional is not based solely on the prognosis of Predigraft.

2.2. Warnings

- Always ensure that you only open websites via a secure SSL/TLS connection. In this case, the Internet address starts with "https". Simple connections that only start with "http" are a security risk.
- Make sure you are using the latest version of your web browser (compatible with Predigraft *as per the technical specifications chapter*) and regularly update your operating system.
- Keep your passwords up to date. Use a separate password for each application and do not use previous passwords.

- Do not click on links in emails from unknown senders, as this could direct you to a website containing malware.

2.3. Description of product labeling

The following symbols may be visible in the application or in the documentation:

Symbol/Text	Meaning
	Manufacturer's address
Predigraft v1.14	Device name and version identification
	Consult the user manual
CE 2797	CE Marking 2797: identification of the notified body

3. Intended use

Predigraft is a medical device intended to be used as a predictive tool to inform healthcare professionals of the probability of survival of allograft kidney transplants following kidney transplantation. These probabilities, along with available standard clinical data, help describe the condition of the allograft, and provide additional information concerning the patient's care and treatment decisions. Specifically, Predigraft provides probabilities of allograft survival at +3 / +5 / +7 years after evaluation, based on the combination of a set of clinical, biological, and histological parameters.

Predigraft is also intended to be used as a telehealth tool after kidney transplantation to facilitate communication between clinicians and patients by providing a customizable alert system.

Warning:
Remote monitoring is not an emergency response system. In the event of a medical problem, patients should contact a healthcare professional or Emergency Medical Services.

3.1. Intended users

The Predigraft solution is intended to be used by:

- Healthcare professionals involved in the treatment and follow-up of kidney transplant patients such as nephrologists, nurses, etc.
- Kidney transplant patients.

3.2. Intended patient population

Patient selection criteria:

- Patient having received a kidney transplant from a living or deceased donor,
- Patient must be at least 18 years old.

3.3. Contraindications

Predigraft cannot be used for the follow-up of patients who have had:

- Previous non-functional kidney transplantation,
- A combined transplant (e.g., kidney - heart transplant, kidney - liver transplant).
- A transplant within the past month.

4. Operating principle and mode of action

4.1. iBox technology

Predigraft was developed using the "integrative BOX" (iBox) technology. The iBox is a predictive algorithm developed by the Paris Transplant Group (INSERM UMR 970; Principal Investigator: Professor Alexandre LOUPY). The algorithm predicts allograft survival at 3, 5, and 7 years after risk assessment with accurate calibration and discrimination (concordance index 0.81; 95% confidence interval - 0.79 to 0.83). It was developed in a cohort of 4000 kidney transplant patients in France and validated in a cohort of 2129 patients in Europe and a second cohort of 1428 patients in three centers in the United State.

4.2. Mode of action

Predigraft is used as a risk monitoring/assessment tool.

During patient follow-up, the healthcare professional uses Predigraft as a tool to be informed of the long-term survival probabilities of the allograft. The risk of allograft loss is assessed based on the biological parameters used in clinical follow-up during routine care, namely: creatinine (to estimate glomerular filtration rate according to the MDRD formula; in ml/min/1.73 m^2) and the ratio of proteinuria to urinary creatinine on a sample (in g/g).

Healthcare personnel are informed of the long-term survival estimates for kidney allograft transplants at the time of each patient visit and can decide to follow-up the patient's evaluation with additional information from an allograft biopsy and measurement of donor-specific anti-HLA antibodies. This decision may be made on the basis of:

- Survival probabilities of the kidney allograft,
- Other parameters non captured in Predigraft,
- Preset alerts.

5. Technical data/Prerequisites

The Predigraft tool for healthcare professionals is available in SaaS (Software as a Service) mode via the web.
It is compatible with devices supporting the following browsers:

Browser	Compatible version
Chrome	≥ Version 81
Firefox	≥ Version 75
Safari	≥ Version 14
Edge	≥ Version 91

An internet connection is required to use Predigraft.The use of Predigraft does not require any training.

6. Authentication/Account creation

When an account is created, the Cibiltech team configures access to the application for two profiles:

1. Team owner
2. Team member

Access rights and functionalities are different for these profiles.

The Cibiltech team creates the "owner" user account and then the team associated with this user. The Cibiltech team creates as many teams as needed. There is one owner per team.

6.1. You are the team owner

When you subscribe, you will receive a link to the "Reset Password" page via email. On this page, enter your email address to receive a reset link. By clicking on the link from your email, you will be redirected to a page where you can enter your password and a confirmation of the password. You are then connected to the application as the "team owner".

6.2. You are a team member

The team owner sends an invitation email to members via the Predigraft interface. If you are in the list of users authorized to create an account on Predigraft, you will receive an invitation link by email.

Click on this link to be redirected to the Account Creation page. You must enter your name, email address (identical to the address to which the invitation was received), password, and password confirmation. You are then connected to the application as a “team member".

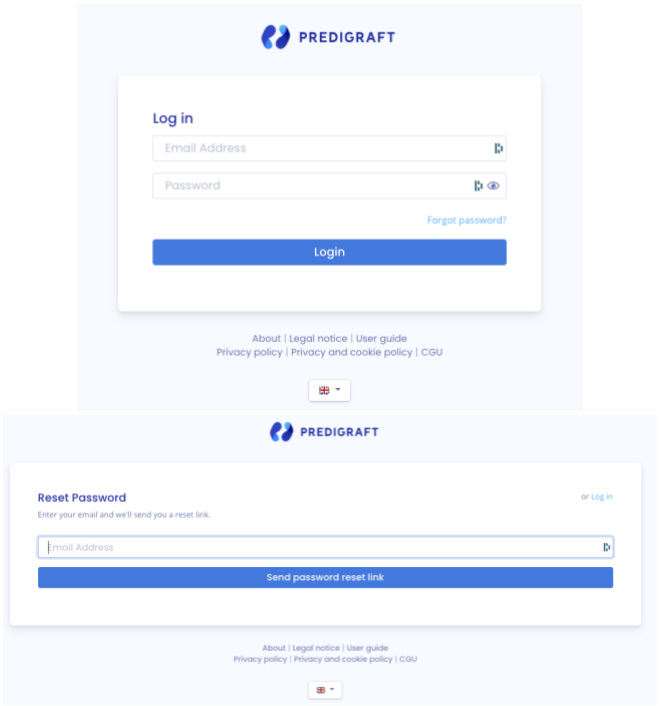
6.3. You are a Predigraft user (owner/member)

To activate your account (owner or member), you must:

- Confirm your email by clicking on a link sent to you by email,
- Read and accept the General Terms and Conditions of Use (GTCU).

Forgot your password?

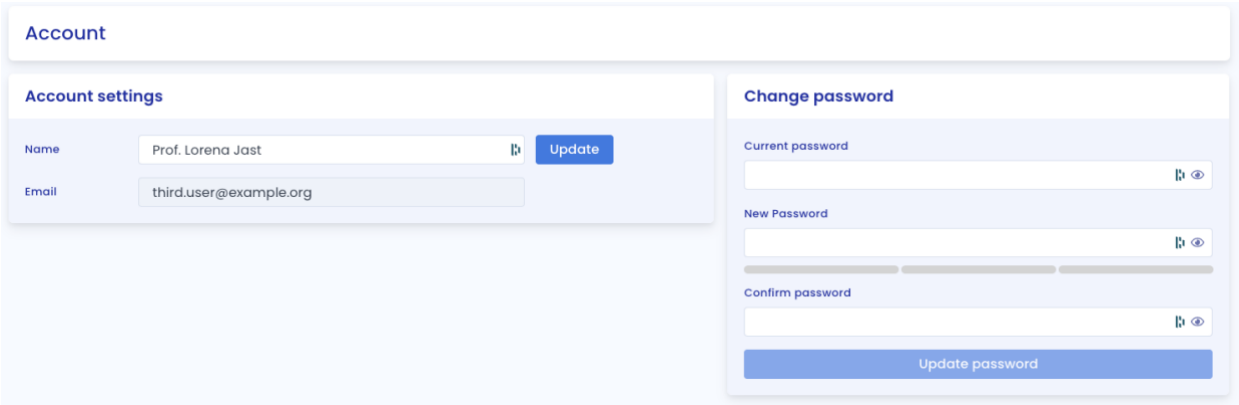
If you have forgotten your password, you can click on "Forgot your password?" on the login page. On the password reset page, enter your email address to receive a reset link. By clicking the link from your email, you will be redirected to a page where you can enter your new password and a confirmation of the password.



Warning: Passwords are personal and confidential. They must not be shared with a third party. They are governed by a confidentiality policy.

Account Setup:

Once logged in, you can go to your personal space in the "Account" tab. Here, you have the option to update account details, including your name and password.



7. Team Management

This module allows healthcare professionals to be part of a (hospital) department. The team owner and members have access to the patients of the team or department. The owner and members of the department have access to the Predigraft reports created for each patient in the department. At the time of subscription, the owner will be assigned to a team.

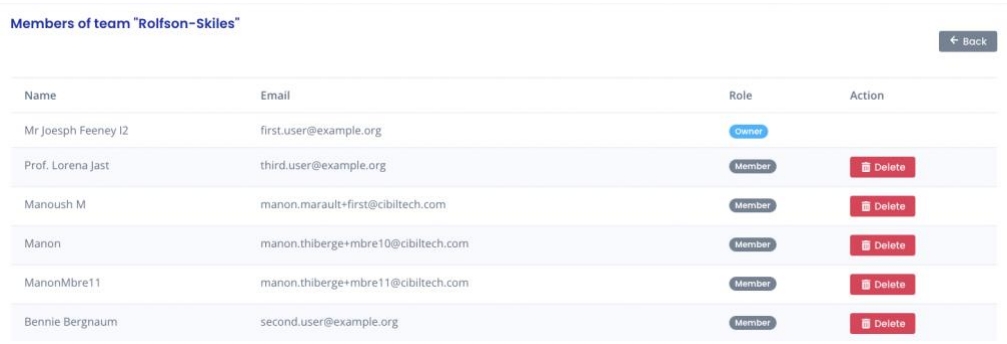
7.1. Team administration

You are a team member

To view the other members of your team, click on your name in the top right corner, click on "My Team" in the drop-down menu, and then click on your team.

On the "Members" page, you can consult the list of team members, including:

- The full name and email address of the member,
- The "owner" badge next to the name of the team owner,
- The "member" badge next to the name of each team member.



You are the team owner

To access the members of your team, click on your name in the top right corner, click on "My Team" in the drop-down menu, and then click on your team.

In the **"Invite to the team"** section you can:

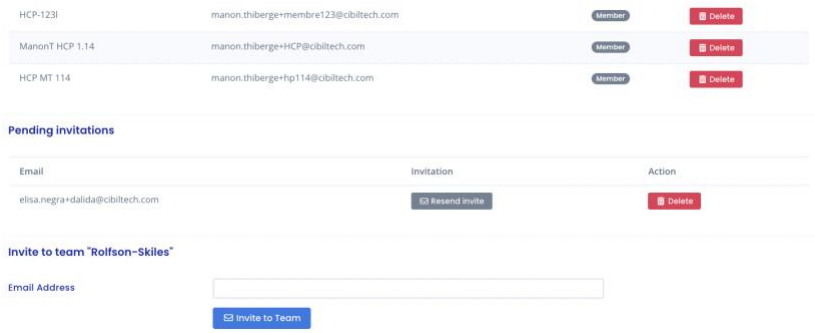
- Enter the email address of a collaborator and click on "send" to send an invitation email to this user. If the user is already part of another team, you cannot invite him/her to an additional team.

In the **"Pending Invitations"** section, you can:

- View the email addresses of all collaborators invited join the team,
- Delete the invitation: the invited collaborator will no longer be allowed to create an account on Predigraft and will not be able to join your team.

In the **"Members"** section, you can consult the list of team members and:

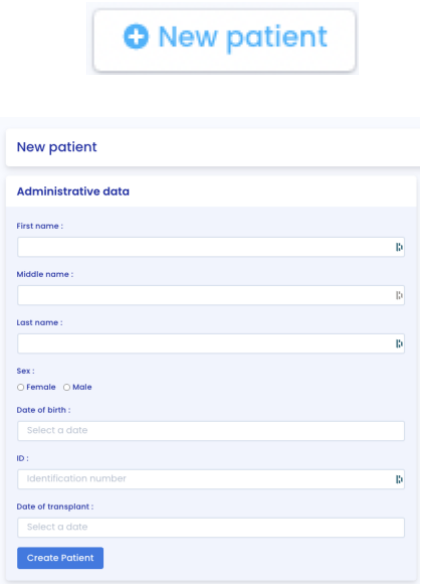
- See the full name and email of the member,
- Click on the "delete" button to remove a member from the list of team members. You cannot remove yourself from the team.



8. Patient Management

8.1. Patient file

8.1.1. Creation of a patient file

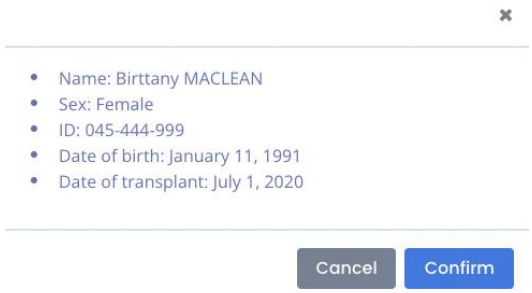


By clicking on the top right button "new patient", the user can create a new patient.

The following information must be completed in order to create the patient record:

- First name,
- Middle name (optional),
- Last name,
- Sex,
- Date of birth,
- ID (must be unique within a team/department),
- Date of transplant.

Click on "Register this patient". A window appears to confirm the information that will be entered into the patient record. Click "Confirm" to create the patient. Click "Cancel" to make changes to the patient information.


Name: Birttany MACLEAN
Sex: Female
ID: 045-444-999
Date of birth: January 11, 1991
Date of transplant: July 1, 2020
Cancel
Confirm

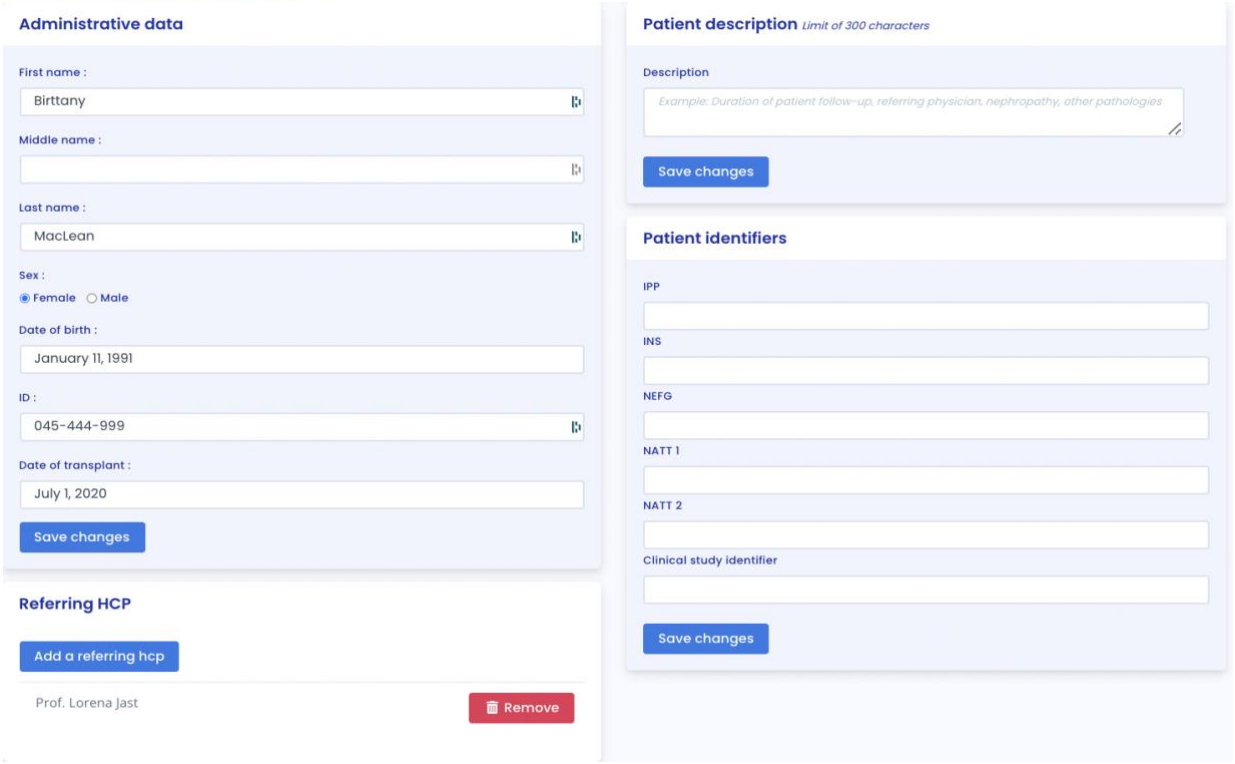
8.1.2. Modification of a patient record

To edit a patient record, click on the patient from the patient list to access his or her record. Click on "Modify" in the title bar. You can modify the following information in the patient record:

- Administrative data:
  - First name,
  - Middle name (optional),
  - Last name,
  - Sex,
  - Date of birth,
  - ID (must be unique within a team/department),
  - Date of transplant.
- Brief patient description:
  - Description (optional).
- Patient ID:
  - PPI (Permanent Patient Identifier),
  - NEFG of the recipient,
  - NATT,
  - INS,
  - Clinical Study Identifier.
- Referring doctor.

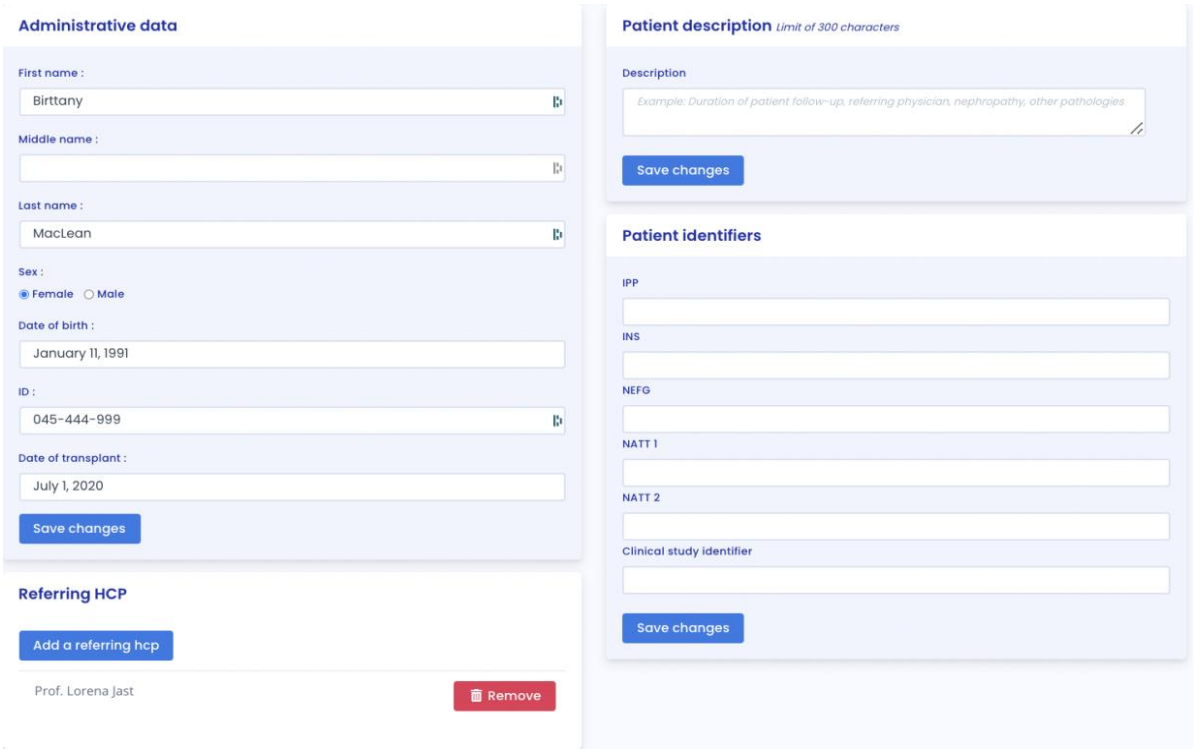
Warning:

- The description field has a limit of 300 characters.
- The IPP field always starts with the number 80 and can contain between 8 and 13 characters.
- The NEFG number field accepts only integer values.
- The NATT number field only accepts integer values.
- The INS number accepts only 15 digits: the first digit can only be 1 or 2 and the 4th and 5th digits can only be between 01 and 12.



In the NATT field you have the option to click "+" to add a second NATT and click "-" to remove it.

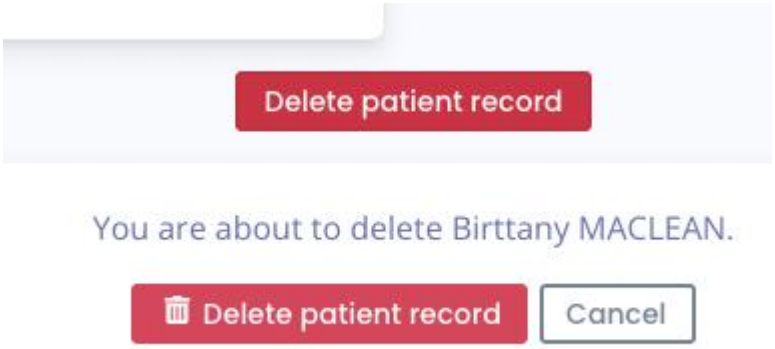
Click on "Save Changes". A window will appear reminding you of the information that will be included in the patient record. Click "Confirm" to apply the changes. Click "Cancel" to continue editing the record. Click on "Save Changes".



8.1.3. Deleting a patient record

To delete a patient record, click on the patient from the patient list to access his or her record.
Click on "Modify" in the title bar.

At the bottom of the Edit Patient Record page, click on "Delete". You must confirm the deletion by pressing the "Delete patient" button.



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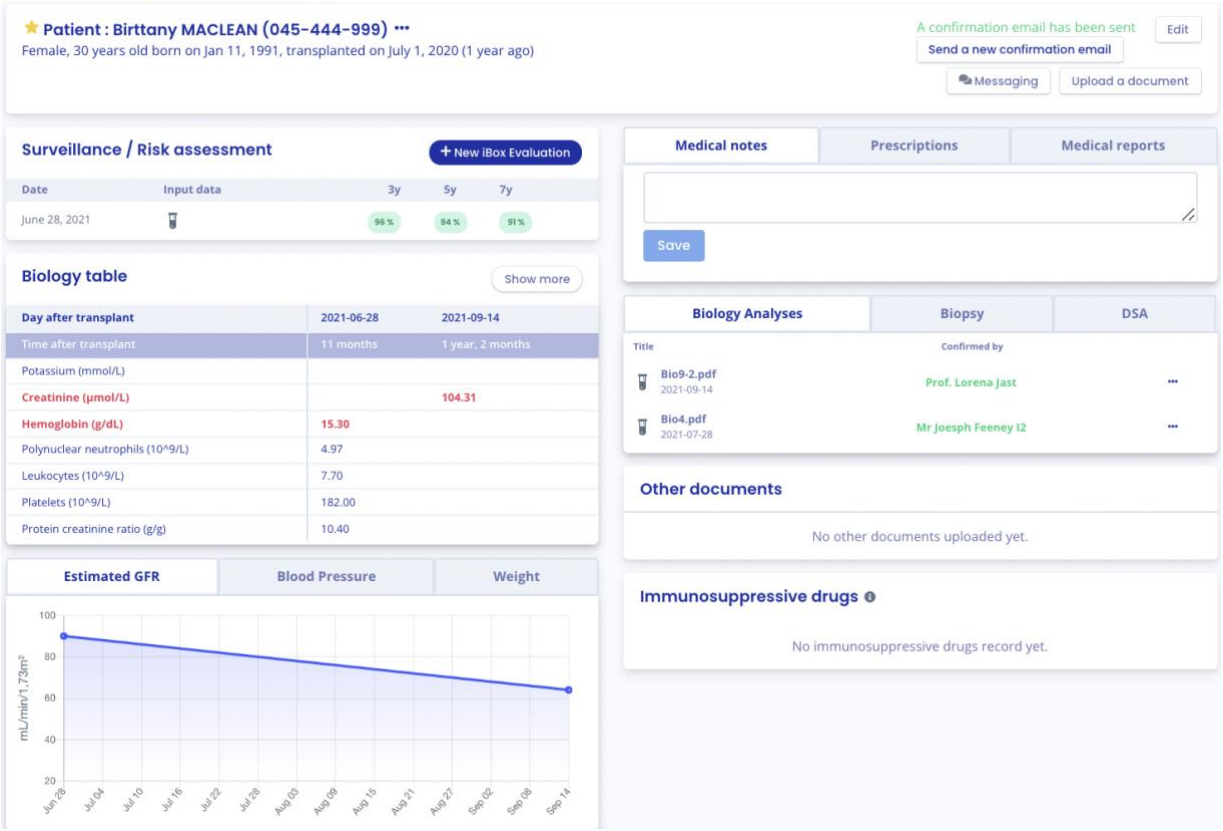
8.2. Managing a patient

Each department has its own patients. The information below is available in the patient file:
- Patient information,
- Messaging,
- Patient alerts,
- Monitoring / Risk Assessment: link to the patient's iBox assessments,
- Estimated glomerular filtration rate (GFR-e) according to MDRD: graphical display of GFR-e values (by default),
- Blood pressure: graphical visualization of blood pressure,
- Weight: graphical visualization of weight,
- Immunosuppressive drugs: visualization graph of immunosuppressive drugs,
- Biological chart,
- Physician's medical notes,
- Prescriptions,
- Reports,
- Biological analyses,
- Biopsy (histological analysis report),
- DSA,
- Other documents.


Patient : Birttany MACLEAN (045-444-999)
Female, 30 years old born on Jan 11, 1991, transplanted on July 1, 2020 (1 year ago)
A confirmation email has been sent
Edit
Send a new confirmation email
Messaging
Upload a document
Surveillance / Risk assessment
+ New iBox Evaluation
Date
Input data
3y
5y
7y
June 28, 2021
96 %
94 %
91 %
Biology table
Show more
Day after transplant
2021-06-28
2021-09-14
Time after transplant
11 months
1 year, 2 months
Potassium (mmol/L)
Creatinine (µmol/L)
104.31
Hemoglobin (g/dL)
15.30
Polynuclear neutrophils (10^9/L)
4.97
Leukocytes (10^9/L)
7.70
Platelets (10^9/L)
182.00
Protein creatinine ratio (g/g)
10.40
Estimated GFR
Blood Pressure
Weight
mL/min/1.73m²
100
80
60
40
20
Jun 28
Jul 04
Jul 10
Jul 16
Jul 22
Jul 28
Aug 03
Aug 09
Aug 15
Aug 21
Aug 27
Sep 02
Sep 08
Sep 14
Medical notes
Prescriptions
Medical reports
Save
Biology Analyses
Biopsy
DSA
Title
Confirmed by
Bio9-2.pdf
2021-09-14
Prof. Lorena Jast
Bio4.pdf
2021-07-28
Mr Joesph Feeney I2
Other documents
No other documents uploaded yet.
Immunosuppressive drugs
No immunosuppressive drugs record yet.

8.2.1. Marking a patient as a starred

In the patient file, this button  located on the top left allows you to add the patient in the "My patients" list or to remove him from this list.

A full star : the patient is in the list "My patients".

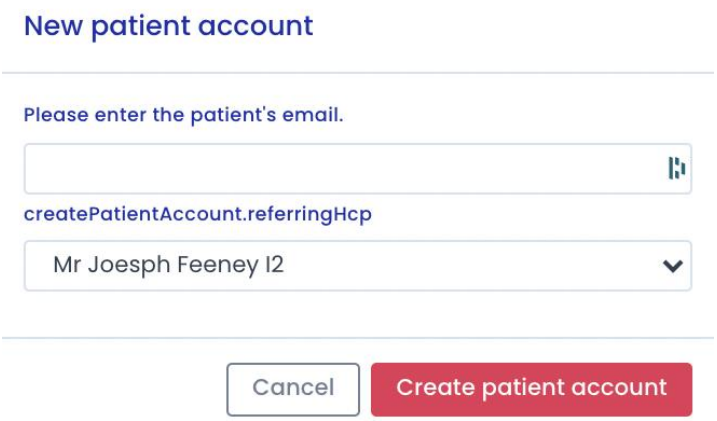
An empty star  : the patient is not in the "My patients" list.

Note: Each user has his own "My patients" list. This list belongs to the user and not to the service. It can also be consulted from the "My patients" button in the main menu on the left (see chapter 12 Managing the "My patients" list).

8.2.2. Granting patient access

From each patient record, you can invite a patient to use the Predigraft patient application.
Click on the "Create a patient account" button in the title bar.

Then fill in the patient's email address.



The button "Create a patient account" is then replaced by the text "A confirmation email has been sent".

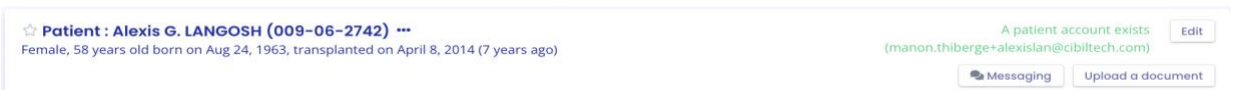
The patient receives an email with the steps to finalize the account creation and confirm the email address.
Once confirmed, the text "A confirmation email has been sent" is replaced with "The patient has an account" and the corresponding patient email address.

Notes:
An error message is displayed when the doctor enters an existing patient email.
To understand the data exchange between the physician interface and the patient interface, see Chapter 14 "Patient Application".
You can send a confirmation email to the patient again if the patient has not received an email. If the patient confirms the email, you cannot change the email address.

8.2.3 Messaging system

You can send messages to your patient through a specialized messaging system. You can access your messaging system from a patient record or from the "Messaging" menu (see the chapter Managing messaging).

From a patient file, click on "Messaging" in the banner of your patient file.

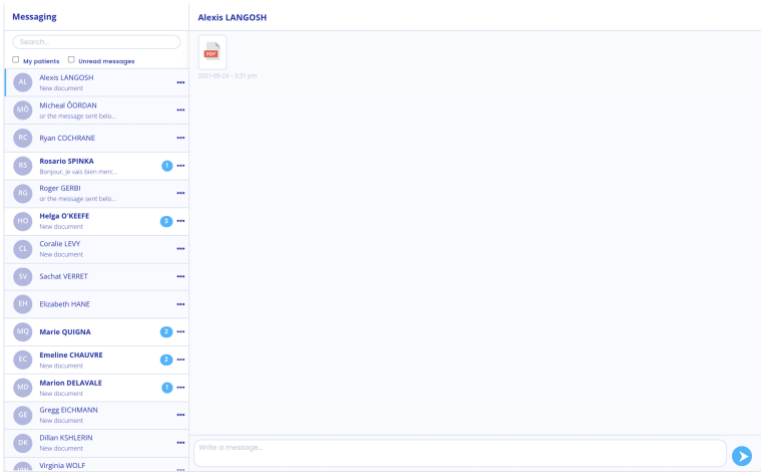


The conversation with your patient is displayed. You can access all the conversations of your patients who have an activated Predigraft account, even those you have never exchanged with before.

You can view only the conversations of your patients in the "My Patients" list by checking the "My Patients" box.

You can display only the unread conversations of your patients by checking the "Unread messages" box.

Note: The "My Patients" filter is enabled by default. The "Unread Messages" filter is disabled by default.



To change the conversation, click on the name of the desired patient. A blue bar will appear on the side, indicating that you are in the conversation.

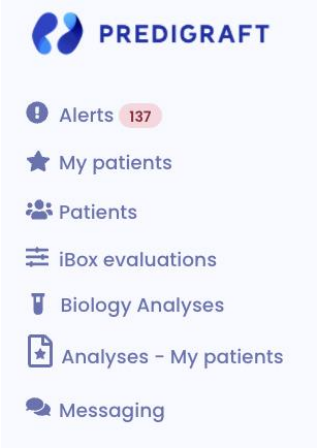
You can also search for a patient by clicking on the search bar at the top left of your message box.

When the patient's name appears in bold, it means that you have an unread message. When you click on it, the patient's name no longer appears in bold.

Note: Conversations are sorted from the most recent message to the oldest.

You can click on the patient's name at the top of the message board to access their patient record.

When one of your patients sends you a message, a red dot in the "Messaging" menu appears. This counter lists the number of unread conversations.



Thus, when you read an initially unread message, the red dot goes down one point.

Warning : If a patient sends you 5 messages, the red dot only takes into account the unread conversation and not the number of unread messages.

When a patient sends you his blood pressure or a weight, this is not considered as a message. The red dot only takes into account the sending of messages and documents.

8.2.4. Alerts

Details of the alerts are available in chapter 16 “Alerts” of this document.

8.2.5. Monitoring/Risk Assessment

By clicking on "New iBox Assessment", you can create an iBox assessment.

The Monitoring/Risk Assessment item lists the patient's iBox assessments. You can click on one of the rows in the list to go to the corresponding iBox assessment.

The date corresponds to the date entered in the first "eGFR" step when the assessment was created.

The data correspond to :

- Biological data. This icon is always present. It corresponds to the report creation steps:

1 and 2 eGFR and proteinuria.

-  Graft-specific anti-HLA antibody (DSA) data. This icon is present if you entered data in step 3 - DSA when creating the report.
-  Histology data. This icon is present if you filled in data in step 4 Histology when creating the report.

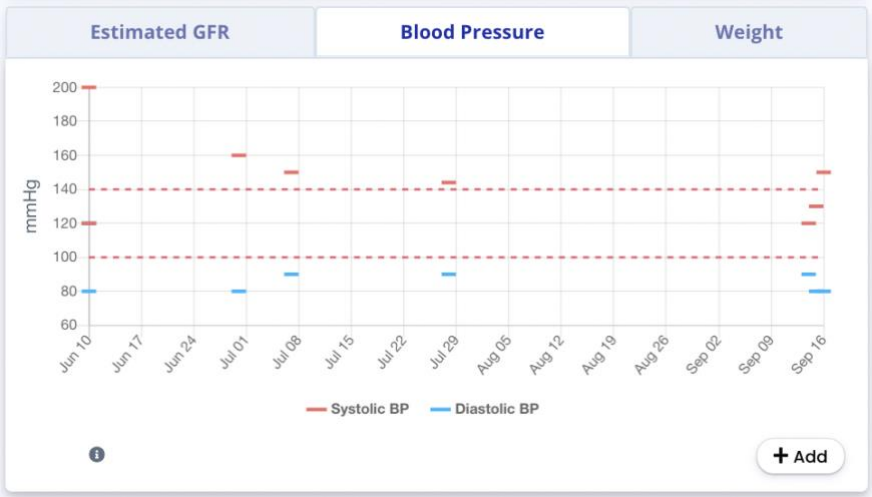
8.2.6. GFR estimated

You can view the Estimated Glomerular Filtration Flow Rate (eGFR) value calculated using the MDRD formula. This value comes from the patient's Predigraft reports, step "eGFR".

You can hover your mouse cursor over the points on the graph to see more detailed information.

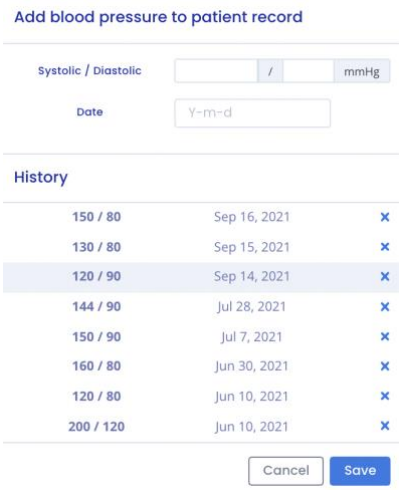
8.2.7. Blood pressure

You can view the patient's systolic and diastolic pressures over time. The dotted red lines are indicative of the recommended minimum and maximum systolic pressure values. You can hover your mouse cursor over the points on the graph to see more detailed information.

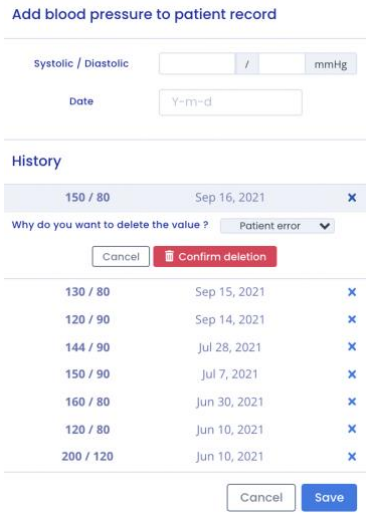


Click the "Add" button to enter systolic and diastolic pressure values for a given date.

By clicking on "Add", you can also delete a blood pressure via the cross on the right.

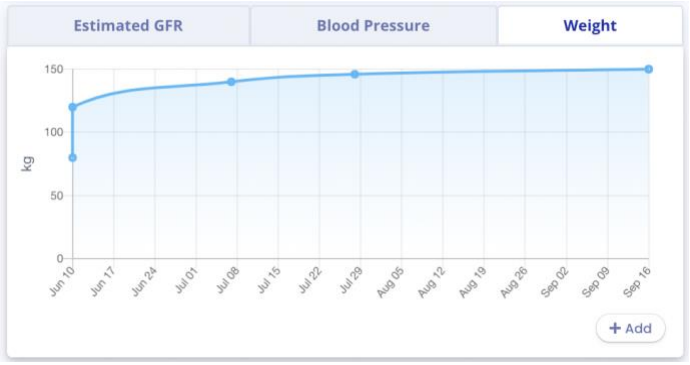


You must indicate the reason for the deletion: Patient Error or Doctor Error, and then confirm the deletion. By default, the reason is "Patient Error."



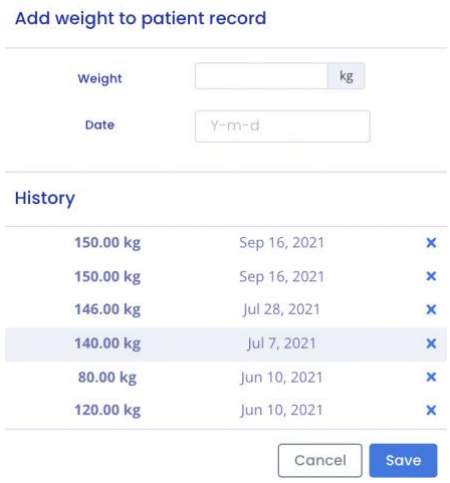
8.2.8. Weight

You can view the patient's weight over time. Hover your mouse cursor over the points on the graph to see more detailed data.

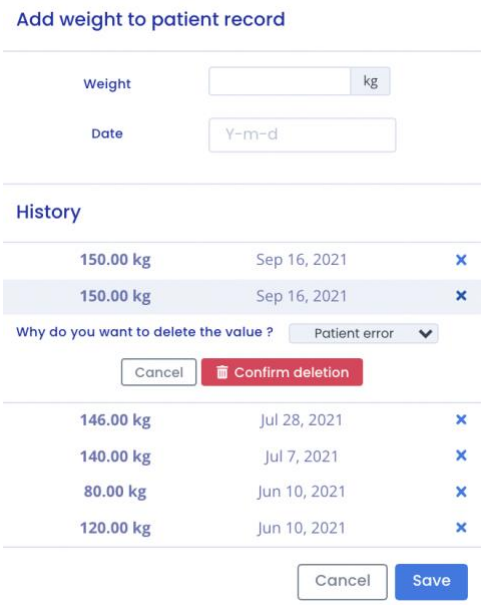


Click on the "Add" button to enter a weight value for a given date.

By clicking on "Add", you can also delete a weight via the cross on the right.



You must indicate the reason for the deletion: Patient error or Doctor error, then confirm the deletion. By default, the reason is "Patient error"."


Add weight to patient record
Weight
kg
Date
Y-m-d
History
150.00 kg
Sep 16, 2021
150.00 kg
Sep 16, 2021
Why do you want to delete the value ?
Patient error
Cancel
Confirm deletion
146.00 kg
Jul 28, 2021
140.00 kg
Jul 7, 2021
80.00 kg
Jun 10, 2021
120.00 kg
Jun 10, 2021
Cancel
Save

8.2.9. Immunosuppressive drugs

You can view the concentrations of immunosuppressive drugs (C_0 Tacrolimus, C_0 Ciclosporin, C_2 Ciclosporin, C_0 Everolimus, C_0 Sirolimus). The dotted red lines indicate the recommended minimum and maximum values for C_0 Tacrolimus.

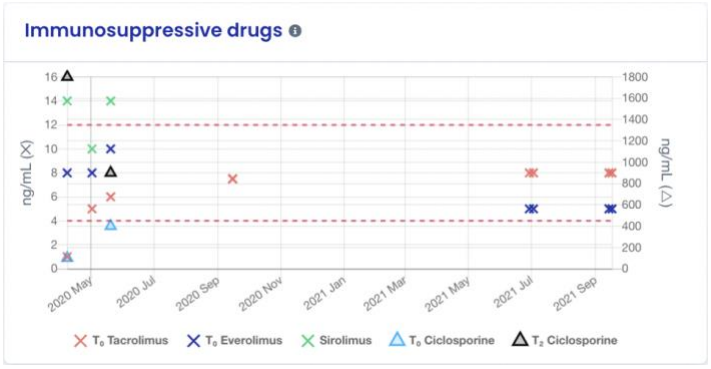
- Patient values corresponding to C_0 Tacrolimus, C_0 Everolimus, C_0 Sirolimus are indicated on the left y axis.

- If the patient has values corresponding to C_0 Cyclosporin, C_2 Cyclosporin, an additional y axis will appear on the right.

You can hover your mouse cursor over the points on the graph to see more detailed data.

The values come from the biological table, you can add more by importing a biological analysis report and validating the data extracted from this report (see chapter 8.2.12 "Biological table").

Example of a patient with T_0 Tacrolimus values:



8.2.10. Mini biological table

From the patient record you can view a mini biological table with seven important data collected from biological analysis reports you have imported:

- Potassium (mmol/L),
- Creatinine (mol/L),
- Hemoglobin (g/dL),
- Polynuclear neutrophils (10^9/L),
- Creatinine protein ratio (g/g),
- Leukocytes (/mm^3),
- Platelets (/mm^3).

8.2.11. Biological table

By clicking on "More" in the mini biological table, you can view all the data collected from biological analysis reports. The entire biological table is composed of different data:
- The date,
- The value filled in with the preview of the biological analysis report next to it,
- The unit of the biological data.

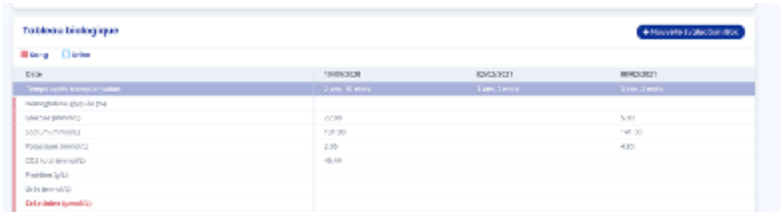
Day after transplant	2018-02-03	2018-02-03	2020-03-20	2020-03-20	2020-04-08	2020-05-02	2020-05-20	2020-08-02
Time after transplant	1 year, 8 months	1 year, 8 months	3 years, 9 months	3 years, 9 months	3 years, 10 months	3 years, 11 months	3 years, 11 months	4 years, 2 months
Associated analysis								
Glycated hemoglobin (%)								
Glucose (mmol/L)					4.92	6.32	4.55	5.09
Sodium (mmol/L)					136.00	141.00	139.00	141.00
Potassium (mmol/L)					4.28	3.90	4.30	4.80
Total CO2 (mmol/L)					21.40	20.00	25.00	
Protein (g/L)					77.10	71.00	61.00	
Urea (mmol/L)								
Creatinine (µmol/L)						161.80		
eGFR (mL/min/1.73m2)			80.00		105.00	37.00	110.00	86.00
Calcium (mmol/L)					2.23	2.50	2.30	
Phosporus (mmol/L)					0.83	0.71	1.22	
Magnesium (mmol/L)								
Uric acid (µmol/L)								
Total bilirubin (µmol/L)						9.06	9.57	
Conjugated bilirubin (µmol/L)							1.71	
ALAT (UI/L)					10.00	15.00	13.00	18.00
ASAT (UI/L)					16.00	15.00	17.00	32.00
Alkaline phosphatase (UI/L)					124.00	86.00	31.00	
Gamma GT (UI/L)					16.30	18.00	17.00	15.00
LDH (UI/L)								

Warning: The data "Creatinine" and "Hemoglobin" are important, so they are shown in red on the screen.

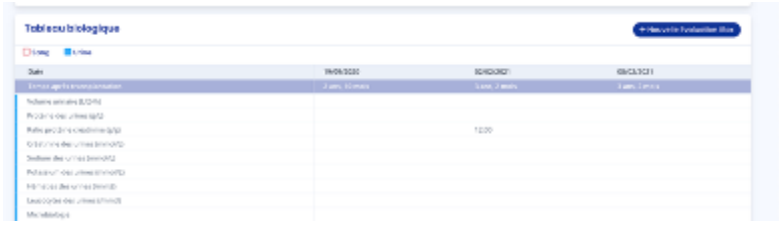
In addition, not all the data (blood and urine) from a biological analysis report are present in this biological table. Here are the data that do not appear in the biological table:
- Chloride,
- Amylase,

- Total cholesterol,
- HDL-cholesterol,
- Dihydroxyvitamin D,
- Prothrombin time,
- APTT (activated partial thromboplastin time),
- Ab antibodies,
- Red blood cells,
- HIV,
- HBV,
- HCV,
- Ciclosporin T0,
- Ciclosporin T2,
- Tacrolimus T0,
- Sirolimus T0,
- Everolimus T0,
- PSA (Prostate Specific Antigen),
- Urea.

If you wish to consult only the hematological data, uncheck the box "Urine".



If you want to see only urine-related data, uncheck the "Blood" box.



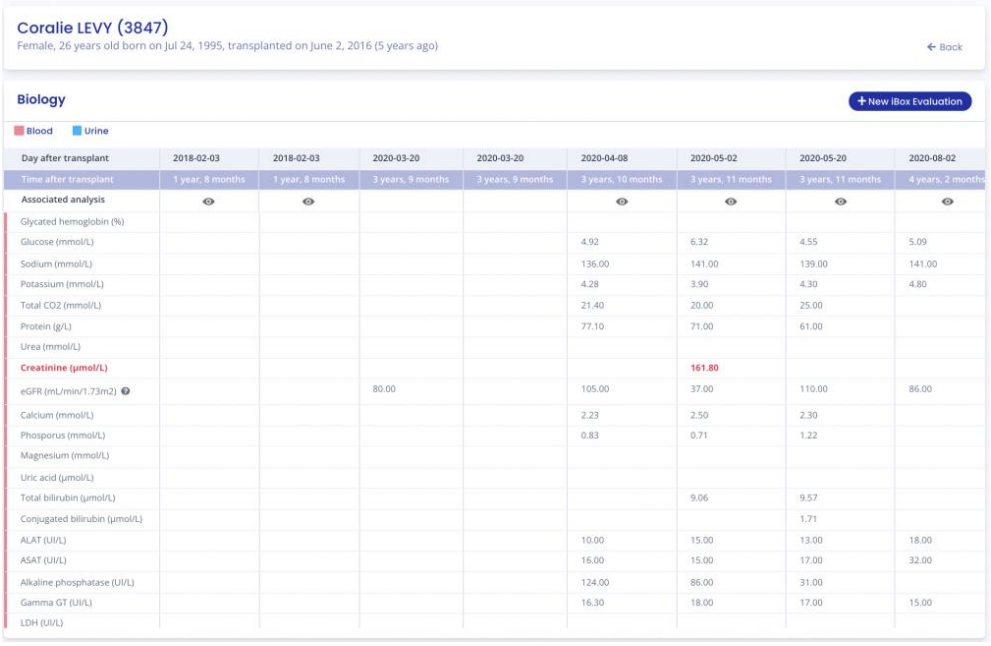
If you want to display the evolution of a specific data in a graphical form, click on the line corresponding to the data. The graph is then displayed at the top of the biological table.

To remove the graph display, you can click on the cross to the right of the graph.

Note: The documents sent by your patient appear in the biological table on the line "associated analysis". If a

document is modified, the document in the biological table is also modified. If a document is deleted, the document in the biological table is also deleted.

Simply press the icon to access the associated analysis.



Day after transplant	2018-02-03	2018-02-03	2020-03-20	2020-03-20	2020-04-08	2020-05-02	2020-05-20	2020-08-02
Time after transplant	1 year, 8 months	1 year, 8 months	3 years, 9 months	3 years, 9 months	3 years, 10 months	3 years, 11 months	3 years, 11 months	4 years, 2 months
Associated analysis								
Glycated hemoglobin (%)								
Glucose (mmol/L)					4.92	6.32	4.55	5.09
Sodium (mmol/L)					136.00	141.00	139.00	141.00
Potassium (mmol/L)					4.28	3.90	4.30	4.80
Total CO2 (mmol/L)					21.40	20.00	25.00	
Protein (g/L)					77.10	71.00	61.00	
Urea (mmol/L)								
Creatinine (µmol/L)						161.80		
eGFR (mL/min/1.73m2)			80.00		105.00	37.00	110.00	86.00
Calcium (mmol/L)					2.23	2.50	2.30	
Phosporus (mmol/L)					0.83	0.71	1.22	
Magnesium (mmol/L)								
Uric acid (µmol/L)								
Total bilirubin (µmol/L)						9.06	9.57	
Conjugated bilirubin (µmol/L)							1.71	
ALAT (UI/L)					10.00	15.00	13.00	18.00
ASAT (UI/L)					16.00	15.00	17.00	32.00
Alkaline phosphatase (UI/L)					124.00	86.00	31.00	
Gamma GT (UI/L)					16.30	18.00	17.00	15.00
LDH (UI/L)								

8.2.12. Medical notes

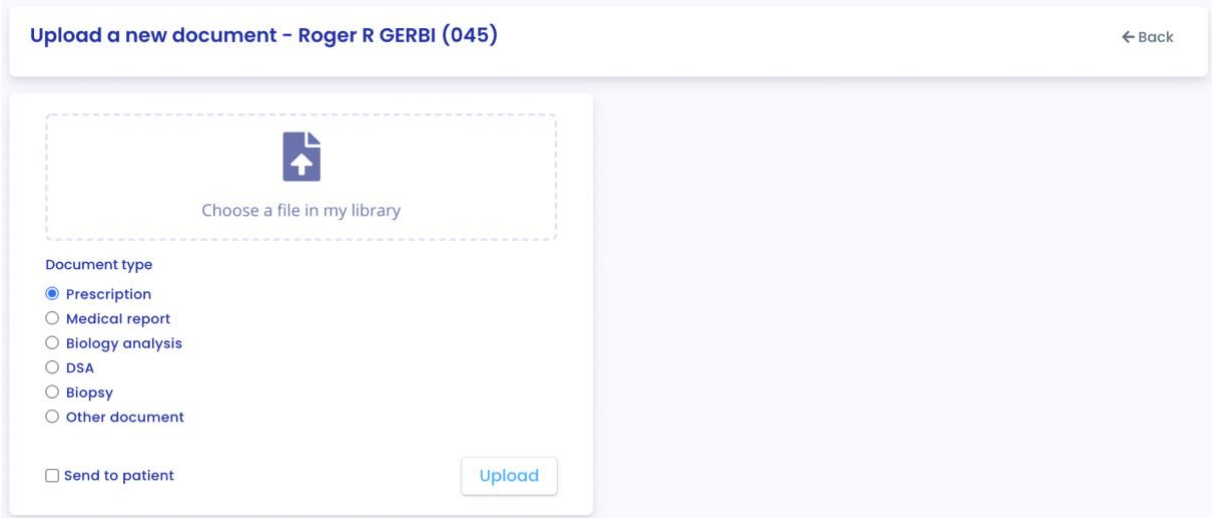
You can add medical notes in the patient record with a maximum of 1500 characters.

When you add a medical note, it is saved and displayed in the medical note history below. Each saved note appears with the date it was saved and the name of the person who wrote the note.
Each healthcare professional can access the note history for each patient on the same team.

Please note: Medical notes cannot be shared and remain confidential. Health professionals can only view them on the patient's file.

8.2.13 Prescriptions

You can add prescriptions in the patient record by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your prescription to import. Select the type of document by checking "Prescription".
You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".



Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

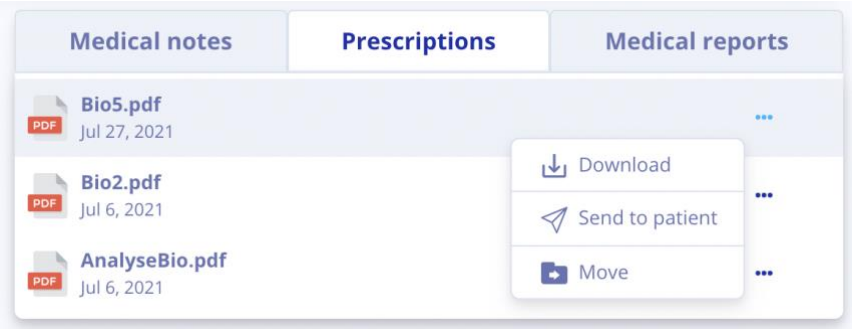
PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported prescriptions, the most recently imported report is at the top of the list.
The list contains the following information:

- Date the document was imported,
- Name of the document.



You can download a prescription or send it to your patient by clicking on the three little dots and selecting "Download" or "Send to patient".

Warning: The "Send to patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You have the possibility to send only the documents you have

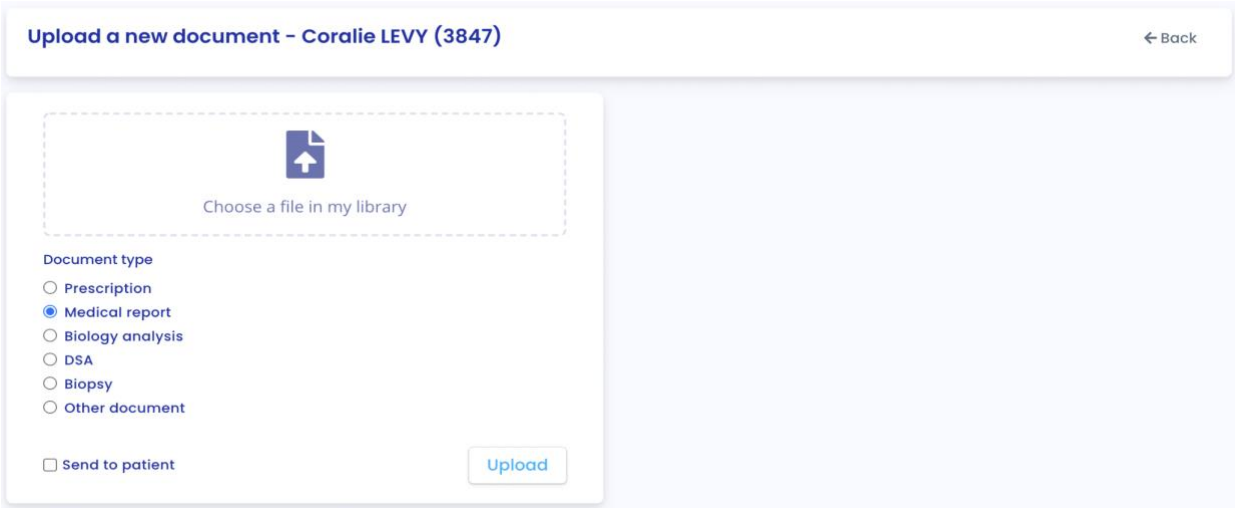
imported.

You can also move a prescription by clicking on the three dots and selecting "Move". By choosing this option, you can then choose a new category:

- Medical report,
- Biological analysis,
- DSA,
- Biopsy,
- Other documents.

8.2.14 Medical reports

You can add reports in the patient record by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your report to import. Select the type of document by checking "Report".
You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".



Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

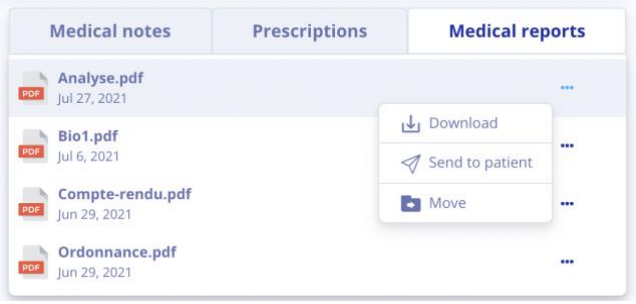
PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported prescriptions, the most recently imported report is at the top of the list.
The list contains the following information:

- Date the document was imported,
- Name of the document.



You can download a report or send it to your patient by clicking on the three small dots and selecting "Download" or "Send to patient".

Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You have the option to send only the documents you have imported.

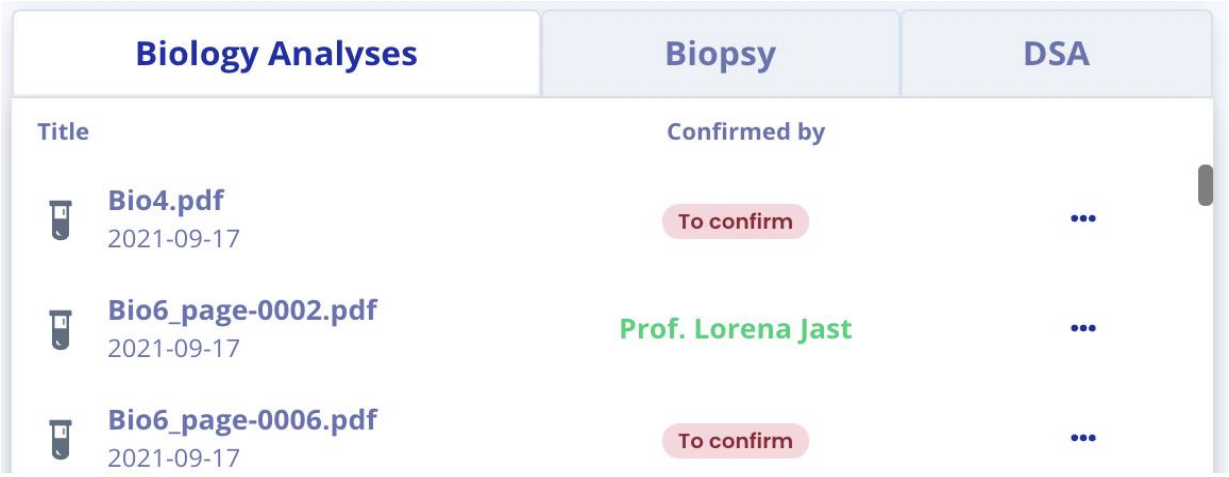
You can also move an order by clicking on the three small dots and selecting "Move". By choosing this option, you can then choose a new category:

- Prescription,
- Biological analysis,
- DSA,
- Biopsy,
- Other documents.

Note: You can view the report by clicking on the line of the document you wish to view. The document will then open in another tab.

8.2.15 Biological analysis

You can view the list of biological analysis reports saved in the patient record.



The date is the date the report was saved in the patient record. The title is the title of the report when it was saved. You can see if the document has been confirmed or not:

- In case of non-confirmation, a "To be confirmed" message appears in the "Confirmed by" column,
- In case of confirmation, the name of the person who confirmed the report appears.

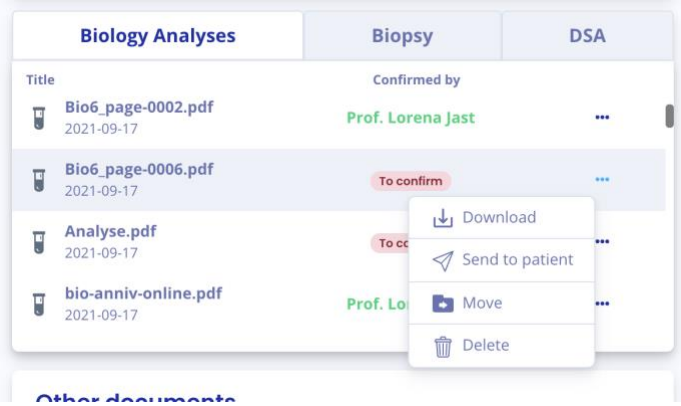
You can delete a biological analysis, provided it has not yet been validated. To do so, click on the three small dots and select "Delete".

You can also download or move the biological analysis by clicking on the three dots and selecting "Download" or "Move". By choosing the option to move a document, you can choose a new category among :

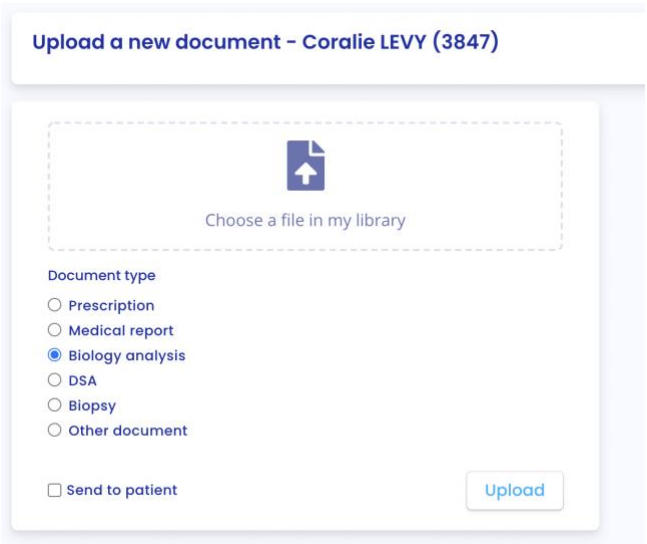
- Prescription,
- Medical report,
- DSA,
- Biopsy,
- Other documents.

You can send a biological analysis to your patient by clicking on the three small dots and selecting "Send to patient".

Please note: The "Send to patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



You can add biological analysis reports by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your biological analysis document to import.
Select the type of document by checking "Biological analysis".
You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".

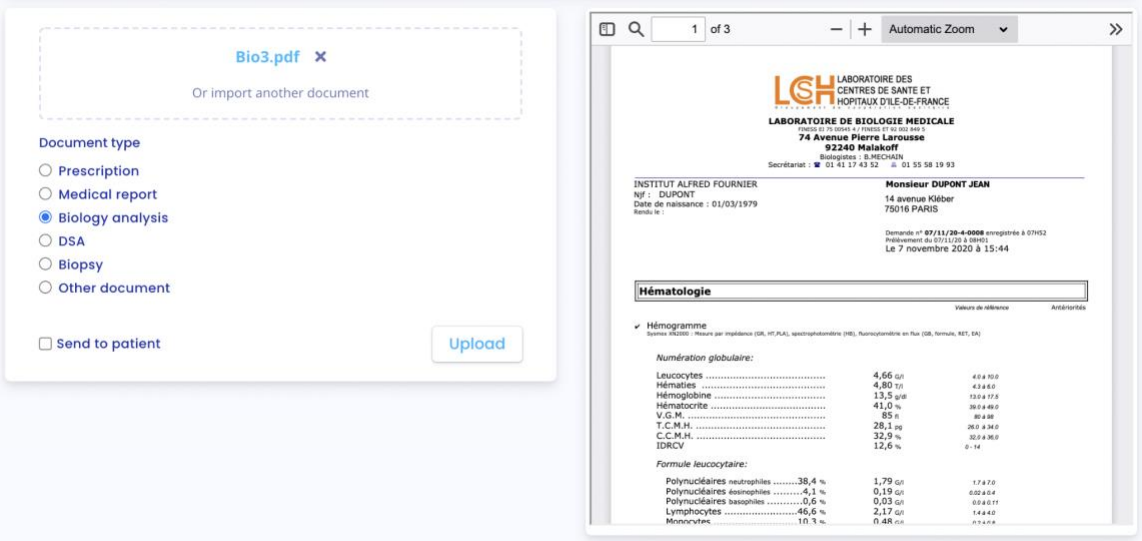


Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

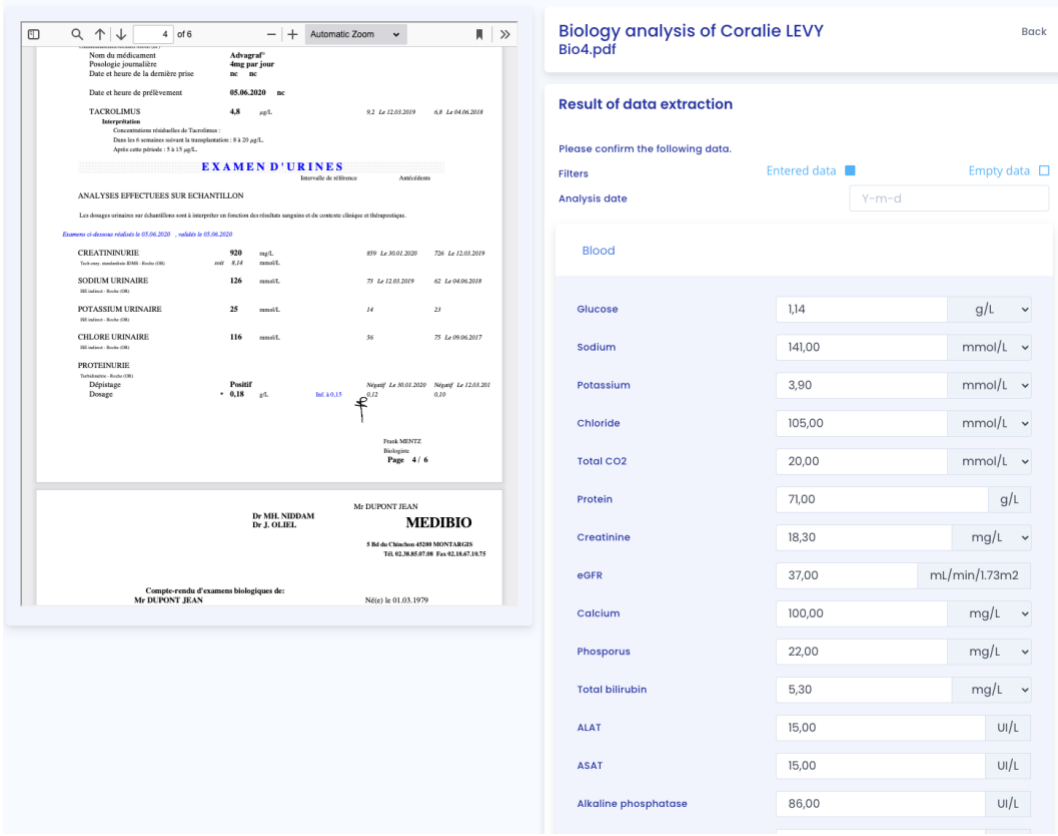


Then click on "Upload" and you will be redirected to a new data validation page.

The data from the biological analysis is analyzed by Predigraft, extracted and grouped into several parts:

- The analysis date,
- A "Blood" part,
- A "Urine" part.

By default, only the data that have been extracted from the biological report are displayed. To add data in the empty fields, click on "Empty data".



You can view all the data of the biological analysis that has been extracted on the right side of the biological analysis report. In case of errors, you can modify the fields (value and unit if available) of the test date, blood data and urine data.
If a data can be recorded in several units, the Predigraft reference unit is the first unit in the list.

You can click on "Save" to save all the data of the biological analysis. In case of inconsistent values during saving, an error message appears. For example:

If the values are recorded successfully, you are redirected to a biological table (see Chapter 8.2.12. "Biological Table").

When you choose a unit different from the reference unit when extracting the biological data, Predigraft records the data in two ways:

- The value as well as the unit you chose,
- The value converted into the reference unit: this value will be displayed in the biological table (for more information on the reference units of the biological table see Appendix 3 of this document).

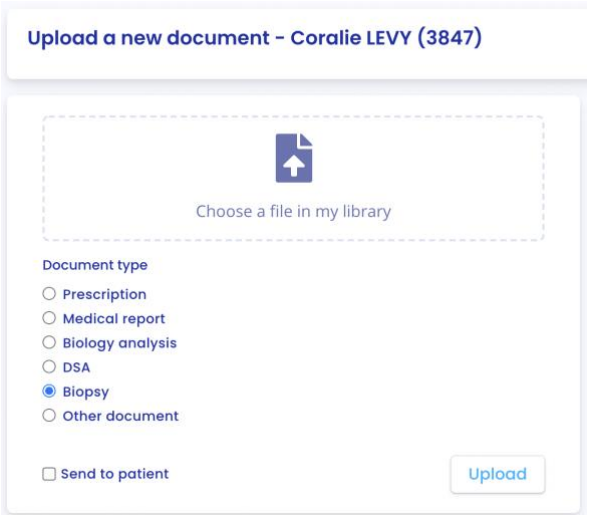
Warning: The data entered in the biological table may differ from the values entered during the extraction due to the choice of the unit.

To modify the values of the extraction of the biological analysis report after recording, from the patient file, click on the corresponding biological analysis report in the list "Biological Analyses". The analysis report opens and you can modify the values.

8.2.16 Biopsy

You can view the list of biopsy reports imported by members of your department.

You can add biopsy reports by clicking on "Import a document" in the patient record banner, you are then redirected to a new page where you can choose your biopsy to import. Select the type of document by checking "Biopsy".
You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".



Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported biopsy reports, the most recently imported report is at the top of the list.
The list contains the following information:

- Date of the document import,
- Type: histological analysis,
- Name of the document.

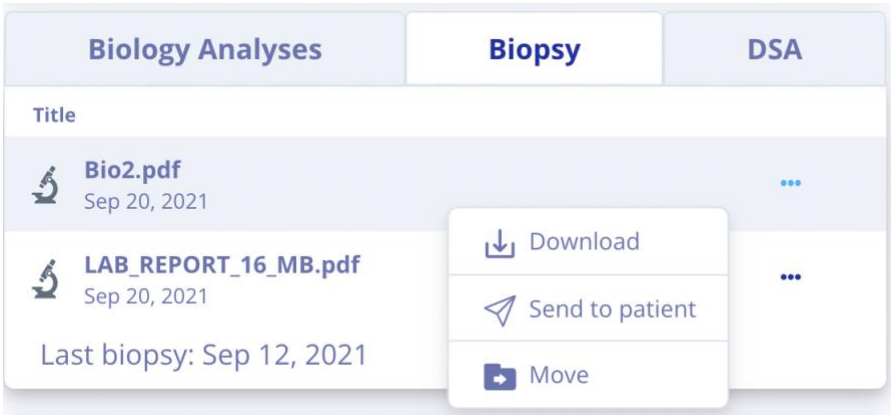
You can download a biopsy by clicking on the three small dots and selecting "Download".
You can also move a biopsy by clicking on the three small dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescription,
- Medical report,
- Biological analysis,
- DSA,
- Other documents.

You can send a biopsy to your patient by clicking on the three small dots and selecting "Send to patient".

Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.

Note: You can view the biopsy by clicking on the line of the document you wish to view. The document will then open in another tab.



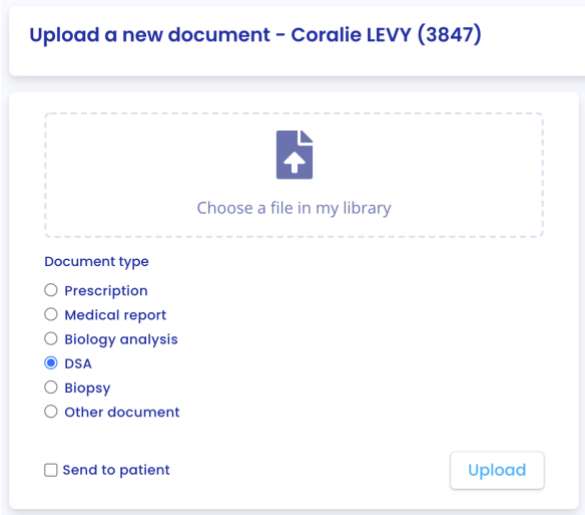
8.2.17 DSA

You can view the list of DSA reports saved in the patient record.

The date is the date the DSA report was saved in the patient record.

The title is the title of the DSA report when it is saved.

You can add DSA reports by clicking on "Import a document" in the patient record banner, you are then redirected to a new page where you can choose your document to import. Select the type of document by checking "DSA".
You have the possibility to share this file with your patient, to do so check the box "Send to patient".

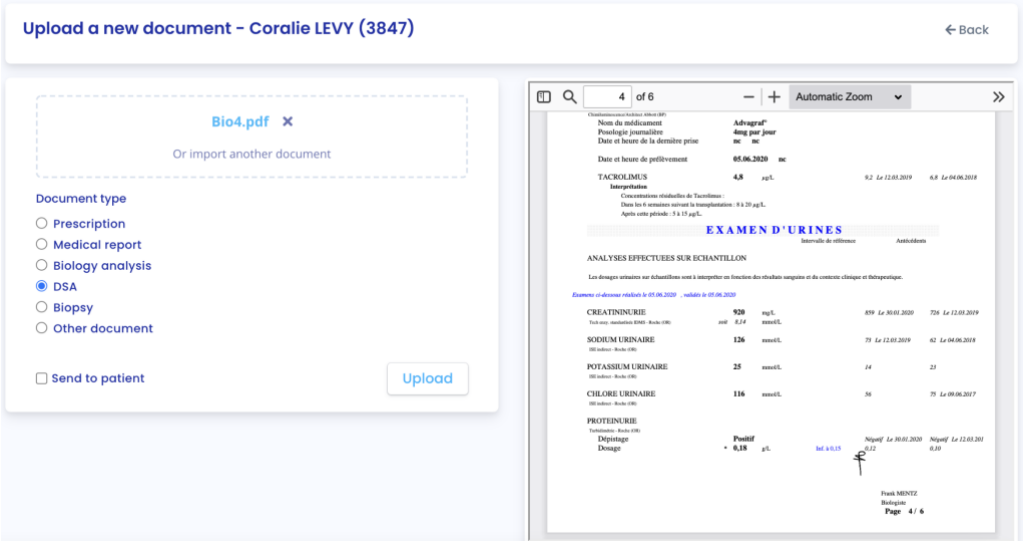


Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.



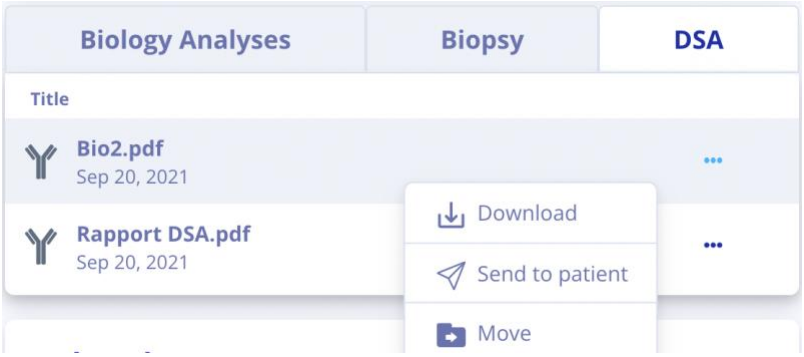
Then click on "Import", you are redirected to the patient record, you can then view the DSA report.

You can download a DSA report by clicking on the three small dots and selecting "Download".
You can also move a DSA report by clicking on the three dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescriptions,
- Medical report,
- Biological analysis,
- Biopsy,
- Other documents.

You can send a DSA report to your patient by clicking on the three small dots and selecting "Send to Patient".

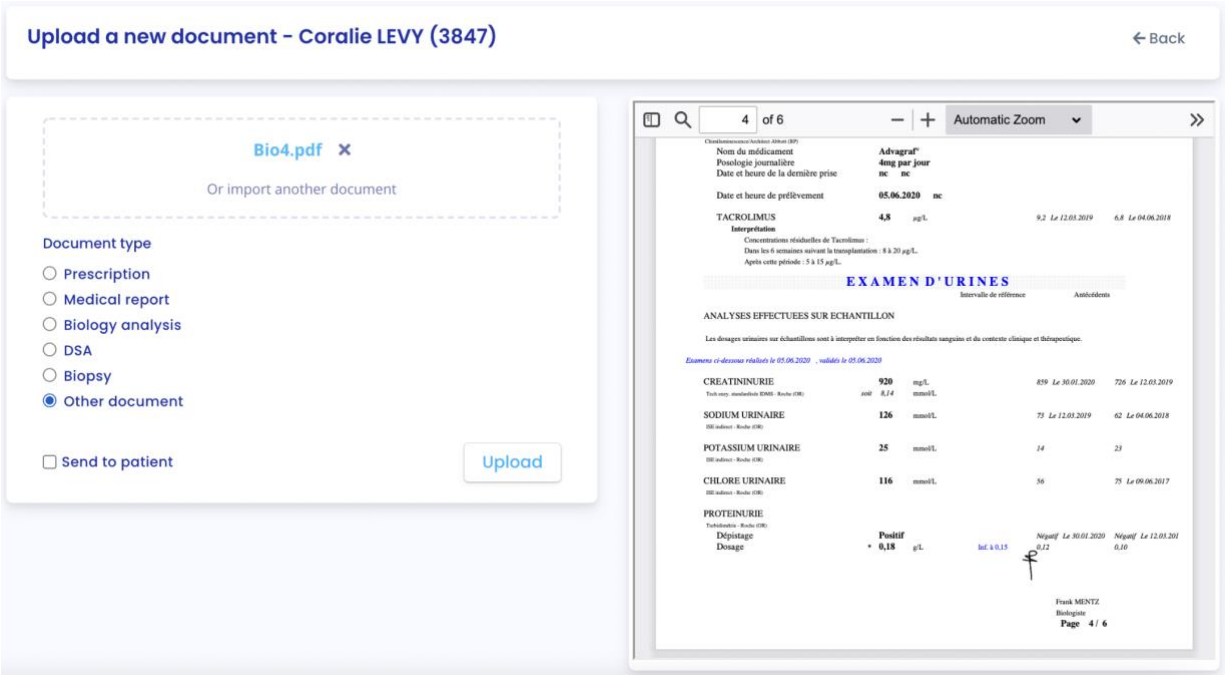
Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



Note: You can view the DSA report by clicking on the row of the document you wish to view. The document will then open in another tab.

8.2.18 Other documents

You can add other documents by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your document to import. Select the type of document by checking "Other document".
You have the possibility to share this file with your patient, to do so check the box "Send to patient".



Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

PDF documents must not exceed 20 MB.

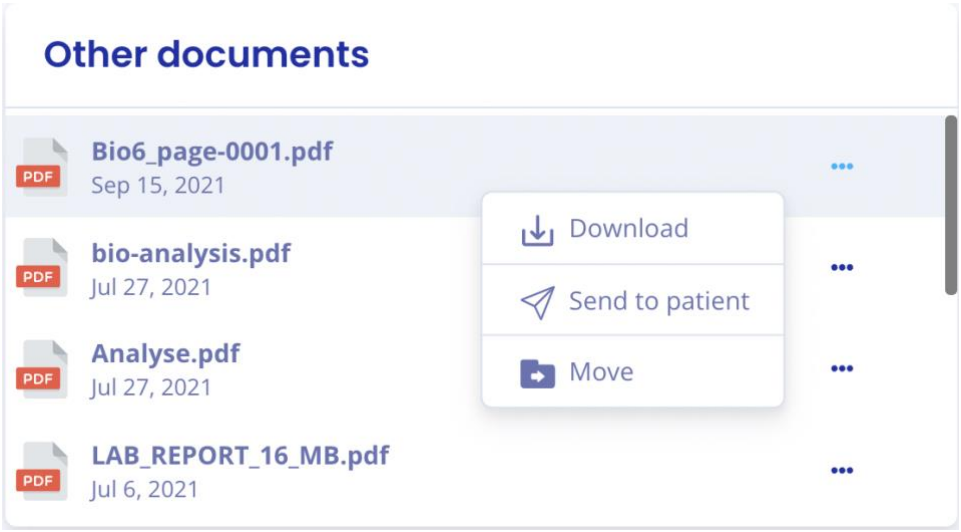
The selected document is displayed on the right.

You can upload a document in the "Other Documents" category by clicking on the three small dots and selecting "Upload".
You can also move a document by clicking on the three dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescription,
- Medical report,
- Biological analysis,
- DSA,
- Biopsy.

You can send a document to your patient by clicking on the three small dots and selecting "Send to patient".

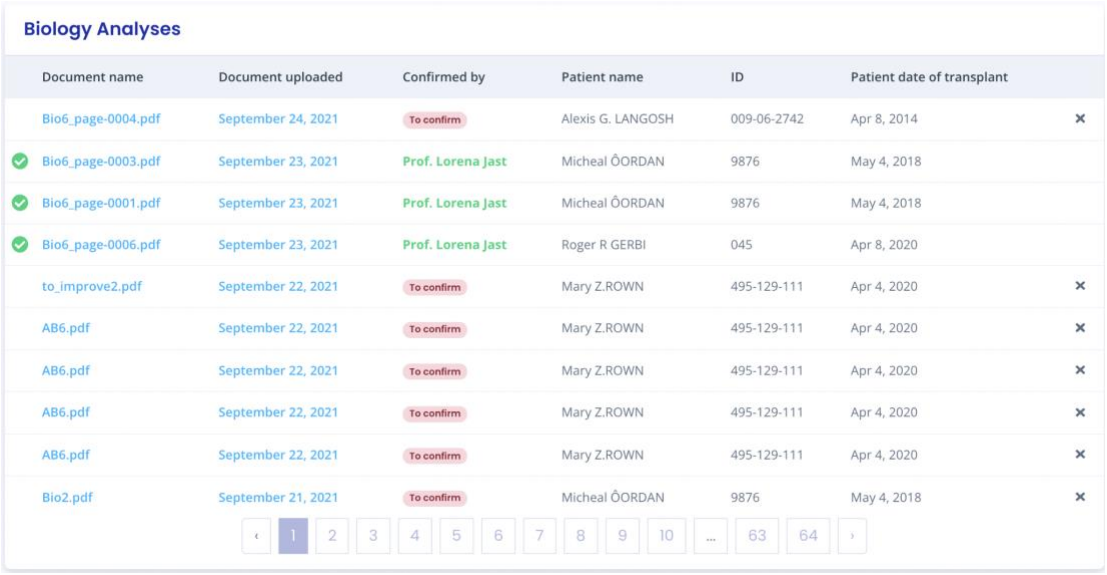
Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



Note: You can view the document by clicking on the line of the document you wish to view. The document will then open in another tab.

9. Biological analysis management

Click on "Bioanalysis" in the main menu on the left to view a list of the bioanalysis reports you have imported, as well as the bioanalysis reports sent by patients in the department via the Patient Application.

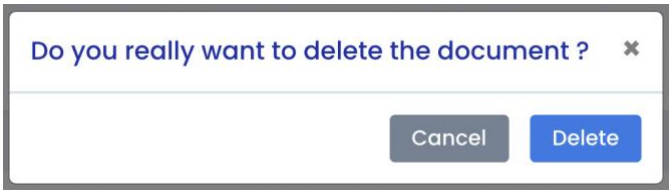


Biological analysis reports are sorted in antechronological order: the most recently imported report appears first.

The list of documents contains the following information:

- A logo indicating whether the biological analysis data has been validated,
- The name of the biological analysis report,
- The date the biological analysis report was received,
- The person who validated the biology report data,
- The patient to whom the Biology Report belongs,
- The patient's ID,
- The patient's transplant date.

You have the possibility to delete a biological analysis from this list by clicking on the cross on the right. A confirmation window appears.



10. Management of biological analyses in "My Patients" list

Click on "Analysis - My Patients" in the main menu on the left to display the list of bioanalysis reports from your "My Patients" list that you have imported, as well as the bioanalysis reports sent by patients from your "My Patients" list via the patient application.

The biological analyses reports are sorted in chronological order: the most recently imported report appears first.

The document list contains the following information:

- The name of the biological analysis report,
- The date of receipt of the biological analysis report,
- The person who validated the data in the Biology Report,
- The patient to whom the Biology Report belongs,
- The patient's ID,
- The patient's transplant date.

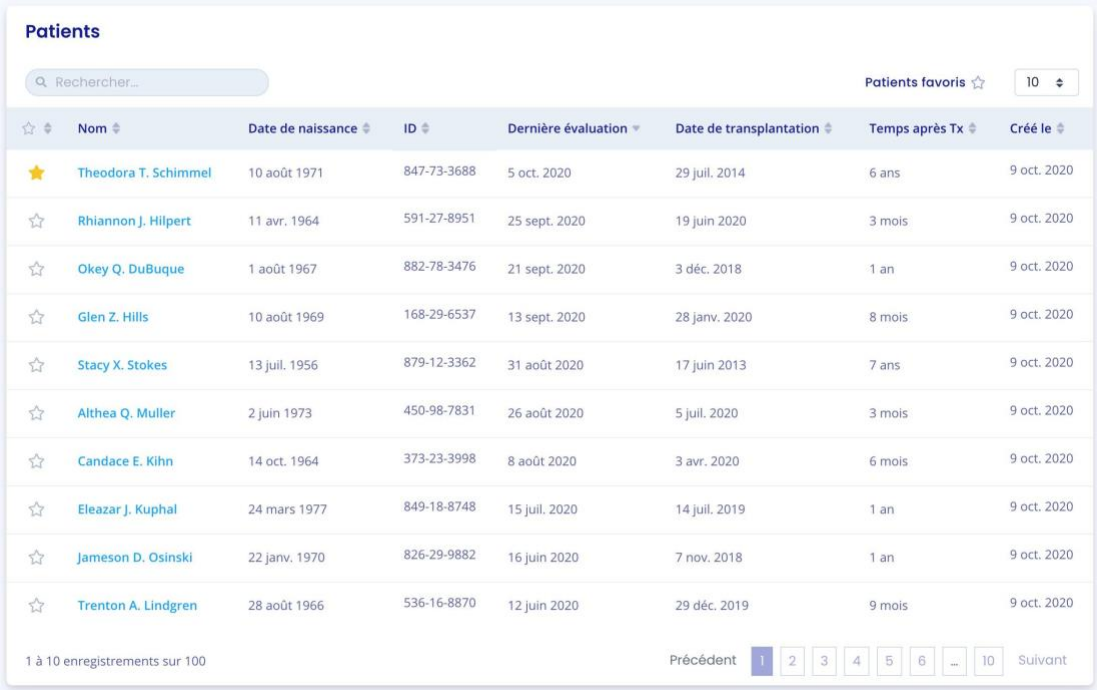
You have the possibility to delete a biological analysis from this list by clicking on the cross on the right. A confirmation window appears.

11. Patient list management

Click on "Patients" in the main menu on the left to view a list of patients in the team/department. The list contains the following information:

- A clickable star to add the patient to the list of favorites,
- Patient's full name,
- Patient's date of birth,
- Patient ID,
- Last evaluation date (indicated in Step 2, eGFR when creating a Predigraft report),
- Date of transplant,
- Patient account (if the account is activated, pending or not invited),
- Date of creation of the patient file.

When the page loads, the list is ordered by the last evaluation date column.



11.1 Search options:

In the search field, you can enter:

- All or part of the patient's name,
- All or part of an ID,
- A date (corresponding to the columns "Last evaluation", "Transplant date", "Created on") in the format dd/mm/yyyy or /mm or /yyyy.

The list of patients corresponding to the entry is displayed by pressing the "Enter" key on your keyboard.

Note: The search function does not apply to the "Time after Tx" column.

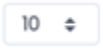
11.2 List of favorites:

Click on  to add the patient to your favorites. Click  to remove the patient from the favorites.

Click 

to display the list of patients saved in the favorites list.

11.3 Display filter:

Click the scroll box on the top right  to change the number of patients displayed on a page. You can display 10, 25, 50, or 100 patients.

Patients

Rechercher...

Patients favoris 10

Nom	Date de naissance	ID	Dernière évaluation	Date de transplantation	Temps après Tx	Créé le
Theodora T. Schimmel	10 août 1971	847-73-3688	5 oct. 2020	29 juil. 2014	6 ans	9 oct. 2020
Carleton A. Gislason	4 sept. 1973	801-62-7750	24 déc. 2019	6 nov. 2014	5 ans	9 oct. 2020
Alessandro G. McCullough	26 juil. 1980	161-11-6771	23 oct. 2019	6 mai 2012	8 ans	9 oct. 2020
Isaiah V. Rath	4 janv. 1978	857-05-2042	15 sept. 2018	8 juin 2017	3 ans	9 oct. 2020
Woodrow H. Leannon	20 oct. 1952	428-60-5016	26 août 2018	14 déc. 2016	3 ans	9 oct. 2020
Ozella F. Cummerata	12 janv. 1969	598-15-1010	25 avr. 2018	16 oct. 2010	9 ans	9 oct. 2020
Edwina G. Batz	3 mai 1953	608-80-0622	16 juin 2017	1 sept. 2011	9 ans	9 oct. 2020
Lexie G. Lynch	11 mai 1980	467-67-5323	30 avr. 2017	8 août 2016	4 ans	9 oct. 2020
Sandra V. Douglas	6 juil. 1957	743-40-3428	18 janv. 2017	2 oct. 2014	6 ans	9 oct. 2020
Agustina O. Macejkovic	27 janv. 1956	017-99-9228	29 déc. 2015	25 août 2015	5 ans	9 oct. 2020

1 à 10 enregistrements sur 10 (filtré parmi 100)

Précédent 1 Suivant

11.4 Order the list:

Click on the column header to change whether the list is displayed in ascending or descending order.

Example: Order names in ascending alphabetical order.

A second click on the Name column allows you to order the list in descending order.

11.5 Browse the list:

To browse the list, click on one of the numbers, "Previous" or "Next" from the list.

12. Managing the "My Patients" list

Click on "My Patients" in the main menu on the left to display the list of patients with . The list contains the following information:

- Clickable star to remove the patient from the "My Patients" list,
- Patient's full name,
- Patient's date of birth,
- Patient's ID number,
- Last date of assessment (most recent date of step 2, eGFR when creating an iBox assessment),
- Date of transplantation,
- Patient account (if the account is activated, pending or not invited),
- Date of creation of the patient record.

Note: As soon as some of your patients are added to this list, you will be automatically redirected to this list when you connect to Predigraft.

12.1 Display filter

Click on to change the number of patients displayed on a page. You can display 10, 25, 50 or 100 patients.

12.2 Ordering the list

Click on the column header to change the display order, ascending or descending, of the list.

Example:
Order the names in ascending order.

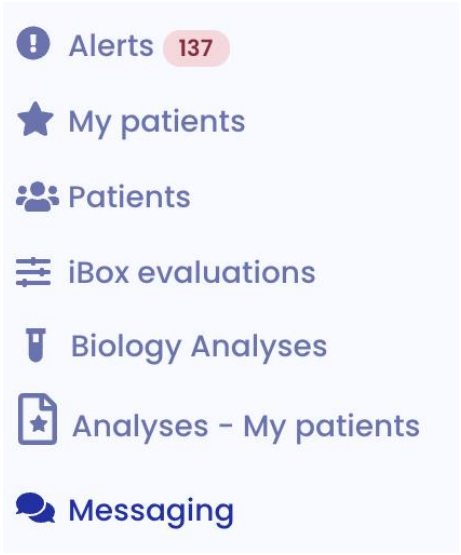
A second click on the Name column allows you to order the list in descending order.

12.4 Browse the list

To browse the list, click on one of the numbers, "Previous" or "Next".

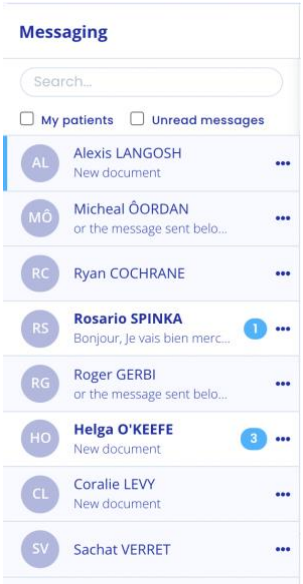
13. Messaging system management

You can also access the messaging system from the "Messaging" menu. Click on "Messaging" in the menu on the left.



When one of your patients sends you a message, a red dot in the "Messaging" menu appears. This counter lists the number of unread conversations. A second blue counter appears in each of your unread conversations and allows you to know the number of unread messages per conversation.
Thus, when you read an initially unread message, the red dot goes down one point.

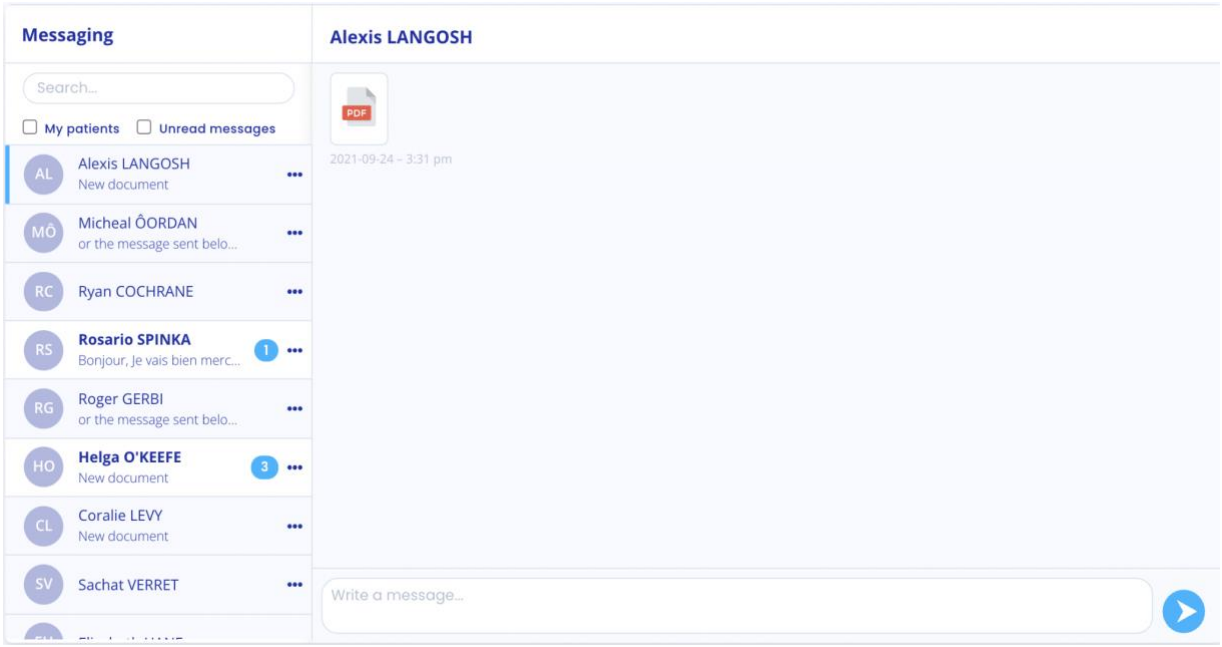
Warning: If a patient sends you 5 messages, the red dot only takes into account the unread conversation and not the number of unread messages. The unread messages per conversation will be indicated by a blue dot next to the conversation.
Adding a weight or blood pressure by your patient is not considered a notification. The red dot is therefore only triggered by a new message or document sent by your patient.



The most recent conversation is displayed. You can access all the conversations of your patients with an activated Predigraft account, even those with whom you have never exchanged before.

You can view only the conversations of your patients in the "My Patients" list by checking the "My Patients" box.

Note: The "My Patients" filter is enabled by default.



To change the conversation, click on the name of the desired patient. A blue bar will appear on the side indicating that you are on the conversation.

You can also search for a patient by clicking on the search bar at the top left of your mailbox.

When the patient's name appears in bold, it means that you have an unread message. When you click on it, the patient's name no longer appears in bold.

Note: Conversations are sorted from the most recent message to the oldest.

Note: You can view a document by clicking on the icon of the document you wish to view. The document will open in a new tab.

14. Report generation

To create a Predigraft report:

- Select a patient from the list to open his or her record.

If the patient has an account on the Predigraft Patient Application and has uploaded biological analysis reports, you can view one of these documents when you create a Predigraft report:

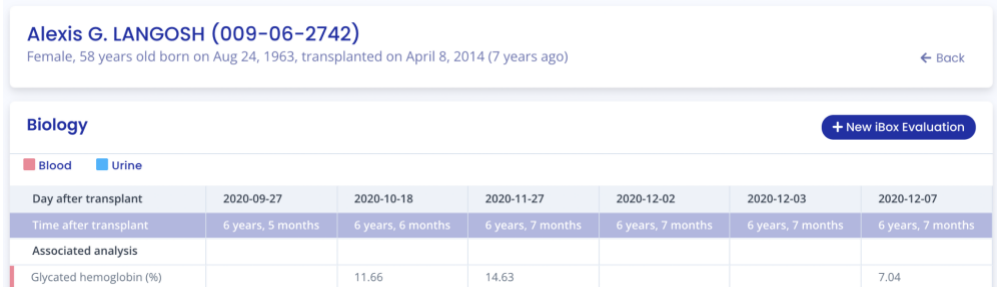
- From the patient record, in the "Analysis reports" item, click on the "+" button of the biological analysis report you want to view.

You can also create a Predigraft report without viewing patient documents:

- From the patient record, click on the "New report" button of the Monitoring / Risk Assessment item.

You will then be directed to the page "New Predigraft report".

You can also generate a new iBox evaluation from the biological table. To do so, click on "Biological Table" and then on the "New iBox Evaluation" button located at the top right of the table.



14.1 Creating a report

Fill out all required fields in the form in order to proceed to the next step.

1. Estimated glomerular filtration flow rate value (eGFR)
2. Proteinuria value
3. DSA value if available, if not check "Not available".
4. Histology information if available, if not check "Not available".

If you have chosen to create an iBox assessment for a patient who does not have imported biology reports, click "Not Available" in the drop-down list :

For steps 1 and 2, you can fill in the following patient information:

- GFR-e,
- Proteinuria.

For step 3, you fill in the patient's DSA information. If you do not have this information, you can check the "Not available" box.

For step 4, you can click in the empty field on the left side of the report creation if you want to import a histology report from your computer and view it next to the form. You can save the histology report to the patient record. Then you can fill in the patient's histology information. If you do not have this information, you can check the "Not available" box.

If you chose to create an iBox evaluation for a patient who has imported biology reports:

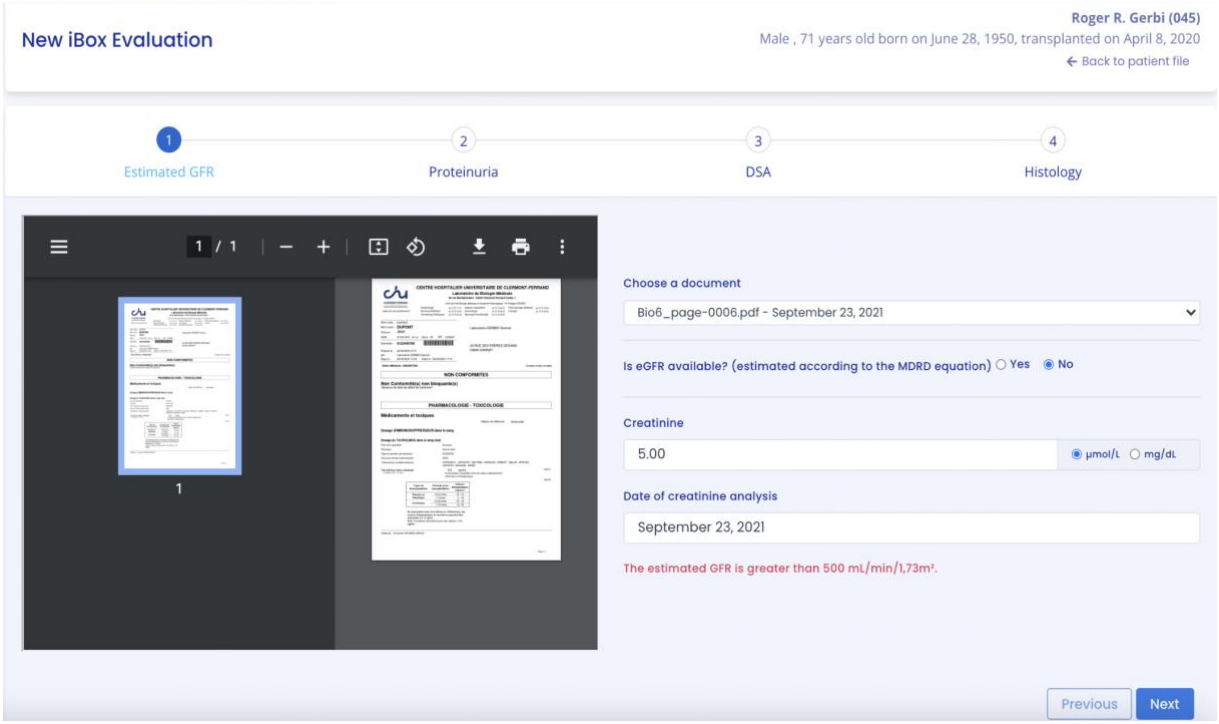
For steps 1 and 2, the biological analysis document displays on the left side of the report creation. You can fill in the following patient information:

- GFR-e,
- Proteinuria.

Warning: The biological analysis report with the most recent date is displayed by default. To choose another report, please click on the arrow, a drop-down menu appears with all the biological analysis reports related to the patient.

Note: The biological analysis reports that you can display are the reports for which the data extracted at the import have been validated. If you have validated the following data, it will already be pre-populated automatically during steps 1 and 2 of the iBox assessment creation:

- GFR date,
- The estimated GFR,
- The creatinine level in the blood,
- Proteinuria date,
- Protein to creatinine ratio in urine
- The creatinine level in urine,
- Protein level in urine.



For step 3, you fill in the DSA information you have about the patient. If you do not have this information, you can check the "Not available" box.

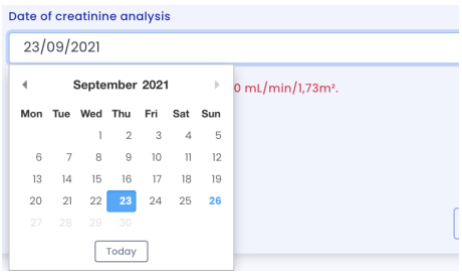
For step 4, you can click in the empty field on the left side of the report creation if you want to import a histology report from your computer and view it next to the form. You can save the histology report to the patient record. Then you can fill in the patient's histology information. If you do not have this information, you can check the "Not available" box.

- Dates

The dates of steps 1, 2, 3 and 4 are mandatory. They cannot be earlier than the date of transplantation. In order to help you enter this information, you have access to a calendar where you can click on the corresponding date:

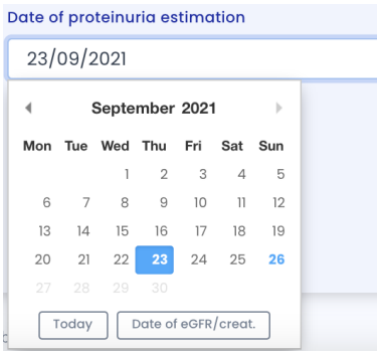
During the 1st step, you can click on :

- A date on the calendar,
- The "Today" button.

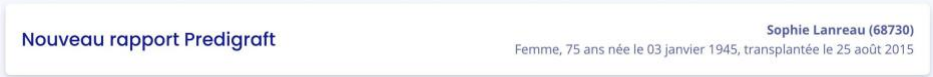


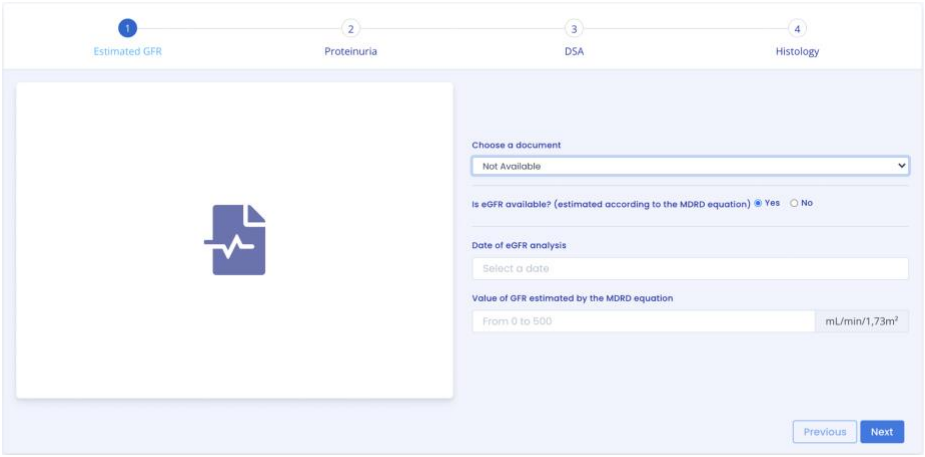
In steps 2, 3 and 4, you can click on :

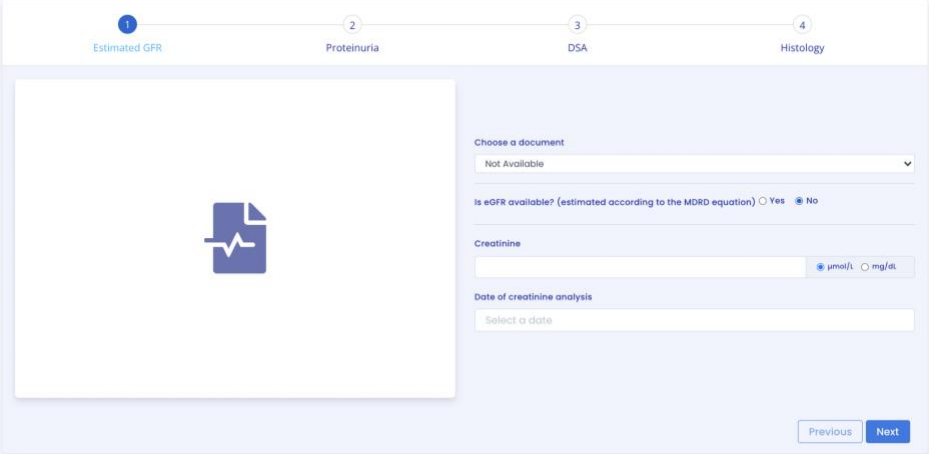
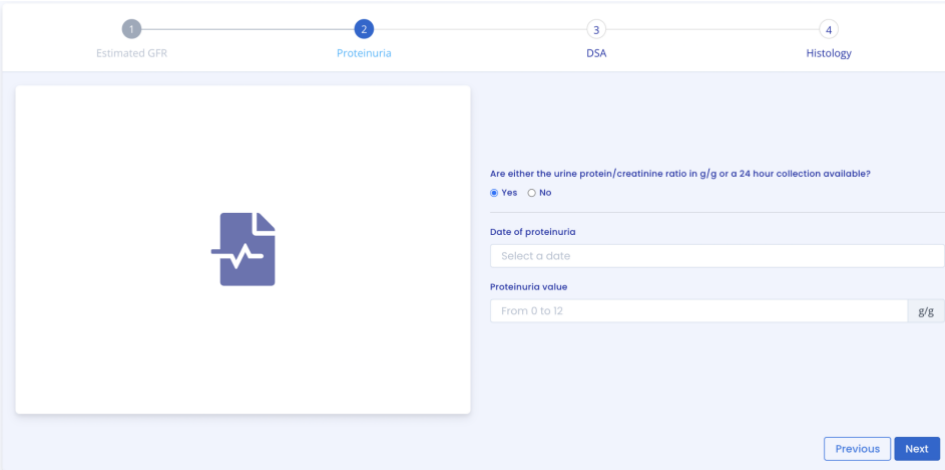
- A date on the calendar,
- The "Today" button,
- The "Date of GFR/creatinine" button (date of the 1st step).



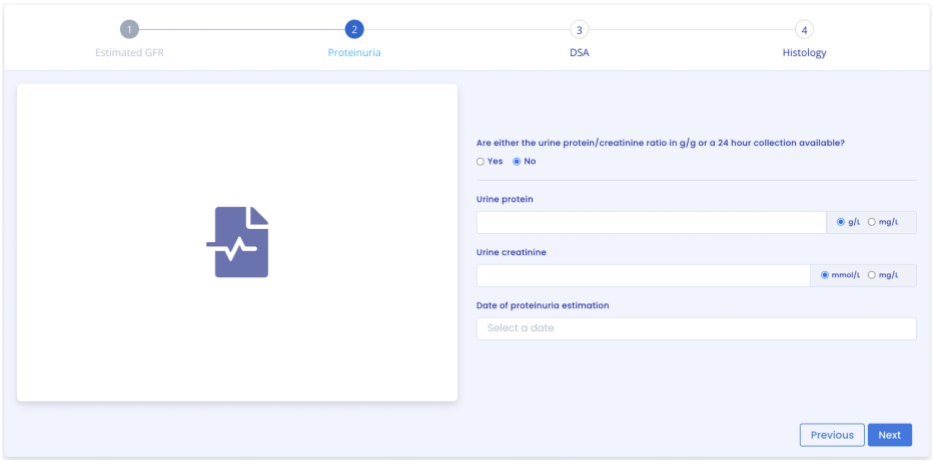
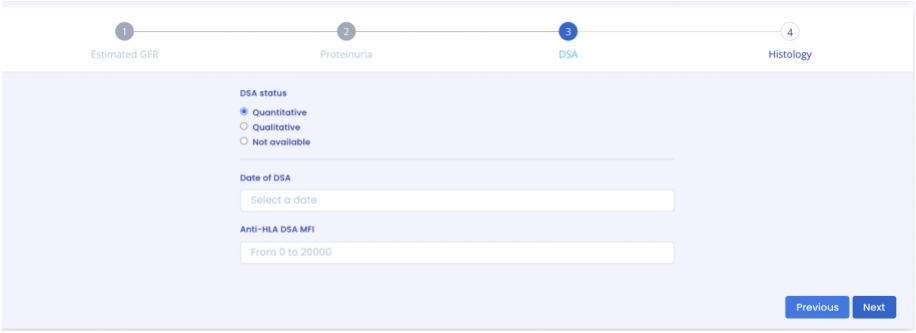
The following screenshots show the necessary steps to create a report without viewing biological analysis reports.

<table>
<tr><td>Title banner</td><td>The title banner is available on all report creation pages.
 
You will see the following patient information:
- Name,
- ID,
- Sex,
- Age and date of birth,
- Date of transplant.</td></tr>
<tr><td>1) Estimated glomerular filtration rate

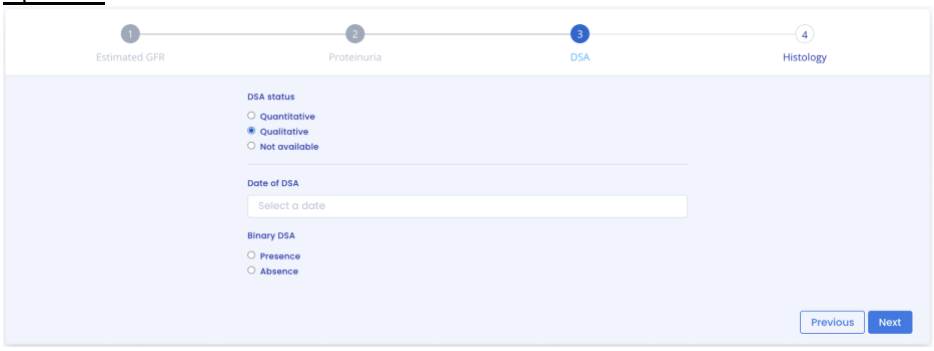
value (eGFR)</td><td>Option 1:
The estimated GFR value must be between 0 and 500. Above 120, a message informs you that the iBox calculation will be done with a GFR equal to 120.
Warning message: "Are you sure that the estimated GFR is above 120mL/min/1.73m²? The iBox calculation will use a GFR equal to 120 mL/min/1.73m²."
Error message: "The estimated GFR must be between 0 and 500."
 
Option 2:</td></tr>
</table>

	 Predigraft applies the MDRD formula from creatinine. Creatinine value is limited: Error message: "Creatinine value must be between 1 and 1300 µmol/L." Error message: "Creatinine value must be between 0.02 and 33.92 mg/dL." GFR is calculated: Success message: "Estimated GFR is <value> mL/min/1.73m² from MDRD equation" or if GFR is between 120 and 500: "Estimated GFR is <value> mL/min/1.73m² from MDRD equation. The iBox calculation will use an estimated GFR equal to 120 mL/min/1.73m²." Error message: "The estimated GFR is greater than 500 mL/min/1.73m²." Error message: "The estimated GFR is less than 0 mL/min/1.73m²." Notes: - The upper limit of 500 mL/min/1.73m² exists to account for extreme cases. - The limit of 120 mL/min/1.73m² for calculating the iBox score was established because the calculation of iBox probabilities and the expected survival benefit at 3, 5, 7 years are unchanged above 120 mL/min/1.73m².
2) Proteinuria value	Option 1:  The proteinuria value should be between 0 and 12.

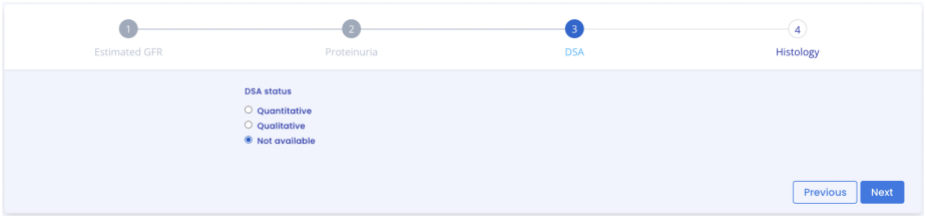
	Error message: Proteinuria must be between 0 and 12 g/g. Option 2:

	 Predigraft calculates proteinuria by the ratio of urine protein to urine creatinine. Urine protein is limited: Error message: "Proteinuria value must be between 0 and 30 g/L." or "Proteinuria value must be between 0 and 30000 mg/L." Urine creatinine is limited: Error message: "Creatinine value must be between 0 and 35 mmol/L." or "Creatinine value must be between 0 and 3959.27 mg/L." Ratio is calculated: Success message: "The urine protein/creatinine ratio is <value> g/g." Error message: "Protein/creatinine ratio in urine must not exceed 12 g/g." Error message: "Protein/creatinine ratio in urine cannot be negative." Note on proteinuria date: Predigraft recommends measuring GFR and proteinuria 15 days apart. Warning message: "The time between the estimated GFR and proteinuria is longer than the recommended 15 days." Error message: "The time between estimated GFR and proteinuria is greater than 30 days".
3) DSA value	<u>Option 1:</u>  The anti-HLA antibody value should be between 0 and 20000.

<table>
<tr><td></td><td>Error message: “The MFI must be between 0 and 20000.”

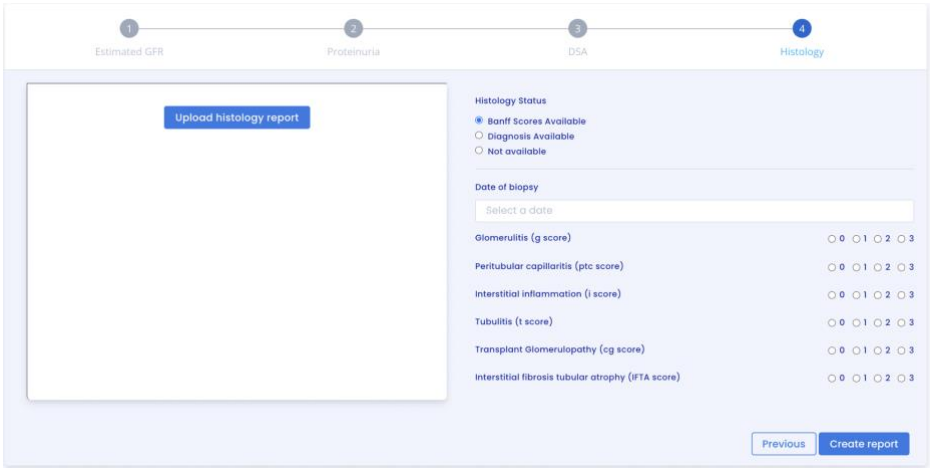
<u>Option 2:</u>
 

"Presence" or "Absence" must be selected.

<u>Option 3:</u>
 

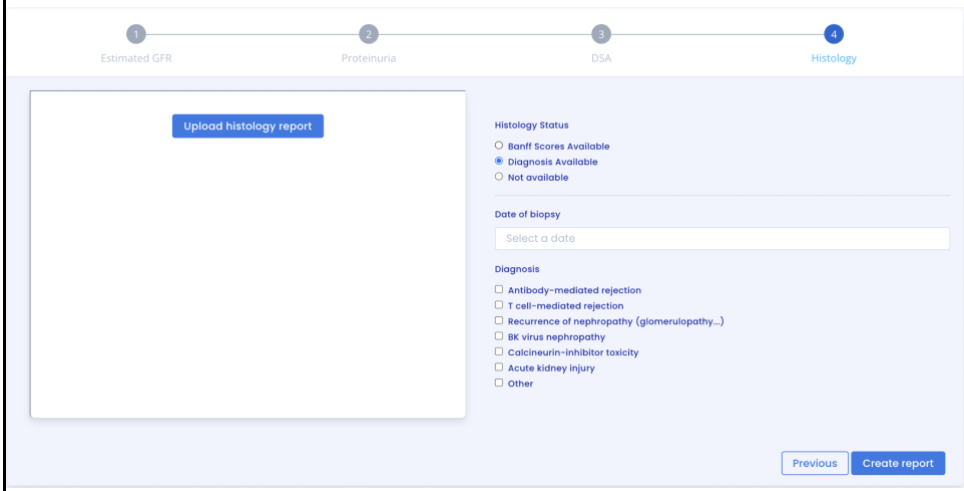
<u>Note on DSA date:</u>
Predigraft recommends measuring GFR and DSA at 2-month intervals.
Warning Message:
The time between the estimated GFR and DSA is more than the recommended 2 month interval.

Error Message:
The time between the estimated GFR and DSA is more than 4 months.</td></tr>
<tr><td>4) Histology information</td><td><u>Option 1:</u></td></tr>
</table>



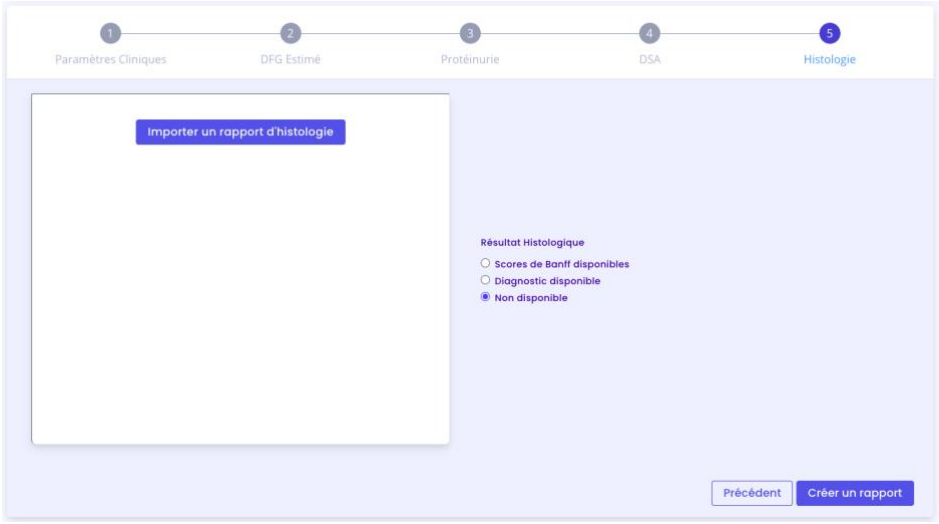
A value of "0", "1", "2" or "3" must be selected for each Banff score.

Option 2:



At least one diagnosis must be selected. "Other" corresponds to any other diagnosis.

Option 3:



Note on histology date:
Predigraft recommends measuring GFR and histology at 2-month intervals. Error Message:
The time between estimated GFR and biopsy must be less than 2 months.

Predigraft selects the iBox algorithmic model corresponding to the input data. The "Create Report" button checks the input data for errors. The generated iBox evaluation contains the results of the iBox algorithm calculation: survival probability at 3, 5 and 7 years post evaluation date (date of step 1).

14. 2 Visualization of results

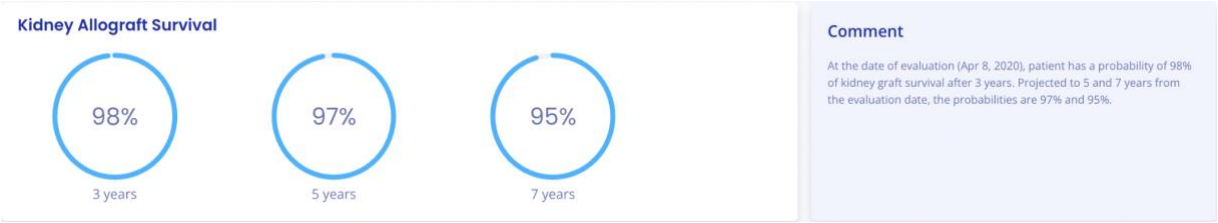
The title banner recalls the patient's name, the date of evaluation (date of step 1) GFR-e), the patient's date of transplantation.

You can print the Predigraft report by clicking on "Print". If you created the iBox evaluation by previewing a biological analysis report, you can download the biological analysis report.

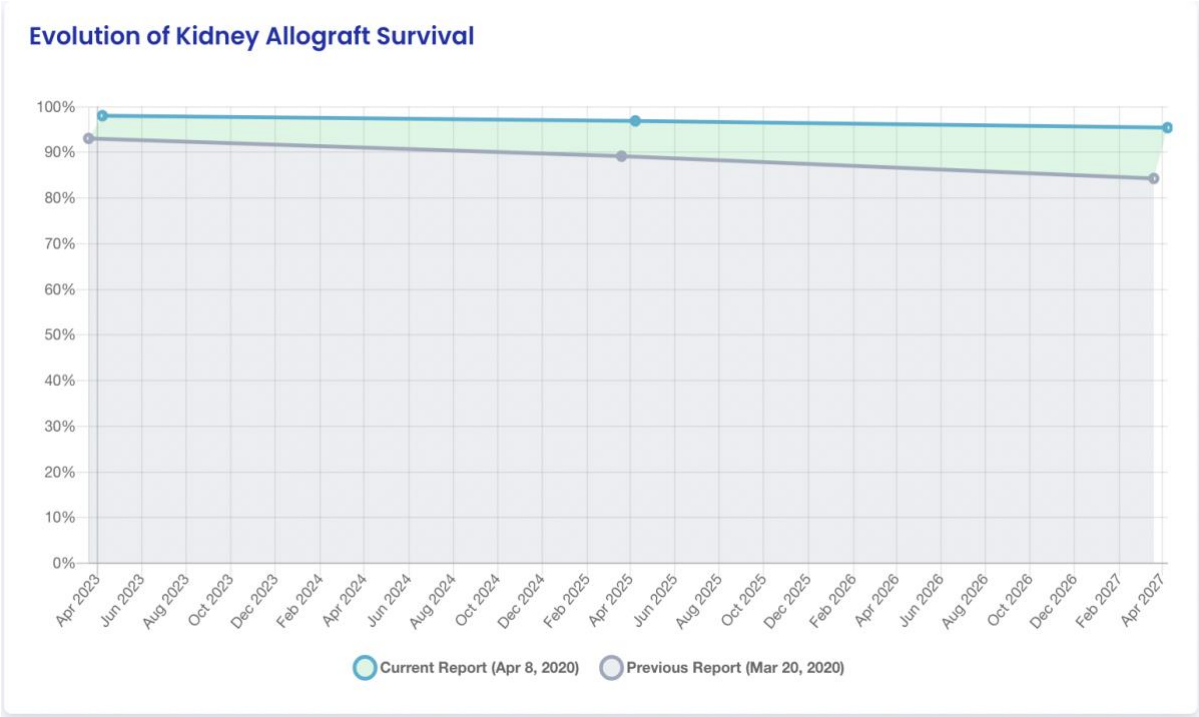
You can delete the report by clicking on "Delete" and specifying the reason in the confirmation window that appears:

- Incorrect data,
- The record is for a different patient,
- The report is a duplicate.

You can visualize the results of the iBox calculation: the probability of kidney graft survival projected at 3 years, 5 years, and 7 years from the evaluation date. The "comments" panel describes the probabilities.



You can view the iBox results of the current report compared to the results of the most recent previous report. The comment panel describes whether the survival probabilities are better or worse since the previous report.



You can visualize the input data that were used to generate the report: date and value for each step of the report creation (Clinical Parameters, Estimated GFR, Proteinuria, DSA, Histology). In the Comment panel, you can find the probability of agreement of the iBox model based on the input data (C-stat). Click on the "publication" link to access the Paris Transplant Group publication about the iBox.

14.3 Automatic iBox generation

You have the possibility to create iBox assessments manually, but also automatically. Indeed, the iBox score being calculated thanks to the proteinuria and the GFR, the calculation can be done automatically by the MDRD equation.
Thus, for each new urine creatinine and urine protein ratio or for each new proteinuria value that you will enter on your patient's form, a new iBox report will be created automatically. However, this new report will be created only if an estimated GFR value is already present on your patient's record and is less than one month old.

In the same way, for each creatinine or estimated GFR value entered in your patient's file, a new iBox report will be created automatically, only if a proteinuria value is already present in your patient's file and is less than a month old.

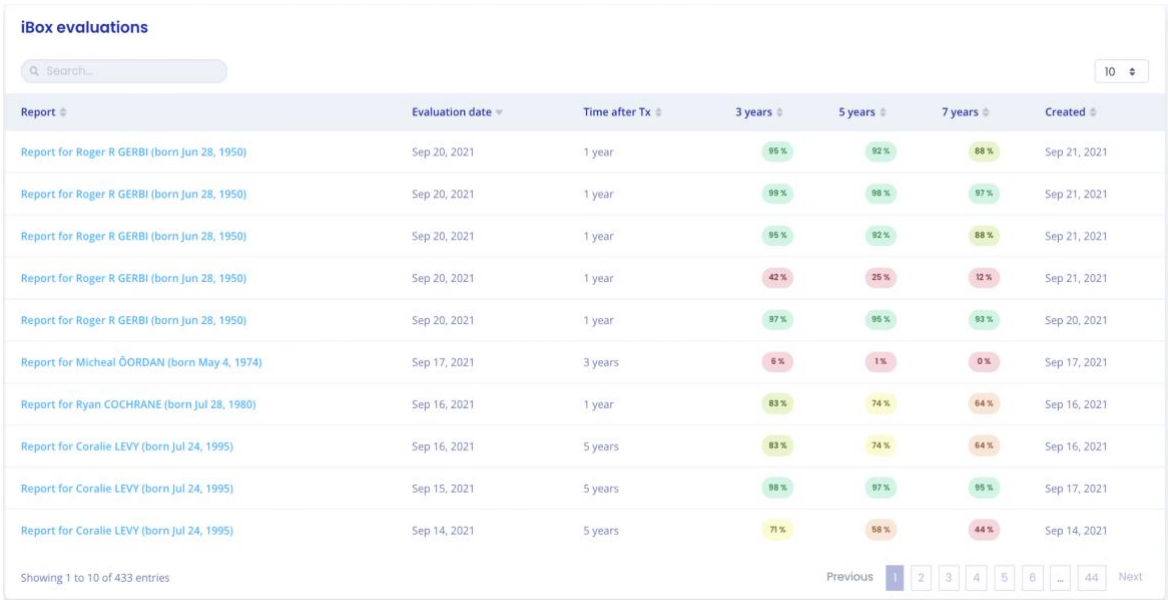
Note: Each report will be displayed in the same place as the manually created reports, and only one report per day will be generated in case of several new data.

15. Managing the list of reports

Click on "Predigraft Reports" on the left sidebar to view a list of reports for all patients in the team/department. The list contains the following information:

- Report: report of <full name of patient> (born on <patient date of birth>),
- Evaluation date: date of step 2) "Estimated GFR" when creating the report,
- Time after Tx: the time between transplant date and evaluation date,
- 3 years, 5 years, 7 years: the probability of renal graft survival at 3 years, 5 years, and 7 years after the evaluation date,
- Created on: the date the report was created.

When the page loads, the list is automatically ordered by the Evaluation Date column.



15.1 Search for:

In the search field, you can enter:

- All or part of a patient's name
- A date corresponding to the columns "Evaluation date", "Time after Tx", "Created on" in the format dd/mm/yyyy or /mm or /yyyy

The list of reports corresponding to the search entry is displayed by pressing the "Enter" key on your keyboard.

15.2 Display filter:

Click on the scroll box on the upper right 

to change the number of reports displayed on a page. You can display 10, 25, 50, or 100 reports.

15.3 Order the list:

Click on the column header to change whether the list is displayed in ascending or descending order.

15.4 Browse the list:

To browse the list, click on one of the numbers, "Previous" or "Next" from the list.

Précédent 1 2 3 4 5 6 ... 10 Suivant

16. Alerts

16.1 Definition of alerts

Predigraft calculates patient alerts when the following data are added to a patient record:

- Weight data
- Blood pressure data
- Values for immunosuppressive drugs C_0 Tacrolimus, C_2 Ciclosporin, C_0 Everolimus or C_0 Sirolimus when creating a Predigraft report
- Kidney function values for estimated GFR and proteinuria when creating a Predigraft report
- Kidney Graft Survival Probability during Predigraft Report creation and iBox calculation

16.2 Alert settings

Predigraft calculates patient alerts based on alert settings. There are three parameter categor:

- Predigraft-level (default): Cibiltech sets the default values
- Team level: the team owner can modify the alert settings for the team. This setting is then applied to all patients in the team.
- Patient-level: department members can change alert settings for each patient. this setting is only valid for the specified patient.

16.2.1 Cibiltech settings: default setting

For the Predigraft level, Cibiltech has defined default values that teams can modify as they see fit.

1) Blood pressure:

- Maximum systolic pressure value: 140 mmHg.
- Maximum diastolic pressure value: 90 mmHg.
- Systolic pressure value for hypertension (Grade 3): 180 mmHg.
- Diastolic pressure value for hypertension (Grade 3): 110 mmHg.

The maximum values for each setting are:

- Maximum systolic pressure value: 250 mmHg
- Maximum diastolic pressure value: 130 mmHg

2) Weight

- Weight gain: 1 kg.
- Weight loss in one month: 5%.
- Weight loss in six months: 10%.

The maximum values for each setting are:

- Weight gain: 20 kg

3) Immunosuppressive drugs

- C0 Tacrolimus minimum threshold: 4 ng/mL
- C0 Tacrolimus maximum threshold: 12 ng/mL
- C2 Ciclosporin minimum threshold: 600 ng/mL
- C2 Ciclosporin maximum threshold: 1200 ng/mL
- C0 Everolimus minimum threshold: 3 ng/mL
- C0 Everolimus maximum threshold: 8 ng/mL
- C0 Sirolimus minimum threshold: 4 ng/mL
- C0 Sirolimus maximum threshold: 12 ng/mL

The maximum values for each parameter are:

- T0 Tacrolimus minimum threshold: 12 ng/mL
- T0 Tacrolimus maximum threshold: 13 ng/mL
- T2 Ciclosporin minimum threshold: 1000 ng/mL
- T2 Ciclosporin maximum threshold: 1500 ng/mL
- T0 Everolimus minimum threshold: 12 ng/mL
- T0 Everolimus maximum threshold: 13 ng/mL
- T0 Sirolimus minimum threshold: 12 ng/mL
- T0 Sirolimus maximum threshold: 13 ng/mL

4) Blood biology data

- Minimum potassium: 3.2 mmol/L
- Potassium maximum: 5.3 mmol/L
- Minimum hemoglobin: 10 g/dL
- Maximum hemoglobin: 16.5 g/dL
- Minimum HbA1c: 4.5 %.
- Maximum HbA1c: 9 %.
- Platelets minimum: 80 000 /mm3
- Platelets maximum: 550 000 /mm3
- Neutropenia (minimum neutrophils): 1 000 /mm3
- Troponin maximum: 0.6 µg/L
- Minimum INR: 1
- Maximum INR: 5

The accepted thresholds for each parameter are :

- Potassium minimum: [3 - 3.5] mmol/L
- Maximum potassium: [4.8 - 5.5] mmol/L
- Hemoglobin minimum: [8.5 - 10] g/dL
- Maximum hemoglobin: [16 - 17.5] g/dL
- HbA1c minimum: [4 - 6] %
- HbA1c maximum: [6.5 - 13.5] %
- Platelets minimum: [10 000 - 150 000] /mm3
- Platelets maximum: [550,000 - 1,000,000] /mm3
- Neutropenia (minimum neutrophils) : [500 - 1,000] /mm3
- Troponin maximum: [0.6 - 2] µg/L
- INR minimum: [1 - 3.5]
- Maximum INR: [3.5 - 5]

5) Renal function (estimated GFR, proteinuria)

- Decrease in estimated GFR: 30%.
- Increase in serum creatinine: 50%.
- *de novo* proteinuria

The maximum values for each parameter are:

- Decrease in estimated GFR: 9999.99%.
- Increase in serum creatinine: 9999.99%.

5) Probability of kidney graft survival

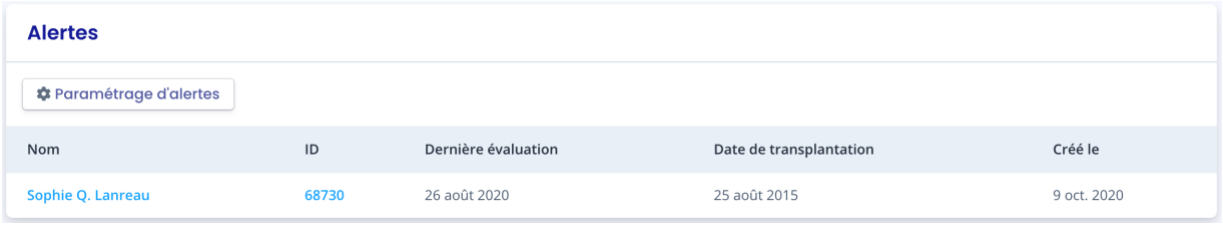
- Decrease in the probability of survival at 3 years: 1%.
- Decrease in the probability of survival at 5 years: 1%.
- Decrease in the probability of survival at 7 years: 1%.

Settings that cannot be changed are:

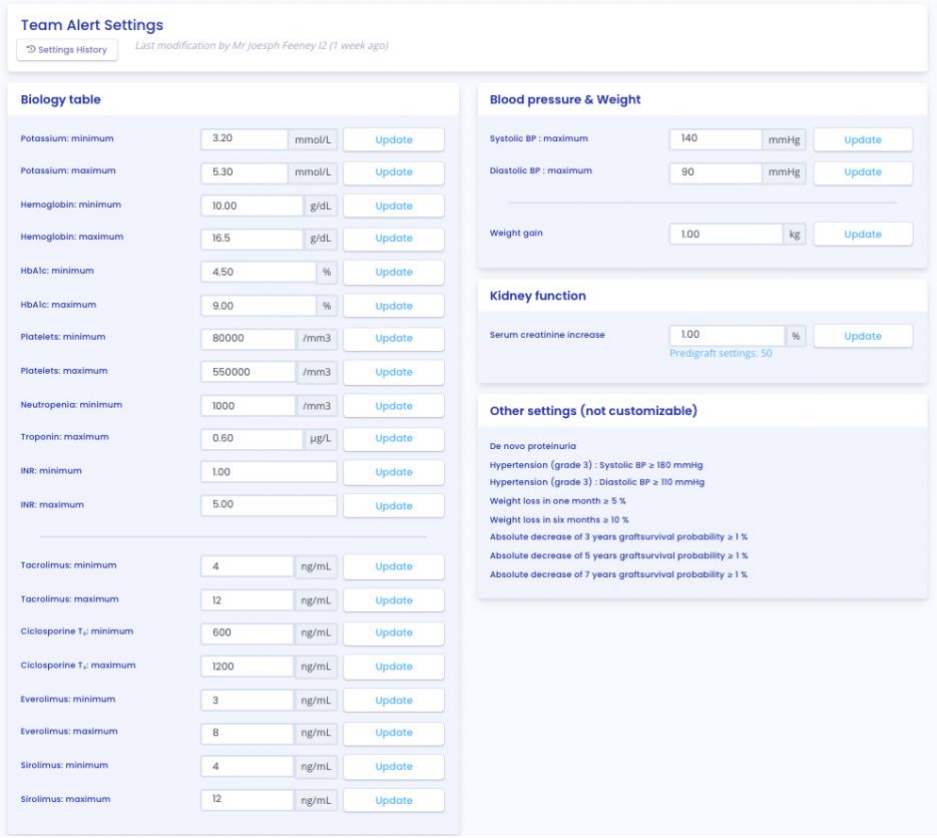
- *de novo* proteinuria
- Systolic pressure for hypertension (Grade 3)
- Diastolic pressure for hypertension (Grade 3)
- Weight loss in one month
- Weight loss in six months
- Decrease in the probability of survival at 3 years
- Decreased probability of survival at 5 years
- Decreased probability of survival at 7 years

16.2.2 Team-level configuration

To set up the team alerts, click on "Alerts" in the left sidebar, then click on "Alert Setup".



You will then be taken to the "Team Alert Settings" page.



To modify a parameter: change the value in the corresponding field and then click on the "Modify" button. A confirmation window will display the following information:

- The parameter value entered,

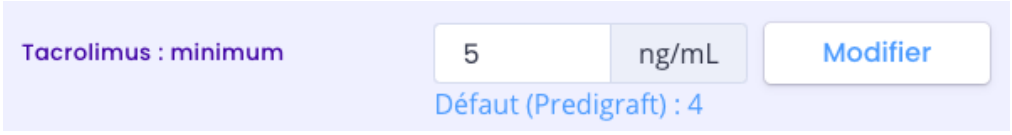
- The calculation that generates the alert.

Example of modification of the minimum Tacrolimus threshold, at the team level:

Click on "Modify for all patients" to confirm, or on "Cancel" to cancel the update.

Once you have updated a parameter, a "Parameter History" button allows you to access the history of changes. Next to the history button, a message indicates the date of the last parameter update, as well as the name of the user who performed the action.

For each parameter that does not apply the default value, the default value will be displayed below: "Default (Predigraft): <Predigraft setting value>".

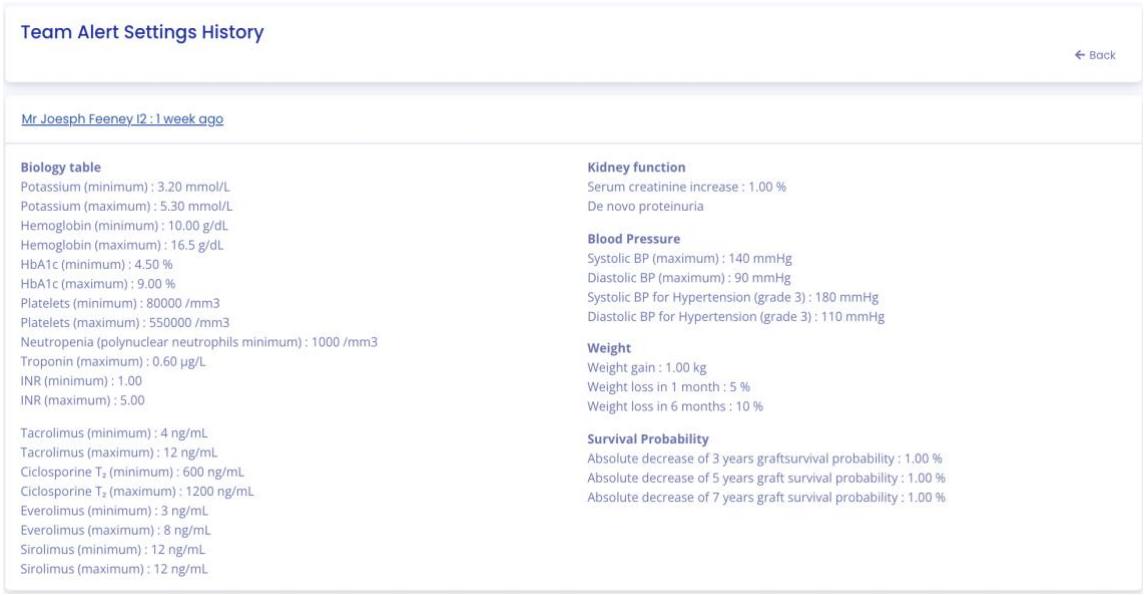


16.2.3 History of team-level configuration

You can access the setting history via the "Alerts" path on the left main menu, "Service Alerts Setting", "Setting History".

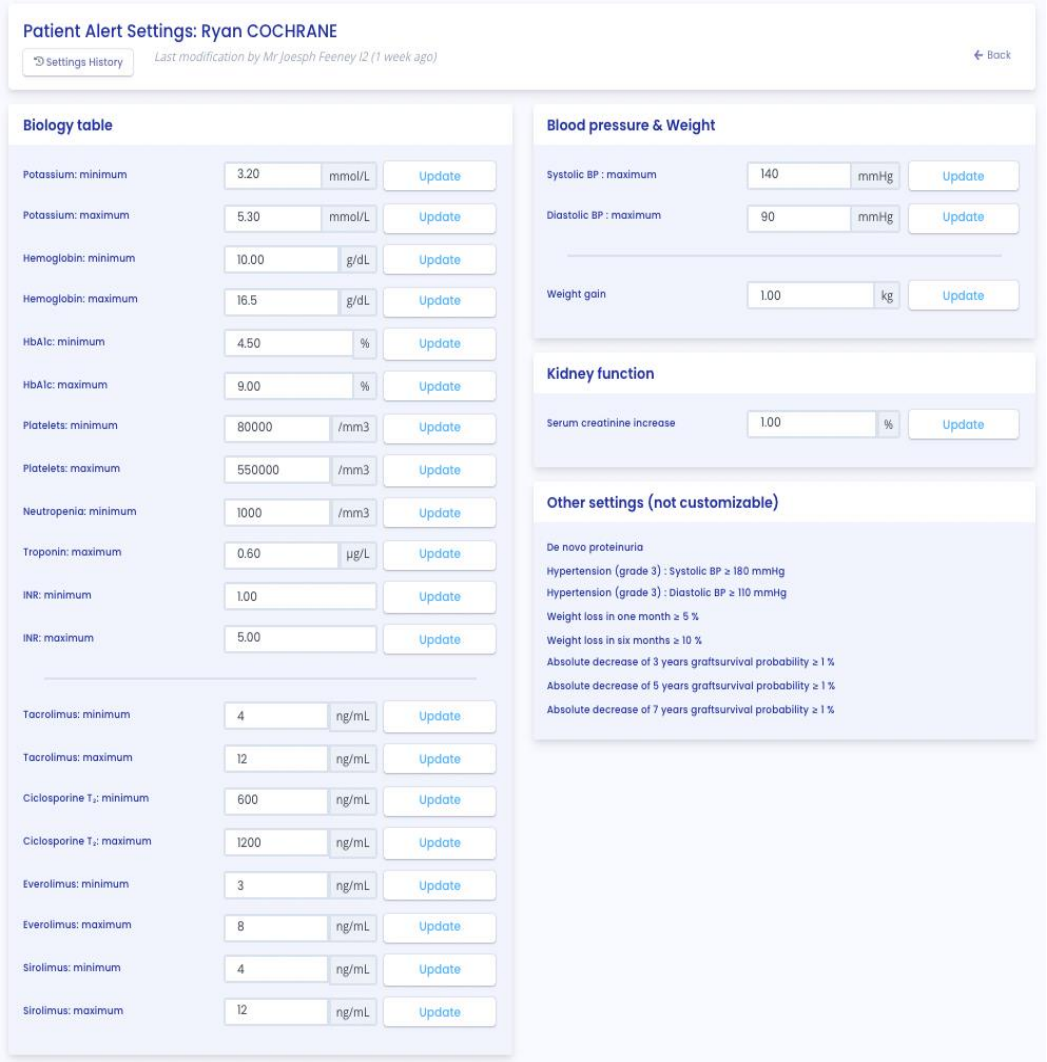
The history is displayed in descending order from the most recent to the oldest. In the history you will see:

- The name of the user who changed the settings,
- The date of the change,
- The list of each alert parameter and corresponding value.



16.2.4 Patient-level configuration

To set up alerts for a patient, access the patient record and click on the three small dots next to the patient's name, then click on "Alert settings". This will take you to the "Alert settings: <full name of patient>".

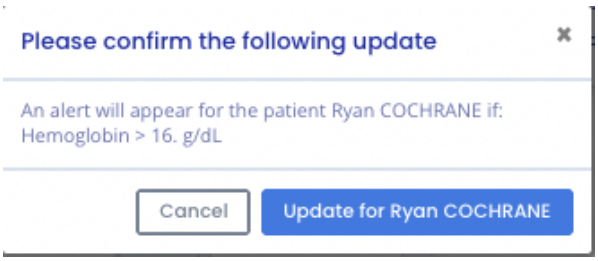


To modify a parameter: change the value in the corresponding field and then click on the "Modify" button. A confirmation window will display the following information:

- The parameter value entered,
- The calculation that generates the alert.

Click on "Modify for <full patient name>" to validate, or on "Cancel" to cancel the update.

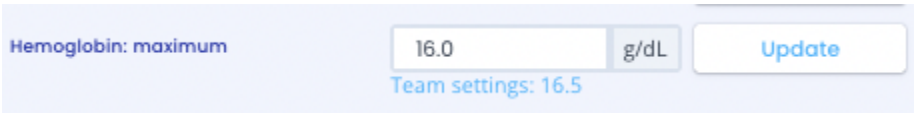
Example of changing the Maximum Systolic Pressure threshold at the patient level:



Once you have updated an alert parameter at the patient level, a "Parameter History" button allows you to access the modification history. The button does not appear if the parameter has only been changed at the team level.

Next to the history button, a message will display the date of the last update to the patient's alert settings as well as the name of the user who performed the action.

Under each parameter that does not have the default value, a text says: "Default (Service): <value of service setting>".



16.2.5 History of patient-level settings

To access a patient's alert history, select a patient's record and click on the three small dots next to the patient's name, then click on "Settings History".

The history is sorted with the most recent modification at the top of the page. The history is a list containing:

- The category of the setting: team/department or patient,
- The name of the user who changed the settings,
- The date of the change.

16.3 Alert calculation for a patient

Alerts are based on the following information (calculations are available in the Appendix).

1) Blood pressure

The software calculates blood pressure alerts from:

- the most recent date of blood pressure and associated systolic and diastolic pressure values

2) Weight

The software calculates weight alerts from:

- the most recent date of weight and the corresponding value
- the previous weight date and the corresponding value

3) Immunosuppressive drugs

The software calculates immunosuppressive drug alerts on the first validation of data extracted from a biological report, if that report is the most recent analysis date:

- date of the biological analysis,
- T_0 Tacrolimus (ng/mL), T_2 Ciclosporin (ng/mL), T_0 Everolimus (ng/mL), T_0 Sirolimus (ng/mL) values.

4) Blood biological data

The software calculates the blood biological data alerts during the first validation of the data extracted from a biological report, if this report is the most recent analysis date:

- date of the biological analysis,
- Potassium value converted to mmol/L,
- Hemoglobin value converted to g/dL,
- HbA1c (Glycated Hemoglobin) value converted to %,
- Platelet count value converted to /mm3,
- Neutrophil count value converted to /mm3,
- Troponin value converted,
- INR value.

5) Kidney function

Software calculates renal function alerts from two Predigraft reports:

- Orders Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

The software selects in both reports: date of estimated GFR, GFR value, creatinine value if filled, proteinuria date, proteinuria value.

6) Probability of kidney graft survival

Software calculates renal function alerts from two Predigraft reports:

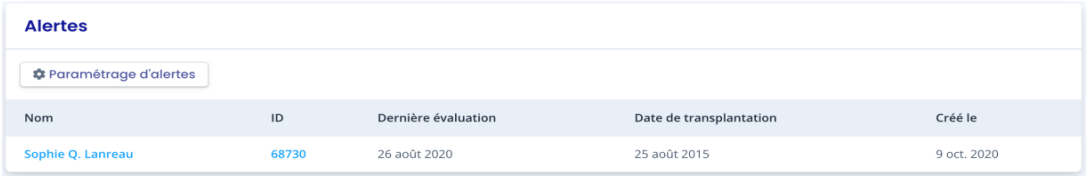
- Orders Predigraft reports by date of assessment (date of step 2) Estimated GFR)
- Selects the most recent report: "current report
- Selects the previous report: "previous report

The software selects from both reports: projected survival probabilities at 3 years, 5 years, 7 years.

16.4 Management of the list of patients on alert

Click on "Alerts" on the left sidebar for a list of patients on alert.

A counter of patients on alert is displayed on the left sidebar Alerts . If the counter is not visible, there are no patients on alert.



The list of patients on alert contains:

- Patient's full name,
- Patient ID,
- Latest assessment date: last date of the "Estimated GFR" stage entered during creation of a Predigraft report for this patient,
- Patient transplant date,
- Date of creation of the patient record.

You can click on one of the lines in the list of patients on alert to access the corresponding patient record.

16.5 Managing an alert

If a patient is on alert, the alerts are visible from the patient record.

Each alert contains:

- The date of creation of the alert,
- Details of the alert,
- A "Mark as read" button.

Mark as read

If you click on "Mark as read", this action is recorded in the database and means that you are aware of the alert. The button is changed to "Read on <date and time> by <user>" and this message is visible to all team members.

An alert marked as read is moved to the alert history page, accessible through the "Alert History" button on the patient page.

Alert History

The Alert History page lists a patient's alerts, displaying the most recent first. The history page lists read alerts (gray) and unread alerts (red). You can read an alert from this page.

16.6 Daily notification of your patients' activity

If you are a member of a team, you will receive a daily email about the Predigraft activity of your patients in the "My Patients" list. This email contains the following information:

- The number of your patients in the "My Patients" list who have a weight or blood

pressure alert,
- The number of documents imported by your patients, present in the "My patients" list, the previous day,
- The number of unread conversations to date with your patients present in the "My Patients" list.

Note: The clinical and biological data as well as the documents are not contained in the email.

If you are the owner of a team, you will receive a daily email about the Predigraft activity of all the patients in your department. This email contains the following information:

- The number of your patients in the "My Patients" list who have an alert on their weight or blood pressure,
- The number of patients not in the "My Patients" list of any member of your team who have alerts on their weight and blood pressure,
- The number of documents imported by your patients, present in the "My Patients" list, the previous day,
- The number of documents imported by patients not in the "My Patients" list of any of your team members,
- The number of unread conversations to date with your patients in the "My Patients" list,
- The number of unread conversations to date with patients not in any team member's "My Patients" list.

Note: Clinical and biological data and documents are not contained in the email.

17. Patient application

From the patient application, the patient can send you clinical and biological data:

- Weight,
- Blood pressure,
- Biological analysis report.

You can directly consult the data sent by the patient in his corresponding patient record.

18. Support/Maintenance

For any questions, requests, or reports of malfunction, please send an email to support@cibiltech.com

MATERIOVIGILANCE: Any incident or risk of serious incident (defined according to article L5212-2 of the Public Health Code) detected during the use of the medical device Predigraft must be reported to the manufacturer at the following address: contact@cibiltech.com

You must report any event to the competent authority of the Member State in which you are established:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pd

19. Personal data

For any questions, requests or statements regarding your personal data, please refer to Cibiltech's Privacy Policy, available online on the company's website: www.cibiltech.com.

20. Appendix

20.1: Input Parameters

1. Transplant and evaluation date

The transplant date must be filled in with the day, month and year.

The evaluation date is the date on which the creatinine measurement was performed. This date may be different from the date of the medical appointment. This date is used as a reference for all other measurements taken. It must be completed with the day, month and year.

2. Estimated glomerular filtration rate (eGFR)

Glomerular filtration rate (GFR) is the primary measure of kidney function. It can be measured or estimated from validated formulas that have been published in scientific journals. The equation that was used to develop and validate the iBox is the one used in the Modification of Diet in Renal Disease (MDRD) study:

Estimated GFR (mL/min/1.73 m²) = $186 \times (Scr/88.4)^{-1.154} \times (Age)^{-0.203} \times$ (0.742 if female) (International Unit)

3. Proteinuria

Proteinuria is a marker of kidney damage. It can be tested with a urine test strip. If positive, it is confirmed and quantified on a 24-hour urine collection (result in mg/24h), or when 24-hour urine collection is not possible, on a urine sample taken at any time of day and by the proteinuria/creatinuria ratio (result in mg/g or mg/mmol).

Proteinuria is measured on the same day as creatinine. A delay of up to 15 days between the measurement of creatinine and the estimation or measurement of proteinuria is tolerated.

4. anti-HLA donor specific antibodies

The presence of donor-specific anti-HLA antibodies (DSA) is assessed regularly after a kidney transplant. The measurement is carried out by solid phase analysis. The current preferred method is flow cytometry using fluorescent microbeads. The result is provided by the HLA laboratory. It can be qualitative (positive or negative) or quantitative. The mean value of the fluorescence intensity (MFI) of the immunodominant DSA (i.e. DSA with the highest MFI) should be reported. The date of the DSA test should not be more than 2 months from the evaluation date.

5. Histology

A pathology report is provided after a kidney transplant biopsy. This report provides a histological description with a diagnostic result as well as a semi-quantitative description of the basic histological lesions according to the Banff classification system. The clinician has the option to enter the reported diagnoses or the Banff histological scores. The date of biopsy should not exceed 2 months from the date of assessment.

20.2 Appendix 2: Calculation of alerts

1) Blood pressure

The software calculates blood pressure alerts from:
- the most recent date of blood pressure and corresponding systolic and diastolic pressure

values Systolic blood pressure is referred to as "SP" below. Diastolic blood pressure is referred

to as "PAD".

Calculation of alerts:

IF PAS > blood_pressure_high_systolic: "On the <DATE>, systolic blood pressure is above the target set for <NAME> FIRST NAME>: <PAS VALUE> mmHg. »
IF PAD > blood_pressure_high_diastolic: "On the <DATE>, diastolic blood pressure is above the target set for <NAME> <FIRST NAME>: <PAD VALUE> mmHg. »

IF PAS >= 180 OR PAD >= 110: "On <DATE>, a grade 3 blood pressure was observed for <NAME> <FIRST NAME> (<PAS VALUE> / <PAD VALUE> mmHg)".

2) Weight
The software calculates Weight alerts from:
- the most recent date of weight and corresponding value
- the previous weight date and the corresponding value

Calculation of alerts:

IF Weight_gain >= Weight_gain_kg:
"< RECENT DATE>: Since the last evaluation date (<PREVIOUS DATE>), a change in weight has been observed for <NAME> <FIRST NAME> (+ <DIFFERENCE BETWEEN WEIGHTS> kg)".
ELSE IF
Difference between dates is one month or less AND
Weight loss >= Weight_loss_percentage_one_month_ago
(5%)
OR
The difference between the dates corresponds to one month to six months AND Weight Loss >= Weight_loss_percentage_six_months_ago (10%):
"< RECENT DATE> : Since the last evaluation date (<PREVIOUS DATE>), weight loss has been observed in <NAME> <FIRST NAME> (- <DIFFERENCE BETWEEN WEIGHTS> kg)".

3) Immunosuppressive drugs

The software calculates immunosuppressive drug alerts on the first validation of data extracted from a biological report, if that report is the most recent analysis date and T_0 Tacrolimus, T_2 Ciclosporin, T_0 Everolimus, T_0 Sirolimus values

Calculation of alerts:

IF T_0 Tacrolimus < trough_levels_low_tacrolimus OR > trough_levels_high_tacrolimus:
"<DATE>: The residual tacrolimus concentration is outside the target defined for <NAME> <FIRST NAME> (T0:
<VALUE> ng/mL).

IF T_2 Cyclosporine < trough_levels_low_cyclosporine OR > trough_levels_high_cyclosporine:
"<DATE> : The concentration of cyclosporine 2 hours after dosing (T2) is outside the target defined for <NAME> <FIRST NAME> (C2: <VALUE> ng/mL).".

IF T_0 Sirolimus < trough_levels__low_everolimus OR > trough_levels__high_everolimus:
"<DATE>: The residual concentration of sirolimus is outside the target defined for <NAME> <FIRST NAME> (T0:
<VALUE> ng/mL).".

IF T_0 Everolimus < trough_levels_low_sirolimus OR > trough_levels_high_sirolimus: "<DATE>: The residual concentration of everolimus is outside the target defined for <NAME> <FIRST NAME> (T0:
<VALUE> ng/mL).

4) Kidney function

The software calculates blood biology data alerts on the first validation of data extracted from a biology report, if that report is the most recent analysis date:

- date of the biological analysis,
- Potassium value converted to mmol/L,
- Hemoglobin value converted to g/dL,
- HbA1c (Glycated Hemoglobin) value converted to %,
- Platelet count value converted to /mm3,
- Neutrophil count value converted to /mm3,
- Troponin value converted to µg/l,
- INR value.

Calculation of alerts :

IF Potassium < bio__potassium__low__mmol_l OR > bio__potassium__high__mmol_l:
"<DATE>: Potassium is below/above the defined threshold: <VALUE> mmol/L."

IF Hemoglobin < bio__hemoglobin__low__g_dl OR > bio__hemoglobin__high__g_dl:
"<DATE>: Hemoglobin is below/above the defined threshold <VALUE> g/dL."

IF HbA1c < bio__hab1c__low__percentage OR > bio__hab1c__high__percentage:
"<DATE>: Glycated hemoglobin is below/above the defined threshold: <VALUE> %."

IF Platelets < bio__platelets__low__per_mm3 OR > bio__platelets__high__per_mm3:
"<DATE>: Platelets are below/above the defined threshold: <VALUE> /mm3."

IF Neutrophils < bio__neutropenia__low__per_mm3:
"<DATE>: Neutropenia was detected: <VALUE>/mm3."

IF Troponin > bio__troponin__high__ug_l:

"<DATE>: Troponin is above the defined threshold (<VALUE> µg/L)."

IF INR < bio__inr__low OR > bio__inr__high:
"<DATE>: INR is below/above the defined threshold <VALUE>."

5) Kidney function

The software calculates renal function alerts from two Predigraft reports:

- Orders the Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

The software selects in both reports: date of estimated GFR, GFR value, creatinine value if informed, proteinuria date, proteinuria value

Calculation of alerts:

IF the GFR value of the current report is reduced by "kidney_function__egfr_reduction" or more, compared to the GFR value of the previous report:
"Kidney function has decreased (decrease in estimated GFR) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>"

IF the serum creatinine value of the current report is increased by "kidney_function__serum _creatinine_increase" or more, compared to the serum creatinine value of the previous report:
"Kidney function decreased (serum creatinine decreased) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

IF proteinuria value was 0 in the previous report and is greater than 0 in the current report:
"Kidney function decreased (de novo proteinuria) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

6) Probability of renal graft survival.

The software calculates renal function alerts from two Predigraft reports:

- Orders the Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

Software selects from both reports: projected survival probabilities at 3 years, 5 years, 7 years.

Calculation of alerts:

IF probability of survival at 3 years of the current report < probability of survival at 3 years of the previous report with a precision of survival_probability__3y_reduction (1%)
OR
5-year survival probability of the current report < 5-year survival probability of the previous report with a precision of survival_probability__5y_reduction (1%)
OR
7-year survival probability of current report < 7-year survival probability of previous report with a precision of survival_probability__7y_reduction (1%) :
"The probability of renal graft survival decreased between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

20.3 Appendix 3: Biological Table Reference Units

Values stored in Predigraft but not displayed in the biological table are shown in italics.

Blood" part

- Glycated hemoglobin: %.
- Glucose: mmol/L
- Sodium: mmol/L
- Potassium: mmol/L
- Total CO2: mmol/L
- Protein: g/L
- Urea: mmol/L
- Creatinine: µmol/L
- eGFR: mL/min/1.73m2
- Calcium: mmol/L
- Phosphorus: mmol/L
- Magnesium: mmol/L
- Uric acid: µmol/L
- Total Bilirubin: µmol/L
- Conjugated Bilirubin: µmol/L
- ALT: IU/L
- AST: IU/L
- Alkaline phosphatase: IU/L
- Gamma GT: IU/L
- LDH: IU/L
- CPK: IU/L
- Amylase: IU/L
- Lipase: IU/L
- Total cholesterol: mmol/L
- HDL total cholesterol: mmol/L
- LDL cholesterol: mmol/L
- Triglycerides: mmol/L
- Troponin: ng/L
- Haptoglobin: g/L
- Ferritin: µg/L
- Saturated transferrin coefficient: %.
- PTH: ng/L
- 25-hydroxyvitamin D: ng/mL
- Di-hydroxyvitamin D: pg/mL
- Patient prothrombin time: seconds
- Prothrombin time control: seconds
- PT: %.
- INR (ratio)
- APTT ratio
- Patient aPTT: seconds
- Control aPTT: seconds
- Fibrinogen activity: g/L
- Anti-Xa: Xa/mL
- CRP: mg/L
- AB antibody assay: titre
- Hematies: 1012/L
- Hematocrit: %.
- Hemoglobin: g/dL

- VGM: fL
- Reticulocytes: 109/L
- Schizocytes : %
- Leukocytes: 109/L
- Neutrophils: 109/L
- Eosinophilic Polynuclei: 109/L
- Basophilic Polynuclear Cells: 109/L
- Lymphocytes: 109/L
- Monocytes: 109/L
- Platelets: 109/L
- BK: log copies/mL
- CMV: log copies/mL
- HIV: log copies/mL
- HBV: log copies/mL
- HCV: log copies/mL
- Ciclosporin T0: ng/mL
- Ciclosporin T2: ng/mL
- Tacrolimus T0: ng/mL
- Sirolimus T0: ng/mL
- Everolimus T0: ng/mL
- PSA : ng/mL

Urine" part

- Urine volume: L/24h
- Urine protein: g/L
- Protein-creatinine ratio: g/g
- Urea: mmol/L
- Urine Creatinine: mmol/L
- Urine Sodium: mmol/L
- Urine potassium: mmol/L
- Urinary red blood cells: /mm3
- Urinary leukocytes: /mm3
- Microbiology (text)