PETER

PaEdiatric Transplant European Registry

Xolomon Electronic data collection tool

User's manual index:

1. Access

Login

To access the Online Registration System you must first request your access keys (email address and password) to the TransplantChild HelpDesk (helpdesk@transplantchild.eu).
Once you have your access keys you can follow these steps (Figure 1):

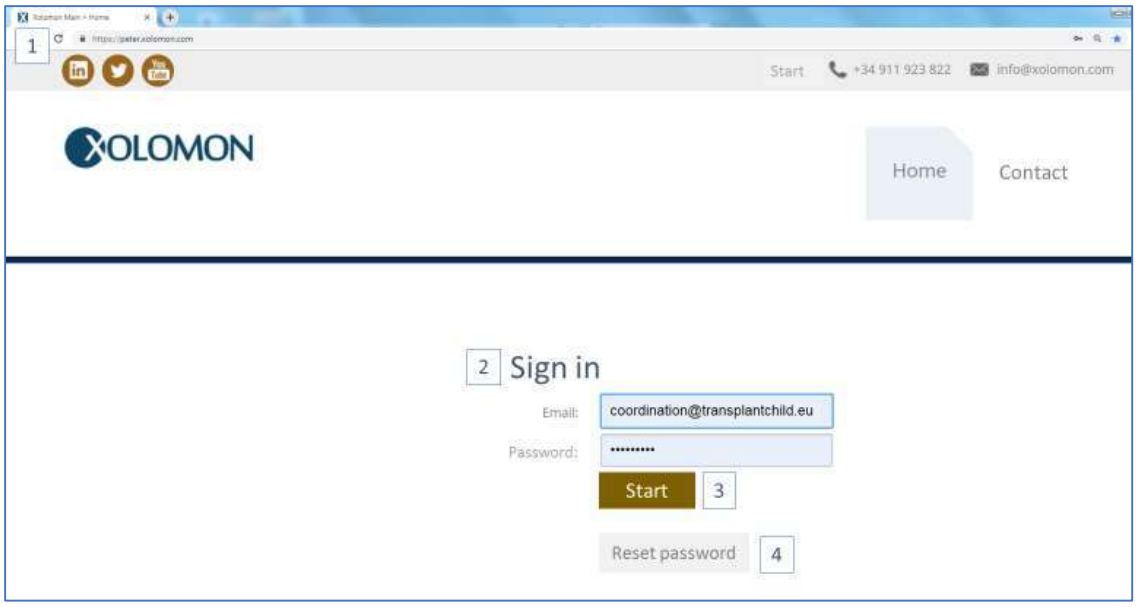

Figure 1. Xolomon home page to access PETER registry

1- Go to **PETER's** home page (https://peter.xolomon.com)
2- Enter your access keys: email address and password*
3- Click "**Start**" and Xolomon application will automatically start
4- *If you do not remember your password select the link "**Reset Password**", complete your **Username** or **Email address**, and you will receive an email with the steps to reset your password.

*If you do not remember your email address, please contact the helpdesk indicating your full name, network centre and position within the organization.

Access to PETER Registry

Once logged in Xolomon app with your organization's username and password, a main information appears in the central panel:

▲ **"Session will be closed after 15 minutes of inactivity. Please, save the information you have entered in the application"**

Now, you can access to PETER patient registry (Figure 2):

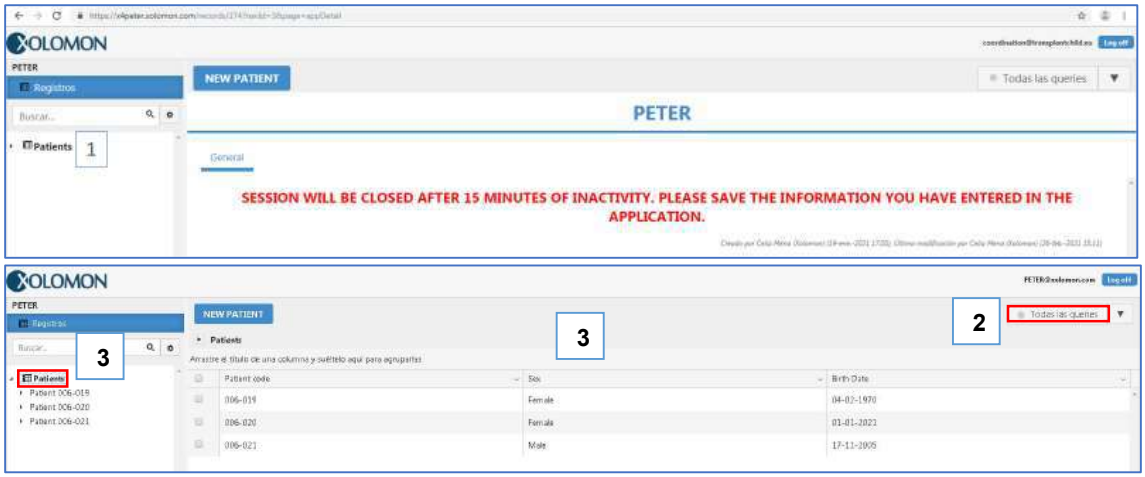

Figure 2. PETER Dashboard, list of patients registered and follow-up charts

1. PETER data will be loaded with the patient's list on the left.
2. Select the grey button (●) **"All queries"** at the top right of the screen.
3. Then scroll down the patient list by clicking on **"Patients"** (on the left column).
4. More detailed information will appear on the central panel.

2. Register a new patient

To register a new patient (Figure 3), you must meet some previous requirements. The patient must have clearly understood the purposes of data collection and must have signed PETER's informed consent.

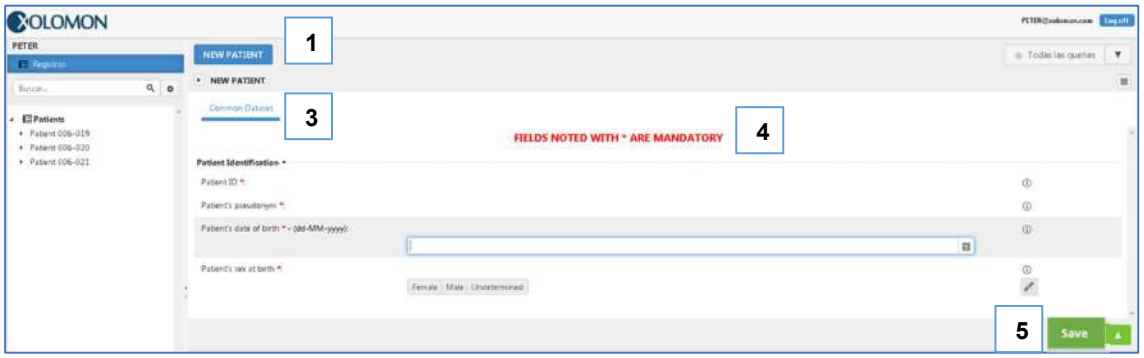

Figure 3. Register a New Patient: Common dataset

1. Click on the blue button at the top of the **NEW PATIENT** panel.
2. The list of fields divided by tabs will be displayed.
3. Complete the required "**Common Dataset**" form.
   - *Patient pseudonym: Automatically generated by the system
   - *Patient's date of birth: Select in the calendar the date of birth of the patient. All patients transplanted after 18 years of age will be excluded
   - *Patient's sex at birth: Sex of the patient at birth
4. Mandatory fields will appear with a red asterisk (*).
5. Once the form is completed, click **Save** at the bottom right to register the patient in PETER. Save

After registering the patient, the transplant information should be included. ▲If the patient has not yet received the transplant, this information should be completed at the time of transplantation or after the patient has been discharged from hospital.

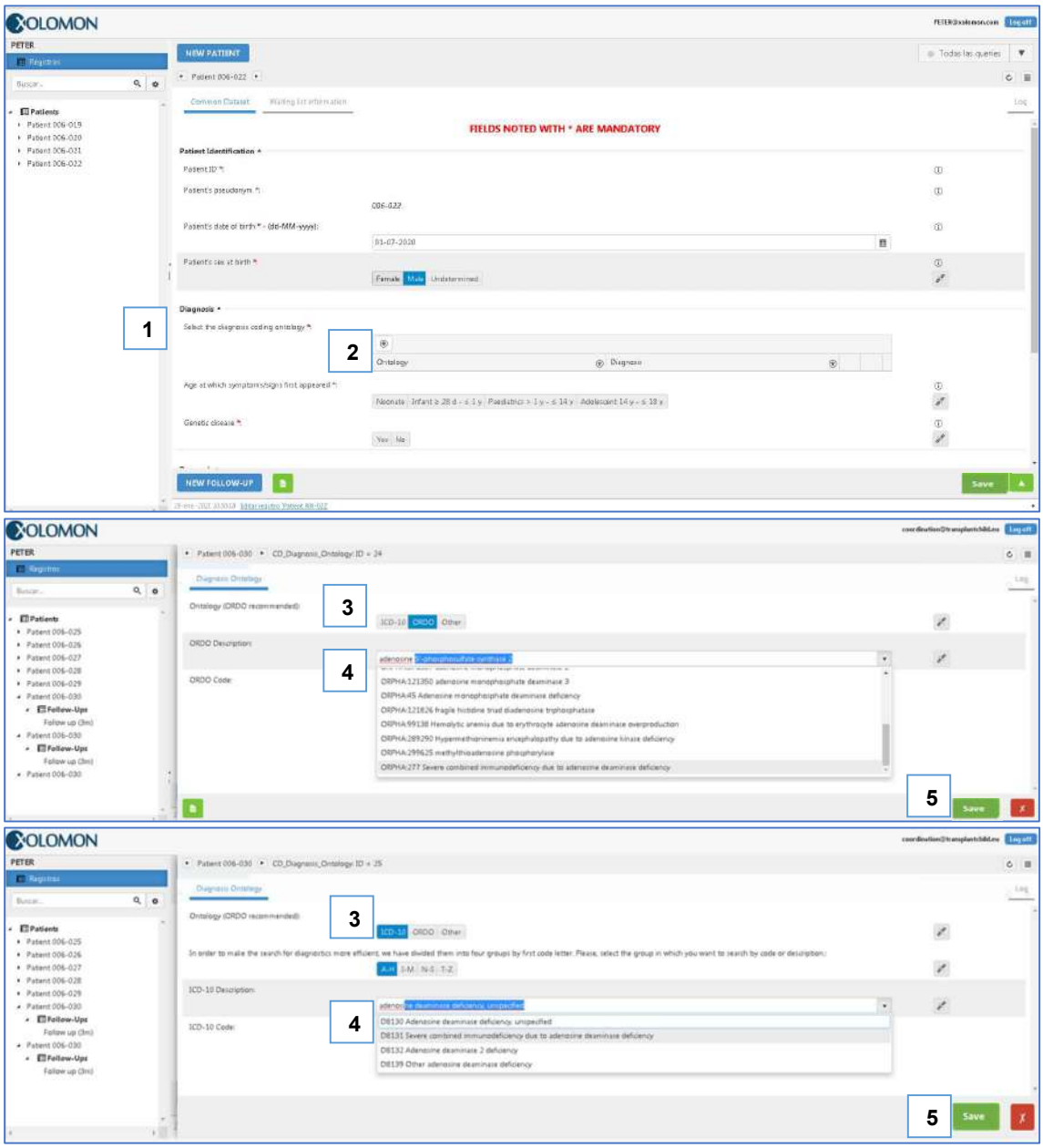

Figure 4.1. Common dataset: diagnosis

1. **Diagnosis** form will be displayed to fill in (Figure 4.1).
2. For each diagnosis, click ⊕ at the top left of diagnosis table.
3. A floating window will appear: select the ontology (ORDO, ICD-10, other).

   ▲ **ICD-10:** In order to make the search for diagnostics more efficient, we have divided them into four groups by first code letter. Please, select the group in which you want to search by code or description
4. Search the diagnosis by description (at least three words) or code (Appendix I. Frequent diagnosis codes by type of transplant).

5. Click **Save** and then **Exit** at the bottom right of the screen.
6. If your patient has more than one diagnosis, please repeat steps **2-5** as necessary.

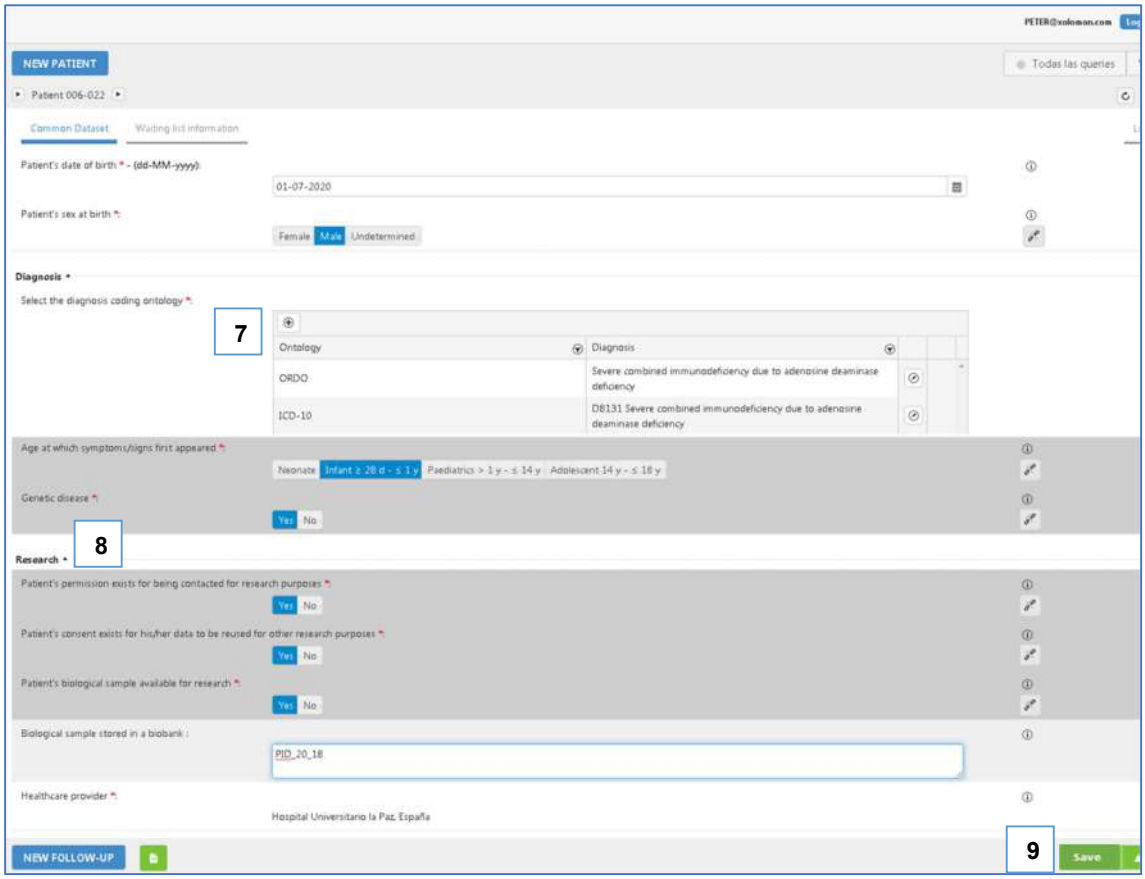

Figure 4.2. Common dataset: research.

7. Any diagnosis that has been registered will appear in the diagnosis table.
8. Once the information in **"Common Dataset"** is completed:

   *Age at which symptoms/signs first appeared: select age category when signs/symptoms were detected by the patient or the family.

   *Genetic disease: is the primary diagnosis a genetic disease? Yes or No.

   *Patient's permission exists for being contacted for research purposes: in case of future research project the patient must be contacted for a new consent.

   *Patient's consent exists for his/her data to be reused for other research purposes: reuse the data of the patient for other research purposes not specified in the registry consent.

   *Patient's biological sample available for research: Are patient biological samples available for research? Yes or No.

   If yes: Biological sample stored in a biobank: Indicate type of sample and Biobank where the samples are stored.

   *Healthcare provider: where the patient is receiving specialized care. Automatically generated by the system (associated to your credentials).
9. Select **Save** at the bottom of the panel.

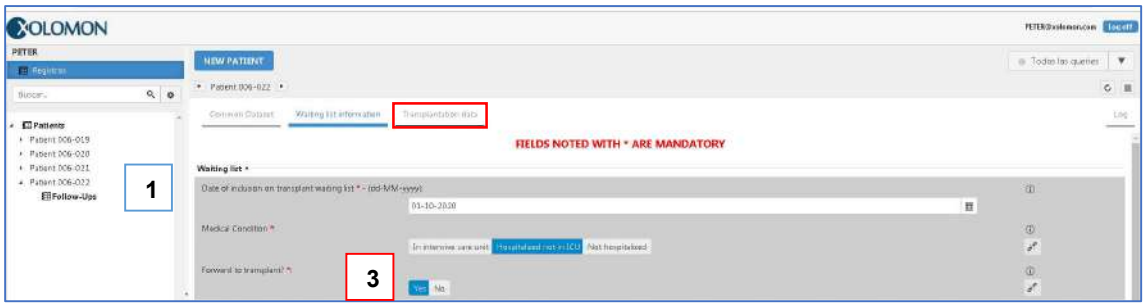

Figure 5.1. Waiting list information.

1. Select the tab "**Waiting list information**" (Figure 5.1).
2. The form will be displayed to fill in the patient's data prior to the transplant:
   *Date of inclusion on transplant waiting list: select in the calendar the date of inclusion for the last transplant indicated for the patient
   *Medical Condition: select the current situation of the patient at the time of inclusion to transplant waiting list
   *Forward to transplant? Yes or no. ▲**Only select yes**, if the patient has already received the transplant
3. If the patient has already been transplanted make sure to check **the Forward to Transplant** field → A new tab "**Transplantation data**" will be created.

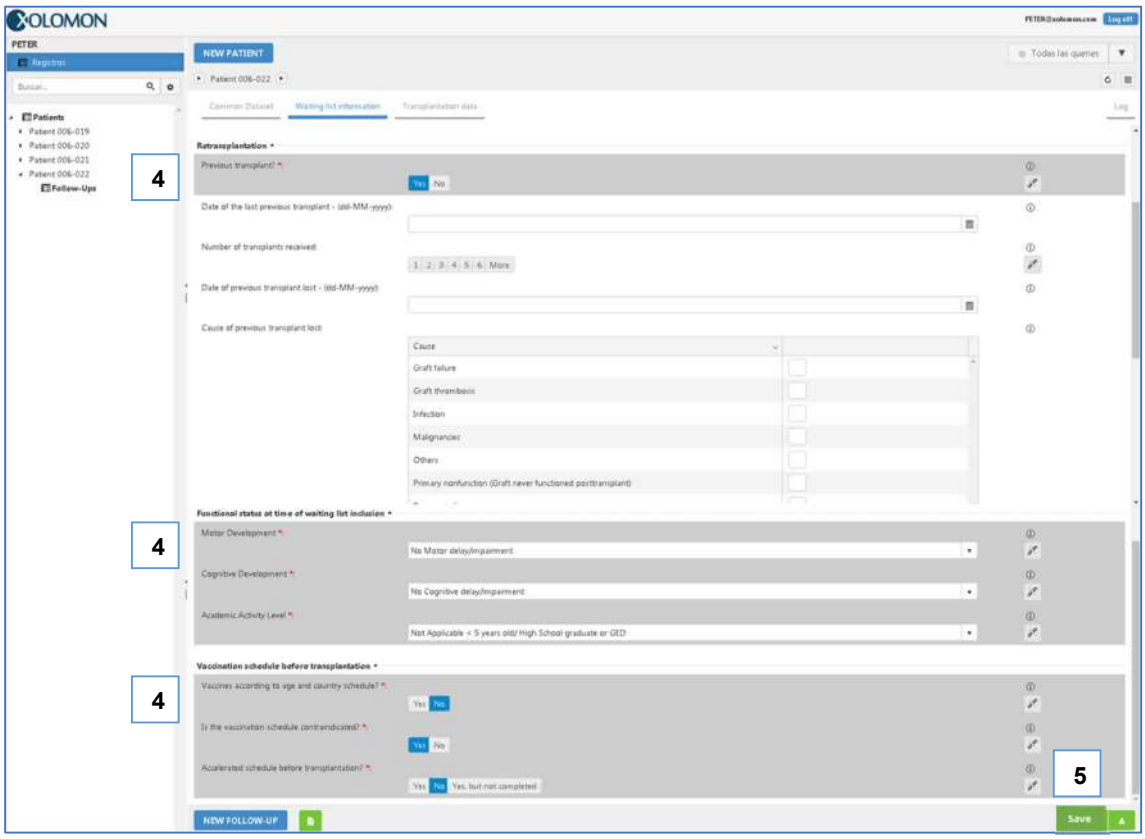

Figure 5.2. Waiting list information.

4. Complete all data in "**Waiting list information**" (Figure 5.2): retransplantation, functional status and vaccination schedule.
   *Previous transplants: If the patient has already been transplanted previously

If yes: Date of the last previous transplant: If patient had received more than one transplant → select the date of the last transplant received.

-Number of transplants received: select how many transplants had the patient received

-Date of previous transplant lost: select in the calendar the date when previous transplant was lost

-Cause of previous transplants lost (multiple check): select cause or causes of the last transplant received

If others: Cause of previous transplants lost description: please, describe other/s causes of graft lost

*Motor Development: physical growth and strengthening of a child's bones, muscles, and ability to move and touch his/her surroundings.

*Cognitive Development: how the children process information, their conceptual resources, perceptual skills, problem solving, etc.

*Academic Activity Level: What is the academic load of the patient compared to other children of his age at this moment?

*Vaccines according to age and country schedule: Has the patient received the corresponding vaccines according to age and country schedule?

If no, *¿Is the vaccination schedule contraindicated?: the patient has any contraindication for vaccination

If no, *Accelerated schedule before transplantation?: if the patient is receiving an accelerated schedule before transplantation

5. Select **Save** at the bottom of the panel

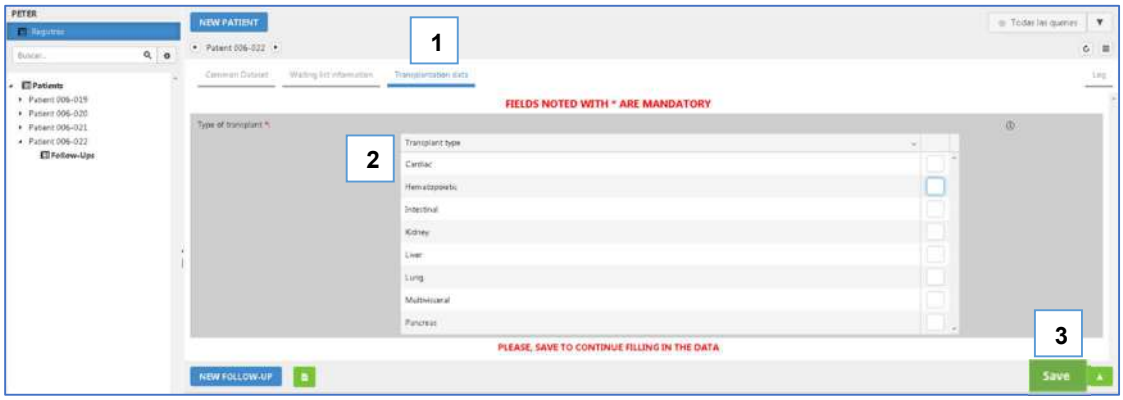

Figure 6. Transplantation data information

1. If the patient has been transplanted select the tab "**Transplantation data**" (Figure 6).
2. The form will be displayed to fill in the patient's transplant data.
3. Select the type of transplant that patient has received and click **Save** at the bottom of the panel.
4. After selecting the type of transplant, specific information for Solid organ transplantation **(SOT)** or Hematopoietic stem cell transplantation **(HSCT)** will be displayed.

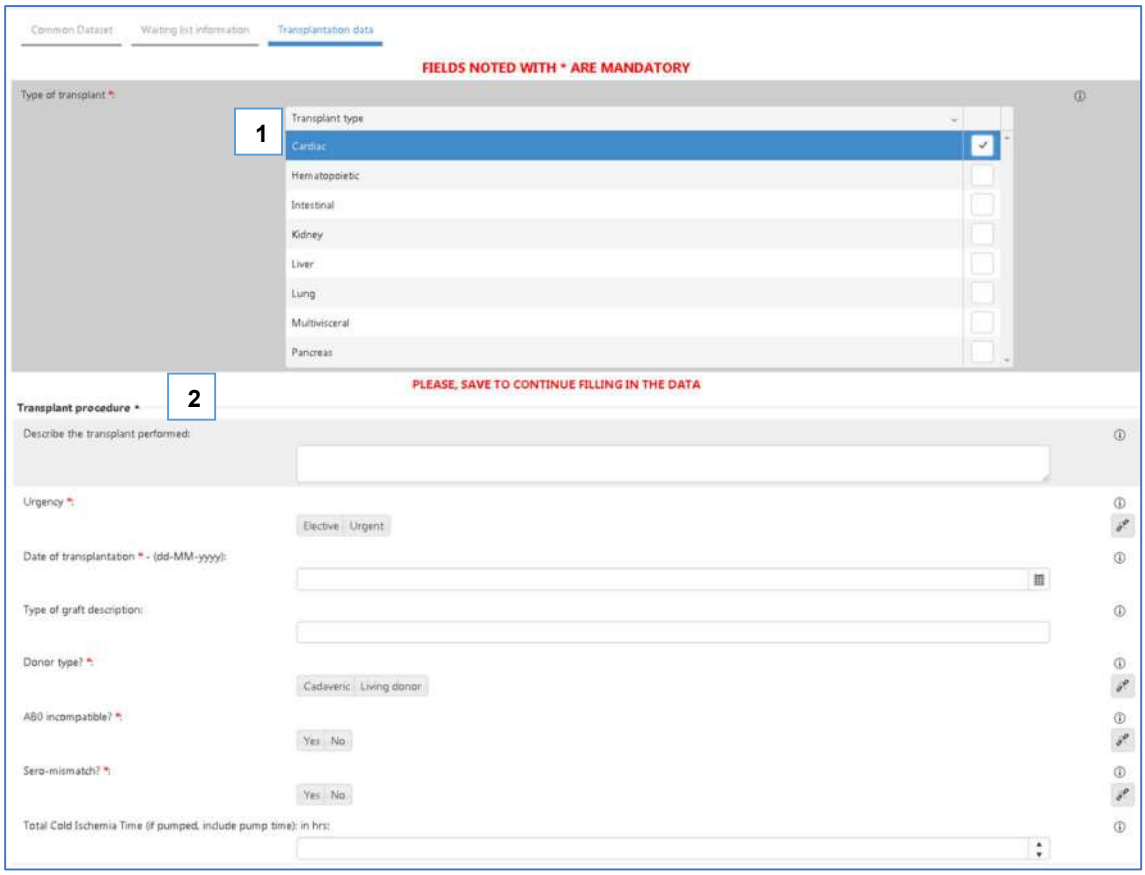

*Figure 7.1. Transplantation data information: **SOT** (transplant pocedure)*

1. If the patient has been received a solid organ graft (cardiac, intestinal, kidney, liver, lung, multivisceral or pancreas), the **SOT** form will be displayed (Figure 7.1).
2. Fill in the patient's transplant data specific information about transplant procedure, induction/immunosuppression treatment and early evolution after transplant.

    Describe the transplant performed: Please describe if transplant procedure has any relevant specifications (combine, etc.)

    *Urgency: Was the transplant urgent or elective for patient?

    *Date of transplantation: select in the calendar the date of transplant procedure.

    *Type of graft description: Describe the specifications of the graft (full, split, organs involved in the multivisceral, etc.)

    *Donor type: Select if the donor was alive or deceased.

    *AB0 incompatible?: Were the donor and the receptor of the same blood type or not?

    *Sero-mismatch?: Had the donor (D) and the receptor (R) any sero-mismatch to CMV or EBV?

        If yes: *Type of sero-mismatch (multiple check): select what kind of CMV or EBV sero-mismatch has D/R.

    *Total Cold Ischemia Time: select how many minutes had been since blood supply cut off of the graft until the time blood supply was restored (if pumped, include pump time)

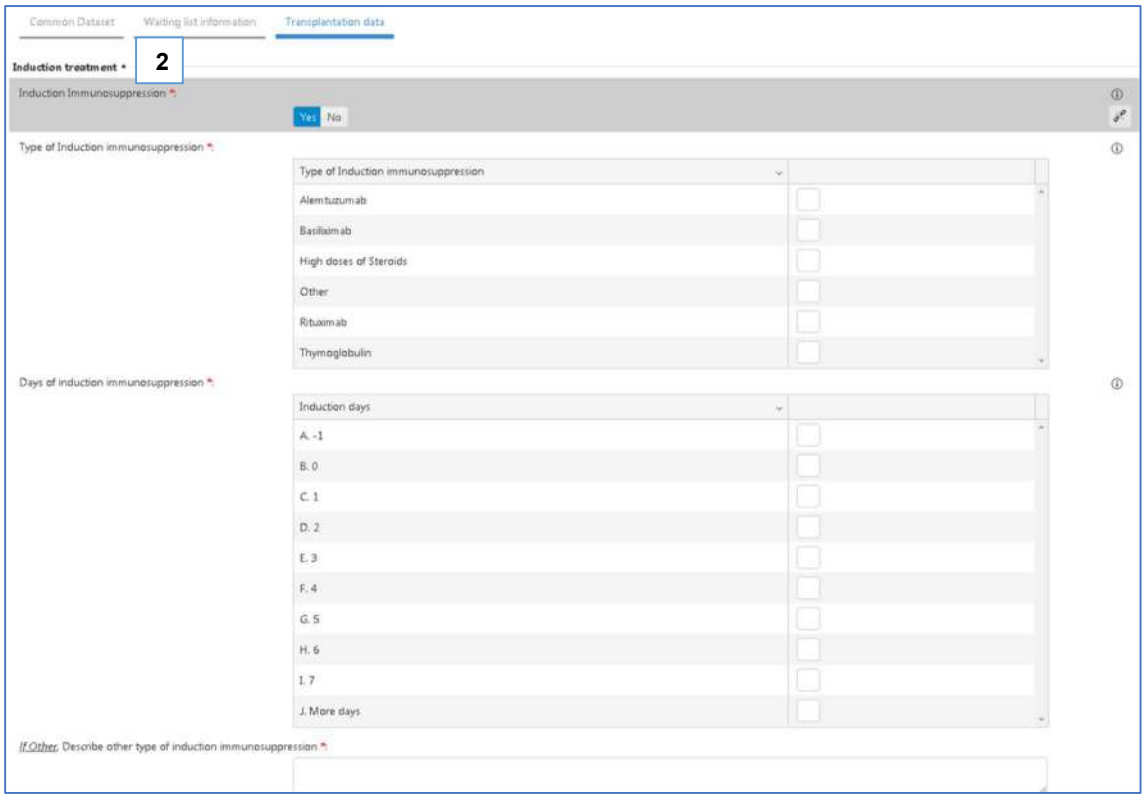

*Figure 7.2. Transplantation data information: **SOT** (induction/immunosuppression)*

*Induction Immunosuppression: had the patient received any immunosuppressive therapy to reduce the risk of allograft rejection? (Figure 7.2)

If yes: *Type of Induction immunosuppression: Select the immunosuppressants used in the induction (multiple check).

If other: *Describe other type of induction immunosuppression: describe other immunosuppressive agents administered.

*Days of induction immunosuppression: Select all the days of induction immunosuppression that have been used.

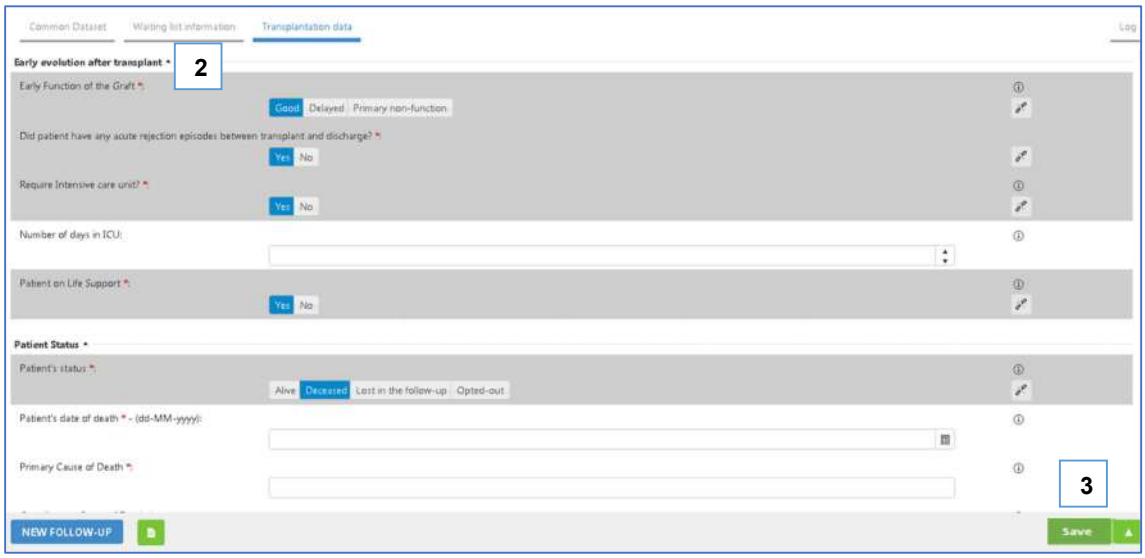

*Figure 7.3. Transplantation data information: **SOT** (early evolution after transplant and patient status)*

*Early Function of the Graft: select the immediate function of the graft after transplantation (Figure 7.3)

*Did patient have any acute rejection episodes between transplant and discharge?

*Require Intensive care unit?: Did the patient require intensive care after the transplant?

If yes: Number of days in ICU: For how many days did the patient stayed on intensive care unit?

*Patient on Life Support: Did the patient require life support after the transplant (mechanical ventilation, extracorporeal circulation etc.)?

*Patient's status: Is the patient alive or not after transplant?

If patient is deceased: *Patient's date of death: date of medical death of the patient

*Primary cause of death: disease or event that started the chain of events that led to death.

*Contributory cause of death: either a consequence or complication of the primary cause, or another disease which might have contributed to the death.

*Transplant related: Was the primary cause of death related to transplant procedure or not?

3. Once the information in **"Transplantation data"** is completed, select **Save** at the bottom of the panel.

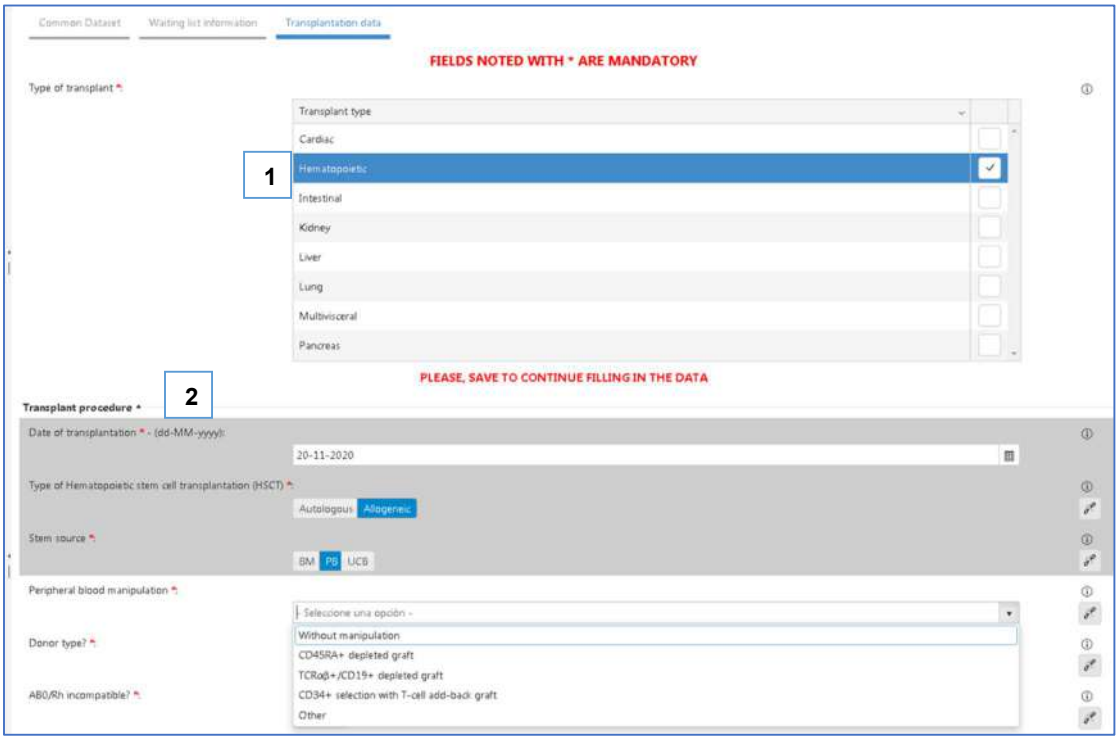

*Figure 8.1. Transplantation data information: **HSCT** (transplant procedure).*

1. If the patient has been received a hematopoietic stem cell transplant, the **HSCT** form will be displayed (Figure 8.1).
2. Fill in the patient's transplant data specific information about transplant procedure, conditioning regimen and early evolution after transplant.

*Date of transplantation: select in the calendar the date of transplant procedure
*Type of Hematopoietic stem cell transplantation (HSCT): select if HSCT is autologous or allogeneic
*Stem source: What kind of stem source was used? BM: bone marrow, PB: peripheral blood or UCB: umbilical cord blood.

If peripheral blood: *Peripheral blood manipulation: select if PB was manipulated or not and what type of peripheral blood was used (CD45RA+ depleted graft, TCRαβ+/CD19+ depleted graft, CD34+ selection with T-cell add-back graft, other)

If other: *Describe other manipulation of PB: if peripheral blood manipulation option was not listed.

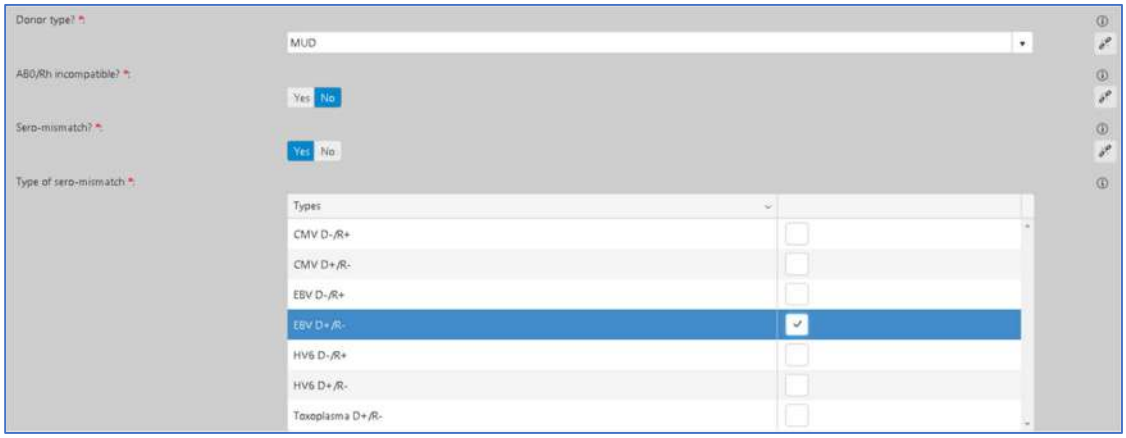

*Figure 8.2. Transplantation data information: **HSCT** (transplant procedure).*

*Donor type?: select the type of donor if: living (D) or cadaveric, related (R)/unrelated (U), match (M)/mismatch (MM)/haplo. (Figure 8.2)
*AB0/Rh incompatible?: Were the donor and the receptor of the same blood type or not?
*Sero-mismatch?: Had the donor (D) and the receptor (R) sero-mismatch for CMV, EBV, HV6 or toxoplasma?

If yes: *Type of sero-mismatch (multiple check): select what kind of sero-mismatch has D/R.

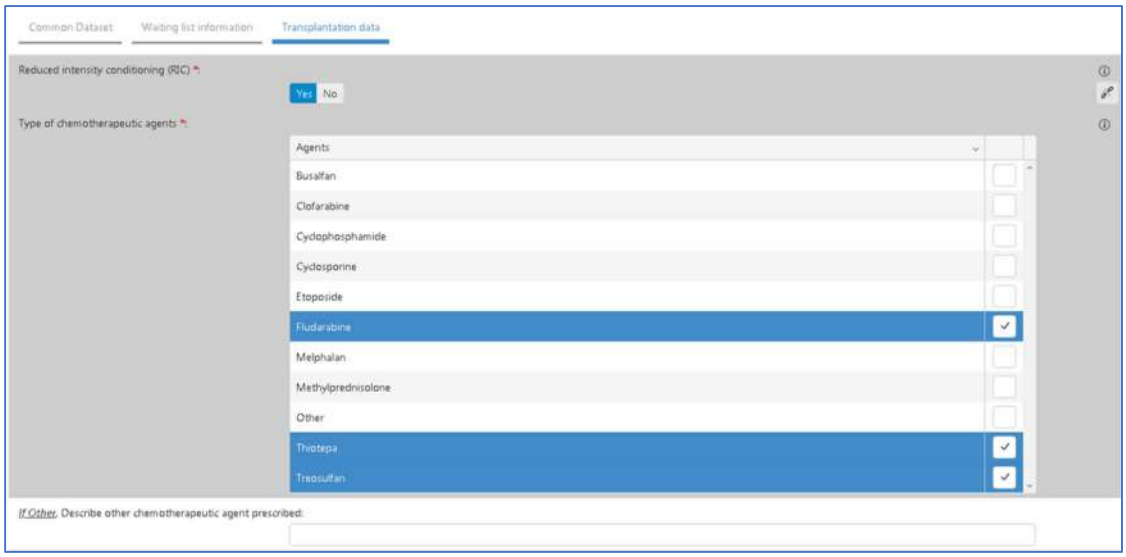

*Figure 8.3. Transplantation data information: **HSCT** (transplant procedure).*

*Reduced intensity conditioning (RIC): Was conditioning regimen a reduced intensity? (Figure 8.3)

*Type of chemotherapeutic agents (multiple check): Select all chemotherapeutic agents used in the conditioning regimen.

If other: Describe other chemotherapeutic agent prescribed, if chemo agent was not listed.

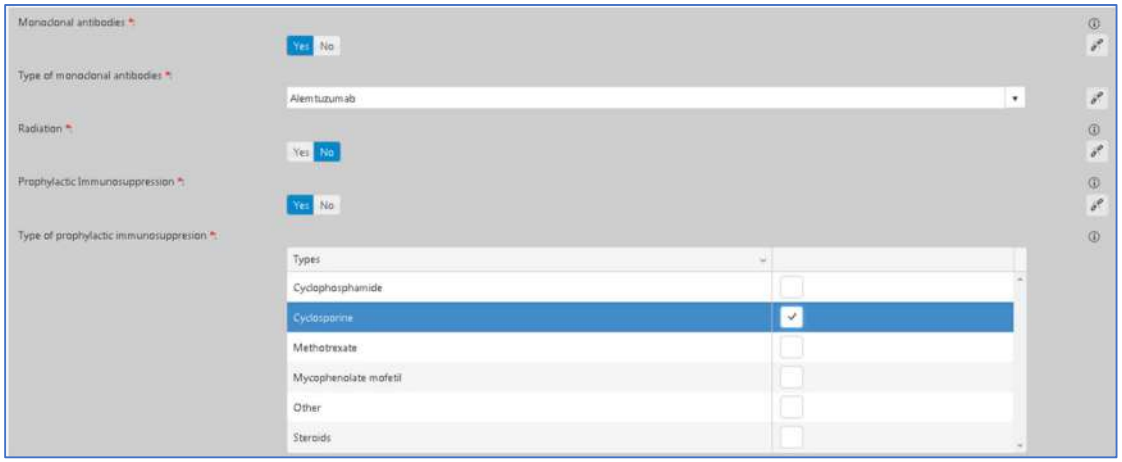

*Figure 8.4. Transplantation data information: **HSCT** (transplant procedure).*

*Monoclonal antibodies: was any monoclonal antibody prescribed in the conditioning regimen? (Figure 8.4)

If yes: *Type of monoclonal antibodies: select which monoclonal antibody was prescribed (Alemtuzumab, antithymocyte globuline, rituximab or other)

If other: *Describe other monoclonal antibody prescribed: if monoclonal antibody was not listed.

*Radiation: Was radiation use in the conditioning regimen?

If yes: *Type of radiation: select the radiation type used in the conditioning regimen Total Body Irradiation-TBI or Total Lymphoid

Irradiation-TLI.

*Prophylactic Immunosuppression: Has the patient received prophylactic immunosuppression to prevent GVHD or not?

If yes: *Type of prophylactic immunosuppression (multiple check): select the prophylactic immunosuppression prescribed.

If other: *Describe other immunosuppressive medication prescribed: if Immunosuppressive medication was not listed.

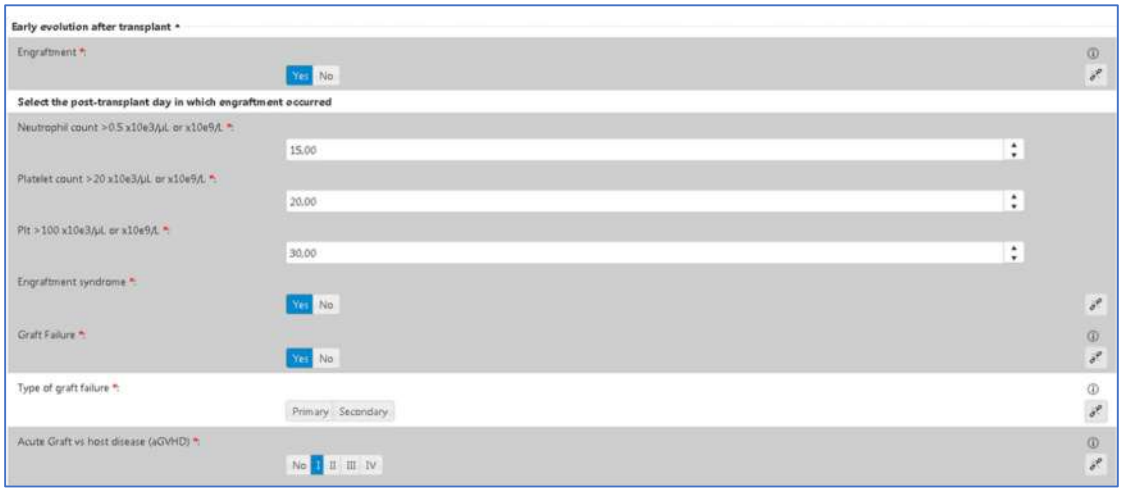

*Figure 8.5. Transplantation data information: **HSCT** (early evolution after transplant).*

*Engraftment: if the engraftment has already happened or not (Figure 8.5)

If yes: *Select the post-transplant day in which engraftment occurred:

*Neutrophil count >0.5 x10e3/µL or x10e9/L

*Platelet count >20 x10e3/µL or x10e9/L

*Plt >100 x10e3/µL or x10e9/L

*Engraftment syndrome: Did patient have engraftment syndrome or not?

*Graft Failure: Did patient have graft failure or not?

If yes: *Type of graft failure: select if patient had primary or secondary graft failure

*Acute Graft vs host disease (aGVHD): Did patient have aGVHD or not? and what was the overall grading (I, II, III, IV)

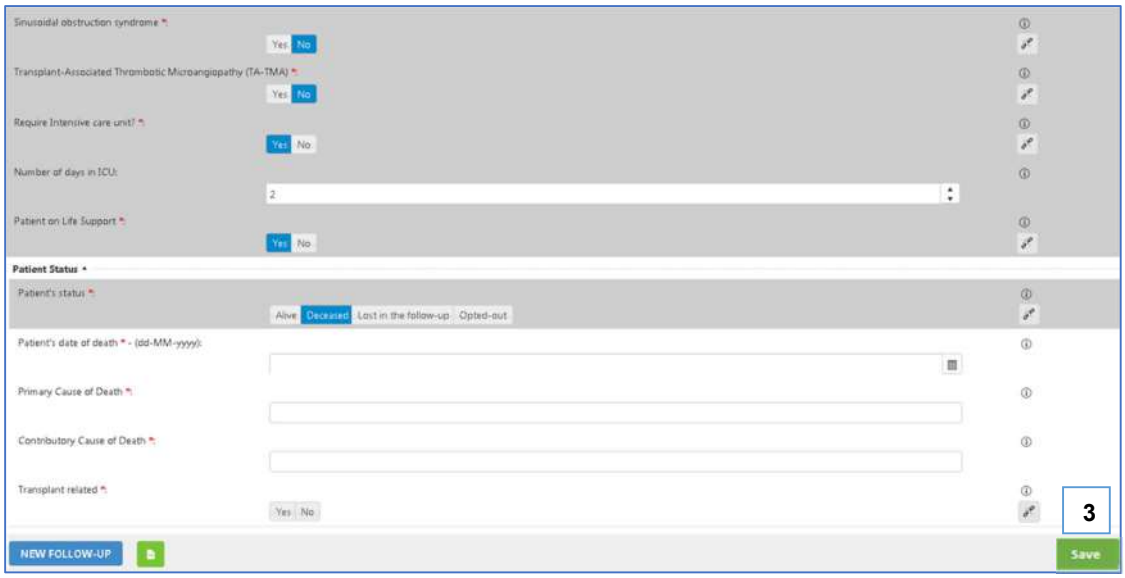

*Figure 8.6. Transplantation data information: **HSCT** (early evolution after transplant and patient status)*

*Sinusoidal obstruction syndrome: Did patient have sinusoidal obstruction syndrome or not?

*Transplant-Associated Thrombotic Microangiopathy (TA-TMA): Did patient have TA-TMA or not?

*Require Intensive care unit?: Did the patient require intensive care after the transplant?

If yes: Number of days in ICU: For how many days did the patient stayed on intensive care unit?

*Patient on Life Support: Did the patient require life support after the transplant (mechanical ventilation, extracorporeal circulation etc.)?

*Patient's status: Is the patient alive or not after transplant?

If patient is deceased: *Patient's date of death: date of medical death of the patient

*Primary cause of death: disease or event that started the chain of events that led to death.

*Contributory cause of death: either a consequence or complication of the primary cause, or another disease which might have contributed to the death.

*Transplant related: Was the primary cause of death relate to transplant procedure or not?

3. Once the information in **"Transplantation data"** is completed, select **Save** at the bottom of the panel

The patient will have been successfully re-registered and will appear in the patient list on the left with their ID.

3. Patient follow up

Once a patient is registered in PETER, a follow-up should be done at 3, 6, 12 months and then annually after transplantation. The information registered is relevant to their condition and the evolution of the transplant.

Figure 9. Register a new follow up

To follow up on a patient, you must follow these steps (Figure 9):

1. Select the patient from the list on the left panel
2. Once selected, your data will appear on the central panel
3. If the patient already has previous **Follow-ups,** they will appear displayed below in the left panel
4. To create a new patient **follow-up,** select "**NEW FOLLOW-UP**"
5. Select which follow up are you going to register
6. Within the follow-up there are 4 different tabs that must be completed with the patient's information
7. Select **Save** at the bottom of the screen.

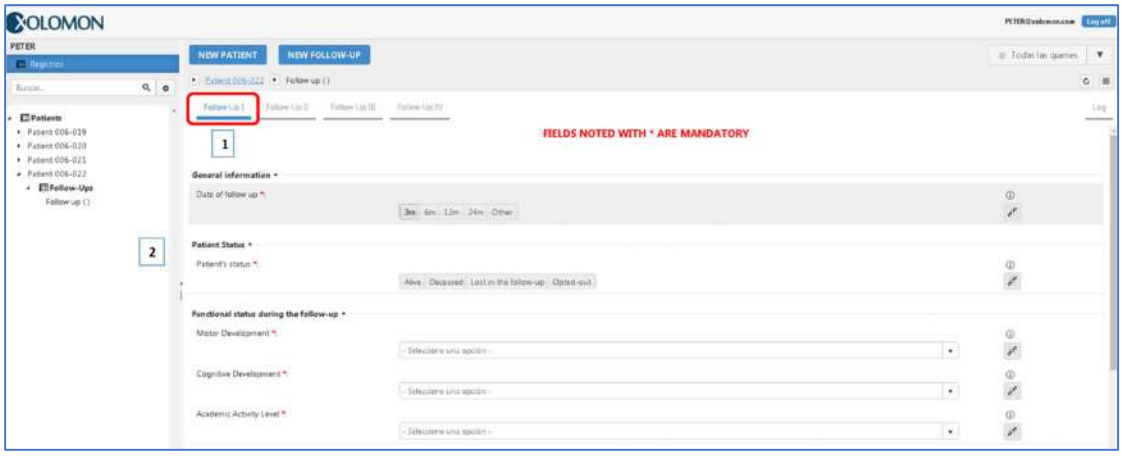

Figure 9.1. Register a new follow up: follow up I

1. Complete all data **"Follow up I"**: patient and functional status, hospitalizations, immunosuppression and medications.

   Patient's status: the patient is alive or not after transplant, or patient has been lost in the follow up or met any exclusion criteria (Opted-out) at a reference time-point of follow-up (Figure 9.1.)

   If patient is deceased: *Patient's date of death: date of medical death of the patient

*Primary cause of death: disease or event that started the chain of events that led to death.
*Contributory cause of death: either a consequence or complication of the primary cause, or another disease which might have contributed to the death.
*Transplant related: Was the primary cause of death related to transplant procedure or not?
If patient is lost in follow up: Describe possible reasons for the lost in the follow-up

Functional status during follow up: motor/cognitive development and academic level at a reference time-point of follow-up
*Motor Development: physical growth and strengthening of a child's bones, muscles, and ability to move and touch his/her surroundings.
*Cognitive Development: how the children process information, their conceptual resources, perceptual skills, problem solving, etc.
*Academic Activity Level: What is the academic load of the patient compared to other children of his age at this moment?

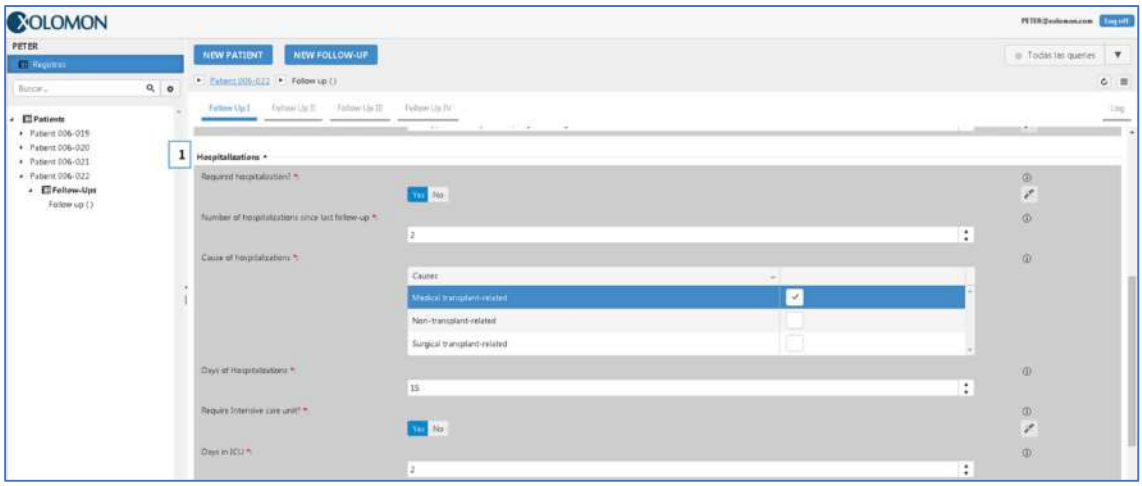

Figure 9.2. Follow up I: hospitalizations

Hospitalizations (Figure 9.2.)
*Required hospitalization?: Has the patient required hospitalizations since last follow up?
If yes: *Number of hospitalizations since last follow-up: Number of hospitalizations required since last follow up?
*Cause of hospitalizations: Select the cause(s) for which the patient has required hospitalizations
*Days of Hospitalizations: The sum of days of hospitalizations since last follow up
*Did the patient require Intensive care unit?: if the patient required intensive care during those hospitalizations
If yes: *Days in ICU: The sum of days the patient stayed at intensive care unit since last follow up.

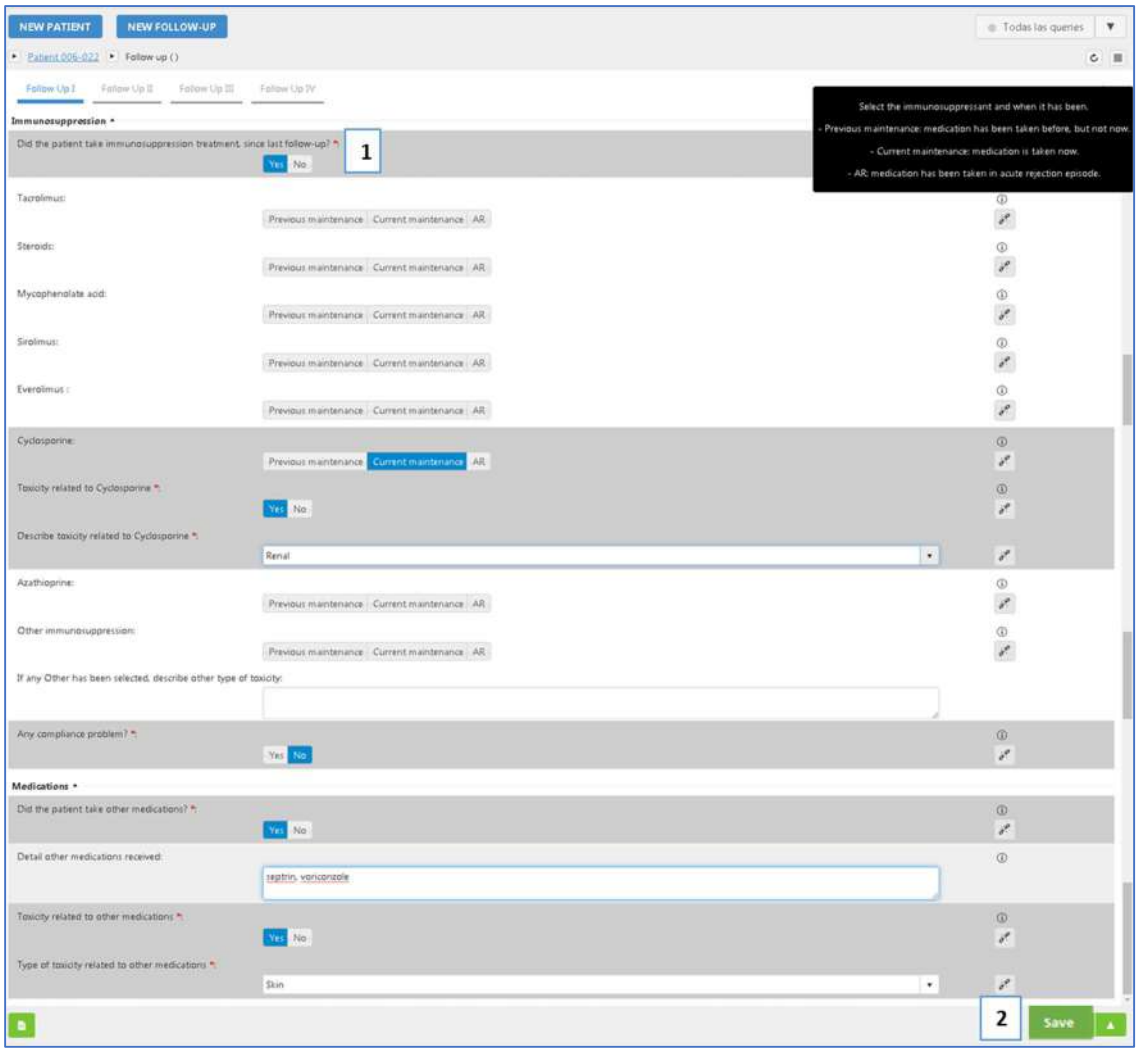

Figure 9.3. Follow up I: immunosuppression and medications

1. Complete all data **"Follow up I"**: immunosuppression and medications (Figure 9.3).

Immunosuppression:

*Did patient take immunosuppression treatment, since last follow-up?

If yes: select all immunosuppressant that patient has received since the last follow up, and when it has been taken.

- Previous maintenance: medication has been taken before, but not now.
- Current maintenance: medication is taken now.
- Acute rejection (AR): medication has been taken in an acute rejection episode.

Immunosuppressants: tacrolimus, steroids, mycophenolate mofetil, sirolimus, everolimus, cyclosporine, azathioprine and other.

If other immunosuppression: Describe if patient has taken any other immunosuppression regimen not listed before.

If any immunosuppressant has been selected:

*Toxicity related to specific immunosuppressant: Did the patient show toxicity to this immunosuppressant since last follow-up?

If yes: *Type of toxicity related to specific immunosuppressant: select all kind of system toxicity (renal, hematological, hepatic, skin,

gastrointestinal, CNS, metabolic, other)
If any other system has been selected: Describe other type of toxicity not listed before.

*Any compliance problem?: the patient had any compliance problem with the medication or not.

Medications:
*Did patient take other medications?: the patient took other medication different from the immunosuppression (for the base disease, secondary complications, etc.)
If yes: Detail other medications received: Describe other medication received by the patient different from the immunosuppression.

*Toxicity related to other medications: Did the patient show toxicity to other medications since last follow-up?
If yes: *Type of toxicity related to specific immunosuppressant: select all kind of system toxicity (renal, hematological, hepatic, skin, gastrointestinal, CNS, metabolic, other)
If any other system has been selected: Describe other type of toxicity not listed before.

2. Select **Save** at the bottom of the screen.

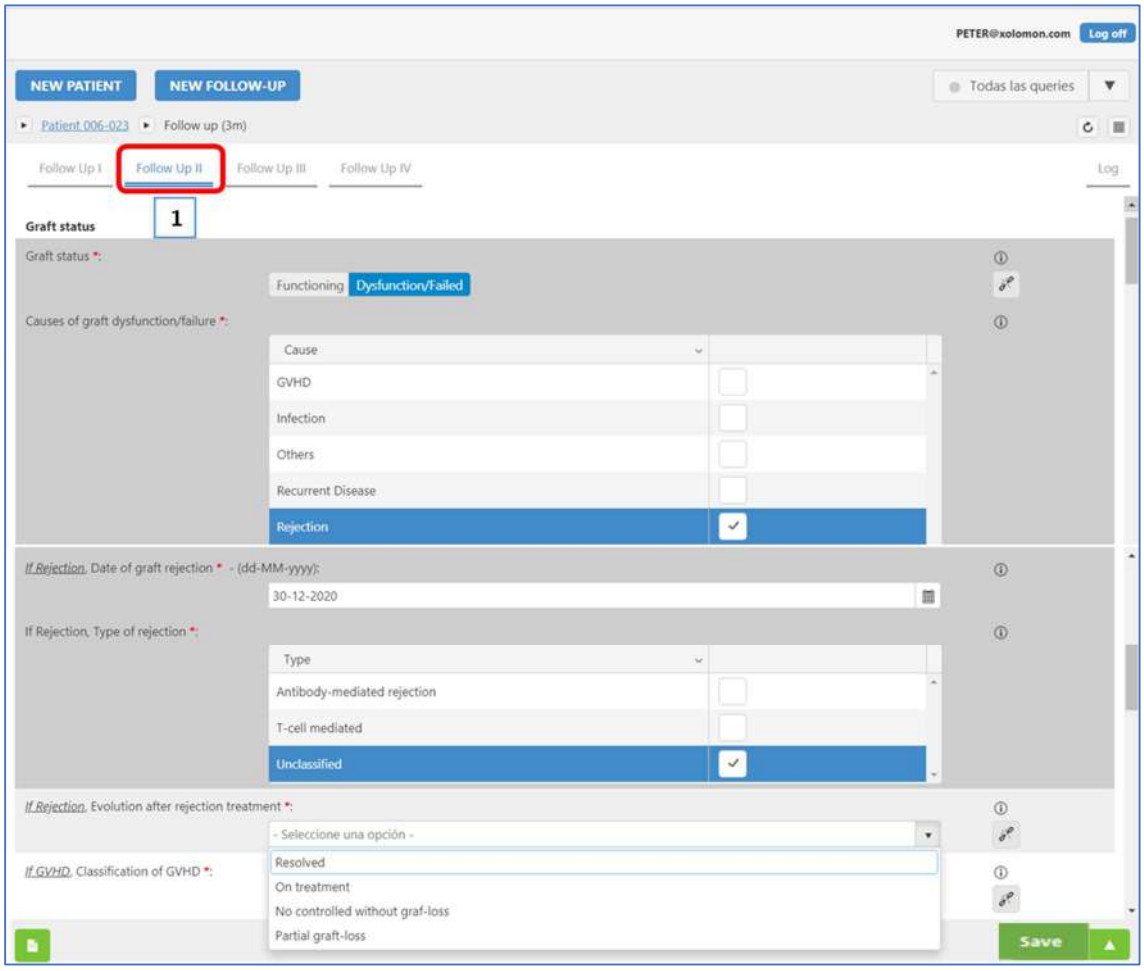

*Figure 10.1. Follow up II: Graft status **(SOT)***

1. Select the tab **"Follow up II"**.
2. If the patient has been received a solid organ transplant, the **SOT graft status** form will be displayed (Figure 10.1.).

   Graft status:

   *Function of the graft at moment of the follow up

   If dysfunction/failed: *Causes of graft dysfunction/failure: Select all causes of graft dysfunction or failure (GVHD, infection, recurrent disease, rejection, other)

   If rejection, *Date of graft rejection: Date when graft rejection was diagnosed

   Type of rejection: select type(s) of rejection (T-cell mediated, antibody-mediated rejection, unclassified)

   *Evolution after rejection treatment: select the evolution of the graft function after rejection treatment (resolved, on treatment, no controlled without graft-loss, partial graft loss)

   If GVHD, *Classification of GVHD: type of graft versus host disease

   *Date of GVHD: Date when graft vs host disease was diagnosed

   If others: *Other(s) causes of failure description: describe other cause of graft failure different from previous listed

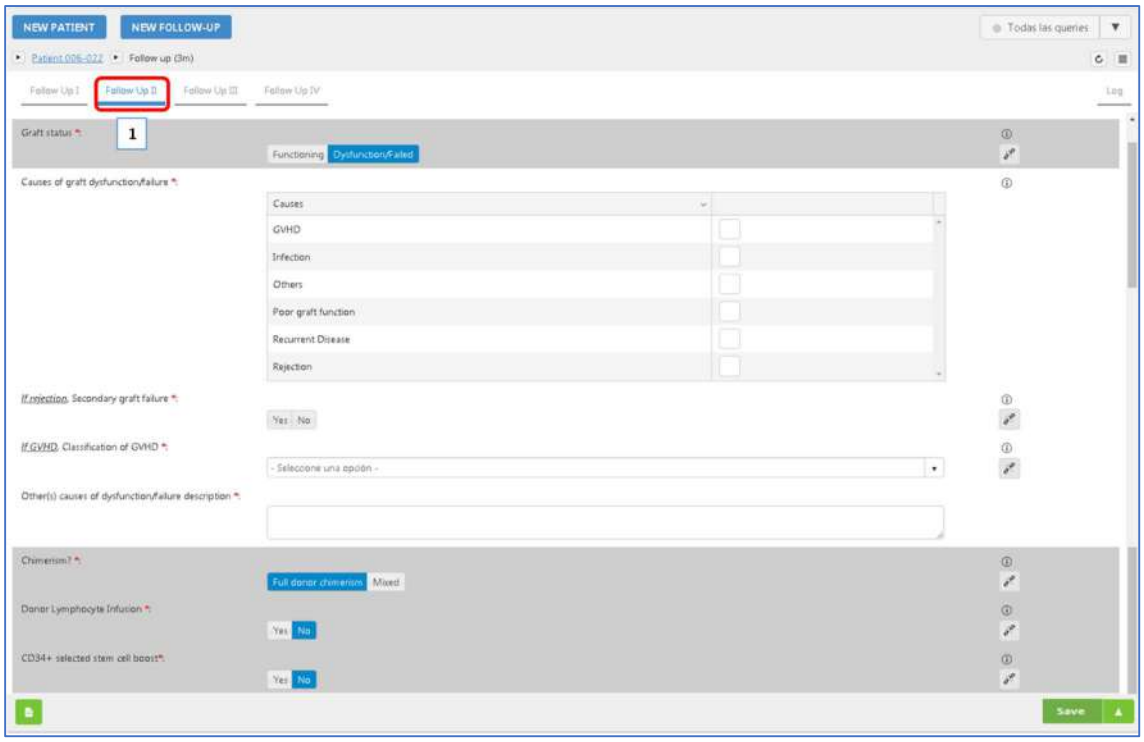

*Figure 10.2. Follow up II: Graft status **(HSCT)***

1. Select the tab **"Follow up II"**.
2. If the patient has been received a hematopoietic stem cell transplant, the **HSCT graft status** form will be displayed (Figure 10.2.).

   Graft status: *Function of the graft at moment of the follow up

   If dysfunction/failed: *Causes of graft dysfunction/failure: Select all causes of graft dysfunction or failure (GVHD, infection, poor graft function, recurrent disease, rejection, other)

   If rejection, *Secondary graft failure : if rejection is due to secondary graft failure or not

If GVHD, *Classification of GVHD: type of graft versus host disease (classic acute GVHD, late onset acute GVHD, classic chronic GVHD, overlap syndrome)

If classic or late onset acute GVHD, *Classification of aGVHD: select overall grade of aGVHD (1, 2, 3, 4)

If chronic GVHD, *Classification of cGVHD: select grade of cGVHD (mild, moderate, severe)

If other: *Other(s) causes of failure description: describe other cause of graft failure different from previous listed

*Chimerism?: graft chimerism at moment of the follow up (Full donor chimerism or mixed)

*Donor Lymphocyte Infusion: if DLI has been used for enhancing graft vs leukemia effect or improve donor mixed chimerism.

If yes: *Improvement after DLI: yes or not

*CD34+ selected stem cell boost (SCB): If SCB has been used or not

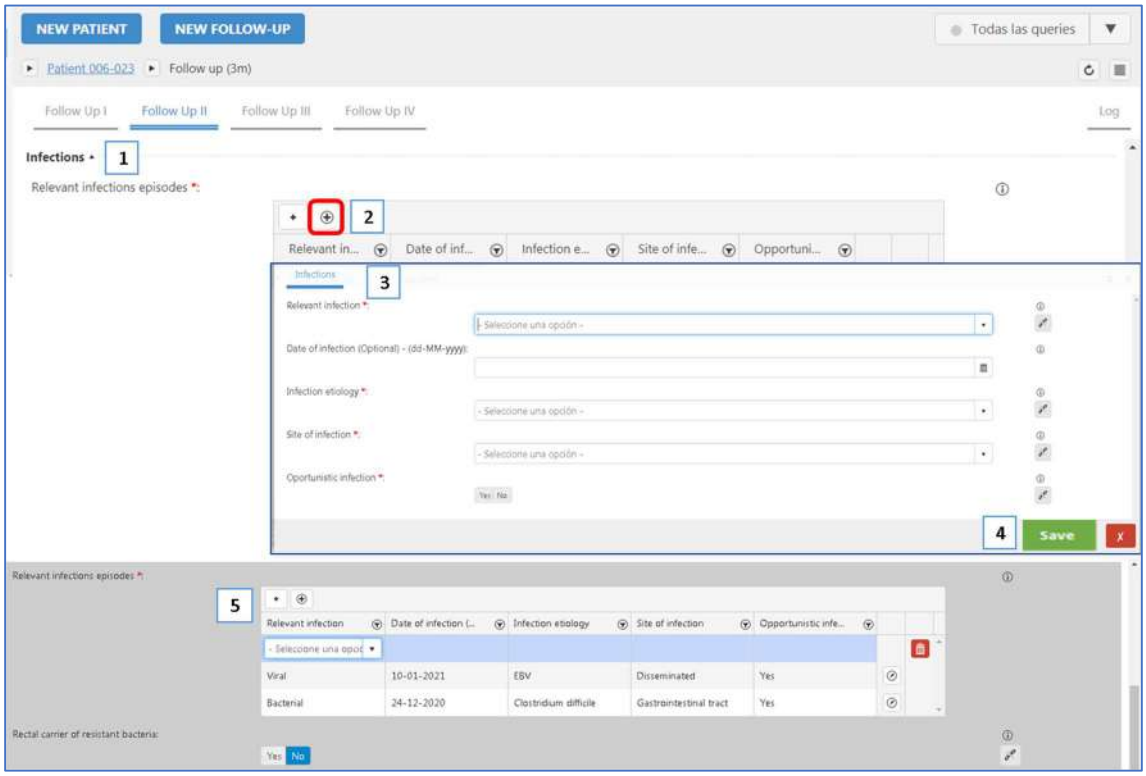

Figure 10.3. Follow up II: infections

1. **Infections** form will be displayed to fill in (Figure 10.3).
2. For each relevant infection, click ⊕ at the top left of infections table.
3. A floating window will appear.

***Relevant infection:** select the type of infection (Bacterial, fungal, viral, parasitic, other)

Date of infection (Optional): select in the calendar the date when infection was diagnosed

***Infection etiology:** select the pathogen responsible of the infection

***Site of infection:** select the primary infection site

***Opportunistic infection**: this infection was caused by opportunistic pathogen or not.

4. Click **Save** and then **Exit** at the bottom right of the screen.
5. If your patient has more than one relevant infection, please repeat steps **2-4** as necessary.

***Rectal carrier of resistant bacteria:** the patient is carrier of rectal resistant Bacteria or not

Figure 10.4. Follow up II: post transplant malignancy

1. **Post transplant malignancy** form will be displayed to fill in (Figure 10.4).

*Original tumour relapse: the patient had suffered a relapse of the original malignancy since last follow up or not

If yes, *Date of relapse: Indicate the date of confirmed diagnosis of relapse

*Post-Tx *de novo* Neoplasia?: the patient has developed a neoplasia (after the transplant) since last follow up or not

If yes, *Date of *de novo* Neoplasia: Date of diagnosis of the neoplasia

Tumour localization: select the localization of tumour.

Type of neoplasia: describe the type of neoplasia (benign, pre-malignant, malignant, histology, etc.)

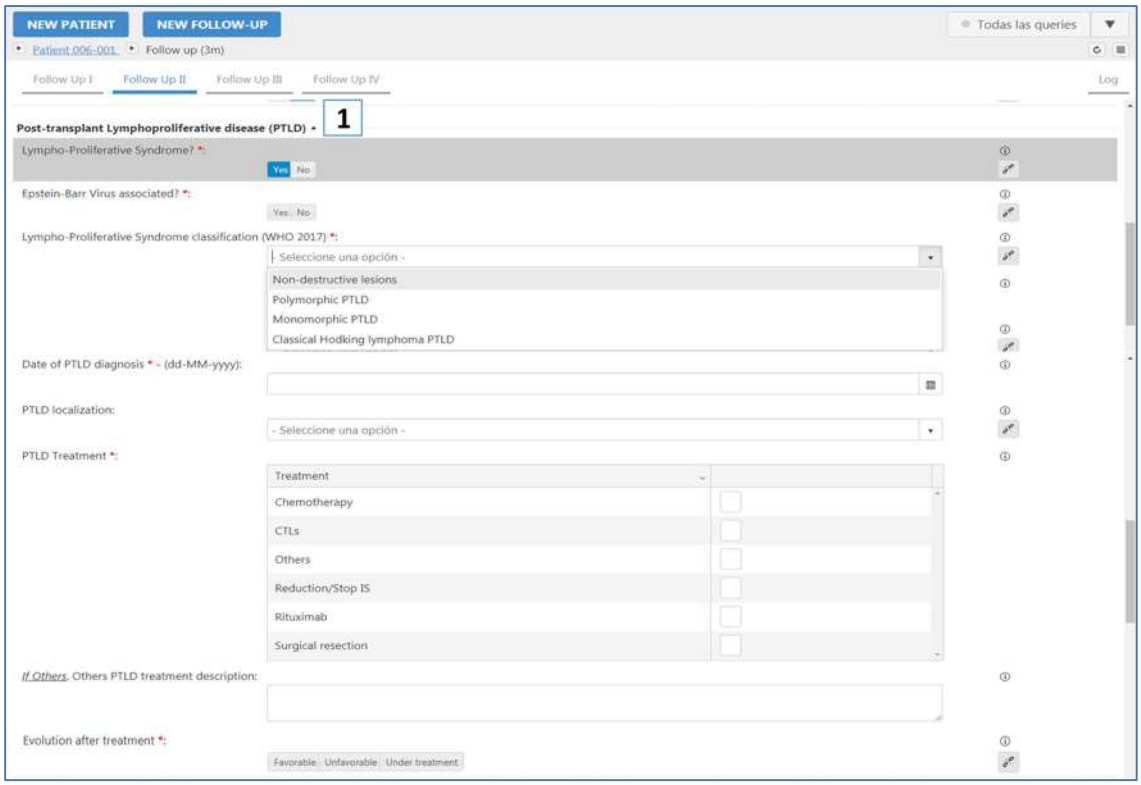

Figure 10.5. Follow up II: post-transplant lymphoproliferative disease (PTLD)

1. **Post-transplant lymphoproliferative disease (PTLD)** form will be displayed to fill in (Figure 10.5).

    *Lympho-Proliferative Syndrome?: the patient has developed a Lymphoproliferative disorder secondary to the transplant or not

    If yes, *Epstein-Barr Virus associated?: PTLD is associated to a primary EBV infection or post-transplant EBV reactivation, or not

    *Lympho-Proliferative Syndrome classification (WHO 2017): select the classification of the disease according to WHO 2017 → Nondestructive PTLD (plasmacytic hyperplasia, florid follicular hyperplasia, and infectious mononucleosis-like PTLD), Polymorphic PTLD, Monomorphic PTLD (B-cell, T-cell, or natural killer-cell types) and classic Hodgkin's lymphoma-like PTLD.

    *Date of PTLD diagnosis: Date when the PTLD was diagnosed to the patient

    *PTLD localization: select the main localization of the PTLD

    *PTLD Treatment: select the treatment(s) received by the patient for PTLD → Reduction/Stop IS, Rituximab only, Chemotherapy, Surgical resection, CTLs, others.

    If others, Others PTLD treatment description: describe other type of treatment different from the listed before

    *Evolution after treatment: select the evolution after PTLD treatment

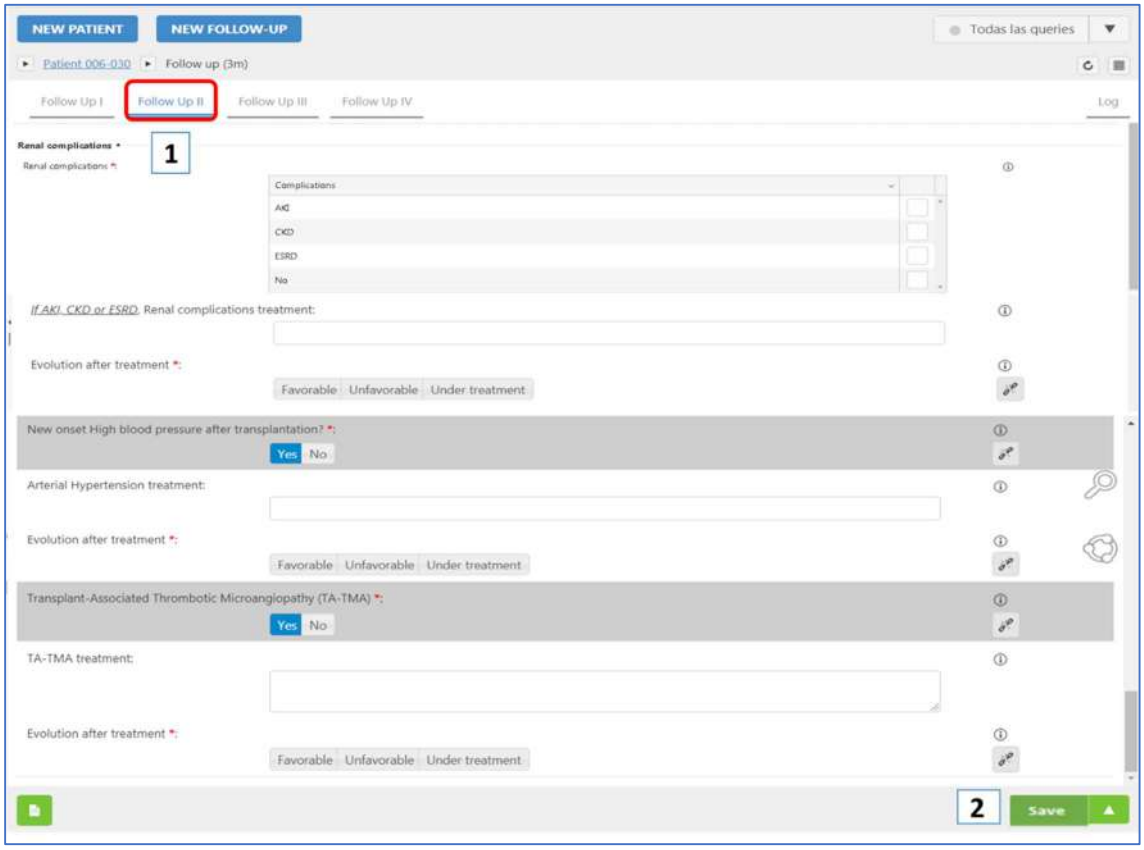

Figure 10.6. Follow up II: renal complications

1. **Renal complications** form will be displayed to fill in (Figure 10.6).
   - *Renal complications: select if the patient has any post-transplant renal complications since last follow up or not. (AKI: acute kidney injury, CKD: chronic kidney disease, ESRD: end-stage renal disease)
     - If AKI, CKD or ESRD, Renal complications treatment: describe the treatment received by the patient for the renal complications
       - *Evolution after treatment: select the evolution of the renal function after treatment
   - * New onset High blood pressure after transplantation?: the patient suffer from high blood pressure after transplantation, since last follow up or not
     - If yes, Arterial Hypertension treatment: describe the treatment prescribed for arterial hypertension
       - *Evolution after treatment: select the evolution after arterial hypertension treatment
   - * Transplant-Associated Thrombotic Microangiopathy (TA-TMA): patient has been diagnosed with TA-TMA since last follow up or not
     - If yes, TA-TMA treatment: describe the treatment received by the patient for TA-TMA
       - *Evolution after treatment: select the evolution after TA-TMA treatment
2. Select **Save** at the bottom of the screen.

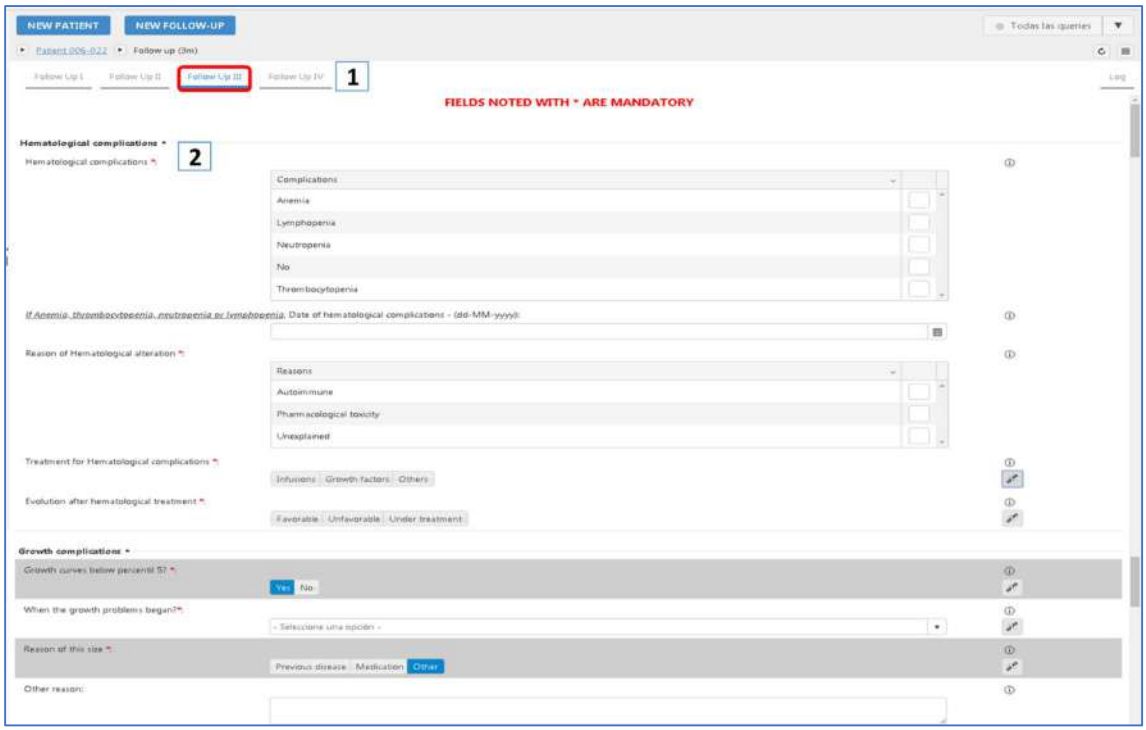

Figure 11.1. Follow up III: hematological and growth complications

1. Select the tab **"Follow up III"**.
2. **Hematological and growth complications** form will be displayed to fill in (Figure 11.1).

*__Hematological complications__: select if the patient has suffered any hematological complication after transplantation since last follow up, or not

If anemia, thrombocytopenia, neutropenia or lymphopenia, Date of hematological complications: indicate the date of the first hematological complication

*Reason of Hematological alteration: select the reason for the hematological complication (autoimmune, pharmacological toxicity or unexplained)

*Treatment for Hematological complications: select the treatment received by the patient for the hematological complication (infusions, growth factors, others)

*Evolution after hematological treatment: select the evolution after treatment of the hematological complication

*__Growth curves below percentile 5th?:__ the patient´s growth curve is abnormal (under percentile 5th) or not

If yes, *When the growth problems began?: In which period time (related to transplant procedure: pre-transplant, during transplant +/-1month or post-transplant) the growth problem began

*Reason of this size: Select if the primary reason for abnormal growth in the patient is previous disease, medications or other

If other, Other reason: Describe the other reason for abnormal growth rate in the patient

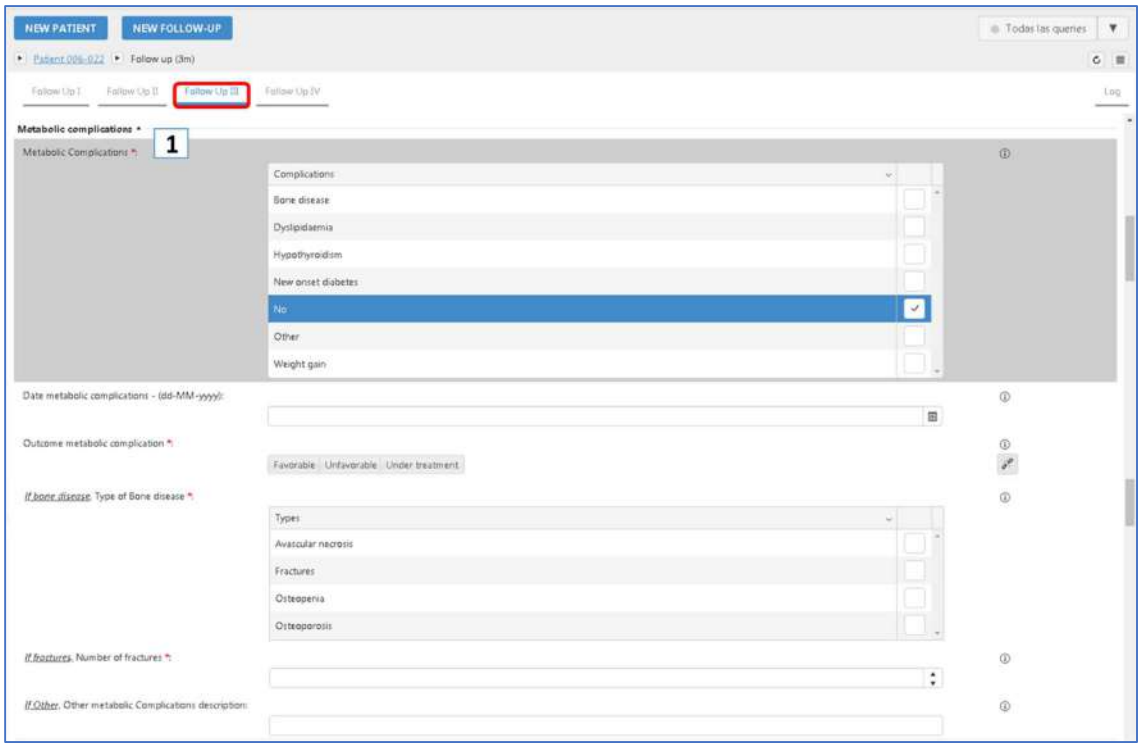

Figure 11.2. Follow up III: metabolic complications

1. **Metabolic complications** form will be displayed to fill in (Figure 11.2).

    ***Metabolic Complications** the patient has been diagnosed with any metabolic complication after transplantation since last follow up or not (New onset diabetes, hypothyroidism, bone disease, dyslipidemia, weight gain, other)

    If metabolic complications, Date metabolic complications: indicate when the metabolic complication started

    *Outcome metabolic complication: select the current outcome of the metabolic complication after treatment

    If Bone disease, *Type of Bone disease: select the type of bone disease secondary to the transplant (avascular necrosis, fractures, osteopenia, osteoporosis)

    If fractures, *Number of fractures: indicate the number of fractures diagnosed in the patient since last follow-up

    If other, *Other metabolic complications description: describe other metabolic complication different from the list above

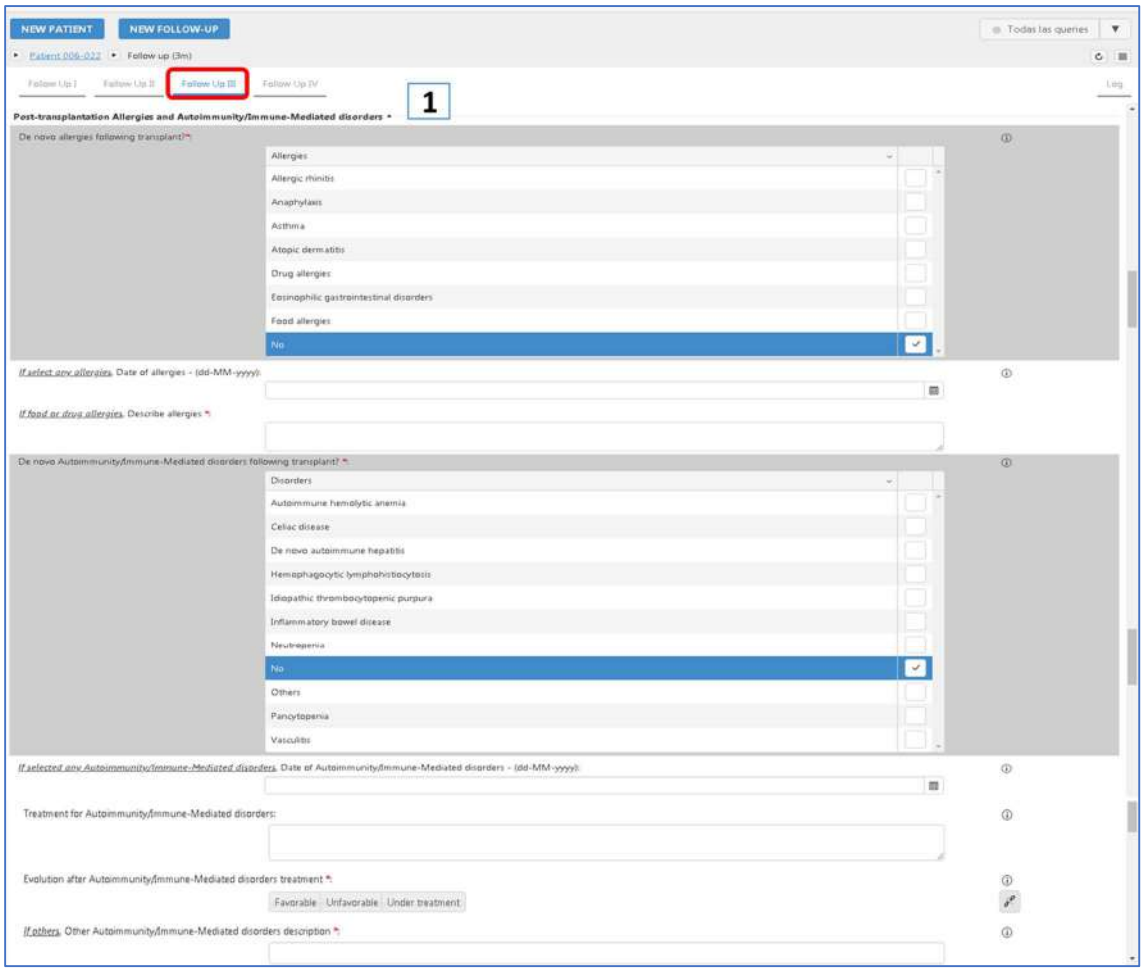

Figure 11.3. Follow up III: post-transplantation allergies and autoimmunity/immune mediated disorders

1. **Post-transplantation allergies and autoimmunity/immune mediated disorders** form will be displayed to fill in (Figure 11.3).
    - **De novo* allergies following transplant?: the patient has suffered any allergy or not
        - If any allergy, Date of allergy: indicate the date when the first allergy began
        - If food o drug allergies, *Describe allergies: describe the current food or drug allergies
    - **De novo* Autoimmunity/Immune-Mediated (AIM) disorders following transplant?: the patient has been diagnosed with any AIM disorder or not
        - If any AIM disorder, Date of AIM disorder: indicate the date when the first AIM disorder began
        - Treatment for AIM disorders: describe the treatment prescribed for AIM disorders
        - *Evolution after AIM disorders treatment: select the evolution after treatment of the AIM disorders
        - If others, *Other AIM disorders description: describe other AIM disorders different from the list above

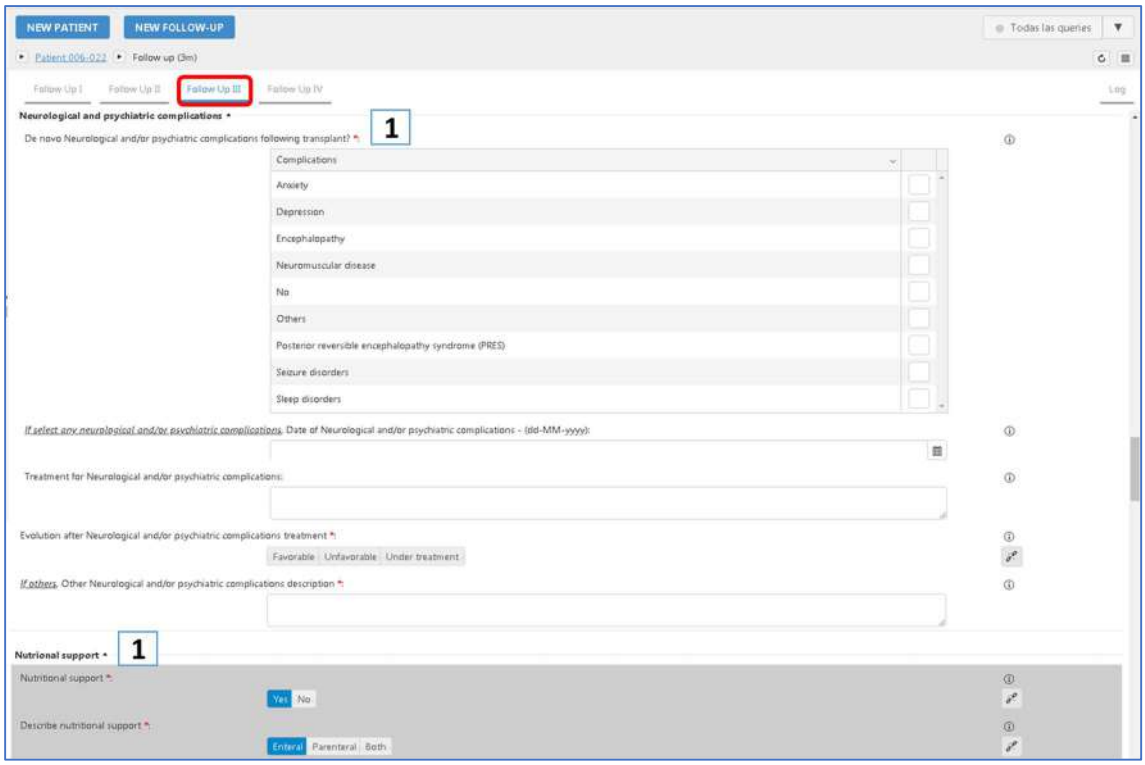

Figure 11.4. Follow up III: neurological and psychiatric complications, nutritional support

1. **Neurological and psychiatric complications, nutritional support** form will be displayed to fill in (Figure 11.4)

*__De novo Neurological and/or psychiatric complications following transplant__? the patient has been diagnosed with any neurological and/or psychiatric complication or not

__If any neurological and/or psychiatric complications__, Date of Neurological and/or psychiatric complications: indicate the date when the first neurological and/or psychiatric complications began

Treatment for Neurological and/or psychiatric complications: describe the treatment for neurological and/or psychiatric complications

*Evolution after Neurological and/or psychiatric complications treatment: select the evolution after treatment of the neurological and/or psychiatric complication

__If others__, *Other Neurological and/or psychiatric complications description: describe other neurological and/or psychiatric complications different from the list above

***Nutritional support:** Does the patient need nutritional support at the moment of follow up? Yes or not

__If yes__, *Describe nutritional support: select the type of nutritional support needed by the patient

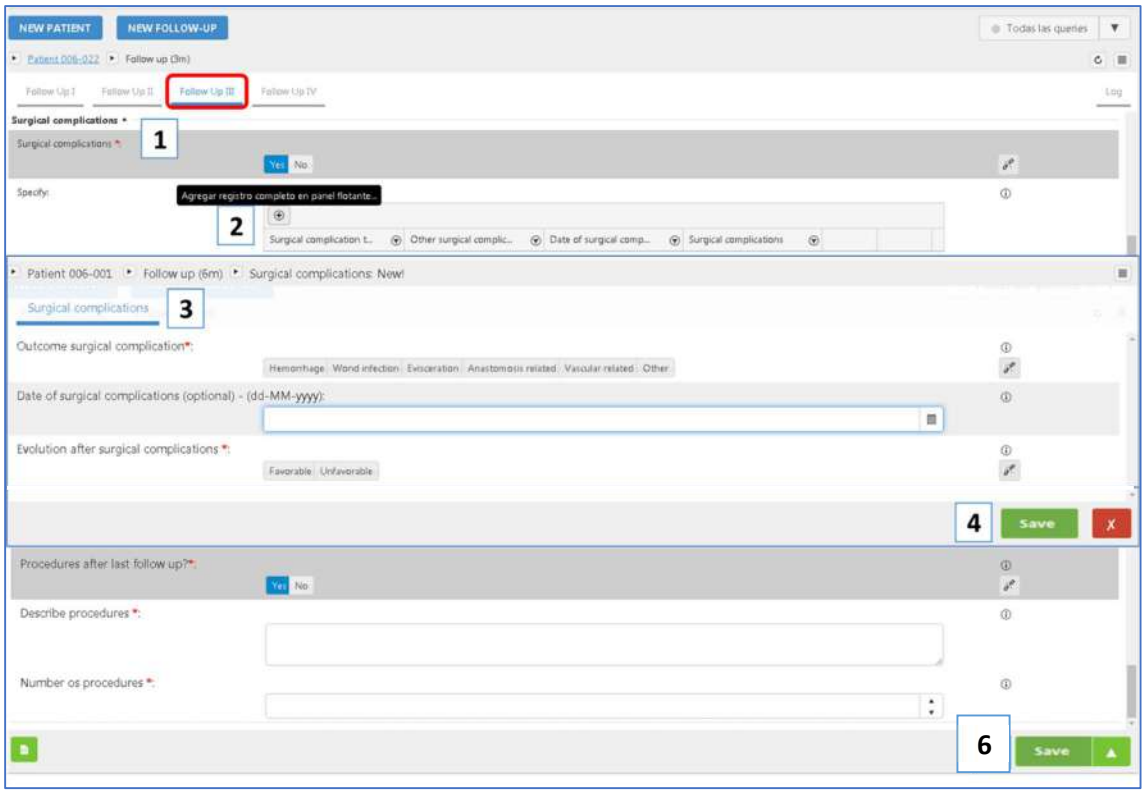

Figure 11.5. Follow up III: surgical complications

1. **Surgical complications** form will be displayed to fill in (Figure 11.5).
   - ***Surgical complications:** the patient has suffered any surgical complication during or after the transplant procedure or not
     - If yes, surgical complication chart has to be displayed
2. For each surgical complication, click ⊕ at the top left of surgical complication table.
3. A floating window will appear.
   - ***Outcome surgical complication:** select the type of surgical complication (Hemorrhage, wound infection, evisceration, anastomosis related, vascular related, vascular related, other)
   - **Date of surgical complications (Optional):** select in the calendar the date when surgical complication was diagnosed
   - ***Evolution after surgical complication:** select the evolution after surgical Complication treatment/surgery
4. Click **Save** and then **Exit** at the bottom right of the screen.
5. If your patient has more than one surgical complication, please repeat steps **2-4** as necessary.
   - ***Procedures after last follow up?:** the patient has had any (surgical) procedures since the last follow-up
     - If yes, *Describe procedures: describe the surgical procedures performed since last follow up
       *Number of procedures: indicate the number of surgical procedures performed since last follow up
6. Select **Save** at the bottom of the screen.

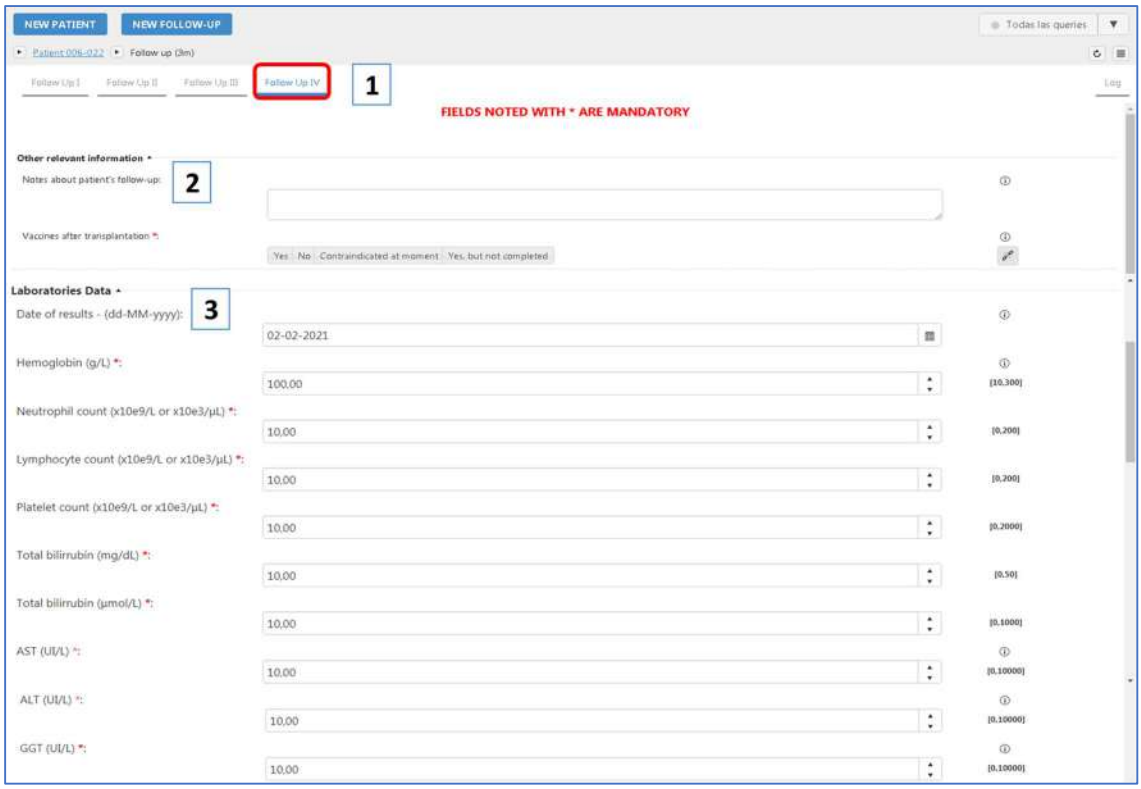

Figure 12.1. Follow up IV: other relevant information and laboratories data

1. Select the tab **"Follow up IV"**.
2. **Other relevant information** form will be displayed to fill in (Figure 12.1).

   Notes about patient's follow-up: Please describe any relevant information of the patient not collected in the form since the previous follow up

   ***Vaccines after transplantation**: the patient has received the corresponding vaccines according to after transplantation calendar or not or they are contraindicated at moment
3. **Laboratories data** form will be displayed to fill in.

   *Date of results: indicate the date of the laboratory findings.

   *Hemoglobin (g/L)

   *Neutrophil count (x10e9/L or x10e3/µL): absolute count of neutrophils

   *Lymphocyte count (x10e9/L or x10e3/µL): absolute count of lymphocytes

   *Platelet count (x10e9/L or x10e3/µL): absolute count of platelet

   *Total bilirubin (mg/dL or µmol/L)

   *AST (UI/L): aspartate aminotransferase

   *ALT (UI/L): alanine aminotransferase

   *GGT (UI/L): gamma glutamyl transferase

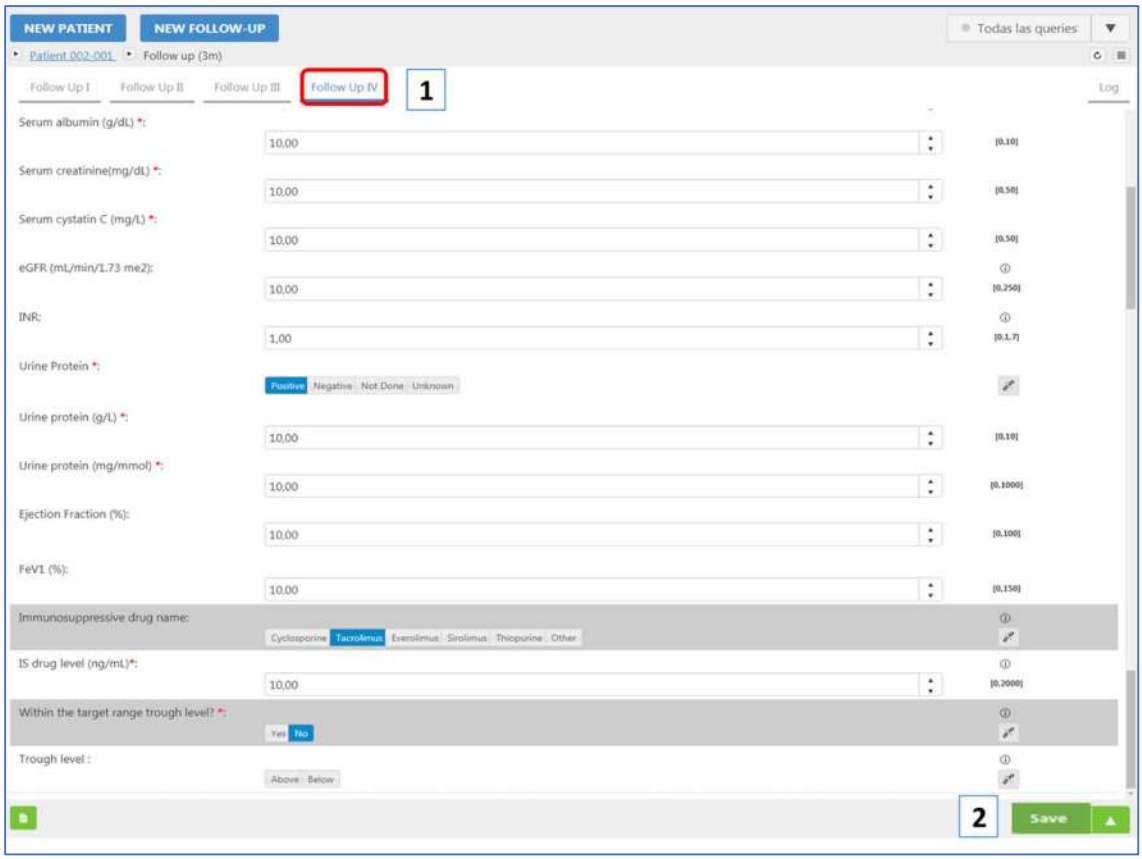

Figure 12.2. Follow up IV: laboratories data

1. Complete **laboratories data** form (Figure 12.2).

*Serum albumin (g/dL)
*Serum creatinine (mg/dL)
*Serum cystatin C (mg/L)
eGFR (mL/min/1.73me2): estimated glomerular filtration rate
*INR: International normalized ratio
*Urine Protein: positive, negative, not done or unknown
If positive, *Urine protein (g/dL or mg/mmol)
Ejection Fraction (%): left ventricle ejection fraction (echocardiogram)
FeV1 (%): forced expiratory volume in the first second (spirometry)
Immunosuppressive drug name: select the current immunosuppression regime of the patient (cyclosporine, tacrolimus, everolimus, sirolimus, thiopurine, other)
For cyclosporine, tacrolimus, everolimus, sirolimus, *IS drug level (ng/mL): immunosuppression levels of the current regime of the patient
*Within the target range trough level?: The IS drug level is within the target range trough level for this moment after transplantation and type of transplant or not
If no, Trough level: The IS drug level is above or below the target range trough level for this moment after transplantation and type of transplant
For thiopurine and other, *IS drug/metabolite level: Describe the immunosuppression levels of the current regime of the patient
*Within the target range trough level?: The IS drug level is within the

target range trough level for this moment after transplantation and type of transplant or not

If no, Trough level: The IS drug/metabolite level is above or below the target range trough level for this moment after transplantation and type of transplant

2. Select **Save** at the bottom of the screen.

Modify patient data

Once a patient is registered in PETER, it is possible to modify their data, both transplant and follow-ups data. To do so, the following steps must be followed:

1. Select the patient from the patient list (left panel).
2. Select the form you need to modify.
    a. In the case of data from "**Common Data set**", "**Waiting list information**" or "**Transplantation data**" they will appear directly in the central panel.
    b. In the case of data of any of the follow-ups carried out, they must be selected under the patient's ID in the left panel.
3. Select the relevant tab and change the corresponding data.
4. When finished select the **Save** button on the bottom right.

The changes made in the forms are recorded in a change control log that can be accessed by selecting the **Log** tab in the upper right part of the screen.