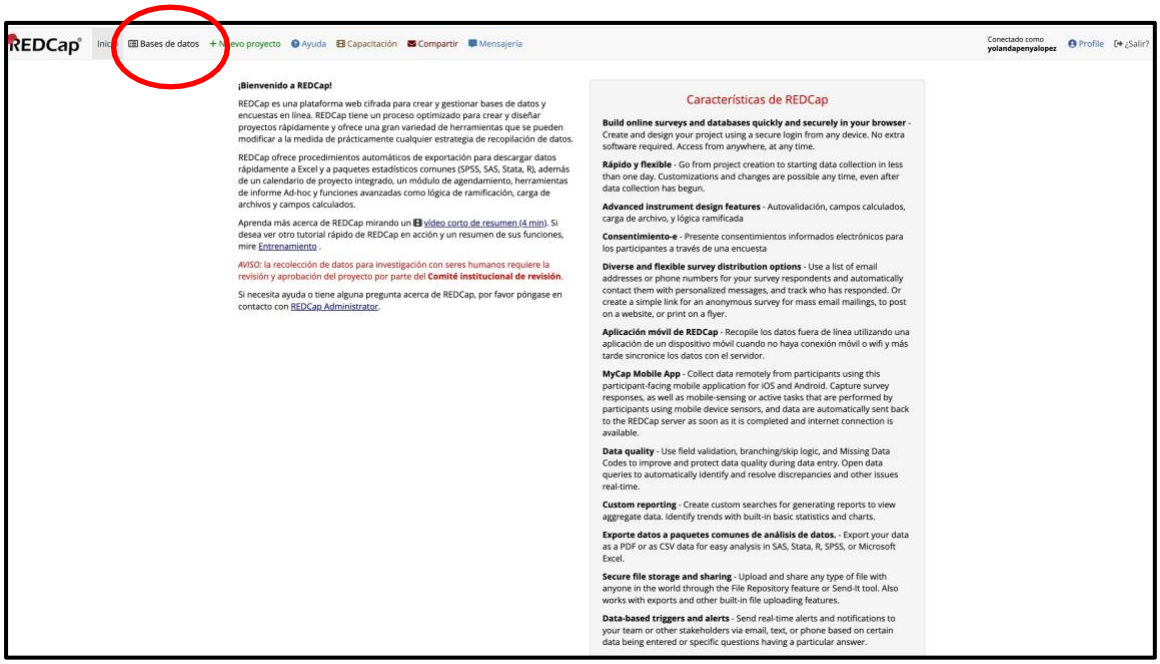
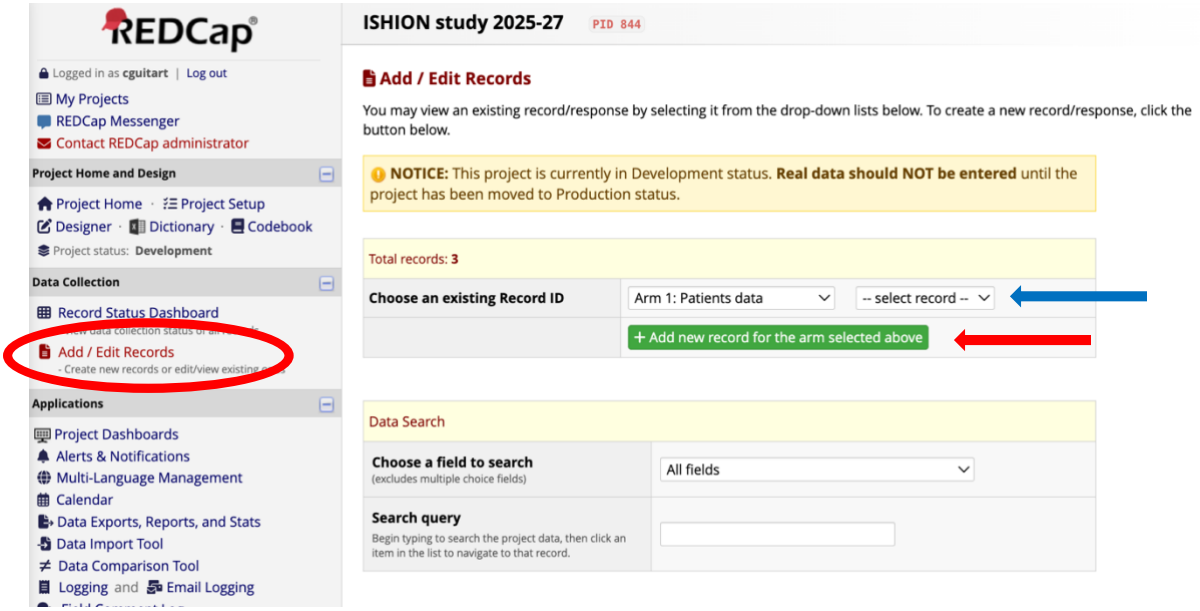
ISHION STUDY REDCap database guide

ACCESS TO THE DATABASE (through the Spanish REDCap software)

Go to Bases de datos (Databases) and select **ISHION** in the next screen.



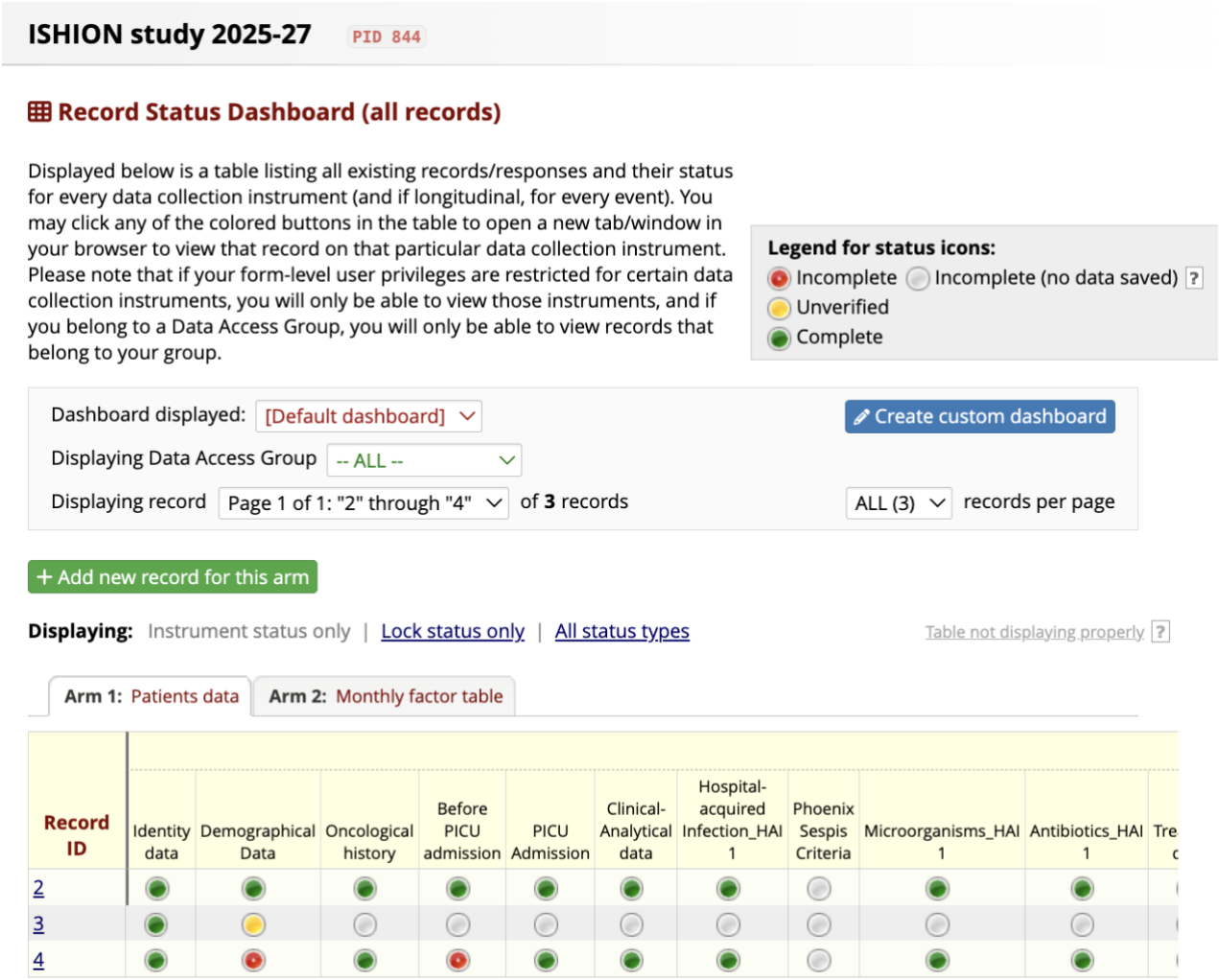
After selecting ISHION, **go to the LEFT COLUMN** and click on **Add/Edit records,** and then **add a new patient through the green button (arrow)** or **look for an existing one above** – **chose an existing Record ID (arm 1: patients' data) – select record (arrow),** open the menu and choose your general patient ID, confirm that it)



DATA COLLECTION – FORMS

- In our sample registry, there are TWO ARMS. ARM 1 is for patient information. ARM 2 is for the monthly factor table.
- Arm 1 consists of the following forms:
    - Identity data
    - Demographical data
    - Oncology history
    - Before PICU admission
    - PICU admission
    - Clinical-Analytical data
    - Hospital-acquired infection_HAI1
    - Phoenix Sepsis Criteria
    - Microorganisms_HAI1
    - Antibiotics_HAI1
    - Treatment day 1-7
    - HAI Extrinsic Risk Factors
    - HAI comorbidities&colonization
    - Hospital-acquired infection_HAI2
    - Microorganisms_HAI2
    - Antibiotics_HAI2
    - Next Generation Secuencing
    - Supportive care
    - Follow-up and outcome
- **In most cases, researchers only will have to fill out the HAI1 forms**. Those patients undergoing more than one HAI during their PICU admission will meet the criteria for the HAI2 forms (Variables related to HAI 2)

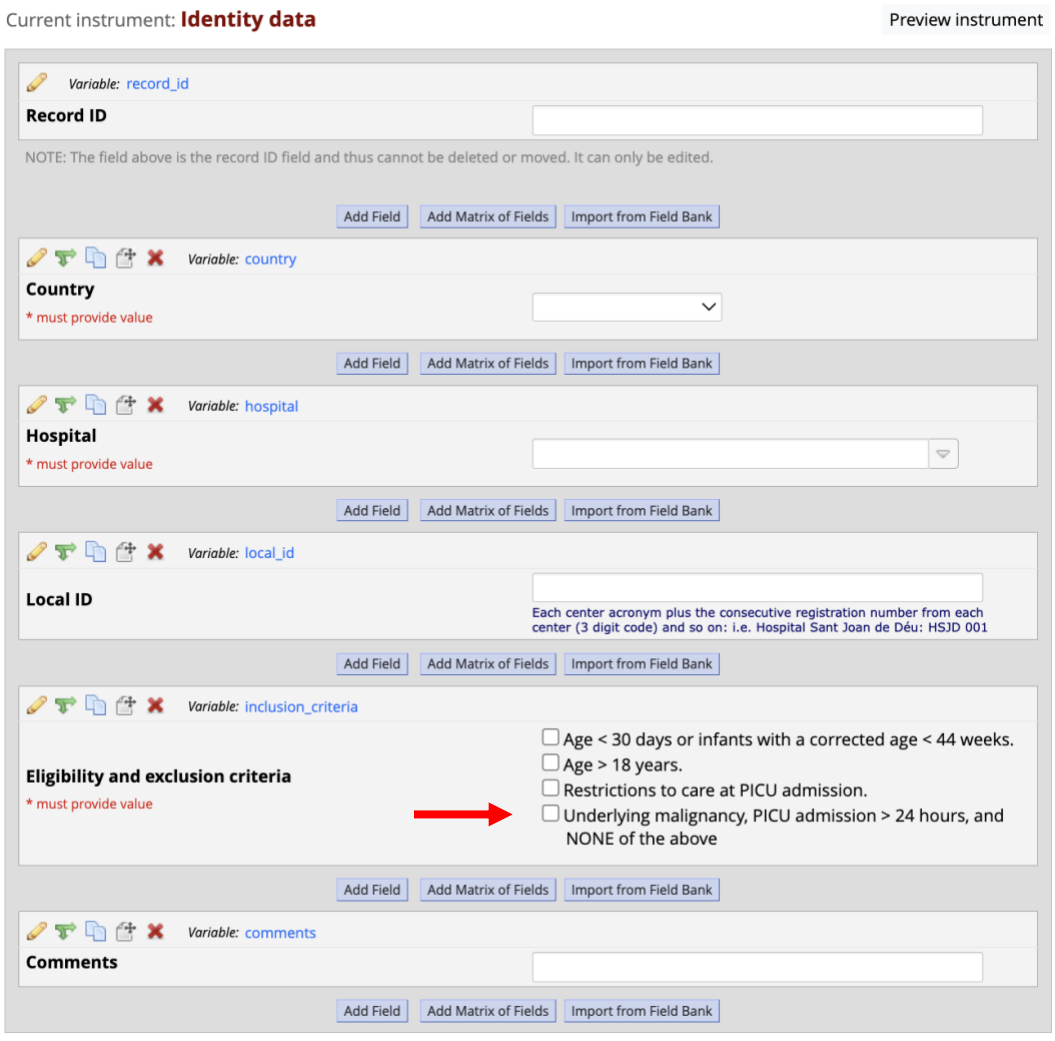
- Form status:
  - Incomplete, empty (grey): denotes that no data has been entered.
  - Incomplete (red): denotes that data entry for the form is not finished.
  - Unverified (yellow): denotes that data has been entered, but not validated, verified, or checked.
  - Complete (green): denotes that all data entry for this form is complete and verified.



SELECT ARM 1

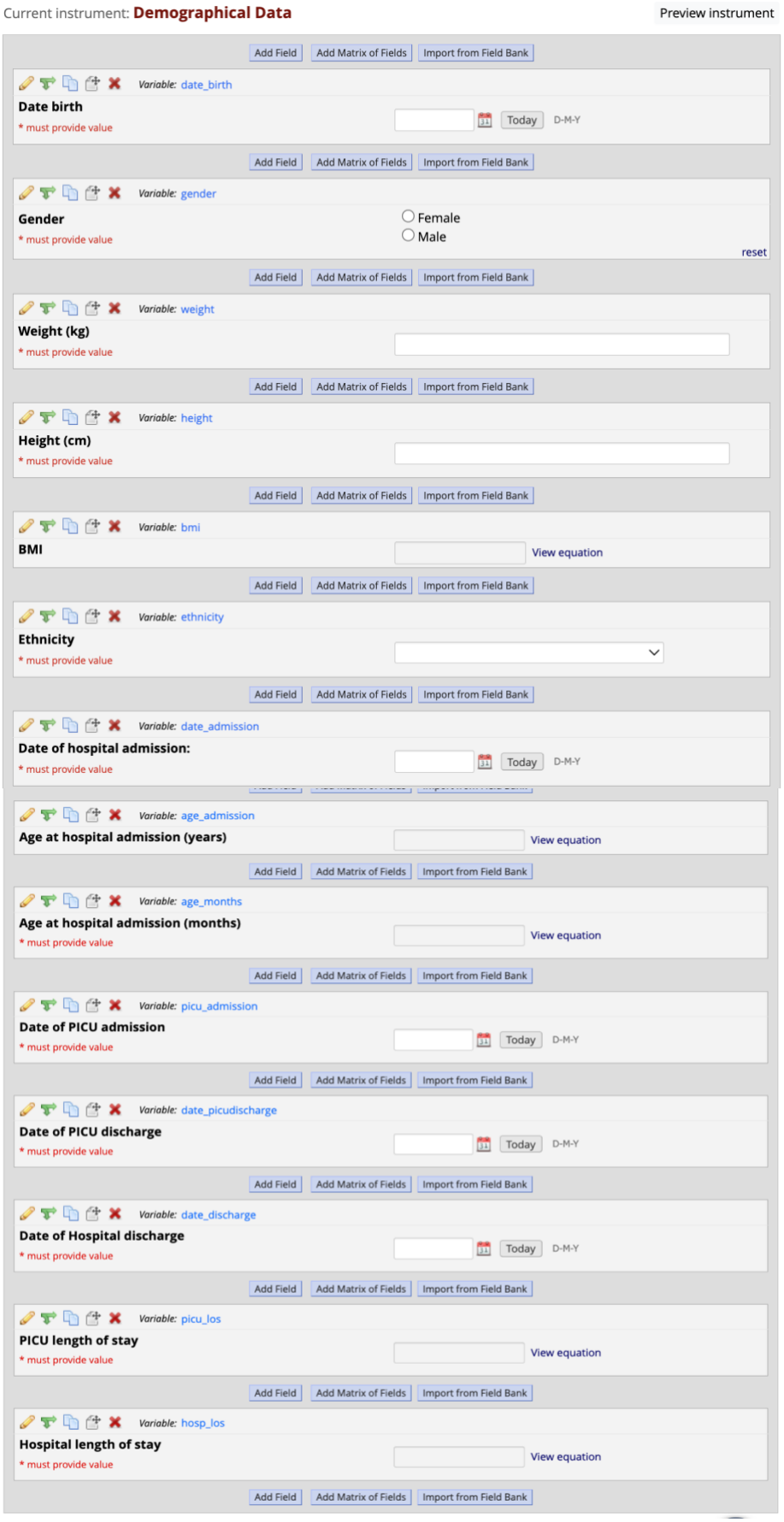
IDENTITY & DEMOGRAPHICAL DATA FORM

- Lead researchers must register in Eligibility & Demographical data form **ALL ONCOLOGICAL consecutive PATIENTS admitted to PICU** since their study start date (the actual date on which the first subject of each site has enrolled)
- **Country, Hospital and Local code fields:** Each site's lead researcher will specify the site and a record number (for example, HSJD 001 stands for Hospital Sant Joan de Déu, ie each hospital name acronym commonly used).
- This form includes:
    - **Eligibility and exclusion criteria field** (more than one option can be selected, from first to 4th option)
    - **All other variables related to patient demographics, comorbidities and outcomes** *will only be displayed if option 4 (arrow) is selected. (Underlying malignancy, PICU admission >24 hours, and NONE of the above in the eligibility and exclusion criteria field → INCLUSION CRITERIA)*



ELIGIBILITY & DEMOGRAPHICAL DATA FORM (II)

- When one patient meets inclusion criteria, all other forms with its variables will open to be filled out.



- **IMPORTANT CONSIDERATION-DATE of BIRTH**: Due to some concerns regarding the Data Protection Law interpretation by some IRB, it is NOT a compulsory field.

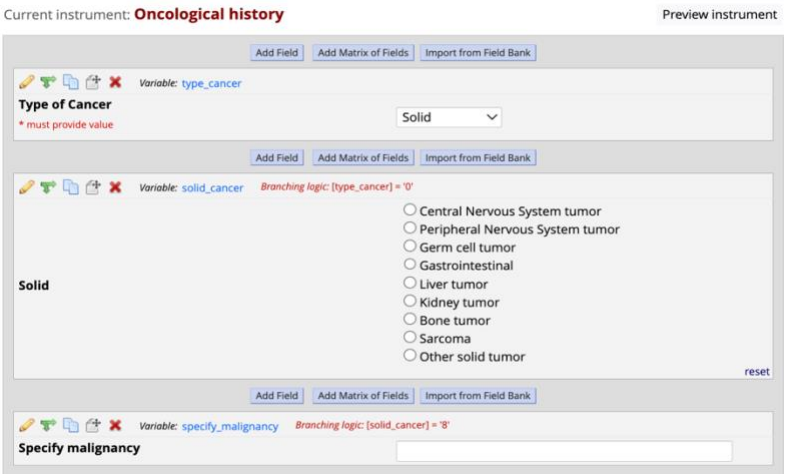
  The hospitals with restrictions regarding the use of the date of birth, might want to know that we will download the database WITHOUT the variable "data of birth" to ensure confidentiality.

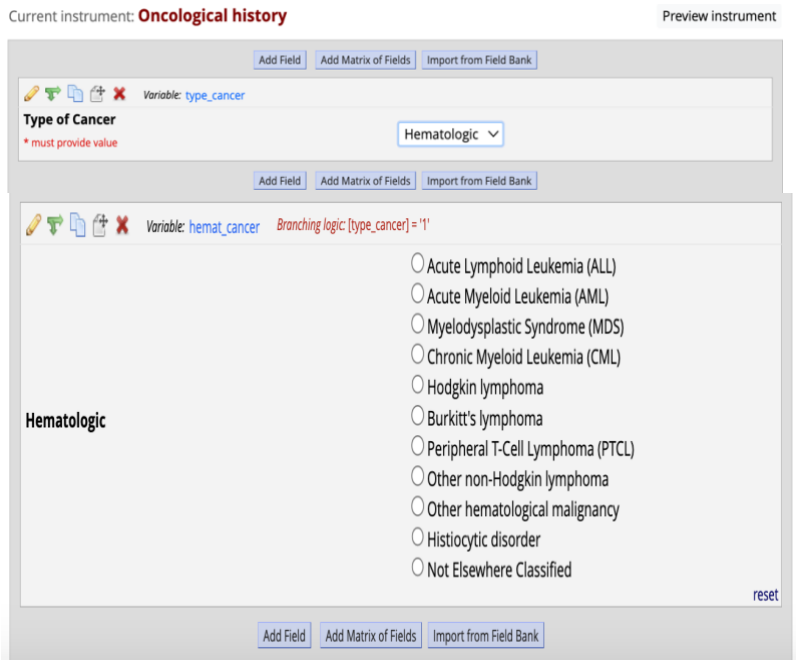
  INTRODUCING DATE of BIRTH is useful as it will permit to automatically calculate the age (months and years), which helps to ensure validate data.

  I.e. my patient is 7 years old. If there is any mistake about the dates, his calculated age (in years) will not be 7 years and his calculated age in months will be not correct.

  It DATE of BIRTH is not introduced, then each researcher must fill out the "manual" age (months) field.

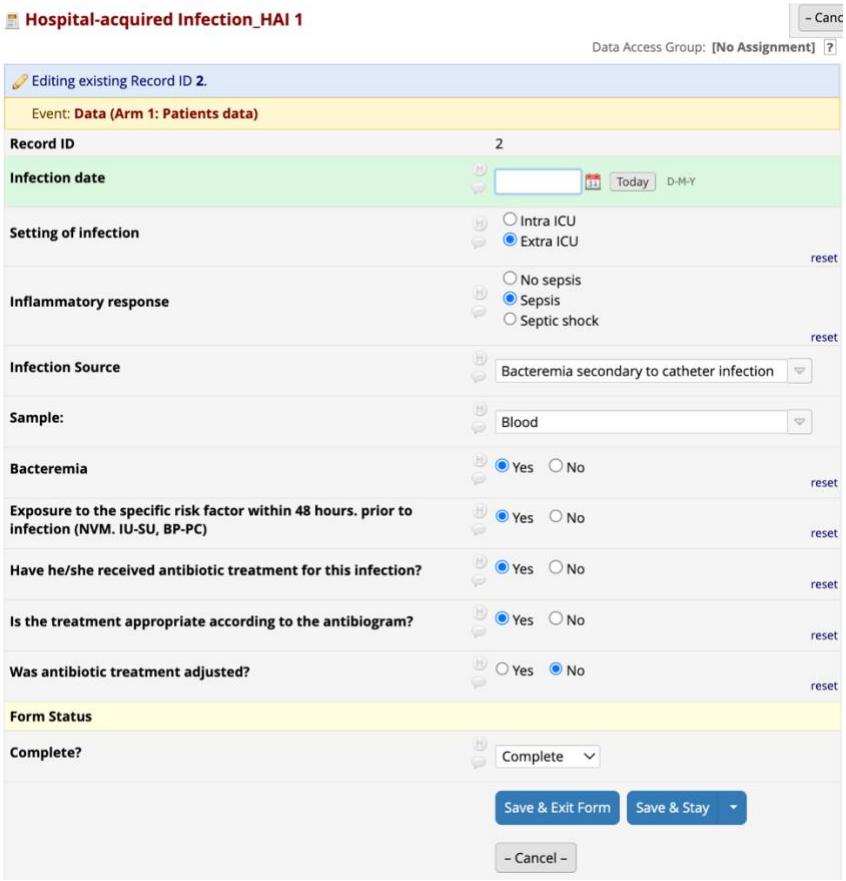
- Some variables will pop up depending on the answers selected in each previous variable. Ie: type of cancer: solid/hematologic: different options will appear.





VARIABLES RELATED TO HAI EPISODE 1 FORM

- This includes:
  - **Clinical data, Phoenix sepsis criteria, microorganisms, antibiotics and treatment day 1 to treatment day 7.**
  - Some variables allow selection of more than one option.



Hospital-acquired Infection_HAI 1

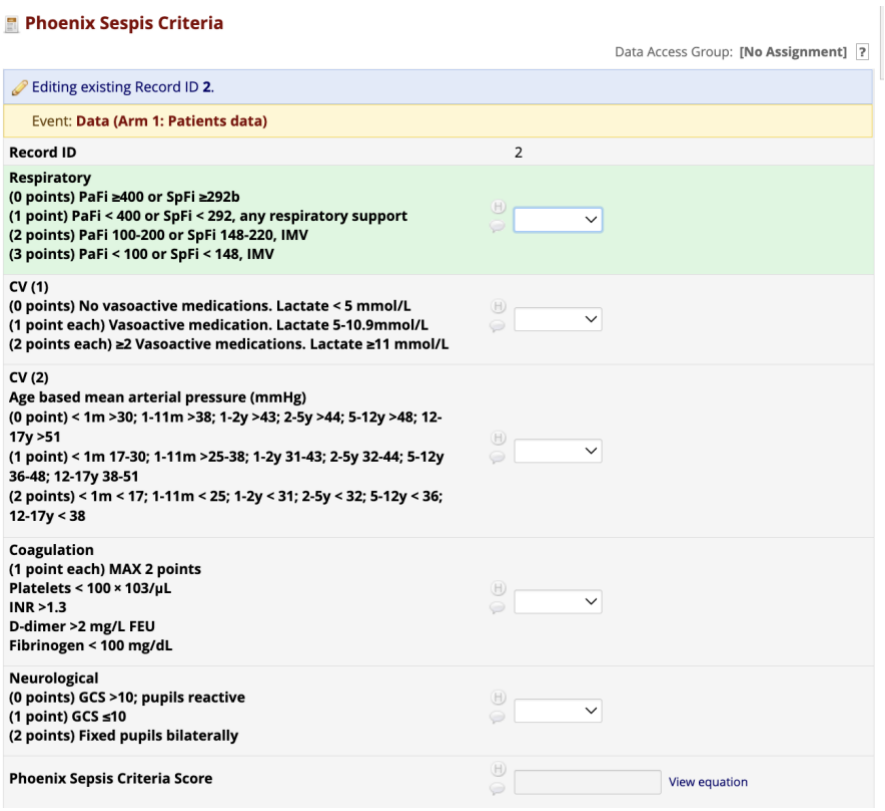
Data Access Group: [No Assignment]

Editing existing Record ID 2.

Event: Data (Arm 1: Patients data)

Record ID	2
Infection date	Today D-M-Y
Setting of infection	○ Intra ICU ● Extra ICU reset
Inflammatory response	○ No sepsis ● Sepsis ○ Septic shock reset
Infection Source	Bacteremia secondary to catheter infection
Sample:	Blood
Bacteremia	● Yes ○ No reset
Exposure to the specific risk factor within 48 hours. prior to infection (NVM. IU-SU, BP-PC)	● Yes ○ No reset
Have he/she received antibiotic treatment for this infection?	● Yes ○ No reset
Is the treatment appropriate according to the antibiogram?	● Yes ○ No reset
Was antibiotic treatment adjusted?	○ Yes ● No reset
Form Status	
Complete?	Complete

Save & Exit Form | Save & Stay | – Cancel –



Phoenix Sespis Criteria

Data Access Group: [No Assignment]

Editing existing Record ID 2.

Event: Data (Arm 1: Patients data)

Record ID	2
Respiratory (0 points) PaFi ≥400 or SpFi ≥292b (1 point) PaFi < 400 or SpFi < 292, any respiratory support (2 points) PaFi 100-200 or SpFi 148-220, IMV (3 points) PaFi < 100 or SpFi < 148, IMV	
CV (1) (0 points) No vasoactive medications. Lactate < 5 mmol/L (1 point each) Vasoactive medication. Lactate 5-10.9mmol/L (2 points each) ≥2 Vasoactive medications. Lactate ≥11 mmol/L	
CV (2) Age based mean arterial pressure (mmHg) (0 point) < 1m >30; 1-11m >38; 1-2y >43; 2-5y >44; 5-12y >48; 12-17y >51 (1 point) < 1m 17-30; 1-11m >25-38; 1-2y 31-43; 2-5y 32-44; 5-12y 36-48; 12-17y 38-51 (2 points) < 1m < 17; 1-11m < 25; 1-2y < 31; 2-5y < 32; 5-12y < 36; 12-17y < 38	
Coagulation (1 point each) MAX 2 points Platelets < 100 × 103/µL INR >1.3 D-dimer >2 mg/L FEU Fibrinogen < 100 mg/dL	
Neurological (0 points) GCS >10; pupils reactive (1 point) GCS ≤10 (2 points) Fixed pupils bilaterally	
Phoenix Sepsis Criteria Score	View equation

Microorganisms_HAI 1

Data Access Group: **[No Assignment]**

Editing existing Record ID **2**.

Event: **Data (Arm 1: Patients data)**

Record ID	2
Pseudomonas Antibiogram * must provide value	☐ Pseudomonas aeruginosa ☐ Burkholderia (Pseudomonas) cepacia ☐ Pseudomonas mallei ☐ Pseudomonas pseudomallei ☐ Pseudomonas putida ☐ Pseudomonas stutzeri ☐ Pseudomonas others ☐ Pseudomonas spp. ☑ No
Acinetobacter_antibiogram * must provide value	☐ Acinetobacter baumannii ☐ Acinetobacter calcoaceticus ☐ Acinetobacter haemolyticus ☐ Acinetobacter lwoffi ☐ Acinetobacter spp. ☑ No
Enterobact_ATBgram * must provide value	☐ Escherichia coli ☑ Klebsiella pneumoniae ☐ Klebsiella oxytoca ☐ Klebsiella ozaenae ☐ Klebsiella spp ☐ Proteus mirabilis ☐ Proteus penneri ☐ Proteus vulgaris ☐ Proteus spp ☐ Enterobacter aerogenes ☐ Enterobacter agglomerans ☐ Enterobacter cloacae ☐ Enterobacter sakazakii ☐ Enterobacter spp ☐ Citrobacter diversus ☐ Citrobacter freundii ☐ Citrobacter spp ☐ Moraxella catharralis ☐ Moraxella spp ☐ Salmonella enteritidis

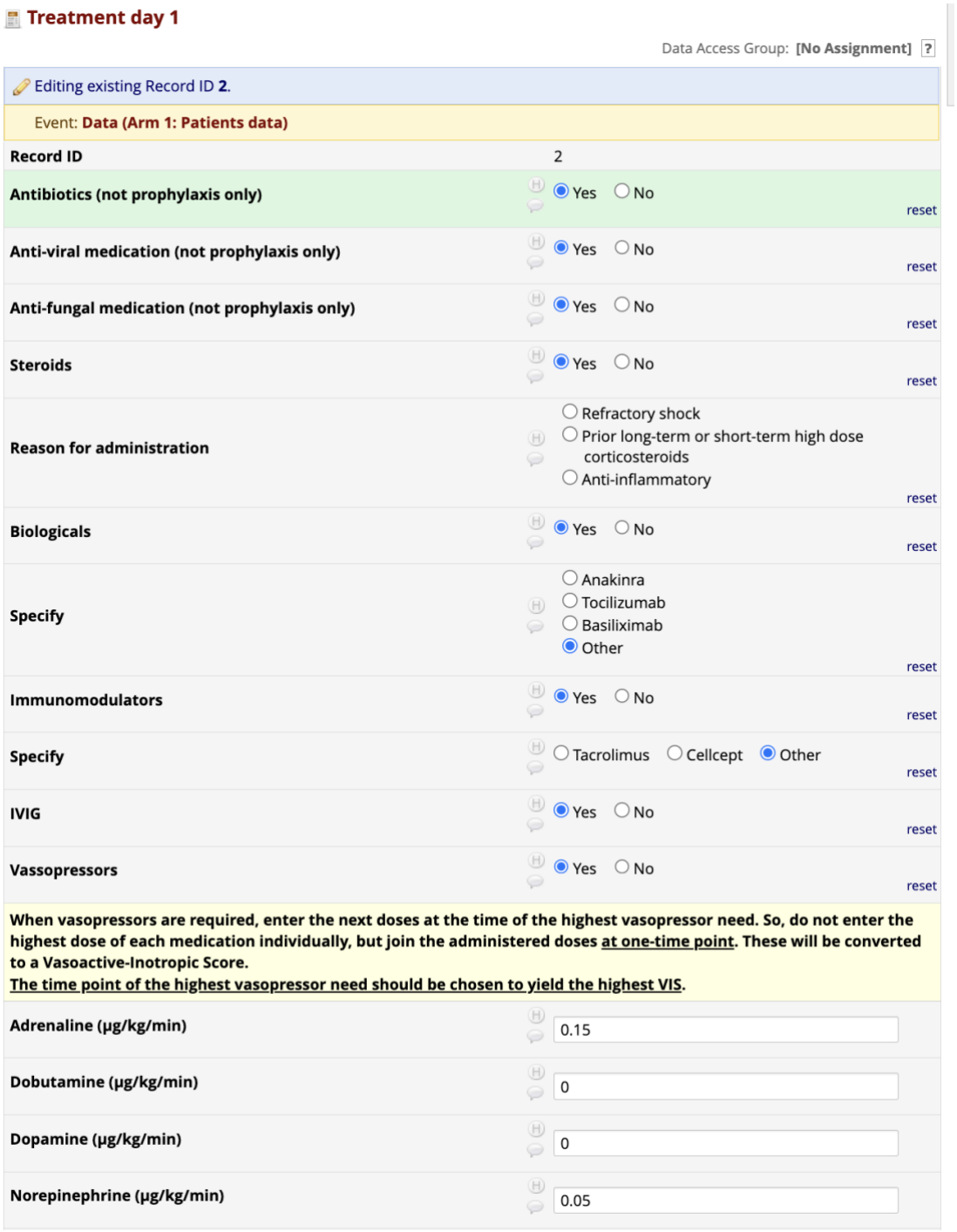
Antibiotics_HAI 1

Data Access Group: **[No Assignment]**

Editing existing Record ID **2**.

Event: **Data (Arm 1: Patients data)**

Record ID	2
Antibiotic 1	Meropenem 161
Antibiotic 2	vancomycin 131
Antibiotic 3	
Initial date:	Today D-M-Y
Final date:	Today D-M-Y
Indication	☐ Extra-ICU infection ☑ Intra-ICU infection ☐ CoVID treatment ☐ Surgical prophylaxis ☐ Other Prophylaxis ☐ Unknown
Reason of antibiotic selection	○ Empirical ○ Directed reset
Confirmation	Yes, it is suitable
Infection	Bacteremia secondary to catheter infection
Antibiotic change	○ Yes ○ Early suspension ◉ No reset



Treatment day 1

Data Access Group: **[No Assignment]**

Editing existing Record ID **2**.

Event: **Data (Arm 1: Patients data)**

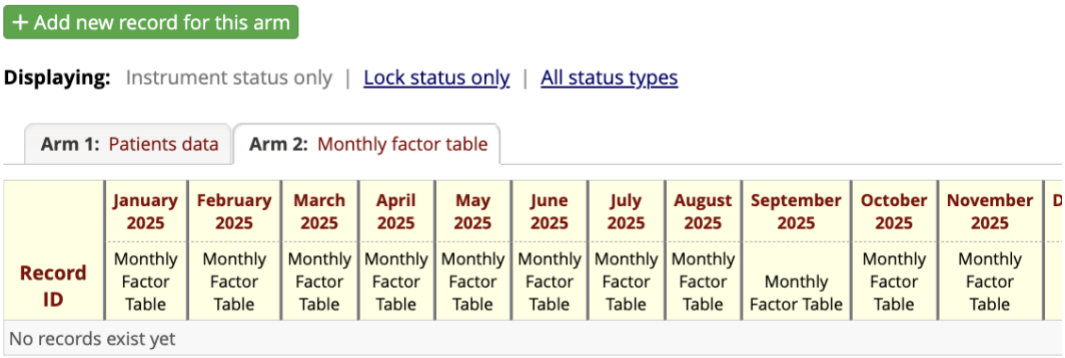
Record ID	2
Antibiotics (not prophylaxis only)	(•) Yes ( ) No reset
Anti-viral medication (not prophylaxis only)	(•) Yes ( ) No reset
Anti-fungal medication (not prophylaxis only)	(•) Yes ( ) No reset
Steroids	(•) Yes ( ) No reset
Reason for administration	( ) Refractory shock ( ) Prior long-term or short-term high dose corticosteroids ( ) Anti-inflammatory reset
Biologicals	(•) Yes ( ) No reset
Specify	( ) Anakinra ( ) Tocilizumab ( ) Basiliximab (•) Other reset
Immunomodulators	(•) Yes ( ) No reset
Specify	( ) Tacrolimus ( ) Cellcept (•) Other reset
IVIG	(•) Yes ( ) No reset
Vassopressors	(•) Yes ( ) No reset
When vasopressors are required, enter the next doses at the time of the highest vasopressor need. So, do not enter the highest dose of each medication individually, but join the administered doses at one-time point. These will be converted to a Vasoactive-Inotropic Score. The time point of the highest vasopressor need should be chosen to yield the highest VIS.	
Adrenaline (µg/kg/min)	0.15
Dobutamine (µg/kg/min)	0
Dopamine (µg/kg/min)	0
Norepinephrine (µg/kg/min)	0.05

OTHER CONSIDERATIONS

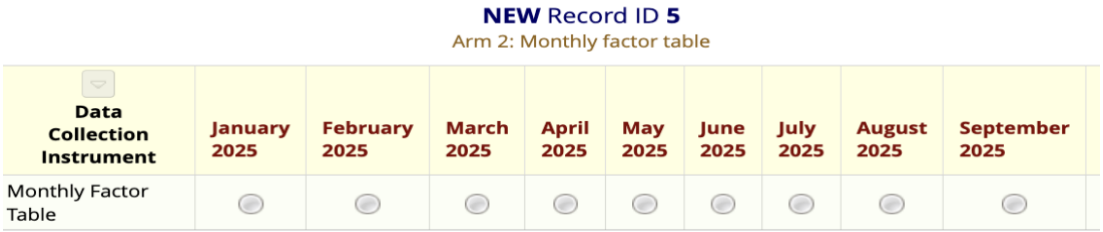
- Patients who require PICU readmission during the period of study will be considered as NEW patients.
- Patients who present MORE THAN ONE HAI DURING their PICU admission, will be candidates to fill out HAI2 forms.
- NOTE: Clinical data, scores and dates will be filled out only ONCE per each PICU admission.

SELECT ARM 2 : for the MONTLHY FACTOR TABLE.

- In ARM 2, lead researchers must enter ONLY ONE RECORD per EACH Hospital.
- Each hospital/cite will have only **ONE RECORD ID** assigned at the FIRST time they create the record: when clicking on **Add new record for this arm (green button).**



- Once the record is created, each researcher will add the information of each month prospectively by **EDITING the SAME record.**
- Inside the RECORD researchers will be able to select each month of each year (2025-27). When clicking each month, the monthly factor table appears, and all the information can be filled.



- Information is related to ONCOLOGICAL patients admitted to each PICU.