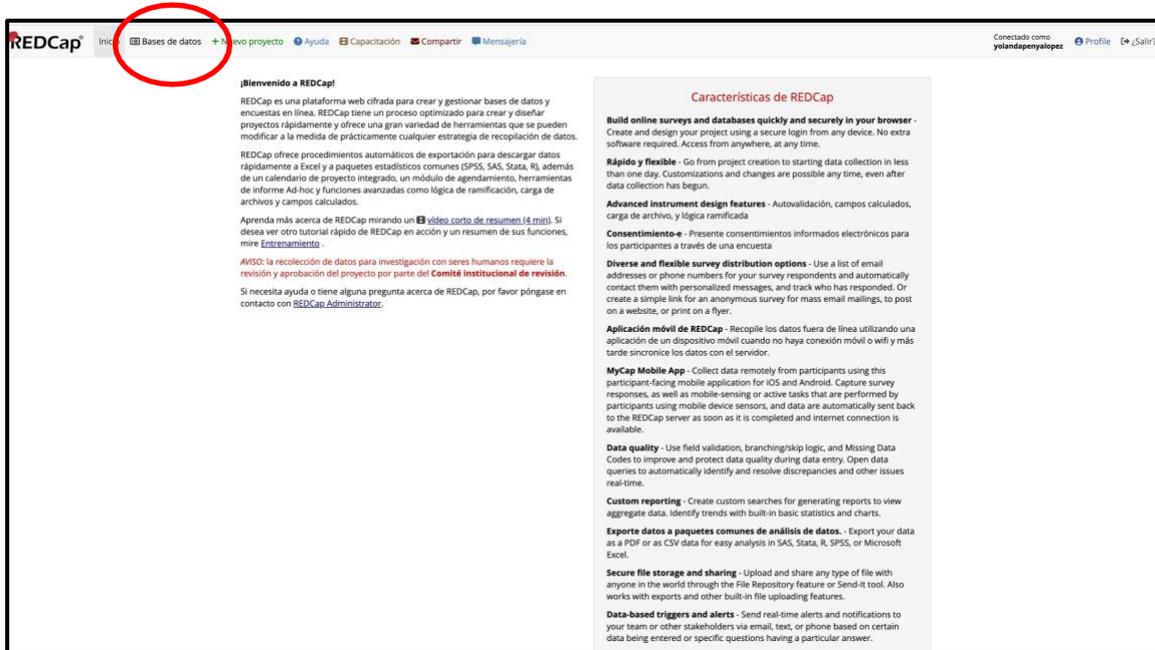


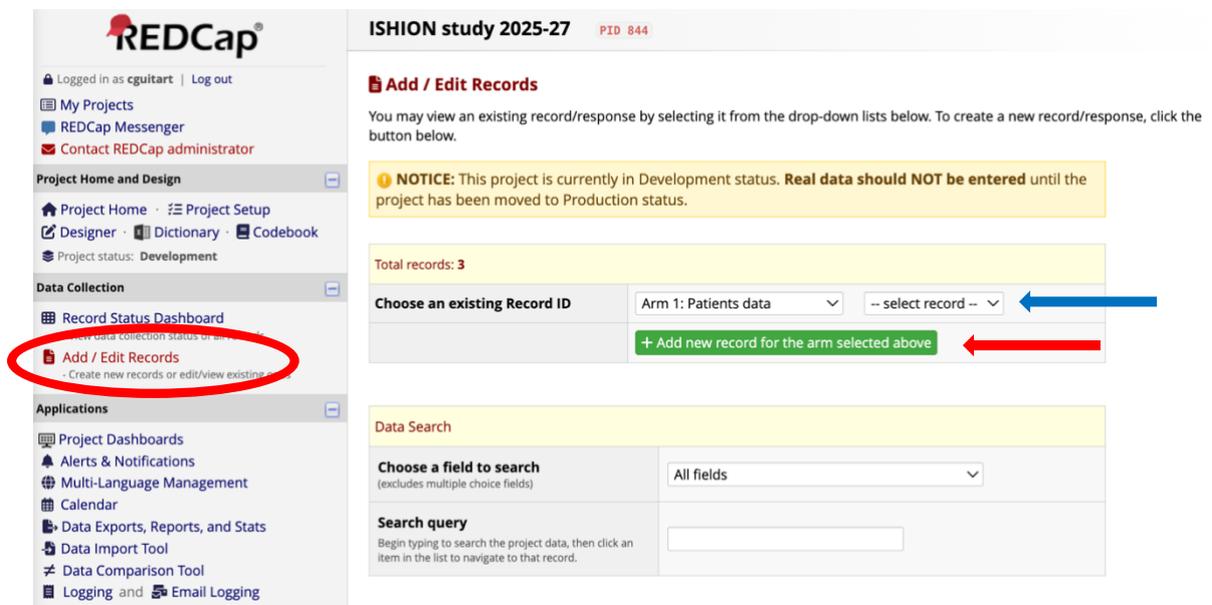
ISHION STUDY REDCap database guide

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 Sequencing
 - 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.

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Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete Incomplete (no data saved) ?
- Unverified
- Complete

Dashboard displayed: [Default dashboard] ▾ Create custom dashboard

Displaying Data Access Group -- ALL -- ▾

Displaying record Page 1 of 1: "2" through "4" ▾ of **3** records ALL (3) ▾ records per page

+ Add new record for this arm

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

[Table not displaying properly ?](#)

Arm 1: Patients data Arm 2: Monthly factor table

Record ID	Identity data	Demographical Data	Oncological history	Before PICU admission	PICU Admission	Clinical-Analytical data	Hospital-acquired Infection_HAI 1	Phoenix Sepsis Criteria	Microorganisms_HAI 1	Antibiotics_HAI 1	Tre
2	●	●	●	●	●	●	●	<input type="radio"/>	●	●	
3	●	●	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
4	●	●	●	●	●	●	●	<input type="radio"/>	●	●	

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)

Current instrument: **Identity data**

[Preview instrument](#)

Variable: record_id

Record ID

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: country

Country

* must provide value

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: hospital

Hospital

* must provide value

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: local_id

Local ID

Each center acronym plus the consecutive registration number from each center (3 digit code) and so on: i.e. Hospital Sant Joan de Déu: HSJD 001

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: inclusion_criteria

Eligibility and exclusion criteria

* must provide value

Age < 30 days or infants with a corrected age < 44 weeks.

Age > 18 years.

Restrictions to care at PICU admission.

Underlying malignancy, PICU admission > 24 hours, and NONE of the above



[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: comments

Comments

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

ELIGIBILITY & DEMOGRAPHICAL DATA FORM (II)

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

Current instrument: **Demographical Data**

[Preview instrument](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *date_birth*

Date birth

* must provide value

Today D-M-Y

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *gender*

Gender

* must provide value

Female
 Male

[reset](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *weight*

Weight (kg)

* must provide value

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *height*

Height (cm)

* must provide value

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *bmi*

BMI

[View equation](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *ethnicity*

Ethnicity

* must provide value

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *date_admission*

Date of hospital admission:

* must provide value

Today D-M-Y

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *age_admission*

Age at hospital admission (years)

[View equation](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *age_months*

Age at hospital admission (months)

* must provide value

[View equation](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *picu_admission*

Date of PICU admission

* must provide value

Today D-M-Y

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *date_picudischarge*

Date of PICU discharge

* must provide value

Today D-M-Y

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *date_discharge*

Date of Hospital discharge

* must provide value

Today D-M-Y

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *picu_los*

PICU length of stay

* must provide value

[View equation](#)

Add Field
Add Matrix of Fields
Import from Field Bank

Variable: *hosp_los*

Hospital length of stay

* must provide value

[View equation](#)

Add Field
Add Matrix of Fields
Import from Field Bank

- **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. I.e: type of cancer: solid/hematologic: different options will appear.

Current instrument: **Oncological history** Preview instrument

Add Field Add Matrix of Fields Import from Field Bank

Variable: type_cancer

Type of Cancer Solid ▾

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: solid_cancer Branching logic: [type_cancer] = '0'

Solid

- Central Nervous System tumor
- Peripheral Nervous System tumor
- Germ cell tumor
- Gastrointestinal
- Liver tumor
- Kidney tumor
- Bone tumor
- Sarcoma
- Other solid tumor

reset

Add Field Add Matrix of Fields Import from Field Bank

Variable: specify_malignancy Branching logic: [solid_cancer] = '0'

Specify malignancy

Current instrument: **Oncological history** Preview instrument

Add Field Add Matrix of Fields Import from Field Bank

Variable: type_cancer

Type of Cancer Hematologic ▾

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: hemat_cancer Branching logic: [type_cancer] = '1'

Hematologic

- Acute Lymphoid Leukemia (ALL)
- Acute Myeloid Leukemia (AML)
- Myelodysplastic Syndrome (MDS)
- Chronic Myeloid Leukemia (CML)
- Hodgkin lymphoma
- Burkitt's lymphoma
- Peripheral T-Cell Lymphoma (PTCL)
- Other non-Hodgkin lymphoma
- Other hematological malignancy
- Histiocytic disorder
- Not Elsewhere Classified

reset

Add Field Add Matrix of Fields Import from Field Bank

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 - Canc

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 reset

Sample: reset

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? reset

Phoenix Sepsis 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 $\geq 292b$
(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 $< 100 \times 103/\mu L$
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 lwoffii
- 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)	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Anti-viral medication (not prophylaxis only)	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Anti-fungal medication (not prophylaxis only)	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Steroids	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Reason for administration	<input type="radio"/> Refractory shock <input type="radio"/> Prior long-term or short-term high dose corticosteroids <input type="radio"/> Anti-inflammatory reset
Biologicals	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Specify	<input type="radio"/> Anakinra <input type="radio"/> Tocilizumab <input type="radio"/> Basiliximab <input checked="" type="radio"/> Other reset
Immunomodulators	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Specify	<input type="radio"/> Tacrolimus <input type="radio"/> Cellcept <input checked="" type="radio"/> Other reset
IVIG	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Vasopressors	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
<p>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 <u>at one-time point</u>. These will be converted to a Vasoactive-Inotropic Score.</p> <p><u>The time point of the highest vasopressor need should be chosen to yield the highest VIS.</u></p>	
Adrenaline (µg/kg/min)	<input type="text" value="0.15"/>
Dobutamine (µg/kg/min)	<input type="text" value="0"/>
Dopamine (µg/kg/min)	<input type="text" value="0"/>
Norepinephrine (µg/kg/min)	<input type="text" value="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.

