User manual
Of the digital data management system LESIONIA
For clinical and epidemiological data related to cutaneous leishmaniasis patients in the MENA region

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About this manual

What for?

This manual is meant to provide a step by step guidance for the users of Lesionia to get started. It also provides tips and guidance on how to enter and handle missing data or data with discrepancies.

What is Lesionia :

Lesionia is an open-source software/Web applications for the collection, management and analysis of clinical and epidemiological data related to patients with confirmed cutaneous leishmaniasis and their negative controls. It was developed in the frame of the PEER518 project. It is conceived to enable researchers within the PEER518 consortium that are based in different countries and acting at different stages of the data life cycle to enter and access the data with respect to the FAIR criteria.
It has been developed by two engineering students: Mr. Maaoui Hariga and Mr. Youssef Ben Salem under the supervision of Dr. Emna Harigua (emna.harigua@pasteur.utm.tn ; harigua.emna@gmail.com).
The source code can be accessed through the GitHub account of Dr. Emna Harigua at: https://github.com/Harigua/LEISIApp.

What is the PEER518 project :

PER518: Diagnosis of Cutaneous Leishmaniasis: Development and Evaluation of Multiplex POC DNA Assays

Objectives: Our aim is to develop species specific and multiplex DNA assays for the concomitant detection and identification of the Leishmania species: L. infantum/L. donovani, L. major and L. tropica, which are the main causal agents of cutaneous leishmaniasis encountered in the Old World (Africa, MENA, Europe and Asia). Such diseases are also of global relevance in more than 98 countries affected.
Methodology: We use novel technologies for the isothermal amplification and detection of DNA that are well adapted to point of care (POC). They do not need specialized equipment, are prone to multiplexing and are rapid in delivering results (<1h).

Impact: Our DNA assays will serve the CL diagnosis in limited resources environment. In fact, accurate species-specific diagnoses also allows for rapid diagnosis, efficient patient management and follow up and accurate reporting to leishmaniasis control programs. Availability of the diagnostics POC tools we aim for would change diagnosis algorithms and improve patient management in Tunisia and many endemic countries, and in travel medicine. It is also well known that the species differently react to the different treatments available. So far reporting does not precise the causal species, so enlarged use of such tools would improve disease epidemiology and burden estimates. Likewise, with more popular DNA tests it becomes possible to adequately and timely react in emerging foci. Clinical trials will be needed to improve robustness of the recommendations.

The PEER518 consortium

The PEER518 consortium is composed of collaborators based in seven institutions:

1. Laboratory of Molecular Epidemiology and Experimental Pathology at Institut Pasteur de Tunis is the central node of the consortium. It is directed by Dr. Ikram Guizani (iguizani@yhoo.com ; ikram.guizani@pasteur.tn), PI of the PEER518 project.
2. Hopital Farhat Hachad, Sousse, Tunisia
3. Hopital La Rabta, Tunis, Tunisia
4. Institut Pasteur du Maroc, Morocco
5. Rafik Hariri Hospital, Beirut, Lebanon
6. Faculty of Public Health, Beirut, Lebanon
7. Faculty of Medicine and Odontostomatology, University of Bamako, Mali
8. Infectious Disease Research Institute, Seattle, USA.

Step-by-step guidance into Lesionia

1. Introduction

This document goes into detail about how to use the Lesionia interface.

N.B: No special characters (e.g: ‘, “, etc) are allowed in all data fields.

2. Code generation

We have generated codes with the following format: **PER**CCCXXX. The PER prefix indicates that these data were collected within the PEER518 project. The following three digits “CCC” correspond to the country code as listed in the table below. The last three digits “XXX” can be assigned randomly to obtain unique identifiers for each patient. When all combinations (999) are used, the last digit in the country code “CCC”, initially set to **1**, can be changed to **2**.

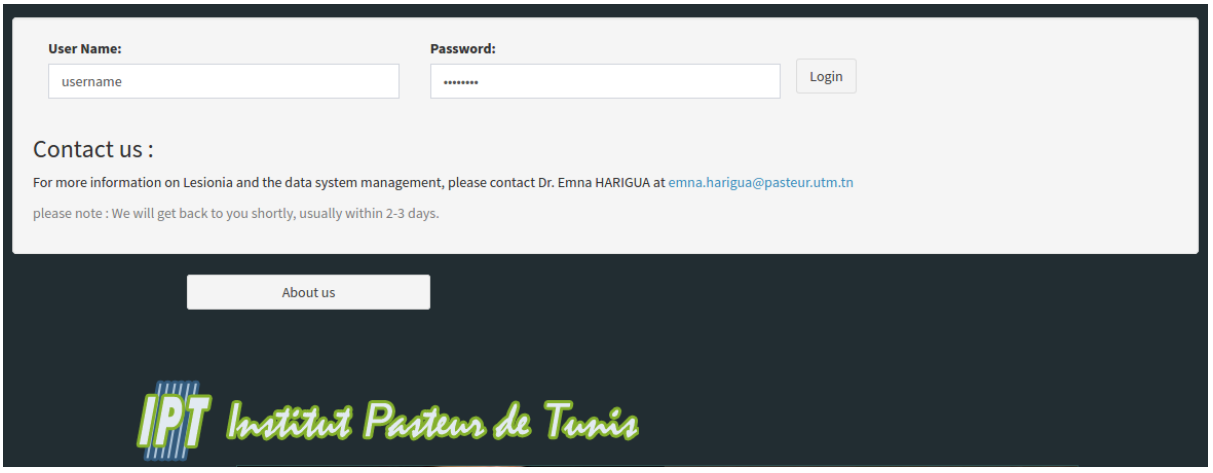
N.B: All patients already entered by the IPT group on behalf of all partners had the last digit of the country code set to 0 (PERCC0XXX)

Hopital Farhat Hachad - Sousse	Hopital La Rabta - Tunis	Rafik el Hariri Hospital and Faculty of Public Health - Lebanon	Institut Pasteur du Maroc - Morrocco
PER341XXX	PER571XXX	PER521XXX	PER621XXX

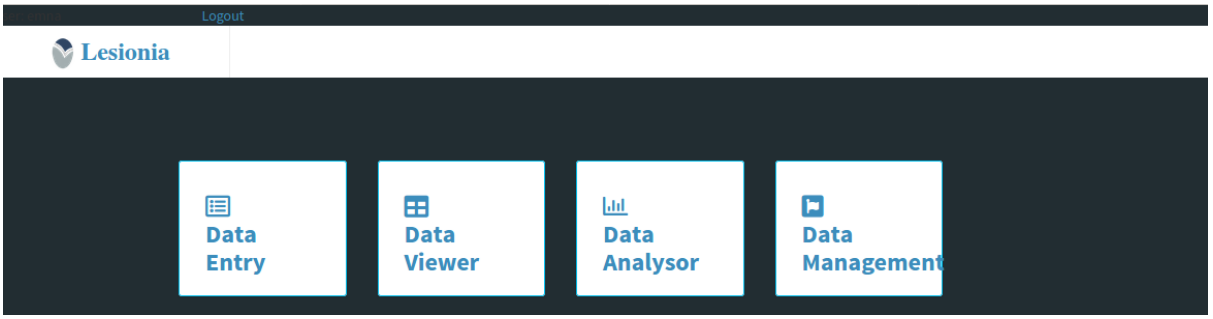
3. Data entry

Data entry can be performed following the steps in sections 1-16.

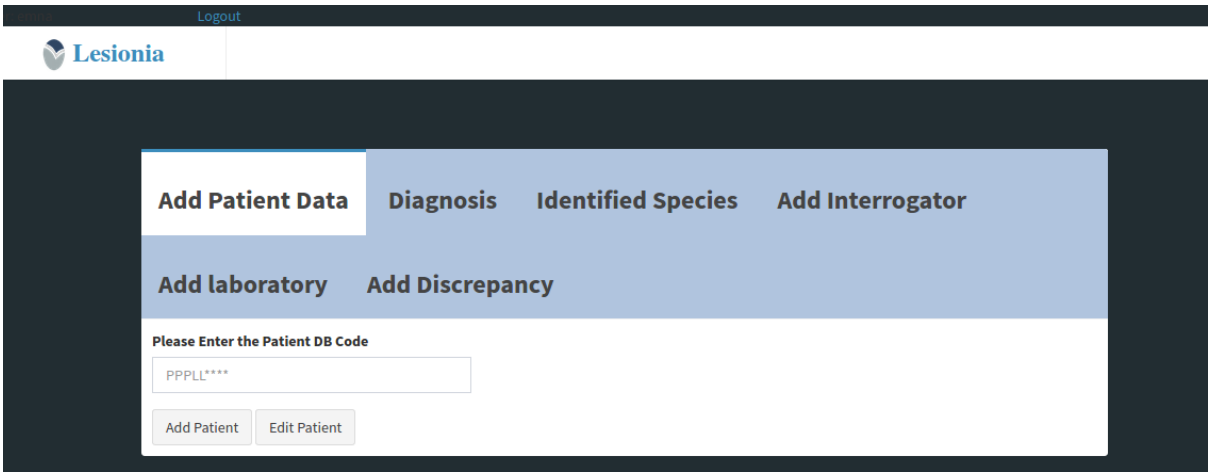
1. Log into your Lesionia account



2. Click on the “Data entry” tab



3. Click on “Add patient”



4. Fill out the digital form with the information presented in the Patient Data section of the paper form

Questionnaire

Patient ID : HLR50/19 **DB code**: PR20125

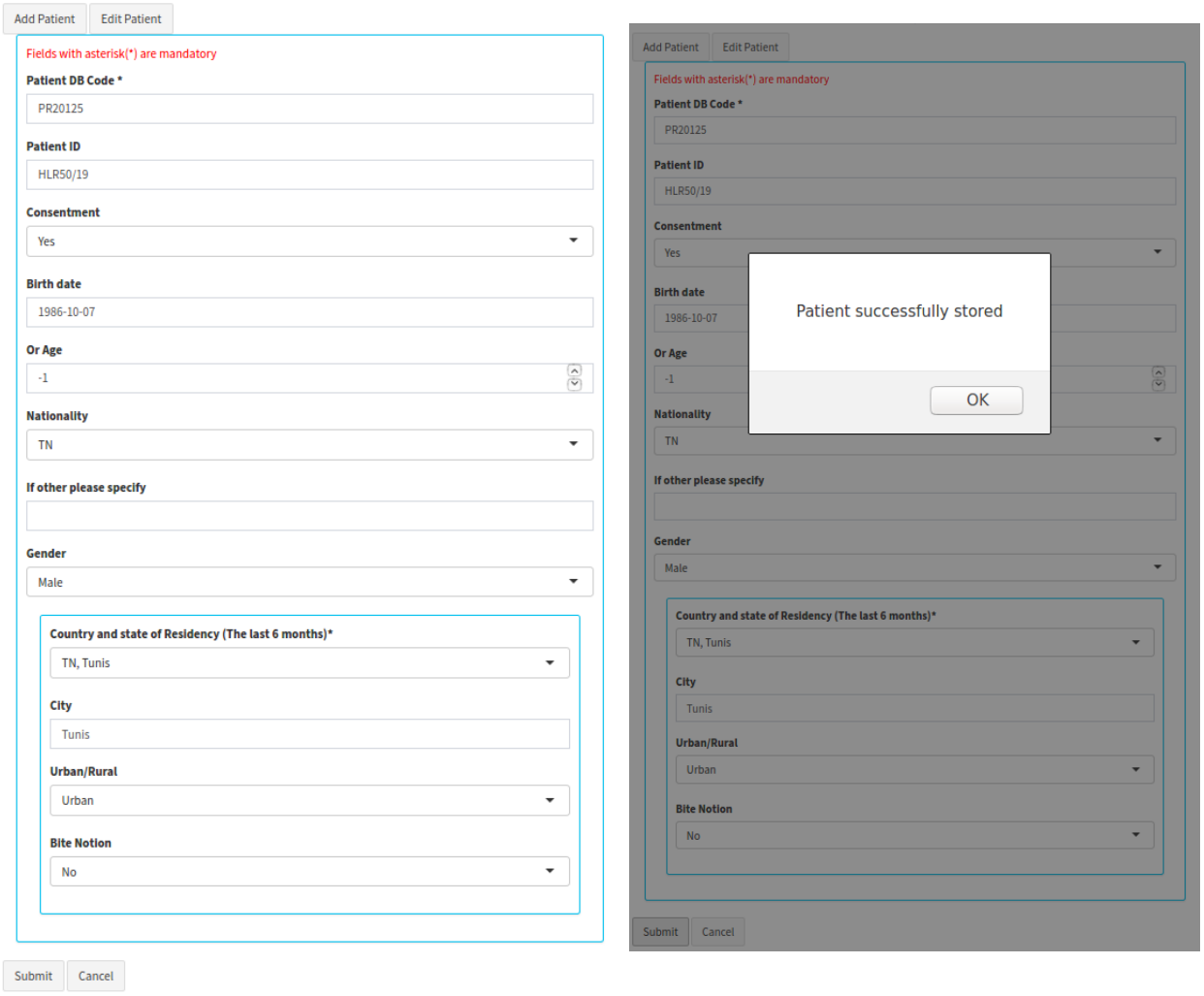
1. Date of consultation 01 /_07/ _2019
2. Hospital : Hopital La Rabta
3. Physician : Dr. Foulen
4. Sampler : Mr. El Foulani

Personal Data (to be hidden)

1. First Name : XXX	2.Last name : XXX	3. Medical file number XXX
4. Phone number : XXX	5.Adress : XXX	

Patient Data

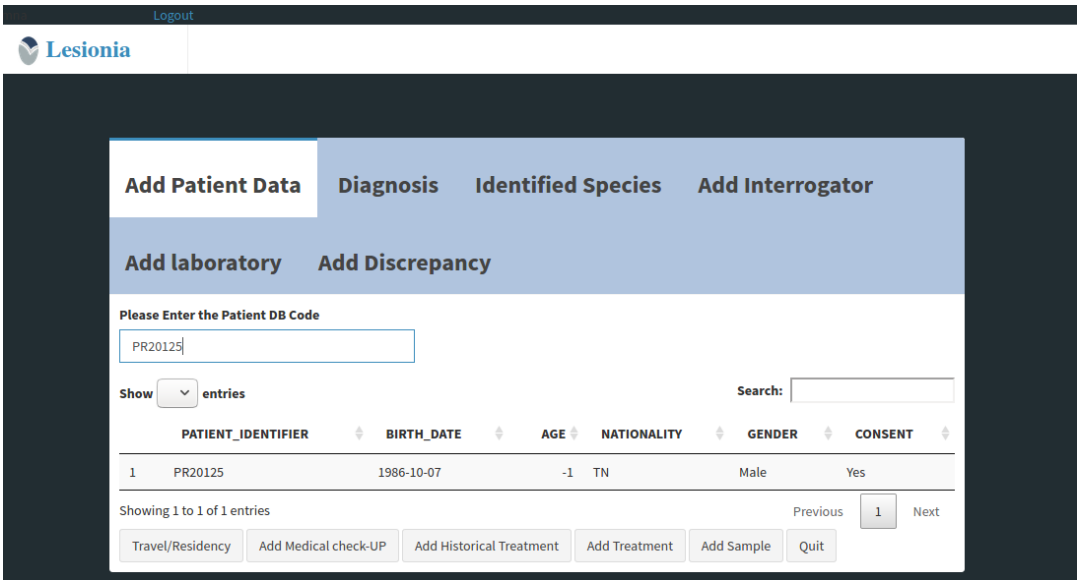
1.Country : Tunisia	2.Governorate : Tunis	3.City : Tunis ☒ Urban ☐ Rural
4. Nationality / Origin: ☒ TN ☐ LB ☐ SY ☐ MA ☐ DZ ☐ Other, specify :		5.Notion of bite: ☐ Yes ☒ No
6. Gender: ☐ F ☒ M	7. Date of birth 07 / 10 /1986	8.Consent: ☒ Yes ☐ No



If you used a patient code that has already been used, an error pop-up will appear indicating that the patient already exist. If you intend to add/modify data for an existing patient, you need to click on “Edit patient” instead of “Add patient” (section 3). If this is an error, and you intend to enter a new patient, you need to generate a code that does not exist.

5. Once you create a new patient, you will be sent to the data entry screen where you need to reenter the “Patient DB Code” to enter data related to travel and residency, medical checkup, historical treatments, post-diagnosis treatments and corresponding sample.

N.B: The patient identifier is case sensitive

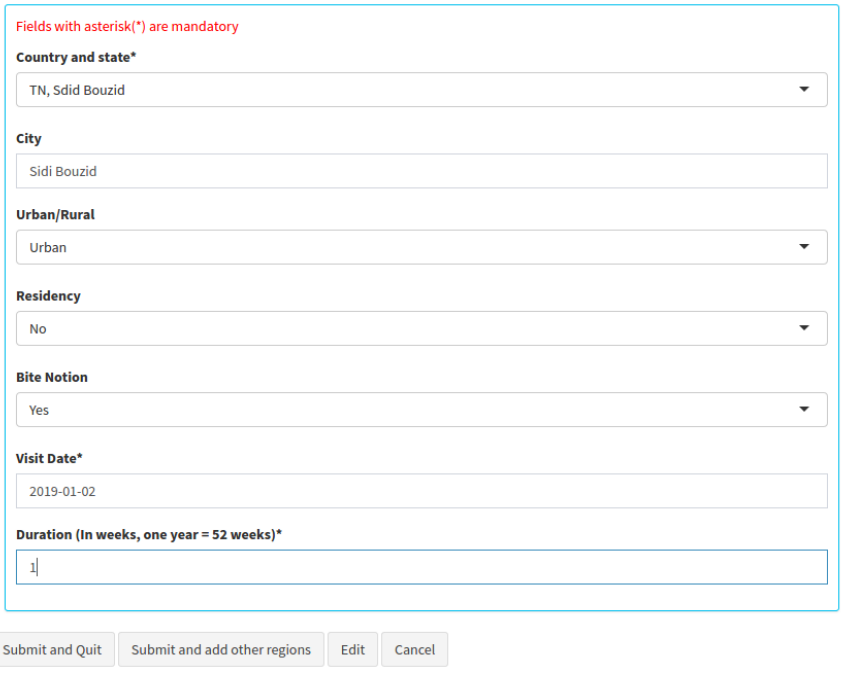


6. Data related to travel and residency can be entered as many times as needed (using the button “Submit and add other regions”)

Epidemiological Data

1. Travel during the last 12 months before the onset of the lesion:

Date of travel	Duration	Country	Governorate	City	Urban/ Rural	Notion of bite : Y/N
02 / 01 / 2019	07 D _ _ M _ _ Y	Tunisia	Sidi Bouzid	Sidi Bouzid	Urban	Y
_ _ / _ _ / _ _ _ _	_ _ D _ _ M _ _ Y					
_ _ / _ _ / _ _ _ _	_ _ D _ _ M _ _ Y					
_ _ / _ _ / _ _ _ _	_ _ D _ _ M _ _ Y					



7. Medical check-up

Clinical Data

1. Patient's clinical state: □ High blood pressure □ Diabetes □Allergy □Pregnancy ☒NtR (*) □ Other, specify .....
2. Presence of animals in the entourage: □ Yes ☒ No if Yes, specify : □ Bovines □ Ovines □ Caprines □ Camels □ Equids □ Hares □Cats □ Dogs □ Foxes □ Other Canids □ Sand rats □ Meriones □ Other rodents □ Gondis □ Hedgehogs □ Bates □ Hyrax □ Other
3. Persons in the entourage who had similar cutaneous lesions or has been diagnosed for Leishmaniasis? : □ Yes ☒ No if Yes, specify Relationship: □ Family □ Neighbor □ Colleague
4. Place of contact: □ Household □ Neighborhood □ Workplace □ On travel

History of treatment given w/o diagnosis, before the present visit to the center / hospital

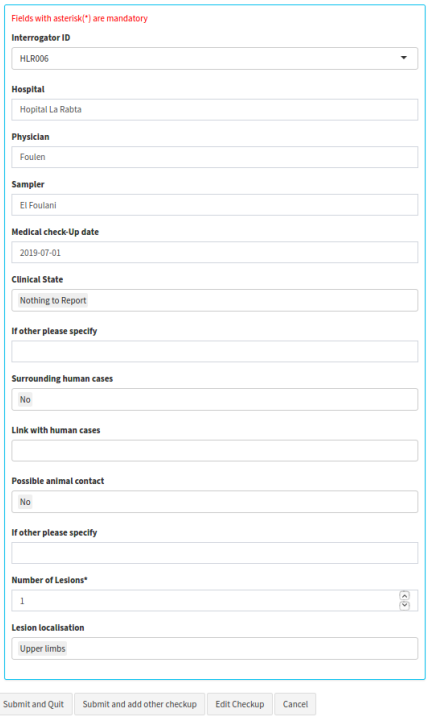
1. Treatment: ☒ Yes □ No, if Yes, specify: ☒ Antibiotic □ Glucantime □ Other, specify ..... Prescribed for Leishmaniasis: □ Yes ☒ No		
2. Date of start of the treatment 07 /06 / 2019	3. Duration of treatment 10 D_ _ M _ _ _Y	4. Injection number (Glucantime) _ _
5. Evaluation, healing □ Yes ☒No if Yes date of healing: _ _ / _ _ / _ _ _ _		

History of diagnosis of the present lesions

1. Before this visit, parasitological/molecular diagnosis has been done □ Yes ☒ No, if Yes, specify how: □ Direct examination □ Positive □Negative Date _ _ / _ _ / _ _ _ _ Laboratory: □ PCR □ Positive □Negative Date _ _ / _ _ / _ _ _ _ Laboratory:
2. Did you receive treatment after such diagnosis? □ Yes □ No, if Yes, specify: □ Antibiotic Duration : _ _ D_ _ M _ _ _Y Posology: Administration route: □ Glucantime Duration : _ _ D_ _ M _ _ _Y Posology: Administration route: □ Other, specify ..... Duration : _ _ D_ _ M _ _ _Y Posology: Administration route:

Interrogator

First name	Last name	Grade	Signature
Foulen	El Foulani	Researcher	

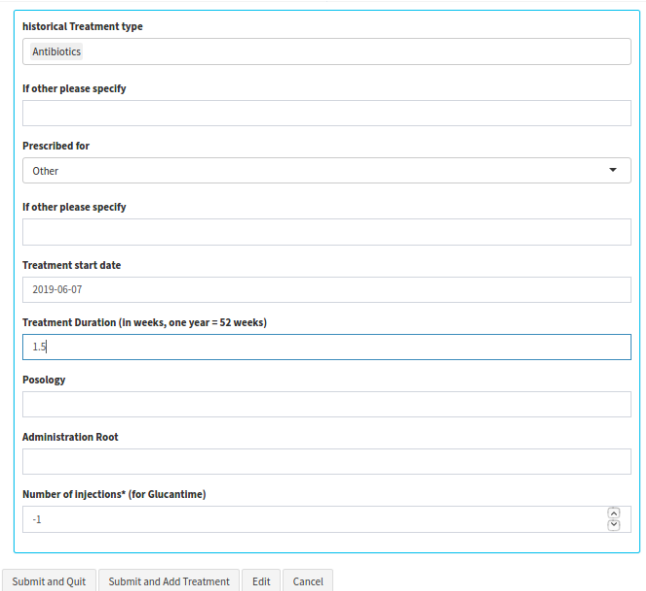


N.B: if your interrogator hasn't been entered to the database yet you can introduce it by following section 14.

8. History of treatments

History of treatment given w/o diagnosis, before the present visit to the center / hospital

1. Treatment: ☒ Yes □ No, if Yes, specify: ☒ Antibiotic □ Glucantime □ Other, specify ..... Prescribed for Leishmaniasis: □ Yes ☒ No		
2. Date of start of the treatment 07 /06 / 2019	3. Duration of treatment _ _10_ _ M _ _ _Y	4. Injection number (Glucantime) _ _
5. Evaluation, healing □ Yes ☒No if Yes date of healing: _ _ / _ _ / _ _ _ _		



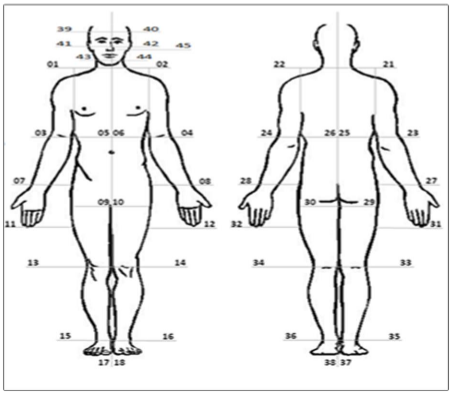
9. Sample

2. Lesion site: ☒ Face ☒ Upper limbs ☐ Lower limbs ☐ Trunk ☐Other, specify.....	3. Number of lesions: 1. . .

Sample Data: (Please indicate data relative to the sampled lesion)

1.Date of onset of the lesion 30 /05 / 2019	2.Lesion site: 03
3. Lesion description: ☒Ulcerative crusty ☐ Dry ☐ Wet ☐ Surrounded by a hyperpigmented rim ☐ Nodules pseudosporotrichoïdes ☐ Pseudotumoral ☐ infected ☐ Surrounded by an erythematous eruption ☐ Other, specify	
4. Sampling method ☒ Scrapping ☐ Aspiration ☐ Biopsy ☐ Dental broch ☐ Swab ☐ other: specify ..... 5.Sample support ☒ TE ☐ Slide ☐ Saline ☐ RNA later ☐ Filter paper	
6. Preliminary results: Direct examination ☒ Positive ☐ Negative Abundance on the smear: ☐++++++ ☐+++++ ☒++++ ☐+++ ☐++ ☐+	
7.Post-diagnosis treatment ☐ Yes ☐ No, if Yes, specify: ☐ Antibiotic Duration : _ _ D_ _M _ _ _Y Posology: Administration route: ☒ Glucantime Duration : 20 D_ _M _ _ _Y Posology: 1 g Administration route: IM ☐ Other, specify ..... Duration : _ _ D_ _M _ _ _Y Posology: Administration route:	

- Please indicate lesion position in the figure
- Please take a picture of the lesion
- Site of sampled lesion: 03
- Lesion Diameter min: 18 mm
- Lesion Diameter max: 25 mm
- Lesion Height: 4 mm



Fields with asterisk(*) are mandatory

Type of sample support: TE

If other please specify:

Sampling Method: Scrapping

If other please specify:

Direct examination result: Positive

Abundance on the smear: ++++

Lesion first appearence: 2019-05-03

Or lesion age(in weeks): -1

lesion Diameter Maximal(millimeter)*: 25

lesion Diameter Minimal(millimeter)*: 18

Lesion Height(millimeter)*: 4

Sampling date*:

Lesion description: Ulcerative crusty

If other please specify:

10. You can add a photo of the sampled lesion

Sample*

Image of lesion sampled

Browse... alep.jpg

Upload complete

Submit Cancel

11. For each sample, storage data can be added

Sample

Quantity in nanogramme: -1

Type: N/A

Container

Rak

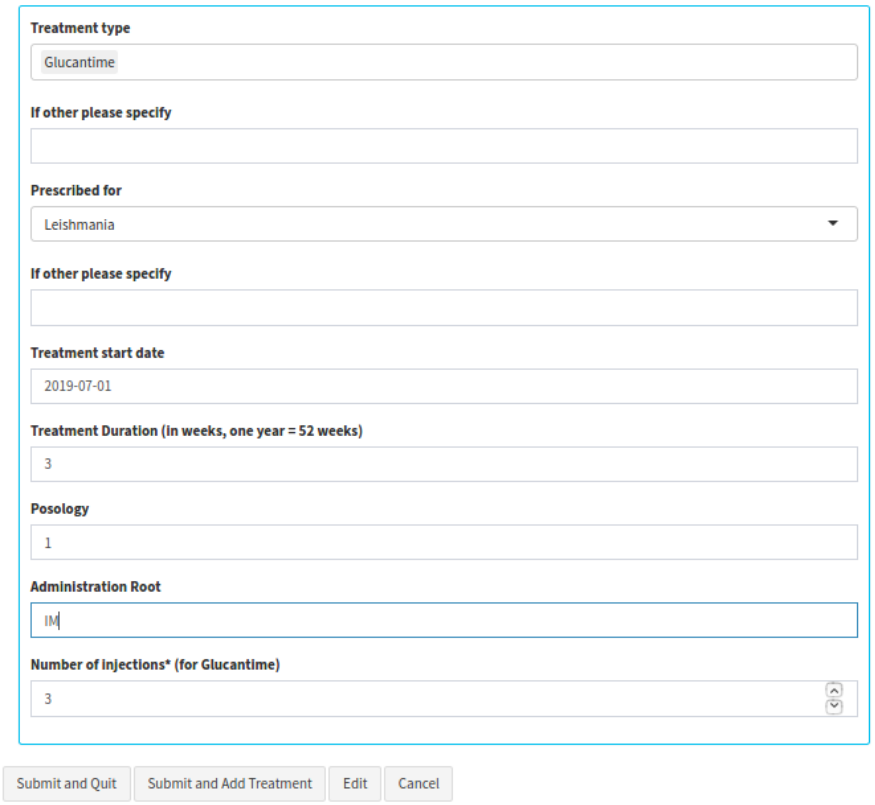
conserve: N/A

Position

Submit Cancel

12. Post-diagnosis treatment

7.Post-diagnosis treatment	□ Yes	□ No,	if Yes, specify:		
□ Antibiotic	Duration : _ _ D_ _M _ _ _Y		Posology:		Administration route:
☒ Glucantime	Duration : 20 D_ _M _ _ _Y		Posology: 1 g		Administration route: IM
□ Other, specify	Duration : _ _ D_ _M _ _ _Y		Posology:		Administration route:

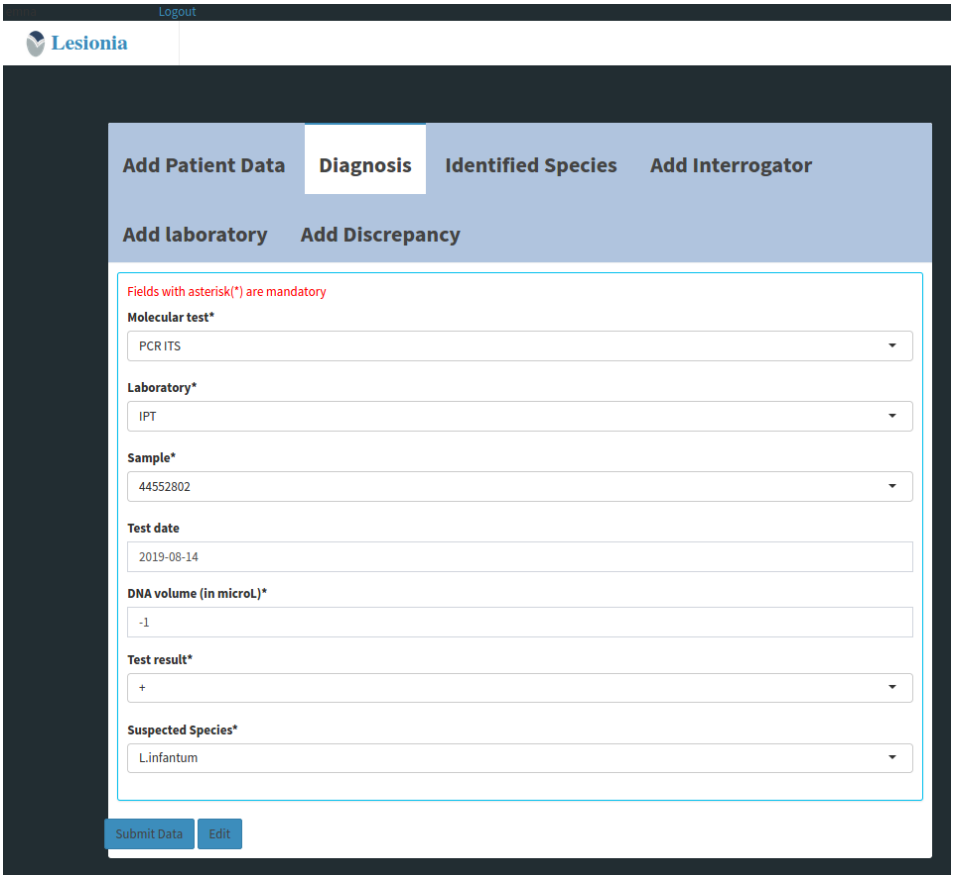


13. To enter data related to molecular diagnosis, go to the diagnosis tab

Diagnosis

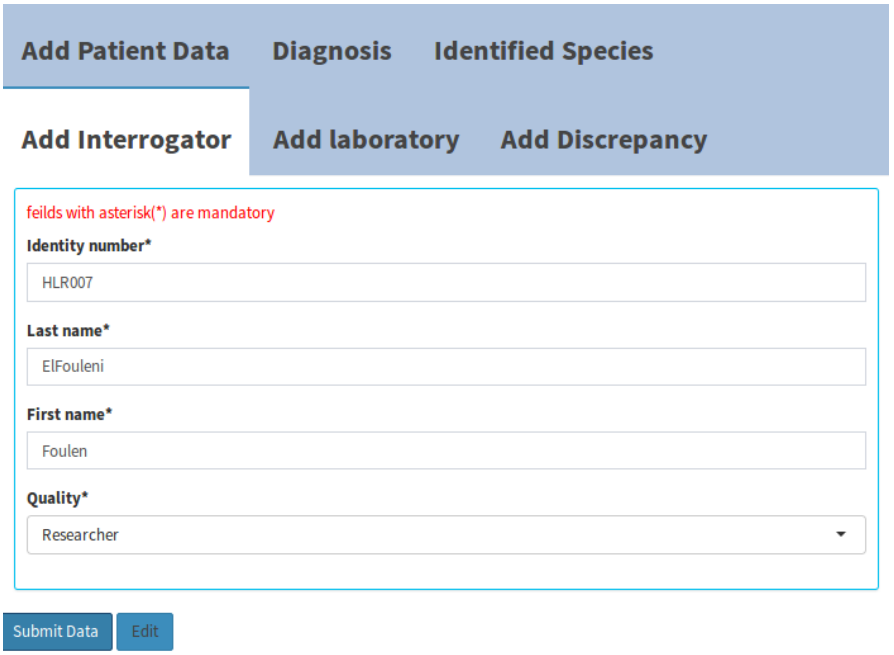
Molecular tests : please indicate (+ve / -ve)

Molecular tests	Molecular detection	Species identification				N/A
		L. major	L. infantum	L. tropica	Other	
PCR ITS	+ve		x			
qPCR	+ve		x			
RPA-LF						



N.B: if your laboratory hasn't been entered to the database yet you can introduce it by following section 15.

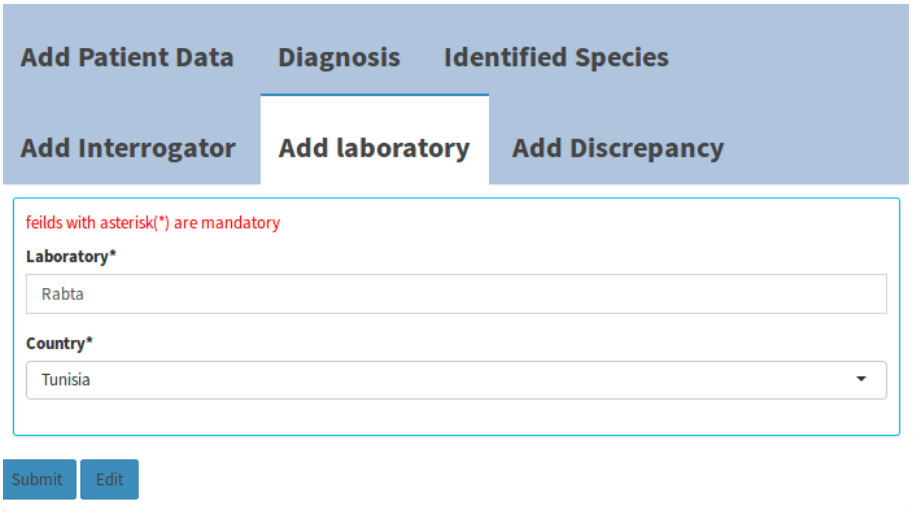
14. You can add an interrogator as follow:



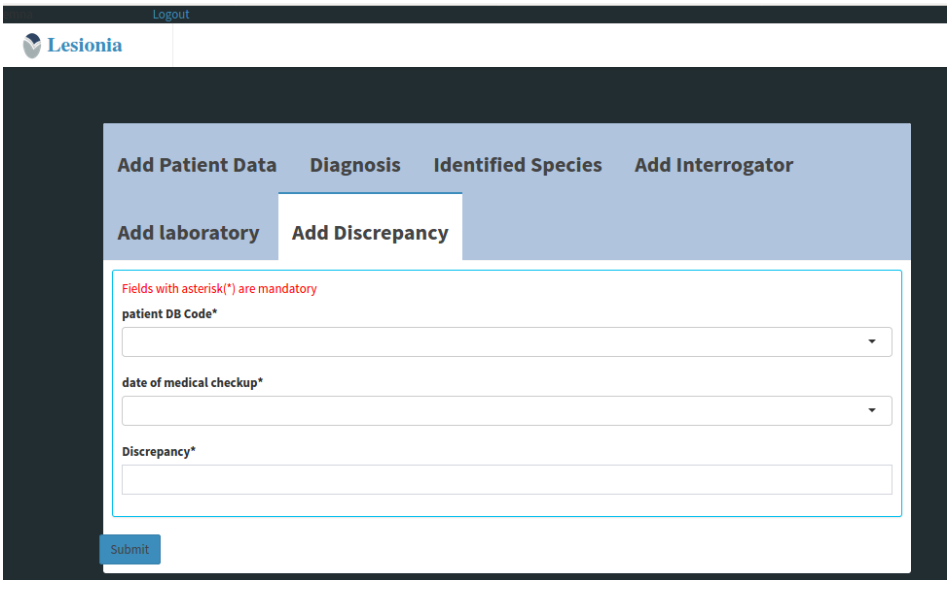
N.B: We used initials of each institution followed by three digits as identifiers for the users as follows:

Hopital Farhat Hachad - Sousse	Hopital La Rabta - Tunis	Rafik el Hariri Hospital - Lebanon	Faculty of Public Health - Lebanon	Institut Pasteur du Maroc - Morocco
HFHXXX	HLRXXX	RHOXXX	LBPXXX	IPMXXX

15. You can add a laboratory as follows :



16. If you are having trouble entering some data, you can add a discrepancy description for later review and manual curation by the data manager

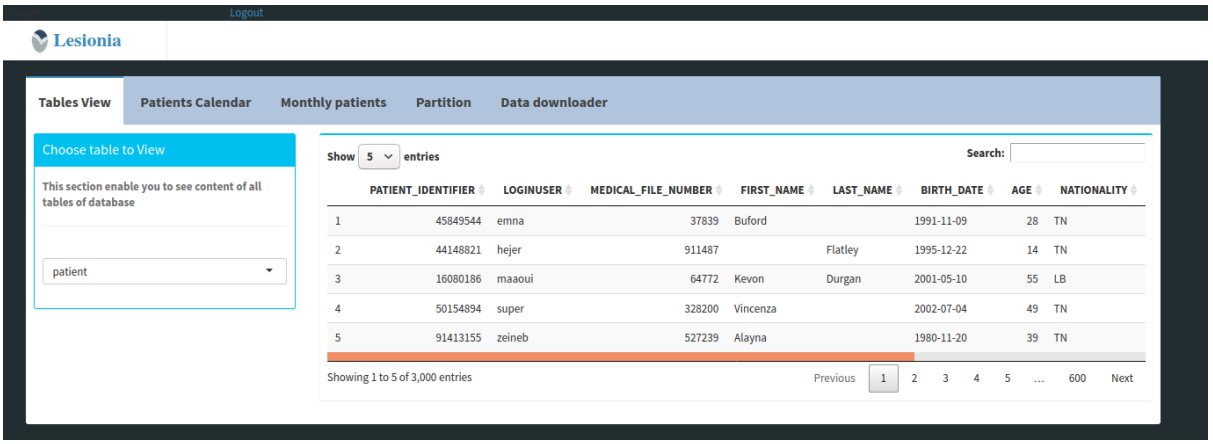


N.B: All "Data entry" forms have an "Edit" button that enables a pop-up that allows the update of existing data if needed.

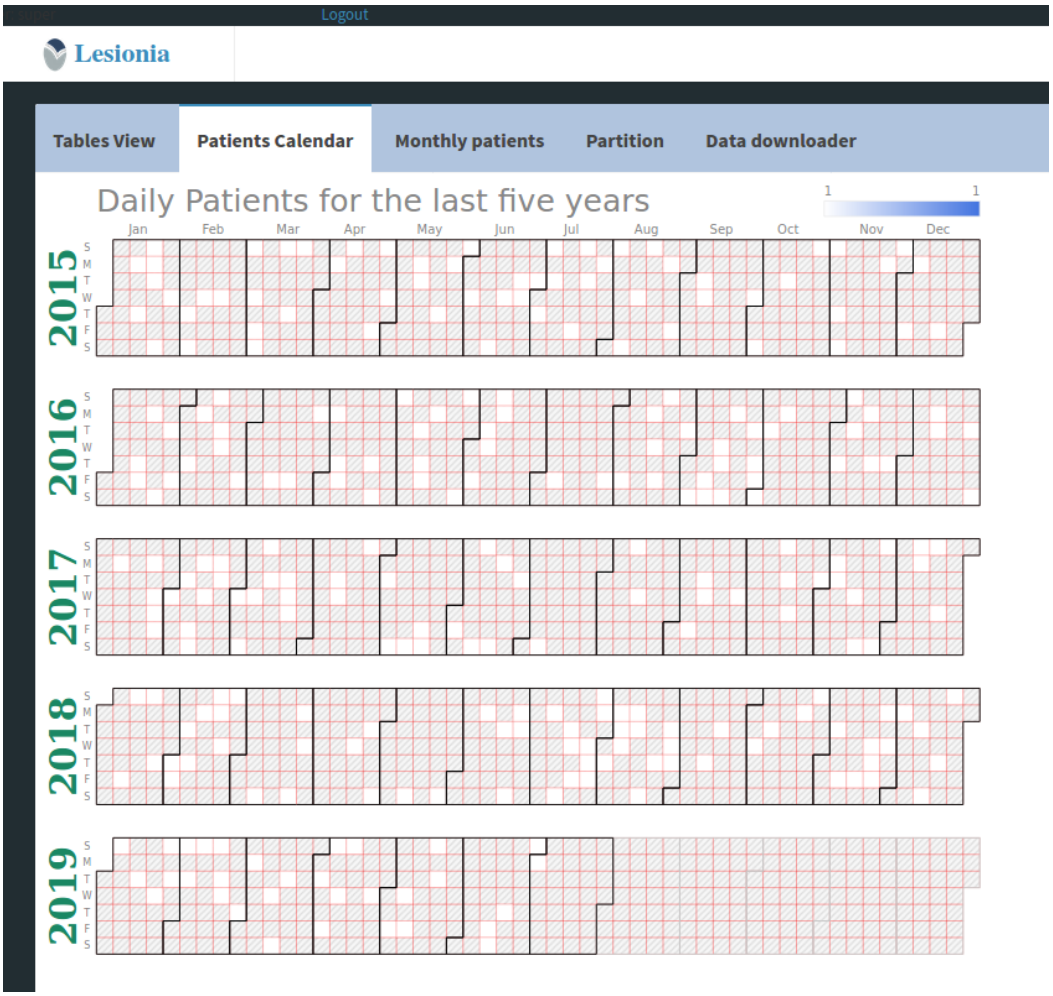
4. Data viewer

17. Data consultancy per table

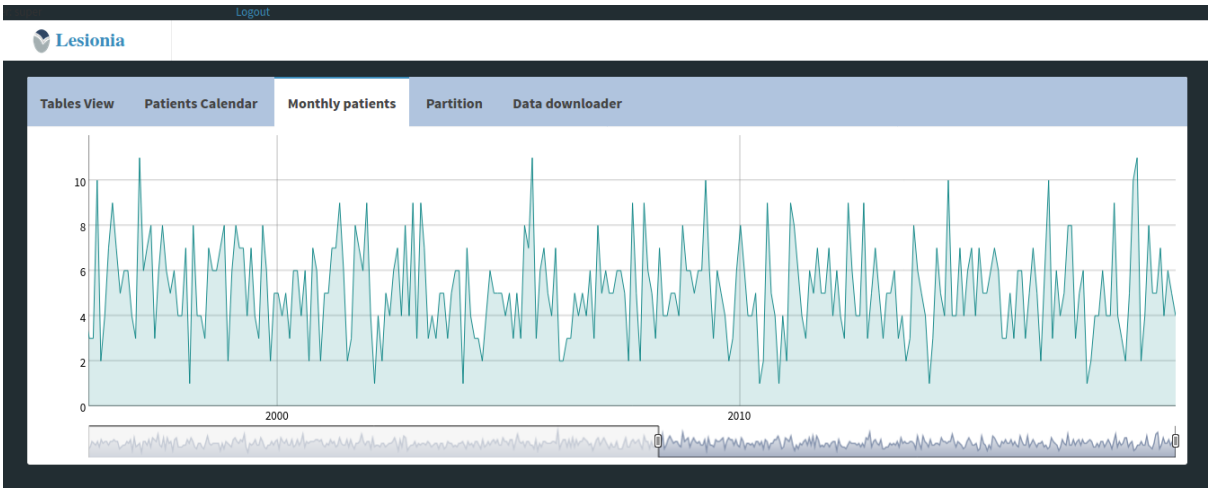
All users can access data in all the tables of the database for consultancy

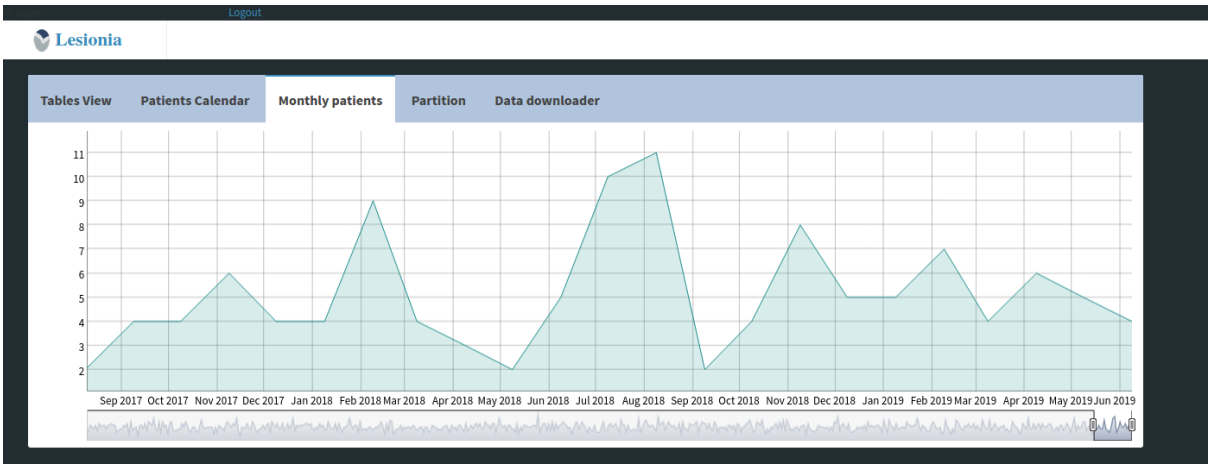


18. Patient calendar



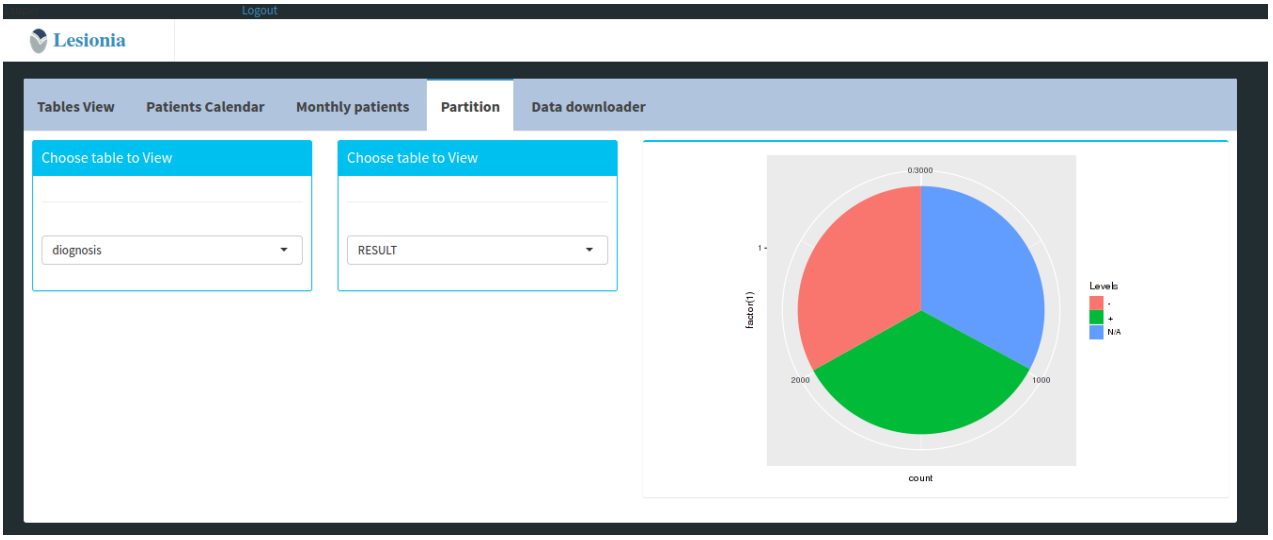
19. Monthly recruited patients





N.B: Patient recruitment can be visualized at different time scales using a simple tuning button

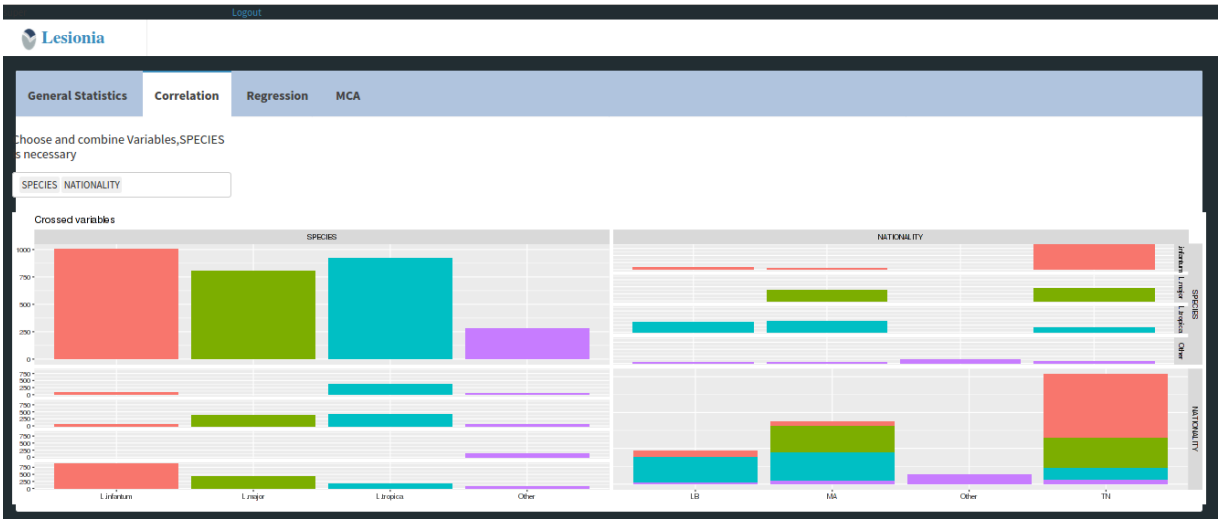
20. Data partition



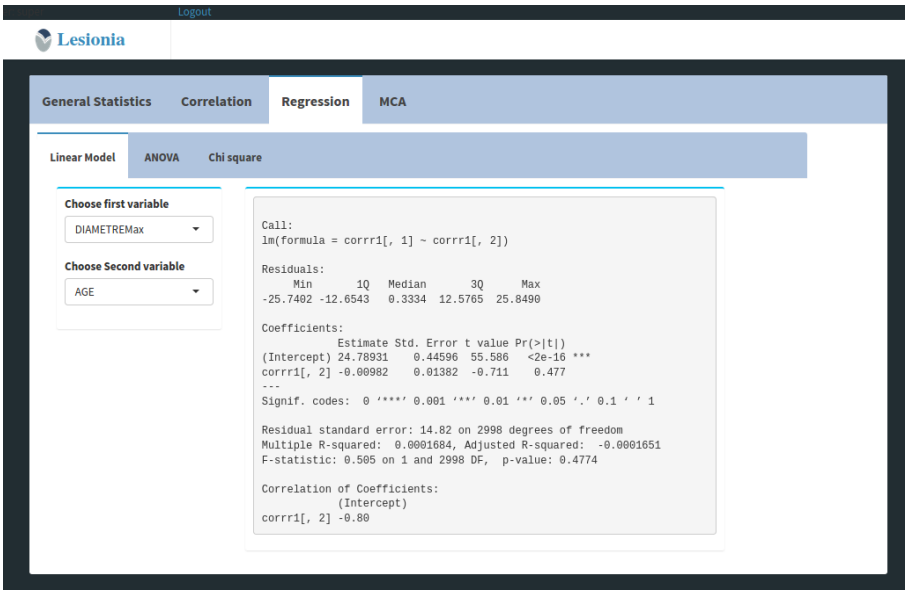
5. Data analysor

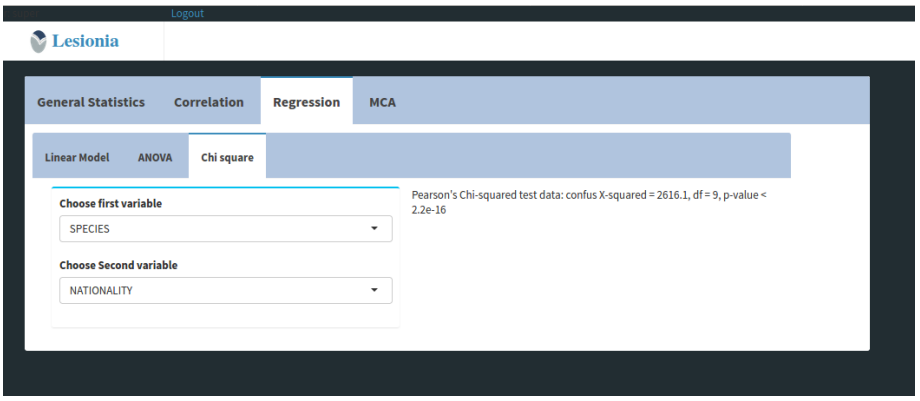
21. General Statistics

22. Correlation analysis



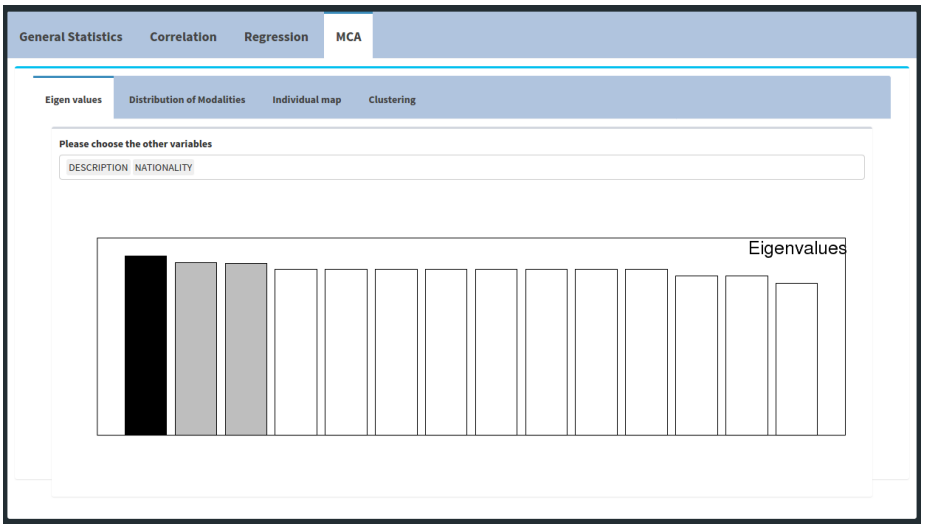
23. Regression

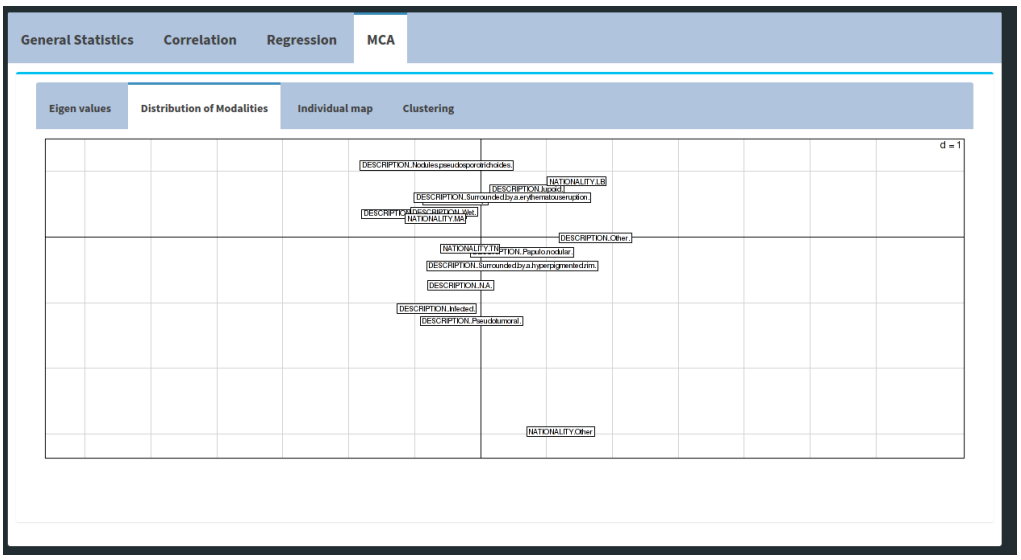




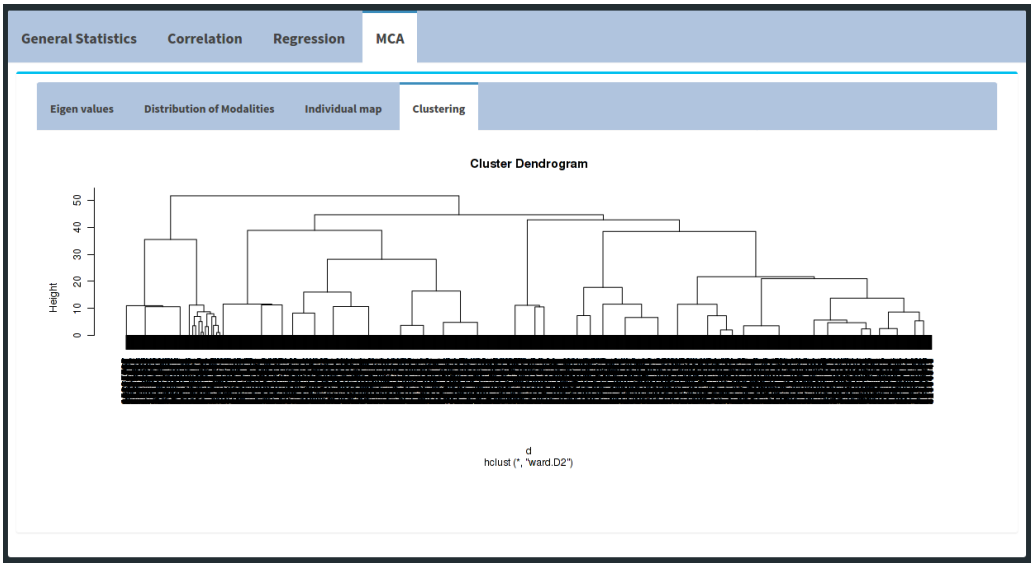
N.B: ANOVA regression analysis is only applied for data with a normal distribution.

24. MCA




General Statistics
Correlation
Regression
MCA
Eigen values
Distribution of Modalities
Individual map
Clustering
d = 1
DESCRIPTION.Nodules:pseudosporotrichoides.
NATIONALITY.LB
DESCRIPTION.Ulcer(s)
DESCRIPTION.Surrounded by a erythematous eruption.
DESCRIPTION.Wart
NATIONALITY.MA
DESCRIPTION.Other.
NATIONALITY.TN
DESCRIPTION.Papulo nodular
DESCRIPTION.Surrounded by a hyperpigmented rim.
DESCRIPTION.N.A.
DESCRIPTION.Infected
DESCRIPTION.Pseudotumoral.
NATIONALITY.Other

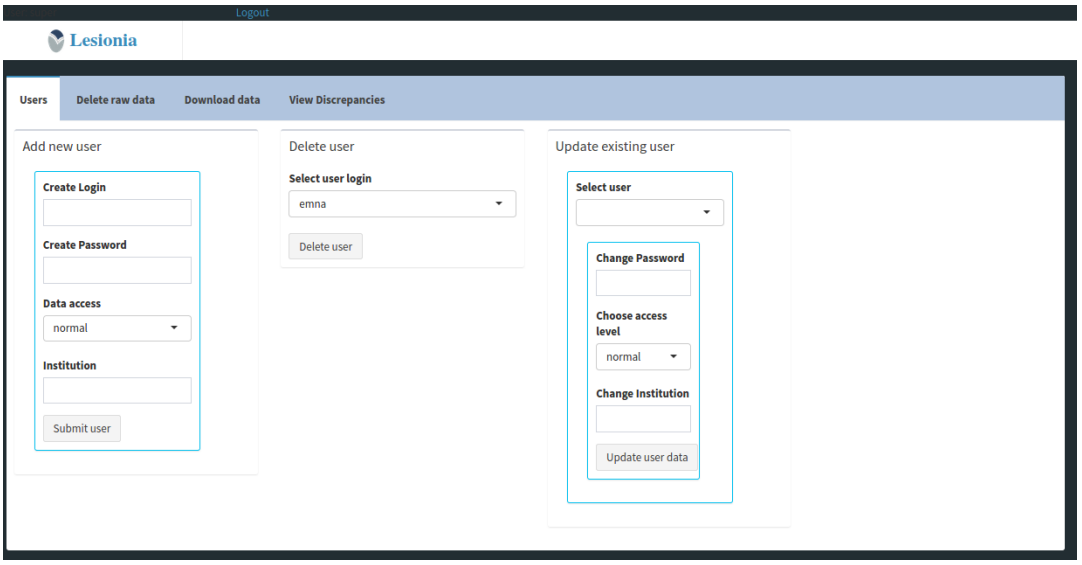

General Statistics
Correlation
Regression
MCA
Eigen values
Distribution of Modalities
Individual map
Clustering
d = 1
L.tropica
L.major
L.infantum
Other


General Statistics
Correlation
Regression
MCA
Eigen values
Distribution of Modalities
Individual map
Clustering
Cluster Dendrogram
Height
0
10
20
30
40
50
d
hclust (*, "ward.D2")

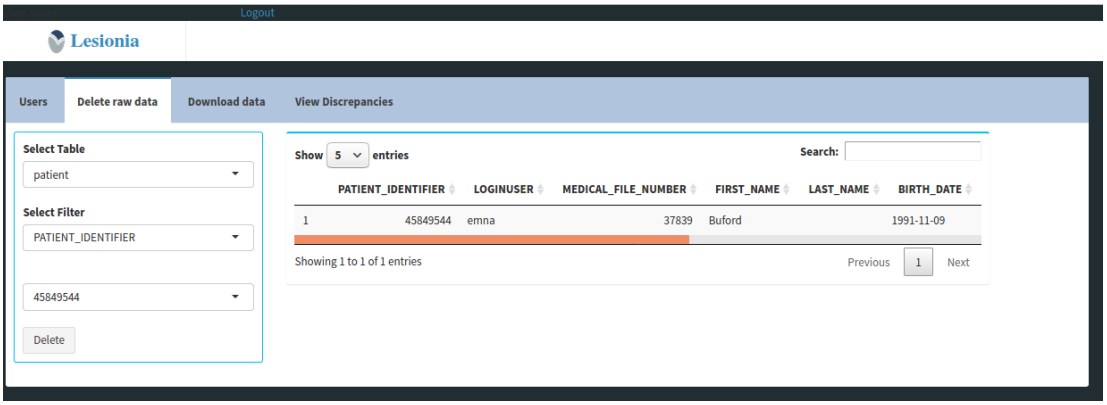
6. Data management

This section can only be access for the super user or users that have the rights to perform data management tasks. It allows to :

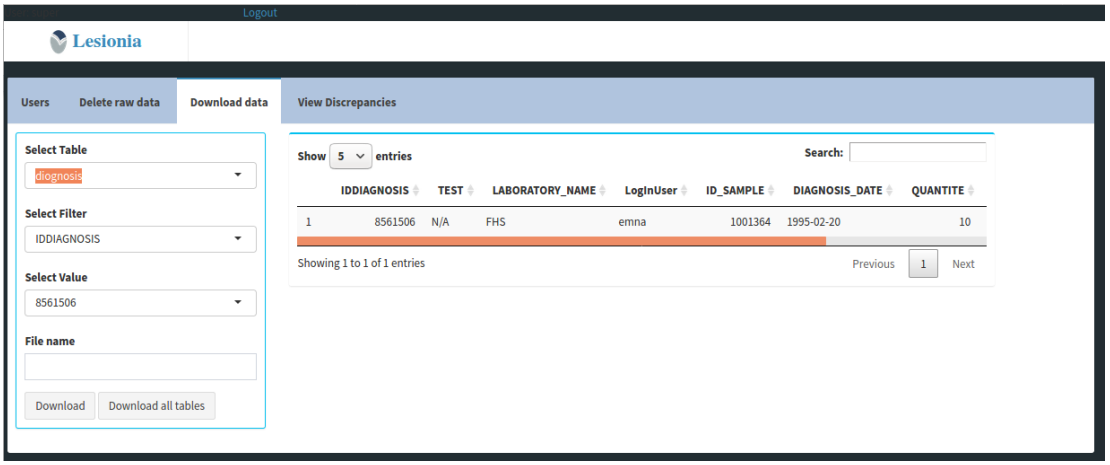
25. Add/delete/update users



26. Delete raw data



27. Download data



7. Miscellaneous

Quick notes that might be helpful while navigating Lesionia

1. The Lesionia logo will take you to the home page

2. You should always log out after using Lesionia

3. If you are using Lesionia on your own server make sure to change the default password of the super user
4. If you are using Lesionia on your own server for your local community make sure to always check the discrepancies with phpmyadmin