



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/LEISIAApp>.

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@yahoo.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: **PERCCCXXX**. 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.

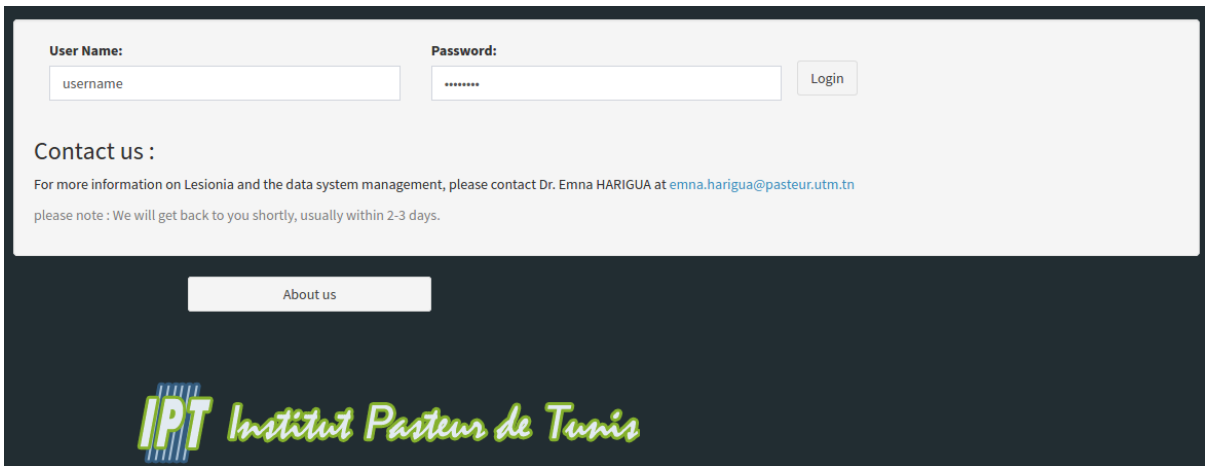
N.B: All patients already entered by the IPT group on behalf of all partners had the last digit of the country code set to 0 (PERCC0XXX)

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



User Name: Password:

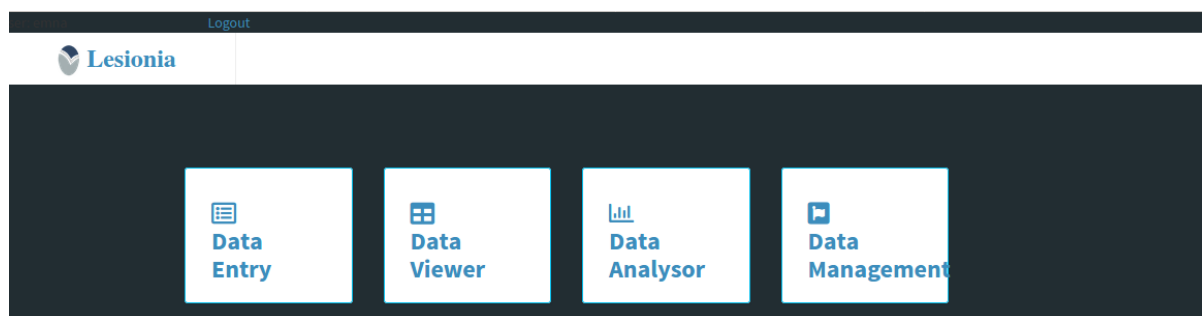
Contact us :

For more information on Lesionia and the data system management, please contact Dr. Emna HARIGUA at emna.harigua@pasteur.utm.tn

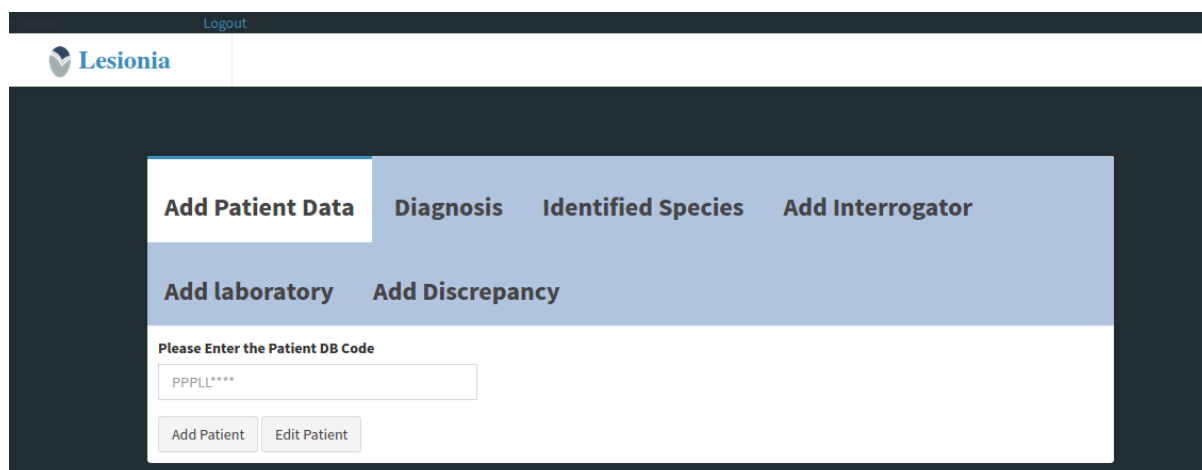
please note : We will get back to you shortly, usually within 2-3 days.

IPT Institut Pasteur de Tunis

2. Click on the “Data entry” tab



- Click on "Add patient"



- 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
-----------------------	------------------

- Date of consultation 01 / 07 / 2019
- Hospital : **Hopital La Rabta**
- Physician : **Dr. Foulén**
- 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. Address : XXX	

Patient Data

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

Add Patient Edit Patient

Fields with asterisk(*) are mandatory

Patient DB Code *

PR20125

Patient ID

HLR50/19

Consentment

Yes

Birth date

1986-10-07

Or Age

-1

Nationality

TN

If other please specify

Gender

Male

Country and state of Residency (The last 6 months)*

TN, Tunis

City

Tunis

Urban/Rural

Urban

Bite Notion

No

Submit Cancel

Add Patient Edit Patient

Fields with asterisk(*) are mandatory

Patient DB Code *

PR20125

Patient ID

HLR50/19

Consentment

Yes

Birth date

1986-10-07

Or Age

-1

Nationality

TN

If other please specify

Gender

Male

Country and state of Residency (The last 6 months)*

TN, Tunis

City

Tunis

Urban/Rural

Urban

Bite Notion

No

Submit Cancel

Patient successfully stored

OK

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.

- 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

Logout

Lesonia

Add Patient Data **Diagnosis** **Identified Species** **Add Interrogator**

Add laboratory **Add Discrepancy**

Please Enter the Patient DB Code

PR20125

Show entries Search:

	PATIENT_IDENTIFIER	BIRTH_DATE	AGE	NATIONALITY	GENDER	CONSENT
1	PR20125	1986-10-07	-1	TN	Male	Yes

Showing 1 to 1 of 1 entries Previous 1 Next

- 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					

Fields with asterisk(*) are mandatory

Country and state*

TN, Sidi Bouzid

City

Sidi Bouzid

Urban/Rural

Urban

Residency

No

Bite Notion

Yes

Visit Date*

2019-01-02

Duration (In weeks, one year = 52 weeks)*

1

7. Medical check-up

Clinical Data			
1. Patient's clinical state: <input type="checkbox"/> High blood pressure <input type="checkbox"/> Diabetes <input type="checkbox"/> Allergy <input type="checkbox"/> Pregnancy <input checked="" type="checkbox"/> NtR (*) <input type="checkbox"/> Other, specify			
2. Presence of animals in the entourage: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No if Yes, specify : <input type="checkbox"/> Bovines <input type="checkbox"/> Ovines <input type="checkbox"/> Caprines <input type="checkbox"/> Camels <input type="checkbox"/> Equids <input type="checkbox"/> Hares <input type="checkbox"/> Cats <input type="checkbox"/> Dogs <input type="checkbox"/> Foxes <input type="checkbox"/> Other Canids <input type="checkbox"/> Sand rats <input type="checkbox"/> Meriones <input type="checkbox"/> Other rodents <input type="checkbox"/> Gondis <input type="checkbox"/> Hedgehogs <input type="checkbox"/> Bates <input type="checkbox"/> Hyrax <input type="checkbox"/> Other			
3. Persons in the entourage who had similar cutaneous lesions or has been diagnosed for Leishmaniasis? : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No if Yes, specify Relationship: <input type="checkbox"/> Family <input type="checkbox"/> Neighbor <input type="checkbox"/> Colleague			
4. Place of contact: <input type="checkbox"/> Household <input type="checkbox"/> Neighborhood <input type="checkbox"/> Workplace <input type="checkbox"/> On travel			
History of treatment given w/o diagnosis, before the present visit to the center / hospital			
1. Treatment: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No, if Yes, specify: <input checked="" type="checkbox"/> Antibiotic <input type="checkbox"/> Glucantime <input type="checkbox"/> Other, specify			
Prescribed for Leishmaniasis: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
2. Date of start of the treatment	3. Duration of treatment	4. Injection number (Glucantime)	
07/06/2019	10_D_M_Y		
5. Evaluation, healing <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No if Yes date of healing: __/__/----			
History of diagnosis of the present lesions			
1. Before this visit, parasitological/molecular diagnosis has been done <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No, if Yes, specify how:			
<input type="checkbox"/> Direct examination <input type="checkbox"/> Positive <input type="checkbox"/> Negative Date __/__/---- Laboratory:			
<input type="checkbox"/> PCR <input type="checkbox"/> Positive <input type="checkbox"/> Negative Date __/__/---- Laboratory:			
2. Did you receive treatment after such diagnosis? <input type="checkbox"/> Yes <input type="checkbox"/> No, if Yes, specify:			
<input type="checkbox"/> Antibiotic	Duration : __D__M__Y	Posology:	Administration route:
<input type="checkbox"/> Glucantime	Duration : __D__M__Y	Posology:	Administration route:
<input type="checkbox"/> Other, specify	Duration : __D__M__Y	Posology:	Administration route:
Interrogator			
First name	Last name	Grade	Signature
Foulen	El Foulani	Researcher	

Fields with asterisk(*) are mandatory

Interrogator ID
HLR006

Hospital
Hospital La Rabta

Physician
Foulen

Sampler
El Foulani

Medical check-up date
2019-07-01

Clinical State
Nothing to Report

If other please specify

Surrounding human cases
No

Link with human cases

Possible animal contact
No

If other please specify

Number of Lesions*
1

Lesion localisation
Upper limbs

Submit and Quit Submit and add other checkup Edit Checkup Cancel

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: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No, if Yes, specify: <input checked="" type="checkbox"/> Antibiotic <input type="checkbox"/> Glucantime <input type="checkbox"/> Other, specify		
Prescribed for Leishmaniasis: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
2. Date of start of the treatment	3. Duration of treatment	4. Injection number (Glucantime)
07/06/2019	10_M_Y	
5. Evaluation, healing <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No if Yes date of healing: __/__/----		

historical Treatment type

Antibiotics

If other please specify

Prescribed for

Other

If other please specify

Treatment start date

2019-06-07

Treatment Duration (in weeks, one year = 52 weeks)

1.5

Posology

Administration Root

Number of injections* (for Glucantime)

-1

Submit and Quit Submit and Add Treatment Edit Cancel

9. Sample

2. Lesion site: <input checked="" type="checkbox"/> Face <input checked="" type="checkbox"/> Upper limbs <input type="checkbox"/> Lower limbs <input type="checkbox"/> Trunk <input type="checkbox"/> 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: <input checked="" type="checkbox"/> Ulcerative crusty <input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> Surrounded by a hyperpigmented rim <input type="checkbox"/> Nodules pseudosporotrichoides <input type="checkbox"/> Pseudotumoral <input type="checkbox"/> infected <input type="checkbox"/> Surrounded by an erythematous eruption <input type="checkbox"/> Other, specify			
4. Sampling method: <input checked="" type="checkbox"/> Scrapping <input type="checkbox"/> Aspiration <input type="checkbox"/> Biopsy <input type="checkbox"/> Dental broch <input type="checkbox"/> Swab <input type="checkbox"/> other: specify			
5. Sample support: <input checked="" type="checkbox"/> TE <input type="checkbox"/> Slide <input type="checkbox"/> Saline <input type="checkbox"/> RNA later <input type="checkbox"/> Filter paper			
6. Preliminary results: Direct examination <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative Abundance on the smear: <input type="checkbox"/> +++++ <input type="checkbox"/> ++++ <input checked="" type="checkbox"/> +++ <input type="checkbox"/> ++ <input type="checkbox"/> +			
7. Post-diagnosis treatment <input type="checkbox"/> Yes <input type="checkbox"/> No, if Yes, specify:			
<input type="checkbox"/> Antibiotic	Duration: _ D _ M _ Y	Posology: _____	Administration route: _____
<input checked="" type="checkbox"/> Glucantime	Duration: 20 D _ M _ Y	Posology: 1 g	Administration route: IM
<input type="checkbox"/> Other, specify	Duration: _ D _ M _ Y	Posology: _____	Administration route: _____

- Please indicate lesion position in the figure

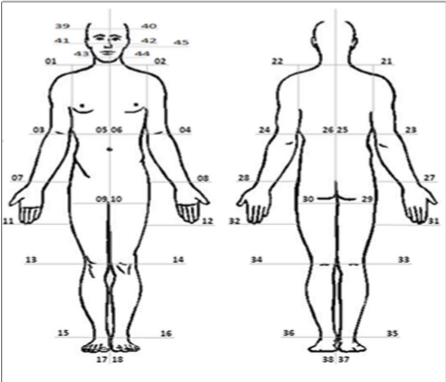
- Please take a picture of the lesion

- 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 appearance: 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:

Treatment type

Glucantime

If other please specify

Prescribed for

Leishmania

If other please specify

Treatment start date

2019-07-01

Treatment Duration (In weeks, one year = 52 weeks)

3

Posology

1

Administration Route

IM

Number of Injections* (for Glucantime)

3

Submit and Quit Submit and Add Treatment Edit Cancel

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						

Logout

Lesonia

Add Patient Data **Diagnosis** Identified Species Add Interrogator

Add laboratory Add Discrepancy

Fields with asterisk(*) are mandatory

Molecular test*

PCR ITS

Laboratory*

IPT

Sample*

44552802

Test date

2019-08-14

DNA volume (in microl)*

-1

Test result*

+

Suspected Species*

L.infantum

Submit Data Edit

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:

Add Patient Data **Diagnosis** Identified Species

Add Interrogator Add laboratory Add Discrepancy

Fields with asterisk(*) are mandatory

Identity number*

HLR007

Last name*

ElFouleni

First name*

Foulen

Quality*

Researcher

Submit Data Edit

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

[Logout](#)

Tables View

Patients Calendar

Monthly patients

Partition

Data downloader

Choose table to View

This section enable you to see content of all tables of database

patient

Show 5 entries

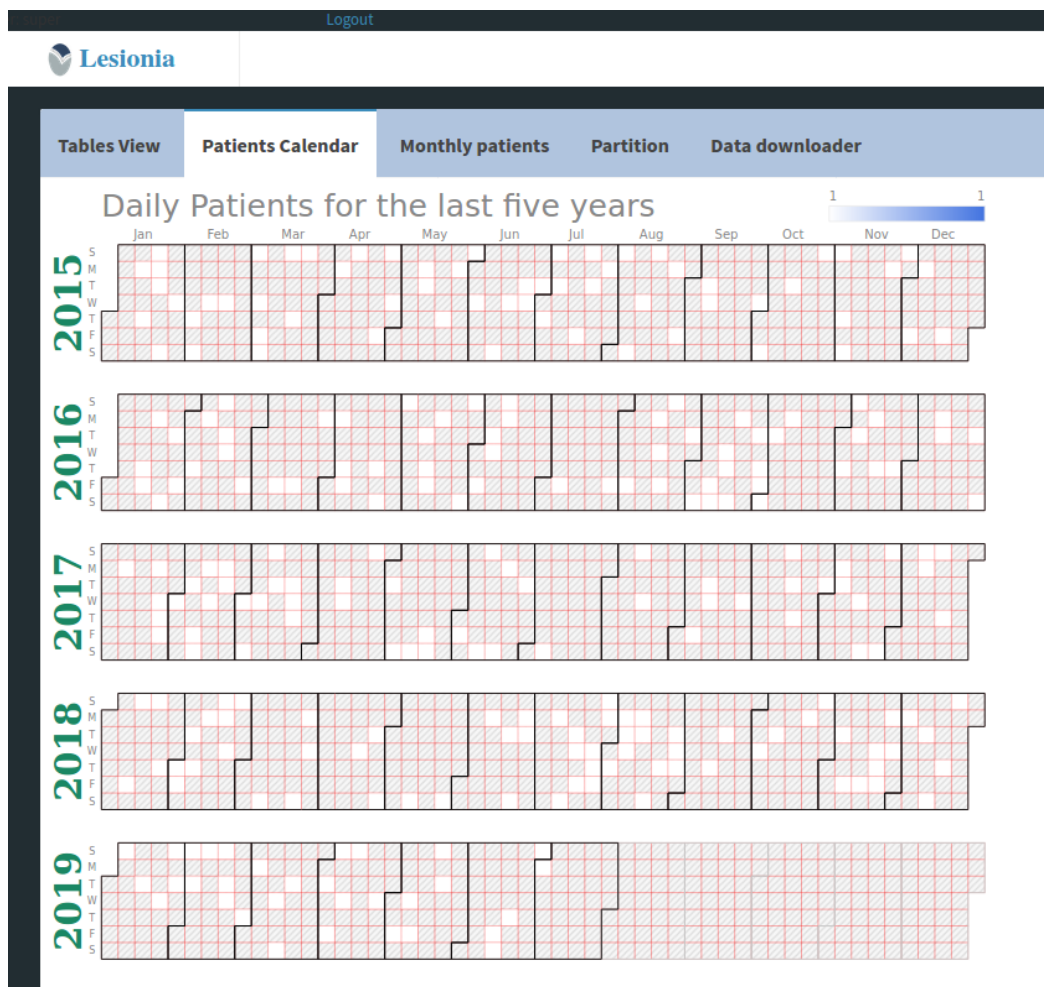
Search:

	PATIENT_IDENTIFIER	LOGINUSER	MEDICAL_FILE_NUMBER	FIRST_NAME	LAST_NAME	BIRTH_DATE	AGE	NATIONALITY
1	45849544	emna	37839	Buford		1991-11-09	28	TN
2	44148821	hejer	911487		Flatley	1995-12-22	14	TN
3	16080186	maaoui	64772	Kevon	Durgan	2001-05-10	55	LB
4	50154894	super	328200	Vincenza		2002-07-04	49	TN
5	91413155	zeineb	527239	Alayna		1980-11-20	39	TN

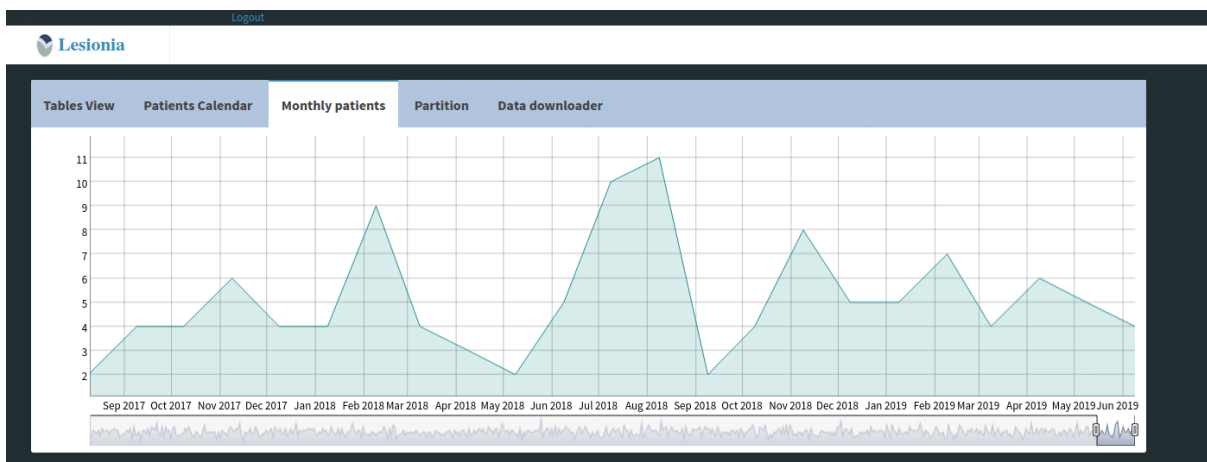
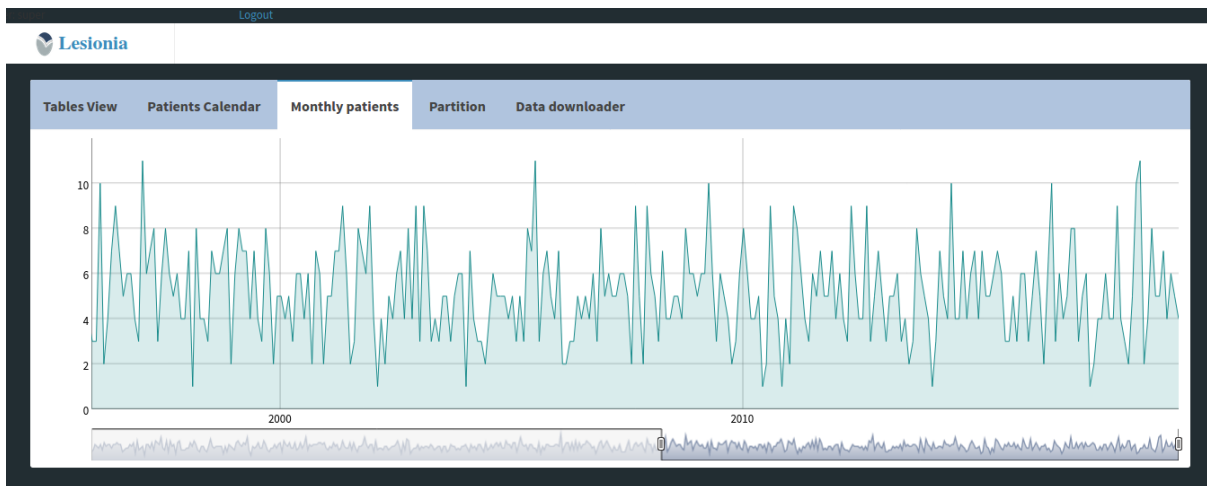
Showing 1 to 5 of 3,000 entries

Previous12345...600Next

18. Patient calendar

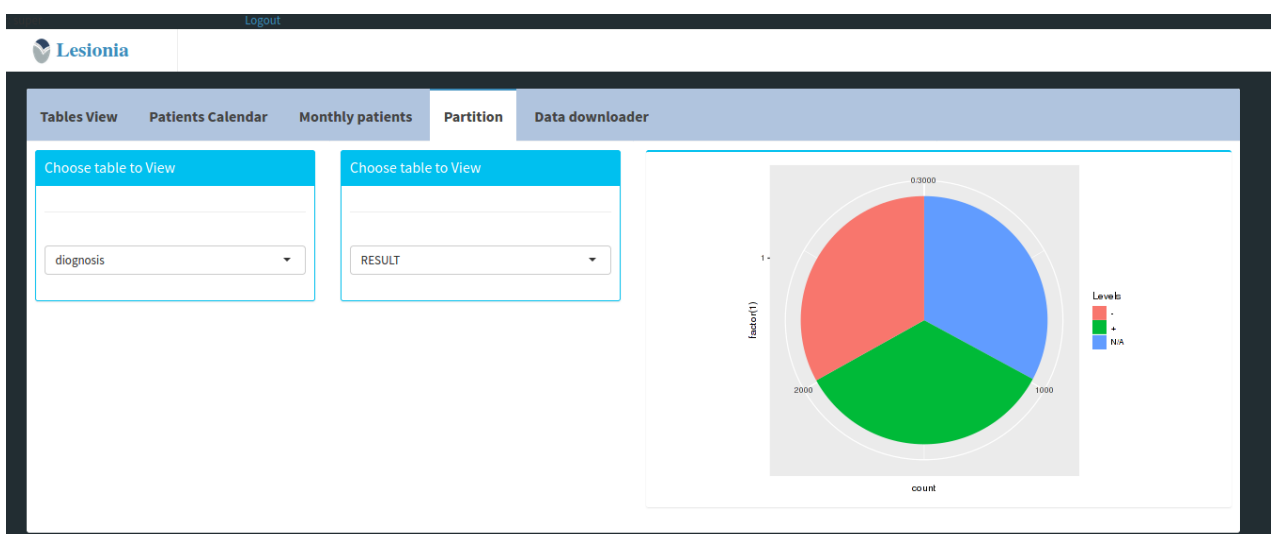


19. Monthly recruited patients



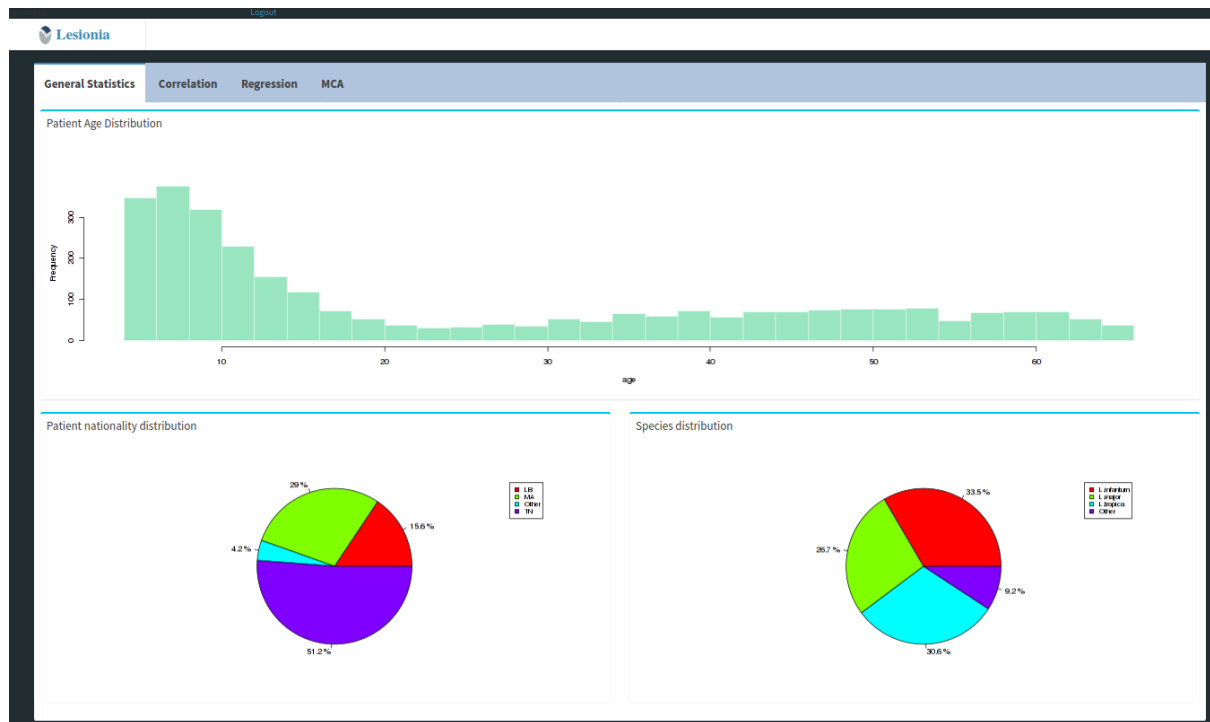
N.B: Patient recruitment can be visualized at different time scales using a simple tuning button

20. Data partition

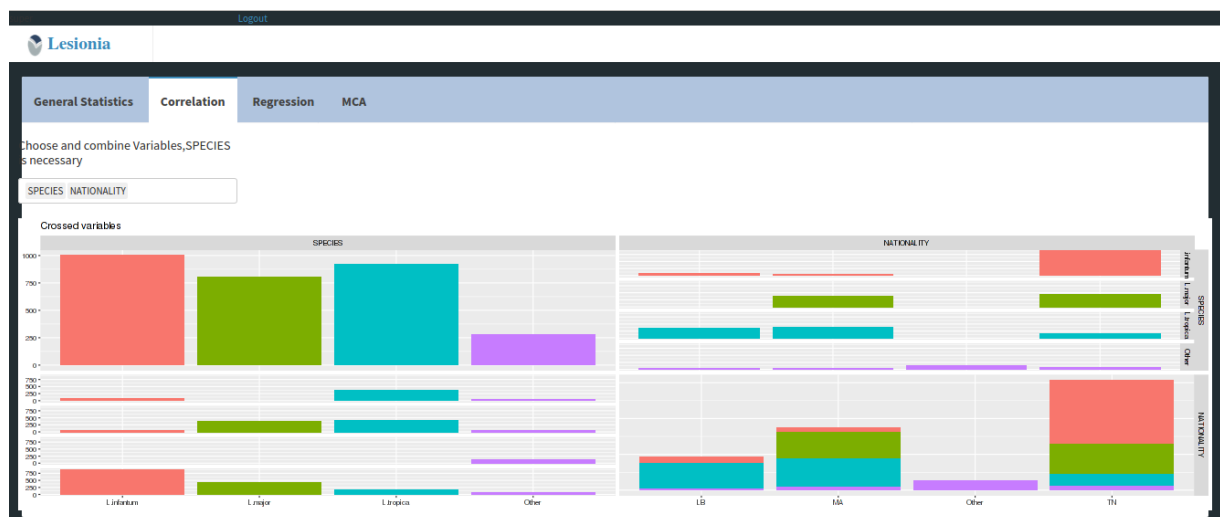


5. Data analyst

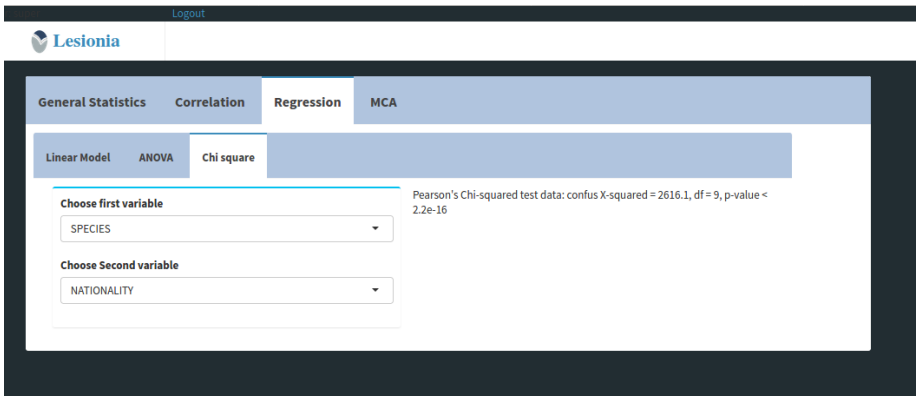
21. General Statistics



22. Correlation analysis

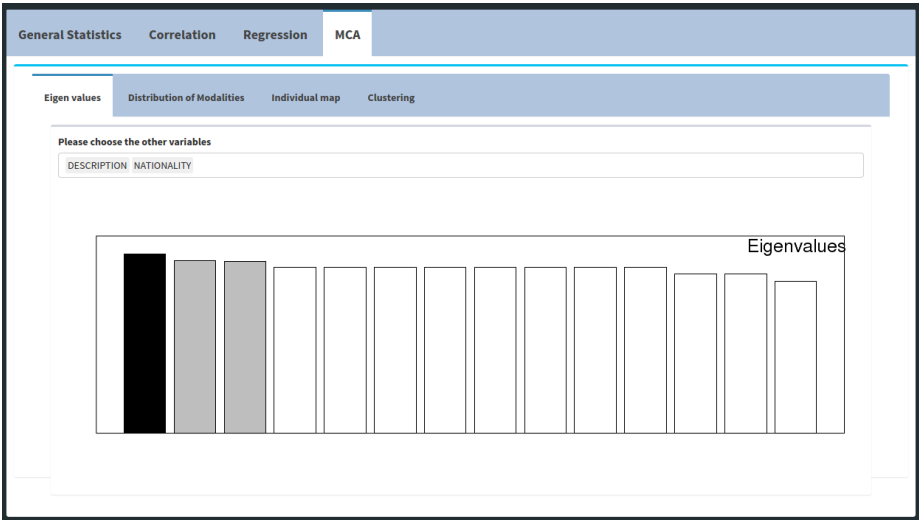


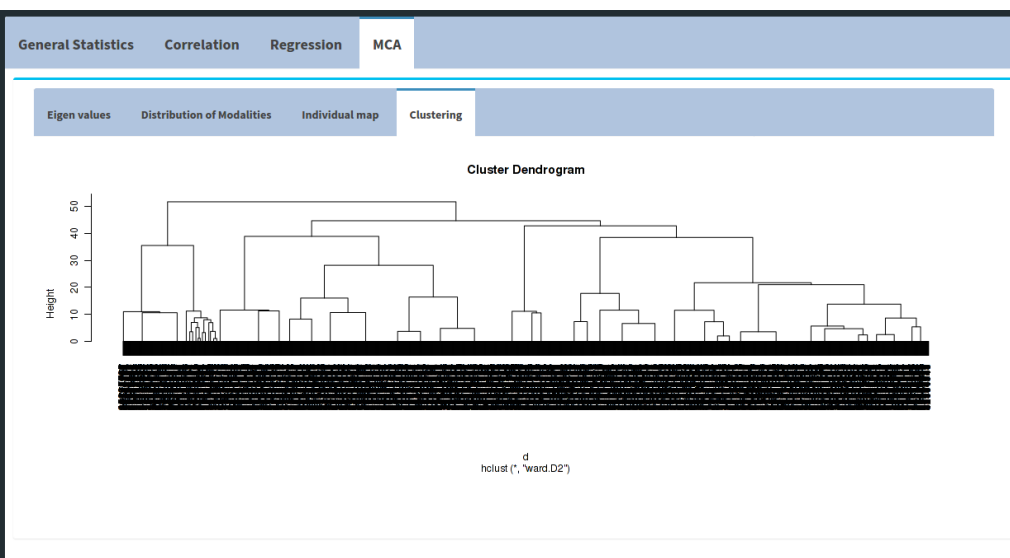
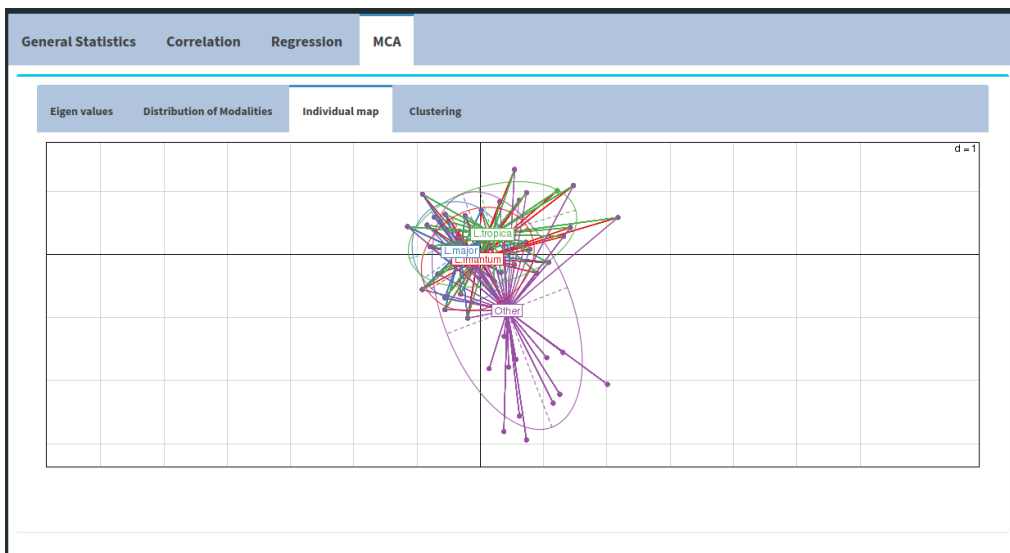
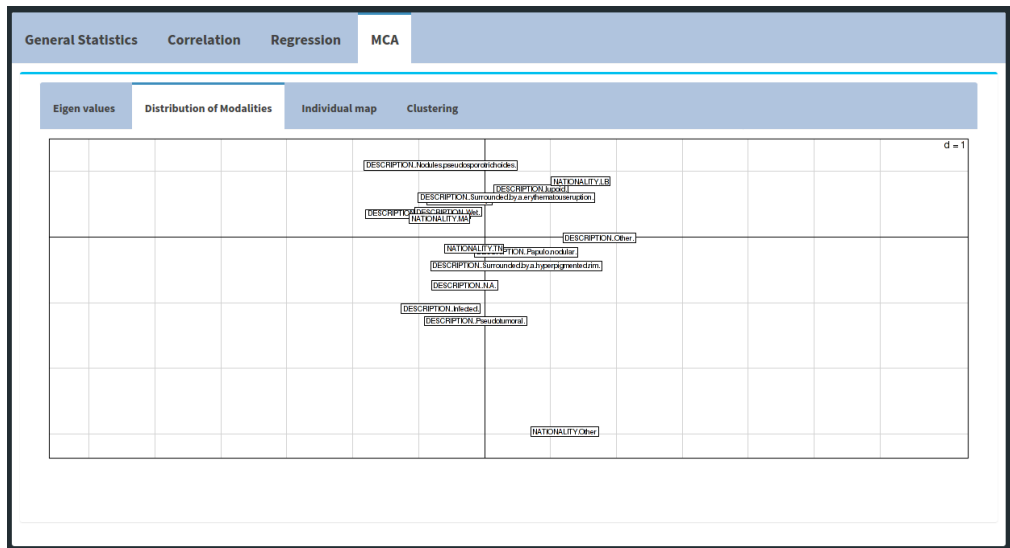
23. Regression



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

24. MCA





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

The screenshot shows the 'Users' management section of the Lesionia application. It features three main panels: 'Add new user', 'Delete user', and 'Update existing user'. The 'Add new user' panel includes fields for 'Create Login', 'Create Password', 'Data access' (set to 'normal'), and 'Institution', with a 'Submit user' button. The 'Delete user' panel has a 'Select user login' dropdown (showing 'emna') and a 'Delete user' button. The 'Update existing user' panel includes a 'Select user' dropdown, 'Change Password', 'Choose access level' (set to 'normal'), 'Change Institution', and an 'Update user data' button. The top navigation bar includes 'Logout', 'Users', 'Delete raw data', 'Download data', and 'View Discrepancies'.

26. Delete raw data

The screenshot shows the 'Delete raw data' interface. On the left, there are filters: 'Select Table' (set to 'patient'), 'Select Filter' (set to 'PATIENT_IDENTIFIER'), and a value '45849544' with a 'Delete' button. The main area displays a table with columns: PATIENT_IDENTIFIER, LOGINUSER, MEDICAL_FILE_NUMBER, FIRST_NAME, LAST_NAME, and BIRTH_DATE. A single entry is shown for patient 45849544, loginuser 'emna', medical file number 37839, first name 'Buford', last name 'Buford', and birth date '1991-11-09'. The table is highlighted in orange. Below the table, it says 'Showing 1 to 1 of 1 entries' with 'Previous' and 'Next' buttons. The top navigation bar includes 'Logout', 'Users', 'Delete raw data', 'Download data', and 'View Discrepancies'.

27. Download data

The screenshot shows the 'Download data' interface. On the left, there are filters: 'Select Table' (set to 'diagnosis'), 'Select Filter' (set to 'IDDIAGNOSIS'), 'Select Value' (set to '8561506'), and a 'File name' field. There are 'Download' and 'Download all tables' buttons. The main area displays a table with columns: IDDIAGNOSIS, TEST, LABORATORY_NAME, LoginUser, ID_SAMPLE, DIAGNOSIS_DATE, and QUANTITE. A single entry is shown for diagnosis 8561506, test 'N/A', laboratory 'FHS', loginuser 'emna', ID sample 1001364, diagnosis date '1995-02-20', and quantity 10. The table is highlighted in orange. Below the table, it says 'Showing 1 to 1 of 1 entries' with 'Previous' and 'Next' buttons. The top navigation bar includes 'Logout', 'Users', 'Delete raw data', 'Download data', and 'View Discrepancies'.

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