

Supplementary Material

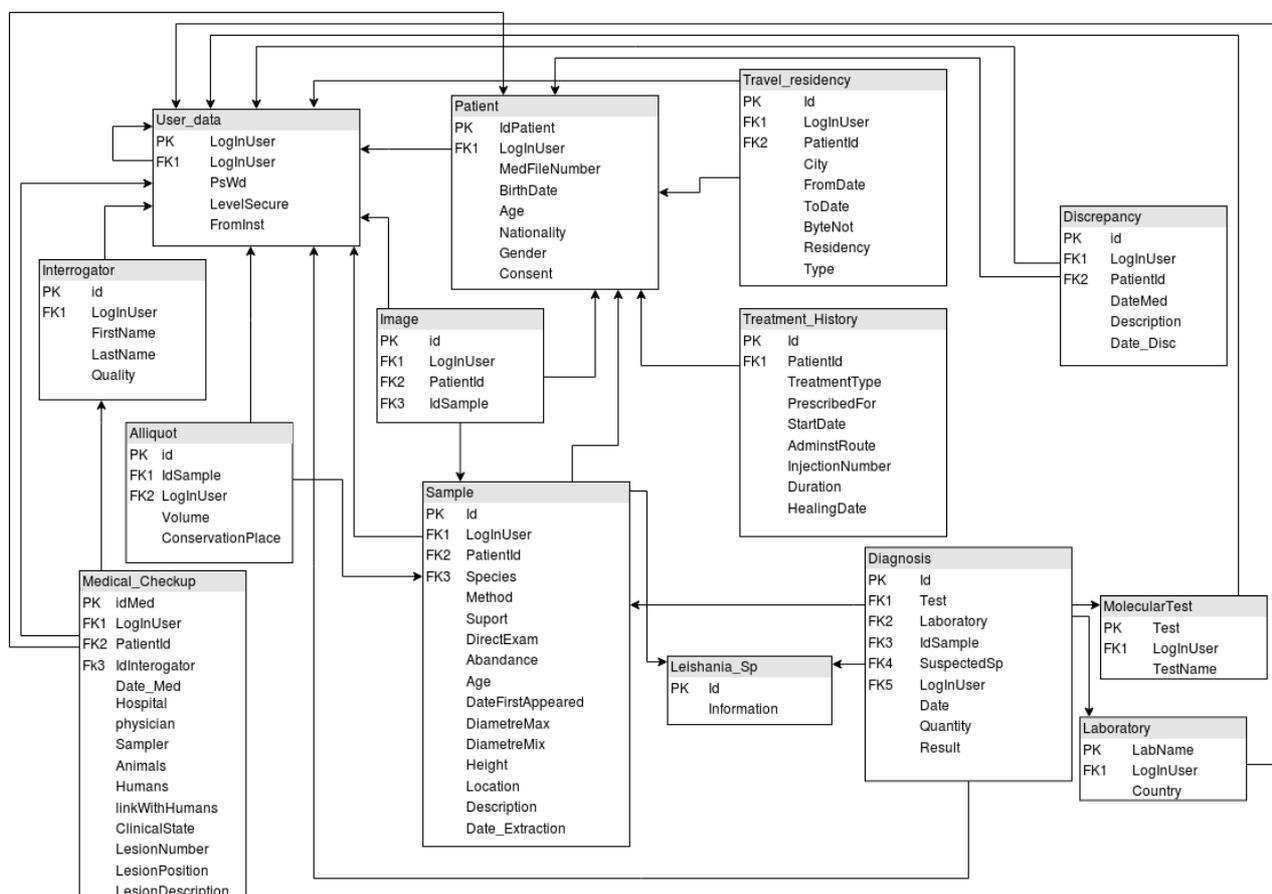
Title: Lesionia: a digital data management system for epidemiological and clinical data collected from patients suspected for cutaneous leishmaniasis

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Supplementary Figure S1. The Conceptual Data Model (CDM) of the database

Table S1. List of partner institutions within the PEER518 consortium

Institution labels	Country	Type/role
MEEP- IPT	Tunisia	Coordinator, End user
HFH Sousse	Tunisia	Sampling site, End user
HLR Tunis	Tunisia	Sampling site, End user
IPM	Morocco	Sampling site, End user
RHU	Lebanon	Sampling site, End user
UPH	Lebanon	Sampling site, End user
TMRC-Mali	Mali	Sampling site, End user & US government supported partner
IDRI	USA	End user & US government supported partner

MEEP-IPT: Laboratory of Molecular Epidemiology and Experimental Pathology Applied to Infectious Diseases, Institut Pasteur de Tunis, Tunisia.

HFH Sousse: Hopital Farhat Hachad, Sousse, Tunisia.

HLR Tunis: Hopital La Rabta, Tunis, Tunisia.

IPM: Institut Pasteur du Maroc, Casa Blanca, Morocco.

RHU: Rafik Hariri University Hospital, Beirut, Lebanon.

UPH: University of Public Health, Beirut, Lebanon.

TMRC-Mali: Tropical Medicine Research Centers (TMRC), Faculty of Medicine and Odontostomatology, University of Bamako, Bamako, Mali.

IDRI: Infectious Disease Research Institute, Seattle, Washington, USA.

Table S2. Data distributions for simulated data

Table	Row	Options	Distribution or probabilities (%)
patient	AGE	5 to 60	Chisq(7,2) + Norm(50,20)
	NATIONALITY	TN, MA, LB, Other	50, 30, 10, 10
	GENDER	Male, Female, N/A	49, 49, 2
sample	Lesion_Age	0 to 15	Chisq(3,2) + Norm(7,2)
	SPECIES for NATIONALITY='TN'	<i>L.infantum</i> , <i>L.major</i> , <i>L.tropica</i> , Other	55, 30, 10, 5
	SPECIES for NATIONALITY='MA'	<i>L.major</i> , <i>L. tropuica</i> , <i>L.infantum</i> , Other	75, 45, 5, 5
	SPECIES for NATIONALITY='LB'	<i>L.tropica</i> , <i>L.infantum</i> , Other	75, 20, 5
	SPECIES for the rest of NATIONALITY	Other	100



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/LEISApp>.

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: **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 HARIQUA at emna.harigua@pasteur.utm.tn

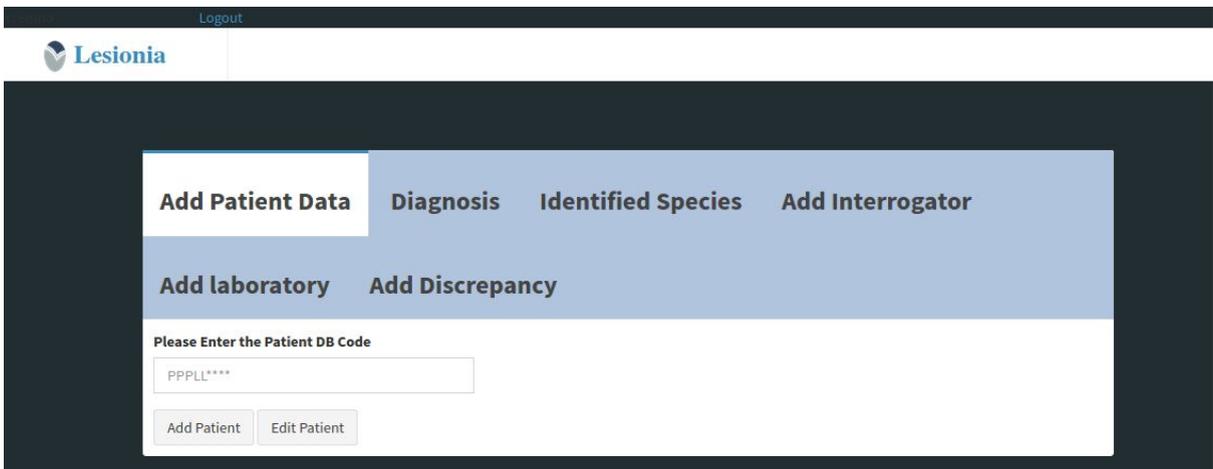
please note : We will get back to you shortly, usually within 2-3 days.

IPT Institut Pasteur de Tunis

2. Click on the “Data entry” tab



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 <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

Lesionia

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, Sdid 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: 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	

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: 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: / /

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

Posology:

Administration Root:

Number of Injections* (for Glucantime): -1

Submit and Quit Submit and Add Treatment Edit Cancel

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 pseudosporotrichoides 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: 20D_M__Y Posology: 1g Administration route: IM
 Other, specify Duration: D_M_Y Posology: Administration route:

- Please indicate lesion position in the figure

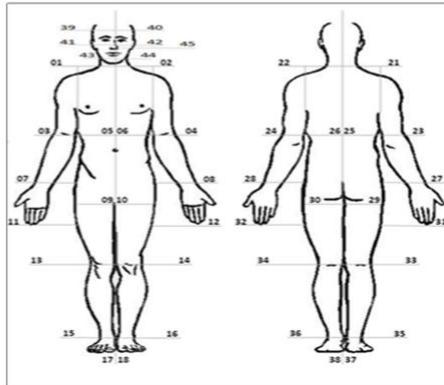
- Please take a picture of the lesion

- Site of sampled lesion: ..03..

Lesion Diameter min: ..1.8.. mm

Lesion Diameter max: ..2.5.. 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:

<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:

Treatment type

If other please specify

Prescribed for

If other please specify

Treatment start date

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

Posology

Administration Route

Number of Injections* (for Glucantime)

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

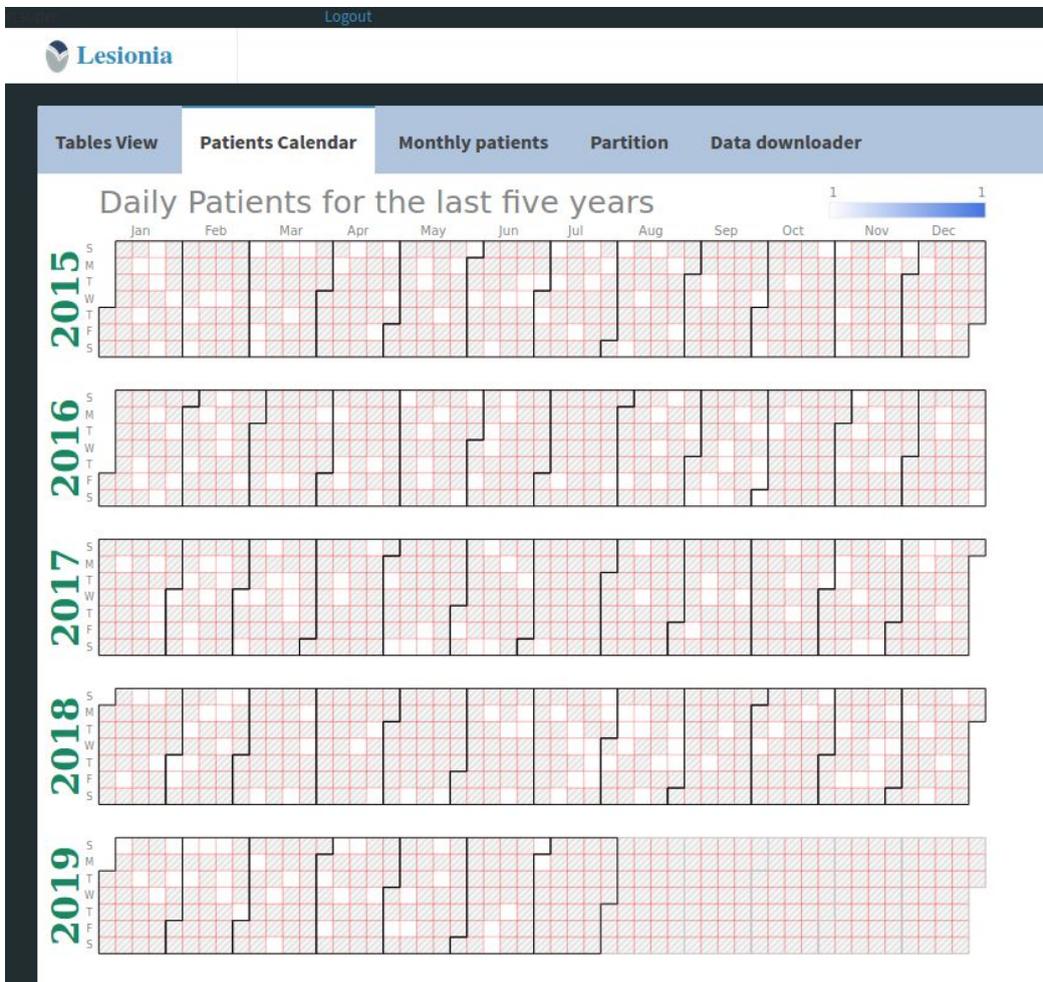
All users can access data in all the tables of the database for consultancy

The screenshot shows the Lesionia Data Viewer interface. At the top, there is a navigation bar with "Logout" and the Lesionia logo. Below the navigation bar, there are tabs for "Tables View", "Patients Calendar", "Monthly patients", "Partition", and "Data downloader". The "Tables View" tab is active, and a sidebar on the left allows users to "Choose table to View" from a dropdown menu, with "patient" selected. The main area displays a table with 5 entries, showing columns for PATIENT_IDENTIFIER, LOGINUSER, MEDICAL_FILE_NUMBER, FIRST_NAME, LAST_NAME, BIRTH_DATE, AGE, and NATIONALITY. The table data is as follows:

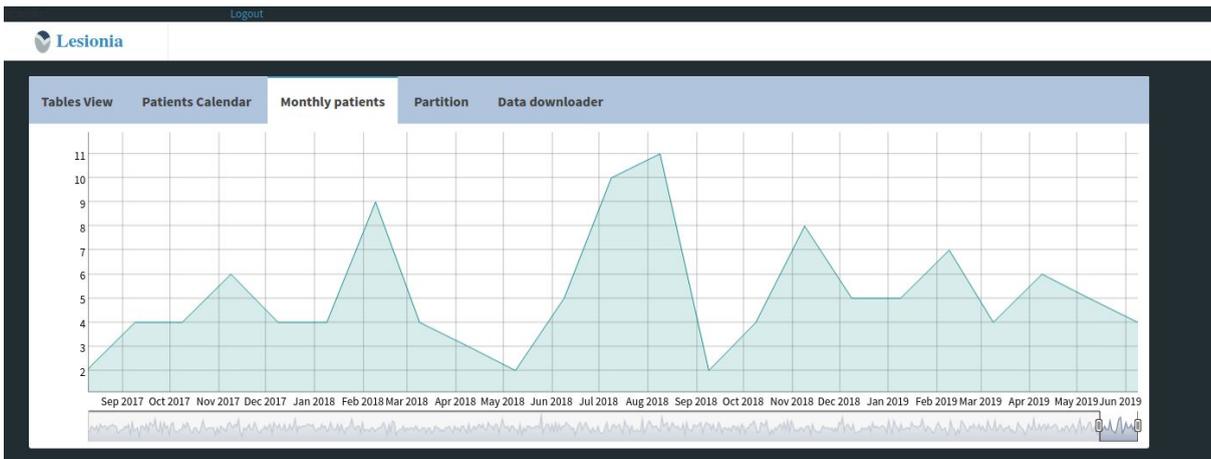
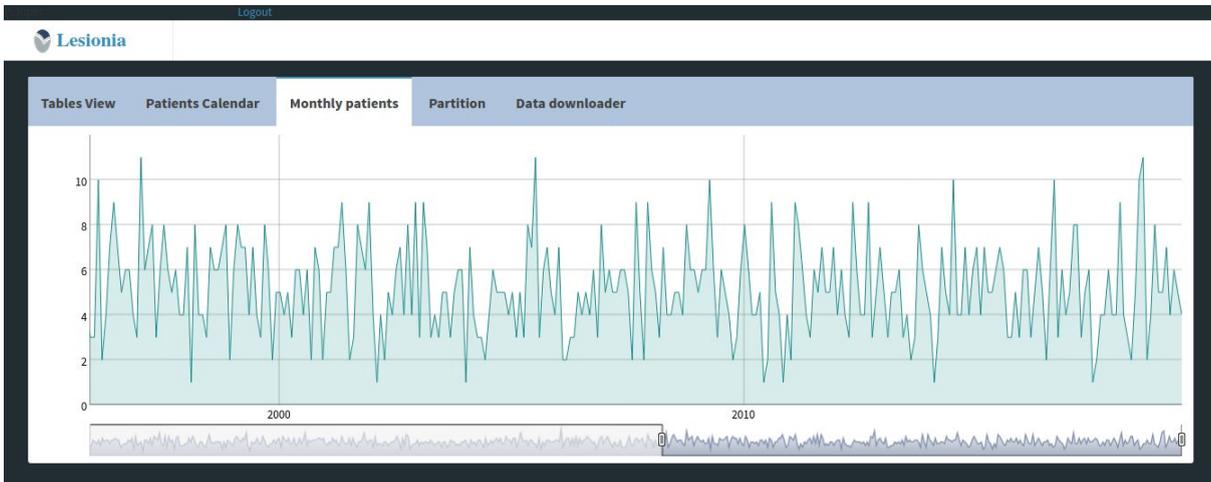
	PATIENT_IDENTIFIER	LOGINUSER	MEDICAL_FILE_NUMBER	FIRST_NAME	LAST_NAME	BIRTH_DATE	AGE	NATIONALITY
1	45849544	emna	37839	Buford		1991-11-09	28	TN
2	44148821	hejer	911487		Flatley	1995-12-22	14	TN
3	16080186	maaoui	64772	Kevon	Durgan	2001-05-10	55	LB
4	50154894	super	328200	Vincenza		2002-07-04	49	TN
5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

At the bottom of the table, it says "Showing 1 to 5 of 3,000 entries" and includes pagination controls for "Previous", "1", "2", "3", "4", "5", "...", "600", and "Next".

18. Patient calendar

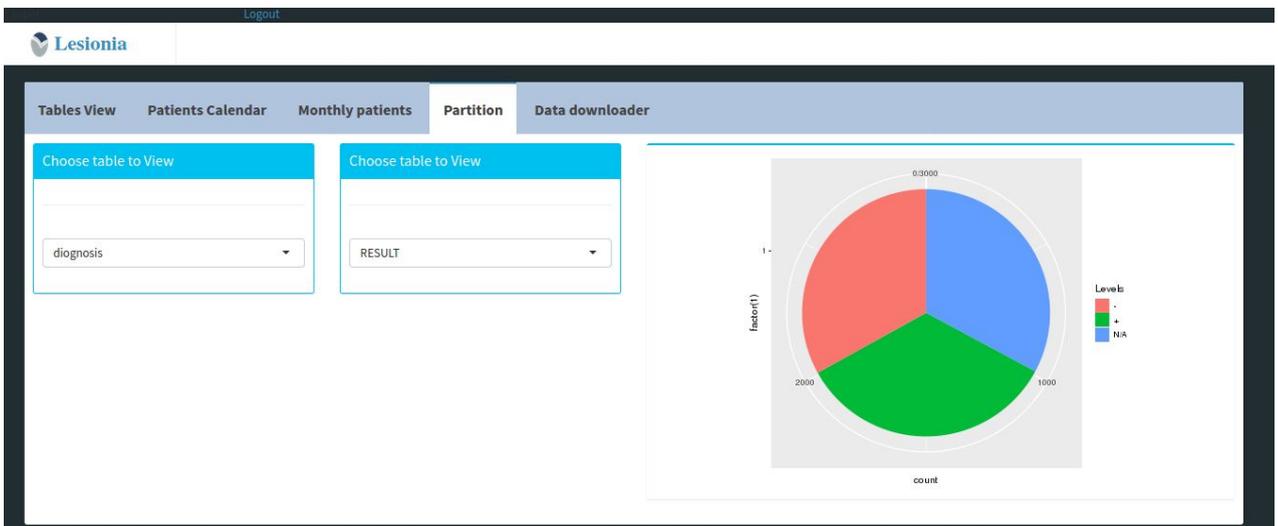


19. Monthly recruited patients



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

20. Data partition

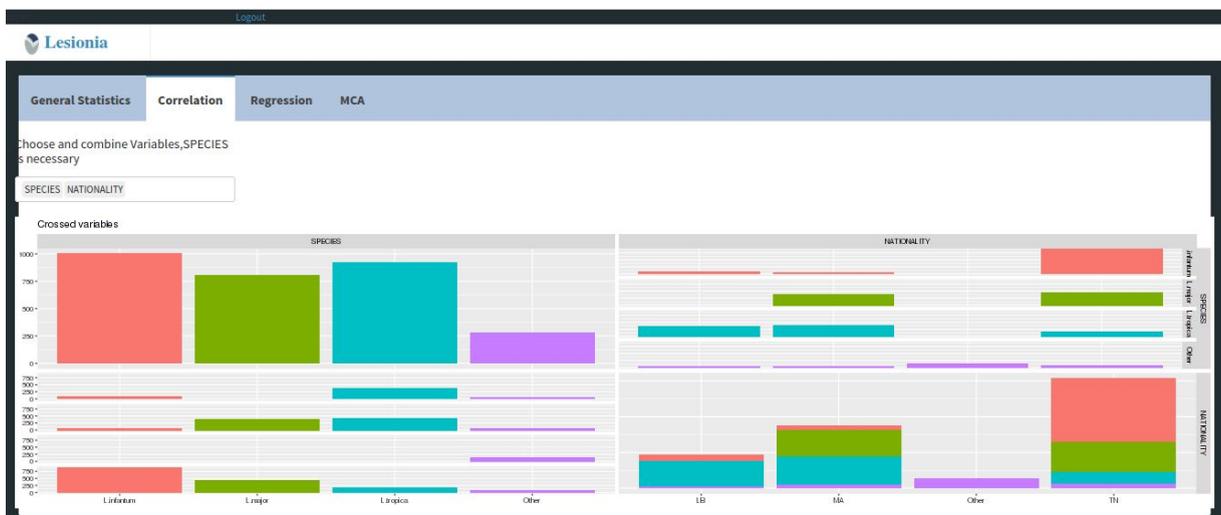


5. Data analyst

21. General Statistics



22. Correlation analysis



23. Regression

Logout

Lesonia

General Statistics Correlation **Regression** MCA

Linear Model ANOVA Chi square

Choose first variable
DIAMETREMax

Choose Second variable
AGE

```
Call:
lm(formula = corrr1[, 1] ~ corrr1[, 2])

Residuals:
    Min       1Q   Median       3Q      Max
-25.7402 -12.6543  0.3334  12.5765  25.8490

Coefficients:
            Estimate Std. Error t value Pr(>|t|)
(Intercept) 24.78931    0.44596  55.596  <2e-16 ***
corrr1[, 2] -0.00982    0.01382  -0.711   0.477
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 14.82 on 2998 degrees of freedom
Multiple R-squared:  0.0001684, Adjusted R-squared:  -0.0001651
F-statistic: 0.585 on 1 and 2998 DF,  p-value: 0.4774

Correlation of Coefficients:
      (Intercept)
corrr1[, 2] -0.80
```

Logout

Lesonia

General Statistics Correlation **Regression** MCA

Linear Model ANOVA Chi square

Choose first variable
SPECIES

Choose Second variable
NATIONALITY

Pearson's Chi-squared test data: confus X-squared = 2616.1, df = 9, p-value < 2.2e-16

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

Please choose the other variables
DESCRIPTION NATIONALITY

Eigenvalues

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 page in the Lesionia system. It features three main sections:

- Add new user:** Includes fields for 'Create Login', 'Create Password', 'Data access' (set to 'normal'), and 'Institution'. A 'Submit user' button is at the bottom.
- Delete user:** Features a 'Select user login' dropdown menu with 'emna' selected and a 'Delete user' button.
- Update existing user:** Includes a 'Select user' dropdown, a 'Change Password' field, 'Choose access level' (set to 'normal'), and a 'Change Institution' field. An 'Update user data' button is at the bottom.

26. Delete raw data

The screenshot shows the 'Delete raw data' section. On the left, there are filters for 'Select Table' (patient), 'Select Filter' (PATIENT_IDENTIFIER), and a value of 45849544. A 'Delete' button is at the bottom. The main area displays a table with the following data:

	PATIENT_IDENTIFIER	LOGINUSER	MEDICAL_FILE_NUMBER	FIRST_NAME	LAST_NAME	BIRTH_DATE
1	45849544	emna	37839	Buford		1991-11-09

Below the table, it says 'Showing 1 to 1 of 1 entries' with 'Previous' and 'Next' navigation buttons.

27. Download data

The screenshot shows the 'Download data' section. On the left, there are filters for 'Select Table' (diagnosis), 'Select Filter' (IDDIAGNOSIS), 'Select Value' (8561506), and a 'File name' field. 'Download' and 'Download all tables' buttons are at the bottom. The main area displays a table with the following data:

	IDDIAGNOSIS	TEST	LABORATORY_NAME	LoginUser	ID_SAMPLE	DIAGNOSIS_DATE	QUANTITE
1	8561506	N/A	FHS	emna	1001364	1995-02-20	10

Below the table, it says 'Showing 1 to 1 of 1 entries' with 'Previous' and 'Next' navigation buttons.

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