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# Lesionia: a digital data management system to enhance collaborative management of epidemiological and clinical data of cutaneous leishmaniases patients

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**Abstract**
Digital Systems for Data Management (DSDM) have become a critical cornerstone in collaborative biomedical research and clinical trials involving multiple investigators, institutions, and populations. DSDM provide unique features that ensure that data meet the standards of FAIR (Findability, Accessibility, Interoperability and Reusability). We herein present Lesionia, a DSDM designed to support the PEER518 consortium that aimed at developing new cutaneous leishmaniases (CL) diagnostics using samples and data collected from patients suspected of having CL in countries in the MENA region and West Africa. The consortium involved nine institutions across five countries: Tunisia, Morocco, Lebanon, Mali, and the USA, and informally Scientists from Algeria and Nigeria. The guidelines on the data to be collected by the clinicians and biologists during the project were used for the development of a Questionnaire that served as a basis for the implementation of a dedicated web-based DSDM.

Lesionia was developed and validated for the management and the analysis of clinical and epidemiological data in the diagnosis of CL. It consists of a relational database, a web-based user interface (WUI) and a tool for experimental data handling and analysis of clinical and epidemiological data of CL cases. The platform was deployed and validated during the PEER518 project using data collected across the involved teams. Lesionia is expandable to include further collaborators, partners, and projects. It is designed for data handling from the consented patient interview and sample collection to the samples' storage and investigation. The WUI permits data entry, fetching, visualization and analysis. Rigorous controls on data entry were implemented to reduce discrepancies. It also offers a set of analysis tools that range from descriptive statistics to variable correlation analysis. Lesionia is accessible in a secure manner to all users of the consortium through a web browser.

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Lesionia will be a valuable tool for collaborative and integrative management of clinical and epidemiological data. It is an open-source software that can broadly serve the scientific community interested in studying, controlling, reporting, and diagnosing CL and similar cutaneous diseases.

**Keywords** Digital data management, Database, Cutaneous leishmaniases, Clinical data, Epidemiology, Statistics

## Background

Leishmaniases constitute a group of largely distributed vector-borne parasitic diseases, endemic in more than 98 countries worldwide. Cutaneous leishmaniases (CL) are considered by the World Health Organization (WHO) among the most neglected tropical diseases (NTD). It is a group of cutaneous diseases with high morbidity rates. CL inflicts a major social burden on human cases and they are associated with illiteracy, poverty, gender discrimination, weakness of the immune system and lack of resources amongst other factors [1]. Lack of diagnostics tools and prompt reporting platforms also contribute to sparse data estimation of CL cases in endemic regions which include countries of the MENA region and sub-Saharan Africa [2–5]. Sparse data on CL also create an impediment to evaluating the disease burden and to the implementation of control strategies [4].

More broadly, epidemiological studies of CL often lack robust and high- quality data, as for most NTDs [6, 7]. Multiple epidemiological studies reported the burden of CL at regional and/or local levels [8–10]. A study from the Global Burden of Diseases Study that focuses on CL was published in 2016 [11]. This study assessed the burden of CL worldwide based on data extracted from literature and official reports up to the year 2013. Karimkhani et al. reported the impact of the disease on individuals using the Disability-Adjusted Life-Years (DALYs) which is the sum of years lived with disabilities and years of life lost. Regions with the highest DALYs per 100 000 people are North Africa and the Middle East, Andean Latin America, western sub-Saharan Africa and South Asia [11]. A recent study by Knight and coll. reported the prevalence of Leishmaniasis in multiple countries in the Middle East, which constitutes a significant public health concern, with cutaneous leishmaniasis being the most common form [12]. The authors highlighted the need for effective control and treatment strategies, including early diagnosis, appropriate therapy, and public health interventions that are heavily dependent on reliable case reporting systems. In fact, the under-reporting of CL cases is a major challenge for an accurate estimation of global burden and the authors pointed out that lacking high-quality data is the most limiting factor. For example, sub-Saharan Africa accounts for least accurate records of case reporting, thus estimates were based on modeling. Nonetheless, the region accounts for 13 of the most affected countries. The MENA (Middle-East and North Africa) region also presents high affection rates by CL, migrants and refugees being the most affected populations (WHO).

Novel approaches in fighting infectious diseases such as CL should include digital solutions for data collection and management. Digital systems for Data Management (DSDM) appeared as part of the solution for a better quality of data. The same approach has been used for Malaria and Dengue fever [13, 14], as well as for studying the spread of *Schistosoma japonicum* in China [15]. DSDM introduction was assessed on different types of studies ranging from geo-spatial mapping of dengue fever spread in Sri-Lanka [16] to disease outbreaks surveillance in Germany [17]. The positive impact of such systems on the management of chronic diseases was also assessed [18, 19]. For the specific context of epidemiological studies of parasitic diseases, Gray et al. presented a DSDM designed to process data collected during field-based surveillance of the transmission of bovine *Schistosoma japonicum* in China [15]. The DSDM consists of a database with a multi-user interface developed using Microsoft Access, VBA, and SQL. The authors demonstrated the relevance of digitizing the data collection and management processes in leveraging on the data quality and its impact on the study reliability [15]. Other groups choose the strategy of using generic systems and/or adapt existing software to their specific needs [20]. With the advent of the COVID-19 pandemic, we have witnessed a major shift in the adoption of digital systems for the management and control of infectious diseases [21–23]. Implementing similar DSDM for the collection and the management of CL-related data is of high importance in addressing the under-reporting of CL-cases worldwide and the mapping of the disease spread and burden.

The present study focused on the development of a DSDM specific to CL cases, called Lesionia. It was developed during the year 2019 for the needs of the PEER518 project consortium. Nonetheless, it can easily scale-up to other consortia and additional cutaneous diseases. The project aimed at developing species-specific point of care diagnostics for CL. The PEER518 project has the main objective of developing and evaluating rapid molecular diagnosis tools for CL, that can be used in low-resources settings. Research studies were designed to evaluate and validate the molecular tools by testing them using clinical samples collected in three countries in the MENA region, namely Tunisia, Morocco and Lebanon [24–28]. The project consortium was led by research and clinical scientists in nine institutions in five countries: Tunisia, Morocco, Lebanon, Mali and the USA. The central node of the consortium is the Laboratory of Molecular Epidemiology and Experimental Pathology Applied to Infectious Diseases (MEEP-lab) at Institut Pasteur de Tunis (IPT), which hosts and coordinates the consortium of the PEER518 project. The MEEP-lab holds a valuable expertise is developing molecular diagnosis tools with a focus on infectious diseases [29–31]. Lesionia consists of a database and a web-based user interface (WUI) that enables clinical, epidemiological and experimental data handling and analysis. It offers a digital platform to facilitate collaborative data management and collection for CL cases. Lesionia was deployed and validated through the PEER518 project using data collected across multiple institutions and countries.

## Implementation

### Data collection: the questionnaire

In the frame of the PEER518 project, patient recruitment took place in five sites located in three countries, namely Tunisia, Morocco and Lebanon (Supplementary table S1). Patients were informed and their written consent was obtained. Clinical samples from suspected cutaneous leishmaniasis patients were collected, anonymously coded then transferred to the MEEP-lab at IPT, along with related data. At the MEEP-lab, species identification was performed or confirmed using different molecular techniques, the results were collected, and the samples were stored. Diagnosis was either established clinically and/or by the standard Giemsa-stained lesion smears examination for parasite detection by microscopy, and a treatment was prescribed. However, molecular diagnosis was awaited for confirmation notably in cases where the smear examination is not conclusive. It is also the only to establish the identity of the causal Leishmania species, and thus precise CL etiology.

Prior to implementing the database and in order to harmonize the data collection process within the consortium and enhance data quality, a consensus agreement took place between clinicians, biologists and bioinformaticians. This approach aimed at defining the data to be collected from patients and how it will be used. A harmonization process was implemented prior to data collection at the different sites, which led to the design of a questionnaire form (Supplementary figure S1). This tool included patient demographic data, residency and travel history, environmental data related to the notion of insect bite and the animals encountered in proximity, clinical data including previous treatments if any, data on the clinical aspect of the lesion(s) suspected to be CL (CL could have different presentations), the sampling method and the diagnosis results. The latter includes direct examination performed at the sampling site and a selection of molecular tests (PCR ITS, qPCR, RPA-LF) that were further performed at the MEEP-lab for species identification. The output of the clinical diagnosis, the molecular diagnosis and the prescribed treatment are collected. Follow-up medical check-ups have also been included in the data collection process in some sites.

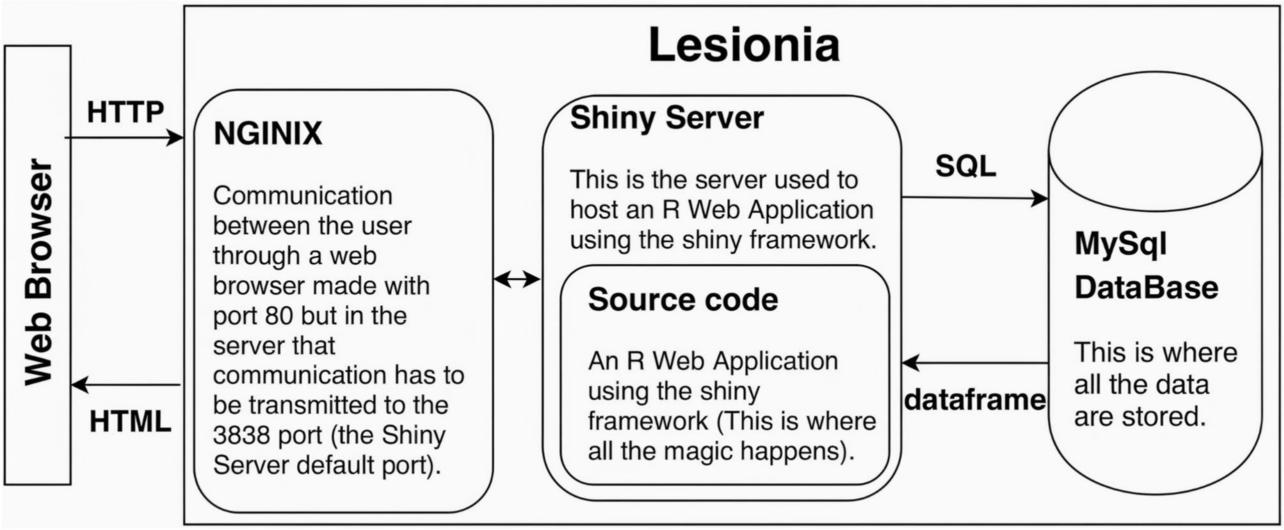
The questionnaire was conceived with respect to the best practices of data collection [32, 33]. First, the questions' order and phrasing were established with practitioners to ensure they can fluently go through them during interviews. We verified that interrogators shall understand the questions consistently. Response fields were reduced to checkboxes with pre-coded responses with a supplementary field for a potential non pre-coded response when it applies. In fact, these formats minimize handwriting, and subsequently spelling and transcription errors during data entry into the database. Units were specified whenever necessary and a canonical format was provided for dates.

### Lesionia

A DSDM called Lesionia was implemented. First, the database was designed based on the Questionnaire structure and implemented using MySQL. The back-end communicates with the database which is hosted on a LEMP server - a variation of the LAMP (Linux (operating system), Apache (HTTP server), MySQL (database) and PHP (programming language)) software bundle that uses Nginx rather than Apache, also known as LNMP (Linux, Nginx, MySQL, PhP). The front-end is designed to be a web-based user interface (WUI) accessible from any web browser. The WUI was developed using the Shiny framework. Briefly, this is a package in R that enables the implementation of server environments that facilitate the hosting and execution of interactive web applications developed in R. It communicates with a shiny-server hosted on the LEMP server which submits a data request to the database. All servers and the database are physically hosted at the MEEP-lab (IPT). Both the front-end and back-end were developed using R. A list of all packages and dependencies were listed in the project repository on Github (https://github.com/Harigua/LEISIApp*)*.

Lesionia consists of multiple components as shown in Fig. 1. The database was designed based on the Questionnaire structure (Supplementary figure S1). It included patient data collected by the clinicians, information on each sample ranging from molecular tests to biobanking in the MEEP-lab and user information including institution affiliations, functions, and role on the PEER518 project. Unique login and passwords were provided for each user by the system administrator to foster a secure connection (Fig. 2).

The WUI of Lesionia is accessible through www.lesionia.pasteur.tn/. It has a homepage that contains the login form and information on the PEER518 project, the



Communication between the user through a web browser made with port 80 but in the server that communication has to be transmitted to the 3838 port (the Shiny Server default port).

This is the server used to host an R Web Application using the shiny framework.

An R Web Application using the shiny framework (This is where all the magic happens).

This is where all the data are stored.

**Fig. 1** Lesionia architecture, including the database, the front-end and back-end components

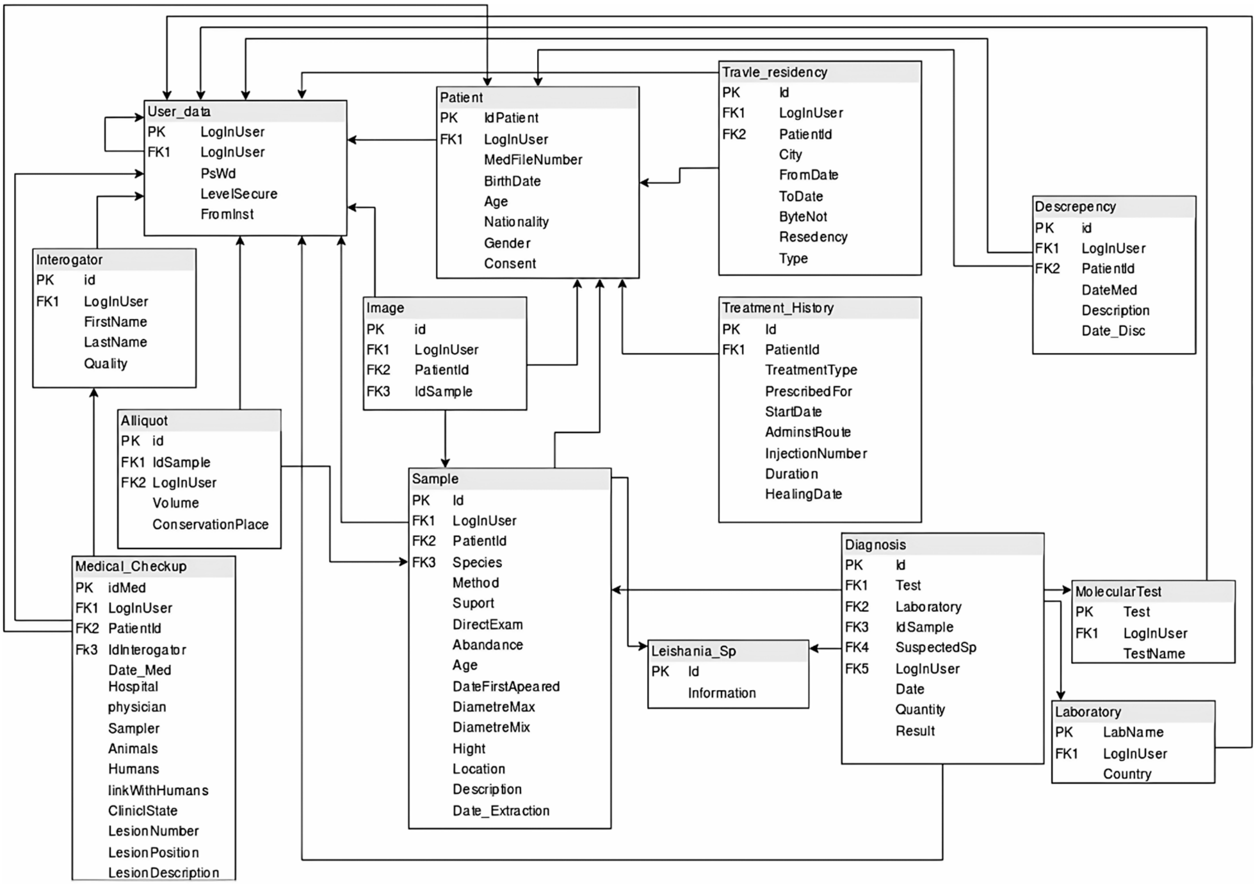


**Fig. 2** The structure of the database implemented within the platform Lesionia. Connections and dependencies between different tables related to different stages of the data collection process can be visualized

consortium and how to contact the system administrator and/or the research team (Fig. 3 (a)).

Using a username and a password previously validated by the system manager, users can access four sections (Fig. 3 (b)): (i) Data management, (ii) Data entry, (iii) Data viewer, (iv) Data analysor. The WUI includes a header that contains the application name 'Lesionia', the name of the currently logged in user and a 'logout' button. The

Contact us :

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

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

Please Enter the Patient DB Code: PER523498

**Fig. 3** Lesionia web-based user interface. (**A**) The homepage appears by default through the link www.lesionia.pasteur.tn/. (**B**) The homepage that appears after logging in. (**C**) The interface behind the "Data entry" section, under the "Add Patient Data" tab, along with necessary tabs for data entry

'Lesionia' button allows the user to go back to the homepage from anywhere during the use of the application and thus to switch between sections.

#### *Data management*

The "Data Management" section has a restrictive access to the super user(s). It permits adding new user(s), editing existing user(s) or deleting user(s). It also permits deleting or downloading data using filters.

#### *Data entry*

"Data entry" is the section that includes all the digital forms and interfaces to enter new data or update existing data. A double-entry system was implemented to minimize the rate of discrepancy. The first entry consists in creating a unique ID for a patient after which the user has to re-enter the unique ID, and an automatic check of the concordance of IDs is performed. If the second entry is not correct, the user will know and correct it accordingly. If the first entry is not correct, the user should report this discrepancy using a dedicated field. Based on the discrepancy report, the system manager could intervene. Noticeably, all data collected and shared within the PEER518 consortium members are anonymized. Personal (identifying) data can only be accessed by the clinicians in their respective health centers. Only codified demographic, epidemiological and clinical data are transferred and shared through the Lesionia platform, i.e. no identifying data is shared which abide with the international General Data Protection Regulation (GDPR) standards.

For each section in the questionnaire, a digital form exists in Lesionia. These forms present multiple fields, out of which those that are mandatory are tagged with an asterisk. Missing data fields can be left blank. Default values are assigned beforehand to indicate that these fields correspond to missing data. These default values are "N/A" or "-1" for data of type character or integer, respectively. Missing data with type date are set to 01-01-1900. This is important for the forthcoming data analysis steps and for the assessment of the data collection procedures. All data in the questionnaire form can be entered in the corresponding tabs of Lesionia interface (Fig. 3 (c)).

#### *Data viewer*

"Data viewer" allows the user to visualize, search and browse all the data within the tables of the database. It also provides statistics on patient recruitment flow, partitions according to nationality, gender and age classes and raw data visualization and download.

#### *Data analysor*

"Data analysor" contains sections dedicated to data analysis, including: (i) General statistics, (ii) Correlation between the SPECIES variable and any other chosen variables, (iii) Regression (Linear model, Chi square) and (iv) Multiple Correspondence Analysis (MCA). Almost all the analyzes are dynamic and can be customized by choosing the variables to be considered. All resulting graphs and figures can be directly downloaded.

In order to assess the reliability of the "Data analysor" functionality, we simulated data for 3000 patients. For some data fields, specific distributions were applied according to preliminary statistics provided by our clinician partners (Supplementary Table S2). Otherwise, uniform distributions were applied. The sample size had no effect on the speed of the application. The statistical analyses obtained with the "Data analysor" were consistent with the sample distributions, thus confirming that all statistical tests were correctly implemented (Fig. 4).

#### *Accessibility and performances*

The Lesionia app is hosted on a server with 31.93 Mb/s upload speed and 45.12 Mb/s download speed that makes its use user-friendly in terms of speed (Supplementary Figure S2). Additionally, it has been tested using different hardware, operating systems (windows, linux, android) and internet settings throughout the project and by different collaborators. It has been easy to access using both ADSL and 2G/3G network connections, either through the use of a personal computer or a mobile device. Noticeably, Lesionia is mobile-friendly which implies that it displays correctly on a mobile device screen (mobile phone, pad, etc.).

### Beyond the diagnosis

Lesionia was designed with a long-term vision of not only serving as a collaborative and an integrative tool for the data collection process during the diagnosis across multiple institutions and also to perform clinical follow-ups. In fact, multiple medical check-ups can be associated with one patient record. This allows the entry of clinical follow-ups to survey the treatment outcome by the medical staff. In addition, multiple sample entries can be associated with one patient and/or one medical check-up. This is useful for patients presenting recidivating lesions or multiple lesions to be sampled during one medical checkup. The biobanking functionality is useful for laboratories that do not have dedicated tools for biobanking and sample management. Along with the built-in real-time analysis these functionalities constitute the integrative feature of Lesionia.

Lesionia is accessible as an open-source software through the following link https://github.com/Harigua/LEISIApp/. To make this software of higher usefulness to the scientific community willing to use it as is or customize it, a user procedure on how to install it on different operating systems (Linux, MacOS and Windows) is

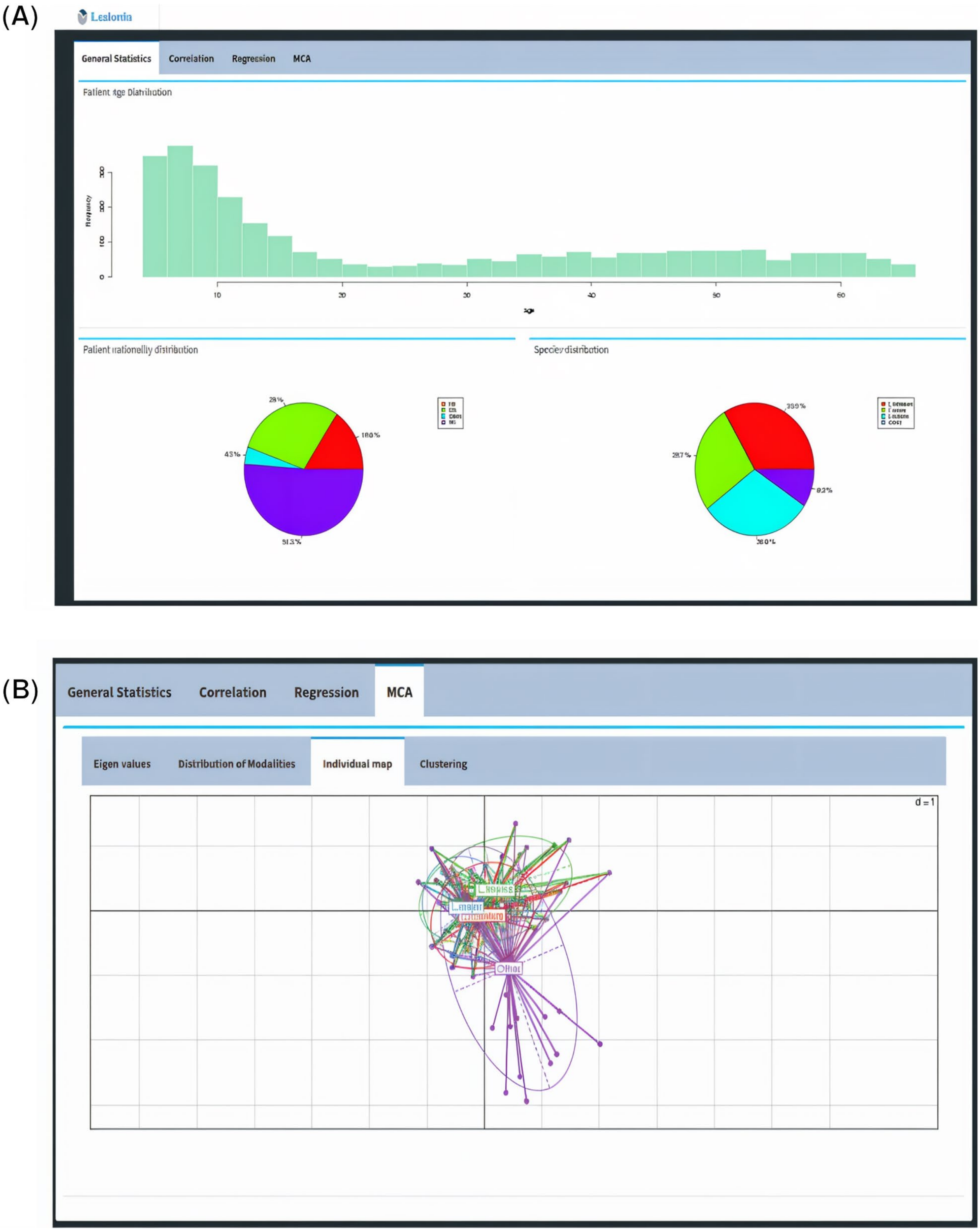


**Fig. 4** The built-in data analysor of Lesionia. (**A**) General statistics results obtained for the simulated data on a 3000-individual sample. (**B**) Multiple correspondence Analysis (MCA) obtained for the simulated sample. Positive samples present different individual maps as compared to negative samples with no discriminative power between the different species, which is in concordance with the simulated data conditions

provided. It can either be installed locally as a desktop application or as a web-based application.

## Discussion

Collaborative research, especially biomedical evaluation of new interventions, often involves activities at multiple centers and research institutions in order to provide confidence in the results. Each member of these collaborative networks generates and collects data from both laboratory studies, observations and clinical evaluations of the new interventions. The data is collected based on approaches, agreed protocols, and approved IRB. This approach provides primary confidence on the observations, inference, conclusions and reproducibility.

In general, each network collaborating partner is required to strictly follow the approved protocols in order to qualify for combined analysis and clinical or public health values of the intervention. Data collected by such network collaborations are required to meet a standard of FAIR (findability, accessibility, interoperability, inter-usability). Digital Systems for Data Management (DSDM) provide platforms to achieve these laudable aims and have become a critical component of network collaborative research. The values of DSDM in low-middle income countries (LMIC) where communication and access to technology are limited is greater and cannot be over emphasized.

The positive impact of implementing DSDM has been demonstrated globally in different fields of biomedical sciences [18, 34]. They proved having an invaluable impact in disease surveillance and evidence-based interventions for control strategy definition throughout the COVID-19 pandemic [21, 22]. Lessons learned include the need for further adoption of reliable, secure, collaborative, integrative and evolutive digital platforms for enhanced response and preparedness in infectious diseases control. Specifically, DSDM provide sustainable systems of data management, reliable tools for data collection and efficient platforms for descriptive and predictive analytics towards transformative epidemic control and preparedness [16, 21, 34–36].

Lesionia herein presented was built to fulfill the need for data centralization, harmonization, and storage across the international consortium of the PEER518 project. It was developed to address critical issues through network collaboration. The demand for remote access, collaboration and interoperability of the collected data predicated the development of Lesionia. In fact, Lesionia is an integrative platform with a built-in tool for data analysis to support the effort on laboratory clinical evaluation and validation of the new diagnostics using samples and data collected from CL cases in several countries. It has been developed in conformity with the standards and requirements of DSDM for health data as compared to similar platforms and tools. These include the double-entry system that ensures data integrity and access security [37, 38], the clinical follow-up functionality of interest in better understanding the efficacy of a given treatment to the different clinical manifestations of CL in different parts of the world [38, 39], the privacy and anonymity of data that guarantee protection of the patients privacy [40, 41], among others.

To the best of our knowledge, only one initiative, besides Lesionia, has focused on developing a digital system for disease monitoring of CL cases [37–39, 42]. It has been conducted by a consortium of researchers in Colombia for the detection and monitoring of treatment outcomes of patients affected with CL. They achieved their goals using two separate mobile applications: (i) the Guaral app served as a screening tool using decision algorithms to fasten the detection of CL cases to be further confirmed [38] and (ii) the Guaral + ST app that is designed to perform treatment follow-up [39]. Efforts to integrate information from both platforms were performed downstream towards a larger coverage of the patient journey, from diagnosis to treatment. In comparison, Lesionia provides a unique platform for data collection that covers the different segments of the patient and sample journey. Interestingly, Lesionia also included the lab segments with the molecular diagnosis experiments and the biobanking feature. Additionally, Lesionia can be used in its present version to serve studies focused on other cutaneous diseases including the skin-NTDs, identified by WHO as public health priority [43]. These include, besides CL, the Buruli ulcer, Yaws, Scabies and Leprosy among others. Furthermore, Lesionia can be customized and adapted to other infectious diseases, including visceral Leishmaniasis or any infectious disease whose diagnosis relies on a combination of clinical and molecular examinations. These efforts can be easily implemented given that all source code is being made available through our public github repository (https://github.com/Harigua/LEISIApp/*)*.

Lesionia currently provides a scalable solution for managing data on neglected tropical diseases, particularly in North Africa and the Middle East. Its success as a DSDM platform was confirmed with the activities along the collaborative data collection process across eleven institutions and seven countries. However, there remains a need to integrate more diseases, expand its geographical scope and resolve challenges related to data security and cross-border sharing for more demanding projects. The collection of data and its validation are key steps that ensure the integrity of the platform. The approach herein described and the lessons learned from our experience will definitely inspire other research groups while designing and implementing their own digital system for clinical and epidemiological data management, thus contributing to public health research efforts.

WHO-Neglected Tropical Diseases 2021–2030 road map identified "*To estimate the burden of the disease by improving surveillance, and establish a patient database to ensure effective monitoring of the impact of control interventions*" as one of the top 3 critical actions to achieve Cutaneous Leishmaniases control [35, 36]. In this context, the democratization of DSDM in the collection and management of data related to infectious disease shall serve as the principal pillar in leveraging artificial intelligence (AI) applications for enhanced data-driven control strategies [44–46]. In fact, data collected with rigorous protocols by groups of experts from various backgrounds is the foundation for the development of AI-based approaches for the generation of novel evidence-based knowledge [47–50]. Applications are various and are dependent on the objectives and the accessible data. Bamorovat and coll. successfully used machine learning (ML) approaches to establish a prognosis for CL cases and thus improved treatment choice and outcome [51]. Modeling approaches in epidemiology and disease surveillance and monitoring also can benefit from data collected through platforms such as Lesionia [52, 53].

## Conclusion

Lesionia as a DSDM platform is a valuable tool for collecting and managing data on clinical and epidemiological profiles which are needed for biomedical and clinical trials of new diagnostics. The platform can be used for management and preparedness of not only CL but other infectious diseases which will bring about research and development of new methods and technologies in LMIC. This will strengthen the core capacities which often occur during disease outbreaks. Lesionia is an open-source software that can broadly serve the scientific community interested in studying, controlling, reporting, and diagnosing CL and similar cutaneous diseases, as part of Public Health efforts, enabling access of network members regardless of where they reside or work.

Lesionia is an integrative platform, providing real-time remote monitoring and multiple opportunities for collaborative patient management and disease control. This demonstrates the possibility of implementing advanced tools with limited budgets in LMIC without requirement for greater resources that are often not available.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13104-025-07208-0.

Supplementary Material 1

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### Author contributions

EHS, YS, IBA and IG conceived the research. EHS, YBS and OS conceived and designed the database. EHS, YBS and MH developed the WUI. MH, HS, HC, IM, ZM, OA, AO, AFM, NH and ML provided user feedback to optimize thequestionnaire format and/or to mitigate the digital system's setbacks. EHS and MH assessed the system's viability and performances. IG leveraged all the financial support. EHS drafted the original manuscript. EHS, YS, OS, IBA, OA, AO and IG reviewed and edited the manuscript. All authors read and approved the final manuscript.

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### Data availability

No datasets were generated or analysed during the current study.

## Declarations

### Ethics approval and consent to participate

Ethical approval was obtained from respective IRBs to each sampling site, under the references 2016/24/I/LRIPT04 of IPT-Tunisia, 51/17 of the "Comité d'éthique pour la recherche biomédicale, Faculté de Médecine et de Pharmacie - Université Mohammed V - Rabat" in Morocco and INV-2017-324 of the Institutional Review Board-Rafik Hariri University Hospital in Lebanon. All methods were carried out in accordance with international General Data Protection Regulation (GDPR). Informed consent was obtained from all subjects and/or their legal guardian(s).

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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