# Increasing Availability Control of Human Biological Samples Using a Mobile Management System

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**Abstract.** Biobanks and biorepositories present major challenges in managing, storing and making available large amounts of samples and associated information. The ability to share these samples is an important issue to improve research using human biological samples. A systematic review of the literature on information management of biobanks and biorepositories provided a wealth of knowledge and stimulated a proposal for a system to support its management process. The SIGIBio (Biobank and Biorepository Information Management Support System) was defined and developed to manage these samples considering the complex treatment of these data, in a mobile system. It features open up possibilities for organizations and researchers to access and share biobank and bio-repositories samples. The SIGIBio system was described in terms of requirements, stages of development, scenarios and technical aspects. The first version of SIGIBio was presented to researchers and a usability test was performed to confirm its applicability and interface aspects. In the future, SIGIBio will be an open and free system that can be adopted by different researchers and organizations.

**Keywords:** Mobile management system · Biobank · Biorepository

## 1 Introduction

In the last decades new challenges in the Healthcare area have appear which increasingly require the support of new technologies of communication and collaboration. Advances in the process of knowledge construction, especially in the areas of genetics, cell therapy, molecular biology and bioinformatics have changed the basic, clinical and translational research course, generating a growing need for storage of biological materials and associated information [1].


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In addition, there is a demand from research institutions for sharing information about stored human biological samples. Nowadays, researchers face difficulties in finding out which organizations have biobanks that contain samples needed for their research projects. This demand can be achieved through the creation of a network of biobanks and biorepositories.

In this context, the objective of this paper is to present the development process of a mobile system (SIBIBio - Biobanking and Biorepository Information Management Support System), which was created to manage relevant information on control of the storage and donation of biological materials for research. Due to the different professional profiles that manage and use biobanks and biorepositories samples, it is very important that the system interfaces are intuitive and have good levels of usability, provide mobility and also have security guarantees for everyone involved in the research.

SIGIBio requirements were defined based in a systematic literature review of the information management of biobanks and biorepositories, which considered papers between 2010 and 2017 [2].

This work is divided into five sections, including this introduction. Section 2 presents the general concepts of biobanks and biorepositories and management systems in this area. In Sect. 3, SIGIBio is described in terms of requirements, stages of development, scenarios and technical aspects. Section 4 reports the usability tests of the SIGIBio. Finally, the conclusions and future works are in the last section.

## 2 Biobanks and Biorepositories

Both biobanks and biorepositories store human biological samples, but they have some differences between them. Biobanks are under the responsibility of an institution, operating without a predetermined deadline. Their stored samples can be requested by researchers for use in many searches. Whereas, biorepositories are under the responsibility of a researcher, existing only while one or more specific researches are being carried out [4].

In Nóbrega's research [2], 51 papers were selected: 21 of these works reported on procedures for managing biobanks and biorepositories and 14 described some biobanks and biorepositories software requirements. These papers stressed the importance of laboratory information management systems or sample management systems, which must be web-based and interoperable. Also, the systems must have security, robustness, audibility and the ability to manage the information contained in modern biobank and biorepository models. In addition, they should follow the ethical aspects of not exposing confidential information from donors or researchers and provide intelligent sample search to increase their use among relevant researches.

Brazil does not have a good public technological structure for the control of storage and loan of biological samples. Therefore, the importance of creating an architecture that facilitates access to the information contained in each biobank and biorepository is highlighted, to reduce the fragmentation of the databases used in research projects and to speed up them [5].

Some systems [6–9] that propose to manage biobanks were analyzed through information available on their own websites. All of these are proprietary software which cost between U$ 75.00 and U$ 245.00 in their most basic monthly plans, as can be seen in Table 1. In addition, none of them supports a network of connected biobanks, as they are not accessible to be used openly by various organizations.

**Table 1.** Comparison of biobank and biorepository management systems

| System name | Main differentials | Monthly cost (basic plan) |
|---|---|---|
| LABA [6] | The request of custom functionality is available; maintains a history of laboratory activities | U$ 195.00 |
| LabCollector LIMS [7] | Enables the use of user groups with different permissions; manages diagrams with the workflows performed in the laboratory | U$ 245.00 |
| Freezer PRO [8] | It has configurable alerts of low number of samples and expiry date, among others; allows us to configure the freezers exactly as they are arranged in the laboratory | U$ 79.00 |
| CloudLIMS [9] | Allows the management of samples batches transferred; manages studies on the samples | U$ 75.00 |

## 3 SIGIBio

SIGIBio was created with the purpose of being a generic system for the control and management of a biobank or biorepository in any organization of any size. SIGIBio main objectives are: generality, to be able to be used in different organizations; mobility, so that it can be accessed in various devices; and availability so that it is possible to perform an optimization of the processes involving the management of biological samples.

Next, the list of requirements is described, enhancing aspects presented in the review, followed by development steps, usage scenarios and technical aspects.

### 3.1 Requirements

The initial requirements of the system were defined based on a review of the requirements analysis proposed by Nóbrega [2]. Thereby, it was decided that the scenario of quality management in the laboratory, although important for the proper functioning of a biobank or biorepository, would be outside the scope of the first system version.

After this review, it was defined that the system should be able to manage: (i) users, access and permissions, (ii) data from institutions and projects, (iii) data from research participants and their collected materials, (iv) biological samples, methodologies and results, and (v) requests and shipments of samples.

In addition, the system should meet the following non-functional requirements: (i) security, so that only authorized users are able to view and change data on the system, using permission levels; (ii) good usability, so that users feel satisfied when using it; (iii) efficiency, with a satisfactory response time; (iv) maintainability, allowing its source code to be easily adaptable for specific cases, or if new requirements or changes to existing requirements arise; (v) mobility and ease of access, when it is possible to access it through the Internet; (vi) use the ICD-10 (International Classification of Diseases) list when referring to diseases.

### 3.2 Development Stages

After defining the list of initial requirements, it was verified that the client-server architecture would be the most adequate for the implementation of the proposed system in this early stage, for being simpler than others. Thus, the data manipulated by it could be stored on a single server, while different clients could access it over the internet. These clients, communicating with the server through an API (Application Programming Interface), can use different platforms, such as mobile or desktop. For the initially proposed scope, it was decided that creating a single responsive website (suited to different sizes and screen resolutions, working well on different devices such as tablets, smartphones and desktops) would be enough as a client.

In these steps, the same development process was applied: (i) modeling and creation of database schemas; (ii) programming the server application; (iii) programming the client application; (iv) visual and usability improvements in the client application; (v) manual tests and corrections of specific problems.

Recent and well-known technologies were considered to facilitate the system development and upgrades. Having the technologies and requirements defined the modules of users' management as access, permissions and management of institutions and projects were implemented.

Finally, with the system running in a simulated environment, a usability test was performed with five experts. They were asked to evaluate the system, and the results of these tests are presented in Sect. 4.

### 3.3 Usage Scenarios

In the current version of the system, there are five modules: (i) management of users, access and permissions, (ii) management of institutions and projects, (iii) management of research participants and collected materials, (iv) management of samples, methodologies and results, and (v) management of samples batches. Figure 1 shows the start screen of the system.


**Fig. 1.** Start screen – SIGIBio

**Management of Users, Access and Permission**

Because secrecy is critical to some of the system information, especially to those related to research participants, this module is essential for the correct functioning of all others. No action (except registering or authenticating) can be performed on the system unless the user is authenticated.

The access control is done through a username and a password, defined during the registration of the user. Permissions control is based on three types of permissions: administrator, internal user and external user.

The administrator can perform any action on the system. It is responsible for approving users, projects, institutions and requested samples batches. In the case of a biobank, it is an employee of the biobank managing institution, being a level above the internal users. On the other hand, in a biorepository, the researcher is responsible for it.

The internal user is responsible for the management of samples, methodologies and results, and is also an employee of the managing institution. He can dispatch new samples batches and receive the returned ones. In addition, in the case of a biobank, it manages the participants who donate samples directly to it, not to a specific project, also managing the materials collected from them.

Finally, the external user can manage or be part of one or more institutions, as well as manage or be part of projects. He can manage participants of his projects, as well as the materials collected from them. Also, he can request samples batches for his projects.

Any user, when registering in the system, must indicate what permission he wishes to have. After registering, an administrator user will evaluate his data and approve or reject his registration. If the new user is approved, he will be able to use all the system features allowed for his permission level (Fig. 2).

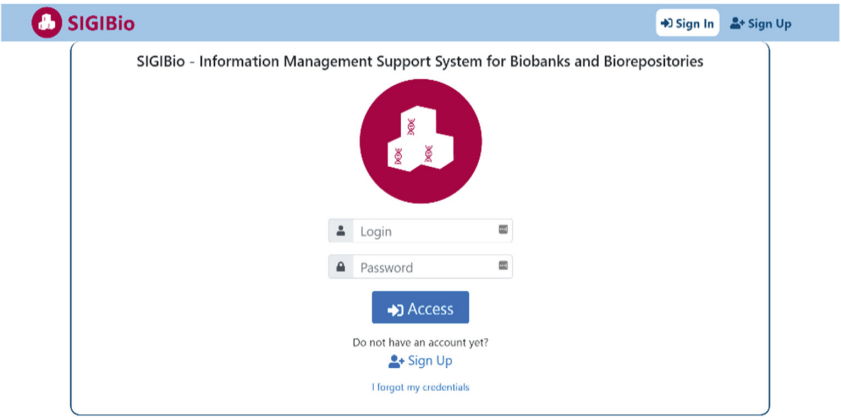


**Fig. 2.** Access screen – SIGIBio

**Management of Institutions and Projects**

An external user can register an institution and manage it. Users can be associated with an institution as their professionals. An institution may have registered projects.

Similarly, an external user can register their projects, associate them with one or more institutions, and manage them. Users can be associated with a project as their professionals. A project can have registered research participants. It may also be in possession of one or more samples batches.

In both cases, the registration is started as pending, and only becomes valid and visible from the moment it is approved by an administrator (Fig. 3).

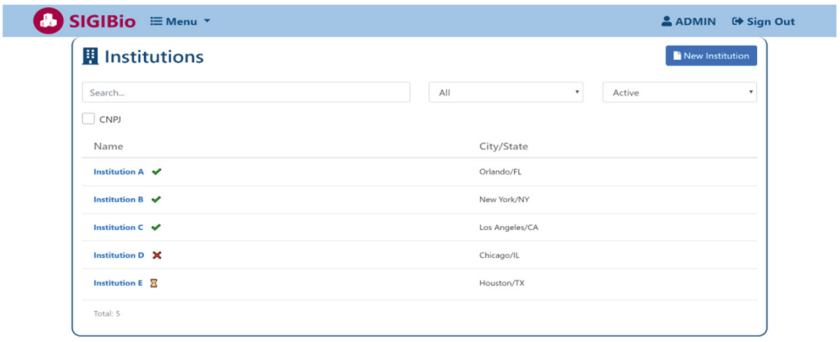


**Fig. 3.** Institutions list screen – SIGIBio

**Management of Research Participants and Collected Materials**

Research participants may be associated to a specific project, being registered by external users, or not associated with any project, donating material directly to the managing institution of the biobank. In this case, an internal user is responsible for registering him.

When registering a participant, a file with his signed ICF (Informed Consent Form) must be attached, as it is the document that proves the participant is aware of the donation and its consequences.

A research participant can donate one or more materials, called collected materials. These will then be processed by an internal user to be transformed into samples that can be used in researches. Figure 4 details some aspects involved is this stage.

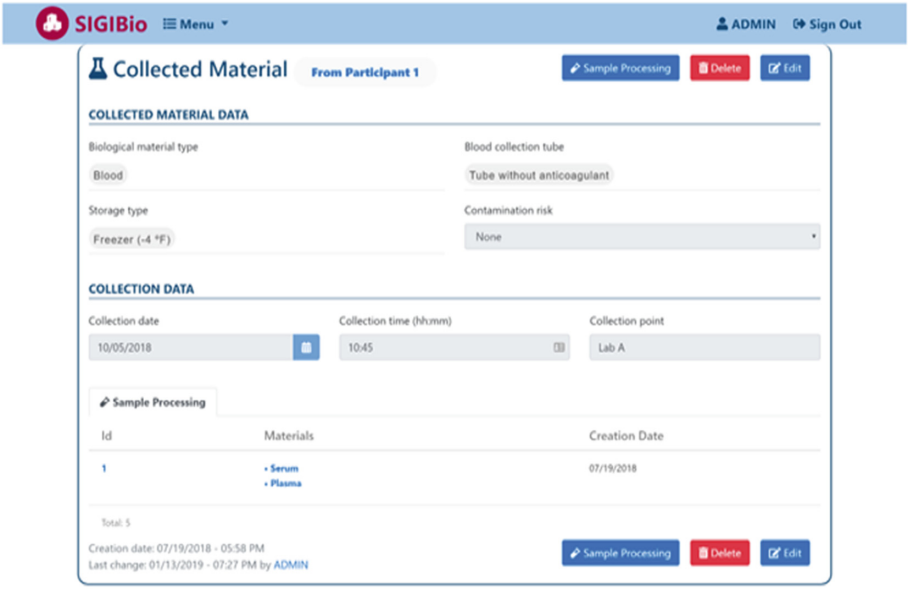


**Fig. 4.** Collected material registration screen – SIGIBio

**Management of Samples, Methodologies and Results**

This is the central module of SIGIBio with the main functionalities. Internal users can manage sample boxes by having a view of their free positions. External users can view available samples to request.

Internal users can register samples from a material collected from a research participant. It should be allocated in a free box position (Fig. 5). They can also manage all sample data, as well as their methodologies and results.

External users may manage methodologies and results of samples that are in a batch intended for a project of this user, in addition to viewing and requesting samples for research.

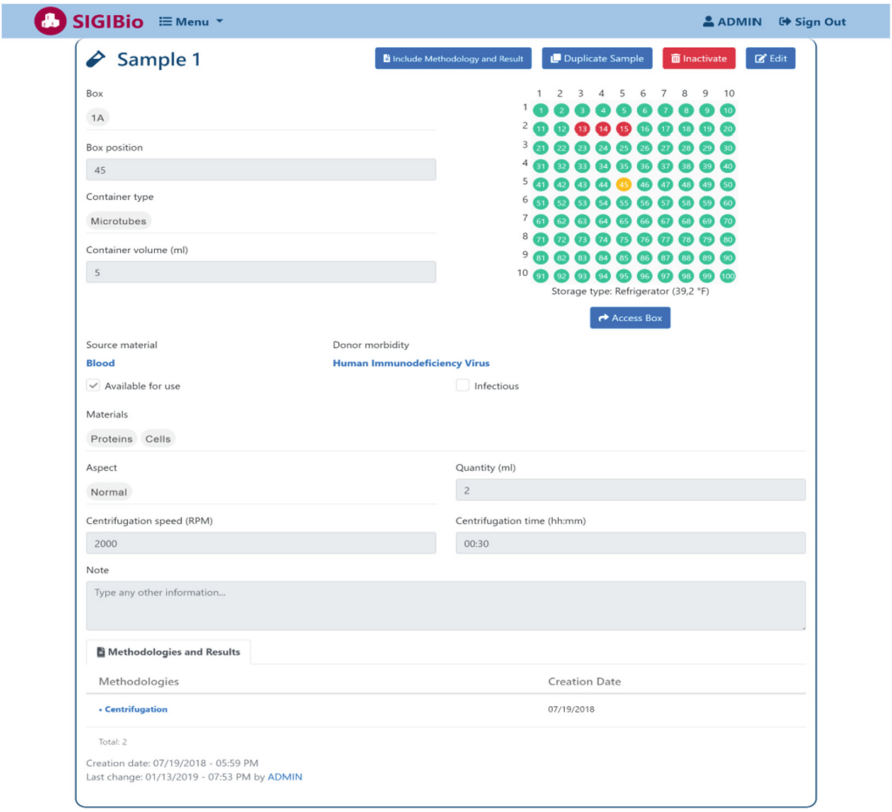


**Fig. 5.** Sample registration screen – SIGIBio

## Management of Samples Batches

External users can request a group of samples for their research projects. The responsible for the lot is the person who requested the sample being one of the professionals assigned to the project. The operation of this module is described in Fig. 6.

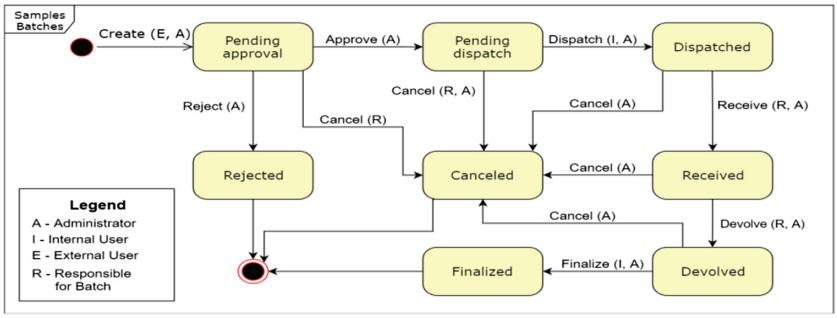


**Fig. 6.** State transition diagram - samples batch

### 3.4 Technical Aspects

Various programming standards have been used to make the development of the system simpler and to make it easier to maintain. Reuse of code through inheritance and auxiliary classes, well-defined names, modularization, separation of layers by responsibility, standardized formatting and small and objective functions were some of the techniques used.

The communication between client and server was implemented using the Hypertext Transfer Protocol (HTTP). Thus, the server provides an API from which the client can access and manage the system data. The server was implemented to offer a RESTful web service, name given to web services that follow the REST (Representational State Transfer) principles. REST is, in short, an architectural style to be used in the World Wide Web that focuses on the components, connectors and data of a system [10].

The database management system was MySQL [11]. It was chosen for being free, open source, widely used in the market and easy to learn and use, among others.

The implementation of the server was done with the platform Node.js [12], which allowed both client and server to be written in the same programming language: TypeScript [13]. This is an open source language developed by Microsoft that provides the necessary features of the latest version of JavaScript and adds features such as better support for data typing and objects orientation. In addition, the Express framework [14] supports web development with Node.js.

The implementation of the client was done in TypeScript with Angular [15], a proper framework for the creation of SPAs (Single Page Applications, which behave like smartphone applications, without complete screen transitions, having only part of the content reloaded) [16]. Using Bootstrap [17], the website is responsive, aiming to bring good usability in both smartphones and desktop computers.

## 4 Usability Tests

After completing the development of the SIGIBio first version, five health research professionals were invited to perform a usability test on the system. According to Nielsen [18], a research on system usability with at least five participants with similar profiles already demonstrates trends that can be significant.

The evaluation methodology used was the SUS (System Usability Scale) [19]. According to Brooke, its creator, usability is somewhat difficult to measure quantitatively. However, there are some points that must be addressed when attempting to measure this property: effectiveness, the ability of users to complete tasks using the system; efficiency, the amount of resources consumed when performing tasks in the system; and satisfaction, the subjective reactions of users when using the system.

And SUS assesses these points quickly and reliably, having been selected for the SIGIBio evaluation for these reasons. Ten statements are made, and the evaluators are instructed to answer each one with scores ranging from 1 to 5, where 1 means completely disagree and 5 means completely agree.

To carry out the usability tests of SIGIBio, the professionals were asked to test all the main functionalities of the following areas of the system: (i) access and users,

(ii) research participants, (iii) collected materials, (iv) samples boxes, (v) samples and (vi) methodologies and results.

After using the system, they were asked to evaluate the system using SUS. Figure 7 shows the statements of the SUS and the answers provided by all participants of the evaluation.

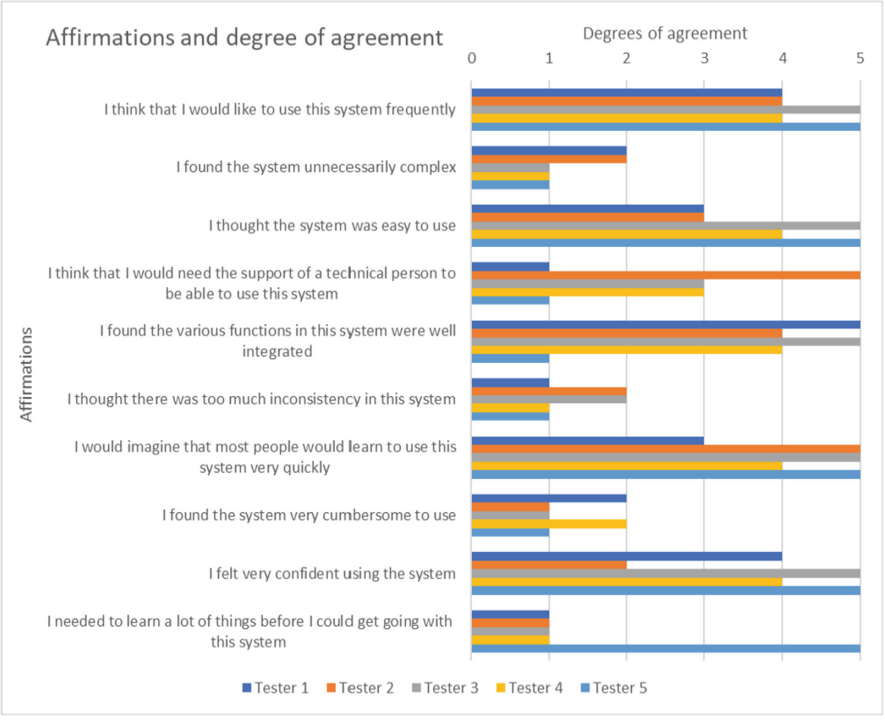


**Fig. 7.** Affirmations of the SUS and degrees of agreement of the invited participants

According to Brooke [19], after collecting these notes, the SUS score of a single participant should be calculated as follows: for each statement of odd index, subtract the value 1 from the given note; for each even index statement, subtract the given note from the value 5; add all new notes and multiply by 2.5. At the end, simply calculate the arithmetic mean between the final scores of each participant. Thus, we arrive at the result shown in Fig. 8.

According to Bangor, Kortum and Miller [20], who carried out an empirical evaluation of this methodology, the SUS applied in web interfaces has the value of 68 points as average grade. As can be seen, the average score of the participants who evaluated SIGIBio is 80 points. Still according to them, this value is between good and excellent.

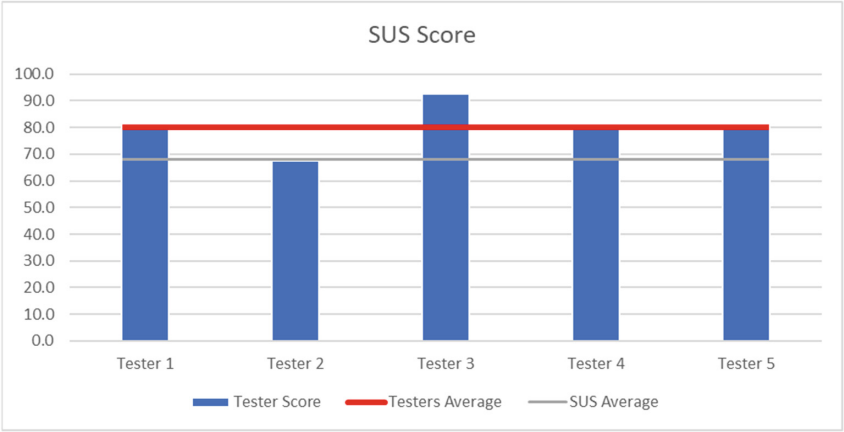


**Fig. 8.** Score of each tester

## 5 Conclusion

The work carried out by Nóbrega [2] justified the need for a system like SIGIBio for institutions that manage biobanks or biorepositories. Thus, it was developed as a tool to facilitate the conduction of researches with biological samples and their management. Professionals who use it spend less time on routine activities related to the handling of biological samples and can make better use of this time on other tasks.

Based on a literature review [2] on what would be important to implement, using modern technologies and development techniques geared towards source code quality and graphical user interfaces, this first version of SIGIBio was developed considering future changes and improvements. In addition, the usability tests showed a good acceptance by the health professionals who evaluated it. There are still several aspects that can be considered to expand and improve the functionality of SIGIBio. Some modules are already planned to be implemented in future releases. The quality management module in the laboratory, as suggested by Nóbrega [2], should have the capacity to manage data related to the management of research laboratories. The statistics module will be able to generate and display reports on the use of SIGIBio, such as which sample types are most requested for searches. Researchers can use the information available in their projects. In addition, managerial decision making will be easier for the administrators of the biobank or the biorepository managed by the system.

In addition to these, there will be the integration module. From it, it is expected that SIGIBio will become the basis for a network of connected biobanks and biorepositories, as suggested by Eder, Gottweis and Zatloukal [3], by disseminating information between institutions and between researchers in a simple and effective way.

Finally, it is important to stress that any tools that facilitate and accelerate the work of researchers help directly in the development of the whole society, since only the research and the dissemination of knowledge are capable of this.

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