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Tese

CASCIFFO - Software Capacitation in Hospital Fernando Fonseca Research Center Initial report

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Abstract

This document presents a thesis made on a joint-project named CASCIFFO, between the Lisbon Superior Institute of Engineering - Instituto Superior de Engenharia Lisboa (ISEL), and the Hospital Professor Doutor Fernando Fonseca (HFF). This project was made possible through the funding earned from the Clinical Investigation Agency Award and Biomedical Innovation (AICIB). This thesis aims to develop a platform and provide innovative mechanisms for interoperability with internal or external information systems, allowing, when desired, data synchronization, index search, identification data management and even access to detailed clinical data, the ability to manage and monitor clinical trials as well as their participants within the Clinical Research Center. The main contribution of this thesis will the optimization and simplicity in managing clinical trials in order to facilitate the researchers efforts in the management of clinical trials. We believe this platform to be an important step in the modernization of the HFF and UIC, bringing change in how the researchers view their institute and its importance. This is an early version of the report which aims to specify the functional requisites offered in the platform CASCIFFO.

Keywords: Management of Clinical Trials, Clinical Research, UIC, HFF

Chapter 1

Introdução

This chapter reviews the introduction of HFF and its Clinical Research Unit and its mission. It also introduces the platform being development in the scope of this thesis, the motive behind it and the main goals to be achived. The end of chapter describes the structure of the document.

1.1 Motive

This thesis is a part of the joint-project CASCIFFO and it's made within the scope of the curricular unit Tese Final de Mestrado (TFM), in the course Mestrado em Engenharia Informática e de Computadores. A strong motivator behind this project is the impact it'll have within the Clinical Research Unit, by facilitating the management and monitoring of clinical trials, CASCIFFO aims to alleviate this burden off the workload of researchers.

1.2 Hospital Professor Doutor Fernando Fonseca

The Hospital Professor Doutor Fernando Fonseca (HFF), first opened in 1995, is a first of the line hospital combining the professionals excelency with the most modern medical practices, searching to answer to a population of over 600.000 inhabitants of the municipalities of Amadora and Sintra [3]. The Institution develops assistance and research activities as well as providing education, pre- and post-graduation training.

1.2.1 HFF's mission

The Hospital's mission is to provide humanized and differentiated health care throughout a person's life cycle, in collaboration with primary and continuing health care, as well as other hospitals in the National Health Service's ("Serviço Nacional de Saúde") network [6].

1.2.2 Clinicial Research Unit

The Clinical Research Unit - Unidade de Investigação Clínica (UIC), created in March 2018, is an internal department within the Hospital that incorporates fundamental concepts of activities in line with the strategic objectives of the institution. The UIC is responsible for managing clinical trials and is characterized by a multidisciplinary team responsible for ensuring accuracy in the scientific planning of the submitted studies, for the fulfillment of clinical best practices by researchers and for the negotiation of contracts for projects financed by external promoters.

1.2.3 UIC's mission

UIC's mission is to promote quality clinical trials in an organized and sustainable manner. It achieves this by following guidelines that value systematic knowledge through the management of interfaces associated with Research, Development, and Innovation. In addition, it also complies with applicable ethical and legal provisions, for the benefit of the Hospital, the Community, the Patients, and the Families/-Caregivers. The goal is to become a reference in the promotion of best practices in hospital clinical research and to consolidate a transversal scientific culture within the institution [6].

1.2.4 Clinical Research

Clinical research is a very important sector to the world of medicine and health care. It's through it that new medicine and new ways of treatment are discovered and tested through strict adherence to scientific accuracy measurements and best practices before being administrated to the general public.

Types of Clinical Research

There are two main types of clinical investigations, without intervention, which includes observational trials ("Estudos Observacionais"), and with intervention, which includes clinical trials ("Ensaios Clínicos"). The distinction between these trials comes down to the type of intervention between the study and the participants. Active intervention occurs when the researchers in a trial introduce any variable, such as a new medicine, that provokes any sort of change within the participant's behavior, health care or mindset. No intervention means that the team of researchers will not intervene in any way with the participants besides only monitoring them. Having stated these differences, we can clearly define observational trials and clinical trials. Observational Trials have no active intervention, they instead contemplate purely the aspect of observation, for example in the evaluation of a potential risk factor. On the other hand, Clinical Trials engage in active intervention, as such they can be characterized as a Clinical Research which involves any intervention that foresees any change, influence or programming of health care, behavior or knowledge of the participating patients or caretakers, with the end goal of discovering the effects

it had on the participant's health. Clinical trials consist of a scientific controlled investigation, done on humans (healthy or ill), with the end-goal of establishing or confirming the safety and efficiency of the experimental medicine [7].

Clinical trials have shown to be a vital tool in the development and testing of vaccinations and treatments for the safety of the entire world population, especially now during the present *Novel Coronavirus (SARS-CoV-2)* pandemic. For this reason, the efficiency and simplicity in managing and monitoring the evolution of a clinical trial is essential.

1.3 Project overview and main goals

CASCIFFO is a joint project between HFF and ISEL and was developed through funding by the Clinical Investigation Agency Award and Biomedical Innovation (AICIB). CASCIFFO is a web-app that aligns with the UIC's goals by promoting efficiency and quality in the management of clinical research. CASCIFFO strives to make the visualization, monitoring, and management of clinical Trials as simple and straightforward as possible. It will allow the UIC/HFF to be modernized, bringing a shift in how patients, researchers, and promoters view and value their institution.

1.3.1 Challenges

The current procedure of a clinical investigation relies on e-mail exchanges between the external and internal parties involved, which adds a considerable amount of effort in the management and monitoring of clinical trials. Another concern is with the scheduling and monitoring of Clinical Trials patients, as there is currently no systematic way of distinguishing the types of appointments made for each patient. In this context, the application CASCIFFO, aims to provide a solution in order to enhance the efficiency in the management and monitoring of clinical research.

1.3.2 Main Goals

The application aims to develop and provide innovative mechanisms for interoperability with internal and external information systems, allowing, when desired, data synchronization, index search, identification data management and even access to detailed clinical data. CASCIFFO consists of two core modules, the front-end and the back-end. The front-end supports interaction with users while the back-end connects to an internal database system to the HFF/UIC and which aggregates the total information of this ecosystem. The interaction with users will depend on their role within the platform, displaying the appropriate information to each one.

1.4 Document Structure

This document is divided into three chapters. The first chapter consists of the introduction of the HFF and UIC, their missions and goals, followed with an overview

of the project and the goals to achieve. The second chapter consists of the intricacies of CASCIFFO, the infrastructure and the functional requirements. Finally the third chapter consists of the conclusion and analysis of the current state of the thesis.

Chapter 2

This chapter consists of a detailed view over the concept and functional requirements of the CASCIFFO platform. It is structured with the following sections:

- Infrastructure: Description of technologies and framework used in the development of CASCIFFO.
- Access control: Identification and categorization of actors and their roles.
- Processes: Identification and detailing of the process flow.
- Functional Requirements: Description of functional requirements.

2.1 Infrastructure

The infrastructure of CASCIFFO, has mentioned previously, consists of two core modules, the front-end and the back-end. The front-end runs on a Node.js environment, using React, a Javascript library for building user interfaces [5], with Typescript to build all front-end functionalities. The dependencies are managed and installed using npm, a software package manager, installer and the worlds largest software library [1]. npm was chosen over yarn [10] due to its larger community and support. The back-end executes on a run-time Java environment, utilizing Spring-web as the basis for building the server. Spring-web facilitates the building and deployment of web applications by removing much of the boilerplate code and configuration associated with web development [9]. CASCIFFO has its own database, utilizing the framework PostgreSQL, a powerful open-source object-relation database system. Postgres was chosen for its earned reputation in its proven architecture, reliability, data integrity and community support [8]. While CASCIFFO has its own databse, the patient and medical staff data will be imported from an internal database, "Admission", within the HFF/UIC. There are restrictions on the amount of queries made on the medical staff information, limiting this procedure to once per day.

2.2 Access control

Within the app CASCIFFO, in order for the management of clinical investigations to progress, it needs to be reviewed by many entities, such as the Administrative

Council ("Concelho administrativo", CA), the Finance and Juridical department. Given this nature of CASCIFFO, there needs to be a well-defined structure of access control, so that each entity can contribute to the management of clinical investigations within the scope of their responsibilities. Each involved entity must have a role and a set of permissions. The roles identified are as follows: the UIC role, given to the investigators who can create and edit clinical investigation proposals; the Team Member role, given to investigators belonging to the team conducting the clinical investigation; the Management role, able to approve and reject clinical investigation proposals; the Finance and Juridical roles, given to collaborators who's function belongs within the Finance and Juridical departments, respectfully; and finally the Superuser role, who has complete access to every feature CASCIFFO has to offer.

2.3 Processes

This section details the types of processes occurring within the scope of the project. There are three identified processes consisting of the life-cycle of a clinical investigation proposal, the Clinical Trials and the contract addenda.

2.3.1 Clinical Investigation Proposals

From the instant a clinical investigation is kicked-off, it follows through a series of states and protocols that must be adhered to, in order to be completely validated. There are two types of clinical investigations: Clinical Trials and Observational Trials. Each state, except the terminal one, has an entity responsible, 'owner', for advancing the state. The flow of states is as follows:

1. Submitted ("Submetido"), 'owner=UIC';
2. Negotiation of financial contract ("Negociação de CF"), 'owner=UIC';
3. Internal validation ("Validação interna"), 'owner=Finance, Juridical';
4. External validation ("Validação externa"), 'owner=UIC';
5. Submission to the CA ("Submissão ao CA"), 'owner=UIC';
6. Internal validation ("Validação interna"), 'owner=CA';
7. Validated ("Validado").

The enumerated set of states corresponds to the life-cycle of a clinical trial Proposal. An Observational Trial Proposal consists of the enumerated states 1, 5, 6 and 7; it lacks a financial component and a promoter.

Taking the example of the submission of a clinical trial Proposal, an investigator starts by creating and submitting a proposal. Once it's submitted, the CA will be notified, via app and email. This state is described as *Submitted*. When the negotiation of the financial contract begins, the principal Investigator, who belongs

to the UIC role, will advance the state to its next step in the proposal's evolution, *Negotiation of financial contract*. When the financial negotiation reaches an agreement of the UIC and external promoter, the investigator advances the state to its next stage, *Internal validation*. Upon advancing, the users with the role of 'Finance' and 'Juridical', which represents the Financial and Juridical internal departments, respectfully, will be notified that a proposal is ready to be evaluated. The evaluation will consist of a simple 'Accept' or 'Refuse' with added justification for the choice. In the case of either user with 'Finance' or 'Juridical' role reject the financial contract, the proposal's will backtrack to *Negotiation of financial contract*, notifying the UIC of the occurrence. Once it's accepted by both roles, the proposal will automatically advance into the next state, *External validation*. In this state the UIC will be notified of the change and asked to verify all the documents, including the final version of the financial contract. The UIC to the external promoter, requesting their signatures. When the reply is received via email, the UIC adds the received signatures and possible additional documents to the proposal in the CASCIFFO platform, advancing it to the next stage *Submission to CA*. In the state *Submission to CA*, the principal investigator will be notified both via the platform and email that a proposal requires their signature. Once the principal investigator submits their signature into the platform, he can advance the proposal's state into *Internal Validation*. The progression to the mentioned state will notify users with the 'CA' role stating that a proposal is ready for its final evaluation. Once a user with the role of 'CA' checks the proposal he can either validate it or not. In case it's not validated, the proposal will become 'canceled' with its life-cycle ending there, however, if it is validated, the proposal can become fully validated once the termination of another process is ends successfully. This process, which can be considered a sub-process, is called the validation protocol. It starts in parallel when the proposal is first submitted. The purpose of this protocol is to validate the clinical investigation's ethical and safety values. It consists in the validation of the proposal by internal and external agencies, the clinical investigations Ethics Comity ("Comissão de Ética para Investigação Clínica", CEIC [2]) and INFARMED, I.P [4] respectfully. The protocol ends when either of the mentioned agencies approves or rejects the proposal. Once it has successfully passed through the described validation protocol, the proposal becomes *Validated* and a Clinical or Observational Trial is automatically created, importing the core information from the proposal. If either process declares the proposal invalid, its state becomes 'canceled', notifying the UIC and showing the root cause of cancellation.

Each proposal is distinguished by six main properties, the principal investigator, the type of investigation, the type of therapeutic service it's integrated into (*i.e.* Oncology), the 'Sigla' which represents the name of the therapeutic or medicine, the partnerships involved in the investigation and the medical team participating in the investigation. Proposals with a financial component must also include the promoter of the investigation, in addition to the properties listed.

2.3.2 Clinical Trials

The life-cycle of a clinical trial is divided into three states: active, completed, and canceled. Starting with the active state, a clinical trial will become available for viewing and editing once its proposal has been accepted. Clinical trials, as a process, consist on the experimentation of new medicine or treatment on a set of participants. These participants can be added to the clinical trial directly from the application. The experimentation requires constant monitoring, through visits, on each participant. These visits can be scheduled either when a participant is added or created afterwards. In addition to monitoring participants, several studies can be made in the scope of the clinical trial, such as scientific articles, presentations, reports, etc.

2.3.3 Addenda to the contract

Throughout the life of a clinical trial, there can be made changes to the study's contract, be it changing the investigator team or other factors that impact the standard run of the study. These changes pass through two entities before being applied; the UIC and the CA. The addenda can only be made once a clinical trial is active, which means its proposal has already been approved. The addenda have five different states: submitted 'Submetido', internal validation by UIC 'Validação interna', internal validation by CA 'Validação interna', the terminal state validated 'Validado' and finally the terminal canceled state 'Indeferido'. The first four mentioned states are sequential, with the last one being an exception state. The sequential flow of states have an entity responsible for advancing their state, the 'owner'. Listed below, in similar fashion to the states presented in the proposal process, is the aforementioned sequence:

1. Submitted ("Submetido"), 'owner=UIC';
2. Internal validation ("Validação interna"), 'owner=UIC';
3. Internal validation ("Validação interna"), 'owner=CA';
4. Validated ("Validado").

2.4 Functional Requirements

This section details the functional requirements and presents a mock user interface (UI) that will satisfy the requirement. The main features of CASCIFFO can be separated into three groups, which are: general functionalities, clinical component and financial component.

1. General features
    - Visualization and management of Clinical Trials as a process;
    - Ability to edit and validate data (edit checks);

- Access control based on different user profiles;
- Access by computer, tablet or smartphone;
- Ability to export information in numerical or graphical mode;
- Ability to customize the form of visualization.

2. Clinical Component

- View detailed characteristics and evolution of clinical trials including the tested medicine or technique in question;
- Monitoring the set of patients included in clinical trials and their characteristics;
- Insertion of patient data in face-to-face or tele-consultation;
- Characteristics of the treatment associated with the clinical trial;
- Monitoring of the patient's behavior under trial and its attendance;
- Monitoring of physical and financial assets;
- Monitoring of visits & recording of adverse events.

2.5 General Features

In this section, the general features mentioned in the document will be described and illustrated through mock-ups.

2.5.1 Visualization and Management of Clinical Trials as a Process

To view and manage a clinical trial as a process, a user needs only to view the general overview of Clinical Trials or clinical investigations Proposals. As in figure 2.1 and figure 2.2, the user has an overview of the all submitted proposals and clinical trials with their main characteristics, such as, the identification, current state, last alteration date, the principal investigator and whether it has partnerships or not.

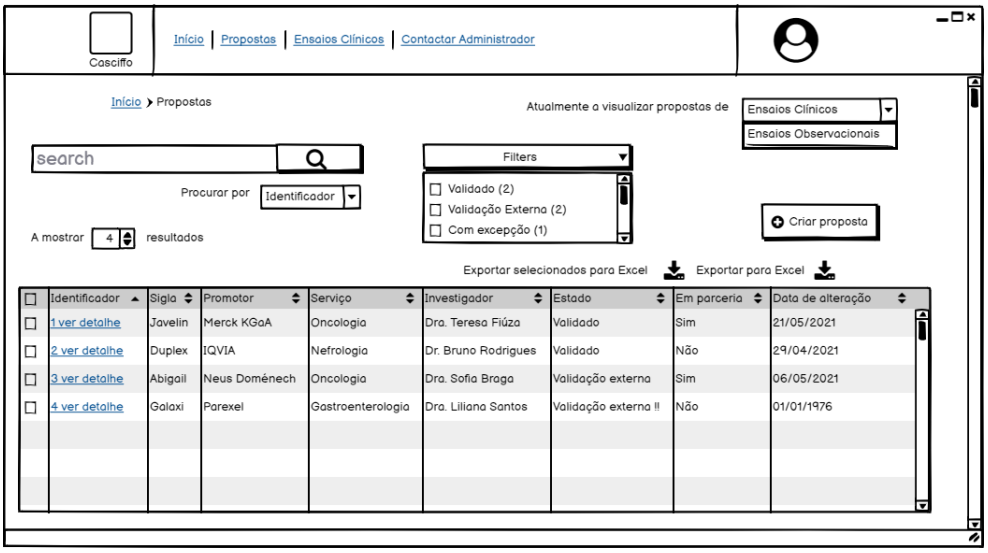

Figure 2.1: Mock overview of clinical investigations proposals.

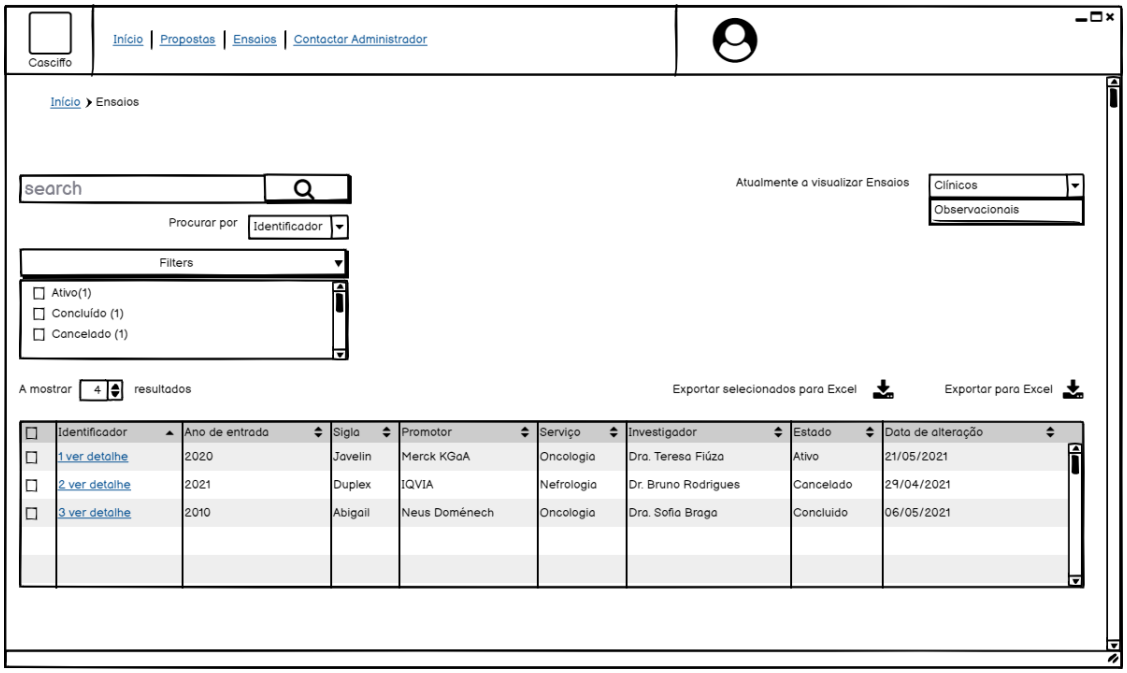

Figure 2.2: Mock overview of clinical trials.

When a user clicks the link view details ("ver detalhe"), he will be redirected to a screen displaying the details of the target clinical investigation.

2.5.2 Ability to edit and validate data (edit checks)

Within the CASCIFFO platform, the UIC and internal departments can view the details of a certain clinical investigation proposal and edit or validate according to their roles. Users with 'UIC' role will be able to create and edit their own Investigations, whereas the internal departments, with roles of 'CA', 'Finance' and 'Juridical' will only be able to validate the proposals. The creation of a proposal starts in the overview of proposals screen, from there a user can click on Create Proposal ("Criar

proposta") and will be redirected to the screen illustrated in figure 2.3. Here an investigator can choose what type of investigation this proposal corresponds to, either an observational or clinical trial. In the case a clinical trial is selected, more options will be shown since clinical trials have a corresponding financial component. The data fields corresponding to the therapeutic area, the service and the pathology of an investigation are restricted to a set of possible inputs. In addition, the members of a medical team also belong to an already defined database, being validated at the time of creation of the medical team for the investigation. Certain fields cannot be changed once a proposal has been submitted, such as the promoter, the partnerships and the type of investigation can only be defined during the creation of a proposal.

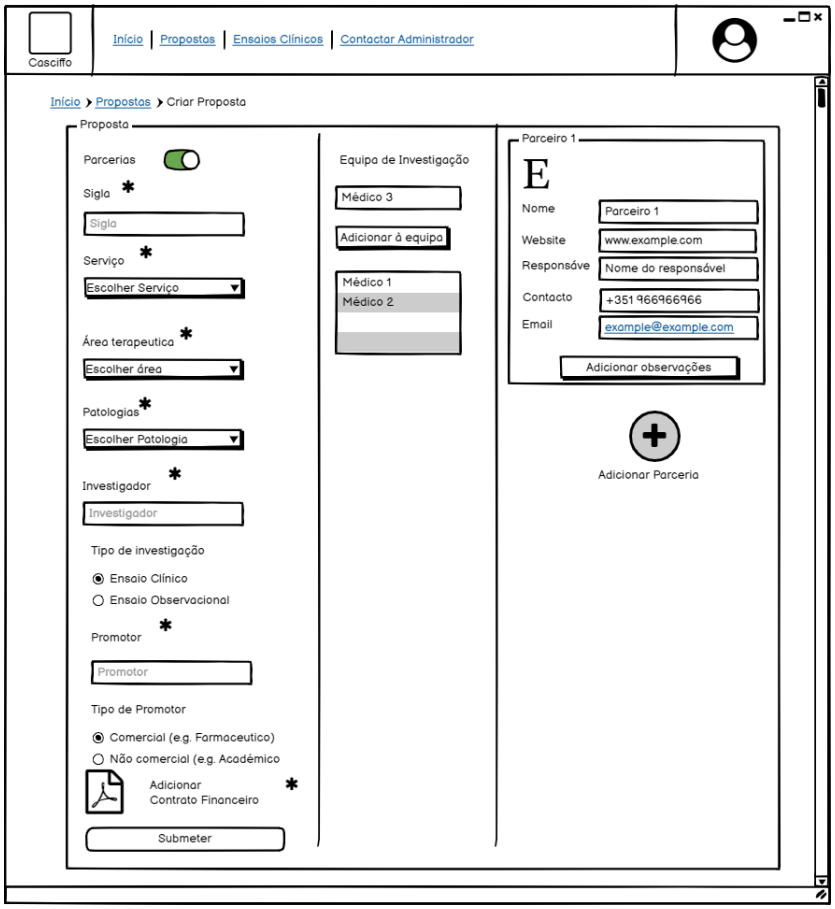

Figure 2.3: Mock creation of a clinical investigation proposal.

2.5.3 Access control based on different user profiles

The access control within the CASCIFFO application is based on roles. As described in section 1, there are defined roles for each type of user. A user with the role 'UIC' can manage their own clinical investigation, being able to edit and have a hand in advancing the state. In addition, it also has an overview over all ongoing investigations, not being able to edit those that weren't created by said user. Once this user logs in, a dashboard showing overall statistics of the platform, *i.e.* number of active clinical trials, number of submitted proposals, etc. The role 'Financial' is responsible for validating and updating the financial components of the investiga-

tions, hence when a user with this role logs in, an appropriate financial management screen will be displayed, whereas the 'Juridical' component validates the juridical component. The role 'CA' is responsible for giving the final decision in whether an investigation proposal can have the go-ahead to begin their clinical trials or observations. A user of role 'CA' once logged in, will be shown a primary screen displaying the overview of clinical investigation proposals awaiting validation. Finally, we have the 'Superuser' role, which besides having the ability to execute every mentioned action, it can also create new types of services, therapeutic areas and pathologies.

2.5.4 Access by computer, tablet or smartphone

CASCIFFO is a web-application which can be accessed via any device or browser. CASCIFFO offers an extended functionality to browsers that support service workers, since it utilizes the Progressive Web Application (PWA) framework, allowing it to be installed and used as an application. Among the features a PWA allows, the framework was chosen by its ability to let an application run in offline-mode and versatility in that it can be installed via the browser, and used in similarity to a standalone mobile app.

2.5.5 Ability to export information in numerical or graphical mode

CASCIFFO offers the ability to export information via excel, and visualize graphic data within the app. There is a feature, shown in figure 2.4 that allows a user to export data, *e.g.* a selected number of clinical investigation proposals. This feature is present in the screens showing listed data, *e.g.* list of clinical investigation proposals, and the details of each clinical investigation, proposal or trial.

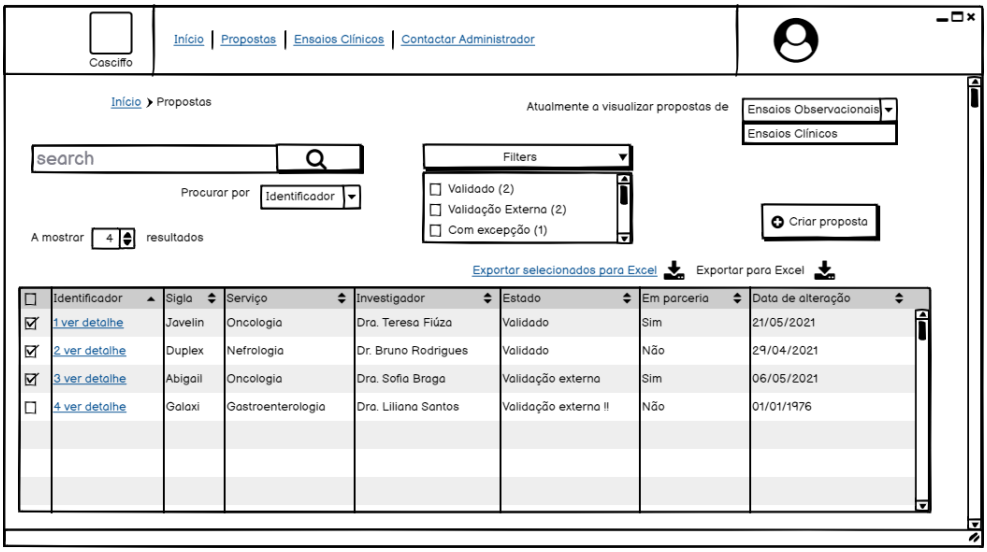

Figure 2.4: Mock screen selecting clinical proposals to export into excel.

2.5.6 Ability to customize the form of visualization

The ability to customize the form of visualization will be available in the initial screen of the app, the Dashboard, where the user will be able to view different types of graphs showing statistics based on the states of clinical investigations.

2.5.7 View detailed Characteristics and evolution of clinical Trials including the tested medicine or technique in question

To view detailed information about a clinical investigation, one needs to first overview the clinical investigations and then click on the details of a desired clinical investigation. Considering this option, the user will be redirected to a screen detailing the study. The evolution of any clinical investigation consists of its proposal followed the trial activity once the proposal has been fully validated. In figure 2.5, the details of a clinical trial proposal can be viewed. The flow of state of a proposal is shown in the form of a bar in a straight forward manner. Each state corresponds to a division, box, in the bar and has three properties: the name of the State; the date it was completed in, if the state has otherwise not been completed, then a sequence of dashes will appear in its place; the deadline at which it should be completed and finally the entity responsible for advancing the state. It is possible to click in the box of a state to display information about the events that occurred during the time the proposal was in that state.

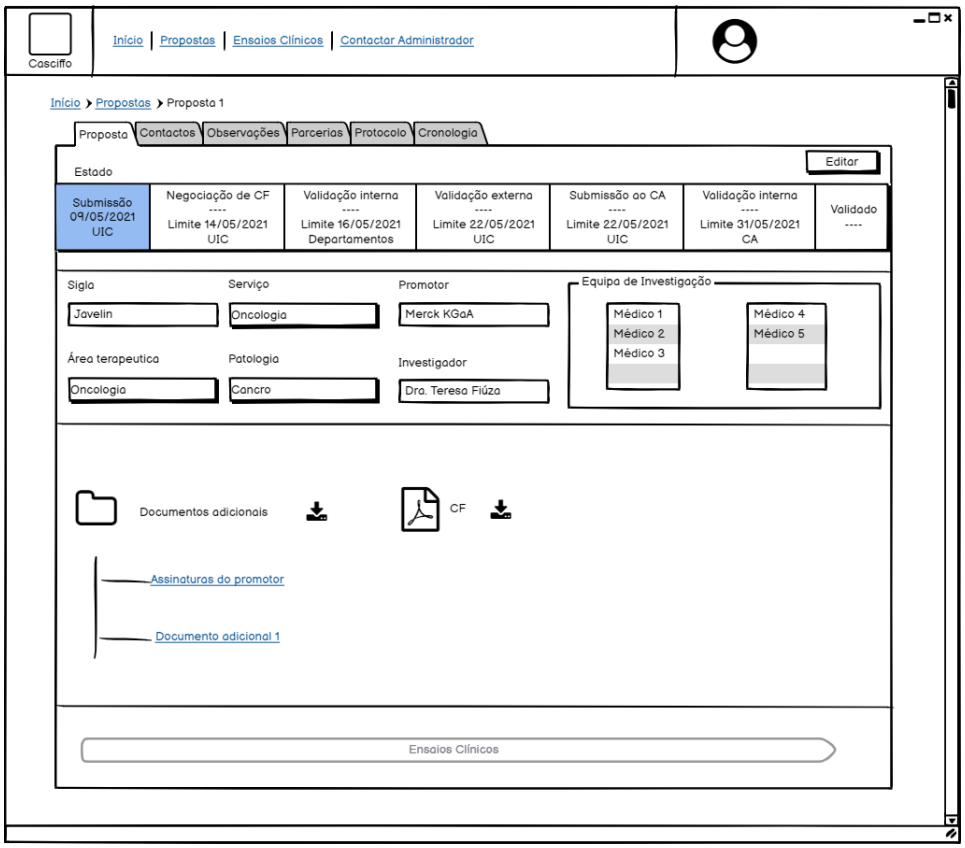

Figure 2.5: Mock overview of a clinical investigation proposal.

A clinical trial proposal considers five components alongside its principal details displayed as tabs and listed below:

- the Contacts ("Contactos") tab which corresponds to comments related to external communications, viewed in figure 2.6;
- the Observations ("Observações") tab which contains comments made in regard to the proposal, viewed in figure 2.7;
- the Partnerships ("Parcerias") tab, where one can find the partnerships involved in the study proposal, viewed in figure 2.8;
- the validation Protocol ("Protocolo") tab, where it can be viewed the current state of affairs of the process described in section 2.5.1, and in figure 2.9;
- the Chronology ("Cronologia") tab that displays the timeline of events, as in figure 2.10. Events include deadlines introduced by the user and the transition of states. The user will have the ability to specify the scope of the timeline, selecting the time range and type of events to view.

All tabs, except the one pertaining to the Protocol validation, will have present the current state of the proposal.

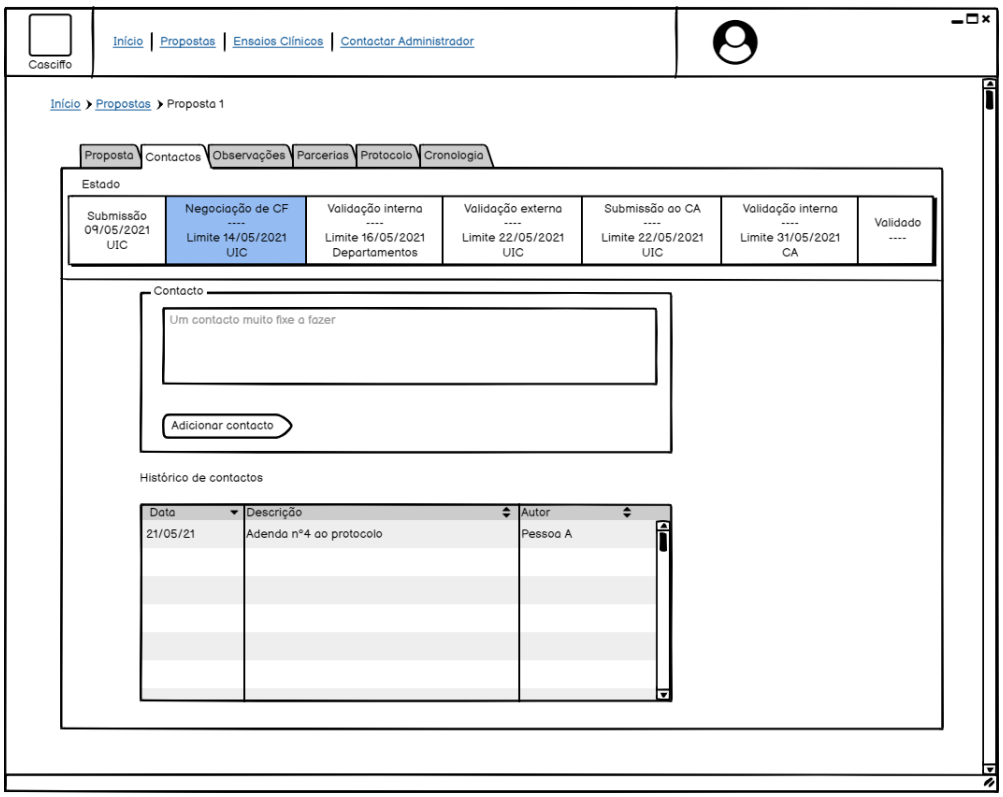

Figure 2.6: Mock overview of the contacts tab.

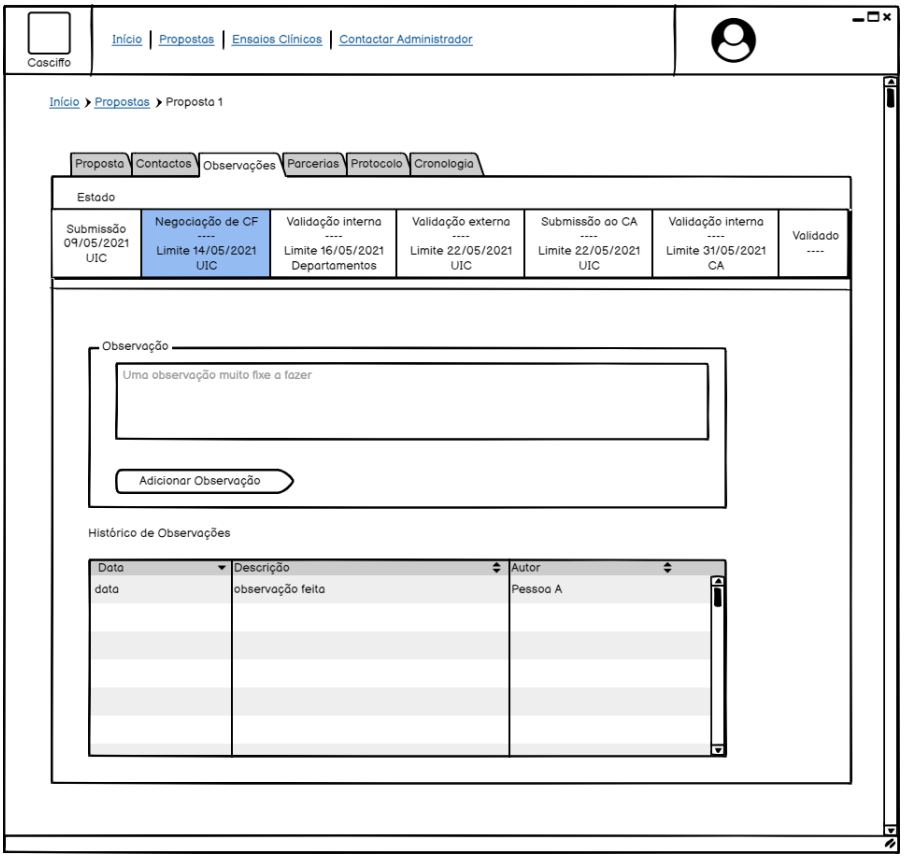

Figure 2.7: Mock overview of the observations tab.

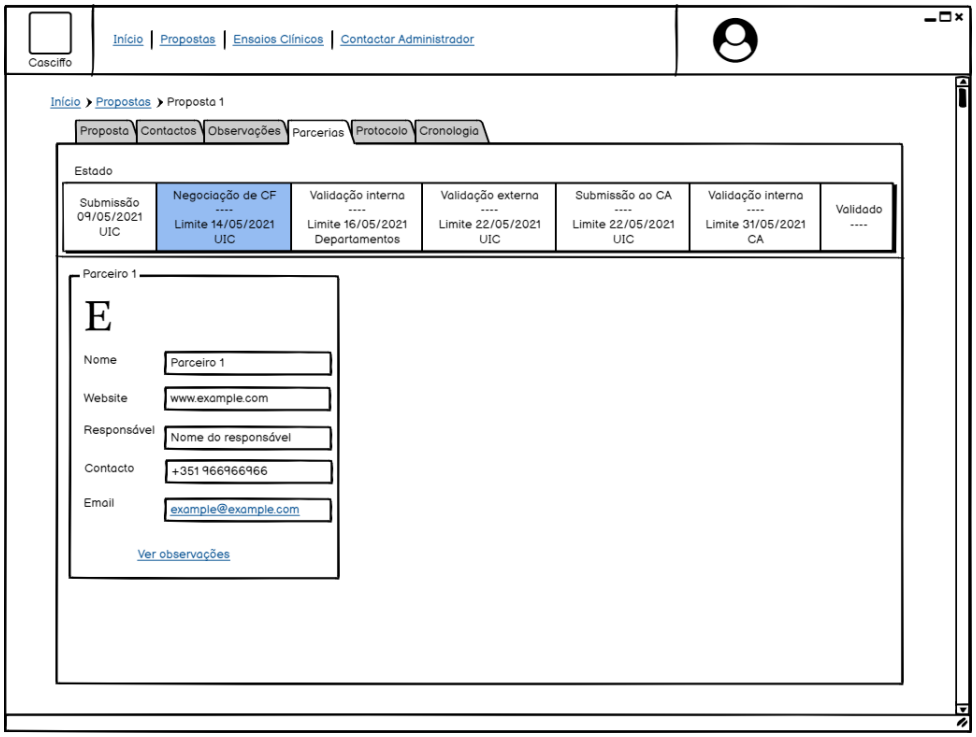

Figure 2.8: Mock overview of the partnerships tab.

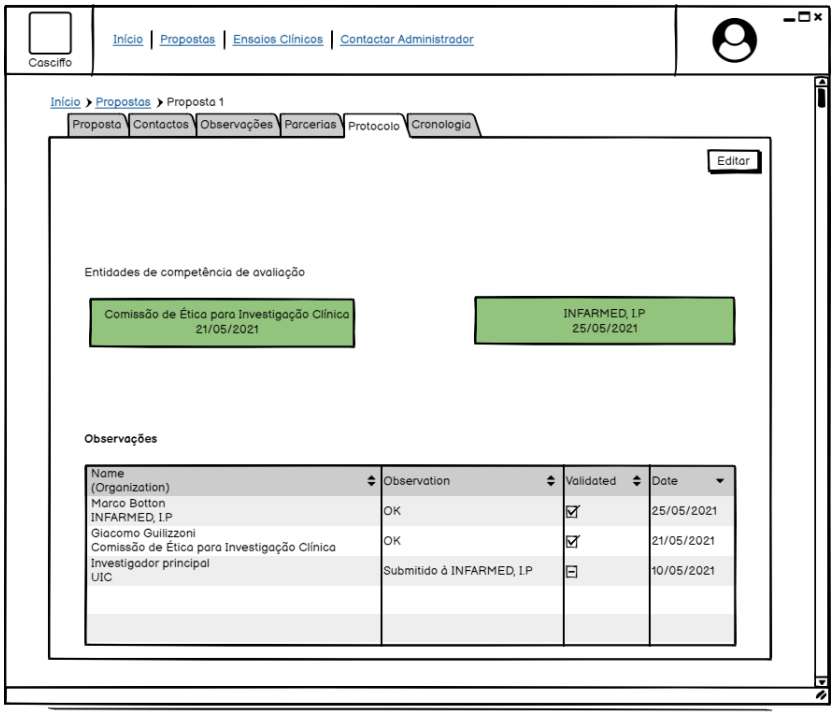

Figure 2.9: Mock overview of the protocol tab.

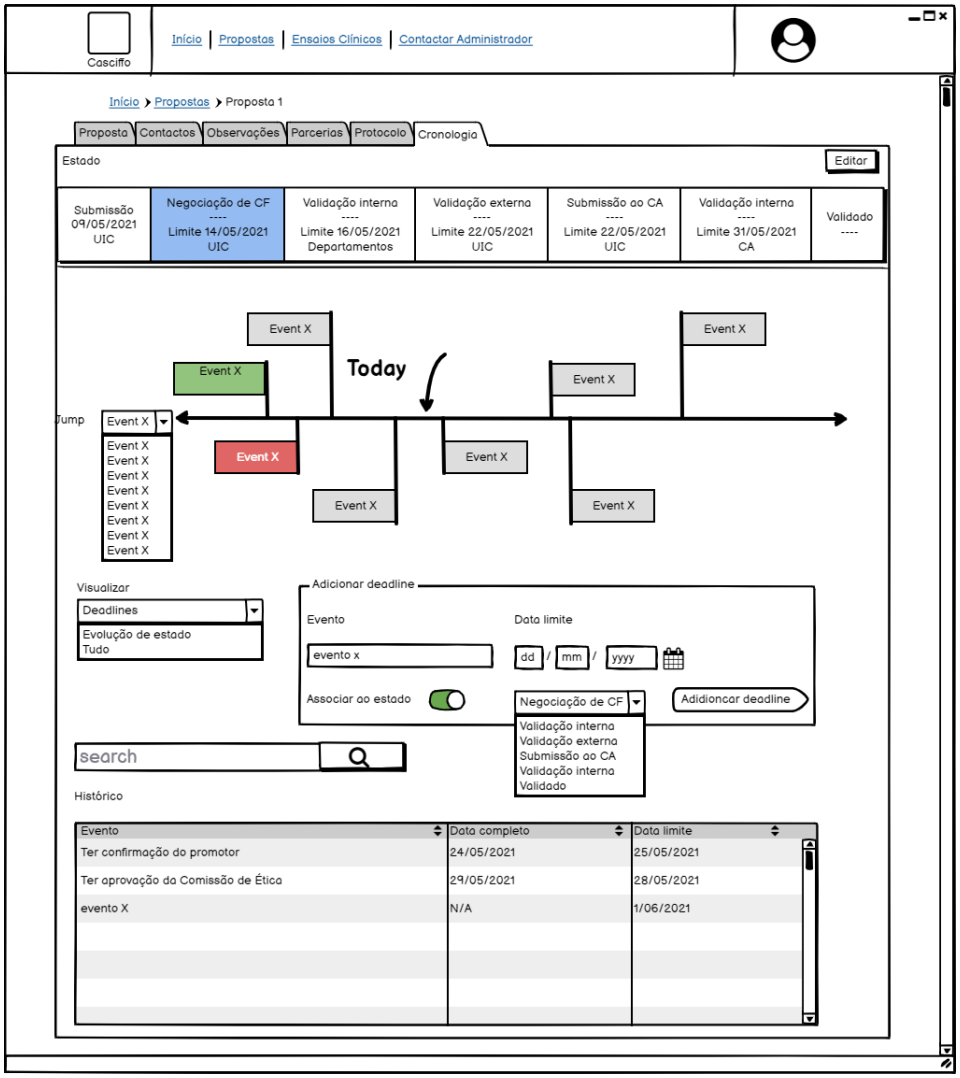

Figure 2.10: Mock overview of the chronology tab.

Once the proposal has reached its successful terminal state, as in section 2.3.1 a clinical trial will be created. To access the newly created trial, the user can either click the button "Ensaio Clínico" from the proposal details screen, as in figure 2.5, or from the overview of clinical trials click on the details of one. In the screen dedicated to the clinical trial and presented in figure 2.11, there are five different tabs:

- the clinical trial tab ("Ensaio Clínico") that displays the characteristics of the study;
- the scientific activities tab ("Atividades científicas"), viewed in figure 2.12, which includes scientific work in the scope of the study, such as articles, thesis, reports, etc.;
- the visits tab ("Visitas") where the investigator team can have an overview of the history and scheduled visits;
- the patients tab ("Pacientes") with the purpose of showing an overview of the participants included in the trial;

- the partnerships tab ("Parcerias"), similar to the proposal's version of partnerships tab, displays the partnerships involved in the study;

- the financial management ("Financiamento"), where one can view the flow of monetary gain from visits and the partition between the investigator team.

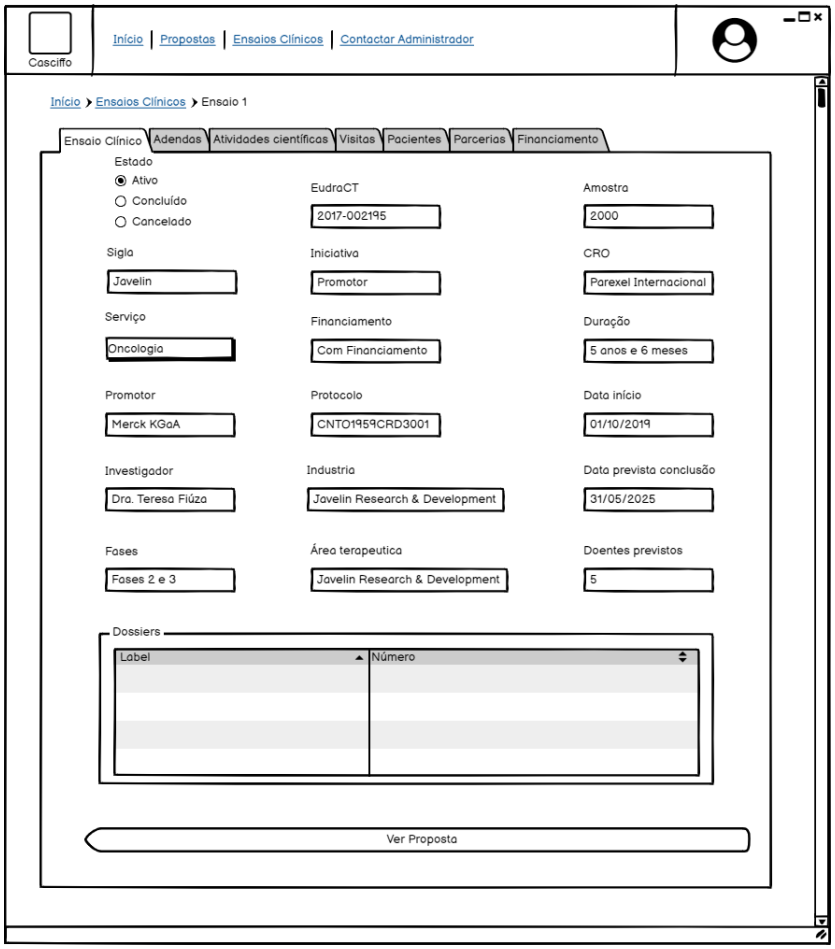

Figure 2.11: Mock overview of the details of a clinical trial.

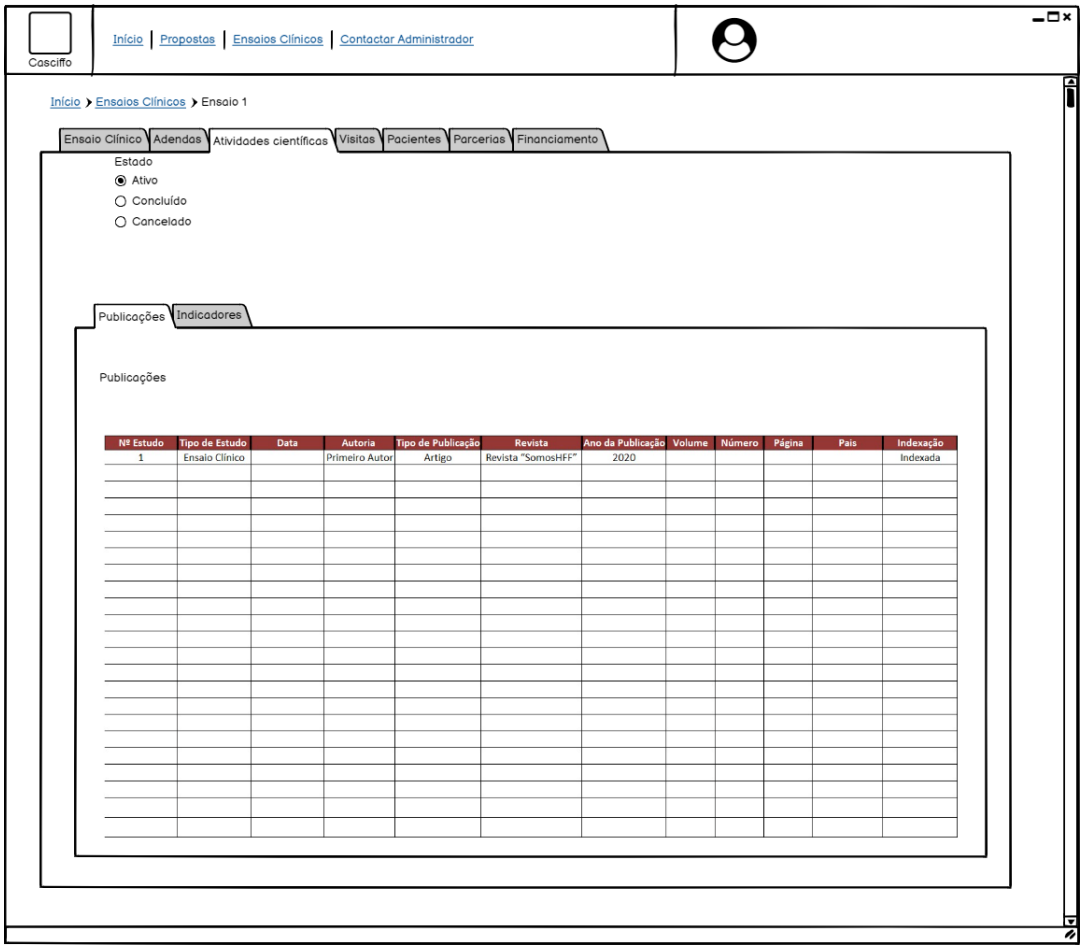

Figure 2.12: Mock overview of scientific activities made within the scope of the investigation.

2.5.8 Monitoring the set of patients included in clinical Trials and their characteristics

The details of the set of patients involved in a clinical trial will be displayed when viewing the details of said clinical trial, under the tab "Pacientes", illustrated in figure 2.13. This tab displays the set of current participants undergoing the clinical trial and information such as the participant number, used to identify the participant throughout the study, the name of the participant, their age, the treatment branch they were assigned to within the scope of the study, their last and the closest upcoming visit. Included in this screen are the buttons Randomize ("Randomizar") and Add ("Adicionar"). The button randomize will randomly assign participants to treatment branches within the study, this one-time procedure is to be used once all the participants have been added to the clinical trial. The button add, will begin the procedure to add a patient. Upon clicking this button, the user will be shown a small box, as illustrated in figure 2.14, where he can input the name of the participant and then is also given the chance to immediately schedule several visits.

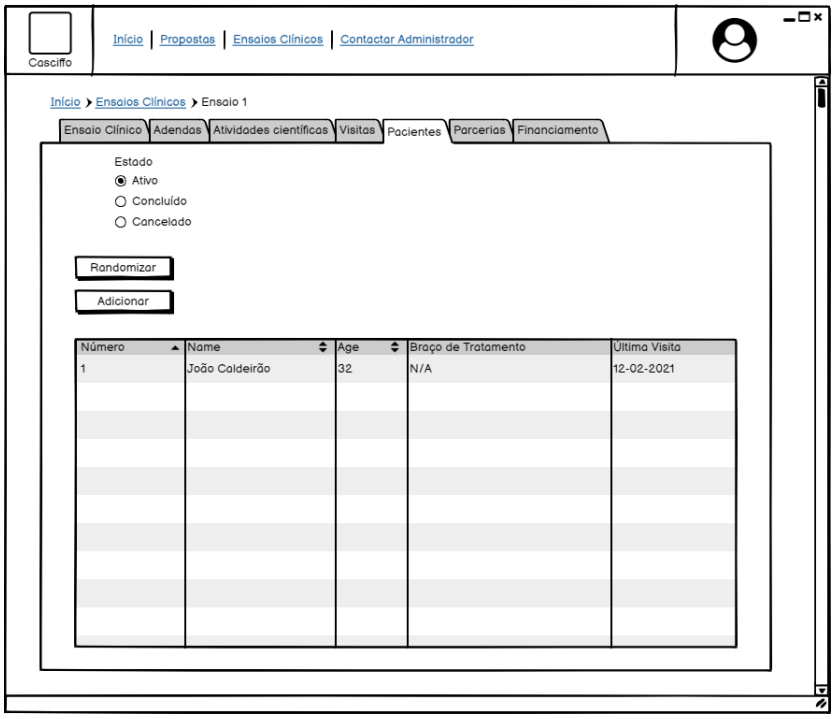

Figure 2.13: Mock overview of all participants included in the study.

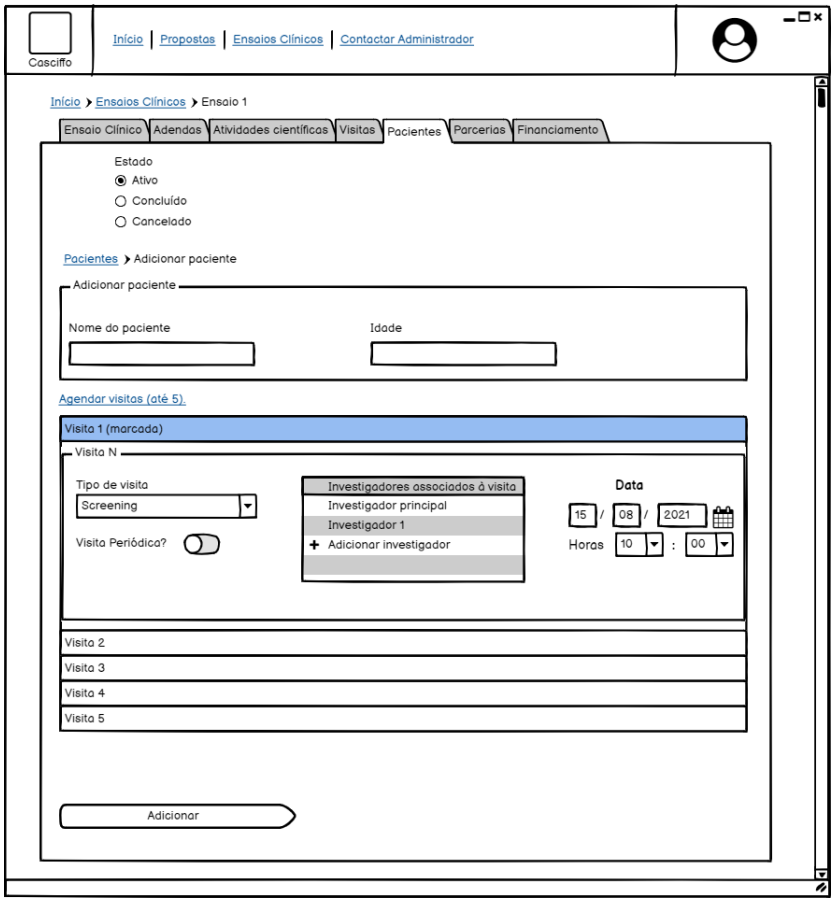

Figure 2.14: Mock screen of adding a new patient as a participant in the study.

2.5.9 Insertion of patient data in face-to-face or tele-consultation

The insertion of patient data in the context of a visit is made by the investigator associated to the mentioned visit. In order to do this, the investigator has to navigate to the details of the visit, from the overview of clinical trials, to the details of the trial followed by the overview of visits and finally the details of the considered visit. Here the investigator can input observational data into the field "Observações" which will represent the observations made throughout the visit or tele-consultation. He is also asked to mark the attendance of the participant by clicking on a simple button "Marcar presença", as illustrated in figure 2.15.

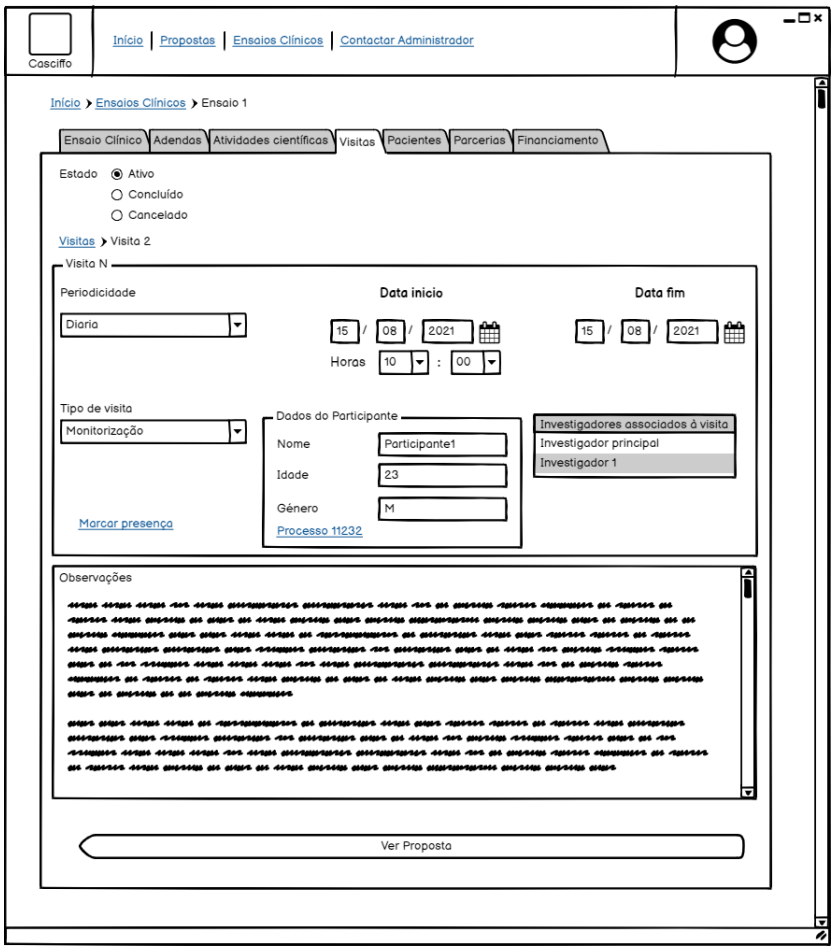

Figure 2.15: Mock overview of a visit's details.

2.5.10 Characteristics of the treatment associated with the clinical trial

The characteristics of the treatment associated with clinical trials consists of three main factors, the service area it is within, the therapeutic field and the pathology the clinical trial aims to investigate/treat. These details can all be found in the detailed view of a clinical trial under the tab "Ensaio Clínico".

2.5.11 Monitoring of the patient's behavior under trial and its attendance

The monitoring of the patient's behavior and its attendance, can be tracked via the visits and in twofold. The first is to filter the visits, under the visits tab, to show only the visits related to the participant in question. The second is to view the details of this participant in particular, from the overview of total participants in the study, clicking on the details of the participant and then checking the tab "Attendance", as in figure 2.16.

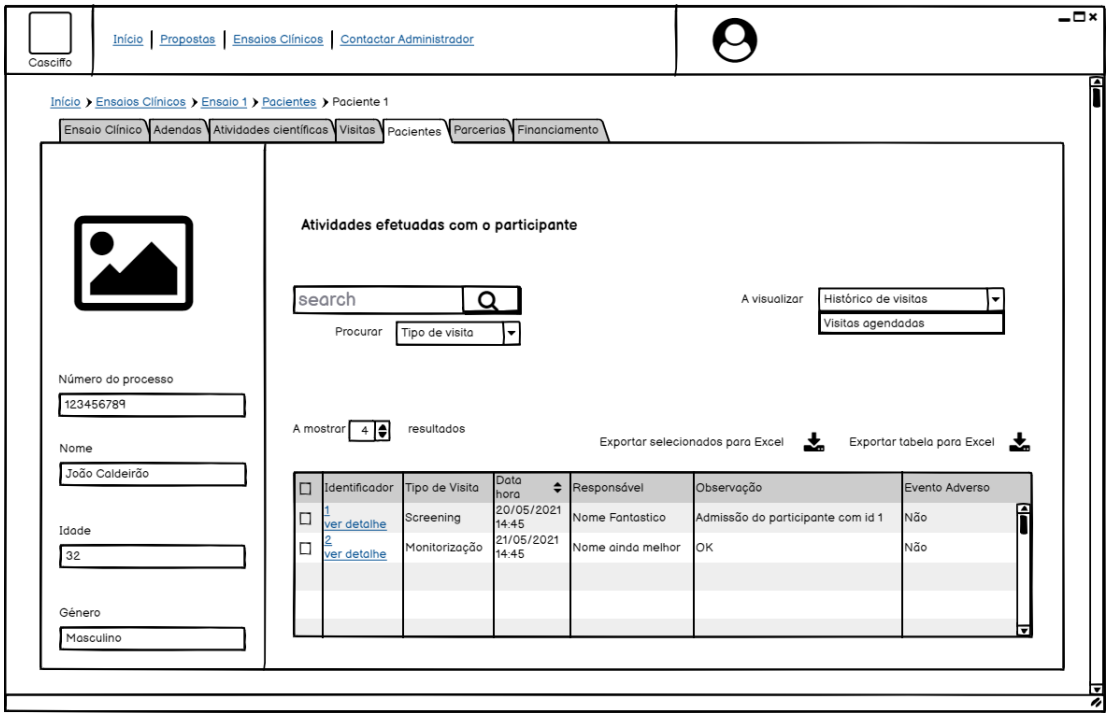

Figure 2.16: Mock overview of patient details.

2.5.12 Monitoring of physical and financial assets

In regard to the monitoring of physical assets, these can be viewed under the tab "Ensaio Clínico" while in the detail page of the clinical trial in question. The assets to be monitored are documentation archives, consisting of three fields: the Volume, a Label and the total Number. CASCIFFO also offers another type of monitoring, the monetary flow. As described in section 2.3.2, each clinical trial has a financial management section that discriminates the earnings made by visit and the partitions of each team member involved in the study. Under the tab "Financiamento", the general monetary information, such as, total balance ("saldo"), amount per participant, etc., is displayed on a top section of the page. Below this section it can be observed another two tabs, differentiating the income made from the investigation team and the clinical trial itself. The first tab "EC", shown in figure 2.17, shows the income made according to the visits done, whereas the second tab "Equipa", illustrated in figure 2.18, shows the income by team member.

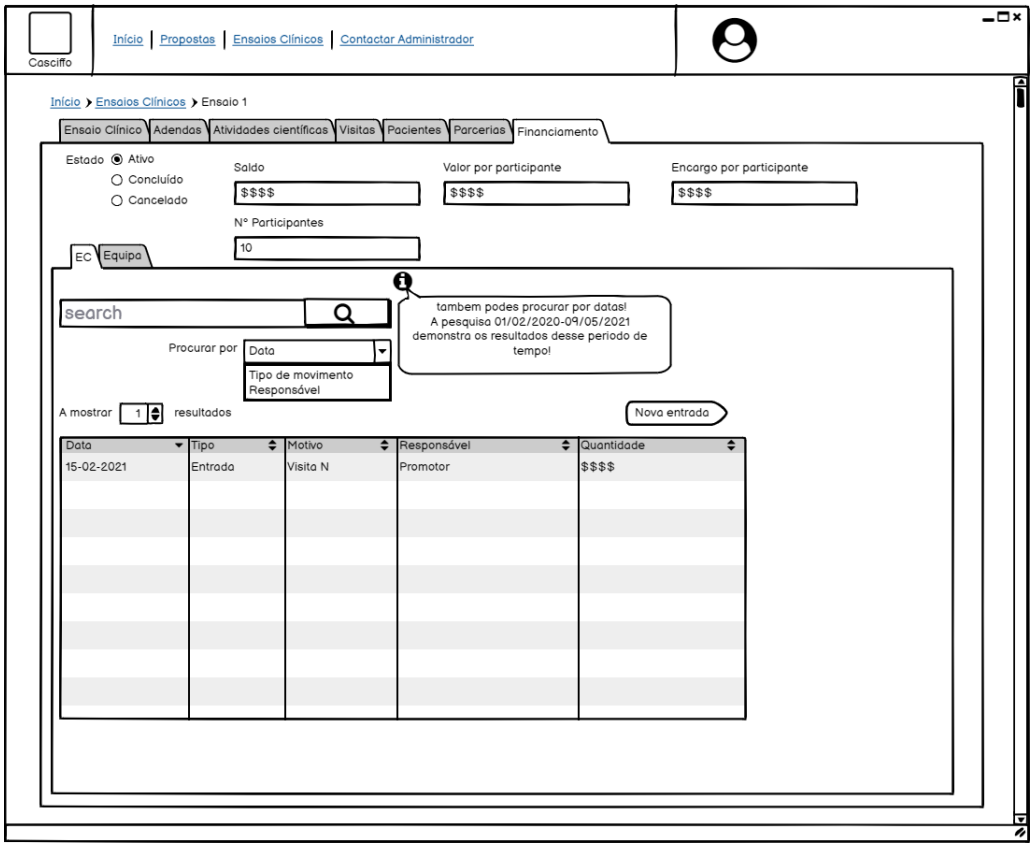

Figure 2.17: Mock detailed view of the income flow made in the investigation.

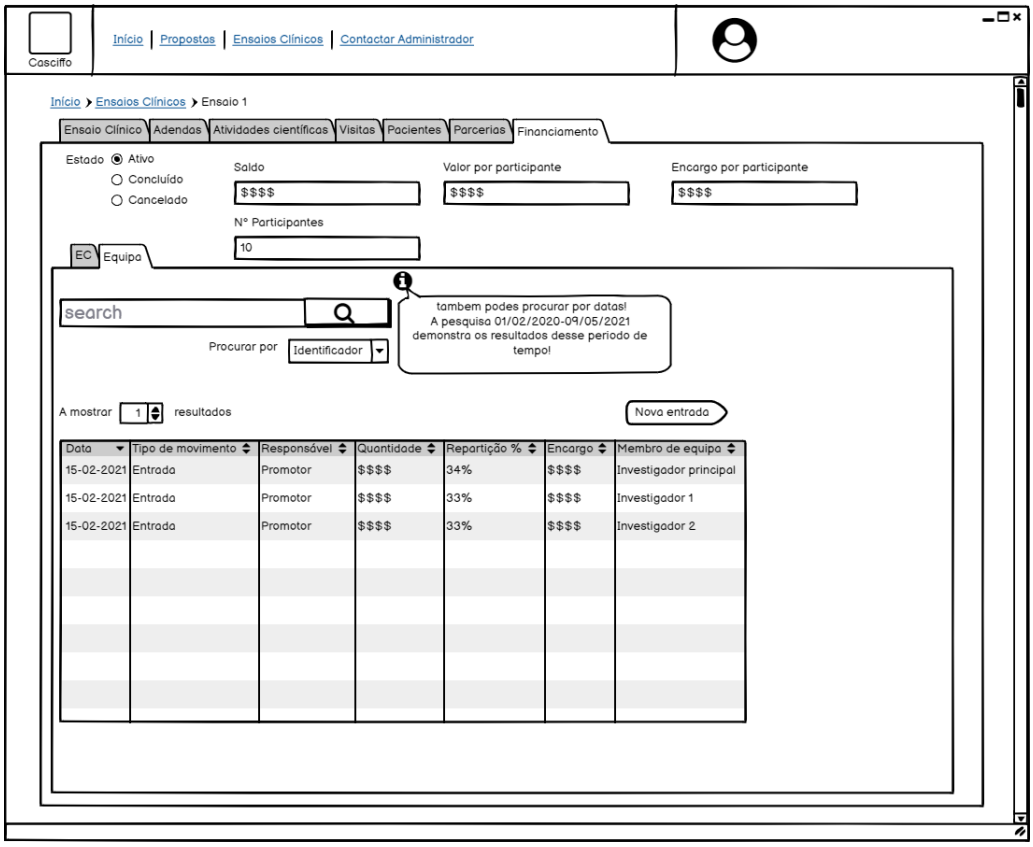

Figure 2.18: Mock detailed view of income flow divided by the investigator team.

2.5.13 Monitoring of visits & recording of adverse events

The monitoring of visits during a clinical trial can be tracked and viewed under the tab "Visitas", in the detailed screen of a clinical trial. In this setting, any investigator (associated to the clinical trial) is able to view and track the past and scheduled visits made by the team. However, only the investigators associated to a visit are able to manipulate them. When creating a visit, that visit will automatically be associated to its creator, giving also the option to associate other investigators to the same visit, allowing them to freely edit the visit details. Along with this option, the investigator is required to fill in the fields depicted in figure 2.19. These fields are as follows: the periodicity ("Períodicidade") that can be turned ON in case the visit is a reoccurring one with the ability to schedule at a custom interval in days; the type of visit ("Tipo de visita"), that has three possible inputs, Screening, indicating the first visit, Monitoring ("Monitorização") indicating a motoring visit and finally a Closeout visit, which indicates the final visit done to a participant. In case the visit is periodic, the field of 'end date' ("Data fim") becomes mandatory to fill.

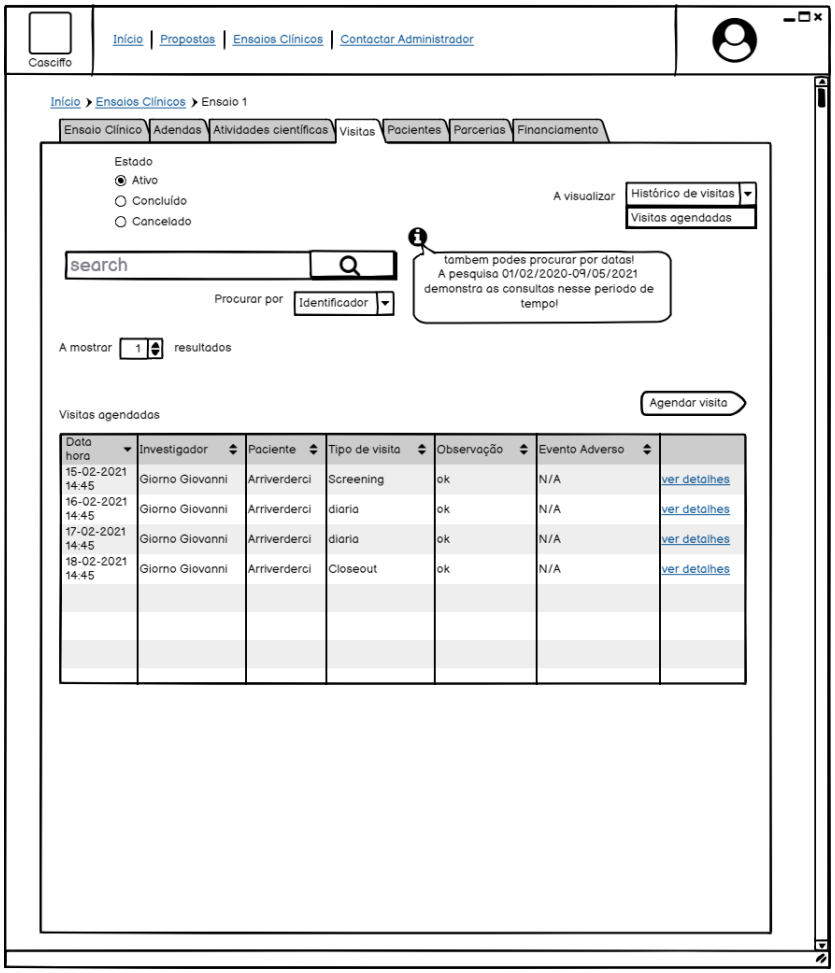

Figure 2.19: Mock overview of visits scheduled in the clinical trial.

When a visit occurs, the associated investigators will have access to the observations ("Observações") field and adverse event ("Evento adverso") warning. In addition to this, the field "Marcar presença" is now available to mark attendance.

Chapter 3

Conclusion

The management and monitoring of clinical trial data, is a arduous task for the researchers within the UIC, who have to contribute a considerable amount of effort and time into organizing the overview of clinical trials. To decrease this burden and optimize the management of clinical trials, the platform CASCIFFO has been proposed. This thesis has given me the chance to input my knowledge acquired throughout my academic path in Licenciatura and Mestrado em Engenharia Informática e de Computadores, being able to consolidate it into the platform CASCIFFO, and making a contribution to a cause I find very important. Throughout the current development of this thesis, I've had the on-going opportunity to meet and discuss with the HF-F/UIC team that is collaborating in the development of CASCIFFO, to solidify the groundwork for the platform. The groundwork consists of how the proposed functional requirements will be met through the usage of mock user interfaces, presented throughout this report. To conclude, the goal of this thesis is being achieved within an acceptable time-frame.

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