FrailSafe eCRF

Clinical Data collection tool

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***Abstract*—In the context of European funded FrailSafe project, to enhance the clinical data collection processes in geographically distributed trials centers, an eCRF software platform has been designed and implemented. The most important features are synthetically described.**

Keywords: eCRF; Cloud; eHealth; Monitoring; Data collection.

I. INTRODUCTION

The Case Report Form (CRF) may be defined as "a printed, optical or electronic document designed to record all of the protocol" [1]. Extending this definition, a CRF could be described as a tool designed to collect data about a patient state during a clinical trial, e.g., the patient information, the measurements and others. It represents a significant instrument for the performance of a clinical trial and its efficiency could positively affect the success of a medical research.

CRF is designed for improving the collection of data in compliance with a research protocol and with regulatory requirements. Moreover, the researchers should be able to test the hypothesis or answer the trial related questions. A CRF represents suitably the essential contents of the defined research and study protocol.

A flexible eCRF has been implemented for FrailSafe project to provide the partners devoted to clinical research of such features.

II. FRAILSAFE ECRF

In the current global scenario of FrailSafe project, the development of an electronic CRF (also known as *eCRF*) has been preferred over a usual paper CRF for the following benefits:

- Eliminate unnecessary duplication of data.
- Reduce the possibility for transcription errors.
- Encourage entering source data during a subject's visit, where appropriate.
- Eliminate transcription of source data prior to entry into an eCRF.
- Facilitate remote monitoring of data.
- Promote real-time access for data review.
- Facilitate the collection of accurate and complete data.
- Possibility to have auto generated data (test results, calculate formulas, etc.).
- Easier data export and data analysis.

As mentioned above, the eCRF aims to support the clinical researchers during the trials by providing them a web application (appearing in this case as a plain website) through which tracking and managing the process of visiting the participants and enhancing the related data collection, as depicted in Figure 1.

With the objective of supporting the trial processes in mind some functional features are needed.

These are:

- Users Management.
- Participants Management.
- Trials Management.
- Devices Management.
- Data Collection.

For enhancing the quality, the reliability, the usability and the security to reach the common goal, some other aspects of the application have been taken into consideration while designing the software.

They are detailed in the following sub-paragraphs.

A. *Cross-platform and Multi-device*

The eCRF is a web application. This means it behaves and looks like a common website and that it can be used through any simple web browser (e.g., Chrome, Firefox, Internet Explorer, Safari and Opera); thanks to that, it is immediately available on every device providing a web browser and an Internet connection (laptop, smartphone, tablet, etc.), not needing any further technical requirements. A mobile-first approach has been followed in the design of the UIs.

B. *Authentication and Encryption of Data*

Security is guaranteed through the usage of authentication means, i.e., a username and a password are needed for accessing to the application and its resources – and through data encryption. Data is encrypted before being stored on database and, in communication, a standard

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protocol for secure communication over a computer network is adopted to protect the privacy and the integrity of exchanged data.

C. *Data quality*

In the eCRF, the clinical staff collects the patient information during the trial in the same ways and means as if doing it on paper - that is through questionnaires, forms, etc. – but displayed instead on a device screen. During the data addition or before saving, the system checks the coherence of the data and in case something is not correct it helps the user with feedbacks. For example, the participant information cannot be inserted in the system if all the mandatory fields are not filled or it is not allowed to type characters in a field that is a measurement value, etc.

D. *Multilanguage*

The eCRF system, for the FrailSafe project, is used in three different countries (France, Greece, Cyprus); so the system can support the different languages to help the clinical staff and the participants to avoid translation errors or misunderstandings during the trials execution.

III. CLOUD INFRASTRUCTURE

For guaranteeing a perpetual availability of the system to the clinical staff, the eCRF is hosted on remote servers. On these latter the collected data, thus, are stored securely and can be used by the system and by the researchers to succeed in the medical research carried on by FrailSafe.

Moreover, the efficiency and the security of the system rely on a number of Cloud services and features.

IV. CONCLUSIONS

In conclusion, this web application is designed and implemented for assessing correctly the objectives of the project and of the related medical research. Moreover, it is worthy to add that the designing and the implementation of the eCRF has been an important experience for those having contributed to its design and implementation. It proved to be a good example of interdisciplinary and collaborative production of a technological tool. It has seen the close participation of clinical and ICT partners, from different countries, making them willingly and passionately working together to reach a common goal, i.e., implementing the clinical trial protocol by the mean of an ICT instrument – showing evidently the benefits of sharing different backgrounds and skills.

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For further details, refer to [2].

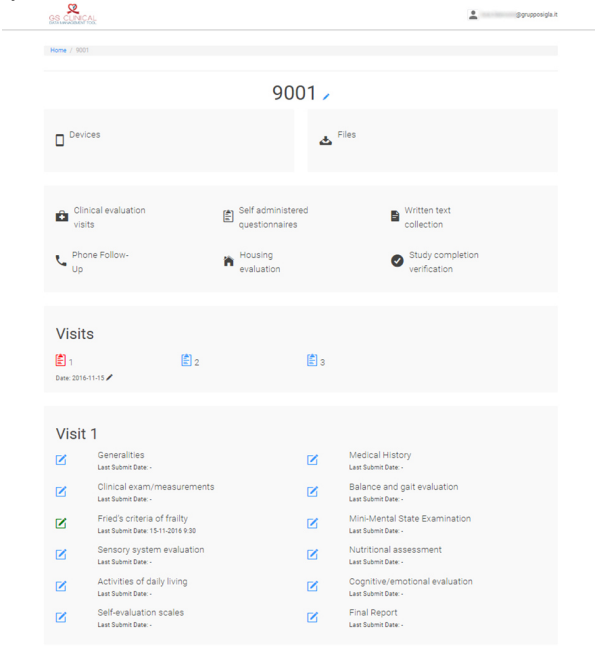

Figure 1. Main Clinical Staff dashboard

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[1] Guideline for Good Clinical Practice, ICH Harmonised Tripartite Guideline, 1996.

[2] www.frailsafe-project.eu

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