

Protocol of Validation Mechanisms Within the Design of an Electronic Case Report Form for the MULTI-SITA Project

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Abstract. With the wide diffusion of web technology, dedicated electronic Case Report Forms (eCRFs) became the main tool for collecting patient data. The focus of this work is to thoroughly consider the data quality in every aspect of the design of the eCRF, with the result of having multiple steps of validation that should produce a diligent and multidisciplinary approach towards every step of data acquisition. This goal affects every aspect of the system design.

Keywords. eCRF, interface design, data quality, validation protocol

1. Introduction

Gathering data is central to the health care process [1], but it comes with the cost of a general complexity, that affects every aspect of the systems used to collect and validate the data [2]. Electronic Case Report Forms (eCRFs) have already proven themselves to be the key tools to achieve the control over the difficulties that the need of large and complete data provokes, however not every design guarantees the same disturbance rejection and completeness of data quality [3]. A strict collaboration in the development of our eCRF with the medical researchers of the Italian Society of Anti-Infective Therapy (*Società Italiana di Terapia Anti-Infettiva, SITA*) constituted a key aspect in the development our common platform (MULTI-SITA project) [4][5].

2. Materials and Methods

The web application is constituted by a client, written in *Blazor*, a Microsoft SQL Server database and an *API RESTful service*, which handles the communications between them. We followed acknowledged design principles for creating an ergonomic GUI [2][3].

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3. Results and Discussion

The Database schema consists in a central entity – the patient – with multiple related forms that represent different aspects of the hospitalization, such as Medical History, Microbiology and Laboratory results. When all those forms are marked as “Completed” the patient can be submitted to the medical revisors, who will be able to generate written queries in case of any error or inconsistency, handing back the patient for correction. Every action is performed through the GUI, ensuring full control and guidance. To achieve the most complete data we have adopted two additional approaches:

- Distinction between NULL and Not Available. As example, each field that can be answered with a Boolean logic, should also be able to be answered with “No data available” and NULL, where the latter will indicate a not compiled field and thence an incomplete form. This allows the user to reset safely its input in case of uncertainty and an asynchronous filling of the same form.
- Most fields with structured data include an “Other” option, i.e., a free text option.

The intrinsic validation mechanisms of web forms, e.g., type compliance or value ranges, could not handle these new implementations, so we developed a higher-level protocol, which operates only after the automatic validation assured the low-level compliance. This validator consists in pure code that performs the additional logic checks required, e.g., if a user chose the “Other” option, they must write the answer in the textbox that bears that value. Whenever a form is saved, the validator determines whether it is Complete or not, and the status is represented through the GUI with a colored indicator. Being based on ad hoc code, this validator includes form-dedicated data examination from a medical point of view, achieving a multi-disciplinary validation. This operative design has been already adopted in 3 multicenter studies with a total of 1200 complete and revised patients from 35 unique participating centers, and 2 more are in development.

4. Conclusion

In conclusion, eCRFs proved themselves to be exceptionally efficient in the management of broad and complex clinical data. Our experience proved that a pervasive collaboration between medical researchers and bioengineers is needed to consciously achieve the most complete and meaningful result. In this poster, the authors want to present the operative approach that resulted from this collaboration, highlighting the main points that constitute it, and the advantages and drawbacks associated with them.

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