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Pay for Performance in Electronic Data Capture for Clinical Trials and Medical Registries

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Abstract. Following the new medical device regulations, vendors need to track their products. Unlike to clinical research, data entry in such registries is done by staff that basically needs to ensure resident's treatment. Enforcing data completeness while entering is not an option anymore. In this work, we suggest an independent pay for performance system, that connects via REST to the registries. It allows to define rules that check data consistency and completeness, and rewards for records that fulfill the requirement. Rewards can be calculated manually or automatically by triggering evens, and they sum up for data entry persons or recruiting centers.

Keywords. Rule Engines, REST, Expert Systems, Value-based Reimbursement, Pay For Performance, Clinical Data Registry

1. Introduction

Clinical trials and medical registries are based on electronic data capture (EDC) systems, where users manually fill the fields with required information, usually using a web-based interface. In clinical trials, as a benefit of EDC, the system enforces completeness and correctness of data. As a drawback of this strict enforcement, storing of already entered information is not possible if required fields are missing. If data is entered by staff that is non-exclusively working on clinical research, such an interface is bothering, and other motivations to achieve data completeness are required. We suggest to apply the pay for performance principle [1] to allow users to stop and continue data entry frequently without any loss of data already entered and to ensure data completeness. Simply, a honorarium is given only for records that fit the expected quality.

2. Related work

The developed system is based on 2 concepts: rule engines and reward strategies.

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2.1. Rule-based expert systems

Rule-based systems (a special case of expert systems) are the simplest form of artificial intelligence. A rule-based system applies rules on the data for knowledge coded into the system [2]. Medicine is one of the first fields where expert systems have been widely applied: *Mycin* [3] is a rule-based expert system developed in 1970. Current knowledge base consists of approximately 400 rules and thousands of facts regarding meningitis infection. Mycin influences state-of-art expert systems. Based on specific questionnaires, the system diagnoses a possible disease and provides related treatment. For this particular task, the simplicity of knowledge representation and straightforward control is sufficient.

2.2. Reward strategy

Encouraging employees is important for the company, since each employee must evolve and be motivated. In addition to regular salaries, there are supplementary opportunities for inspiration:

- *Profit Sharing* is a process of encouraging employees by dividing the overall net profit [6]. Amount of the given reward is calculated based on employees salary and contribution.
- *Stock Options* is a process of purchasing a certain amount of company's shares for a fixed price [5]. This reward program is only applicable to the long-term employees, particularly for their dedication and contributions.
- *Pay for Performance* (or variable pay) or is a type of compensation to the employee for certain performance [4]. The amount of remuneration may vary on the made contribution. The hospital value-based purchasing program [7] is such a system that aims to calculate payment based on the quality of provided services in hospitals, rather than its quantity. This calculation involves patients' grade regarding the faced services. The program evaluates hospital's performance based on two scores:
  - ∗ *Achievement points*: comparison of particular hospital's rating during performance period with all hospitals' rating from baseline period.
  - ∗ *Improvement points*: comparison of particular hospital rating during performance period with its rate from baseline period.

  The system is successfully integrated and still in use. Based on the calculation, it determines the hospitals with high-quality care.

3. Reward system model

All developed incentive strategies can be generalized. They all take into account the existence of the goal and the possibility of its achievement. The process takes into account the complexity of the goal and the degree of its completeness. Including mentioned factors, we can describe our workflow extensively. The goal of our system is to gather all relevant information from the EDC. The level of compliance is defined by healthcare providers. Each eligible information set will be rewarded in the future. The strategy may increase the usage of clinical trial systems and therefore increase the number of inputs.

3.1. Data collection

The rule-based reward system is independent from EDC systems. In order to obtain the data, the reward system connects to the targeted system and exchanges information such as:

- *Departments* are healthcare providers, also known as recruiting centers.
- *User* is a person, who provides the patient-related information. Basically users are compensated by reward system.
- *Patient* is a person that requires medical treatment. It is also known as a research area or a study group.
- *Visit* is a set of modules grouped by a specific medical criterion. The medical definition of a visit is to support communication with a patient during treatment or diagnosis period in order to examine or to monitor a given treatment or disease.
- *Module* is a specific form containing medical questions. Modules are grouped visits.
- *Field* refers to the question inside of the form (module). Each module has a list of specific questions, where the field is a particular element in that questionnaire. Each field has a specific data type. Each developed rule has its own application area, which is limited by the data type of particular field.

In order to establish connection to the other systems, we used representational state transfer (REST) architecture, which is often used in Web-based applications [8].

3.2. Rule generation process

Rule engines were applied in order to reduce the complexity of the search process, inside of the clinical trial systems. A rule is a principle or regulation guiding conduct, action, procedure, arrangement, etc. [9].

Information is called eligible for the health care providers if it is meeting predefined criteria, which is described in the rules. Therefore, we can imply that the aim of the rule is to obtain the set of required information, which is also known as clusterization process. Execution of the rules is performed only after completion of the data extraction process. This sequence is important since rules are applied directly to the patient-related data. Reward system distinguishes rules by their complexity, which means that the main feature among the rules is the number of their conditions. The system supports 3 type of rules:

- *Simple rules* are composed only of a single condition and they are limited by the data type of the applied object. This limitation prevents erroneous application of the numerical rules towards to string rules. The reward system contains the following rules:
  - *Existence* rule checks the existence of the value inside of the particular field.
  - *Strict Value* rule compares the object's value with the provided one in advance.
  - *Higher Boundary* tests whether the given value is higher than the extracted value.
  - *Lower Boundary* tests whether the given value is lower than the extracted value.

- *Complex rules* are combinations of rules, both simple and complex, that are connected with each other with a specific condition. Based on the condition, complex rules are distinguished into 2 types:
  - *Combination Rule AND* is used whenever all elements of the complex rule have the same priority of execution.
  - *Condition Rule OR* is satisfied when at least one of the provided rules will match.
- *Interconnected rules* separate visits into 2 types, rewardable and responsible. Aim of these rules is to bring dependency among visits. Interconnected rules have 3 types:
  - *Weak mapping* is the basic type of interconnected rule. The main idea of this rule is to select rewardable and responsible visits. *Rewardable* visit is the one whose price is taken into account when the rule is satisfied by the information inside of *responsible* visit.
  - *Full mapping* is used, when its required to compare two fields from two different visits. The application process of this rule is the sequential selection of the rewardable and responsible fields and the required condition. A typical example of this rule can be the patient whose weight differed between the first visit and the second.
  - *Full mapping with parameter* is an extension of the *Full mapping* rule. This rule type brings additional parameter to the applied condition among the compared two fields. Including the example provided in the rule above, we can add an additional parameter, such as the weight difference, in particular 20 kg.

3.3. Reward process

The determination of the required information is the first step in the reward process. This step uses predefined rules and loops inside of the clinical trial system. Its aim is the identification of the targeted group of patients. The patient's belonging to the required information set is determined by the match of his data with the applied rule. If the patient's affiliation is true, then its identification number along with the number of the corresponding rule is added to the appropriate reward set.

The calculation of the payment amount entirely depends on rules and departments. It is performed since the price is tied to visits and is not part of the applicable rule. Including the data hierarchy we can conclude that the user, whose information about the patient will meet the requirements of the rule, will receive the amount from his belonging department.

4. Results

Reward systems visualizes processed information in pdf representation. Contents of these files include reward amount and list of eligible visits (Fig. 1).

Each report belongs to one particular department and all information is linked to the recruiting user of that department. The system has been used to pay for performance in an medical device follow-up registry. In a quarterly process, 802 visits of 622 subjects

recruited by 24 users in 6 centers were processed. In total 6 rules were applied, and 70% of visits have been rewarded.

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eReport R01-05-10: Abrechnungsübersicht

Benutzer	Stadt	Gesamt	Zahlbar	Bezahlt	Zu zahlen	Total [€]	Vergütung [€]
[redacted]	Berlin	347	334	191	143	6,550.00	7,794.50
[redacted]	Berlin	85	73	63	10	300.00	357.00
[redacted]	Berlin	161	160	147	13	390.00	464.10
Summe						7,240.00	8,615.60

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eReport Pay-01-02: Visitenübersicht 31-12-2018

Zeitraum	Visite	Visitendatum	Zahlbar	Bezahlt
005-PAT-0001	Baseline	2017-08-14	Ja	12-21-2017
005-PAT-0001	End of Trial	-----	Nein	-----
005-PAT-0001	Follow-Up	-----	Nein	-----

Figure 1. Payment Overview and Valid Visits

Together with the accessibility of the generated invoices in the native reward system, there is also a possibility to obtain them via REST request. Usage of this procedure is limited due to the existence of authentication. The reward system is also capable of sending the generated files, via e-mails, to the responsible users.

5. Conclusions

Rule based reimbursement or reward system is targeted to increase the usage of clinical trial systems. Together with the reimbursement functionality, it is called unique due to the absence of integration restrictions, ease of use and simplicity. The REST architecture allows to use the externally stored information sets, extract their data, and use them for further processing. The rule engines, on the other hand, give an opportunity to define the patterns. These developed rules may have a large set of conditions and can be adjusted based on the given requirements. Our reward system provides visualization and transmission options of the obtained results in both reward and native registry or EDC systems, where transmission is the process of transferring invoices to the other users by emails.

In future, we want to add additional features such as debts: Visits that have already being reimbursed might be no longer valid if the rules were changed. So, it takes a counter called debt. The purpose of this object is to recalculate the paid visits and the corresponding subtraction of the existing ineligible ones.

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