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ezTrial

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1. Introduction

1.1 Purpose

ezTrial provides users with a web-based clinical trial management service, which is simple to operate and can be conveniently accessed from the internet. The service provides the function of creating and designing multiple clinical trials with predefined study plans, and is able to integrate customized phase assignment rules within each trial. The service provides easy to use visit-scheduling and recording functions with user friendly interface, and the recorded data can later be searched and exported for further analysis. The service also provides the progress report function for consistent data tracking. All the data are securely stored in the database and protected by user-specific authorizations and permissions.

1.2 Definitions, acronyms, and abbreviations

User: when an individual owns an account to access the ezTrial service, the account is referred to as an User. Each user is assigned a role to limit the level of access. The roles are: Administrator, Doctor, Nurse, Researcher and Sponsor.

Trial: is a research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease.

Phase: is a path within a certain stage of a trial in which the patients participate in. For example a Treatment stage could have an Arm1 phase and an Arm2 phase which represents two distinct medication treatment groups in the Treatment stage.

PhaseGroup: is a certain scheduled stage in a trial in which the patients of that trial participate in. A trial may own more than one phaseGroup, and the phaseGroups follow an ordered sequence according to its study plan. For example, a trial could be divided into two phaseGroups, in the order of Screening and Treatment.

Visit: is an event in which a patient makes an appointment with a doctor, the doctor performs checks on the patient and records the result data on forms. On the ezTrial service, a visit is created and registered under the visit management function, and is scheduled according to the trial's study plan.

VisitMeta: is a configuration element use to store visit information such as the interval of the visit and the forms to be filled out on this visit.

MRN: is an abbreviation for Medical Record Number.

FormGroup: is a concept element use to group different forms together so that the

common dataTypes on these forms can be searched simultaneously.

Case number: is an unique serial number that is generated by the system to indicate a patient's identity.

2. Overall description

Clinical trials are conducted to allow safety and efficacy data to be collected for new drugs or devices. These trials can only take place once satisfactory information has been gathered on the quality of the non-clinical safety, and Health Authority/Ethics Committee approval is granted in the country where the trial is taking place.

Depending on the type of product and the stage of its development, investigators enroll healthy volunteers and/or patients into small pilot studies initially, followed by larger scale studies in patients that often compare the new product with the currently prescribed treatment. As positive safety and efficacy data are gathered, the number of patients is typically increased. Clinical trials can vary in size from a single center in one country to multicenter trials in multiple countries.

In response, clinical trial management systems are developed to manage a large amount of data involved in the operation of a clinical trial. It maintains and manages the planning, preparation, performance, and reporting of clinical trials, with emphasis on keeping up-to-date contact information for participants and tracking deadlines and milestones such as those for regulatory approval or the issue of progress reports.

2.1 Service perspective

ezTrial is a stand-alone web service which serves as a clinical trial management system. This service is aimed for Institutions or hospitals conducting clinical trials requiring a software system to manage the research process.

2.2 Service components

The ezTrial service consists of the following components:

1. System management: this part of the service consists of administrative and design functions that only users with the administrator role are permitted to operate on these functions, which are listed below:
 - I. User management: this function displays all the users on the ezTrial Service with paging, and allows the administrator to search for users by their names. This function also allows the administrator to create and modify users on this service, and allows the administrator to edit user Pii permissions. A user is specified with a role and a selection of trials that can be accessed by this user. The Pii permission is a function that limits the level of data access for a user by referring to doctors. The user can either access the complete data of a patient, the masked data of a patient or

cannot access the patient at all.

- II. Institution management: this function displays all the institutions on the ezTrial Service with paging, and allows the administrator to search for institutions by their names. This function also allows the administrator to create, modify and delete institutions on this service. Institutions are used when the administrator is creating or modifying an user to indicate which institution the user belongs to.
- III. Configuration management: this function allows the administrator to define elementary components that can be used when building a trial. This functions further consists of the following functions:
 - i. Term management: this function displays all the term categories and terms on the ezTrial Service with paging, and allows the administrator to search for term categories and Terms by their names. This function also allows the administrator to create, modify and delete term categories and terms on this service. The administrator is also able to input the ICD9 and/or the SNOMED code for a term . Terms are used as dataSelections when creating a dataType with the Collection data format or as diagnoses belonging to a specific trial.
 - ii. DataType management: this function displays all the DataTypes on the ezTrial Service with paging, and allows the administrator to search for dataTypes by their names. This function also allows the administrator to create, modify and delete dataTypes on this service. DataTypes are divided into five data formats: Boolean, Date, Number, String and Collection and are used as questions when creating a form which can be filled out later in the trial.
 - iii. FormTemplate management: this function displays all the formTemplates on the ezTrial Service with paging, and allows the administrator to search for formTemplates by their names. This function also allows the administrator to create, modify and delete formTemplates on this service. The creation of a formTemplate is similar to the creation of a form and serves as a template when the administrator wishes to create a form with similar sections and dataTypes to the formTemplate.
 - iv. Form management: this function displays all the forms on the ezTrial Service with paging, and allows the administrator to search for forms by their names. This function also allows the administrator to modify and delete forms on this service, and allows the administrator to set the dataTypeMappers of a form or create a new version of a form. The

administrator is required to set the `dataTypeMapper` of a form if the form has its special search option enabled, and the `dataTypeMapper` function maps a number `dataType` to a date `dataType`. Once a form has been filled out, its structure cannot be modified; however the new version function allows the administrator to create an identical and modifiable copy of the original form and replaces the original form, which will be deactivated but not deleted. Note that if the new version form belongs to a certain phase then this new version form will take over the place of the original form and appear in the “Unfilled Form Record” sector.

- v. **FormGroup management:** this function displays all the `formGroups` on the ezTrial Service with paging, and allows the administrator to search for `formGroups` by their names. This function also allows the administrator to modify and delete `formGroups` on this service. `FormGroup` allows the administrator to group forms together so that interrelated data can be searched and analyzed. The user builds a `FormGroup` by selecting the forms he/she wishes to group together, and from all the `dataTypes` among the group of selected forms, the user selects specific `dataTypes` he/she wishes to include in the `FormGroup`.
- IV. **Trial management:** this function allows the administrator to create, modify and disable trials on this service. The administrator builds the trial work flow from this function. This functions further consists of the following functions:
 - i. **Diagnosis management:** this function allows the administrator to create, modify and delete diagnoses which belongs to a specific trial. Diagnoses are used when creating or editing a patient to note the patient’s diagnostic results. Diagnoses are also used in the advanced search function to search for patients with specific diagnoses.
 - ii. **Randomization management:** this function allows the administrator to create, modify and delete Randomization sequences which belongs to a specific trial. Randomization is commonly used when assigning a patient to the treatment phase, where the patient will need to be randomly assigned to a control group or a treatment group. Depending on the randomization method, the administrator will need to create one or more randomization sequences and these randomization sequences will work together with the rules defined for the assignment conditions of this trial.

- iii. PhaseGroup management: this function displays all the phaseGroups belonging to a specific trial and allows the administrator to create, modify and delete phaseGroups within the trial. PhaseGroups represents the stages of a trial in which the patients participates in, and are therefore displayed in an ordered sequence. The administrator chooses to create a phaseGroup and append it to the last position of the sequence or insert it to a position somewhere in between.
- iv. Phase management: this function displays all the phases belonging to a specific phaseGroup with paging, and allows the administrator to search for formGroups by their names. The administrator is also allowed to create, modify and delete phases within the phaseGroup. While phaseGroups represents the stages of a trial, phases are the number or paths within a stage. For example there might be a Treatment phaseGroup which represents the treatment stage, and within the treatment stage there might be an Arm1 phase and an Arm2 phase which represents two kinds of medication treatment paths.
- v. Form management: this function displays all the forms on the ezTrial Service with paging, and allows the administrator to search for forms by their names. This function also allows the administrator to create, modify and delete forms belonging to a specific trial or phase, and allows the administrator to set the dataTypeMappers of a form or create a new version of a form. The administrator creates a form by the following ways:
 - i. Create directly: the administrator builds the form by creating sections within the form, and select dataTypes to place within each section.
 - ii. Create from formTemplate: the administrator builds the form by selecting a formTemplate such that a form will be created as an exact copy of the formTemplate.

The administrator is required to set the dataTypeMapper of a form if the form has its special search option enabled, and the dataTypeMapper function maps a number dataType to a date dataType. Once a form has been filled out, its structure cannot be modified; however the new version function allows the administrator to create an identical and modifiable copy of the original form and replaces the original form, which will be deactivated but not deleted.

Note that if the new version form belongs to a certain phase then this new version form will take over the place of the original form and appear in the “Unfilled Form Record” sector.

- vi. FormGroup management: this function displays all the formGroups on the ezTrial Service with paging, and allows the administrator to search for formGroups by their names. This function also allows the administrator to create, modify and delete formGroups belonging to a specific trial. FormGroup allows the administrator to group forms together so that interrelated data can be searched and analyzed. The user builds a formGroup by selecting the forms he/she wishes to group together, and from all the dataTypes among the group of selected forms, the user selects specific dataTypes he/she wishes to include in the formGroup.
 - vii. VisitMeta management: this function displays all the visitMetas belonging to a specific phase and allows the administrator to create, modify and delete visitMetas belonging to a specific phase. VisitMetas represent the configurations of scheduled visits, and are therefore displayed in an ordered sequence. The administrator chooses to create a visitMeta and append it to the last position of the sequence or insert it to a position somewhere in between. When editing a visitMeta, the administrator selects forms that belong to the phase and sets these forms to be filled out for this visitMeta.
2. User settings: this part of the service provides functions that allow users to modify personal data, switch current trials and allows users with the role of administrator or doctor to transfer patients, which are listed below:
 - I. Personal data maintenance: this function allows the user to modify his/her own data, which includes: name, job title, phone number, cell phone number, email address and password.
 - II. Switch trial: this function allows user to change from the current trial he/she is in to other trials that this user owns. The change will persist when the user logs out and logs in again.
 - III. Transfer patients: this function allows the administrator or the doctor to transfer patients between trials. When the user has the role of an administrator, he/she must first select a doctor, and then select a trial to transfer from, and a trial to transfer to. The system lists out all the patients that belongs to the selected doctor and whom are in the from-trial and not yet in the to-trial. Otherwise when the user has the role of a doctor, he/she only requires to select a trial to transfer from, and a trial to transfer to, and

the system lists out all the patients that belongs to this doctor and whom are in the from-trial and not yet in the to-trial. The user selects the patients that he/she wishes to transfer from the list and execute the transfer function and the selected patients will be created in the to-trial.

3. Patient management: this part of the service provides functions to schedule visits for the patients and to create, modify and withdraw patients. The functions are listed below:
 - I. Patient record: this function displays patients that are scheduled for today's visit or display patients by other search results. The user is able to search for patients by their last name, first name, MRN, and phaseGroup. The user is also able to search for patients who have delayed their visits. This function allows the user to create and register a visit for a patient and allows the user to fill out forms that belong to the current trial and forms that belong to a certain visit. Forms belonging to the current trial indicate that these forms might be filled out any time during the entire trial process, and the user is provided with a historic record interface to view and modify the trial forms that has been filled out during the trial. The user is also provided with a visit record interface to keep track of the forms that belong to the visit level. The interface is organized in the order of scheduled visits, and within each visit, the interface displays forms in a "Unfilled Form Record" sector and a "Filled Form Record" sector. If the user needs to modify the content of a form once it has been filled out, he/she is required to state the reason of why the content of the form has to be modified.
 - II. Patient maintenance: this function further consists of the following functions:
 - i. Patient information: this function displays all patients that belong to the current trial and have not been withdrawn. The user is able to search for patients by their last name, first name, MRN, or phaseGroup. This function also allows the user to create and modify patients belonging to a certain trial, and allows the user to assign patients to the next phase, or withdraw patients. The function of creating a patient requires the user to input an identity number, and the system uses this number to check for existing patients in the current trial or in other trials. If the patient already exists in the current trial, then the creation function will be switched to the function of modifying this existing patient. Otherwise if the patient exists in other trials, then the creation function continues, however, when the patient has been created and saved to the current trial, the

system will send an email to the doctor who own the patient in other trials to inform that this patient has been recruited into this trial. The function of assigning patients to the next phase is a rule-based function which is configured according to the trial work flow. A patient will be successfully assigned to the next patient if he/she meets the assignment condition defined in the rule, otherwise the patient is not assigned, and in both situations, the system alerts the user with a message regarding the assignment outcome of the patient. The function of withdrawing patients allows the user to terminate the patients' involvement in the trial conduct such that the patients are no longer the subjects to the visit scheduling process. The user is able to note the withdraw status and reason when withdrawing a patient.

- ii. Withdrawn patients: this function displays all patients that belong to the current trial and have been withdrawn. The user is able to search for patients by their last name, first name, MRN, or phaseGroup. The user is also allowed to modify the withdraw status and reason of a patient.
4. Data analysis: this part of the service provides functions to search of patients and export patient data, which are described below:
 - I. Advanced search: this function allows the user to search for patients in the current trial by building a criterion or add it to the criteria list and search for patients altogether according to the criteria list. A criterion is a query sentence composed of the following subjects:
 - i. Patient data: this criterion consists of patient's case number, Id number, MRN, last name, first name, gender, birthday, phone number, zip code, address, doctor, nurse, diagnosis and Arm combined with an operator and a value to complete the query sentence. For example, if the user wants to search for male patients, then he/she builds the query by selecting "Gender", "is" and "male".
 - ii. Form: the user builds this criterion from the forms in the current trial with the search option enabled, the sections of a specific form, the dataTypes from a specific section, an operator and a value to complete the query sentence.
 - iii. Form special search: the user builds the criterion from the forms in the current trial with the special search option enabled, the sections of a specific form, the dataTypes from a specific section, a filter, an operator and a numeric value to complete the query sentence.
 - iv. FormGroup: the user builds this criterion from the formGroups in the

current trial with the search option enabled, the dataTypes from a specific formGroup, an operator and a value to complete the query sentence.

- v. FormGroup special search: the user builds this criterion from the formGroups in the current trial with the special search option enabled, the dataTypes from a specific formGroup, a filter, an operator and a numeric value to complete the query sentence.

Each criterion can be combined with other criteria by using either the AND expression or the OR expression. If the user chooses to combine a new criterion using the OR expression then he/she must first select an existing criterion from the criteria list and combine the new criterion to the existing criterion. While the user can always search for patients using the patient data criterion, the other four criteria may not always be available depending on how the trial is designed. After the user has executed the search, a list of patients will be displayed as the search results. The user then selects specific patients and continues to the export function to export form data for the selected patients.

- II. Export data: this function allows the user to export form or formGroup data for patients in the current trial. The user enters this function in two ways as described below:

- i. From the advanced search function: The user enters the export data function following the advanced search function. The search result provides a list of patients that match the search criteria and the user selects specific patients that he/she wishes to export their form or formGroup data.
- ii. Directly: The user enters the export data function directly, so that all the patients in the current trial are included for export.

The user selects the forms and/or formGroups he/she wishes to export and continues in two ways as described below:

- i. Export: The user exports the selected form and/or formGroup data directly and all the dataTypes within a form or formGroup will be included. The data will be exported in an Excel spreadsheet format.
- ii. Select dataTypes: The user is allowed to further select specific dataTypes from forms and/or formGroups that he/she wishes to export. After the dataTypes have selected, the user exports the data composed of the selected dataTypes from the selected forms and/or formGroups in an Excel spreadsheet format.

- 5. Progress report: