Available for users on 2014-11-11

New functionality

List of new functionality that has been added to this release.

The possibility to include randomization in studies has been added to this release of Viedoc:

Designer

- The designer can configure a study for randomization. This includes defining the randomization form and any un-blinded roles in the study.
- The randomization configuration defined is validated for uniqueness (so that two different configurations are not defined with the same name).

Admin

- The administrator can define an administrator role to configure the randomization for the study. This will typically be done by an un-blinded statistician.
- The administrator (typically the un-blinded statistician) can configure factors and outcome for the randomization list.
- The administrator (typically the un-blinded statistician) can generate, upload and view the randomization list for the study.

Clinic

· Site staff can randomize patients in the study.

Updated functionality and bug fixes

List of new functionality that has been updated in this release.

The following bugs have been corrected in this release of Viedoc:

- · ODM import was not linking forms to modified activities in the study design
- ODM import threw an error if a statictext variable was added to any item group

Known limitations

List of limitations that have been found with this and earlier releases of Viedoc, and will be changed in future releases.

- The export preview feature is heavy to load and might cause the application to feel
 unresponsive
- Only one (selected) language can be imported from each CDISC ODM file
- Only one (selected) design can be imported from each CDISC ODM file
- When the study workflow is saved, the language in the design settings are lost and have to be reset
- Visibility conditions (entry conditions) cannot be set for activities in common events.
- The next and previous links may not correctly reflect the number of subject filtered in some instances. Going back to subject selection and re-selecting a patient solves the problem.
- Opening a form might fail in some instances when using IE 8.
- The PDFs generated as Empty CRFs will not display all code list items for radio and checkboxes if these have been configured with many code list items in a vertical layout.
- The code list tables for dropdowns are not displayed completely in the CRF PDF if the code list has many items.

Signoff

Signature Confirmation by the product owner.

Uppsala, Sweden 2014-11-04

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Henrik Blombergsson PCG Solutions