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.

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