RadPlanBio portal - User Documentation

22nd April 2015

Contents

1 Overview of RadPlanBio

The RadPlanBio platform is a web-based solution for exchanging and sharing medical cancer treatment research data in order to allow multi-centric studies. The idea is to deliver a study management and electronic data capture system with special extensions dedicated to safe upload of medical DICOM files.

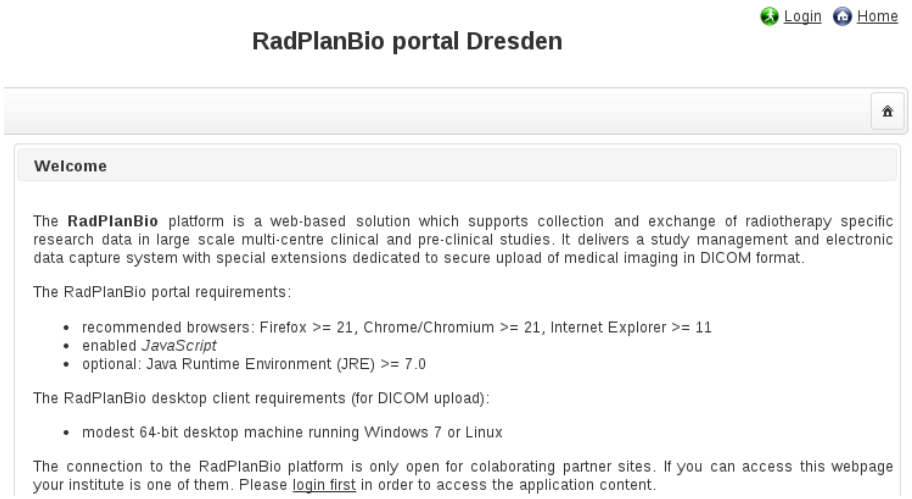

Figure 1: RadPlanBio portal home page.

1.1 Getting Started with RadPlanBio

This section explains how to log in, change your current active study and be aware of new things happening in RadPlanBio IT infrastructure.

1.1.1 Log In to RadPlanBio

To access the RadPlanBio platform, in your web browser go to the RadPlanBio-portal home page. If you do not know the URL address, please contact the local administrator of RadPlanBio at your site.

In order to navigate to the RadPlanBio login form, please click on first or second login link on the home page as it is highlighted in the Fig. **??**.

Afterwards you will be asked to provide your authentication credentials (user name and password) which will grand you role based access to the RadPlanBio features.

Note: RadPlanBio provides multiple authentication methods. The default way is to use the OpenClinica user account. With this account user can access complete range of RadPlanBio features (e.g. study as well as imaging data). However RadPlanBio is modular and could be deployed also to the environment without OpenClinica (with limited functionality), e.g. when different EDC system is used. For such a scenarios the user will have to connect with different authorisation method.

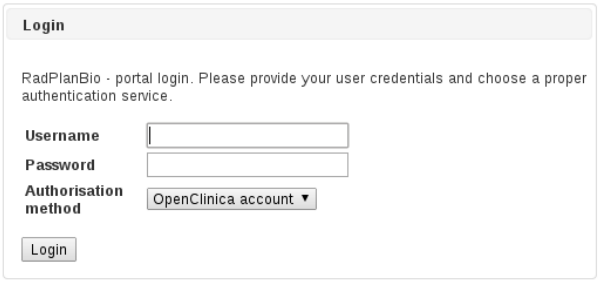

Figure 2: RadPlanBio portal login page.

1.1.2 Change a Current Active Study

When you use RadPlanBio, you usually work within a specific Study and partner site. The name of the current active Study is above the main menu at left side of the screen. In order to change the active study you have to click on the name of the active study in top menu, see Fig. **??**, which cause that the option ***Change Study/site*** will be shown. This option navigates to the study overview page, see **??**, where it is possible to change the active study for RadPlanBio (this change is also propagated to OpenClinica EDC tool).

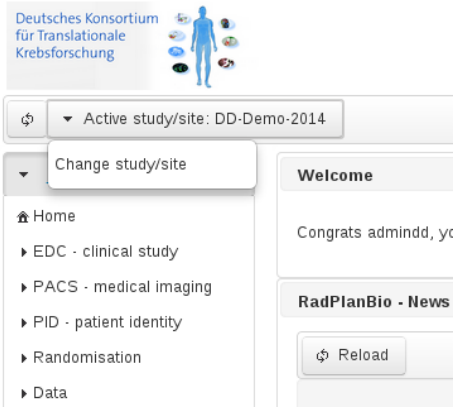

Figure 3: Change user active study in RadPlanBio.

1.1.3 Read RSS news

RadPlanBio has a simple RSS module, Fig. **??**, where administrator can publish important news about development and maintenance of RadPlanBio platform. This news are shown at the RadPlanBio home page, to get there just click on the ***Home*** option in main menu at the lefts side of the screen.

Figure 4: RadPlanBio RSS news.

Note: there is also a direct link to the RSS source in the footer of RadPlaBio portal. This link can be used to subscribe for RSS news updated from standard RSS viewer software.

1.1.4 Log Out of RadPlanBio

To log out from RadPlanBio, click ***Logout*** (above the bread crumb navigation, on the right). To use RadPlanBio again, log back in.

1.2 RadPlanBio Page Layout

The layout of RadPlanBio portal main page is separated to several areas with predefined features. Every page contains of the following areas depicted in Fig. **??**: Top of page (Header) - a), Top menu (Below the header) - b), Main menu (Left side) - c), Body of page - d), Bottom of page (Footer) - e).

Figure 5: RadPlanBio page layout.

1.2.1 Top of Page

The top of the page is the header area of the page. It contains (from left to right):

- RadPlanBio logo which navigates back to the RadPlanBio home page
- RadPlanBio partner site title
- Notification of logged user with login/ logout and home button

1.2.2 Top Menu

Below the top page header there is a top menu. This menu consists of:

- Notification of current active study for user (left)
- Bread crumb navigation to show where in the hierarchy of the menu the user is currently

1.2.3 Main Menu

The main menu is located at left side of the screen. It consists from the tree structured menu items which points to the concrete RadPlanBio modules. Which options are available depends on the type of logged user.

- Home
- EDC - clinical study
-
  - Open data capture tool
  - Studies/Subjects/Events
- PACS - medical imaging
  - DICOM studies
- PID - Patient identity

  - Search patient PID
- Randomisation
  - Patient randomisation
- Data
  - Query builder

1.2.4 Body of Page

What you see in the body of the page is depending on the module which you are accessing.

1.2.5 Bottom of Page

The bottom of the page contains:

- Home: RadPlanBio portal home page
- RadPlanBio Platform: Short introduction into the RadPlanBio project
- Licence: Licensing rules
- Software: List of software for download (RadPlanBio desktop client)
- Help: Link the on-line manual you are reading right now
- RSS: Direct link to RSS source for RadPlanBio portal
- Impressum:
- Contact: Send an email to RadPlanBio portal administration
- Version Number: The version number is for the RadPlanBio portal software you are using

2 EDC - OpenClinica

RadPlanBio's EDC module provide the direct integration with OpenClinica EDC software used for the purpose of study data management. It shows and overview of studies the user is allow to access as well as study subject information. This module allows registration a new study subjects utilising patient identity management system to provide patient unique PID.

2.1 Studies Overview

In order to browse the studies in RadPlanBio system, the user has to navigate to the ***Studies/Subjects/Events*** menu item from the main menu of RadPlanBio portal, see Fig. **??**.

The workflow for accessing studies via the RadPlanBio portal is as following:

1. Select the main study definition form combo box (only studies which you have access to are shown).
2. Select a study site from list of the sites in data table.
3. (Optional) activation of the study. see below the sub section **??**.
4. Afterwards you can see study details (sub section **??**) or navigate to study subject overview tab (sub section **??**).

2.1.1 Study details

It is possible to get a brief overview of study setting by clicking on details button in study data table, see Fig. **??**. The dialogue with study details is using study meta-data to display specific set of study parameters (e.g. how the generation of study subject ID should be done). Administrators can attach documents for each study which can be downloaded from this dialogue.

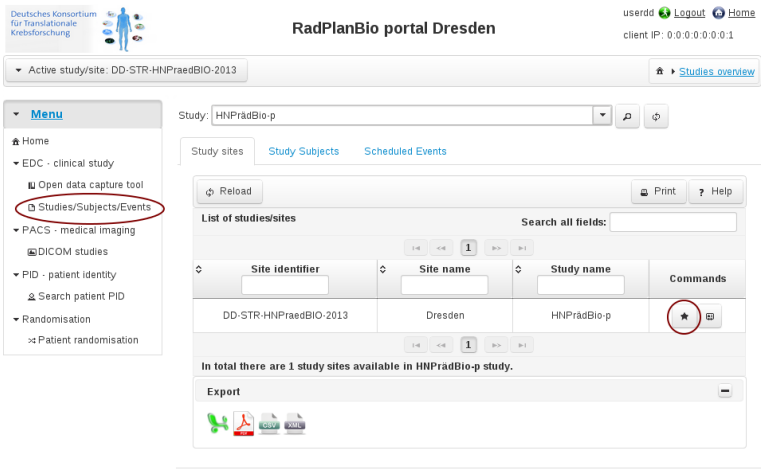

Figure 6: Overview of studies available for logged in user in RadPlanBio.

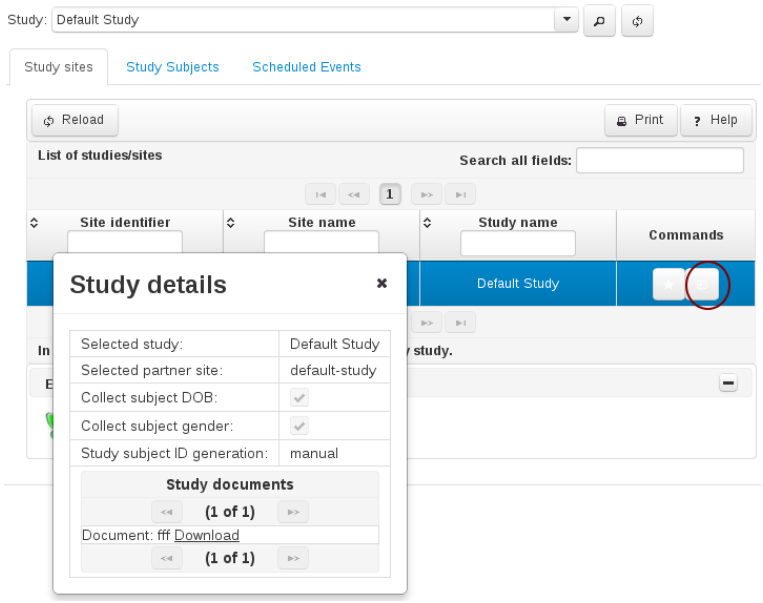

Figure 7: Study details dialogue where one can see study parameters and download study associated documents.

2.1.2 Changing Current Active Study

In order to change the currently active study of the user. He has to use study overview feature and find a new study he would like to active (selecting main study definition from combo box and selecting the study site from data table). The Fig. **??** depict the button with the ***Star*** icon which is use to active a new study.

2.2 Study Subjects Overview

In this tab you will see an overview of subjects which has been enrolled into the previously selected study and site, Fig. **??**.

2.2.1 Explanation of possible ID types

At this place it is important to explain that there are three types of patient identifiers which are used in RadPlanBio. Each of the type has its own purpose and one should understand what is the meaning of it:

- Study Subject ID: is identifying subject within one study. It can be automatically generated or manually specified (depending on study configuration). One patient taking part in multiple studies will have different Study Subject ID in each study. This ID has nothing to do with patient identity and cannot be use to obtain first or last name of patient no matter what.

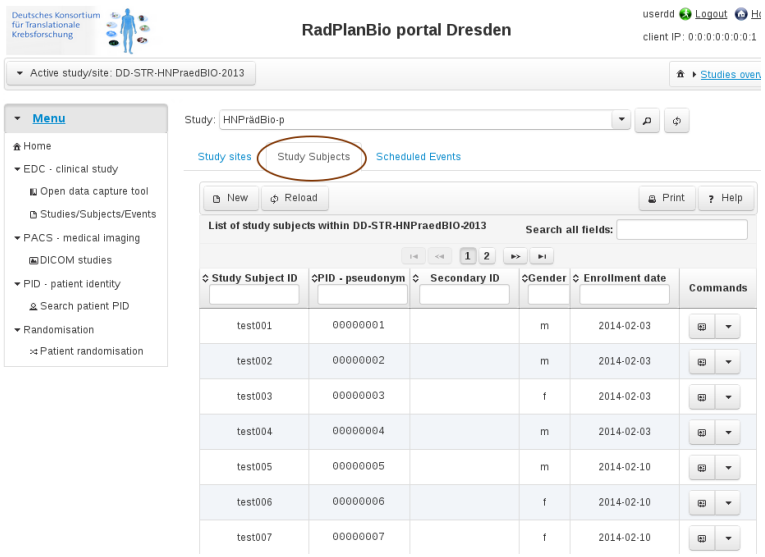

Figure 8: Study subjects.

- PID - pseudonym: is a unique identifier of the patient in RadPlanBio platform. One patient taking part in multiple studies will have the same PID in each one of them. It is generated from patient identity data (first name, last name, etc.) by patient identity management system in RadPlanBio. It is possible to not to use identity management system and manually provide PID, but in this case one has to guarantee the uniqueness of PID per patient and store the identity association somewhere outside of RadPlanBio. PID is also used in case of DICOM Patient ID flag when DICOM imaging data are uploaded.
- Secondary ID: sometimes it is useful to store patient ID from different systems (e.g. hospital information system such as Orbis) and associate this ID to our study subject. And for this case we have a possibility to use this secondary ID field.

2.2.2 Registering a New Study Subject

Before the new subject can be enrolled to the study, it is usually necessary to generate PID for this subject (When PID generator aka patient identity management system is used), see Fig. **??**. The user is asked to fill some basic identity data. The optional identity data (like place or residence, ZIP code and maiden name) are recommended if they are available for data entry personnel in order to guarantee uniqueness of generated PID. After data is provided the click on button ***Generate*** will trigger the process. The algorithm is trying to figure out if the patient with provided identity data is already in registered in the system (return his PID) or if it is new patient (generate new PID). After PID is provided the second ***Submit*** button is responsible for triggering the enrolment of the subject to the study.

2.2.3 Reading Study Subject Identity

Once the patient is successfully registered and enrolled into the study it is easy to get get back his identity details when necessary (according to PID), see Fig. **??**. The identity information stored in patient identity management system is retrieved when the user click on ***Depseudonymize the subject*** button.

2.3 Scheduled Study Subject Events Overview

This tab is showing the table of events which have been scheduled for subject in this study. No more functionality is implemented here right now.

2.4 Direct access OpenClinica

By clicking on ***Open data capture tool*** link in the main menu at the left side of the page, you can directly navigate to OpenClinica EDC system.

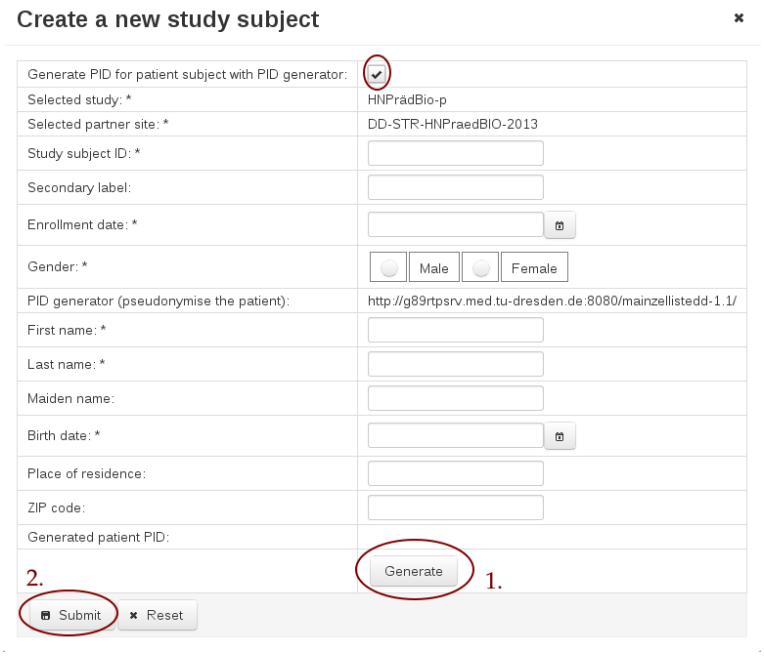

Figure 9: Register and enrol a new subject to the study.

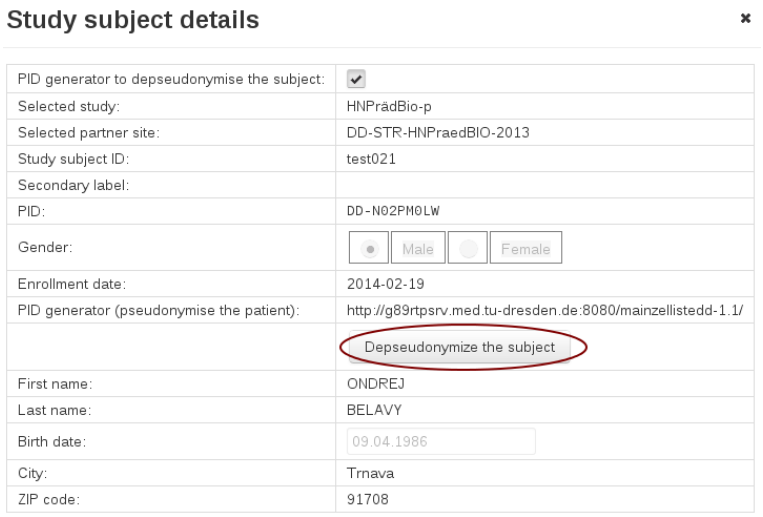

Figure 10: Read back the patient identity.

3 PACS - medical imaging

RadPlanBio has PACS module which provides integration with research PACS system where all the study related DICOM data are uploaded with RadPlanBio desktop upload tool. RadPlanBio uses following information linking in order to store association between imaging data/ clinical study data/ and patient identity:

- DICOM patient ID: during upload of DICOM data the pseudonymisation step is performed which also ensures that all DICOM patient ID tags in original file are replaced with selected RadPlanBio patient pseudonym.
- DICOM study UID: the old study UID are replaced with randomly generated new study UID.

These two types of identifier are saved in CRF for specific study event with DICOM eCRF to ensure that we can always find appropriate study related imaging RadPlanBio research PACS.

Note: this replace and storing of DICOM ID is done automatically via the RadPlanBio desktop upload tool.

Once imaging data is successfully stored within RadPlanBio the user can navigate them by invoking ***DICOM studies*** menu item from main menu. Here the user can browse DICOM studies, see Fig. **??** or study series, of

selected patient in currently active study. This DICOM data are able for download or viewing in integrated DICOM viewer.

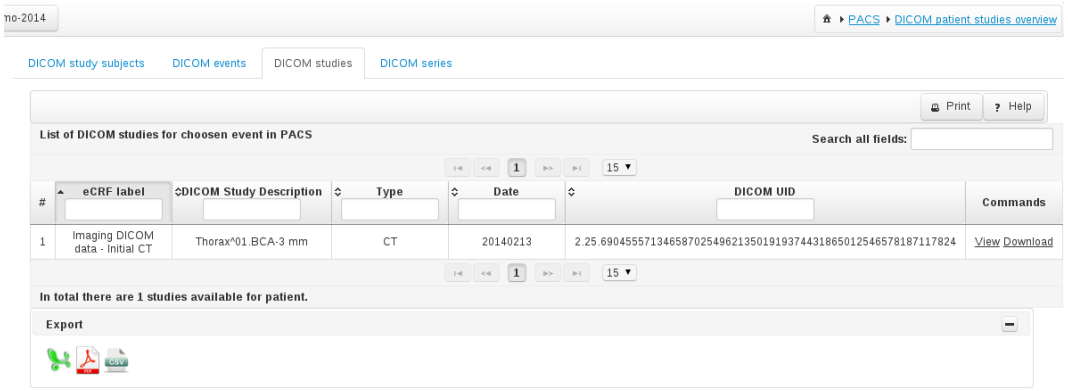

Figure 11: Overview of DICOM studies for subject within study and event.

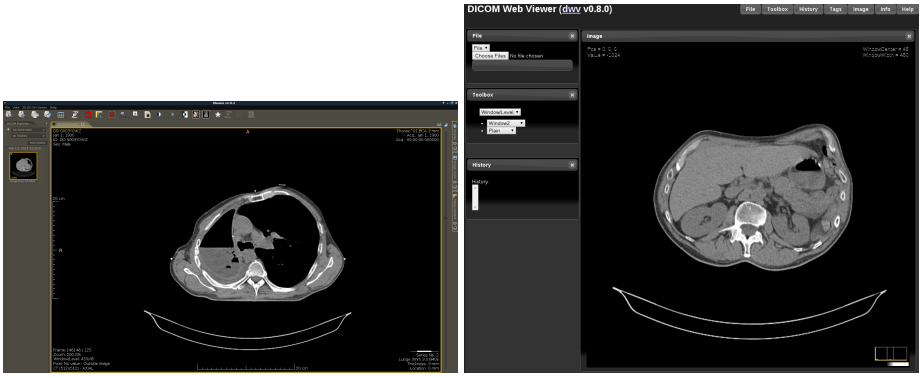

Figure 12: RadPlanBio supported web DICOM viewers Weasis (Java web-start) DWV (HTML5).

4 PID - Patient identity

RadPlanBio PID module is used to safely access the information from RadPlanBio patient identity management system. In section **??**, it was described how a new PID pseudonym is generated and patient is enrolled as a subject of specific clinical trial.

4.1 PID - explanation

PID (patient identifier, person identifier, pseudonym) is a unique identification string which is used across the subsystems in RadPlanBio in order to pseudonymise the patient identity. This means that patient identity is stored only in one place, so called, patient identity database. On the other hand when we want to associate some data in RadPlanBio to the specific patient (it can be clinical study data from CRF or DICOM data) we use the PID which uniquely represent the patient instead of real identity data.

4.2 Getting PID of registered patient

From time to time the data entry personnel knows the identity of the registered patient and need obtain PID pseudonym associated to this patient while it was registered. This is possible by navigation to the ***Search patient PID*** menu item in the main menu as it is displayed in Fig. **??**.

5 Randomisation

RadPlanBio-Portal randomisation module can be used to randomise subjects into treatment arms according to defined set of stratification criteria. The module is available only for those clinical trials which have been configured

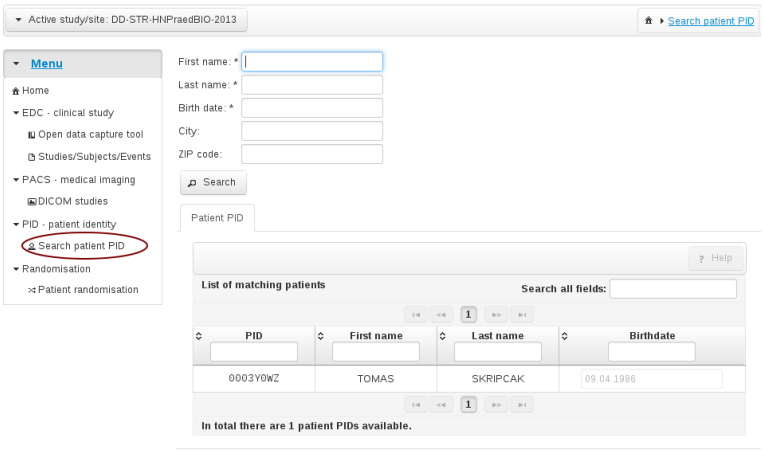

Figure 13: Lookup of PID when we know the identity information of registered patient.

as randomised.

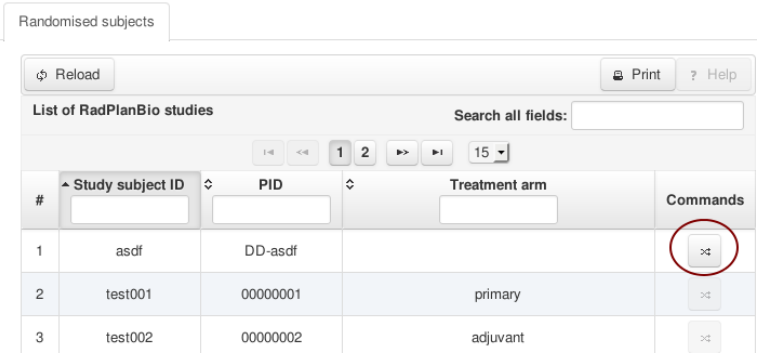

Figure 14: Randomisation module overview.

5.1 Randomise study subject

Once you enter the randomisation module you will be able to see the list of currently registered study subject within your active study as displayed in Figure **??**. The user can distinguish whether the subject was already randomised by examining his treatment arm property.

For non randomised subjects the command button at the right side of each subject data row will trigger dialogue allowing to enter necessary stratification criteria for the randomisation process, see Figure **??**.

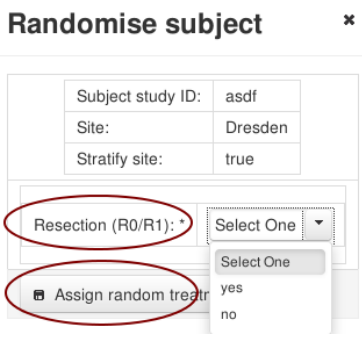

Figure 15: Randomisation dialogue with stratification details.

After clicking on assign random treatment arm button, the randomisation takes place and assign one of possible study treatment arms to the subject. After this step the treatment arm for subject is stored within RadPlanBio. In the current version of RadPlanBio it is however still necessary to manually copy this information into OpenClinica EDC system. Within OpenClinica there are two solutions for how the treatment arm of the patient can be stored:

1. Treatment arm as subject group class: OpenClinica EDC system provides the ability to defined subject group classes. During setup of a concrete study one can declare treatment group class with treatment arm options and use this data element to store the randomisation result, see Figure **??**.

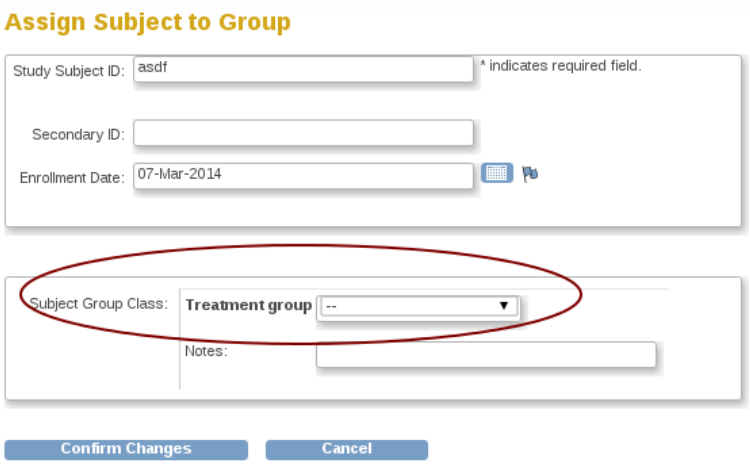

Figure 16: Randomised treatment arm as study subject group in EDC.

2. Treatment arm as eCRF item field: Randomisation result can be also stored within one of the eCRFs of a specific study. During a setup of the study one has to create eCRF field element which can store the randomised treatment arm option, see Figure **??**.

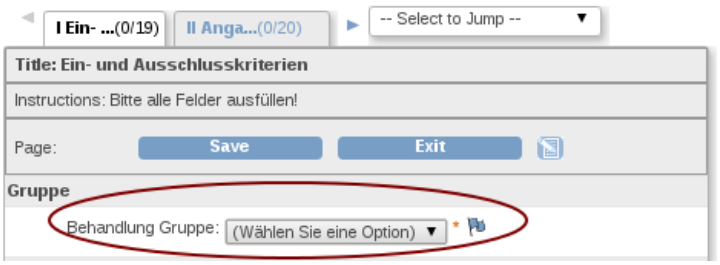

Figure 17: Randomised treatment arm as EDC eCRF field.

The choice which option to use (even both of them could be used together) depends on a concrete setup of randomised clinical trial.

6 How To

This section provides some generic but usefull information about a specific usage of RadPlanBio.

6.1 DICOM upload for dummy patient (step-by-step guide)

Some studies in RadPlanBio require for the partner site a testing DICOM imaging or treatment plan upload before it can join the real study data collection. For such reason every partner site has an access to the ***Demo Study*** where such testing procedures can be performed. The whole process of DICOM upload for a dummy patient consists of three steps which are described in details below:

- Patient registration and enrolment into a study

  1. Login with your user credentials into RadPlanBio portal.
  2. On the left side (tree menu) click on ***EDC - clinical study – Studies/Subject/Events*** item to access an overview of studies that are available for you.
  3. From ***Study*** (combobox) select the study with name ***Demo Study*** (this is where the dummy patient will be created).

4. From the data table which will be shown below select your parter site by clicking on appropriate data table row.
5. Click on ***Study Subjects*** (tab) to get an overview of subjects already enrolled into a study.
6. Click on the ***New*** (button) to register a new subject.
7. Enter all the required dummy subject fields:
   - Study subject ID: you can use something like [PartnerSiteIdentifier]-DUMMY-001 (e.g. DD-DUMMY-001).
   - Enrolment date: e.g. today.
   - Gender: select one.
   - First name: dummy.
   - Last name: patient.
   - Birth date: choose any.
8. Click on the ***Generate*** button to obtain unique patient pseudonym – it will be shown in the generated patient PID field.
9. Click on the ***Submit*** button to enrol pseudonymised patient into a study.

- Scheduling the imaging study event

1. From the left menu in RadPlanBio portal website select ***EDC - clinical study – Open data capture tool***.
2. EDC system (OpenClinica) website will open.
3. In ***Subject Matrix*** you should be able to see subject enrolled into a currently active study. It should be Demo Study: [PartnerSite]. If it is not you should change the active study by clicking on the ***Change Study/Site*** link in upper menu.
4. Click on empty document icon for specific subject row in DE Imaging column. And click on schedule to schedule this study event (data collection is only possible for scheduled events).
5. Fill up some details for event (date) and schedule event for this subject.

- Uploading treatment plan (or different DICOM imaging) for registered subject with scheduled imaging study event:

1. Start the RadPlanBio client application and login with your user credentials.
2. Click on the button ***Upload DICOM data...***.
3. From the ***Study*** (combo box) select the ***Demo Study***.
4. From data table displayed below select your site.
5. Go to the next ***Study Subject*** (tab).
6. Select the ***dummy*** subject you have created in the first step.
7. Go to next ***Study Events*** (tab).
8. Select the scheduled ***DE Imaging*** study event.
9. Go to the next ***DICOM*** (tab), here select the element ***Treatment plan*** (or if you need to upload another DICOM modality select the appropriate element).
10. Go to the next ***Summary*** tab.
11. Click on the button ***Upload DICOM*** data.
12. Navigate to the folder on your computer where the treatment plan (or another DICOM study) you want to upload is stored. Select the folder and click ***OK***.
13. Files within folder will be analysed and the structure of underlying DICOM study will be displayed in a tree view. Select the whole study or all necessary DICOM modalities (for treatment plan upload at least CT, RTDOSE, RTPLAN, RTSTRUCT modalities are required. When selection is done click ***OK***.
14. Treatment plan is analysed and checked for consistency. The next dialogue will show you how treatment plan will be de-identified (patient pseudonym generated in the fist step will be used).
15. You may want to click on buttons to preserve the descriptions of DICOM study and series. Otherwise these descriptions are going to be removed during the de-identification process.
16. When this is done click ***OK***, the question will be shown to ensure that study and series descriptions do not contain any patient identity data.

17. Next you will be asked to harmonise the naming of organs contours from provided RTSTRUCT series.
18. Each named contour should be mapped with appropriate standard name. For specific contours (e.g. GTV, PTV, ...) it is possible to provide an additional information. Dual organs it is possible to choose between left/right in additional info combo box.
19. After original contours names are mapped to standard names click ***OK***.
20. Question is displayed to ensure about the correctness of provided mapping, after click on ***yes*** the pseudonymisation followed by the upload of data procedure will start.
21. After upload is finished the ***Data transfer was successful*** message will be displayed.