

RDC Basics

Navigating the RDC Environment

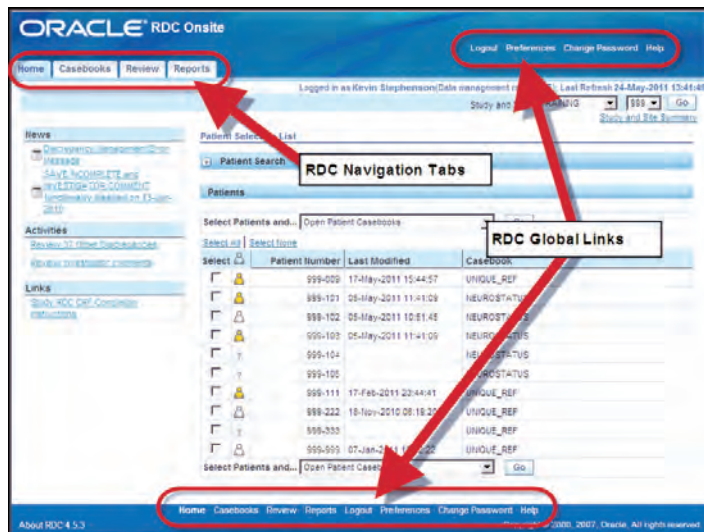
On the RDC home page you will see four navigation tabs:

- Home
- Casebook
- Review
- Reports

These global links also allow you to log out of the system, change your password and access online RDC help.

Tip: By remembering to use the links provided at both the top and bottom of each tab window, you will save yourself time during daily navigation.

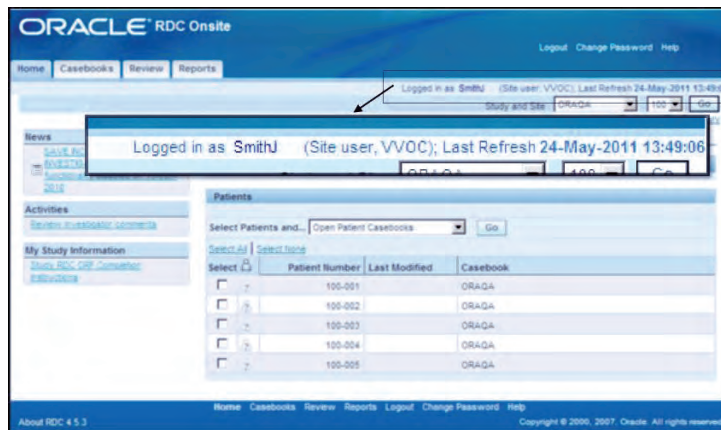
The Global Links found at the top and bottom of each tab window. These links allow you the flexibility to access information via the tabs or via the hyperlinks.



Session Details

The Session Details include:

- The name of the person logged in
- His or her role
- The date/time the session was last updated



Important: If you are sharing a computer with someone else, please review this area of the screen to ensure that you are the person logged into the session prior to beginning data entry. By doing so, all actions performed during the session are associated with the correct username.

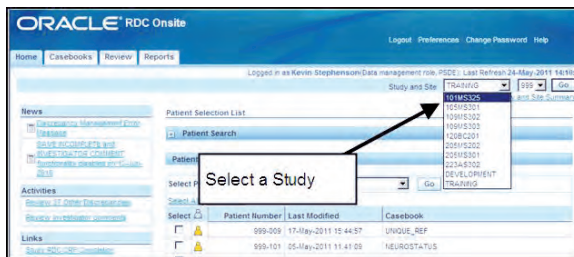
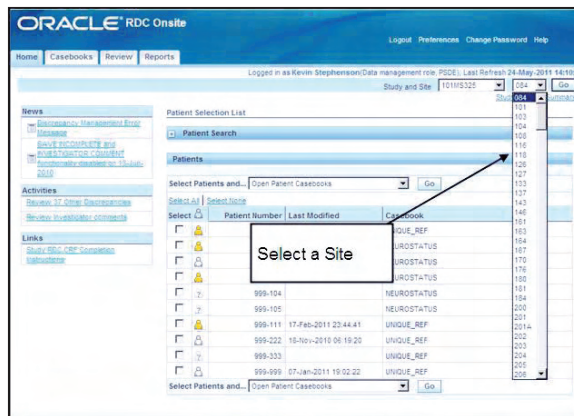
Finding Your Study and Site

If you have access to more than one study or site in the application, you need to select the appropriate study and site from the drop-down lists located at the top right of the screen.

The **Go** button is only required if the Study or Site selected have been changed.

The patient list displays for the Study and Site selected.

Once the correct patient number is located, use the check box in front of the patient icon to select that patient.



Then **Select Patients and...** **Open Patient Casebooks** then click **Go**.

ORACLE® RDC Onsite

Home | Logout | Preferences | Change Password | Help

Logged in as **Administrator** | **Study: 201-100** | **Site: 201-100** | **Go**

First select your Study and Site then press "Go"

Patients Selection List

Then select the patients you are interested in....

Select Patients and... **Open Patient Casebooks** **Go**

Select	Patient Number	Last Modified	Casebook
<input checked="" type="checkbox"/>	201-100	28-May-2011 14:08:21	2010 TRAINING
<input checked="" type="checkbox"/>	201-101	07-Jun-2011 15:10:07	2010 TRAINING
<input checked="" type="checkbox"/>	201-102	05-Jun-2010 14:29:31	2010 TRAINING
<input type="checkbox"/>	201-103		
<input type="checkbox"/>	201-104		
<input type="checkbox"/>	201-110		
<input type="checkbox"/>	201-111		
<input type="checkbox"/>	201-112		2010 TRAINING
<input type="checkbox"/>	201-113		2010 TRAINING
<input type="checkbox"/>	201-114		2010 TRAINING

Finally "Select Patients..." and "Open Patient Casebooks" by pressing "Go"

<http://rdcsupport.biogenidec.com>

The Casebook Spreadsheet will then display.

The screenshot shows the ORACLE RDC Onsite Casebook Spreadsheet interface. The top navigation bar includes links for Home, Casebooks, Review, and Reports. The user is logged in as Kevin Stephenson with a Data management role. The interface displays a table of patient casebooks for the study '2010 TRAINING' at the 'SCREENING' visit. The table includes columns for Patient Number, DOV, Inc. Exc., Demography, Medhist_Yn, Medh2, Vitals_Scr, Phys_Exam, Chemistry, and Medhist. Three patients are listed: 201-100, 201-101, and 201-102. The bottom of the screen shows the footer with 'About RDC 4.5.3' and 'Copyright © 2005, 2007, Oracle. All rights reserved.'

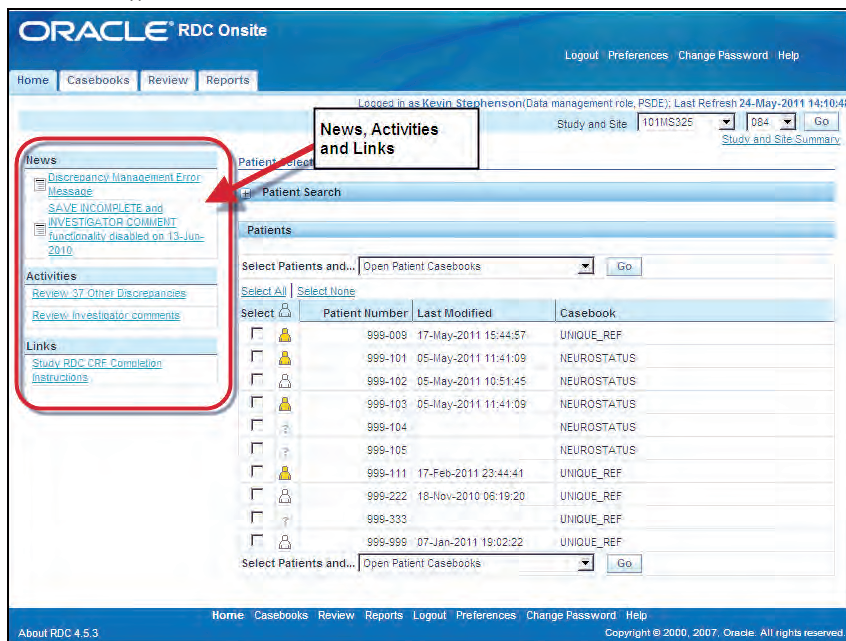
Select	Patient	Number	DOV	Inc. Exc.	Demography	Medhist_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemistry	Medhist
<input type="checkbox"/>	201-100	1	2	3	4	5	6	7	7.1		
<input type="checkbox"/>	201-101	1	2	3	4	5	6	7	7.1		
<input type="checkbox"/>	201-102	1	2	3	4	5	6	7	7.1	8	

NOTE: You have now accessed the Casebooks tab.

The available CRFs for the first scheduled visit (Screening in this case) are automatically displayed.

News, Activities and Links

RDC contains hyperlinks



ORACLE® RDC Onsite

Logout | Preferences | Change Password | Help

Home | Casebooks | Review | Reports

Logged in as Kevin Stephenson(Data management role, PSDE); Last Refresh 24-May-2011 14:10:48

Study and Site | 101MS325 | 084 | Go | Study and Site Summary

News, Activities and Links

News

- Discrepancy Management Error Message
- SAVE INCOMPLETE and INVESTIGATOR COMMENT functionality disabled on 13-Jun-2010

Activities

- Review 37 Other Discrepancies
- Review Investigator comments

Links

- Study RDC CRF Completion Instructions

Patients

Select Patients and... Open Patient Casebooks Go

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	999-009	17-May-2011 15:44:57	UNIQUE_REF
<input type="checkbox"/>	999-101	05-May-2011 11:41:09	NEUROSTATUS
<input type="checkbox"/>	999-102	05-May-2011 10:51:45	NEUROSTATUS
<input type="checkbox"/>	999-103	05-May-2011 11:41:09	NEUROSTATUS
<input type="checkbox"/>	999-104		NEUROSTATUS
<input type="checkbox"/>	999-105		NEUROSTATUS
<input type="checkbox"/>	999-111	17-Feb-2011 23:44:41	UNIQUE_REF
<input type="checkbox"/>	999-222	18-Nov-2010 06:19:20	UNIQUE_REF
<input type="checkbox"/>	999-333		UNIQUE_REF
<input type="checkbox"/>	999-999	07-Jan-2011 19:02:22	UNIQUE_REF

Select Patients and... Open Patient Casebooks Go

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News

- In the News section you may see communications targeted at users of the study database displayed.
- This may include details of protocol amendments, changes to the electronic casebook or notifications of scheduled down-time. The title is displayed as a hyperlink which can be clicked on in order to view the associated detail.

Activities

- The Activities section provides a number of shortcuts to enable you to quickly access information in RDC; simply click on the appropriate hyperlink to select data for review.
- The activities you see listed in this section will be appropriate for your role within the study.

Links

- The Links section enables you to access other information relevant to the study and outside of RDC such as the CRF Completion Instructions for your study.

Home Navigation Tab – The Patient Search Filter

The Patient Search filter allows you to select an individual or a range of patient numbers by

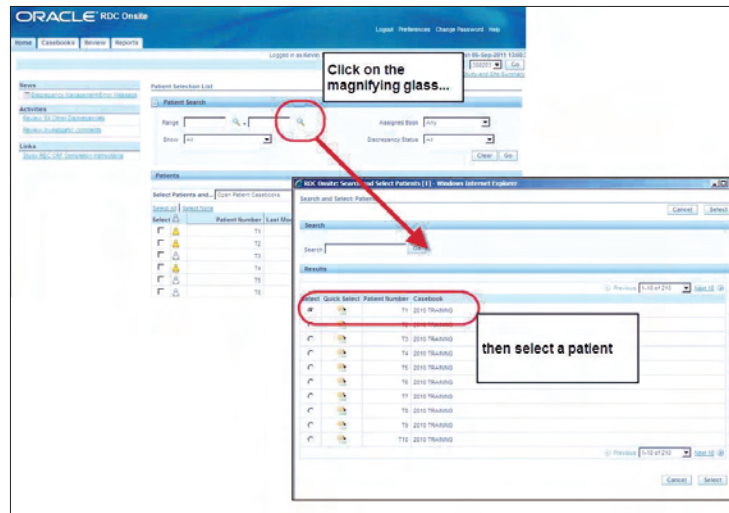
- Typing in a patient number
OR
- Selecting the patient number(s) from the magnifying glass feature

Search for a Specific Patient: To perform a search for a specific patient number, click the **Select** button and a list of available patient numbers displays. Select the desired patient by clicking the radio button.

Search for a Range of Patients: To search a range of patients click the Magnifying Glass icon. In order to display a range of patient numbers, you must choose both a starting patient number and an ending patient number.

Tip: You can also type in the patient number as well.

If you selected a patient range, you will see multiple patient numbers in the Patients list. This area contains all patients for the study and site that have been selected from the study information drop down lists and/or via the Patient Search fields.



In the Patients list area found below the Search window, you may also choose a group of patient numbers by selecting the **< Previous** or **Next >** hyperlinks or by selecting the next numeric range from the drop down list.

Note: The drop-down list displays the number of available patients and not the assigned patient number.

ORACLE® RDC Onsite

Logged in as Kevin Stephenson(Data management role, PSDE); Last Refresh 24-May-2011 15:08
Study and Site | DEVELOPMENT | 101 | Go

Home Casebooks Review Reports

Patient Selection List

Patient Search
 Range [] - [] Assigned Book: Any
 Show All Discrepancy Status: All
[Clear](#) [Go](#)

Patients
 Select Patients and... Open Patient Casebooks [Go](#)
[Select All](#) | [Select None](#)

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	101-191		Unassigned
<input type="checkbox"/>	101-192		Unassigned
<input type="checkbox"/>	101-193		Unassigned
<input type="checkbox"/>	101-194		Unassigned

Previous 50
 1-50 of 274
 51-100 of 274
 101-150 of 274
151-200 of 274
 201-250 of 274
 251-274 of 274
 Next 50

You may choose a group of patient numbers by selecting the <Previous 50 or Next 50> hyperlinks or by selecting the numeric range from the drop down list

To check the **Discrepancy Status** of CRF pages use drop-down list box.

By selecting an option from the **Discrepancy Status** drop-down list, you are able to sort the eCRFs so you view only those that are clean or those that contain discrepancies actionable to yourself (Active) or a user in a different role (Other).

The screenshot shows the ORACLE RDC Onsite web application. The top navigation bar includes links for Home, Casebooks, Review, and Reports. The user is logged in as Kevin Stephenson with a role of Data management role, PSDP. The last refresh was on 24-May-2011 at 15:08:18. The current study and site are DEVELOPMENT and 101. The main content area is titled 'Patient Selection List' and includes a 'Patient Search' section with a range and show filter. A red box highlights the 'Discrepancy Status' dropdown menu, which is open and shows options: All, Active, Other, Open(Active & Other), and Clean(None or Closed). A red arrow points to the 'Active' option. A text box with the text 'Use the drop down to select the discrepancy status' is overlaid on the interface. Below the search section, there is a table with columns for Patient Number, Last Modified, and Casebook. The table shows several rows of patient data, including patient numbers 101-200 through 101-204, all with a status of 'Unassigned'.

Patient Number	Last Modified	Casebook
101-200	09-May-2011 14:08:57	DISCREPANCIES
101-201		Unassigned
101-202		Unassigned
101-203		Unassigned
101-204		Unassigned

“Select Patients and...”

The **Select Patients and...** drop-down list enables you to choose the information you want to see for the selected patients.

From the drop down list you may

- View patient casebooks
- CRFs that contain discrepancies
- Run a Patient Data Report or Blank Casebook Report.

Select the check box for the patient and a click on the **Go** button initiates the action you have requested.

Tip: To select all patients on the list click the **Select All** hyperlink or place a checkmark in the Select box in front of each desired patient icon.

The screenshot shows the 'ORACLE RDC Onsite' interface. At the top, there's a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports'. Below this, a status bar indicates the user is logged in as Kevin Stephenson (Data management role, PSDE) and shows the last refresh time. The main area is titled 'Patient Selection List'. It includes a 'Patient Search' section with fields for 'Range', 'Assigned Book', and 'Discrepancy Status', along with 'Show' and 'Go' buttons. A red box highlights the 'Select Patients and...' dropdown menu, which is open, showing a list of actions: 'Open Patient Casebooks', 'Open Patient Casebooks', 'Review Entered CRFs', 'Review Investigator Comments', 'Generate Patient Data Report', 'Generate Blank Casebook Report', 'Review MedDRA / ADVERSE_EVENT_S', 'Review MedDRA / CHED', 'Review MedDRA / CNONDRUGTRT', 'Review WHODRUG20 / CHED', and 'Review WHODRUG20 / CNONDRUGTRT'. Below the dropdown, there's a table with columns for 'Select', 'Patient', and 'Casebook'. The table lists several patients with checkboxes in the 'Select' column and various actions in the 'Casebook' column. The 'Go' button is visible at the bottom right of the table area.

Casebooks Navigation Tab – Search Patient Casebooks

You are able to select additional search filters from this tab.

This section displays patients and their numbers in rows and corresponding visit related CRFs in columns. Users can navigate across patients and visits.

Note: If multiple patients were selected on the Home tab, then the Search window denotes this and continues searching **only** on those patient numbers.

In order to perform a completely new search, click the **Clear** button in the Search window to reset all search options.

ORACLE RDC Onsite

Home Casebooks Casebook Tab

Logout Preferences Change Password Help

Logged in as Kevin Stephenson(Data management role, POCE) Last Refresh 24-May-2014 16:32:41

Study and Site DEVELOPMENT T01 Go

Study and Site Summary

Patient Casebooks

Search

Patient: Range 101-101 101-330 Assigned Book Any Show All

CRF Status: Entry All Discrepancy All Location All

CRF Source: Casebook All Visit All CRF Item

Clear Go

Patients and CRFs for a visit

Casebook Spreadsheet

Patients: Previous 11-20 of 120 Next Casebook View: 200 TRADITGO Visit: SCREENING CRFs: Previous 1-10 of 10 Next

Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page Refresh

Patient	DOV	Inc_Exc	Demography	Medhist_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemab	Medhist	Ecq_Prior
101-111	1	2	3	4	5	6	7	8	9	8
101-112	1	2	3	4	5	6	7	7.1	8	8
101-113	1	2	3	4	5	6	7	8	9	8
101-114	1	2	3	4	5	6	7	8	9	8

Patient Navigation

If the list of patients is longer than the page can display, use the <Previous or Next> at the upper left of the **Casebook Spreadsheet** to navigate across patients.

The screenshot displays the ORACLE RDC Onsite web application. At the top, the 'Casebooks' tab is highlighted with a red circle and labeled 'Casebook Tab'. Below the navigation bar, the 'Patient Casebooks' section contains search filters for Patient Range (101-101 to 101-330), Assigned Book, CRF Status, CRF Source, and Visit. The 'Casebook Spreadsheet' section is highlighted with a red box and labeled 'Patient Navigation'. It features 'Previous' and 'Next' buttons for navigating between pages of patients. A dropdown menu is open, showing a list of patient ranges from '1-10 of 120' to '101-114'. The spreadsheet table below has columns for Inc_Exc, Demography, Medhist_Yn, Medh2, Vitals_Scr, Phys_Exam, Chemistry, Medhist, and Ecg_Prior. The table is currently displaying data for the 'SCREENING' visit.

Inc_Exc	Demography	Medhist_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemistry	Medhist	Ecg_Prior
2	3	4	5	7	6		5	8
2	3	4	5	6	6	7.1		
2	3	4	5	7	6	7.1	5	
4	3	4	5	6	7	7.1	5	

CRF Navigation

This same style of navigation is used if the number of columns is insufficient for all CRFs to display on the screen.

The screenshot displays the ORACLE RDC Onsite web application. The top navigation bar includes links for Home, Casebooks, Review, and Results. The 'Casebooks' tab is highlighted with a red circle and labeled 'Casebook Tab'. Below the navigation bar, the user is logged in as Kevin Stephenson. The main content area is titled 'Patient Casebooks' and contains a search section with filters for Patient Range (101-101 to 101-330), CRF Status (Entry, All, Discrepancy, Approval, Verification), and CRF Source (Casebook, Visit, CRF Name). A red arrow points from the 'CRF Navigation' label to the 'CRFs' dropdown menu in the 'Casebook Spreadsheet' section, which is also circled in red. The 'Casebook Spreadsheet' section shows a table of patient data with columns for Patient Number, DOV, Inc_Exc, Demography, Medhist_Yn, Medh2, Vitals_Scr, Phys_Exam, Chemistry, Medhist, and Ecg_Prior. The table is filtered for '2010 TRAINING' and 'SCREENING' visit type. The 'CRFs' dropdown menu is set to '1-10 of 10'.

Select	Patient	Number	DOV	Inc_Exc	Demography	Medhist_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemistry	Medhist	Ecg_Prior
<input type="checkbox"/>	101-111		1	2	3	4		7	6		5	8
<input type="checkbox"/>	101-112		1	2	3		5	6	8	7.1		
<input type="checkbox"/>	101-113		1	2	3	4	5	7	8	7.1	5	
<input type="checkbox"/>	101-114									7.1		

Visit Navigation

To view CRFs for a particular visit, select the visit from the **Visit** drop down list at the upper right of the **Casebook Spreadsheet**. You can view the list of CRFs for selected patients during a particular visit. The name or number of the visit appears in the column header.

The screenshot displays the ORACLE RDC Onsite Casebook Spreadsheet interface. A red box highlights the 'Visit' drop-down list, which is currently set to 'SCREENING'. The list includes the following options: SCREENING, SCREENING02, DAY 0, DAY 1, WEEK 2, WEEK 3, WEEK 4, WEEK 5, WEEK 6, WEEK 7, WEEK 8, WEEK 9, WEEK 10, EARLY WITHDRAWAL, STUDY MEDICATION, END OF TREATMENT, END OF STUDY, ADVERSE EVENTS, CONCOMITANT MED, CONCOMITANT TRT, RECORD OF DEATH, UNIQUE, and HOSPITALIZATION. A red arrow points from a text box labeled 'Navigate visits using the Visit drop-down list' to the drop-down menu. The main table shows patient data for three patients (201-100, 201-101, 201-102) across various columns including DOV, Inc_Exc, Demography, Medhist_Yn, and Medh2. The 'Medh2' column header is highlighted in red, corresponding to the selected visit.

ORACLE RDC Onsite

Home Casebooks Review Reports

Logged in as Kevin Stephenson(Data management role, PSDE); Last Refresh 24-May-2011 16:33:32

Study and Site DEVELOPMENT 201 Go

Study and Site Summary

Navigate visits using the Visit drop-down list

Casebook Spreadsheet

Patients: Previous 1-3 of 3 Next

Casebook View: 2010 TRAINING

Visit: SCREENING

CRFs: Previous 1-9 of 9 Next

Select Patients and... Generate Patient Data Report Go Add Visit Page

Select All Select None

Select	Patient	Number	DOV	Inc_Exc	Demography	Medhist_Yn	Medh2	Chemistry	Medhist
<input type="checkbox"/>	201-100		1	2	3	4	5	7.1	
<input type="checkbox"/>	201-101		1	2	3	4	5	7.1	
<input type="checkbox"/>	201-102		1	2	3	4	5	7.1	

About RDC 4.5.3

Home Casebooks Review Reports Logout Preferences

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Refresh

The **Refresh** button is used to update the CRF icon status on your display.

The screenshot shows the ORACLE RDC Onsite web application. At the top, there's a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports'. A user is logged in as Kevin Stephenson. The main area is titled 'Patient Casebooks' and contains a search section with various filters like Patient Range, CRF Status, and CRF Source. Below this is the 'Casebook Spreadsheet' section, which displays a table of patient data. A red circle highlights the 'Refresh' button in the spreadsheet's action bar. A callout box labeled 'Casebook "Refresh"' points to this button.

Casebook "Refresh"

Select	Patient	Number	DOV	Inc_Exc	Demography	Medhist_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemstry	Medhist	Ecg_Prior
<input type="checkbox"/>	101-111	1	2	3	4	7	6	5	8			
<input type="checkbox"/>	101-112	1	2	3	4	5	6	7.1	5			
<input type="checkbox"/>	101-113	1	2	3	4	5	6	7.1	5			
<input type="checkbox"/>	101-114	1	2	3	4	5	6	7.1	5			