



Chameleon Information Management Services Limited

InfoFlex Version 5 Studies Tutorial

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Document control

Document name	Studies Tutorial
Confidentiality	Customer
Owner	HV
Version	1.3
Last revised by	JW
Last revised date	15 June 2010
Status	Final

Document history

Date	Doc version	Editor	Change
28/8/2007	1.1	HV	1 st release for v5.01.0584
1/10/2008	1.2	JW	Minor changes and screenshot updates for revised database
15/6/2010	1.3	JW	5.40.0100 removal of closed option for studies (screenshot update)

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1. INTRODUCTION

Studies are a way of grouping subjects and events. The purpose of the study is to ensure that users only view the patients and the data that are relevant to their designs, and to enable patient data to be shared where appropriate. It provides a way of filtering the groups of patients and events that are available to users in Data Entry and Data Analysis. However, studies are a design tool and will not be evident to the Data Entry user.

Subjects and their events can belong to one or more studies. A data view shows all the subjects and their events that belong to a particular study or set of studies, but does not show the subjects and events that belong to other studies.

Adding studies is an optional step in the design process. Domains which contain data for only one specialty, or where all users need to view all the data will not need to have studies defined.

It is advisable to design how studies will be used before data is entered in your domain.

1.1 Why use studies?

If no studies were defined, then all patients and all their events would be visible in all data views.

Keeping patients together - single study data views

If your domain contains patients from different specialties, each specialty might want to view only their own patients.

By defining a study for each specialty, you will ensure that diabetes users only see diabetes patients, and endoscopy users see only endoscopy patients.

You can also define a variety of different data views for the same specialty to cater for the differing needs of e.g. secretary and consultant. The studies will ensure that any patient entered by the secretary will also be visible to the consultant.

Restricting access to generic events

If your data view contains generic events (e.g. referrals), you need to know which study the generic events are relevant to. For example, in a Diabetes data view, you might only be interested in Diabetes referrals, not referrals for other specialties. In Data Entry, whenever you add an event to a patient, that event is marked as belonging to whichever studies are assigned to the current data view. The generic event will only ever be visible in data views which have the same study.

Sharing patients - multi study data views

In some instances, it is useful for one specialty to have access to a patient's data from a different specialty. Data views can be set up which contain events from a number of different studies. Patients who are registered in any of the studies represented in the data view will be visible. Any new patients who are registered from this data view will be registered in all the studies represented in the data view.

1.2 How to Use Studies

Broadly, there are four ways of using studies:

1. The studies are chosen at the data view level;
2. The studies are chosen at the event level;
3. The studies are chosen according to the patient data added;
4. Events in an external study are made visible within a data view.

The latter two techniques are used in conjunction with the previous ones. We would recommend that studies are set at the data view level, and that events are generic where possible and shared across groups of patients.

1. Set studies at a data view level and use generic event definitions.

Event definitions can belong to a study, or they can be 'generic' (i.e. they do not belong to a study). If the event definition is generic it indicates that the event is shared across different groups of patients. For example, a Referral event would be a generic event. Studies are chosen at the data view level, rather than the event level.

In this scenario, studies are chosen directly for each data view. A patient belongs to a study by virtue of which data view the data was entered in.

2. Set studies at the event definition level.

Event Definitions can belong to a study, indicating that a particular event is tied to a particular group of patients or specialty. For example, in a Cancer design, an event definition may be linked to one particular tumour site, and so it could be assigned to the study for that tumour site.

In this scenario, studies are set in the event definition. This causes the study to automatically be assigned to any data view that contains the event definition. In data entry, the data view determines which study a patient and their events belongs to. So effectively, the patient belongs to a study by virtue of which events they have.

3. Setting studies based on Data

A patient can be added to studies or removed from studies depending on the contents of the patient's data. In this scenario, the study that the patient belongs to can change dynamically according to the data entered for that patient.

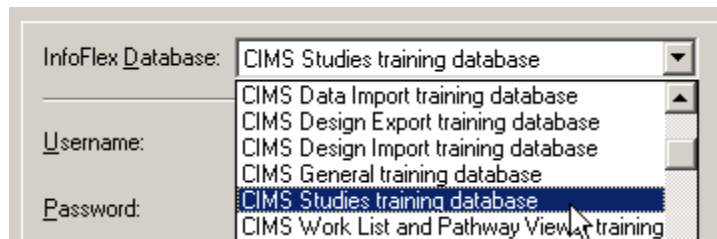
4. Allow external events from another study to be visible in a data view.

This is a method of being able to see a patient's events that belong to another study, but not change their study membership, or create them in the wrong data view. It would be used in conjunction with the other methods.

2 USING DOMAINS WITHOUT STUDIES

To illustrate the potential problems of domains without studies, we will perform some data entry across different specialties in a domain without studies defined.

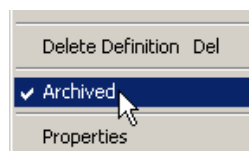
This training course uses the **CIMS Studies training database**.



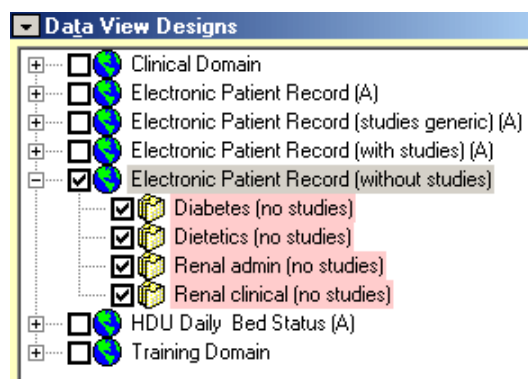
The Username is **training** and the Password is **training**.

2.1 Non-study domains

- Log on to the **CIMS Studies Training** database.
- Go to the **Design Management** module.
- Find the **Data View Designs** panel.
- Close any open domains and data views by unticking the boxes.
- Archive all the domains except the **Electronic Patient Record (without studies)** domain by right clicking each domain in turn and switching on **Archived** from the menu.

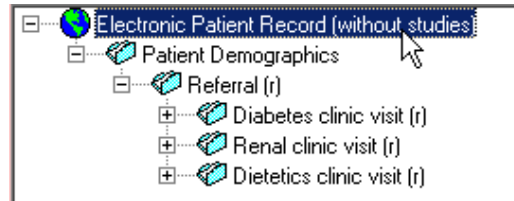


- Expand the **Electronic Patient Record (without studies)** domain by pressing the plus button.
- Display the four data views which are attached to it, by ticking the boxes.

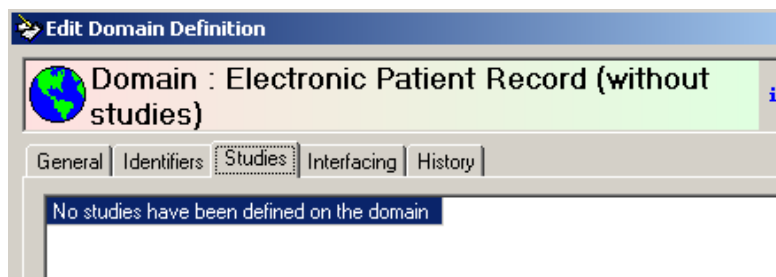


The domain and four data views will be shown on the right hand side of the window. Familiarise yourself with the structure of the data views and see which events they have in common.

- Edit the Domain definition for the **Electronic Patient Record (without studies)** domain, by double-clicking on the domain, or selecting **Edit Definition...** from the menu.

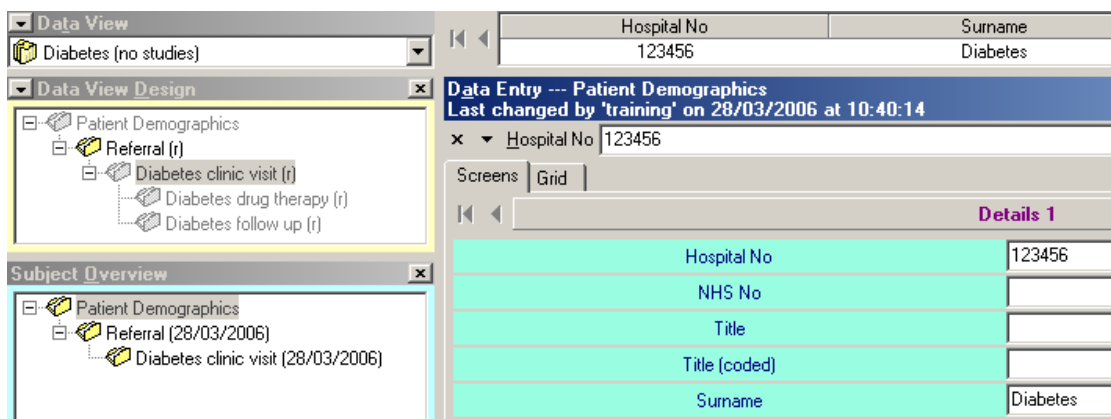


- Go to the **Studies** tab. See that there are no studies defined on the domain

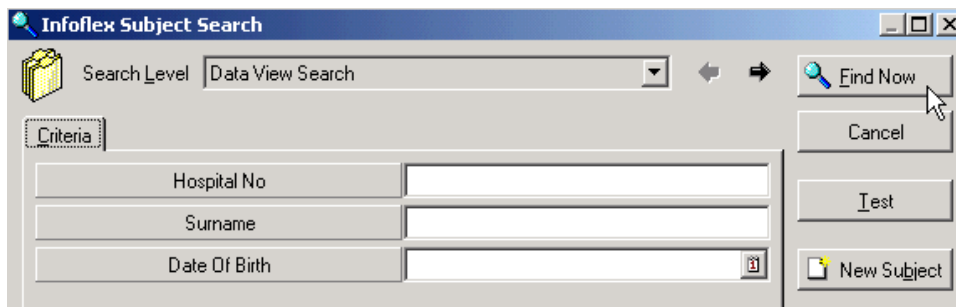


2.2 Adding Patients to the domain with no studies

- Go to the **Data Entry** module.
- Select the data view **Diabetes (no studies)**. Add a new patient to the data view.
- Enter the hospital number **123456** and the surname **Diabetes**.
- Attach a **Referral** event with Appointment date of today's date and specialty of **1 - diabetes**.
- Attach a **Diabetes clinic visit** event with Date of clinic visit event of today's date.

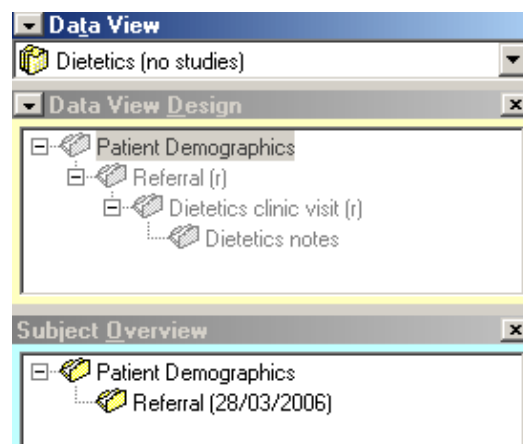


- Select the **Dietetics (no studies)** data view.
- Search for all subjects in the data view.



The diabetes patient you just added will be returned. The diabetes referral you attached will be displayed on the subject tree, but the **Diabetes clinic visit** event will not appear since that event does not exist in the data view.

Patient 123456 in the Dietetics data view



This illustrates what happens if no studies are defined in a domain which contains several different specialties: there is no way to prevent patients from different specialties being seen by other specialties.

The Referrals added in one data view will be available in all the other data views that show Referrals, regardless of which specialty they should belong to.

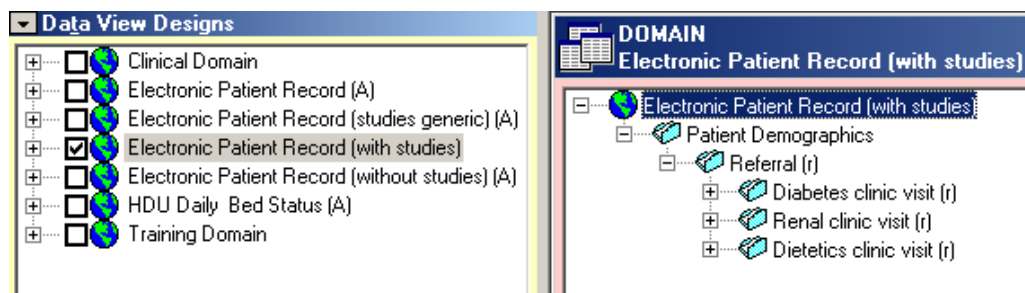
3 CREATING STUDIES IN DESIGN MANAGEMENT

3.1 Introduction

This chapter introduces the basic functionality of using studies in **Design Management**. It shows you how to view the studies in the domain, create and delete studies, assign event definitions to studies and add studies to data views.

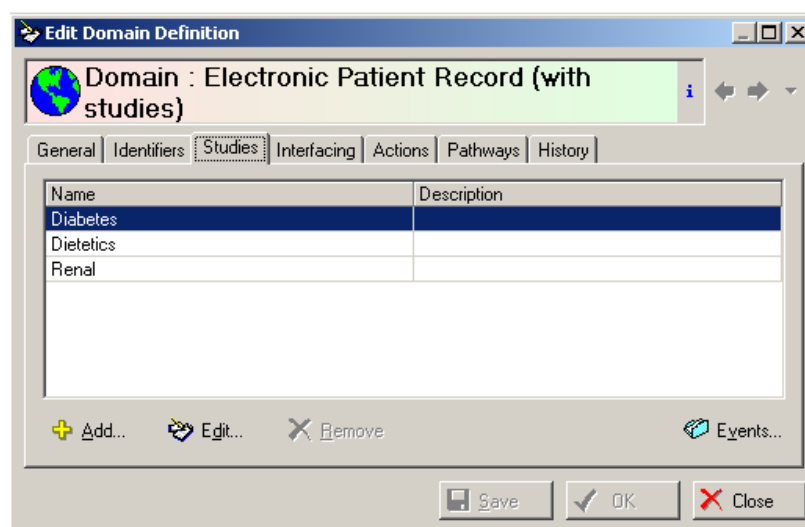
3.2 Viewing Studies in a Domain

- Go to the **Design Management** module.
- In the **Data View Designs** window, select the domain **Electronic Patient Record (with studies)**.
- Unarchive the domain, and close and archive the other domains as in the diagram.



The studies that have been defined in the domain can be found by editing the domain definition.

- Double-click on the domain **Electronic Patient Record (with studies)** to edit the definition.
- Select the **Studies** tab.



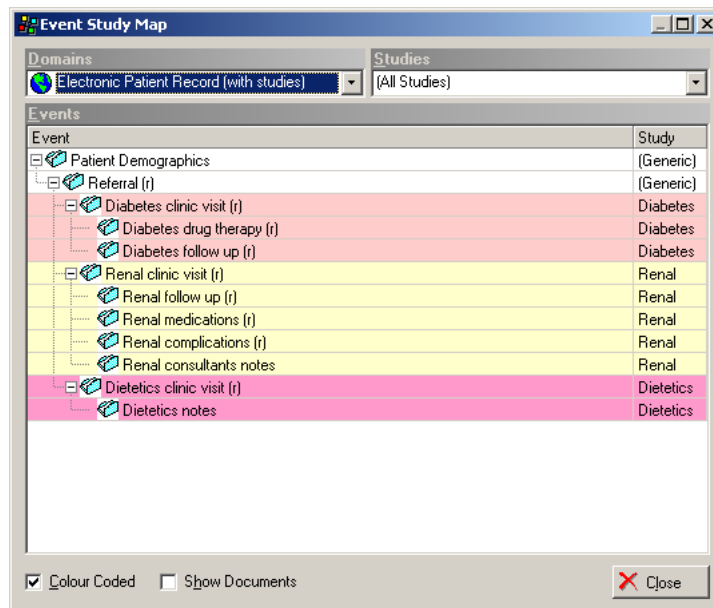
Three studies have been defined in this domain: **Diabetes**, **Dietetics** and **Renal** studies.

3.3 Viewing the Event Study Map

We can see whether there are any events which have been assigned to studies by using the **Event Study Map**.

➤ Press the **Events** button: 


The **Event Study Map** is shown. The colour coding helps to show which event belongs to which study.

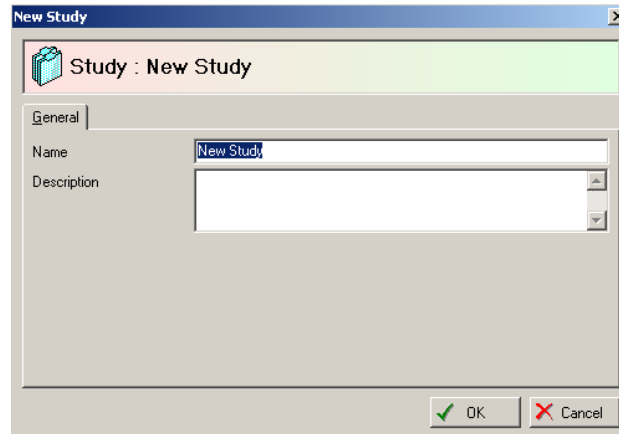


This map can also be shown by selecting the **Event Study Map** button in the toolbar: 

3.4 Adding a new study

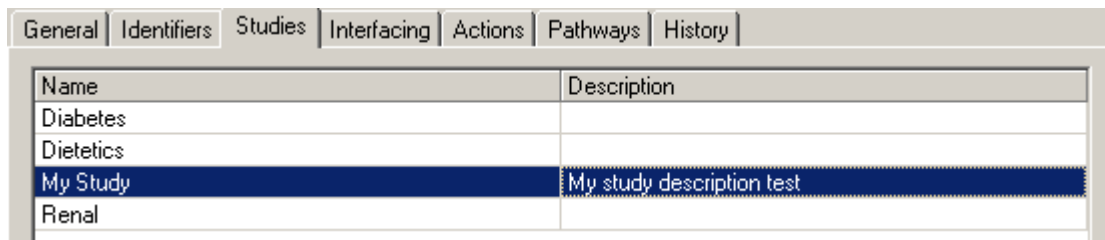
You can add a new study from the **Studies** tab in the **Edit Domain Definition** dialog.

- Press the  **Add...** button to display the **New Study** dialog



- Edit the name and Description of the dialog – call the new study "**My Study**" and press **OK**.

The new study will now appear in the list of studies.



Name	Description
Diabetes	
Dietetics	
My Study	My study description test
Renal	

You can edit the name or description press the **Edit...** button. You could also remove the study by pressing the **Remove....** button. Notice that you can only remove studies that have not been used.

- Select **OK** and to save the study and close the dialog.

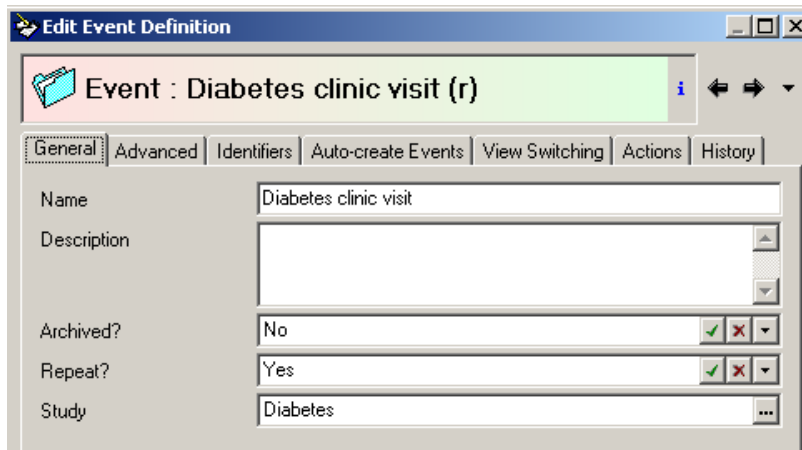
3.5 Assigning Events to Studies

An event definition can be assigned to a study in the **Edit Event Definition** dialog.


- Select the Event **Diabetes clinic visit** from the **Electronic Patient Record (with studies)** domain.

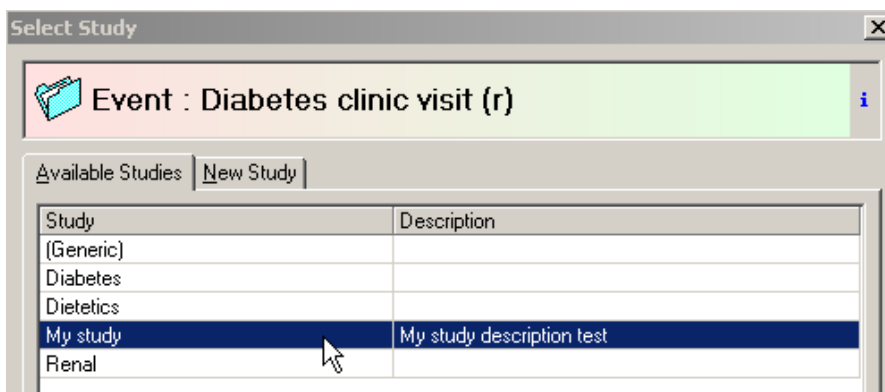
 Diabetes clinic visit (r)

- Edit the definition by double-clicking on it, or right-click and select **Edit Definition....**



Notice in the **Study** property, the **Diabetes clinic visit** event belongs to the **Diabetes** study. If there was already data entered for this event, the **Study** property would be greyed out and so could not be changed.

- Change the **Diabetes clinic visit** event so that it now belongs to the study you created. You can do this by pressing the button: 
- Select the new study **My Study** and press the **OK** button. Save the edited event definition.



Study	Description
(Generic)	
Diabetes	
Dietetics	
My study	My study description test
Renal	

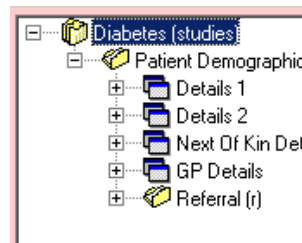
- View the **Event Study Map** to see which events now belong to **My Study**.

Once an event has been assigned to a study, any child events will automatically be assigned to the same study.

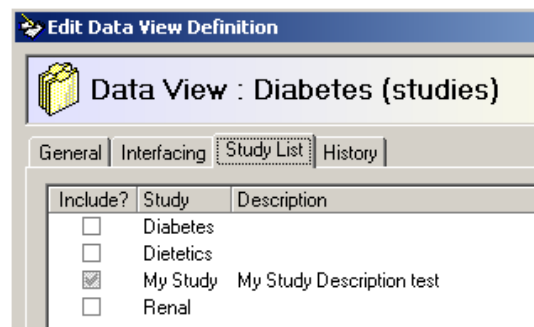
3.6 Assigning studies to data views

Data views contain a **Study list** which shows which studies are assigned to that data view.

- In the **Design Management** module, open the **Diabetes (studies)** data view and select the data view.
- Edit the data view definition by double-clicking on the data view (or choose **Edit Definition....**)



- Go to the tab called **Study list**.



Whenever a data view contains an event definition that belongs to a study, the study is automatically added to the data view's study list. It cannot be removed and so although a tick is visible, the check box is greyed out because the user cannot change it.

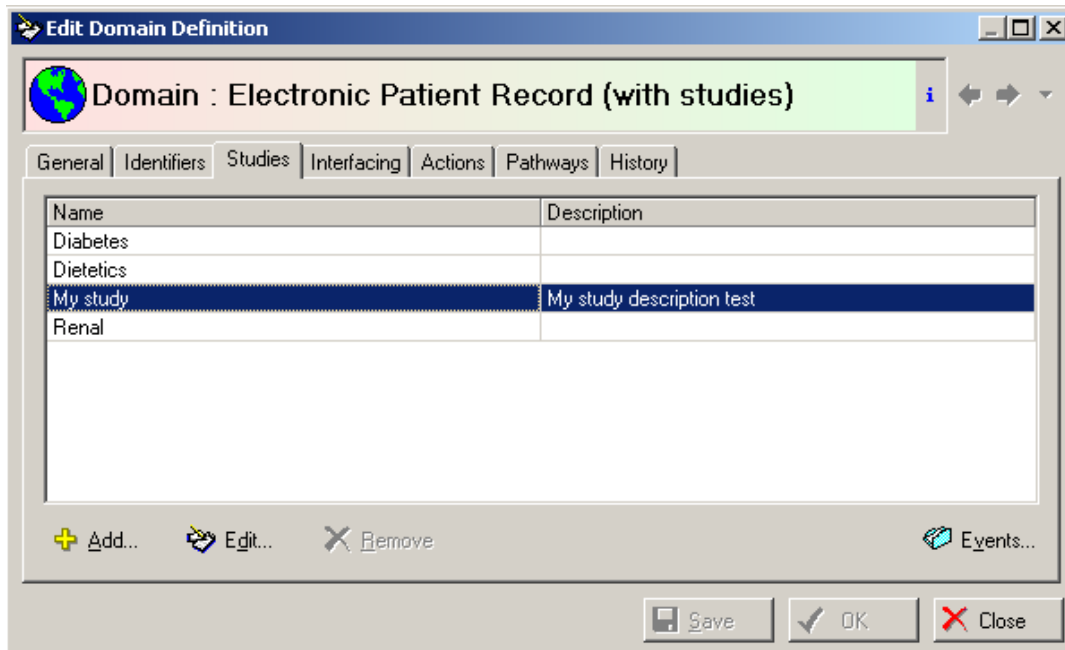
In the **Diabetes (studies)** data view, the study called **My Study** that you created is ticked because the event **Diabetes clinic visit** is in the data view, and this event belongs to your study.

You can add further studies to the data view by ticking the check boxes against other studies.

3.7 Removing Study Definitions

You can remove study definitions via the **Studies** tab of the Domain Definition. However, they must not be in use or have data in them.

- Try to remove the study you created. Notice that the **Remove** button is greyed out.



There is not yet any data in this domain. However, there are event definitions that have been assigned to the study. This stops the study from being deleted.

- Go back to the **Diabetes clinic visit** event definition. Put the study back to being **Diabetes**.
- Look again at the **Study List** in the **Diabetes (studies)** data view. It now has a tick against the **Diabetes** study and does not have one against **My Study**.
- Now go back to the Domain Definition. You should now be able to remove the study you created called **My Study**.
- Remove the study. Check in the **Event Study Map** that the events are back to the way they were.

4 STUDIES IN DATA ENTRY

This chapter gives a brief summary of how studies affect Data Entry. These principles will be illustrated in the subsequent chapters.

4.1 Study Membership of Subjects and Events

A subject belongs to one or more studies. If no studies have been defined in the domain, the subject belongs to the **Generic** study.

A subject's events belong to one or more studies. An event belongs to a study because of the data view in which the event was created. Even if the event definition in Design Management is generic, individual events (as seen in Data Entry) can belong to one or more studies. If no studies have been defined in the domain, the events belong to the **Generic** study.

4.2 Viewing Subjects and Events

The subjects available in a data view will be all the subjects who are in any of the studies assigned to the data view. The events that are visible in the subject overview are the ones that are represented in the data view, and that belong to any of the studies assigned to the data view.

Note that there may be subjects who are not visible in a data view, because the subject does not belong to any of the studies assigned to the data view.

A subject may have events that are not visible in a data view, because the events do not belong to any of the studies assigned to the data view. For example, the subject may have more than one referral, and the referrals may be in different studies.

Remember also that a subject may have several events that are not visible in a data view, simply because the event is one that is not represented in the data view.

4.3 Adding Subjects and Events

If you add a subject to a data view, then the subject automatically belongs to all of the studies in the data view's study list. Any event added to a subject in that data view automatically belongs to all of the studies in the data view's study list.

When you add an event to a subject then as well as the event belonging to all the studies in the data view's study list, the parent event, grandparent event, etc will also now belong to all these studies. And so will the subject as well.

4.4 Modifying Subjects and Events

Modifying existing subjects and events that are already visible in a data view does not change their study membership.

4.5 Deleting Subjects and Events

If you delete a subject or an event, it will remove the subject or event from all of the studies that are assigned to the data view. If the subject does not belong to any other studies, then they will no longer be available in any data view, but can still be found in a Domain search.

4.6 Searching for Subjects and Events

If you do a subject search at the data view level, you will find all the subjects that belong to any of the studies in the data view's study list.

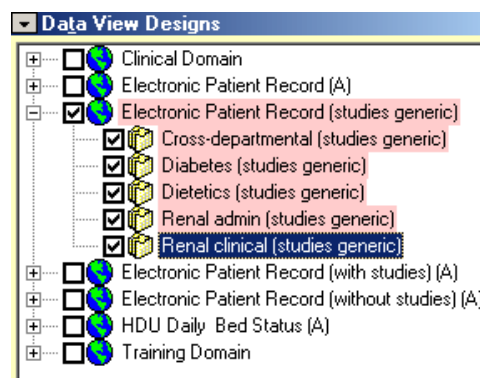
If you do a domain search then you find all subjects in the domain. Note that if you choose to add a subject to the current data view from the domain search then this adds the subject and root event to the studies on the data view's study list. It does not add any other events belonging to the subject to those studies.

5 SETTING STUDIES AT THE DATA VIEW LEVEL

In the next chapter we are going to use a domain that has studies defined, however all the event definitions are generic ones – i.e. they have not been assigned to a study. Studies are used by setting them at the data view level.

5.1 Example of a Domain using studies with generic event definitions

- Go to the **Design Management** module
- Unarchive the **Electronic Patient Record (studies generic)** domain and close and archive the other domains to prevent confusion.
- Display the **Electronic Patient Record (studies generic)** domain and the five data views which are attached to it. Familiarise yourself with the event structures.



Notice that there are two Renal data views, and there is one Cross-departmental data view containing the events from all the specialties.

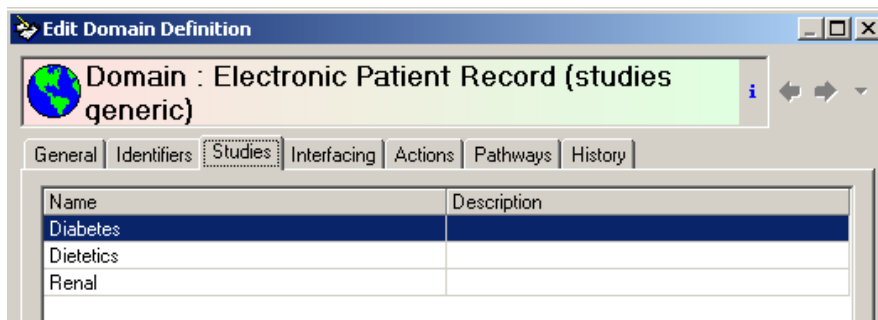
All the event definitions in this domain are generic – i.e. they have not been assigned to a study.

- View the **Event Study Map** to verify that there are no event definitions assigned to studies.

Event	Study
Patient Demographics	(Generic)
Referral (r)	(Generic)
Diabetes clinic visit (r)	(Generic)
Diabetes drug therapy (r)	(Generic)
Diabetes follow up (r)	(Generic)
Renal clinic visit (r)	(Generic)
Renal follow up (r)	(Generic)
Renal medications (r)	(Generic)
Renal complications (r)	(Generic)
Renal consultants notes	(Generic)
Dietetics clinic visit (r)	(Generic)
Dietetics notes	(Generic)

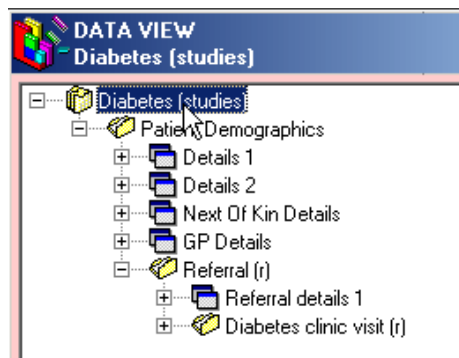
However, there are three studies defined on the domain.

- Edit the Domain Definition and view the **Studies** tab.

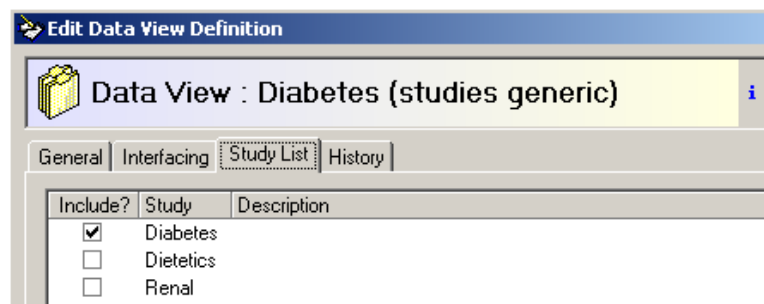


Studies are used in this domain by assigning studies directly to data views.

- Select the **Diabetes (studies)** data view



- Edit the definition by double-clicking (or selecting **Edit Definition**). Select the **Study list** tab.



Notice that the Diabetes study has been ticked to assign the Diabetes study to the **Diabetes (studies generic)** data view. The user is able to select which studies they wish to assign to the data view because the event definitions represented in the data view are all generic.

- Inspect the other data views in the domain so that you can see which studies are assigned to them.

5.2 Adding Patients in Data Entry

Now that we have understood how the studies are assigned to data views, we can see what happens when we start adding patients in Data Entry.

- Go to the **Data Entry** module. Select the **Diabetes (studies generic)** data view.
- Add a new subject. Enter the hospital number **123456** and the surname **Diabetes**.
- Attach a Referral event with Appointment date of **15/08/2007** and specialty of **1 - diabetes**.
- Attach a Diabetes clinic visit event with Date of clinic visit event of **15/08/2007**.

As each event is saved, it is marked as belonging to the Diabetes study and no other study, because the only study assigned to this data view is the Diabetes study. It does not matter whether the event definitions in Design Management are generic or belong to a study. The subject and their events in the subject overview all belong to the Diabetes study.

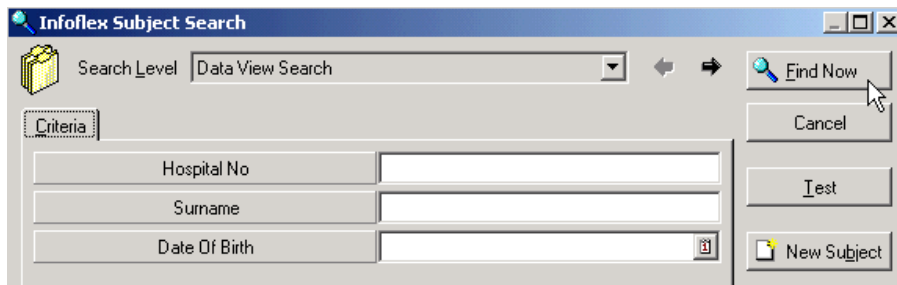
Initial Summary for Patient 123456

Data view:	Diabetes (studies generic)	Renal admin (studies generic)	Dietetics (studies generic)	Cross-Departmental (studies generic)
Studies	Diabetes	Renal	Dietetics	Renal + Diabetes + Dietetics
Data view Design				
Events in Domain	Events in data view	Events in data view	Events in data view	Events in data view
		None	None	

Key: ● Event in Diabetes Study ● Event in Dietetics Study ● Event in Renal Study ●●● Event in all three studies

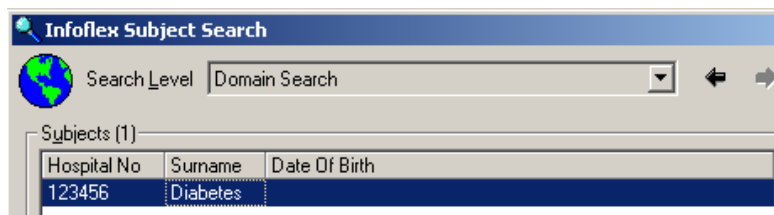
5.3 Keeping patients in different specialties separate

- Select the **Dietetics (studies generic)** data view. Search for all subjects in the data view. 



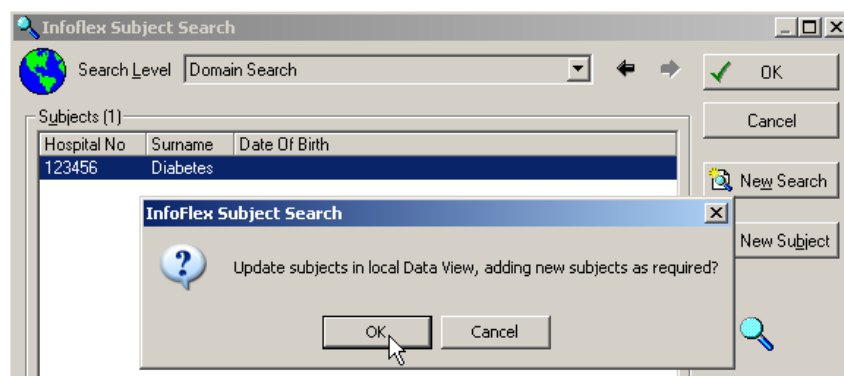
The study list of the **Dietetics (studies generic)** data view is just the dietetics study. When InfoFlex searches for any patients in the data view, it will look for any subject marked as being in the dietetics study.

One patient is found in the search but this patient exists in the domain, not in the **Dietetics (studies generic) data view**. We can tell this because the search has become a domain search, something which only happens when no patients meeting the criteria are found in the data view.



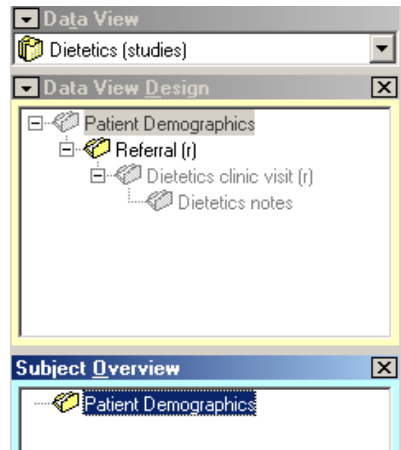
This is different from the earlier exercise in non-study data views, when the diabetes patient was found in the Dietetics data view. The difference is due to the study mechanism having marked the patient as belonging to the diabetes study, which means that the patient will only be found in data views where the diabetes study is represented (as long as the search is carried out at a data view level).

- Double click the patient and click **OK** to the message **Update subjects in local Data View, adding new subjects as required?**



When you select OK, the subject is added to all the studies in the current data view. However, only the root event - **Patient Demographics** will be added to the data view's studies. The other events belonging to the subject do not get added, and so won't be available in the data view.

The subject overview is displayed, however, only the Patient Demographics event is shown.



- The Referral event is in the Diabetes study, and so is not displayed in the Dietetics data view.
- The Diabetes clinic visit is also in the Diabetes study, and in any case is not an event which is represented in this data view.

Summary for Patient 123456 after adding subject to Dietetics data view

Data view:	Diabetes (studies generic)	Renal admin (studies generic)	Dietetics (studies generic)	Cross-Departmental (studies generic)
Studies	Diabetes	Renal	Dietetics	Renal + Diabetes + Dietetics
Events in Domain	Events in data view	Events in data view	Events in data view	Events in data view
		None		

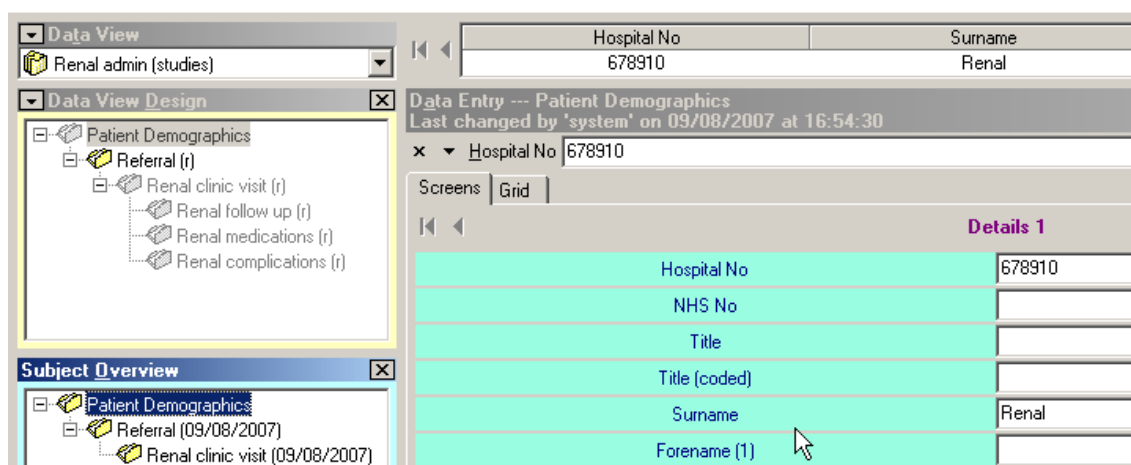
Key: Event in Diabetes Study Event in Dietetics Study Event in Renal Study Event in all three studies

- Go to the **Renal Admin (studies generic)** data view. Verify that the patient **123456** is only present in a domain search, and not in a data view search.

5.4 Keeping patients together

The following exercise shows that a patient that has been added in one data view, will be available in another data view if it has the same study in the data view's study list.

- Add a new patient to the **Renal admin (studies generic)** data view.
- Enter the hospital number **678910** and the surname **Renal**.
- Attach a Referral event with Appointment date of tomorrow's date and specialty of **3 - renal**.
- Attach a Renal clinic visit event with Date of clinic visit event of tomorrow's date.



As each event was saved, the event is marked as belonging to the Renal study because this is the only study in the data view's study list.

- Select the **Renal clinical (studies generic)** data view.

The **Renal clinical (studies generic)** data view has just the Renal study in its study list, like the **Renal admin (studies generic)** data view. So both data views will show the same set of patients.

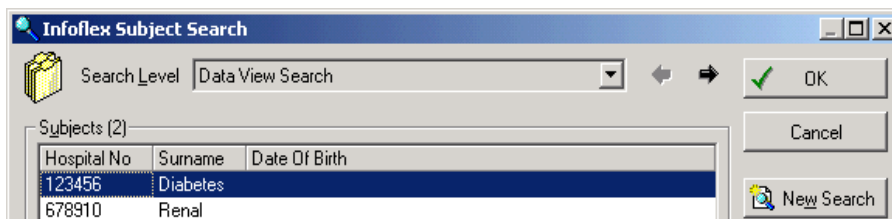
- Search for all subjects in the data view.

InfoFlex searches for any patients marked as belonging to the Renal study. The patient you have just entered is found since it is marked as belonging to the Renal study. The Referral event and Renal clinic visit events you added are shown since they were also marked as belonging to the Renal study and are represented in the data view.

5.5 Multi-study data views

The **Cross-departmental (studies generic)** data view has all three studies assigned to it: **Dietetics**, **Diabetes** and **Renal**.

- In the Data Entry module, select the **Cross-departmental (studies generic)** data view.
- Search for all patients in the data view.



All the patients you have added in the previous exercises are found because the Cross-departmental data view contains subjects that belong to **any** of the studies represented in it.

- Add a new patient with hospital number **5555** and surname **Cross**.
- Attach a **Referral** event date 08/08/2007.

As each event was saved it was marked as belonging to all three studies assigned to the data view.

Summary for Patient 55555

Data view:	Diabetes (studies generic)	Renal admin (studies generic)	Dietetics (studies generic)	Cross-Departmental (studies generic)
Studies	Diabetes	Renal	Dietetics	Renal + Diabetes + Dietetics
Events in Domain	Events in data view	Events in data view	Events in data view	Events in data view
Patient Demographics Referral 08/08/2007	Patient Demographics Referral 08/08/2007	Patient Demographics Referral 08/08/2007	Patient Demographics Referral 08/08/2007	Patient Demographics Referral 08/08/2007

Key: ● Event in Diabetes Study ● Event in Dietetics Study ● Event in Renal Study ●●● Event in all three studies

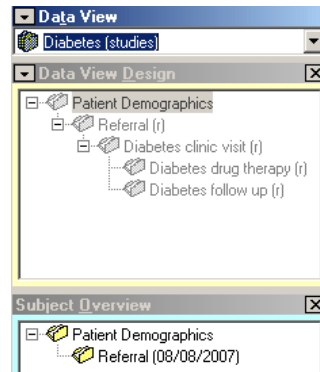
We will verify what the diagram above tells us by looking for the patient in another data view and seeing which events are visible.

- Select the **Diabetes (studies generic)** data view.
- Search for all patients in the **Diabetes (studies generic)** data view.

The patient with surname **Cross** is found.

- Select the patient **Cross**.

The subject overview will display the Referral event added in the Cross-departmental data view, since this event was marked as belonging to the diabetes study (as well as the other two studies).



- Go to the **Dietetics (studies generic)** data view and check that you can find the patient Cross in the data view, and that the referral event is visible.

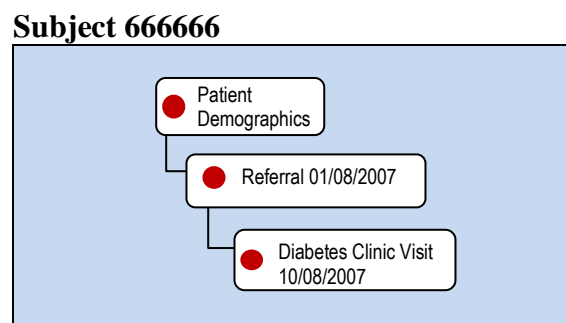
This illustrates that it is important that data entry is carried out from appropriate data views to ensure that patients and their events are registered in the correct studies.

5.6 Adding events in different studies

The next example shows that a patient can have more than one event of a particular type but in different studies.

- Go to the Data Entry module and select the **Diabetes (studies generic)** data view.
- Add a new subject with hospital number **666666** and surname **Severall**.
- Add a Referral Event with date **01/08/2007**. Select Specialty **1- Diabetes**.
- Add a Diabetes Clinic visit with date **10/08/2007**.

The events in the domain for this patient are currently as follows:



- Now select the **Renal Admin (studies generic)** data view.

Patient **666666** will not be in the **Renal Admin (studies generic)** data view, because we have only added him to the Diabetes study.

- Do a Domain Search for patient **666666**. Add the patient to the **Renal Admin (studies generic)** data view.

Notice that you do not see the Referral 01/08/2007. This is because we have just added the subject and his Patient Demographics event to the Renal study. The Referral is still only in the Diabetes study.

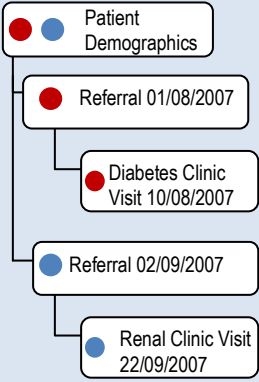
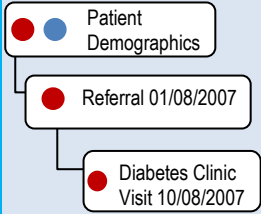
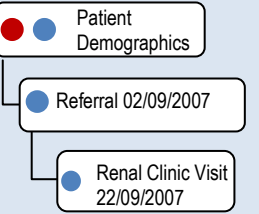
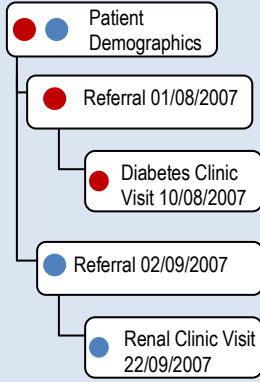
- Still in the **Renal Admin (studies generic)** data view, add a Referral event with date **02/09/2007**, choose specialty **3 - Renal**.
- Add a **Renal clinic visit** with date **22/09/2007**.

Now the patient has two referrals, however they belong to different studies, so you will only see both of the referrals in a data view which shows both Renal and Diabetes studies.

- Look at each of the data views, **Cross-Departmental (studies generic)**, **Renal Admin (studies generic)**, **Renal Clinical (studies generic)**, and **Diabetes (studies generic)**. Find the patient **666666** and notice which events you can see.


The diagram on the following page summarises what you can see in each data view.

Summary of Patient 666666


Data view:	Diabetes (studies generic)	Renal admin (studies generic)	Dietetics (studies generic)	Cross-Departmental (studies generic)
Studies	Diabetes	Renal	Dietetics	Renal + Diabetes + Dietetics
Events in Domain	Events in data view	Events in data view	Events in data view	Events in data view
			<p>None</p>	

Key:

 Event in Diabetes Study

 Event in Dietetics Study

 Event in Renal Study

 Event in all three studies

6 SETTING STUDIES AT THE EVENT LEVEL

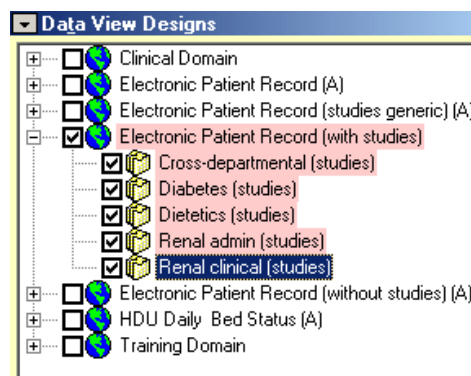
In the previous chapter, the event definitions in Design Management were generic, and the user could choose which studies should be in a data view's study list. Now we will look at what happens when event definitions belong to a study rather than being generic.

If a data view contains an event definition that has been assigned to a study, the study will automatically be in the data view's study list, and cannot be removed.

Once the data view has studies assigned to it, it does not matter whether they came about automatically because of event definitions belonging to a study, or because the user chose to add the study to the data view. *The behaviour in Data Entry is the same.*

6.1 Example of a Domain with Events definitions belonging to studies

- Go to the **Design Management** module.
- Unarchive the **Electronic Patient Record (with studies)** domain and close and archive any other ones.



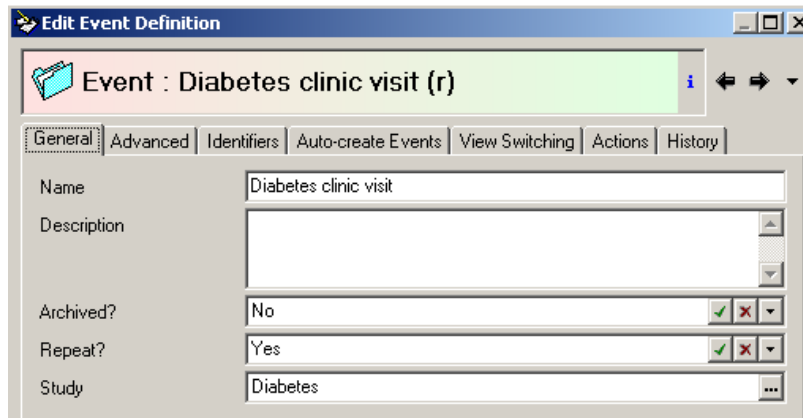
Notice that the structure of this domain is very similar to the **Electronic Patient Record (studies generic domain)**. The difference is in how the studies are set.

- View the **Event Study Map** for this domain.

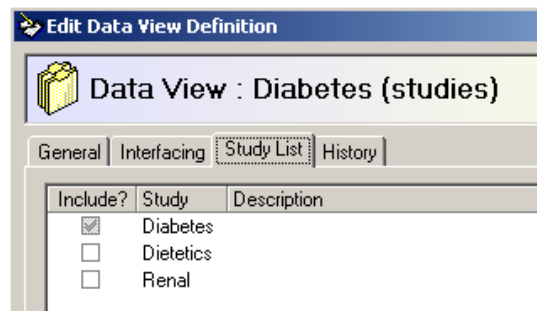
Event	Study
Patient Demographics	(Generic)
Referral (r)	(Generic)
Diabetes clinic visit (r)	Diabetes
Diabetes drug therapy (r)	Diabetes
Diabetes follow up (r)	Diabetes
Renal clinic visit (r)	Renal
Renal follow up (r)	Renal
Renal medications (r)	Renal
Renal complications (r)	Renal
Renal consultants notes	Renal
Dietetics clinic visit (r)	Dietetics
Dietetics notes	Dietetics

Whereas in the previous chapter, all the event definitions were generic, in this domain some of the events definitions have studies assigned to them.

- Select the **Diabetes Clinic Visit** event from the **Electronic Patient Records (with studies)** domain.
- Double-click to edit the definition. Notice that this event is assigned to the Diabetes study.



- Select the **Diabetes (studies)** data view and double-click to edit the definition. Select the **Study List** tab.



Notice that the Diabetes study is automatically assigned to the **Diabetes (studies)** data view. It cannot be removed. This is because the data view contains an event that belongs to the Diabetes study – **Diabetes Clinic visit**.

- Inspect the Study lists of the other data views in this domain.

Notice that the study lists for each data view happen to be the same as for the **Electronic Patient Record (with studies)** domain.

6.2 Adding Patients and study membership

Go back and try the exercises from the previous chapter (5.2 Adding Patients in Data Entry) to the end of chapter 5.

The studies that the patients and events belong to will be the same as before. This is because the study list of the data view determines which studies the subjects and events belong to. All the data views have the same study lists as before.

7 SETTING STUDIES BASED ON DATA

Sometimes the study that a patient should be in depends on some value in the patient's data. So instead of deciding before data entry which study the patient belongs to, you may wish to assign the patient to a study dynamically according to values the patient has in particular data items.

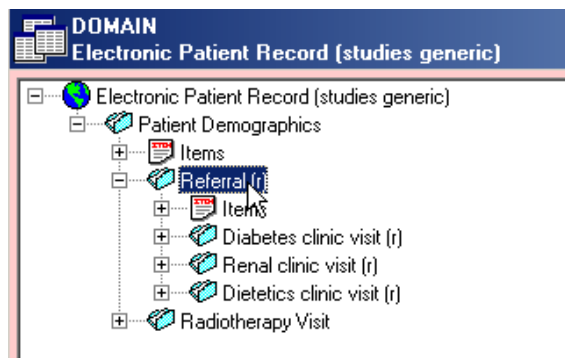
For example, there may be a Cancer design where referral and diagnosis details are entered in some general data view. When the primary diagnosis is entered then this will indicate whether the patient should also belong to another study which is dependent on the tumour site, e.g. breast, lung, colorectal etc.

The assigning of studies can be set up to happen depending on the patient's data. The value of a data item can trigger which study a subject or event is assigned to when an event is saved. This behaviour is accessed by adding an action to an event.

7.1 Setting up an Action to change the studies dynamically

This example goes through the steps needed to add a patient to the Renal study if the Specialty in the Referral event is set to **3 - Renal**.

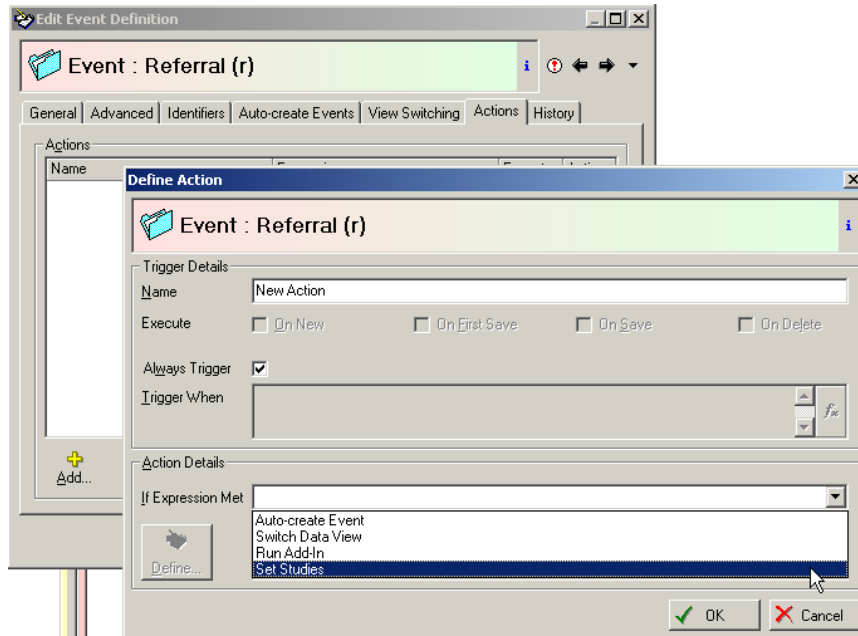
- Go to the **Design Management** module.
- Ensure that the domain **Electronic Patient record (studies generic)** is unarchived and the other domains are archived.
- Edit the definition for the **Referral Event**.



➤ Go to the **Actions** tab and add a new Action:

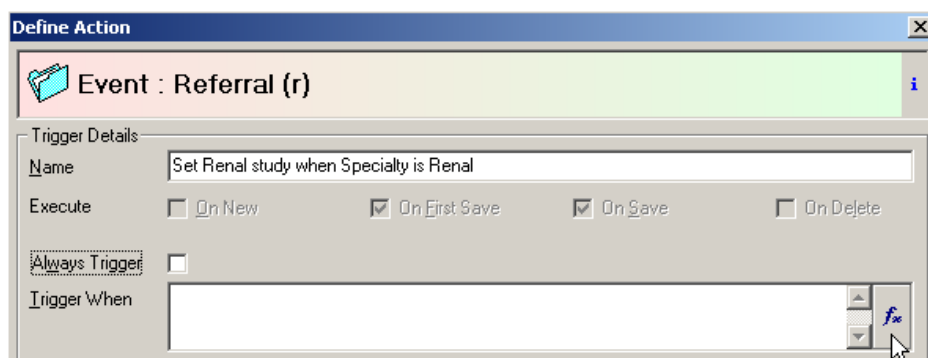


➤ In the window called **Define Action**, select **Set Studies** as the type of Action, in the drop down list next to **If Expression Met**.



This type of action happens when the event is first saved, and whenever it is subsequently saved.

➤ Now type in a name for your action, e.g. "Set Renal study when Specialty is Renal".

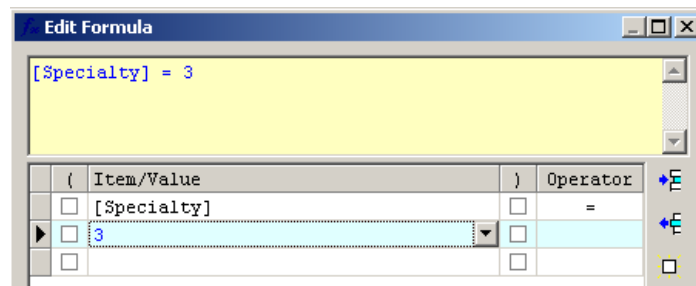


If the **Always Trigger** check box is ticked it means that this action will happen every time the Referral event is saved. However in this case, we want to only trigger the action when there is a particular value for a data item when the event is saved. We do this by creating a formula in the **Trigger When** box.

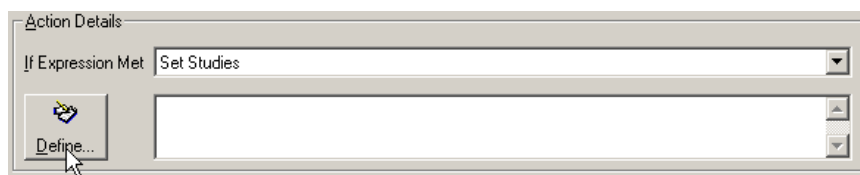
➤ Uncheck the **Always Trigger** check box.

➤ Press the  button to define a formula.

- Use the **Edit Formula** dialog to define your action trigger as in the diagram below:

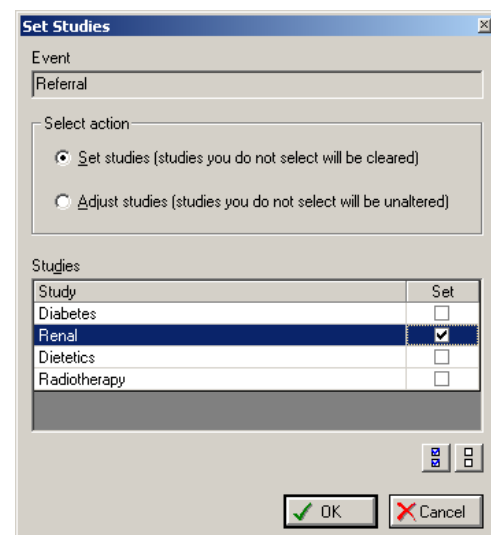
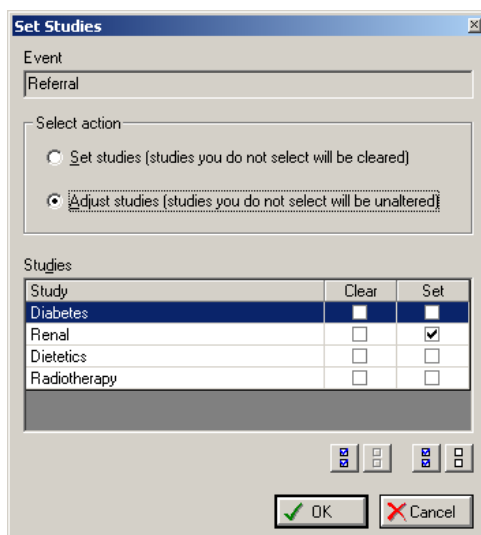


- Press OK to return to the **Edit Action** dialog.
- Now define the action by pressing the **Define...** button.



There is a choice of whether to **Adjust studies** or **Set studies**.

- When you choose **Adjust studies**, it means that InfoFlex will set or clear the studies that you choose, but any studies that you have not asked to be cleared or set will be left alone.
- When you choose **Set studies**, then the studies that you pick will be set and any other studies that are on the event are cleared.



Your choice of which action to pick will depend on what is required in the design you are building. Remember that if the action involves clearing a study, then the event will no longer belong to that study once the action has been triggered and so may no longer still be in the current data view.

- Choose **Set Studies** and tick the **Renal** box. Press **OK**.
- Press **OK** to the **Edit Action** dialog, and save and close the edited event definition.

7.2 Triggering the set studies action in Data Entry

In Data Entry, the action will be triggered whenever the event is saved. If the event is added to a study, then the event's parent event and so on up the event tree will also be added to a study, and so will the subject.

- Go to the **Data Entry** module, select the **Cross Departmental (studies generic)** data view.
- Add a patient with hospital number **444444** and surname **Dynamic**.
- Add a Referral Event with the date **01/02/2008**. Leave the **Specialty** blank for now. Save the event.

At this point, both the Patient Demographics and the Referral event for patient **444444** will be in all three studies: **Renal**, **Diabetes** and **Dietetics**, because the subject has been added in the **Cross Departmental** data view.

- Go to the **Diabetes (studies generic)** data view and check that you can find the patient **444444** and their Referral event in this data view.
- Go back to the **Cross-Departmental (studies generic)** data view and find patient **444444** again.
- In the Referral event edit the data item called **Specialty** and select **3 – Renal**. Save the event.

On saving the Referral event, the set studies action will be triggered because the formula is true. The Referral event will be added to the Renal study and removed from all other studies.

- Go to the **Diabetes (studies generic)** data view and check that you can no longer find the Referral for patient **444444** in the data view.
- Go to the **Renal Admin (studies generic)** data view and check that you can still find the Referral for patient **444444** in the data view.

The diagram below summarises the study membership before and after the **Set Studies** action was triggered.

Summary of Patient 444444

Data view:	Diabetes (studies generic)	Renal admin (studies generic)	Cross-Departmental (studies generic)
Studies	Diabetes	Renal	Renal + Diabetes + Dietetics
Events in Domain Before Action triggered	Events in data view	Events in data view	Events in data view
Events in Domain After Action triggered	Events in data view	Events in data view	Events in data view

Key: ● Event in Diabetes Study ● Event in Dietetics Study ● Event in Renal Study ● ● ● Event in all three studies

7.3 Exercise

Create an action on the Referral event in the **Electronic Patient Record (studies generic)** domain. Make the action to add the Referral to the **Diabetes** study whenever a Referral has a Specialty of **1 - Diabetes**.

Test with a patient that was entered in the **Renal** data view. The patient will not normally be in the **Diabetes** study. When the specialty is set as **1 - Diabetes** and the event is saved, then the Referral will be added to the **Diabetes** study. Test the effect of the action by going to the **Diabetes** data view and looking for the patient and referral.

Make a diagram like the one above to show the study membership before and after the action. Verify it by checking in each data view for your test patient.

8 VIEWING EXTERNAL EVENTS FROM A DIFFERENT STUDY

There are occasions where it would be useful if we could see a particular event in our data view that really belongs to a different study. For example suppose we would like to know whether any of our Diabetes patients has had a Radiotherapy Visit event. We do not want to see all patients that have had a Radiotherapy Visit, just the ones in the Diabetes study.

Suppose all the Radiotherapy visits are added in a separate Radiotherapy data view which has its own Radiotherapy study. This will mean that all the Radiotherapy visit events are in the Radiotherapy study.

We will need clearly need to add a Radiotherapy Visit event view to the Diabetes data view. However, this is not sufficient, because the Radiotherapy visit events would be in a different study, and so would not be visible in the Diabetes data view.

If we added the Radiotherapy study to the Diabetes data view, we would see all the Radiotherapy visit events. However, we would end up seeing all the Radiotherapy patients, as well as the Diabetes ones.

We will call the Radiotherapy visit in this example an 'external event'. We want to be able to see the Radiotherapy visit as an external event in the Diabetes data view.

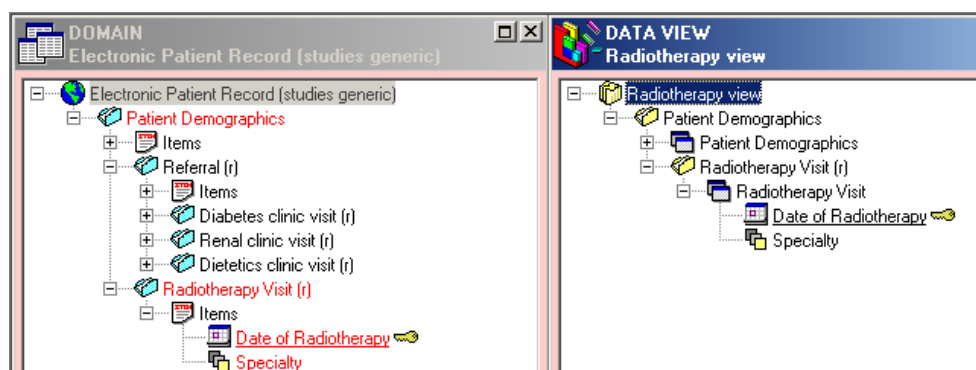
The following example shows how to solve this problem.

8.1 Adding a Radiotherapy Event and data view

First we need to add a Radiotherapy Event and data view to our **Electronic Patient Record (studies generic)** domain to illustrate this example.

- Go to the **Design Management** module
- Select the **Electronic Patient Record (studies generic)** domain and add a new repeat event called "**Radiotherapy visit**" as a child of the **Patient Demographics** event.
- Make the primary identifier of the Radiotherapy visit a date item called "**Date of Radiotherapy**". Make a coded item called "**Specialty**" which uses the code called **Specialty**.
- Unarchive the events and data items.
- Create a new data view called **Radiotherapy view**. Add the **Patient Demographics** event and data items but do not copy in all its child events.
- Add the **Radiotherapy Visit** event to the **Radiotherapy view**.
- Unarchive the **Radiotherapy view** data view.

The new event and data view looks like this:



- Now add a new study called **Radiotherapy** to the domain.
- Add the **Radiotherapy** study to the study list of the data view **Radiotherapy view**.
- Ensure that all the events in the domain are generic. Use the event study map to check.
- Remove any actions that you set up on the Referral Event in the previous chapter.
- Go to the **User Management** module and ensure that the **Training** user has Read/Change/Create/Delete permissions for the **Radiotherapy view** data view.

Permissions				
Functions Objects				
Object	Read	Change	Create	Delete
[-] Study Views	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Clinical Domain	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Electronic Patient Record (A)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Electronic Patient Record (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Cross-departmental (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Diabetes (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Dietetics (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Radiotherapy view	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Renal admin (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
[+] Renal clinical (studies generic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

8.2 Adding Patients to the Radiotherapy data view and to the Diabetes data view

Next we will add some patients in Data Entry – some with a diabetes referral and some without.

- Go to the **Data Entry** Module, Select **Diabetes (studies generic)** data view.
- Add a patient with hospital number **777777** and surname **Diabetes-RT1**.
- Add a Referral with date **10/10/2007** and Diabetes clinic visit of **10/11/2007**.
- Now go to the **Radiotherapy view** data view.
- Find patient **777777** by doing a domain search. Add them to the data view.
- Add a Radiotherapy visit with date **11/11/2007**.

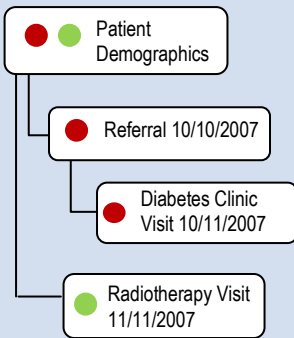
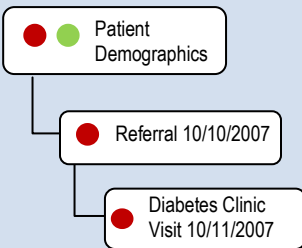
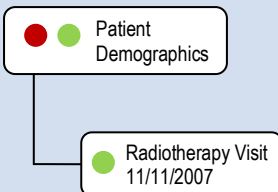
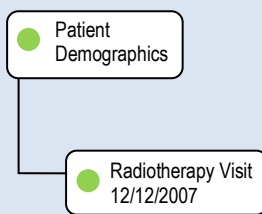
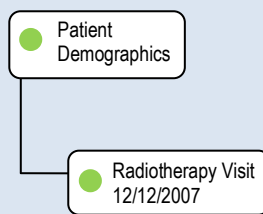
The patient **777777** represents our patient which has had a Diabetes referral and a Radiotherapy visit.

- Add a new subject to the Radiotherapy view **888888** with surname **Radiotherapy1**.
- Add a Radiotherapy visit with date **12/12/2007**.

The patient **888888** represents our patient which has only had a Radiotherapy visit.

The diagram below shows the subjects and their study membership.

Summary for Patients 777777 and 888888
Before making Radiotherapy Visit an external event in Diabetes data view.

Data view:	Diabetes (studies generic)	Radiotherapy View
Studies	Diabetes	Radiotherapy
Data view Design	Patient Demographics Referral (r) Diabetes clinic visit (r) Diabetes drug therapy (r) Diabetes follow up (r)	Patient Demographics Radiotherapy Visit
Subject 777777 Diabetes-RT1 Events in Domain 	Events in data view 	Events in data view 
Subject 888888 Radiotherapy1 Events in Domain 	Events in data view None	Events in data view 

Key: ● Event in Diabetes Study ● Event in Radiotherapy Study ●● Event in Diabetes and Radiotherapy Study

The problem is that we want to see the Radiotherapy Visit of patient **777777 - Diabetes-RT1** in the Diabetes data view, without seeing the Radiotherapy Visit of patient **888888 – Radiotherapy1** in the Diabetes data view.

8.3 Viewing External Events

New functionality has been developed so that external events from a different study can be seen in a data view without compromising the data view's study list. This is a way of viewing events that belong to another speciality.

To do this, the event definition for the external event should have the following properties:

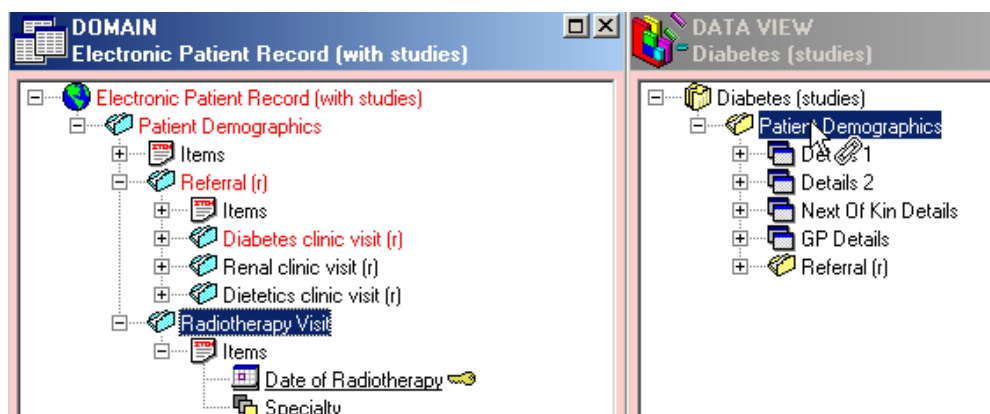
- It should be a generic event, not belonging to a study, so that it can be represented in different data views without adding a further study to a data view;
- The Event view for the external event should be write-protected in the viewing data view, so that it cannot be created in that data view. For example, if an external event, such as a Radiotherapy Visit was created in the Diabetes data view, it would no longer be external, because it would now belong to the Diabetes study.

8.4 Adding an External Event

To add an **external event** definition to a data view, we first add the event to the data view, and then protect it to make it read-only.

In the following example, we will make the Radiotherapy visit event an external event in the Diabetes data view.

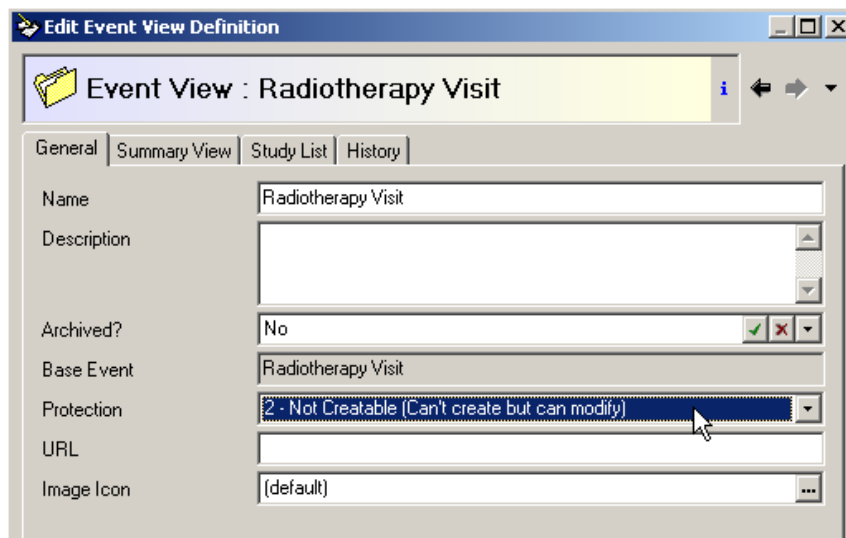
- Go to the **Design Management** module.
- Drag the **Radiotherapy Visit** event from the domain into the **Diabetes (studies generic)** data view.



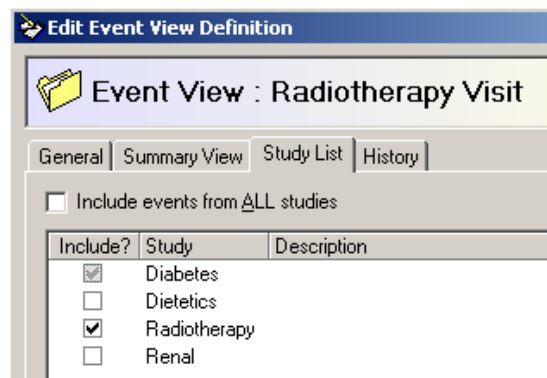
Because the Radiotherapy Visit is a generic event, this does not add the **Radiotherapy** study to the **Diabetes** data view.

- Edit the event view definition of the **Radiotherapy Visit** event view, in the **Diabetes (studies generic)** data view.

- In the **Protection** property of the Event view, choose **2 – Not Creatable (Can't create but can modify)**



- Without closing the dialog, select the **Study List** tab.
- Place a tick in the Radiotherapy study box



Notice that the **Study List** already contained the Diabetes study. This is automatic because the event view study list has to contain all the studies that are in the data view's study list.

Adding a tick against another study in the Event View means that you want to be able to view a subject's events that belong to the ticked study even though it is not one of the studies assigned to the current data view.

By ticking the **Radiotherapy** box we are saying that we want to see any Radiotherapy Visit events that belong to the Radiotherapy study even though we are in the Diabetes data view which normally just shows diabetes study events.

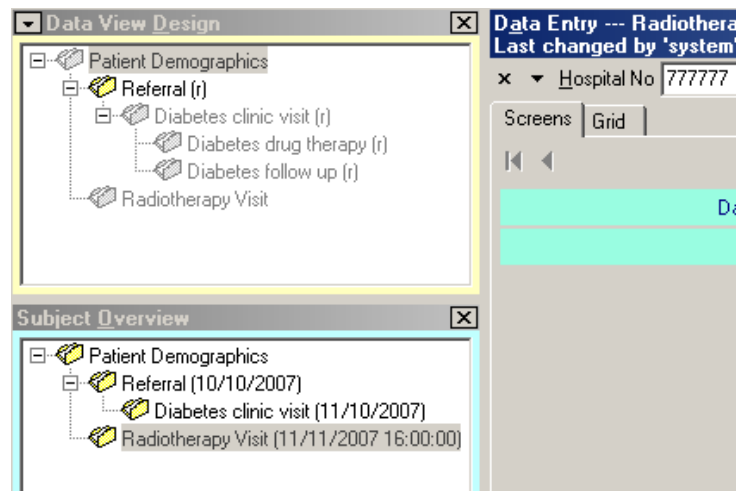
We will still only see the subjects that are in the Diabetes study though.

- Save and close the **Edit Event View Definition** dialog.

8.5 Viewing the External Events in Data Entry

- Go to the **Data Entry** module and select the **Diabetes (studies generic)** data view.
- Find patient **777777**.

Notice that you can now see the patient's Radiotherapy visit.

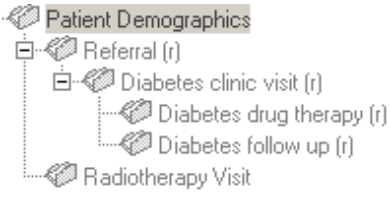

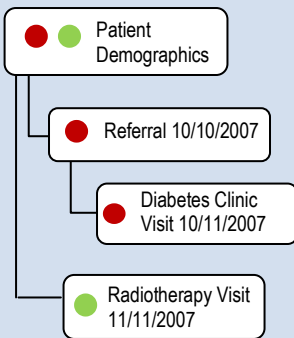
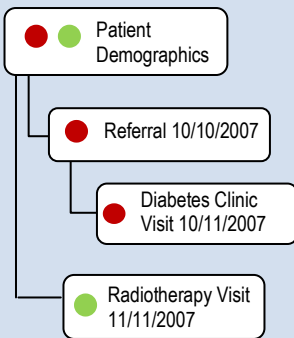
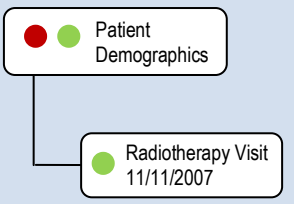
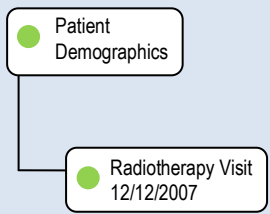
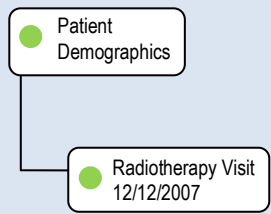


You will not be able to add Radiotherapy visit events while in the **Diabetes** data view because we protected it.

- While in the **Diabetes (studies generic)** data view, do a Subject Search for all subjects in the data view. Notice that you do not find the patient **888888**. This is because this subject is not in the **Diabetes** study.
- Go to the **Radiotherapy View** data view and search for all subjects. Notice that you can still see both subjects **777777** and **888888** and their Radiotherapy visits. We have not changed the study membership of their events.

See the diagram below for a summary of the two patients.

Summary for Patients 777777 and 888888
After making Radiotherapy Visit an external event in the Diabetes data view.

Data view:	Diabetes (studies generic)	Radiotherapy View
Studies	Diabetes	Radiotherapy
Data view Design		
<p>Subject 777777 Diabetes-RT1 Events in Domain</p> 	<p>Events in data view</p> 	<p>Events in data view</p> 
<p>Subject 888888 Radiotherapy1 Events in Domain</p> 	<p>Events in data view</p> <p style="text-align: center;">None</p>	<p>Events in data view</p> 

Key: ● Event in Diabetes Study ● Event in Radiotherapy Study ●● Event in Diabetes and Radiotherapy Study

9 CONCLUSIONS

Studies are a useful but optional step in the Design Process. They allow grouping of subjects and their events according to specialty. Without them, all subjects would be available in all data views. The studies themselves are not visible to the Data Entry user but they benefit from their use.

It is easiest to decide how studies should be implemented in the design before data is entered into the domain – otherwise existing subjects and events may not belong to the correct study and so may not be visible in the data view that they should be seen in.

We would recommend that studies are set at a data view level and that event definitions stay generic where possible for the following reasons:

1. The focus on generic events maximises design efficiency, sharing common data items where appropriate and then just using data views to give speciality-specific views of events.
2. It allows more flexibility in choosing which studies to assign to data views.
3. Viewing external events from another study in a data view relies on the underlying event definitions being generic.