GUIDE TO RADAR DATA ENTRY FOR POST-TRANSPLANT CMV

Contents

Key Contact

For all and any questions about data entry, please contact Garry King (Senior RaDaR Data Manager) on

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RaDaR – Recruitment Resources

A useful link for everything to do with recruitment and data entry for RaDaR is Recruitment Resources | The UK Kidney Association. General RaDaR training material slides and video available there. The parent page for this has lots of information for RaDaR and the UK Kidney Association Rare Renal | The UK Kidney Association

CMV resources on Rare Renal website

Patient Information on CMV

Clinician Information on CMV

Information on the Post-transplant Cytomegalovirus Rare Disease Group

CMV Inclusion / Exclusion criteria

Inclusion Criteria:

1. Kidney transplant recipients from 2016 onwards. Of note, patients whose transplants have failed can be included. Patients already recruited to RaDaR do not need new consent to be included in this group if they fit the inclusion and exclusion criteria.

2. CMV infection in first year after kidney transplantation

Exclusion Criteria:

1. Multi-organ transplant recipients

RaDaR database usage notes

- All fields indicated must be examined for completion for this cohort. Where data is missing, it must be documented. Please make a note in the Metadata comments free text field, which can be found in the Demographics tab.
- To start entering data, click on the 'Patient' tab from the RaDaR front page, which will take you to the list of patients that are currently recruited to your site. You can select the filter on the right for CMV cohort if you wish.
- You can search for a patient in multiple ways as shown on the right-hand side of the page, or you can select a patient by clicking on the patient RaDaR number or name.
- Where possible, please use the lists provided to enter coded data such as medications, results and comorbidities.
- Where a field is marked with a * data is essential to be able to save the record. All other data is desirable, but please note where fields are only for the use of the RaDaR team, such as the 'Cleaned by date' in the Pathology tab.

Renal IT System Feed

- Some sites have a renal IT system that allows results to be fed automatically into RaDaR. If the results' feed from the site's renal IT system is enabled many of the labs and observation fields will be automatically populated saving a lot of manual entry. This is indicated by a link symbol next to the patient's RaDaR number in the patient list screen. This feed is also known as the PV link.
- If this feed is not enabled, contact the local Renal System Administrator and request that 'Send to PV flag is set'.
- Where a results field is not available in the site's renal IT system, data must be entered manually.

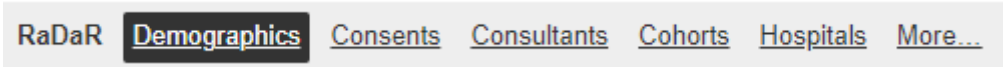
Recruitment to RaDaR

Sites will be sent lists of existing RaDaR patients (belonging to other cohorts) with transplant recorded on their Radar record. Once checked, patients meeting the CMV Inclusion / Exclusion criteria on their clinical record can be added to the Post-Transplant CMV cohort. No further consent required.

In this case, to recruit into CMV cohort, search for patient on radar. Add the CMV cohort to their record. Go to primary diagnosis on the CMV row and add relevant diagnosis with diagnosis date and how diagnosis was confirmed. Continue to add all tabs and fields required.

For patients new to Radar:

1. Consent - Download the appropriate Patient Information Sheets (PIS) from Recruitment Resources | The UK Kidney Association and give to patient
2. Download consent forms from Recruitment Resources | The UK Kidney Association These should be printed with Hospital / Trust letterheads.
3. Obtain consent from patient. This can be done by post, face-to-face or via email where the site is set up for e-consent Electronic Consent | The UK Kidney Association
4. Copies of consent form for patient and medical record are to be retained in the local site file.
5. Log in to https://nww.radar.nhs.uk
6. Go to the Patients tab and click on Recruit Patient
7. Enter the required details and click Search. Enter the patient's details manually if their record is not found. Where the patient has already been recruited to RaDaR but their current site isn't listed, contact Garry King who will add the site to the record.
8. Select the appropriate Renal Unit and Cohort (Rare Disease Group /diagnosis)
9. Confirm that the patient has been consented by selecting the applicable Consent check box.
10. Click on the green Cohort tab for condition-specific data entry instructions. Fill in the Demographics, Primary Diagnosis and Consultant tabs as a minimum for all patients.
11. Further data entry instructions for new and existing patients follow.



Demographics

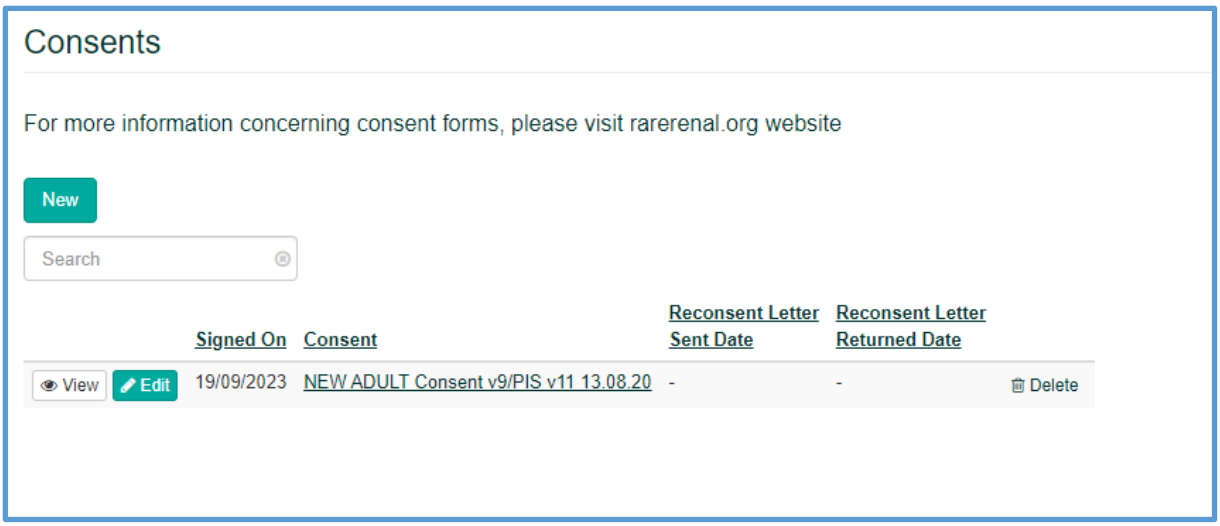
- This is the first page presented for each patient. Check that the DOB is correct and if the patient's postal or email addresses need a new entry. If a patient is deceased but this isn't indicated, you can input the date of death and cause of death, if known.
- You'll see there are two lines for the patient details with two different data sources. If there are differences between these lines, they indicate either there is a mistake either in the data that has been entered into RaDaR, which can be edited; or there is a mistake with the information the patient's site holds. Whichever is incorrect should be addressed. If the site information is incorrect, ask the data manager for the site to correct as necessary.
- You can use the Metadata Comments on this page to add any information about anomalies – such as missing blood tests. Please put your initials and date against any comments you add.

Consent

For patients to be recruited to RaDaR and for any data to be entered for them into RaDaR, the patient should have signed a valid RaDaR consent form. You can check this by selecting the 'Consent' tab. The latest consent forms, patient information sheets, letters and RaDaR protocol can be found in Criteria and Consent | The UK Kidney Association

Please note that all consents are still valid even though some are labelled 'OLD'. The only consents that are no longer valid for current results are parent/guardian consents for people who are now aged 18 or older. **Any patients who are aged 18 or older and ONLY have a parent/guardian consent** should be asked to reconsent as an adult.

Please note that the Recruited date is automatically generated for patients and it is important that the Consent signed on date is as close as possible to the Recruited date in order for RaDaR to receive as much of the patient data as possible.



Consultant

Please add the patient's consultant. If the consultant's name is not in the dropdown, then please contact Garry King with the details so it can be added to the list.

Cohorts

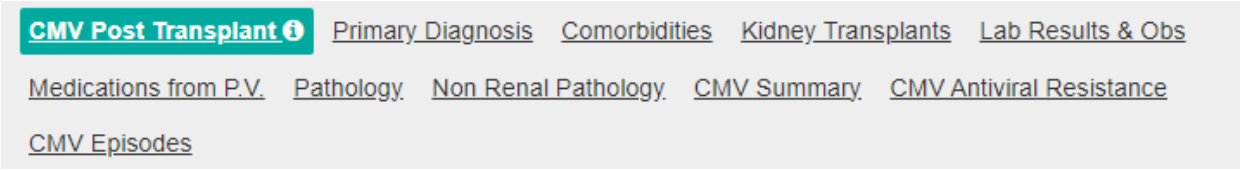
If patient exists in Radar already but not for CMV then, this tab is where you add patient to the CMV cohort. For patients new to Radar, this page is auto populated during the registration process.

Hospitals

If patient exists in Radar already then, this page may need to be updated to reflect where the patient is now treated. For new patients, this page is auto populated during the registration process.

Data Entry tabs and fields

The next pages go through the specific tabs and fields required for full data enrichment of the record for CMV cohort



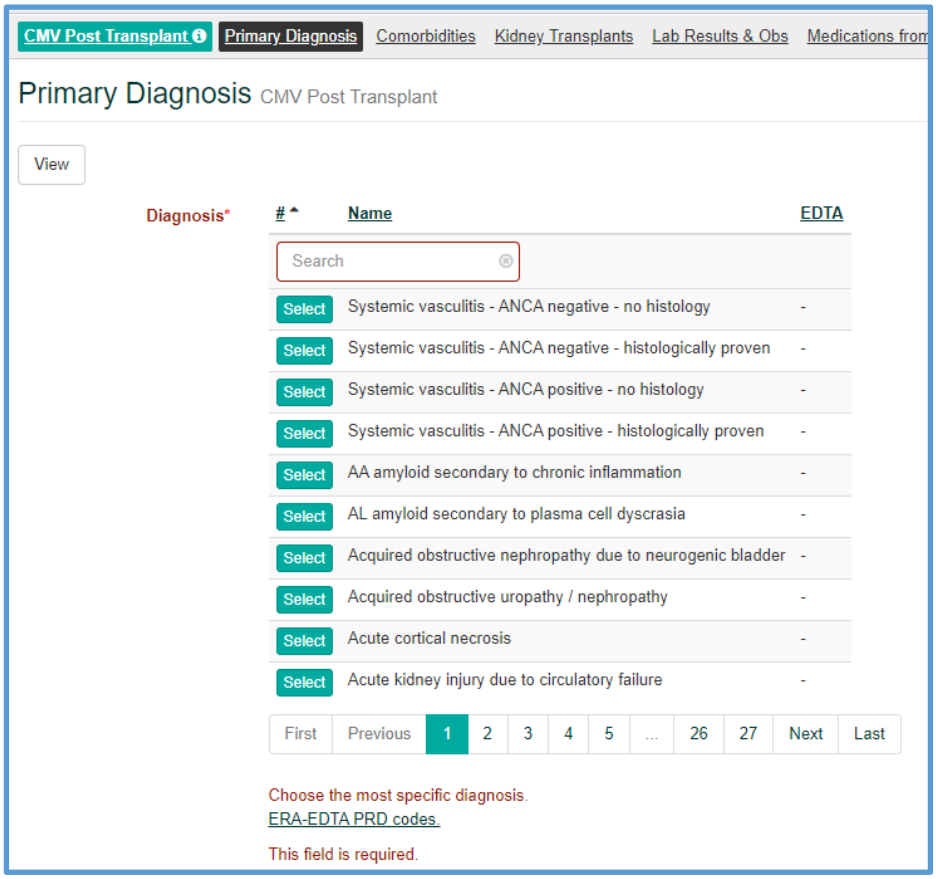
Primary diagnosis

The primary diagnosis in the CMV cohort is the main kidney condition.

Start typing in box to search for correct diagnosis. This should be confirmed by clinical picture or by biopsy.

Check if a biopsy has been carried out and 'Confirmed by biopsy' is correctly indicated.

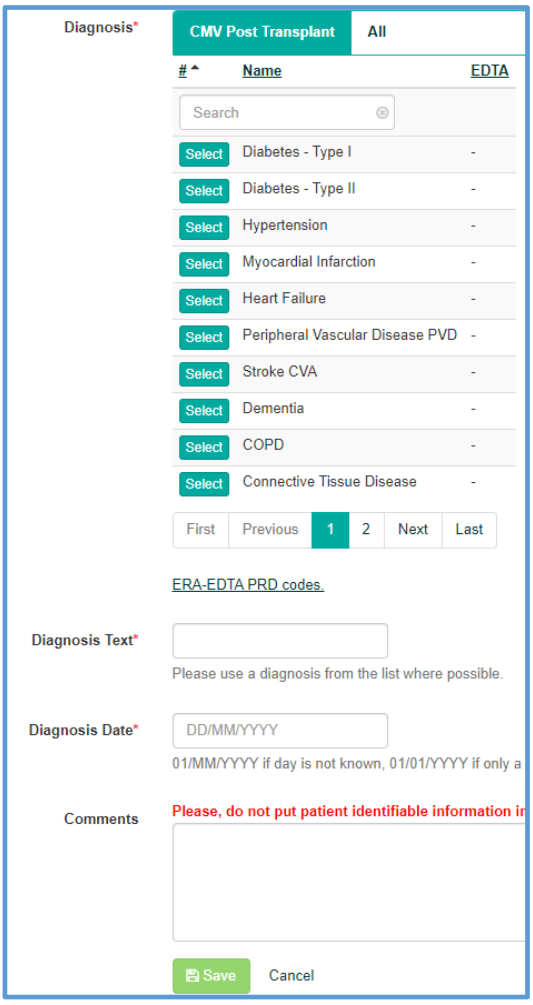
- Where 'Confirmed by biopsy' is 'Yes', ensure that a pathology report has been added to the Pathology tab.
    - If there is no pathology report, please indicate this is the case in the free text in the Primary Diagnosis tab and keep a note of which patients this applies to.



Comorbidities

Please ensure all comorbidities are entered in this tab.

- Click on 'New' and a list of possible comorbidities will appear.
- Select CMV-specific comorbidities tab and select each comorbidity present in turn on patient record. Please note, there are 2 pages of CMV-specific comorbidities. Clicking page 2 or next will take you to next page.
- Select any other comorbidities present from the All list. Start typing in the search box and relevant diagnosis options will appear.
- When entering diagnosis details, you will need to enter a date of diagnosis before you can save the entry. If the full date of diagnosis is not available, enter 01/01 for day and month, then the year as known, this will indicate that precise details are not available.
- Once you click save, a summary appears and if you want to add more co-morbidities click on the List button and you will return to the page where you can then select New to add another.
- All co-morbidities that have been added will be visible. If you need to change something, click Edit then Save once updated.



It is possible to add a comorbidity that isn't listed, but using the free text isn't advised and where possible, please use the populated list.

Kidney Transplants

All transplant history should be recorded, and applicable histology entered in Pathology tab. Please ensure Accession number is noted in Pathology tab

- Date of transplant
- Transplant Hospital
- Type
- Episode of CMV infection
- Date of failure if relevant
- Graft loss and cause if relevant

Recipient HLA and Donor HLA – this will be auto populated from NHSBT unless that transplant was performed outside of UK. In this case, add recipient HLA and Donor HLA.

Episode of CMV infection- fill in date when CMV viraemia first detected

Recurrence- this refers to whether the patient has developed recurrence of primary renal disease in the transplant kidney e.g. recurrent IgA nephropathy

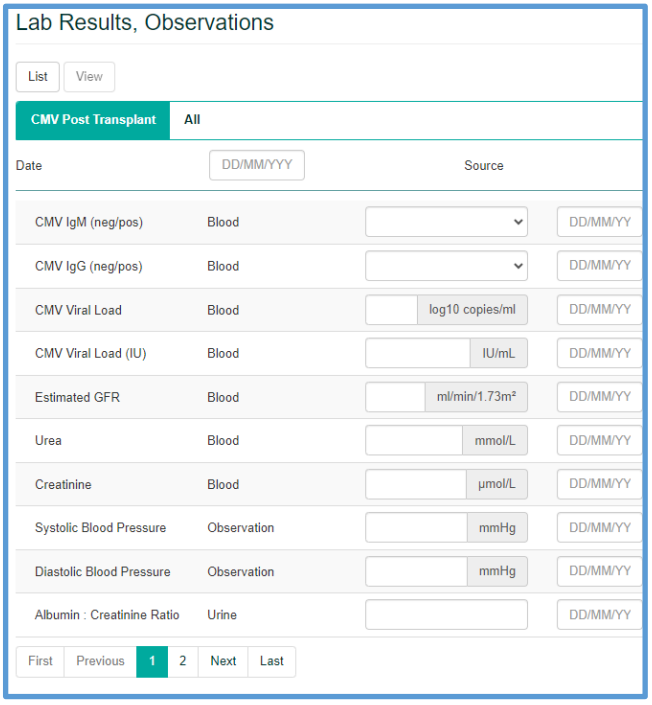
Lab Results and Observations

- CMV viral loads for the duration of the CMV episode
- CMV IgG

This may be auto populated for your unit. If not, please enter all results including blood pressure from the date when CMV first detected for 6 months. Add the CMV Viral Load results including when the viraemia has resolved. For example, if CMV viral load <10 or undetectable, enter 0.

To add a result, you must click 'New' in the top left-hand corner. The first screen that appears is for the study specific labs and obs only (template). This enables you to input relevant labs and obs in one go. Please note there are two pages to the template. Please note you do not need a full complement if you only have a couple of results to input, it will still save what you have. Please make sure the date entered is the date of the result and that you are using the correct unit of measurement.

Note that the 'Save' button is in the top right position, not at the bottom of the page.



Medications

This may be auto populated for your unit. If not, please enter all medications and doses from the date when CMV first detected for 6 months.

To enter medications:

First search for the drug in the search box. It is possible to enter the drug name in the free text 'Drug Text', but this is not advised and, wherever possible, the drug from the list should be used.

Enter all other details if known in the fields provided and click Save at the bottom of the page.

Pathology

Please enter where relevant reports are available. Ensure all relevant pathology reports are input with Accession number (Reference Number). Please make sure native or transplant is indicated.

Cut and paste all kidney transplant histopathology reports from local clinical system into Histological Summary field. These should be since the time of transplantation. PDFs cannot be uploaded.

Enter data for renal transplant biopsy samples taken since the time of transplantation.

Non-renal Pathology

Please enter where relevant reports are available. Cut and paste all other organ histopathology reports since the diagnosis of CMV viraemia. PDFs cannot be uploaded.

Enter data for any non-renal transplant biopsy samples taken since the time of transplantation.

CMV Summary

All fields need to be entered.

CMV status prior to transplantation:

- D+R+ select this if donor CMV IgG is positive and recipient CMV IgG is positive before transplantation
- D+R- select this if donor CMV IgG is positive and recipient CMV IgG is negative before transplantation
- D-R+ select this if donor CMV IgG is negative and recipient CMV IgG is positive before transplantation
- D-R- select this if donor CMV IgG is negative and recipient CMV IgG is negative before transplantation
- Unknown select this if donor CMV IgG and/ or recipient CMV IgG is unknown before transplantation

CMV management strategy:

- Prophylaxis–select this if patient received medication to prevent CMV infection after transplantation. Then select whether valganciclovir was used or another drug. If other, please specify. Start date–this is the date that prophylaxis began. End date–this is the date that prophylaxis stopped.
- Surveillance– select this if patient did not receive medication to prevent CMV infection and patient was monitored with CMV blood tests after transplantation
- Other–select this if CMV management strategy did not include prophylaxis all surveillance and detail CMV management strategy in Free text box
- Prophylaxis–if prophylaxis was selected as CMV management

Immunosuppression at time of transplantation:

Tick all medications that were prescribed at the time of transplantation

CMV Antiviral Resistance

Testing for CMV antiviral resistance – select yes if performed and no if not performed.

Date of CMV antiviral resistance testing

Results of CMV antiviral resistance testing - cut and paste report since the diagnosis of CMV viraemia. PDFs cannot be uploaded.

Testing for UL97 and UL54 gene mutations – select yes if UL97 and UL54 gene mutations were assessed.

Date of Testing for UL97 and UL54 gene mutations

Results of Testing for UL97 and UL54 gene mutations - cut and paste relevant section of report, if available. PDFs cannot be uploaded.

CMV Episodes

Episode start Date–fill in date when CMV first detected by virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen

CMV clinical presentation–cytopenias include either low haemoglobin, low white blood count or low platelet which is attributed to CMV infection.

Is this CMV recurrence–CMV recurrence is defined as new CMV infection in a patient with previous evidence of CMV infection who has not had virus detected for an interval of at least 4 weeks during active surveillance

CMV diagnosis:

- CMV infection- select this if evidence of CMV replication regardless of symptoms (differs from latent CMV); defined as virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen.
- CMV disease (viral syndrome/ tissue invasive) - select this if evidence of CMV infection with attributable symptoms. CMV disease can be further categorized as a viral syndrome (ie, fever, malaise, leukopenia, and/or thrombocytopenia), or as tissue invasive (end organ) disease.
- Refractory CMV infection- select this if CMV viremia (DNAemia or antigenemia) that increases; defined as >1 log10 increase in CMV DNA levels in blood or serum between peak viral load within the first week and the peak viral load at ≥2 weeks as measured in the same laboratory with the same assay) after at least 2 weeks of appropriately dosed antiviral therapy.
- Refractory CMV disease- select this if Refractory CMV disease: worsening in signs and symptoms or progression into end-organ disease after at least 2 weeks of appropriately dosed antiviral therapy.

Immunosuppression before CMV episode–select immunosuppression medication prescribed when CMV infection first detected by blood tests

Treatment Medication – Up to 3 medications for treatment of CMV infection can be added.

- Treatment Medication side effects – select yes if any side effects or adverse event related to the medication. Fill in treatment side effect comment with details of the side effect or adverse event. This could be a known side effect of the medication or a side effect/ adverse event not previously known to be related to the medication but is considered related by the clinical team.
- Max daily dose – fill in the maximum daily dose of the treatment given in mg.
- Start Date
- End Date

Secondary prophylaxis
Select **no** if no medication to prevent CMV infection after completion of treatment and resolution of viraemia.
Select **valganciclovir** if prescribed to prevent CMV infection after completion of treatment and resolution of viraemia.

Select **other** if other medication prescribed to prevent CMV infection after completion of treatment resolution of viraemia. Use free text box to add medication name. Add Start Date; End Date.

Immunosuppression 6 months after CMV episode

Select immunosuppression medication prescribed 6 months after CMV infection first detected by blood tests

Was there an immunosuppression dose reduction after 6 months?

Select yes if dose of any immunosuppressive medication was reduced. For example, if patient was taking tacrolimus 5 mg twice daily, Mycophenolate mofetil 500 mg twice daily and prednisolone 5 mg daily before CMV episode and then was taking Tacrolimus 4 mg twice daily and prednisolone 5 mg daily 6 months after CMV episode, then 'yes' should be selected for 'was there an immunosuppression dose reduction after 6 months' as the dose of tacrolimus was reduced. Select non applicable, if data not available.

Was there a temporary immunosuppression dose reduction within 6-month period?

Select yes if the dose of any immunosuppressive medication was temporarily reduced within the 6 months after CMV viraemia first detected. For example, if patient was taking tacrolimus 5 mg twice daily, Mycophenolate mofetil 500 mg twice daily and prednisolone 5 mg daily before CMV episode and at 6 months after the CMV episode but Mycophenolate mofetil was temporarily stopped or dose reduced to 250 mg twice daily within the 6 month period, then 'yes' should be selected for 'was there a temporary immunosuppression dose reduction within 6 month period'. Select non applicable, if data not available.

CMV outcome 6 months after CMV episode:

- Viraemia completely resolved–select this if no virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen present 6 months after episode start date (allow window of +/- 1 month)
- Viraemia continuing- select this if virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen present 6 months after episode start date (allow window of +/- 1 month)
- Permanent organ damage – select this if CMV infection has led to end organ damage eg loss of vision related to CMV retinitis
- Transplant failure- select this if kidney transplant has failed within 6 months after CMV first detected.
- Patient died–select this if patient as died within 6 months after CMV first detected.
- Other–select this if any other outcome experienced or if combination of the above outcomes. Use CMV outcome comments for free text further explanatory notes

CMV outcome 12 months after CMV episode:

- Viraemia completely resolved–select this if no virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen present 12 months after episode start date (allow window of +/- 1 month)

- Viraemia continuing- select this if virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen present 12 months after episode start date (allow window of +/- 1 month)
- Permanent organ damage – select this if CMV infection has led to end organ damage eg loss of vision related to CMV retinitis
- Transplant failure- select this if kidney transplant has failed within 12 months after CMV first detected.
- Patient died–select this if patient as died within 12 months after CMV first detected.
- Other–select this if any other outcome experienced or if combination of the above outcomes. Use CMV outcome comments for free text further explanatory notes