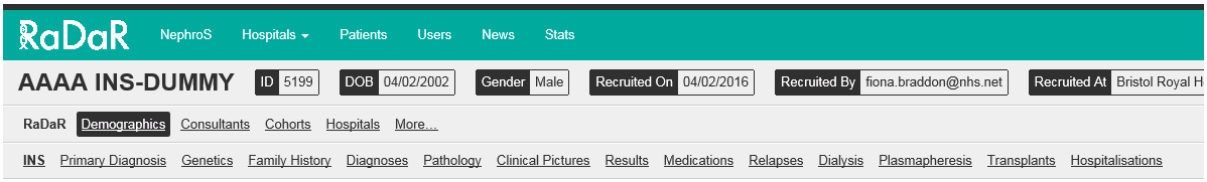
Guide to RaDaR2 data entry for Idiopathic Nephrotic Syndrome (INS) patients

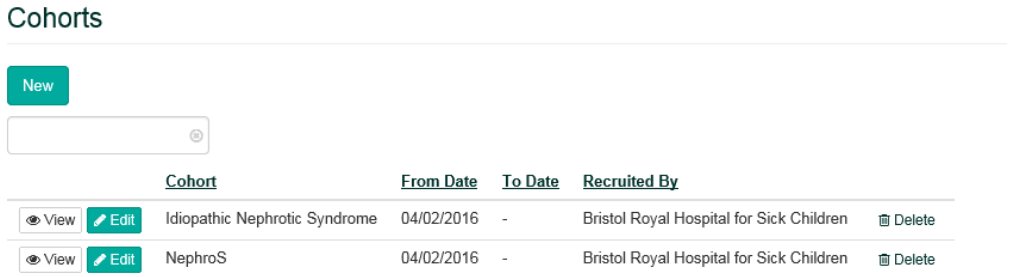


Recruiting a patient to RaDaR – INS cohort

- RaDaR2 accessed via log in: https://nww.radar.nhs.uk (NHS computers only)
- Go to the 'patients' tab and click 'Recruit patient'
- Enter the required details and click 'Search'
- Enter the patient's details manually if their record has not been found
- Select the appropriate Renal Unit and Cohort (diagnosis)
- Confirm the patient has been consented by selecting the 'Consent' check box

For NephroS

- Patient need to be additionally added to the NephroS cohort i.e. NephroS patients belong to both INS and NephroS cohorts.
- Go to Cohort tab, scroll down to select NephroS.
- 'From date' is the date of NephroS consent.



Patient View

- If the patient is already on Patient View (PV), their data will be auto populated
- If they are not on PV, contact your local Renal System Administrator and request that 'Send to PV flag is set' and that PV login details are sent out if required

- Anything with a red * next to it, must be completed before the page can be saved.
- For all data entry, for each tab you need to click on the "New" button (generally top left hand corner)
- **Questions regarding data entry?** Please contact Liz Colby (NephroS Study Coordinator) – Liz.Colby@Bristol.ac.uk, 0117 331 3106.

Index

Data Entry – Time Points

Absolute minimum at time of registration

- Demographics – including patient address
- Primary diagnosis

Baseline data to complete as soon after recruitment as possible

- Consultants
- Genetics
- Family History
- Diagnosis
- Pathology (All reports available)
- Clinical picture (At diagnosis and recruitment)
- Results
- Medications

For some patients:

- Relapse
- Dialysis
- Plasmapheresis
- Transplants

Follow-Up data

- **Prospectively: every 6 months from recruitment date**
- Update: Demographics, Primary diagnosis (if disease progression), Genetics, Family History, Diagnosis (extra renal features), Pathology
- Clinical picture
- Update Medication
- For some patients: Relapse, Dialysis, Plasmapheresis, Transplant

- **Retrospectively: every 6 months from date of diagnosis.**
- We appreciate that for some patients this will be a lot of data to backfill. Please concentrate on getting information at time of diagnosis and capturing information going forward from recruitment date. As time allows, focus on significant changes retrospectively with the ultimate aim of a clinical picture every 6 months from date of diagnosis.

Information required in each tab

Demographics

Please complete these fields:

- Name
- Date of Birth
- (Date of Death)
- Gender
- Ethnicity
- Patient #'s (NHS, Hospital…)
- Aliases (e.g. name changes)
- Address

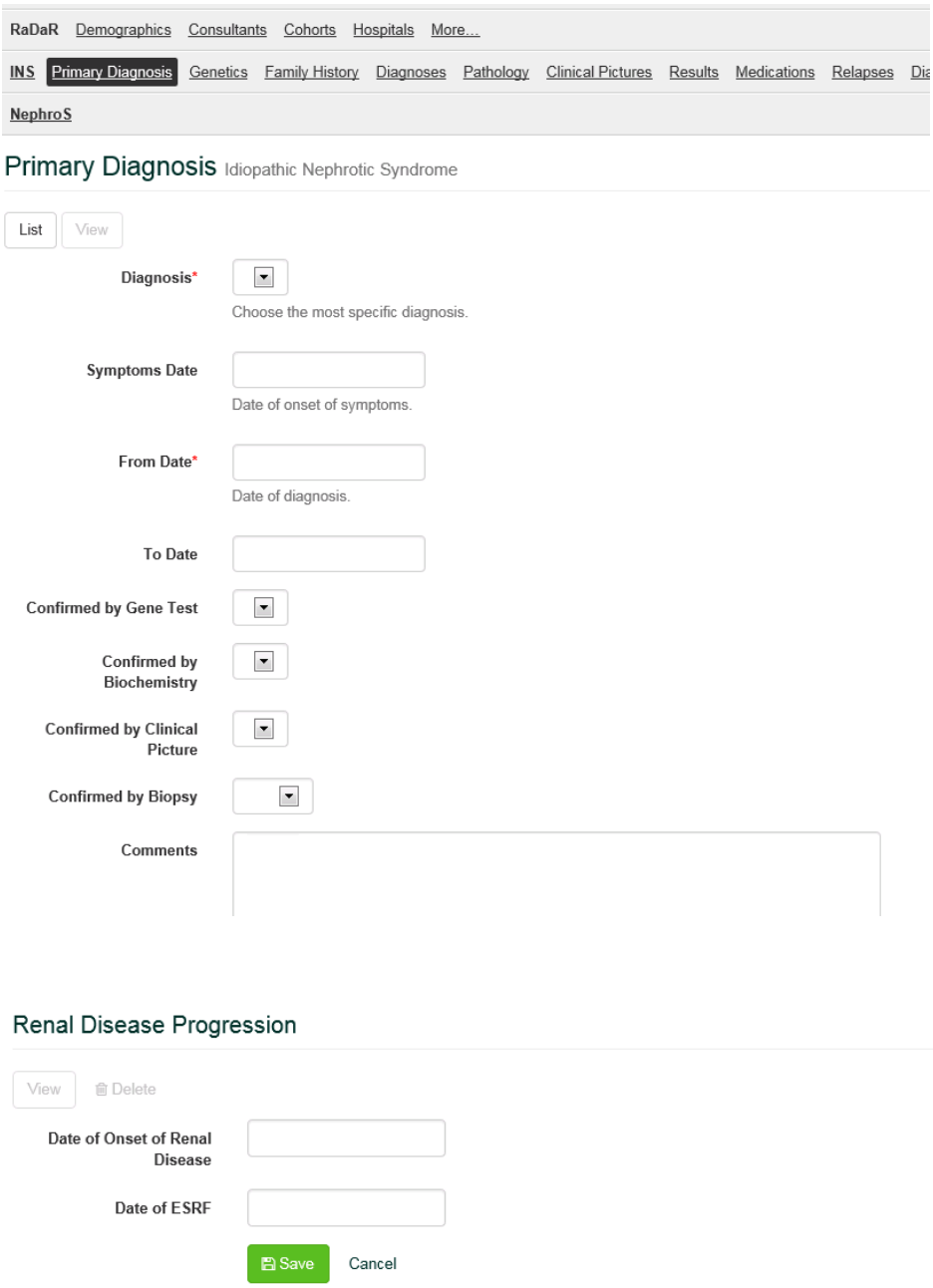
Consultants

Add patient's caring consultant by clicking on New. If their consultant is not listed please email Liz Colby (Liz.Colby@bristol.ac.uk) so they can be added.

Hospitals

Add another hospital if patient is seen at DGH/ transferred to another hospital for treatment.

Primary Diagnosis



Primary Diagnosis

Options:

- Idiopathic Nephrotic Syndrome (but if known, please use detailed SR/SSNS options below)
- SRNS – Presumed Steroid Resistant (steroids not tried e.g. Congenital Nephrotic Syndrome or patient presented in end-stage renal failure)
- SRNS – Primary Steroid Resistant
- SRNS – Secondary Steroid Resistant
- SSNS – Frequently Relapsing
- SSNS – Partial Steroid Resistant
- SSNS – Steroid Dependent
- SSNS – Steroid Sensitive
- Date of Symptom Onset
- Date of Diagnosis
- Confirmed by Gene Test (Yes/No) (For INS/NephroS leave blank)
- Confirmed by Biochemistry (Yes/No) (For INS/NephroS leave blank)
- Confirmed by Clinical Picture (Yes/No) (For INS/NephroS leave blank)
- Confirmed by Biopsy (Yes/No). If select yes a further options tab will appear. Please select an option: Minimal Change, FSGS, Mesangial Hypertrophy, Other (please state). (Nb. Please also complete pathology tab).
- Comments (free text box to give further details of above)

If diagnosis changes e.g. disease progression – please 1) give the 'old' diagnosis end date and 2) add a new diagnosis (rather than edit) so that no information is lost.

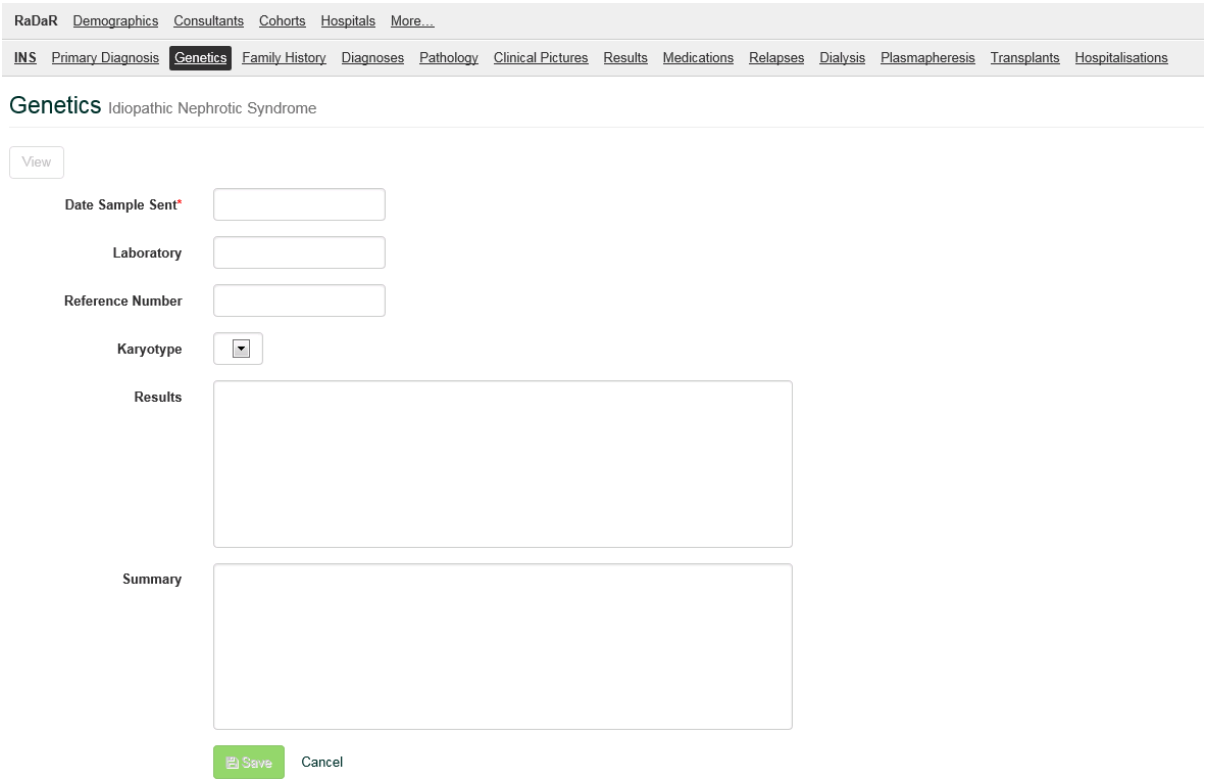
Renal Disease Progression

- Date of onset of renal disease (not applicable to INS/NephroS cohort)
- Date of ESRF (defined as CKD stage 5 / estimated glomerular filtration rate < 15 ml/min/1.73m^2 or onset or renal replacement therapy if earlier). If not an ESRF then please leave blank.

Genetics

Please add all genetic reports available for the patient (e.g. karyotyping, NHS SRNS gene panel results.)

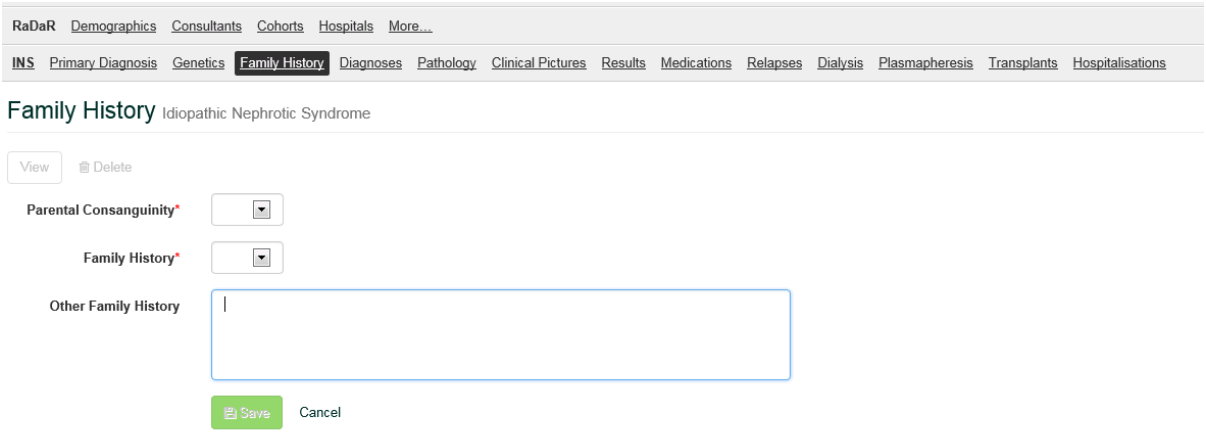
- Date Sample Sent
- Laboratory where sample was sent
- Reference number
- Karyotype (XX, XY, not done, other (please state in summary box))
- Results – please copy and paste genetic report findings into this box
- Summary



Family History

Include family history:

- Consanguinity **of parents** (i.e. are the parents related to each other) (Yes/No)
- Family History of Nephrotic Syndrome (Yes/No)
  In 'Other Family History' comments box please include details of:
- Family History of proteinuria
- Family History of other syndromes
- If other family members have renal disease and are registered on the RaDaR database, please list their RaDaR number along with relationship.

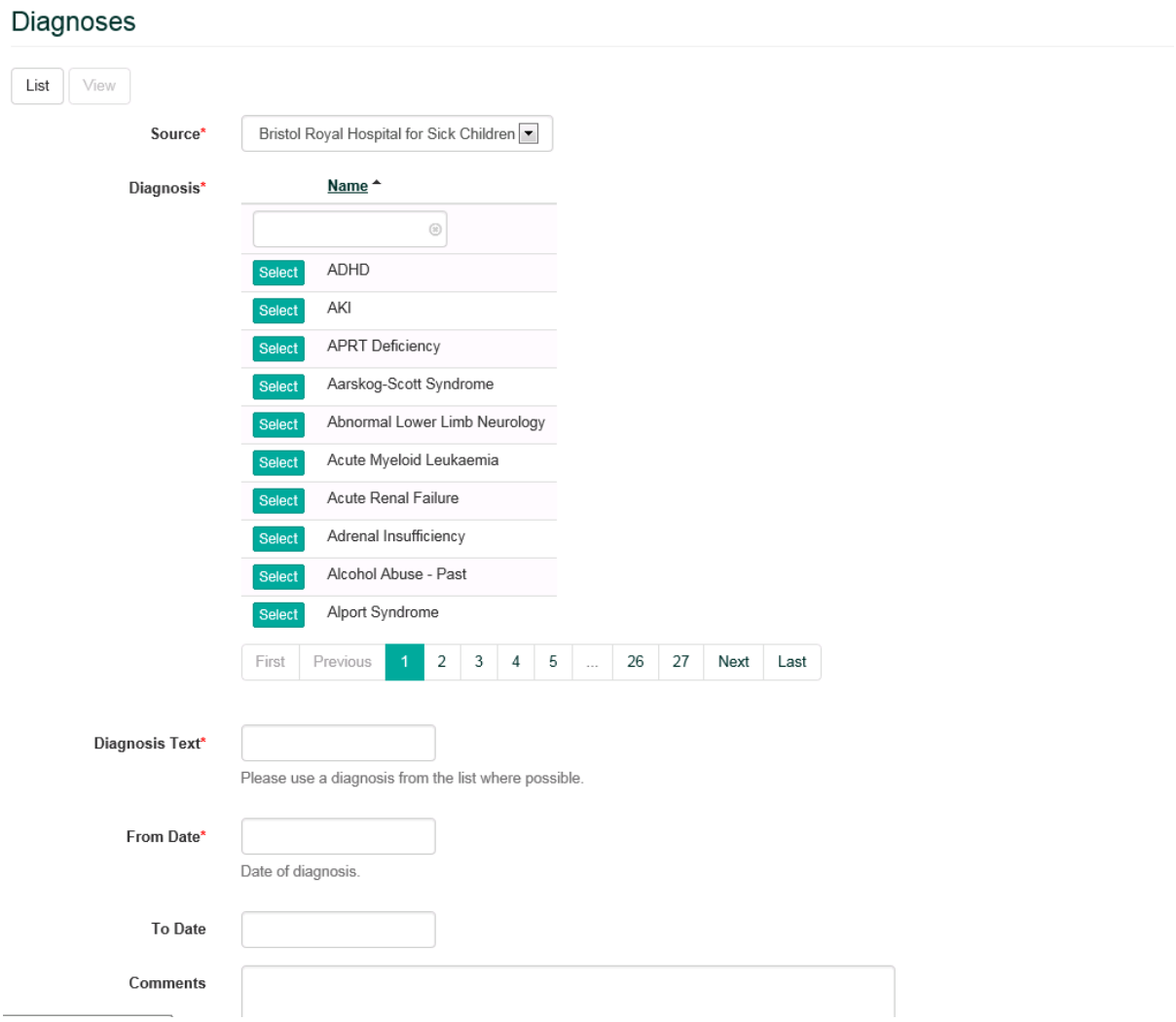


Diagnosis

This is for comorbidities, the patient's primary diagnosis should be included in the primary diagnosis tab.

- Add significant diagnoses and extra renal features with dates. **A list of the most important diagnoses to capture are listed below the screenshot.**

Please use the list when possible, if not write in diagnosis text (e.g. ocular problems). The important diagnoses to capture are listed below. Please note: You do not need to look through every page. Start typing in the "Diagnosis" box and it will search through the pre-populated list. If the term is not listed, use the free-text "Diagnosis Text" box (please use a diagnosis from the list where possible).



Important diagnoses to capture:

- Alport Syndrome
- Atypical Haemolytic Uraemic Syndrome
- Asthma
- Bilateral Sesoryneural Deafness
- Deafness
- Dent Disease

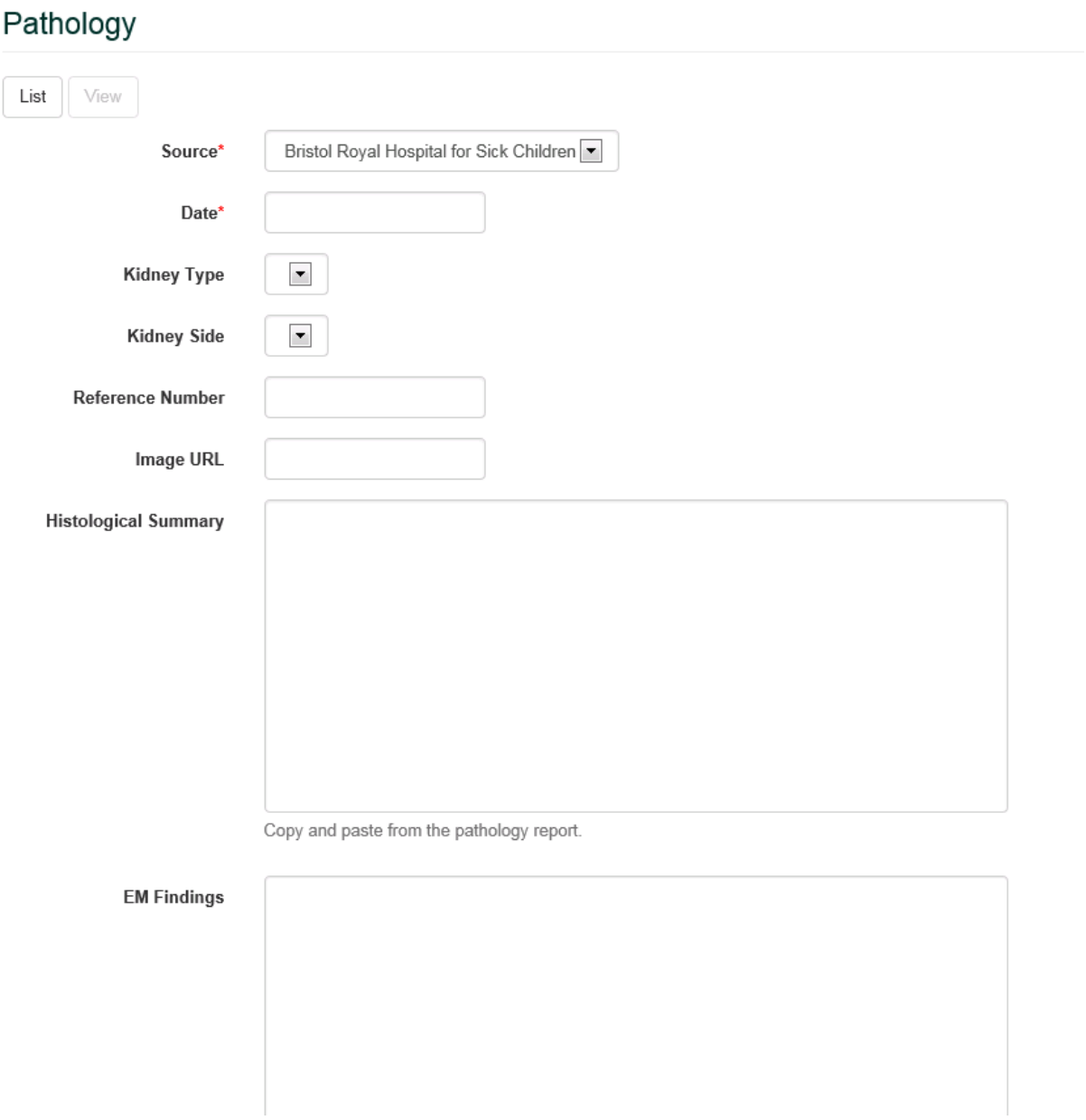
- Developmental Delay
- Charcot Marie Tooth Disease
- Epilepsy
- Epileptic Encepalopathy
- Frasier Syndrome
- Gonadoblastoma
- Haematuria
- Learning Difficulty
- Lowe Syndrome
- Nail-Patella Syndrome
- Male Pseudohermaphroditism
- Mental Retardation Syndrome
- Microcephaly
- Microcoria
- Pierson Syndrome
- Thrombocytopenia

Pathology

Include all biopsy reports (new entry for each separate procedure).

Please ensure no patient identifiers are included in the report.

- Date of biopsy
- Kidney Type (Transplant, Native)
- Kidney Side (Right, Left)
- Reference number
- Image URL (please leave blank)
- Histological summary: Please copy and paste full biopsy report including biopsy conclusion. **Please do not include any patient identifiers.**
- Electron Microscopy (EM) findings (normally given as a supplementary/additional report). Please copy and paste any additional reports.



Clinical Pictures

Follow-up ideally every 6 months from date of diagnosis or as patients attend for follow-up appointments. We appreciate that some patients may have years of follow-up data so there may be a delay in uploading this information.

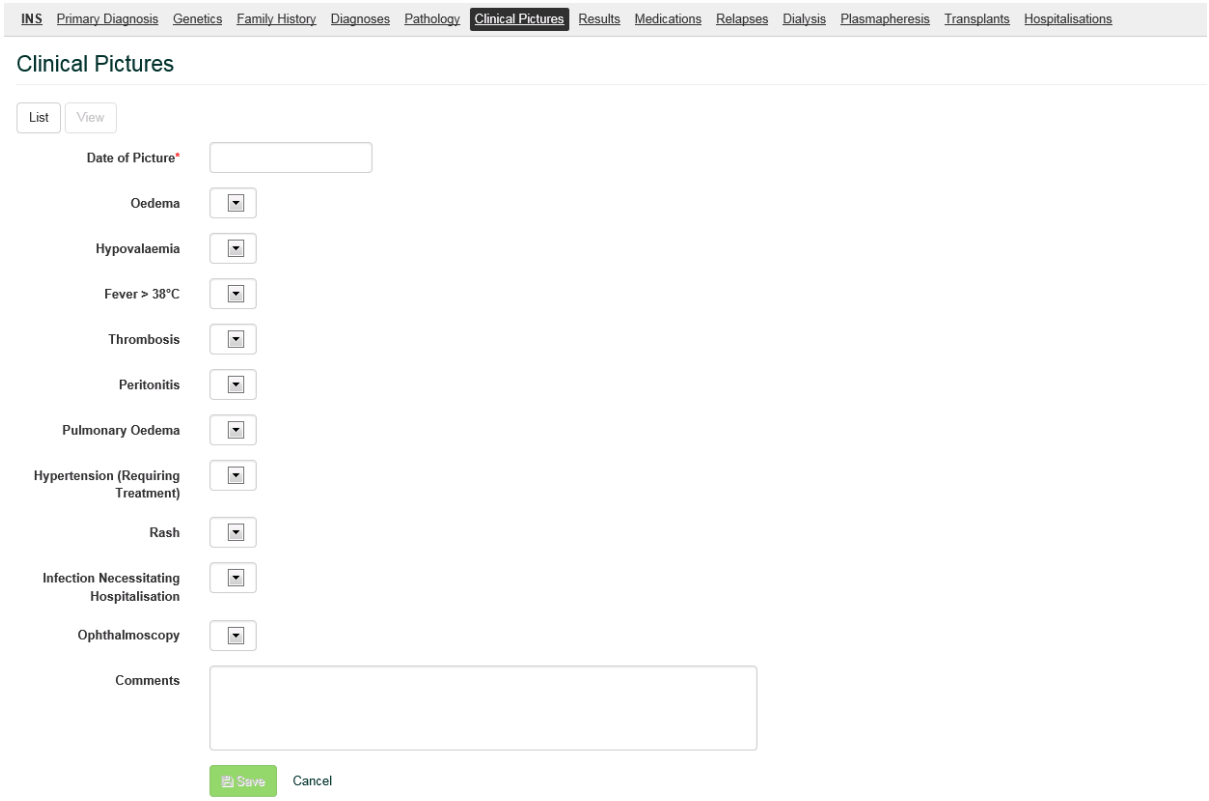
In order of priority:

1) At time of diagnosis
2) At time of registration and 6-monthly going forward (or less frequently depending when patients are seen in clinic).
   Nb. It is extremely helpful to have a Clinical Picture (and lab results) completed for all dates when NephroS blood samples (particularly Lithium Heparin) are submitted so we can correlate our research findings using the samples with the patient's clinical status.
3) At significant times of acute illness prior to recruitment
4) 6 monthly from date of diagnosis to recruitment date (depending on data availability)

Yes/No responses to checklist. These are if these symptoms are present at the date of the clinical picture.

In the comments box – copy and paste clinic letter (please include details of any relapses and response to medications given however please ensure this information is also captured on the 'Relapse' and 'Medication' tabs).

Please remove any patient identifiers within the clinic letter e.g. replace names with an X.



Results

- **Please input (every 6 months): - Height,**
  - Weight,
  - BP (diastolic and systolic).

To add a result, you must click 'New' in the top left hand corner rather than the '+' button. Then 'select' which result you want to input. You don't need to scroll through every page to find the result name - just start typing in the box below "available" and it will search from the list.

- **Other bloods and urine results: should auto-populate with PV link.** For those centres not on PV, important results to capture (if available):

Albumin	Alb	Blood	g/L
Creatinine	Creatinine	Blood	µmol/L
Ciclosporin (Cyclosporine)	Ciclo	Blood	ng/mL
Creatinine Clearance	CCL	Blood	ml/min/1.73m²
Estimated GFR	eGFR	Blood	ml/min/1.73m²
Tacrolimus	Tacro	Blood	ng/mL
White Blood Cell Count	WBC	Blood	10^9/L
Albumin : Creatinine Ratio	ACR	Urine	mg/mmol
Protein : Creatinine Ratio	PCR	Urine	mg/mmol
Urine Protein	UPROT	Urine	g/L
Haematuria	UDHAEM	Urine Dipstick	-
Proteinuria	UDPROT	Urine Dipstick	-
Height	Height	Observation	cm
Weight	Weight	Observation	kg
Diastolic Blood Pressure	BPdia	Observation	mmHg
Systolic Blood Pressure	BPsys	Observation	mmHg

Medications

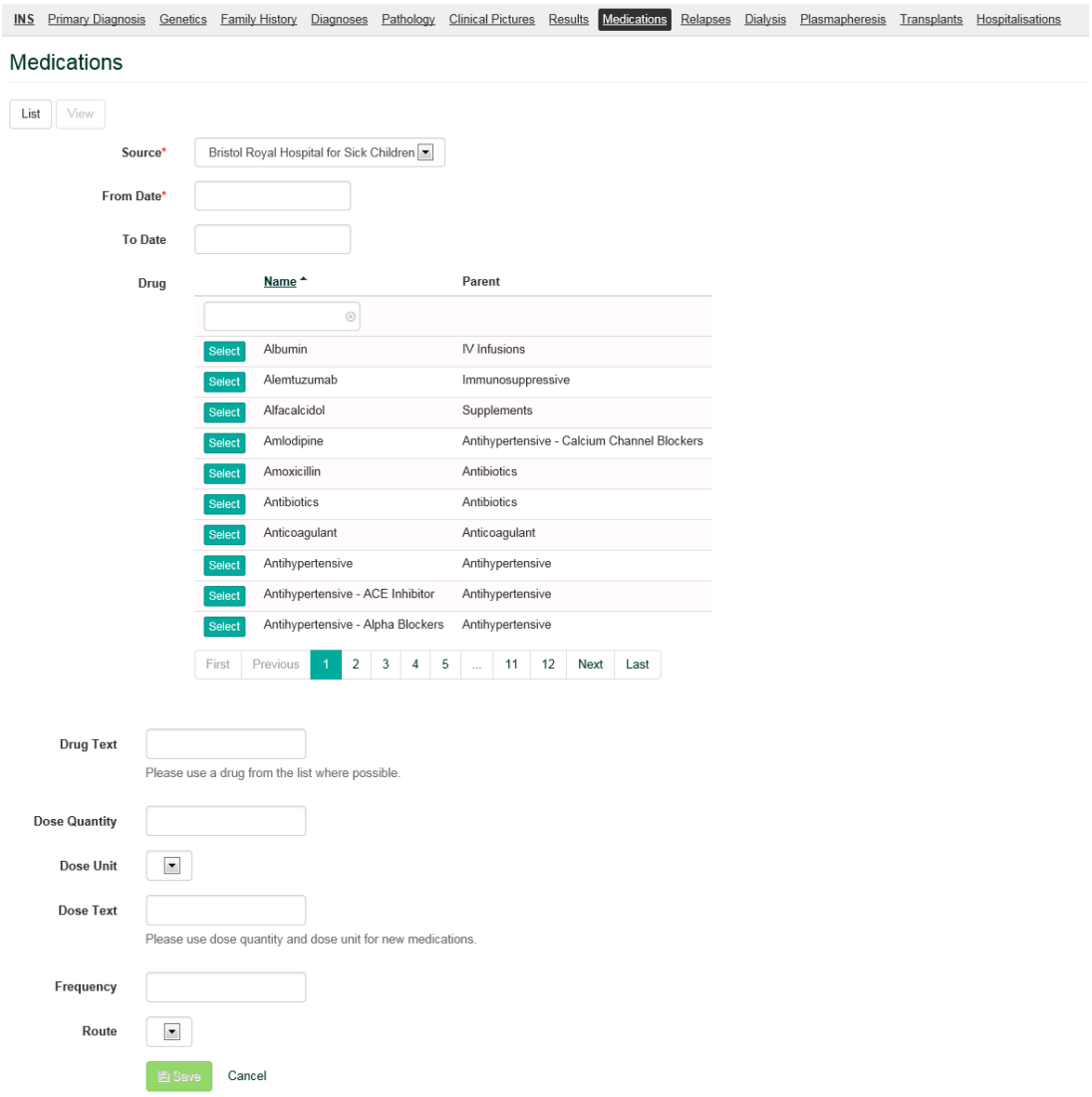
Please include mediations since date of diagnosis. This should be auto-populated by PV but if not, **a list of the most important medications to capture is on the next page (page 14).** You don't need to scroll through the list to find the drug name. Just start typing in the box below "Name" and it will search the list.

Information to capture:

- Date medication started
- Date medication stopped

Please include treatment during and after relapse episode.

- Dose Quantity
- Dose Unit
- Dose text (can input details of weaning regime in here)
- Frequency
- Route (Oral, Intravenous, Intramuscular, Subcutaneous, Per Rectum, Topical, Patch)



Most important drugs to capture in 'Medications' tab:

Immunosuppressives

- Methyl Prednisolone
- Prednisiolone
- Ciclosporin
- Tacrolimus
- Mycophenolate Mofetil - MMF
- Corticosteroids
- Cyclophosphamide
- Alemtuzumab
- Azathioprine
- Basiliximab
- Daclizumab
- Eculizumab
- Rituximab
- Sirolimus

Please only use the general 'Immunosuppressive' choice, if no details about the actual drug given can be found.

Anti-hypertensives (especially ACE inhibitors (ACEi) and Angiotensin receptor blockers (ARBs))

- Lisinopril
- Captopril
- Enalapril
- Ramipril
- Irbesartan
- Losartan
- Candesartan Cilexetil
- Olmesartan
- Eprosarten
- Telmistartan
- Valsartan

These are more general terms used in the table: Antihypertensive, Antihypertensive - ACE Inhibitor, Antihypertensive - Angiotensin II Receptor Antagonist. Please use specific drug name if at all possible. Use these only if filling in retrospective data where it is unknown which drug was used.

Other

- Albumin IV infusion
- Levamisole

Relapses

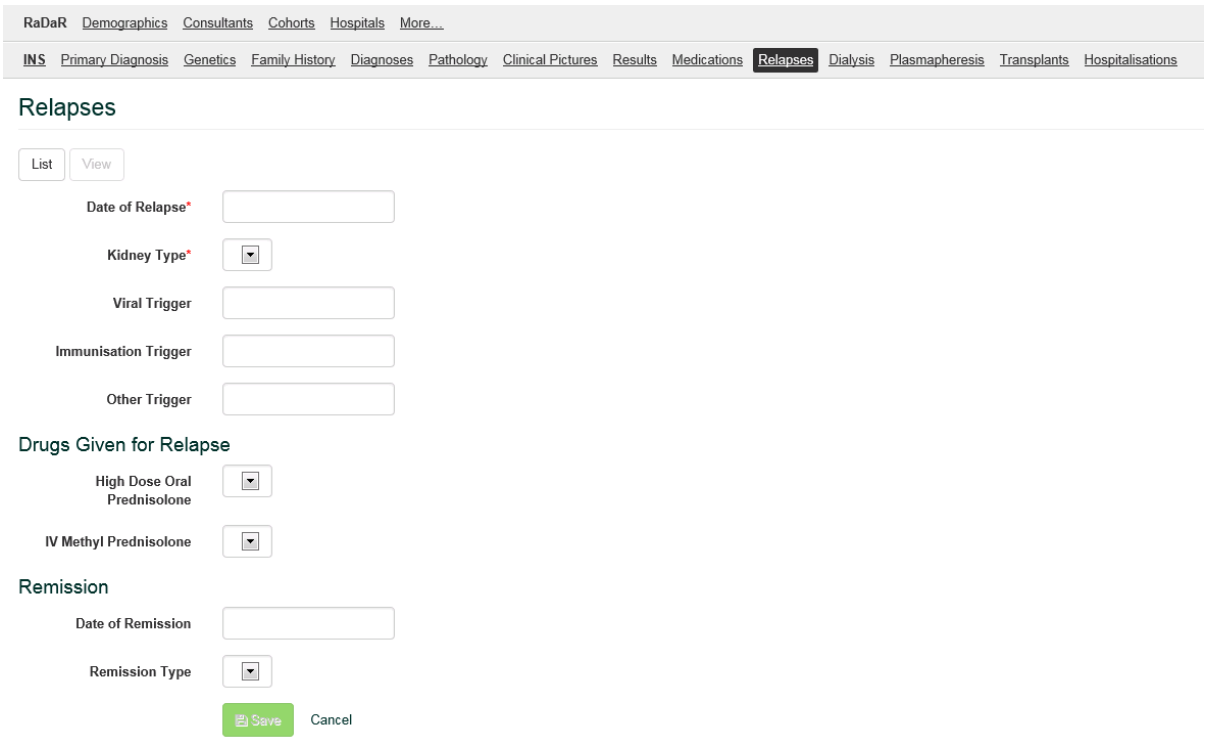
- Date of Relapse
- Kidney Type (Transplant, Native)
- Viral trigger, immunisation trigger, other trigger – please state
- Drugs given for relapse (specific to the relapse) – High Dose Oral Prednisolone, IV Methyl Prednisolone
- Date of Remission
- Remission type (complete, partial, none)

Definition of remission:

- **Full remission: Trace or negative urinary protein on dipstick or urine protein:creatinine ratio <20mg/mmol within 6 months of commencing therapy**

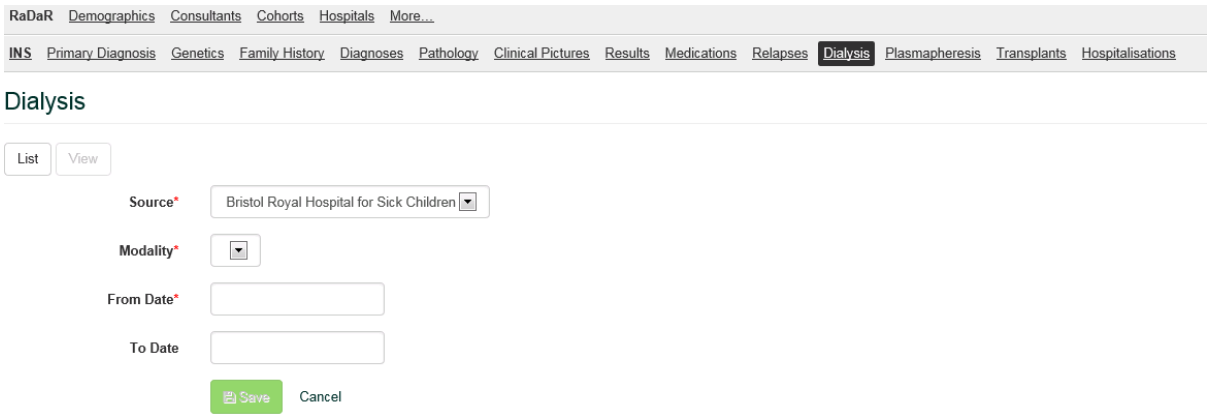
- **Partial Remission: Urinary protein 1+ or more (or urine protein:creatinine ratio>20mg/mmol) but serum albumin >25 within 6 months of commencing therapy**

NephroS patients: If possible, please take relapse blood samples at these episodes.



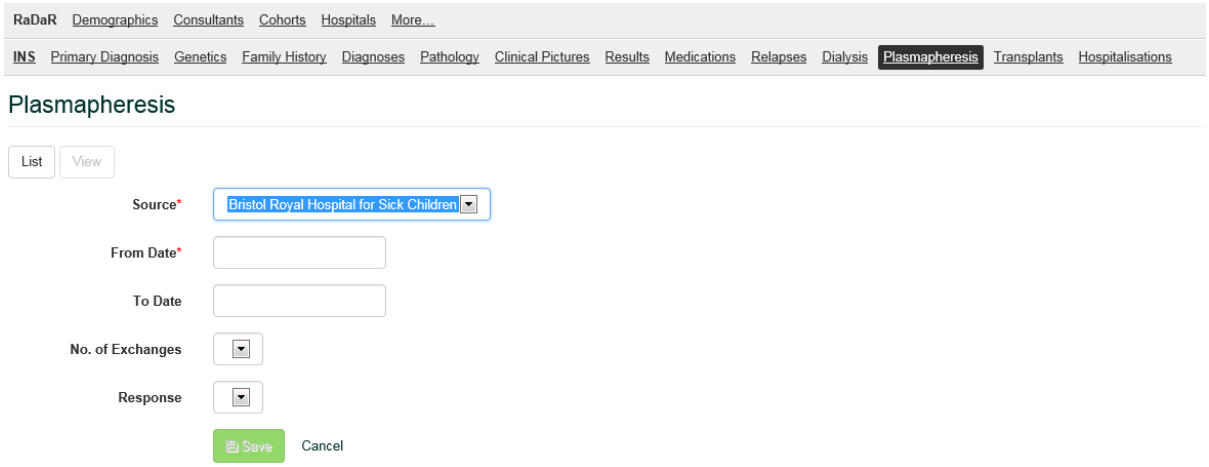
Dialysis

- Date
- Modality (choose from)
    - Haemodialysis
    - Haemofiltration
    - Haemodiafiltration
    - Ultrafiltration
    - CAPD
    - Assisted CAPD
    - APD
    - Assisted APD
    - Peritoneal Dialysis – Type unknown
    - Hybrid CAPD with HD
    - Hybrid APD with HD
    - Hybrid APD with CAPD



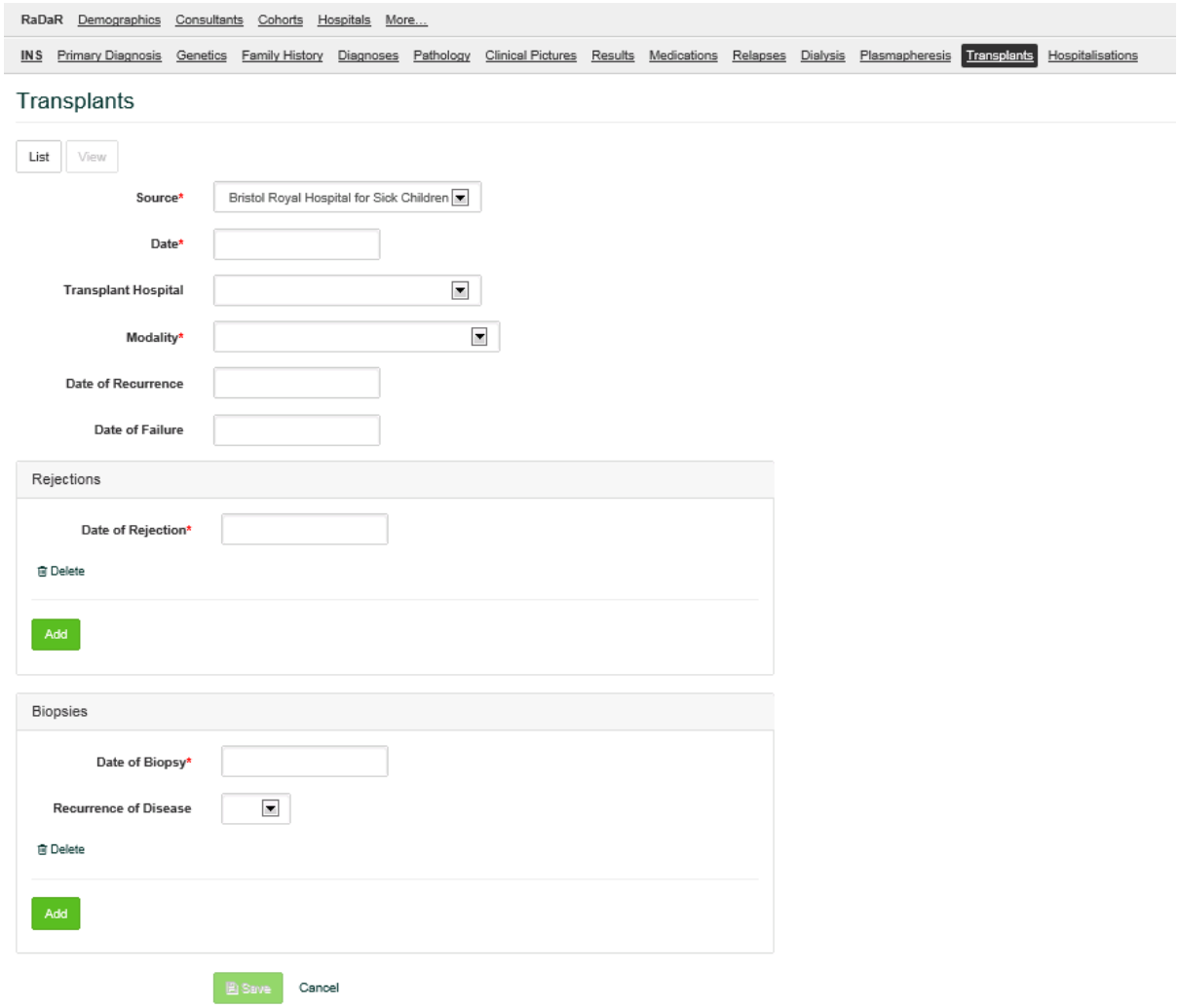
Plasmapheresis

- From/To date
- Number of exchanges (frequency of treatment)
- Response (Complete, Partial, None)



Transplants

- Date
- Transplant Hospital
- Modality:
    - Live - Sibling
    - Live – Father
    - Live – Mother
    - Live – Child
    - Live – Other Relative
    - Live – Genetically unrelated
    - Live – With transplant of other organ
    - Live – non UK
    - Cadaver
    - Cadaver – With transplant of other organ
    - Non-heart beating
    - Unknown
- Date of recurrence
- Date of failure



Hospitalisations

Any renal hospitalisations are likely to be covered in the other RaDaR/INS tabs. However, if there is any renal related hospital admissions that aren't covered please include here.

- Date of admission
- Date of discharge
- Reason for Admission
- Comments