

**Paediatric Oncology Shared Care Service Level Agreement - for inclusion
within POSCU operational Policy**

Measure 14-7A-102

The North and South Thames Children's Cancer Network Coordinating Groups (CCNCG) have agreed a shared care configuration for their Children's Cancer Networks (CCN) with the London Specialised Commissioning Group (LSCG).

Principal Treatment Centre Configuration

The South Thames CCN has a single Principal Treatment Centre at the Royal Marsden Hospital with St George's Hospital, serving the Cancer Network populations of South West London, South East London, Kent and Medway, Sussex and Surrey, West Sussex and Hampshire. There is a single chemotherapy service for the PTC hosted by the Royal Marsden. The joint paediatric oncology chemotherapy committee (JPOC) ensures parity across sites.

The North Thames CCN has a single Principal Treatment Centre at Great Ormond Street Hospital with University College London Hospital, serving the Cancer Network populations of North Central London, North West London, North East London, and defined areas of Mount Vernon and Essex Cancer Networks. There is a single chemotherapy service for the PTC hosted by GOSH.

Great Ormond Street Hospital provides services for all patients under 1 year old within the North and South Thames CCNs. Children under the age of 1 are referred directly to GOSH. Shared care remains with relevant POSCU in North or South Thames and all future follow-up for these patients is with shared care between that POSCU and GOSH.

The LSCG has agreed pathways of care outside of the Principal Treatment Centres for patients who require specialist treatment for bone sarcoma, retinoblastoma, choriocarcinoma and liver cancer.. This is outlined in the table below.

Specialised Commissioning Group	Cancer Network	Principal Treatment Centre	Services
London SCG	North London	Royal National Orthopaedic Hospital with UCLH	Bone sarcoma diagnostics and surgery
	North East London	Royal London Hospital	Retinoblastoma surgery & retinoblastoma radiotherapy
	South East London	Kings College Hospital	Surgery for Liver cancer
	North West London	Charing Cross Hospital	Treatment of choriocarcinoma

Proton Beam therapy is currently provided outside of the UK and referral is via a national referral panel. There is a plan to establish a London service by 2014/15.

Children's Cancer Network	Host Specialised Commissioning Group	Host Cancer Network	PTC	Linked services	Trust and Location
South Thames Children's Cancer Network	London SCG	South West London	Royal Marsden & St George's Children's PTC	4 MDTs; Solid Tumour, haem-onc, BCNS, Late effects	Royal Marsden Hospital, Sutton
				Paediatric oncology surgery	St George's Hospital, Tooting
				Paediatric Neurosurgery	AMU, St George's Hospital, Tooting Kings College Hospital, London
				Paediatric Intensive Care Unit	St George's Hospital, Tooting Or via Children's PICU Retrieval service
				Paediatric Haemodialysis	Renal CAP dialysis & PICU at SGH or PICU retrieval to GOSH/ GSTT
				Paediatric Radiotherapy	Royal Marsden Hospital, Sutton
				Blood and Bone Marrow Transplantation <ul style="list-style-type: none"> ▪ PBSCT ▪ Bone Marrow 	Royal Marsden Hospital, Sutton – malignant care and aplastic anaemia
				Sarcoma Specialist MDT/surgery <ul style="list-style-type: none"> ▪ Bone ▪ Soft Tissue 	Bone & Soft Tissue University College London (Euston Rd) / Royal National Orthopaedic Hospital Soft Tissue: Royal Marsden Hospital, / St Georges Hospital
				Retinoblastoma	Barts and the London with GOSH / RMH
				Paediatric Liver Surgery	Kings College Hospital, London
				Choriocarcinoma (confirmed diagnosis)	Charing Cross Hospital, London
				Under 1 year old's	GOSH
				North Thames Children's Cancer Network	London SCG
2 MDTs; Sarcoma diagnostic, sarcoma treatment	University College London (Euston Rd)				
Paediatric oncology surgery	GOSH				
Paediatric Neurosurgery	GOSH				
Paediatric Intensive Care Unit	GOSH				
Paediatric Haemodialysis	GOSH				
Paediatric Radiotherapy	University College London (Euston Rd)				
Blood and Bone Marrow Transplantation <ul style="list-style-type: none"> ▪ PBSCT ▪ Bone Marrow 	GOSH				
Sarcoma Specialist MDT/surgery <ul style="list-style-type: none"> ▪ Bone ▪ Soft Tissue 	Bone & Soft Tissue University College London (Euston Rd) / Royal National Orthopaedic Hospital Soft Tissue: Royal Marsden Hospital, / Chelsea				
Retinoblastoma	Barts and the London with GOSH / RMH				
Choriocarcinoma (confirmed diagnosis)	Charing Cross Hospital, London				
Paediatric Liver Surgery	Kings College Hospital, London				

Paediatric Oncology Shared Care Unit Configuration

The North and South Thames PTCs have established shared care arrangements for children with District General Hospitals across the region, which allows patients to receive agreed treatments closer to home.

The POSCU catchment areas described are for the dominant flows, although in practice flows from other primary care organisation areas occur related to the range of paediatric services provided at the POSCU.

SOUTH THAMES CHILDREN'S CANCER NETWORK – CONFIGURATION OF POSCUS								
Cancer Network	POSCU Host Trust	CCG or Borough catchment areas	Level of care delivered (1,2,3)	Service option (for level 1 POSCUS)	Community services			
					Chemotherapy		Supportive/palliative care	
					Acute Trust team outreach service	CCG or Borough service	Acute Trust team outreach service	CCG or Borough service
SWLCN	Epsom Hospital (Epsom and St Helier University Hospital NHS Trust)	Surrey (mid)	Level 1	Option 2				
	Kingston Hospital NHS Foundation Trust	Kingston Richmond & Twickenham	Level 1	Option 1				
	Croydon University Hospital (Croydon Health Services NHS Trust)	Croydon	Level 1	Option 1				
SELCN	King's College Hospital NHS Foundation Trust	Lambeth / Southwark Lewisham / Greenwich	Level 2	n/a				
	Queen Elizabeth Hospital, Woolwich (South London Healthcare NHS Trust)	Bexley / Bromley / Greenwich	Level 1	Option 1				
SWSH CN	Royal Surrey County Hospital NHS Foundation Trust	Surrey (West) Hampshire (NE)	Level 1	Option 1				
	St Peter's Hospital (Ashford and St Peter's Hospitals NHS Foundation Trust)	Surrey (NW)	Level 1	Option 1				
	Frimley Park Hospital NHS Foundation Trust	Surrey (NW) Hampshire	Level 1	Option 1				
	East Surrey Hospital (Surrey and Sussex Healthcare NHS Trust)	Surrey (Mid / East)	Level 1	Option 1				
SCN	Royal Alexandra Children's Hospital (Brighton & Sussex University Hospitals NHS Trust)	Brighton & Hove East Sussex Downs & Weald	Level 2	n/a				
	Conquest Hospital (East Sussex Healthcare NHS Trust)	Hastings & Rother East Sussex Downs & Weald	Level 1	Option 1				
	Worthing Hospital (Western Sussex Hospitals NHS Foundation Trust)	West Sussex Teaching	Level 1	Option 1				
K&M CN	Medway NHS Foundation Trust	Medway	Level 1	Option 1				
	The Tunbridge Wells Hospital (Maidstone & Tunbridge Wells NHS Trust)	West Kent	Level 1	Option 1				
	William Harvey Hospital Queen Elizabeth The Queen Mother Hospital (East Kent University NHS Foundation Trust)	Eastern & Coastal Kent	Level 1	Option 1				

NORTH THAMES CHILDREN'S CANCER NETWORK – CONFIGURATION OF POSCUS								
Cancer Network	POSCU Host Trust	CCG or Borough catchment areas	Level of care delivered (1,2,3)	Service option (for level 1 POSCUS)	Community services			
					Chemotherapy		Supportive/palliative care	
					Acute Trust team outreach service	CCG or Borough service	Acute Trust team outreach service	CCG or Borough service
North London	The Whittington Hospital NHS Trust	Camden / Islington	Level 1	Option 1				
	North Middlesex University Hospital NHS Trust	Haringey / Enfield	Level 1	Option 1				
	Barnet Hospital (Barnet and Chase Farm Hospitals NHS Trust)	Barnet / Enfield	Level 1	Option 1				
	The Princess Alexandra Hospital NHS Trust	West Essex	Level 1	Option 1				
North East London	The Royal London Hospital (Barts Health NHS Trust)	City & Hackney Tower Hamlets	Level 2	n/a				
	Newham University Hospital (Barts Health NHS Trust)	Newham	Level 1	Option 1				
	Whipps Cross University Hospital (Barts Health NHS Trust)	Waltham Forest	Level 1	Option 1				
	Queen's Hospital, (Barking, Havering and Redbridge University Hospitals NHS Trust)	Barking & Dagenham / Redbridge / Havering	Level 1	Option 1				
North West London	St Mary's Hospital (Imperial College Healthcare NHS Trust)	Westminster / Brent / Kensington & Chelsea / Ealing	Level 2	n/a				
	Chelsea & Westminster Hospital NHS Trust Foundation Trust	Kensington & Chelsea / Hammersmith & Fulham / Ealing	Level 1	Option 1				
	Hillingdon Hospital (The Hillingdon Hospitals NHS Foundation Trust)	Hillingdon	Level 1	Option 1				
	Northwick Park Hospital (North West London Hospitals NHS Trust)	Brent & Harrow / Ealing	Level 1	Option 1				
Essex	Basildon University Hospital (Basildon and Thurrock University Hospitals NHS Foundation Trust)	South West Essex	Level 1	Option 1				
	Broomfield Hospital (Mid-Essex Hospital Services NHS Trust)	Mid Essex	Level 1	Option 1				
	Southend University Hospital NHS Foundation Trust	South East Essex	Level 1	Option 1				
Mount Vernon	Watford General Hospital (West Hertfordshire Hospitals NHS Trust)	Hertfordshire (West)	Level 2	n/a				

Pan-Thames Agreement between Principal Treatment Centres (PTCs) and Paediatric Oncology Shared Care Units (POSCUs).

This agreement is intended primarily to designate the responsibilities of each unit. In addition, it highlights the essential role played by Shared Care Units in providing care to patients with cancer and their families. Commissioners, networks and trusts need to consider shared care arrangements and ensure the local model and associated resources are sustainable in the long term.

1. Objectives

- To formalise the relationship between the PTCs and their associated POSCUs.
- To develop and implement mechanisms to enable the smooth and timely progression of patients and carers between all care settings.
- To develop and implement mechanisms to ensure that information about individual patients is communicated effectively to all those involved in the patient's care.
- To initiate development of shared care services across children and young people's cancer services.

2. Governance Structures

Agreement Ratification

Children's Cancer Networks

The NICE Guidance, Improving Outcomes in Children and Young People with Cancer (CYPIOG) states there will be a structure of children's cancer networks (CCN), each of which will incorporate more than one Cancer Network.

The CCN will establish a CCN Co-ordinating Group (CCNCG), with representation from the PTC and each of its associated POSCUs, Specialised Commissioning Groups and the constituent Cancer Network teams.

The CCNCG Terms of Reference defines the relationship between the constituent organisations on issues relating to children's cancer services, including links to community and palliative services and co-ordination across the area encompassed within the CCN, with clear accountability to the CCN.

The CCNCG must approve and formally sign-off shared-care agreements, in addition to sign off between the PTC and POSCU.

The Children's Cancer Network and POSCU Meetings

Each POSCU will participate in its local Cancer Network Paediatric Tumour Working Group (or equivalent meeting). These forums need to exist to allow discussion of operational issues between PTCs and POSCUs: In addition the PTC will agree when representatives will attend MDTs and / or outreach clinics. The level of POSCU will partly determine frequency and type of meeting.

3. Responsibilities

3.1 Principal Treatment Centre

3.1.1 Oncology / malignant haematology

Essential Resources: PTC

- All PTCs must comply with the requirements to be recognised as a CCLG centre. In order to facilitate support between Shared Care Units and PTCs there will be a defined link person(s) at the PTC for each POSCU.
- PTCs will have staff resources as described in the NICE guidance Improving Outcomes in Children and Young People with Cancer (August 2005), and the Children's Cancer Quality Measures.

Critical Mass: PTC

- PTCs will manage sufficient numbers of patients to maintain a workforce with cancer expertise across the full range of paediatric cancers and adolescent cancers with appropriate clinical support services and age-appropriate facilities.

Service Provision: PTC

- To arrange timely access of any child with a new diagnosis or suspected cancer to an appropriate PTC or, exceptionally, to locate a bed in another tertiary oncology centre.
- Children will be managed in the age-appropriate PTC linked to the referring POSCU from the outset wherever possible.
- To manage the investigation, diagnosis and staging of disease
- To manage treatment decisions and initiate cancer therapy, offering inclusion in relevant national or international therapeutic trials.
- To obtain informed consent to treatment.
- To deliver chemotherapy in an inpatient /daycare and outpatient setting.
- To plan and deliver radiotherapy where indicated
- To provide specialist paediatric/TYA surgical services, both for therapeutic indications and for supportive care
- To provide a specialist service for clinical interventional procedures e.g. central venous access device insertions / removals
- To manage clinical problems arising from treatment for the patients at highest risk of serious complications
- To provide support to POSCUs in the management of clinical problems arising from treatment, where appropriate admitting patients at the PTC for ongoing care.
- To provide high dependency / critical care support as required
- To provide timely, written communication to the POSCU for individual patients
- To provide a treatment plan and flow sheet for each patient
- Notification of changes in treatment to the POSCU
- To ensure there are identified key workers for each patient
- To work effectively with local community nursing teams to plan and deliver patient care
- To provide specialist symptom control and palliative care support appropriate to the PTC function.
- To work effectively with POSCUs and Community services when planning palliative care for patients, and to be knowledgeable about local palliative care arrangements and provision.

- To enter patients in clinical trials and retain responsibility for conduct of the clinical trials
- To provide information to parents and patients re. relevant protocol, or clinical trial, including side effects of treatment
- To obtain informed consent for treatment and entry into clinical trials (see Appendix 1 for specific provisions)
- To prescribe all chemotherapy; where chemotherapy is administered in Shared Care Unit, prescriptions and relevant information are forwarded to the appropriate personnel in POSCU.
- To keep POSCU informed and updated on all matters relating to patients and relevant modifications of treatment.
- To report all data to CCLG.
- To support the POSCU lead consultant in research governance issues surrounding paediatric oncology clinical trials in which the POSCU participates directly
- To nominate lead POSCU clinicians as CCLG associate members
- To support education and training for POSCU staff, after dialogue on needs for each POSCU.
- To continue to update and inform the POSCU through visits from PTC team members and annual study days.
- To provide education, social and psychological support to patients and their families
- To provide specific, written patient / parent information, with copies to the POSCU team
- To provide regularly updated Supportive Care Protocols agreed by a multi-professional group including shared care representation
- Maintain an up to date log of all shared care units, including the institution, responsible clinician(s), and nursing staff.
- Issue an agreement recognising and defining the relationship between the PTC and POSCU.
- To work effectively with commissioners, cancer networks and other stakeholders in planning of services, and meeting operational standards such as monitoring of pathways.
- To provide data to the CCN for the purpose of service monitoring relating to; performance against waiting times; cancer registration; specified clinical outcome audits; clinical trial entry rates; patient reported outcome measures; data required to support designation processes.

3.1.2 PTCs undertaking paediatric Blood or Bone Marrow Stem Cell Transplantation:

- To provide clinical haematological and immunology support to manage paediatric and young people's BMTs, working in tandem with paediatric and young people's oncology services
- To provide an appropriate physical environment to support immuno-compromised patients. Together with appropriate clinical support services, equipment and laboratory infrastructure to meet JACIE standards including, selection of donors, handling of transplant materials, patient selection and treatment and audit.

3.1.3 Long Term Follow Up: PTC

- The PTC will develop a Long Term Follow Up (LTFU) strategy ensuring consistency of approach across the networks covered by the service. LTFU is an essential requirement in providing complete patient care. Models of care are being established to enable effective, appropriate care in view of the increasing numbers of survivors, the range of ages and individual risks of recurrence and long term sequelae.
- PTCs will lead on assessing patient dependency and the LTFU clinical needs and producing suitable patient plans with POSCUs. It is envisaged that POSCUs will be involved jointly with PTCs in planning delivery and location of LTFU care for patients.

3.1.4 Community and Palliative Care Services: PTC

- Services for children with cancer in the Community are often provided by both DGH paediatric teams as well as community based teams. Each PTC should keep a directory of what community services are available and the system for accessing these through POSCUs and community services for patients.
- PTCs need to work effectively with POSCUs and Community teams. PTC will provide specialist palliative care support working with POSCUs and Community services

3.2 Paediatric Oncology Shared Care Units (POSCUs)

3.2.1 Oncology / Malignant Haematology

The role of the POSCU will vary depending on the clinical expertise and infrastructure available to support paediatric cancer care, but it is expected that all POSCU services will have action plans to achieve national guidance, including NICE Improving Outcomes in Children and Young People with Cancer (August 2005).

There are 3 levels of POSCU as defined in the Manual for Cancer services:

POSCU Level 1 Services

- *inpatient supportive care including care of children with febrile neutropenia*
- *outpatient supportive care*
- *outpatient follow up*
- *outpatient oral chemotherapy*
- *outpatient IV bolus chemotherapy*
- *exclusions - day care infusional chemotherapy, inpatient chemotherapy and all exclusions listed in level 3.*

Allowable options from the above:

- 1. all the above services*
- 2. opt out of outpatient IV bolus chemotherapy only*
- 3. opt out of outpatient IV bolus chemotherapy and inpatient supportive care including care of children with febrile neutropenia*
- 4. opt out of all chemotherapy and inpatient supportive care including care of children with febrile neutropenia*

NB: The implication of this is that any service that is providing outpatient IV bolus chemotherapy should also provide care of children with febrile neutropenia

POSCU Level 2 Services

- as for level 1 and in addition day care infusional chemotherapy
- exclusions - inpatient chemotherapy and all exclusions listed in level 3.

POSCU Level 3 Services

- as for level 2 and in addition inpatient 24-hour chemotherapy
- an intrathecal chemotherapy service in a POSCU is an option for level 3 (only) providing the following are fulfilled:
 1. compliance with HSC 2003-010, as verified by a satisfactory peer review against the ITC measures (Manual for Cancer Services 2004, section 3C-3, or any measures which supersede it);
 2. paediatric anaesthetic service on site;
 3. agreement by CCNCG.

Level 3 Exclusions, for instance services which should only be offered in a PTC

1. final diagnosis and determination of treatment plan;
2. chemotherapy regimens or other procedures which would be rendered unacceptably hazardous or have their effectiveness reduced by reason of the limits of infrastructure or experience available at any of the POSCUs; these regimens and/or procedures should be specified at any one time for the CCN by the CCNCG;
3. stem cell transplantation;
4. recruitment to, and co-ordination of, phase I, II and III clinical trials;
5. radical radiotherapy.

Essential Resources: POSCU

- There should be a designated lead consultant paediatrician, who should be encouraged to become an Associate Member of the CCLG. There should be written arrangements for cover by a named deputy consultant paediatrician.
- There should be a named lead POSCU nurse, who should be encouraged to become a member of PONF/CCLG. There should be written arrangements for cover by a named deputy senior nurse.
- There should be a named pharmacist responsible for paediatric chemotherapy in the POSCU. There should be written arrangements for cover by a named deputy paediatric pharmacist.
- The nursing skill mix should ensure that sufficient numbers of staff have relevant cancer related training.
- POSCUs with more than one site must have integrated care pathways and close team working across the sites
- Lead staff should attend appropriate network and local forums relating to children's & young people's cancer services
- Lead staff should identify and liaise with the lead for young people's cancer services

Critical Mass: POSCU

- POSCUs will need to develop the infrastructure commensurate with the level of shared care offered. Therefore POSCUs will need to demonstrate effective use of this resource within their network. In the future, POSCUs that develop

extended roles would be expected to treat higher numbers of patients to develop and maintain expertise and warrant the use of resources.

- It is recognised that Cancer Networks and Commissioners will need to take account of critical mass and specific local factors, such as location of acute paediatrics and geography, in recommending designation of POSCU services. If Commissioners / cancer networks decide designation of smaller POSCUs is the only option then a risk assessment should be undertaken to ensure the POSCU can deliver the stated level of service safely and effectively.

Service Provision: POSCU

A key role of the POSCU is to support a holistic approach to care and co-ordinate the different clinical, psychological and social supports required by the patients and their carers.

- To identify the child with suspected cancer, with appropriate and timely referral to the relevant PTC
- To provide in-patient and day-case supportive care according to PTC-designated Supportive Care Guidelines, including management of intercurrent infections and blood product support
- To manage continuing treatment and problems arising during treatment with appropriate support from the PTC
- To perform and manage scheduled clinical investigations
- To manage central venous line insertions and removals (designated POSCUs only)
- To deliver planned chemotherapy treatments in daycare and outpatients in agreement with the PTC. This will need to be in line with the level of POSCU service provided and agreed specifically with the PTC.
- It is anticipated that the majority of POSCUs will not deliver intrathecal chemotherapy as they will not have the infrastructure to meet DoH risk management guidelines. Where POSCUs intend to deliver this level of care this needs to be specifically identified and agreed between the PTC and POSCU.
- To work effectively with PTCs, Community and local services when planning palliative care for patients.
- To ensure PTCs are updated on the provision of local palliative care services.
- To provide counselling for families and choice for patients regarding social and psychological support.
- To provide written information to patients and their families.
- To maintain effective links with palliative care services, Social Services, schools and other community based services,
- To provide timely, written communication with PTC about issues encountered in the POSCU.
- To notify delays and other changes in treatment to the PTC.
- To provide data to the CCN for the purpose of service monitoring relating to; performance against waiting times; cancer registration; specified clinical outcome audits; clinical trial entry rates; patient reported outcome measures; data required to support designation processes.

3.2.2 Long Term Follow Up: POSCU

- This is a necessary requirement in providing complete patient care. The PTC should lead on LTFU models of care to enable effective, appropriate care in view of the increasing numbers of survivors, range of ages and individual risks of long term sequelae.

- PTCs will lead on assessing patient dependency and the LTFU clinical needs and producing suitable patient plans. It is envisaged that POSCUs will be involved jointly with PTCs in planning delivery and location of LTFU care for patients.

3.2.3 Community and Palliative Care Services: POSCU

- Services for children with cancer in the Community can be provided by both DGH paediatric teams as well as community based teams.
- POSCUs need to work effectively with Community teams. Each POSCU should map the community and palliative services available and have effective systems in place for accessing these for patients.

**Principal Treatment Centre / Paediatric Oncology Shared Care Unit
Shared Care Agreement**

An agreement between Hospital POSCU

North Thames PTC and South Thames PTC

1) PTC Responsibilities

As defined above

2) POSCU Responsibilities

As defined above in Section 3.2 and as agreed below

POSCU Role – for children and teenagers treated within the service

Level of POSCU Service	Sub Options	Please state Y/N for level provided
Level 1	Full	
	Opt out OP IV bolus chemo	
	Opt out OP IV bolus & IP supportive care including Febrile Neutropenia	
	Opt out all chemo & IP supportive care including FNP	
Level 2	Full	
	Central venous line insertions	
	Central venous line removals	
Level 3	Full including Lumbar punctures + prescription /administration of intrathecal chemotherapy	
	Opt out administration of intrathecal chemotherapy	
	Central venous line insertions	
	Central venous line removals	

3) Community and Palliative Care Services

Please provide list of community and Palliative services linked to this POSCU

Community Services	Clinical Commissioning Group (CCG) served	Nurses giving chemo employed by Acute Trust YES / NO	Nurses giving chemo employed by CCG. State which CCG.
1.			
2.			
3.			

Palliative Care Services	CCGs or Boroughs served
1.	
2.	
3.	

We have read and understand the responsibilities of PTCs and POSCUs and we are satisfied there is agreement about the level and type of care to be provided.

Dr

Lead Consultant POSCU

Date

Dr Nicholas Goulden



Lead Consultant PTC

Date

Chair North Thames Children's Cancer Network

Date

Original to be returned to the POSCU and copy to be retained by the PTC and North Thames Children's Cancer Network

Appendix 1

Clinical Trials

This section relates to specific provisions for the shared care of patients recruited into a clinical drug trial. The statements are an interim position awaiting formal decision on minimum requirements to meet research regulations as they relate to the POSCU setting which will need to be addressed at a national level.

The majority of paediatric patients are entered into clinical trials. There has been a recent change in trial management and most paediatric cancer clinical trials open in the UK are run through and/or sponsored by the CRUK Clinical Trials Unit in Birmingham. ,

Clinical Trials of Investigational Medicinal Products (CTIMP) are regulated by the EU Directive on Clinical Trials; in the UK specifically regulated by “The Medicines for Human Use (Clinical Trials) Regulations 2004”. The conduct of a CTIMP requires regulatory approval from the MHRA (The Medicines and Healthcare Products Regulatory Agency) in the form of a Clinical Trials Authorisation (CTA) and ethical favourable opinion form NRES (National Research Ethics Services). A national “Children’s Cancer Research Network” has also been recently established for England.

In keeping with Good Clinical Practice and the regulatory framework on CTIMPs, it is necessary that the Principal Treatment Centre (PTC) stipulates the responsibilities of the Shared Care Unit (POSCU) in relation to patient care and reporting of data. This will vary slightly for each particular trial, but general principles will apply. Sponsors of CTIMPs need to be informed about shared care arrangements for patients entered into one of their sponsored CTIMP.

Responsibilities of the PTC

- To notify the POSCU of entry of a patient into a clinical trial
- To provide the POSCU with information including patient trial number, identification of medicines in the treatment regimen considered to be the IMP/s in the trial protocol; copies of relevant documentation such as consent to trial entry, treatment regimen and trial protocol if necessary;
- To identify senior pharmacists qualified to give advice regarding the prescription and delivery of, and accountability for all medicines to be administered to patients at the POSCU, identifying if applicable any IMP/s
- To give clear guidance at the outset according to the Rules and Guidance for Pharmaceutical Manufacturers and Distributors, the “Orange Guide”, for all trial treatment regimen related medicines (non-IMPs and IMPs).
- To inform POSCU of necessary data to be collected for a particular patient and the likely timing of data collection by data managers within the PTC
- To provide robust mechanisms to allow timely communication of possible SAEs and SARs by the POSCU to the PTC at all times

Responsibilities of the POSCU

- To ensure training in 'Good Clinical Practice' (GCP) in Clinical Trials is updated in all members of staff with responsibility for and involvement in direct clinical care of patients on a clinical trial and in trial specific procedures.
- To nominate senior paediatric pharmacists with appropriate GCP training to ensure guidance on assembly and administration of medicines (non-IMPs and IMPs) is followed; and to ensure accountability records for IMPs.
- To identify those patients enrolled into a clinical trial at the PTC.
- To identify administered investigational medicinal products (IMPs) within the local care setting.
- To keep detailed clinical records on any experienced adverse events, as well as any side effects related to the treatment. Severity should be defined by the current version of Common Toxicity Criteria (CTC).
- To provide data for patients on clinical trials (e.g. results of investigations, details of blood product administration; details of chemotherapy administration, laboratory results) as requested by data managers at the PTC.
- To notify the PTC of any modifications to treatment made at the POSCU.
- Immediate and close liaison with the PTC in the event of a serious adverse event and severe/unexpected toxicities, as defined in the protocol relevant to the patient concerned.
- To comply to GCP in clinical trials principles at all times.

Abbreviations/Definitions:

BMT	Bone marrow transplant
CCLG	Children`s Cancer and Leukaemia Group
CTIMP	Clinical Trial Investigational Medicinal Product
CYP	Children and Young People
CYPCN	Children`s and Young People`s Cancer Network
CYPIOG	NICE guidance, Improving Outcomes for Children and Young People with Cancer
DGH	District General Hospital
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
Level 1	Please refer to Children`s Cancer Measures Document
Level 2	
Level 3	
LTFU	Long Term Follow Up
MDT	Multidisciplinary Team
MHRA	Medicines and Healthcare Products Regulatory Authority
NICE	National Institute of Health and Clinical Excellence
NRES	National Research Ethics Service
PONF	Paediatric Oncology Nurses Forum
POSCU	Paediatric Oncology Shared Care Unit
PTC	Principal Treatment Centre