The ROYAL MARSDEN

NHS Foundation Trust

Welcome to the Drug Development Unit (DDU)

For patients on clinical trials

Patient Information



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Introduction

Welcome to the Drug Development Unit (DDU). The DDU specialises in caring for patients who are participating in Phase 1 cancer drug trials and comprises Oak Ward, Oak Day Unit and Outpatient Clinics including a Joint Consultant Clinic on Wednesdays (JCC) and a new patient clinic on Fridays known as Johann de Bono Friday (JDBF).

The DDU is staffed by a team of nurses, doctors, study manager, data managers, laboratory technicians and other staff, who are dedicated to supporting all our patients and their families during the period in which they are participating in one of the trials.

Coming into hospital and taking part in a trial can be an anxious time for patients and their families. The DDU team want to ensure that the time you are under our care is comfortable and runs as smoothly as possible. We hope this guide will provide you with the information you need during your time on any one of our trials, however if you have any gueries, please ask a member of our team.

Ward team

The nursing staff on the ward (identified by their uniform) include:



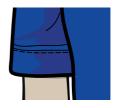
Matron

Navy blue uniform with red piping



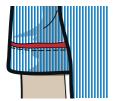
Ward and Day Unit Sisters

Navy blue and white spotted uniform



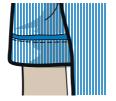
Clinical Nurse Specialist, CNS

Navy blue uniform



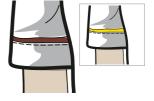
Senior Staff Nurse

Blue and white striped uniform with red piping



Staff Nurse

Blue and white striped uniform with navy piping



Health Care Assistant

White blouse or shirt with brown or yellow piping

Other members of the ward team include:

- Doctors: Consultants and Clinical Fellows
- Advanced Nurse Practitioners (ANP)
- Study Managers
- Data Managers

- Ward Receptionist
- Catering Host / Hostess
- Catering Supervisor
- Allied Health Professionals (for example physiotherapists, occupational therapists, dietitians, therapeutic massage therapists)

All ward staff will be wearing name badges for easy identification.

Clinical Nurse Specialist (CNS)

We are experienced cancer nurses with expertise in Phase 1 trials. Our role is to offer emotional support, information and practical advice whilst under the care of the Drug Development Unit and during transition between other teams involved in your care.

How can we help?

- By providing information on Phase 1 trials
- Being a point of contact for advice about symptoms or side effects
- Offering a telephone clinic for support in between hospital visits
- Providing emotional and psychological support for you and your family
- Referring you to support services both in the hospital and your local community
- Providing information about financial issues
- Signposting you to further information and relevant services
- Promoting wellbeing and complementary therapies
- Liaising with all healthcare professionals involved in your care.

Your experience within DDU

Once you have been referred to the DDU, you will be invited to attend the new patients' clinic (JDBF) where one of the doctors will explain the nature of Phase 1 drug trials and give you an information sheet. You may also meet the CNS during this visit.

If you agree to participate in a Phase 1 trial, you will be allocated to a trial as and when a slot becomes available, and you will subsequently be invited to attend the joint consultant clinic (JCCP) where once again you will see a doctor. You may also see the CNS and/or one of the study managers. At this appointment you will be given a patient information sheet, this information sheet is a trial specific information sheet that each patient will get outlining the trial that they are consenting for.

After you have consented, you will need to undergo a screening process to ensure that you meet the criteria for the trial. This mainly takes place on the Oak Day Unit but you may also have to go to other hospitals close by. If you need to go to another hospital, transport can be arranged for you if you would like. Tests may include blood tests, heart tracing, eye tests, heart scans, scans of the area affected by cancer and other physical assessments. The study manager assigned to your trial will write to you with all the information regarding these tests and provide you with a timetable. Once your eligibility is confirmed, you will be given a start date. On this day you will likely be admitted to Oak Ward.

You have the right to withdraw your consent at any time during this process. Please be assured that the care you receive or any future treatment will not be compromised by your decision to withdraw.

Ward orientation

Oak Ward is a nine bedded ward consisting of two single sex bays with four beds, and one single room for patients who require isolation for medical reasons. It opens at 8am on Mondays and closes at 8pm on Fridays.

Upon arrival to the unit, please go to the reception desk on Oak Ward. The receptionist will confirm your arrival and, if your bed is ready, will take you to your bed and inform the nurse who is assigned to you. If your bed is not ready, you will be asked to wait in the waiting area and your assigned nurse will be informed.

Nurse call handset

The nurse call handset can be used for getting help. Pressing the large orange button will alert the ward staff that you need assistance. This also controls your overhead light and you will be shown how to use this on admission.

Emergency pull cord

If you need assistance while in the bathroom, please pull the red emergency pull cord and a member of the nursing team will come as quickly as possible.

Bed operation

The position and height of the bed can be adjusted using the electronic handset attached to the bed via a coiled lead. A member of the nursing team will be happy to show you how to use this.

Daily ward routine

- The day staff shift is from 8am until 8.30pm and includes a detailed patient handover.
- The night staff shift is from 8pm until 8.30am and includes a detailed patient handover.

Some of the handover will take place at your bedside when the nursing staff provide the next shift of nurses with important information about your care. It is important that we involve you in these discussions in order to ensure you are kept up to date with plans and progress.

Visiting

The ward has an open visiting policy, however please respect the needs of other patients on the ward with regard to noise. Please be aware that the ward asks that no more than three visitors attend at any one time and that all visitors leave by 9pm. If there are any exceptional circumstances, please speak to the nurse in charge.

Discharge

On the day of discharge, you may be asked to leave your bed at around 10am and complete some of your trial specific assessments on the Day Unit. This will only be done if we require your bed for another patient admission. It will not affect your care or the time of your next appointment. If you have been given drugs to take home, a nurse will go through these with you; what they are for, how and when to take them and anticipated side effects.

Day care orientation

Oak Day Unit is located on Oak Ward and has five reclining chairs and one examination couch for patients. It is open Monday to Friday from 8am to 6pm, with appointments starting from 8.30am.

Clinic appointments

You will be seen on the day unit for screening, dosing and safety visits. On arrival please go to the reception desk on Oak Ward. The receptionist will confirm your appointment and inform the nursing team of your arrival. You will be asked to sit in the waiting area until a day care nurse is available. Please note that it is a busy unit and we would appreciate you keeping to your appointment times. However, if this is not possible and you are unable to keep to the time you have been allocated, please call Oak Ward.

At each appointment you will be seen by a nurse and, on occasions, a health care assistant who will take a set of bloods, carry out vital observations and any trial specific assessments. You will also be questioned about your general wellbeing. The nurse will aim to see you and carry out the initial assessments as close as possible to your appointment time. You will then see a doctor or Advanced Nurse Practitioner (ANP).

The doctor or ANP will generally see you after your blood results have come through. As with the ward, the waiting times for this may be up to two hours or during busy periods it may take longer. On occasions, to prevent excessive waiting times, the doctor or ANP will see you before your blood results have come back,

but please do not go home until a member of the team has confirmed that you may leave. You can sit in the waiting area or alternatively you may arrange a time with the nurses for you to come back. You can also arrange for the nurses to call your mobile when you are needed.

Treatment: Assessments

Due to the nature of Phase 1 trials, during your first cycle, particularly on day 1, you will be regularly assessed within the first 24 hours after treatment. This will include having regular trial specific bloods tests, heart tracings, scans and in some cases biopsies. Please refer to your patient information sheet for specific assessments and their frequency for your particular trial.

Trial blood samples

To obtain the frequent and regular bloods samples often required during your admission, a venous access device, such as a plastic cannula (small tube), is generally inserted into one of your veins until all blood samples have been obtained, at which point it will be removed. If you already have a permanent central venous access device, this will be used instead. If however, your drug is given intravenously, the venous access device in which the drug is given through cannot be used to take your trial specific bloods. On these occasions you will need to have a second venous access device, going into a different vein.

Drug waiting times

If you are due to collect oral drugs at a particular visit, please note that once your drug has been confirmed with pharmacy, oral drugs may take up to one hour to be dispensed. During busy periods, this may take longer. If your treatment requires the administration of an intravenous drug, waiting times may be up to four hours from the time the drug is confirmed with the pharmacy, which is only done once blood results are back. With some trials you may be allowed to have your bloods taken the day before; if this is the case, you will be informed and an appointment will be made for the day before.

Supportive treatments

On occasions, you may require supportive treatments such as blood transfusions, intravenous fluids or bisphosphonate infusions. The waiting times for intravenous fluids and bisphosphonate infusions are much shorter, and if known in advance, the drug can be preordered. Blood transfusions, on the other hand, will take longer. You will initially need to have a blood sample taken for a cross match, to ensure you are given blood that is compatible with you. This can be taken the day before the blood transfusion, in which case your blood is generally available within half an hour of your arrival on the day of transfusion. If, however, you are cross matched and require the blood to be transfused on the same day, you may have to wait three to four hours for the blood to become available.

Before leaving Oak Day Unit

Please check the when your next appointment is. If you do not know, you can ask at reception and we will be able to find out for you.

Special diets

If you have a special diet and the standard menus do not support this, then please tell the nursing staff or the ward host as soon as possible so they can arrange for a member of the Catering or Dietetic Department to come and see you.

For infection control reasons, there are no facilities available to heat up or store food brought by patients or relatives in the ward kitchen.

Palliative care support services in the community

We strongly recommend all patients who are participating in Phase 1 trials to have local palliative care support in place. If you do not, we will discuss this service with you and will be happy to make the referral on your behalf.

Hospital facilities

Mobile phones

Mobile phone signals can interfere with some types of medical equipment. For that reason, there are clearly signposted areas where we ask patients not to use mobile phones. Please observe these instructions. Our staff use a cordless internal phone system that does not affect medical equipment. When you use your mobile phone, please be considerate to others around you.

Wi-Fi

The Trust has patient accessible Wi-Fi. Please ask a member of staff to advise you if you need assistance. You can bring in your laptop, computer tablet or smart phone. We do kindly ask if you do bring these devices in, and wish to use the sound function that you bring headphones to show consideration to other patients.

Daily newspapers

If you would like any newspapers or magazines, these can be bought from the gift shop located on the ground floor adjacent to the main entrance also sells a selection of magazines (open 10am – 4pm).

Security and valuables

Ward security

The main entrances to the wards are monitored by closed circuit television. The entrance doors to the ward are always closed but are sensor monitored for entrance and exit. To exit the ward, press the green button or silver exit button. However, if the sensors fail there is a buzzer (intercom press) to gain entry into the ward. The unit is closed at weekends and bank holidays.

Valuables

Please do not bring very expensive items or large amounts of money with you when coming to the hospital. If you do need to bring valuables or money with you, please tell a member of the ward staff.

They will arrange for your valuables to be collected and taken for safekeeping. We will ask you to sign a property disclaimer and give you a receipt for your items. You can withdraw them any time between 9am and 4.30pm, Monday to Friday. Please note that we cannot store laptop computers in the safe.

Some wards provide bedside lockers which incorporate a safe to store valuables. Please ask staff to show you how to use this facility. Unfortunately, we cannot accept responsibility for loss or damage to personal property of any kind, including money and laptop computers, regardless of how the loss or damage may occur.

General trial specific information

Appointment time and dates

Please do not change any appointment times, dates or assessments without speaking with the study manager. Your appointments will be booked to ensure the trial is being carried out in accordance with the trial protocol. If the times are changed, this will impact the protocol and could affect the evaluation of data. In most cases there will be a time frame in which to carry out specific assessments.

The study manager will communicate with you at all times to ensure that the appointments you are given are both within the specified time frame and suitable for you. If you have a holiday planned, please ensure you inform the study manager so that appointment times can be scheduled around this. There may be occasions when this is not possible, so please always contact the study manager before booking holidays.

Oral trial drugs

 Never take your trial drug on a day you have an appointment or admission with the DDU. You may take all other medication.
 Once you have been seen by the doctor or ANP and blood results have come back, you will be told whether or not to take your drug.

- Never independently change the dose you have been prescribed. If you are unwell or unable to take it, please call Oak Ward or The Royal Marsden Macmillan Hotline and you will be given advice. This may include any or some of the following: to stop taking the drug, to attend the unit or, if you live some distance away, you may be asked to go to your GP, or in an emergency to go to your local Accident and Emergency department.
- Always bring all your trial drug supplies with you, including empty bottles or blister packs, and give them to the nurse who is looking after you. On each visit, the nurse assigned to you will need to perform a drug accountability check to ensure you are taking the drug as prescribed. Please let the nurse know whether any doses have been missed or if any tablets or capsules have been lost.

Drug diaries

If you have been given a drug diary, please ensure you complete it accurately. The nurses will show you how to do this, but please ask if you are unsure.

Always bring in **all** completed drug diaries to every appointment and admission.

Fasting restrictions

Some trials impose fasting restrictions, either for the blood tests needed before you have the drug, for the drug itself or sometimes both. If this is the case with your trial drug, you will be told this regularly at your appointments. At screening this will be discussed with you during your initial admission and again at your clinic appointments. In addition, this will be stated in the patient information sheet. Please note that if you are told to **fast**, this means you can only drink plain water. With some trials you may also be allowed black, sugarless tea or coffee, and you will be advised if this is the case. If you are told to take 'nothing by mouth' (NBM), this means you must refrain from eating or drinking anything. Please do check with the nurses if you are uncertain.

Other drugs

Please be aware of any other medication you are taking since your last appointment. The doctors need to be made aware of them in case of any potential interaction with your trial drugs.

General information

Infection control

Strict infection control is essential, therefore please observe the following:

- Use alcohol hand gel on entering and leaving the unit.
- Before, or on arrival, please notify the receptionist and the nurse
 if you have had an inpatient admission to another hospital since
 your last visit or if you have any flu-like or respiratory symptoms
 or diarrhoea.

Fire procedures

Weekly fire alarm test

A fire test is performed every Tuesday morning and will sound for up to 20–30 seconds.

Fire alarm activation

In the event the fire alarms do go off, a nurse will advise you on what to do. Please do not evacuate the ward unless you are told to do so by a member of the ward team.

Smoking

The Royal Marsden operates a strict no smoking policy anywhere in the hospital and its grounds. This includes the use of e-cigarettes.

Catering

Nutrition is an important part of your recovery and all our meals are designed in conjunction with our Consultant Dietitian to provide the right balance of energy, protein and other nutrients.

If you are unable to find suitable foods on the menu, our catering staff will be happy to discuss alternative options with you. There is also a call order menu that can be accessed out of normal meal times.

We will ask you some questions about your nutrition and weight on admission and we may refer you to a dietitian if you need a personal review.

When you are staying overnight on the ward, meals will be provided.

Meal times

Breakfast 8am – 9am

Lunch 12.30pm – 2pm

Supper 6pm – 7pm

The Trust operates a protected meal times policy. This is a period over lunch and supper times when all non-urgent activity on the ward is minimised to prevent any unnecessary interruptions to meal times.

The protected meal times are:

Lunch 12.30pm – 2pm

Supper 6pm – 7pm

Please let the nurse looking after you know if you need assistance with your meals. A red napkin will be placed on your meal tray to make all staff aware.

Patients and visitors can purchase meals or light snacks and drinks from one of the Trust's catering outlets.

The **Fontanella Café** is situated on the ground floor by the main reception. Open 7.30am to 5.30pm, Monday to Friday, and Saturday 8am – 2pm.

The **Cherry Tree Restaurant** is also on the ground floor by the main reception. Open 7.30am to 11am for breakfast and 12pm to 3pm for lunch, Monday to Friday.

Vending options are available throughout the day; vending is located in the Cherry Tree seating area.

For infection control reasons we are unable to heat up or store any food brought in by patients or relatives in the ward kitchen.

Interpreting service

We offer a telephone and face to face interpreting service for those patients whose first language is not English. Please ask the nurse looking after you if you need this service.

Spiritual needs

The Royal Marsden cares for patients and relatives with many different religious needs. A resident Anglican chaplain is always on call. Part-time Roman Catholic, Free Church and Jewish and Muslim chaplains visit the hospital regularly. Representatives from any faith can always be sent for. The chaplains can also provide a variety of non-Christian reading matter and devotional aids.

A multi-faith prayer room is available in the hospital, located on the third floor west wing. The hospital chapel is always open for a time of quiet reflection and prayer. Everyone is welcome to use both the prayer room and the chapel. If you do not feel well enough to walk, arrangements can be made to take you in a wheelchair.

There are regular chapel services on Sundays, Holy days and special occasions, and also lunchtime concerts of recorded music. The ward team will know the times of these events, which are also advertised on the notice boards. You are welcome to invite your relatives and friends to accompany you.

The sacraments of Holy Communion, Reconciliation and Anointing of the Sick are always available at your bedside.

If you would like a chaplain or religious leader to come and see you, please ask a member of the ward team who will be happy to arrange this.

Travel expenses

Public transport fares will be covered by the trial sponsor, so please keep tickets or receipts. In addition, mileage for the return journey from your home address to the hospital will also be covered. This is calculated using the AA route finder. Please ask the study manager of your trial for the exact amount paid per mile. Finally, your parking at the hospital will also be paid. These expenses can be claimed from the date you are consented to the trial until your final visit on the trial.

You will be given an expenses form at your screening visit, so please keep all receipts from the date you have signed consent. Please note that generally it takes approximately one month for expenses to be processed and we would appreciate if you could batch them into monthly claims. If this is a problem, please speak to the sister or senior staff nurses on either Oak Ward or Oak Day Unit.

Processed claims can be collected from Oak Ward reception. Payments can either be collected from the cashier's office or will be sent to your home via cheque if over £350.

On occasions you may need to have trial related assessments at other hospitals. The receptionists on Oak Ward will book a taxi for these journeys. You will not be asked to pay for these as they are pre-paid.

Car parking

Because of the limited number of parking spaces available, we ask patients to consider coming to the Sutton hospital by public transport or taxi rather than by car. If you do wish to drive, follow these instructions:

• There is a controlled parking zone in the area around the hospital, making on-street parking difficult. Car parking space for patients and visitors at the hospital is limited.

- There are different patient and visitor parking accessed via Downs Road at the main hospital entrance and via Cotswold Road at the Oak Cancer Centre entrance. Please check for signage to ensure you are parked correctly.
- The Royal Marsden is now within the governments ULEZ zone to improve air quality in London, most patients can claim back charges. Please speak to a member of staff if you need more information about this.
- There are a number of reserved spaces for short stay drop off at the front of the hospital and the Oak Centre for Children and Young People via Downs Road, and at the Oak Cancer Centre via Cotswold Road. These spaces are time limited, please check for signage to ensure you are parked correctly.
- All other drivers at Sutton need to use the main car park, which has a barrier controlled entrance and exit system. There are a number of disabled spaces within the car park.

Making comments

On discharge you will be provided with a friends and family card to provide any comments you may have on any aspect of your stay in hospital. You can put this in the box positioned on the ward should you wish this to be anonymous.

Some patients and family members may wish to be more formally involved with patient and public involvement to shape our service provision. If you or a family member is interested, please contact Mary van Zyl via Oak Ward on 020 8642 6011.

If you are dissatisfied

If there are any aspects of your stay in hospital that you are dissatisfied with, please discuss initially with the Ward Sister or the nurse in charge.

Written concerns

If you would prefer to register your concerns in writing please address them to:

The Patient Advice and Liaison Officer (PALS) The Royal Marsden NHS Foundation Trust Fulham Road London, SW3 6JJ

Compliments

We would be delighted to hear from you, please feel free to send any letters of praise to the ward sister, at the address above.

By acting on your comments, suggestions and concerns we hope we can work with you to improve our services for future patients.

Contact details

If you have any questions or concerns about your trial, please get in touch and a member of the medical team will be happy to speak to you.

Oak Ward 020 8915 6000 / 6001

Clinical Nurse Specialists 020 8642 6011 ext 4378 / 1330 / 1344

Email dducns.oak@nhs.net

Opening times Monday to Friday, 8am – 8pm

The Royal Marsden Foundation Trust, Downs Road, Sutton, Surrey, SM2 5PT

At your screening appointment we will give you a card with our out of hours contact details for weekends and bank holidays along with the unique CCR number of the trial your are allocated to.

MyMarsden

MyMarsden is a new, free patient app and website which will transform the way that patients can engage with our services and experience their care.

Using MyMarsden, patients can access parts of their Royal Marsden healthcare record from their own computer, tablet of mobile phone at any time.

www.royalmarsden.nhs.uk/mymarsden

The Royal Marsden Hotline: 020 8915 6899

You can ring the hotline 24 hours a day, 7 days a week.

Call us straight away if you are feeling unwell or are worried about the side effects of cancer treatments.

This service provides specialist advice and support to all Royal Marsden patients, as well as to their carers, and both hospital and community-based doctors and nurses caring for Royal Marsden patients.

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This booklet is evidence based wherever the appropriate evidence is available, and represents an accumulation of expert opinion and professional interpretation.

Details of the references used in writing this booklet are available on request from:

The Royal Marsden Help Centre

Telephone: Chelsea 020 7811 8438 / 020 7808 2083

Sutton 020 8661 3759 / 3951

Email: patientcentre@rmh.nhs.uk

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The information in this booklet is correct at the time of going to print.

Should you require information in an alternative format, please contact The Royal Marsden Help Centre.

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