Delete this line, then print on Trust/Hospital headed paper

Personalising treatment for myeloma patients based on how well they initially respond to a period of NHS treatment and their overall fitness level

Randomised study treatment

We would like to invite you to **continue to take part in iFIT and receive further treatment**

*For NHS site reference: **iFIT1** (MRD+ and FIT/UNFIT) – DRd until PD / Dara-Tec / Dara-Tal*

Thank you for taking part in iFIT so far. You have now completed 6 cycles of the NHS treatment DRd (daratumumab, lenalidomide and dexamethasone).

This information explains the further treatment you could receive, based on your recent tests. The tests show that you have current detectable myeloma cells in your bone marrow (MRD positive), and that you have a suitable level of fitness (fit/unfit categories).

We will test whether new immunotherapy treatments are more effective in treating myeloma compared to continuing DRd treatment. Immunotherapy treatments help your own immune system fight diseases.

It is completely up to you whether you continue to take part in this research. Your usual care won't be affected if you decide not to continue.

There are some different risks in continuing to take part in the research, compared with your usual care. Discuss the possible risks with your hospital doctor.

If you agree to take part, you can change your mind at any time and stop all or some parts of the research. If you want to change your level of involvement, let your hospital doctor or nurse know.

How will we use information about you?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this (See **Appendix 1** in the **'Study Registration'** document).

To help you understand the research, the information is split into several documents:

iFIT document	**This document**	**When will I receive this?**	**What is being asked of me?**
Bone marrow sharing		When having tests to find out if you have myeloma	Do you agree to share a sample of your bone marrow from your planned tests?
Study registration		If you are diagnosed with myeloma	Do you agree to be monitored whilst having the NHS treatment DRd, and for us to collect your data and samples?
Randomised study treatment	✓	After completing a period of the NHS treatment DRd	Do you agree to continue to take part in the research and be randomly allocated to a further treatment based on your data?
Additional information [optional - you don't have to read this before you make your decision]		At the same time as the 'Study registration' document above	Nothing is being asked of you here. This is additional information you may find interesting or helpful.

Large-print and electronic versions of all documents are available. Visit https://ctru.leeds.ac.uk/ifit.

Ask your hospital doctor or nurse if you need another paper copy of the '**Study registration**' or '**Additional information**' documents. You were given a copy of these when you joined the research. These contain information that is still applicable to you now.

Please look through all the information in this '**Randomised study treatment**' document before you decide whether you would like to continue. There is space on page 19 of this document to add questions or notes.

We may update this information during the research. For example, if we learn something new about the treatments. We will tell you about any important updates and give you the chance to choose if you still want to take part or not.

Once you have read the information, your hospital doctor or nurse will talk to you about the research again and you can ask any questions you like.

Contents page

Who can I contact if I have more questions?

If you have any questions about this research, please talk to your **<<enter Consultant, Doctor, Nurse, Researcher>>**:

<< Enter name >>

<< Enter contact details >>

Can I receive any of the other further treatments?

Unfortunately, no. You are only able to receive one of the further treatments described in this document. These further treatments are based on your response to the NHS treatment DRd and your level of fitness. Neither you nor your hospital doctor can change this.

You do not have to continue to take part in this research if you do not want to.

If I want to, will I definitely be able to continue to take part?

Unfortunately, no. Although you will be allocated one of these further treatments based on your initial response and fitness, your hospital doctor will still need to carry out some tests and ask you some questions. They need to make sure you are suitable and that it is safe for you to take part. You may have had some of these tests already and may not need to have them again.

These tests include blood tests, urine tests, bone marrow samples, imaging scans, and pregnancy tests (if you are female and are able to have children).

If your hospital doctor decides the research is not suitable for you, or if you decide not to take part, your hospital doctor will discuss your alternative treatment options with you.

What further treatment could I receive?

If you decide to continue to take part in this research, your hospital doctor will not decide what treatment you get out of the options listed here. Instead, you would get one of the treatments by chance (randomly).

This means if you agree to continue to take part, you will have an equal chance of getting any of the treatments. You should only agree to continue to take part if you are happy with this.

We do this so that we can do a fair test of which treatment is best. We only do this because we do not know which of the treatments is best.

This process is called ‘randomisation’, and you will be randomised to one of the following treatments:

1. **Continuing Daratumumab, lenalidomide (also known as Revlimid®) and dexamethasone (DRd) as long as your myeloma remains under control.** This could be a few months or several years.

   This is continuing the NHS treatment that you would likely receive even if you were not taking part in this research.

   You will continue your treatment as you have been. However, the daratumumab **injection** will be reduced to once a month (on day 1 of each 28-day cycle).

OR

2. **Daratumumab plus a new immunotherapy treatment called teclistamab for 18 cycles.** After 18 cycles you will stop the treatment, and you will continue to be closely monitored by your hospital doctor around every 28 days.

   Each treatment cycle lasts 4 weeks (28 days) and you will receive:

- Daratumumab on day 1
- Teclistamab on days 1, 3, 8, and 15 of the first cycle, and day 1 of the second cycle onwards.

  Teclistamab is given as an **injection** under the skin. It is started slowly, with two smaller doses (step-up doses) given before the first full dose. It will be given alongside daratumumab, which is also given as an **injection** under the skin. You may need to come into hospital on these days. You need to be monitored closely when starting teclistamab. This may mean being admitted to hospital for a period of time (usually about a week) or being monitored closely as an outpatient depending on your hospital’s usual practice.

OR

3. **Daratumumab plus a new immunotherapy treatment called talquetamab for 18 cycles.** After 18 cycles you will stop the treatment, and you will continue to be closely monitored by your hospital doctor around every 28 days.

   Each treatment cycle lasts 4 weeks (28 days) and you will receive:

- Daratumumab on day 1
- Talquetamab on days 1, 3, 8 and 15 of the first cycle, days 1 and 15 of the second to the sixth cycle, and day 1 of the seventh cycle onwards.

  Talquetamab is given as an **injection** under the skin. It is started slowly, with three smaller doses (step-up doses) given before the first full dose. It will be given alongside

daratumumab, which is also given as an **injection** under the skin. You may need to come into hospital on these days. You need to be monitored closely when starting talquetamab. This may mean being admitted to hospital for a period of time (usually about 9 days) or being monitored closely as an outpatient depending on your hospital's usual practice.

Before the start of each cycle of treatment, your hospital doctor will carry out some tests (including a blood test) to make sure it is safe and suitable for you to continue receiving treatment. This will also happen when you are not receiving treatment but are still being closely monitored by your hospital doctor, to see how you are doing.

You will continue to receive the treatment as planned, if the tests show you are tolerating the treatment, and your myeloma remains under control.

Other treatments are available. Talk to your hospital doctor about this.

You will be given some additional medications to help combat the possible side effects of these myeloma treatments. Your hospital doctor will decide exactly which treatments you need for this.

Occasionally on receiving new information, your hospital doctor may consider it be in your best interests that you stop taking any further study treatment.

What else will happen?

- **Blood and bone marrow samples**

We will collect samples of your blood and bone marrow aspirate (fluid) at the following times:

- After 6 cycles of treatment (blood only),
- After 18 cycles of treatment,
- After 30 cycles of treatment, or 12 28-day periods of continuing to be closely monitored by your hospital doctor after treatment, and
- If you are no longer responding to treatment.

We will take up to an additional 4 teaspoons (20mL) of blood and 2 teaspoons (10mL) of bone marrow aspirate (fluid) each time.

It is expected that most of the blood samples will be taken at the same time as your routine hospital tests. These should not require any additional needle punctures.

You would likely have a bone marrow sample taken if you are no longer responding to treatment, even if you were not taking part in this research. However, the extra bone marrow samples for this research allow us to see how well you are responding to the treatment. Parts of

the samples will also be used in laboratory research to understand who responds best to which treatments.

- **Questionnaires**

We will ask you to complete a total of 6 further sets of questionnaires. This will be at 3, 6, 12, 18, 24 and 30 months from randomisation (when you are allocated by chance to a further treatment). If you stop treatment or stop being closely monitored by your hospital doctor, we will still ask you to complete these questionnaires around the time they would have been due.

This is to help us determine the impact of this research on your emotional and physical wellbeing, and how you have used healthcare services. The questionnaires are confidential. Your hospital doctor or nurse will not see what you have written.

You may continue to complete the questionnaires on paper, or you may now change to completing the questionnaires online.

If you choose to complete the questionnaires online, we will collect your email address and/or mobile number, and you will be sent a link to complete by the method you prefer. You will receive up to 3 reminders to complete each questionnaire.

Please let your hospital doctor or nurse know if you change your email address or phone number during the research. Otherwise, we might not be able to send questionnaires to you in this way.

A guide to completing your questionnaires using the online method is provided in the '**Additional information**' document.

- **Data collection**

We will collect further data about you and your health.

Your hospital doctor will look at some information about you, and if you have any other illnesses. They will also ask you some questions about your lifestyle. This is a way of determining your level of fitness. This will happen after every 6 cycles of treatment or period of being closely monitored by your hospital doctor, for a maximum of 6 times.

What are the possible benefits of continuing to take part?

People with myeloma often wish to know whether novel immunotherapy treatments are effective in treating myeloma. Immunotherapy treatments help your own immune system fight diseases.

By continuing to take part, you will help us answer this important question, even if you are not randomised (by chance) to receive one of the immunotherapy treatments (teclistamab or talquetamab).

We are doing this research because we do not know which of the treatments is best. We want to find out which treatment is best at the end of the research. It might be that the treatment you get in the research is better, but we won't know until the end of the research.

Teclistamab is currently funded by the NHS for myeloma patients after at least three prior treatments. Talquetamab is not currently funded by the NHS. By continuing to take part in this research, you may be treated with teclistamab or talquetamab earlier than would be the case in your usual care. However, we do not know for sure if this is better than usual care.

The following information is about **teclistamab** and **talquetamab** treatments.

Refer to the '**Study registration**' document for risks and side effects associated with daratumumab, lenalidomide and dexamethasone, as well as other information we want to make you aware of. Talk to your hospital doctor or nurse if you need another copy of the '**Study registration**' document.

What are the potential risks and unwanted effects of teclistamab and talquetamab?

This research involves treatments that you could get in your usual care at some point. In this research they are being used in a different way. So if you take part, there may be some extra risks compared to your usual care.

As with all research like this, the new treatment may not work as well as the best current treatments. But they might be as good as, or better, than current treatments. We are doing the research because we don't know which is best.

All treatments for myeloma have some possible side-effects. There is always a chance of finding out about new side-effects, including potentially serious ones. This is the case even in treatments that are commonly used.

If we find out about a serious new side-effect during this research, your hospital doctor or nurse will let you know. They will give you a chance to say if you want to carry on taking part. The treatments are quite new, so we might find out about new side-effects during the research.

You can find a full list of known possible side-effects of the treatments on page 15. You should look through these carefully before you agree to take part in this research. Especially if you have concerns about certain side-effects.

Always tell your hospital doctor about any health events you have experienced during your time in the research or afterwards. For example, if you have to go to hospital for any reason. This is to help us protect your safety and the safety of other people with myeloma.

Some of the most potentially common and/or **serious** side-effects are:

- **Injection Site Reactions –** risk with daratumumab, **teclistamab and talquetamab**

Injection site reactions may occur when a treatment is given by injection. Side effects may include but are not limited to:

- Redness
- Itching
- Rash

- Swelling
- Inflammation
- Discomfort
- Bruising
- Hardening of the skin at the site of injection

- **Cytokine Release Syndrome (CRS) –** risk with **teclistamab and talquetamab**

CRS is a complication that can happen due to the activation of immune cells. Rarely, CRS can be severe, life threatening, or even lead to death.

The signs and symptoms of CRS are:

- Fever
- Chills
- Abnormal blood pressure
- Trouble breathing
- Elevated heart rate
- Tiredness or weakness
- Headache
- Nausea or vomiting
- Wheezing
- Abnormal liver function tests

CRS has occurred in approximately 72% of patients treated with teclistamab and 77% of patients treated with talquetamab. Most cases occurred within the first few doses, and most have been mild or moderate. Your hospital doctor will help to prevent CRS by giving you:

- Lower doses of teclistamab or talquetamab (called step-up doses) when you start that treatment
- Medications including steroids, paracetamol/acetaminophen, and an antihistamine, before the step-up doses

Your hospital doctor will check and monitor you for symptoms of CRS. If you have CRS, your hospital doctor will give you medication to treat it. They will explain the side-effects of this medication to you. You may need to stop taking the study treatment for a certain period of time or altogether.

- **Immune effector Cell-Associated Neurotoxicity Syndrome (ICANS) –** risk with **teclistamab and talquetamab**

ICANs is a condition that affects the brain. Most cases of ICANS have been mild or moderate, but ICANS can be severe, life threatening, or even lead to death.

The signs and symptoms of ICANs are:

- Feeling confused, less alert, disorientated or sleepy
- Decreased consciousness
- Difficulty speaking and understanding speech
- Difficulty writing
- Loss of ability to carry out skilled movement and gestures

ICANS have occurred in approximately 3% of patients taking teclistamab and 10% of patients taking talquetamab. Your hospital doctor will check and monitor you for symptoms of ICANS.

- **Infection –** risk with daratumumab, **teclistamab and talquetamab** (highest risk with teclistamab)

The treatments may cause your immune system to not produce enough antibodies or white blood cells. Antibodies and white blood cells help fight infections. Decreases in antibodies or white blood cells can increase the risk of infections. Due to this, there may be a greater risk of getting an infection or getting a more severe infection.

Tell your hospital doctor if you:

- Have an infection or have a history of frequent infections
- Feel sick or think you may have fever
- Are diagnosed with COVID-19 or have been in contact with someone with COVID-19.

Severe infections, including fatal infections, have been reported.

It is important to try to prevent getting an infection as much as possible. This includes washing hands and avoiding crowded spaces as much as possible.

Reactivations of viruses have been observed with **teclistamab** and daratumumab.

Hepatitis B reactivation could result in severe liver infection or death. Your hospital doctor will test you for the hepatitis B virus before you start treatment. If you test positive for the virus, you will be closely monitored for signs of infection. Tell your hospital doctor if you have any of the following symptoms:

- Worsening tiredness
- Yellowing of the skin or the white part of your eyes

Other viruses that you have been exposed to in the past can also return including cytomegalovirus and herpes zoster virus (shingles).

The reactivation of a virus can cause progressive multifocal leukoencephalopathy (PML). This can be fatal and cases have been reported with **teclistamab**. Your hospital doctor will monitor you for signs of PML. They may stop your treatment if they think you have PML. Tell your hospital doctor if you have any of the following symptoms:

- Changes in vision

- Difficulty speaking
- Weakness in an arm or leg
- Changes in the way you walk
- Problems with your balance
- Changes in sensation
- Memory loss
- Confusion

Your hospital doctor may give you medication to prevent infections. This includes antibiotics and antivirals. Your hospital doctor may recommend a treatment called intravenous immunoglobulin (IVIG) which provides replacement antibodies which may help in fighting off infections.

- **Skin and Nail Problems** – risk with **talquetamab**

Skin and nail changes are commonly seen with **talquetamab**. They usually start within 1-3 months of starting the treatment. Skin changes may include dry skin, skin peeling, itching, and rash. Palmar-plantar erythrodysaesthesia (PPE), also called “hand foot syndrome,” can cause redness, swelling, and blistering of the hands and feet. Nail changes may include nail loss, peeling, ridging, discoloration, breaking, loosening and shedding of the nails, and nail separation from the skin.

In addition, rashes may occur at the site of the injection, or may be widespread.

Your hospital doctor may give you lotions, steroid creams or steroid pills, and may also consult a dermatologist.

- **Oral Toxicity** – risk with **talquetamab**

Oral side effects may include dry mouth, dysgeusia (altered taste), ageusia (loss of taste), stomatitis (mouth swelling), mouth and throat pain, and difficulty swallowing.

Your hospital doctor may give medicines to help these side effects, such as saliva stimulating agents, steroid mouth wash, and/or they may suggest a consultation with a nutritionist.

- **Immune-related effects** – risk with **teclistamab and talquetamab**

Immune-related side effects can happen when the immune system is stimulated by drugs that bind immune cells. Side effects may include rash, abnormal liver function tests, thyroid and/or adrenal dysfunction, inflammation in the lung or colon, and neuropathy.

Your hospital doctor will monitor and treat you for these side effects during treatment with teclistamab or talquetamab.

- **Allergic reactions** – risk with daratumumab, **teclistamab and talquetamab**

Teclistamab and talquetamab treatments could cause allergic reactions.

Anaphylaxis is the worst type of allergic reaction. It can happen suddenly and may even cause death. Some allergic reactions may happen after several days and may include fever, rash, muscle aches, and joint pain.

Your hospital doctor will decide the best way to treat an allergic reaction.

Anaphylactic reaction has not been reported in clinical studies of daratumumab, teclistamab or talquetamab. Therefore, the frequency is not known.

- **Infusion related reactions –** see '**Study registration**' document
- **Anaphylactic and severe skin reactions** – see '**Study registration**' document

What else should I be aware of?

If you receive **teclistamab** or **talquetamab** treatment, this would mean **more hospital visits** than if you were not taking part in this research.

You may need to stay in hospital, or remain near to the hospital or healthcare facility **for 48 hours**, after each of the first few doses of **teclistamab** or **talquetamab**. This is usually for a continuous period of 7-10 days.

Neurological side effects may make it **unsafe for you to drive or operate machinery**. As these side effects are more likely to occur at the start of treatment, you should not drive a car or operate machinery from the first step-up dose (lower dose) of **teclistamab** until 48 hours after the first full dose. For **talquetamab**, you should not drive a car or operate machinery from the first step-up dose (lower dose) and for 48 hours after the first full dose. If you experience any neurological side effects at any other time during treatment, you should also not drive a car or operate machinery until your hospital doctor tells you otherwise.

If you receive treatment with **teclistamab or talquetamab** you will **not be able to donate blood, sperm, or eggs** until 100 days after the last dose is given. You will not be able to donate eggs for 6 months after treatment with teclistamab.

You must not receive any live vaccinations 30 days before joining the research and for 3 months after you have completed all treatment. Examples of common 'live' vaccines include the chicken pox, yellow fever, shingles (Zostavax), and the measles, mumps and rubella (MMR) vaccines. **Check all vaccinations with your hospital doctor.**

If you receive teclistamab or talquetamab treatment, you will be given a **teclistamab or talquetamab card** that you should carry with you at all times.

Full details of known potential treatment side effects

Refer to the '**Study registration'** document for risks and side effects associated with DRd therapy, as well as other information you should be aware of. This table is only for the treatments daratumumab, teclistamab and talquetamab. The severity of side effects can vary but some may be life-threatening or result in death.

The frequency of side-effects is usually described as **very common** (seen in at least 1 of every 10 patients), **common** (seen it at least 1 of every 100 patients), **uncommon** (seen in at least 1 of every 1,000 patients), **rare** (seen in at least 1 of every 10,000 patients).

Side-effects in **bold** below are further described in the risks and unwanted effects section above.

Side effect group	Side effect	Related to **daratumumab**	Related to **teclistamab**	Related to **talquetamab**
Infections	Infection of the upper respiratory tract such as nose, sinuses, throat, or upper airway	Very common	Very common	Very common
	Infection of the lungs (pneumonia)	Very common	Very common	Common
	Infection of the lower airway (bronchitis)	Very common		
	Urinary tract infection	Common	Very common	
	Flu-like symptoms (including fever, cough, muscle aches/pain, headache, and chills)	Very common	Very common	Very common
	Sepsis (a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs)	Common	Common	Common
	COVID-19	Very common	Very common	Very common
	Cytomegalovirus infection	Uncommon		
	Liver infection (hepatitis) in those patients who are carriers of the hepatitis B virus	Uncommon		
	Cellulitis (bacterial skin infection that causes redness, swelling, and pain in the infected area of the skin)		Common	
	Progressive multifocal leukoencephalopathy (PML)		Uncommon	

Side effect group	Side effect	Related to **daratumumab**	Related to **teclistamab**	Related to **talquetamab**
	Bacterial infection			Very common
	Fungal infection			Very common
	Viral infection			Common
Blood and the lymphatic system (part of the body's immune system)	Low white blood cells (including neutropenia, lymphopenia, leukopenia); may increase the risk of getting an infection	Very common	Very common	Very common
	Low platelets (thrombocytopenia); may increase the risk of bleeding and bruising (thrombocytopenia)	Very common	Very common	Very common
	Low red blood cells (anaemia)	Very common	Very common	Very common
	Fever with low white blood cells (febrile neutropenia)		Common	Common
	Altered levels of substances that help your blood to clot (Hypofibrinogenaemia)		Common	Very common
	Bleeding		Very common	Common
The immune system	**Anaphylactic reaction**	Rare		
	Hypogammaglobulinemia, a condition with your immune system in which not enough gamma globulin proteins (also known as antibodies) are produced. Decreases in gamma globulin proteins can increase the risk of infections.	Common	Very common	Very common
	Cytokine Release Syndrome		Very common	Very common
How the body uses food, produces important chemicals, and gets the nutrients it needs to stay healthy	Loss of appetite	Very common	Very common	Very common
	High blood glucose levels (hyperglycaemia)	Common		
	Low blood glucose levels (hypoglycaemia)		Common	
	Low blood calcium levels (hypocalcaemia)	Common	Common	
	Loss of body fluids, also known as dehydration	Common		
	Low blood potassium levels (hypokalaemia)		Very common	Very common
	Low blood sodium levels (hyponatraemia)		Common	
	Low blood magnesium levels (hypomagnesaemia)		Very common	Very common
	High blood calcium levels (hypercalcaemia)		Very common	
	Low blood phosphate levels (hypophosphataemia)		Very common	Very common

Side effect group	Side effect	Related to **daratumumab**	Related to **teclistamab**	Related to **talquetamab**
	High blood potassium levels (hyperkalaemia)		Common	
	Low blood albumin (hypoalbuminaemia)		Common	
	Fatigue or lack of energy	Very common	Very common	Very common
	Weight loss			Very common
The brain and how we think and behave	Insomnia	Very common		
The nervous system	Abnormal sensation including numbness/tingling of hands, feet, or limbs (peripheral neuropathy, paresthesia)	Very common	Very common	Very common
	Headache	Very common	Very common	Very common
	Dizziness	Common		Very common
	Fainting	Common		
	Immune effector cell-associated neurotoxicity syndrome (ICANS)		Common	Very common
	Abnormal brain function (encephalopathy)		Common	Very common
	Decreased ability to move (motor dysfunction)			Very common
	Pain		Very common	Very common
The heart	Irregular heartbeat (atrial fibrillation)	Common		
The blood vessels	High blood pressure (hypertension)	Common	Very common	
	Low blood pressure (hypotension)		Very common	
The lungs and airways	Cough	Very common	Very common	Very common
	Shortness of breath (dyspnoea), including wheezing	Very common	Very common	Very common
	Fluid in lungs (pulmonary oedema)	Common		
	Low oxygen level (hypoxia)		Common	
	Oral pain			Very common
The digestive system, including the stomach, intestines and any other part of the body	Diarrhoea	Very common	Very common	Very common
	Constipation	Very common	Very common	Very common
	Nausea	Very common	Very common	Very common
	Vomiting	Very common	Very common	Very common

Side effect group	Side effect	Related to **daratumumab**	Related to **teclistamab**	Related to **talquetamab**
involved in digesting food and absorbing nutrients	Inflammation of the pancreas (pancreatitis) or blood tests that suggest this, e.g. raised amylase	Common	Common	
	Stomach pain		Very common	Very common
	Dry mouth			Very common
	Mouth swelling (stomatitis)			Very common
	Trouble swallowing (dysphagia)			Very common
	Altered taste (dysgeusia)			Very common
	Abnormal liver blood tests		Common	Very common
The skin and the layer of tissue just beneath it	Rash, a noticeable change in the texture or colour of your skin	Very common		Very common
	Itchy skin (pruritus)	Common		Very common
	Skin disorder			Very common
	Dry skin (xerosis)			Very common
	Nail disorder			Very common
	Hair loss			Common
The muscles, bones, joints and tissues that connect different parts of the body	Back pain	Very common		
	Sudden muscle movement (muscle spasm)	Very common	Very common	
	Joint pain (arthralgia)	Very common		
	Muscular pain in the chest	Common		
	Pain in muscles or bones (musculoskeletal pain)		Very common	Very common
	Swelling of hands, feet, or limbs (oedema peripheral)	Very common	Very common	Very common
	Lack of strength (asthenia)	Very common		
Other	**Injection site reaction:** local reaction reported as mild pain or a burning sensation at the site of injection in the abdominal wall. Redness and hardening of the skin at the injection site was also observed and usually disappeared within a few hours after the administration	Common	Very common	Very common
	Infusion-related reactions	Unknown		

Any questions?

You can use this space to write down any questions/notes you have about the research. You can then share them with your hospital doctor or nurse.

Space for questions/notes

Delete this line, then print on Trust/Hospital headed paper

CANCER RESEARCH UK | ctru University of Leeds | LEEDS CLINICAL TRIALS UNIT | Blood cancer UK

Participant ID:	Initials:
Date of Birth:	NHS number (or CHI number for Scotland):
ISRCTN:	Principal Investigator:

PARTICIPANT INFORMED CONSENT DOCUMENT FOR RANDOMISATION (iFIT1)

Please initial for each statement

1. I confirm that I have read through this randomised study information document and have had the opportunity to ask questions. _ _ _ _ Initials

2. I agree to a copy of this Consent Form being securely sent to the Leeds Clinical Trials Research Unit. I understand that this will show my name and signature. _ _ _ _ Initials

3. I agree to continue my participation in the research and receive one of the further treatments by chance (randomly). _ _ _ _ Initials

Patient (to be completed by the patient):

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the research to the above-named patient and they have indicated their willingness to participate.

Signature……

Name (block capitals)……

Date……

Witness:

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes; original stored in Investigator Site File)