Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
ANIMATE

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

(●) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Is this a commercially sponsored Phase 1 or Phase 1/2a trial involving healthy volunteers?

( ) Yes (●) No

2b. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2c. Please answer the following question:

Is this trial subject to advice from the Expert Advisory Group on Clinical Trials and the Commission on Human Medicine prior to authorisation from MHRA? ○ Yes ◉ No

2d. Please answer the following question:

Is this a trial of a gene therapy medicinal product? ○ Yes ◉ No

2e. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ◉ Yes ○ No

• Does the study involve exposure to radioactive materials? ◉ Yes ○ No

b) Will you be taking new human tissue samples (or other human biological samples)? ◉ Yes ○ No

c) Will you be using existing human tissue samples (or other human biological samples)? ◉ Yes ○ No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which applications do you require?

- ☑ IRAS Form
- ☑ Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines
- ☐ Confidentiality Advisory Group (CAG)
- ☐ Her Majesty's Prison and Probation Service (HMPPS)
- ☑ Administration of Radioactive Substances Advisory Committee (ARSAC)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

SUBSTANTIAL AMENDMENT FORM [1]

NOTIFICATION OF A SUBSTANTIAL AMENDMENT TO A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE EUROPEAN UNION

For official use:

Date of receiving the request:	Grounds for non acceptance/negative opinion:
	Date:
Date of start of procedure:	Authorisation/ positive opinion:
	Date:
Competent authority registration number of the trial:	Withdrawal of amendment application:
Ethics committee registration number of the trial:	Date:

To be filled in by the applicant:

*This form is to be used both for a request to the Competent Authority for authorisation of a **substantial** amendment and to an Ethics Committee for its opinion on a **substantial** amendment. Please indicate the relevant purpose in Section A.*

A TYPE OF NOTIFICATION

A.1 Member State in which the substantial amendment is being submitted:

United Kingdom

A.2 Notification for authorisation to the competent authority: ☑

A.3 Notification for an opinion to the ethics committee: ☑

(1) Cf. Section 3.7.b of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (OJ, C82, 30.3.2010, p.1) hereinafter referred to as 'detailed guidance CT-1'.

B TRIAL IDENTIFICATION *(When the amendment concerns more than one trial, repeat this form as necessary.)*

B.1 Does the substantial amendment concern several trials involving the same IMP? [2] ○ Yes ◉ No

B.2 EudraCT number:	2017-002544-32
B.3 Full title of the trial:	A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy (ANIMATE)
B.4 Sponsor's protocol code number:	UCL/15/0515
B.4 Sponsor's	

protocol version number:	3.0
B.4 Sponsor's protocol date:	10/12/2019

(2) Cf. Section 3.7. of the detailed guidance CT-1

C IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE REQUEST

C.1 Sponsor

Organisation:	University College London
Contact Given name:	Managing
Contact Family name:	Director
Address:	Joint Research Office, Gower Street
Town/city:	London
Post code:	WC1E 6BT
Telephone:	02034479995
Fax:	02034479937
E-mail:	ctc.sponsor@ucl.ac.uk

C.2 Legal representative [3] of the sponsor in the European Union for the purpose of this trial (if different from the sponsor)

Name of organisation:
Contact Given name:
Contact Family name:
Address:
Town/city:
Post code:
Telephone:
Fax:
E-mail:

(3) As stated in Article 19 of Directive 2001/20/EC.

D APPLICANT IDENTIFICATION, (please tick the appropriate box)

D1. Request for the competent authority

D.1.1 Sponsor ☐
D.1.2 Legal representative of the sponsor ☐
D.1.3 Person or organisation authorised by the sponsor to make the application. ☑
D.1.4 Complete below:

Name of organisation CRUK & UCL Cancer Trials Centre
Contact Given name Emma

Contact Family name	Lawrie
Address	CRUK & UCL Cancer Trials Centre, 90 Tottenham Court Road
Town/city	London
Post code	W1T 4TJ
Telephone	02076799880
Fax	02076799861
E-mail	ctc.animate@ucl.ac.uk

D2. Request for the Ethics Committee

D.2.1 Sponsor ☐

D.2.2 Legal representative of the sponsor ☐

D.2.3 Person or organisation authorised by the sponsor to make the application. ☑

D.2.4 Investigator in charge of the application if applicable[4]:

- Co-ordinating investigator (for multicentre trial): ☐
- Principal investigator (for single centre trial): ☐

D.2.5 Complete below:

Name of organisation	CRUK & UCL Cancer Trials Centre
Given name	Emma
Family name	Lawrie
Address	CRUK & UCL Cancer Trials Centre, 90 Tottenham Court Road
Town/city	London
Post code	W1T 4TJ
Telephone	02076799880
Fax	02076799861
E-mail	ctc.animate@ucl.ac.uk

(4) According to national legislation.

E SUBSTANTIAL AMENDMENT IDENTIFICATION

E.1 Sponsor's substantial amendment information for the clinical trial concerned:

Code Number: Amendment 6
Version: Protocol v4.0
Date: 2020/05/28

E.2 Type of substantial amendment

E.2.1 Amendment to information in the CT application form ○ Yes ◉ No

E.2.2 Amendment to the protocol ◉ Yes ○ No

E.2.3 Amendment to other documents appended to the initial application form ◉ Yes ○ No

If yes specify:
Patient Information Sheet (PIS) v5.0
Informed Consent Form (ICF) v4.1
ARSAC Form

E.2.4 Amendment to other documents or information: ◉ Yes ○ No

If yes specify:

New document - Pregnancy Monitoring Information Sheet for Patients v1.0
New document - Pregnancy Monitoring Informed Consent form for Patients v1.0
Updated RSI
Patient Videos

E.2.5 This amendment concerns mainly urgent safety measures already implemented[5]: ○ Yes ◉ No

E.2.6 This amendment is to notify a temporary halt of the trial[6]: ○ Yes ◉ No

E.2.7 This amendment is to request the restart of the trial[7]: ○ Yes ◉ No

(5) Cf. Section 3.9. of the detailed guidance CT-1.
(6) Cf. Section 3.10. of the detailed guidance CT-1
(7) Cf. Section 3.10. of the detailed guidance CT-1

E.3 Reasons for the substantial amendment:

E.3.1 Changes in safety or integrity of trial subjects ○ Yes ◉ No

E.3.2 Changes in interpretation of scientific documents/value of the trial ○ Yes ◉ No

E.3.3 Changes in quality of IMP(s) ○ Yes ◉ No

E.3.4 Changes in conduct or management of the trial ◉ Yes ○ No

E.3.5 Change or addition of principal investigator(s), co-ordinating investigator ◉ Yes ○ No

E.3.6 Change/addition of site(s) ◉ Yes ○ No

E.3.7 Other change ◉ Yes ○ No

E.3.7.1 If yes specify:
Updated RSI

E.3.8 Other case ○ Yes ◉ No

E.3.8.1 If yes specify:

E.4 Information on temporary halt of trial:[8]

E.4.1 Date of temporary halt

E.4.2 Recruitment has been stopped ○ Yes ○ No

E.4.3 Treatment has been stopped ○ Yes ○ No

E.4.4 Number of patients still receiving treatment at time of the temporary halt in the MS concerned by the amendment

E.4.5 Briefly describe:

Justification for a temporary halt of the trial *(free text)*:

The proposed management of patients receiving treatment at time of the halt *(free text)*:

The consequences of the temporary halt for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product *(free text)*:

(8)Cf. Section 3.10. of the detailed guidance CT-1

F DESCRIPTION OF EACH SUBSTANTIAL AMENDMENT[9]

Please use this section to detail each substantial amendment which is being notified. If you are notifying more than one substantial amendment, please use the "Add Amendment" button as required

Substantial amendment 1

Previous and new wording:*(tracked)*

The protocol has been amended from version 3.0 to version 4.0. See protocol v4.0 tracked changes for previous wording. New wording is as follows in table:

Protocol version no.	Date	Amendment no.	Protocol Section (no./title)	Summary of main changes from previous version.
4.0	28/05/2020	6	TMG page 1	Amendment to Dr Beth Phillips' job title and location. Addition of new Trial Coordinator
			4.2.2 Required documentation	Removal of 'Clinical Trial Site Agreement' as the trial uses the model Non-commercial agreement
			8.2 Treatment Summary	Clarification that PET-CT scans should be conducted 'during' cycle 4
			8.4 Treatment discontinuation criteria	Added back in G4 lipase abnormalities, as lipase testing has been added back into assessments.
			8.5.1 Autoimmune complications	Removal of wording 'summary of product characteristics' and replaced with 'relevant appendix within the Investigator Brochure'
			8.5.1.8 Management of myocarditis	Addition of section to manage myocarditis. Current Investigator Brochure v18 has new guidance for managing myocarditis. Section created based on information within IB.
			8.5.1.9 Management of other immune-related adverse reactions	Removal of wording 'summary of product characteristics' and replaced with 'relevant appendix within the Investigator Brochure' Removed reference to myocarditis

				as this now has a separate standalone section for toxicity management
			9.2 Assessment of eligibility for nivolumab treatment	• Clarification added for timing of eligibility assessment; 'Once registered on trial and after completion of…' • Added confirmation that the PET-CT scan is to include neck, chest, abdomen and pelvis. • Added clarification to stipulate the ceCT scan areas; neck, chest, abdomen and pelvis (NCAP). • Added in details to inform sites to contact UCL CTC if the timeframe of assessments is outside those stipulated. • Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests. • Hep C testing; amended from 'Hepatitis C DNA' & 'HCV DNA' to 'Hepatitis C RNA' & 'HCV RNA'. DNA wording used in error, Hep C is a RNA virus.
			9.3 Assessments prior to cycle 1of Nivolumab	• Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests.
			9.4 Assessments during nivolumab treatment	• Clarification added to heading; 'Assessments during **Nivolumab** Treatment'. • Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests. • ceCT4 scan times have been added to reflect the fact that these should be in keeping with the timings of the PET4 scan. • Various minor re-wording to provide clarity of assessment timing.

			9.5 Assessments on completion of nivolumab treatment	• Clarification added to heading; 'Assessments during **Nivolumab** Treatment'. • Added details of the CT guided biopsy, which was previously missed • Added in wording to provide clarification that the ceCT scan should be conducted as well as PET-CT; 'Contract enhanced CT scan to be carried out at least 11-13 days after last trial treatment administration, and sent to the PET core lab for central review. This should be performed at the same imaging session as the PET-CT if feasible. If performed at the same session, the ceCT scan should be performed after the low dose PET-CT (see trial Imaging Manual and Sample Tracking Website Manual for details).'
			9.6.2 Patients who receive nivolumab	Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests.
			9.7 Assessments at time of disease progression	Added details of the CT guided biopsy, which was previously missed
			11.3 Timelines for Data Return	Reference to section 14.2 has been amended to reflect the renamed title; 'For Cause On-Site Monitoring' has been renamed 'Triggered On-Site Monitoring'
			12.4.1 Autoimmune events due to nivolumab	Duplication of paragraph, 'The following adverse events of special interest for Nivolumab must be reported on the appropriate AE of Special Interest form within **24 hours of confirmed diagnosis'** therefore removed
			14.1 Centalised Monitoring	Reference to section 14.2 has been amended to reflect the renamed title; 'For Cause On-Site Monitoring' has been renamed 'Triggered On-Site Monitoring'

			14.2 For Cause On-Site Monitoring	Section renamed. Was ‘For Cause On-Site Monitoring’ now reads ‘Triggered On-Site Monitoring’
			15 Withdrawal of patients	New paragraph added 15.1 – ‘Patients who do not start treatment’ There are now 6 sub-sections to section 15
			16.4 Withdrawal from Trial Participation by a Site	Removal of ‘CTSA’ and replaced with ‘site agreement (mNCA)’ to reflect the correct type of contract used within the trial
			19 Ethical and Regulatory considerations	Data protection Act updated from 1998 to 2018 to reflect the new update. And addition of the General Data Protection Regulation (EU)2016/679 (GDPR) (*changes previously missed in error from v2.1 protocol amendment*)
			19.5 Patient Confidentiality & Data Protection	DP Act date updated to 2018, and addition of GDPR.
			21 Funding	Removal of ‘CTSA’ and replaced with ‘site agreement (mNCA)’ to reflect the correct type of contract used within the trial
			Appendix 1 Abbreviations	Addition of the following: GDPR - General Data Protection Regulation mNCA - Model Non-Commercial Agreement
			Appendix 2.1 tables ‘Patients who receive nivolumab’ footnote 4 & ‘Investigations during treatment’ footnote 2	Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests. Hep C testing; amended from ‘‘HCV DNA’ to ‘HCV RNA’. DNA wording used in error, Hep C is a RNA virus.
			Appendix 2.2 table ‘Patients who do not receive nivolumab’ footnote 4	Lipase testing has been added back in to assessments. This is due to some sites conducting lipase instead of amylase tests. Hep C testing; amended from ‘HCV DNA’ to ‘HCV RNA’. DNA wording used in error, Hep C is a

				RNA virus.

New wording:
See table in above section

Comments/ explanation/ reasons for substantial amendment:

Substantial amendment 2

Previous and new wording:*(tracked)*
Patient Information Sheet (PIS) amended from v4.0 to v5.0. See patient information sheet v5.0 tracked changes for previous wording.

New wording:
Section 3, on Page 7: added new wording 'The assessments and scans you have will be looking to see if your disease has progressed. and gotten worse. If it has you will then have another CT scan and then a biopsy will be taken to confirm relapse. The biopsy will help us to know whether the PET scans are correctly identifying the presence of your disease.'
Section 5, on page 9 added new wording 'The company also reports that some patients have experienced life-threatening kidney failure after receiving nivolumab which has been life threatening in some instances, so it is important that you tell your doctor if you feel unwell. Your kidney function will be monitored closely with blood tests during the trial.'and 'Another common complication of treatment with nivolumab is iInflammation of the lungs is commonly experienced, and. Iin some instances, this has been life-threatening and even fatal.
Other events experienced by a very small number of people (>1/10,000 to < 1/1,000) that have been fatal include; myocarditis (inflammation of the heart), muscle inflammation and the rapid breakdown of muscle tissue leading to a toxic build-up of chemicals.'
Further Information, on page 17 added links to patient videos
Appendix 2, on pages 19 & 20 added in added in new possible side effects and amended wording of some existing side effects to clarify.
Appendix 4, on page 24 added extra tests for CT guided biopsy which was previously missed off in error.

Comments/ explanation/ reasons for substantial amendment:

Substantial amendment 3

Previous and new wording:*(tracked)*
Pregnancy Monitoring Information Sheet (PMIS) v1.0 - new document

New wording:
New document

Comments/ explanation/ reasons for substantial amendment:
New document, not previously included in error.

Substantial amendment 4

Previous and new wording:*(tracked)*
Pregnancy Monitoring Informed Consent Form (PMICF) v1.0 - new document

New wording:
New document

Comments/ explanation/ reasons for substantial amendment:
New document, not previously included in error.

Substantial amendment 5

Previous and new wording:*(tracked)*

Reference Safety Information (RSI) updated. Previous version used as RSI was Nivolumab Investigator Brochure version 16 dated 23 June 2017. This is being replaced as RSI with the current Nivolumab Investigator Brochure version 18 dated 25 June 2019.

New wording:

Refer to Nivolumab Investigator Brochure v18

Comments/ explanation/ reasons for substantial amendment:

Nivolumab Investigator Brochure (IB) v16 is presently used as RSI. Current nivolumab IB v18 contains pertinent changes to the safety information and therefore needs to be implemented as the RSI.

Substantial amendment 6

Previous and new wording:*(tracked)*

Amendment to the ARSAC form Part B, section 3, B1 & C1, see below:

B. Other ionising radiation

B1. Details of other ionising radiation

Procedure	No of procedures	Estimated procedure dose*(use national Diagnostic Reference Levels where available)*
PET-CT scan	Up to 3	~~The total dose received by patients in this study will be 94.8 mSv, from this total the 63.6 mSv is the additional dose received by participating in the study~~. 7.6 mSv (effective dose or target tissue dose per administration)
CT scan as part of PET/CT	Up to 3	8 mSv (protocol dependent)
Contrast enhanced CT scan	Up to 3	~~21 mSv~~ 26 mSv
CT guided biopsy	Up to 2	10 mSv

C. Dose and risk assessment

DOSE AND RISK ASSESSMENT

This study requires exposures to ionising radiation which are detailed in A1 and B1. Most of the total radiation dose required by the study is additional to routine clinical care. The total protocol dose is 146 mSv. This is equivalent to 63 years of average natural background radiation in the UK.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of taking part in this study is estimated as 0.7 %. For comparison, the natural lifetime cancer incidence in the general population is about 50 %.

Specifically, all patients in the study will have at least two FDG-PET/CT scans as part of the study protocol. Patients with a positive PET 4 scan will receive a third FDG-PET/CT. For patients who have 2 PET/CT scans both would be considered part of routine clinical care. For patients who have 3 scans, the additional scan to monitor response halfway through nivolumab treatment would be additional to routine clinical care. The radiation dose for an FDG PET-CT is 16 mSv therefore the total dose for 3 PET-CT scans is 3 x 16 mSv = 48 mSv.

Up to 3 contrast enhanced neck, chest-abdo-pelvis CT scans would be carried out during the study. These scans are additional to routine clinical care. The dose for each CT scan is 26 mSv so the radiation dose from the 3 CT scans is 3 x 26 mSv = 78 mSv.

Also, the patient may have up to 2 CT guided biopsies, 1 of which is considered part of routine clinical care and the second is optional as part of the trial. The effective dose from a CT biopsy will vary depending on protocol and patient factors so an upper bound estimate of 10mSv will be used for the risk assessment. For the two CT biopsies, the radiation dose is 2 x 10 mSv = 20 mSv.

The total dose received by patients from all examinations is 48 + 78 + 20 mSv = 146 mSv, of which 104 mSv is the additional dose received by participating in the study.

New wording:

See above table for new wording. Updated ARSAC form also included.

Comments/ explanation/ reasons for substantial amendment:

to include the CT guided biopsy (previously missed in error) and amend the contrast enhanced CT procedure dose.

Substantial amendment 7

Previous and new wording:*(tracked)*

Informed Consent Form (ICF) amended from v4.0 to v4.1. See informed consent form v4.1 tracked changes for previous wording.

New wording:

Section 11: Women of childbearing potential only, replaced the words 'unborn trial' with 'unborn child'

Comments/ explanation/ reasons for substantial amendment:

Typo noted and wording corrected.

(9)Cf. Section 3.7.c. of the detailed guidance CT-1. The sponsor may submit this documentation on a separate sheet.

G CHANGE OF CLINICAL TRIAL SITE(S)/INVESTIGATOR(S) IN THE MEMBER STATE CONCERNED BY THIS AMENDMENT

Type of change:

G.1.1 Addition of a new site

G.1.1.1 Principal investigator (provide details below)

Given name	Gamal
Middle name(if applicable)	
Family name	Sidra
Qualification (MD...)	FRCPath (UK), MRCP (UK), MB, SEM, Sofia
Professional address	Haematology Department, Lincoln County Hospital, Greetwell Road, Lincoln LN2 5QY
Given name	Patrick
Middle name(if applicable)	
Family name	Medd
Qualification (MD...)	BSc, PhD, MBBS, MRCP (UK), FRCPath
Professional address	Department of Haematology, DCL, Level 7, Derriford Hospital, Plymouth, PL6 8DH
Given name	Syeda
Middle name(if applicable)	Yasmin
Family name	Hasan
Qualification (MD...)	MBBS, MRCPath, FRCP, FRCPath
Professional address	Department of Haematology, Pathology Department, Sandwell General Hospital, Lyndon, B714HJ
Given name	Nagesh
Middle name(if applicable)	
Family name	Kalakonda
Qualification (MD...)	MBBS, MRCP(UK), FRCPath
Professional address	Clatterbridge Cancer Centre, Royal Liverpool University Hospital, Prescot Street, Liverpool, L7 8XP
Given name	Dominic
Middle name(if applicable)	
Family name	Culligan
Qualification (MD...)	MBBS, MRCP(UK), MD, MRCPath, FRCPath
Professional address	Department of Haematology, Clinic E, Aberdeen Royal Infirmary, Foresterhill, Aberdeen AB25 2ZH

G.1.2 Removal of an existing site

G.1.2.1 Principal investigator (provide details below)

Given name	
Middle name(if applicable)	
Family name	
Qualification (MD...)	
Professional address	

G.1.3 Change of co-ordinating investigator (provide details below of the new coordinating investigator)

Given name	
Middle name(if applicable)	
Family name	
Qualification (MD...)	
Professional address	

G.1.3.6 Indicate the name of the previous co-ordinating investigator:

G.1.4 Change of principal investigator at an existing site (provide details below of the new principal investigator)

Given name	Elizabeth (Beth)
Middle name(if applicable)	Helen
Family name	Phillips
Qualification (MD...)	FRCPath, MRCP, MB BS, BSc
Professional address	The Christie NHS Foundation Trust, The Christie Hospital, Dept 26, Wilmslow Rd M20 4BX

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Kim Linton

Given name	Nicolas
Middle name(if applicable)	
Family name	Martinez-Calle
Qualification (MD...)	MD
Professional address	Nottingham Uni Hosp NHS Trust, Hucknall Road, The Centre for Clinical Haem, Notts NG51PB

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Andrew McMillan

H CHANGE OF INSTRUCTIONS TO CA FOR FEEDBACK TO SPONSOR

H.1 Change of e-mail contact for feedback on application*

H.2 Change to request to receive an .xml copy of CTA data ○ Yes ◉ No

H.2.1 Do you want a .xml file copy of the CTA form data saved on EudraCT? ○ Yes ◉ No

H.2.1.1 If yes provide the e-mail address(es) to which it should be sent (up to 5 addresses):

H.2.2 Do you want to receive this via password protected link(s)[10]? ○ Yes ◉ No

If you answer no to question H.2.2 the .xml file will be transmitted by less secure e-mail link(s)

H.2.3 Do you want to stop messages to an email for which they were previously requested? ○ Yes ◉ No

H.2.3.1 If yes provide the e-mail address(es) to which feedback should no longer be sent:

(*This will only come into effect from the time at which the request is processed in EudraCT).

(10) This requires a EudraLink account. (See eudract.emea.europa.eu for details)

I LIST OF THE DOCUMENTS APPENDED TO THE NOTIFICATION FORM (cf. Section 3.7 of detailed guidance CT-1)

Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es).

I.1 Cover letter ☑

I.2 Extract from the amended document in accordance with Section 3.7.c. of detailed guidance CT-1 (if not contained in Part F of this form) ☐

I.3 Entire new version of the document[11] ☑

I.4 Supporting information ☑

I.5 Revised .xml file and copy of initial application form with amended data highlighted ☑

I.6 Comments on any novel aspect of the amendment if any :

(11) Cf. Section 3.7.c. of the detailed guidance CT-1

J SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es).

J.1 I hereby confirm that/ confirm on behalf of the sponsor that (delete which is not applicable)

- The above information given on this request is correct;
- The trial will be conducted according to the protocol, national regulation and the principles of good clinical practice; and
- It is reasonable for the proposed amendment to be undertaken.

J.2 APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY*(as stated in section D.1):* ☐

J.2.1 Signature [12]: .....

J.2.2 Print name:

J.2.3 Date:

This section was signed electronically by Mrs Emma Lawrie on 28/05/2020 16:29.

Job Title/Post: Trial Coordinator

Organisation: UCL & CRUK Cancer Trials Centre

Email: e.lawrie@ucl.ac.uk

J.3 APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE *(as stated in section D.2)***:** ☐

J.3.1 Signature [13]: .....

J.3.2 Print name:

J.3.3 Date:

This section was signed electronically by Mrs Emma Lawrie on 28/05/2020 16:29.

Job Title/Post: Trial Coordinator

Organisation: UCL & CRUK Cancer Trials Centre

Email: e.lawrie@ucl.ac.uk

(12) On an application to the Competent Authority only, the applicant to the Competent Authority needs to sign.
(13) On an application to the Ethics Committee only, the applicant to the Ethics Committee needs to sign.