Radiation Assurance Research Exposure Form

F1: To be completed by the applicant

This section is to be completed by the applicant before submission of the application for Radiation Assurance. The HRA will then conduct a consistency review of the application prior to assigning the study for review by a lead CRE and MPE and any additional reviewers required.
Give as much information as possible referring to the notes at the end of each part of F1. These give guidance regarding the level of detail required within the tables.
If you require additional rows to be provided please email radiation.assurance@hra.nhs.uk, specifying which areas of the form require additional rows and how many.

Short study title	An Open-Ended Study
IRAS project ID	654321
EudraCT number (CTIMPs only)	2021-123456-78
Estimated start date	September 2021
Estimated end date	August 2026
Median length of participation *(how long are participants in the study?)*	Average length of participation is around 13-14 months, allthough participants may be involved for longer than the time specified based on how long it takes their disease to progress.
Is this submission a pre-regulatory approval submission to Radiation Assurance or an amendment? *If it is related to an amendment, please provide the sponsor amendment reference as listed on the notice of substantial amendment form*	Pre-regulatory approval submission

Prognosis, median life-expectancy and median time-to-progression	
Age (specify numerically e.g. 21 – 60 years)	18+
Sex	Male and female
Where applicable: Median time to disease progression Median survival times (where relevant) Maximum time in the study	 13-14 months 25-30 months Until disease progression, development of unacceptable side effects or patient choice; followed up yearly for survival

Does this study involve:	Yes	No
Radiology? *If "Yes", complete part 1*	☒	☐

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Radioactive substances? *If "Yes", complete part 2*	☒	☐
Radiotherapy? *If "Yes", complete part 3*	☒	☐
Non-ionising radiation? *If "Yes", complete part 4*	☒	☐

	Y	N
Do the participant information sheets have a radiation risk statement?* *If yes, please insert below:*	☐	☒

*If no, the MPE will provide a radiation risk statement for the participant information sheet (PIS) in C1. This should be added to the PIS prior to authorisation being requested. The MPE and CRE should not authorise the IRAS form until the PIS has been updated accordingly.

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Part 1: Radiology ionising radiation imaging procedures

1	2	3	4	5	6	7	8
Participant cohort[a]	Procedure[b]	Body part / exam protocol[c]	Frequency / study point[d]	Maximum possible examinations for maximum possible time in study[e]	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points[f]	Reporting & copy images required[g]
All cohorts	Triple-phase contrast-enhanced CT scan	Chest, abdomen and pelvis	Screening, week 12, every 9 weeks to end year 2, every 12 weeks to end year 3, every 16 weeks to end year 4, every 6 months to end year 5 and annually thereafter (plus at the end of treatment)	24 HRA guidance note: This is the maximum number that a participant could receive before any follow-up scans.	11 HRA guidance note: This is the maximum number of scans that a participant would receive based on their median time in the study as based on the timeframe on page 1, which for this study is 13-14 months	5 HRA guidance note: This is the number of scans that participants would receive as part of their normal care.	RECIST 1.1
All cohorts (annually until disease progression). HRA guidance note: This row is to account for any scans for open-ended studies that would take place until a participant's disease progressed or worsened. In this case, a participant will receive one scan per year, meaning '1' should be entered in column 5 as this is the maximum number of scans a participant will receive per year.	Triple-phase contrast-enhanced CT scan	Chest, abdoment and pelvis	Annually until disease progression	1	N/A	0	RECIST 1.1

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All cohorts	CT scan (as part of FDG PET-CT)	Whole body	Screening, week 12, every 9 weeks to end year 2, every 12 weeks to end year 3, every 16 weeks to end year 4, every 6 months to end year 5 and annually thereafter (plus at the end of treatment)	24	11	5	RECIST 1.1
All cohorts (annually until disease progression)	CT scan (as part of FDG PET-CT)	Whole body	Annually until disease progression	1	N/A	0	RECIST 1.1
All cohorts	CT-guided biopsy	Lung	Screening and disease progression	2	2	0	N/A

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information 'Years 3—17', for example.

	Y	N
Is a phantom scan/study required as part of the trial? If 'yes' please give details in the table below	☐	☒

Comments (to include variations between sites):

Notes

[a] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.
[b] e.g. 'Triple-phase CT scan' not 'CT scan'.
[c] e.g. 'Chest, abdomen and pelvis', not 'torso'. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.
[d] e.g. 'Baseline, then every 8 weeks'.
[e] The entry should be the same as IRAS A19 column 1.
[f] This should be the number of examinations in column 5 that could be considered routine care. The entry should be the same as IRAS A19 column 2.
[g] e.g. 'RECIST'.

F1: To be completed by the applicant

Part 2: Administration of radioactive substances or brachytherapy (including non-imaging procedures such as GFR)

1	2	3	4	5	6	7	8	9
Participant cohort[a]	Procedure[b]	Radioactive substance / Radio-pharmaceutical	Body part / exam protocol[c]	Frequency / study point[d]	Maximum possible examinations for maximum possible time in study[e]	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points[f]	Specify any study protocol-specific reporting and / or data processing required?[g]
All cohorts	FDG PET-CT (As part of FDG PET-CT)	F-18 fludeoxyglucose	Whole body	Screening, week 12, every 9 weeks to end year 2, every 12 weeks to end year 3, every 16 weeks to end year 4, every 6 months to end year 5 and annually thereafter (plus at the end of treatment)	24	11	5	RECIST 1.1
All cohorts (annually until disease progression)	FDG PET-CT (as part of FDG PET-CT)	F-18 fludeoxyglucose	Whole body	Annually until disease progression	1	N/A	0	RECIST 1.1

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information 'Years 3—17', for example.

Y	N

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Is there any requirement for pre-trial site validation? e.g. submission of phantom study and / or other QA procedure(s), camera system calibration / accreditation, data transfer testing? If 'yes' please give details in the table below	☐	☒

Comments (to include variations between sites):

Notes

[a] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

[b] e.g. MUGA study, whole body phosphonate bone scan, GFR study, dynamic renogram, total body FDG PET/CT, amyloid brain PET/CT. Not cardiac scan, bone imaging, renal function test, PET/CT, brain PET.

[c] e.g. 'Chest, abdomen and pelvis', not 'torso'. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.

[d] e.g. 'Baseline, then every 8 weeks'.

[e] The entry should be the same as IRAS A19 column 1.

[f] This should be the number of examinations in column 6 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

[g] e.g. e.g. lesion scoring, SUV analysis, quantification, structured reporting

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Part 2 continued: Administration of radioactive substances

The following questions are duplicated from IRAS (Part B Section 3 - A2 and A3 and ARSAC form). These sections are expected to be completed prior to MPE/CRE review and they should be consistent with the information in IRAS.

	Y	N
Will any of the study participants be patients?	☒	☐

If yes, please complete the table below for the patient group involved in the study. Where multiple patient groups are involved please contact radiation.assurance@hra.nhs.uk so that additional tables can be added:

Details of patients to be studied	
Number (whole study)	500
Age range (specify numerically e.g. 21 – 60 years)	18+
Sex	Male and female
Clinical condition	Lung cancer

	Y	N
Will any of the study participants be healthy volunteers?	☐	☒

If yes, please complete the table below for the healthy volunteer group involved in the study. Where multiple healthy volunteer groups are involved please contact radiation.assurance@hra.nhs.uk so that additional tables can be added:

Details of healthy volunteers to be studied	
Number (whole study)	N/A
Age range (specify numerically e.g. 21 – 60 years)	N/A
Sex	N/A

What steps will you take to exclude individuals who are pregnant or who could become pregnant during the study? *Give details of screening procedures and advice to be given to women of child-bearing age* (to be copied into IRAS A3)
Female participants must be excluded/discontinued from the trial in the event of a positive pregnancy test result. A blood or urine pregnancy test will be performed before the start of and during the study for females who are able to have a baby. In order to participate in the study, they must adhere to the contraception requirements described in the protocol.

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Part 3: Radiotherapy procedures (include number of treatment fractions, all pre-treatment imaging e.g. CT, PET/CT, 4DCT and all on-treatment imaging)

Use separate rows as necessary for each treatment phase and/or treatment arm(s), and for each imaging modality whether pre-treatment or on-treatment.

1	2	3	4	5	6	7	8	9
Participant cohort[a]	Procedure[b]	Treatment site and phase	Dose prescription(s), protocol[c]	Technique, protocol[d or e]	Dose prescription, routine care[c]	Technique, routine care[d or e]	Number of exposures, protocol[f, g]	Number of exposures, routine care[f, h]
All cohorts	Pre-treatment imaging	Radiotherapy planning CT scan of lungs	N/A	3DCT	N/A	3DCT	1	1
All cohorts	Treatment	Radiotherapy treatment of the lungs	15Gy in 20 fractions over 4 weeks	3D Conformal Radiotherapy	15Gy in 25 fractions over 5 weeks	3D Conformal Radiotherapy	20	25
	Please Select:							
	Please Select:							
	Please Select:							
	Please Select:							

	Y	N
Are there any radiotherapy QA requirements for the trial? If yes, please brief details of pre-trial QA e.g. outlining, planning and / or phantom measurements plus any on-going trial QA and data transfer requirements in the comments box	☐	☒

Comments (to include variations between sites):

Notes

[a] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

[b] e.g. radiotherapy treatment, planning CT (include repeat CT planning scans if part of protocol e.g. for adaptive radiotherapy), treatment verification.

[c] Completion of this field is required for treatment procedures only. E.g. 50 Gy in 25 fractions over 5 weeks, include for each phase of treatment or trial arm.

[d] e.g. single applied field, electron, 3D conformal, IMRT, volumetric/arc therapy.

[e] e.g. 3D or 4D for planning CT; kV, MV or CBCT for verification.

[f] where this relates to the radiotherapy treatment you should specify the maximum number of fractions, not number of treatments. Where this relates to pre or on-treatment imaging you should specify the maximum number of exposures.

[g] The entry should be the same as IRAS A19 column 1.

[h] This should be the number of examinations in column 8 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

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Part 4: Non-ionising radiation imaging procedures (to aid feasibility at sites)

Give as much information as possible. Refer to the notes at the end of section F1 which give guidance regarding the level of detail required within the table.

1	2	3	4	5	6	7	8
Participant cohort[a]	Procedure[b]	Scan extent –body part / exam protocol[c]	Frequency / study point[d]	Maximum possible examinations for maximum possible time in study[e]	Maximum examinations for median time in study	Approximate number routine care – including frequency / time points[f]	Reporting & copy images required[g]
All cohorts	Contrast-enhanced MRI	Chest, abdoment, pelvis	Screening, week 12, every 9 weeks to end year 2, every 12 weeks to end year 3, every 16 weeks to end year 4, every 6 months to end year 5 and annually thereafter (plus at the end of treatment)	24	11	5	RECIST 1.1
All cohorts (yearly until disease progression)	Contrast-enhanced MRI	Chest, abdomen, pelvis	Annually until disease progression	1	N/A	0	RECIST 1.1

If the study has an open ended design which makes it impossible to determine the maximum examinations required by the protocol you should use a separate row for every year for which the study will be open. Where there is no year to year variation, it is acceptable to title the information 'Years 3—17', for example.

Notes

[a] e.g. 'cohorts 1 - 3' or 'all cohorts'. Where there are no cohorts then 'N/A' would be acceptable.

[b] e.g. 'Triple-phase CT scan' not 'CT scan'.

[c] e.g. ‘Chest, abdomen and pelvis’, not ‘torso’. Where a whole body scan is utilised it should be clear if this is head-to-toe, head-to-pelvis, or neck-to-pelvis.
[d] e.g. ‘Baseline, then every 8 weeks’.
[e] The entry should be the same as IRAS A19 column 1.
[f] This should be the number of examinations in column 6 that could be considered routine care. The entry should be the same as IRAS A19 column 2.

[g] e.g. ‘RECIST’