

Trial Feasibility Assessment to assist with understanding the impact the trial will have on UHPNT and supporting services.

Oncology

Date form issued by R&D [Click here to enter a date.](#)

Date form needs to be returned to R&D [Click here to enter a date.](#)

Protocol Title:	
Version:	
PI name:	
R&D ref:	

Trial Duration, including follow-up _____mths

Purpose of Form

This form has been designed to highlight everything additional to standard care for the duration of the **whole study** and will assist R&D in accurately costing the study, recouping the cost of running the study, working out any cost savings and ensuring the necessary support services are in place.

Dept	Investigation	Impact (please describe everything that is ADDITIONAL to standard care) Please also consider the frequency of testing	Please indicate if bloods are local or central
Labs	Haematology		
	Chemistry		
	Microbiology		
	Central PK/PD sampling		
Imaging	CT TAP	Details: Number if not in trial <input type="checkbox"/> Number if in trial <input type="checkbox"/> Not applicable <input type="checkbox"/>	
	CT Brain	Details:	

		Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
MRI	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
PET	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
Ultrasound	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
Bone	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
X-ray	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
Nuclear Medicine	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
		<i>Please highlight if GFR is requested in protocol rather than eGFR.</i>		
Mammography	Details:	Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
RECIST reporting requirements of trial	Frequency	<input type="text"/>		
Life expectancy of patient group				

	Average survival on standard care Click here to enter text. <i>(This is required in order to accurately assess the impact of any additional radiation the patient is subjected to as part of the trial)</i>			
Investigations	Physical examinations by Dr	How many are required throughout the trial? Click here to enter text.		
	ECG's	How many are required throughout the trial? <input type="text"/>	Do ECG's need to be done in triplicate? Yes <input type="checkbox"/> No <input type="checkbox"/>	
		Is central review required? Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Cardiology e.g. ECHO / MUGA	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
	Medical Photography	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
	Audiology	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
	Ophthalmology	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
	Dental Assessment	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>
Swallowing Assessment	Details: Number if not in trial <input type="text"/>	Number if in trial <input type="text"/>	Not applicable <input type="checkbox"/>	
Biopsies /				

Tissue Sampling	
QOL questionnaire	<i>Please indicate how many are required, frequency and if electronic or paper.</i>
Consent	Screening <input type="checkbox"/> Full Study <input type="checkbox"/> Biomarker Study <input type="checkbox"/> Other <input type="checkbox"/> Click here to enter text.

Treatment	Radiotherapy	Number of anticipated fractions / dose if not in trial	Number of anticipated fractions / dose if in trial (all arms)
	Activity		
	Complexity of RT		
	Will this trial impact on RT Tariff?		
	Pharmacy / Drugs	Standard Care	<i>Trial Treatment arms, please include dosing regimens, extra infusions, timings of infusions (to help plan for chemo chair time etc) and impact of pharmacy. Please also consider if there is a cost saving to running this study</i>
	Anticipated Supportive Medication requirements	Standard Care	Trial treatment arms

PI comments

Is there and increased risk of illness / hospital admission / overnight stay if the patient participates in this trial?

Unlikely Click here to enter text.

Possible Click here to enter text.

Probable Click here to enter text.

Considering the profile of the IMP / intervention are additional referrals to other clinical specialties likely e.g. Dermatology / Cardiology?

PI signature _____

How many patients do you expect to **screen** in total?

How many patients do you expect to recruit in total?

Form completed by _____

Signed _____

Date ____/____/____