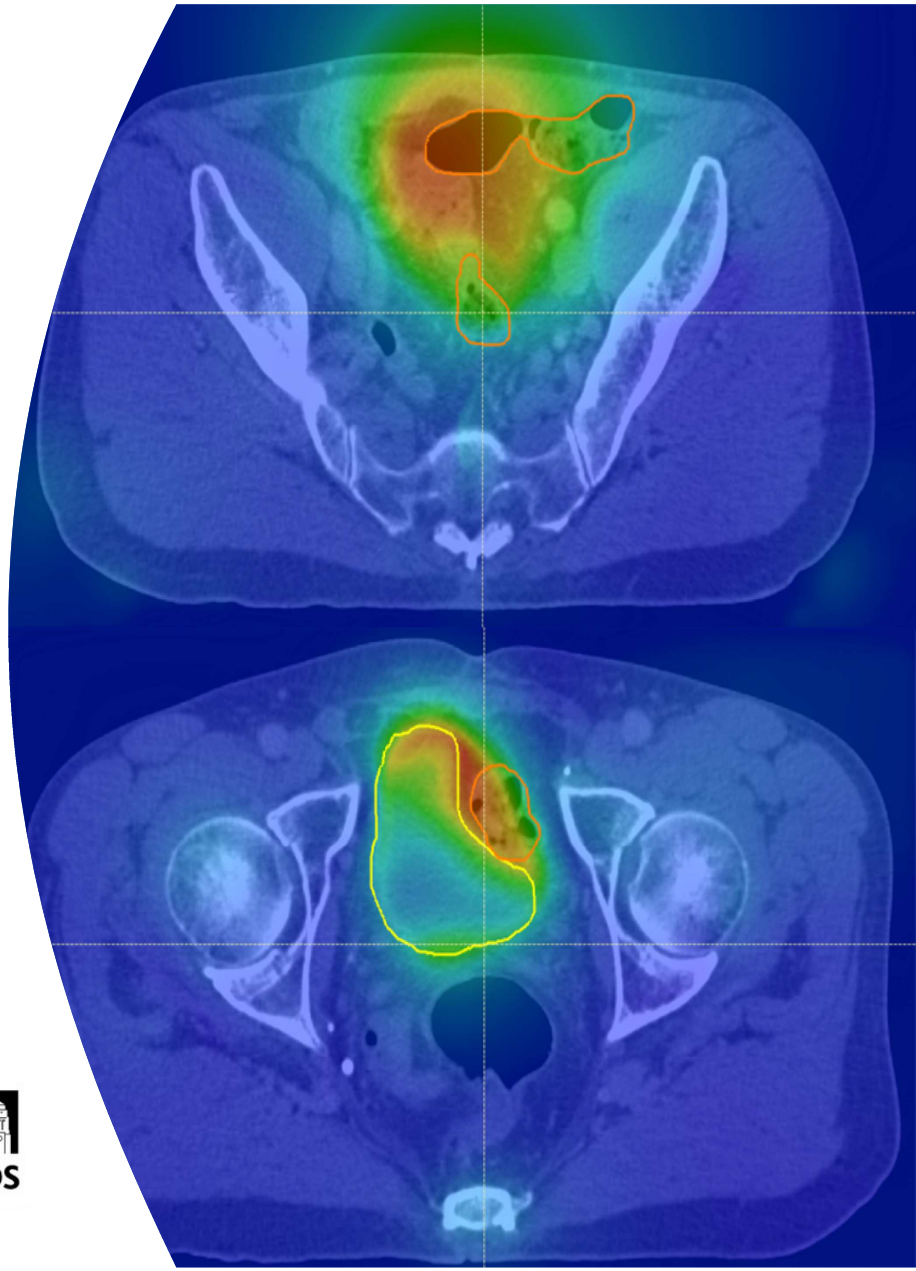
Systematisk inddragelse af patienter i kliniske studier – engelske erfaringer

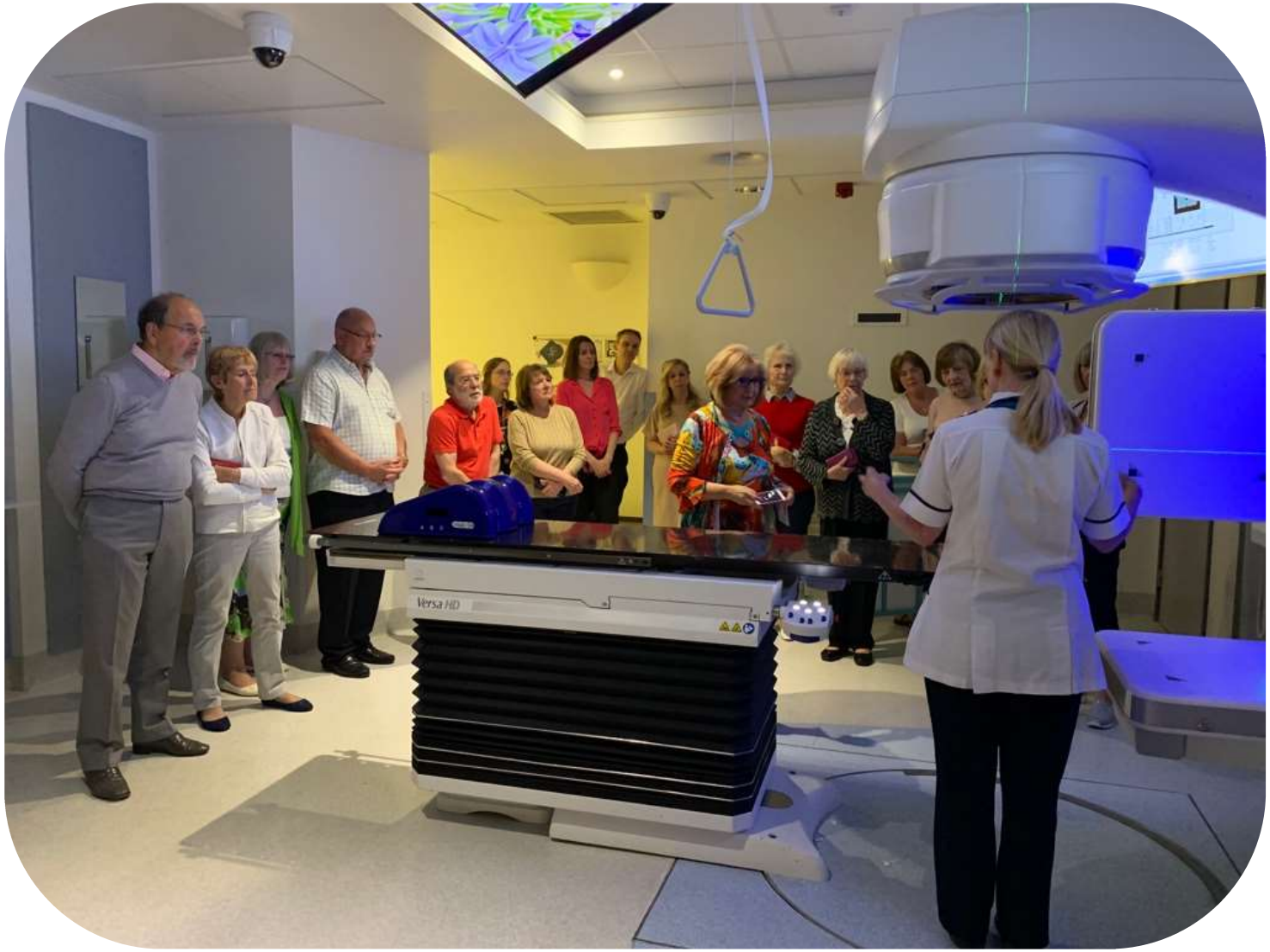
Ane Appelt
Associate Professor, University of Leeds
Danske Kræftforskningsdage 2022
@cancerphysicist



CANCER RESEARCH UK | RADNET LEEDS

Together we will beat cancer

UNIVERSITY OF LEEDS


Versa HD

APHRODITE – sidste møde inden fondsansøgning

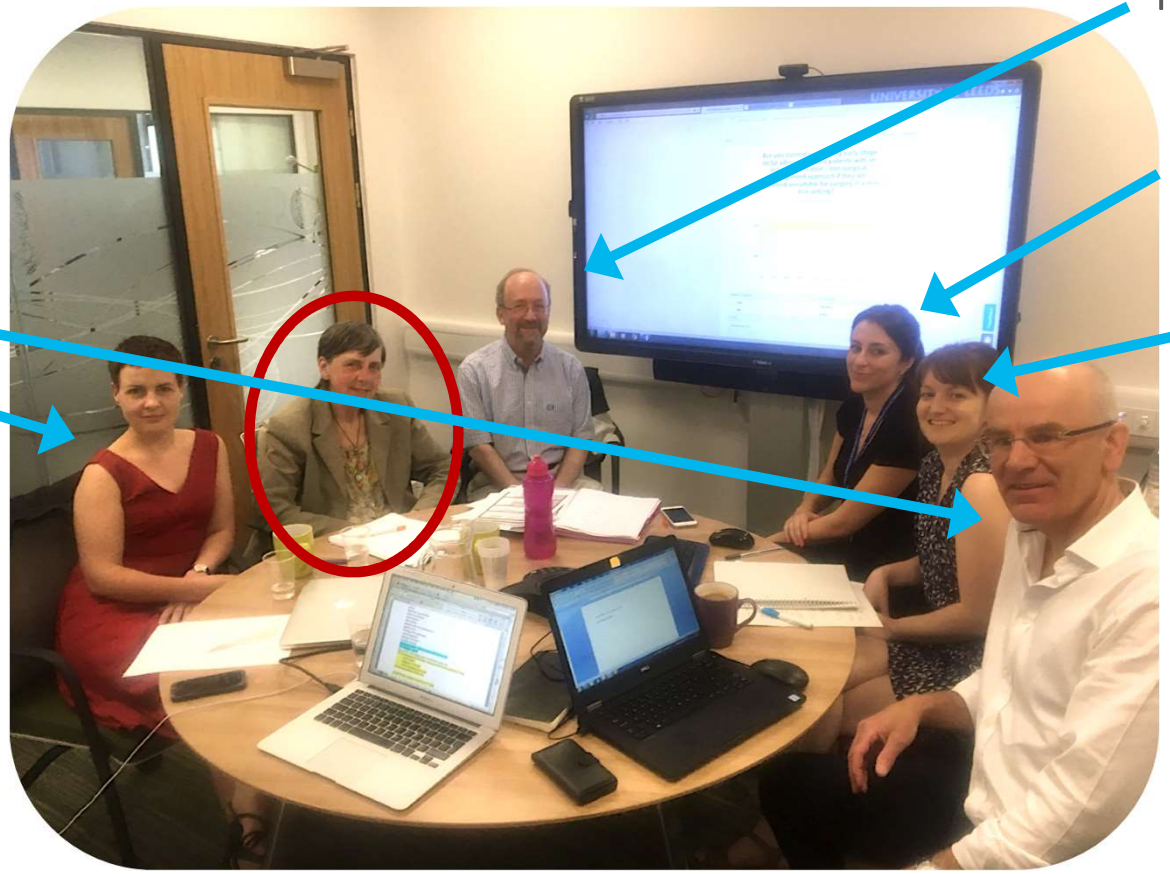
Professor i onkologi

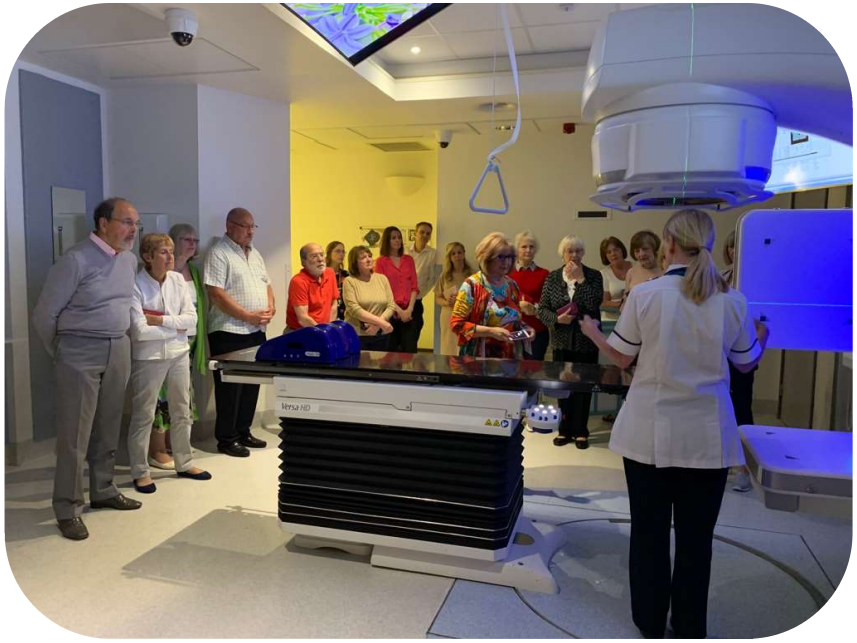
Senior trial manager

Statistiker

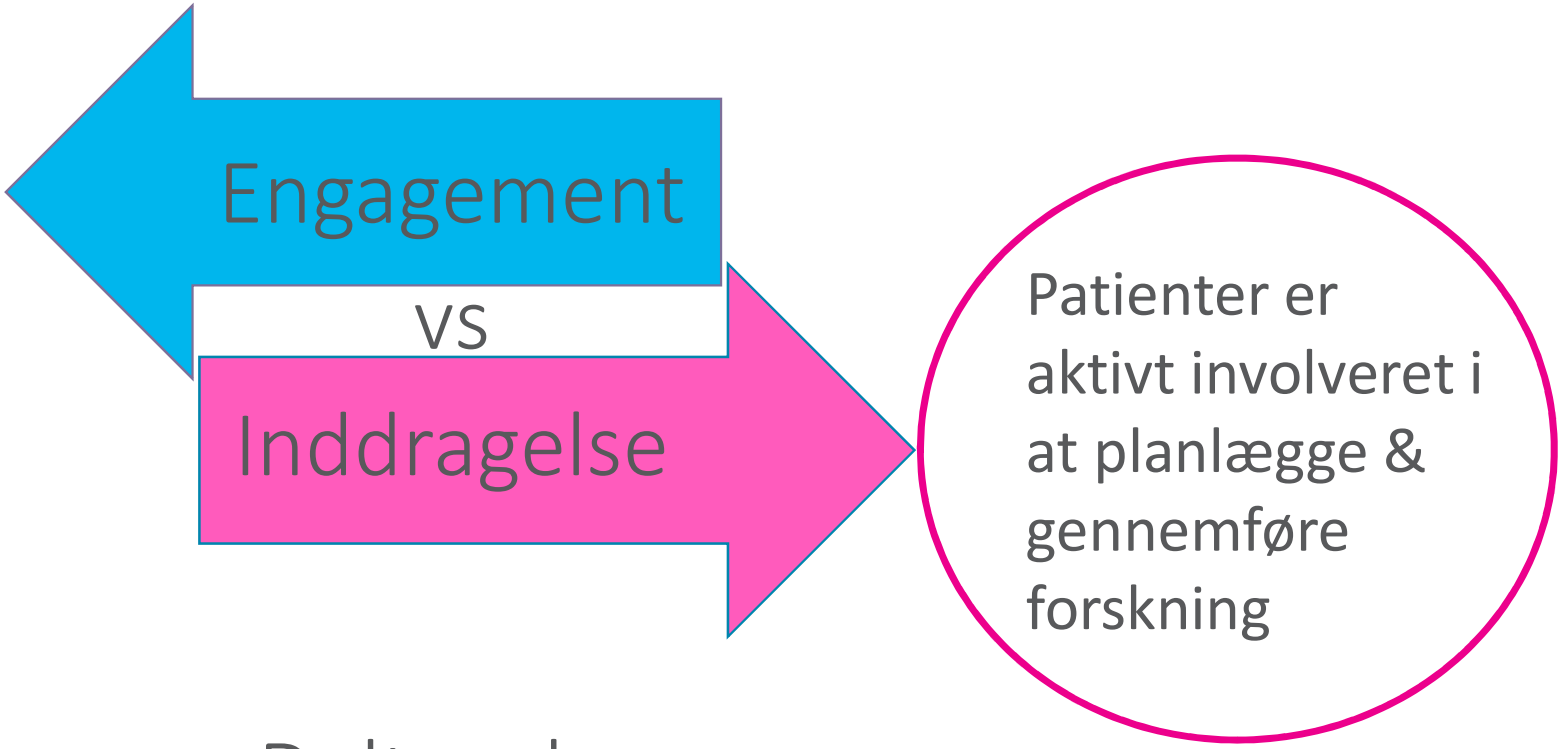
Primære investigatorer

Monica Jefford
Patient-repræsentant





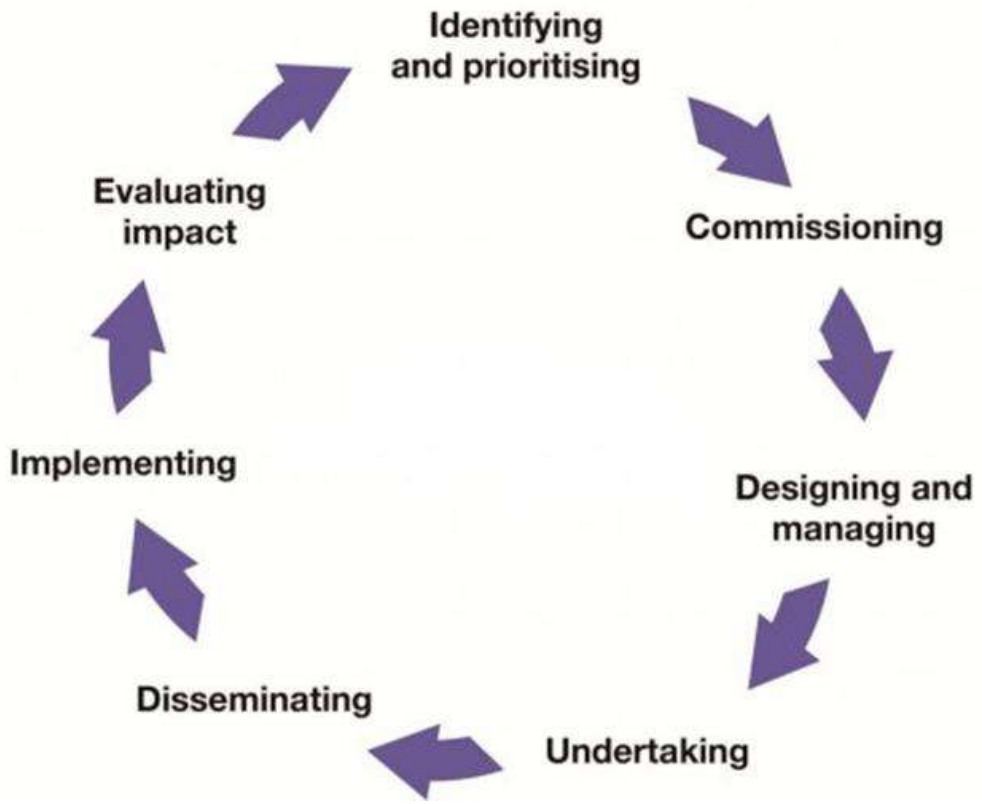
Information og viden om forskning formidles til offentligheden



Deltagelse

Deltagelse i forskningsprojekt – f.eks. som del af behandling

SYSTEMATISK BIDRAG TIL ALLE ASPEKTER AF FORSKNING



INVOLVE (2012) Briefing notes for researchers

PATIENTINDFLYDELSE - PRIORITERING AF FORSKNING

- Åbent arrangement – "hvad skal vi priotisere indenfor forskning i tarmkræft?"
- 360 deltagere – patienter, pårørende og andre
- 25 forskningsspørgsmål
- "Hvor vigtigt er dette?" – scoret på 5-punkt skala

Tiernan et al. Use of a modified Delphi approach to develop research priorities for the association of coloproctology of Great Britain and Ireland. Colorectal Dis. 2014

PATIENTINDFLYDELSE - PRIORITERING AF FORSKNING

#1 spørgsmål

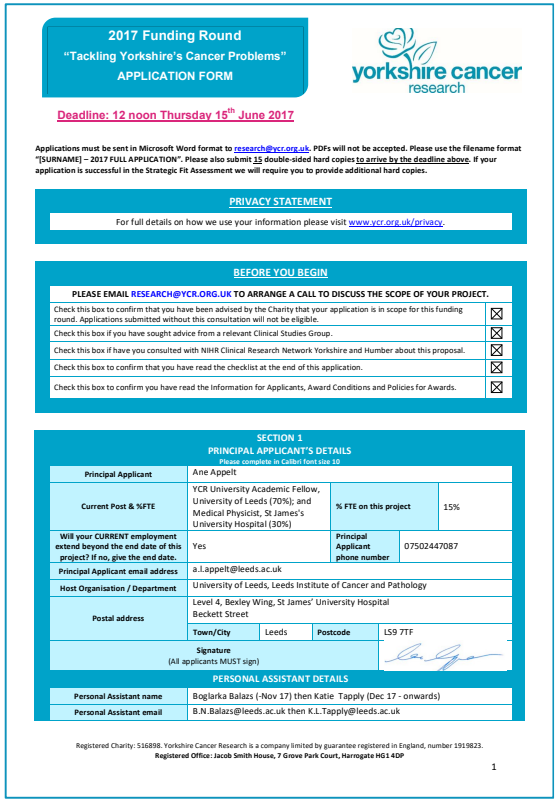
'hvordan behandler vi bedst tidlig endetarmskræft?'

APHRODITE

A Phase II trial of Higher RadiOtherapy Dose In The Eradication of early rectal cancer

PATIENTREPRÆSENTANT PÅ FONDSANSØGNING

APHRODITE



2017 Funding Round
"Tackling Yorkshire's Cancer Problems"
APPLICATION FORM

yorkshire cancer research

Deadline: 12 noon Thursday 15th June 2017

Applications must be sent in Microsoft Word format to research@ycr.org.uk. PDFs will not be accepted. Please use the filename format "[SURNAME] – 2017 FULL APPLICATION". Please also submit 15 double-sided hard copies to arrive by the deadline above. If your application is successful in the Strategic Fit Assessment we will require you to provide additional hard copies.

PRIVACY STATEMENT

For full details on how we use your information please visit www.ycr.org.uk/privacy.

BEFORE YOU BEGIN

PLEASE EMAIL RESEARCH@YCR.ORG.UK TO ARRANGE A CALL TO DISCUSS THE SCOPE OF YOUR PROJECT.

Check this box to confirm that you have been advised by the Charity that your application is in scope for this funding round. Applications submitted without this consultation will not be eligible.	☒
Check this box if you have sought advice from a relevant Clinical Studies Group.	☒
Check this box if have you consulted with NIHR Clinical Research Network Yorkshire and Humber about this proposal.	☒
Check this box to confirm that you have read the checklist at the end of this application.	☒
Check this box to confirm you have read the Information for Applicants, Award Conditions and Policies for Awards.	☒

SECTION 1
PRINCIPAL APPLICANT'S DETAILS
Please complete in Calibri font size 10

Principal Applicant	Ane Appelt		
Current Post & %FTE	YCR University Academic Fellow, University of Leeds (70%); and Medical Physicist, St James's University Hospital (30%)	% FTE on this project	15%
Will your CURRENT employment extend beyond the end date of this project? If no, give the end date.	Yes	Principal Applicant phone number	07502447087
Principal Applicant email address	a.l.appelt@leeds.ac.uk		
Host Organisation / Department	University of Leeds, Leeds Institute of Cancer and Pathology		
Postal address	Level 4, Bexley Wing, St James' University Hospital Beckett Street		
	Town/City: Leeds	Postcode: LS9 7TF	
Signature (All applicants MUST sign)			

PERSONAL ASSISTANT DETAILS

Personal Assistant name	Boglarka Balazs (-Nov 17) then Katie Tapply (Dec 17 - onwards)
Personal Assistant email	B.N.Balazs@leeds.ac.uk then K.L.Tapply@leeds.ac.uk

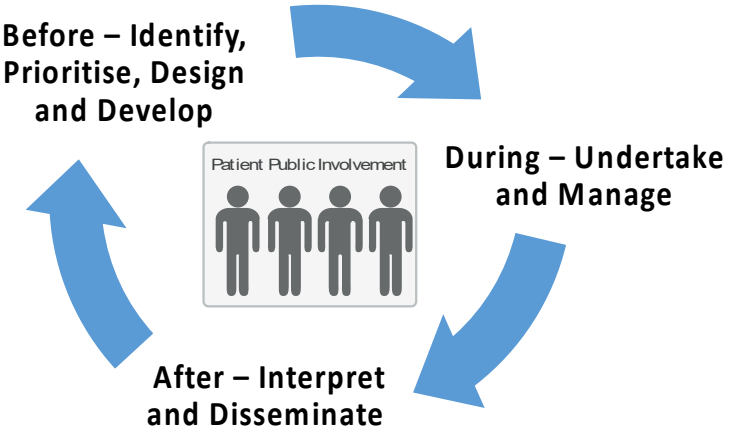
Registered Charity: 516898. Yorkshire Cancer Research is a company limited by guarantee registered in England, number 1919823.
Registered Office: Jacob Smith House, 7 Grove Park Court, Harrogate HG1 4DP

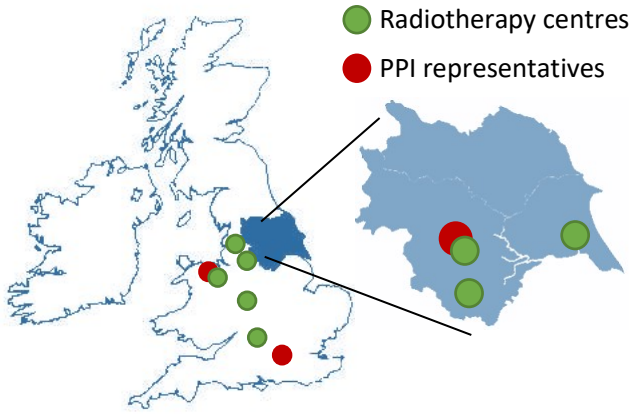
1

Medansøger på fondsansøgning

PROSPEKTIV PLAN FOR PATIENTINDDRAGELSE

Patient and public involvement (PPI)





Before

- PPI integral to all aspects of study design
- Patient with bowel cancer and established PPI portfolio closely involved
- Contribution to proposal, protocol, patient info, consent form, patient information sheet, questionnaires, newsletter

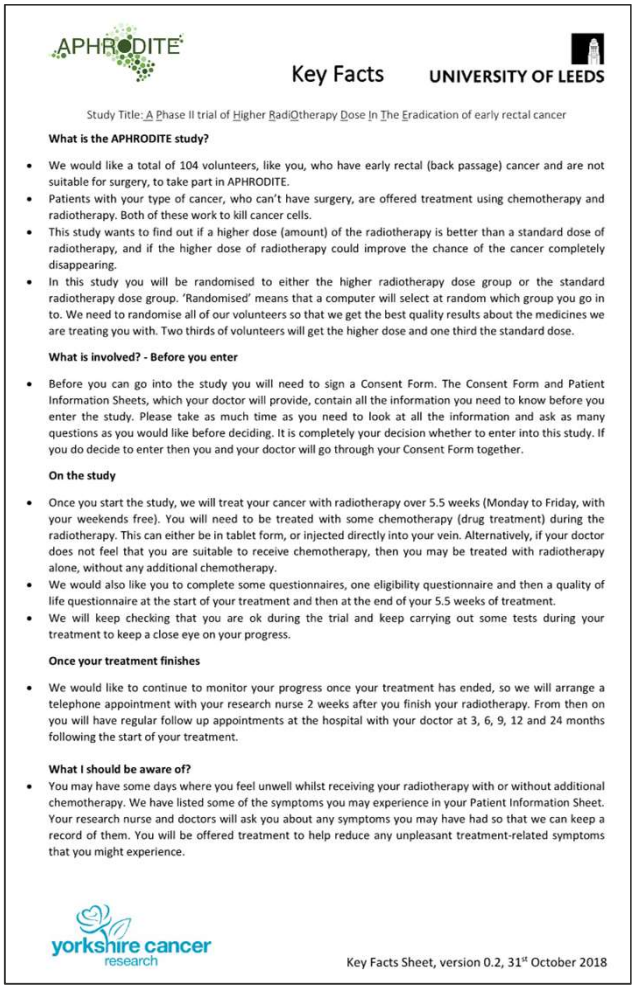
During

- PPI membership of Trial Management Group and meeting attendance
- Assurance of user friendly literature, with continuous review
- Challenges identified and dealt with at earliest stage
- Research buddies – visit recruiting sites and 'report back'
- Partner in patient perspective survey implementation

After

- Contribution to data analysis as guided by researcher
- Comment on any lay publication
- Presentation of findings in user friendly format
- Presentation and discussion across venues
- Involvement with bowel cancer community; talks at patient forums
- Development of next stage of research with continuing PPI input

GENNEMSYN AF PATIENTMATERIALE



APHRODITE

Key Facts

UNIVERSITY OF LEEDS

Study Title: A Phase II trial of Higher RadiOtherapy Dose In The Eradication of early rectal cancer

What is the APHRODITE study?

- We would like a total of 104 volunteers, like you, who have early rectal (back passage) cancer and are not suitable for surgery, to take part in APHRODITE.
- Patients with your type of cancer, who can't have surgery, are offered treatment using chemotherapy and radiotherapy. Both of these work to kill cancer cells.
- This study wants to find out if a higher dose (amount) of the radiotherapy is better than a standard dose of radiotherapy, and if the higher dose of radiotherapy could improve the chance of the cancer completely disappearing.
- In this study you will be randomised to either the higher radiotherapy dose group or the standard radiotherapy dose group. 'Randomised' means that a computer will select at random which group you go in to. We need to randomise all of our volunteers so that we get the best quality results about the medicines we are treating you with. Two thirds of volunteers will get the higher dose and one third the standard dose.

What is involved? - Before you enter

- Before you can go into the study you will need to sign a Consent Form. The Consent Form and Patient Information Sheets, which your doctor will provide, contain all the information you need to know before you enter the study. Please take as much time as you need to look at all the information and ask as many questions as you would like before deciding. It is completely your decision whether to enter into this study. If you do decide to enter then you and your doctor will go through your Consent Form together.

On the study

- Once you start the study, we will treat your cancer with radiotherapy over 5.5 weeks (Monday to Friday, with your weekends free). You will need to be treated with some chemotherapy (drug treatment) during the radiotherapy. This can either be in tablet form, or injected directly into your vein. Alternatively, if your doctor does not feel that you are suitable to receive chemotherapy, then you may be treated with radiotherapy alone, without any additional chemotherapy.
- We would also like you to complete some questionnaires, one eligibility questionnaire and then a quality of life questionnaire at the start of your treatment and then at the end of your 5.5 weeks of treatment.
- We will keep checking that you are ok during the trial and keep carrying out some tests during your treatment to keep a close eye on your progress.

Once your treatment finishes

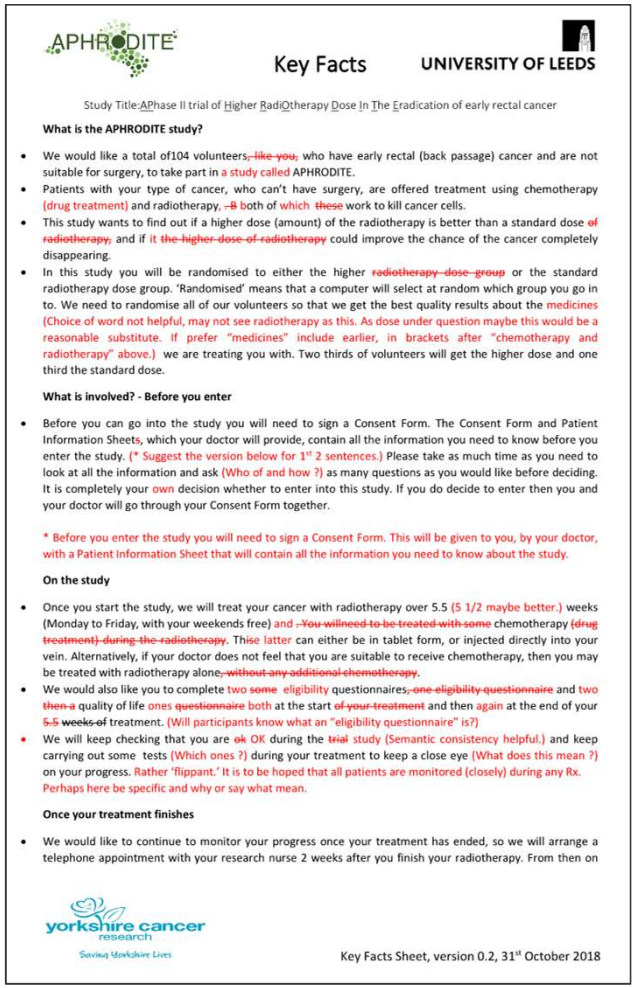
- We would like to continue to monitor your progress once your treatment has ended, so we will arrange a telephone appointment with your research nurse 2 weeks after you finish your radiotherapy. From then on you will have regular follow up appointments at the hospital with your doctor at 3, 6, 9, 12 and 24 months following the start of your treatment.

What I should be aware of?

- You may have some days where you feel unwell whilst receiving your radiotherapy with or without additional chemotherapy. We have listed some of the symptoms you may experience in your Patient Information Sheet. Your research nurse and doctors will ask you about any symptoms you may have had so that we can keep a record of them. You will be offered treatment to help reduce any unpleasant treatment-related symptoms that you might experience.

yorkshire cancer research

Key Facts Sheet, version 0.2, 31st October 2018



APHRODITE

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- We would like a total of104 volunteers~~, like you,~~ who have early rectal (back passage) cancer and are not suitable for surgery, to take part in a study called APHRODITE.
- Patients with your type of cancer, who can't have surgery, are offered treatment using chemotherapy (drug treatment) and radiotherapy, ~~. B~~both of which ~~these~~ work to kill cancer cells.
- This study wants to find out if a higher dose (amount) of the radiotherapy is better than a standard dose ~~of radiotherapy,~~ and if it ~~the higher dose of radiotherapy~~ could improve the chance of the cancer completely disappearing.
- In this study you will be randomised to either the higher ~~radiotherapy dose group~~ or the standard radiotherapy dose group. 'Randomised' means that a computer will select at random which group you go in to. We need to randomise all of our volunteers so that we get the best quality results about the medicines (Choice of word not helpful, may not see radiotherapy as this. As dose under question maybe this would be a reasonable substitute. If prefer "medicines" include earlier, in brackets after "chemotherapy and radiotherapy" above.) we are treating you with. Two thirds of volunteers will get the higher dose and one third the standard dose.

What is involved? - Before you enter

- Before you can go into the study you will need to sign a Consent Form. The Consent Form and Patient Information Sheet~~s~~, which your doctor will provide, contain all the information you need to know before you enter the study. (* Suggest the version below for 1st 2 sentences.) Please take as much time as you need to look at all the information and ask (Who of and how ?) as many questions as you would like before deciding. It is completely your own decision whether to enter into this study. If you do decide to enter then you and your doctor will go through your Consent Form together.

  * Before you enter the study you will need to sign a Consent Form. This will be given to you, by your doctor, with a Patient Information Sheet that will contain all the information you need to know about the study.

On the study

- Once you start the study, we will treat your cancer with radiotherapy over 5.5 (5 1/2 maybe better.) weeks (Monday to Friday, with your weekends free) and ~~. You willneed to be treated with some~~ chemotherapy ~~(drug treatment) during the radiotherapy~~. Th~~is~~e latter can either be in tablet form, or injected directly into your vein. Alternatively, if your doctor does not feel that you are suitable to receive chemotherapy, then you may be treated with radiotherapy alone~~, without any additional chemotherapy~~.
- We would also like you to complete two ~~some~~ eligibility questionnaires~~, one eligibility questionnaire~~ and two ~~then a~~ quality of life ones ~~questionnaire~~ both at the start ~~of your treatment~~ and then again at the end of your ~~5.5 weeks of~~ treatment. (Will participants know what an "eligibility questionnaire" is?)
- We will keep checking that you are ~~ok~~ OK during the ~~trial~~ study (Semantic consistency helpful.) and keep carrying out some tests (Which ones ?) during your treatment to keep a close eye (What does this mean ?) on your progress. Rather 'flippant.' It is to be hoped that all patients are monitored (closely) during any Rx. Perhaps here be specific and why or say what mean.

Once your treatment finishes

- We would like to continue to monitor your progress once your treatment has ended, so we will arrange a telephone appointment with your research nurse 2 weeks after you finish your radiotherapy. From then on

yorkshire cancer research

Saving Yorkshire Lives

Key Facts Sheet, version 0.2, 31st October 2018

YDERLIGERE PATIENTMATERIALE

Website

APHRODITE

A Phase II trial of Higher RadiOtherapy Dose In The Eradication of early rectal cancer

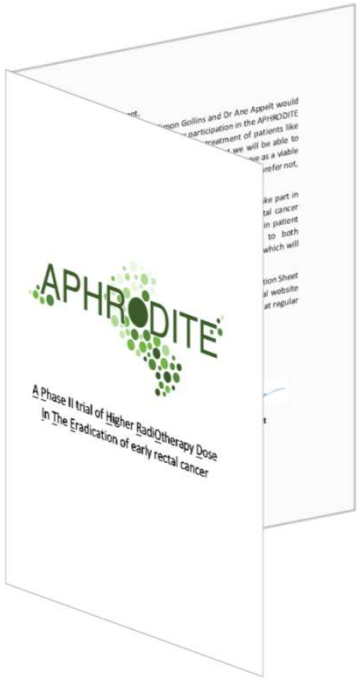
IRAS ID: 250957

Hello and thank you for taking the time to visit the APHRODITE website. Here you will find useful information about the APHRODITE trial.

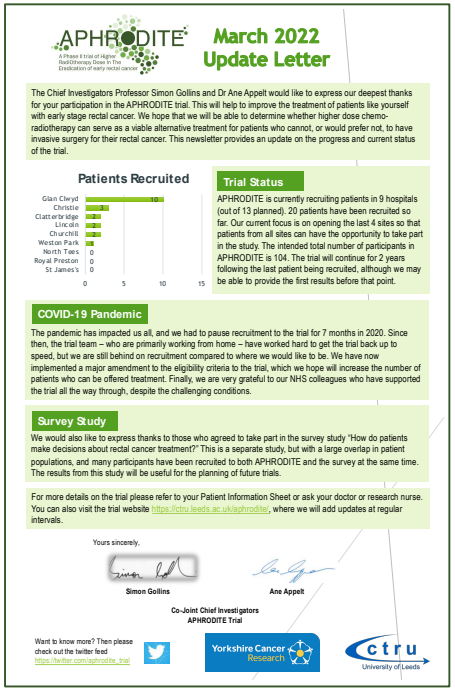
If you are taking part in the trial, we would like to say a huge THANK YOU for your help in developing ways in which we can improve cancer treatments.

https://ctru.leeds.ac.uk/aphrodite/

Thank you cards



Newsletter



APHRODITE

March 2022 Update Letter

The Chief Investigators Professor Simon Gollins and Dr Ane Appelt would like to express our deepest thanks for your participation in the APHRODITE trial. This will help to improve the treatment of patients like yourself with early stage rectal cancer. We hope that we will be able to determine whether higher dose chemo-radiotherapy can serve as a viable alternative treatment for patients who cannot, or would prefer not, to have invasive surgery for their rectal cancer. This newsletter provides an update on the progress and current status of the trial.

Patients Recruited

Glan Clwyd 12
Christie 3
Clatterbridge 2
Lincoln 2
Churchill 2
Weston Park 1
North Tees 0
Royal Preston 0
St James's 0
0 5 10 15

Trial Status

APHRODITE is currently recruiting patients in 9 hospitals (out of 13 planned). 20 patients have been recruited so far. Our current focus is on opening the last 4 sites so that patients from all sites can have the opportunity to take part in the study. The intended total number of participants in APHRODITE is 104. The trial will continue for 2 years following the last patient being recruited, although we may be able to provide the first results before that point.

COVID-19 Pandemic

The pandemic has impacted us all, and we had to pause recruitment to the trial for 7 months in 2020. Since then, the trial team – who are primarily working from home – have worked hard to get the trial back up to speed, but we are still behind on recruitment compared to where we would like to be. We have now implemented a major amendment to the eligibility criteria to the trial, which we hope will increase the number of patients who can be offered treatment. Finally, we are very grateful to our NHS colleagues who have supported the trial all the way through, despite the challenging conditions.

Survey Study

We would also like to express thanks to those who agreed to take part in the survey study "How do patients make decisions about rectal cancer treatment?" This is a separate study, but with a large overlap in patient populations, and many participants have been recruited to both APHRODITE and the survey at the same time. The results from this study will be useful for the planning of future trials.

For more details on the trial please refer to your Patient Information Sheet or ask your doctor or research nurse. You can also visit the trial website https://ctru.leeds.ac.uk/aphrodite/, where we will add updates at regular intervals.

Yours sincerely,

Simon Gollins

Ane Appelt

Co-Joint Chief Investigators
APHRODITE Trial

Want to know more? Then please check out the twitter feed
https://twitter.com/aphrodite_trial

Yorkshire Cancer Research

ctru University of Leeds

Open access Protocol

BMJ Open

A Phase II trial of Higher RadiOtherapy Dose In The Eradication of early rectal cancer (APHRODITE): protocol for a multicentre, open-label randomised controlled trial

Eleanor M Hudson ,[1] Samantha Nesbitt,[1] Sarah Brown ,[1] Ravi Adapala,[2] Simon P Bach,[3] Carole Burnett,[4] Alwyn Burrage,[5] Alexandra Gilbert,[6] Maria Hawkins ,[7] Debra Howard,[8] Monica Jefford,[9] Rohit Kochhar,[10] Mark Saunders,[11] Jenny Seligmann,[6] Alexandra Smith,[1] Mark Teo,[4] Edward JD Webb ,[12] Amanda Webster,[8] Nicholas West,[6] David Sebag-Montefiore,[6] Simon Gollins,[13] Ane L Appelt[6]

Så hvordan støtter man bedst op om (mere) patientindragelse i klinisk forskning????

GØR DET NEMT!

(AT KOMME I GANG)

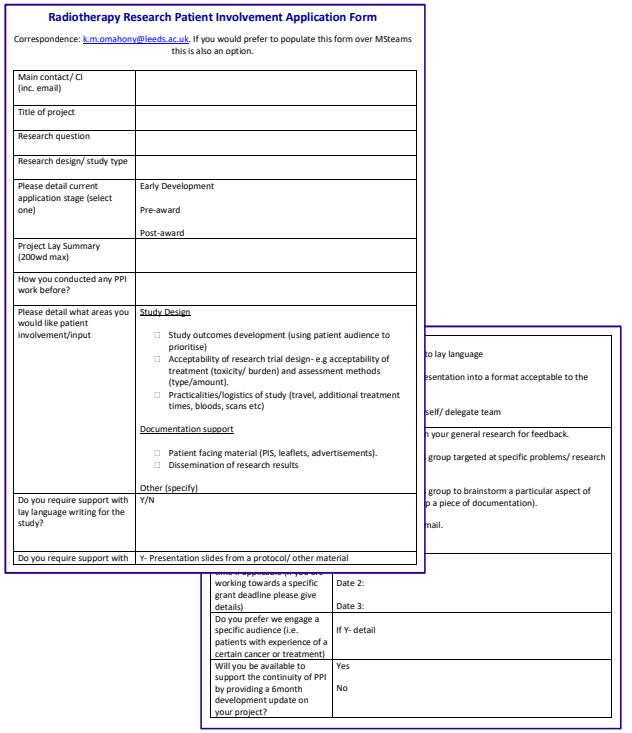
Sørg for at de rette strukturer og støtte er til rådighed – for forskere OG patientrepræsentanter

LEEDS RADIOTHERAPY RESEARCH
PATIENT & PUBLIC INVOLVEMENT GROUP

Hyppige møder (6x årligt)

Åbne arrangementer

Simpel proces for at bede om hjælp



Radiotherapy Research Patient Involvement Application Form

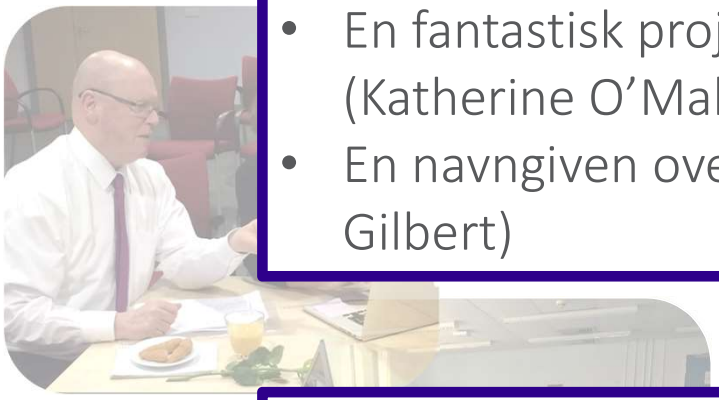
Correspondence: k.m.omahony@leeds.ac.uk. If you would prefer to populate this form over MSteams this is also an option.

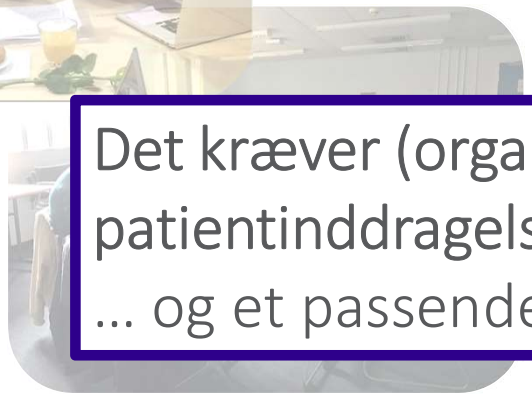
Main contact/ CI (inc. email)	
Title of project	
Research question	
Research design/ study type	
Please detail current application stage (select one)	Early Development Pre-award Post-award
Project Lay Summary (200wd max)	
How you conducted any PPI work before?	
Please detail what areas you would like patient involvement/input	Study Design ☐ Study outcomes development (using patient audience to prioritise) ☐ Acceptability of research trial design- e.g acceptability of treatment (toxicity/ burden) and assessment methods (type/amount). ☐ Practicalities/logistics of study (travel, additional treatment times, bloods, scans etc) Documentation support ☐ Patient facing material (PIS, leaflets, advertisements). ☐ Dissemination of research results Other (specify)
Do you require support with lay language writing for the study?	Y/N
Do you require support with	Y- Presentation slides from a protocol/ other material
working towards a specific grant deadline please give details)	Date 2: Date 3:
Do you prefer we engage a specific audience (i.e. patients with experience of a certain cancer or treatment)	If Y- detail
Will you be available to support the continuity of PPI by providing a 6month development update on your project?	Yes No

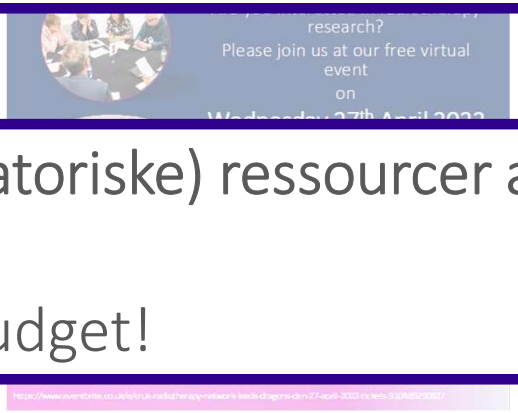
LEEDS RADIOTHERAPY RESEARCH
PATIENT & PUBLIC INVOLVEMENT GROUP

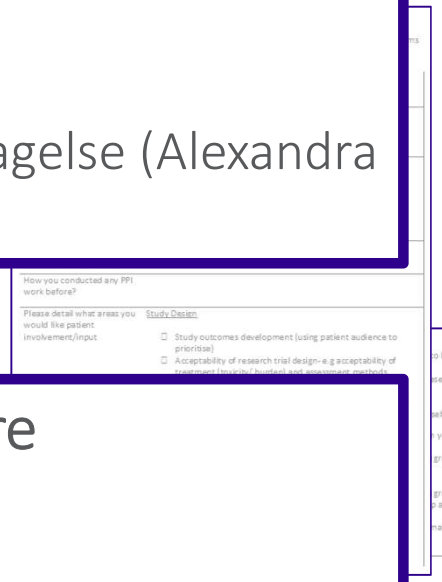
Alt dette gøres muligt af

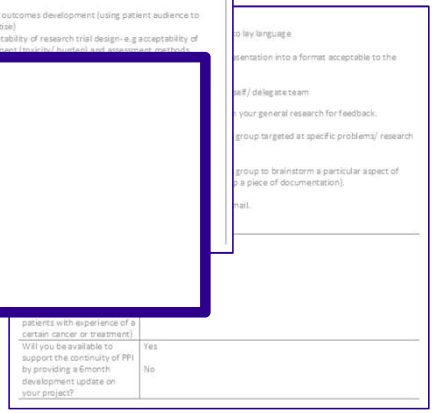
- En fantastisk projektleder i forskningsgruppen (Katherine O'Mahony)
- En navngiven overlæge som leder af patientinddragelse (Alexandra Gilbert)











Det kræver (organisatoriske) ressourcer at sikre patientinddragelse

… og et passende budget!

DET ER DET HELE VÆRD!

Crocker et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. BMJ. 2018;363:k4738.
Brett et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. Health Expect. 2014 Oct;17(5):637-50.
Brett Jet al. A systematic review of the impact of patient and public involvement on service users, researchers and communities. Patient. 2014;7(4):387-95.

TAK!

Til vores fantastiske patientrepræsentanter

Til alle mine kollegaer som bidrager til arbejdet med patientinddragelse

Ane Appelt
Associate Professor, University of Leeds
Danske Kræftforskningsdage 2022
@cancerphysicist

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Together we will beat cancer

UNIVERSITY OF LEEDS