

Pan London Early Rectal Cancer Meeting
1st November 2018



Avoiding major surgery and improving quality of life in patients with early rectal cancer



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How to set up and access support for PRESERVE in your hospital

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CLINICAL TRIAL SET UP

- Problems with recruitment?
- Why can Salisbury give advice about setting up a clinical trial?
- Why should we do it?
- Some advice on how to do it?



Lasagna's Law

Clinical trials systematically
overstate the numbers of patients
available for a trial



The size of the problem?

‘something like 1/3 of trials fail to recruit to their original target within the specified time’

Campbell MK et al. Recruitment to Randomised Trials: Strategies for trial involvement and participation. The STEPS study. *Health Technology Assessment*, 11, 48.

‘19% of registered trials that closed or terminated in 2011 either failed to meet accrual goals (85% of expected enrolment) or were terminated early due to insufficient accrual’

Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human subjects protections: An empirical analysis of recently closed trials. *Clin Trials*. 2015;12(1):77-83



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Catchment area - 250,000

Beds - 400

Colorectal cancer - 150 per year



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Colorectal Studies - last 5 years 'success stories'.

- DREAMS - closed
- MERCURY 2 - closed
- FOXTROT - in follow up
- ROCCS - in follow up
- MARVEL - in follow up
- MINSTREL - recruiting
- ADD-ASPIRIN -recruiting
- IMPRESS - recruiting
- SERENADE - recruiting
- SAILOR - open
- TRACC - recruiting
- TRIGGER - recruiting
- CIPHER - recruiting
- PLATO (ACT III)



It's not all success....

SAILOR - not recruited yet

HiPS - recruiting but slowly

BACCHUS - closed early due to poor recruitment



Why do it?

'Every NHS patient a research patient'

Equipoise and the pursuit of knowledge

Patient interest / demand

'Filthy lucre'



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Money

Funder	£ 2015/16
CRN:Wessex delivery & contingency funding	613,171.69
CRN:Wessex ETCs	4,589.92
NIHR RCF funding	20,000.00
Non-commercial research grant income	33,736.42
Commercial income	110,387.47
TOTAL	781,885.50



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Funding success

'now e-mailing to advise you that Salisbury Hospital has received £34,092 as a non-commercial performance premium for studies that closed having recruited to time and target'

'The network has £1.1 million of contingency funding to distribute to support additional NIHR portfolio research in 2017/18'



COO Wessex CRN April 2017



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FUNDING

Interventional studies earn 11 points per patient

Current value is £80 per point



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How to do it?

YOU CAN'T DO IT ALL
YOURSELF



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How to do it?

BUT YOU CAN BE THE
CATALYST



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How to do it - principles

Help is available



Salisbury 5 year R&D strategy 2016

- Increase the number of studies
- Increase the number of active research departments
- Increase the numbers of PIs
- Increase the numbers of commercial studies



Salisbury 5 year R&D strategy

	2008/09	2015/16
Small acute Trusts	19/24	3/24
CRN: Wessex	15/19	5/22
National	285/468	100/558



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How to do it - principles

Help is available

Build a team / bridges



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Build a team



PRESERVE

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Build a team

- Radiologists
- Pathologists
- Surgical colleagues
- Clinical and medical oncologists
- Clinical nurse specialists
- Clinical trials nurses / assistants
- SECRETARY

PRESERVE

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How to do it - principles

Help is available

Build a team / bridges

Build time / processes



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How to do it - principles

Help is available

Build a team / bridges

Build time / processes

Build an ethos - 'what trial/s is this patient eligible for'



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How to do it - set up

Feasibility form - be honest about your capabilities and numbers

Communicate / Collaborate

Delegate - appropriately

Do things in a timely fashion



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How to do it - recruitment

Build an ethos - 'what trials is this patient eligible for?'

Use the MDT as a forum

Empower your team

Ask your organisation for time / help in recruiting - after all they are paid for it

Don't be afraid to ask the patient



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What motivates the patient?

- Active arms vs placebo
- Learning more about their condition
- Condition being more closely monitored
- Trials give them the attention of acknowledged experts
- Trials give them the only access to new treatments



SUMMARY

- The Trust / Network wants to help you
- Patients are often poorly informed but willing to help
- Don't do it all - be the catalyst.
- The more you do the easier it gets



Thank you

Questions?



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