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

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

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Salisbury NHS Foundation Trust
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’


‘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’


Salisbury Hospital Foundation Trust

Catchment area - 250,000

Beds - 400

Colorectal cancer - 150 per year
## 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’

Money

<table>
<thead>
<tr>
<th>Funder</th>
<th>£ 2015/16</th>
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</thead>
<tbody>
<tr>
<td>CRN:Wessex delivery &amp; contingency funding</td>
<td>613,171.69</td>
</tr>
<tr>
<td>CRN:Wessex ETCs</td>
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<tr>
<td>NIHR RCF funding</td>
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<tr>
<td>Non-commercial research grant income</td>
<td>33,736.42</td>
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<tr>
<td>Commercial income</td>
<td>110,387.47</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>781,885.50</strong></td>
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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’

FUNDING

Interventional studies earn 11 points per patient

Current value is £80 per point
How to do it?

YOU CAN’T DO IT ALL YOURSELF

How to do it?

BUT YOU CAN BE THE CATALYST
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

<table>
<thead>
<tr>
<th></th>
<th>2008/09</th>
<th>2015/16</th>
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<tbody>
<tr>
<td>Small acute Trusts</td>
<td>19/24</td>
<td>3/24</td>
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<tr>
<td>CRN: Wessex</td>
<td>15/19</td>
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<td>National</td>
<td>285/468</td>
<td>100/558</td>
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How to do it - principles

Help is available

Build a team / bridges
Build a team

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

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
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?