Key Trial & Data Management Considerations for Planning Surgical Trials

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**ROLARR**

**RO**botic versus **LA**paroscopic **R**esection for **R**ectal Cancer

- Randomised
- Same operation carried out in two different ways
- International

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**GLiSten**

Next **G**eneration intraoperative **L**ymph node staging for **S**tratified colon cancer surgery

- Exploratory dose-finding study
- CTIMP
- International
Sacral nerve stimulation versus the FENIX™ magnetic sphincter augmentation for adult faecal incontinence: a Randomised Investigation

- Randomised
- Two CE marked devices
- Two different operations

Liver Resection Surgery Versus Thermal Ablation for Colorectal Liver Metastases

- Randomised
- Surgery versus ablation
- International
Protocol

Our protocols were pragmatic i.e. designed to reflect standard practice as much as possible:

• Trial assessments
• Non-prescriptive

Key Considerations:
• Timing of consent, randomisation and treatment
• How flexible can the treatment definitions be?
Adverse Events

*Definition: Any untoward medical event in a participant*

Adverse events termed *complications* in our protocols

**Issues**

- Interpretation of definitions
- Concern from surgeons that this was sensitive information

**Key Considerations:**

- Working definition of complications
- Classification of complications
- Monitoring of complications
Protocol
Adverse Events
Learning Curve
Data Collection
Learning Curve

Issue: Recognised effect in surgical trials that can introduce bias into a trial

Key Considerations:

• Establish a minimum baseline level of experience

• Can this be easily gained?

• Ongoing collection of procedure experience
  • Frequency
  • Detail required
Protocol
Adverse Events
Learning Curve
Data Collection
Data Collection

Issue: Need for upfront descriptions of each operative procedure and stages of the operation.

Considerations:
• Clear definitions for each stage of the operation
• Clear definitions for surgical endpoints
• Guidance/standardised assessment processes where required
# Theatre Procedure and Timings

Please use 24 hr clock

<table>
<thead>
<tr>
<th>Time into anaesthetic room</th>
<th>Time of wound closure completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours:Minutes</td>
<td>Hours:Minutes</td>
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</table>

<table>
<thead>
<tr>
<th>Time of first incision</th>
<th>Time patient left theatre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours:Minutes</td>
<td>Hours:Minutes</td>
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**Was there a laparoscopic part of the operation?**

- Yes
- No

*Total duration of laparoscopic surgery* is defined as from the creation of pneumoperitoneum to the completion of laparoscopic mobilisation. It does not include the use of laparoscopy for formation of anastomosis or creation of ileostomy.

**If yes: Total duration of laparoscopic surgery**

- [ ] [ ] min

**Was there more than one episode of laparoscopic surgery during the operation?**

- Yes
- No

**Was there a robotic part of the operation?**

- Yes
- No

*Total duration of robotic surgery* is defined as the total time that the robot is docked to the patient.

**If yes: Total duration of robotic surgery**

- [ ] [ ] min

**Was there more than one episode of robotic surgery during the operation?**

- Yes
- No

**Which system was used?**

- [ ] da Vinci™ standard
- [ ] da Vinci™ S
- [ ] da Vinci™ Si

Total number of robotic arms used
<table>
<thead>
<tr>
<th>Was there a conversion to open?*</th>
<th>□ Yes</th>
<th>□ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes: Stage</td>
<td>□</td>
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<tr>
<td>Reason</td>
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<tr>
<td></td>
<td>□ Operative difficulty, describe:</td>
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<tr>
<td></td>
<td>□ Operative complication <em>(Please record details on pages 8 and 9)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Robotic malfunction complication, describe:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Other, describe</td>
<td></td>
</tr>
</tbody>
</table>

*An intraoperative conversion to open is defined as the use of a laparotomy wound for any part of the dissection. The use of a limited laparotomy wound to facilitate a low staples anastomosis and/or specimen extraction is permissible and not defined as an open conversion.

Completed by [Name] Date [Day] [Month] [Year]
Thank you!