## Healthcare research study: commercial sponsor

### Overview

**DAY 0: IRAS Submission**
- **DAY 30: R&D approval**
- **DAY 60: First patient**

<table>
<thead>
<tr>
<th><strong>FEASIBILITY</strong></th>
<th><strong>WORK-UP</strong></th>
<th><strong>GOVERNANCE</strong></th>
<th><strong>RECRUITMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop proposal</td>
<td>Coordinate work-up</td>
<td>Run governance checks</td>
<td>Initiate site and recruitment</td>
</tr>
<tr>
<td>Assess feasibility</td>
<td>Submit to IRAS</td>
<td>Issue Trust permission</td>
<td>Capture accruals</td>
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<tr>
<td>Apply for funding</td>
<td>Authorise IRAS submission</td>
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<td>Close site</td>
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<tr>
<td><strong>CPI (study team)</strong></td>
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<td>Report / archive / publish</td>
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<tr>
<td>Assess feasibility</td>
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<td>Finalise study logistics</td>
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<td>Brief trial team</td>
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<td><strong>ICH Division</strong></td>
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<tr>
<td>Divisional review</td>
<td>Authorise IRAS submission</td>
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<td>Reaffirm feasibility</td>
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<td>Confirm portfolio eligibility</td>
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<tr>
<td><strong>SID</strong></td>
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<tr>
<td>Assess College costs</td>
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<td><strong>Sponsor</strong></td>
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<tr>
<td>Select study site</td>
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<td><strong>Ext. orgs</strong></td>
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<td>Select study site</td>
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<tr>
<td><strong>Support services</strong></td>
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<tr>
<td>Advise on costs/feasibility</td>
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<td>Process support request</td>
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<td>Confirm service approval</td>
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<td><strong>JRO (NHS team)</strong></td>
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<td>Assist with feasibility</td>
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<td>Agree contract</td>
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<tr>
<td>Coordinate study work-up</td>
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<td><strong>JRCO</strong></td>
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<td>Arrange peer review</td>
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<td>Receive valid IRAS</td>
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</table>

**30 calendar days**

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Healthcare research study: commercial sponsor

Feasibility

C/IPI (study team)
- Assess feasibility
- Assess resources/capacity

ICH/T Divisions
- Enter on Documas
- Divisional review
- Confirm portfolio eligibility

SID
- Advise College costs

Sponsor
- Site opportunity

Ext. orgs
- Advise service costs/feasibility

Support services
- Assist with feasibility

JRO (NHS team)
- Assist with feasibility

JRCO
- Review feasibility

Work-up

Site pre-selected?
- YES
- Submit feasibility assessment
- YES
- Decide
- NO
- Cancel study

Site selected?
- YES
- Approve study work-up
- YES
- Site pre-selected?
- NO
- Enter on Documas
- Advise College costs
- Advise service costs/feasibility
- YES
- Assess resources/capacity
- YES
- Divisional review
- YES
- Enter on Documas
- YES
- Divisional review
- YES
- Enter on Documas

RETURN TO MAP OVERVIEW

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Feasibility Thursday, 16 July 2015
## Healthcare research study: commercial sponsor

### Work-up
- CI/PI (study team):
  - Log receipt (valid submission)
  - Initiate governance review
- JRO (NHS team):
  - Confirm contract / funding
- JRCo:
  - Initiate governance review

### Governance
- Complete governance review
- Check policy / procedure / legal reqs
- Issue approvals, eg REC / MHRA / ARSAC
- Reaffirm feasibility
- Resolve study queries
- Initiate governance review

### Recruitment
- YES
  - Issue Trust approval
  - Approve trial
- NO
  - Cancel study (no R&D approval)
  - Suspend
  - YES
  - Issue Trust approval

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**Governance Thursday, 16 July 2015**

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