## Healthcare research study: Trust-sponsored

### FEASIBILITY
- Develop protocol
- Assess feasibility
- Assess costing
- Apply for funding

### WORK-UP
- Coordinate study work-up
- Prepare documentation
- Plan study logistics
- Submit forms to IRAS

### GOVERNANCE
- Finalise study logistics
- Brief trial team
- Run governance checks
- Issue Trust permission

### RECRUITMENT
- Initiate recruitment
- Capture accruals
- Close site
- Report / archive / publish

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

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Feasibility

CI/PI (SID study team)
- Develop research idea
  - Develop protocol
  - Assess feasibility
    - Assess resources / capacity
    - Assess costing (create InfoEd)
    - Enter on Documas
    - Divisional review
    - Confirm portfolio eligibility

ICH Divisions

Ext. orgs

Support services
- Cost service agreements
- Advise service costs / feasibility

JRO (funding)
- Review costing (InfoEd)
- Negotiate contract / agreements
- Approve grant application
- Submit funding application

JRCO (sponsor)
- Confirm sponsorship

Feasibility Thursday, 16 July 2015

RETURN TO MAP OVERVIEW

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## Feasibility

<table>
<thead>
<tr>
<th>CIPI (SID study team)</th>
<th>CHT Divisions</th>
<th>Ext. orgs</th>
<th>Support services</th>
<th>JRO (funding)</th>
<th>JRCo (sponsor)</th>
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<tbody>
<tr>
<td>Funding awarded</td>
<td>Feasibility process &lt;&lt;&lt;&lt;</td>
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<td>Coordinate study work-up</td>
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<td>Plan patient recruitment / logistics</td>
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<td>Prepare study documents</td>
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<td>Prepare to hire study staff</td>
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<td>Reaffirm feasibility</td>
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<td>Process request for services</td>
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<td>Set-up award</td>
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<td>Negotiate service agreements</td>
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<td>Complete study work-up</td>
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<td>Approve submission</td>
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<td>Process approvals, eg REC / MHRA / ARSAC</td>
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## Work-up

- STUDY-WIDE CI submits REC / R&D (IRAS)
- LOCAL PI submits SSI (IRAS)

## Governance

- LOCAL PI submits SSI (IRAS)
- Process approvals, eg REC / MHRA / ARSAC
- Log receipt (valid submission)
- Governance process >>>

**RETURN TO MAP OVERVIEW**

**DAY 0**

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<thead>
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<th>Governance</th>
<th>Recruitment</th>
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<td>ICHT Divisions</td>
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<td>Ext orgs</td>
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**Governance process**: Initiate project

**FPFV**: 30 calendar days

**LPLV**: 20 days

**Archiving / publication**: 30 calendar days

**Day 30**: Initiate project

**Day 60**: Close site

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