Your study life cycle - when and how we optimise delivery

**HRA Approval**

- Define research idea and study methodology
- Cost research activities proposed in study methodology to secure appropriate funding or budget
- To access our support - set-up your project in IRAS and select ‘YES’ to project filter Q5b
- Complete and submit CRN Portfolio Application Form (PAF) to enable assessment of eligibility for our free support. Commercial studies also need to complete the CPMS submission.
- Submitting the PAF as early as possible before IRAS application maximises the impact of our support on overall study delivery
- Finalise study documentation to enable study approval application

**Your study**

- Confirmation of potential portfolio eligibility status provided
- Provide potential sites with protocol to assess prior to listing on IRAS application
- Prepare IRAS application for all necessary study approvals
- Submit IRAS Application for HRA Approval
- Sponsor provides local information pack to NHS organisation (R&D + PI team) and their Local CRN
- Study site arranges their capacity and capability to participate in the study, working with the Local Clinical Research Network (LCRN) as appropriate to apply ‘Good Practice Principles’
- Confirmation of study support for each site by LCRN
- Study site confirms capacity and capability for study via agreement of Statement of Activities/Execute Model Agreement
- Study site ready to start
- First Participant First Visit (FPFV)
- Last Participant First Visit (LPFV)
- Study Follow-up
- Study Closure

**Our Study Support Service**

- **Early Contact & Engagement**
  - Support includes:
    - **Commercial**: Industry costing template validation
    - **Non-commercial**: AcoRD support
- **Early feedback**
  - From our clinical and delivery experts to optimise study design for delivery in the NHS
- **Site identification**
  - From 240+ NHS organisations and 10,000+ General Practices in the NHS in England
- **Optimising planning**
  - **Non-commercial** - Support assessment carried out for optimal study delivery
  - **Commercial studies** - Assessment delivered via Site Intelligence service.
- **Effective study set-up**
  - **Confirmation** of selected study sites to enable provision of support
  - **Agreement** of key dates and targets to enable performance management
  - **Facilitation** of practical arrangements to support consistent set-up and delivery across study sites
- **Performance monitoring**
  - **Activate** performance monitoring plan
  - **Review** study performance regularly
  - **Performance closure review** to capture lessons learned for future studies

Find out more at t: 0113 343 4555 e: supportmystudy@nihr.ac.uk w: supportmystudy.nihr.ac.uk

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