### Roadmap For Post Funding Line
**Grant Score- Human Subjects Research**

1. **01** Begin IRB Review
   - Getting Started with IRB
   - EIRB Login

2. **02** Create Consent Document(s) using EIRB templates (attach to EIRB)

3. **03** Create Source Documents/Case Report Forms (attach to EIRB if needed)

4. **04** Create Marketing Materials (Needs UK Public Relations Review and Approval)
   - PR Review and Approval

5. **05** Create Database (ie. REDCap)
   - REDCap Login

6. **06** Create Electronic Regulatory Notebook (CHS Template Provided)

7. **07** Register Study on ClinicalTrials.gov

8. **08** Request Center for Clinical and Translational Science (CCTS) Services If Needed
   - Request CCTS or CRSO

9. **09** Note: CCTS Requests Indemnification Review Following trial agreement

10. **10** Conduct Research

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**Is your study a Clinical Trial?**

Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

The following questions should be used to determine whether a study meets the NIH clinical trial definition:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answers are all "yes" the study is a clinical trial. If any answers are "no" the study is not a clinical trial.