

Agreeing programme scope

A sponsor is considering continued access after a study. One team plans for existing participants; another expects new requests to be included. A provider has estimated work for the first group. The teams have not agreed one scope.

Illustrative industry scenario. Fictional example created to explain a decision; not a client case study.

The decision

The sponsor programme owner is asked to coordinate a documented scope decision with the responsible functions before commissioning the detailed assessments. This example records a proposed next step, not an approved programme.

A practical next step

If scope is open, compare two options: continuity for existing participants, and a broader proposal including new requests. For each, identify the population, activities, assumptions and questions needing specialist assessment. If scope is agreed, assess that specific proposal and reconcile the provider estimate against it.

Illustrative scope brief

The working option is to assess continuity for existing participants. Treat new requests as a separate scope decision. The proposed output is one agreed assessment brief listing the intended population, activities, exclusions, responsible functions and information still needed. A wider scope must not silently inherit the narrower estimate.

Limits and review

The current estimate covers only one proposed population. Neither option has been assessed here for regulatory feasibility, clinical eligibility, safety arrangements, supply or operational readiness. Scope agreement tells the teams what to assess; it does not answer those assessments.

Responsibility and review

The proposed owner is the sponsor programme owner, with the relevant decision-makers. First, circulate both scope options and reconcile the assumptions. Review before detailed assessments and external commitments; reopen the brief if the intended population or activities change.

Use this brief to agree the next decision with the responsible team.

Discuss your requirements: enquiries@iaeconsults.co.uk

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