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Requirements for the business case and technical plan to support future applications for funding from UK Vaccine Network

1. What is needed in the business case and technical plan?

The aim of the in-depth evaluation is to help ensure that the project delivers the milestones described in the Stage 2 application in relation to cost, time, and quality.

It will ensure that plans beyond this point have been well designed. Plans must give an accurate prediction of the cost and timelines for the project though subsequent stages of development to licensure or to a point when the technology is sold to another entity.

It is recognised that projects might be subject to technical failure at any point and that this is the norm in vaccine development. In such cases, plans would have to be redesigned at that future point in time. For this review the assumption will be made that each work package will deliver successfully in relation to cost, time and quality.

Reviewers will assess whether this is likely based on technical data presented by you. If a reviewer believes that a particular work package is unlikely to deliver because of poor supporting data or because of poor future design, they will highlight this in their evaluation. You should consider including appropriate contingencies within your plans.

It is also recognised that the further away the plans are from the current Technical Readiness Level (TRL), the less accurate the cost and time lines will be. Details should be based on best knowledge and practice at such developmental points, for example, the cost of a Phase 2 or Phase 3 clinical trial will be based on current costs and timelines for such work packages. In this case consideration should also be made to ensure that such trials will go ahead and be completed successfully.

For example:

- has consideration been made to ensure all approvals and contracts are in place
- that a vaccine will be manufactured and is of sufficient quality and stability to be used
- the completion of the analysis of clinical samples has been costed, contracted and included in timelines

It is not required that all contracts are in place for future work. It is necessary to have considered what future contracts will be required and include this in your business case and technical plan.

The review will ensure that all the elements of work necessary for the proposal to succeed have been included in the plan.

The review will include but will not be restricted to an assessment:

- of the technical data generated to date, to ensure that the project is mature enough for the next stage of the development to take place without delay or any need to repeat or complete additional pieces of work now or the future

- of whether all the necessary materials and contractors are in place to allow the Stage 2 project to complete on time and to cost
- of whether the design of the project for Stage 2 funding includes all the necessary elements and has appropriate cost, risk mitigation, quality assurance and time-lines
- that the long-term development plans are based on good science, appropriate time-line and costs, adequate risk mitigation and will be carried out to a satisfactory quality standard

This review will include all downstream requirements to minimise the probability of unforeseen technical failures.

2. What you need to consider in your business case and technical plan to ensure that the assessors can complete their review

Proposals to the 'SBRI Vaccine technology for diseases with epidemic potential' call will be at various stages along the developmental path. Regardless of the stage achieved at the time, each proposal must provide:

a) All relevant data generated to date

b) Detailed plans

A list of what may be necessary to consider in your detailed plans is shown below. However, depending on the deliverables of each project, some of these items may not be necessary and other requirements might be needed.

Assessment of a new Vaccine platform

- data demonstrating proof of concept
- reasoning behind the assertion of the mode of action
- desk-based assessment of toxicology

Hit-to-Lead & Lead Optimization

- evidence of mechanism of action (MOA) and mode of resistance
- desk-based assessment of possible immunological effects beyond the target immunity
- medicinal chemistry planning and demonstration of satisfactory execution
- in vitro or in vivo exploratory toxicology
- animal efficacy, pharmacodynamics and pharmacokinetic (PK/PD)
- genomics, metagenomics, microbiome and bioinformatics
- vaccine development
- conceptual design of manufacturing pathway
- desk-based scoping estimate of cost of goods, for example +/- 30%

Related Pre-clinical work

- in vitro screening
- animal efficacy models, standard and custom
- synthetic route scouting
- defined basis for comparability (proof of concept to full-scale manufacture)

Related Project management support

- review of Target Product Profiles (TPPs) and Critical Quality Attributes (CQAs)
- design of screening assays and cascades
- development of appropriate project milestones
- basic stability information (preferred storage temperature and probably shelf life)

Preclinical

Scientific advice and guidance

- toxicology study design, data interpretation and issue resolution
- compliance of toxicology studies with GLP regulations
- PK/PD study planning
- choice of dosage form
- stability studies (materials for primary packaging, temperature, time)
- in vivo absorption, distribution, metabolism, elimination, toxicity (ADMET) studies planning
- review of study protocols/reports

Preclinical Services

- animal efficacy models – standard and custom
- safety studies
- active Pharmaceutical Ingredient scale-up
- identification of critical control points in the manufacture

Chemistry, manufacturing and controls (CMC)

- guidance on process development, scale up, pilot scale manufacturing and phase appropriate specification setting, such as Active Pharmaceutical Ingredient (API), Investigational Medicinal Products (IMP), Drug Product (DP)
- CMC project plan review and gap analysis (execution, quality and closeout plans)
- advice on reference, working and master cell banks, quality control and release
- review of quality systems, as well as audit findings and remediation plans

Clinical

Clinical planning

- trial design, protocol, investigator's brochure, informed consent

Regulatory support and guidance

- transit trials for finished product
- pre-submission package
- regulatory documents for example investigational new drugs (INDs)
- facilitate Interactions for Informal advice with regulatory bodies in UK, US, Europe and India
- support in formal regulatory interactions
- evidence of batch reproducibility

c) Quotations and plans from potential future sub-contractors

d) Written advice from Vaccine development technical experts

e) Relevant scientific advice provided by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency EMA

Costs to seek such advice can be included in the bid.

3. Review of the business case and technical plan as part of the selection process for Stage 2 funding

The business case and technical plans will vary and depend upon the current Technical Readiness Level (TRL) of the vaccine candidate, technology or platform.

Business case and technical plans will be assessed by independent expert assessors.

If a plan is considered satisfactory the application will be considered for further Stage 2 based on the following questions:

Is the start of Stage 2 funding dependent upon the outputs of Stage 1 funding?

- If no, the application will be considered for Stage 2 funding in a Strand 1 portfolio review.
- If yes, was that work technically satisfactory for Stage 2 work to start on time?

If the answer to the point above is yes, was the work carried out to the required cost and did the project team report appropriately?

- If yes, the application will be considered as part of a Strand 1 portfolio review for Stage 2 funding
- If no, the application will not be considered as part of a Strand 1 portfolio review for Stage 2 funding

Based on the feedback provided you can resubmit a revised business case and technical plan for review. If a revised business case and technical plan is considered satisfactory following a second review, it will then be submitted to a Strand 2 portfolio review for Stage 2 funding.

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4. Information needed to further support the independent technical review of projects seeking Stage 2 funding

Proposals seeking Stage 2 funding will be assessed on the outputs of Stage 1 which include the business case and technical plan and the progress made against the relevant technical milestones.

The business case and technical plan should include a detailed description of what is to be carried out during the technical programme in Stage 1, the outputs expected, the milestones to be met and how they relate to the successful delivery of Stage 2 of the project.

In order to help the independent expert assessors complete their assessments, the final report for the technical program of work carried out in Stage 1 should highlight the outputs in relation to the milestones during this period. This information will enable the assessors to assess the likely success of Stage 2 of this SBRI call, and beyond, in terms of cost, time and quality.

5. Timelines and the process for project selection of this 2-stage SBRI call

The timelines and the process for project selection for this 2-stage SBRI call are as shown below.

The business case and technical plan must be completed by 31 September 2024 for assessment. This assessment will be completed by 28 Feb 2025.

If this assessment determines that the business case and technical plan is not satisfactory or likely to deliver, you will be given feedback and you will be able to resubmit your plans for reassessment. This must be complete by 28 May 2025.

It should be noted that no additional funds will be provided by the Department of Health and Social Care (DHSC) to support a resubmission. If you recognise that you are unlikely to meet the milestones described in the technical programme in Stage 1, you will be allowed to resubmit your business case and technical plan by 28 May 2025 for reassessment.