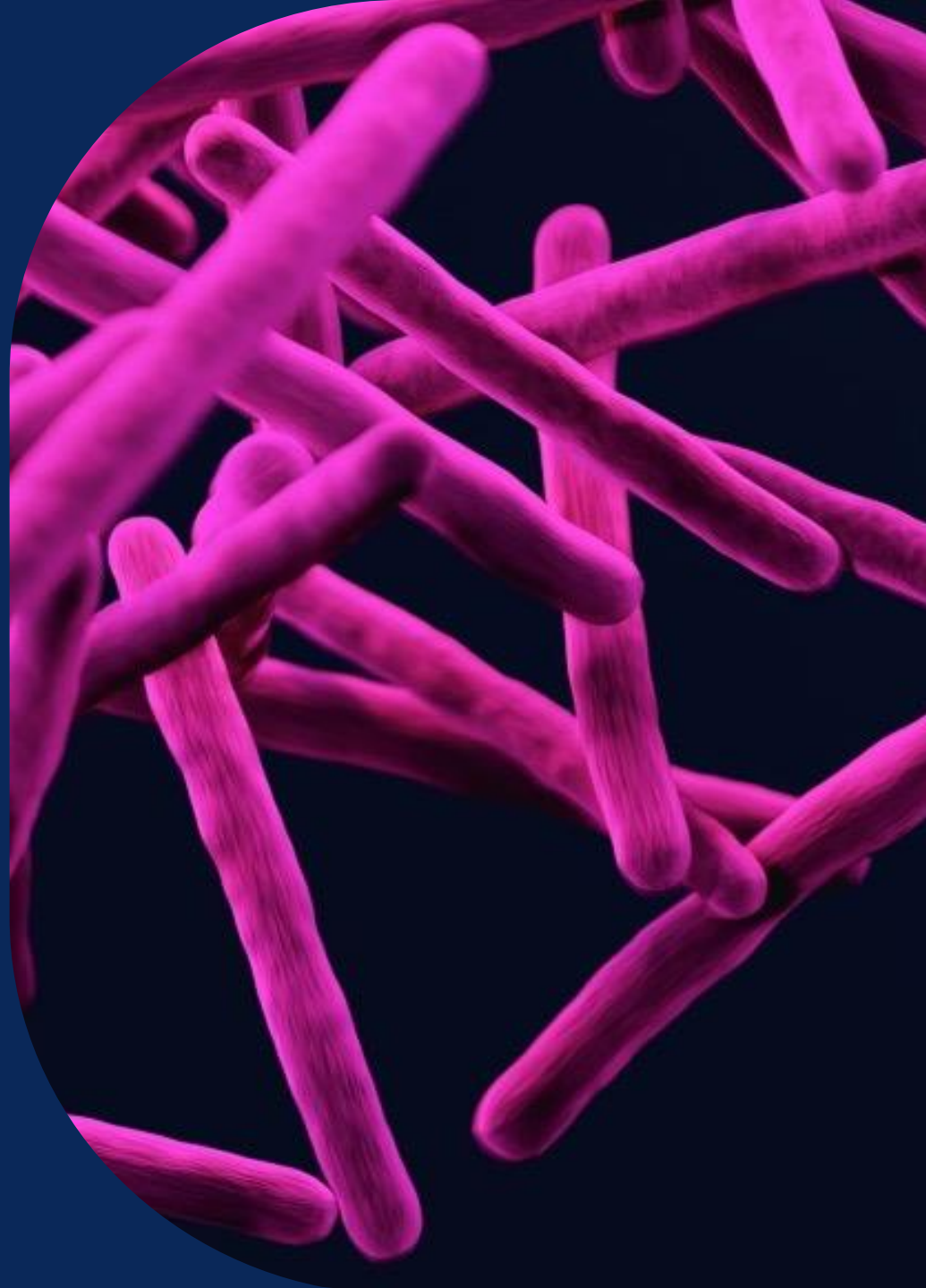
Writing a successful translational grant funding proposal

Grand Challenges Africa Drug Discovery Accelerator Convening Meeting

Accra, Ghana - 11th March 2025



Dr Laura Stennett

Senior Business Manager, Partnerships Team, LifeArc

Agenda

- Introduction – my background and introduction to LifeArc
- What is translational research and Technology Readiness Levels
- Identifying funding opportunities
- The funding process and writing a grant funding application
- Anatomy of a typical funding application
- Summary and top tips for success
- Q&A

My background

Academia:

- First Class Honours Biomedical Science with Intercalated Year Degree from University of Warwick, UK
- PhD in Cancer Imaging from King's College London, UK

Industry:

- Compound Profiling and Cellular Pharmacology Group, Centre for Therapeutics Discovery, MRC Technology
- Commercial Partnerships Team, Cancer Research UK
- LifeArc Technology Transfer Fellow, Technology Transfer Business Manager
- Senior Business Manager, Technology Transfer Team, Partnerships

Introduction to LifeArc

We help promising scientific ideas reach the next phase of development through investment, partnerships and expertise for health conditions that need it most.

We bridge the gaps between the lab and the patient:

advancing early scientific discoveries to a point where they can be developed into the next generation of diagnostics, treatments and cures.

What is translational research?

Fundamental vs Translational Research

Fundamental Research:

- Hypothesis driven research motivated by a gap in knowledge or understanding.
- Generally, the intention is to progress human knowledge and contribute to our overall understanding of health and disease.
- Often termed ‘blue skies’

Translational Research:

- Aims to take discoveries, ideas and insights from the lab and apply these basic research results to the development of new therapeutics and diagnostics for the treatment or prevention of human disease.
- Focused on achieving patient impact from basic scientific discoveries.
- Often termed ‘bench to bedside’

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Fundamental vs Translational Research

There are several differences between fundamental and translational research funding:

Fundamental

- Projects can be focused on a single discipline
- Funding calls may have a broader remit
- Funding for the project is often more flexible, allowing researchers to ‘follow the science’
- May be a broader range of funding opportunities available due to lower risk
- Funding guaranteed for a period of time

Translational

- Often multi-disciplinary in nature and requires different expertise and collaboration
- Funding calls are often for a defined scope
- Projects are more rigid/clearly defined and milestone based
- Funding for the project is often tranched and tied to the achievement of defined milestones.
- Funding can be stopped if milestones are not met.
- Must consider intellectual property (IP) and future development and commercialisation

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What is considered ‘translational’ research?

Translational research typically includes projects focused on target validation through to clinical trials.

Target identification may be considered translational research if focused on:

- Identification of probable novel drug targets
- Understanding mode-of-action of enigmatic drug candidates

Translation of a therapeutic can take between 10-15 years and will often require multiple sources of funding to get through pre-clinical and clinical development.

The more developed the asset is and further down the translational path you are, the more expensive research becomes.

Early clinical trials may be funded via grants although late-stage clinical trials usually require separate funding due to the associated high costs.

Tabana et al., 2023

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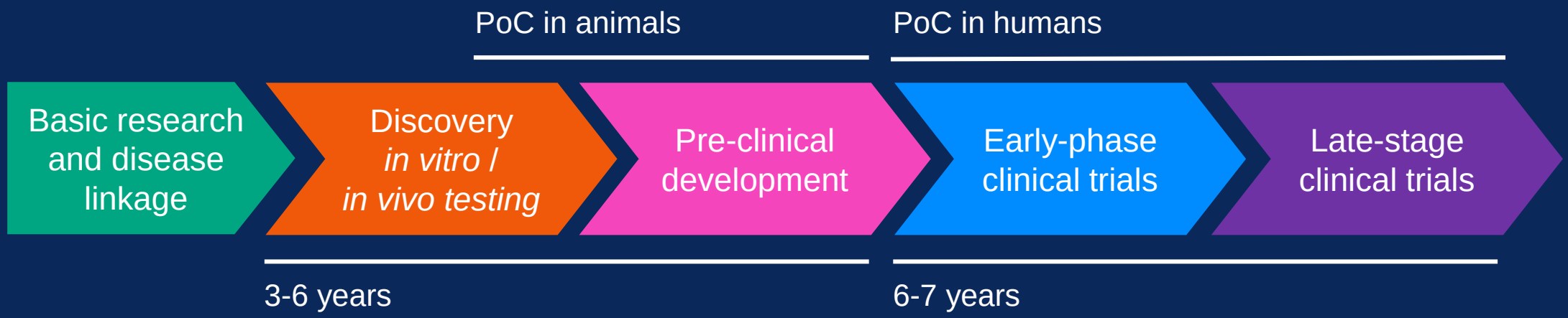
Translational Research Pathway & Technology Readiness Levels



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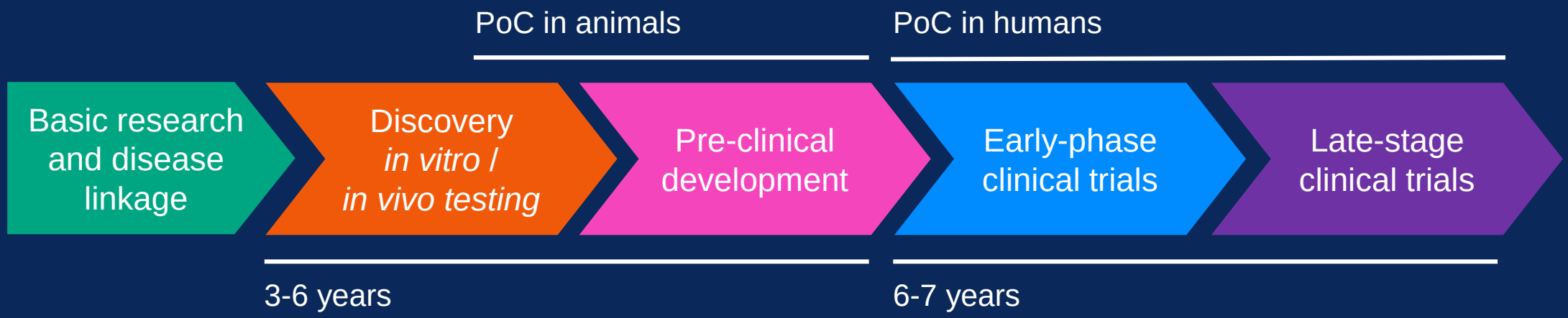
Translational Research Pathway & Technology Readiness Levels



Research Laboratory				Simulated world			Real world	
TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9
Basic principle	**Technology concept formulated**	**Proof of concept demonstrated**	**Technology validated in the lab – hit to lead**	**Early prototype / field data / lead optimisation**	**Clinical studies**	**Late-stage validation**	**Pre-Commercial**	**Commercialisation**

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Technology Readiness Levels

Low

TRL 1

Basic Principle

Basic principles are observed and reported.

No evidence of a translational approach.

No technology is anticipated as a project output.

Early Stage

TRL 2

Technology concept formulated

A translational hypothesis which is as yet untested.

E.g. target and/or biomarker identification projects, validation of non-validated targets etc.

TRL 3

Proof of concept demonstrated

Initial PoC *in vitro* and *in vivo.*

Further work on targets with evident validation.

E.g. biomarker validation and refinement of diagnostic signatures

Moderate

TRL 4

Technology validated in the lab

Evidence of a clear technological approach. Further validation and PoC.

E.g. identified initial hits against a target or even lead molecule.

TRL 5

Early prototype / field data

Evidence of a more clearly defined asset. Possible registration of IP Rights. Technology is well-validated and laboratory development is at an advanced stage.

E.g. lead optimization stage for therapeutic projects.

High

TRL 6

Clinical studies

Early clinical trials incl. preparation & submission for IND application**.**

TRL 7

Late-stage validation

Later stage clinical trials demonstrating safety and efficacy.

TRL 8

Pre-Commercial

Regulatory approvals, end-user engagement**.**

TRL 9

Commercialisation

Market authorisation and product launch.

Technology has reached the market.

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Questions?

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Identifying funding opportunities for translational research

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Sources of translational funding

Universities/Research Institutions

- Often smaller pots of funding
- Intended to allow researchers to leverage larger/international grants
- Internal funding and candidates

Charities and foundations

- Fund translation through annual grant calls and/or specific one-off funding calls
- Funding may come with attached Ts&Cs, including IP considerations and publication requirements

Industry funding

- Typically aligned with strategic areas of focus

Identifying the right funding opportunity

Make a habit of routinely checking the websites of relevant funders for open or upcoming calls.

Build your network in the translational research space and explore opportunities for collaboration.

Take time to evaluate funding opportunities that are available:

- Funding remit and project scope
- Funding amount – total available and no. of projects
- Application deadline

Targeted approach for success:

- Saves time and enhances the quality of proposals
- Increases chances of securing funding

Subscribe to funding alerts via email / newsletters

Tools such as Google Alerts can be used to identify grant funding opportunities

Create an alert – Google Search Help

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The funding process

Writing a high-quality application

Grantsmanship is an artform and requires practice to craft a written proposal that tells a compelling story.

Funders will be evaluating three main components in the application:

SCIENCE

The science underlying your proposed technology

PLAN

The work plan to be funded to progress the technology

IMPACT

Further steps you're taking to ensure you realise the potential of your technology for patient impact

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The funding process

Stage 1: Initial application / Expression of Interest (EOI)

- Submission of initial application – short application, a few pages long
- Application review by funding committee and shortlisting

- Committee will have mixed expertise depending on remit
- Give a project overview, unmet need and highlight strengths of the proposal and any gaps to be addressed
- Non-confidential and confidential sections
- Highlight any IP/commercialisation considerations

The funding process

Stage 2: Full application

- Submission of full application
- Peer review and/or panel review of application
  - Peer review: written comments from experts in the field which is intended to guide the final funding decision. Scientific and subject matter experts, clinicians.
  - Panel review: consists of an expert review panel with a range of experience and skillsets. Scientific and subject matter experts, industry leaders, IP experts
- Application reviewed by funding organisation – science, project plan, downstream development, IP and commercialisation strategy
- Yes/No decision made by funding organisation – may be conditional

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How are funding decisions made?

- Most funding decisions are made, first and foremost, based on the science and research proposal.
- Funders will also consider how the proposed project fits the criteria and scope of the funding call.
- Reviewers will look at whether the project team is able to deliver the research (expertise, facilities and partnerships?).
- The IP and downstream development and commercialisation strategy is then considered.

Note – for larger funding calls, funders may use a scoring system to rank project proposals.

Before you start applying….

Review…

The funding call remit to ensure your proposed project is in scope

Applicant eligibility to ensure that you are eligible for funding

Confirm…

The amount of funding available for projects and eligible costs

The number of projects anticipated to be funded

Familiarise yourself with…

The application process, deadlines anticipated timelines

Any supporting documents and funding call guidance

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Questions?

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Anatomy of a grant funding application

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Overview:

1. Project summary and objectives
2. Project team
3. Rationale
4. Target Product Profile (TPP)
5. Project Plan
6. Deliverability
7. Competition and Intellectual Property (IP)
8. Downstream development

1. Project summary and objectives

Project summary – non confidential

- Provides a high-level overview of the project scope and aims.
- Often considered a ‘lay’ or plain English summary for a general audience. NIHR guidance

Technical summary

- Tailored to a specialist reader who may be an expert in the field.
- Provides relevant background and the problem you are trying to address, including the indication(s) targeted and your research method.
- What are the main objectives of the project?

Non-confidential project summaries are often used to identify and manage any conflicts of interest

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1. Project summary and objectives

- Provides important context for your project proposal, drawing out key information from later sections.
- Background should be well researched, and data and references used to support the narrative.

What is the unmet patient need you are trying to address?

Potential for clinical impact - how will you address the unmet patient need?

Why is your approach better than the current gold standard?

How will your project plan address the unmet need identified?

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2. Project team

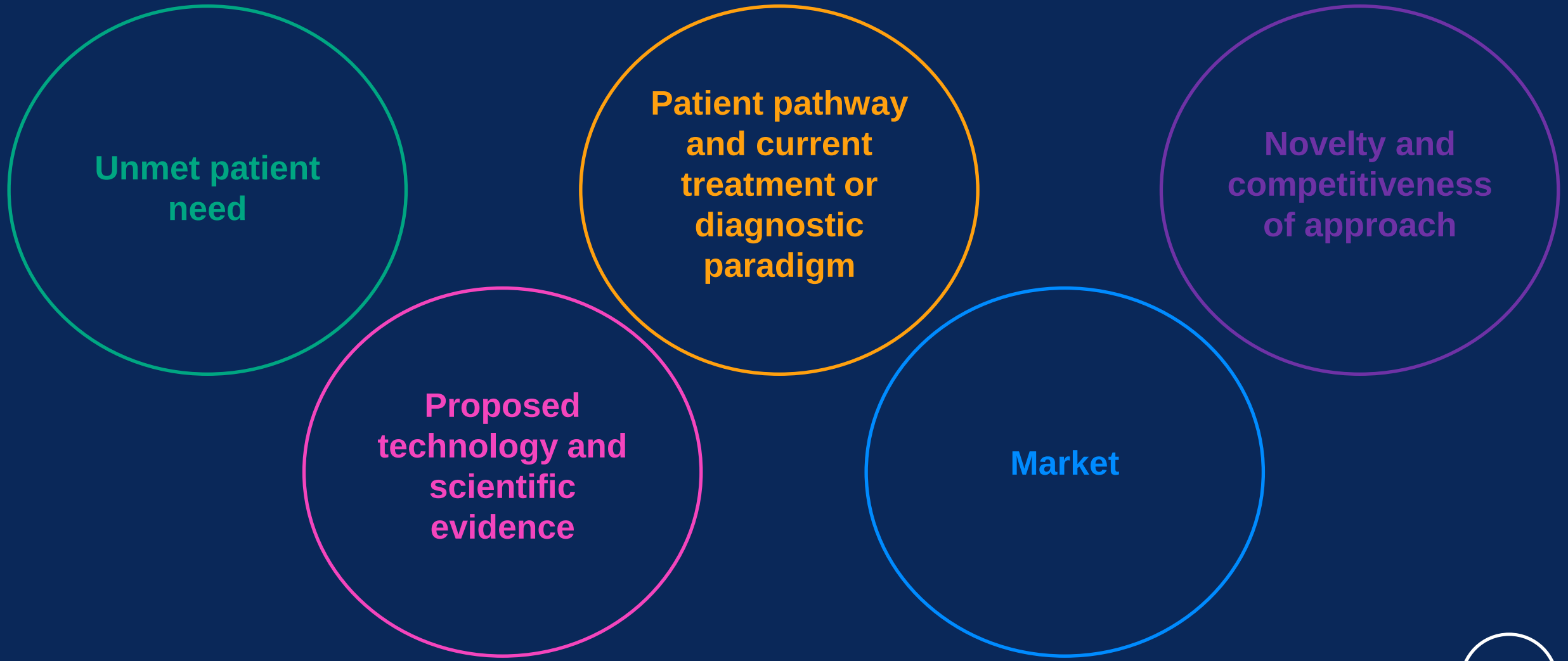
- Who is the Principal Investigator and Co-Investigators for the project?
- Relevant contact details for the project team and their associated Institutions
- What expertise do the project team have to deliver the project?

Having the right expertise is essential

Collaborations are essential and expected to build multi-disciplinary teams

If additional expertise are required, how will you obtain these?

3. Rationale for project



3. Rationale: unmet patient need

What is the unmet patient or clinical need you are seeking to address?

How does your proposed solution meet this need?

Consider:

- The current treatment options and, if there is one, what is the current standard of care?
  - How does your technology improve on the current standard of care?

- Is your solution a platform technology or could be applied to other indications?

3. Rationale: scientific evidence

Proposed technology:

- Technical description of the technology including type of approach, target, use, components, biomarker and sample types

Evidence for scientific rationale:

- Evidence linking the target to clinical indications and outcomes (own and external data)

Stage of development:

- Summarise the work that has been done to date, including assay development and verification, screening, types of samples tested (own data)

Key references:

- Include key supporting literature (own and external research)

Provide all relevant background information and supporting evidence, including diagrams of work processes, prototypes, unpublished data etc.

Ensure you provide sufficient data to justify the proposal, particularly if the work is unpublished.

Don’t be afraid to highlight gaps and insistencies but highlight where these are to be addressed in the project plan, or for which a rationale can be provided.

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3. Rationale: patient pathway

The patient pathway is the route or path a patient will take to receive treatment.

It is important to understand and articulate how your invention fits into the patient pathway, which should be reflected in your application:

- Where do patients typically receive treatment?
  - In hospitals? In primary care? Treated within the community?
- What tests are currently used to diagnose patients and inform treatment decisions?
- Who makes treatment decisions and are likely to be the end users of your proposed solution or intervention?
  - Doctor(s)? Nurse(s)? Other health care professional(s)? Technical specialists?
- Have you had any engagement with end-users or patients?
  - Consider public and patient engagement plans for the project

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3. Rationale: understand the market

Look at the drug discovery market and pipeline:

- What is the current biggest drug on the market (if there is one!). Is there room for your technology?
- What competing solutions are being developed in academia and industry and their development status.

Potential for a strong market position makes the application more fundable.

New Drugs for Human African Trypanosomiasis: A Twenty First Century Success Story

Emily A Dickie [1], Federica Giordani [1], Matthew K Gould [1], Pascal Mäser [2], Christian Burri [2,3], Jeremy C Mottram [4], Srinivasa P S Rao [5], Michael P Barrett [1,*]

Drug Development Strategies for Malaria: With the Hope for New Antimalarial Drug Discovery—An Update

Swaroop Kumar Pandey [1,✉], Uttpal Anand [2], Waseem A Siddiqui [3], Renu Tripathi [4]

Review Article | Published: 27 April 2022

Anti-tuberculosis treatment strategies and drug development: challenges and priorities

Véronique A. Dartois ✉ & Eric J. Rubin

Pandey SK et al., 2023; Dartois & Rubin 2022, Dickie et al.

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3. Rationale: competitiveness

- Clearly demonstrate how your technology solves the problem you have identified and how this is novel.
- What is the competitive advantage of your proposed solutions compared to competing solutions being developed?
- Consider and identify the extent to which your approach is innovative and timely.

Sustaining innovation

Improvement to existing technology or product

Disruptive innovation

Groundbreaking novel technology which creates a new market

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4. Target Product Profile (TPP)

Outlines the desired profile or characteristics of a target product that is aimed for a particular disease or diseases.

TPPs state the intended use of the product, the target population(s) and other desired attributes, including safety and efficacy-related characteristics.

What do you hope your product/solution will look like?

Defines the essential attributes of a clinically successful product, which can form the basis of a development plan.

Allows for the development of clear, achievable milestones.

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4. Target Product Profile (TPP)

Indication(s)

Which disease(s) will you target?

Population(s)

Which types of patients will you target and where do they live?

Clinical efficacy

What is the level of efficacy required and how will it be measured?

Safety and tolerability

What level of acceptability is there for adverse events

i.e. side effects?

Dosing frequency and treatment duration

How often and how long must the treatment be given?

Route of administration

What is an acceptable way to administer the treatment to the patient population?

Stability

How long is the shelf life of the drug(s) and what storage conditions are required?

Price

Will it be affordable to the target population or health system?

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4. Target Product Profile (TPP)

The academic literature and online sources can be used provide guidance as to what a TPP for a novel therapeutic or diagnostic might look like for a given indication.

Perspective | Open access | Published: 05 June 2024

Defining the next generation of severe malaria treatment: a target product profile

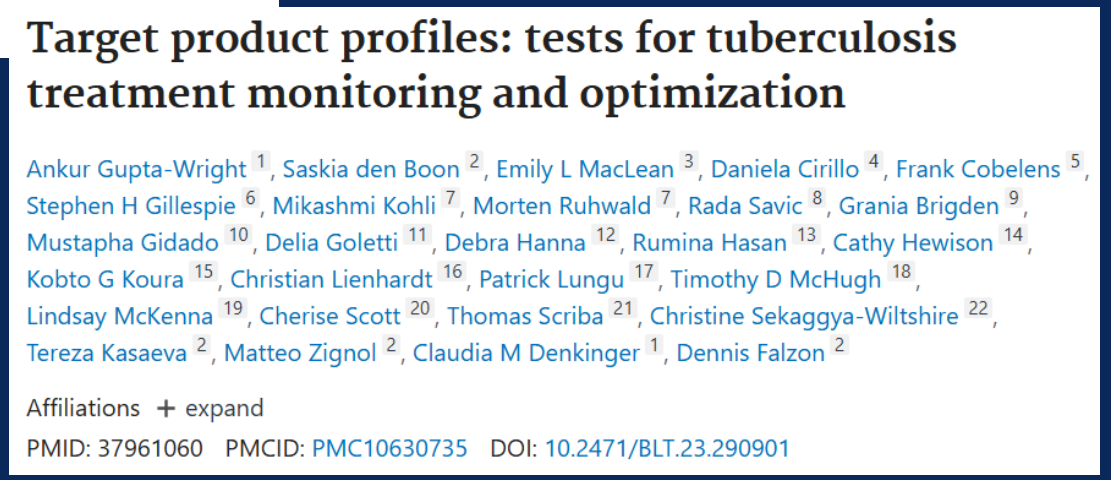
Jane Achan, Aïssata Barry, Didier Leroy, George Kamara, Stephan Duparc, Wiweka Kaszubska, Preeta Gandhi, Bénédicte Buffet, Patrick Tshilab, Bernhards Ogutu, Terrie Taylor, Sanjeev Krishna, Naomi Richardson, Hanu Ramachandruni & Hans Rietveld

Malaria Journal **23**, Article number: 174 (2024) | Cite this article

World Health Organization

TARGET PRODUCT PROFILE

for a **gambiense human African trypanosomiasis** test to identify individuals to receive widened treatment



Target product profiles: tests for tuberculosis treatment monitoring and optimization

Ankur Gupta-Wright [1], Saskia den Boon [2], Emily L MacLean [3], Daniela Cirillo [4], Frank Cobelens [5], Stephen H Gillespie [6], Mikashmi Kohli [7], Morten Ruhwald [7], Rada Savic [8], Grania Brigden [9], Mustapha Gidado [10], Delia Goletti [11], Debra Hanna [12], Rumina Hasan [13], Cathy Hewison [14], Kobto G Koura [15], Christian Lienhardt [16], Patrick Lungu [17], Timothy D McHugh [18], Lindsay McKenna [19], Cherise Scott [20], Thomas Scriba [21], Christine Sekaggya-Wiltshire [22], Tereza Kasaeva [2], Matteo Zignol [2], Claudia M Denkinger [1], Dennis Falzon [2]

Affiliations + expand

PMID: 37961060 PMCID: PMC10630735 DOI: 10.2471/BLT.23.290901

Source: DNDi ; WHO WHO HAT TPP Achan et al., 2024; Gupta-Wright et al., 2023

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4. Example TPP - HAT

Attribute	Desired (Ideal)	Acceptable (Minimal)
Mechanism of Action	- Multitarget - Cidal	- Unique target (but not uptake via P2-transporter only)
Efficacy & product benefit	- Effective against stage 1 and 2 - Broad spectrum (gambiense and rhodesiense) - Clinical efficacy > 95% at 19 month follow-up - Effective in melarsoprol refractory patients	- Effective against stage 2 - Effective against gambiense only - Clinical efficacy no worse than current treatments (define)
Safety and tolerability	- <0.1% drug related mortality - Safe during pregnancy and for lactating women - No monitoring for AEs	- 1% drug related mortality - Safe during pregnancy and for lactating women - Weekly simple lab testing (field testing)

Source: DNDi

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4. Example TPP - HAT

Attribute	Desired (Ideal)	Acceptable (Minimal)
Dosing / administration / regimen	- Formulation adapted to adults and children - < 7 days p.o. once daily (DOT) - < 7 days i.m. once daily	- Formulation adapted to adults and children - <20 days p.o. (DOT) - < 20 days i.m. - < 5 days i.v. if no toxicity
Delivery system / product presentation / market configuration	Stability in Zone 4 for > 3 years	Stability in Zone 4 for < 12 months
Pricing / cost of goods (COGs)	< 30€ / course (only drug cost)	< 100€ / course < 200€ / course ok if very good on other criteria

Source: DNDi

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5. Project plan

Proposed project:

- Project overview should outline the intended plan of work broken down into distinct work packages.

Work packages:

- A work package is a sequence of activities that leads to a key project deliverable/milestone.

- Each work package summary should include the duration and details of experimental design e.g. assays, sample types, power calculations etc. as well as milestone criteria.

- Milestones are a key component of the project plan – make sure they are clearly defined and measurable ‘SMART’ milestones.

Defined work packages and milestones are required as funding is often released in tranches, upon completion of the work package if the defined milestones are met.

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5. Project plan: SMART milestones

Specific: objectives should be specific and written in clear, concise and understandable terms

Measurable: measurable outcomes allow determination of delivery. Set realistic and justifiable success criteria: Target value range and acceptable (cut-off) values.

Achievable: objectives must be realistic – don't be too ambitious!

Relevant: tasks and deliverables must focus on progressing the project along an appropriate (critical) development path.

Timely (deadlines not durations): objectives should have a realistic timeframe with an end date assigned to them.

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5. Project plan: SMART milestones

Poor milestones	SMART milestones
Establish a primary screening assay that is fit for purpose	Primary drug screening assay established with transient cell transfection. Ideal: assay established in 384 well format with Z'>0.7 at month 6. Acceptable: assay established in 96 well format with Z'>0.5 at month 6
Evaluate hits from High Throughput Screen	Re-evaluate hits in single shot and full EC50 mode in primary assay. Re-confirmed hits ranked according to EC50 and chemical characteristics (see TPP for measurables). Completed at month 12.

Source: DNDi

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5. Project plan: SMART milestones

Poor milestones.	SMART milestones
Establish a primary screening assay that is fit for purpose	Primary drug screening assay established with transient cell transfection. Ideal: assay established in 384 well format with Z'>0.7 at month 6. Acceptable: assay established in 96 well format with Z'>0.5 at month 6.
Evaluate hits from High Throughput Screen	Re-evaluate hits in single shot and full EC50 mode in primary assay. Re-confirmed hits ranked according to EC50 and chemical characteristics (see TPP for measurables). Completed at month 12.

What are you going to achieve?

In what format?

What is the ideal and acceptable outcome measure of the milestone?

By when will you achieve the milestone?

Source: DNDi

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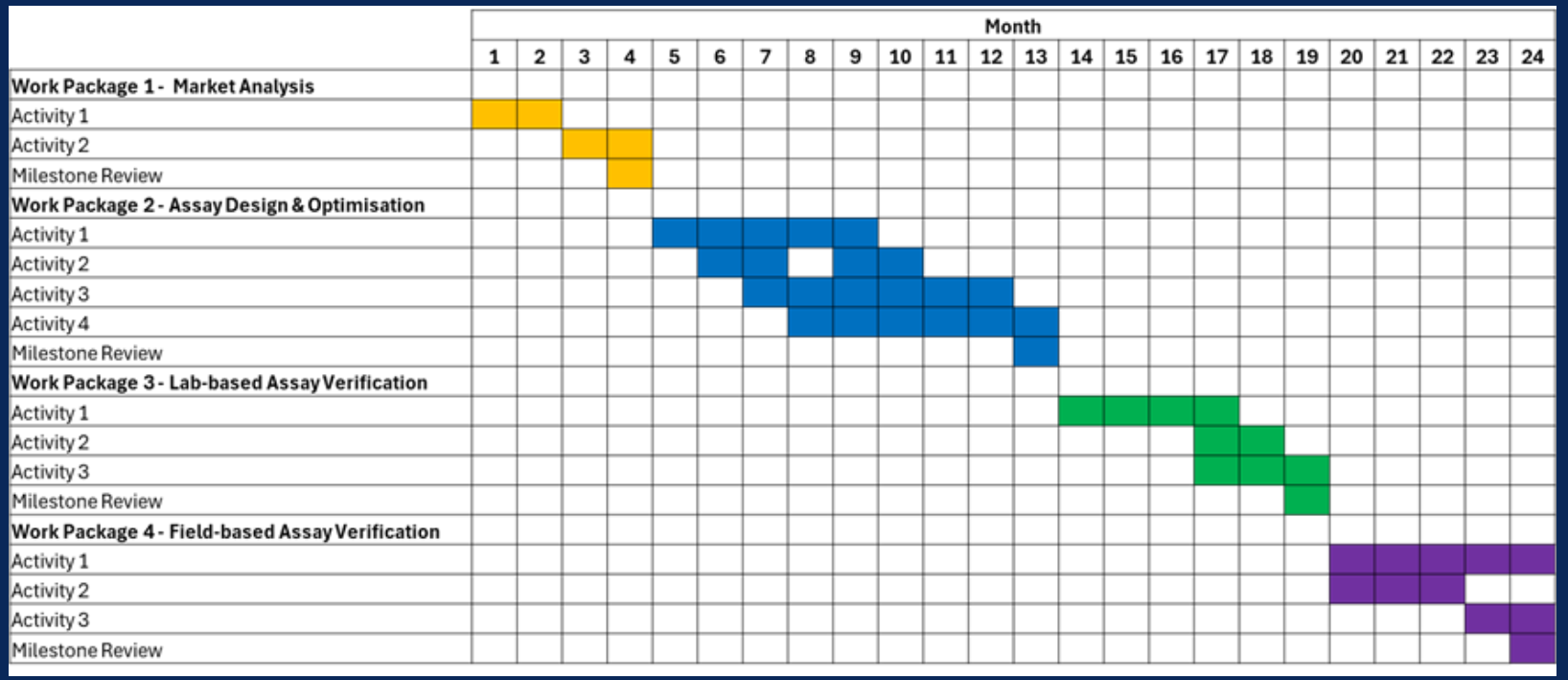
5. Project plan: Gantt chart

Gantt charts are often used to help reviewers understand the project structure.

Provides a visual representation of how the information flows between work packages, activities and milestones, and where key decision points are within the project.

Should include a timeline of all work packages and activities, milestones and go/no-go criteria



6. Deliverability: Resources

Consider and describe the resources that will be required to undertake and deliver the project:

- Tangible resources: may include specific cell lines, animal models, equipment, infrastructure.

- Collaborators: articulate the roles and responsibilities, skills and expertise of all collaborators involved in the project.

Are the resources and expertise required for the project in hand?

- If not, how will you go about obtaining the resources required for the project?
- What gives you confidence that they will be available when required?

Important to describe how the **scientific or clinical environment(s)** in which the research will be undertaken and the **resources and expertise available to you** will increase the chances of project success.

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6. Deliverability: Management

Consider how the project will be managed and what experience the team has of managing similar projects.

Are there any key risks to delivering the project that need to be considered?

- How likely are these risks to occur?
- What would the impact of these risks be on the successful completion of the project?
- How will these risks be managed?
- What mitigation plans will be in place?

6. Deliverability: Financial support

Include a summary breakdown of costs for each project milestone.

Some funders require a breakdown of funding by expense category and year, including for each collaborator on the project.

It is often required for quotes to appended to your application for outsourced work, which should include milestones and payment schedule.

Important to refer back to the eligible costs outlined in the funding call. Are all costs covered? Direct costs only?

7. Competition and IP

Funders want to understand:

- The competitive advantage your technology has over related technologies or other solutions currently in development which are intended to address the same problem you have identified.

- If there are any barriers, from an IP perspective, on the route to patient benefit.

The generation of protectable intellectual property is not always an essential requirement for translational funding, but a strong IP position may make your application more fundable.

What is Intellectual Property (IP)?

Intellectual Property (IP) refers to creations of the mind, such as inventions, literary and artistic works, designs, symbols, names and images.

Inventions are products or processes that provide a new way of doing something or offers a new technical solution to a problem that surpasses trivial solutions.

IP is protected by law, enabling people to earn recognition or financial benefit from what they invent or create.

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What is Intellectual Property (IP)?

Types of Intellectual Property include:

Patents

A patent is an exclusive right granted for an invention.

Patents benefit inventors by providing them with legal protection of their inventions.

Territory-specific.

WIPO

Trademarks

Legal protection for symbols, words or phrases that identifies and distinguishes the source of goods of one party from another.

Trademarks | USPTO

Copyright

Protects original works of authorship as soon as they are fixed in a tangible form of expression.

The owner has exclusive legal rights to copy, distribute, adapt, display and perform the work.

U.S. Copyright Office

Trade Secrets and Know-How

Trade secrets cover confidential (often commercial) information not generally known or readily ascertainable by others.

Know-how can be a form of trade-secret. Refers to practical knowledge, skills and expertise (that are not necessarily documented in a tangible form).

Trade secret

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Intellectual Property considerations

- Consider the background IP required for your project and the foreground IP that will be generated. *Is access to third-party owned patents, know-how (data/methods/compound structures), materials etc. required?*

- IP strategy needs to be a long-term consideration that extends beyond the current project. *How will your technology/IP be protected in the future?*

- Your IP and commercialisation plan needs to be considered in the context of plans for wider dissemination/publication of your research.

- Seek expert advice and support in preparing your grant proposal from your research and/or technology transfer/commercialisation office, where possible.

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8. Downstream development

Important to articulate a credible route to achieving patient impact:

Route to market

What is your strategy for achieving patient impact?

Further collaboration?

Partnering/licensing?

Regulatory and manufacturing consideration

Consider the regulatory pathway for approval.

How and when will you engage with the relevant National Regulatory Authorities?

Engagement of CROs for manufacture for clinical development?

Onward funding

Comment on plans for securing further funding for downstream development.

What are the potential sources of further funding?

Other deliverables

Consider other deliverables such as knowledge generation and dissemination and how this aligns with your IP strategy.

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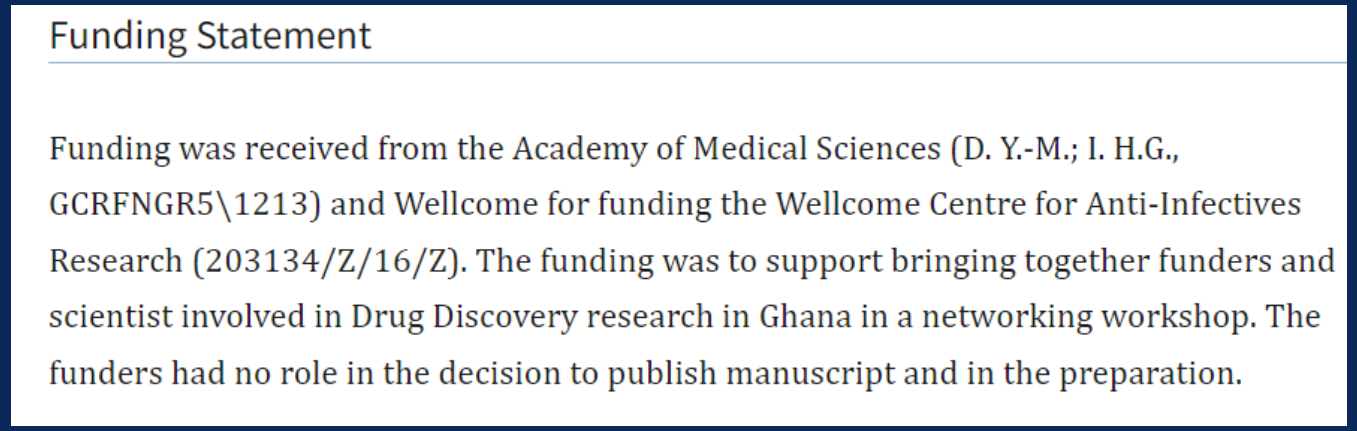
Post-award considerations

Successfully applying for, and receiving, grant funding is just the start…

- Contracting – takes time!
- Project and stakeholder management
- Reporting requirements
- Acknowledge sources of funding in publications resulting from the project



Funding Statement

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Amewu RK et al., 2022

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Summary

Top tips for success: project

Understand the unmet medical need

Consider current clinical pathway and the added value of the technology.

Deliverability

How will the project be conducted and by who?

Project team must contain all necessary expertise.

Success criteria and milestones

Incorporate clear, achievable SMART milestones

Articulate the rationale

Why will your solution work?
TPP should link the need to the rationale.

Route to patients

Access to future funding?
Competition?
IP and downstream development

Top tips for success: proposal

Craft a compelling narrative

Be concise and clear to convey the importance and potential impact of your project

Develop a clear and realistic budget

Align costs to key milestones and justify with clear explanations.

Ensure budget aligns with project scope

Avoid inflating costs or including unnecessary expenses.

Review and edit for clarity and coherence

Clear, concise, coherent.
Seek feedback on narrative.

Submitting a polished and professional proposal

Double check submission guidelines before pressing send.

Thank you for listening!

lifearc.org

Laura Stennett (Quarcoopome) PhD