University of Oxford

Medical and Life Sciences Translational Fund

Applicant Guidance for Case for Support application form

Projects will be scored from **0-9 (0=lowest; 9=highest)** based on their potential for transition from discovery research to translational development through preliminary work or feasibility studies. Please refer to the '**What are the panel looking for?' hints under each section of the case for support form** when completing your application.

Panel scores and definitions

Score	Score definitions
9	The application is **exceptional**; it **very strongly** meets all of the assessment criteria to the highest standard. The panel agrees that it is difficult to articulate how the application could be improved.
8	The application is **outstanding**; it very **strongly** meets all of the assessment criteria.
7	The application is **excellent**; it **strongly** meets all of the assessment criteria.
6	The application is **very good**; it meets the assessment criteria **well but with some minor weaknesses**/limitations.
5	The application is **good**; it meets the assessment criteria well but with **some clear weaknesses/limitations**.
4	The application is **adequate**; it meets the assessment criteria but with clear weaknesses/limitations.
3	The application is **weak**; it meets the assessment criteria but with **significant weaknesses**/limitations.
2	The application is **poor**; it meets the assessment criteria but has **major weaknesses**/limitations.
1	The application is **unsatisfactory**; it **does not meet one or more of the assessment criteria**.
0	The application is **unsatisfactory**; it **does not meet any** of the assessment criteria.

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Reviewers are asked to consider the following criteria when assessing your project(s):

- **Strength of rationale and quality of science**
  Objective and Approach: Is the proposed approach an effective way of meeting the plan's objectives and is it based on a good scientific rationale? How innovative is the plan, or is it a tried and tested approach? Is the preliminary data promising and robust?
- **Unmet need or translational opportunity**
  Is there a clear unmet need, translational challenge or opportunity being addressed? For proposals within the Translating Biosciences Research strand, references to clinical impact and unmet medical need should be interpreted in the context of the relevant biosciences sector, user community, industry need or area of application.
  If the need is not significant now, will it become so in the future? Would addressing this need provide significant clinical, scientific, societal, agricultural, industrial or commercial benefit and/or alleviate an important development bottleneck?
- **Project planning and execution**
  Project Plan: Does the plan propose reasonable go/no-go milestones? Do the milestones follow the SMART principle? Are the milestone timings appropriate and are the success criteria necessary and sufficient to judge progression? Are the proposed probabilities of milestones being met reasonable?
  Project and Risk Management: Do the applicants have or likely will have the necessary project management experience to deliver the plan? Has the individual or group established a high-quality track record in the field? Does the applicant have the relevant team/expertise in place to deliver the proposed milestones?
  Resource requirements, deliverability and Environment: Has the team identified and secured reasonable access to necessary resources/skills? Has the applicant recognised appropriate stakeholders (such as industry partners and key academic collaborators) to contribute in propelling the translational activity of the project? Is the budget realistic for the scale and complexity of the project? Have the applicants set out a clear and reasonable case for the requested levels of staffing and overall resources?
- **Future commercial opportunity or potential clinical, societal or global health impact**
  Competition and market: Have the applicant identified the key competing solutions and their status or are they aware of other similar or complementary research underway elsewhere? Has the applicant identified the key competitive advantages/USPs of their proposed solution? Is the cost higher than for competing solutions? Have safety and tolerability been considered? How likely is it that the proposed solution, if achieved, would be widely adopted?
- **IP position**
  Intellectual Property**:** Is there an appropriate intellectual property strategy in place to optimise the chances of downstream funding/partnering and ultimate exploitation? Is the research academic-led where industry is involved?

- **Downstream project planning/support:**
  Likelihood of developing a full proposal to be submitted to the MRC DPFS award scheme, or similar follow-on funding schemes, within the required timescale and budget.

  Does the applicant have a clear plan towards clinical impact, practical application and/or commercialisation following completion of MLSTF?

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It is highly recommended that you watch the following training videos before applying:

- Tips for MLSTF Applicants
- The Winning Translational Grant Application: What the Reviewers are looking for?
- Entrepreneur in Residence Masterclass Series 2022
- Intellectual Property

Confidential and non-confidential lay summary

Please refer to the following sources to produce a clear, succinct and impactful lay summary:

- https://www.nihr.ac.uk/documents/plain-english-summaries/27363
- https://www.medsci.ox.ac.uk/for-staff/resources/translational-research-office/news-training-events/tips-for-mlstf-applicants

Case for support form

SECTION 1.1: Scientific Justification and Project Developmental Plans

What are the panel looking for?

Please use this section to include additional information that is not already in the confidential/ non confidential summary

Please include scientific background information and justification such as:

- The unmet clinical need, translational challenge or sector-specific need addressed by the project,
- Background data and progress to date,
- MLSTF project objectives, milestones, go/no-go success criteria and proposed end-point outcomes.
- Next steps in the development plans post MLSTF

For applications submitted through the Translating Biosciences Research strand, references to clinical need should be interpreted in the context of the relevant biosciences sector, user community, industry need or area of application

You will need to append the following as separate PDFs:

- Supporting data and information (figures / tables) (1 page maximum)
- A comprehensive Gantt chart on the milestones and timeline of your project (1 page maximum, see link to an example at the end of this form)

Additional TRO training resources:

- The Milestone Mindset in a Translational Funding Application

SECTION 1.2: Please list the key risks to delivering the project

What are the panel looking for?

Please list the key risks associated with the project and describe:

- The likelihood of each risk occurring during the course of the project (unlikely–highly likely)
- The potential impact of each risk on the successful completion of the project (low, moderate or high)
- How the risks will be managed and what mitigation plans will be put in place

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SECTION 1.3: To be completed if your project involves significant use of AI

What are the panel looking for?

Significant use of AI in an MLSTF project refers to the integration of artificial intelligence as a core enabling technology that fundamentally shapes the project's functionality, development and value proposition. AI should therefore represent a major component of the proposed innovation rather than an additional or supporting feature.
Please provide the following information:

- A clear intended use statement, including the target users, beneficiaries and anticipated impact.
- A description of the data used to develop, train, validate and/or operate the AI component of the project.
- A description of the AI methods, models or tools being used, including the rationale for their selection.
- Details of how model performance, robustness and reliability will be assessed, including any training, testing and validation strategy, where applicable.
- Details of any third-party software, code, models or datasets used within the project and any associated permissions, licences or restrictions.
- A description of any innovative elements of the AI approach and how these contribute to the translational objectives of the project.

For projects involving AI-enabled bioscience tools, data-intensive bioscience, engineering biology, imaging technologies or other non-clinical applications, responses should be provided in the context of the relevant area of application.

Additional TRO training resources:

Applicants are strongly encouraged to undertake the TRO Masterclass in AI and Digital Health before completing this section. The Masterclass provides practical guidance on preparing AI-focused translational funding applications and includes resources that may assist with responding to the questions in this section.

• **Masterclass in AI and Digital Health:** https://canvas.ox.ac.uk/courses/295372

SECTION 2: Competitiveness of the approach

What are the panel looking for?

Please include a discussion around market competition such as;

- Will the proposed research offer significant advantages over current methodologies and which are the main competitive solutions?
- Academic and industry solutions should be considered for this discussion

Additional TRO training resources:

- Understanding the market size and opportunity of your technology

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SECTION 3: Industry engagement

What are the panel looking for?

- If you have an existing industrial collaborator, please provide details of the collaboration and describe the partner's contribution to the project. Please also describe any formal research collaboration agreements that are in place.
- If discussions with industry are ongoing, please provide details of the organisations involved and any interest expressed in the proposed technology, product, service or approach
- Please describe any planned future engagement with industry and how this may support the translational development, adoption or commercialisation of the project.
- Have you had any involvement with a University of Oxford spinout company, such as holding a position, equity or other interests? If so, you are required to provide details of an appropriate conflict management plan to enable governance review.

SECTION 4: Regulatory management

What are the panel looking for?

Have you consulted with the appropriate regulatory body/ies (e.g. MHRA) or another relevant regulatory expert?

If so, please summarise the outcome of the discussions; if not, please summarise why this is not necessary at this stage

Additional TRO training resources:

- Effective Regulatory Strategies

SECTION 5: Data Management Plan

If you have ticked 'Yes', please state:

How will data generated, collected or acquired through the proposed research be stored, managed, protected and, where appropriate, shared? Please describe any relevant data governance, anonymisation, confidentiality, access management or security arrangements.

Please provide a data management plan that clearly explains how you will comply with the University's published data management policies and any other relevant legal, ethical, regulatory or contractual requirements.

SECTION 6: Justification for support

What are the panel looking for?

What resources (e.g. models, equipment, infrastructure, datasets, specialist expertise or external partnerships) are required to undertake the proposed project?

Why is the MLSTF scheme an appropriate scheme for your proposal?

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SECTION 7: Sources of matched funding

What are the panel looking for?

Please provide examples of sources that could include: Industry cash or in-kind, internal/external awarded grants, Departmental support.