



# Guide to submitting your diagnostic development application

Background on MRC Technology



The benefits of collaborating with MRC Technology



What MRC Technology looks for in a diagnostic development project



**MRC Technology has an outstanding reputation as a commercial partner**

**Working with our expert teams, and our state-of-the-art resources**

## **MRC Technology**

### **Introduction**

MRC Technology ([www.mrctechnology.org](http://www.mrctechnology.org)) is an independent life science medical research charity, offering professional services to organisations within the academic, charity, biotechnology and pharmaceutical sectors globally.

MRC Technology bridges the gap between basic medical research and commercialisation, helping early discoveries progress to clinical application. To date MRCT have generated over £700 million which has been used to fund further research.

### **Links with industry**

Our IP and expertise has been acquired by all of the world's leading pharmaceutical companies and we have participated in the creation of 18 start-ups including the UK's largest and most successful biotech companies, CAT, UCB-Celltech and more recently BiCycle Therapeutics.

We have helped industry develop many healthcare treatments including Keytruda®, Avastin®, Actemra® and Tysabri®, with many more in the pipeline.

### **Collaborations**

We are currently seeking collaborations with academic organizations, SMEs and industrial partners from all over the world.

Collaborators will be able to work closely with our scientific experts and will be part of the team as projects progress.

This is a truly collaborative model and any research tools, value or income generated will be accessible by researchers or shared with your organisation.

## **Gain access to**

### **Our expertise & facilities**

MRC Technology's diagnostics laboratory in Edinburgh is focused on collaborative diagnostic assay development and validation in either a biotechnology/drug discovery or a platform setting.

Our teams of scientists have expertise in diagnostic assay development under a compliant controlled environment, medicinal chemistry and pharmaceutical company drug discovery expertise.

We will progress diagnostic opportunities towards pre-clinical proof of concept thereby mitigating the investment risk to industry.

- ***Diagnostic assay development specialists with expertise in an array of disease areas and detection technologies***
- ***Assay development to industry quality standard***
- ***Robust assay development, standardisation and validation***
- ***Customised assay development tailored to a specific platform***
- ***Scientific and clinical network***
- ***Quality management***
- ***Dedicated project management***
- ***Business development to commercialise your opportunity***
- ***Potential tools for research use***

# What MRCT looks for in a diagnostic development project

## Key criteria

### Technology Readiness

MRCT develops diagnostic assays against defined molecular targets. Ideally the components to develop the diagnostic assay will be available e.g. oligonucleotides, proteins and test samples.

### Novelty

MRCT develops diagnostics against novel targets or targets where a novel assay offers clinical benefits like higher sensitivity. We are interested initially in RNA/DNA-based diagnostics.

### Unmet medical need

MRCT will consider any disease area, providing there is unmet medical need. However, currently priority will be given to those diagnostics in the areas of oncology, infectious disease and precision medicine.

## Contact Us

If you have a diagnostic assay you think may be suitable for inclusion in our programme please do not hesitate to contact our dedicated team. They will also be able to arrange 1-1's with a member of our scientific team to discuss your application.

#### Email

[diagnostics@tech.mrc.ac.uk](mailto:diagnostics@tech.mrc.ac.uk)

#### Telephone

0131 311 7029

#### Application Forms

[www.callfordiagnostics.org](http://www.callfordiagnostics.org)

Further information on MRCT and our core services is available on our website: [mrctechnology.org](http://mrctechnology.org)

## Other considerations

### Market need

It is important to understand how the diagnostic test will lead to an improved clinical outcome. The resulting assay must also address a market need and have a unique position over other similar tests in the field.

### Target validation

Data that shows clinical significance of the analyte target is desirable. If data is emerging then a proposed mode of action and rationale regarding how the target fits with clinical utility is desirable. In addition, clarity around the target sensitivity required to perform clinically meaningful tests is needed.

### Access to reagents and controls

Reagents, controls and test material required to develop the assay should be readily available. To that end, sources of materials at scale are desirable. Ideally, these will include binding molecules, reporter systems, controls, clinical samples and sources of purified analyte.

### Team

Understanding the extent and experience of your in-house team will help us identify what gaps (if any) will be required as the project progresses through to a commercial end point. In addition understanding whether any members of your team would be involved in transferring the technology through the development life cycle or involved in subsequent business development or technical sales.

### Freedom to operate

MRCT will carry out searches of the relevant intellectual property around the proposed diagnostic target (including reagents and assays) and other markers against the clinical condition. It is important that MRCT and our collaborators have the necessary freedom-to-operate before commencing a diagnostic development project.

### Potential to generate protectable intellectual property

It is important that there is existing IP protection or the potential to generate patentable IP around the relevant diagnostic assay or target analyte developed under the program.

### Partnerability

MRCT has the capability to progress diagnostic assay development projects to the point of demonstrating clinical utility and early clinical validation. We then seek to identify a partner to progress this further.

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