

**BUSINESS CASE TEMPLATE**

**Version 4**

**September 2020**

**Business case format**

In order for the Cheshire and Warrington Local Enterprise Partnership (LEP) to appraise funding proposals, all Promoting Organisations applying for funding from the LEP are required to complete this Business Case. The template is based on the Government’s Green Book appraisal process and allows for a transparent, robust and consistent assessment of all applications for funding over £100k.

This template should be completed in accordance with the guidelines laid down in the HM Treasury’s Green Book. [https://www.gov.uk/government/publications/the-green-bookappraisal-and-evaluation-in-central-governent](NULL)

For projects seeking less than £100k, there is a “business case light” which should be used.

The form comprises seven sections: -

A: Project Overview

B: Strategic Case

C: Economic Case

D: Financial Case

E: Management Case

F: Commercial Case

G: Sustainability and Inclusivity Case

H: Evidence and Supporting Information

Please complete the form as fully as possible ensuring that all information requested is included. If there are elements that you are not yet in a position to complete please indicate clearly when this information will be available.

Where additional information is requested, such as location maps or Gantt charts, please supply these as separate documents or files, rather than attempting to embed them within this form.

Additional information may be requested for projects seeking funding from specific streams. Details will be provided in the call for projects.

**Note that all project proposals must align to the priorities identified within the LEP’s Strategic Economic Plan.**

On completion, please return the form to the LEP as instructed in the call process which will be published on the LEP website.

1. **Decision Making Process**



**Section A: Project Overview**

This section asks you for basic information on your Project, including a brief description, type of Project, Project location and contact details for further information.

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| **A1: Project Name** | **MDC Validation Centre of Excellence** |
| **A2: Promoting Organisation** | ***Name of Organisation:***  Medicines Discovery Catapult Limited |
| **A3. Accountable Body** | ***Please provide details of the project’s Accountable Body (if different from the Promoting Organisation)***  As above |
| **A4: Contact Details** | ***Please provide BOTH the contact details for the project manager and for the person who will be responsible for signing the contract if a grant offer is made:***  ***Project Manager:***  Name: David Moore  Tel: 01625 708416  Email: david.moore@md.catapult.org.uk  ***If offered a grant, please confirm the name and role of the person who will sign the contract, along with the registered company address:***  Name: Chris Molloy  Role: Chief Executive Officer  Registered company address: Mereside, Alderley Park, Alderley Edge, Macclesfield, Cheshire SK10 4TG |
| **A5: Project Description** | ***Please give a brief description of your Project and specifically what the funding is being applied for:*** *(in no more than 100 words)*  There is a desperate need for validation and commercialisation of infectious diseases innovations that require dedicated facilities, facile access for C&W SMEs and trained experts. Capitalising on the success of the Lighthouse Lab, we propose to create a new Validation Centre of Excellence for innovative diagnostics, biomarkers and complex medicines and develop the UK’s onshore diagnostic capability and capacity and the associated supply chain. The project will create a Biosafety Level-3 (BSL3) laboratory and national facility for testing and validation of new diagnostics, biomarkers and innovative therapeutics for disease, particularly highly infectious pathogens, including respiratory viruses such as COVID-19. Our proposal will enable retention of the newly created diagnostics talent pool from AP Lighthouse, as well as attracting new businesses into the C&W area. |
| **A6: Total Project Cost** | ***Please indicate the total cost of your project broken down between capital and revenue:***   |  |  | | --- | --- | |  | ***(£k)*** | | Capital | 6,125 | | Revenue | 5,240 | | **Total** | **11,365** | |
| **A7: Funding Requested from the LEP** | ***Please confirm the total amount of funding being requested from the LEP***  £5,050,000 Percentage 44.4% of total project costs  **Please state which fund you are applying to if known:**  MHLCG Getting Building Fund |
| **A8: Details of other funding sources** | ***Please detail other funding sources and their status and any constraints:***   |  |  |  |  | | --- | --- | --- | --- | | **Funding Source** | **Amount (£k)** | **Secured y/n** | **Constraints** | | MDC | 1,075,000 | y | Operational costs and equipment for build out | | MDC | 5,239,610 | y | Operational costs 5-years post-build, offset by income | | **Total** | **6,314,610** | **y** |  |   We also anticipate an additional in-kind contribution from Alderley Park Limited in the form of costs related to the strip out and preparation of the lab space. In-kind costs are equivalent to approximately **£900,000**. |
| **A9: Proposed start and finish dates** | ***Please state when you intend to start the project, the duration and the proposed finish date. In the management case you will be asked to provide more detailed milestones:***  **Proposed construction start date:** 01/08/21  **Proposed construction finish date:** 31/09/21 (14 month duration)  **Proposed operation start date:** 01/10/21  **Project finish:** 31/03/27  Please ensure you have noted any specific deadlines associated with the funding you are applying for and that the project can be delivered within these timescales.  ***You should allow a minimum of 3 months from the submission of your application for a funding decision.*** |
| **A10: Project location** | ***Please provide a short description of area covered by the Project*** *(in no more than 100 words)*  The project is based at Medicines Discovery Catapult at the Mereside Campus, Alderley Park.  Alderley Park is currently undergoing a £247m investment. The Park offers more than 1m sq. ft of high specification lab space, a range of scientific services and an accelerator delivering a comprehensive programme of business support for start-ups and scale-ups. It is also home to a vibrant and fast-growing community of over 60 established and 150 pre-start-up companies.  The newly re-developed 150,000 sq. ft ‘Glasshouse’, opened in February 2020, offers high specification, collaborative workspace to tech companies and forward-thinking, innovative businesses.  ***Please supply a location map and where possible a map showing the site boundary (and Mapinfo Table(s) where available).*** *If possible please highlight existing transport infrastructure and other points of particular interest to the bid e.g. development sites, areas of existing employment, constraints etc.*  **Site Map:**    **Alderley Park:**    **Transport Links:** |
| **A11: Project Type** | **Life Science** |
| **A12: State aid** | ***It is the applicant’s responsibility to confirm that any grant offered would be state-aid compliant.*** Further advice can be found here: [https://www.gov.uk/guidance/state-aid](NULL)  Please state whether the grant if offered would be state-aid compliant and the basis for your assumption:  MDC is a research organisation (RO) as defined in the European Commission's Framework for State aid for Research and Development and Innovation ("R&D&I Guidelines" – 2014/C 198/01 [section 1.3 para ee]). The R&D&I Guidelines allow State funding to be supplied to ROs without qualifying as State aid essentially because an RO is not considered an economic undertaking for State aid purposes (for its core activities of R&D, collaboration, dissemination and knowledge transfer). |

**B: Strategic Case**

This section should set out in more detail the rationale for making the investment and evidence on the strategic fit of the Project.

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| **B1: Policy Fit** | ***Please state how the project fits with Local, Regional and National Policies:***  **Local:**  In alignment with the C&W SEP and draft LIS, this proposal will elevate Alderley Park as an outward-facing location providing businesses with both practical and advisory support, further building on Alderley Park’s reputation as a place where innovation is encouraged to grow and flourish.  One of the early priorities of the C&W Local Industrial Strategy is to accelerate the discovery and development of new products (therapeutics and diagnostics) through the creation of a Centre of Excellence at Alderley Park with the Catapult. Working with MDC, there is an opportunity for C&W to deliver on this priority and to support innovators from SMEs and academia, to create new products and new jobs at Alderley Park. The proposed Centre of Excellence will nurture and sustain innovation and economic growth.  Additionally, the draft LIS predicts that the professional, scientific and technical activities sector could, following efforts to boost productivity, contribute to the largest single-sector economic boost of £1.1bn. The Centre of Excellence provides a fantastic opportunity to contribute to this economic boost through its ability to increase sector productivity, both through its development of the UK’s onshore diagnostic capability and as a centre for innovative diagnostics, biomarkers and complex medicine development. Importantly, this will address the issue of skills mismatch and ageing population the local area faces through attracting young, skilled graduates to the area and allowing them to develop fruitful well-paid scientific careers.  Moreover, this proposal aligns with the C&W SEP in its plan to upgrade infrastructure, with a view to meet future national and international demands from industry and consumers in a reliable and affordable fashion, all the while continuing to support the Science and Innovation sector so crucial to the local area.  **Regional:**  The Northern Powerhouse is an internationally recognised globally competitive and thriving economic area, with a huge ambition for growth and significant untapped potential. The proposed Centre of Excellence will supplement the Northern Powerhouse through encouraging additional national and international investment and expanding on job creation. Attracting additional scientific talent to the North will help to drive productivity, boosting the region’s economic growth and securing a platform for continued innovation. This will be a significant step towards addressing the issues of talent retention, as described by the Northern Health Science Alliance. Although our educational institutions deliver a strong talent pipeline, we need to improve retention rates by offering good career development opportunities, achieved by growing our significant economic clusters around Leeds, Liverpool, Manchester, Newcastle and Sheffield.  The proposed Centre of Excellence will serve as a significant boost to both the Manchester and Cheshire’s Life Science corridor and the Liverpool City Region’s Health and Life Sciences economic clusters, complementing the Northern Powerhouse’s plans for continued development towards a supportive business environment and innovation in the Life Sciences.  The Strength in Places Fund (SIPF) is a UKRI pathfinder programme that invests in research and innovation projects to boost research and innovation capacity in specific areas of the UK, in order to drive economic growth in those areas. It does this by funding consortia of research organisations, businesses and local leadership, to do research and innovation that will have an impact on local economic growth.  Wave 1 funded projects include the University of Liverpool-led consortium – Delivering Integrated Solutions for Human Infections (SIPF investment: £19m). Based in the Liverpool City Region and Cheshire and Warrington, this academia/industry/NHS North West consortium will deliver integrated solutions for human infections. It will boost economic and regional productivity by creating eight specialist, commercially sustainable research platforms for infectious disease therapeutics in north-west England that transform the efficiency of new product discovery, development, evaluation and impact assessment. The project will generate jobs and value for the Liverpool City Region and Cheshire and Warrington and attract substantive international investment. The MDC Validation Centre of Excellence is highly complementary to this programme and will support and validate the outputs from the Liverpool SIPF award.  **National:**  **UK Industrial Strategy**  The Industrial Strategy aims to boost productivity by backing businesses to create good jobs and increase the earning power of people throughout the UK with investment in skills, industries and infrastructure. The validation centre will do this primarily in the north west by retaining lighthouse lab employees, creating more jobs (for the construction and the running of the facilities) and increasing GVA within the C&W area. The facilities themselves will enable research into restricted class 3 pathogens, streamlining the process of benchtop to market, improving the diagnostic sector within the UK and the SMEs who work in this area.  COVID-19 Bounce Back  The COVID-19 diagnostics screening in MDC Lighthouse Labs is one example of a high profile, national diagnostics programme. Accurately identifying disease is critical to early intervention and better treatment outcomes. We will build on the success of Lighthouse Labs by creating a centre in which innovative companies with novel biomarker ideas can validate and underpin the science, by testing their concept on otherwise inaccessible patient material, in a high protection lab environment, with access to key technologies. The Validation Centre will enable them to create commercially and clinically validated diagnostic tools to bring rapidly to market and support the bounce-back of UK industry.  ISCF – Accelerating Detection of Disease  The accelerating detection of disease challenge was set up to address the issue of late diagnosis and poor survival rate of chronic diseases. It aims to establish a 5-million strong volunteer cohort offering support to researchers looking to improve the early detection allowing the prevention or early intervention, of chronic diseases in individuals before any symptoms present using AI and data. This challenge and the validation centre will complement each other. The validation centre offering validation of the suggested treatments from the challenge, allowing faster time to patient and the challenge providing access to potential 5 million volunteers for biobanking resources.  UKRI R&D Roadmap – Levelling  In Alignment with the UK Research and Development Roadmap, this proposal will significantly contribute to R&D “levelling up” of the North-West region. This will have the greatest improvements in the regions of Liverpool and Warrington, as UKRI analysis describes these as medium and low level respectively. Moreover, this project further fulfils the levelling up criteria by providing both tailored support for these regions (academic proximity to commercial/start-up infrastructure) and facilitating R&D interventions that are in concert with wider national goals.  Wellcome Trust Global Health Challenges  As announced on the 19th of October, 2020, the Wellcome Trust, is enlarging its focus to include goal-oriented, as well as basic research. The London-based philanthropy, which spends more than £1 billion per year, said today it will boost funding for research on infectious diseases, the health effects of global warming, and mental health. As part of the refreshed strategy, Wellcome will spend more money on researching neglected tropical diseases and pushing for “clinical trials with greater participant diversity.” It also hopes to make an impact in new areas. The Wellcome Trust has huge sway in the UK research system, and in a sense, where Wellcome moves, others follow. Given the Wellcome Trust’s focus on Infectious Disease, the proposed Validation Centre and BSL3 facility are very timely from a policy perspective. |
| **B2: Need for intervention** | ***What are the current problems or market failures to be addressed by your Project? Describe any economic, transport, skills, environmental, social problems or opportunities which will be addressed by the Project. Please provide quantitative examples of how the problems will be addressed by your Project.***  (Limit: 1 side of A4).  The UK is facing an economic shockwave due to COVID-19, with the OECD predicting the UK to suffer the worst economic damage of any country in the developed world. Between March 2020 and April 2020, GDP fell by 20.4%, equivalent to a fall of approximately £30 billion in Gross Value Added. The monthly decline in GDP in April 2020 was three times greater than the fall experienced during the 2008 to 2009 Global Financial Crisis (-6.9%).  The UK is currently at COVID-19 alert level-4 (a high or rising level of transmission). As the economy opens up, businesses and schools reopen, workers return, the productivity and economic recovery of the UK will be increasingly reliant on government-led initiatives in diagnostics, such as the UK Lighthouse Labs Network. Long-term, it is hoped that new therapeutic developments and vaccines will offer a return to normality (or close to normality).  However, many new vaccines, diagnostics and therapeutic strategies require access to BSL-3 facilities and specific technical expertise in respiratory pathogens and assay development. Unfortunately, despite there being numerous lab facilities around the country, the majority are based within the NHS, universities or large pharma, and none are equipped or set up to support UK SMEs in a facile manner. A recent Science Signalling commentary (DOI: 10.1126/scisignal.abe4242) also highlights this issue in the UK’s response to COVID-19, and points out in particular, “the lack of appropriate biosafety facilities”.  Due to the unprecedented nature of the pandemic, evidence in this burgeoning area of demand is scarce, but reports are now starting to highlight the UK’s lack of facilities and expertise (see Section H2). During the first wave of the COVID-19 pandemic, MDC was inundated with SMEs nationally that were unable to access these facilities and expertise. To date, there has been no government led attempt to build such laboratories and a clear supply/demand issue, which must be addressed, remains.  We have provided three letters of support demonstrating the need and demand for the project regionally. University of Manchester has a backlog of at least 20 projects that urgently need access to a facility and expertise, as we propose. Evotec explored building their own facility at Alderley Park, but could not balance the commercial risk short-term – we are in discussion with Evotec around occupancy of two of the six proposed BSL-3 labs. Infex Therapeutics have a number of programmes that will make use of the facility and bridge to initiatives ongoing at Liverpool School of Tropical Medicine.  The C&W area accounts for 14% and 3% of all life sciences employees in the Northern Powerhouse and England, respectively. Combined, these companies have raised £62M since Jan 2011, have an estimated employee count of 614 and a reported turnover of £82M. COVID-19 has impacted almost 50% of these companies, putting at risk over 250 jobs and an annual turnover of > £20M. A number of these companies have pivoted into COVID-19 related research and commercial initiatives, and will also require access to labs and expertise.  Our intervention – to build a BSL-3 Validation Centre of Excellence – addresses the need and demand three-fold:   1. Supporting innovative companies, both in C&W and nationally, to validate new technologies without the requirement for surrogates or pseudoassays will enable more robust validation and faster speed to market. 2. By establishing a facility to support new diagnostic development and therapeutic screening, we will move faster towards new solutions that enable a return to normality (for example point of care diagnostics, better therapeutics). This will result in a return to productivity in the region and a strong ‘v-shaped’ economic recovery. 3. Long-term, a facility is needed to support industry in tackling the threat of other highly infectious/dangerous pathogens, such as TB, AMR, future SARS/MERS outbreaks, or even the bubonic plague, as recently seen in Mongolia/China.   **Long-term, our BSL-3 Validation Centre of Excellence will support the future of R&D in infectious disease and establish the NorthWest as the leading infectious disease R&D cluster in the UK.** |
| **B3: Objectives of the project** | ***What is the project seeking to achieve and what are the current arrangements?***  This Life Science project proposes to build a new Validation Centre of Excellence for innovative diagnostics, biomarkers and complex medicines. The project objectives are to:   * Increase by 2022 the UK’s diagnostics testing capacity through the development of a new national category 3 facility; * Support 45 businesses’ innovations to commercialisation by 2027; * Increase regional net additional GVA by £11.8m by 2027; and * Create 24.5 new addditional high value jobs in the region by 2027.   The Centre will contain:   |  |  |  | | --- | --- | --- | | State-of-the-art biomarker, bioimaging and pathology equipment scarcely available to new spin-outs and SMEs | A Biosafety Level-3 facility to enable testing/validation/screening using rare virology assets and high-risk patient biosamples | Biobanking facility, which will enable innovators to access disease materials safely and ethically, creating a nationally prominent resource for innovators working on COVID-19 diagnostics and next-generation medicines |   In supporting the region's innovators through this new Validation Centre of Excellence, we will create a runway for regional investment and growth in life sciences. Future development of this Centre could also lead to small-scale manufacturing; this would not be within the time scale of the current funding window but would add high-volume job creation. |
| **B4: Future LEP Challenges / Opportunities Addressed by Project** | ***Are there any problems you have identified that will occur in the future that your Project is intended to address? (e.g. congestion, road safety, access to services and opportunities, skills shortages, climate change etc.).***  (limit: 1 side of A4)  Our project addresses a number of future challenges and opportunities:  **Access to samples for SMEs**  A recent study carried out by MDC showed that 90% of SMEs that were asked had struggled to access patient samples and/or data, having a huge effect on their ability to carry out their projects and get their innovation to market. This was further noted during the height of the COVID-19 pandemic when we were inundated with requests for COVID-19 patient samples. The biobanking facilities that the validation centre will enable innovators to access disease materials safely and ethically, creating a nationally prominent resource for innovators working on COVID-19 diagnostics and next-generation medicines.  **Retraining for skilled jobs**  Similar to the lack of infrastructure, supply chain and diagnostics industry, the UK suffered from a severe skills shortage in diagnostic assay development and qualified biomedical scientists. In January 2019, the Association of the British Pharmaceutical Industry (ABPI) published a report on the UK skills gap:  “The UK is falling behind Europe and the rest of the world in terms of numbers of students studying many STEM subjects vital for discovering the advanced treatments and technologies of the future.”  Along with skills shortages, Brexit also represents a critical threat to job growth in the UK, in an industry which invests significantly more in R&D than any other sector.  Our Validation Centre of Excellence will work alongside the Alderley Park based Lighthouse Lab, which is recruiting up to 1,000 new scientists, to support, train and upskill the work force.  Additional broader challenges are expected:  **COVID-19 re-emergence**  COVID-19 reached the UK in late January and the country endured a three-month long lockdown from March 23 to get the virus under control. Every region of the UK has been affected, with London facing the biggest peak initially. Despite falling cases nationwide, on June 29 Leicester became the first city in Britain to be plunged back into lockdown after public health officials expressed alarm at a significant rise in positive COVID-19 tests.  Since then, a number of regions have been placed back into local lockdown following a spike in cases, as the virus threatens a second wave. Furthermore, newly emerging mutations have been shown to affect transmission of the virus, with significant implications on diagnostic, therapeutic and vaccine design. For example, the D614G mutation is one where the aspartic acid residue at position 614 is replaced by glycine. A number of studies have now shown that the D614G mutation has higher infectivity, which may account for its rapid rise to the dominant position in all regions where it has emerged – constant surveillance of new mutations will be necessary (diagnostics) and depending on the strength of the immune response, an annual vaccine may become common place (as is with the flu).  Our Validation Centre of Excellence will enable researchers to address this significant future challenge.  **COVID-21 / Future Pandemics**  The UK response to COVID-19 has been widely criticised, in particular the weak UK diagnostics sector. Through years of sector neglect, IP leakage and offshoring of R&D, issues were exposed ranging from lack of supply chain infrastructure through inability to scale. The Lighthouse Labs were a desperately needed initiative and now represents one of the largest testing initiatives in the world.  There have been a number of epidemics and pandemics since 2000, such as SARS in 2002-2004, Avian Influenza (bird flu) 2003–2019, Swine flu in 2009–2010 and Middle East Respiratory syndrome (MERS) in 2012–present, as well as COVID-19 (2019–present).  By establishing a multipurpose facility, working and engaging with the regional and national Infectious Disease sector, the Centre will enable a faster response to future epidemics / pandemics. |
| **B5: Wider Geographic Impact** | ***Please provide information on any potential impacts the project may have outside of Cheshire and Warrington, for instance does it involve partnership working with another LEP or organisation, is it a pilot which could be rolled out nationally. You should indicate those areas that will directly benefit, areas that will indirectly benefit and those areas that may be impacted adversely.*** Please provide as Map info layer if possible.  **Areas that will directly benefit:**  The project is based in Cheshire & Warrington; however, the MDC has a national remit. The impact is primarily through company growth and value creation by enabling the validation of new technologies.  The primary area to benefit will be Alderley Park, the home of MDC and the Alderley Park Lighthouse Lab. Building upon the regional local industrial strategy the Centre will support and grow a cluster of world-leading expertise in diagnostics and therapeutics for infectious disease.  MDC is a government-funded national infrastructure set up to accelerate innovative drug discovery, connecting the UK drug discovery community and transform ideas into better medicines for patients, faster. MDC has additionally invested ~£25M at Alderley Park outside of Lighthouse created 90 jobs since 2017. MDC has a track record in delivering economic growth through supporting the success of its partner companies; currently, it interacts with and supports 70 companies nationally, of which 19 are based in Cheshire East. To date, MDC has delivered over £6.5M in brokered income and > £30M in investment through technology and business support.  **Areas that will indirectly benefit:**  COVID-19 has shown that to overcome a pandemic, a national effort is required. In line with the current remit of MDC, the Centre will be set-up as a national testing and validation centre, supporting the development of novel technologies for future infectious disease challenges across the UK.  Given the national remit of the MDC, we anticipate wider geographic impact through business as usual activities (supporting SMEs in commercial and collaborative research and development projects). The recent publicity around the proposed Validation Centre has attracted significant interest from companies and research organisations across the country.  **Areas that may be impacted adversely:**  There is a threat that by creating such an attractive and productive environment for life sciences at Alderley Park, that it detracts from other regions abilities to retain talent and high growth potential companies. However, we given the level of demand and limited supply, we do not envisage any displacement and through our support we can elevate the whole sector rather than detract from one region to support another. |
| **B6: Fit with other projects and programmes** | ***Does the project fit with any other projects or programmes and if so how and how will you ensure maximum alignment and benefit?***  **MDC Strength in Places Fund – Transforming complex medicines productivity in Cheshire and Warrington**  MDC has a Phase 1 SIPF programme funded (£50k seedcorn) and is in the process of bidding for Phase 2 funding (SIPF investment: £12m). Our overall objective in the SIPF bid is to provide an innovation launchpad in the C&W region to promote new spinouts and help existing businesses increase productivity in complex medicines development. The Validation Centre of Excellence will enable the expansion of the SIPF bid into the area of infectious disease and diagnostic technologies.  **The UK Lighthouse Labs Network**  The Lighthouse Labs are a national diagnostic lab network, supported by the scientific community, to support the fight against COVID-19. The three Lighthouse Labs have been created in Cheshire East, Milton Keynes, and Glasgow, constructed through a partnership with the Medicines Discovery Catapult (MDC), Department of Health, UK Biocentre and the University of Glasgow. The development is closely supported by both the NHS and Public Health England.  MDC has, through creating the Lighthouse, delivered in 2020 a new ~£70M p.a. diagnostics investment setup into Alderley Park, East Cheshire. The MDC Lighthouse has created 300 high-value life sciences jobs (NVQ level equivalent 4/5) to date in 2020 and has plans to create another 200 in this financial year.  The proposed project and Centre will act as a pipeline for new diagnostic and therapeutic technologies to support the national effort against COVID-19.  MDC is also preparing a large Strength in Places Fund application with a focus on complex medicines development.  **South Manchester Manufacturing (University of Manchester)**  Plans are underway to develop a South Manchester Manufacturing Innovation Park, focussed on scaling up new medical and healthcare technologies from the laboratory to large-scale production. It will act as a physical research translation, skills and manufacturing hub linked to the existing SME ecosystem of south GM and Cheshire and be a magnet for inward investment by multinationals undertaking medicines manufacturing and other health-tech activities. Our proposed Validation Centre will provide the infrastructure and expertise to demonstrate proof of concept, acting as a pipeline feeding new technologies to the South Manchester Manufacturing cluster for scale-up.  **IKON consortium (University of Liverpool)**  The Liverpool City region was recently successful in their SIPF bid that will create eight specialist, commercially sustainable research platforms for infectious diseases therapeutics in North West England, that will go on to transform the efficiency of new product discovery, development, evaluation and impact assessment. The validation centre will provide the infrastructure needed for IKON to be successful through validation and commercialisation of findings. We will work alongside the Liverpool consortium to maximise the regional benefit for both projects.  **GM&C Life Sciences Fund**  The GM&C Life Sciences Fund is a seed and early-stage venture capital fund targeting life sciences businesses located in the Greater Manchester and Cheshire & Warrington region. The Fund is managed by Catapult Venture Managers ("Catapult Ventures") and is currently invested in 18 companies based at Alderley Park. The long-term outputs from our project include new IP generation, company incorporation and growth. The GM&C Life Sciences Fund will be integral to supporting these new companies and innovations through the development life cycle. |

**C: Economic Case**

This section should set out the case for the Project in supporting and accelerating the economic growth of Cheshire & Warrington. It is important that the benefits provided by the proposed project take account of issues including deadweight and displacement and as such benefits and outputs should be shown as net.

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| **C1: Proposed project Outputs** | *Please state the proposed direct and indirect outputs expected to be generated by the project and how you have calculated these. We will require outputs to be monitored for a minimum of five years unless otherwise agreed.*  The capital works will provide:   * New lab floorspace (CAT3 Labs - 6,179 SQFT, CAT2 Labs - 1,055 SQFT); * Office and Ancillary Space (915 SQFT); and * Gross constuction employment of 23 PYEs (Person Year Equivalents) calculated using a standard industry co-efficient of 1 PYE for £235K of expenditure.   Once operational, the project will create economic benefit in a number of ways:   * based on prior experience, and consultation with potential clients (see Letters of Support) and operators of testing facilities elsewhere, MDC estimates that each of the six labs will accomodate 5 projects each year with an average value of £67,000 per project. This provides an annual income of c £2m to the project (See Financial Case Section D5 for detail); * the operation of the Labs will require a staff of **7 FTEs** to be employed by MDC. These staff will conduct the testing services for private and academic clients; * again based on prior experience and consultation with local commercial and academic partners, the project is expected to result in the formation of a number of new businesses, both private start-ups and academic spin-outs, seeking to benefit from the facilities and services of the Lab. A conservative estimate of one new start per annum has been applied, with a similarly conservative estimate of **5 FTE jobs created in each new business** (based on metrics from Beauhurst); * the services provided by the Lab will deliver benefit to commercial partners (existing businesses) and it is likely that the projects may also create downstream activity and benefit for MDC and other partners in the region. However, scaling thes benefits is problematic due to the nature of companies in the sector, the long term nature of R&D activities in this field and the IP based nature of company valuation. We have therefore not included any ex-ante estimates of the economic impacts arising from uplift in company performance as a result of the services, but expect that this will be a significant source of economic benefit for the region; * in a similar vein, the project will result in downsteam investment into diagnostic and therapeutic projects within the regions, both within MDC and across commercial and research partners. This will, in time, generate further economic benefits but these have not been scaled at this time due to the inherent variability in their scale and uncertainty over timeframes; * the project will also likely bring new investment into the region as companies are attracted to the facility and this services. Again, the uncertainty over these impacts is such that we have not included these within the BCR calculations; and * finally, creating the new facility within the region will help to secure as well the longer term future of the Lighthouse Lab which has a total workforce in the region of 1,000. The safeguarding of these jobs in C&W is a key benefit, but has not been included due to the challenges of measuring and tracking this impact.   With these issues in mind, the economic appraisal has focussed on the GVA impacts of the project based on:   * GVA impacts from construction works; * GVA impacts from the facility itself; and * GVA impacts from new business creation.   The key project outputs will be:   * 30 projects completed per annum for five years; * 32 new high value jobs in the life sciences diagnostics and therapeutics asctor; and * additional GVA for the Cheshire and Warrington region.   We have considered the likely additionality of these impacts and in light of the lack of available evaluation evidence have made a number of reasonable assumptions as follows:   * for construction impacts, we have assumed overall additionality of 60%, most of which is due to deadweight rather than discplacement as we have assumed that local contractors will benefit. This is broadly in line with previous evidence from the NW England; * for the employment at the facility we have assumed 100% additionality as it is clear that without the project, these jobs will not be created at all; and * for the employment within new businesses we have made a conservative assumption of 70% additionality . While previous appraisals have tended closer to 50% the unique nature of the project offer is such that it is highly unlikely that these new businesses would set up in the region in the absence of the proposed Lab facility.   Construction PYEs have been converted into one off GVA impacts by using a GVA per employee figure of £91,900 from the Cheshire & Warrington LEP Consolidated Industrial Strategy Evidence Base (p22).  (http://www.871candwep.co.uk/content/uploads/2019/01/Consolidated-CWLEP-evidence-base-methodology-and-appendices-final-version-for-publication-14.02.19.pdf).  Employment at the facility and in new start businesses have been converted into GVA impacts in the NW using GVA per employee of £119,700 for the scientific research and development sector from the Cheshire & Warrington LEP Consolidated Industrial Strategy Evidence Base (p22). These impacts are cumulative across the project (i.e. occur each year) until the contract end (2027). In reality, the GVA impacts from the project will persist beyond the contract end, but these have not been included in the BCR calculation.  O**ptimism bias**  Rather than apply a formal optimism bias calculation, we have instead excluded a range of benefits that would be difficult to evidence at the ex-ante stage. These include:   * safeguarding jobs at the Lighthouse Lab; * uplift in company valuations and performance as a result of using the Lab services; * inward investment from companies attracted to accessing the Lab and its services; and * downstream business opportunities for MDC and its partners in the region as a result of follow-on projects.   In addition, as noted, the appraisal period mathes the contact period of five years post capital completion (to 2027). The economic impacts arising from the facility will persist beyond this period, but have not been included here due to the challenge of tracking pst contact. It would be expected, howver, that ex-post evaluation would identify these effects.  As a result of these issues, it is highly likely that the appraisal underestimate sthe potential economic impacts of the project, and should be considered conservative. |
| **Proposed Outputs:**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Output** | **Year 0** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** | **Total** | | Construction jobs created | 23 | 0 | 0 | 0 | 0 | 0 | **10** | | Jobs created direct | 1 | 5 | 1 | 0 | 0 | 0 | **7** | | Jobs created in start-ups |  | 5 | 5 | 5 | 5 | 5 | **25** | | Jobs supported/safeguarded |  | 25 | 25 | 25 | 25 | 0 | **100** | | Total projects delivered | 1 | 10 | 30 | 30 | 30 | 30 | **131** | | Businesses supported |  | 5 | 10 | 10 | 10 | 10 | **45** | | New business created/relocated to C&W |  | 1 | 1 | 1 | 1 | 1 | **5** |   **BCR Calculations**  The benefits were calculated as described above and set out below over the contract period of the project, and both the LEP costs and the totoal net GVA were discounted using HM Treasury Social Time Preference Rate (3.5%) . The BCR for the project is **2.04**.   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Construction Phase** | | | **Operational Phase** | | | | | **Total** | |  | **2020** | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** |  | | LEP Costs | 522,270 | 4,458,457 | 86,214 |  |  |  |  |  |  | | **Discounted Costs** | **522,270** | **4,307,688** | **80,482** |  |  |  |  |  | **4,910,439** | |  |  |  |  |  |  |  |  |  |  | | Net Construction jobs | | | 14 |  |  |  |  |  | 14 | | Net Jobs in Lab (@100%) | | | 1 | 6 |  |  |  |  | 7 | | New Business Starts | | |  | 1 | 1 | 1 | 1 | 1 |  | | Net Jobs in new starts (70%) | | |  | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 17.5 | | Net Annual GVA (new starts) | | | 1,286,600 | 418,950 | 418,950 | 418,950 | 418,950 | 418,950 |  | | Cumulative GVA (new starts) | | |  |  | 418,950 | 837,900 | 1,256,850 | 1,675,800 |  | | GVA Facilty | | | 119,700 | 837,900 | 837,900 | 837,900 | 837,900 | 837,900 |  | | Total GVA | | | 1,406,300 | 1,256,850 | 1,675,800 | 2,094,750 | 2,513,700 | 2,932,650 | 11,880,050 | | **Discounted GVA** | | | **1,312,796** | **1,133,607** | **1,460,363** | **1,763,723** | **2,044,897** | **2,305,036** | **10,020,422** | | **BCR** | | | | | | | | | **2.04** |   As noted, theBCR calculation does not include jobs supported/safeguarded due to the difficulty in tracking this metric post-project, and also doe snto include the additional benefis descriebd above due to the difficulty in scaling these with sufficient accuracy.  We will include outputs from this project in our standard IUK/UKRI reporting; however, this is not a requirement and we will ensure outputs and KPIs are not double-counted in line with funding terms and conditions. | |
| **C2: Wider benefits of the project** | ***Please describe the expected benefits of the project and how these will be measure e.g. improved travel times, unlocking land for development, reduce Co2 emissions, reduce car use, improved educational attainment, increase in businesses attracted to Cheshire and Warrington etc.***  **Societal:**  Benefits include long-term improvements in health outcomes from the discovery and development of innovative new diagnostics and therapeutics, and therefore quality of life, longevity and productivity. This is particularly important in C&W, where we are increasingly reliant on an ageing workforce. Building upon the investments in MDC and Lighthouse, the new Centre of Excellence will act as a magnet, attracting the best young talent to the region and rebalancing the workforce.  **Technical:**  The validation centre will build on the success of Lighthouse Labs by creating a centre in which innovative companies with novel biomarker ideas can validate and underpin the science, by testing their concept on otherwise inaccessible patient material, in a high protection lab environment, with access to key technologies. The Validation Centre will enable them to create commercially and clinically validated diagnostic tools to bring rapidly to market.  **Job safeguarding:**  The Lighthouse Labs support >500 jobs in the region, which will train and upskill the workforce enabling them to find new jobs in the Life Sciences once the Lighthouse Labs have delivered its core outputs. The more innovative roles are likely to be subsumed into new opportunities generated through the MDC SIPF bid and others supporting the wider infrastructure through the Validation Centre.  Thus, it is envisaged that providing valuable training, experience and R&D opportunities for Lighthouse staff through the Validation Centre, we will contribute to long-term safeguarding and placement of over 100 jobs in the region, in the 5–10 years post-project. Whilst the UK has many BSL3 facilities the majority do not take on work from outside their organisation resulting not only in a shortage of BSL3 capacity but also of scientists able to work safely with the pathogens requiring these facilities. This centre will make inroads to remedy both of these issues.  The business clients are likely to be SME’s with limited in-house capabilities and thus one of the draws of working with the validation centre is the ability to access world-class facilities and capabilities in the Medicines Discovery Catapult and the large collection of SME’s and CRO’s in Alderley Park and the wider region for down-steam analysis of the samples coming out of the validation centre. This will lead to further investment in jobs and capabilities safeguarding high-value jobs in the region.  **Business support:**  The North West is ranking third both in terms of turnover and number of employees in the diagnostics sector (53 companies) behind the South East and East of England. The Greater Manchester/Cheshire region accounts for over half of these companies. Having access to CLT3 facilities will benefit this sector and anchor high-value jobs in the region.  During the height of lockdown, we saw an influx of requests for cat 3 facilities, resulting in Cheshire and Warrington missing out on regional income. By providing the facility and expertise to local businesses to validate their diagnostic and therapeutic technologies, they will be able to more readily progress their R&D programmes.  **Economic:**  With the significant cluster of life science companies and innovators already present at Alderley Park, the Validation Centre will act as a magnet for the region. With additional companies and staff moving to the region, we anticipate further downstream economic benefits and flow through the regional economy in terms of general goods and services.  The facility based at AP will enable C&W-based CRO’s to widen service offerings through access to the facility. We have already received significant interest from Evotec (see letters of support), with respect to this option.  **Environmental:**  No direct environmental benefits are assumed from this project; however, by bringing organisations together in a cluster of expertise and fostering innovative collaborative R&D, we expect to see efficiency gains across the development life cycle and consequently, energy savings (reduced carbon footprints).  **How the benefits will be measured:**  The benefits we will measure include:   * Number of new businesses attracted to the region (#) * Staff growth of supported businesses (GVA / FTE) * Growth of individual businesses supported (£ Market cap/valuation) * Brokered funding following supported project (£ Grants / Investment secured) * Revenue (£)   MDC already tracks these metrics or variations of each for UKRI reporting purposes. We use tools, such as Beauhurst, to track companies that we have interacted with and supported. We also have an in-house business intelligence analyst to support sector impact analysis. Before project kick-off, we will undertake a baselining exercise using these tools to establish the current state of the market in Cheshire and Warrington.  We also use sector surveys and include an impact clause in our standard T&C’s and collaboration agreements that enable a retrospective analysis of company performance. For example, information that may be requested, but not limited to, includes effects, changes or benefits to the company, the economy, society, public policy or services, health and the environment. It may also include revenue flow between the company and a third-party in the form of financial investment into the company, or grants obtained by the company. |
| **C3: Value for Money** | ***As set out in the LEP’s Assurance Framework we are required to assess the value for money of projects using a Benefit Cost Realisation (BCR) calculation.***  **BCR:**  The benefit-cost ratio of 2.04, comparing PV of benefits vs PV of public costs (not including MDC in-kind contribution), represents excellent value for money for an infrastructure/capital project. Funding leverages nearly £100M in government funding (Lighthouse and MDC) for infrastructure, technical and scientific expertise and business support based in a key LEP strategic geography (Alderley Park) and sector (Life Sciences). The NorthWest is a life science Powerhouse, but COVID-19 has ravaged local industry, with nearly 50% of companies reporting a negative impact on business. With a large population of innovators to draw from, a Centre of Excellence to support the validation and translation of novel diagnostics, biomarkers and complex medicines will encourage and foster new business activity (pivoting) and growth (start-ups).  NPV of public costs = £4,910,439 against NPV of benefits = £10,020,422 (5 yearsof operationl post capital build)  **BCR = 2.04**  Non-monetary benefits have not been included in the NPV of benefits. |
| **C4: Options Assessment** | ***Please describe what alternative delivery options and funding sources have been considered and why these have been rejected. Also please detail the options considered for delivering the project at different scales and why these options have been rejected. How have you prioritised the options considered in order to reach an optimal solution?***  The project is wholly dependent on external funding, as neither Alderley Park nor MDC has the funds for such an ambitious project. The organisations that the project is set to benefit are primarily small biotech’s, which are equally unable to fund the project – especially given the financial constraints on the sector from the pandemic; therefore, a public-private partnership is not possible at this stage.  Bank loans and other financial options are not feasible, given that the Centre will be run for public benefit on a not-for-profit basis.  ***detail the options considered for delivering the project at different scales and why these options have been rejected***  Our objectives include providing facile access to BSL-3 facilities for companies and supporting the validation of new diagnostic and therapeutic technologies for infectious diseases.  With respect to our objectives, alternative options include:   * **Facilitating access to existing facilities rather than building a new one**   As reported in 2008 (House of Commons report on Biosecurity in UK research labs), there are approximately 347 laboratories around the UK that are built to operate at BSL-3. A large proportion of BSL-3 capacity is held by a small number of universities and research institutes, e.g. two universities have 84 BSL-3 laboratories between them, and one institute has 60 BSL-3 laboratories. The National Health Service (NHS) has 170 BSL-3 laboratories mainly for diagnostics. Most such laboratories, however, are small, dedicated to particular uses, or in need of modernisation. Complicating matters further, there is no reliable directory of BSL-3 facilities, let alone resources to quickly screen near-term availability and cost for third-party use.  Likewise, the expertise to run such a Centre or services within the Centre is not readily available to UK companies. The cost to set up, train staff and maintain a BSL3 lab is too prohibitive for SMEs to take on. With Sars-Cov-2, industry and academic demand for a Validation Centre that provides the expertise and equipment to rapidly test and develop new diagnostic and therapeutic technologies is high, and demand is expected to continue as innovators pivot towards infectious disease in general.   * **Focus on non-BSL3 activities within existing MDC facilities**   The cost for building, setup, staff training and maintenance of a lower safety rated lab, for example, a BSL2, is substantially lower; consequently, the barriers to accessing these facilities is significantly lower. In that respect, the sector is well served by existing CROs.   * **Build in a different location at a different scale (both bigger and smaller)**   The location for the Centre, Alderley Park, was selected due to the strategic alignment between MDC, AP/Bruntwood and the Cheshire and Warrington Local Industrial Strategy. Alderley Park had a range of lab spaces available that allowed for detailed planning against space requirements. Due to the nature of businesses at Alderley Park, we can piggyback on infrastructures, such as site security and waste handling processes.  The location also builds upon the emergence of modern place-based thinking around innovation. The importance of local knowledge spillovers, knowledge exchanges and knowledge diffusion processes within key geographical arenas are a crucial ingredient of the economic growth process. The Validation Centre will complement the world-leading and exciting cluster of businesses and innovators at Alderley Park to further drive innovation in infectious disease technologies.   * **Do nothing**   Scientists need a safe and effective way to handle dangerous pathogens in a controlled environment. A Biosafety Level 3 (BSL-3) lab is designed to meet these special requirements.  By doing nothing, we would not be able to address the urgent need for access to these facilities and expertise; nor would we be able to validate technologies against infectious pathogens, instead we would have to rely on pseudo or isolated fragments – whilst valuable, this does not ultimately represent the pathogen itself.  By doing nothing, the companies and innovators that we seek to support will have to find alternative facilities and expertise within the UK. This will drive companies and their employees outside of Cheshire and Warrington and put long-term growth in this burgeoning area of national importance at risk.  ***How have you prioritised the options considered in order to reach an optimal solution?***  We have prioritised our options based on:   * Ability to meet objectives * Deliverability within timescale * Fit within budget * Minimal disruption to existing businesses   Furthermore, we have prioritised maximising BSL3 space at cost of BSL2 and offices, as this is the hardest capability to access for both commercial and academic projects. Additionally, the space needed to deliver BSL3 labs is not scalable – a large area is needed to provide changing areas and waste decontamination and therefore, it is not cost-effective to build one or two BSL3 labs.  Building six BSL3 labs allow a maximum number of labs without additional air handling costs and additional change/waste facilities. We have therefore maximised the useable lab space against the budget available and limited office space, a decision made easier given the availability of office space and shared working areas already in place at Alderley Park. |
| **C5: Contingency Planning** | ***If LEP monies are not available for your Project, do you have a contingency plan for this Project? If your answer is 'no' please comment on the potential impacts of this Project not being implemented.***  Our project is contingent on LEP monies. Without this funding, the project will not proceed.  The impact will be felt in terms of regional growth, productivity and talent. But perhaps more importantly, this critical ‘piece of the puzzle’ in the fight against COVID-19, future pandemics, the emergence of antimicrobial resistance and other highly infectious diseases will remain a major barrier to innovation. |

D: Financial Case

**This section requires you to demonstrate how the project will be financed**

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| **D1: Project Costs** | ***Please detail the total project costs including, development costs, post completion maintenance costs and evaluation.***  Total project costs of approximately £6,125,000 comprise of construction, monitoring, legal and equipment costs (see table below for breakdown).  Our post-project operational costs for the facility are approximately £1,047,922 per annum. These costs will be met by revenue from operation of the facility. Profits will be reinvested in the facility.  ***Please provide details of a funding profile (by year) for the Project in terms of:***   * ***Total annual cost*** * ***LEP funding sought*** * ***Promoting Organisation contributions*** * ***Third Party contributions (public and private).***   ***If applicable please show capital and revenue costs as separate lines.*** *You may attach the funding profile as a separate annex if required.*  Project costs (including LEP funding sought and MDC contributions), annual post-project running costs, and 5-year cash flow profile are detailed below. |
| **Construction-specific costs:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | 2020 (£) | 2021 (£) | 2022 (£)\* | Total (£) | | Construction/Development Costs | *471,240.00* | *3,018,493.80* | *77,206.50* | *3,566,940.30* | | Project Monitoring | *36,029.70* | *90,074.25* | *9,007.43* | *135,111.38* | | Construction Monitoring | *0* | *46,323.09* | *0* | *46,323.09* | | Equipment |  | *1,298,565.53* | *376,385* | *1,674,950.53* | | Legals | *15,000.00* | *5,000.00* | *0* | *20,000.00* | | Total Capital Cost | ***522,269.70*** | ***4,458,456.67*** | ***462,598.93*** | ***5,443,325.30*** | |  |  |  |  |  | | Operational Cost |  | *430,384.17* | *258,230.50* | *688,614.67* | | Project Evaluation |  | *6250* | *3750* | *10,000* | | Cumulative Project Costs | ***522,269.70*** | ***4,895,090.84*** | ***724,579.43*** | ***6,141,939.97*** | |  |  |  |  |  | | LEP GBF Grant | *522,269.70* | *4,458,456.67* | *86,213.93* | *5,066,940.30* | | MDC Funding |  | *436,634.17* | *638,365.50* | *1,074,999.67* | | Cumulative Income | ***522,269.70*** | ***4,895,090.84*** | ***724,579.43*** | ***6,141,939.97*** |   \*Project completion by April 2022  **Annual operational and maintenance cost:**   |  |  | | --- | --- | | Cost Category | Total (£) | | Staffing\* | 414,000 | | Overheads (20% of labour) | 82,800 | | Maintenance and service costs | 50,000 | | Lease / utilities | 486,122 | | Project evaluation & auditing | 15,000 | | Total annual costs | **1,047,922** |   \*Staffing includes Principal Scientist x1, Lead Scientist x1, Scientist x3, x2 Ops.  **Cashflow forecast (including 5-year post-project period):**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | (£) | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | Total | | LEP Grant income | 522,270 | **4,895,091** | 86,213 |  |  |  |  | 5,066,940 | | Operating Income |  |  | 2,000,000 | 2,000,000 | 2,000,000 | 2,000,000 | 2,000,000 | 10,000,000 | | CAPEX | (522,270) | (4,895,091) | (462,599) | (250,000) | (250,000) | (250,000) | (250,000) | (5,443,325) | | OPEX |  |  | (1,047,922) | (1,047,922) | (1,047,922) | (1,047,922) | (1,047,922) | (5,239,610) | | Gross profit | **0** | **0** | **575,692** | **702,078** | **702,078** | **702,078** | **702,078** | **5,022,371** | |  |  |  |  |  |  |  |  |  | | Depreciation | 0 | 0 | (334,990) | (384,990) | (434,990) | (484,990) | (534,990) | (2,174,950) | | Earnings before tax | **0** | **0** | **240,702** | **317,088** | **267,088** | **217,088** | **167,088** | **1,209,053** | |  |  |  |  |  |  |  |  |  | | Tax | 0 | 0 | (45,733) | (60,247) | (50,747) | (41,247) | (31,747) | (229,720) | | Net Earnings\*\* | **0** | **0** | **194,969** | **256,841** | **216,341** | **175,841** | **135,341** | **979,333** |   \*Assuming flat line revenue projection based on maximum occupancy  \*\*Earnings will be invested in maintaining/replacing equipment at end-of-life and upgrading the facility as and when needed. The facility will be run on a not-for-profit, but long-term sustainable basis. | |
| **D2: Promoting Organisation Contributions** | ***Please provide detail of your contribution to the project and whether this has been secured and whether there are dependencies***  MDCs contribution is an in-kind contribution of staff time (labour + overheads) and laboratory kit to fit out the facility. The contribution is secured, and recruiting is underway.  Post-project, we are committed to funding the ongoing running costs of the facility, which we anticipate will cost approximately £1m per year. The cost of running the facility and replacing / upgrading equipment will be offset by revenue generation – the Centre will be run on a not-for-profit basis with all earnings reinvested for future impact and regional growth.  ***Project promoters must demonstrate that they can commit a minimum contribution fund of at least one third of the total Project cost. The LEP grant will be fixed, any cost increases incurred after Final Approval will be borne in full by the promoting authority. If the project costs fall below the approved level then the LEP grant will reduce pro-rata.***  MDC will provide up to £1,050,000 in-kind during the project period and an additional £5,239,610 through operating the Centre over the following 5-year period. In this respect, MDC will at a minimum, match the value of the fund over the reporting period. |
| **D3: Third Party Contributions and Leverage** | ***Please provide further details on any third party contributions for your Project. This should include evidence to show how any third party contributions are being secured, the level of commitment and when they will become available. Please include contributions of cash and in-kind (e.g. land and buildings). Also provide information on any additional resources that your project will leverage in as a result of the initial investment.***  The project is leveraging the in-kind contribution from Alderley Park Limited in the form of costs related to the strip out and preparation of the lab space. The value of this work is valued at approximately **£900,000.** |
| **D4: Calculation of costs** | ***How have your costs been calculated? What risk allowance has been applied to the project cost (e.g. QRA / Optimism Bias, Contingency)?***  Development/Construction costs are at the feasibility stage, cost plan developed based on initial design appraisals. Next stage of design development will de-risk the cost plan. High-Level Cost Plan developed +/-15% – Industry-standard Project Contingencies included within high-level cost plan.  ***How will cost overruns be dealt with? How will these costs be shared with any third party funding partners?***  We will monitor the project and highlight risks weekly through a dedicated project monitoring role. In doing so, we capture risks to overspend early and can intervene as appropriate. We have options to value engineer the project down in cost if required, and MDC will underwrite any overspend once these options are exhausted.  ***Are the final costs of the project known? And if not when will they be known. The BCR will need to be recalculated when the final costs are confirmed (i.e. post tender)***  Project costs are not yet finalised (feasibility stage); however, we anticipate achieving cost certainty by March 2021. |
| **D5: Project Income** | ***Is the project likely to generate and income? If so please provide the details below along with the assumptions (please note that any income should be recorded in the outputs section in C2)***  There will be no income generation from the capital build-out phase; however, we expect to generate income through operating the facility to enable long-term sustainability (see section C2, wider benefits).  SMEs and academic innovators will be able to access the services and facility on fee-for-service and/or collaborative terms. Income will be in the form of commercial fee for service revenue to MDC, as well as competitive R&D grants to both MDC and beneficiaries. MDC currently operates on a similar business model (CRD/Commercial activity split). MDC is classed as a Research Technology Organisation, funded by UKRI to support SMEs and academic innovators in commercially valuable R&D programmes. Consequently, MDC is run on a not-for-profit basis – revenue is reinvested in staff, equipment and infrastructure to further drive R&D.  Income derived from the new facility is based on a capacity model incorporating six BSL-3 labs. The facility will support validation of therapeutics, diagnostics and potentially vaccine candidates for SMEs and academic innovators looking to translate their findings to the market.  Capacity assumptions include 30 projects per year (5 per lab), split 15:85 between CRD and Commercial projects. Stakeholder engagement to date has indicated that this level of market demand is a fair assumption.  Total annual income of approximately £2m is derived from a mix of CRD and commercial activities as described above.  Pricing is project-specific rather than defined fixed-fee services, which is necessary given the diverse range of R&D projects anticipated. A bottom-up approach is used to cost staff, overheads, materials and capital equipment usage.  Commercial projects are costed at fair market rates to ensure accessibility and inclusivity for regional SMEs. Income is based on MDC historical averages, with an additional uplift due to the added cost of running and maintaining a BSL-3 facility. We anticipate 27 new commercial projects per year valued at £63k each (Total commercial income: £1.7m / year).  CRD projects typically larger multi-year projects, but costed on cost-recovery basis. Based on MDC averages for CRD, we anticipate three new CRD projects per year valued at £100k per year (Total CRD income: £300k / year).  Alternative business models are also being investigated, including the potential for long-term occupancy, or embedded staff for SMEs that need facile access. |

**E: Management Case – Delivery**

This section is asking you to explain the proposed management and delivery arrangements

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| **E1: Current Project Status** | ***Please state Project status*** ***e.g. Is the Project at the conceptual stage? Has a business case been developed? What if any internal and external approvals does it require? Is the project reliant on external funding? If so, has a bid for funding been submitted/ was it successful?***  The construction element of the project is currently at feasibility stage-2, validation surveys have commenced, initial design concepts are agreed in principle with cost plans and cash flow profiles in the development phase. Construction delivery procurement strategies have been agreed in principle, whilst not confirmed.  A timeline for delivery is included in F3: Commercial case and Gantt chart is provided below: |
|  | |
| **E2: Delivery Plan** | ***Please provide a Project programme and phasing showing key activities and milestones. (please note these are only indicative and you should tailor the table to your own project)***   |  |  |  | | --- | --- | --- | | **Milestone** | **Start** | **Finish** | | Project start | 01.08.2021 | — | | Agree scope of project | 01.08.2020 | 01.09.2020 | | Stakeholder Consultation | 01.09.2020 | Ongoing (Sept 2020-Sept 2021) | | Options analysis | 01.09.2020 | 23.10.2020 | | Develop Business case | 01.09.2020 | 02.11.2020 | | Appraisal of the business case | 02.11.2020 | 09.11.2020 | | Secure Funding | 23.11.2020 | 30.11.2020 | | Procurement process/es | 07.11.2020 | ongoing | | Issues Contract | 30.11.2020 | 04.01.2021 | | Construction finish | — | 31.09.2021 | | Operation start | 01.10.2021 | — | | Monitoring, reporting and evaluation | 04.01.2021 | 31.03.2027 | |
| **E3: Project Dependencies** | ***Please detail any project dependencies e.g. planning permission required, funding approval required, land purchase etc. along with expected completion dates:***  Dependencies are provided below. Critical external dependencies are highlighted in **bold**.   |  |  | | --- | --- | | ***Dependency*** | ***Date expected to completed*** | | Internal approval | 17.06.2020 | | GBF application | 15.07.2020 | | Business case | 17.11.2020 | | **Funding approval** | 30.11.2020 | | Pre-agreement (lease) | 04.01.2021 | | Lease negotiation | 28.02.2021 | | Contracting / procurement | 15.03.2021 | | **Building strip-out** | 12.02.2021 | | Construction / fit-out | 13.09.2021 | | **HSE / CTSA sign off** | 13.09.2021 | | Equipment installation (lab) | 01.11.2021 | | Recruitment (operations) | Ongoing | | Facility operational | 31.03.2022 (latest) | |
| **E4: Other Partners Involved in Project Delivery** | ***Please provide details the roles of any delivery partners, the status of the commitment to the projects and any fees involved, along with how they will be paid.***  No other delivery partners are involved.  MDC is currently engaging with Alderley Park Limited, working to secure tenancy of space that will facilitate delivery and operation of the project. Early engagement has provided both parties with positive collaborations around the best use of the site and existing facilities at Alderley Park. Pre agreements are at an advanced stage of negotiation, with APL in full support of the project. |
| **E5: Project Governance** | ***Please provide the proposed project management structure and what experience you have of delivery similar projects. Please also detail ongoing management arrangements e.g. monthly project board meetings:***  **General Summery/Experience:**  With over 27 years’ experience in the construction industry, David Hillier is a senior construction professional with all-round Project Management skills in; Project Management, Building Surveying, Procurement, Cost Management, Design and Planning.  His experience and knowledge in lab fit-out means he is best placed to work with the appointed design and construction team, ensuring all aspects of Project Delivery are managed and coordinated in a professional and diligent manner.  **Prior Experience:**  Project Manager/Client Representative – Lab Modifications, rationalization, cooling Installations and upgrades at **Wolfson Molecular Imaging Centre, Manchester**. Management of Laboratory rationalization and fit out works facilitating mechanical & electrical upgrade works, site co-ordination of the delivery and installation of PET/CT Scanner upgrade. Contract Value - Confidential.  Client Representative/Employers PM - **The Light House Labs** at Alderley Park. Working with key stakeholders, design and construction teams to coordinate delivery of laboratory and commercial spaces including the installation of specialist lab equipment, ranging from PCR Machines to Hamilton Robotics. International and regional coordination of installation program with OEM. Construction and commercial legal processes supported. Contract Value – Confidential.  Building Surveying/Employers Representative Role - Fire reinstatement works to Listed Building **PCB Laboratory** **Sackville Street Building, Manchester**. Design and specifications, negotiated tender, liaison with key UoM stakeholders, insurance partner including assessment, management and authorization of associated claims. Contract Value - Confidential.  Project Manager Delivery/Client-Side PM – Enabling/Strip Out and Validation Works, Fit Out Refurbishment and relocation of Office and Specialist Laboratory Space for **Medicines Discovery Catapult at Alderley Park**. This project included Cat2 Laboratories. CatA and CatB Fit Out and the Soft Landing of Specialist Equipment Including Mass Spectrometry, Microscopy Tissue Processing and General Analytical Lab equipment. Coordination of cradle to grave site acquisition through to delivery and operational process. Full coordination of OEM’s equipment. Contract Value – Confidential.**Project Delivery - Construction:**  Project Management/Project Monitoring and Construction Monitoring Roles to be delivered by in house Property Project Management resource. The person: an experienced construction professional with all-round Program Management skills is currently engrained in the existing business model, responsible for the delivery and execution of Specialist Laboratory and Commercial Fit Outs at Alderley Park on behalf of MDC.  Regular reporting processes will be adopted at design and construction stages, ongoing weekly reporting will be developed with Project Management Board papers and Risk Register Analysis delivered monthly.  Weekly liaison with key stakeholders and Senior Leadership Team Members to be undertaken, the person undertaking the above roles will be an integral part of all stages of the delivery process.  **Project Delivery – Operation:**  MDC is overseen by an experienced management team with proven expertise across private, academic and public sectors in biotech, large pharma discovery, advanced informatics, clinical research, diagnostics and large-scale consortium building. MDC has also built an effective sector engagement function and has developed robust support structures to ensure its interventions and projects are established, run and monitored effectively.  Since 2018, MDC has:   * Participated in 160 partnered projects with 86 organisations across the UK * Created over 400 highly skilled jobs * Launched three Drug Discovery Syndicates (in the fields of psychiatry, cystic fibrosis and hearing disorders) * Enabled partners working with MDCto raise over £50 million in new venture investment * Delivered the largest diagnostics laboratory testing project in UK history * Provided industrial and technical training and development for software developers, students and researchers * Delivered internationally recognised recommendations on the industry use of healthcare data   The overall responsibility for delivery of projects is MDC’s leadership and management teams. Day to day project management is via dedicated project management and account management support; we use project tools (MS Project, PPMA) and methodologies (Prince2 and AGILE).  The operation of the facility will be in line with exisiting MDC operations.  An overview of MDC project governance is provided below. |
| **MDC Project Governance** | |
| **E6: Stakeholder consultation and Engagement** | ***Please detail what stakeholder engagement you have undertaken.***  ***How will you deal with any objections? How will you keep stakeholder updated and engaged during the delivery of the scheme?***  ***Letters of support for the project should be appended.***  We have engaged with several stakeholders in the North West from both commercial and academic/healthcare organisations, these include Evotec, Infex therapeutics, University of Manchester, Liverpool School of Tropical Medicine, University of Leeds and Manchester University NHS Foundation Trust and several SMEs. These have all been incredibly supportive of the scheme because, except for the Liverpool School of Tropical Medicine, the organisations have limited access to the capabilities offered by the scheme but strong demand from customers/researchers. Liverpool School of Tropical Medicine has a Strength in Places project on anti-infection therapeutics with work packages being delivered out of businesses at Alderley Park, they are therefore interested in the proximity of the scheme to planned research. Potential opportunities have been discussed with these organisations including fee for service projects, long term funding of labs/staff to deliver larger-scale projects and significant collaborative grant opportunities.  To date, there haven’t been any objections to the scheme but if these arise, we will arrange a meeting with the relevant organisation(s) to understand and resolve any concerns. We have established relationships with all the major stakeholders and therefore will continue regular discussions with these either face to face or via video conference (as appropriate with local COVID-19 restrictions) whilst the scheme is delivered.  Letters of support are appended to Section H1. |
| **E7: Risk management** | ***Please detail your approach to risk management:***  All partners will practice on-going, comprehensive risk mitigation and management process. Risk management involves an initial risk assessment, on-going risk identification, development of risk strategies and contingency actions to manage the risk factors. Project Manager will maintain the risk management plan and issues logbook, and monitor change management activities and adjustments to project targets.  Typical factors that impact the risk profile include:   * Internal and external staff applied to the project team * Management structure * Complexity of the system to be implemented * Degree of integration with existing applications required * Solution deployment and the effect on the business   ***Please detail the top 5 risks and issues and how you are managing these. If available please append the project risk register***  The fundamental risks in this project are:   1. Takes longer to complete than planned (time) 2. Costs more than anticipated (cost) 3. Does not deliver the business requirements and functions expected (impact & income)   We have initially identified 20 risks, the top 5 of which are described below, followed by our complete Risk Register .  **Technical**  RISK—Completion of Validation and Strip-Out CATA works delayed.  MITIGATION—Project Management of landlord led Validation and Strip-Out CATA works. Project Monitoring role to be defined and implemented as a formal request to the landlord. As long as delays are known in advance, the team can plan accordingly. There is a time contingency planned in the deliverable dates. Delays to project delivery impact commercial feasibility but not project feasibility.  **Managerial**  RISK—Current/future lockdown restrictions delays build-out due to unavailable materials  MITIGATION—Project Manager will be in continuous communications with builders and contractors to monitor the situation, procure material and identify multiple suppliers to avoid this.  **Commercial**  RISK—Rivals develop a similar solution  MITIGATION—MDC has a huge pool of customers already that have highlighted the need and interest in using the Validation Centre. As a not-for-profit government organisation, MDC is also seen as a neutral partner with no invested interests and a good track record of helping UK businesses thrive; thus, more attractive for SMEs/start-ups over other companies. Similarly, the prohibitive capital cost and expertise required to run such a facility is the reason why the gap in the market currently exists.  **Regulatory**  RISK—Our biobank does not adequately address new GDPR requirements  MITIGATION—We do not anticipate collecting or holding any personal data and data protection will be built in by design. If personal data is processed (collected, stored, deleted, shared etc), we will undertake a Privacy Impact Assessment before processing to ensure appropriate measures are put in place to comply with the legislation.  **Environmental**  RISK—Poor disposal of used components from our development work and commercialisation  MITIGATION—We have strong health, safety, environment and quality policies. We will ensure that this is followed throughout the project. The company has appropriate SOPs and handling procedures in place to ensure that work is conducted with minimal risk to the environment. |
| **Risk Register and Scoring:**  Likelihood (L) and Impact (I) are rated 1–3 (1 being low and 3 being high). Severity (S) = Likelihood × Impact, giving a score from 1–9 (Score of 9 being a major risk requiring extra management time and monitoring). Severity after mitigation (AM)   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | # | Description | L | I | S | Mitigation | AM | | Technical | | | | | | | | 1 | Negotiate mutually convenient provision of conventional lease for rental and operational use of proposed facility | 2 | 2 | **4** | Early engagement with key stakeholders in order to negotiate away complex clauses. Initial Heads of Terms to be agreed in principle prior to January 2021. HOT’s to underpin conventional lease agreement | 1 | | 2 | Confirmation of construction works brief, budget and timescales | 2 | 2 | **4** | Appointed design team to progress to next stage of design development, establishing detailed design criteria enabling initial cost plan to be developed reducing cost and program risk. | 2 | | 3 | Site limitations, services, infrastructure | 2 | 3 | **6** | Project Management of landlord led Validation and Strip Out CATA works. Project Monitoring role to be defined and implemented. as a formal request to the landlord. | 2 | | 4 | Completion of Validation and Strip Out CATA works. As programmed | 2 | 3 | **6** | Project Management of landlord led Validation and Strip Out CATA works. Project Monitoring role to be defined and implemented as a formal request to the landlord. As long as delays are known in advance, the team can plan accordingly. There is a time contingency planned in the deliverable dates. Delays to project delivery impact commercial feasibility but not project feasibility. | 2 | | 5 | Establish requirements for any long lead in items i.e. Autoclave. Establish procurement provisions | 2 | 3 | **6** | Work with the appointment design team to clarify and establish a firm brief and requirements, establish procurement governance and address highlighted long lead in items. | 3 | | 6 | Project Cost and Program Management | 2 | 2 | **4** | Establish Project Monitoring Role on behalf of client team providing continued risk management services, monitoring and evaluating potential impact of delays and project overspend. | 2 | | Managerial | | | | | | | | 1 | Staff shortfall / recruiting issues | 1 | 3 | **3** | A robust staff-hiring process is already in place at MDC and was able to quickly hire 500+ staff members for the Lighthouse lab. The contracts for these staff members will have expired when hiring for validation centre ensuring access to a pool of skilled candidates. | 1 | | 2 | Misinterpretation leads to technical errors by partners or subcontractors | 1 | 3 | **3** | Monthly progress meetings combined with daily stand-ups, where necessary, will ensure technical information is clear and accessible. Progress reviewed regularly. | 2 | | 3 | Key team member incapacitated | 1 | 3 | **3** | Standards and progress reports and shared data will ensure smooth handover. Regular team feedback ensures the Project Manager understands progress. | 2 | | 4 | Change management overload | 1 | 3 | **3** | Change requests by users or providers may impact the project by increasing complexity of the project and distracting key resources. | 2 | | 5 | Resources required to meet technical needs exceed expectation | 1 | 2 | **2** | Project Manager will continually assess tasks and resources to ensure technical needs are met. Match funding is met by revenues and cash reserves. Contingency planning has been built within the cost plan. Cost overruns will be underwritten by MDC provided value engineering solutions have been exhausted. | 1 | | 6 | Current/future lockdown restrictions delays build-out due to unavailable materials | 2 | 3 | **6** | Project Manager will be in continuous communications with builders and contractors to monitor situation, procure material and identify multiple suppliers to avoid this. | 3 | | 7 | Local objection to Cat 3 facilities | 1 | 3 | **3** | Facilities at Alderley Park already identified, and purpose supported by management. | 1 | | Commercial | | | | | | | | 1 | Demand for facilities are low | 1 | 3 | **3** | The timing of this validation centre co-insides with COVID-19 pandemic, which has highlighted that the UK was unprepared for a pandemic but also has poor diagnostic capabilities with poor access to cat-3 capabilities. This emphasises improvements are needed for current and future viral pathogens diagnostics and availability of cat-3 facilities. Other facilities that we propose are those that have been shown to hinder commercialisation of products by regional SMEs. | 2 | | 2 | Rivals develop similar solution | 2 | 3 | **6** | MDC has a huge pool of customers already that have highlighted the need and interest in using the validation centre. As not-for-profit government organisation MDC is also seen as neutral partner with no invested interests and a good track record of helping UK businesses thrive. thus, more attractive for SMEs/start-ups over other companies. Similarly, the prohibitive capital cost and expertise required to run such a facility is the reason why the gap in the market currently exists. | 3 | | 3 | Market forces impact the project (reduced income) | 2 | 2 | **4** | Market changes, such as a sudden downturn in the market may impact the ability to commercialise. We will ensure that there is international presence so to reach to other markets. | 2 | | 4 | Economic benefits not achieved | 1 | 3 | **3** | Economic benefits have been calculated taking into account bias and are realistic. Monthly monitoring and annual evaluation will allow close tracking of benefits and change management will be implemented where required. Substantial flexibility in the use of the facility is implicit in design and will enable MDC to pivot to where the market dictates. | 3 | | Social / regulatory | | | | | | | | 1 | Our biobank does not adequately address new GDPR requirements | 1 | 3 | **3** | We do not anticipate collecting or holding any personal data and data protection will be built in by design. In the event that personal data is processed (collected, stored, deleted, shared etc), we will undertake a Privacy Impact Assessment before processing to ensure appropriate measures are put in place to comply with the legislation. | 3 | | 2 | Procedural policies delay build-out | 1 | 3 | **3** | Experienced procurement team who are aware of timelines and have already begun necessary procedure to ensure project runs to time. | 1 | | Environmental | | | | | | | | 1 | Poor disposal of used components from our development work and commercialisation | 1 | 2 | **2** | We have a strong health, safety, environment and quality policy. We will ensure that this is followed throughout the project. The company has appropriate SOPs and handling procedures in place to ensure that work is conducted with minimal risk to the environment. | 1 | | |
| **E8: Monitoring and Evaluation** | ***Please detail proposed arrangements for monitoring progress of the project and post project evaluation. The LEP requires that the evaluations are paid for by the applicant and made publicly available, including on the LEP website.***  Monitoring and evaluation evidence and reports will be actively owned by the Project Manager and the team responsible for delivery. Data and findings will be reported regularly (short monthly reports, and quarterly reports). Reports will be timed to correspond to decision points where they can be of maximum use. Major findings will also be reported to the LEP, as appropriate.  We will use independent evaluation consultants to monitor the outputs. MDC is currently working with SQW, a leading independent provider of research, analysis and advice in economic and social development.  We will establish a Theory of Change and collect baseline data to enable accurate post-project evaluation. The evaluation will follow the guidance as set out in the Green Book and Magenta Book. The core evaluation questions are:   * to what extent were outputs delivered and when? * to what extent were the anticipated outcomes produced and by when? * what continuing change is expected as a result of the above? * how well did the process of delivering the outputs and outcomes work? * were there significant unintended effects? * what social value was created as defined in the economic dimension? * what level of confidence can be attributed to the estimates of impact, including social value? * what was the cost to the public sector as defined in the financial dimension?   Evaluation reports, and the research that informs them, will be placed in the public domain in line with government transparency standards.  Supported-company impact data will be gathered annually through surveys and requests for information. Impact monitoring is implicit in all contractual agreements between MDC and partners/clients as detailed below:  Impact monitoring is set out in a clause whereby the party/parties agree to comply with all reasonable requests made by MDC to provide such information (not including Confidential Information other than financial information for the purpose of this clause) as MDC may reasonably require addressing the requirements placed on it as a result of the Project. Such information may include, but shall not be limited to, effects, changes or benefits to the party/parties, the economy, society, public policy or services, health and the environment. It may also include revenue flow between the party/parties and a third-party in the form of financial investment into the party/parties, grants obtained by the party/parties, a sale of intellectual property or products where MDC has provided materials direction, contacts, advice, expertise or input that has led to such deal. |

**F: Commercial Case**

**This section details how the project will be procured and risks managed.**

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| **F1: Products and Services** | **What goods and or services are being procured?**  The project procurement will be split by construction services and equipment purchases.  Procurement of construction services will include the competitive selection of a qualified building firm.  Procurement of equipment will include essential lab equipment, such as autoclaves, microbiological safety cabinets, refrigerators/freezers, and incubators, as well as specialist equipment, such as a flow cytometer, microscopes and imaging equipment. |
| **F2: Procurement processes** | **Please state how each key element of the project will be procured**  MDC has a detailed procurement policy that can be provided upon request.  As an organisation that currently receives over 50% of our funding from Innovate UK, all contracts for supplies, services and works are covered by the EU Procurement Directive, whose aim is to ensure open competition throughout the European Union. The EU Procurement Directive is transposed into UK law through the Public Contracts Regulations 2015, as amended from time to time.  For construction services, OJEU threshold is £4,733,252; for equipment purchases, OJEU threshold is £189,330  For lab equipment approx. 3–4 months are needed for anything >£25K and up to £189,330. Approximately 6 months is normally required for procurement exceeding the OJEU threshold. We only envisage 1 item potentially being over the threshold (high-content imager).  Furthermore, the EC also has issued guidance on using the public procurement framework in the emergency related to the COVID-19 crisis ([European Commission Guidance](NULL)), which sets out a framework for accelerated procurement given the urgent requirement for the Centre. |
| **F3: Procurement Timetable** | **Please provide all the key milestones. The table below is an example and should be amended as required:**  Procurement timelines are detailed below.   |  |  |  | | --- | --- | --- | | **Milestone** | **Start** | **Finish** | | **Establish requirements** | 01.09.20 | 02.11.20 | | **Draft Invitation to tender** | 02.11.20 | 13.11.20 | | **Issue tender** | 13.11.20 | 13.11.20 | | **Tender Period** | 16.11.20 | 19.02.21 | | **Tender evaluation** | 02.03.21 | 15.03.21 | | **Contract award** | 15.03.21 | 15.03.21 | |
| **F4: Value for Money** | **How will you ensure value for money?**  Irrespective of the sources of our funding, all MDC staff need to ensure they obtain value for money by following the procedures outlined above.  These procedures cover any order placed or let for goods, services and works, which results in expenditure being committed. This includes hiring or leasing.  All MDC staff involved in any form of purchasing must obtain value for money on behalf of MDC. Competition is the major element in obtaining value for money, however, the process needs to be appropriate to the value of the procurement.  **Value for money in procurement involves:**   * getting the right product, service or work; * of the right quality; * in the right quantity; * at the right time; * at the right place; and * under the right contractual terms.   **MDC staff shall obtain value for money by ensuring:**   * MDC contracts and available frameworks are utilised; * procurements are subjected to suitable competition; * economies of scale are exploited; * the requirement is not over or under specified; * suitable contractual protection; and * compliance with relevant MDC procedures and the Public Contracts Regulations. |
| **F5: Procurement and contract management** | **How will the procurement be managed and the subsequent management of the contract/s?**  **If externally please confirm that the costs for this have been secured and included in Section D.**  MDC has an in-house Legal and Procurement team that manages all procurement. The project is also supported by a consultant on a short-term contract to ensure adequate management resource is available.  **Main Contractor Award Criteria**  Whilst in development, the Main Contractor tender process will incorporate a robust suite of measurable award criteria, each area of assessment will be weighted in line with its relevance and importance within the delivery process.  The points below highlight key delivery considerations likely to be included in the Main Contractor bidding process.  A grading will be applied to each of the areas.   * Project Delivery/Plan * Organisation and key skills * Health & Safety * Commercial * Quality Assurance * Environment and social impact * Aftercare Commitment * MDC communication/engagement * Risk * Pricing Schedule: Strip Out and Validation * Preliminaries Book * Interview – Presentation/Unseen Questions   The main aim of contract management is to ensure MDC get the goods, services or works as detailed within the contract, and the contract provides MDC with value for money. To achieve this MDC must optimise the efficiency, effectiveness and economy of the contract, whilst developing a relationship with suppliers which facilities continuous improvement and innovation.  The following three areas have a key role in successful contract management:   * service delivery management; * relationship management; and * contract administration.   The size, value and organisational risk should determine the level of contract management, this will determine the frequency and content of supplier review meetings. Factors such as value, length of the contract, business criticality/dependency, number of customers / end-users, public visibility, openness to complaints or challenges, risk, performance criteria and compliance with requirements of other governing bodies should be considered. Guidelines for the appropriate level of contract management are provided below:   * low-level contract management - ensure compliance to the contract by monitoring management information (Ml) from the supplier/ end-user feedback, managing delivery and compliance of the contract using four high-level indicators i.e. cost, quality, delivery, service; * medium level contract management - managing the performance of the contract and the supplier through Ml monitoring / end-user feedback and by expanding four high-level indicators coupled with a minimum of one performance review meeting held per annum; * high-level contract management - strategic management of the contract and the supplier to ensure effective service delivery. This may include opportunities to develop the supplier and provide an opportunity to gain better market knowledge. Use a combination of Ml monitoring and end-user feedback to scrutinise the performance in support of regular review meetings.   Both parties must agree on procedures for reporting contract issues/ complaints with clear reporting and escalation procedures. The objective is to have a relationship in which both parties co­operate to ensure that issues are recognised and resolved quickly and effectively. Whatever the nature of the problem, it is vital that:   * issues are reported to the supplier as soon as they occur; * issues are tracked, and trends highlighted to the supplier; * approaches to resolving issues are clear and documented; and * escalation procedures are followed. |
| **F6: Procurement Risks and issues** | **Please details steps you have taken to ensure there are appropriate supplier in the market that can deliver within the project timescales. Are there likely to be any supply issues and if so how will you manage these:**  Construction-related risks will be identified within the Project Risk Register that will be managed and coordinated by the Project PM, risks around the selection and appointment of the principal contractor will be discharged by applying a PQQ process. A two-stage procurement process is in development whereby the selected contractor will need to commit and provide supporting evidence ensuring commitment to the delivery program. There is a risk that tenders come in over budget; however, this is mitigated by the accurate cost estimates gathered to date. |
| **F7: Asset Ownership** | **Who will own the assets when the project is complete? What if any are the proposals for assets disposal post project completion and have any costs associated with this been accounted for in section D?**  Medicines Discovery Catapult. No assets to be disposed of during the project. Post-project capital equipment will be depreciated in line with our standard procedures (2 years for IT, 2–4 years for lab equipment) and disposed of responsibly at end-of-life. |

**G: Sustainability and Inclusivity**

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| **G1: Environmental Impact of the project** | **What steps have you taken to mitigate the environmental impact of the project? E.g. have you looked at the use of sustainable resources, lower carbon materials, how waste can be reduced etc:**  The project team will adopt suitable and necessary measures to mitigate the environmental impact of the project. Main Contractors will be requested to propose and comply with best practice, work closely with supply chains on sustainability issues. All contractors will ensure government guidelines on sustainable procurement are met.  Typical examples of processes and policies to be adopted will be:   * Comply with legislative requirements. * Record waste with a measurable and achievable % target for recycling. * Promote efficiency through reducing, re-using and recycling materials. * Encourage use of both locally sourced and environmentally sustainable products/ materials.   Life science research is inherently ‘dirty’ in terms of waste products and energy use. In driving the creation of a cluster of innovation and expertise, clean growth must be considered by design. CO2 emissions will be minimised (renewable sources), and energy efficiencies maximised (LED bulbs, insulation and ventiliation), through standard measures where possible.  As a network, the Catapults are developing an ambitious strategy to ensure UK innovators capture the economic benefit of the transition to a Net Zero economy. This is realised through our unrivalled combined knowledge of multiple industry sectors and our whole systems approach. Outputs from this strategy work will be implemented as appropriate. |
| **G2: Carbon Savings** | **Will the project produce any carbon savings and if so how will these be achieved and how have they been calculated.**  Carbon savings are yet to be determined. Carbon savings are likely to be achieved by following best practice in sustainable construction, as outlined above, as well as through implementation of the Catapult networks Net Zero strategy when finalised.  **Carbon Savings per annum:** TBA  **Basis of calculation:** TBA  **How they will be achieved:** TBA |
| **G3: More efficient processes** | **Will the project make any resource savings? E.g. reduce water/energy consumption/ waste produced**  The Project Team will work to make energy savings where feasibly practical, both through design initiatives and technical applications throughout construction and with a view to long-term operation of the facility. Efficiencies in energy consumption will be a key design requirement.  The design and contracting team will be required to propose and implement measurable and achievable initiatives as part of the design and construction stages. Design development of MEP Services will be integral to achieving these savings.  Medicines discovery is inherently inefficient, typically taking 13 years to get a new therapeutic to market with an attrition rate over 90%. One of the central aims of MDC is to increase efficiency of technology and drug development.By centralising services and expertise, MDC can better control staff training and project execution, thereby increasing reliability, reproducibility and efficiency of experiments for regional SMEs and innovators. |
| **G4: Innovation** | **Will there be any new/ innovative technology used to reduce the environmental impact of the project?**  The design and technical stages of the project are to seriously consider new technologies available to the industry, both Alderley Park Limited and MDC are committed to long term environmental strategies that look to reduce the environmental impact of any project.  Green and reusable technologies will be important design and operation considerations, project operations and programming techniques will be implemented minimising construction activities.  The outputs from the Catapult network Net Zero activities are expected to identify new innovative technologies and approaches to reduce the environmental impact of long-term operations. MDC will work closely with the Energy Systems Catapult in evaluating and implementing these options. |
| **G5: Travel** | **Will the project reduce road mileage and or provide low carbon/ sustainable alternatives such as public transport, walking and cycling,**  **car sharing, low emission vehicles, low carbon fuels and technologies?**  No, the project is not expected to reduce road mileage.  **Will the project improve access to services and facilities for vulnerable or disadvantaged groups or individuals?**  Alderley Park has disabled access and facilities for both co-worker space and the conference centre. |
| **G6: Inclusivity** | **What steps are you taking to ensure inclusive growth (e.g. local labour clauses, use of SME)**  Whilst design and construction stages are at the feasibility stage, and procurement and tender criteria in development, the use of SME’s and local labour resource is to be considered a priority. Procurement strategies will consider measurable criteria and key performance indicators which create and maintain achievable levels of local labour resource. The design and technical development stages (next steps) are to consider and implement these strategies.  Operationally, projects must have a high impact on the sector and region as well as matching MDC’s capacity to deliver them. A rigorous and transparent process has been implemented to review the project opportunities arising from the sector. The senior management team meets monthly and the Board subcommittee meets at least quarterly to review the pipeline of opportunities and select those that should be progressed and review those that are ongoing. An important aspect of this process will be to understand, where possible, net present value and the commercial/patient opportunity.  MDC will add value by working with regional SMEs and translational academics to jointly progress valuable therapeutic assets and by co-developing and validating new IP on a fee for service and collaborative basis. |
| **G7: Workforce** | **Will the project provide employment opportunities for local people?**  The project will also create at least seven new jobs in the C&W region for the setup and operation of the centre. In addition on average 5 FTEs will be created in each new business, directly creating 25 new FTEs. Thus, the centre will generate 32 new high value jobs in the region. In addition, the build will allow local construction companies to compete for the contract, which will provide a minimum 10 construction jobs for the buildout of the centre. Long-term, we envisage this project will safeguard up to 100 jobs of local people currently working in the LHL through the generation of other down stream opportunities, such as jobs within CRO’s and service companies for the analysis of samples and materials coming out of projects within the validation centre.  **Will it promote or support equal employment opportunities?**  MDC has an Equal Opportunities and Diversity Policy, which will be followed throughout project delivery and post-project operations.  Our policy states that there should be no discrimination against or harassment of anyone or job applicant either directly or indirectly on the grounds of any of the protected characteristics as outlined in the Equality Act (2010):   * disability * gender * sexual orientation * gender reassignment status * marriage and civil partnership * pregnancy and maternity status * race (colour, nationality or national or ethnic origin) * religion or belief * age   Breaches of the Company’s equal opportunities policy and procedures and any unfair or unlawful discrimination will not be tolerated and will be dealt with under the Company’s disciplinary procedures. In serious cases, this could lead to the dismissal of the relevant individual.  The policy shall also apply to Employees or contractors working at the Company’s premises.  **Will it promote healthy working lives (including health and safety at work, work-life/home-life balance and family friendly policies)?**  We operate a flexible working policy to support the balance of work and home life. The policy sets out the framework whereby employees can request variations to work hours or work patterns. MDC supports a balance between work and other priorities, such as caring responsibilities, leisure activities, further learning and other interests.  Consideration of requests for flexible working will take into account the impact on the organisation, work colleagues and any other relevant factors. We will not always be able to agree to such requests, but we will follow the appropriate process and employee rights are governed by statute in this area.  **Will it offer employment opportunities to disadvantaged groups and pay above living wage?**  We are fully committed to providing a harmonious working environment that offers equal treatment and equal opportunities for all and where everyone is treated with respect and dignity. Our aim is that remuneration, recruitment, development and retention should not be affected by irrelevant considerations and stereotyping. |
| **G8: Learning opportunities** | **Will the project offer any learning opportunities including engaging local schools and colleges?**  The immediate project will not offer learning opportunities; however, post-project operations will provide numerous and regular opportunities to engage with the public, patients, schools, colleges and industry.  The Centre will be open to secondments, from both academia and industry, and results from research and development will be published and communicated at conferences.  We will also maintain a webpage providing regular updates and educational blog posts. |

**H: Evidence and supporting information**

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| **H1: Evidence** | ***Please list here and provide copies of all technical reports documenting the evidence base for the Project and the Project’s performance***  **Design**  We have a detailed floor plan and design, which is available to view on request in person only. As the Centre could be used for pathogens listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, we are unable to share the floor plan via email or print. We are taking guidance from Counter Terrorism Security Advisers and HSE to ensure compliance with all security and health & safety requirements.  **Letters of Support** |
| **H2: Supporting Information** | ***Please include any additional facts which may assist the Local Enterprise Partnership to assess this Project against strategic fit and deliverability.***  The Academy of Medical Sciences recently published a meeting report on the Changes needed to improve UK COVID-19 testing and build strong diagnostic services, now and for the future.  ([https://acmedsci.ac.uk/more/news/changes-needed-to-improve-uk-covid-19-testing-and-build-strong-diagnostic-services-now-and-for-the-future](NULL))  They brought together 23 leading experts, to share learnings from the past ten months and discuss what changes should be made to strengthen future diagnostic testing services.  Recommendations from the meeting include:   * Enhancing collaboration across the NHS, universities and industry to make best use of their combined strengths. Representatives from these three sectors must be involved in the development of future testing strategies, with greater transparency and timely communication of decisions to all involved. This will inform academia and industry about how they can most usefully contribute. * Making sure that local laboratories can play their part in COVID-19 testing and support national approaches. * Developing and adopting more innovative ways of testing for COVID-19, for example pooling multiple samples for testing, testing for several viruses at the same time and improving packaging to speed up the analysis of samples. * Adopting a more flexible approach to regulation – also known as laboratory accreditation – so that as many laboratories as possible can contribute to national testing without unnecessary delays. * Providing longer term testing contracts to reduce any risks for companies wanting to carry out COVID-19 testing, and to enable them to contribute to current efforts. * Ensuring a sustainable workforce with a strategy to bring staff into testing laboratories, providing much needed career opportunities, including for recent graduates, in a challenging jobs market.   The proposed project closely aligns with these recommendations, particularly around fostering collaboration, adopting innovative approaches and developing a sustainable workforce.  Looking ahead, there is an even greater opportunity provided by the pandemic to position the UK as a leader in diagnostics in the long-term. This opportunity is consistent with the government’s ambition to build a large-scale diagnostics industry in the UK as outlined in Pillar 5 of the strategy to scale up COVID-19 testing programmes.  ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/878121/coronavirus-covid-19-testing-strategy.pdf](NULL))  Investing in the UK’s diagnostic infrastructure, from discovery and development to evaluation and adoption, would ensure its future sustainability and could leverage further investment from the private sector into the UK diagnostics industry. It would enable the rapid remobilisation of resources in the event of future epidemics, and allow for the advances in collaboration, innovation, regulatory agility, skills and infrastructure made throughout the COVID-19 pandemic to be repositioned to meet the UK’s broader diagnostics demands for cancer, cardiovascular, and other disease areas.  **Global Market Opportunity**  The primary market sector that the project aims to impact on is the infectious disease diagnostics market. Infectious diseases are the second leading cause of worldwide deaths, killing around 17 million people a year (WHO). In the UK, infectious diseases account for 7% of deaths and costs about £30 billion annually (2017, houses of parliament). The global infectious disease market was valued at $15.57 billion in 2018 with expectations to rise to $25.43 billion by 2027 (CAGR 5.6%). It is likely that this will be worth even more as the COVID-19 pandemic was not accounted for in these predictions. Most of the infectious disease diagnostics market is accounted for by assays, kits and reagents (76.7%), but also includes instruments (15.6%) and services and software (7.7%).  North America account for the largest share of this market at 45.4%, attributed to the presence of a highly developed healthcare system, increasing prevalence of infectious diseases, the presence of a large number of leading national clinical laboratories, and easy accessibility to technologically advanced instruments in the region. However, within Europe we have good infiltration in the market at 26.6%.  Abbott Laboratories (US) Thermo Fisher Scientific (US), Danaher Corporation (US) and Diasorin (Italy) are key players in this market.  The increases in this market are primarily driven by the increasing global prevalence of infectious diseases, shift in focus from centralised laboratories to decentralised point-of-care testing, and growth in funding for research on infectious disease diagnostics. Advances in genomics and proteomics, growing awareness about personalised medicine, and growth opportunities in emerging markets are expected to present further opportunities in the market.  Many of the currently available diagnostic techniques are slow, involve complex procedures, and lack specific identification of causative agents, this has been highlighted globally through the COVID-19 pandemic. Owing to this, spread of disease is enabled and also results in patients receiving broad-spectrum antimicrobial therapy resulting in the emergence of super-resistant microbes.  The validation centre of excellence is aimed at validation and diagnostics of category 2 and 3 diseases. In worst case scenario, the validation centre was only able to focus on one disease there is still a huge market to infiltrate (table 1). However, as a centre for infectious diseases and the lack of testing facilities nationally, it is likely that we will break into multiple disease markets.  ***Despite COVID-19 only being discovered less than a year ago, the COVID-19 diagnostic market is valued at $19.8 billion, with a CAGR rate of 3.1% by 2027***.  Qiagen (Germany), one of the leading providers of sample and assay technologies for molecular diagnostics, seen their sales increase by 26% during the pandemic that they attribute primarily to significant demand for supplies for COVID-19 testing.  **Table 1: The global diagnostics market value of the most common infectious diseases**   |  |  |  |  | | --- | --- | --- | --- | | *Disease* | *Current market value ($ billion)* | *CAGR* | *Estimated market value ($ billion)* | | Hepatitis | 5 (2020) | 6.5% (2017-2025) | 7 | | HIV | 3 (2020) | 9.5% (2020-2025) | 4 | | Malaria | 0.6 (2018) | 5.4% (2019-2026) | 1 | | Tuberculosis | 2 (2016) | 4.6% (2017-2025) | 3 | | Influenza | 0.7 (2020) | 7.8% (2020-2025) | 1 | | HPV | 0.6 (2017) | 7.6%(2020-2027) | 1 | | Total | 11 |  | 17 | |