Appendix A3

Assurance Panel Summary

Scheme Details

Project Name	Gene Therapy Innovation & Manufacturing Centre – Phase 1	**Type of funding**	Grant and Loan
Grant Recipient	The University of Sheffield	**Total Scheme Cost**	£14.2m
MCA Executive Board	Business Investment	**MCA Funding**	£1.5m
Programme name	Business Support	**% MCA Allocation**	10.5%

Appraisal Summary

Project Description	
The UoS is seeking £1.5m from the MCA to cover the shortfall in capital expenditure. The FBC states that the MCA's funding contribution will *"enable the immediate and critical purchase of all specialist technical equipment for the GTIMC's R&D laboratory and cleanrooms, costed at £1.5m"*. Alternative funding avenues have been explored but the project team has demonstrated that these are not viable.	
Strategic Case	
Options assessment	Estimates of the financial cost and benefits associated with each option would have allowed for a more meaningful comparison with the preferred option. Overall, the rationale behind the preferred option appears to be reasonable. The alternatives, while theoretically possible, appear highly likely to result in a reduction of outputs/outcomes.
Statutory requirements and adverse consequences	The scheme has already received Sheffield City Council Planning permission (26th May 2021). One active risk is that the GTIMC will need to gain a manufacturing licence for its Good Manufacturing practices (GMP) compliant cleanrooms from the Medicines and Healthcare products Regulatory Agency (MHRA) prior to any commercial activity being undertaken. Without this, the facility cannot become operational and project outcomes/impacts would not be achieved. To mitigate this, the applicant is in discussions with MHRA and has also commissioned Exmoor Pharma Ltd, a leading technical consultancy specialising in cell and gene therapies, to prepare the submission (Autumn/ Winter 2022). The GTIMC will also have to agree regulatory processes to cover operational activities undertaken in the production of medicinal products. However, this has been mitigated through transferring existing (accredited) processes from CGT Catapult to the Sheffield facility. In summary, the project team has clearly thought through the legal risks which may threaten delivery of the project – all of which have been addressed appropriately. It is unclear whether the MCA's funding would be required prior to securing a manufacturing license from the GMP. If it is only required after, this would greatly reduce the risk posed to the MCA.

Confirmation of alignment with agreed MCA outcomes (Stronger, Greener, Fairer).	The FBC states that the GTIMC will increase in GVA of £28m by 2027 (£85m by 2036), generate three 'high value' spinouts by 2027 (10 by 2036), and create 35 direct net 'high value' new jobs by 2024 (after completion of Phase I). These outcomes align with the RAP's 'stronger' aspiration to '*create not just a bigger economy but a better one: higher-tech, higher skill, and higher-value*'. The FBC also states that interaction between GTIMC, manufacturing and pharma businesses will lead to increased inward investment creating a higher density and growing innovation cluster. This will result in a favourable and high-value dynamic ecosystem. Again, this is well aligned to the RAP's 'stronger' aspiration, and also to the SEP's desired outcome of increasing investment in R&D and innovation. The GTIMC will establish an 'Advanced Therapies' training programme in collaboration with Advanced Therapies Apprenticeship Community (ATAC) and Advanced Therapies Skills Training Network (ATSTN) and recruit 12-15 taught students per annum on the MSc in Advanced Therapies. This activity aligns with the SEP's desired outcome to improve skills and education progression and to see a higher proportion of working-age residents possess higher qualifications. The project will have an average wage 46% higher per annum than the SCR average. This outcome supports the RAP's 'fairer' aspiration particularly in relation to 'widening opportunity' and SEP's desired outcomes relating to raising average wages and to increase the number of higher level jobs. Finally, the project is located within the Advanced Manufacturing Innovation District (AMID) which is one of the MCA's strategic growth areas (as identified in the Strategic Economic Plan). The FBC could be strengthened by making more explicit the link to the 'greener' theme.

Value for Money

Monetised Benefits:

VFM Indicator	**Value**	***R/A/G***
Net Present Social Value (£)	£18.1m	*G*
Benefit Cost Ratio / GVA per £1 of SYMCA Investment	13.1 (or 8.7 with optimism bias (50%)	*G*
Cost per Job (£) *(Infrastructure / Business Investment projects)*	£23.2k (or £34.8k with optimism bias (50%)	*G*

Value for Money Statement

Taking consideration of the monetised and non-monetised benefits and costs, and the uncertainties, does the scheme represent value for money?

The GTIMC will create high-value new jobs in South Yorkshire, providing progression opportunities for local people (the average GTIMC salary will be 46% higher than the current SCR average).

The business case is supported by an Economic Impact Assessment (EIA), conducted by Steer-ED. The EIA argues that the project offers strong value for money, with a net GVA figure of £28m by 2027 – this is double the total project cost, representing good value for money, especially in relation to the 10% MCA investment. In addition to that GVA figure (which is drawn from an estimation for the jobs generated), the EIA also considers impacts to manufacturing and research. These 'halo' benefits are quantified at over £10m per year, although they are reported as a "low certainty" opportunity for "transformational growth" rather than being a forecast added to the main GVA figure.

Impact by 2031	**£m**
Annual gross GVA	9.5
Annual net GVA	3.6
Cumulative gross GVA (Over 10 years)	65.1
Cumulative net GVA (Over 10 years)	24.8
Cumulative net, discounted GVA	19.6
Net Present Value (benefit minus costs)	18.1

The benefit-cost-ratio of 13.1 (or 8.7 when taking into account optimism bias), represents a substantial, positive return on investment. The cost-per-job of £23.2k, (or £34.8 with optimism bias) also represents good value-for-money against standard benchmarks.

As noted in an update from the applicant, the difference between the do-nothing and preferred options on number of jobs is relatively slight, but the broader 'halo' benefits to research and manufacturing through the creation of spinouts and inward investment are largely lost if the preferred option does not go ahead. These halo benefits are not quantified and weighted for likelihood, but their impact is expected to be transformational both strategically and economically (+£10m per annum).

The MCA and the applicant will explore how the grant can be recovered (in part or in full) if any exploitable IPR generated by the Gene Therapy Innovation & Manufacturing Centre (GTIMC) is successfully exploited by the University of Sheffield or any subsidiary company, such that University of Sheffield is in a position to repay the investment in order to allow the MCA to invest in other projects.

Risk

What are the most significant risks and is there evidence that these risks are being mitigated?

The FBC (section 6.7) summarises the top five delivery risks, their impact and the mitigation measures.

- *Risk 1: Failure that the building design fulfils the requirements of the project brief. This has been mitigated through appointing external specialist consultants (Exmoor Ltd) to review and feedback during design development.*
- *Risk 2: Failure to achieve MHRA accreditation, a statutory requirement, prior to commercial activity commencing. This has been mitigated through appointing external specialist consultants (Exmoor Ltd) and inviting a specialist to join the GTIMC board to provide advice and guidance*
- *Risk 3: Viral manufacturing process not being established in Sheffield due to failure to procure equipment. This is being managed through the existing Cell & Gene Therapy Catapult platform being transferred to the Sheffield facility.*
- *Risk 4: Failure to appoint an experienced management team. This has been mitigated by engaging a specialist recruitment agency (NextPhase) to help with recruitment of staff.*
- *Risk 5: Failure to meet the Project/building programme resulting in delayed to the overall project programme. Design is moving to RIBA stage 3, planning application submitted, contractor selection in progress with projected start date on site of August 10th, 2021 and building completion May 2022.*

In summary, the project has made good progress and the project team has demonstrated they are able to manage risks effectively. The assessment indicates that while the impact of these risks occurring would be high, the steps in place to manage the risks implies that the likelihood of them occurring is low.

Do the significant risks require any contract conditions? (e.g. clawback on outcomes)

A risk log is provided in Appendix A.3. One risk identified would be failure to achieve MHRA accreditation, a statutory requirement, prior to commercial activity commencing. This would require a redesign of the building resulting in delays and further financial cost. If possible, the MCA may wish to explore the option of allocating funding but only releasing once MHRA accreditation is achieved. This would reduce the risk to the MCA. No clawback conditions are anticipated by the assessor.

Are there any significant risks associated with securing the full funding for the scheme?

There are no significant risks associated with securing the full funding. The FBC (section 5.3) indicates that, with the exception of the MCA funding, the other remaining sources of funding have largely been secured.

Are there any key risks that need to be highlighted in relation to the procurement strategy?
In the accompanying risk register, two risks are identified in relation to procurement. The first risk relates to end users of the GTIMC procuring alternative research equipment. This would have an impact on the design of the building and cost of the project. The project team will manage this risk through UoS governance structures who will be called upon to approve changes to the design. The second, and perhaps more important, risk relates to contractor and sub-contractor insolvency which would result in delays and financial implications. This risk will be managed through due diligence checks undertaken at the procurement stage.

Overall, the risks associated with the procurement strategy are being appropriately managed and the likelihood of them occurring is small.

Delivery

Is the timetable for delivery reasonable and has the promoter identified opportunities for acceleration?

Overall, the delivery plan – and therefore the realisation of downstream benefits – looks tight, with almost immediate start-on-site. However, the UoS has provided reasonable evidence which indicates that it is confident that all aspects will be delivered against the plan. The senior management and the University Executive Board are fully committed to delivering this project, the University has mobilised a strong team of Estates, external contractors and experts to ensure successful completion of the project to timelines, and contractors have been made aware of the MRC/LifeArc milestones and timelines. The Assessor is satisfied that the timescales are deliverable and contingency plans are in place to mitigate any risks.

Is the procurement strategy clear with defined milestones?

Procurement on the design phase has already been completed. eXmoor Ltd to support the design, accreditation and equipment specification for GTIMC with due diligence checks completed, including financial security. Thus, minimising delays to the design, accreditation and equipment specification for GTIMC.

The FBC indicates that procurement arrangements are yet to be finalised. For example, no decision has been made in relation to what procurement procedure will be used (e.g., open, restricted, use of frameworks, use of PINs, competitive dialogue and competitive procedure with dialogue). Similarly, procurement documents are yet to be drafted. The project team indicates that contractual obligations will be agreed at the time of awarding the tender. Due diligence checks will also be undertaken at tender on main contractor and subcontractors.

As yet no equipment has been procured. However, the FBC indicates that University’s terms and conditions will be in place for the purchase of all equipment. There will be no financial risk to the University or MCA. Completion of the equipment procurement will be approximately July 2022.

What is the level of cost certainty and is this sufficient at this stage of the assurance process? Has the promotor confirmed they will cover any cost overruns?

Section 5.1 in the FBC indicates the project meets the 95% cost certainty threshold. However, the project team has been unable to achieve full cost certainty due to equipment costs being based on estimates using list prices. Furthermore, given that procurement will commence in September 2021, the project team has not yet received any formal quotes or tenders. The Assessor has identified an increase in equipment cost as a possible risk. However, the FBC indicates that the equipment budget will be managed to ensure it remains within the overall equipment budget envelope. Any overspends will be borne by the Faculty of Medicine, University of Sheffield therefore no additional liability will fall to the MCA.

Has the promoter demonstrated clear project governance and identified the SRO? Has the SRO or other appropriate Officer signed of this business case?

Overall, the promotor has demonstrated clear project governance. The FBC has identified key individuals responsible for the delivery of the project (including the SRO) as required. However, more detail could be provided in terms of how the various key individuals will engage with the successful contractor to ensure delivery. How will governance structures operate once the building is operational?

Has public consultation taken place and if so, is there public support for the scheme?

Section 6.8 in the FBC indicates that the project has undertaken various public consultation activities. Notably, Sheffield City Council led a 12 week consultation process provided the opportunity for the public to comment on the GTIMC proposal during the planning application stage. Furthermore, the SCR Strategic Business Case has also been placed on the University of Sheffield, Partnerships & Regional Engagement pages with opportunities to provide comments (Annex 4). However, the outcome of the consultations (i.e., comments received) have not been provided so the Assessor is unable to comment on whether there is public support for the project. To strengthen the case further, the Assessor recommends detailing the outcome of the consultation and providing feedback to concerns raised where necessary.

Are monitoring and evaluation procedures in place?

A management committee will maintain oversight of the work of GTIMC and its progress against its strategic aims, including delivery of the SCR contracted outputs. Furthermore, within the University a Project Executive Committee also meets monthly and has oversight of the capital project to ensure the building works remain on programme and within budget.

In terms of evaluation, the FBC indicates that an independent consultant will be engaged in 2025 to undertake an evaluation of the economic impact of GTIMC and that objectives outlined in the business case have been realised. SCR MCA will be consulted and provided with copies of all evaluation reports.

While the outputs/outcomes and milestones are clearly defined, the Assessor has identified some areas where additional information could be provided to strengthen the case. In terms of monitoring, additional information could be provided on what data will be collected to evidence progress on the outputs/outcomes/milestones. Furthermore, many of the milestones relate to project construction.

Legal

A detailed assessment of Subsidy Control is provided in Annex 13. The assessment concludes that, based on a four part test, the grant would be to the University, rather than subsidy to one or more commercial entities.

Recommendation and Conditions

Recommendation	Full approval (proposal for 50% of grant to be repaid in 2028 when the three high value spin outs will have launched successfully)
Payment Basis	Grant on defrayal
Conditions of Award (including clawback clauses)	

The following conditions must be satisfied before contract execution.

1. ***Confirmation that all other funds have been secured***

The following conditions must be satisfied before drawdown of funding.

2. ***MCA funds must not be released before full MHRA accreditation***

The following conditions must be included in the contract

3. ***Agreed schedule of inclusive and environmental commitments***
4. ***Clawback on outcomes***
5. ***Agreement that the applicant will cover any cost overruns***
6. ***Agreed percentage of grant repayment in the event of increased profits when the 3 high value spinouts have been launched.***