**Appendix 3**

**Medicines Discovery Catapult**

**Specification for IMPACTT project - IMmunity Profiling of pAtients with Covid-19 for Therapy and Triage**

1. **Introduction:**

During the COVID-19 pandemic, it has become clear that some infected patients suffer severe and occasionally fatal reactions, while others appear to have less severe and, in some cases, no symptoms.

Oncimmune, who are leading on IMPACTT, are experts in serological antibody profiling. These profiles give unique insights into a patient's past exposure to the virus, disease status and response to therapy, including potential immune-related adverse events.

Using proprietary SeroTAG(TM) high through-put antibody profiling platform the aim of IMPACTT is to profile the immune systems of 3,000 patients falling into three symptom categories (mild/moderate/severe) to identify signatures indicative of each category.

MDC has partnered with Oncimmune on the IMPACTT project in order to provide the patient samples and clinical data to create the largest severity-based COVID biobank and national samples and data registry.

1. **Requirements:**

We are looking for appropriate tender responses for the provision of SARS-COV-2 patient samples in order to appoint suppliers onto a Framework Agreement, with the aim of providing clinical samples for immune profiling. SARS-COV-2 samples are required to be delivered by the end of March 2021, however MDC / Oncimmune may accept samples at a later date, this is subject to review. It is anticipated that a maximum of six (6) suppliers will be appointed to the framework agreement; however, MDC reserves the right to appoint fewer or more than this number if it is deemed to be in MDC’s best interest. Following successful appointment to the Framework Agreement, the services will be called off in accordance with section 11 within the ITT.

The successful Supplier(s) will provide samples directly to MDC’s collaboration partner Oncimmune Limited and for this purpose will enter into a separate material transfer agreement (MTA) with MDC and Oncimmune in the form set out in appendix 7.

The **essential** specifics of the samples required are as follows:

* 1ml (ideally as 2 x 500µl) of serum or plasma from patients previously diagnosed with SARS-COV-2
* Collected in red top serum or lavender top EDTA plasma tubes
* Pour off tubes can be stored at 4-8oC for up to 4 weeks
* Samples frozen and stored at -20oC or below.
* Samples to be shipped on dry-ice and labelled and packaged in accordance with UN3373
* Virus inactivated

The **desirable** specifics of the samples required are as follows:

* Samples to be collected from mixed UK ethnicity patients, ensuring black, Asian, and minority ethnic (BAME) are included in the cohort, due to the increased risk these ethnicities have.
* Samples should be processed according to Onc-80304g
* 1000 patients with mild symptoms\*, not present in other symptom cohorts
* 1000 patients with moderate symptoms\*\*, not present in other symptom cohorts
* 1000 patients with severe symptoms\*\*\*, not present in other symptom cohorts
* Sequential samples, for any patients but especially severe
* Samples to be stored in 2D-barcoded Micronic tubes
	+ Cap supplier: thermo fisher (product code: 4470WHI) (or equivalent)
	+ Tube supplier: thermo fisher (product code: 3745) (or equivalent)

**Essential** Patient data required with samples:

* Gender
* Age/DOB (over 18)
* All medication details prior to or at time of blood draw (for COVID-19 and other health conditions)
* COVID-19 diagnostic test result
* Underlying health conditions, in particular risk factors such as:
	+ Diabetes
	+ Asthma
	+ Smoking status
	+ COPD
	+ Any sort of lung disease
	+ Chronic kidney disease
	+ Hypertension
	+ Cardiovascular disease
* Date of blood draw
* Date of COVID-19 symptom onset
* COVID-19 symptom at time of blood draw:

- Loss of sense of taste or smell
- Headache
- Diarrhoea

 - fever (body temperature >37.8°C)

- acute persistent cough

- breathing difficulties such as shortness of breath

* Date (month) of death (if applicable)

**Desirable** Patient data required with samples:

* COVID-19 diagnostic test ID/name and manufacturer(s)
* Date of sample acquirement for diagnostic test(s)
* Any symptom escalation post blood draw, with dates
* Date of symptom cessation i.e. information on long covid/post-covid-19-syndrome
* Covid-19 associated symptoms including onset and cessation dates e.g. post-covid-19-fibrosis
* Patient data:
	+ BMI
	+ Ethnicity
	+ Blood type
	+ Place of residence (e.g. town)

\***Mild:** Patient not hospitalised and has no symptoms, or has mild symptoms reflective of COVID-19 [1]. Mild symptoms may include one or a combination of the following:
- Loss of sense of taste or smell;
- Headache;
- Diarrhoea.

\*\***Moderate:** Patient not hospitalised and does not have a requirement for supplemental oxygen, but has presented with moderate symptoms reflective of COVID-19 [1]. Moderate symptoms may include one or a combination of the following:

- fever (body temperature >37.8°C)

-respiratory tract symptoms (acute persistent cough and/or breathing difficulties, such as shortness of breath or influenza like illness);

\*\*\***Severe**: Patient has been hospitalised with symptoms reflecting COVID-19, and may have required oxygen supplement, mechanical ventilation, multi-organ support or the patient died in hospital following admission with COVID-19 symptoms [1].

## **Mandatory and Desirable Requirements**

* 1. Mandatory Criteria

For your tender submission to be evaluated, your organisation **must** meet the following criteria:

* Evidence of samples being collected under an existing Ethics approval (from IEC, IRB or equivalent body within the source region) for the purposes of the IMPACTT;
* Evidence of commercial consent in place;
* Details of established quality systems and supporting documentation (for example but not limited to pathology QC checking of samples, SOPs, standard MTA);
* Logistics/shipping capability and ability to deliver the samples (ideally in two aliquots, one being 500 μl and the other any remaining volume) within an agreed period directly to Oncimmune Limited or to any other destination notified by Oncimmune Limited or MDC;
* Evidence of samples being deactivated by an accepted virus deactivation protocol prior to shipping to Oncimmune Limited; and
* Agreement to the terms of the MTA as set out in appendix 7.
	1. Desirable Criteria
* Details of quality certification, for example, ISO 9001:2015 Quality Management Systems, ISO13485 Quality Management Systems – Medical Devices (or equivalent)
* Details of established processes around traceability and end to end tracking
1. **Quality Assurance**
	1. Sample Collection

It is desirable that samples are collected and processed according “Section 1. Venepuncture protocol” and “Section 2. Specimen processing” of Onc-80304g SOP appendix 8. If collection is carried out via a different protocol it is essential that the details of collection are provided.

* 1. Sample Storage

It is desirable that samples are stored according to “Section 3. Sample storage” in Onc-80304g SOP appendix 8. If the samples are stored differently, it is essential that the details of collection are provided.

* 1. Sample Shipment

Samples will be batch shipped to minimise shipping costs, at appropriate intervals as agreed at the outset by Oncimmune and MDC and in accordance with the terms of the MTA.

1. **Legislation / Regulations**

The Tenderer must ensure compliance to the following regulations:

Data Protection Act 2018/GDPR/Human Tissue Act 2004 (UK only, or equivalent for the region of collection).

1. **Licences**

Please provide evidence of the following licences as may be required by all applicable legislation and regulations within your tender submission:

Human Tissue Authority licence (UK only, or equivalent for the region of collection).

**References**

[1] Laing, A.G., Lorenc, A., del Molino del Barrio, I. et al. A dynamic COVID-19 immune signature includes associations with poor prognosis. Nat Med 26, 1623–1635 (2020). https://doi.org/10.1038/s41591-020-1038-6