

## Private and Confidential

Dr H Vinod Bhat Vice Chancellor Manipal Academy of Higher Education Manipal, India

E-mail: <u>clinical.research@indiaalliance.org</u> Telephone: +91 40 4018 9445 Our Ref: IA/CRC/20/1/600002 24 September 2021

Dear Dr Bhat,

DBT/ Wellcome Trust India Alliance (hereinafter referred to as 'the India Alliance') has agreed to award a Clinical/Public Health Research Centres Grant for 60 months under your sponsorship for the study entitled, **"Center for Rare Disease Diagnosis, Research and Training"** submitted by the following (hereinafter referred to as 'Grantholders')

## Principal Investigator (PI): Dr Katta Girisha, Manipal Academy of Higher Education

Co-Investigator 1: Dr Anju Shukla, Manipal Academy of Higher Education Co-Investigator 2: Dr Akhilesh Pandey, Institute of Bioinformatics Co-Investigator 3: Dr Aarti Sevilimedu, Dr. Reddy's Institute of Life Sciences

The India Alliance (IA) reserves the right to amend any terms and conditions in this Award Letter. In the event of any conflict between the provisions of this Award Letter and of the Award Conditions, the provisions of the Award Conditions shall take precedence.

# An award of up to ₹9,99,99,999.00 has been provided to the Manipal Academy of Higher Education, Manipal (hereinafter referred to as 'Lead Host Institution') for this purpose.

The Grant has been given a start date of **01 October 2021** and the funds are detailed in the Schedule A annexed to this letter.

The following details along with the enclosed **Award Conditions** outline the framework in which the Grant will operate.

- 1 Terms
- 2 Costs
  - 2.1 Ring-Fenced Funds
  - 2.2 Transferable Funds
- 3 Payment
- 4 Anti-Corruption and Anti-Bribery
- 5 Application Reviews
- 6 Contact

# 1. Terms of the Award

Note: The required documents, as listed under 1.1 and 1.2, have to be submitted before the start date of the Grant. In the absence of these, the Grant will not be activated on the indicated date.

## 1.1. Before Activation

- 1.1.1. This award must be activated no later than **01 October 2021**. The activation of the award is conditional to the submission of the following by the Grantholder:
- 1.1.2. <u>Acceptance</u> Duly signed completed Grant Start Certificate (format attached). This certificate should be signed by all Grantholders and authority concerned at each Host Institution and received at the India Alliance Hyderabad office before **30 September**

Admn. Office DBT/Wellcome Trust India Alliance 8-2-351/N/1, Nishant House, 2nd Floor, Rd No. 2, Banjara Hills, Hyderabad, T.S. 500034 4 +91 40 40189445/6/7 # +91 40 40189449 Regd. Office : DBT/Wellcome Trust India Alliance Department of Biotechnology, C.G.O Complex, Block 2. Lodhi Road. New Delhi - 110003

**2021**. The India Alliance reserves its right to not compensate the Grantholders for any expenses incurred prior to receiving the duly completed Grant Start Certificate.

- 1.1.3. <u>A formal agreement or MoU</u> between the participating institutions stating that they will have the mechanisms to set up sub-contracts, transfer funds, maintain accounts and report the funds that will be sent to the Host Institution of PI from India Alliance.
- 1.1.4. <u>Composition of Advisory Board</u> along with Consent of all members to be part of the board.
- 1.1.5. <u>Ethical Approval</u> Submission of any and all necessary approvals and sanctions obtained from the relevant authorities in compliance with the applicable national and international regulations for carrying out research involving stem cells / human biological samples / conduct of human clinical trials / conduct of clinical trials on animals / performance of any procedures on animals and humans, in the prescribed format (attached). In the absence of a valid ethical approval, an undertaking from the Sponsor of respective institution must be provided in the prescribed format stating that the Host Institution has the mechanism in place to ensure that the Grantholders shall comply with any conditions imposed by the relevant authorities that provide the ethical sanctions for the conduct of research and that the Grantholders will not commence the aforementioned experiments, unless they submit the appropriate approvals to the India Alliance.
  - 1.1.5.1. Projects involving clinical trials: It is the responsibility of the Sponsoring Host Institution and the Grantholders that projects having a clinical trial component shall comply with all applicable national and international regulations. A confirmation from Sponsor of respective institution is required that the Grantholder will not commence the trial, unless they submit the appropriate approvals to the India Alliance, and that institutional ethical committees and administrators have mechanisms in place for protection of human participants, assessment and analysis in case a serious adverse event is reported during the course of the project. The costs incurred to procure insurance for clinical trials may be taken from the funds provided by India Alliance. However, it is clarified that India Alliance will not be responsible or liable in any manner whatsoever for any direct or indirect injury caused to the volunteer(s) or any third person during the course of or in relation to the clinical trial.
- 1.1.6. <u>Privacy</u> A letter from the Grantholder addressed to the India Alliance giving his/her explicit consent for the collection of sensitive personal data, for example name, date of birth, age, email id etc (as per Section 2 (1) (i) of IT Rules 2011, IT Act 2000) of the Grantholder by the India Alliance and the right to retain the said information for a period of 15 years for the effective implementation of the Grant (included in Grants Start Certificate format).

## 1.2. Before release of Funds

- 1.2.2. A joining report from the Host Institution in the format provided by the India Alliance (when the Grantholder joins the Host Institution if was not associated with the same Host Institution)
- 1.2.3. A completed Payment Details Form provided by the India Alliance.

# 1.3. During the Grant

- The Host Institution shall inform the India Alliance of
- 1.3.1. any change in the position of the Grantholder at the Institution. The Grantholders should hold an academic or research post and have a salary, or the guarantee of a salary, for the duration of the award period.
- 1.3.2. Submit Spend Reports by May 31 of each year detailing all the expenses incurred up to March 31 of the year in the form provided by the India Alliance. In cases where funds are transferred to other Host Institutions from the Lead Host Institution, India Alliance will accept only one consolidated Spend Report from the Lead Host Institution. It is the responsibility of the Lead Host Institution to coordinate with other Host Institutions and provide a record of expenditure.
- 1.3.3. Ensure that the approvals required from the relevant authorities are in compliance with the applicable national and international regulations for carrying out research involving stem cells/ human biological samples/ conduct of human clinical trials/ conduct of clinical

trials on animals/ performance of any procedures on animals and humans are obtained before the conduct of any such procedures or research experiments are performed.

- 1.3.4. Invest the funds received from India Alliance in the form of an interest-bearing account in a nationalized bank.
- 1.3.5. The Grantholder and Host Institution shall, at all times, keep indemnified the India Alliance against any losses, liability damages or compensation (including legal costs) payable as direct or indirect consequences of any accident, death or injury involving their employees or any other third party, and resulting directly or indirectly from or by any act, omission or operation conducted by or on its behalf. Further, Grantholders shall, at all times, indemnify and keep indemnified India Alliance against all liability, losses or, damages, compensation, etc. payable as a result of any infringement fany Intellectual Property Rights (IPR) of any third party while carrying out its responsibilities/work in relation to the Project and this Agreement.
- 1.3.6. Funds utilized to procure insurance for clinical trials may be charged to the India Alliance funds. However, it is clarified that India Alliance will not be responsible or liable in any manner whatsoever for any direct or indirect injury caused to any volunteer(s) or any third person during the course of or in relation to a clinical trial

## The Grantholder has to inform the India Alliance of -

Grants and Fellowships

- 1.3.7. Any Grants/Fellowships which he/she intends to take from other funding organizations by providing -
  - 1.3.7.1. The name of funding organization along with the scheme and award amount
  - 1.3.7.2. The title, abstract, duration and any overlap with India Alliance project
  - 1.3.7.3. Grantholders, who currently have or secure additional funding through other schemes of India Alliance, need to submit modified time commitment information to each of the funded projects

## Annual Reports

- 1.3.8. The Grantholder shall on a yearly basis send to the India Alliance the following
  - 1.3.8.1. Research Report to be received by India Alliance by November 30 of each year unless otherwise specified by India Alliance. The PI is expected to report the consolidated progress in the project that may be conducted in multiple Host Institutions.
  - 1.3.8.2. Spend Reports to be submitted by May 31 of each year detailing all the expenses incurred up to March 31 of the year in the form provided by the India Alliance.

## Annual Review Meetings

1.3.9. The India Alliance will periodically organize meetings for all its Grantholders. Information on the meetings will be made available well in advance and attendance by the Grantholder facing mandatory review is obligatory. A mid-term review would be done in Year 3.

## **Cancellation**

- 1.3.10. The India Alliance continuously evaluates the Grantholder's progress. Funding after the third year will be contingent upon a satisfactory review of progress made during the first half of Grant (Award Condition on Monitoring and Evaluation);
- 1.3.11. The India Alliance reserves its right to not release the next installments of the funds unless the required Annual Reports are filed by the date detailed in the Award Letter and the India Alliance shall not be responsible for any delay in the release of funds.
- 1.3.12. India Alliance reserves its right to cancel the funding if the Grantholders violate any of the Award Letter and Award Conditions.

## **1.4. Upon Completion of the Grant**

The closure process and documents required towards successful completion of the award would be shared with Grantholders by the India Alliance towards the end of the Grant.

- 1.4.1. The Host Institution is required to submit an <u>Audited Spend Report</u> indicating all the expenditures incurred on the Grant during the tenure.
- 1.4.2. The Grantholder shall be required to submit the Research Report detailing the highlights of this project and other accomplishments in the format provided by India Alliance.
- 1.4.3. The India Alliance reserves its right to not release the eligible retained funds (based on actual expenditure incurred) unless documents required to be submitted under clause of this letter 1.3 above reach the office within three months of the end of Grant.

## 1.5. Post-Grant

- 1.5.1. The Grantholder is required to inform India Alliance about the outputs from its funded research even after the completion of funding.
- 1.5.2. The Grantholder is required to abide by the policies on Open and unrestricted access to published research and intellectual property and patenting on outputs from India Alliance funded research.

## 2. Costs

The Award provides funding for directly incurred costs on the Grant, including its associated research project. Directly incurred costs are auditable actual costs; that are explicitly identifiable as arising from the conduct of a project (e.g. staff salaries, equipment, materials, travel). The award is cash-limited.

India Alliance would send funds to only the Lead Host institution. That institution should have the ability to set up sub-contracts, transfer funds, maintain accounts and report these on behalf of all participating institutions. If the project includes an overseas collaborator, the sponsoring institution would coordinate with that as well.

The host institution(s) should demonstrate commitment by supporting the project with cash (e.g. a matching grant) or kind beyond the usual support for space and utilities.

These funds are not to be utilized to create physical spaces (examples: labs or buildings).

# There will be no provision for a no-cost extension of the programme if funds are unutilized at the end of its term. The unutilized funds shall be returned to IA.

The award is divided into two primary types of funds: (1) ring-fenced and (2) transferable.

## 2.1. Ring-fenced Funds

These funds can usually be used only for the purposes detailed below:

- 2.1.1. Personal Support Contribution
  - 2.1.1.1. In case where India Alliance has agreed to pay part of salary for a Grantholder [only where the Host Institution expects the Grantholder to generate part of salary from extramural funds]. If during the term of the Grant, the Host Institution begins to pay the entire salary to the Grantholder, then the India Alliance contribution would turn to zero. In this scenario the Grantholder may be permitted to claim in the penultimate year of the Grant, upon providing suitable scientific justification, the ring-fenced funds so accrued on account of the reduced contribution by India Alliance.
  - 2.1.1.2. It is the responsibility of the Grantholder and the Host Institution, to determine how the emoluments should be presented for tax purposes.
- 2.1.2. Expenses incurred by the partner Host Institution- support by India Alliance;

To enable the partner Host Institution to meet some of the expenses in connection with the project, a sum of 10% of the total funds is being made available. These funds should be applied in such a way that they support the Grantholder's research, e.g. by contributing to costs for laboratory infrastructure, utilities, or administrative support relating to the research. It is required that charges made against this heading must be based on the actual expenditure incurred on the research funds on the Grant and not on the allocations described on the payment profile and at no point will India Alliance release any additional funds. The interest earned, if any, by the Host Institution on the India Alliance funds will be adjusted annually before making future disbursements.

## 2.2. Transferable Funds

- 2.2.1. Budgets detailed under 'Transferable funds' are indicative only and movement of funds between budget headings is allowed. Grantholders are provided the flexibility to use 'Transferable Funds' as required for the pursuit of their research goals with two exceptions:
  - 2.2.1.1. Funds may not be used to purchase, maintain or perform procedures on animals not included in the award letter. Permission from the India Alliance office must be obtained prior to implementation of any changes.
  - 2.2.1.2. Grantholders may not support any additional staff without prior permission from the India Alliance.

### Research Staff

2.2.2. All research staff associated with the Award shall be paid as per the salaries indicated on the India Alliance website or Government of India guidelines as revised from time to time (whichever is higher). The contract of employment of research staff shall be coterminous with that of the Grant.

### Flexible Funding Allowance

2.2.3. The Flexible Funding Allowance (FFA) is intended to increase financial flexibility available to Grantholders, and to simplify Grant administration. The FFA can be used to meet unanticipated directly incurred costs that would assist in meeting the goals of the research. This includes, but is not limited to, publication costs, travel and training fees for research staff, and other miscellaneous costs.

## Travel to Meetings

2.2.4. These funds are for attendance of scientific meetings, or for short working visits to other laboratories, for the Grantholder and any staff employed on the Grant. It is a matter for the Grantholder to decide as and when the funds should be used. Visits to the India Alliance office and for India Alliance events are expected to be funded from this budget.

Materials & Consumables, Equipment and Animals

2.2.5. Funds provided for materials, consumables, equipment and animals are also transferable. Animals purchased, maintained and/or used for the research purposes cannot exceed the number requested in the Grant.

## 3. Payment

All payments on the award will be made electronically via bank transfer to the account provided by the Host Institution in the Payment Details Form.

The India Alliance will provide funds pro-rata on a yearly basis following the financial year (1 April - 31 March) cycle. Equipment cost will generally be released in equal payments in the first two installments, unless specified otherwise by the Grantholder. All other ring-fenced and transferable funds will be released in yearly installments. A provisional payment profile of the disbursements will be released by India Alliance, at the time of release of payments.

2% of total transferable funds and overheads are withheld from the penultimate installment. The India Alliance will not release the eligible retained funds (based on actual expenditure incurred) unless reports required under Clause 1.4 of this letter reach the office within three months of the end of Grant. The formats for the final reports will be shared closer the Grant end date.

The first two installments will be released in whole, regardless of the amount spent by the Grantholder. From the third installment onwards, if any amount from the previous year is unspent, this will be carried forward and the balance will be adjusted against the next installment.

# 4. Anti-Corruption and Anti-Bribery

The Grantholder and Host Institution will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to India Alliance or its funded project or Host Institution, including by assisting any party to secure an improper advantage.

# 5. Application Reviews

The India Alliance application process relies on the co-operation of the scientific community in providing referees' comments on proposals, and the Grantholder's success with this application is partly due to the goodwill of scientists in providing comments. As a holder of an India Alliance Grant, the Grantholder is therefore expected to undertake review of research proposals submitted to the India Alliance upon request.

### 6. Contact

The India Alliance staff would be glad to meet with the Grantholders at any time, either at their laboratory or at the India Alliance offices in Hyderabad or Delhi. These visits would be to ensure that a good working relationship is built between the India Alliance, Grantholder and the Host Institution.

For further clarifications regarding the Grant, please write to clinical.research@indiaalliance.org

Best wishes,

Dr Madhavan Chalat Senior Grants Advisor

Cc: PI

All co-PIs All other Sponsors <u>The Wellcome Trust / DBT India Alliance</u> Mr Nataraj Bollam (Finance Manager) Mr Soumya Prakash Dalua (Manager – Operations (Grants Process))

Encl Award Conditions Payment Details Form Grant Start Certificate Schedule A- Sanctioned budget details Ethics approval format

# SCHEDULE A

# **RING-FENCED FUNDS:**

	Total (₹)
Contribution towards Personal support for Grant holders	
Post 1 – Dr Katta Girisha	0.00
Post 2 - Dr Anju Shukla	0.00
Post 3 - Dr Akhilesh Pandey	0.00
Post 4 - Dr Aarti Sevilimedu	0.00
CONTRIBUTION TOWARDS INSTITUTIONAL OVERHEADS	90,90,909.00
Sub Total (A)	90,90,909.00

#### TRANSFERABLE FUNDS:

Maintenance and procedure	50,000.00
Purchase: 5 animals @ INR 70,000/animal	3,50,000.00
Danio rerio	
ANIMALS	
MATERIALS & CONSUMABLES	4,98,19,330.00
TRAVEL COSTS	20,00,000.00
FLEXIBLE FUNDING ALLOWANCE	20,00,000.00
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Post 17 – JRF for 60 months	18,60,000.00
Post 14 – Post Doc for 60 months	33,60,000.00
Post 15 – Post Doc for 60 months	40,20,000.00
Post 14 – Post Doc for 60 months	40,20,000.00
Post 12 – Technician for 60 months	12,00,000.00
Post 12 – Technician for 60 months	14,88,000.00
Post 11 – JRF for 60 months	18,60,000.00
Post 10 – Post Doc for 60 months	40,20,000.00
Post 9 – Post Doc for 60 months	33,60,000.00
Post 8 – Post Doc for 60 months	34,96,800.00
Post 7 – SRF for 36 months	15,62,400.00
Post 6 – JRF for 24 months	9,22,560.00
STAFF SALARY SUPPORT Post 5 – Technician for 60 months	12,00,000.00
	Total (₹)