

Indian Council of Medical Research (ICMR), New Delhi

DIVISION OF BMS

Call for Letters of Intent (LOI) on Venous thromboembolism

Background

Venous thromboembolism (VTE) is a common and potentially life-threatening condition. It is quoted as a major health problem and one of the most common preventable causes of hospital deaths. VTE has rarely evoked such consideration in India. It continues to be underdiagnosed and undertreated. Awareness among Indians regarding this potentially life-threatening disease is low. Contrary to earlier belief, the incidence of VTE in Asia and India is comparable to that in Western countries. The risk of VTE is especially high in hospitalized patients, in a majority of whom it is clinically silent. It is one of the commonest causes of unplanned readmission and preventable death.

In light of the above fact, the expert committee on VTE at Indian Council of Medical Research, New Delhi also felt the urgent need to work and explore this important area. Additionally, in lieu of current pandemic, studies have suggested that there is increased risk of thromboembolism associated with coronavirus disease 2019 (COVID-19). However, overall arterial and venous TE rates of COVID-19 and effect of TE on COVID-19 mortality is unknown.

The intent of this LOI is to support studies in this area and establish a network of institution involved in to VTE related work and research. The Network partners will be purposefully and strategically picked up across the country. This network would include medical colleges, tertiary health care institutes and academically active corporate hospitals with well-established coagulation lab, radiological/imaging settings and good diagnostic facilities. This opportunity is open to those working on VTE also clinical as well as basic researchers desirous of developing and honing their skills in VTE research.

Objective of call for LOI

- i. To establish a network of institution involved in to VTE related work and research. Comprising both clinical sites and basic science institutions.
- ii. LOI shall explore the institutional interest to establish a surveillance network of VTE with existing clinical facilities, diagnostic facilities and management facilities for VTE.
- iii. This LOI will also seek for basic science laboratories and institutions with VTE related existing research facilities and capabilities.
- iv. This network intent to support scientists and clinicians who work as multidisciplinary teams to solve the pressing public health problem of VTE.

LOIs will be screened based on clarity of questions asked/ hypothesis, relevance and innovative approaches, ability to implement the approaches, background of the investigator and feasibility of doing rigorous research in his present setting. The Network members will be identified in transparent and pre-defined criteria. While experience in the area will be valued but will not be limiting for the right proposal

Mechanism of selection of institute under LOI:

- i. An expert group will shortlist the potential network partners. The selected centers may be invited to submit a subsequent standard grant application form which the Expert committee will make the final recommendations. The competent authority would give the final approval at ICMR as per rule.
- ii. The Network will be linked to basic science state of art research institutions to carry forward genetic, hematologic, path-physiological and drug development research.
- iii. Thus a multi-centric and multi-departmental network is proposed coordinated by the ICMR secretariat
- iv. A networking meeting of all the selected participants would then be facilitated by ICMR to develop

multi-approach, multi-disciplinary program towards an identified goal with both short term and long term objectives clearly defining the scientific approaches.

A. Call for LOIs to be part of National VTE Network (Multidisciplinary & Multicentric study)

This network will be established with the following objectives:

- i. To establish a surveillance network of VTE and related thrombotic manifestations to conduct various studies pertaining to disease burden estimation, analysis of disease outcome statistics, Identification of prognostic factors and study of various factors affecting outcome complications.
- ii. To establish a network of tertiary and secondary care hospitals database related to VTE by developing a hospital-based network. It would help to develop a comprehensive clinical and demographic profile for VTE.
- iii. The applicant should suggest two pressing research questions that have clinical, public health and laboratory relevance.
- iv. It will help to create clinical profile of patients.
- v. To establish an extensive database related to VTE by developing a hospital-based registry

B. LOIs for Basic Clinical Research laboratories (Multi-centric approach)

This would intent to involve Multidisciplinary approaches that integrate genomic, cellular, biochemical, and biophysical strategies to advance fundamental understanding and translate knowledge to patient care are needed to provide optimal insight to the field and to the patients, the ultimate beneficiaries of these efforts. This network will be established with the following objectives:

- i. To establish a national VTE network to carry forward the basic science studies (including genetic, hematologic, metabolomics, proteomic, other pathophysiologic and drug development studies)
- ii. Identify the role of novel biomarkers to predict VTE recurrence risk
- iii. Distinguish mechanisms of in situ thrombosis vs embolization
- iv. To encourage research in important clinical problems like Heparin-induced thrombocytopenia (HIT), thromboembolic manifestations of Covid-19, thromboembolic events associated with Covid vaccines
- v. Explore the efficacy of VTE treatment strategies based on thrombus characteristics instead of duration
- vi. Identify causes of breakthrough VTE despite adequate prophylaxis
- vii. Mechanistic studies to determine the factors responsible for VTE in Indian context and then point no. ii, iii, iv, can be added as sub-points.

Pre-requisites for application for A (Medical/clinical institute)& B (Basic science)

- i. The interest group would need to prove the availability of required infrastructure/clinical facility to carry out the work.
- ii. The interested group would have to prove the partnership among the stakeholders involved in proposed study.
- iii. A 2-3 page concept note for the proposed study has to be submitted on the research area with its importance/relevance in the subject. This concept note should include why and how their institute would be useful for network. What kind of novel study can be conducted by their institute.
- iv. One of the lead investigators should be a stakeholder from the requested institute. The composition of the research team must be multidisciplinary and should include at least one of each subject expert from public health, pathologist, clinician, radiologist, Hematologist and a biochemist. All should have defined roles and responsibilities as part of the network.
 - Each research study shall have an integral component on strengthening capacity of researchers, as well as institution;
 - Each letter of intent shall describe the roles and responsibilities of each team member – in the planning,

conduct and successful development of the study, as well as in the utilization of the study-findings.

- Application to Call of LOI should be submitted through proper channel and necessary approvals from the competent authorities of institute. Only One group/Institute may apply under A / B above.

C. Call for concept notes for Individual Research laboratories (Single site studies)

This is intended to receive letter of interest from the individual researchers with the aim to focus on the following but not limited to it:

- To generate evidence for effect of genetic make-up and molecular pathophysiology of VTE on the Indian population and further compare with the global knowledge on VTE. (24 Months)
- The studies based on correlating genetic and acquired risk factors for occurrence of VTE in Indian population would be taken up. (24 Months)
- To determine the effects of exposure to environmental compounds, food and lifestyle(24 Months)
- Identify new targets for anticoagulant therapies (12Months)
- Robust Animal model studies for understanding the mechanism and pathophysiology of VTE (36 Months)
- Covid-19 related research in area of Heparin-induced thrombocytopenia (HIT), thromboembolic manifestations of Covid-19, thromboembolic events associated with Covid-19 vaccines etc. (18-24 Months)

Prerequisites for application

Any investigator at individual level is eligible to apply with following conditions:

- A 2 page concept note to be submitted with need and relevance of the proposed study along with the expected outcome.
- Each research study shall have an integral component on strengthening the knowledge in the subject area and the capacity of researchers.
- The study can be a collaborative effort for basic science researcher and a clinical expert.

How to Apply: Interested investigators/scientists/clinical researchers working in recognized R & D Institutions can submit the LoIs through email as per details given below. Three hard copies along with soft copy of same should be sent to **Dr. Nabendu Chatterjee, HEAD BMS Division, ICMR, New Delhi-110029** with kind attention to Dr. Heena Tabassum, Scientist ‘C bearing the Advertisement No. and Title of the call for LoIs **by 7th August, 2021.** (Email: vte.bms@gmail.com)

Proforma

1	Name and Designation:
2	Project/ Programme: <i>Title in which you want to involve</i>
3	Broad area of working and strength of the institution : (100 words)
4	Details of institute about their research background and achievements : (250 words)
5	Team Composition :
6	Names(s), Institute address, Contact numbers, brief CV of the identified experts/ the Investigator(s) from Biochemistry, Clinical, Epidemiologist, Public health, Pathology, Basic science (A one page CV of the investigators)
7	Role & Responsibility of each member/department/institute
8	What is the novelty in your approach? (200 words)
9	Why the research topic chosen should be Prioritized ? (200 words)
10	Institute capacity in the terms of Infrastructure, patient load, Basic science lab, Clinical facility, Digital Database management , Ethical issues etc.
11	Feasibility of doing the study in your present institution/workplace (100 words)
12	Best 10 publications in the last 3 years in relevant areas