EoI No. ICMR/EoI/PM/43/Factor VIII LFA/2026
Dated 16th November 2026

Invitation for Expression of Interest (EoI)

For

Transfer of Technology
Of

A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A
(Diagnostics)

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

CONTENTS

Sl. No	Section	Page No.
1	Letter of Invitation	3
2	Background	4
3	Objective	4
4	Broad Scope of Work	4
5	Intellectual Property Rights	6
6	Process involved in Partnership/Collaboration/Technology Transfer	6
7	Publication	6
8	Data Rights	7
9	Details of documents to be furnished	7
10	Rejection Criteria	7
11	Evaluation Methodology	8
12	Pre-Qualification Criteria (PQC)	8-9
13	Disclaimer	9
14	Arbitration	9
15	Contacts for enquiry	10
16	Expression of Interest (Format – 1)	11-12
17	Authorization Letter (Format – 2)	13
18	Undertaking with regard to Blacklisting (Format-3)	14
19	Undertaking with regard to Non-Conviction (Format – 4)	15
20	Undertaking with regard to laboratory facility (Format – 5)	16
21	Production Capacity Undertaking (Format-6)	17
22	Schedule A - Technology Details	18

Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research (ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations, companies, manufacturers for undertaking **'Transfer of Technology'** for commercialization of **A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A** useful in **point-of-care diagnosis of hemophilia A.**

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in).

Schedule for the Proponents is as under:

EoI Document Number	ICMR/EoI/PM/43/Factor VIII LFA/2026
Date of Publication	Date: 16/11/2026
Last date of submission	Date: 07/12/2026

Note:
Interested applicants are invited to submit their Expression of Interest (EoI) through the Medical Innovation Patent Mitra portal (https://patentmitra.icmr.org.in/companyeoiregistration/). Applicants must first register by providing requisite company information, including details of the authorized representative. Upon successful registration, applicants are required to complete and submit the e-EoI form available on the portal.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the Competent Authority ICMR and duly notified on its website.

2. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

K J Somaiya Hospital and Research Center, Mumbai has developed a technology entitled "**A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A**" (hereinafter) referred to as **"Technology".**

ICMR under its "Medical Innovations Patent Mitra" initiative will facilitate K J Somaiya Hospital and Research Center, Mumbai to enter into any form of **exclusive/non-exclusive agreements** with eligible manufacturing companies hereinafter referred to as the **"Company"** through a defined agreement for Licensing/Commercialization of "**A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"**, hereinafter referred to as the **'Product',** Institute/University/Organization's IP Policy.

3. Objective

To license the 'Technology' for **A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A,** useful in **point-of-care diagnosis of hemophilia A**, for commercialization and marketing activities.

4. Scope of Work

i. ICMR under its "Patent Mitra" scheme is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking Transfer of technology and commercialization of the Technology/product entitled "**A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A".**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A".**

iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a "Exclusive/Non-Exclusive" basis with single/multiple companies to enable wider outreach of the Technology/product entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"** for societal benefit and public health use. All the related issues shall be governed by Institute/University/Organization's IP Policy.

iv. K J Somaiya Hospital and Research Center, Mumbai has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of the Technology/product entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A".**

Role of Institute/University/Organization:

i. K J Somaiya Hospital and Research Center, Mumbai will provide expert guidance & technical support for the production of the Technology/product entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"**, in all phases. Such technical oversight by K J Somaiya Hospital and Research Center, Mumbai would accelerate the development of the Product and its commercialization.

ii. K J Somaiya Hospital and Research Center, Mumbai would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.

iii. K J Somaiya Hospital and Research Center, Mumbai would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through

its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.

iv. K J Somaiya Hospital and Research Center, Mumbai would provide technical support in development of technology/ product and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.

v. ICMR shall have no financial implications unless otherwise specified.

Role of Company

i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or otherwise.

ii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the Technology/Product "**A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"**, in a set milestone.

iii. The Company agrees to share the technical data with ICMR/K J Somaiya Hospital and Research Center, Mumbai and participate in all discussions in a professional and mutually agreed-upon manner.

iv. The Company agrees to allow authorized personnel/scientist/team of ICMR/K J Somaiya Hospital and Research Center, Mumbai to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization.

5. Intellectual Property Rights

It is submitted that in case of transfer of Technology, K J Somaiya Hospital and Research Center, Mumbai is the sole owner of the said Technology, including any underlying Intellectual Property(ies) and commercialization rights.

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

K J Somaiya Hospital and Research Center, Mumbai legally possess the rights and authority to retain full or part of the 'Technology' by itself or to assign at its discretion full or part of the Technology including any patent(s) or intellectual property rights(s) or the invention(s). ICMR under it's "Medical Innovations Patent Mitra" Initiative will facilitate exclusive/non-exclusive License Agreements with selected companies including transfer of the

Technology through suitable Agreement(s).

In case of collaboration between K J Somaiya Hospital and Research Center, Mumbai and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by K J Somaiya Hospital and Research Center, Mumbai and the Company. All such provisions related to intellectual property rights shall be governed by Institute/University/Organization's IP Policy.

6. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers are invited to join hands with K J Somaiya Hospital and Research Center, Mumbai for co-development/ further development & commercialization of Technology/ Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/technology transfer, etc. Consideration by the company/manufacturer shall be as per the IP Policy of the K J Somaiya Hospital and Research Center, Mumbai.

7. Publication

i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).

ii. Support of ICMR must be duly acknowledged in all publications by the Company.

iii. ICMR/ Institute Scientists can be given due to advantage of authorships in the publications arising out of Licensing/co-development.

8. Data Rights

i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding.

ii. Data rights shall be jointly owned by K J Somaiya Hospital and Research Center, Mumbai and Licensee/Co-developer, in case of joint funding.

iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

9. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)

ii. Authorization Letter (Format – 2)

iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Non-Conviction (Format – 4)
v. EoI document with each page duly stamped and signed by the Authorized signatory.
vi. Undertaking with regard to laboratory facility (Format – 5)
vii. Production Capacity Undertaking (Format-6)
viii. Supporting documents, as mentioned in Format-1
ix. MSME Certificate (if applicable)
x. Concept note on business plan- A brief concept note on R&D, clinical studies, planning & execution, production, marketing etc. with timeline (not more than 5 pages)
xi. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

10. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EoI.
ii. Not in the prescribed format.
iii. Not properly stamped and signed.
iv. Received after the expiry of due date and time.
v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
vii. Applications not fulfilling the terms of the document will be summarily rejected.
viii. Any other non-compliance.

11. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted.

12. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria (General)**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)

General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India.	Registration of firm/ organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable
2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have proven prior experience of manufacturing and/or R&D with manufacturing during the last three years, either in-house or through agreed collaboration and must have marketed same/similar products in the past with a good track record.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
Specific Criteria (Based on the nature of the Proposal)		
9.	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)

10.	Capacity to produce at least……(quantity) per week	Undertaking (As per format – 6)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

13. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.

ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.

iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.

iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

v. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

14. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.

15. Contacts

In case of any clarification required, please contact:

For scientific issues-
Dr. Shrimati Shetty
Email: shrimati@somaiya.edu
Mobile No.: 9820800727

For Technical issues-
Medical Innovations Patent Mitra Team,
Email: patentmitra.hq@icmr.gov.in

Format-1

Expression of Interest

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for Transfer of Technology for the Technology entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"** and manufacturing, commercialization of Diagnostic assay/ Kit useful in **point-of-care diagnosis of hemophilia A.**

Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your transfer of technology and do hereby express the interest to undertake the research & development/manufacture/ sale /commercialization of the product as mentioned in the EoI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	**Documents required**	**Type of document attached**	**Page No.**
1	Company Incorporation Certificate from ROC/Partnership deed etc.		

2	GST Registration or GST exemption certificate/ PAN Card.		
3	DCGI/CDSCO license for the existing products available in the market		
4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for las three financial years, Income Tax return.		
5	Proof of a registered office and a manufacturing Unit in India.		
6	GMP / GLC and ISO Certification. Registration copies of both		
7	Authorization Letter	As per format – 2	
8	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	MSME Certificate (if have any)		
11	Business Plan	A brief concept note on planning & execution, production, marketing etc. (not more than 5 pages)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-2

Authorization Letter

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory

Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology entitled **"A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A"** and commercialization of Drug/ Vaccine candidate/Device/ Diagnostic assay/ Kit *(only tick whichever is applicable)* useful in **point-of-care diagnosis of hemophilia A.**

Mr./Ms./Mrs./Dr…….is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s……. (Company Name) ……., who's signature is below.

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

Format-3

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.
Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

It is hereby confirmed and declared that M/s…… (Company Name) currently has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard to Non-Conviction

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Non-Conviction.
Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-5

Undertaking with regard to laboratory facility

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.
Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

It is hereby confirmed and declared that M/s…..... (Company Name) do have

i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick BSL-2/BSL-3/ABSL-3/GMP/GLP/ Other* (if other please specify) and

ii. Adequate no. of experienced staff/skilled manpower to undertake manufacture/ research/ commercialization of the Technology entitled "**A lateral flow immunoassay method for detection of factor VIII inhibitors in hemophilia A".**

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

*The Laboratory/ facility requirement will depend on the technology/ product

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.
Ref: ICMR/EoI/PM/43/Factor VIII LFA/2026, dated _____

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of …… (Name of Technology/ Product), minimum …….(mention the quantity per week/per month).

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

SCHEDULE-A
TECHNOLOGY DETAILS

i. **About Technology/Product/Process:**

The technology is a strip-based lateral flow immunoassay (LFIA) point-of-care test designed for the detection of neutralizing Factor VIII (FVIII) inhibitors in hemophilia A patients. Unlike conventional clot-based assays such as the Nijmegen modified Bethesda assay (NBA), the test selectively detects functional (neutralizing) FVIII inhibitors and does not identify nonneutralizing FVIII antibodies. The test is equipment-free, semi-quantitative, and provides results within 10 minutes through naked-eye interpretation. It is unaffected by nonfactor therapies, including emicizumab, and can therefore be used in patients receiving emicizumab prophylaxis where conventional clot-based assays are ineffective. Requiring only a small volume of blood and offering a highly cost-effective testing solution, the technology enables rapid inhibitor detection in diverse healthcare settings, including home care, hospitals, clinics, and primary healthcare centers. The technology has been validated in-house and addresses the need for an accessible point-of-care diagnostic solution for FVIII inhibitors.

ii. **Need and utility of the Technology from Public health perspective:**

Hemophilia A patients require regular assessment of their FVIII inhibitor status because the choice of treatment differs significantly between inhibitor-positive and inhibitor-negative cases. Conventional testing methods, such as the Nijmegen modified Bethesda assay (NBA), are expensive, time-consuming, and available only in select laboratories, often requiring patients to travel long distances for testing. The proposed LFIA-based kit offers a highly cost-effective alternative, with a laboratory testing cost of approximately 120 INR compared to 2000-15000 INR for conventional assays. As an equipment-free, portable, naked-eye test, it can be deployed at primary healthcare centers and other decentralized healthcare settings, improving access to diagnosis. The test remains effective in patients receiving nonfactor therapies and can support timely treatment decisions during breakthrough bleeds and peri-operative management. By reducing testing costs, improving accessibility, and enabling rapid diagnosis, the technology has the potential to significantly benefit hemophilia A patients and strengthen the availability of inhibitor testing across healthcare settings.

iii. **Technology Readiness level (TRL):** TRL-4 (Validated In-house)

iv. **Validation Status and outcome:**

The technology has undergone in-house validation using 599 blood samples, comprising normal healthy controls; samples with non-neutralizing antibodies; hemophilia A patients with and without inhibitors, including patients on emicizumab; and hemophilia B patients without inhibitors. Compared with the gold-standard Nijmegen modified Bethesda assay, the test recorded 98 true-positive, 490 true-negative, 5 false-positive, and 6 false-negative results, demonstrating 94% sensitivity, 98% specificity, 95%

positive predictive value, 99% negative predictive value, and 98% overall accuracy. Interference testing further showed no interference from FVIII, cholesterol, bilirubin, tranexamic acid, FEIBA, recombinant Factor VIIa, or emicizumab at the tested concentrations. Overall, the internal validation results support the test's ability to detect FVIII inhibitors with high sensitivity, specificity, and accuracy, including in samples containing commonly encountered potentially interfering factors.

v. **IP Filing Status/Publications**

Indian Patent Application: IN 202621005360

Filing Date: 19/01/2026

Publications:

1. Kharat, S., Jivani, F., Patil, K., Saini, G. K., Dhawlarker, A., Bharankar, J., & Shetty, S. (2026). A rapid point-of-care test for the diagnosis of factor VIII inhibitors in hemophilia A patients. Journal of thrombosis and haemostasis: JTH, 24(8), 2766–2778. https://doi.org/10.1016/j.jtha.2026.04.014

****