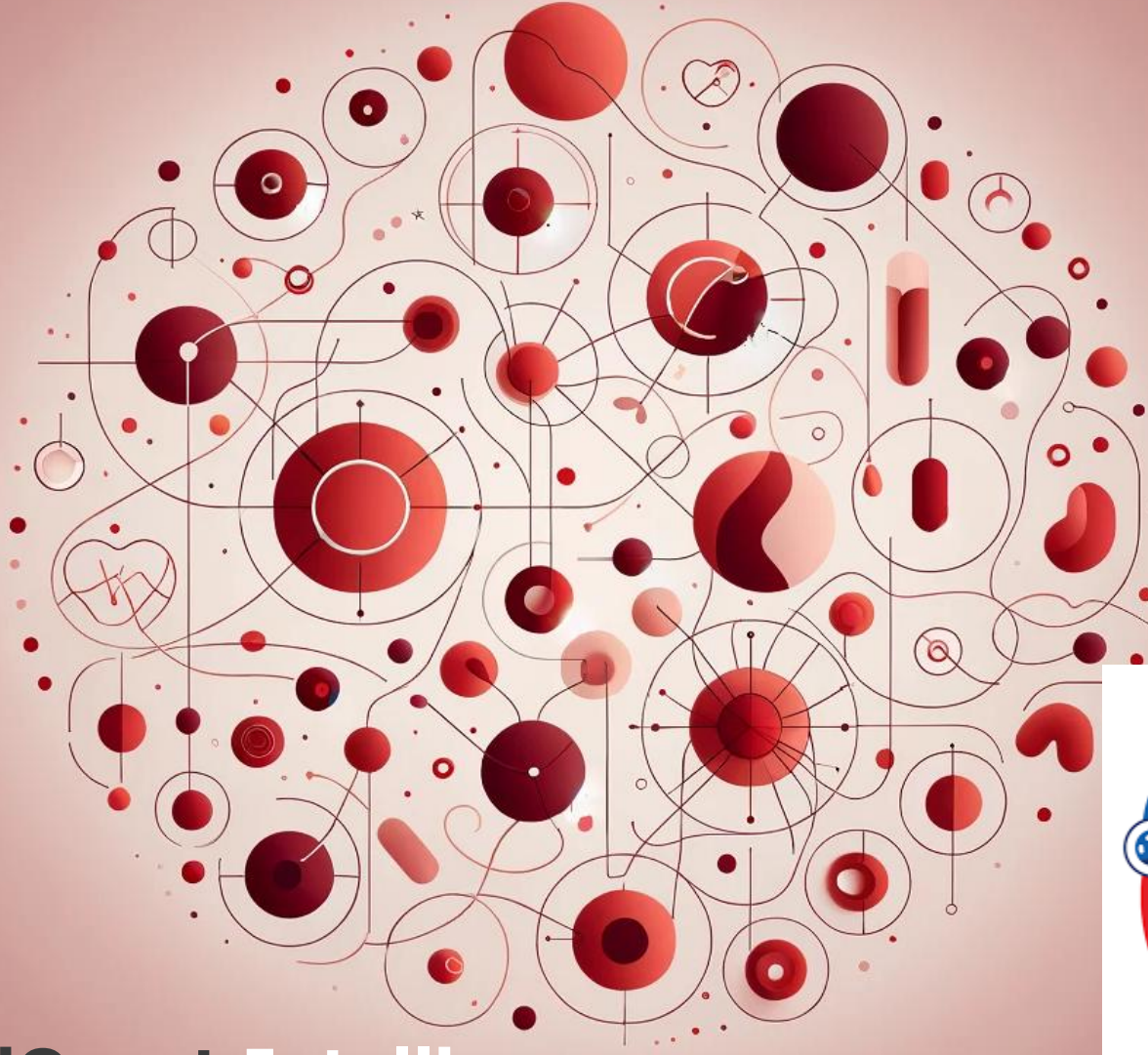


ISTH 2026 Preview – Clinical and AI / ML



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- **Will VWD prophylaxis move beyond replacement-based thinking?**

- ISTH 2026 will feature VGA039, a Protein S antibody being evaluated with four-week subcutaneous dosing in VWD. The strategic question will be whether hemostatic rebalancing can create a credible alternative to VWF/FVIII replacement-based prophylaxis, particularly if bleed reduction, dosing burden, and safety signals remain clinically consistent



- **Hemophilia prophylaxis will increasingly center on convenience, control, and mechanism?**

- ISTH 2026 will place Mim8/denecimig, concizumab, NXT007, marstacimab, SR604, and Inno8 in focus across oral and late-breaking presentations. The tension will be whether FVIIIa mimetics, TFPI inhibition, activated Protein C modulation, and oral FVIII mimicry can differentiate on route, dosing interval, thrombin generation, pediatric applicability, and complex-care use rather than low annualized bleeding rate alone



- **Oral FVIII mimicry could raise the competitive threshold for non-factor prophylaxis?**

- The Inno8 late-breaking presentation will test whether an orally administered FVIII mimetic can show favorable early safety, pharmacokinetic, and pharmacodynamic signals. If the data are directionally consistent, the discussion will shift toward how much injection burden patients and clinicians will continue to accept in hemophilia prophylaxis



- **Future anticoagulants will face sharper efficacy-versus-bleeding scrutiny**

- ISTH 2026 will include future-anticoagulant data across Factor XIa inhibition, Factor XII targeting, and VTE prevention after orthopedic surgery, including SB-01, REGN9533, asundexian-related work, and SHR-2004. The unresolved issue will be whether reduced bleeding risk can be paired with enough efficacy in specific clinical settings rather than being treated as a class-wide advantage



• **ADAMTS13-centered care will become more operational across TTP and VWF biology**

- Sessions on VWF/ADAMTS13 activity, recombinant ADAMTS13, iTTP management, anti-ADAMTS13 antibody monitoring, and diagnostic testing will move the discussion beyond specialist biology. The question will be whether earlier testing, prophylaxis integration, and complex-case management can create clearer decision points across cTTP, iTTP, and VWD-adjacent thrombotic microangiopathy care



• **ITP strategy will be tested beyond platelet response alone**

- Data on ianalumab plus eltrombopag in second-line primary ITP and rilzabrutinib cardiovascular safety analyses in persistent/chronic ITP will keep durability, response kinetics, safety, and treatment burden in focus. The strategic tension will be whether B-cell targeting, BTK inhibition, and TPO receptor agonist strategies can support clearer sequencing beyond platelet response alone



Key Sessions To Watch

Date	Session Title (short)	Type	Author / Institution	Why Watch
11 July 2026	Concizumab explorer10 pediatric hemophilia	Oral Session	Sonata Šaulytė Trakymienė	Important pediatric readout for non-factor prophylaxis in hemophilia A/B with inhibitors
11 July 2026	Mim8 / denecimig FRONTIER4 adults and adolescents	Oral Session	Jerzy Windyga	Could strengthen the case for flexible denecimig dosing across weekly, every-two-week, and monthly schedules
12 July 2026	VLX-1005 in heparin-induced thrombocytopenia	Late-breaking	Steven McKenzie	Introduces 12-lipoxygenase inhibition as a differentiated approach in HIT
12 July 2026	SHR-2004 after total knee arthroplasty	Late-breaking	Dr. Dongxing Xie	Phase 3 data may clarify SHR-2004's role in post-surgical VTE prevention
12 July 2026	Marstacimab BASIS KIDS pediatric hemophilia	Late-breaking	Prof. Gili Kenet	Key pediatric expansion signal for marstacimab in hemophilia A/B, with or without inhibitors
12 July 2026	SR604 Phase IIb hemophilia	Late-breaking	Lijun Xia	A close watch for whether activated Protein C modulation can stand apart from other rebalancing strategies
12 July 2026	Inno8 oral FVIII mimetic	Late-breaking	Christian Keicher	Early signal on whether oral FVIII mimicry can challenge injection-based prophylaxis models
12 July 2026	Ianalumab plus eltrombopag in VAYHIT2	Oral Session	Francesco Zaja	Could refine second-line ITP sequencing across B-cell targeting and TPO receptor agonist strategies
12 July 2026	VGA039 four-week subcutaneous dosing in VWD	Oral Session	Allison Wheeler	One of the clearest tests of whether VWD prophylaxis can move toward rebalancing rather than replacement alone



Industry-Sponsored Sessions & Focus Areas – ISTH 2026





ISTH 2026– Competitive Landscape at a Glance (1/2)

Name	Sessions	Companies / Assets	Why It Matters
VWD prophylaxis and hemostatic rebalancing	Multiple	VGA039/latacibart; VWF/FVIII replacement strategies; VWD prophylaxis programs	VWD discussions will test whether prophylaxis can move beyond replacement-based care toward rebalancing and more individualized long-term prevention
Hemophilia non-factor prophylaxis and rebalancing	Multiple	Mim8/denecimig; concizumab/Alhemo; NXT007; marstacimab; SR604; Inno8	Competition will increasingly center on dosing interval, route of administration, thrombin generation, pediatric use, perioperative confidence, and thrombotic safety
Oral and next-generation FVIII mimetic approaches	Multiple	Inno8; Mim8/denecimig; NXT007	FVIII mimetic presentations will test whether newer approaches can improve convenience and functional hemostasis without increasing clinical-management complexity
FXI/FXIa and FXII pathway anticoagulation	Multiple	asundexian; milvexian; abelacimab; osocimab; SB-01; REGN9533; SHR-2004	Future anticoagulant discussions will focus on where bleeding-sparing mechanisms can deliver enough efficacy across VTE prevention, secondary stroke prevention, and post-surgical prophylaxis



ISTH 2026– Competitive Landscape at a Glance (2/2)

Name	Sessions	Companies / Assets	Why It Matters
ADAMTS13, TTP, and VWF biology	Multiple	Recombinant ADAMTS13; VWF/ADAMTS13 activity testing; iTTP and cTTP management approaches	The field will test whether ADAMTS13-centered care can become more operational through earlier testing, prophylaxis integration, and complex-case management
ITP and immune-mediated platelet disorders	Multiple	Ianalumab plus eltrombopag; rilzabrutinib; TPO receptor agonist strategies	ITP sessions will test whether treatment strategy can move beyond platelet response toward durability, safety, treatment burden, and clearer sequencing
AI/ML diagnostics and digital hemostasis tools	Multiple	LLM/NLP VTE identification; sepsis-induced DIC prediction; HIT peptide development; TTP diagnosis support; PE screening; hemophilia PK and arthropathy tools	AI activity will matter where it can improve diagnostic confidence, risk prediction, laboratory workflow, or longitudinal monitoring
Hemophilia gene therapy and long-term evidence	Multiple	HEMGENIX; etranacogene dezaparvovec; AAV gene therapy; registries; PAES; PROMs	Gene therapy discussions will focus on durability, real-world implementation, patient-reported outcomes, and post-approval evidence rather than launch-era efficacy alone



Key Industry-Sponsored Sessions at ISTH 2026 (1/7)

✓ • **Sanofi:**

- Focus Areas: : iTTP, Hemophilia Rebalancing, Autoimmune Cytopenias & Ultra-Long Half-Life Factor Real-World Evidence
- The program will cover iTTP management, emerging treatment approaches, complex case discussions, rebalancing agents in hemophilia, autoimmune cytopenias, and real-world insights with an ultra-long half-life factor. The company will signal a broad hemostasis and immune-hematology agenda across TTP, hemophilia, autoimmune cytopenias, and factor-based care

✓ • **Roche / Chugai:**

- Focus Areas: Hemophilia A, Sustained Protection, Joint Health & Active Life
- The session will emphasize early foundation of care, sustained protection, joint health, and active-life considerations in hemophilia A. The companies will reinforce long-term protection and functional outcomes as newer hemophilia prophylaxis options compete on convenience and dosing flexibility



Key Industry-Sponsored Sessions at ISTH 2026 (2/7)

✓ • **Octapharma:**

- Focus Areas: VWD Prophylaxis, FVIII, Fibrinogen Replacement, FXa Inhibitor Reversal & Acute Hemostatic Management
- Sessions will emphasize **personalized VWD prophylaxis**, severe VWD definitions, pharmacokinetic modeling, **FVIII evidence**, fibrinogen replacement, **FXa inhibitor reversal**, thrombin generation, and cardiac surgery bleeding. The company will reinforce a **hemostatic-therapy strategy** spanning chronic bleeding-disorder prophylaxis and **acute bleeding intervention**

✓ • **Takeda:**

- Focus Areas: **Pediatric VWD, VWD Prophylaxis & cTTP Prophylaxis**
- Sessions will highlight **pediatric VWD bleeding burden**, daily impact, treatment pathways, practical management, **VWD prophylaxis, and modern prophylaxis integration** in cTTP. The company will connect **early disease recognition** with **long-term prophylaxis strategies** across VWD and congenital TTP



Key Industry-Sponsored Sessions at ISTH 2026 (3/7)

✓ • Warfen:

- Focus Areas: High-Sensitivity D-Dimer, VTE Exclusion, Clinical Decision Rules & Global Harmonization
- The session will center on high-sensitivity D-dimer use in VTE exclusion, clinical decision rules, and global harmonization. The company will position diagnostics standardization as a practical lever for improving VTE rule-out pathways

✓ • CSL:

- Focus Areas: HEMGENIX, Hemophilia Gene Therapy, Patient-Reported Outcomes, VWD & IDELVION
- Presentations will focus on HEMGENIX real-world strategies, gene therapy implementation, registries, PAES, PROMs, VWD biology, clinical unmet needs, and a decade of IDELVION real-world evidence. The company will emphasize real-world evidence, long-term outcomes, patient experience, and implementation readiness across its hemophilia and VWD portfolio



Key Industry-Sponsored Sessions at ISTH 2026 (4/7)



• Pfizer:

- Focus Areas: Complex Hemophilia Care, Breakthrough Bleeds, Surgery & Thrombotic Risk
- The session will address breakthrough bleed management, thrombotic risk, surgical procedures, and complex hemophilia scenarios. The company will frame future hemophilia differentiation around practical confidence in complex clinical situations, not only prophylaxis efficacy



• Sobi:

- Focus Areas: Hemophilia A & Redefining Clinical Outcomes
- The session will explore how clinical outcomes in hemophilia A may need to be redefined. The company will emphasize the need to assess hemophilia treatment beyond bleed frequency and include broader measures of clinical value and patient impact



Key Industry-Sponsored Sessions at ISTH 2026 (5/7)



• Novo Nordisk:

- Focus Areas: Concizumab / Alhemo, FVIIIa Mimetic Therapy, Thrombin Generation, Precision Dosing & Patient Autonomy
- Sessions will focus on concizumab, breakthrough bleeds, joint outcomes, thrombin generation, steady-state control, precision dosing, FVIIIa mimetic design, clinical data, device-enabled autonomy, and patient-reported needs. The company will position non-factor prophylaxis around dosing control, functional hemostasis, and patient autonomy



• Sysmex:

- Focus Areas: HIT IgG Testing, ADAMTS13 Activity & Routine Coagulation Analyzer Workflows
- The session will highlight the HISCL HIT IgG assay and rapid automated ADAMTS13 activity testing on a routine coagulation analyzer. The company will emphasize faster integration of HIT and ADAMTS13 testing into routine laboratory workflows



Key Industry-Sponsored Sessions at ISTH 2026 (6/7)



• **Novartis:**

- Focus Areas: Immune Thrombocytopenia, Current Practice, Unmet Needs & Disease-Modifying Treatment Direction
- Sessions will focus on current ITP therapies, **unmet needs**, global management perspectives, access, real-world decision-making, **emerging science, novel targets, and future disease-modifying approaches**. The company will position ITP as a disease area where future competition will depend on **durability, sequencing logic**, and **broader care-pathway improvement** rather than platelet response alone



• **PeerVoice:**

- Focus Areas: **Factor XIa Inhibition & Secondary Stroke Prevention**
- The program will focus on the **rationale for Factor XIa inhibition**, clinical-trial evidence, **secondary stroke prevention**, and cross-specialty clinical implications. PeerVoice will frame **FXIa inhibition as an anticoagulation strategy** that will still need to prove the right balance between **thrombosis prevention and hemostasis preservation**





Key Industry-Sponsored Sessions at ISTH 2026 (7/7)



• **LFB Biomedicaments:**

- Focus Areas: **VWD Outcomes, Real-World Experience & Care Across Ages**
- The session will examine how VWD care success may be redefined through **clinical experience, real-world evidence, and lessons across age groups**. The company will position VWD management around **practical outcomes and care optimization** rather than product availability alone



• **Kedrion Biopharma:**

- Focus Areas: **Hereditary Factor X Deficiency, Women and Girls, Pediatric Patients & Plasminogen Deficiency Type 1**
- Sessions will focus on **hereditary factor X deficiency** in women, girls, neonates, and children, **severe early-life bleeding**, fetal intracranial hemorrhage, genetic evaluation, and **plasminogen deficiency type 1**. The company will reinforce a **rare-disease strategy** centered on under-recognized bleeding and fibrinolytic disorders with **high diagnostic and management complexity**



New Entrants

Asset / Company	2026 Presence
SR604	Late-Breakthrough Session: Long-acting prophylaxis through targeted activated protein C modulation: phase IIb results of SR604 in hemophilia
SHR-2004	Late-Breakthrough Session: Efficacy and safety of SHR-2004 for venous thromboembolism prevention after elective total knee arthroplasty: results from a randomized, double-blind, active-controlled phase 3 study
REGN9533	Oral Session: Safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses of REGN9533, a monoclonal antibody targeting Factor XII (FXII), in healthy adults: Results from a Phase 1, randomised, double-blind, placebo-controlled study
Ianalumab	Oral Session: Kinetics of platelet response with ianalumab plus eltrombopag vs eltrombopag alone in patients with primary immune thrombocytopenia (ITP) treated in the second-line setting in the randomized, double-blind, phase 3 VAYHIT2 study
HMB-003	Oral Session: A long-acting peptide plasmin inhibitor with extended antifibrinolytic activity enabling once-per-cycle subcutaneous treatment for heavy menstrual bleeding: Preclinical development of HMB-003
REGN7508	Poster: A Novel Monoclonal Antibody (REGN7508) Targeting FXI Reduces Clotting During Hemodialysis Ex vivo



AI/ML Trends & Strategic Watchpoints at ISTH 2026





AI / Digital Health Angle at ISTH 2026 (1/2)

- **AI and digital-health presentations at ISTH 2026 will represent a diagnostics, prediction, and workflow-efficiency signal rather than a broad digital-health adoption theme. AI activity will cluster around machine learning, LLM/NLP-based VTE identification, sepsis-induced DIC prediction, AI-guided HIT peptide development, pulmonary embolism screening, TTP diagnosis support, hemophilia pharmacokinetic prediction, and digital arthropathy assessment**
- **AI activity at ISTH 2026 will be strategically relevant because it will focus on practical thrombosis and hemostasis problems where diagnostic workflows, risk prediction, and image-based assessment remain difficult to standardize. The most important signal will be whether these tools can move beyond retrospective modeling and show validation strong enough to support clinical or laboratory workflow adoption**
- **Key sessions include:**
 - AI in thrombosis and hemostasis: Inspiration for our society
 - From data to decision: Insights through machine learning
 - CLOT: A Clot Learning and On-Guard Tracking system for stratifying blood clots prior to coagulation assays
 - Large language model (LLM)-based natural language processing (NLP) improves identification of overall and recurrent venous thromboembolism in medical records



AI / Digital Health Angle at ISTH 2026 (2/2)

- Development of clinically practical machine learning model for early prediction of sepsis-induced disseminated intravascular coagulation
- Overcoming a long-standing challenge: AI-guided development of peptides targeting heparin-induced thrombocytopenia
- Development of an automated machine learning approach to aid thrombotic thrombocytopenic purpura diagnosis
- Multimodal deep learning for pulmonary embolism screening using chest X-ray and electrocardiogram data
- Assessment of artificial intelligence capabilities in predicting pharmacokinetic curves in patients with hemophilia
- Development of a multimodal digital twin platform for dynamic arthropathy prediction and personalized therapeutic optimization in hemophilia A patients
- **Sessions suggest AI and digital tools are increasingly being used to improve:**
 - Early prediction of sepsis-induced DIC and critical-care thrombotic risk
 - Laboratory workflow support through clot stratification before coagulation assays
 - Disease-specific diagnostic support in HIT, TTP, pulmonary embolism, and antiphospholipid syndrome
 - Hemophilia monitoring through pharmacokinetic prediction, digital arthropathy tools, and joint-assessment standardization



What We're Watching for Post-ISTH 2026

- Whether **VGA039/latacibart** generates enough **safety, PK/PD, and bleed-reduction consistency** to strengthen the case for **four-week subcutaneous prophylaxis as a VWD rebalancing strategy**
- Whether **hemophilia non-factor and rebalancing approaches**, including Mim8/denecimig, concizumab, NXT007, marstacimab, SR604, and Inno8, demonstrate meaningful differentiation on **dosing interval, route of administration, thrombin generation, pediatric use, perioperative relevance, and thrombotic safety**
- Whether **oral FVIII mimicry with Inno8** produces early **safety, pharmacokinetic, and pharmacodynamic evidence** strong enough to challenge **injection-based assumptions** in hemophilia prophylaxis.
- Whether **Factor XI/XIa and Factor XII pathway** presentations clarify **where bleeding-sparing anticoagulation** can deliver sufficient **efficacy**, particularly across **VTE prevention, secondary stroke prevention, cancer-associated thrombosis, and post-surgical prophylaxis**
- Whether **ADAMTS13-centered** sessions translate into **clearer care-pathway implications** for cTTP, iTTP, and VWF/ADAMTS13 biology, especially around **earlier testing, prophylaxis integration, antibody monitoring, and complex-case management**



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