Innere Medizin II, Hämatologie, Onkologie, Klinische Immunologie und Rheumatologie

Post ASH 2025 Orlando

Hämostaseologie

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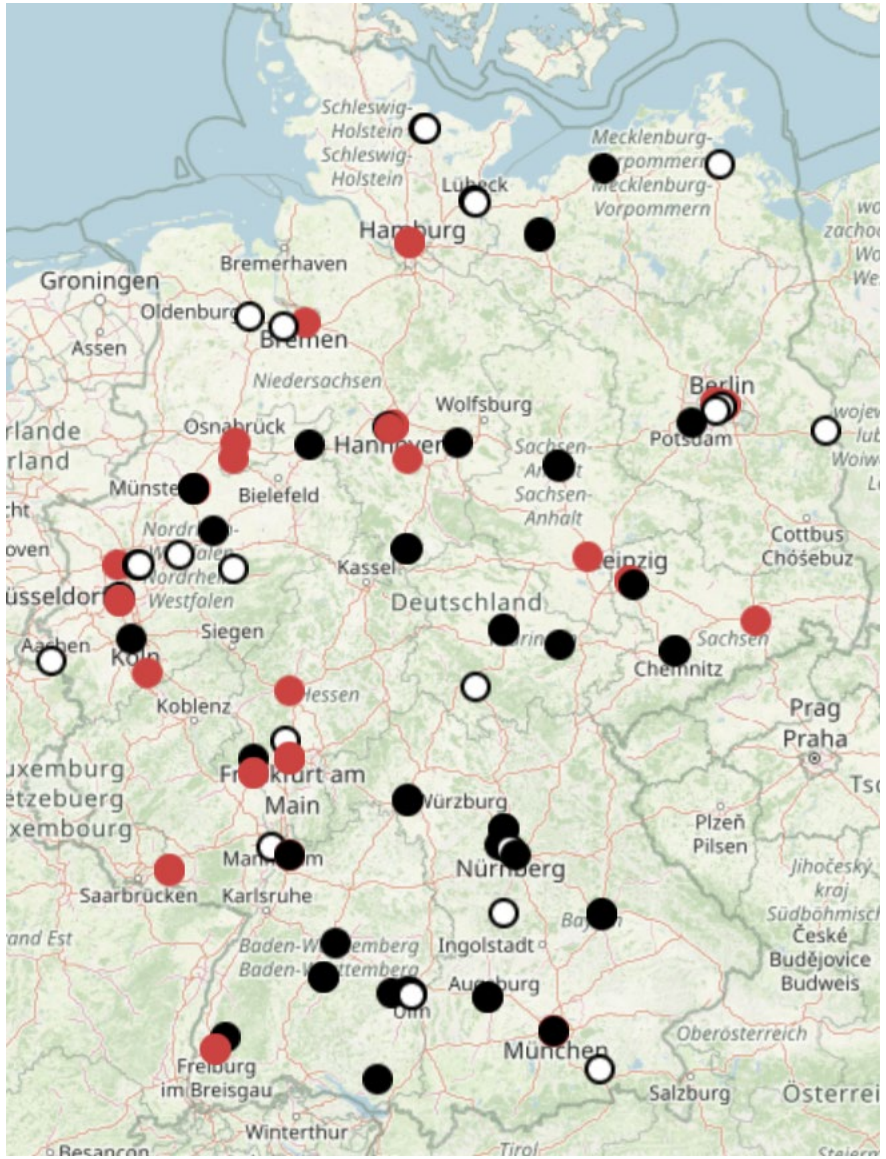
Comprehensive
Cancer Center
Tübingen - Stuttgart

Hämophilie

Hämophiliezentren in Deutschland



Hämophilie Steckbrief

Hämophilie A	FVIII	1:5.000 männl. Geburten
Hämophilie B	FIX	1:30.000 männl. Geburten

FVIII <1 % schwer, FVIII 1 - 5 % mittelschwer, FVIII >5 % - <40 % leicht

Hämophilie Steckbrief

Hämophilie A FVIII 1:5.000 männl. Geburten
Hämophilie B FIX 1:30.000 männl. Geburten

FVIII <1 % schwer, FVIII 1 - 5 % mittelschwer, FVIII >5 % - <40 % leicht

Bedarfsbehandlung
Dauerbehandlung (Prophylaxe)

Faktorenpräparate (Plasma, rekombinant)
- Standardhalbwertzeit
- Verlängerte Halbwertzeit

Bispezifische monoklonale Antikörper

Gentherapie

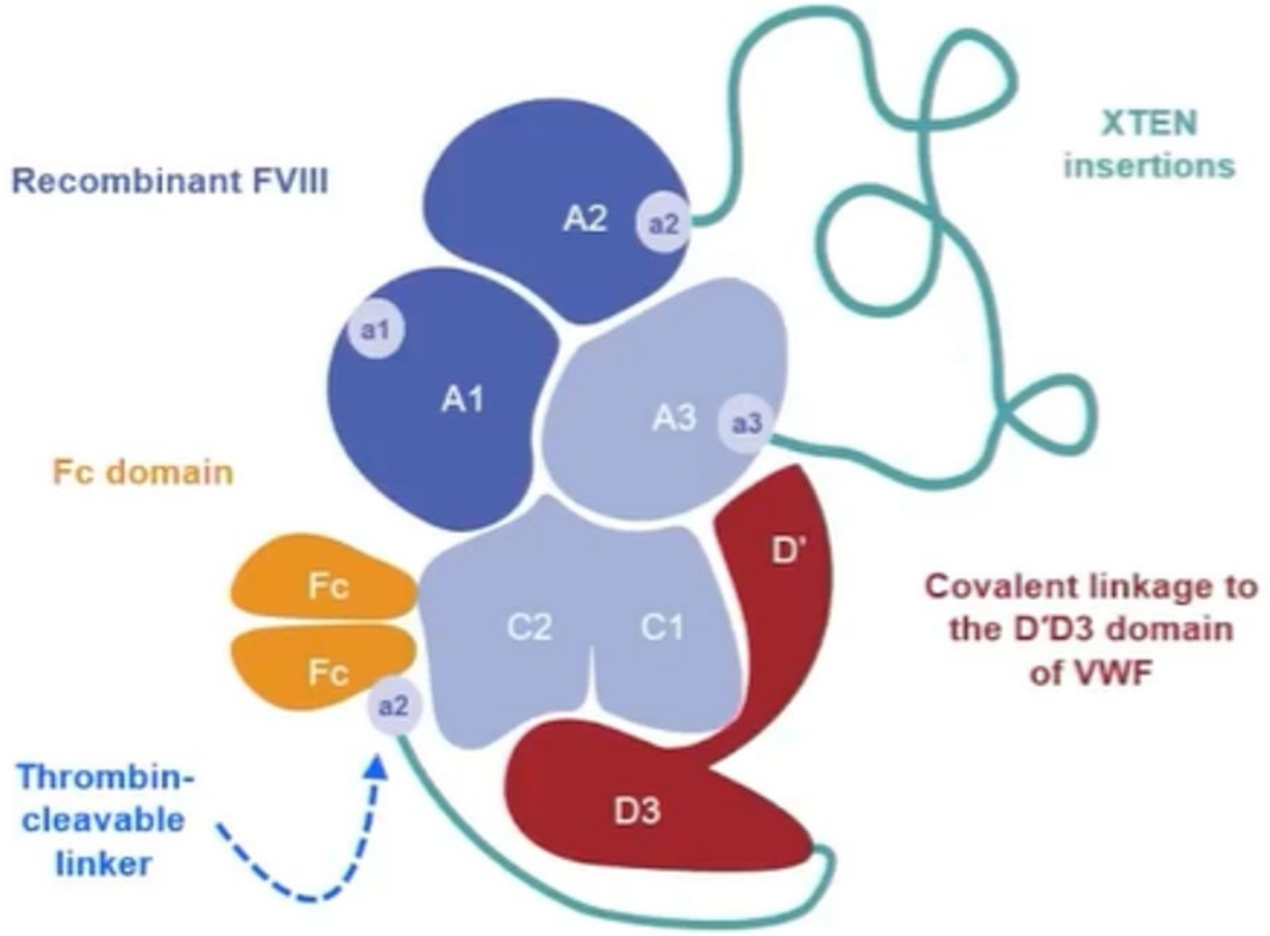
…

Hämphilie A

Efanesoctocog alfa (Altuvoct)

Lynn Malec. 539 Clinical outcomes up to 4 years of once-weekly efanesoctocog alfa prophylaxis in previously treated adults, adolescents, and children with severe hemophilia A: Interim analysis of the Phase 3 XTEND-ed long-term extension study

Hämphilie A Efanesoctocog alfa (Altuvoct)



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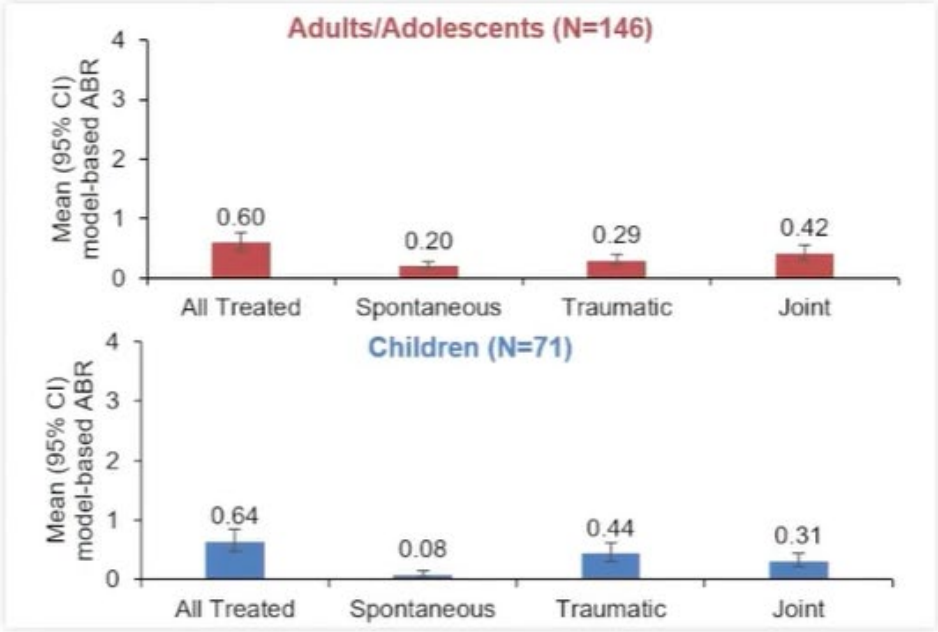
Hämphilie A Efanesoctocog alfa (Altuvoct)

Low Bleed Rates (ABR <1) Were Maintained With Weekly Efanesoctocog Alfa Prophylaxis

Summary of ABRs in XTEND-ed Arm A in adults, adolescents, and children

- In adults/adolescents, mean **overall ABR** during **XTEND-ed** was **0.60** consistent with the low overall ABR of **0.71** in XTEND-1 Arm A[1]

- In children, mean **overall ABR** during **XTEND-ed** was **0.64** consistent with the low ABR of **0.61** in XTEND-Kids[2]



Data cut: February 21, 2025.
ABR, annualized bleed rate; CI, confidence interval.
1. von Drygalski A, et al. *N Engl J Med*. 2023;388(4):310-318. 2. Malec L, et al. *N Engl J Med*. 2024; 18;391(3):235-246.

American Society *of* Hematology

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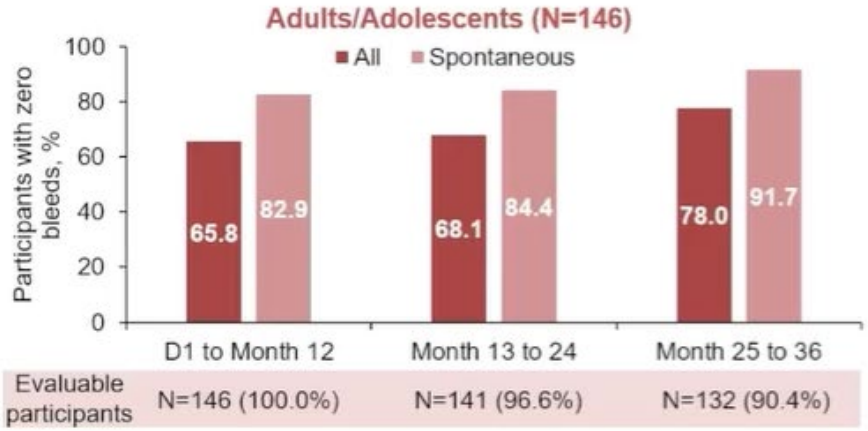
Hämphilie A Efanesoctocog alfa (Altuvoct)

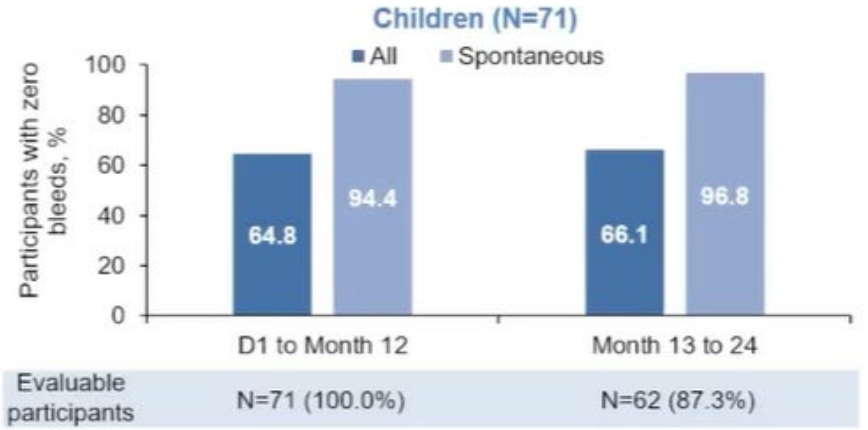
Percentage of Participants With Zero Bleeds Remained High With Long-Term Weekly Prophylaxis With Efanesoctocog Alfa

- The mean (SD) percentage of adults and adolescents with zero bleeds per 6-month interval* was
  - 80.7% (4.83) for all bleeds
  - 91.7% (3.10) for spontaneous bleeds

- The mean (SD) percentage of children with zero bleeds per 6-month interval** was
  - 77.1% (5.19) for all bleeds
  - 97.7% (0.63) for spontaneous bleeds

Summary of percentage of participants from XTEND-ed Arm A with zero bleeds by 12-month intervals





Data cut: February 21, 2025.
*Over 36 months. **Over 24 months.

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Hämophilie A

Emicizumab (Hemlibra®)

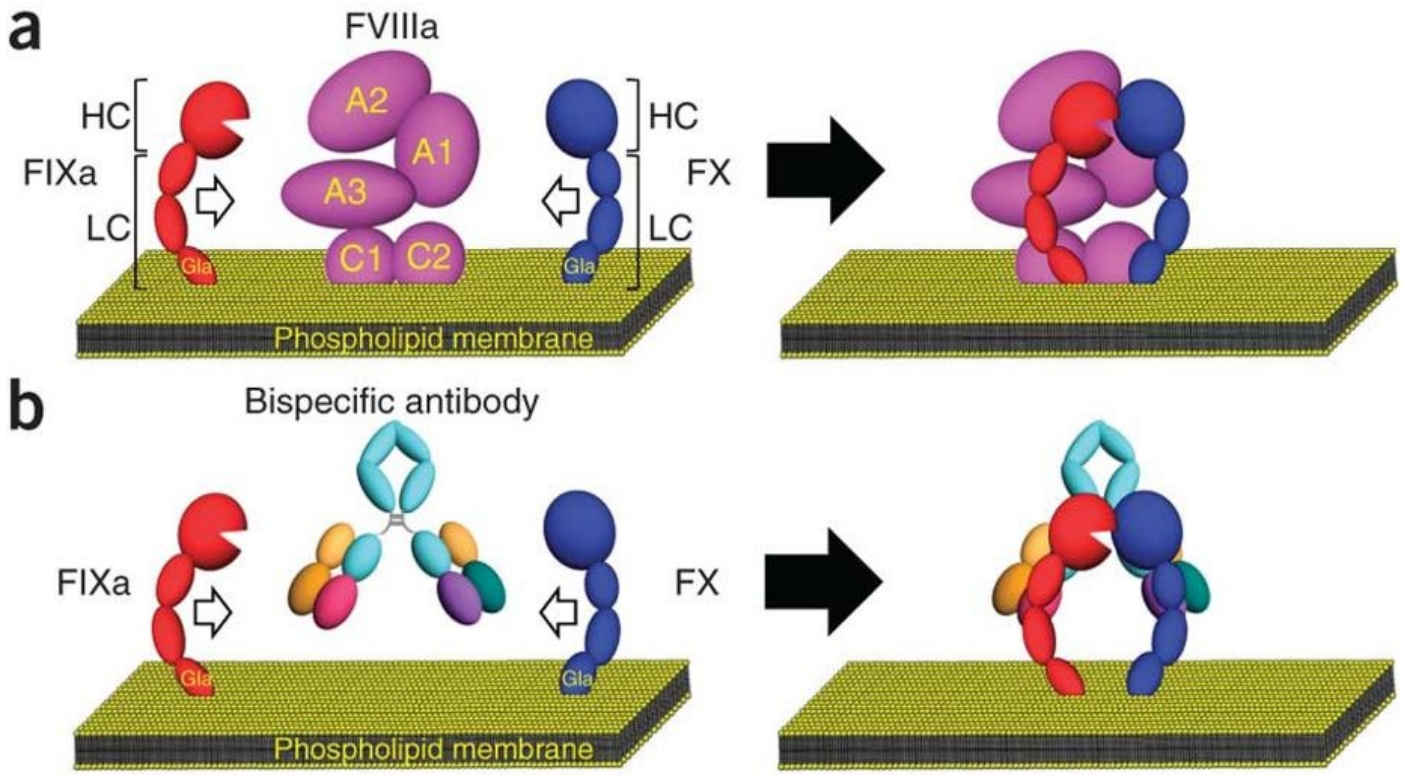
Gili Kenet. 305 Emicizumab prophylaxis in pups and mtps with severe haemophilia: The pednet real world experience in 80 infantsl.

Hämophilie A

Emicizumab (Hemlibra®)

Bispezifischer, monoklonaler Antikörper

HWZ 26,7 Tage



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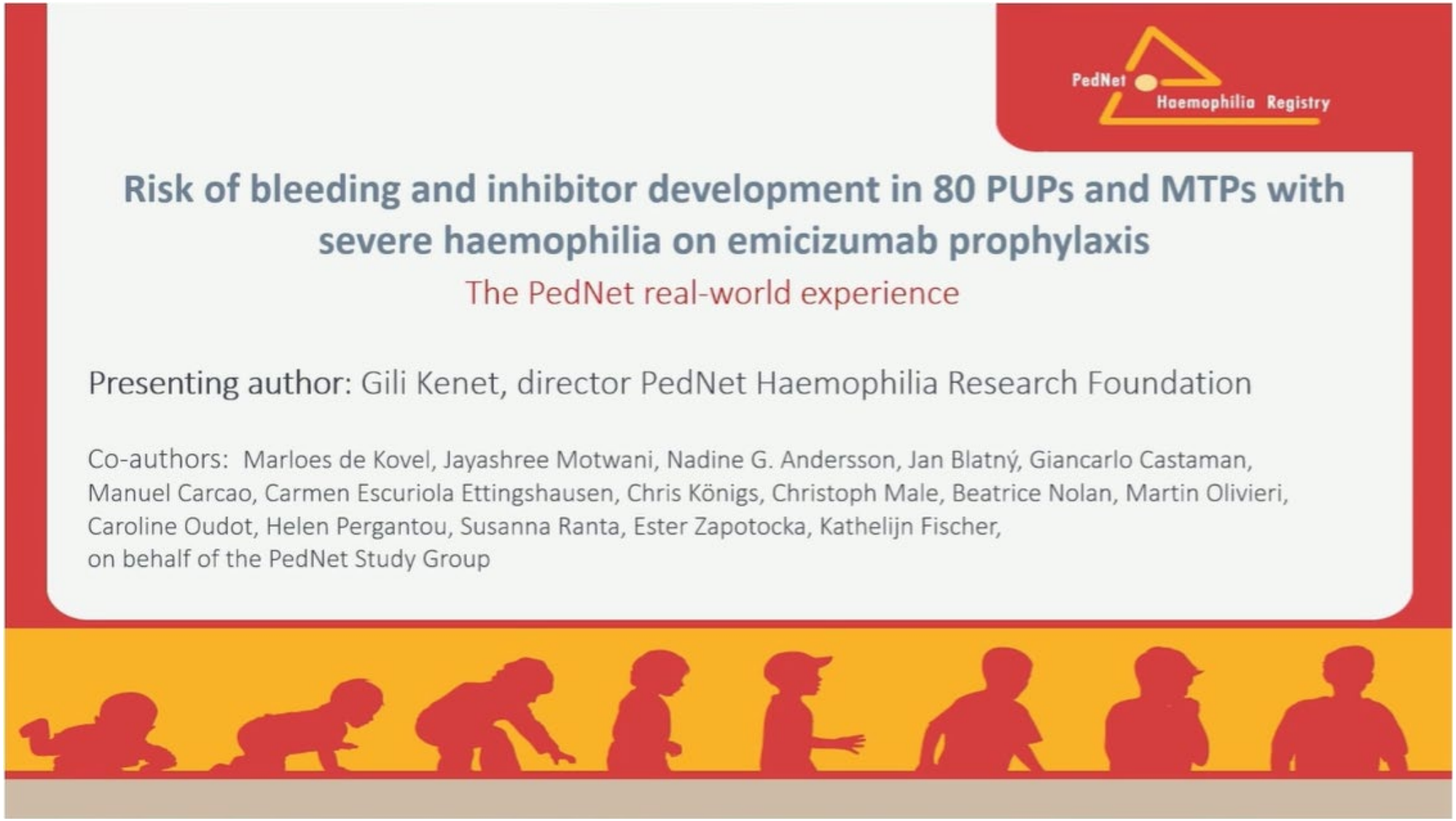
Hämophilie A

Emicizumab (Hemlibra®)



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Hämophilie A

Emicizumab (Hemlibra®)

PedNet 9

Patient outcomes – Bleeding & AE

	PUP	MTP	Total
Children included	39	41	80
Bleeding			
No treated bleeds	24 (62%)	21 (51%)	45 (56%)
No treated joint bleeds	36 (92%)	38 (93%)	74 (93%)
ICH or life-threatening bleeds	0 (0%)	0 (0%)	0 (0%)
Emicizumab related side effects			
Anti-drug antibodies	0 (0%)	0 (0%)	0 (0%)
Thrombotic events	0 (0%)	0 (0%)	0 (0%)

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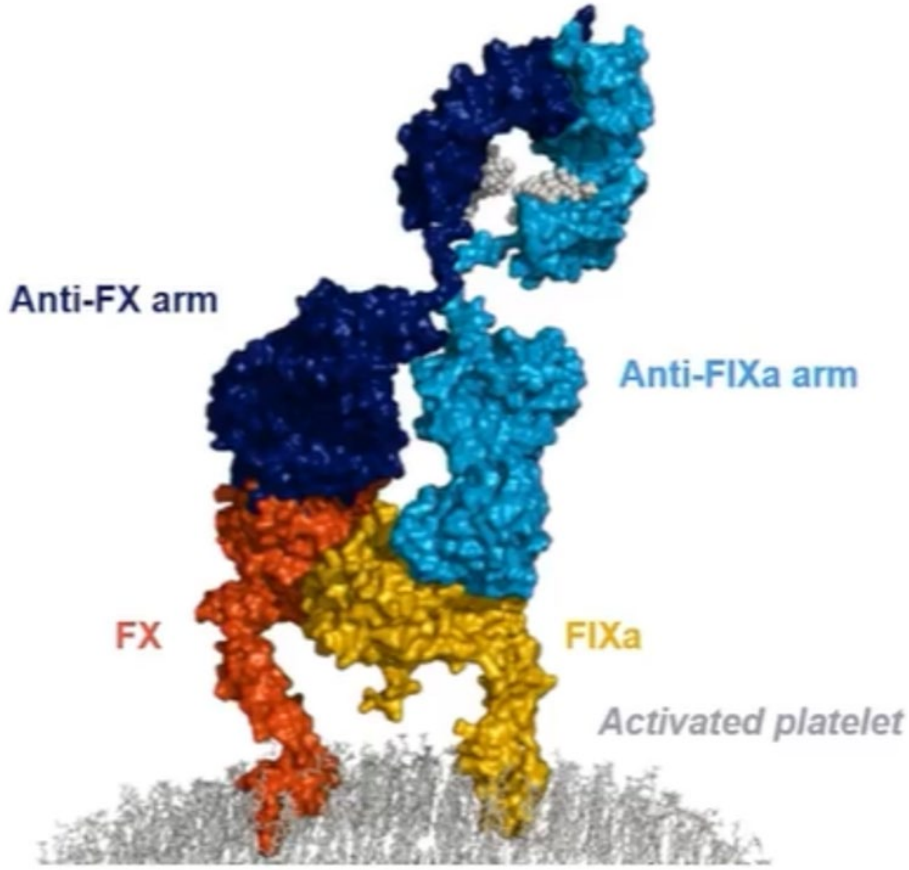
Hämophile A

Mim8 Phase 3

Steven Lentz. 537 Mim8 prophylaxis in adults and adolescents with hemophilia A: 52-week efficacy and safety outcomes from the phase 3 FRONTIER2 study

Hämophile A

Mim8 Phase 3



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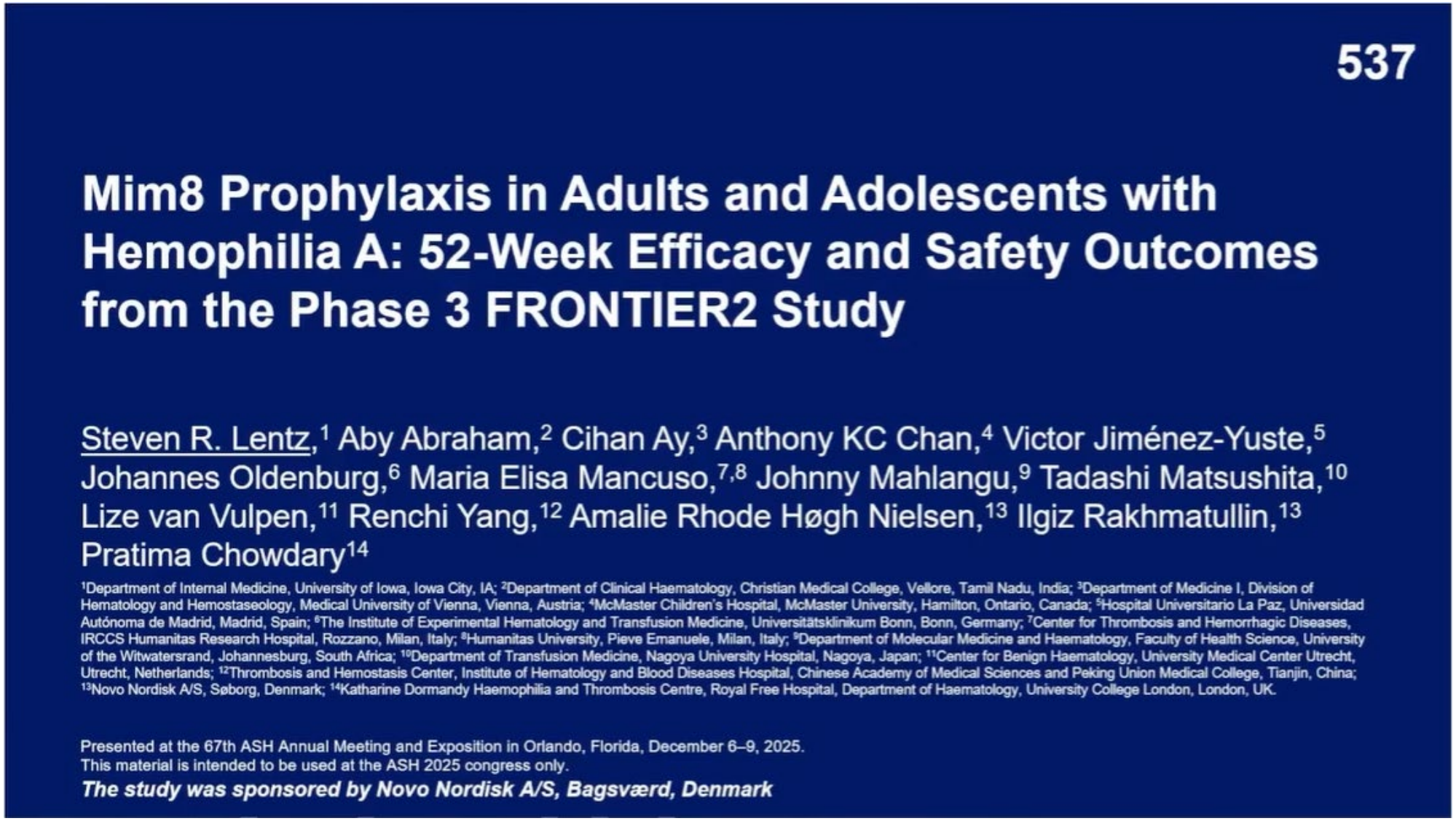
Hämophile A

Mim8 Phase 3



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Mim8 Prophylaxis in Adults and Adolescents with Hemophilia A: 52-Week Efficacy and Safety Outcomes from the Phase 3 FRONTIER2 Study

Steven R. Lentz,[1] Aby Abraham,[2] Cihan Ay,[3] Anthony KC Chan,[4] Victor Jiménez-Yuste,[5] Johannes Oldenburg,[6] Maria Elisa Mancuso,[7,8] Johnny Mahlangu,[9] Tadashi Matsushita,[10] Lize van Vulpen,[11] Renchi Yang,[12] Amalie Rhode Høgh Nielsen,[13] Ilgiz Rakhmatullin,[13] Pratima Chowdary[14]

[1]Department of Internal Medicine, University of Iowa, Iowa City, IA; [2]Department of Clinical Haematology, Christian Medical College, Vellore, Tamil Nadu, India; [3]Department of Medicine I, Division of Hematology and Hemostaseology, Medical University of Vienna, Vienna, Austria; [4]McMaster Children's Hospital, McMaster University, Hamilton, Ontario, Canada; [5]Hospital Universitario La Paz, Universidad Autónoma de Madrid, Madrid, Spain; [6]The Institute of Experimental Hematology and Transfusion Medicine, Universitätsklinikum Bonn, Bonn, Germany; [7]Center for Thrombosis and Hemorrhagic Diseases, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy; [8]Humanitas University, Pieve Emanuele, Milan, Italy; [9]Department of Molecular Medicine and Haematology, Faculty of Health Science, University of the Witwatersrand, Johannesburg, South Africa; [10]Department of Transfusion Medicine, Nagoya University Hospital, Nagoya, Japan; [11]Center for Benign Haematology, University Medical Center Utrecht, Utrecht, Netherlands; [12]Thrombosis and Hemostasis Center, Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Tianjin, China; [13]Novo Nordisk A/S, Søborg, Denmark; [14]Katharine Dormandy Haemophilia and Thrombosis Centre, Royal Free Hospital, Department of Haematology, University College London, London, UK.

Presented at the 67th ASH Annual Meeting and Exposition in Orlando, Florida, December 6–9, 2025.
This material is intended to be used at the ASH 2025 congress only.
The study was sponsored by Novo Nordisk A/S, Bagsværd, Denmark

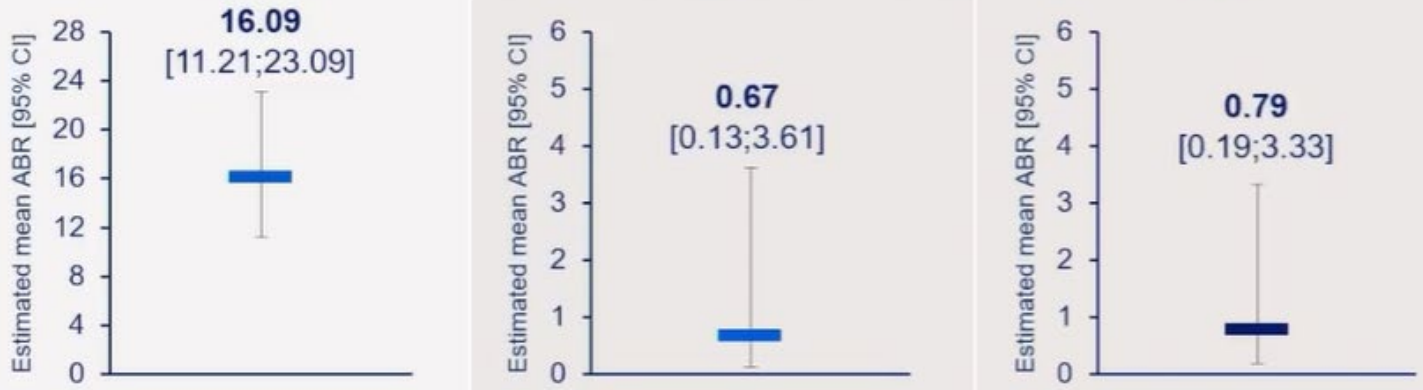
Steven Lentz. 537 Mim8 prophylaxis in adults and adolescents with hemophilia A: 52-week efficacy and safety outcomes from the phase 3 FRONTIER2 study

Hämophile A Mim8 Phase 3

A reduction in mean estimated ABR was observed upon transitioning to Mim8 QW and QM in the extension period

Pre-study on-demand group (Arm 1)

	Main (Weeks 0–26)	Extension (Weeks 26–52)	
	On-demand (n=18)	**Mim8 QW** (n=8)	**Mim8 QM** (n=10)
Mean treatment analysis period (years)	0.50	0.51	0.51
Median ABR	12.24	0.00	0.00



Estimated mean ABR was calculated using a negative binomial regression model. Analysis is only done if there is at least one bleed in the treatment group.
%, percentage of participants; ABR, annualized bleeding rate; CI, confidence interval; QM, once-every-month; QW, once-every-week.

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Hämophilie A

NXT007 Phase I/II

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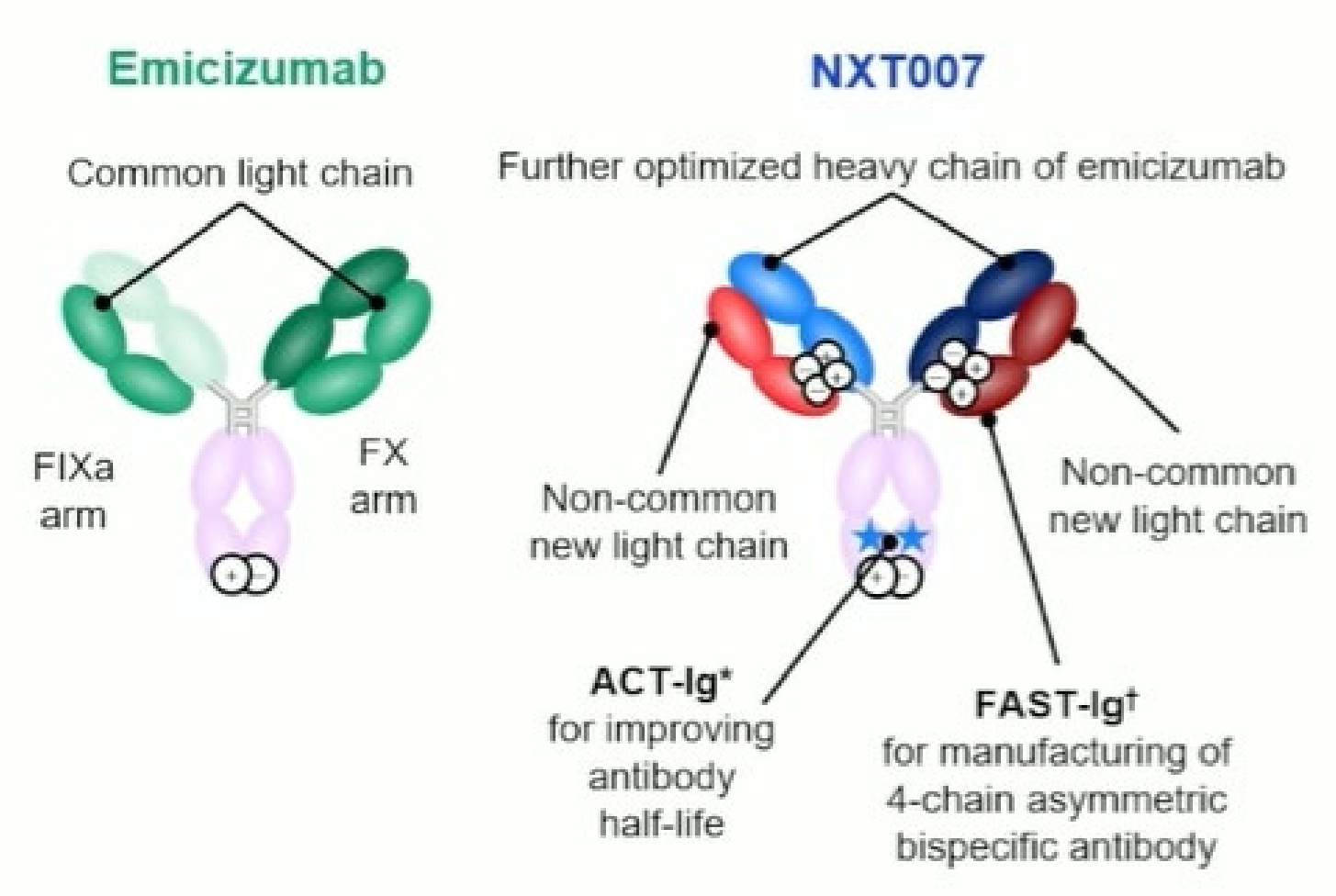
Hämophilie A

NXT007 Phase I/II



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Hämophilie A NXT007 Phase I/II

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Maria Elisa Mancuso,[1,2] Davide Matino,[3] Dan Hart,[4] Francisco José López-Jaime,[5] Christophe Schmitt,[6] Amy Shapiro,[7] Giuliana Ventriglia,[6] Anna Kiialainen,[6] Laura Young,[8] Olivier Catalani,[6] Mark Belletrutti,[9] Tom Chu,[10] Jerzy Windyga,[11] Víctor Jiménez-Yuste,[12] Michaela Lehle,[6] Janice M. Staber[13]

[1]Humanitas University, Pieve Emanuele, Milan, Italy; [2]Center for Thrombosis and Hemorrhagic Diseases, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy; [3]McMaster University, Hamilton, ON, Canada; [4]Roche Products Ltd, Welwyn Garden City, UK; [5]Hospital Universitario Regional de Málaga, Málaga, Spain; [6]F. Hoffmann-La Roche Ltd, Basel, Switzerland; [7]Indiana Hemophilia and Thrombosis Center, Indianapolis, IN, USA; [8]Auckland City Hospital, Auckland, New Zealand; [9]Department of Pediatrics, University of British Colombia, Vancouver, BC, Canada; [10]Genentech, Inc., South San Francisco, CA, USA; [11]Department of Hemostasis Disorders and Internal Medicine, Laboratory of Hemostasis and Metabolic Diseases, Institute of Hematology and Transfusion Medicine, Warsaw, Poland; [12]La Paz University Hospital-IdiPaz, Autónoma University, Madrid, Spain; [13]Stead Family Department of Pediatrics, Carver College of Medicine, University of Iowa, Iowa City, IA, USA

Presented at the 67th ASH Annual Meeting | December 6–9, 2025

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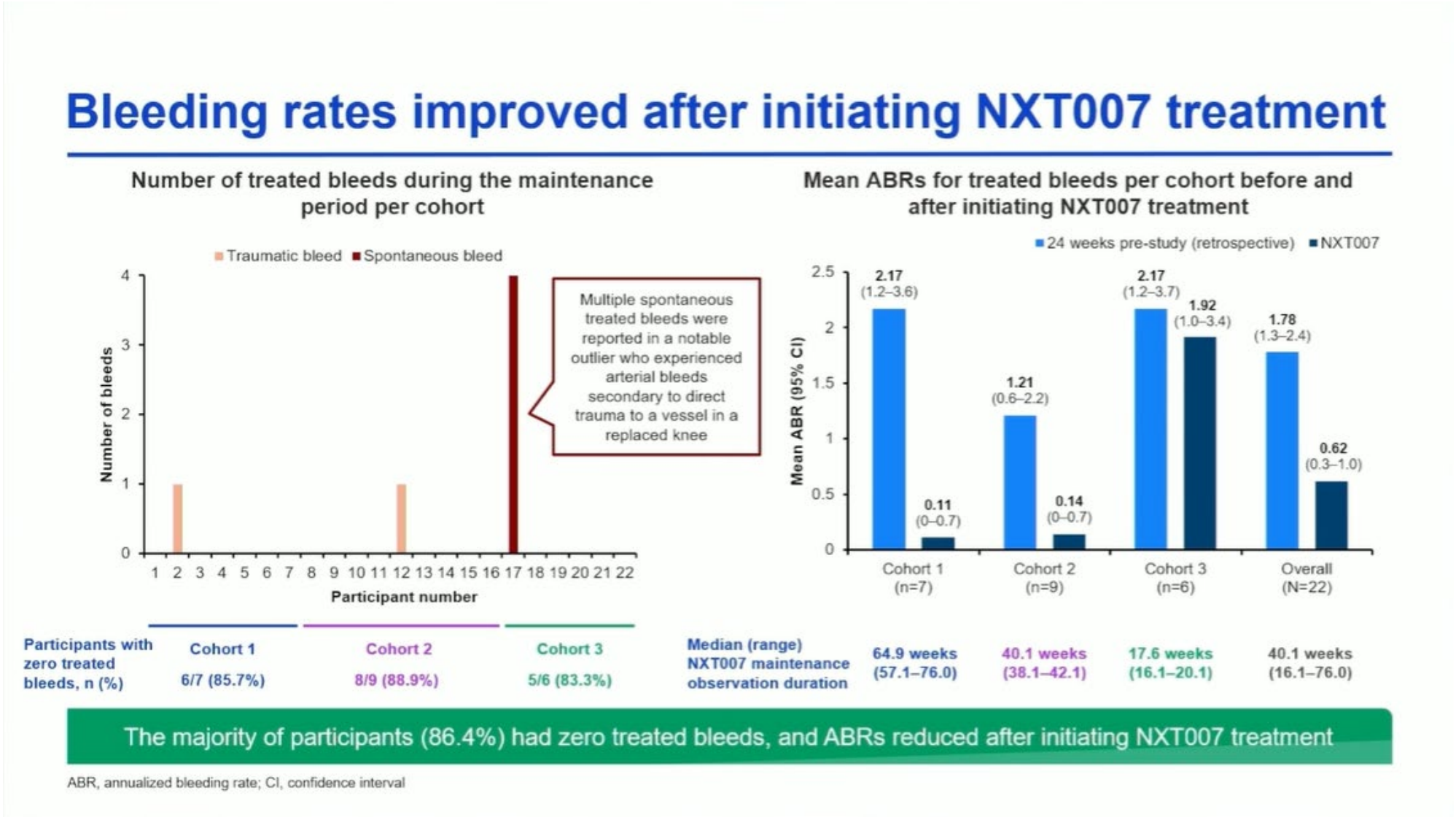

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Hämophilie B

Gentherapie

Steven Pipe. 538 End-of-study analysis of the HOPE-B trial confirms the durable efficacy and safety of etranacogene dezaparvovec hemophilia b gene therapy over 5 years.

Hämophilie B Etranacogen dezaparvovec (Hemgenix®)

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Helping hematologists conquer blood diseases worldwide

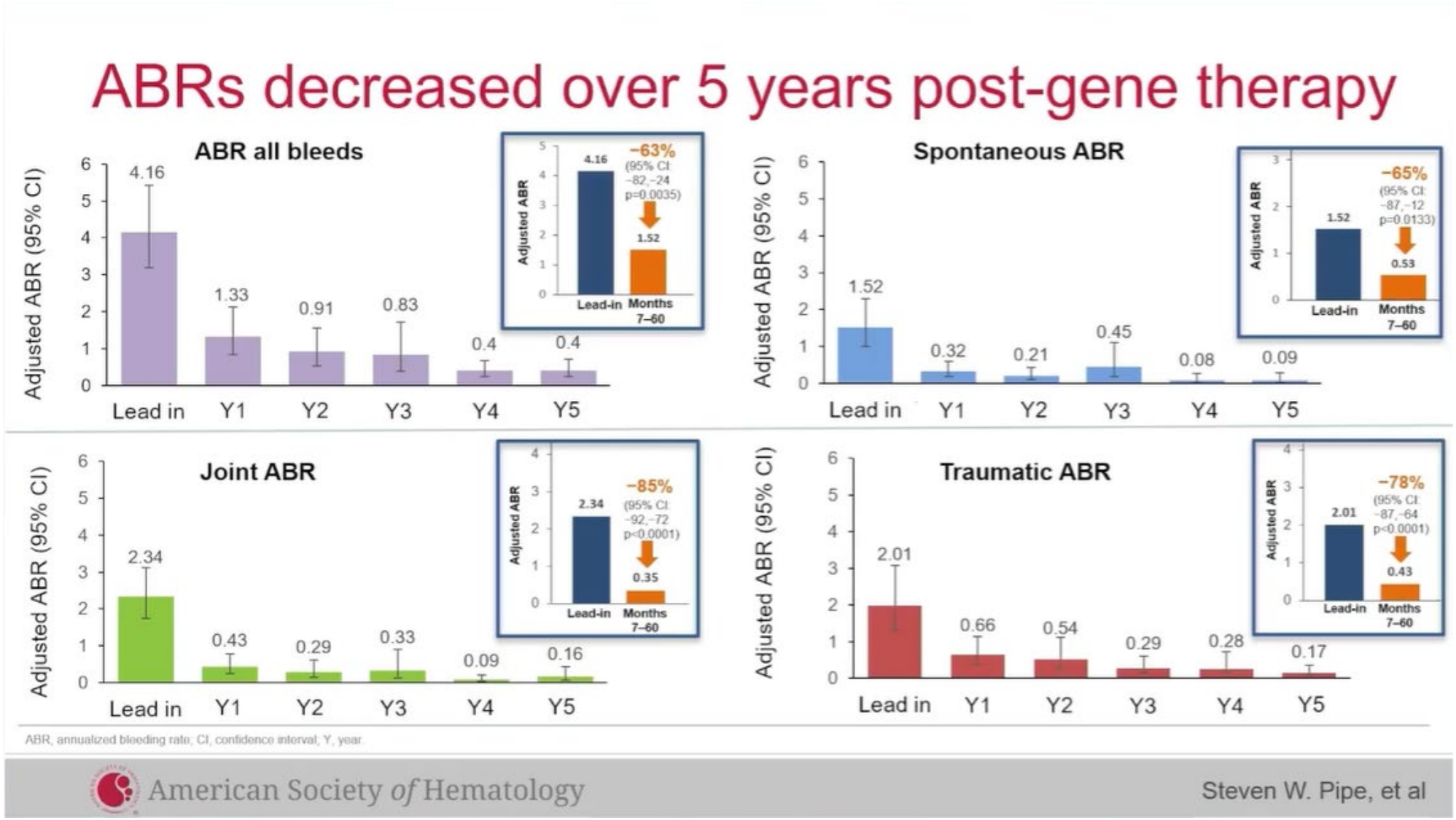
End-of-Study Analysis of the HOPE-B Trial Confirms the Durable Efficacy and Safety of Etranacogene Dezaparvovec Hemophilia B Gene Therapy Over 5 Years

Steven W. Pipe[1]; Wolfgang Miesbach[2]; Michael Recht[3ab]; Frank Leebeek[4]; Nigel S. Key[5]; Giancarlo Castaman[6]; Susan Lattimore[7]; Michiel Coppens[8ab]; Sandra Le Quellec[9]; Sean Gill[9]; Vaibhav Mahajan[9*]; Douglass Drelich[9]; Paul E. Monahan[9]

[1]University of Michigan, Ann Arbor, MI; [2]University Hospital Frankfurt, Frankfurt, Germany; [3a]Yale School of Medicine, New Haven, CT; [3b]National Bleeding Disorders Foundation, New York, NY; [4]Erasmus University Medical Center Rotterdam, Rotterdam, Netherlands; [5]University of North Carolina, Chapel Hill, NC; [6]Careggi University Hospital, Florence, Italy; [7]Oregon Heath & Science University, Portland, OR; [8a]Amsterdam UMC, University of Amsterdam, Amsterdam, The Netherlands; [8b]Amsterdam Cardiovascular Sciences, Pulmonary Hypertension & Critical Care, Amsterdam, The Netherlands; [9]CSL Behring, King of Prussia, PA. *At the time of research.

Steven Pipe. 538 End-of-study analysis of the HOPE-B trial confirms the durable efficacy and safety of etranacogene dezaparvovec hemophilia b gene therapy over 5 years.

Hämophilie B Etranacogen dezaparvovec (Hemgenix®)



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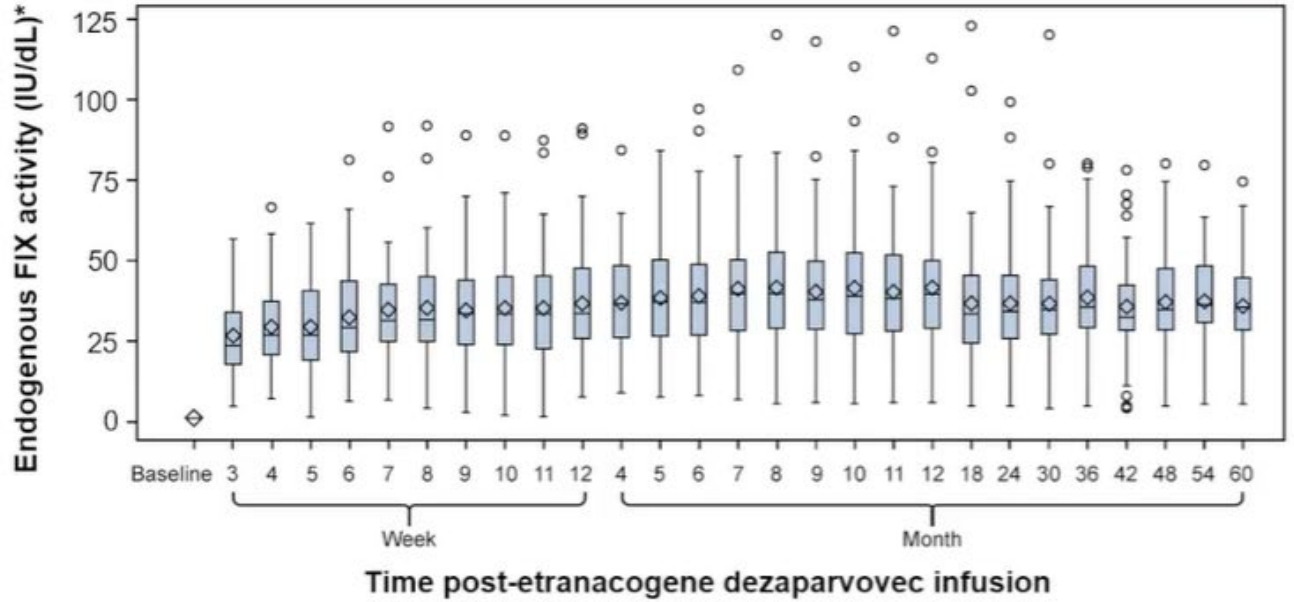
Hämophilie B Etranacogen dezaparvovec (Hemgenix®)

Endogenous FIX activity was stable over 5 years

Mean (SD) FIX activity was 39.0 (18.7) IU/dL at month 6 and 36.1 (15.7) IU/dL at year 5



Number of participants with data: 54 43 49 51 47 46 48 46 44 46 51 48 45 51 47 45 51 50 50 50 50 50 49 48 50 47 47 48

*Assessed by one-stage assay. Only results from samples not taken within 5 half-lives of exogenous FIX use were included. Please note that any points outside of the whiskers (1.5 x IQR) were plotted individually.
FIX, factor IX; IU, International unit; SD, standard deviation.

American Society *of* Hematology Steven W. Pipe, et al

Steven Pipe. 538 End-of-study analysis of the HOPE-B trial confirms the durable efficacy and safety of etranacogene dezaparvovec hemophilia b gene therapy over 5 years.

Thromboembolien

VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

Francis Couturaud. 740 Apixaban or rivaroxaban for extended anticoagulation in patients with venous thromboembolism: A post hoc analysis of the renove clinical triall.

VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

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67th ASH Annual Meeting
Orlando,
OC, December 8, 2025

APIXABAN OR RIVAROXABAN FOR EXTENDED ANTICOAGULATION IN PATIENTS WITH VENOUS THROMBOEMBOLISM: A POST HOC ANALYSIS OF THE RENOVE CLINICAL TRIAL. THE RENOVE TRIAL

Philippe Girard, M.D*., Emilie Presles, M.S., Olivier Sanchez, M.D., Ph.D., Jeannot Schmidt M.D., Ph.D., Nicolas Meneveau M.D., Ph.D., Alice Ballerie M.D., Marie-Antoinette Sevestre M.D., Ph.D., Sandrine Acassat. M.D., Gilles Pernod M.D., Ph.D., Isabelle Mahe M.D., Ph.D., CécileTromeur M.D., Ph.D., Patrick Mismetti M.D., Ph.D., Silvy Laporte M.D., Ph.D.,
Francis Couturaud M.D., Ph.D., for the RENOVE Investigators*

* *In memory*

CLINICALTRIALS.GOV #: NCT03285438
EudraCT #: 2017-002433-31

INNOVTE INvestigation Network On Venous Thrombo-Embolism · F-CRIN · Inserm Institut national de la santé et de la recherche médicale · GETBO UMR 1304 · CHU BREST · UBO Université de Bretagne Occidentale

Francis Couturaud. 740 Apixaban or rivaroxaban for extended anticoagulation in patients with venous thromboembolism: A post hoc analysis of the renove clinical triall.

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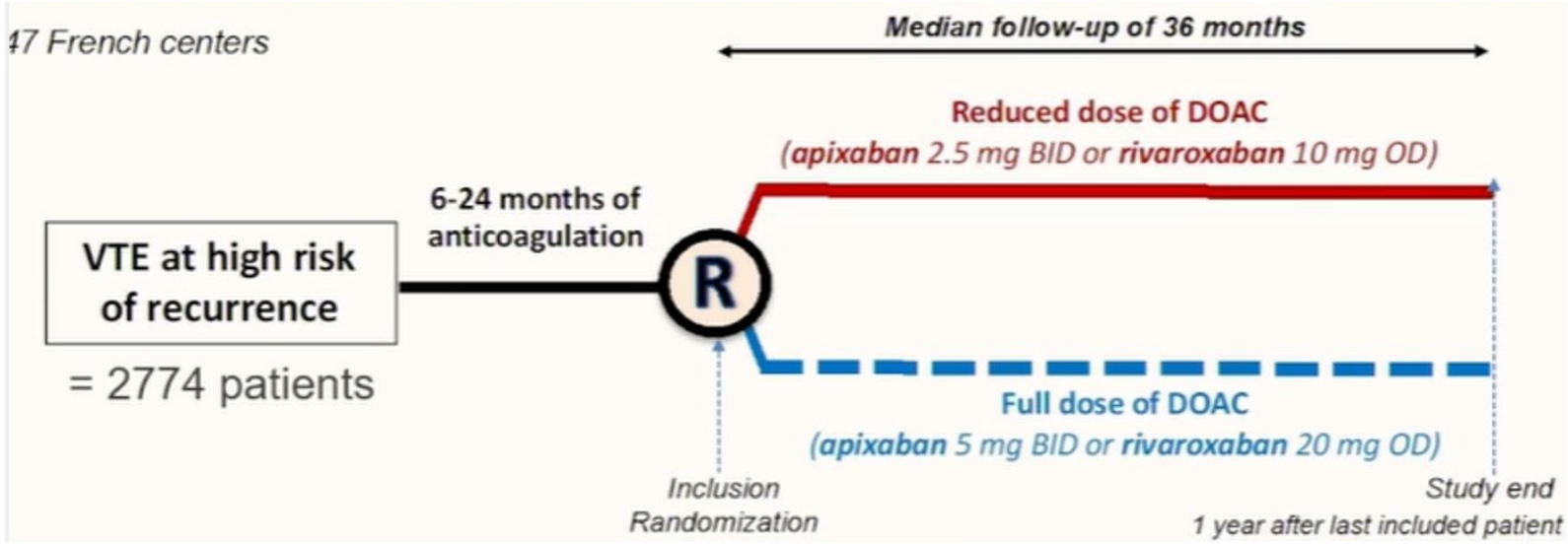

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VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

RENOVE - trial

Main findings from RENOVE trial

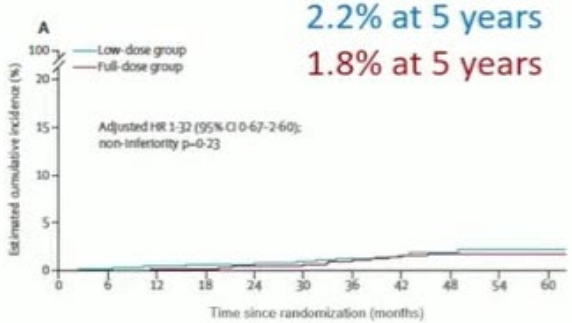
Recurrent VTE

aHR (95%CI): **1.32** (0.67-2.60)

P-NONINF= 0.23

2.2% at 5 years

1.8% at 5 years

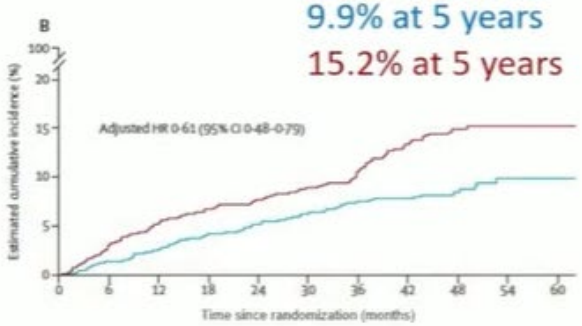


Bleeding

aHR (95%CI): **0.61** (0.48-0.79)

9.9% at 5 years

15.2% at 5 years

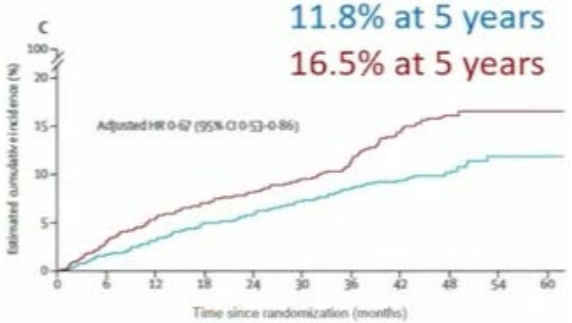


Net clinical benefit

aHR (95%CI): **0.67** (0.53-0.86)

11.8% at 5 years

16.5% at 5 years



Couturaud et al. Lancet 2025;405:725-35.

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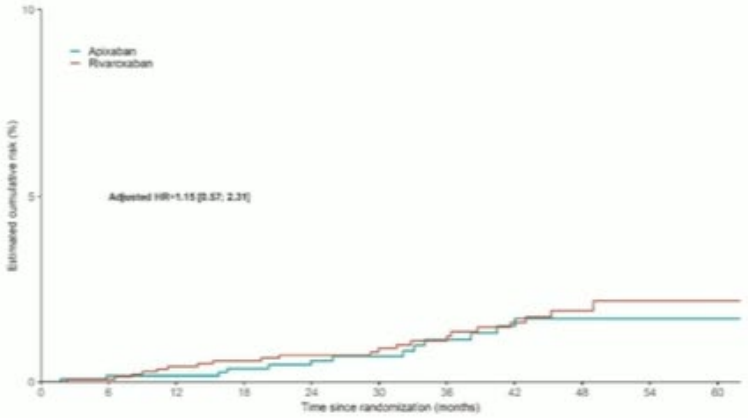
VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

RENOVE - trial

Recurrent VTE

5-year cumulative incidence

	Patients with reduced or full dose DOAC	
	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)
Recurrent VTE - n (%)	21 (**2.2**)	13 (**1.7**)
HR (95% CI)	**1.19** (0.59 - 2.37)	
Adjusted HR (95% CI)*	**1.15** (0.57 - 2.31)	



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VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

RENOVE - trial

Recurrent VTE

5-year cumulative incidence

	Patients with reduced or full dose DOAC		Full dose		Reduced dose	
	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)	(N=755)	(N=630)	(N=758)	(N=625)
Recurrent VTE - n (%)	21 (**2.2**)	13 (**1.7**)	9 (**1.7**)	6 (**2.0**)	12 (**2.7**)	7 (**1.4**)
HR (95% CI)	**1.19** (0.59 - 2.37)		**1.07** (0.38 - 3.01)		**1.29** (0.51 – 3.27)	
Adjusted HR (95% CI)*	**1.15** (0.57 - 2.31)		**1.08** (0.38 - 3.07)		**1.20** (0.47 - 3.08)	

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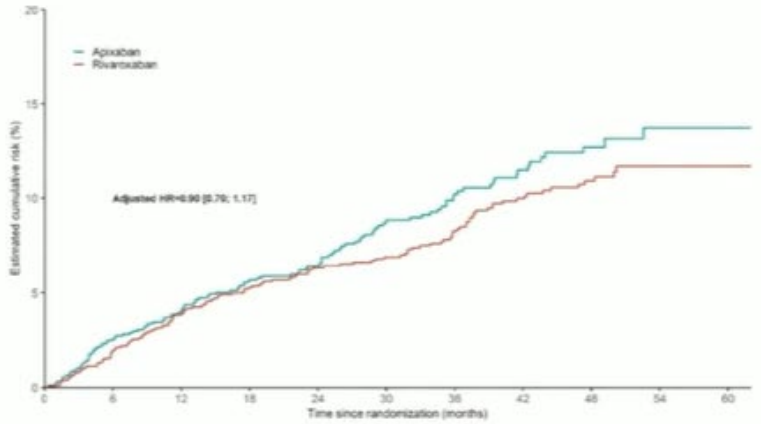
VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

RENOVE - trial

Primary outcome – clinically relevant bleeding

5-year cumulative incidence

	Patients with reduced or full dose DOAC	
	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)
Clinically relevant bleeding, n(%)	132 (**11.7**)	118 (**13.7**)
HR (95% CI)	**0.85** (0.67 - 1.10)	
Adjusted HR (95% CI)*	**0.90** (0.70 - 1.17)	



Francis Couturaud. 740 Apixaban or rivaroxaban for extended anticoagulation in patients with venous thromboembolism: A post hoc analysis of the renove clinical triall.

VTE Apixaban oder Rivaroxaban zur verlängerten Antikoagulation

RENOVE - trial

Primary outcome – clinically relevant bleeding

5-year cumulative incidence

	Patients with reduced or full dose DOAC		Full dose		Reduced dose	
	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)	(N=755)	(N=630)	(N=758)	(N=625)
Clinically relevant bleeding, n(%)	132 (**11.7**)	118 (**13.7**)	84 (**14.0**)	70 (**16.5**)	48 (**9.0**)	48 (**11.0**)
HR (95% CI)	**0.85** (0.67 - 1.10)		**0.91** (0.67 - 1.26)		**0.77** (0.51 - 1.15)	
Adjusted HR (95% CI)*	**0.90** (0.70 - 1.17)		**0.99** (0.71 - 1.38)		**0.81** (0.53 - 1.23)	

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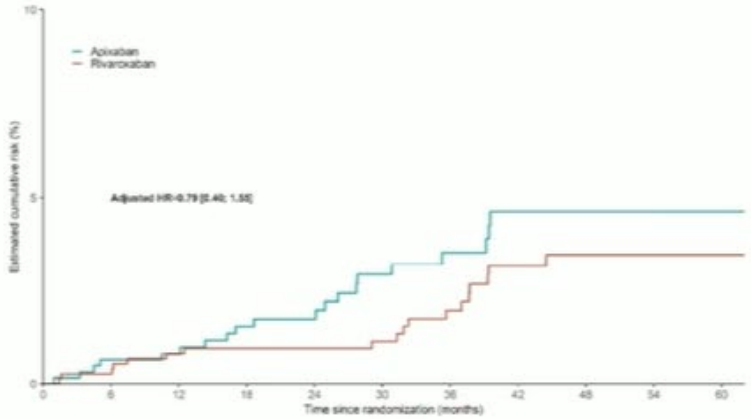
RENOVE - trial

Major bleeding

5-year cumulative incidence

	Patients with reduced or full dose DOAC	
	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)
Major bleeding - n (%)	26 (**2.5**)	27 (**3.9**)
HR (95% CI)	**0.72** (0.42 - 1.23)	
Adjusted HR (95% CI)*	**0.82** (0.46 - 1.44)	



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RENOVE - trial

Major bleeding

5-year cumulative incidence

	Patients with reduced or full dose DOAC		Full dose		Reduced dose	
	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban	Rivaroxaban	Apixaban
All RENOVE study population	(N=1513)	(N=1255)	(N=755)	(N=630)	(N=758)	(N=625)
Major bleeding - n (%)	26 (**2.5**)	27 (**3.9**)	18 (**3.5**)	20 (**4.6**)	8 (**1.6**)	7 (**3.0**)
HR (95% CI)	**0.72** (0.42 - 1.23)		**0.66** (0.35 - 1.25)		**0.85** (0.31 - 2.36)	
Adjusted HR (95% CI)*	**0.82** (0.46 - 1.44)		**0.79** (0.40 - 1.55)		**0.87** (0.30 - 2.50)	

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VTE und Krebs

Vergleich DOAK und NMH

Rupesh Subash. 24 Comparative safety and effectiveness of direct oral anticoagulants and low-molecular weight heparin in patients with venous thromboembolism and cancer in europe.

VTE und Krebs

Vergleich DOAK und NMH

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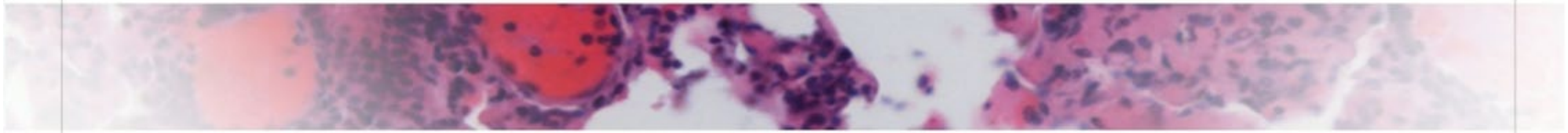

Comparative safety and effectiveness of direct oral anticoagulants and low-molecular weight heparin in patients with venous thromboembolism and cancer in Europe (VICTORIE)

Rupesh Subash. 24 Comparative safety and effectiveness of direct oral anticoagulants and low-molecular weight heparin in patients with venous thromboembolism and cancer in europe.

VTE und Krebs Vergleich DOAK und NMH

Data Sources

- Norwegian National Patient Registry (NPR) linked to National Prescription Database (NPD)
- Swedish NPR linked to NPD
- Finnish NPR linked to NPD
- UK Clinical Practice Research Datalink (CPRD) Aurum linked to Hospital Episode Statistics (HES)
- German Social Health Insurance databases (AOK Plus and GWQ)

Each countries data source was linked at the patient level.

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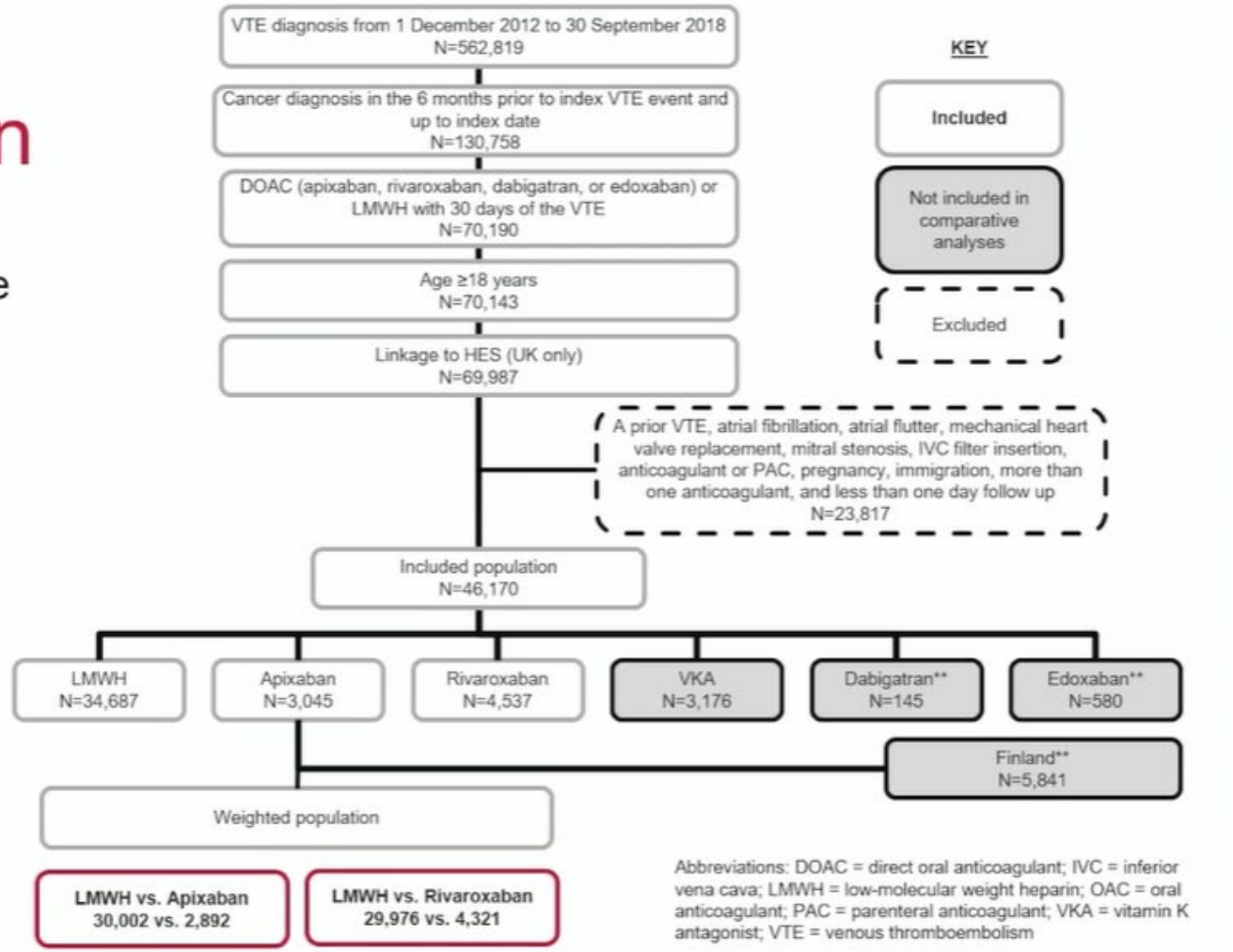
Patient Attrition

- After IPTW, 30,002 and 2,892 patients were in the LMWH-apixaban weighted comparison, and 29,976 and 4,321 patients in the LMWH-rivaroxaban weighted comparison, respectively.



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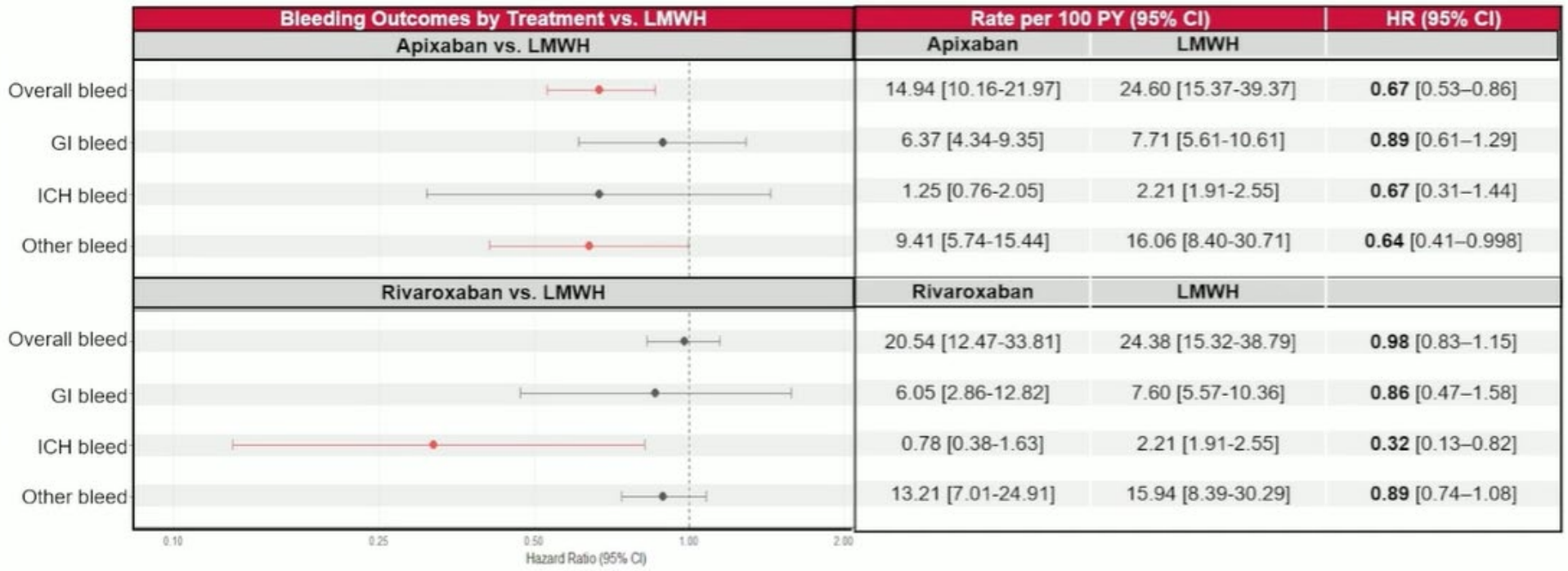
Bleeding Incidence Rates and Hazard Ratios



- rVTE was underpowered for comparative analysis.
- Apixaban was associated with a lower risk of overall and other bleeding, with similar risks for GI and ICH compared to LMWH.
- Rivaroxaban had a similar risk of overall, GI, and other bleeding compared to LMWH, but a lower risk of ICH.

Abbreviations: CI = confidence interval; GI = gastrointestinal; HR = hazard ratio; ICH = intracranial hemorrhage; LMWH = low-molecular weight heparin; PY = person-year

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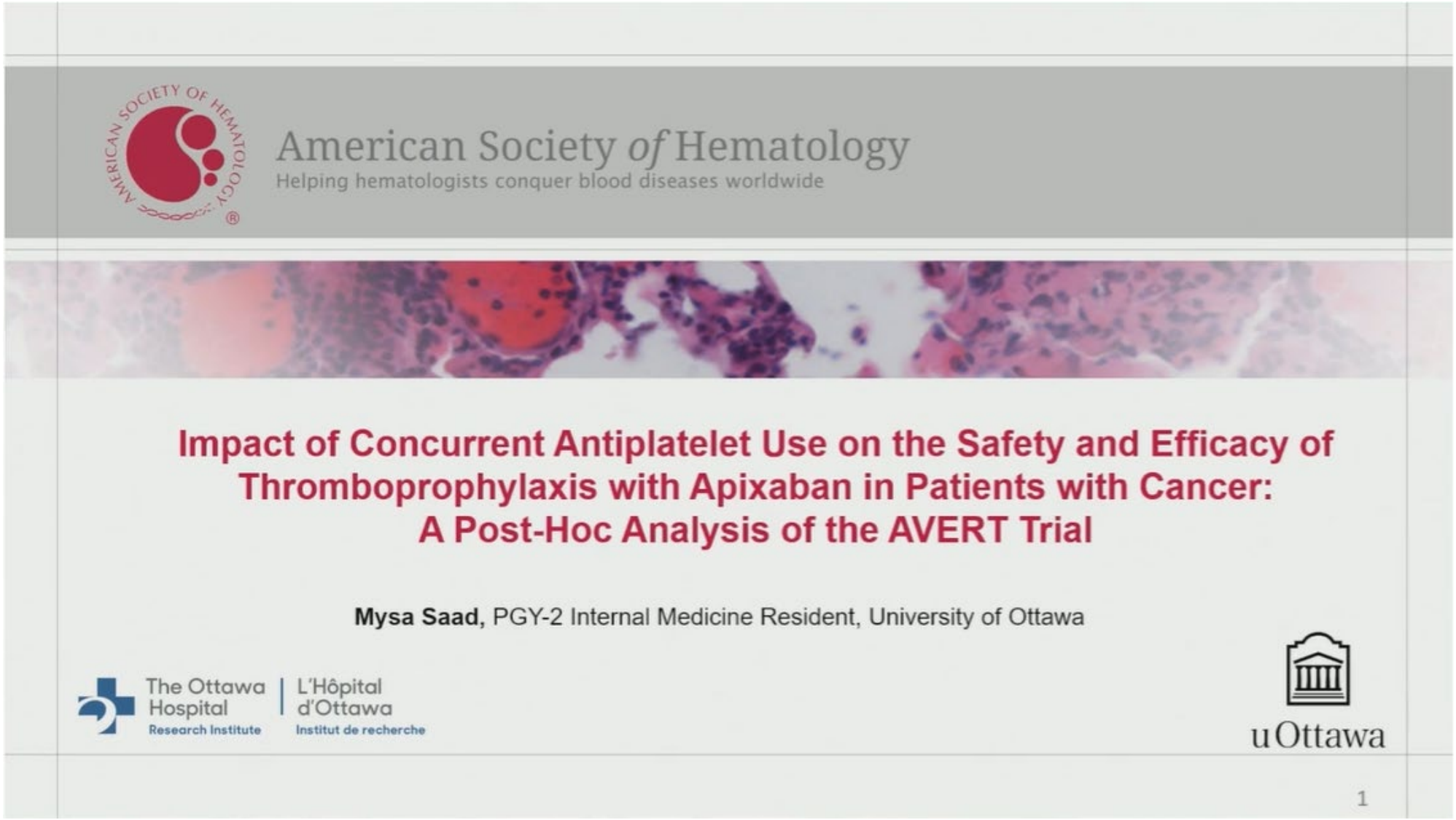
VTE und Krebs Thrombozytenaggregationshemmern/NSAIDs + Apixaban

Mysa Saad. 741 Impact of concurrent antiplatelet/NSAID use on the safety and efficacy of thromboprophylaxis with apixaban in patients with cancer: A post-hoc analysis of the AVERT trial.

VTE und Krebs Thrombozytenaggregationshemmern/NSAIDs + Apixaban



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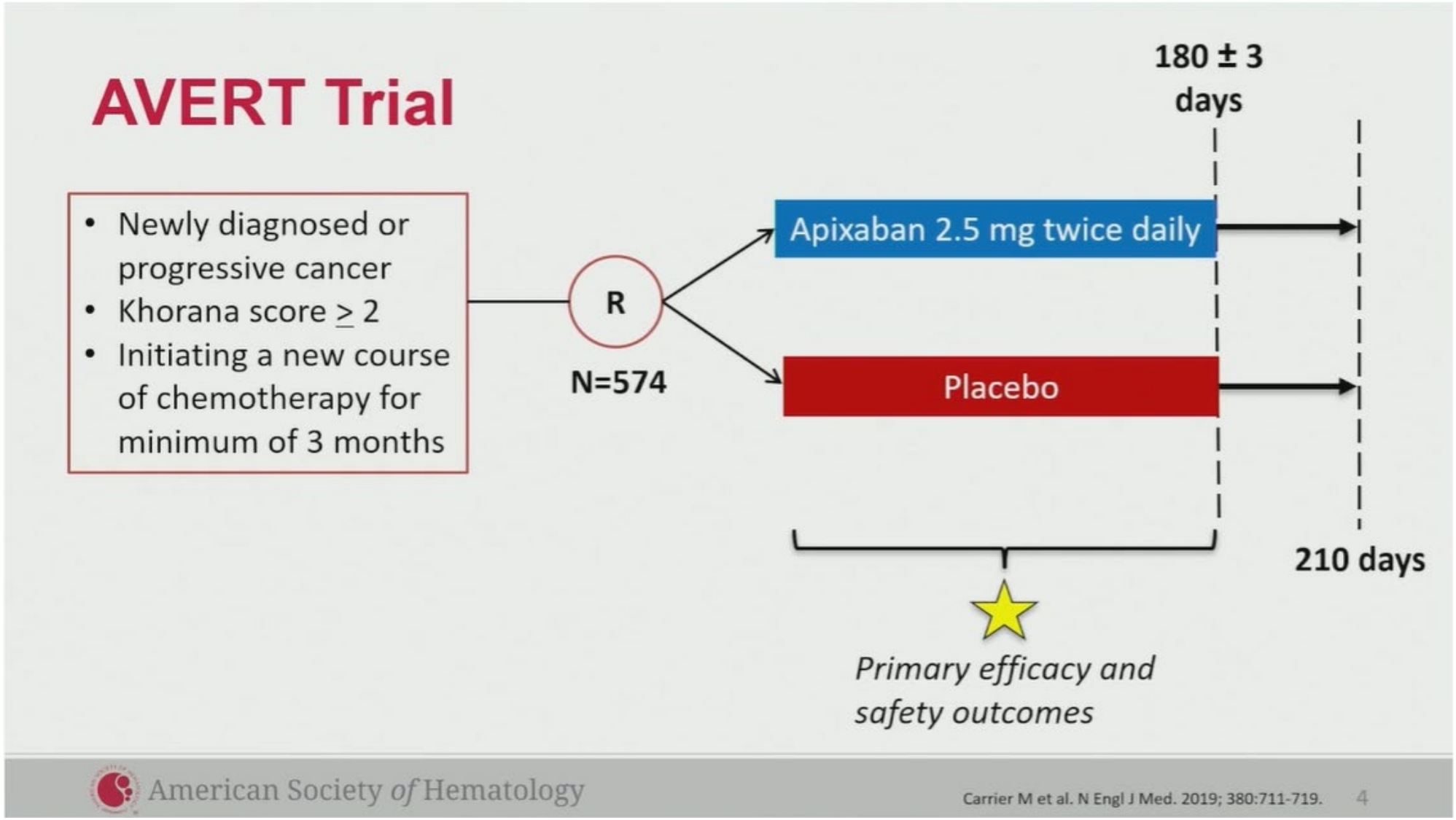

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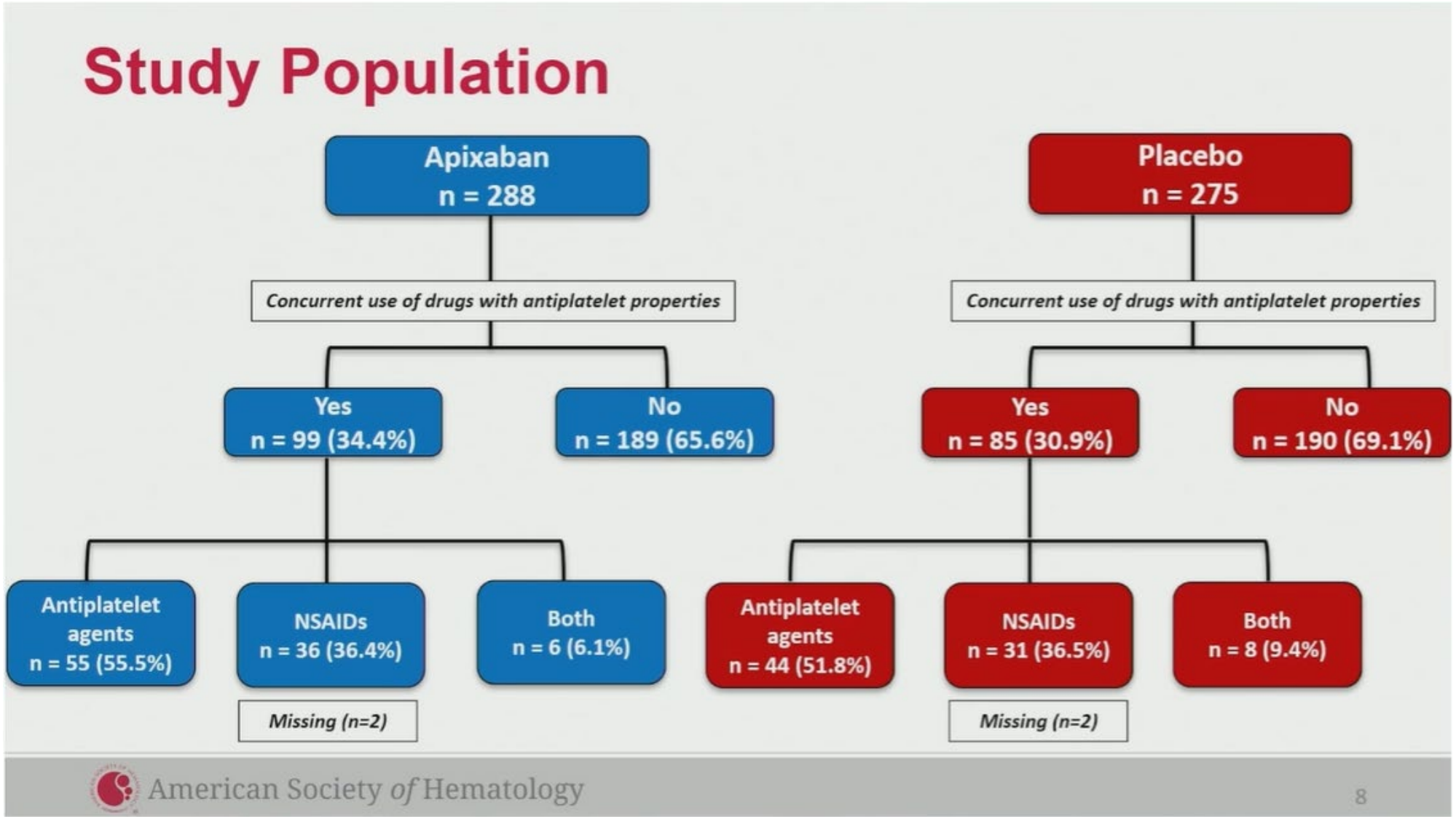

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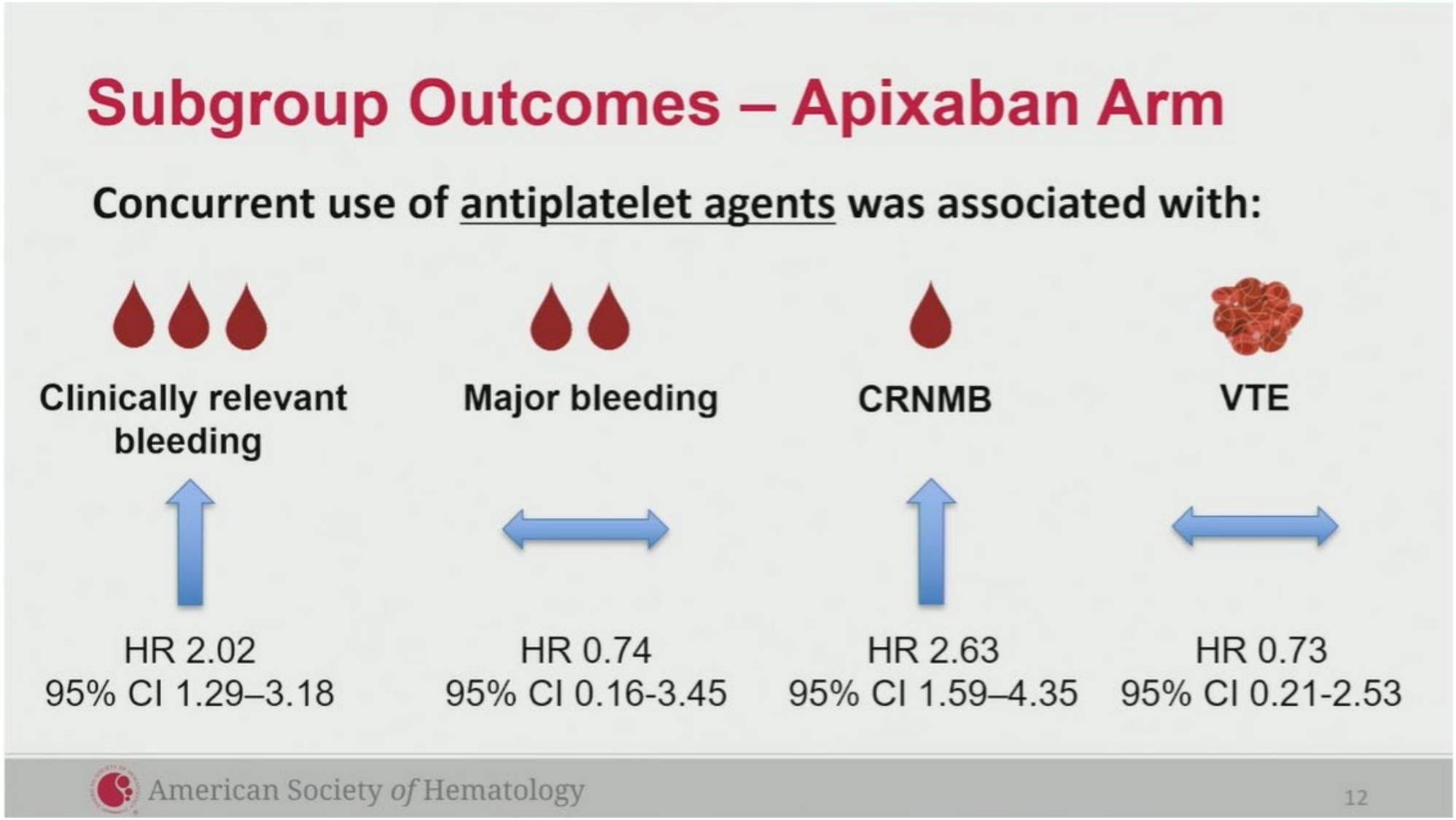

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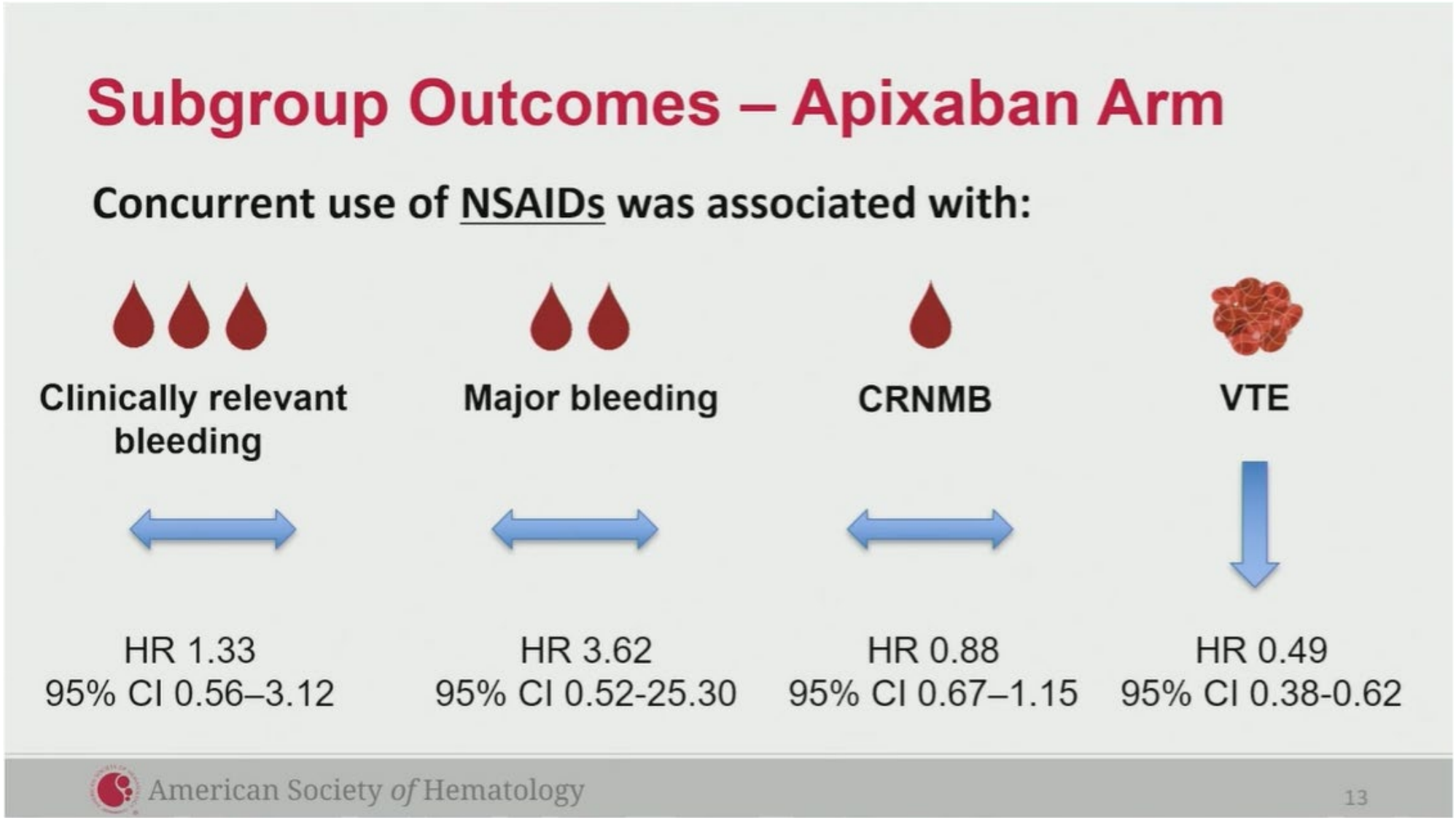

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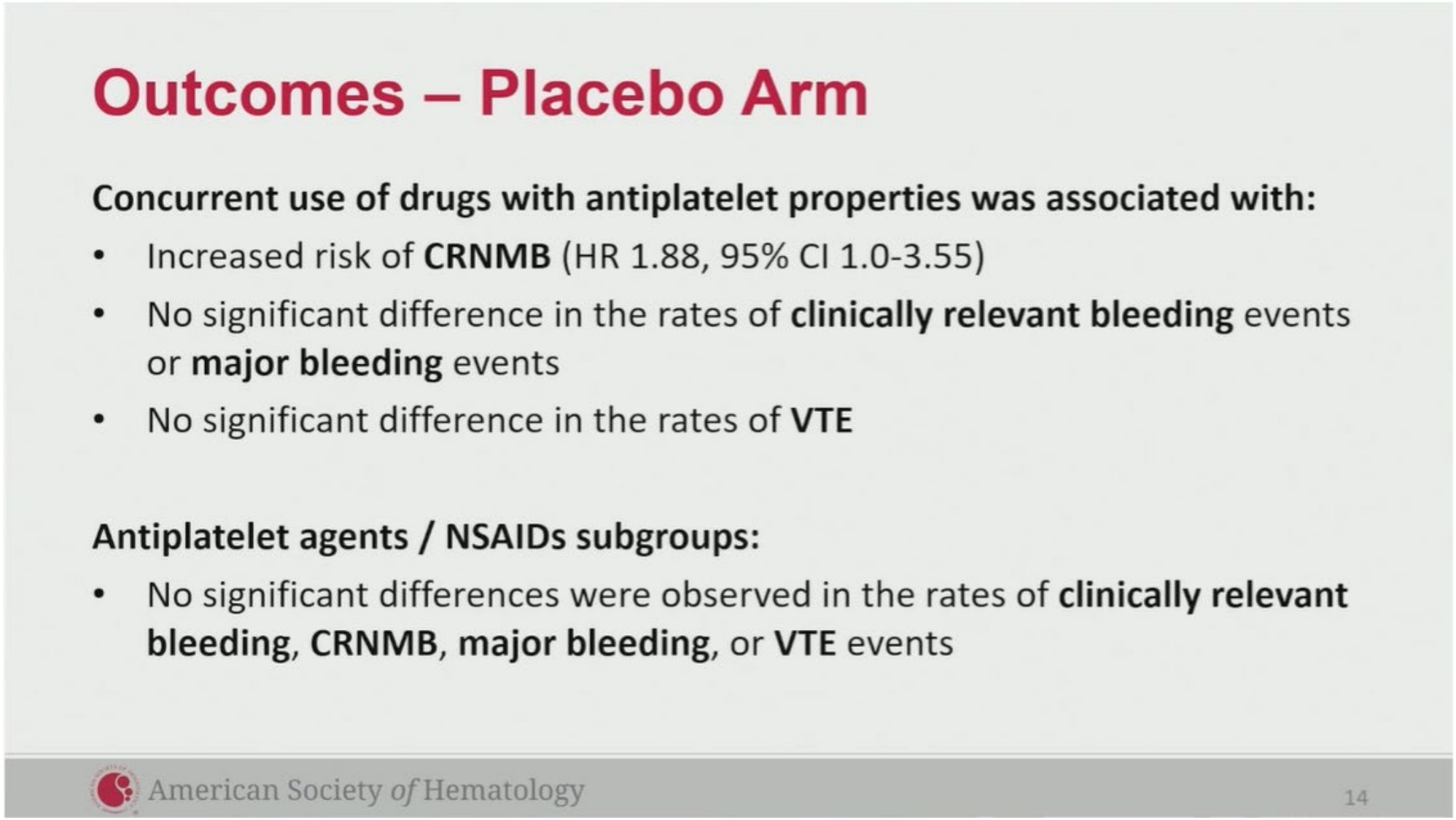

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APS DOAK oder Warfarin APS mit niedrigem Risiko

Renu Bhargavi Boyapati. 953 Real-world outcomes of direct oral anticoagulants versus warfarin in patients with singlepositive antiphospholipid antibody syndrome: A trinetx cohort analysis.

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METHODS

- Three parallel, retrospective cohort studies using the TriNetX global network (National EHR based database).
- Adult patients (≥18 years) with APS and isolated positivity for aCL, LAC, or aB2GP1 antibodies who were newly initiated on DOACs were compared to those started on warfarin.
- Propensity score matching was performed 1:1 for demographics and key comorbidities.
- Follow up: 2 years
- Statistical analysis utilized Kaplan-Meier survival curves with log-rank tests and hazard ratios (HR) with 95% confidence intervals;
- $p < 0.05$ was considered significant.

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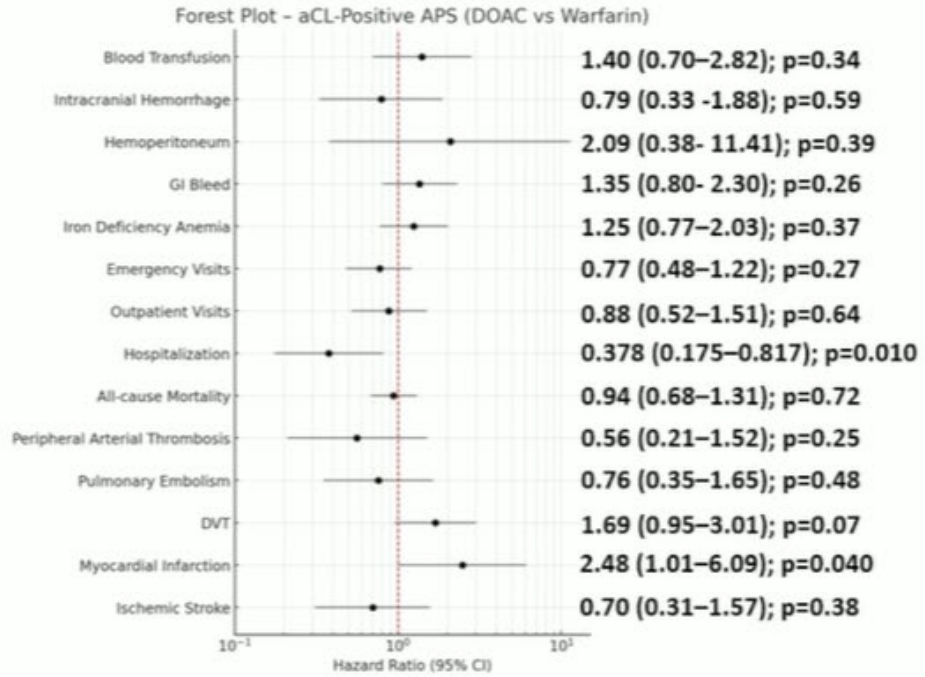
Results - Anticardiolipin (aCL) positive APS

No Statistically significant difference in most outcomes except for

LOWER RISK of Hospitalization

INCREASED RISK of Myocardial Infarction

- DOAC: 15 patients
- Warfarin: 10 patients



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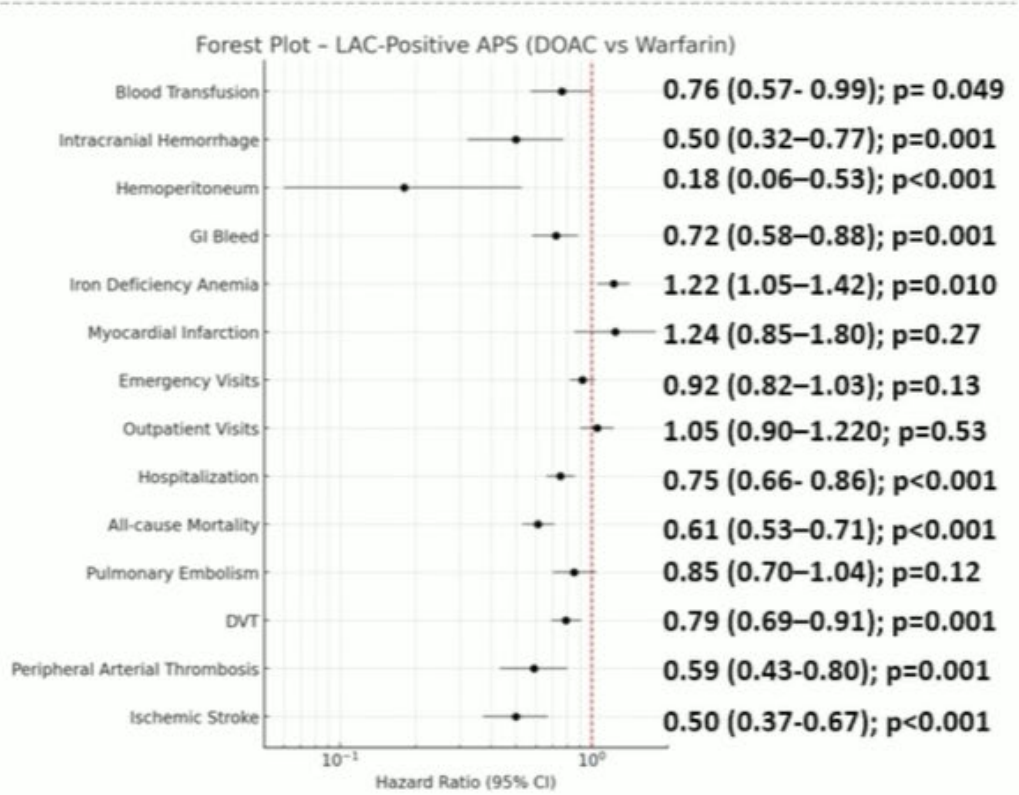
Lupus Anticoagulant (LAC) Positive APS

No Statistically significant difference in rates of MI, PE
Emergency visits, outpatient visits.

LOWER RISK of ICH, GI Bleed, Hemoperitoneum, Blood transfusion
Arterial thrombosis, Ischemic stroke, DVT, Hospitalization, all-cause mortality.

INCREASED RISK of iron Deficiency anemia



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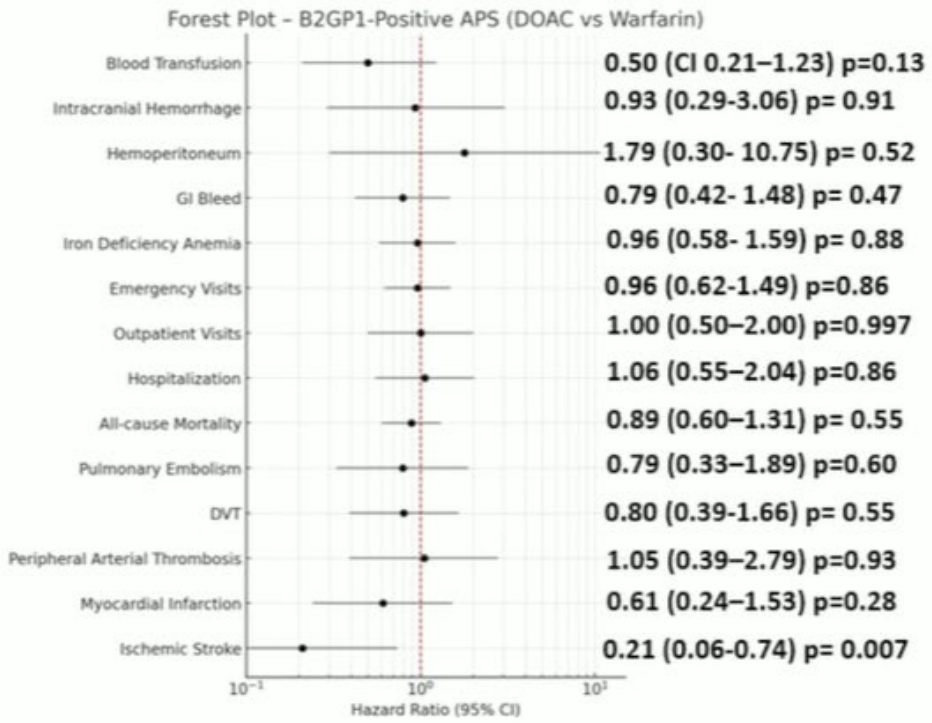
Anti-Beta 2 Glycoprotein (aB2GP1) Positive APS

No Statistically significant difference in most of the outcomes

LOWER RISK of Ischemic stroke

INCREASED RISK: NONE



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Innere Medizin II, Hämatologie, Onkologie, Klinische Immunologie und Rheumatologie

Post ASH 2025 Orlando

Hämostaseologie

Christoph Faul

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TÜBINGEN

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