Development and implementation of common data elements for venous thromboembolism research: on behalf of SSC Subcommittee on official Communication from the SSC of the ISTH

Gal, G. le; Carrier, M.; Castellucci, L.A.; Cuker, A.; Hansen, J.B.; Klok, F.A.; ... ; ISTH CDE Task Force

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RECOMMENDATIONS AND GUIDELINES

Development and implementation of common data elements for venous thromboembolism research: on behalf of SSC Subcommittee on official Communication from the SSC of the ISTH

Grégoire Le Gal[1] | Marc Carrier[1] | Lana A. Castellucci[1] | Adam Cuker[2] | John-Bjarne Hansen[3] | Frederikus A. Klok[4] | Nicole J. Langlois[1] | Jerrold H. Levy[5] | Saskia Middeldorp[6] | Marc Righini[7] | Sam Walters[8] | for the ISTH CDE Task Force

[1]Department of Medicine, Ottawa Hospital Research Institute, University of Ottawa, Ottawa, ON, Canada

[2]Department of Medicine and Department of Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

[3]K.G.Jebsen - Thrombosis Research and Expertise Center (TREC), Department of Clinical Medicine, UiT - The Arctic University of Norway, Tromsø, Norway

[4]Department of Medicine - Thrombosis and Hemostasis, Leiden University Medical Center, Leiden, the Netherlands

[5]Departments of Anesthesiology, Critical Care, and Surgery, Duke University School of Medicine, Durham, NC, USA

[6]Department of Vascular Medicine, Amsterdam Cardiovascular Sciences, Amsterdam UMC, Amsterdam, the Netherlands

[7]Division of Angiology and Hemostasis, Geneva University Hospitals and Faculty of Medicine, Geneva, Switzerland

[8]Breakthrough Healthcare, Baltimore, MD, USA

Correspondence
Grégoire Le Gal, Division of Hematology, General Campus, Box 201A, The Ottawa Hospital, 501 Smyth Road, Ottawa ON K1H 8L6, Canada.
Email: glegal@toh.ca

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Abstract

Clinical research in venous thromboembolism (VTE) is hindered by variability in the collection and reporting of data and outcomes. A consistent data language facilitates efficiencies, leads to higher quality data, and permits between-study comparisons and evidence synthesis. The International Society on Thrombosis and Haemostasis (ISTH) launched an international task force of more than 50 researchers to develop common data elements for clinical research in venous thromboembolism.

The project was organized in seven working groups, each focusing on a topic area: General Core Data Elements; Anticoagulation and Other Therapies; Chronic VTE and Functional Outcomes; Diagnosis of VTE; Malignancy; Perioperative; and Predictors of VTE. The groups met via teleconference to collaboratively identify key data elements and develop definitions and data standards that were structured in a project-specific taxonomy. A Steering Committee met by teleconference and in-person to determine the overall scope of the project and resolve questions arising from the working groups. ISTH held an open public comment period to enable broader stakeholder involvement and feedback. The common data elements were then refined by the working groups to

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create a set of 512 unique data elements that are publicly available at http://isth.breakthrough.healthcare.

The ISTH VTE Common Data Elements are intended to be a living project with ongoing curation, future expansion, and adaptation to meet the needs of the thrombosis and hemostasis research community.

KEYWORDS

analysis, data, clinical research, common data elements, standardization, venous thromboembolism

1 | BACKGROUND

Clinical research data elements vary across studies and this variation often impedes efforts to conduct meta-analysis, introduces the possibility of misinterpretation, and increases the time and cost to develop studies. The use of consistent, consensus-based data standards can alleviate these burdens to facilitate more effective global evidence synthesis in thrombosis and hemostasis research. To achieve the aim of creating common research data standards for worldwide venous thromboembolism (VTE) clinical research, the International Society on Thrombosis and Haemostasis (ISTH) launched the VTE Common Data Elements (CDEs) project in November 2018. The VTE CDE project represents a collaboration of more than 50 VTE researchers worldwide to develop a core set of clinical research data elements that would achieve the following goals:

1. Improve the quality and consistency of VTE clinical research data, creating opportunities for comparison and combination of clinical research data;
2. Accelerate study design and start-up for clinical research projects and meta-analyses that aggregate data;
3. Simplify data collection, leading to more rapid study completion and lower costs; and
4. Harmonize key outcomes to provide commonly understood and universal endpoints.

Using the CDEs developed in this project, researchers can rapidly construct databases and case report forms (CRFs) for their studies, leading to faster study creation and the ability to more effectively combine study datasets for meta-analysis using common terms, definitions, data types, and selection sets.

Government agencies and private nonprofit organizations have made considerable strides in clinical research data standards over the past two decades. The Clinical Data Interchange Standards Consortium (CDISC) has created international terminology standards and the Clinical Data Acquisition Standards (CDASH) that govern consistent data collection across studies to provide traceability and transparency.[1] The United States National Institutes of Health (NIH) facilitates and hosts a variety of CDE sets covering specific clinical conditions, including the National Institutes for Neurological Disorders and Stroke (NINDS) CDEs.[2] The ISTH closely evaluated the NINDS CDE framework and methods when designing the VTE CDE project, given NINDS' well-structured approach and success in developing more than 10 000 CDEs.

ISTH made the determination to develop VTE CDEs based on the limited availability of existing data standards for VTE research, and the need for thrombosis- and hemostasis-specific expertise in the development of said standards. Where possible and appropriate, ISTH leveraged existing CDEs addressing clinical condition-agnostic variables such as patient demographics, study administration, and common clinical concepts. In doing so, ISTH was able to focus the majority of its attention on VTE-specific considerations for data standards and harmonization in this project.

2 | METHODS

The VTE CDE project was designed to foster collaboration and consensus across the global VTE research community, to increase the rate of adoption of the CDEs and engage researchers in their ongoing refinement and expansion. The ISTH retained the services of Breakthrough Healthcare, a United States–based consulting organization, to organize and facilitate this project.

2.1 | Governance and technical expertise

The ISTH, in partnership with INVENT, the International Network of Venous Thromboembolism Clinical Research Networks (invent-vte.com) assembled a project Steering Committee composed of VTE clinical research experts, with attention taken to ensure fair representation by region, gender, and clinical focus areas. The Steering Committee's charge included establishing the project's framework and scope and overseeing the work of seven working groups focusing on specific content areas within the CDEs. The Steering Committee held an in-person working session at the 2019 ISTH Clinical Congress in Melbourne, Australia, to review the project's status and address outstanding questions from the working groups.

The working groups created for this project and their areas of focus were as follows:

- Anticoagulation and Other Therapies: Therapies for treatment and primary and secondary prevention of VTE

- Chronic VTE and Functional Outcomes: The definition of outcomes in chronic VTE, including functional outcomes, quality of life, chronic thromboembolism (eg, post-thrombotic syndrome, chronic thromboembolic pulmonary hypertension [CTEPH]), and monitoring and diagnostic mechanisms for chronic VTE
- Diagnosis of VTE: Diagnostic studies and clinical prediction rules commonly used to diagnose VTE, including imaging studies, ultrasound, pulmonary angiography, probability and prognostic rules, and standardizing the definition of confirmed (recurrent) deep vein thrombosis (DVT)/ pulmonary embolism (PE)
- General Core Data Elements: Foundational common data elements in the following categories: (a) demographics, (b) history, (c) physical examination, (d) adverse events, (e) protocol deviations, and (f) study discontinuations
- Malignancy: Cancer-associated thrombosis, including active cancer definitions, VTE-related mortality in the context of cancer, cancer-specific VTE risks, and cancer-specific treatments for VTE
- Perioperative: Pre-surgical, surgical, and post-surgical aspects of VTE (including post-acute intensive care unit, arterial thrombosis, bridging anticoagulation, and surgical risk stratification)
- Predictors of VTE: Transient and permanent risk factors specific to patients with VTE, including genetic, environmental, and acquired predictors, as well as comorbidities

These working groups met once monthly via teleconference over a 6-month period to first identify key CDEs for their respective topic areas, and then develop definitions and data standards using existing clinical research studies and CRFs as a guide. The working groups organized their CDEs and collaborated using Breakthrough Clinical Data Engine, a cloud-based application for the development and publication of clinical data standards.

2.2 | CDE standards model

Using the NINDS CDE standards as a starting point, the ISTH developed a CDE data model that allows for the rapid creation of CDEs within an easy-to-navigate taxonomy developed specifically for the project. The taxonomy organizes CDEs based on a hierarchy of subject, topic, and subtopic. The subjects identified as descriptive of the overall concepts represented in the CDEs are as follows:

- Adverse Events: severity, frequency, and outcomes of adverse events due to exposure to study interventions
- Assessments: the use of standardized clinical evaluation tools and their associated results
- Conditions: history and present status of medical conditions, and family history of said conditions
- Demographics: general patient descriptors including age, sex, race, location, and other demographic information
- History: conditions and exposures with a relationship to the development of new or recurrent VTE and its associated severity
- Imaging and Diagnostic Studies: radiological studies and their associated interpretations
- Interventions: non-surgical, non-pharmacotherapeutic interventions
- Laboratory: clinical and anatomic pathology orders and their associated results
- Malignancy: cancer-specific data including detailed diagnoses and staging
- Mechanical Prophylaxis: use of mechanical prophylaxis in the treatment of VTE
- Mortality: the incidence and contributing factors to patient mortality
- Nonsurgical Bleeding: instances and severity of bleeding events not related to surgery, and associated risk
- Pharmacotherapy: administration and prescription of drug products relevant to VTE
- Physical Exam: findings such as height, weight, blood pressure, and other items assessed during physical examination
- Pregnancy: data elements specific to pregnant study subjects, such as gestational age
- Procedure: history of procedures as well as procedure-specific assessment instruments and their associated results
- Study: administrative data elements for study management, including eligibility, discontinuation, randomization, and informed consent
- Venous Thromboembolism: VTE diagnostic descriptors including anatomic site

This taxonomy provided a uniform organization of clinical concepts that spanned working groups, reducing duplication of effort and ensuring consistency across the groups (Table S1 in supporting information). Please note that this is not a list of CDEs (see http://isth.breakthrough.healthcare for the CDE catalog). The ISTH identified the key metadata associated with CDEs that are needed to provide a usable standard, and the Working Groups developed these metadata for each CDE (Table 1), to create fully qualified and defined CDEs (Figure 1).

CDEs were developed to provide definitional consistency while maintaining flexibility to suit different study designs. In some instances, a clinical concept is represented in more than one way to ensure that overly restrictive design isn't a barrier to use. For example, multiple CDEs are provided for DVT location, with differing levels of specificity as needed for individual studies (Figure S1 in supporting information). CDEs can be combined to build complex clinical concepts, and can be repeated within a study to capture observations that occur more than once (Figure S2 in supporting information).

When CDEs describe a quantitative observation, such as a clinical laboratory test result, the CDE is assigned a measurement type such as centimeters, kilograms, or units per liter. We expect that researchers will use the measurement types that are already in use within their respective institutions, but when sharing data using the CDEs it is expected that these measurements will be converted to the common measurement type for each CDE. Similarly, while we

TABLE 1 CDE metadata

Metadata title	Metadata definition
CDE name	The unique, descriptive name assigned to each CDE
Definition	The definition and coding instructions for each CDE
Suggested CRF label	A recommended format for representing the CDE on a CRF
Data type	The format in which the CDE's data should be stored. Includes numeric, free text, select one value, select multiple values, and date and time.
Measurement type	For CDEs with a data type of numeric, the unit of measurement for the CDE
Selections	For CDEs with a data type of select one value or select multiple values, the list of permitted values for the CDE
CDE ID	The unique identifier for each CDE, in the format Subject ID: Topic ID: Subtopic ID: Element ID.
Subject	The broad subject area for each CDE
Topic	The topic area within a given subject for each CDE
Subtopic	The subtopic within a topic area for each CDE
References	The literature supporting the design of a CDE

define specific data types for each CDE (eg, decimal, date and time), study design and information technology needs may dictate the use of other data types for a specific study. As with measurement types, researchers should plan to convert their data into the standard data type for each CDE before publishing results or sharing datasets.

2.3 | Public comment

To build consensus and allow for a greater breadth of expertise to inform the CDEs, the ISTH conducted a public comment period for the CDEs from November 2019 through January 2020. During this time, the ISTH received more than 200 comments related to specific CDEs, including extensive feedback provided by the Division of Blood Disorders at the U.S. Centers for Disease Control and Prevention. The Steering Committee and project team reviewed all comments and made adjustments to the CDEs as appropriate and in scope for the project.

3 | RESULTS

The working groups identified and developed definitions for 485 CDEs. Where possible, existing CDEs were leveraged from NINDS and other data standards organizations to ensure consistency and interoperability. Definition and metadata development were focused on CDEs that are of specific relevance to VTE, such as VTE-specific assessments, laboratory markers, comorbidities, and diagnostic modalities. Metadata standards were defined, including data types (eg, numeric, free text, selection list), selection lists, recommended CRF labels, and measurement types (eg, milligrams per deciliter). Where appropriate, references were provided for individual CDEs to provide explanation for their design and structure.

Following the public comment period, an additional 27 CDEs that addressed identified gaps and were within the project's scope were approved by the relevant working groups and the Steering Committee. This resulted in a total of 512 CDEs. The ISTH has published the first version of the VTE CDEs for research use at http://isth.breakthrough.healthcare. This CDE portal provides researchers with access to all CDEs and their definitions, downloadable spreadsheets of CDEs, instructions for using the CDEs, and the ability to submit comments and questions to ISTH. As the CDEs are adopted for broad research use, the ISTH will develop new versions based on research need and interest from the thrombosis and hemostasis community. To further facilitate adoption of these CDEs, the ISTH will submit them to the NIH National Library of Medicine's Common Data Element Resource Portal. If accepted, these CDEs will join 11 similar CDE initiatives as NIH-supported resources for clinical research data standards.[4] Finally, the ISTH seeks to integrate these CDEs into its REDCap research registry platform,[5] providing access to these standards during the construction of clinical research registries.

The ISTH encourages research teams to cite their use of the ISTH VTE CDEs for both dissemination and tracking purposes. We recommend that researchers cite their usage as follows:

- In publications: Indicate in the Methods or Acknowledgments section that the study "used the International Society on Thrombosis and Haemostasis Common Data Elements for Venous Thromboembolism (http://isth.breakthrough.healthcare)" and if appropriate refer to a citation for this publication in the References section. If possible, also list "ISTH VTE Common Data Elements" as a keyword when submitting the manuscript.
- In presentations: Mention that the ISTH VTE Common Data Elements were used in the study and include the website URL (http://isth.breakthrough.healthcare).

CDE Details:

Nonsurgical Bleeding Event Severity

Definition
The severity level of a nonsurgical bleeding event.
Suggested CRF Label
Bleeding Event Severity
Datatype
Select One Value
References

Definition of clinically relevant non-major bleeding in studies of anticoagulants in atrial fibrillation and venous thromboembolic disease in non-surgical patients: communication from the SSC of the ISTH
Definition of major bleeding in clinical investigations of antihemostatic medicinal products in non-surgical patients

CDE ID
15:38:6:31
Subject
Nonsurgical Bleeding
Topic
General
Subtopic
Characteristics

Permissible Values

Value	Definition
Clinically-relevant non-major	Clinically relevant non-major bleeding is defined as any sign or symptom of hemorrhage that does not meet criteria for major bleeding but does meet at least one of the following criteria: (a) Requiring medical intervention by a healthcare professional (b) Leading to hospitalization or an increased level of care (c) Prompting a face to face (i.e., not just a telephone or electronic communication) evaluation
Major	Major Bleeding is defined as bleeding that meets one or more of the following criteria: (a) Fatal bleeding (b) Symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intra-articular, pericardia!, or intramuscular with compartment syndrome (c) Bleeding causing a fall in hemoglobin level of 2.0 g/dL (1.24 mmol/L) or more, or leading to transfusion of two or more units of whole blood or red cells

FIGURE 1 Fully defined nonsurgical bleeding event severity Common Data Elements

- In ClinicalTrials.gov: Include "ISTH VTE Common Data Elements" in the Keywords provided by the Sponsor section when submitting information about the study to www.clinicaltrials.gov.

4 | DISCUSSION

The CDEs developed during this project span the breadth of VTE clinical research topics, but are by no means comprehensive. One of the key challenges during this project was to address a sufficient number of clinical topics in VTE to make the CDEs useful, while limiting the project's scope to ensure that it could be completed within a 1-year timeframe. During the development of the CDEs, working groups identified many areas for CDE development that were not deemed in scope for the first version of this project, such as pregnancy and women's health, heparin-induced thrombocytopenia, detailed malignancy concepts, or unusual site thromboses. The ISTH intends to make the VTE CDEs a living project, and will evaluate additions to the CDEs in specific topic areas based on community feedback and clinical research needs.

The ISTH will solicit input from the community regarding new clinical research topics for CDE development, to expand the utility and benefits of data standards across clinical conditions and research areas. Many of the topics within the CDEs would benefit from input from non-thrombosis and hemostasis researchers, including malignancy, pharmacotherapy, and women's health. The first version of the CDEs was developed by researchers specializing in adult clinical thrombosis, but in future iterations the ISTH will reach out to the broader research community to identify overlapping standards and engage in co-development across medical specialty areas. As an example, pediatric hematologists could suggest the addition of variables related to pediatric and neonatal thrombosis and hemostasis.

Ongoing curation of the CDEs will include review of researcher comments and analysis of CDE use in research studies. The ISTH will make adjustments to the CDEs as issues and gaps are identified. This could include new standardized definitions (eg, the recently

published Scientific and Standardization Committee (SSC) definition of Death from PE in clinical trials[6]), or scoring systems once validated and adopted by researchers in clinical studies. We will develop a version control framework to ensure definitions are traceable across changes to the CDE library. Curation challenges also include cross-referencing the CDEs with other data standards, including CDASH and CDISC terminology, to introduce further consistency without sacrificing the specific needs and considerations of thrombosis and hemostasis research. Finally, future efforts may include mapping CDEs to electronic health record (EHR) vocabularies such as SNOMED CT and LOINC, providing researchers with a structured guide to EHR data extraction for research studies. At present, inconsistency across EHRs and research institutions present significant limitations to this integration, but we anticipate that opportunities for EHR-driven research studies will continue to mature in the future.

5 | CONCLUSION

Through a structured development approach incorporating the expertise of international researchers, ISTH has developed a comprehensive catalog of VTE data elements that are available for immediate use. The VTE CDEs provide consistent, accessible data standards for use in the design of clinical research protocols. Through the use of CDEs, researchers can expedite study design, improve the reliability of their data, and create opportunities for meaningful meta-analyses and data sharing across institutions. ISTH will continue to work with the research community to improve upon these CDEs and develop CDEs in support of new clinical research topics based on community need. As the CDEs continue to evolve, they will grow in complexity to include new clinical topics, links to other structured vocabularies, and harmonization across other clinical research data standards that further the needs of the thrombosis and hemostasis research community.

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VTE CDE Project Steering Committee: Dr Grégoire Le Gal (Chair), The Ottawa Hospital, Canada; Dr Marc Carrier, The Ottawa Hospital, Canada; Dr Lana Castellucci, The Ottawa Hospital, Canada; Dr Adam Cuker, University of Pennsylvania, United States; Prof. John-Bjarne Hansen, The Arctic University of Norway, Norway; Dr Erik Klok, LUMC, the Netherlands; Dr Jerrold Levy, Duke University Medical Center, United States; Dr Saskia Middeldorp, Amsterdam UMC, Amsterdam, the Netherlands; Prof. Marc Righini, Geneva University Hospital, Switzerland.

Anticoagulation and Other Treatments Working Group: Dr Adam Cuker (Lead), University of Pennsylvania, United States; Dr Lisa Bauman Kreuziger, Blood Center of Wisconsin, United States; Prof. Sam Schulman, McMaster University, Canada; Dr Leslie Skeith, University of Calgary, Canada; Dr Neil Zakai, University of Vermont, United States; Dr Nicoletta Riva, University of Malta, Malta; Prof. Jonathan Douxfils, University of Namur, Belgium;

Chronic VTE and Functional Outcomes Working Group: Dr Erik Klok (Lead), LUMC, the Netherlands; Dr Susan Kahn, Jewish General Hospital, Canada; Dr Arina Ten Cate-Hoek, Maastricht University Medical Centre, the Netherlands; Prof. Stavros Konstantinides, University Medical Center Mainz, Germany; Dr Waleed Ghanima, Ystfold hospital, Norway; Dr Irene Lang, MedUniWien, Austria; Dr Jean-Philippe Galanaud, Sunnybrook Health Sciences Centre, Canada.

Diagnosis of VTE Working Group: Prof. Marc Righini (Lead), Geneva University Hospital, Switzerland; Dr Thomas Moumneh, Centre Hospitalier Universitaire d'Angers | CHU Angers, France; Dr Erik Klok, LUMC, the Netherlands; Dr Esteban Gandara, Hospital Privado de Comunidad, Mar del Plata, Argentina; Prof. Paolo Prandoni, Arianna Foundation on Anticoagulation, Italy; Dr Char Witmer, The Children's Hospital of Philadelphia (CHOP), United States.

General Core Data Elements Working Group: Dr Lana Castellucci (Lead), The Ottawa Hospital, Canada; Dr Alejandro Lazo-Langner, University of Western Ontario, Canada; Dr Helia Robert-Ebadi, Geneva University Hospitals and Faculty of Medicine, Switzerland; Dr Fionnuala Ní Áinle, Rotunda Hospital, Ireland; Dr Cynthia Wu, University Of Alberta Hospital, Canada.

Malignancy Working Group: Dr Marc Carrier (Lead), The Ottawa Hospital, Canada; Dr Tzu-Fei Wang, The Ohio State University, United States; Dr Jeffrey Zwicker, Beth Israel Deaconess Med Ctr / Harvard Med School, United States; Dr Mandy Lauw, Amsterdam UMC/Erasmus MC, the Netherlands; Dr Cihan Ay, Medical University of Vienna, Austria; Dr Gabriela Cesarman Maus, National Cancer Institute, Mexico; Prof. Pantep Angchaisuksiri, Ramathibodi Hospital, Mahidol University, Thailand.

Perioperative Working Group: Dr Jerrold Levy (Lead), Duke University Medical Center, United States; Dr Marie Steiner, University of Minnesota, United States; Dr Raquel Bartz, Duke University Medical Center, United States; Dr Jean Connors, Brigham and Women's Hosp/Harvard Medical School, United States; Prof. Marc Samama, Cochin University Hospital, France; Dr Alex Spyropoulos, Northwell Health at Lenox Hill Hospital, United States; Dr David Faraoni, Hospital for Sick Children, University of Toronto, Canada; Prof. Toshiaki Iba, Juntendo University, Japan.

Predictors of VTE Working Group: Prof. John-Bjarne Hansen (Lead), The Arctic University of Norway, Norway; Dr Clive Kearon, Juravinski Hospital Clinic, Canada; Prof. Suzanne Canniegeter, Leiden University Medical Center, the Netherlands; Prof. Pierre Morange, CHU Timone, France; Dr Sigrid Brækkan, University of Tromsø, Norway; Dr Vania Morelli, UiT The Arctic University of

Norway, Norway; Dr Fernanda Orsi, Universidade Estadual de Campinas, Brazil.

Steering Committee Members are part of the International Network of VENous Thromboembolism Clinical Research Networks (INVENT-VTE, https://www.invent-vte.com) that exists to promote international collaboration between academic research networks.

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CONFLICTS OF INTEREST

G. Le Gal's institution has received research funding from Pfizer, Bristol-Myers Squibb, Bayer, and consultancy fees on his behalf from Bayer, Bristol-Myers Squibb, Pfizer, LEO Pharma, and Sanofi outside the submitted work. A. Cuker serves as a consultant for Synergy. His institution has received research support on his behalf from Alexion, Bayer, Novartis, Novo Nordisk, Pfizer, Sanofi, and Spark. M. Carrier's institution has received research funding on his behalf from BMS, Pfizer, and Leo Pharma. His institution has also received consultancy fees on his behalf from Leo Pharma, Bayer, BMS, Sanofi, Servier, and Pfizer. L. A. Castellucci's institution has received consultancy fees on her behalf from Bayer, BMS, LEO Pharma, Pfizer, Sanofi, and Servier. F. A. Klok reports research grants from Bayer, Bristol-Myers Squibb, Boehringer-Ingelheim, Daiichi-Sankyo, MSD and Actelion, the Dutch Heart foundation, the Netherlands Organisation for Health Research and Development and the Dutch Thrombosis association, all outside the submitted work. J. H. Levy serves on advisory committees for Haima, Instrumentation Laboratories, Janssen, Octapharma, Leading Biosciences, and Merck. S. Middeldorp's institution received grants and fees on her behalf from GSK, BMS/Pfizer, Aspen, Daiichi Sankyo, Bayer, Boehringer Ingelheim, Sanofi, and Portola. S. Walters is president of Breakthrough Healthcare, and serves as a paid consultant to the ISTH and the American Society of Hematology.

AUTHOR CONTRIBUTIONS

G. Le Gal and S. Walters wrote the first draft and supervised the manuscript. M. Carrier, L. A. Castellucci, A. Cuker, J. B. Hansen, F. A. Klok, J. H. Levy, and M. Righini served as members of the VTE CDE Steering Committee, and led the seven VTE CDE working groups. S. Middeldorp served as a member of the VTE CDE Steering Committee. NJ Langlois provided research data expertise and reviewed the CDEs. S. Walters served as the consultant facilitating this project. All authors supplied additional information, edited the manuscript, and contributed to critical review and revision of the manuscript.

ORCID

Grégoire Le Gal https://orcid.org/0000-0002-9253-248X
Marc Carrier https://orcid.org/0000-0001-8296-2972
Frederikus A. Klok https://orcid.org/0000-0001-9961-0754
Nicole J. Langlois https://orcid.org/0000-0002-4953-6549
Jerrold H. Levy https://orcid.org/0000-0003-3766-4962
Saskia Middeldorp https://orcid.org/0000-0002-1006-6420
Marc Righini https://orcid.org/0000-0003-1211-2969

TWITTER

Grégoire Le Gal @grelegal

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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