



Initial strides for invent-VTE: Towards global collaboration to accelerate clinical research in venous thromboembolism

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ABSTRACT

Venous thromboembolism (VTE) represents a major global burden of disease and requires collaborative efforts to conduct large, high-quality investigator-initiated and academically sponsored studies addressing the most relevant clinical questions. Owing to increasing regulatory requirements, the highly competitive nature of peer-reviewed funding and costs associated with conducting large, multinational clinical trials, completing practice-changing research constitutes a growing challenge for clinical investigators. As clinical trialists interested in VTE, we founded INVENT (International Network of Venous Thromboembolism Clinical Research Networks) in an effort to promote and accelerate patient-oriented, investigator-initiated, international collaborative research, to identify, prioritize and answer key clinical research questions for patients with VTE. We report on our activities to formalize the INVENT network and our accomplishments in our first year.

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1. Introduction

Venous thromboembolism (VTE) is a common disease accounting for major global morbidity and mortality. Clinical trials have resulted in important advances in the prevention, diagnosis and treatment of VTE; however, large international clinical trials in this area are predominantly sponsored by the pharmaceutical industry. Academic clinical trialists are finding it increasingly difficult to complete practice-changing research. Obtaining peer-reviewed funding is highly competitive and large clinical trials require substantial budgets; consequently, very few projects are funded. The regulatory burden is high, discouraging clinician-investigators from conducting academic trials and increasing the costs of these trials. In response to these challenges and to ensure that questions of interest to clinicians and patients are addressed, we, as clinical trialists in the area of VTE, sought to establish an international network of national VTE clinical research networks to enhance worldwide collaborations and facilitate the conduct of large international trials.

2. Methods

We obtained peer reviewed funding (CIHR grant #ISP 112124) to conduct a strategic planning exercise with the leaders of currently established and emerging national venous thrombosis clinical research networks. The meeting participants, representing Canada, Australia, France, Germany, Italy, the Netherlands, Norway, the United States, and the International Society on Thrombosis and Haemostasis) completed a survey using SurveyMonkey® (SurveyMonkey.com, San Mateo, California). The survey was intended to stimulate thinking prior to a face-to-face meeting and generate initial ideas about aspirations, tools, processes and potential barriers to international research collaboration that could motivate dialogue at the meeting.

In December 2015, a 2-day meeting was held in Orlando, Florida, United States, where representatives from each national network reported on the structure, management, resources, activities and interests of their networks. We developed a process for defining our strategic priorities by identifying the top five aspirations for our proposed international network of networks. We discussed barriers to successful research collaboration and potential tools to eliminate these barriers. By consensus, the participants agreed to name the collaborative research group **INVENT** (International Network of **VEN**ous Thromboembolism Clinical Research Networks).

We used small group breakout sessions for an in-depth discussion of aspirations. Each group generated a list of five major aspirations for INVENT. All working groups presented their top five aspirations, and we generated a combined list. We then proceeded to a voting exercise whereby each participant identified their top three aspirations. The top aspiration was given three points, the second aspiration two points and the third aspiration one point. The results were tallied and the five top aspirations were identified. These aspirations were further refined in a general sessions with input from all participants to arrive at the final list.

Next, the participants broke into working groups to discuss the tools and processes required to achieve these aspirations. These were presented to the larger group and a list of the most relevant tools and processes for each of the network's aspirations was generated.

3. Results

The pre-meeting survey was completed by twelve individuals (92.3% response rate). During breakout sessions, the group generated a common list of eight aspirations ([Appendix A](#)) and the voting and refinement exercises resulted in the final list of top-5 aspirations for INVENT ([Box 1](#)).

Participants were aware of the challenges of international clinical research collaboration; differences in language, geography, time zones,

Box 1

Top-5 INVENT aspirations.

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- Be the recognized international driver and accelerator for patient-oriented, investigator-initiated clinical VTE research
 - Be endorsed and supported by the leading scientific societies and top granting agencies worldwide
 - Be the key facilitator for international collaboration among VTE clinical investigators, including networking for young investigators
 - Be the international leader in promoting the development of national VTE networks
 - Identify key unanswered clinical VTE research questions and design/conduct the studies to answer them
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clinical practice and culture would require consideration for global teamwork. They recognized that to succeed, the network would need to build relationships, allow academic autonomy and ensure fair recognition for contributions. More tangible barriers to international clinical research were the costs and difficulty in navigating the differing regulations across countries, and the difficulty in securing funding for large, expensive international trials. The key tools identified to facilitate the network being able to reach its aspirations included communication, funding, operations and culture.

3.1. Communication

For communications, it was felt important that, in addition to regular INVENT council meetings via teleconference and face-to-face at international conferences, larger gatherings inclusive of members of each of the represented networks be arranged to provide brainstorming opportunities and to allow formal and informal collaborations to be established for research studies and initiatives. Communication with potential members through the development of an INVENT website (www.INVENT-VTE.com) was felt to be important to keep potentially interested network members up to date with network activities, potential collaborative projects, ongoing projects and biographies of potential collaborators.

3.2. Funding

Funding is critical for sustaining the network's activities and, most importantly, developing mechanisms to permit timely completion of large investigator-initiated trials. One possible model, that we termed "Wiki funding", involves multiple investigators securing funding from organizations in their home countries or regions (e.g. European Union) to complete large trials rather than submitting a single application requesting funding for a globally-conducted study. We would also facilitate and coordinate joint requests to global pharmaceutical companies for funding of trials that might be of mutual interest to the academic community and shareholders of pharmaceutical companies.

3.3. Operations

Given the absence of core funding for INVENT during the initial stages, we agreed to seek/develop social media tools to allow investigators to identify, connect and collaborate with potential collaborators. To facilitate the conduct of research, we planned to develop shared tools for adjudication and ultimately case report forms, randomization tools and web based clinical trial management tools.

3.4. Culture

We identified a clear preference that INVENT be viewed as an open source group with a welcoming atmosphere all investigators but especially for early career investigators. We aimed to develop terms of reference for authorship and leadership on network studies that are reflective of our culture and the work and activity that goes into completion of these tasks, with congenial dispute resolution

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