



International Network of  
**VENous Thromboembolism**  
Clinical Research Networks

## 2021 Dragons' Den Competition

**Deadline to Submit: Extended to June 7, 2021**

### Rationale

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Clinical studies, and especially randomized controlled trials (RCT), frequently require international collaboration and participation from multiple clinical centers to meet sample size requirements in a timely manner. Conducting clinical research in multiple countries offers the advantages of faster participant recruitment and study completion, and greater generalizability of results.

**INVENT aspires to be the international driver and accelerator for patient-oriented, investigator-initiated clinical venous thromboembolism (VTE) research and aims to be the key facilitator for international collaboration among VTE clinical investigators.**

### Competition

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INVENT will be hosting a virtual, public competition for INVENT Study Endorsement & Funding, to be held on July 8, 2021 – 16:00-17:00 UTC / GMT). One endorsed study will be offered a \$40,000 (CAD) International Collaboration grant. A \$20,000 (CAD) grant will be awarded to the second highest rated application.

#### **2021 Program Details**

**Date:** Thursday, July 8, 2021

**Time:** 12:00-13:00 (EST) | 16:00-17:00 (UTC / GMT)

**Location:** Virtual

Applicants will be invited (see '**Eligibility**' and '**Application Process**' below) to present a proposal of their research study to potentially be endorsed by the INVENT Network and/or be awarded an International Collaboration grant. Each applicant will have 5 minutes to present their proposal. After each presentation, the presenter will be probed by **three INVENT Dragons** with pointed questions geared towards determining if the proposed study is well designed, feasible, and will be practice-changing.

Simultaneously, the audience, using an interactive polling system, will rate each proposed study on its potential to change practice. After the final presentation, the audience will be asked to vote for the project that is most likely to change practice.

### Eligibility

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- **Applicants:** The proposed study must be supported/developed by members of two or more national VTE research network members of INVENT. Applicants must be committed to international collaboration, ethical research practices, and fair recognition of co-investigators' research contributions.



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- **Study stage:** Research at any stage of development is eligible for endorsement by the INVENT Network. Investigators may apply for approval of a preliminary protocol, a study with a fully developed protocol, or one that is actively recruiting participants.
- **Research design:** Academically-driven clinical research studies that are seeking to recruit participants in multiple countries must be one of the following designs:
  1. Randomized controlled trial (RCT) or a pilot trial to inform an RCT;
  2. Quasi-experimental (non-randomized) study evaluating a treatment, intervention, management strategy or diagnostic strategy. Participants in one or more groups are managed uniformly as prescribed by the protocol, with a specific hypothesis, e.g. “risk of recurrent VTE will be less than 2% over 90 days if using this strategy”.
- **Competing studies:** Ideally, the proposed study is unique and does not replicate or compete with an ongoing study. Applicants are expected to make efforts to identify other studies that are in progress that are seeking to answer the same or a similar research question. Justification for undertaking a similar study must be provided.

## Application Process

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The applicant sends an application package consisting of the following documents:

1. A completed INVENT [Study Endorsement Application form](#)
2. A completed [one-page structured study summary](#) (as per suggested template)
3. Full study protocol (in whatever form is available at time of application)<sup>1</sup>
4. A letter or e-mail from the Applicant’s National Network indicating national support for the study.

**Deadline for Applications: Originally May 14, 2021 – Extended to June 7, 2021.**

Please send complete applications to [info@invent-vte.com](mailto:info@invent-vte.com).

## Study Endorsement

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All studies presented at the Dragons’ Den competition will be subjected to the INVENT study approval process intended to identify studies that align with the Network’s aspirations and which the Network will endorse. The formal review process (see ‘**Review and Approval Process for Study Endorsement**’ below) provides a mechanism for INVENT Council Members to jointly determine which applicants will be invited to participate in the Dragons’ Den competition, and which studies the network will eventually promote and support, as well as select for an international collaboration grant.

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<sup>1</sup>If only a preliminary proposal is being submitted for consideration, it is not necessary to submit a full protocol.



## Review and Approval Process for Study Endorsement

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1. The INVENT Staff and Chair conduct an initial review for completeness, clarity, and eligibility.
  - The proposal may be sent back to proponents for refinement/comments/questions prior to review and endorsement.
2. Upon approval by the Chair, the INVENT Staff circulates the application via email to two main reviewers.
  - Both reviewers will complete the INVENT study endorsement evaluation form.
  - The first reviewer should provide a thorough critique of the study and may review the full protocol if they judge it to be necessary to have complete understanding of the study.
  - The secondary reviewer may provide additional comments and critique to the first reviewer's evaluation.
3. Once the main reviewers have completed their evaluations, based on mean review scores (cut-off is 7 out of 10), the application will either be rejected or be circulated to the full Council with the study summaries for review and commentary (if any).
4. Eligible applicants may be invited to present at the Dragons' Den competition. INVENT reserves the right to limit the number of applicants that will be invited to participate in the Dragons' Den event and hence be eligible for the International Collaboration grant. However, all complete and eligible proposals will be considered for INVENT endorsement.
5. At an INVENT Council Meeting to follow the Dragons' Den competition, a full Council vote will be conducted to establish support for the study and approval for endorsement. The vote may occur at an INVENT Council Meeting (teleconference or in-person) or votes may be cast electronically (e.g. by email response or digital poll). The top ranked study will be offered a single \$40,000 International Collaboration prize. The second highest rated study will be offered a \$20,000 prize.
6. INVENT Council will be given a minimum of 7 days to review before casting a vote.
7. All Council members may vote, in-person, by electronic means, or by proxy, to approve a study, regardless of their involvement or interest in the study. For the voting process, quorum is 30% (in-person or by proxy) and a majority vote in one where more than half of the members of Council present and voting vote in the affirmative.

## Post-Approval Procedures

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1. Applicants requesting approval of a research idea or preliminary proposal are expected to provide additional study details once the proposal is developed. Studies that have already received approval will not require formal review again.
2. If a pilot study is endorsed by INVENT, the subsequent full study/trial of a similar design will not require formal review by Council. A structured summary describing the full study (as per template) is to be submitted by the principal investigator to [info@invent-vte.com](mailto:info@invent-vte.com). The Chair or Vice-Chair will confirm INVENT's endorsement of the full trial.
3. INVENT support is to be acknowledged in publications and presentations as follows: *The International Network of Venous Thromboembolism Clinical Research Networks (INVENT) endorsed and supported this study.*



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### **INVENT Support of Endorsed Studies**

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1. A letter of endorsement will be provided (upon request, the letter may be tailored to include in a funding application, etc.).
2. A study summary will be posted on the INVENT website (lay summary encouraged).
3. The study will be promoted to members via e-mail and social media platforms.
4. Endorsed studies will have access to INVENT resources, e.g. use of adjudication platform at “academic rate.”
5. INVENT Council Members will actively promote endorsed studies within their national networks.



## 2021 Dragons' Den Competition

### Study Endorsement Application

Application Details		
Study Title		
Study Team	Name of Principal Applicant:	Name of Study Collaborator(s):
	Primary institution, position/rank, department and/or faculty of <b>principal applicant</b> :	Primary institution, position/rank, department and/or faculty of <b>collaborator(s)</b> :
Principal Applicant Information	Mailing address:	National Research Network of Principal Applicant:
	Phone:	E-mail Address:
Study Information	Recruitment start date (actual or estimated) (dd/mm/yyyy):	Total sample size (if known):
	Countries/Networks committed to participate:	Countries/Networks potentially interested in participating:
	Name of sponsoring institution:	Trial Registry Number (if applicable):



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## Applicant Statement

*Provide rationale for seeking INVENT endorsement and describe efforts to identify competing studies that are ongoing (e.g. registry search)*

*Provide a description for the intended use of \$40,000 international collaboration grant.  
(300 words max.)*



<b>Study Progress</b>	
<b>Study Funding</b>	<input type="checkbox"/> No funding secured <input type="checkbox"/> Partial funding secured <input type="checkbox"/> Full funding secured
<b>Ethics Approval</b>	<input type="checkbox"/> No application for ethics approval submitted <input type="checkbox"/> Application(s) submitted and awaiting approval <input type="checkbox"/> Approval granted in one centre <input type="checkbox"/> Approval granted in multiple centres
<b>Regulatory Approval</b>	<input type="checkbox"/> Not required <input type="checkbox"/> Not known if regulatory approval will be required <input type="checkbox"/> Application will be required but has not yet been submitted <input type="checkbox"/> Application(s) submitted and awaiting regulatory approval <input type="checkbox"/> Approval granted from one regulatory body <input type="checkbox"/> Approval granted by multiple regulatory bodies
<b>Scientific Review</b>	<input type="checkbox"/> No formal peer review of the protocol <input type="checkbox"/> Formal peer review of the protocol is currently in progress <input type="checkbox"/> Formal peer review of the protocol has been completed
Please include any other relevant details about study progress, if applicable (e.g. number of sites actively recruiting) ( <i>limit: 100 words</i> )	



## 2021 Dragons' Den Competition

### Study Summary

<b>Study Title</b>		
<b>Study Rationale</b> (250 words or 1500 characters including spaces limit)		
<b>Research Question</b>		
<b>Population</b>		
<b>Eligibility Criteria</b>		
<b>Interventions</b> (all study arms including the control group)		
<b>Study Design</b>		
<b>Length of Follow-Up</b>		
<b>Outcomes</b>	<b>Primary</b>	<b>Secondary</b>
<b>Power Calculation</b>		
<b>Statistical Analyses</b>		





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## Application Submission Checklist

Please use the following checklist to ensure you are submitting all the required materials with your application.

- Study Endorsement Application
- One-page structured Study Summary
- Full Study Protocol
- Written documentation demonstrating support of the study from your National Network

Send your completed application to [info@invent-vte.com](mailto:info@invent-vte.com) with subject line:  
"Dragons' Den Competition Application: Name of Study"