

## SUPPLEMENTARY DOCUMENTS

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**Population Health Research Institute Coordinating Centre:** V. Harvey (Trial Coordinator), J.

Vincent, S. Dragic-Taylor, S. Molnar, S. Pettit, J.R. Wells

**Trial Monitoring Committee:** R. Roberts, Chairperson (McMaster University), F. McAlister

(University of Alberta), D. Sackett (McMaster University), J. Wright (University of Oxford)

**Participating Countries, Centres, and Investigators (recruitment in brackets): BELGIUM (47) –**

*Cliniques Universitaires Saint-Luc (32):* L. Veevaete, B. le Polain de Waroux, A. Dekleermaker; *UZ*

*Brussel (15):* P. Forget, M. Reul; **CANADA (983) –** *Juravinski Hospital and Cancer Centre (293):* D.

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*Healthcare (134):* A. Adili, V. Khanna, D. Conen, J. Farrell; *Sunnybrook Health Sciences Centre (81):*

H.J. Kreder, S. Choi, S. Shadowitz, J.S. Lee; *Thunder Bay Regional Health Sciences Centre (37):* D.

Puskas, C. Cullinan, K. Droll; *St. Michael's Hospital (44):* A. Nauth, T. Daniels, M.R. Vicente; *William*

*Osler Health System, Etobicoke General Hospital (13):* A. Sharma; *Vancouver General Hospital (5):*

P. Guy; *Kingston Health Sciences Centre (75):* M. Sivilotti, M. Jaeger; S. Mann, F. Howells; *Markham*

*Stouffville Hospital (58):* L.M. McLean, H. Shirali; *London Health Sciences Centre, Victoria Hospital*

*(92):* G.K. Dresser, D.W. Sanders, E.H. Schemitsch, W. Kishta; *The Ottawa Hospital, General*

*Campus (60):* C. Gallant, S. Halman, K.M. McIlquham, V. Thiruganasambandamoorthy; *QE II Health*

*Sciences Centre (25):* C.P. Coles, K. Trask; *Humber River Hospital (2):* A.W. Duncan; *University of*

*Alberta (30):* M.J. Jacka, M. Menon; *Concordia Hospital (12):* T.R. Turgeon; *University of Calgary*

*(13):* N.J. White; *Grand River Hospital (8):* S. Giilck; *Royal Victoria Hospital (1):* G. Crawford;

**CHINA (28) –** *Beijing Chaoyang Hospital (28):* J. Zhou; **COLOMBIA (1) –** *Fundación Cardioinfantil (1):*

J.M. Muñoz McCausland; **FRANCE (46) –** *Centre Hospitalier Lyon Sud (43):* P. Chaudier, M. Douplat;

*Nîmes University Hospital (3):* P. Landais; **HONG KONG (12) –** *The University of Hong Kong, Queen*

*Mary Hospital (12):* C.X. Fang; **INDIA (471) –** *PGIMER (23):* M.S. Dhillon; *Rabindranath Tagore*

*International Institute of Cardiac Sciences, Kolkata (9):* S.U. Singh; *JIPMER (45):* S. Adinarayanan,

D. Sharma; *Government TD Medical College Alappuzha (50)*: M. Stephen, M. Ashraf; *Sancheti Institute for Orthopaedics & Rehabilitation (102)*: C.V. Pradhan, M.P. Borate, A. Shyam; *Bangalore Baptist Hospital (44)*: Niranjan M.; S.A. Hiremath, Z.K. Varghese; *SPARSH Hospital (16)*: S. Patil; *All India Institute of Medical Sciences (40)*: V. Sharma, K. Farooque, R. Malhotra; *Christian Medical College & Hospital Ludhiana (100)*: R.A. Pandey, A.R. Kumar, P. George; *Government Medical College, Trivandrum (35)*: P.M. Menon; *Seven Star Hospital (7)*: R.P. Dashputra; **ITALY (93)** – *IRCCS San Raffaele Scientific Institute (25)*: G. Gioia, E. Colnaghi; *ASST Settelaghi, Varese (14)*: M. Binda; *IRCCS Galeazzi Orthopedic Institute (46)*: M. Turiel; *Humanitas Research Hospital (8)*: M. Cecconi; **MALAYSIA (67)** – *University Malaya Medical Centre (49)*: C.S. Kumar, P.S. Loh, K.H. Chee; *Hospital Pulau Pinang (18)*: M.L. Lee; **NETHERLANDS (35)** – *Deventer Hospital (35)*: Y.V. Kleinlugtenbelt, E.B.M. Landman; **PAKISTAN (244)** – *Shifa International Hospital (78)*: K.A. Janjua, A.S. Khan, S.H. Orakzai, M. Ashraf; *Aga Khan University (166)* P.M. Hashmi, R.H. Lakdawala, M.J. Khattak, H. Rashid, D. Begum; **POLAND (86)** – *SPZOZ Myślenice (81)*: J.W. Rycombel, W. Satora, W. Ambroży, A. Grzelak; *Medical University in Lodz (1)*: W. Machala; *SPZOZ Szpital Powiatowy w Bochni im M. Wieckiej (4)*: J. Gućwa; **SOUTH AFRICA (131)** – *University of Witwatersrand (114)*: G. Firth, A. Grisillo-Biscardi, G. Karera, M. Fourtounas; *Groote Schuur Hospital (12)*: M. Nejthardt; *Tygerberg Hospital, Stellenbosch University (5)*: S. Chetty; **SPAIN (534)** – *Vall d'Hebron University Hospital (300)*: Jordi Teixidor-Serra, V. Molero-García, J. Minguell-Monyart, Y. García-Sánchez, J.A. Porcel-Vázquez, J. Selga-Marsà, M. Villar-Casares, J. Mestre-Torres; *Hospital Universitario Costa del Sol (17)*: E. Guerado, E. Cruz; *Hospital de la Santa Creu I Sant Pau (26)*: E. Popova, J.D. Caso, J.L. Higa-Sansone, R. Anaya; *Hospital Universitari Mútua Terrassa (41)*: P. Castellón, M. Bernaus, S. Quintas; *Parc Taulí Hospital Universitari (87)*: P. Torner, F.A. Marcano-Fernández, M. Jornet-Gibert, J. Cámara-Cabrera; *Consorti Sanitari del Garraf (37)*: A. D. Andrés, O.M. Pérez, L.A. Ivanov; *Hospital Clínico Universitario de Valladolid (26)*: H.J. Aguado; **THAILAND (36)** – *Ramathibodi Hospital (36)*:

P. Sa-ngasoongsong; **UNITED KINGDOM (82)** – *Chelsea and Westminster Hospital (17)*: M.P. Vizcaychipi; *Peterborough City Hospital (6)*: M.J. Parker; *West Middlesex University Hospital (32)*: M.A. Kadry, S. Thayaparan; *Sherwood Forest Hospitals (11)*: J. John; *Calderdale & Huddersfield NHS Foundation Trust (16)*: A.S.E. Mayor; **UNITED STATES (76)** – *Tufts Medical Center (15)*: S.P. Ryan; *The Ohio State University (13)*: S.D. Bergese; *Lahey Hospital & Medical Center (3)*: A.J. Marcantonio; *University of Maryland (18)*: G.P. Slobogean; *University of California San Francisco (27)*: M.T. Marmor; **VENEZUELA (29)** – *Hospital Universitario de Caracas (29)*: I.A. Escalante Elguezabal, C.G. Sanchez Valenciano

**Ethics Committees:** **BELGIUM** - *Comité d'Éthique Hospitalo-Facultaire; Commissie Medische Ethiek; CANADA* - *Hamilton Integrated Research Ethics Board; Sunnybrook Health Sciences Centre Research Ethics Board; Thunder Bay Regional Health Sciences Centre Research Ethics Board; St. Micheal's Hospital Research Ethics Board; William Osler Heath System Research Ethics Board; University of British Columbia Clinical Research Ethics Board; Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board; Markham Stouffville Hospital Research Ethics Board; Western University Health Science Research Ethics Board; Ottawa Health Science Network Research Ethics Board; Conjoint Health Research Ethics Board; Nova Scotia Health Authority Research Ethics Board; Humber River Hospital Research Ethics Board; University of Alberta - Health Research Ethics Board - Biomedical Panel; The University of Manitoba Biomedical Research Board; Tri-Hospital Research Ethics Board; Royal Victoria Regional Health Centre Research Ethics Board **CHINA** - *Institutional Review Board of Beijing Chao-Yang Hospital;* **COLOMBIA** - *Comité de Ética en Investigación Clínica;* **FRANCE** - *Comité de protection des personnes Sud Méditerranée III;* **HONG KONG** - *Institutional Review Board of the University of Hong Kong;* **INDIA** - *Institute Ethics Committee (Human Studies) JIPMER, Puducherry; Postgraduate Institute of Medical Education and Research, Chandigarh; NH-Rabindranath Tagore International Institute of Cardiac Sciences Ethics Committee;**

*Institutional Ethics Committee, TDMC, Alappuzha; Sancheti Institutional Review Board; Bangalore Baptist Hospital Institutional Review Board; Institutional Ethics Committee, Sparsh Hospital, Bangalore; Institute Ethics Committee All India Institute of Medical Sciences; Institutional Ethics Committee of Christian Medical College & Hospital, Ludhiana; Human Ethics Committee Government Medical College, Thiruvananthapuram; Rahate Surgical Hospital Institutional Ethics Committee;*

**ITALY** - *Comitato Etico dell'Ospedale San Raffaele – Milano; Comitato Etico dell'Insubria; Comitato Etico dell'Istituto Clinico Humanitas; MALAYSIA* - *Jawatankuasa Etika & Penyelidikan Perubatan;*

**NETHERLANDS** - *Medisch-ethische toetsingscommissie METC Isala Zwolle; PAKISTAN* - *Institutional Review Board & Ethics Committee SIH; Ethics Review Committee of The Aga Khan University; Poland* - *Komisji Bioetycznej UJ; Komisji Bioetycznej przy Uniwersytecie Medycznym w Łodzi; Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej w Krakowie; SOUTH AFRICA* - *The University of Witwatersrand, Human Research Ethics Committee; University of Cape Town Human Research Ethics Committee; Stellenbosch University Health Research Ethics Committee; SPAIN* - *Comité de Ética de Investigación con Medicamentos del Hospital Universitario Vall d'Hebron; Comité de Ética de la Investigación Costa del Sol; Comité Ético de Investigación Clínica del Hospital de la Santa Creu I Sant Pau; Comité Ético de Investigación con Medicamentos de Fundació Assistencial Mútua Terrassa; Comité Ético de Investigación Clínica de la Corporació Sanitària Parc Taulí de Sabadell; Comité Ético de Investigación de la Fundació Unio Catalana Hospitals; Comité Ético de Investigación Clínica del Área de Valladolid; THAILAND* - *Committee on Human Rights Related to Research Involving Human Subjects, Mahidol University; UNITED KINGDOM* - *NHS Health Research Authority, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee; UNITED STATES* - *Tufts Health Sciences Campus Institutional Review Board; Ohio State Biomedical Sciences Institutional Review Board; Lahey Clinic, Inc. Institutional Review Board; University of Maryland, Baltimore Institutional Review*

*Board; Western Institutional Review Board; VENEZUELA - Comité de Bioética del Hospital*

*Universitario de Caracas*