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The GARFIELD-AF Investigators

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Determinants and clinical outcomes of patients who refused anticoagulation: findings from the global GARFIELD-AF registry

Patricia Apenteng ,[1] Saverio Virdone,[2] John Camm,[3] Keith A A Fox,[4] Jean-Pierre Bassand,[5] Alexander G G Turpie,[6] Seil Oh,[7] Marianne Brodmann,[8] Frank Cools,[9] Antonio C P Barretto,[10] Jørn Nielsen,[11] Sylvia Haas,[12] Gloria Kayani,[13] Karen S Pieper,[13] Ajay K Kakkar[13]

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For numbered affiliations see end of article.

Correspondence to
Dr Patricia Apenteng; p.n.k.apenteng@bham.ac.uk

ABSTRACT

Objective There is a substantial incidence of stroke in patients with atrial fibrillation (AF) not receiving anticoagulation. The reasons for not receiving anticoagulation are generally attributed to clinician's choice, however, a proportion of AF patients refuse anticoagulation. The aim of our study was to investigate factors associated with patient refusal of anticoagulation and the clinical outcomes in these patients.

Methods Our study population comprised patients in the Global Anticoagulant Registry in the FIELD (GARFIELD-AF) registry with CHA_2DS_2-VASc≥2. A logistic regression was developed with predictors of patient anticoagulation refusal identified by least absolute shrinkage and selection operator methodology. Patient demographics, medical and cardiovascular history, lifestyle factors, vital signs (body mass index, pulse, systolic and diastolic blood pressure), type of AF and care setting at diagnosis were considered as potential predictors. We also investigated 2-year outcomes of non-haemorrhagic stroke/systemic embolism (SE), major bleeding and all-cause mortality in patients who refused versus patients who received and patients who did not receive anticoagulation for other reasons.

Results Out of 43 154 AF patients, who were at high risk of stroke, 13 283 (30.8%) did not receive anticoagulation at baseline. The reason for not receiving anticoagulation was unavailable for 38.7% (5146/13 283); of the patients with a known reason for not receiving anticoagulation, 12.5% (1014/8137) refused anticoagulation. Diagnosis in primary care/general practitioner, Asian ethnicity and presence of vascular disease were strongly associated with a higher risk of patient refusal of anticoagulation. Patient refusal of anticoagulation was associated with a higher risk of non-haemorrhagic stroke/SE (adjusted HR (aHR) 1.16 (95% CI 0.77 to 1.76)) but lower all-cause mortality (aHR 0.59 (95% CI 0.43 to 0.80)) compared with patients who received anticoagulation. The GARFIELD-AF mortality score corroborated this result.

Conclusion The data suggest patient refusal of anticoagulation is a missed opportunity to prevent AF-related stroke. Further research is required to understand the patient profile and mortality outcome of patients who refuse anticoagulation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A total of 25%–35% of patients with atrial fibrillation (AF) at high risk of stroke do not receive guideline-recommended anticoagulation to reduce the risk of AF-related stroke. This is largely attributed to clinician's choice; however, a proportion of these patients refuse anticoagulation.

⇒ Little is known about factors associated with patient refusal of anticoagulation and clinical outcomes in these patients.

WHAT THIS STUDY ADDS

⇒ The strongest determinant of patient refusal was the clinician speciality at diagnosis. Patients diagnosed with AF at a primary care facility had a higher likelihood of refusing anticoagulants than patients diagnosed at a cardiology clinic.

⇒ Patient refusal of anticoagulation was associated with a higher risk of non-haemorrhagic stroke/systemic embolism, but lower all-cause mortality compared with patients who received anticoagulation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Understanding the reasons patients refuse anticoagulation may inform shared decision-making and improve uptake of anticoagulation.

⇒ The findings regarding all-cause mortality warrants further investigation.

INTRODUCTION

Reducing the risk of an atrial fibrillation (AF)-related stroke is central to the management of AF and guidelines recommend anticoagulation in patients at risk of AF-related stroke.[1 2] There have been significant advances in the past decade in the prevention of AF-related stroke and patients with AF are now more often receiving guideline-recommended therapy.[3] Nevertheless, there remains a treatment gap of up to 25%–35%

of high-risk patients not receiving anticoagulation, with large variations across countries.[3]

There is a substantial incidence of stroke and mortality in patients with AF at risk of AF-related stroke who do not receive anticoagulation.[4 5] At least 20% of all ischaemic strokes occur in patients with AF not receiving anticoagulation.[6 7] In the Global Anticoagulant Registry in the FIELD (GARFIELD-AF) registry, anticoagulation treatment compared with no anticoagulation treatment was associated with decreased all-cause mortality and non-haemorrhagic stroke/systemic embolism (SE) among patients with a CHA_2DS_2VASc score of ≥2.[8] In the UK, 26% of AF-related strokes among patients not receiving anticoagulation in 2017 and 2018 were fatal.[9]

The reasons why patients with AF do not receive guideline-recommended anticoagulation therapy has been largely attributed to a decision made by the patients' physician.[10] The reasons that clinicians may decide not to prescribe anticoagulation include contraindications to anticoagulant policy, perceived low risk of stroke, risk of falls, bleeding risk, concomitant antiplatelet (AP) therapy and previous bleeding event.[10] Patient refusal of anticoagulation is a factor in the AF treatment gap that is less acknowledged in the literature. In practice, there is a cohort of patients who refuse anticoagulation when recommended by the treating clinician.

Factors affecting patient refusal of anticoagulation and the impact of outcomes is not well understood, in part because these data are not usually collected or reported in clinical studies. Observational studies in AF in the past decade have primarily centred around treatment patterns, outcomes and the burden of AF, and where treatments decisions have been investigated the focus has been on clinical/clinician-related factors.

Using data from the GARFIELD-AF registry, this paper investigates the factors associated with patient refusal of anticoagulation and the clinical outcomes of patients who refused anticoagulation versus patients who received anticoagulation and patients who did not receive anticoagulation for other reasons.

METHODS

Study design

The GARFIELD-AF is an international prospective observational study of patients ≥18 years with newly diagnosed AF and ≥1 investigator determined risk factor for stroke.[11] Participants were consecutively enrolled in ≥1000 centres in 35 countries and followed for a minimum of 2 years. Newly diagnosed AF was defined as diagnosis of non-valvular AF up to 6 weeks prior to entry into the registry.

Data sources

Data collected at baseline comprised demographics, body mass index (BMI), type of AF, care setting of diagnosis, treatment strategy initiated at diagnosis, reason for treatment decision (including the reason not to treat) and medical history.

Stroke risk was calculated retrospectively using CHA_2DS_2-VASc score-based variables: heart failure, hypertension, age ≥75 years and 65–74 years, diabetes mellitus, prior stroke, transient ischaemic attack or thromboembolism, left ventricular ejection fraction <40%, vascular disease and female gender. HAS-BLED scores were calculated retrospectively using the variables hypertension, abnormal renal/liver function, stroke, bleeding history, medication usage predisposing to bleeding (aspirin, clopidogrel, nonsteroidal anti-inflammatory drugs) age >65 and heavy alcohol use.

Statistical analysis

Patients not receiving anticoagulation were divided into patients who refused anticoagulation and patients not taking anticoagulants for other reasons. Patient baseline characteristics are described by patients who received anticoagulation, patients who refused anticoagulation and patients who did not receive anticoagulation for other reasons. Continuous variables are expressed as median, first and third quartile (Q1; Q3). Categorical variables are expressed as frequencies and percentages.

Time at risk was censored at study end (ie, 2 years), lost to follow-up or occurrence of the event of interest, whichever came first. Given the low proportion of treatment discontinuation and lost to follow-up, we did not truncate at earlier time points. Crude all-cause mortality rate is reported as 1–Kaplan-Meier rate. For cardiovascular (CV) and non-CV death, we calculated cumulative incidence functions considering death from other causes as a competing event. For non-haemorrhagic stroke/SE and major bleeding outcomes, we calculated cumulative incidence functions considering death from any cause as a competing event. The cause of death distribution is reported as the frequency and proportion among people who died by baseline treatment (online supplemental table S1).

For the identification of predictors for oral anticoagulant (OAC) refusal, a prediction modelling approach has been adopted. More specifically, two logistic regression models were developed using least absolute shrinkage and selection operator methodology. The list of potential predictors includes a wide range a demographics and medical history information and is reported in online supplemental table S2. The first (model 1) included the following information as potential predictors: demographics (sex, age, ethnicity), medical and CV history, lifestyle factors (smoking and alcohol consumption), vital signs (BMI, pulse, systolic (SBP) and diastolic blood pressure (DBP)), type of AF and care setting specialty/location at diagnosis. The second (model 2) added the country of enrolment as a potential covariate (online supplemental table S3). All continuous covariates were tested for linearity and appropriate transformations were applied as needed. The performance of the developed models was evaluated though the use of c-index with 95% CI for a measure of discrimination. Calibration curves were used to show how well the predicted values

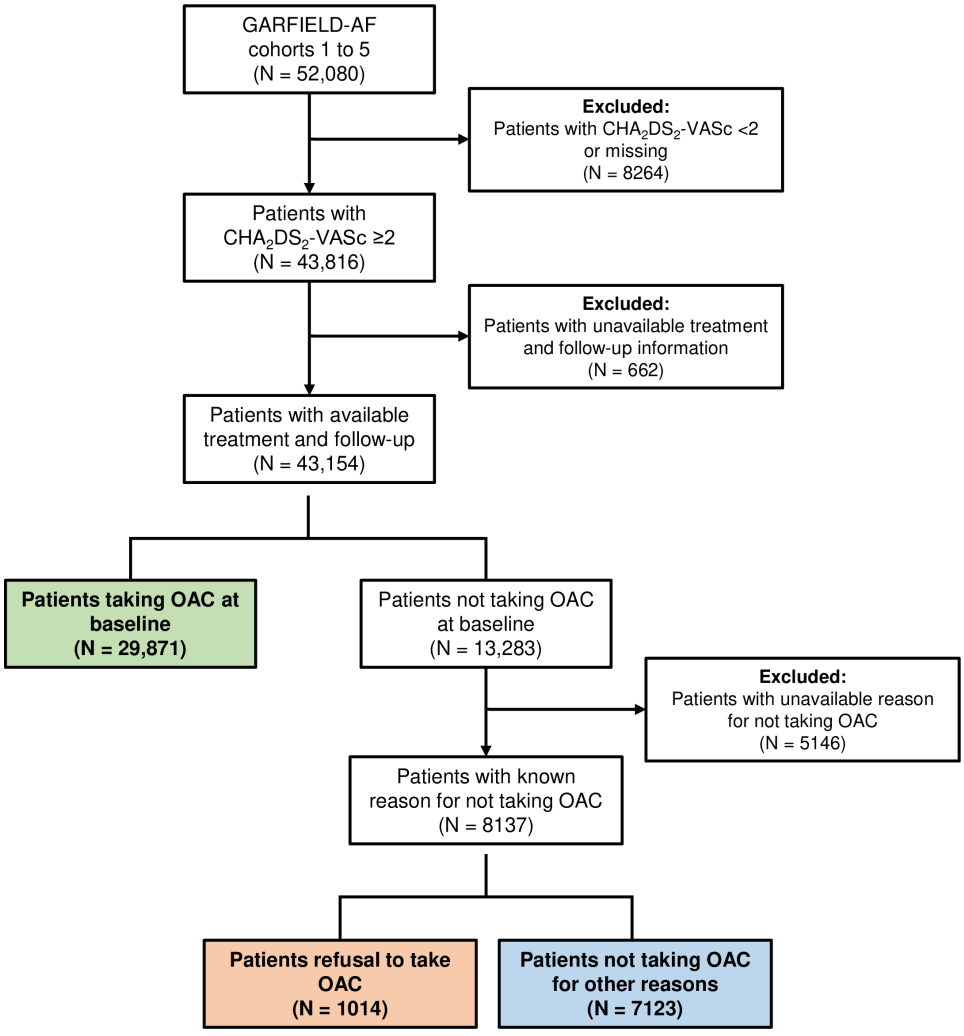

Figure 1 Flow chart for the selection of the study population The flow chart depicts the total cohort of patients in the GARFIELD-AF registry from which exclusion criteria were administered to arrive at final patient population for analysis. The green, blue and orange boxes indicate the patients that were considered for the analysis. GARFIELD-AF, Global Anticoagulant Registry in the FIELD-Atrial Fibrillation; OAC, oral anticoagulant.

were calibrated to the observed proportions (online supplemental figure S1).

For the comparison of clinical outcomes between patients who received OAC, who refused OAC and who did not receive OAC for other reasons, a casual inference methodology has been applied. More specifically, we analysed 2-year outcomes of non-haemorrhagic stroke/SE, major bleeding and all-cause mortality in patients at high risk of stroke, defined a CHA_2DS_2-VASc score ≥2, excluding female as a factor. Association estimates were obtained through a Cox proportional hazards model using a propensity method of overlap weighting to balance covariates in the population.[12] This applied method overlaps weights and optimises the efficiency of comparisons by defining the population with the most overlap in the covariates between treatment groups. This scheme eliminates the potential for outlier weights by avoiding a weight based on a ratio calculation using values bounded by 0 and 1. Thus, when using overlap weights, many of the concerns regarding the assessment and the trimming of the weights are eliminated. Online supplemental figure S2 reports the absolute standardised differences of the variables included in the weighting scheme and online supplemental figure S3 shows the estimated propensity of refusing OAC. To account for the nested structure of our dataset, our calculation of propensity score through logistic regression included country of enrolment. We also made use of a robust sandwich variance estimator to account for the correlation induced in the data by the weighting of country information.

Only complete cases were presented in descriptive tables. Multiple imputation by fully conditional specification was applied.[13] SEs were obtained by combining estimates across five imputed datasets. The missingness proportion for the baseline variables is reported in the supplementary material (online supplemental table S4). The study population of this analysis has a relatively low proportion (<3%) of missing data for most baseline characteristics, with the exception of lifestyle information (ie, smoking and alcohol use; 8 and 14%, respectively) and

Table 1 Baseline characteristics by baseline anticoagulation and reason anticoagulation was not used

Baseline characteristic	Patients on OAC (N=29 871)	Patients not on OAC	
		Patient refusal to take AC (N=1014)	Other reason for not taking AC (N=7123)
Sex, n (%)			
Male	15 089 (50.5)	524 (51.7)	3409 (47.9)
Female	14 782 (49.5)	490 (48.3)	3714 (52.1)
Age, median (Q1; Q3), years	73.0 (67.0; 79.0)	72.0 (65.0; 78.0)	72.0 (65.0; 80.0)
Ethnicity, n (%)			
Caucasian	20 115 (69.0)	608 (60.4)	3659 (52.3)
Hispanic/Latino	1945 (6.7)	40 (4.0)	574 (8.2)
Asian	6530 (22.4)	342 (34.0)	2641 (37.8)
Afro-Caribbean/mixed/other	566 (1.9)	17 (1.7)	117 (1.7)
Body mass index, median (Q1; Q3), kg/m²	27.2 (24.2; 31.2)	27.0 (23.9; 30.5)	26.1 (23.3; 29.7)
Systolic blood pressure, median (Q1; Q3), mm Hg	133.0 (120.0; 146.0)	135.0 (120.0; 145.0)	132.0 (120.0; 145.0)
Diastolic blood pressure, median (Q1; Q3), mm Hg	80.0 (70.0; 89.0)	80.0 (70.0; 86.0)	80.0 (70.0; 86.0)
Pulse, median (Q1; Q3), bpm	85.0 (71.0; 106.0)	78.0 (68.0; 94.0)	80.0 (70.0; 100.0)
Type of atrial fibrillation, n (%)			
Permanent	4453 (14.9)	165 (16.3)	759 (10.7)
Persistent	4995 (16.7)	92 (9.1)	804 (11.3)
Paroxysmal	7681 (25.7)	355 (35.0)	2294 (32.2)
New onset (unclassified)	12 742 (42.7)	402 (39.6)	3266 (45.9)
Care setting specialty at diagnosis, n (%)			
Internal medicine/neurology/geriatrics	6136 (20.5)	181 (17.9)	1507 (21.2)
Cardiology	19 556 (65.5)	613 (60.5)	4520 (63.5)
Primary care/general practice	4179 (14.0)	220 (21.7)	1096 (15.4)
Care setting location at diagnosis, n (%)			
Hospital	16 509 (55.3)	625 (61.6)	4326 (60.7)
Office/AC clinic/thrombosis centre	10 062 (33.7)	329 (32.4)	2094 (29.4)
Emergency room	3300 (11.0)	60 (5.9)	703 (9.9)
Medical history, n (%)			
Heart failure	7451 (24.9)	277 (27.3)	1664 (23.4)
Vascular disease*	4800 (16.1)	178 (17.7)	1358 (19.2)
Prior/current MI	3745 (12.6)	153 (15.1)	1111 (15.8)
Carotid occlusive disease	1046 (3.5)	38 (3.8)	200 (2.8)
CABG	1136 (3.8)	31 (3.1)	212 (3.0)
Stenting	2200 (7.4)	68 (6.7)	629 (8.9)
VTE	950 (3.2)	10 (1.0)	122 (1.7)
Prior stroke/TIA/SE	4178 (14.0)	124 (12.2)	821 (11.5)
Prior bleeding	574 (1.9)	28 (2.8)	446 (6.3)
Hypertension	24 660 (82.6)	836 (82.4)	5624 (79.0)
Hypercholesterolaemia	13 326 (45.8)	425 (43.4)	2793 (40.4)
Diabetes	7825 (26.2)	254 (25.0)	1614 (22.7)
Cirrhosis	135 (0.5)	3 (0.3)	70 (1.0)
Moderate to severe CKD	3605 (13.4)	118 (13.5)	770 (12.7)
Dementia	443 (1.5)	11 (1.1)	212 (3.0)
Hyperthyroidism	515 (1.8)	13 (1.3)	123 (1.8)

Continued

Table 1 Continued

Baseline characteristic	Patients on OAC (N=29 871)	Patients not on OAC	
		Patient refusal to take AC (N=1014)	Other reason for not taking AC (N=7123)
Hypothyroidism	2002 (6.8)	51 (5.1)	419 (6.0)
Heavy alcohol consumption, n (%)	432 (1.7)	11 (1.2)	148 (2.4)
Current smoker, n (%)	2358 (8.6)	97 (10.0)	563 (8.5)
AC use, n (%)			
NOAC	12 037 (40.3)	–	–
VKA	17 834 (59.7)	–	–
Antiplatelet use, n (%)	6733 (22.5)	805 (79.4)	5010 (70.3)
CHA_2DS_2-VASc score, median (Q1; Q3)	4.0 (3.0; 4.0)	3.0 (3.0; 5.0)	3.0 (2.0; 4.0)
HAS-BLED score, median (Q1; Q3)†	1.0 (1.0; 2.0)	1.0 (1.0; 2.0)	2.0 (1.0; 2.0)
GARFIELD-AF mortality score, median (Q1; Q3)‡	6.6 (4.0; 11.3)	5.2 (3.1; 8.8)	5.7 (3.1; 11.0)
GARFIELD-AF stroke score, median (Q1; Q3)§	2.3 (1.7; 3.3)	2.2 (1.6; 3.1)	2.3 (1.6; 3.3)
GARFIELD-AF major bleeding score, median (Q1; Q3)¶	1.2 (0.9; 1.7)	1.3 (0.9; 1.8)	1.4 (0.9; 2.0)

Baseline characteristics by baseline anticoagulation and reason anticoagulation was not used.
*Defined as coronary artery disease or peripheral vascular disease.
†The risk factor 'Labile INRs' is not included in the HAS-BLED score as it is not collected at baseline. As a result, the maximum HAS-BLED score at baseline is 8 points (not 9).
‡Represent the expected probability of death within 2 years follow-up assuming common treatment across groups.
§Represent the expected probability of non-haemorrhagic stroke/SE within 2 years follow-up assuming common treatment across groups.
¶Represent the expected probability of major bleeding within 2 years follow-up assuming common treatment across groups.
AC, anticoagulants; CABG, coronary artery bypass graft ; CKD, chronic kidney disease; MI, Myocardial infarction ; NOAC, non-vitamin K anticoagulants; OAC, oral anticoagulants; SE, systemic embolism ; TIA, transient ischaemic attack; VKA, vitamin K antagonist.

vital signs (SBP, DBP, heart rate; approximately 6%). All analyses were performed using SAS Enterprise Guide (V.8.2).

RESULTS

A total of 52 080 participants were recruited to the GARFIELD-AF registry from 35 countries between 2010 and 2016. 82.9% (43 154/52 080) had complete risk information and a high risk of stroke ($CHA_2DS_2VASc \geq 2$, excluding female sex as a factor); of these 30.8% (13 283/43 154) did not receive anticoagulation at baseline. The reason for not receiving anticoagulation was unavailable for 38.7% (5146/13 283); of the patients with a known reason for not receiving anticoagulation, 12.5% (1014/8137) refused anticoagulation (figure 1). The remaining patients were not taking anticoagulation for other reasons—mainly related to physician's choice (87.5%) (online supplemental figure S4).

Patient baseline characteristics

The median (Q1; Q3) age of participants who refused anticoagulation and patients who did not receive anticoagulation for other reasons were similar, 72.0 (65.0; 80.0) and 72 (65; 78) years, respectively (table 1). The median (Q1; Q3) age of patients who received anticoagulation was 73.0 (67.0; 79.0). 34% of patients who refused anticoagulation were of Asian ethnicity whereas Asians comprised 22.4% of patients receiving anticoagulation and 37.8% of patients not receiving anticoagulation for other reasons. Cardiometabolic parameters including BMI, SBP and DBP were similar across the groups (table 1). The patients across the three groups had similar medical history with regard to information collected in the registry (table 1).

The median (Q1; Q3) CHA_2DS_2-VASc score was 3.0 (3.0; 5.0) in patients who refused anticoagulation and 4.0 (3.0; 4.0) in patients who received anticoagulation. The median (Q1; Q3) HAS-BLED score was 1.0 (1.0; 2.0) in both patients who refused anticoagulation and patients who received anticoagulation and 2.0 (1.0; 2.0) in patients not receiving anticoagulation for other reasons. The GARFIELD-AF score for mortality, indicating the expected risk of dying within 2 years follow-up, was higher in patients on anticoagulation than in patients refusing anticoagulation (median GARFIELD-AF mortality score: 6.6% vs 5.2%, respectively).

Antithrombotic therapy at baseline

Of the patients who received anticoagulants, 59.7% received vitamin K antagonist (VKA) and 40.3% received non-VKA OAC. 79.4% (805/1014) of patients who refused anticoagulation were receiving APs compared with 70.3% (5010/7123) in patients not receiving anticoagulation for other reasons. Of the patients who

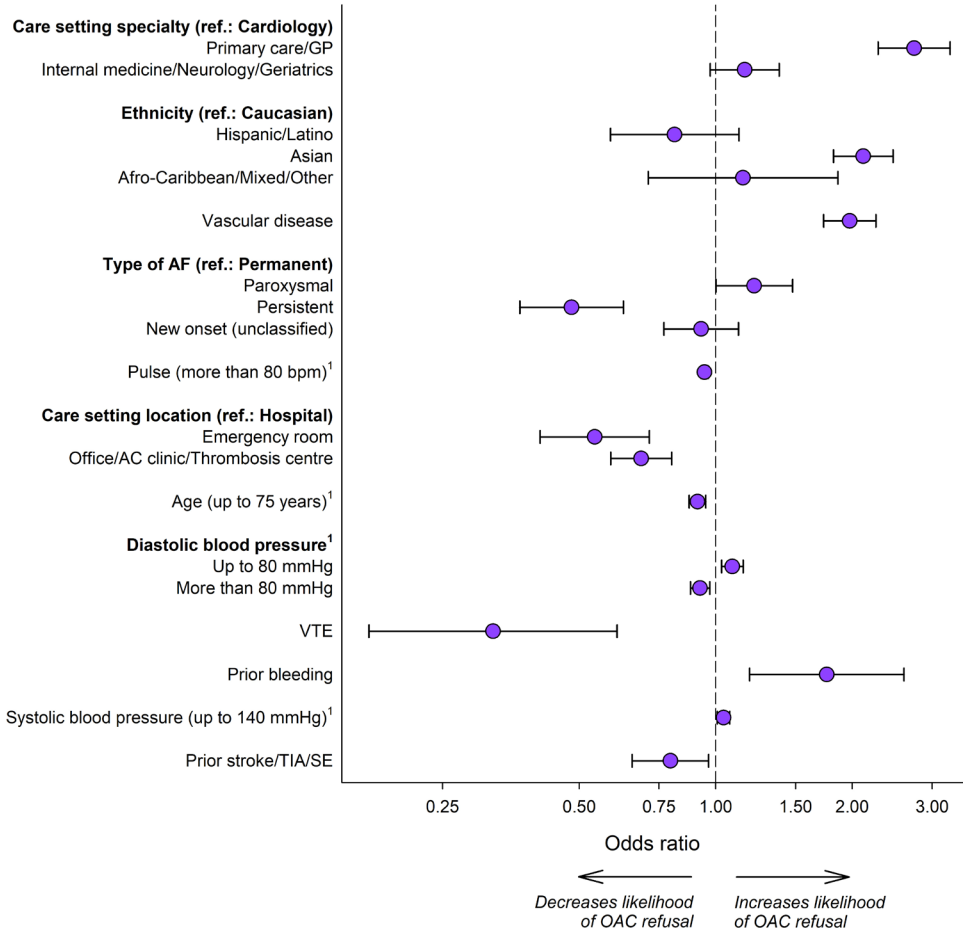

Figure 2 ORs for components of the OAC refusal model. [1]HRs with 95% CIs are based on incremental units of '5'. The reference is indicated in parenthesis and is marked by the dotted line. The analysis compared patients who were on OAC (N=29 871) and patients who refused OAC (N=1014). AC, anticoagulants; GP, general practitioner; OAC, oral anticoagulant; SE, systemic embolism; TIA, transient ischaemic attack.

refuse anticoagulants, 635 (62.6%) received aspirin, of which 289 (45.5%) were on aspirin before enrolment and 346 (54.5%) received aspirin within 1 month of enrolment. Out of the 3980 who did not receive anticoagulants for other reason, 1562 (39.3%) were on aspirin before enrolment and 2418 (60.7%) received aspirin within 1 month of enrolment (data not shown).

Table 2 Crude OR for OAC refusal by CHA2DS2-VASc score and symptoms at diagnosis

CHA2DS2-VASc score	OR (95% CI)
CHA2DS2-VASc score=2	1 (ref.)
CHA2DS2-VASc score=3	0.94 (0.79 to 1.12)
CHA2DS2-VASc score≥4	0.89 (0.76 to 1.05)
Symptoms at diagnosis	OR (95% CI)
No symptoms	1 (ref.)
At least one symptom	1.21 (1.04 to 1.41)

Crude OR for OAC refusal by CHA_2DS_2-VASc score and symptoms at diagnosis.
OAC, oral anticoagulants

Information on the status of other APs was unavailable at the time of enrolment.

Factors associated with patient refusal of anticoagulation

The strongest determinant of anticoagulation refusal was primary care setting at diagnosis, with patients diagnosed in primary care/general practitioner (GP) having a higher likelihood of refusing anticoagulation compared with patients diagnosed in cardiology (figure 2). Asian ethnicity, vascular disease and a history of bleeding were also strong determinants of patient refusal of anticoagulation. Patients with paroxysmal AF compared with permanent AF were more likely to refuse but those with persistent AF were less likely. Patients with a history of VTE, higher pulse, younger age, more abnormal DBPs (both high and low) and patients diagnosed outside of the in-hospital setting were least likely to refuse anticoagulation (figure 2).

There were no significant differences in refusal for patients with a $CHA_2DS_2VASc=2$ compared with patients with a score of 3 and patients with a score of ≥4 (table 2). Patients with at least one symptom were more likely to refuse anticoagulation compared with patients with no symptoms.

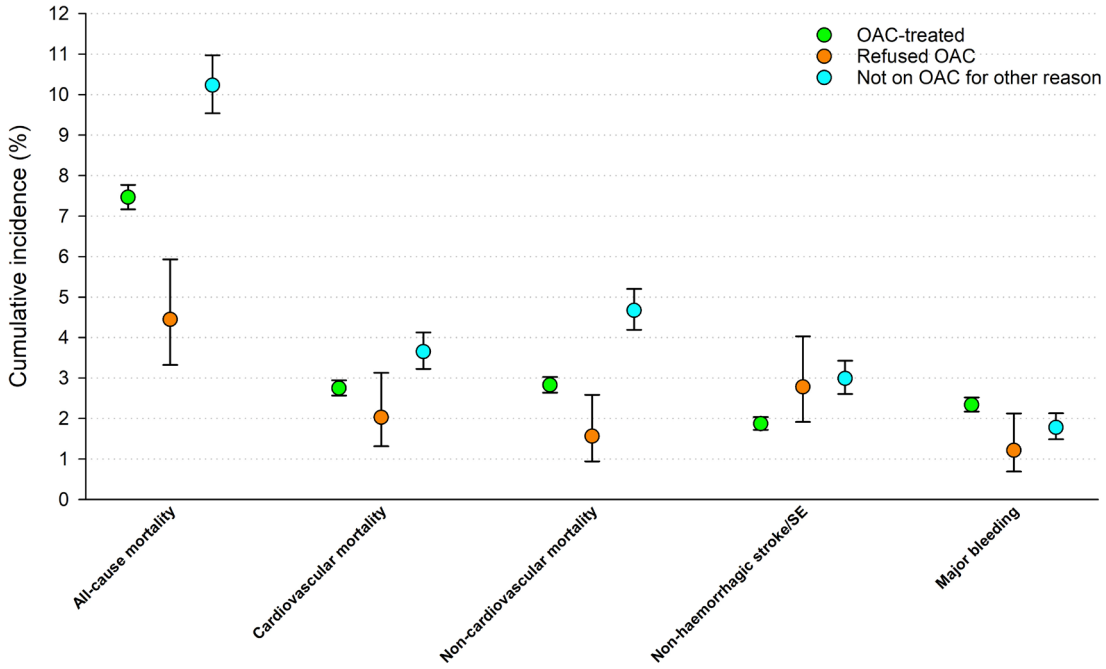

Figure 3 Cumulative incidence within 2 years of follow-up baseline anticoagulation status. The green filled circles depict OAC-treated patients, orange filled circles depict patients who refused OAC and the blue filled circles depict patients who did not receive OACs for other reasons. OAC, oral anticoagulant; SE, systemic embolism.

Geographical variations in patient refusal

There were variations in patient refusal at country level with 5 out of the 35 participating countries having a refusal rate of ≥3% (online supplemental figure S5) (UK, Germany, South Africa, Russia and China). In contrast, France and Belgium had the lowest rates of patient refusal at ≤0.5%.

Clinical outcomes at 2 years

The crude rates of all-cause mortality, non-haemorrhagic stroke/SE and major bleeding within a 2-year follow-up in patients who refused anticoagulation were 4.4% (95% CI 3.3% to 5.9%), 2.8% (95% CI 1.9% to 4.0%) and 1.2% (95% CI 0.7% to 2.1%). Patients who received anticoagulation had a non-haemorrhagic stroke/SE rate of 1.9% (95% CI 1.7% to 2.0%). The rates of all-cause mortality and major bleeding were higher in patients who received anticoagulants when compared with patients who refused anticoagulants. Patients not on anticoagulation for reasons other than patient refusal had and all-cause mortality rate of 10.2% (95% CI 9.5% to 11.0%) and non-haemorrhagic stroke/SE rate of 3.0% (95% CI 2.6% to 3.4%) (figure 3).

After adjustment for country, demographic and lifestyle factors, clinical measures at diagnosis and medical history, patient refusal was associated with non-significant higher stroke/SE (adjusted HR, (aHR) 1.16 (95% CI 0.77 to 1.76) and significantly lower all-cause mortality aHR 0.59 (95% CI 0.43 to 0.80) and non-significant lower major bleeding (0.68 (95% CI 0.38 to 1.22), compared with patients who received anticoagulation (figure 4A). Patients not receiving anticoagulation for other reasons had higher all-cause mortality and stroke/SE, but lower major bleeding compared with patients who received anticoagulation (figure 4B).

DISCUSSION

Summary

In this global observational prospective study of patients with newly diagnosed AF, the overall rate of patient refusal was low (2.3% of patients at high risk of stroke), though patient refusal accounted for 12.5% of patients at high risk of stroke and not receiving anticoagulation. Diagnosis in primary care/GP, Asian ethnicity and presence of vascular disease were strongly associated with a higher risk of patient refusal of anticoagulation. In our study population, patient refusal of anticoagulation was associated with a non-significant higher rate stroke/SE but a lower all-cause mortality compared with patients who received anticoagulation. Patients who did not receive anticoagulation for reasons other than patient refusal had the worse stroke/SE and mortality outcomes.

Strengths and limitations

The key strength of this study was early inclusion of patients, within 6 weeks of diagnosis of AF in the GARFIELD-AF study population. This ensured that we were capturing disease burden early on by including patients who may not survive long after an AF diagnosis.

The main limitation of this study is that the analysis is intention to treat, based on therapy initiated at diagnosis, and does not account for treatment changes during the 2-year follow-up. Also, despite having applied appropriate propensity score methodology to balance confounding

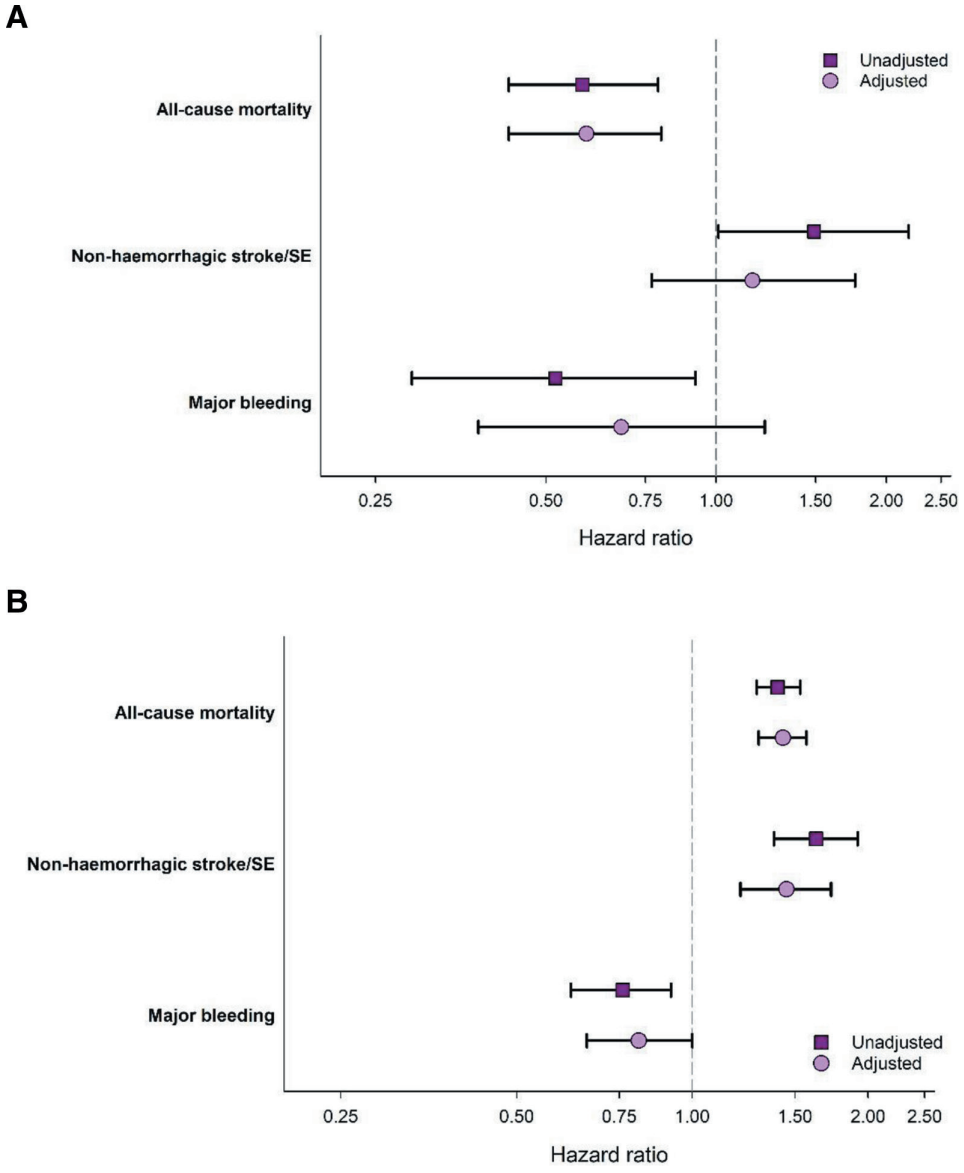

Figure 4 Unadjusted and adjusted HRs of 2-year outcomes (A) patients who refused anticoagulation versus patients who received baseline anticoagulation (ref.) and in (B) patients who were not anticoagulated for reasons other than refusal versus patients who received baseline anticoagulation (ref.). Purple filled squares depicts unadjusted data and pick filled circles depict adjusted data. Adjusted HR was obtained using an overlap-weighted Cox model. Variables included in the weighting scheme are: country and cohort enrolment, sex, age, ethnicity, type of AF, care setting specialty and location, congestive heart failure, acute coronary syndromes, vascular disease, carotid occlusive disease, prior stroke/TIA/SE, prior bleeding, VTE, hypertension, hypercholesterolaemia, diabetes, cirrhosis, moderate to severe CKD, dementia, hyperthyroidism, hypothyroidism, current smoking, heavy alcohol consumption, BMI, heart rate, systolic and diastolic blood pressure at diagnosis. AF, atrial fibrillation; BMI, body mass index; CKD, chronic kidney disease; SE, systemic embolism; TIA, transient ischaemic attack,; VTE, venous thromboembolism.

factors across groups, we cannot exclude the presence of unobserved confounding.

Another potential limitation of this study was the lack of data on the patients' decision for refusal of anticoagulants. Sociocultural factors, including personal beliefs, concerns of bleeding, especially given the older age of the study group could have played a role in their decision to refuse anticoagulants therapy.[14] Further, cost of care with anticoagulants especially in the countries where patients more often pay out of pocket could have also been a factor for refusal.[15] Finally, the study did not collect sufficient data on history of non-CV disease to ascertain if that contributed to their decision to refuse treatment. In addition, there are likely to be other unobserved confounders, which could have impacted patient's decision to refuse OAC, that we are unable to consider for this study.

Comparison with existing literature

The overall rate of patient refusal in our study is lower than previously reported studies. A study on rates of anticoagulant use in older Thai adults with non-valvular

AF reported that patient refusal was the reason 21% of patients were not anticoagulated.[16] A study on patients attitudes towards prevention of AF-related stroke and bleeding risk in AF found 12% of patients would not consider antithrombotic therapy regardless of its' efficacy in preventing AF-related stroke due to being 'medication averse'.[17] These differences may be due to geographical factors as our study found variations in the rate of patient refusal by country and ethnicity.

To our knowledge, this is the first study to investigate outcomes in patients who refused anticoagulation. The findings of higher stroke/SE in patients who refuse anticoagulation is consistent with the evidence on the benefits of anticoagulation in patients with AF at risk of stroke. The differences in outcomes of patients who refused anticoagulation and patients who did not receive anticoagulation for other reasons would suggest that there may be unobserved confounders associated with patient refusal. The findings regarding lower mortality in patients who refused anticoagulation, while corroborating the baseline GARFILED-AF mortality score, are counterintuitive and need to be interpreted with caution. The findings may be impacted by the geographical variation within the global study population, considering the fact that there were significant variations in outcomes across countries within the GARFIELD-AF registry even after adjustment for baseline characteristics and antithrombotic treatment.[18]

Implications for practice and research

While clinicians may decide to prescribe anticoagulation according to AF management guidelines, the final decision lies with the patient. Patient refusal of anticoagulation is a valid outcome of shared decision-making; however, it is a missed opportunity to prevent AF-related stroke. Exploring patients' reasons for refusal during the decision-making process will open the discussion to allow clinicians to address any concerns. This is important particularly in the primary care setting as our study found diagnosis in a primary care setting to be the strongest determinant of anticoagulation refusal. Furthermore, current AF guidelines now recommend anticoagulants as the only appropriate pharmacologic antithrombotic therapy in patients with AF, and as such there is no alternative for patients who refuse anticoagulant therapy.[19]

Further investigation of patient refusal of anticoagulation in routine national datasets may provide insights relating to more homogeneous populations and may also allow investigation of crossover of patients who initially refused anticoagulation and consideration of a wider range of predictors such as deprivation and physical activity. Further studies are required to understand the reasons for the refusal. An improved understanding of why patients refuse anticoagulation currently will enrich shared decision-making and increase the likelihood that patients receive the care they need in a manner that is consistent with research evidence and their values and preferences.

Author affiliations
[1]Institute of Applied Health Research, University of Birmingham Institute of Applied Health Research, Birmingham, UK
[2]Department of Statistics, Thrombosis Research Institute, London, UK
[3]Cardiology, St Georges Hospital, London, UK
[4]Cardiology, University of Edinburgh and Royal Infirmary, Edinburgh, UK
[5]Department of Cardiology, University of Besançon, Besançon, France
[6]Department of Medicine, McMaster University, Hamilton, Ontario, Canada
[7]Internal Medicine, Seoul National University Hospital, Seoul, Korea (the Republic of)
[8]Division of Angiology, Medical University of Graz, Graz, Austria
[9]AZ Klina, General Hospital Klina, Brasschaat, Belgium
[10]Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, Sao Paulo, Brazil
[11]Department of Cardiology, University of Copenhagen, Kobenhavn, Denmark
[12]Haemostasis and Thrombosis Research Group, Institute for Experimental Oncology and Therapy Research, Formerly Technical University, Munich, Germany
[13]Thrombosis Research Institute, London, UK

Twitter Patricia Apenteng @p_apenteng

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ORCID iD
Patricia Apenteng http://orcid.org/0000-0003-0835-3495

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Supplementary file

Table S1. Primary cause of death distribution in patients who deceased throughout 2-years follow-up by baseline anticoagulation and reason anticoagulation was not used.

Cause of death	Patients on OAC (N = 2180 deaths)	Patients not on OAC	
		Patient refusal to take anticoagulants (N = 44 deaths)	Other reason for not taking anticoagulants (N = 707 deaths)
Primary cause of death			
Cardiovascular	786 (36.1)	20 (45.5)	245 (34.7)
Non-cardiovascular	805 (36.9)	15 (34.1)	313 (44.3)
Unknown primary cause	589 (27.0)	9 (20.4)	149 (21.1)

Table S2. List of potential predictors for the OAC refusal models

Demographics
- Sex
- Age
- Ethnicity
- Country of enrolment (only for Model 2)

Medical and Cardiovascular History
- Hypertension
- Diabetes
- Moderate to severe CKD
- History of bleeding
- Heart failure
- Acute coronary syndromes
- Carotid occlusive disease
- Venous thromboembolism
- Vascular disease
- Prior stroke/TIA/SE
- Hypercholesterolemia
- Cirrhosis
- Hyperthyroidism
- Hypothyroidism
- Dementia

Lifestyle factors
- Current smoking
- Heavy alcohol consumption

Vital signs
- BMI (kg/m^2)
- Pulse (bpm)
- Systolic blood pressure (mmHG)
- Diastolic blood pressure (mmHG)

Atrial fibrillation diagnosis
- Type of atrial fibrillation

Care setting at diagnosis
- Care setting specialty
- Care setting location

Table S3. Wald Chi-square – degrees of freedom (DF) for components of the OAC refusal model

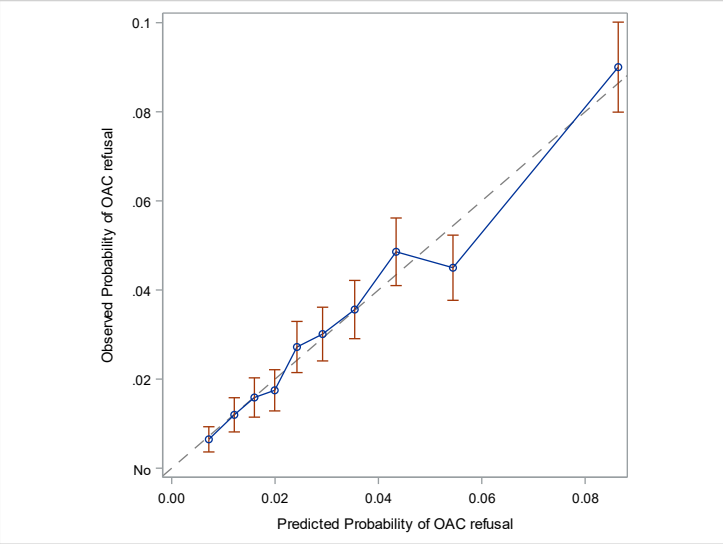
Model components	Wald chi-square − DF	
	Model 1	**Model 2**
Country of enrolment	-	889
Type of AF	58	94
Care setting specialty	116	27
Pulse	34	14
VTE	11	13
Prior bleeding	7	13
Care setting location	32	8
Diastolic blood pressure	15	8
Prior stroke/TIA/SE	4	6
Vascular disease	100	4
Systolic blood pressure	5	-
Age at AF diagnosis	17	-
Ethnicity	99	-
C-statistic (95% CI)	*0.70 (0.68-0.71)*	*0.82 (0.81-0.84)*

Table S4. Missingness proportion for selected variables in the study population

Variable	N (%)
Country	0 (0.0)
Cohort	0 (0.0)
Sex	0 (0.0)
Race/ethnicity	854 (2.2)
Type of AF	0 (0.0)
Care setting location	0 (0.0)
Care setting specialty	0 (0.0)
Heart failure	0 (0.0)
Vascular disease	180 (0.5)
ACS	151 (0.4)
Carotid occlusive disease	293 (0.8)
Prior stroke/TIA/SE	0 (0.0)
Prior bleeding	55 (0.1)
VTE	58 (0.1)
Hypertension	18 (0.05)
Hypercholesterolaemia	1014 (2.7)
Diabetes	0 (0.0)
Cirrhosis	431 (1.3)
CKD	4086 (10.7)
Dementia	125 (0.3)
Hyperthyroidism	595 (1.6)
Hypothyroidism	604 (1.6)
Alcohol consumption	5566 (14.6)
Smoking status	3133 (8.2)
Antiplatelet therapy	0 (0.0)
Age	0 (0.0)
SBP	2269 (6.0)
DBP	2269 (6.0)
Pulse	2550 (6.7)

Figure S1. Calibration plots for OAC refusal model 1 (a) and model 2 (b)

(a) Model 1



(b) Model 2

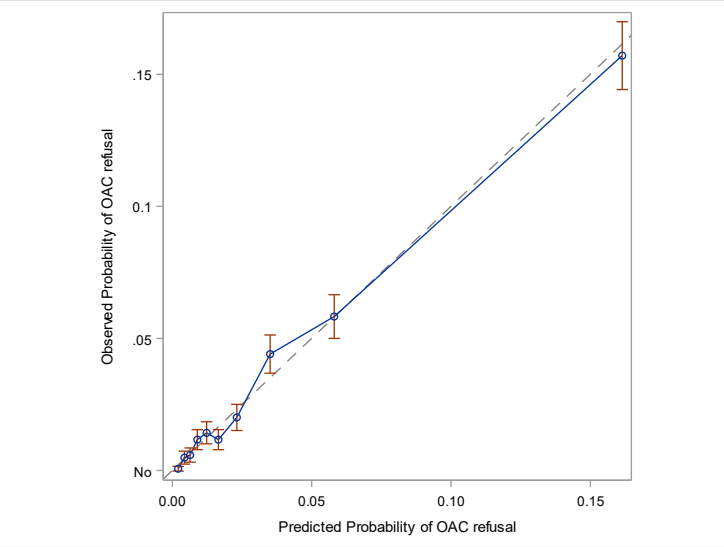


Figure S2. Balance of variables associated with OAC refusal (ref.: OAC-treated) at baseline before and after propensity score weighting

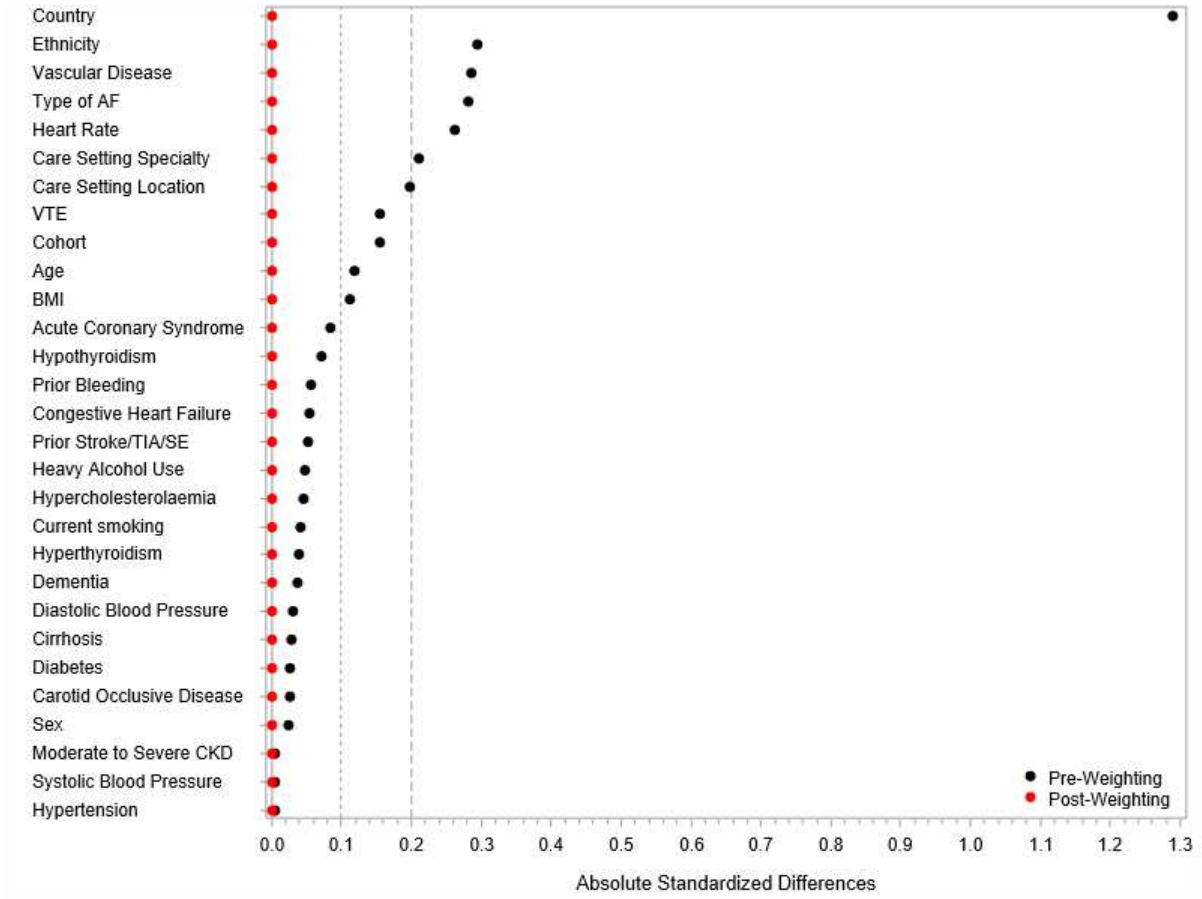


Figure S3. Propensity score comparing OAC refusal vs OAC-treated

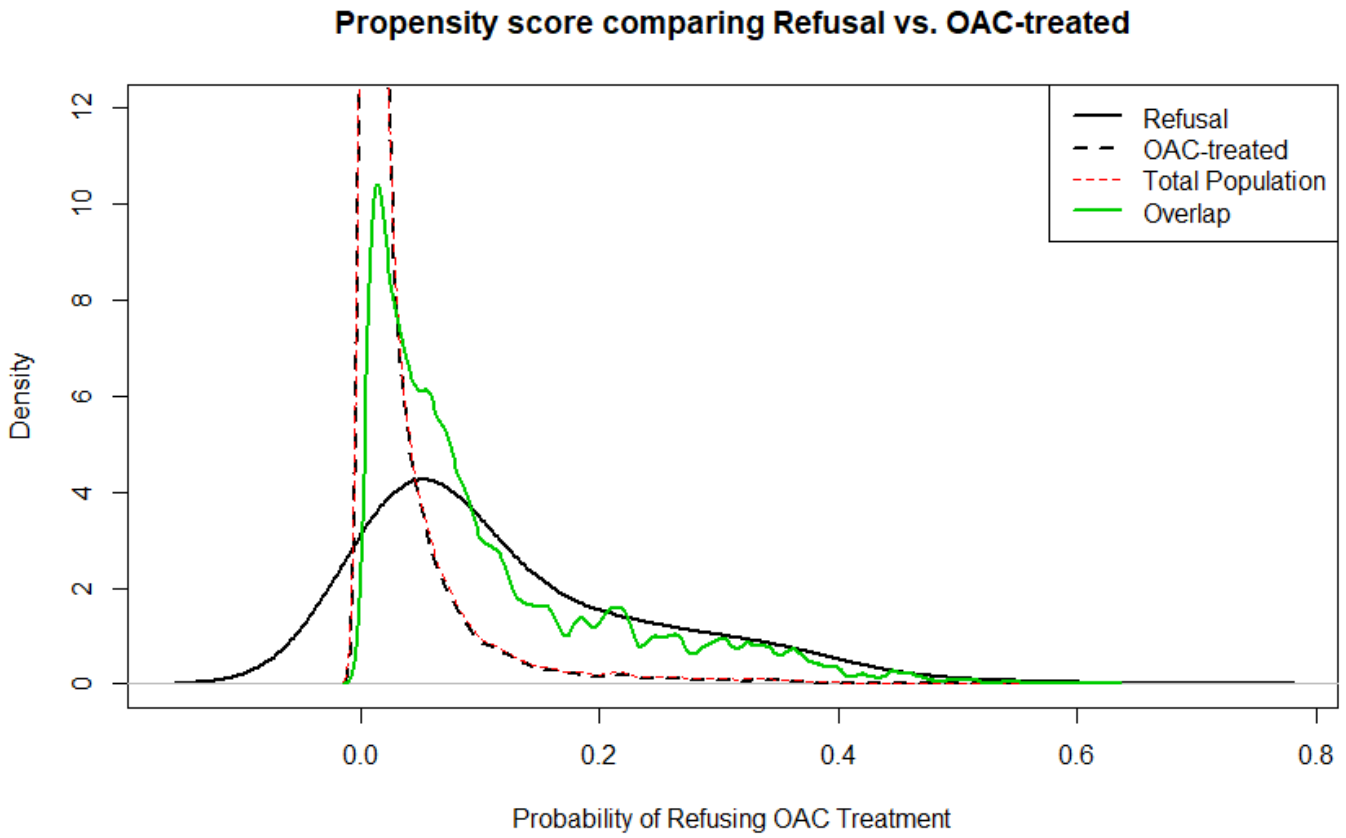


Figure S4. Distribution of reason for not taking anticoagulants among patients with available reason

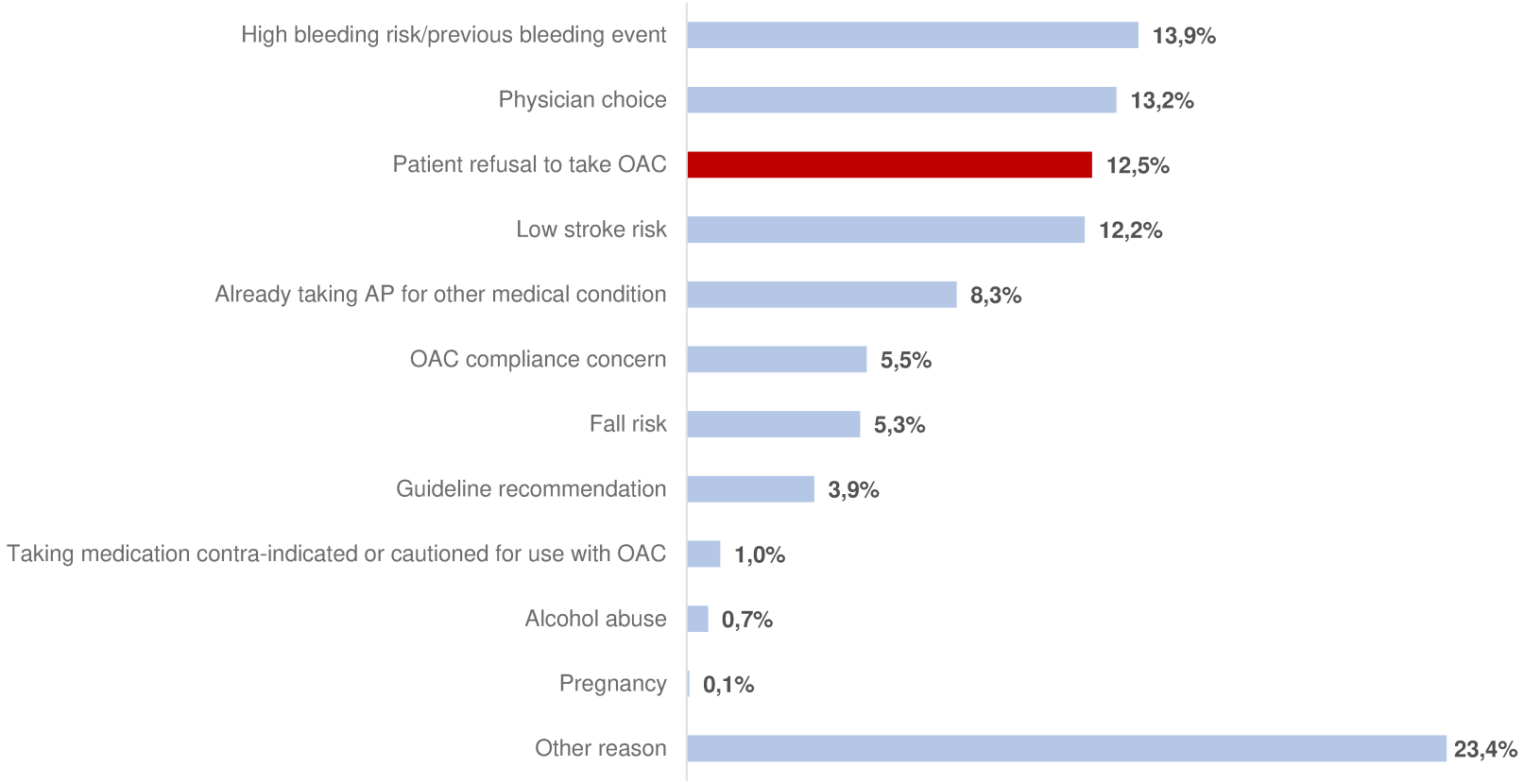
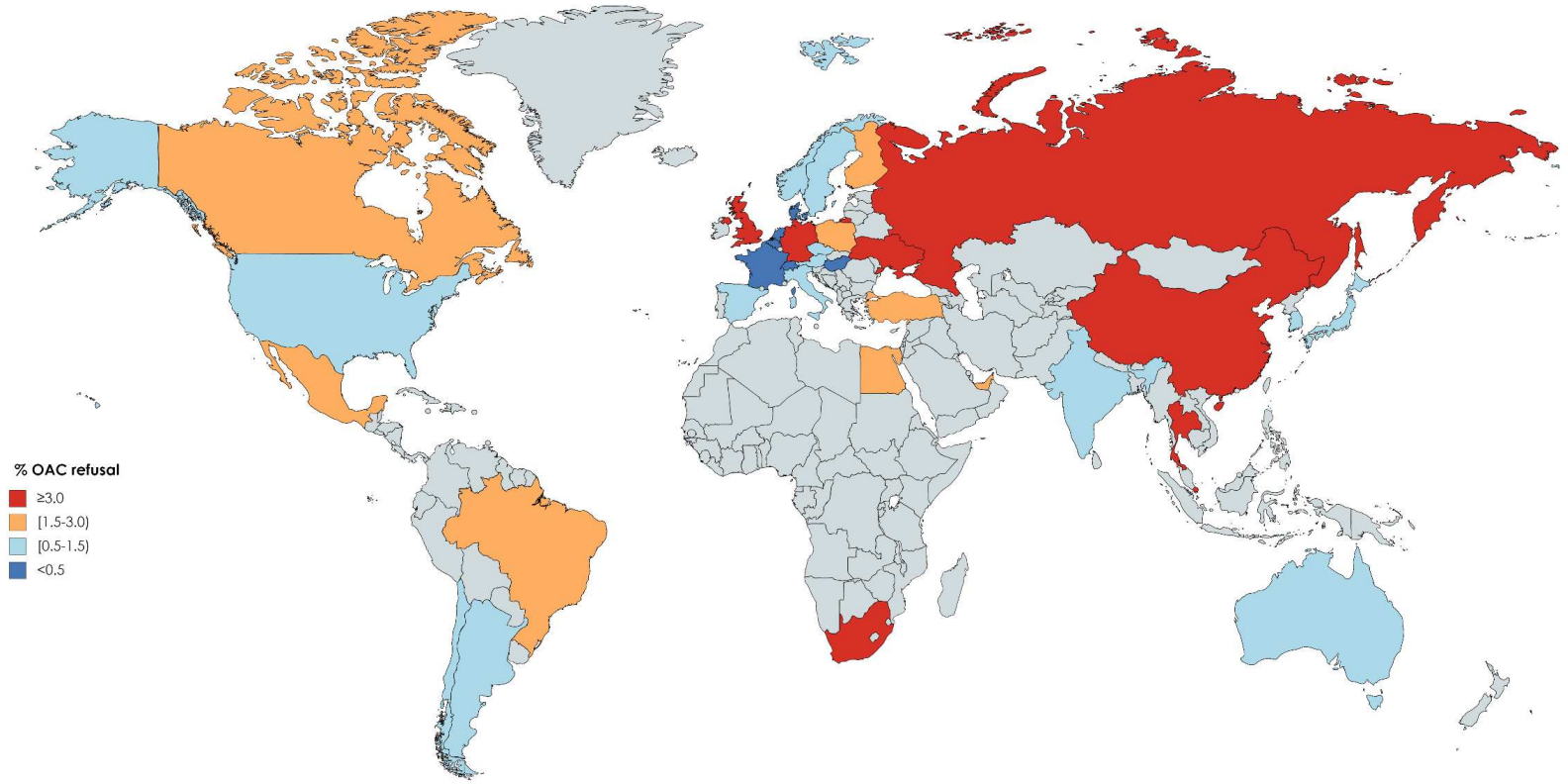


Figure S5. Distribution of patients who refused anticoagulation in the whole study population[1] by country



[1]% OAC refusal is the number of patients who refused OAC divided by the total number of patients (on and off OAC at baseline), in each country.
OAC = anticoagulation

GARFIELD-AF Registry Investigators

Global Steering Committee

Ajay K. Kakkar (UK) (Chair), Jean-Pierre Bassand (France), A. John Camm (UK), David A. Fitzmaurice (UK), Keith A.A. Fox (UK), Bernard J. Gersh (USA), Samuel Z. Goldhaber (USA), Shinya Goto (Japan), Sylvia Haas (Germany), Werner Hacke (Germany), Lorenzo G. Mantovani (Italy), Frank Misselwitz (Germany), Karen S. Pieper (USA), Alexander G.G. Turpie (Canada), Martin van Eickels (Germany), Freek W.A. Verheugt (the Netherlands).

Audit Committee

Keith A.A. Fox (UK), Bernard J. Gersh (USA).

GARFIELD-AF National Coordinators:

Hector Lucas Luciardi (Argentina), Harry Gibbs (Australia), Marianne Brodmann (Austria), Frank Cools (Belgium), Antonio Carlos Pereira Barretto (Brazil), Stuart J. Connolly, John Eikelboom (Canada), Ramon Corbalan (Chile), Zhi-Cheng Jing (China), Petr Jansky (Czech Republic), Jørn Dalsgaard Nielsen (Denmark), Hany Ragy (Egypt), Pekka Raatikainen (Finland), Jean-Yves Le Heuzey (France), Harald Darius (Germany), Matyas Keltai (Hungary), Jitendra Pal Singh Sawhney (India), Giancarlo Agnelli and Giuseppe Ambrosio (Italy), Yukihiro Koretsune (Japan), Carlos Jerjes Sánchez Díaz (Mexico), Hugo Ten Cate (the Netherlands), Dan Atar (Norway), Janina Stepinska (Poland), Elizaveta Panchenko (Russia), Toon Wei Lim (Singapore), Barry Jacobson (South Africa), Seil Oh (South Korea), Xavier Viñolas (Spain), Marten Rosenqvist (Sweden), Jan Steffel (Switzerland), Pantep Angchaisuksiri (Thailand), Ali Oto (Turkey), Alex Parkhomenko (Ukraine), Wael Al Mahmeed (United Arab Emirates), David Fitzmaurice (UK), Samuel Z. Goldhaber (USA).

GARFIELD-AF National Investigators:

China
Dayi Hu, Kangning Chen, Yusheng Zhao, Huaiqin Zhang, Jiyan Chen, Shiping Cao, Daowen Wang, Yuejin Yang, Weihua Li, Hui Li, Yuehui Yin, Guizhou Tao, Ping Yang, Yingmin Chen, Shenghu He, Yong Wang, Guosheng Fu, Xin Li, Tongguo Wu, Xiaoshu Cheng, Xiaowei Yan, Ruiping Zhao, Moshui Chen, Longgen Xiong, Ping Chen, Yang Jiao, Ying Guo, Li Xue, Zhiming Yang.

India
Praveen Jadhavm, Raghava Sarma, Govind Kulkarni, Prakash Chandwani, Rasesh Atulbhai Pothiwala, Mohanan Padinhare Purayil, Kamaldeep Chawla, Veerappa Annasaheb Kothiwale, Bagirath Raghuraman, Vinod Madan Vijan, Jitendra Sawhney, Ganapathi Bantwal, Aziz Khan, Ramdhan Meena, Manojkumar Chopada, Sunitha Abraham, Vikas Bisne, Govindan Vijayaraghavan, Debabrata Roy, Rajashekhar Durgaprasad, A.G. Ravi Shankar, Sunil Kumar, Dinesh Jain, Kartikeya Bhargava, Vinay Kumar, Udigala Madappa Nagamalesh, Rajeeve Kumar Rajput.

Japan
Yukihiro Koretsune, Seishu Kanamori, Kenichi Yamamoto, Koichiro Kumagai, Yosuke Katsuda, Keiki Yoshida, Fumitoshi Toyota, Yuji Mizuno, Ikuo Misumi, Hiroo Noguchi, Shinichi Ando, Tetsuro Suetsugu, Masahiro Minamoto, Hiroyuki Oda, Susumu Adachi, Kei Chiba, Hiroaki Norita, Makoto Tsuruta, Takeshi Koyanagi, Kunihiko Yamamoto, Hiroshi Ando, Takayuki Higashi, Megumi Okada, Shiro Azakami, Shinichiro Komaki, Kenshi Kumeda, Takashi Murayama, Jun Matsumura, Yurika Oba, Ryuji Sonoda, Kazuo Goto, Kotaro Minoda, Yoshikuni Haraguchi, Hisakazu Suefuji, Hiroo Miyagi, Hitoshi Kato, Tsugihiro Nakamura, Tadashi Nakamura, Hidekazu Nandate, Ryuji Zaitsu, Yoshihisa Fujiura, Akira Yoshimura, Hiroyuki Numata, Jun Ogawa, Yasuyuki Kamogawa, Kinshiro Murakami, Yutaka Wakasa, Masanori Yamasawa, Hiromitsu Maekawa, Sumihisa Abe, Hajime Kihara, Satoru Tsunoda, Katsumi Saito, Hiroki Tachibana, Ichiro Oba, Takashi Kuwahata, Satoshi Higa, Masamichi Gushiken, Takuma Eto, Hidetoshi Chibana, Kazuaki Fujisawa, Yuhei

Shiga, Hirokuni Sumi, Toshihisa Nagatomo, Yoshihiko Atsuchi, Toshiro Nagoshi, Kazuhisa Sanno, Fumihiro Hoshino, Naoto Yokota, Masahiro Kameko, Toshifumi Tabuchi, Munesumi Ishizawa, Yoshitake Fujiura, Daisuke Ikeda,Taku Seto, Tetsu Iwao, Norio Ishioka, Koichi Oshiro, Keizo Tsuchida, Yutaka Hatori, Motoshi Takeuchi, Hiroto Takezawa, Shinjiro Nagano, Masaaki Iwaki, Yuichiro Nakamura, Naomasa Miyamoto, Toshifumi Taguchi, Ko Ashida, Naoto Yoshizawa, Jun Agata, Seishiro Matsukawa, Osamu Arasaki, Shuji Fukuoka, Hirofumi Murakami, Kazuya Mishima, Yoshiki Hata, Ichiro Sakuma, Kotaro Obunai, Ichiro Takamura, Mitsuyuki Akutsu, Toshihide Unoki, Yoshinori Go, Makoto Ikemura, Shoji Morii, Shigeru Marusaki, Hideo Doi, Mitsuru Tanaka, Takaaki Kusumoto, Shigeo Kakinoki, Chiga Ogurusu, Kazuya Murata, Masaki Shimoyama, Masami Nakatsuka, Yutaka Kitami, Yoichi Nakamura, Hiroshi Oda, Rikimaru Oyama, Masato Ageta, Teruaki Mita, Kazuhiko Nagao, Takafumi Mito, Junichi Minami, Mitsunori Abe, Masako Fujii, Makoto Okawa, Tsuneo Fujito, Toshiya Taniguchi, Tenei Ko, Hiroshi Kubo, Mizuho Imamaki, Masahiro Akiyama, Takashi Ueda, Hironori Odakura, Masahiko Inagaki, Yoshiki Katsube, Atsuyuki Nakata, Shinobu Tomimoto, Mitsuhiro Shibuya, Masayuki Nakano, Kenichiro Ito, Masahiro Matsuta, Motoyuki Ishiguro, Taro Minagawa, Masamichi Wada, Hiroaki Mukawa, Masato Mizuguchi, Fumio Okuda, Teruaki Kimura, Kuniaki Taga, Masaaki Techigawara, Morio Igarashi, Hiroshi Watanabe, Toshihiko Seo, Shinya Hiramitsu, Hiroaki Hosokawa, Mitsumoto Hoshiai, Michitaka Hibino, Koichi Miyagawa, Hideki Horie, Nobuyoshi Sugishita, Yukio Shiga, Akira Soma, Kazuo Neya, Tetsuro Yoshida, Kunio Akahane, Sen Adachi, Chiei Takanaka, Takashi Ueda, Saori Matsui, Hirofumi Kanda, Masanori Kaneko, Shiro Nagasaka, Atsushi Taguchi, Shuta Toru, Kazuyuki Saito, Akiko Miyashita, Hiroki Sasaguri, Jin Nariyama, Taketo Hatsuno, Takash Iwase, Kazuki Sato, Kazuya Kawai, Tomobumi Kotani, Tsuyoshi Tsuji, Hirosumi Sakai, Kiyoshi Nishino, Kenichi Ikeda, Kazuo Maeda, Tomohiro Shinozuka, Takeshi Inoue, Koichi Kawakami, Hiromichi Kitazumi, Tsutomu Takagi, Mamoru Hamaoka, Jisho Kojima, Akitoshi Sasaki, Yoshihiro Tsuchiya, Tetsuo Betsuyaku, Koji Higuchi, Masaaki Honda, Koichi Hasegawa, Takao Baba, Kazuaki Mineoi, Toshihiko Koeda, Kunihiko Hirasawa, Toshihide Kumazaki, Akira Nakagomi, Eiji Otaki, Takashi Shindo, Hiroyoshi Hirayama, Chikako Sugimoto, Takashi Yamagishi, Ichiro Mizuguchi, Kazunori Sezaki, Isamu Niwa, Ken Takenaka, Osamu Iiji, Koichi Taya, Hitoshi Kitazawa, samu Ueda, Hirokazu Kakuda, Takuya Ono, Seizo Oriso, Junya Kamata, Toshihiko Nanke, Itaru Maeda, Yoshifusa Matsuura, Hiroki Teragawa, Yasuyuki Maruyama, Kazuo Takei, Hajime Horie, Tetsutaro Kito, Hiroshi Asano, Koji Matsushita, Masaichi Nakamura, Takashi Washizuka, Tomoki Yoshida, Masato Sawano, Shinichi Arima, Hidekazu Arai, Hisanori Shinohara, Hiroyuki Takai, Nobufusa Furukawa, Akira Ota, Kentaro Yamamoto, Kenji Aoki, Taku Yamamoto, Takeaki Kasai, Shunji Suzuki, Shu Suzuki, Nitaro Shibata, Masayuki Watanabe, Yosuke Nishihata, Toru Arino, Masaki Okuyama, Tetsushi Wakiyama, Tomoko Kato, Yasuo Sasagawa, Takeshi Tana, Yoshihito Hayashi, Shinichi Hirota, Yukihiko Abe, Yoshihiro Saito, Hirohide Uchiyama, Hiroshi Takeda, Hiroshi Ono, Shuichi Tohyo, Naoto Hanazono, Seiichi Miyajima, Hisashi Shimono, Takuma Aoyama, Yasunobu Shozawa, Yawara Niijima, Osamu Murai, Osamu Murai, Hideko Inaba, Katsumasa Nomura, Masatsugu Nozoe, Kazuo Suzuki, Toshiyuki Furukawa, Toshihiko Shiraiwa, Nobuhisa Ito, Shunichi Nagai, Kiyoharu Sato, Shiro Nakahara, Yujin Shimoyama, Naoko Ohara, Teruhiko Kozuka, Hideaki Okita, Masato Endo, Tsutomu Goto, Makoto Hirose, Emiko Nagata, Noriyuki Nakanishi, Toshizumi Mori, Shuichi Seki, Katsuhiro Okamoto, Osamu Moriai, Yoko Emura, Tsuyoshi Fukuda, Haruhiko Date, Shuichi Kawakami, Sho Nagai, Yuya Ueyama, Tetsuro Fudo, Mitsuru Imaizumi, Takuo Ogawa, Shunsuke Take, Hideo Ikeda, Hiroaki Nishioka, Norihiko Sakamoto, Kiyomitsu Ikeoka, Nobuo Wakaki, Masatake Abe, Junji Doiuchi, Tetsuya Kira, Masato Tada, Ken Tsuzaki, Naoya Miura, Yasuaki Fujisawa, Wataru Furumoto, Susumu Suzuki, Akinori Fujisawa, Ryosai Nakamura, Hiroyasu Komatsu, Rei Fujiki, Shuichi Kawano, Keijiro Nishizawa, Yoji Kato, Junya Azuma, Kiyoshi Yasui,Toshio Amano, Yasuhiro Sekine, Tatsuo Honzawa, Yuichiro Koshibu, Yasuhide Sakamoto, Yukihiro Seta, Shingo Miyaguchi, Kojuro Morishita, Yasuko Samejima, Toyoshi Sasaki, Fumiko Iseki, Toshiyuki Kobayashi, Hiroshi Kano, Jaeyoung Kim, Hiroshi Yamaguchi, Yoichi Takagi, Yoko Onuki Pearce, Yasuyuki Suzuki, Takayuki Fukui, Toru Nakayama, Hideaki Kanai, Yoshiyuki Kawano, Tetsuji Ino, Hironori Miyoshi, Yasufumi Miyamoto, Masahito Shigekiyo, Shimato Ono, Yoshiyuki Kawano, Yutaka Okamoto, Satoshi Ubukata, Kojiro Kodera, Tatsuo Oriuchi, Naoki Matsumoto, Koichi Inagaki, Atsushi Iseki, Tomohiro Yoshida, Toshihiro Goda, Tsukasa Katsuki, Atsushi Sato, Etsuo Mori, Toshio Tsubokura, Hiroshi Shudo, Shunichi Fujimoto, Tomohiro Katsuya, Yoshiyuki Furukawa, Hiroshi Hosokawa, Jun Narumi, Kiichiro Yamamoto, Masaki Owari, Takuya Inakura, Takafumi Anno, Kazuyuki Shirakawa.

Singapore

Chi Keong Ching, Toon Wei Lim, David Foo, Kelvin Wong, Tan Yuyang.

South Korea

Seil Oh, Hui Nam Park, Woo-Shik Kim, HyeYoung Lee, Sung-Won Jang, Dae Hyeok Kim, Jun Kim, DongRyeol Ryu, Jaemin Shim, Dae-Kyeong Kim, Dong Ju Choi, Yong Seog Oh, Myeong-Chan Cho, Hack-Lyoung Kim, Hui-Kyung Jeon, Dong-Gu Shin, Sang Weon Park, Hoon Ki Park, Sang-Jin Han, Jung Hoon Sung, Hyung-Wook Park, Gi-Byoung Nam, Young Keun On, Hong Euy Lim, JaeJin Kwak, Tae-Joon Cha, Taek Jong Hong, Seong Hoon Park, Jung Han Yoon, Nam-Ho Kim, Kee-Sik Kim, Byung Chun Jung, Gyo-Seung Hwang, Chong-Jin Kim.

Thailand
Sakda Rungaramsin, Peerapat Katekangplu, Porames Khunrong, Thanita Bunyapipat, Wanwarang Wongcharoen, Pinij Kaewsuwanna, Khanchai Siriwattana, Waraporn Tiyanon, Supalerk Pattanaprichakul, Khanchit Likittanasombat, Doungrat Cholsaringkarl, Warangkana Boonyapisit, Sirichai Cheewatanakornkul, Songkwan Silaruks, Pisit Hutayanon, Seksan Chawanadelert, Pairoj Chattranukulchai, Boonsert Chatlaong, Yingsak Santanakorn, Khompiya Kanokphatcharakun, Piya Mongkolwongroj, Sasivimon Jai-Aue, Ongkarn Komson.

Turkey
Armagan Altun, Ali Aydinlar, Ramazan Topsakal, Zeki Ongen, Sadik Acikel, Durmus Yildiray Sahin, Ozcan Yilmaz, Mehmet Birhan Yilmaz, Hasan Pekdemir, Mesut Demir, Murat Sucu, Levent Sahiner, Ali Oto, Murat Ersanli, Ertugrul Okuyan, Dursun Aras.

Argentina
Florencia Rolandi, Adrian Cesar Ingaramo, Gustavo Alberto Sambadaro, Vanina Fernandez Caputi, Hector Luciardi, Sofia Graciela Berman, Pablo Dragotto, Andres Javier Kleiban, Nestor Centurion, Rodolfo Andres Ahuad Guerrero, Leonel Adalberto Di Paola, Ricardo Dario Dran, Javier Egido, Matias Jose Fosco, Victor Alfredo Sinisi, Luis Rodolfo Cartasegna, Oscar Gomez Vilamajo, Jose Luis Ramos, Sonia Sassone, Gerardo Zapata, Diego Conde, Guillermo Giacomi, Alberto Alfredo Fernandez, Mario Alberto Berli, Fabian Ferroni.

Brazil
Dário Celestino Sobral Filho, Jefferson Jaber, Luciana Vidal Armaganijan, Costantino Roberto Frack Costantini, André Steffens, Weimar Kunz Sebba Barroso de Souzaem, João David de Souza Neto, José Márcio Ribeiro, Marcelo Silveira Teixeira, Paulo Rossi, Leonardo Pires, Daniel Moreira, José Carlos Moura Jorge, Adalberto Menezes Lorga Filho, Luiz Bodanese, Marcelo Westerlund Montera, Carlos Henrique Del Carlo, Jamil Abdalla Saad, Fernando Augusto Alves da Costa, Renato Lopes, Gilson Roberto de Araújo, Euler Roberto Manenti, Jose Francisco Kerr Saraiva, João Carlos Ferreira Braga, Alexandre Negri, Carlos Moncada, Dalton Precoma, Fernando Roquette, Gilmar Reis, Roberto Álvaro Ramos Filho,: Estêvão Lanna Figueiredo, Roberto Vieira Botelho, Cláudio Munhoz da Fontoura Tavares, Helius Carlos Finimundi, Adriano Kochi, César Cássio Broilo França, Fábio Alban, Guido Bernardo Aranha Rosito, João Batista de Moura Xavier Moraes Junior, Rogério Tadeu Tumelero, Lilia Maia,: Roberto Simões de Almeida, Ney Carter do Carmo Borges, Luís Gustavo Gomes Ferreira.

Chile
Ramón Corbalán, Benjamin Aleck Joseh Stockins Fernandez, Humberto Montecinos, Fernando Lanas, Martín Larico Gómez, Carlos Astudillo, Carlos Conejeros, Patricio Marin Cuevas, Alejandro Forero, Claudio Bugueño Gutiérrez, Juan Aguilar, Sergio Potthoff Cardenas, German Eggers, Cesar Houzvic, Carlos Rey, Germán Arriagada, Gustavo Charme Vilches.

Mexico
Carlos Jerjes Sanchez Diaz, Jesus Jaime Illescas Diaz, Raul Leal Cantu, Maria Guadalupe Ramos Zavala, Ricardo Cabrera Jardines, Nilda Espinola Zavaleta, Enrique Lopez Rosas, Guillermo Antonio Llamas Esperón, Gerardo Pozas, Ernesto Cardona Muñoz, Norberto Matadamas Hernandez, Adolfo Leyva Rendon, Norberto Garcia Hernandez, Manuel de los Rios Ibarra, Luis Ramon Virgen Carrillo,
David Lopez Villezca, Carlos Hernandez Herrera, Juan Jose Lopez Prieto, Rodolfo Gaona Rodriguez, Efrain Villeda Espinosa, David Flores Martinez, Jose Velasco Barcena, Omar Fierro Fierro, Ignacio Rodriguez Briones, Jose Luis Leiva Pons, Humberto Alvarez Lopez, Rafael Olvera Ruiz, Carlos Gerardo Cantu Brito, Eduardo Julian Jose Roberto Chuquiure Valenzuela, Roxana Reyes Sanchez, Alberto Esteban Bazzoni Ruiz, Oscar Martin Lopez Ruiz, Roberto Arriaga Nava, Jesus David Morales Cerda, Pedro Fajardo Campos, Mario Benavides Gonzalez.

Austria
Marianne Brodmann, Kurt Lenz, Claus Hagn, Johannes Foechterle, Heinz Drexel, Kurt Huber, Andrea Podczeck-Schweighofer, Michael Winkler, Bruno Schneeweiss, Alfons Gegenhuber, Wilfried Lang, Sabine Eichinger-Hasenauer, Peter Kaserer, Josef Sykora, Heribert Rasch, Bernhard Strohmer.

Belgium
Luc Capiau, Geert Vervoort, Bart Wollaert, Frank Cools, Geert Hollanders, Jan Vercammen, Dirk Faes, Yohan Balthazar, Marc Delforge, Olivier Xhaet, Harry Striekwold, John Thoeng, Kurt Hermans, Georges Mairesse, Wim Anné, Ivan Blankoff, Michel Beutels, Stefan Verstraete, Peter Vandergoten, Philippe Purnode, Pascal Godart, Tim Boussy, Philippe Desfontaines, Alex Heyse, Joeri Voet, Axel De Wolf.

Czech Republic
Eva Zidkova, Petr Jansky, Rudolf Spacek, Vilma Machova, Ondrej Ludka, Josef Olsr, Lubos Kotik, Blazej Racz, Richard Ferkl, Jan Hubac, Ilja Kotik, Zdenek Monhart, Hana Burianova, Ondrej Jerabek, Jana Pisova, Iveta Petrova, Vratislav Dedek, Michaela Honkova, Petr Podrazil, Petr Reichert, Jindrich Spinar, Miroslav Novak, Vaclav Durdil, Katarina Plocova, Jiri Lastuvka.

Denmark
Jørn Nielsen, Steen Husted, Helena Dominguez, Ulrik Hintze, Søren Rasmussen, Næstved Sygehus, Arne Bremmelgaard, John Markenvard, Jan Børger, Jorgen Solgaard, Ebbe Eriksen, Thomas Løkkegaard, Michael Bruun, Jacob Mertz, Morten Schou, Helena Dominguez, Michael Olsen.

Finland
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Germany
Sebastien Schellong, Harald Darius, Georg Koeniger, Andreas Kopf, Uwe Gerbaulet, Bernd-Thomas Kellner, Thomas Schaefer, Jan Purr, Enno Eißfeller, Heinz-Dieter Zauzig, Peter Riegel, Christoph Axthelm, Gerd-Ulrich Heinz, Holger Menke, Andreas Pustelnik, Stefan Zutz, Wolfgang Eder, Guenter Rehling, Dirk Glatzel, Norbert Ludwig, Petra Sandow, Henning Wiswedel, Cosmas Wildenauer, Steffen Schoen, Toralf Schwarz, Adyeri Babyesiza, Maximilian Kropp, Hans-Hermann Zimny, Friedhelm Kahl, Andreas Caspar, Sabine Omankowsky, Torsten Laessig, Hermann-Josef Hartmann, Gunter Lehmann, Hans-Walter Bindig, Gunter Hergdt, Dietrich Reimer, Joachim Hauk, Holger Michel, Praxis Dres. Werner Erdle, Wilfried Dorsch, Janna Dshabrailov, Karl-Albrecht Rapp, Reinhold Vormann, Thomas Mueller, Peter Mayer, Uwe Horstmeier, Volker Eissing, Heinz Hey, Heinz Leuchtgens, Volker Lilienweiss, Heiner Mueller, Christian Schubert, Herrmann Lauer, Thomas Buchner, Gunter Brauer, Susanne Kamin, Karsten Mueller, Sylvia Baumbach, Muwafeg Abdel-Qader, Hans-Holger Ebert, Carsten Schwencke, Peter Bernhardt, Laszlo Karolyi, Britta Sievers, Wilhelm Haverkamp, Jens-Uwe Roehnisch.

Hungary
Andras Vertes, Gabor Szantai, Andras Matoltsy, Nikosz Kanakaridisz, Zoltan Boda, Erno Kis, Balazs Gaszner, Ferenc Juhasz, Gizella Juhasz, Sandor Kancz, Zoltan Laszlo, Zsolt May, Bela Merkely, Ebrahim Noori, Tamas Habon, Peter Polgar, Gabriella Szalai, Sandor Vangel, Andras Nagy, Gabriella Engelthaler, Judit Ferenczi, Mihaly Egyutt.

Italy
Giuliana Martini, Leone Maria Cristina, Eros Tiraferri, Rita Santoro, Sophie Testa, Giovanni Di Minno, Marco Moia, Teresa Maria Caimi, Maria Tessitori, Giancarlo Agnelli, Roberto Cappelli, Daniela Poli, Roberto Quintavalla, Franco Cosmi, Raffaele Fanelli, Vincenzo Oriana, Raffaele Reggio, Roberto Santi, Leonardo Pancaldi, Raimondo De Cristofaro, Giuliana Guazzaloca, Angelo De Blasio, Jorge Salerno Uriate, Flavia Lillo, Enrico Maria Pogliani, Grzegorz Bilo, Michele Accogli, Antonio Mariani, Mauro Feola, Arturo Raisaro, Luciano Fattore, Andrea Mauric, Fabrizio Germini, Luca Tedeschi, Maria Settimi, Sergio Nicoli, Paolo Ricciarini, Antonio Argena, Paolo Ronchini, Claudio Bulla, Filippo Tradati, Massimo Volpe, Maria D'Avino, Maria Grazia Bongiorni, Silva Severi, Alessandro Capucci, Corrado Lodigiani, Enrico Salomone, Gaetano Serviddio, Claudio Tondo, Giuseppe Ambrosio, Paolo Golino, Carmine Mazzone, Saverio Iacopino.

The Netherlands
Hugo ten Cate, J.H. Ruiter, Andreas Lucassen, Henk Adriaansen, Maarten Bongaerts, Mathijs Pieterse, Coen van Guldener, Johannes Herrman, S.H.K. P.R. Nierop, Pieter Hoogslag, Walter Hermans, B.E. Groenemeijer, W. Terpstra, Cees Buiks, L.V.A. Boersma.

Norway
Eivind Berge, Per Anton Sirnes, Erik Gjertsen, Torstein Hole, Knut Erga, Arne Hallaråker, Gunnar Skjelvan, Anders Østrem, Beraki Ghezai, Arne Svilaas, Peter Christersson, Torbjørn Øien, Svein Høegh Henrichsen, Jan Erik Otterstad, Jan Berg-Johansen.

Poland
Janina Stepinska, Andrzej Gieroba, Malgorzata Biedrzycka, Michal Ogorek, Beata Wozakowska-Kaplon, Krystyna Loboz-Grudzien, Jaroslaw, Wieslaw Supinski, Jerzy Kuzniar, Roman Zaluska, Jaroslaw Hiczkiewicz, Lucyna Swiatkowska-Byczynska, Lech Kucharski, Marcin Gruchala, Piotr Minc, Maciej Olszewski, Grzegorz Kania, Malgorzata Krzciuk, Zbigniew Lajkowski, Bozenna Ostrowska-Pomian, Jerzy Lewczuk, Elzbieta Zinka, Agnieszka Karczmarczyk, Malgorzata Chmielnicka-Pruszczynska, Iwona Wozniak-Skowerska, Grzegorz Opolski, Marek Bronisz, Marcin Ogorek, Grazyna Glanowska, Piotr Ruszkowski, Grzegorz Skonieczny, Ryszard Sciborski, Boguslaw Okopien, Piotr Kukla, Krzysztof Galbas, Krzysztof Cymerman, Jaroslaw Jurowiecki, Pawel Miekus, Waldemar Myszka, Stanislaw Mazur, Roman Lysek, Jacek Baszak, Teresa Rusicka-Piekarz, Grzegorz Raczak, Ewa Domanska, Jadwiga Nessler, Jozef Lesnik.

Russia
Vera Eltishcheva, Roman Libis, Gadel Kamalov, Dmitry Belenky, Liudmila Egorova, Alexander Khokhlov, Eduard Yakupov, Dmitry Zateyshchikov, Olga Barbarash, Olga Miller, Evgeniy Mazur, Konstantin Zrazhevskiy, Tatyana Novikova, Yulia Moiseeva, Elena Polkanova, Konstantin Sobolev, Maria Rossovskaya, Yulia Shapovalova, Alla Kolesnikova, Konstantin Nikolaev, Oksana Zemlianskaia, Anna Zateyshchikova, Victor Kostenko, Sergey Popov, Maria Poltavskaya, Anton Edin,
Elena Aleksandrova, Oksana Drapkina, Alexander Vishnevsky, Oleg Nagibovich, Petr Chizhov, Svetlana Rachkova, Mikhail Sergeev, Borys Kurylo, Alexey Ushakov.

Spain
Xavier Vinolas, Pere Alvarez Garcia, Maria Fernanda Lopez Fernandez, Luis Tercedor Sanchez, Salvador Tranche Iparraguirre, Pere Toran Monserrat, Emilio Marquez Contreras, Jordi Isart Rafecas, Juan Motero Carrasco, Pablo Garcia Pavia, Casimiro Gomez Pajuelo, Luis Miguel Rincon Diaz, Luis Fernando Iglesias Alonso, Angel Grande Ruiz, Jordi Merce Klein, Jose Ramon Gonzalez Juanatey, Ines Monte Collado, Herminia Palacin Piquero, Carles Brotons Cuixart, Esther Fernandez Escobar, Joan Bayo i Llibre, Cecilia Corros Vicente, Manuel Vida Gutierrez, Francisco Epelde Gonzalo, Carlos Alexandre Almeida Fernandez, Encarnacion Martinez Navarro, Jordi Isart Rafecas, Juan Jose Montero Alia, Maria Barreda Gonzalez, Maria Angels Moleiro Oliva, Jose Iglesias Sanmartin, Mercedes Jimenez Gonzalez, Maria del Mar Rodriguez Alvarez, Juan Herreros Melenchon, Tomas Ripoll Vera, Manuel Jimenez Navarro, Maria Vazquez Caamano, Maria Fe Arcocha Torres, Gonzalo Marcos Gomez, Andres Iniguez Romo, Miguel Angel Prieto Diaz.

Sweden

Mårten Rosenqvist, Alexander Wirdby, Centrumkliniken, Jan Lindén, Kerstin Henriksson, Micael Elmersson, Arnor Egilsson, Ulf Börjesson, Gunnar Svärd, Bo Liu, Anders Lindh, Lars-Bertil Olsson, Mikael Gustavsson, Lars Andersson, Lars Benson, Claes Bothin, Ali Hajimirsadeghi, Björn Martinsson, Marianne Ericsson, Åke Ohlsson, Håkan Lindvall, Peter Svensson, Katarina Thörne, Hans Händel, Pyotr Platonov, Fredrik Bernsten, Ingar Timberg, Milita Crisby, Jan-Erik Karlsson, Agneta Andersson, Lennart Malmqvist, Johan Engdahl, Jörgen Thulin, Aida Hot-Bjelak, Steen Jensen, Per Stalby.

Switzerland
Jan Steffel, Johann Debrunner, Juerg H. Beer, Dipen Shah.

Ukraine
Iurii Rudyk, Vira Tseluyko, Oleksandr Karpenko, Svitlana Zhurba, Igor Kraiz, Oleksandr Parkhomenko, Iryna Kupnovytska, Nestor Seredyuk, Yuriy Mostovoy, Oleksiy Ushakov, Olena Koval, Igor Kovalskiy, Yevgeniya Svyshchenko, Oleg Sychov, Mykola Stanislavchuk, Andriy Yagensky, Susanna Tykhonova, Ivan Fushtey.

United Kingdom
Will Murdoch, Naresh Chauhan, Daryl Goodwin, Louise Lumley, Ramila Patel, Philip Saunders, Bennett Wong, Alex Cameron, Philip Saunders, Niranjan Patel, P Jhittay, Andrew Ross, M S Kainth, Karim Ladha, Kevin Douglas, Gill Pickavance, Joanna McDonnell, Laura Handscombe, Trevor Gooding, Helga Wagner, Cumberlidge, Colin Bradshaw, Catherine Bromham, Kevin Jones, Shoeb Suryani, Richard Coates, Bhupinder Sarai, W Willcock, S Sircar, John Cairns, A Gilliand, Roman Bilas, E Strieder, Peter Hutchinson, Anne Wakeman, Michael Stokes, Graham Kirby, Bhaskhar Vishwanathan, Nigel Bird, Paul Evans, M Clark, John Bisatt, Jennifer Litchfield, E Fisher, Tim Fooks, Richard Kelsall, Neil Paul, Elizabeth Alborough, Michael Aziz, C Ramesh, Pete Wilson, Simon Franklin, Sue Fairhead, Julian Thompson, Hasan Chowan, Gary Taylor, Dawn Tragen, Matt Parfitt, Claire Seamark, Carolyn Paul, Mark Richardson, Angus Jefferies, Helen Sharp, Hywel Jones, Claire Giles, Matthew Bramley, Philip Williams, Jehad Aldegather, Simon Wetherell, William Lumb, Phil Evans, Frances Scouller, Neil Macey, Stephen Rogers, Yvette Stipp, Richard West, Philip Pinney, Paul Wadeson, John Matthews, Preeti Pandya, Andrew Gallagher, T Railton, Emyr Davies, Jonathan McClure, Marc Jacobs, Claire Hutton, R Thompson, Bijoy Sinha, Keith Butter, Susan Barrow, Helen Little, David Russell, Ulka Choudhary, Ikram Haq, Paul Ainsworth, Claire Jones, Phil Weeks, Jane Eden, Lisa Gibbons, Janet Glencross, Alison MacLeod, K Poland, Conor Mulolland, A Warke, Paul Conn, D Burns, R Smith, R Kamath, Jonathan Webster, Ian Hodgins, Stephen Vercoe, Paul Roome, Hilary Pinnock, Jayesh Patel, Amar Ali, Nigel Hart, Richard Davies, Nigel De-Sousa, Catherine Neden, Mark Danielsen, Purnima Sharma, Sophia Galloway, Charlotte Hawkins, Raife Oliver, Martin Aylward, Mira Pattni, Gordon Irvine, Shahid Ahmad, Catherine Rothwell, Fiaz Choudhary, Sabrina Khalaque, Stephanie Short, Sharon Peters, Warwick Coulson, Neil Roberts, Amy Butler, Steven Coates, Ben Ward, Daniel Jackson, Steve Walton, Diane Shepherd, Toh Wong, Mark Boon, Melanie Deacon, David Cornelius, Sarah Davies, Ben Frankel, Nick Hargreaves, Henry Choi, Jon Sumner, Tim Myhill, Salah Estifanos, Diane Geatch, Justin Wilkinson, Richard Veale, Karen Forshaw, Rob Hirst, Kashif Zaman, Catherine Liley, Rebecca Wastling, Paul McEleny, Andre Beattie, Philip Cooke, Mike Wong, Mark Pugsley, Chaminda Dooldeniya, Greg Rogers, James Bennett, Polly Jacobs, Rajesh Muvva, Matthew Adam, Robin Fox, Nicolas Thomas, Simon Cartwright, Rory Reed, Simon Randfield, Christine A'Court, Ann Flynn, Andrew Halpin, Shoeb Suryani, Simon Dobson, Louise Lomax, Minnal Nadaph, Iain Munro, Jane Goram, Helen Stoddart, Phil Simmons, John Shewring, Emma Bowen-Simpkins, Mark Rickenbach, Polly Jacobs.

Australia
Adam Blenkhorn, Bhuwanendu Singh, Penny Astridge, William van Gaal, Walter Abhayaratna, Philip Thomson, Ron Lehman, Jens Kilian, David Coulshed, Andrei Catanchin, David Colquhoun, Hosen Kiat, David Eccleston, John French, Bronte Ayres, Peter Blombery, Thanh Phan, James Rogers, David O'Donnell, Sang Cheol Bae, Harry Gibbs, Patrick Carroll, Greg Starmer, Margaret Arstall, Maurits Binnekamp, Astin Lee.

Canada
John Eikelboom, Robert Luton, Milan Gupta, Amritanshu Shekhar Pandey, Stephen Cheung, Rolland Leader, Philippe Beaudry, Félix Ayala-Paredes, Joseph Berlingieri, John Heath, Germain Poirier, Miranda du Preez, Bradley Schweitzer, Reginald Nadeau, Ripple Dhillon, Tomasz Hruczkowski, Andrea Lavoie, Ratika Parkash, James Cha, Benoit Coutu, Paul MacDonald, Brian Ramjattan, Jorge Bonet, Saul Vizel, Paul Angaran, Sameh Fikry.

Egypt
Ahmed Mowafy, Azza Katta, Mazen Tawfik, Moustafa Nawar, Mohamed Sobhy, Seif Kamal Abou Seif, Tarek Khairy, Ahmed Abd El-Aziz, Nasser Taha, Ashraf Reda, Atef Elbahry, Mohamed Setiha, Mohamed Gamal El Din, Magdi Elkhadem, Adel El-Etreby.

South Africa
David Kettles, Junaid Bayat, Heidi Siebert, Adrian Horak, Ynez Kelfkens, Riaz Garda, Barry Jacobson, Thayabran Pillay, Michele Guerra, Louis van Zyl, Hendrik Theron, Andrew Murray, Rikus Louw, Deon Greyling, Pindile Mntla, Siddique Ismail, Fayzal Ahmed, Johannes Engelbrecht, Shambu Maharajh, Wessel Oosthuysen, Rehana Loghdey, Veronica Ueckermann.

United Arab Emirates
Wael Al Mahmeed, Abdullah Al Naeemi, Ghazi Yousef, Nooshin Bazargani, Munther AlOmairi, Rajan Maruthanayagam, Rupesh Singh, Ahmed Naguib, Mohamed Ibrahim, Amrish Agrawal, Mukesh Nathani, Ehab M. Esheiba, Adel Wassef, Rajeev Gupta.

United States
Michael Cox, Scott Beach, Peter Duffy, Stephen Falkowski, Kevin Ferrick, Miguel Franco, W. Michael Kutayli, Annette Quick, Niraj Sharma, Vance Wilson, Stephen Miller, Mark Alberts, Edwin Blumberg, Roddy Canosa, Ted Gutowski, Rodney Ison, Jorge Garcia, Paul Mullen, Howard Noveck, Pamela Rama, Rajneesh Reddy, Marcus Williams, Daniel Nishijima, Keith Ferdinand, Ihsan Haque, Robert Mendelson, Sridevi Pitta, Daniel Theodoro, Charles Treasure, Moustafa Moustafa, Cas Cader, Walter Pharr, Alisha Oropallo, George Platt, Jaspal Gujral, James Welker, Firas Koura.

GARFIELD-AF Ethics Committee List

Sponsor	Protocol #	Project Code	Region	Sub-Region	Country	Submission Requirement Type	Authority/Committee Name
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	RA	CCIS Comision Conjunta de Investigacion en Salud
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	RA	CCIS Comision Conjunta de Investigacion en Salud
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	RA	CCIS Comision Conjunta de Investigacion en Salud
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	RA	CCIS Comision Conjunta de Investigacion en Salud
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	CEC	Comite Independiente de Etica
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Argentina	Others	
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Australia & New Zealand	Australia	Central IRB	Metro South Health Service District Human Research Ethics Committee
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Australia & New Zealand	Australia	Central IRB	University of Wollongong & Illawarra HREC
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Australia & New Zealand	Australia	Central IRB	
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Australia & New Zealand	Australia	Central IRB	Metro South Health Service District Human Research Ethics Committee
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Austria	CEC	Ethikkommission der Medizinischen Universität Graz

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Belgium	CEC	Ethisch Comité UZA
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Brazil	CEC	
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Brazil	CEC	
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Brazil	CEC	
Thrombosis Research Institute	TRI08888	IPAA4663	USA/Canada	Canada	Canada	Central IRB	WIRB
Thrombosis Research Institute	TRI08888	IPAA4663	USA/Canada	Canada	Canada	Central IRB	WIRB
Thrombosis Research Institute	TRI08888	IPAA4663	USA/Canada	Canada	Canada	Central IRB	WIRB

Thrombosis Research Institute	TRI08888	IPAA4663	USA/Canada	Canada	Canada	Central IRB	WIRB
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	South America	Chile	RA	Instituto de Salud Pública de Chile
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Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Czech Republic	RA	Statni ustav pro kontrolu leciv
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Denmark	CEC	De Videnskabsetiske Komitéer for Region Hovedstaden
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Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Denmark	CEC	De Videnskabsetiske Komitéer for Region Hovedstaden
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Denmark	CEC	De Videnskabsetiske Komitéer for Region Hovedstaden
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Denmark	CEC	De Videnskabsetiske Komitéer for Region Hovedstaden
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Denmark	CEC	De Videnskabsetiske Komitéer for Region Hovedstaden
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Finland	CEC	Pirkanmaan sairaanhoitopiirin eettinen toimikunta
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Finland	CEC	Pirkanmaan sairaanhoitopiirin eettinen toimikunta
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Finland	CEC	Pirkanmaan sairaanhoitopiirin eettinen toimikunta
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Finland	CEC	Pirkanmaan sairaanhoitopiirin eettinen toimikunta
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	France	CEC	Comité Consultatif sur le Traitement de l'information Recherche/Santé
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	CEC	Egeszsegugyi Tudomanyos Tanacs Tudomanyos es Kutatasetikai Bizottsag
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	Orszagos Gyogyszereszteti es Elelmezes-egszsegugyi Intezet
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Hungary	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	India Region	India	RA	Directorate General of Health Services (India)
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	India Region	India	RA	Directorate General of Health Services (India)

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Italy	CEC	Comitato Etico delle Aziende Sanitarie dell'Umbria di Perugia
Thrombosis Research Institute	TRI08888	IPAA4663	Japan	Japan	Japan	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Japan	Japan	Japan	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Southeast Asia	Korea, Republic of	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)

Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)

Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Latin America	Central America	Mexico	RA	COFEPRIS - Comision de Autorizacion Sanitaria (Mexico)
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Netherlands	CEC	
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Norway	CEC	REK Sør-øst
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Norway	CEC	REK Sør-øst
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Poland	CEC	Terenowa Komisja Bioetyczna przy Instytucie Kardiologii
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Russian Federation	CEC	IIC of Ethic Assessment of Clinical Researches
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Southeast Asia	Singapore	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Africa	South Africa	RA	MCC - Medicines Control Council (South Africa)
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Africa	South Africa	RA	MCC - Medicines Control Council (South Africa)

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Africa	South Africa	RA	MCC - Medicines Control Council (South Africa)
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Spain	CEC	CEIC Hospital Universitario Virgen de la Victoria
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Spain	CEC	CEIC Hospital Universitario Virgen de la Victoria
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm

Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Sweden	CEC	Regionala etikprövningsnämnden i Stockholm
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Western Europe	Switzerland	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Asia Pacific	Southeast Asia	Thailand	RA	
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Turkey	CEC	Malatya Klinik Arastirmalar Etik Kurulu
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Turkey	RA	Turkish Ministry of Health
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Turkey	CEC	Malatya Klinik Arastirmalar Etik Kurulu
Thrombosis Research Institute	TRI08888	IPAA4663	Europe/Middle East/Africa-EMEA	Eastern Europe/Middle East	Ukraine	CEC	Central Ethics Commission of the Ministry of Health of Ukraine

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