ORIGINAL RESEARCH

Impact of Spontaneous Extracranial Bleeding Events on Health State Utility in Patients with Atrial Fibrillation: Results from the ENGAGE AF-TIMI 48 Trial

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***Background*—**The impact of different types of extracranial bleeding events on health-related quality of life and health-state utility among patients with atrial fibrillation is not well understood.

***Methods and Results*—**The ENGAGE AF-TIMI 48 (Effective Anticoagulation With Factor Xa Next Generation in Atrial Fibrillation–Thrombolysis in Myocardial Infarction 48) Trial compared edoxaban with warfarin with respect to the prevention of stroke or systemic embolism in atrial fibrillation. Data from the EuroQol-5D (EQ-5D-3L) questionnaire, prospectively collected at 3-month intervals for up to 48 months, were used to estimate the impact of different categories of bleeding events on health-state utility over 12 months following the event. Longitudinal mixed-effect models revealed that major gastrointestinal bleeds and major nongastrointestinal bleeds were associated with significant immediate decreases in utility scores (−0.029 [−0.044 to −0.014; $P<0.001$] and −0.029 [−0.046 to −0.012; $P=0.001$], respectively). These effects decreased in magnitude over time, and were no longer significant for major nongastrointestinal bleeds at 9 months, but remained borderline significant for major gastrointestinal bleeds at 12 months. Clinically relevant nonmajor and minor bleeds were associated with smaller but measurable immediate impacts on utility (−0.010 [−0.016 to −0.005] and −0.016 [−0.024 to −0.008]; $P<0.001$ for both), which remained relatively constant and statistically significant over the 12 months following the bleeding event.

***Conclusions*—**All categories of bleeding events were associated with negative impacts on health-state utility in patients with atrial fibrillation. Major bleeds were associated with relatively large immediate decreases in utility scores that gradually diminished over 12 months; clinically relevant nonmajor and minor bleeds were associated with smaller immediate decreases in utility that persisted over 12 months.

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Key Words: anticoagulation • bleeding • quality of life • utility

Contemporary management of atrial fibrillation (AF) imposes many challenges. Anticoagulation in patients with AF involves a careful balance between maximizing the benefit with respect to the prevention of stroke while minimizing the bleeding risk. Several novel oral anticoagulants have been approved and released on the market as

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An accompanying Tables S1, S2, and Appendix S1 is available at http://jaha.ahajournals.org/content/6/8/e006703/DC1/embed/inline-supplementary-material-1.pdf

*A complete list of the ENGAGE AF-TIMI 48 Trial Investigators is provided in Appendix S1.

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Clinical Perspective

What Is New?

- The impact of different types of extracranial bleeding events on health-state utility among patients with atrial fibrillation was examined using data from the ENGAGE AF-TIMI 48 (Effective Anticoagulation With Factor Xa Next Generation in Atrial Fibrillation–Thrombolysis in Myocardial Infarction 48) trial.
- Compared with clinically relevant nonmajor and minor bleeds, major gastrointestinal and nongastrointestinal bleeds were associated with larger immediate decrements in utility scores that decreased gradually over the year following the bleeding event and were no longer statistically significant at 12 months.
- In contrast, clinically relevant and minor bleeding events were associated with smaller but statistically significant initial decreases in utility that persisted for 12 months.

What Are the Clinical Implications?

- These findings have potential use in future studies of the net clinical benefit and cost-effectiveness of alternative strategies for stroke prevention in patients with atrial fibrillation.

alternatives to warfarin in recent years; in a meta-analysis, the novel oral anticoagulants significantly reduced stroke/systemic embolic event (SEE), mortality and intracranial hemorrhage (ICH), while gastrointestinal bleeding was increased.[1] Relative to warfarin, the novel oral anticoagulants have the additional benefit of greater ease of use.

Prior studies have revealed that patients with AF have impaired quality of life (QOL) and that QOL scores are influenced by age, sex, and baseline medical conditions.[2–6] Few studies have examined the impact of adverse events such as bleeding on QOL in patients with AF[7] and little is known about the impact of different types of bleeding events on QOL, and whether and how that impact changes over time. Insight into the impact of different categories of nonfatal bleeding events on health-state utility in patients with AF receiving oral anticoagulant therapy may provide a framework to improve understanding of the net clinical benefit and cost-effectiveness of novel oral anticoagulant therapies relative to warfarin.

The ENGAGE AF-TIMI 48 (Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation-Thrombolysis in Myocardial Infarction 48) Trial was a 3-arm, randomized, double-blind, double-dummy trial comparing 2 once-daily dose regimens of edoxaban (higher dose [60 mg] and lower dose [30 mg]) to warfarin with respect to the prevention of stroke or systemic embolism in patients with AF. We used data from ENGAGE AF-TIMI 48 to examine the impact of different categories of extracranial bleeding events on health-state utility scores for patients with AF, and how the impact of bleeding events on health-state utility changes over time since the event.

Methods

Study Population

The design, methods, and clinical results of the ENGAGE AF-TIMI 48 trial have been described previously.[8,9] Briefly, patients from 1393 centers in 46 countries were enrolled between November 2008 and November 2010. Eligible patients were randomly assigned in a 1:1:1 ratio to receive warfarin, dose-adjusted to achieve an international normalized ratio of 2.0 to 3.0 or to receive higher-dose 60 mg, or lower-dose 30-mg edoxaban regimens; the dose of edoxaban in each arm was reduced by 50% in patients with anticipated increased exposure based on creatinine clearance, body weight, and concomitant permeability glycoprotein inhibitor use. Patients with a high risk of bleeding such as history of prior ICH, major bleeding or peptic ulcer disease within 1 year, hemorrhagic disorders, thrombocytopenia, need for dual antiplatelet therapy, severe renal failure, moderate or severe hepatic insufficiency, active infective endocarditis, uncontrolled hypertension (blood pressure >170/100 mm Hg), or recent severe trauma, major surgery, or deep organ biopsy within the previous 10 days, were all excluded. The study was approved by the institutional review board at each site, and all patients provided written informed consent before participation.

Quality of Life Assessments

Quality of life was assessed using the self-administered EuroQol 5 Dimension questionnaire, which was completed at baseline and at 3-month intervals for up to 4 years (median 2.8 years) by a subsample of ≈80% of patients from the overall trial population. The EuroQol 5 Dimension questionnaire is a generic health status measure consisting of 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) that can be converted to utilities using an algorithm developed for the US population.[10] Utilities are preference-based health status measures and range from 0 to 1, with 1 representing perfect health and 0 corresponding to the worst imaginable health state.[11] The EuroQol 5 Dimension questionnaire has been extensively validated and frequently used to assess health-state utility and health-related QOL in health economic studies for patients with cardiovascular disease.[12] For the purposes of this study, only patients who had baseline and at least 1 follow-up QOL assessment were included in the study population.

Bleeding End Points

The primary safety end point in ENGAGE AF–TIMI 48 was adjudicated major bleeding. Spontaneous bleeding events requiring medical attention were adjudicated by an independent and blinded clinical events committee, according to prespecified criteria as defined by the International Society on Thrombosis and Haemostasis.[13] The specific event categories included major gastrointestinal bleeding, major nongastrointestinal bleeding, and clinically relevant nonmajor (CRNM) bleeding. Major bleeds include symptomatic bleeding in a critical area or organ, such as intraspinal, intraocular, retroperitoneal, intraarticular, or pericardial, or intramuscular with compartment syndrome and/or bleeding causing a decrease in hemoglobin level of 2 g/dL (1.24 mmol/L) or more, or leading to transfusion of 2 or more units of whole blood or red blood cells. CRNM bleeds are acute or subacute clinically overt bleeds that do not meet the criteria for major bleed but prompt a clinical response, in that they lead to at least 1 of the following: a hospital admission for bleeding; a physician-guided medical or surgical treatment for bleeding; or a change in antithrombotic therapy (including interruption or discontinuation of study drug). Bleeding events that did not require medical attention were classified as minor bleeding, without clinical events committee adjudication.

Statistical Analysis

Baseline clinical and demographic characteristics and QOL scores were compared between patients included versus excluded from this QOL study, and within the QOL study between those with versus without bleeding events, using 2-sample Student *t* tests for continuous variables and χ^2 or Fisher exact tests for categorical variables. Standardized differences, assuming a threshold of 10% for a clinically meaningful difference,[14] were calculated for the comparison of baseline characteristics in the study sample versus those patients excluded from the analysis, in order to evaluate the importance of statistically significant differences given the large sample sizes in both groups.[15] Longitudinal mixed effect models were used to examine the impact of different categories of bleeding events on QOL scores by modeling bleeding events as time-varying covariates.[16] These models incorporate all available health status data from all follow-up time points, and accommodate missing data under the assumption of missing at random. Variables included in the models were baseline QOL score, bleeding status, and time relative to the bleeding event. Linear, quadratic, and cubic effects of follow-up time were considered, as well as all corresponding interactions between follow-up time and bleeding status. The interactions between bleeding status and time elapsed since the bleeding events were added to the models to assess any changes in the impact of bleeding events over time. In addition, age, sex, and all other baseline clinical characteristics listed in Table were included in the model development. The models were optimized using a backward selection process and only variables with $P<0.1$ were retained.

To avoid potential confounding of other vascular events on the estimated impact of bleeding events on QOL outcomes, patients who experienced any stroke, transient ischemic attack, myocardial infarction, or systemic embolic event were censored on the date of the first thrombotic event. In addition, patients who experienced multiple bleeding events of either the same or different types were censored on the date of the second bleeding event. Any QOL measures on or after the date of censoring were thereby excluded from the analysis.

All analyses were performed using SAS for Windows version 9.4 (SAS Institute, Cary, NC), and a 2-tailed $P<0.05$ was considered statistically significant for all comparisons.

Results

Patient Population and Baseline QOL

A total of 21 105 patients were enrolled in the ENGAGE AF–TIMI 48 trial, of whom 10 706 had baseline and at least 1 follow-up EQ-5D collected. Most of the standardized differences between the patients included versus excluded from the QOL study were <10%; only the standardized differences in creatinine clearance, CHADS2 score, dyslipidemia, and hypertension were slightly higher than 10% (Table S1). These results suggest no substantial difference between the 2 cohorts. Patients excluded specifically because of having no follow-up QOL assessments (n=236) had lower mean baseline EQ-5D utility scores than those included in the analysis (0.836 versus 0.808, $P=0.004$); because the analysis adjusts for baseline score, this is unlikely to impact our findings. There were 2492 patients in the QOL study population for whom a spontaneous nonintracranial bleed was reported as a first event; 207 of these were major gastrointestinal bleeds, and 152, 1419, and 714 were major nongastrointestinal, CRNM, and minor bleeds, respectively. One hundred thirty-seven ICH were observed in the study population, though only 23 of these ICH events were the first event for the patient; therefore, ICH bleed was not analyzed because of small sample size.

For each bleeding category, patients with versus without a bleeding event were older and more likely to have a history of non-ICH bleeding history and prior coronary artery bypass graft at baseline (Table). Baseline EQ-5D utility scores did not differ for patients with versus without a bleeding event. Completeness of QOL data collection was high (>90%)

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Table. Demographic and Clinical Characteristics of the Patients

Characteristic	Major GI Bleeding			Major Non-GI Bleeding*			CRNM Bleeding			Minor Bleeding		
	Event (N=207)	No Event† (N=9801)	*P* Value	Event (N=152)	No Event† (N=9836)	*P* Value	Event (N=1419)	No Event† (N=8874)	*P* Value	Event (N=714)	No Event† (N=9418)	*P* Value
Age, y, mean±SD	74.6±8.6	70.3±9.5	<0.001	73.6±8.8	70.4±9.5	<0.001	72.1±9.2	70.2±9.5	<0.001	72.3±9.2	70.3±9.5	<0.001
Male	61.4	61.5	0.974	69.7	61.4	0.035	60.2	61.7	0.291	61.9	61.4	0.777
Previous use of vitamin K antagonist	64.7	58.8	0.084	64.5	58.8	0.156	62.6	58.2	0.001	67.1	58.4	<0.001
Diabetes mellitus	38.2	36.6	0.639	40.8	36.5	0.281	38.3	36.4	0.159	40.9	36.3	0.014
Dyslipidemia	57.5	54.7	0.421	58.6	54.6	0.335	58.4	54.3	0.003	65.4	54.0	<0.001
Hypertension	95.2	95.0	0.933	95.4	95.1	0.853	93.9	95.2	0.051	94.1	95.1	0.252
Prior MI	13.5	11.3	0.328	11.8	11.3	0.848	11.6	11.5	0.883	10.8	11.4	0.632
Prior stroke	16.4	18.3	0.485	17.8	18.3	0.864	18.3	18.3	0.952	17.1	18.4	0.401
Prior transient ischemic attack	11.1	12.2	0.649	12.5	12.1	0.895	13.5	12.0	0.107	14.8	12.1	0.031
Prior PAD	7.7	4.2	0.014	3.9	4.3	0.849	4.2	4.2	0.996	4.8	4.2	0.503
Congestive heart failure	61.8	60.0	0.584	48.0	60.1	0.002	51.2	61.1	<0.001	47.9	60.6	<0.001
Prior CAD	38.8	33.5	0.106	37.5	33.5	0.303	35.5	33.4	0.120	35.3	33.5	0.338
Prior CABG	14.0	7.3	<0.001	13.8	7.4	0.002	10.0	7.2	<0.001	14.8	7.1	<0.001
History of ICH bleed	0.0	0.1	1.000	0.0	0.1	1.000	0.2	0.1	0.407	0.1	0.1	0.584
History of non-ICH bleed	17.4	9.0	<0.001	13.2	9.0	0.078	16.8	8.3	<0.001	16.1	8.8	<0.001
History of gastrointestinal bleed	5.8	3.0	0.018	4.6	3.0	0.225	5.1	2.8	<0.001	5.3	2.9	<0.001
Creatinine clearance in mg/dL, mean±SD	69.4±28.4	79.1±32.4	<0.001	76.2±38.7	78.9±32.2	0.307	76.1±31.0	79.2±32.5	<0.001	76.8±31.1	79.1±32.5	0.074
CHADS2 score (0–6), mean±SD	3.0±1.1	2.8±1.0	0.004	2.9±1.0	2.9±1.0	0.259	2.9±1.0	2.8±1.0	0.386	2.9±1.0	2.9±1.0	0.488
EuroQol-5D utility, mean±SD	0.821±0.166	0.837±0.152	0.147	0.843±0.159	0.837±0.152	0.619	0.843±0.147	0.836±0.153	0.110	0.833±0.163	0.837±0.152	0.522

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; CHADS2, scoring system for the long-term risk of stroke in atrial fibrillation: acronym stands for Congestive heart failure, Hypertension, Age≥75y, Diabetes mellitus, and prior Stroke; CRNM, clinically relevant nonmajor; EuroQol 5 Dimension questionnaire; GI, gastrointestinal; ICH intracranial hemorrhage; MI, myocardial infarction; PAD, peripheral arterial disease.

*Only extracranial bleeds are included.

†The sample sizes for the "no event" categories differ according to the category of bleed because of censoring in data selection. All results are % of patients unless otherwise specified.

throughout the entire study period among the 10 706 patients who were included in this analysis (Table S2), although it tended to be slightly lower for patients with versus without major gastrointestinal bleeding events beginning at the 6-month follow-up and thereafter.

Impact of Bleeding on Quality of Life

After adjusting for baseline score and clinical and demographic characteristics, results from the longitudinal mixed effect models revealed that all categories of bleeding events were associated with a significant immediate reduction in EQ-5D utility (Figure). Major gastrointestinal and nongastrointestinal bleeding events had similar immediate impacts on utility (−0.029 [95% CI: −0.044–0.014; $P<0.001$] and −0.029 [95% CI: −0.046 to −0.012; $P=0.001$], respectively). CRNM and minor bleeding events were associated with smaller but measurable immediate impacts on utility (−0.010 [95% CI: −0.016 to −0.005; $P<0.001$] and −0.016 [95% CI: −0.024 to −0.008; $P<0.001$], respectively).

Figure demonstrates the estimated impact of bleeding over time, for each of the categories of bleeding events. For major gastrointestinal and nongastrointestinal bleeds, the impact on utility scores consistently decreased in magnitude over time; while the impact of major nongastrointestinal bleeds was no longer statistically significant at 9 months, the impact of major gastrointestinal bleeds on utility scores remained borderline significantly (−0.011 points, $P=0.058$) at 12 months. The impacts of CRNM and minor bleeding events on utility were smaller but persisted throughout 12 months with no clear temporal trend.

Discussion

Bleeding is the most common complication associated with anticoagulation management in patients with AF. The frequent (3-month intervals) assessment of QOL with the EQ-5D questionnaire in the ENGAGE AF—TIMI 48 trial allowed us to estimate the impact of extracranial bleeding events on health-state utility over the course of 12 months following the event. All categories of bleeding events were associated with significant immediate decreases in EQ-5D utility. Compared with CRNM and minor bleeds, major gastrointestinal and nongastrointestinal bleeds were associated with larger immediate decrements in utility scores that decreased gradually over the year following the bleeding event and were no longer statistically significant at 12 months. In contrast, CRNM and minor bleeding events were associated with smaller but statistically significant initial decreases in utility that persisted for 12 months. The persistence of this decrease is unexpected, and may be because of unmeasured confounding in the population that experiences minor bleeds. The larger relative magnitude of the impact of minor versus CRNM bleeds on utility may be related to the fact that by definition, CRNM bleeding events require some degree of medical intervention, whereas minor bleeding events do not.

To put the estimated immediate disutilities associated with major, CRNM, and minor bleeding events of −0.020, −0.010, and −0.016 from our study in context, a study of complication-specific changes in utility based on longitudinal data from patients with type 2 diabetes mellitus reported decreases in EQ-5D-derived utility scores ranging from −0.026, −0.045, and −0.049 for myocardial infarction, congestive heart failure, and renal failure, to −0.083, −0.099, and −0.122 for

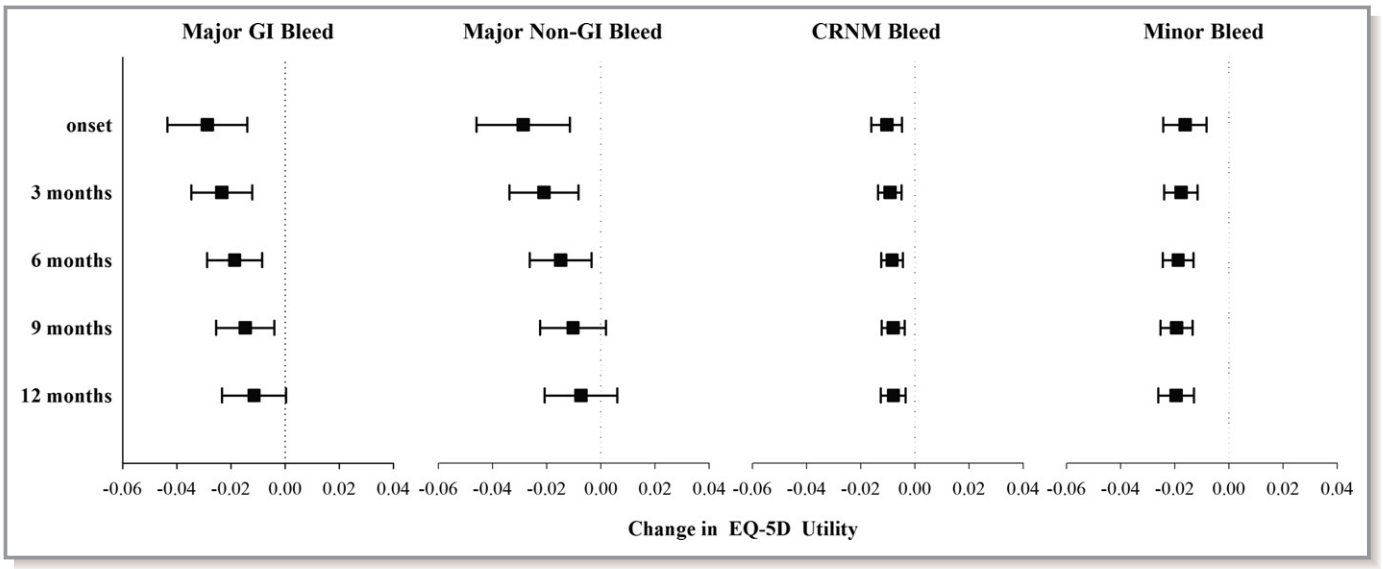

Figure. Estimated impact of bleeding events on EQ-5D utility. EQ-5D indicates EuroQol 5 Dimension questionnaire; GI, gastrointestinal; CRNM, clinically relevant nonmajor.

blindness, stroke, and amputation, respectively.[17] The estimated immediate decreases in EQ-5D utility scores with bleeding events from our study are comparable to estimates reported in other studies involving other patient populations. For example, using data from the TRANSLATE-ACS (Treatment With Adenosine Diphosphate Receptor Inhibitors: Longitudinal Assessment of Treatment Patterns and Events After Acute Coronary Syndrome) study, Amin et al[18] reported that among patients who underwent percutaneous coronary intervention for acute myocardial infarction, bleeding events, classified according to the Bleeding Academic Research Consortium (BARC) criteria, that occurred between discharge and 6 months postacute myocardial infarction were associated with a mean reduction in utility scores of 0.033 points at 6 months. More severe bleeding events (BARC types 3 or 4) were associated with larger decrements in utility (−0.045 points), whereas even minor bleeds (BARC type 1) were associated with smaller but still detectable decreases in utility. A similar finding was observed for patients with acute myocardial infarction with respect to nuisance bleeding, which was found to be independently associated with worse QOL at 1 month.[19] Our study is unique, however, given its examination of the trajectory of QOL outcomes over 12 months following the bleeding event. The lack of statistical significance with respect to the estimated utility decrements at 9 months for major nongastrointestinal bleeds and at 12 months for major gastrointestinal and major nongastrointestinal bleeds may be because of the relatively small number of events (207 and 152 major gastrointestinal and nongastrointestinal bleeds, respectively, as compared with 1419 and 714 CRNM and minor bleeds, respectively) or survivor bias resulting from a higher death rate for patients with more severe bleeds.

These estimates of the pattern of utility changes over time for bleeding events in patients with AF have implications for the estimation of quality-adjusted life years in cost-effectiveness studies. In recent years, studies of the cost-effectiveness of anticoagulation or other approaches to stroke prevention in patients with AF have generally applied utility estimates from a limited number of available sources including the Beaver Dam Health Outcomes Study and the national catalog of preference-based scores for chronic conditions in the United States.[20–26] However, both of these sources are based on data obtained from general community populations, and therefore the utility/disutility estimates may not pertain to patients with AF. Moreover, in cost-effectiveness analyses, the impact of bleeding events is often assumed to be transient.[23,24,27] For example, published cost-effectiveness analyses comparing apixaban and edoxaban versus warfarin assumed disutilities of −0.1511 lasting 2 weeks for major extracranial hemorrhage, −0.0582 lasting 2 days for CRNM bleeds, and −0.013 lasting 2 days for minor bleeds.[28,29] Even with the assumption of no impact on utility beyond 1 year for all categories of extracranial bleeds, results from the current study suggest that disutilities for all categories of bleeds from the patient's perspective may be greater in magnitude than previously assumed. This could have an impact for the evaluation of net clinical benefit, comparative effectiveness, and cost-effectiveness evaluation of alternative anticoagulation strategies, for which chronic utility and temporary disutility weights are or might be used to combine different clinical events into a common metric.

Results from an analysis of data from the RE-LY trial examining the impact of therapy with dabigatran versus warfarin on health-state utility in patients with no major clinical events found no evidence to suggest that the relative complexity and inconveniences of management with warfarin versus dabigatran yielded any measurable decrement in health-state utility.[30] The double-blind double-dummy design of the ENGAGE AF-TIMI 48 trial precluded us from exploring the impact of international normalized ratio monitoring and dose adjustment on QOL in our analysis.

Study Limitations

This study should be considered in light of several important limitations. The ENGAGE AF-TIMI 48 trial enrolled subjects with AF at medium or high risk of thromboembolic events, and excluded subjects with AF caused by a reversible disorder, severe renal dysfunction, a high risk of bleeding, and moderate or severe mitral stenosis. Our results may not apply to patients outside of the select enrolled trial population. The EuroQol 5 Dimension questionnaire is a simple, generic health status questionnaire, for which each of the 5 component domains is measured on a 3-level scale (indicating no problem, some or moderate problem, and extreme problem); as a result it may have limited ability to delineate minor but important clinical differences in health status. Despite adjustment for potential confounders in all models, there remains the possibility of unmeasured confounding. The exclusion of patients with no or limited QOL information might introduce the possibility of selection bias. Since we observed slightly more missing data in patients with a major gastrointestinal bleed, it is possible that the missing data could affect our results if the assumption of missing at random does not hold, though this seems unlikely given the high rate of QOL data collection across all bleeding categories and follow-up time points. This study considered only the first bleeding event within a patient; thus the results may not accurately relate to the impact of a second bleeding event of either the same or different type on health-state utility.

Conclusions

In summary, in this large-scale prospective study of patients with AF, we found that all categories of bleeding events were

associated with measurable immediate decreases in health-state utility. Major gastrointestinal and nongastrointestinal bleeds had relatively large immediate decrements, which decreased in magnitude over time and were no longer statistically significant at 12 months. CRNM and minor bleeding events were associated with smaller initial decrements in utility that remained statistically significant and relatively consistent in magnitude through 12 months after the bleeding event. Collectively, these findings have potential use in future studies of the net clinical benefit and cost-effectiveness of alternative strategies for stroke prevention in patients with AF.

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Disclosures

Dr Kwong is an employee of Daiichi Sankyo. Dr Antman reports receiving grant support through his institution from Daiichi Sankyo. Dr Ruff reports receiving consulting fees from Daiichi Sankyo, Bristol-Myers Squibb, and Boehringer Ingelheim and grant support through his institution from Daiichi Sankyo. Dr Giugliano reports receiving consulting fees from Daiichi Sankyo, Janssen Pharmaceuticals, and Merck; lecture fees from Bristol-Myers Squibb, Daiichi Sankyo, Merck, and Sanofi; and grant support through his institution from Daiichi Sankyo, Merck, Johnson & Johnson, Sanofi, and AstraZeneca. Dr Cohen reports receiving institutional grant support from Daiichi Sankyo. Dr Magnuson reports receiving institutional grant support and consulting fees from Daiichi Sankyo. The remaining authors have no disclosures to report.

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Supplemental Material

Table S1. Demographic and clinical characteristics between patients in the study population and those excluded from analysis*

Characteristic	Study population (N=10706)	Patients excluded (N=10399)	Standardized Difference (%)
Age, years, (mean ± SD)	70.6 ± 9.5	70.6 ± 9.3	0.8
Male	61.4	62.4	2.0
Previous use of vitamin K antagonist	59.1	58.8	0.5
[Diabetes mellitus	36.7	35.5	2.4
Dyslipidemia	55.1	49.6	11.1
Hypertension	94.9	92.3	10.8
Prior MI	11.6	11.5	0.3
Prior Stroke	18.3	19.0	1.9
Prior transient ischemic attack	12.4	10.9	4.7
Prior PAD	4.3	3.7	3.2
Congestive heart failure	59.5	55.4	8.2
Prior CAD	34.1	32.5	3.4
Prior CABG	8.0	5.8	8.6
History of ICH bleed	0.1	0.2	1.6
History of non-ICH bleed	9.9	9.8	0.2
History of gastrointestinal bleed	3.2	2.8	8.1
Creatinine clearance in mg/dL, (mean ± SD)	78.6 ± 32.4	74.9 ± 30.4	11.8
CHADS2 score (0-6) , (mean ± SD)	2.9 ± 1.0	2.8 ± 0.9	10.2

**All results are % of patients unless otherwise specified.*

GI indicates gastrointestinal; CRNM, clinically relevant non-major, SD, standard deviation; PAD, peripheral arterial disease; CAD, coronary artery disease; CABG, coronary artery bypass graft; ICH intracranial hemorrhage, CHADS2, scoring system for the long-term risk of stroke in atrial fibrillation, acronym stands for Congestive heart failure, Hypertension, Age>75, Diabetes mellitus, and prior Stroke

Table S2. Quality of life compliance by bleeding status

Time (month)	Major GI bleeding			Major non-GI bleeding			CRNM bleeding			Minor bleeding		
	Event (N=207)	No event* (N=9801)	p-value	Event (N=152)	No event* (N=9836)	p-value	Event (N=1419)	No event* (N=8874)	p-value	Event (N=714)	No event* (N=9418)	p-value
3	100.0	100.0	1.000	100.0	100.0	1.000	100.0	100.0	1.000	100.0	100.0	1.000
6	86.5	93.9	< 0.001	93.4	93.8	0.811	94.3	93.4	0.192	95.4	93.7	0.069
9	86.8	93.4	< 0.001	91.3	93.4	0.311	94.7	93.0	0.020	93.9	93.3	0.481
12	89.7	93.8	0.015	93.2	93.8	0.748	93.8	93.6	0.743	94.5	93.7	0.405
15	90.6	93.8	0.059	95.2	93.8	0.498	94.8	93.5	0.071	93.3	93.8	0.607
18	90.9	94.2	0.051	95.1	94.2	0.634	93.7	94.1	0.559	93.7	94.2	0.608
21	90.8	94.1	0.054	91.5	94.1	0.190	94.2	94.0	0.713	93.9	94.0	0.941
24	89.7	94.4	0.005	90.8	94.4	0.065	94.7	94.1	0.381	93.3	94.3	0.278
27	92.6	94.8	0.195	95.0	94.8	0.910	93.9	94.8	0.188	94.3	94.7	0.622
30	89.7	94.6	0.008	94.7	94.6	0.941	94.4	94.5	0.884	94.7	94.5	0.897
33	87.3	95.4	< 0.001	95.2	95.3	0.797	94.7	95.4	0.436	95.5	95.3	0.838
36	90.5	96.0	0.030	95.6	96.0	0.700	94.7	96.1	0.163	96.7	95.9	0.540
39	85.7	95.5	0.022	100.0	95.3	1.000	94.3	95.7	0.345	96.6	95.2	0.453
42	88.2	93.4	0.321	100.0	93.5	1.000	93.8	93.6	0.937	93.1	93.7	0.776
45	100.0	94.3	1.000	100.0	94.5	1.000	93.9	94.0	1.000	95.0	94.7	1.000
48	100.0	84.6	1.000		85.7	NA	100.0	80.0	0.523	100.0	84.6	1.000

***** *the sample sizes for the "no event" categories differ according to the category of bleed due to censoring at the time of events. All results are % of patients.*

GI indicates gastrointestinal, CRNM, clinically relevant non-major

Appendix

The members of the Operations, Executive, Steering, Data Monitoring, Clinical Events Committees, countries, participating centers, Principal Investigators, and Primary Study Coordinators of the ENGAGE AF-TIMI 48 trial were as follows:

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Steering Committee: *Argentina* – E. Paolasso (deceased); *Australia* – P. Aylward; *Belgium* – H. Heidbuchel; *Brazil* – J.C. Nicolau; *Bulgaria* – A. Goudev; *Canada* – D. Roy, J. Weitz; *Chile* – R. Corbalán; *China* – Y. Yang; *Colombia* – R. Botero; *Croatia* – M. Bergovec; *Czech Republic* – J. Ŝpinar; *Denmark* – P. Grande, C. Hassager; *Estonia* – J. Voitk; *Finland* – H. Huikuri, M. Nieminen; *France* – J.J. Blanc, J.Y. LeHeuzey; *Germany* – V. Mitrovic; *Greece* – D. Alexopoulos; *Guatemala* – G. Sotomora; *Hungary* – R. Kiss; *India* – B. SomaRaju; *Israel* – B. Lewis; *Italy* – P. Merlini, M. Metra; *Japan* – Y. Koretsune, T. Yamashita; *Mexico* – A. García-Castillo; *Netherlands* – T. Oude Ophuis; *New Zealand* – H. White; *Norway* – D. Atar; *Peru* – M. Horna; *Philippines* – N. Babilonia; *Poland* – W. Ruzyllo; *Portugal* – J. Morais; *Romania* – M. Dorobantu; *Russian Federation* – M. Ruda; *Serbia* – M. Ostojic; *Slovakia* – T. Duris; *South Africa* – A. Dalby; *South Korea* – N. Chung; *Spain* – J.L. Zamorano; *Sweden* – S. Juul-Möller; *Switzerland* – T. Moccetti; *Taiwan* – S.A. Chen; *Thailand* – P. Sritara; *Turkey* – A. Oto; *Ukraine* – A. Parkhomenko; *United Kingdom* – R. Senior.

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Canada- 774 patients 54 centers

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d'investigation clinique de la Mauricie, Trois-Rivières, QC; S Lam, H Lam, Calgary West Medical Centre, Calgary, AB; T Lichtenstein, P Roberts, The Medical Arts Health Research Group, Kelowna, BC; R Luton, S Douglas, London, ON; P Ma, M Seib, Heart Health Institute, Calgary, AB; C MacCallum, J Matthews, Eastern Health, St. John's, NL; P Malette, T Vaillancourt, Medicor Research Incorporated, Sudbury, ON; C Maranda, E Studenikow, Cardiology and Research, Westmount, QC; A Mawji, A Morely, Pharmaceutical Integrated Research Company, London, ON; D Morrison, M Roth, Beamsville Medical Centre, Beamville, ON; M Mucha, J Krider, Trainyards Health and Wellness Center, Ottawa, ON; A Najarali, U Lamoureux, PIRC Research Office- Brampton, Brampton, ON; R Nicholson, A Morely, Pharmaceutical Integrated Research Company, Kitchener, ON; G O'Hara, P Banville, Quebec Heart Institute, Quebec City, QC; W O'Mahony, R Bolton, Corunna Medical Research Center, Corunna, ON; R Parkash, L Carroll, Queen Elizabeth II Health Sciences Centre, Halifax, NS; Y Pesant, V Sardin, Recherche Médicale St-Jérôme Incorporated, St-Jérôme, QC; P Polasek, L Turri, Kelowna Cardiology Research, Kelowna, BC; A Qureshi, C Nethercott, PIRC Research Office- Brampton, Listowel, ON; J Ricci, B Bozek, Scarborough Cardiology Research, Scarborough, ON; D Rupka, C Marchand, Fraser Clinical Trials Incorporated, New Westminster, BC; D Shu, G Silverio, Gain Medical Centre, Coquitlam, BC; R St-Hilaire, A Morissette, Centre Hospitalier Beauce-Etchemin, Saint-Georges, QC; J Sussman, P Kailey, Toronto, ON; G Syan, C Bobbie, G.S. Cardiac Lab Medicine Professional Corp., Sudbury, ON; M Talajic, D David, Montreal Heart Institute, Montreal, QC; P Talbot, M Tremblay, Centre de Recherche Clinique de Québec, Québec, QC; I Teitelbaum, J Teitelbaum, JJ Dig Research, Toronto, ON; G Velthuysen, L Giesbrecht, Holley Clinic, Quesnel, BC; R Wahby, A Morley, Dorchester Medical Center, Dorchester, ON; S Wharton, T Caterini, The Wharton Medical Clinic Clinical Trials, Hamilton, ON; T Woodford, J Mabee, Pharmaceutical Integrated Research Company, Liverpool, NS.

Chile- 254 patients 14 centers

W Balboa, L Retamal Matus, Hospital Victoria, Victoria; C Bugueño, P Mondaca Mondaca, Hospital San Juan de Dios La Serena, La Serena; J Cobos, C Obreque, Hospital El Pino, Santiago; **R Corbalan**, A Parada, Hospital Clinico Pontificia Universidad Catolica de Chile, Santiago; F Florenzano, P Arratia Diaz, Hospital del Salvador, Santiago; M Lopetegui, C Rebolledo, Hospital San Borja Arriaran, Santiago; L Manriquez, L Manríquez Silva, Hospital Regional de Rancagua, Rancagua; D Martinez,R Romero Llamas, Clinica Iquique, Iquique; M Opazo, M Carmona Pérez, Hospital Naval Almirante Nef, Viña del Mar; C Pincetti, G Torres Carrasco, Centro de Investigacion Clinica del Sur, Temuco; S Potthoff, J Zapata Staub, Corporacion de Beneficencia Osorno, Osorno; M Rodriguez, Y Campisto, Hospital Dr. Sotero del Rio, Santiago; B Stockins, C Lara Lara, Hospital Dr. Hernan Henriquez Aravena, Temuco; P Yovaniniz, M Grandon Azua, Hospital Barros Luco Trudeau, Santiago.

China- 469 patients 33 centers

F Bai, GL Xu, The Second Hospital of Lanzhou University, Lanzhou; JZ Chen, XD Xie, The First Affiliated Hospital of College of Medicine, Zhejiang University, Hangzhou; XP Chen, X Zhang, West China Hospital, Sichuan University, Chengdu; YG Dong, C Feng, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou; GS Fu, P Zhang, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, Hangzhou; K Hong, ZG You, The Second Affiliated Hospital of Nanchang University, Nanchang; L Hong, Y Qiu, Renmin Hospital of Jiang Xi Province, Nanchang; XJ Jiang, Z Qu, Ren Min Hospital of Wu Han University, Wuhan; L Li, H Liu, The First Affiliated Hospital of Guangxi Medical University, Nanning; TF Li, YQ Kong, The Affiliated Hospital of Hainan Medical College, Haikou; WM Li, B Liu, The

1st Affiliated Hospital of Harbin Medical University, Harbin; ZQ Li, Y Liu, People's Hospital of Liaoning Province, Shenyang; DN Liao, XJ Gu, Changzheng Hospital, The Second Military Medical University, Shanghai; L Liu, ZH Lu, The People's Hospital of Guangxi Zhuang Autonomous Region, Nanning; SM Ma, ZY Yang, Shengjing Hospital of China Medical University, Shengyang; DM Wang, SY Qi, Bethune International Peace Hospital, Shijiazhuang; GP Wang, XJ Shi, The First Hospital Affiliated to Liaoning Medical College, Jinzhou; M Wei, D Huang, Shanghai No.6 People's Hospital, Shanghai; SL Wu, YE Li, Guangdong Provincial People's Hospital, Guangzhou; JH Xu, JY Gu, Tong Ji Hospital of Tongji University, Shanghai; YM Xu, YZ Liang, The 2nd Hospital of Tianjin Medical University, Tianjin; K Yang, AY Li, The Third Xiangya Hospital of Central South University, Changsha; **YJ Yang**, X Zheng, Cardiovascular Institute & Fuwai Hospital Chinese Academy of Medical Sciences, Beijing; Y Zheng, M Gao, The First Hospital of Jilin University, Changchun; YH Yin, YP Xu, The Second Affiliated Hospital of Chongqing Medical University, Chongqing; B Yu, LL Li, The 2nd Affiliated Hospital of Harbin Medical University, Harbin; ZY Yuan, H Qiang, The 1st Hospital Affiliated to Xi'an Medical University, Xian; HQ Zhang, YN Lin, The 1st Affiliated Hospital of Wenzhou Medical College, Wenzhou; Z Zhang, H Kang, The 1st Hospital Affiliated to Lanzhou University, Lanzhou; RP Zhao, RJ Han, Baotou Central Hospital, Baotou; XL Zhao, JQ Wang, Beijing Tong Ren Hospital Affiliated to Capital Medical University, Beijing; ZQ Zheng, BG Li, The First Affiliated Hospital of NanChang University, Nanchang; SX Zhou, YL Zhang, The Second Affiliated Hospital of Zhongshan University, Guangzhou.

Colombia- 141 patients 11 centers

J Accini, M Accini, Consultorio Privado-Jose Luis Accini, Baranquilla; N Cano, L León Pineda, Hospital Santa Sofia, Manizales; J Delgado Restrepo, C Arroyave, Instituto Corbic, Medellín; R Fernández Ruiz, I Aldana Diaz, Clinica Cardiovascular Santa Maria, Medellin; H Hernandez, P Delgado, Instituto Corazon de Bucaramanga, Bucaramanga; C Jaramillo Muñoz, A Builes, Promotora Medica Las Americas SA, Medellin; F Manzur, E Rivera Rodriguez, Centro de diagnostico cardiologico Ltda, Cartagena; M Moncada Corredor, D Lopez Giraldo, Fundacion Centro de Investigacion Clinica CIC, Medellín; L Orozco Linares, J Fonseca, Foqus LTDA, Bogotá Cundinamarca; A Quintero, C Gonzales, Fundación del Caribe para la Investigación Biomédica, Barranquilla; G Sanchez Vallejo, I Perdomo Mejia, Centro de Estudios Clinicos del Quindio, Armenia.

Croatia- 127 patients 11 centers

J Bagatin, V Carevic, Clinical Hospital Centre Split, Split; S Car, M Jeric, General Hospital Varazdin, Varazdin; N Ciglenecki, S Tusek, Special Hospital for Medical Rehabilitation, Krapinske Toplice; J Ferri Certic, I Romic, General Hospital Dubrovnik, Dubrovik; I Francetic, K Makar Ausperger, University Hospital Center Zagreb, Zagreb; V Jelic, S Jaksic Jurinjak, General Hospital Karlovac, Karlovac; A Knezevic, B Buksa, General Hospital Zadar, Zadar; P Samardzic, K Cvitkusic Lukenda, General Hospital Dr. J. Bencevic, Slavonski Brod; R Steiner, D Kirner, Clinical Hospital Osijek, Osijek; K Sutalo, Z Bakliza, General Hospital Dr.Tomislav Bardek, Koprivnica; H Vrazic, **M Bergovec**, T Lucijanic, University Hospital Dubrava, Zagreb.

Czech Republic- 1173 patients 39 centers

M Bar, P Brodova, Neurologicka ambulance Bormed, Ostrava- Trebovice; L Berka, V Kunkelova, Ordinace pro choroby srdce a cev, Jindrichuv Hradec; M Brtko, M Brtko, Fakultni nemocnice Hradec Kralove, Hradec Kralove; H Burianova, H Burianova, Poliklinika Humanitas, Bilovec; O Cermak, O Cermak, Nemocnice Slany, Slany; L Elbl, L Elbl, Kardiologicka

ordinace, Brno- Lesna; R Ferkl, R Ferkl, Interni ambulance, Trutnov; J Florian, J Florian, Nemocnice Cesky Krumlov, Cesky Krumlov; L Francek, L Francek, Kromerizska nemocnice a.s., Kromeriz; L Golan, L Golan, Kardiologie, Revnice; P Gregor, P Gregor, Fakultni nemocnice Kralovske Vinohrady, Praha; M Honkova, M Honkova, Kardiologicka a interni ambulance, Praha 1; J Hubac, J Hubac, Interni ambulance, Chrudim; J Jandik, J Jandik, Oblastni nemocnice Nachod, Nachod; P Jarkovsky, P Jarkovsky, Ustredni vojenska nemocnice Praha, Praha 6; Z Jelinek, Z Jelinek, Nemocnice Hranice a.s., Hranice; O Jerabek, O Jerabek, Poliklinika RAVAK, Pribram 8; R Jirmar, R Jirmar, Poliklinika Malešice, Praha 10; R Kobza, R Kobza, Mediscan s.r.o., Praha 11; M Kochrt, G Kostkova, Interni ordinace, Teplice; Z Kosek, Z Kosek, Kardiologicka ambulance, Mlada Boleslav; P Kovar, P Kovar, Poliklinika Modrany, Praha 4; R Kuchar, R Kuchar, INNEra s.r.o., Benesov; J Kvasnicka, J Kvasnicka, Kardiologicka ambulance, Praha 10; O Ludka, O Ludka PhD., Privatni interni ambulance, Brno; V Machova, E Krocova, InterKardioML s.r.o., Marianske Lazne; M Melichar, M Melichar, Interni ambulance, Pardubice; R Nechanicky, R Nechanicky, Nemocnice s poliklinikou Semily, Semily; J Olsr, J Olsr, General practitioner s.r.o., Ostrava; K Peterka, K Peterka, Nemocnice Havlickuv Brod p.o., Havlickuv Brod; I Petrova, I Havlova, Kardiologicka ambulance, Usti nad Labem; J Pisova, J Pisova, Kardiologicka ambulance, Hradec Kralove; P Podrazil, E Jirsova, Interni ambulance, Praha 6; P Reichert, P Reichert, Krajska zdravotni a.s.Nemocnice Teplice p.o., Teplice; J Slaby, J Slaby, Oblastni nemocnice Kolin, Kolin; R Spacek, R Spacek, Nemocnice Na Frantisku, Praha 1; **J Spinar**, R Labrova, FN Brno- Bohunice, Brno; P Vodnansky, D Samkova, Kardiologicka ordinace, Pardubice; E Zidkova, E Zidkova, Ordinace interniho lekarstvi, Praha 5.

Denmark- 219 patients 11 centers
K Dodt, Horsens Sygehus, Horsens; H Christensen, L Christensen, Bispebjerg Hospital, København NV; C Hassager, A Loof, Rigshospitalet, København Ø; H Ibsen, H Madsen, Holbæk Sygehus, Holbæk; H Iversen, T Veng-Olsen, Glostrup Hospital, Glostrup; H Nielsen, R Olsen, Bispebjerg Hospital, København NV; K Overgaard, V Petrovic, Herlev Hospital, Herlev; I Raymond, D Raae, Frederiksberg Hospital, Fredriksberg; N Sand, A Svenningsen, Sydvestjyds Sygehus Esbjerg, Esbjerg; C Torp-Pedersen, U Jakobsen, Gentofte Hospital, Hellerup; H Wiggers, K Serup-Hansen, Skejby Sygehus- Aarhus University Hospital, Aarhus N.

Estonia- 191 patients 6 centers
J Kaik, A Stern, Fertilitas AS, Haabneeme; R Kolk, R Kolk, Tartu University Hospital, Tartu; E Laane, L Rivis, Orthopaedic and Clinical Research Center, Tartu; M Paumets, **J Voitk**, M Laheäär, North Estonia Medical Centre Foundation, Talinn; A Rosenthal, R Rajasalu,Tallinn; V Vahula, E Ratnik, Pärnu Hospital, Pärnu.

Finland- 42 patients 7 centers
H Huikuri, S Kaarleenkaski, Oulun yliopistollinen sairaala, Oulu; E Hussi, S Valpas, Etelä-Karjalan keskussairaala, Lappeenranta; P Jäkälä, T Lappalainen, Itä-Suomen yliopisto Kuopion kampus Kliininen tutkimuskesk, Kuopio; A Mäenpää, J Viitaniemi, Seinäjoen keskussairaala, Seinäjoki; K Nyman, T Sankari, Keski-Suomen keskussairaala, Jyväskylä; H Rasi, O Salminen, Terveystalo Tampere, Tampere; V Virtanen, H Nappila, Finn-Medi 1, Tampere.

France- 110 patients 14 centers
J Le Heuzey, Hôpital Européen Georges Pompidou, Paris, 75; B Agraou, F El Jarroudi, Centre Hospitalier Général, Valenciennes, 59; P Amarenco, P Boursin, Hopital Bichat, Paris, 75; D Babuty, M Boyer, Hopital Trousseau, Tours Cedex, 37; A Belhassane, F El Jarroudi, Centre

Hospitalier de Cambrai, Cambrai, 59; H Berbari, H Berbari, Hopital d'Instruction des Armees Percy, Clamart Cedex, 92**; J Blanc**, P Dias, Chu de Brest- Hôpital de la Cavale Blanche, Brest Cedex, 29; D Coisne, N Berger, Chu Poitiers- Hôpital de la Milètrie, Poitiers, 86; E Decoulx, M El Jarroudi, CH Chatiliez Tourcoing, Tourcoing, 59; S Dinanian, M Arfaoui, Hopital Antoine Beclere, Clamart, 92; J Hermida, E Deruche, Centre Hospitalier Sud, Amiens, 80; S Kacet, S Corbut, Hospital Cardiologique Chru Lille, Lille Cedex, 59; J Poulard, S Leparree, Centre Hospitalier d'Abbeville, Abbeville, 80; R Roudaut, C Duprat, Hôpital du Haut l'Eveque (Cardiologie), Pessac, 33.

Germany- 913 patients 55 centers

A Al-Zoebi, A Wurow, Kardiologische Praxis, Wermsdorf, SN; P Bernhardt, U Dichristin, Universitaetsklinikum Ulm, Ulm, BW; J Berrouschot, S Vierbeck, Klinikum Altenburger Land, Altenburg, TH; J Beyer-Westendorf, B Sehr, Universitaetsklinikum Dresden, Dresden, SN; M Bouzo, P Schnelzer, Muenchen, BY; R Braun, K Ladenburger, Unterschneidheim, BW; M Buhr, D Weihrauch, Kardiologische Praxen im Spreebogen, Berlin, BE; C Contzen, M Kara, Synexus ClinPharm International GmbH, Frankfurt, HE; W Daut, D Ayasse, Kallstadt, RP; E Degtyareva, P Kranz, Synexus ClinPharm International GmbH, Leipzig, SN; T Drescher, B Herfurth, Gemeinschaftspraxis, Stuhr, HB; M Faghih, M Faghih, Hausarztzentrum, Essen, NW; K Forck-Boedeker, K Schneider, pro scientia med, Luebeck, SH; R Fuchs, W Manuela, Orgamed System Fuchs & Partner KG, Giengen, BW; C Grigat, A Otto, Clinical Research Hamburg GmbH, Hamburg, HH; A Hartmann, M Peitz, Klinikum St. Georg Leipzig, Leipzig, SN; H Heuer, U Dieckheuer, St. Johannes Hospital- PS, Dortmund, NW; U Hoffmann, S Dorn, Universitaetsklinikum Mannheim, Mannheim, BW; S Hoffmann, M Schuppe, Vivantes Klinikum im Friedrichshain, Berlin, BE; T Horacek, P Fink, Evangelisches Krankenhaus, Witten, NW; J Junggeburth, S Schmid, Bad Woerrishofen, BY; W Jungmair, B Schoen, Kardiologische Praxis, Bad Homburg, HE; U Kleinecke-Pohl, P Meusel, Gemeinschaftspraxis Kleinecke-Pohl Kirsch Benner-Hemsen, Koeln, NW; H Koenig, F Bauch, Synexus Clinical Research GmbH, Berlin, BE; H Koenig, F Bauch, Synexus ClinPharm International GmbH, Potsdam, BR; I Lohrbaecher-Kozak, B Grosse, Synexus Clinical Research GmbH, Dresden, SN; S Lueders, U Venneklaas, St. Josefs-Hospital, Cloppenburg, NI; M Luttermann, M Wulf, Wardenburg, NI; O Maus, K Hoefer, Innomed Leipzig GmbH, Leipzig, SN; G Meissner, U Braemer, Synexus ClinPharm International GmbH, Magdeburg, ST; U Meyer-Pannwitt, E Frahm, Mare Klinikum, Kiel, SH; **V Mitrovic,** S Vogt, Kerckhoff Klinik GmbH, Bad Nauheim, HE; A Muegge, S Barbera, St. Josef-Hospital- PS, Bochum, NW; M Mueller-Glamann, K Raddatz, Gemeinschaftspraxis Drs. Krohn/Mueller-Glamann, Hamburg, HH; R Piechatzek, D Lewinsky, Synexus ClinPharm International GmbH, Goerlitz, SN; W Pohl, W Pohl, Gemeinschaftspraxis Dr. Al-Nakkash Dr. W. Pohl Dr. C Pohl, Dresden, SN; N Proskynitopoulos, M Kuhlmann, Gemeinschaftspraxis, Nienburg, NI; K Rack, H Pilipenko, Internistische Praxis, Augsburg, BY; A Rinke, A Kühlenborg, Synexus ClinPharm International GmbH, Bochum, NW; A Schaefer, N Szymanowski, Essen, NW; S Schellong, R Frommhold, Staedtisches Klinikum Dresden-Friedrichstadt, Dresden, SN; I Schenkenberger, T Finsterbusch, K Dreykluft, Klinische Forschung Berlin, Berlin, BE; C Schiewe, C Schiewe, Hamburg, HH; A Schmidt, M Schmidt, Offenbach, HE; A Schreckenberg, J Hellmers, Internistische Praxisgemeinschaft, Weyhe, NI; H Seibert, G Gold, Kassel, HE; H Sohn, M Baylacher, Ludwig-Maximilians-Universitaet, Muenchen, BY; S Spitzer, K Bonin, Facharztzentrum Dresden-Neustadt GBR, Dresden-Neustadt, SN; R Stoehring, R Stoehring, Kardiologische Praxis, Bad Homburg, HE; J Taggeselle, C Zarpentin, Markkleeberg, SN; R Veltkamp, I Ludwig, Universitaetsklinikum Heidelberg, Heidelberg, BW; Voehringer, M Buchholz, DRK Kliniken

Berlin Westend, Berlin, BE; K Weyland, Ingelheim, RP; B Winkelmann, B Buelow-Johansen, ClinPhenomics GmbH & Co. KG, Frankfurt, HE; C Wolde, K Winter, Heidelberg, BW.

Greece- 51 patients 7 centers
D Alexopoulos, E Mavronasiou, Patras University Hospital, Patra; P Bourlios, A Tziortziotis, General Prefectural Hospital of Trikala, Trikala; C Karamitsos, E Exarchou, General Hospital of Larissa, Larissa; K Kifnidis, A Daskalaki, General Hospital of Athens Asklipio Voulas, Athens; N Moschos, K Dimitra, General Hospital of Rhodes, Rhodes; C Olympios, E Kartsagkoulis, Genaral Hospital of Elefsina Attikis Thriasio, Athens; V Pyrgakis, K Korantanis, General Hospital of Athens G. Gennimatas, Athens.

Guatemala- 136 patients 7 centers
O Ayau Milla, V de Leon Ramirez, Zacapa; I Guzman Melgar, T Jimenez, Edificio Plaza Dorada, Guatemala City; A Ovando Lavagnino, S Guevara, Liga del Corazon, Guatemala City; M Rodas Estrada, T Jimenez, Clinica Privada Dr. Rodas Estrada, Guatemala City; M Sanchez, J Mayen Pozuelos, CardioQuetzal, Quetzaltenango; C Sanchez Samayoa, L Guerra, Clinicas Hospital Centro Medico, Guatemala City; L Velasquez Camas, S Padilla Almaraz, Unicar, Guatemala.

Hungary- 464 patients 21 centers
P Dioszeghy, E Muskoczki, Josa Andras Oktatokorhaz Egeszsegugyi Szolg. Nonprofit Kft., Nyiregyhaza; I Edes, J Szatmari, Debreceni Egyetem Orvos- es Egeszsegtudomanyi Centrum, Debrecen; J Fiok, A Varga, Sopron Medical SMO Erzsebet Korhaz, Sopron; N Kanakaridisz, M Kosztyu, UNO Medical Trials Kft., Budapest; E Kis, J Felfoldine Feil, Tolna Megyei Onkormanyzat Balassa Janos Korhaza, Szekszard; **R Kiss**, A Jakal, Honvedelmi Miniszterium Allami Egeszsegugyi Kozpont, Budapest; M Koczka, M Koczka, Mako; I Kovacs, M Baranyai, Vas Megyei Markusovszky Korhaz Nonprofit Zrt, Szombathely; Z Kovacs, Z Kovacs, Bajai Szent Rokus Korhaz, Baja; G Lupkovics, H Horvathne Karakai, Zala Megyei Korhaz, Zalaegerszeg; A Matoltsy, T Kiss, Kanizsai Dorottya Korhaz, Nagykanizsa; M Medvegy, K Kiss, Pest Megyei Flor Ferenc Korhaz, Kistarcsa; B Merkely, E Kolumban, Semmelweis Egyetem, Budapest; A Nagy, A Nagy, Bacs-Kiskun Megyei Onkormanyzat Korhaza, Kecskemet; A Palinkas, S Rostasne Toth, Erzsebet Korhaz-Rendelointezet, Hodmezovasarhely; A Sayour, A Bognar, Magyar Imre Korhaz, Ajka; T Simor, D Ruzsa, Pecsi Tudomanyegyetem Altalanos Orvostudomanyi Kar, Pecs; T Sipos, T Sipos, Rethy Pal Korhaz, Bekescsaba; I Szakal, I Szakal, Selye Janos Korhaz, Komarom; J Tomcsanyi, A Marosi, Budai Irgalmasrendi Korhaz, Budapest; A Vertes, M Kincses, Fov.Onk.Egyesitett Szt. Istvan es Szt Laszlo Korh.-Rend.Int., Budapest.

India- 690 patients 65 centers
S Malhan, Sheth Vadilal Sarabhai Hospital and Municipal Medical Colleg, Ahmedabad, Gujarat; J Abdullakutty, N.H., Lissie Hospital, Cochin, Kerala; D Agarwal, R Ranka, S. P. Medical College & Associated Group of Hospitals, Bikaner, Rajasthan; J Arneja, A Memon, Arneja Heart Institute, Nagpur, Mahara; V Arora, R Shree, Max Devki Devi Heart & Vascular Institute, New Delhi, Delhi; G Avvaru, A Shaikh, Yashoda Hospital, Hyderabad, Andh Prad; P Babu, B Rao, Dr. Ramesh Cardiac and Multi Speciality Hospital Ltd., Vijayawada, Andh Prad; R Babu, J Reddy, Medwin Hospital, Hyderabad, Andh Prad; D Banker, T Sheth, Banker's Heart Institute, Vadodara, Gujarat; P Benjarge, S Surushe, Krishna Hospital & I. C. U., Aurangabad, Mahara; A Bharani, R Solanki, MGM Medical College and MY Hospital, Indore, Madh Prad; V Bhargava,

A Rathi, Care Hospital (Nagpur), Nagpur, Mahara; A Biniwale, M Bhuti, Biniwale Clinic, Pune, Mahara; N Calambur, **B Somaraju**, N Karnwal, Care Hospital, Hyderabad, Andh Prad; M Chopda, N Mali, Chopda Medicare & Research Centre, Nashik, Mahara; N Goyal, A Saini, Speciality Clinic, New Delhi, Delhi; J Gupta, P Singh, S. R. Kalla Memorial General Hospital, Jaipur, Rajasthan; S Hadan, P Savanth, Yenepoya Speciality Hospital, Mangalore, Karna; S Hardas, G Thakor, Ruby Hall Clinic, Pune, Mahara; J Hiremath, A Ghume, Poona Hospital and Research Centre, Pune, Mahara; R Jain, M Pahuja, CHL - Apollo Hospital, Indore, Madh Prad; S Joseph, D Oommen, Little Flower Hospital, Cochin, Kerala; J Joseph, R Thomas, Caritas Hospital, Kottayam, Kerala; H Joshi, Iby, Apollo Hospitals International Ltd., Gandhinagar, Gujarat; V Kale, N Raut, Lokmanya Hospital, Pune, Mahara; B Kandekar, S Kandekar, Nobel Hospital, Ahmednagar, Mahara; R Kishore, H Krishnan, Narayana Hrudayalaya Institute of Medical Sciences, Bangalore, Karna; V Kotiwale, V B, Kles's Dr. Prabhakar Kore Hospital and Med. Res. Centre, Belgaum, Karna; R Kulkarni, M Deokar, Moraya Multispeciality Hospital, Pune, Mahara; G Kulkarni, A Lawande, Shree Hospital, Pune, Mahara; P Kumar, M Karpuram, Osmania General Hospital, Hyderabad, Andh Prad; A Kumar, J Francis, Lakeshore Hospital and Research Centre, Cochin, Kerala; M Kumbla, A Anthony, Omega Hospital, Mangalore, Karna; P Lavhe, M Kale, Avanti Institute of Cardiology, Nagpur, Mahara; H Mardikar, P Bhaskarwar, Spandan Heart Institute, Nagpur, Mahara; A Mathur, P Sharma, Escorts Heart Institute & Research Centre, New Delhi, Delhi; J Menon, V Francis, Mar Augustine Golden Jubilee Hospital, Ernakulam, Kerala; D Namjoshi, S Shelke, Criti Care Hospital, Mumbai, Mahara; J Narendra, P J, S. A. T. Hospital, Shimoga, Karna; S Natarajan, V Francis, G. Kupuswami Naidu Memorial Hospital, Coimbatore, Tamilnadu; A Oomaan, P Gurusamy, Apollo Hospitals, Chennai, Tamilnadu; B P. R., J Angel, Frontier Lifeline & Dr. K.M. Cherian Heart Foundation, Chennai, Tamilnadu; M Padinhare Purayil, S Shams, West Fort Hi-Tech Hospital Ltd., Thrissur, Kerala; U Pandurangi, R Sababathi, Institute of Cardiovascular Diseases Madras Medical Mission, Chennai, Tamilnadu; P Parekh, B Jasani, Care Hospital, Surat, Gujarat; N Patki, A Babbar, Deenanath Mangeshkar Hospital and Research Centre, Pune, Mahara; B Pinto, H Kharalkar, Bandra Holy Family Hospital and Research Center, Mumbai, Mahara; R Premchand, H Jambula, Krishna Institute of Medical Sciences, Hyderabad, Andh Prad; M Rao, A Vuriya, Queen's NRI Hospital, Vishakhapatnam, Andh Prad; A Ravi Shankar, R E R, Mysore Medical College and Research Institute, Mysore, Karna; R Reddy, S Bekal, Mediciti Hospital, Hyderabad, Andh Prad; D Roy, A Barai, Rabindranath Tagore International Institute of Cardiac Scien, Kolkata, W Bengal; D Saha, R Gadepalli, Nizam's Institute of Medical Sciences, Hyderabad, Andh Prad; H Sant, D Jadhav, Medipoint Hospital Pvt Ltd , Pune, Mahara; M Sarna, T Arora, Monilek Hospital and Research Centre, Jaipur, Rajasthan; J Sawhney, R Singh, Dharmavira Heart Centre, New Delhi, Delhi; K Sethi, N Bansal, Delhi Heart and Lung Institute, New Delhi, Delhi; A Sethia, S Sethia, Indore, Madh Prad; G Shetty, R Sudheer, St.John's Medical College and Hospital, Bangalore, Karna; G Singh, R Gupta, Dayanand Medical College and Hospital, Ludhiana, Punjab; A Srinivas, V G, Vikram Hospital & Heart Care, Mysore, Karna; A T.P., L Thankaraj, Sri Gokulam Heart Centre, Trivandrum, Kerala; S Varma, A Kaur, Sadbhavna Medical and Heart Institute, Patiala, Punjab; M Vijan Vinod, B Thakur, Vijan Cardiac Center, Nashik, Mahara; I Zanwar, A Dharmarao, Hardas Heart Centre, Pune, Mahara.

Israel- 283 patients 20 centers

S Atar, E Lasri, Western Galilee Hospital- Nahariya, Nahariya; D Dicker, D Marcoviciu, Rabin Medical Center, Petach Tikva; M Elias, G Avraham Ron, HaEmek Medical Center, Afula; a Francis, R Ghantous, Holy Family Hospital, Nazareth; A Goldhaber, M Goldhaber, Shuali Community Clinic- Clalit Health Services, Ra'anana; S Gottlieb, S Rouwaida, Bikur Cholim

Hospital, Jerusalem; E Grossman, T Dagan, Chaim Sheba Medical Center, Tel-Hashomer; Y Hasin, M Roshrosh, Poriya Government Hospital, Tiberias; T Hayek, A Majdoub, Rambam Health Care Campus, Haifa; E Klainman, I Genin, Gefen- Cardiac Center, Givatayim; M Lahav, T Gilat, Rabin Medical Center, Petach Tikva; **B Lewis**, M Ben Ari, The Lady Davis Carmel Medical Center, Haifa; M Lishner, M Karny, Sapir Medical Center Meir Hospital, Kfar Saba; E Ouzan, H Givoni, Hadassah Universtiy Hospital- Ein Kerem, Jerusalem; Y Rozenman, S Logvinenko, Wolfson Medical Center, Holon; E Schiff, J Sterlin, Bnai Zion Medical Center, Haifa; M Shochat, I Aloni, Hillel Yaffe Medical Center, Hadera; M Swissa, V Belatsky, Kaplan Medical Center, Rechovot; D Tsalihin, D Kisos, Ben Yair Community Clinic- Clalit Health Services, Beer-Sheva; D Zeltser, N Platner, Tel-Aviv Sourasky Medical Center, Tel-Aviv.

Italy- 169 patients 24 centers

A Berni, F Giovannelli, Azienda Ospedaliera Sant Andrea, Roma, RM; G Boriani, E Cervi, Ospedale S. Orsola- Malpighi, Bologna; G Comi, L Peruzzotti, Fondazione San Raffaele del Monte Tabor, Milano, MI; C Cuccia, C Forgione, Fondazione Poliambulanza Istituto Ospedaliero, Brescia, BS; R De Caterina, D De Pace, Azienda Ospedaliera Universitaria G. D'Annunzio, Chieti, CH; S De Servi, M Mariani, A.O. Ospedale Civile di Legnano, Legnano, MI; A Di Lenarda, C Mazzone, ASS 1 Triestina, Trieste, TS; G Di Pasquale, M Di Niro, Ospedale Maggiore C.A. Pizzardi, Bologna, BO; L Fattore, B Bosco, Ospedale San Giuseppe e Melorio, Santa Maria Capua Vetere, CE; V Grassia, E Murena, Ospedale Santa Maria Delle Grazie, Pozzuoli, NA; Laffi, G Gaggioli, Azienda Ospedaliera Villa Scassi, Genova, GE; G Lo Pinto, F Raggi, Ente Ospedaliero Ospedali Galliera, Genova, GE; P Marino, G Francalacci, A.O. Maggiore della Carità di Novara, Novara, NO; **P Merlini,** M Babbolin, Azienda Ospedaliera Ospedale Niguarda Cà Granda -2, Milano, MI; M Metra, M Bulgari, Spedali Civili di Brescia, Brescia; M Penco, E Lioy, Policlinico Casilino, Roma, RM; P Perrone Filardi, C Marciano, Università degli Studi di Napoli-Federico II, Napoli, NA; S Pirelli, G Paradiso, Azienda Ospedaliera Istituti Ospitalieri di Cremona, Cremona, CR; G Piseddu, L Fenu, Ospedale Ss. Annunziata Az. USL 1, Sassari, SS; A Raisaro, K Granzow, IRCCS Policlinico San Matteo, Pavia, PV; M Rasura, S Cannoni, Università La Sapienza-Ospedale Sant Andrea, Roma, RM; S Severi, M Breschi, Ospedale della Misericordia, Grosseto, GR; V Toschi, M Gagliano, A.O. Ospedale San Carlo Borromeo, Milano, MI; V Zacà, F Furiozzi, A.O.U. Senese Policlinico Santa Maria alle Scotte, Siena, SI.

Japan- 1010 patients 99 centers

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Tokyo Metropolitan Geriatric Hospital, Itabashi-ku Tokyo; T Haruna, Y Nakahara, TazukeKoufukai Igakukenkyujo Kitano Hospital, Osaka-shi Osaka; Y Hashimoto, Y Shimazu, Tesshokai Kameda Clinic, Kamogawa-shi Chiba; Y Hiasa, Y Oga, Tokushima Red Cross Hospital, Komatsushima-shi Tokushima; T Higashikata, Y Nakagawa, Komatsu Municipal Hospital, Komatsu-shi Ishikawa; A Hirayama, A Kawaguchi, Nihon University Itabashi Hospital, Itabashi-ku Tokyo; Y Iesaka, C Miyamoto, Tsuchiura Kyodo General Hospital, Tsuchiura-shi Ibaraki; T Iijima, K Higuchi, Fujioka General Hospital for outpatient, Fujioka-shi Gunma; H Ino, H Noguchi, Kanazawa University Hospital, Kanazawa-shi Ishikawa; T Inomata, K Nakamura, Kitasato University Hospital, Sagamihara-shi Kanagawa; Y Ishibashi, T Nozaki, Iwate Medical University Hospital, Morioka-shi Iwate; Y Ishii, H Tomita, Asahikawa City Hospital, Asahikawa-shi Hokkaido; S Ishimaru, M Ise, Hokkaido Social Insurance Hospital, Sapporo-shi Hokkaido; K Itamoto, T Ito, Teine Keijinkai Hospital, Sapporo-shi Hokkaido; Y Ito, M Onishi, TOYOTA Memorial Hospital, Toyota-shi Aichi; K Iwade, Y Sakuma, NHO Yokohama Medical Center, Yokohama-shi Kanagawa; T Iwasaki, H Nagatome, Cardiovascular Hospital of Central Japan, Shibukawa-shi Gunma; S Kakinoki, C Adachi, Otaru Kyokai Hospital, Otaru-shi Hokkaido; S Kamakura, F Nakahara, National Cerebral and Cardiovascular Center, Suita-shi Osaka; M Kamijo, S Iida, Chubu Rosai Hospital, Nagoya-shi Nagoya; K Kamiyama, R Fujii, Ijinkai Nakamura Memorial Hospital, Sapporo-shi Hokkaido; K Kato, A Ishida, JLHWO Yokohama Rosai Hospital, Yokohama-shi Kanagawa; Y Kazatani, Y Ichikawa, Ehime Prefectural Central Hospital, Matsuyama-shi Ehime; H Kitazawa, C Igarashi, Tachikawa General Hospital, Nagaoka-shi Niigata; Y Kobayashi, R Kikuchi, Showa University Hospital, Shinagawa-ku Tokyo; M Kohno, S Tamura, Kagawa University Hospital, Kita-gun Kagawa; **Y Koretsune**, I Yumoto, NHO Osaka National Hospital, Osaka-shi Osaka; M Kurabayashi, E Koya, Gunma University Hospital, Maebashi-shi Gunma; T Masuyama, Y Kaneno, Hyogo College of Medicine Hospital, Nishinomiya-shi Hyogo; K Matsuda, E Ebina, MATSUDA Med Clinic, Sapporo-shi Hokkaido; H Meno, M Satake, Japanese Red Cross Fukuoka Hospital, Fukuoka-shi Fukuoka; T Mita, M Takeda, Mita Medical-Cardiovascular Clinic, Sapporo-shi Hokkaido; N Miyamoto, T Kimizu, Saino Clinic, Tokorozawa-shi Saitama; Y Miyauchi, S Sakamoto, Nippon Medical School Hospital, Bunkyo-ku Tokyo; M Munemasa, J Murata, NHO Okayama Medical Center, Okayama-shi Okayama; Y Nagai, Y Sakata, Rinku General Medical Center, Izumisano-shi Osaka; S Naito, H Oyama, Gunma prefectural Cardiovascular Center, Maebashi-shi Gunma; Y Nishi, T Nagase, Seiwakai Nagata Hospital, Yanagawa-shi Fukuoka; J Ochiai, H Junko, Nagoya Ekisaikai Hospital, Nagoya-shi Nagoya; T Ogawa, M Sugeno, Fukushima Koseikai Fukushima Dai Hospital, Fukushima-shi Fukushima; H Oguro, M Tanabe, Shimane University Hospital, Izumo-shi Shimane; K Okada, Y Moriyama, Ohda Municipal Hospital, Ohda-shi Shimane; K Okajima, M Nakashima, Hyogo Brain and Heart Center, Himeji-shi Hyogo; O Okazaki, H Wada, National Center for Global Health and Medicine Hospital, Shinjuku-ku Tokyo; K Okishige, S Kitani, Yokohama City Minato Red Cross Hospital, Yokohama-shi Kanagawa; K Okumura, Y Narita, Hirosaki University School of Medicine & Hospital, Hirosaki-shi Aomori; H Onaka, H Moriyama, Takatsuki Red Cross Hospital, Takatsuki-shi Osaka; Y Ozaki, I Tanikawa, Fujita Health University Hospital, Toyoake-shi Aichi; S Sakagami, A Nakano, Kanazawa Medical Center, Kanazawa-shi Ishikawa; S Sakuragi, N Hayashi, NHO Iwakuni Clinical Center, Iwakuni-shi Yamaguchi; S Sakurai, H Ooki, Aizawa Hospital, Matsumoto-shi Nagano; T Sasaki, N Oosawa, NHO Takasaki General Medical Center, Takasaki-City Gunma; A Satoh, E Fujimoto, Shunkaikai Nagasaki Kita Hospital, Nishisonogi-gun Nagasaki; Y Seino, M Narumi, Nippon Medical School Chiba Hokusoh Hospital, Inzai-shi Chiba; T Shirai, M Shigenari, Tokyo Metropolitan Police Hospital, Nakano-ku Tokyo; Y Shoji, J Ueda, Makabe Hospital, Higashimatsushima-shi Miyagi; K Sugi,

E Miyazaki, Toho University Ohashi Medical Center, Meguro-ku Tokyo ; K Sumii, H Asakura, MAZDA Hospital of MAZDA Co. Lted, Aki-gun Hiroshima; M Takagi, S Mohri, Osaka City University Hospital, Osaka-shi Osaka; W Takahashi, K Yoshida, NHO Shinshu Ueda Medical Center, Ueda-shi Nagano; A Takahashi, N Kishi, Yokosuka Kyosai Hospital, Yokosuka-shi Kanagawa; T Takahashi, Y Sakurai, Yokohama Medical Center, Yokohama-shi Kanagawa; K Takeda, A yahata, Kagawa Prefectural Central Hospital, Takamatsu-shi Kagawa; T Takenaka, K Yamagishi, NHO Hokkaido Medical Center, Sapporo-shi Hokkaido; S Takeuchi, E Watanabe, Nagaoka Chuo General Hospital, Nagaoka-shi Niigata; K Tanaka, M Uchida, Tokyo Metropolitan Cancer and Infectious diseases Center Kom, Bunkyo-ku Tokyo; J Tanouchi, Y Nishiya, Osaka Rosai Hospital, Sakai-shi Osaka; H Tsuboi, K Yoshida, Ogaki Municipal Hospital, Ogaki-shi Gifu; N Tsuboi, K Terakura, Social Insurance Chukyo Hospital, Nagoya-shi Aichi; M Uematsu, S Yasumoto, Kansai Rosai Hospital, Amagasaki-shi Hyogo; Y Ueyama, M Onishi, Ueyama Clinic, Suita-shi Osaka; K Usuda, Y Sakai, Toyama Prefectural Central Hospital, Toyama-shi Toyama; M Yagi, A Sato, Sendai Cardiovascular Center, Senndai-shi Miyagi; H Yagi, T Kuroda, Koseikai Takeda Hospital, kyoto-shi Kyoto; H Yamabe, Y Sakamoto, Kumamoto University Hospital, Kumamoto-shi Kumamoto; T Yamada, R Yamano, Osaka General Medical Center (Kyuseiki Sogo Iryo C), Osaka-shi Osaka; T Yamagishi, S Sasaki, Isesaki Municipal Hospital, Isesaki-shi Gunma; Y Yamamoto, Y Ito, Kyoto Second Red Cross Hospital, Kamigyo-ku Kyoto; a Yamashina, M Takiguchi, Tokyo Medical University Hospital, Shinjuku-ku Tokyo; **T Yamashita**, K Matsuda, The Cardiovascular Institute Hospital, Minato-ku Tokyo; T Yonehara, K Tanaka, Saiseikai Kumamoto Hospital, Kumamoto-shi Kumamoto; H Yoshino, H Nomura, Kyorin University Hospital, Mitaka-shi Tokyo; K Yoshioka, Y Fujiwara, Tokai University Hospital, Isehara-shi Kanagawa.

Mexico- 190 patients 13 centers

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Netherlands- 153 patients 10 centers

M Alhakim, I van Welsen, Flevoresearch, Almere; T Bruning, A Jones, Maasstad Ziekenhuis Zuider, Rotterdam; C Buiks, C Buiks, Huisartsenpraktijk Buiks, Ewijk; J de Groot, I Radder, Academisch Medisch Centrum, Amsterdam; R de Vos, R de Vos, Huisartsenpraktijk de Vos, Dordrecht; R Hazeleger, R Daniels, VieCuri Medisch Centrum Venlo, Venlo; B Kietselaer, L Muijs, Maastricht University Medical Center, Maastricht; H Mannaerts, E Kooiman, Ziekenhuis Amstelland, Amstelveen; H Mevissen, H Mevissen, Huisartsenpraktijk Westerhave, Wildervank; D van der Heijden, H Hofmeyer, Rijnland Ziekenhuis Leiderdorp, Leiderdorp.

New Zealand- 131 patients 10 centers
R Anscombe, T O'Meeghan, M Kjentjes, Hutt Valley Health Hospital, Lower Hutt; J Benatar, **H White**, L Borthwick, Auckland City Hospital, Auckland; R Doughty, M Copley, Auckland City Hospital, Auckland; R Fisher, R Monkley, Waikato Hospital, Hamilton; B Green, D Scott, Dunedin Hospital, Dunedin; A Hamer, J Tomlinson, Nelson Hospital, Nelson; H Hart, A Turner, North Shore Hospital, Auckland; D Scott, R Cammell, Middlemore Hospital, Otahuhu; R Troughton, L Skelton, Christchurch Hospital, Christchurch; C Young, K Kennett, P3 Research Limited (Tauranga), Tauranga.

Norway- 34 patients 4 centers
D Atar, H Claussen, Ullevål universitetssykehus, Oslo; K Hofsøy, R Melbue, Hålogalandsykehuset HF, Harstad; J Sandvik, H Thunhaug, Nordland Hjertesenter AS, Bodø; A Tveit, S Enger, Sykehuset Asker og Bærum Bærum sykehus, Rud.

Peru- 173 patients 11 centers
G Bustamante, M Tejada Guillen, Clinica San Borja, Lima 41; J Cabrera, R Esteves Mendoza, Clínica Vesalio, Lima; C Chavez, C Luna, Hospital Nacional Daniel Alcides Carrion, Callao; J Lema, A Carrion, Hospital Nacional Arzobispo Loayza, Lima; N Llerena, S Araoz Bedregal, Consultorio Privado Dr. Nassil Llerena Navarro, Arequipa; F Medina Palomino, J Rodriguez, Clinica Medica Cayetano Heredia, Lima; J Minchola, C Bautista, Clinica San gabriel, Lima; S Negron Miguel, B Honores Armas, Centro Medico Naval Cirujano Mayor Santiago Tavara, San Borja; A Rodriguez, N Romero, Hospital Nacional Alberto Sabogal Sologuren, Callao; P Torres, K Fernandez Rodriguez, Consultorio Privado Dr Pedro Torres, Arequipa; P Yanac Chavez, **M Horna**, S Delgado, Hospital Alberto Sabogal Sologuren, Callao.

Philippines- 125 patients 8 centers
N Babilonia, CM Sambaz, Philippine Heart Center, Quezon; R Barcinas, M Zapanta, Alexian Brothers Health and Wellness Center, Davao; R Coching, M Vallenas, Davao Doctors Hospital, Davao; G Matiga, C Enad, Perpetual Succour Hospital - Cebu, Cebu; G Rogelio, F Joaquin, St. Luke's Medical Center, Quezon; A Roxas Jr., L Gilo, The Medical City, Pasig; R To, M Aquino, The Medical City, Pasig; L Villamor, K Nario, Cebu Doctors' University Hospital, Cebu.

Poland- 1278 patients 49 centers
J Adamus, J Korzeniowska-Adamus, Centrum Med. Ostrobramska NZOZ Magodent, Warszawa; J Baszak, J Baszak, NZOZ Przychodnia Specjalistyczna Medica, Lublin; M Bronisz, B Cieslak, Publiczny Specjalistyczny ZOZ w Inowroclawiu, Inowroclaw; B Busz- Papiez, A Krzystolik, Indywidualna Specjalistyczna Praktyka Lekarska B.Busz-Papiez, Szczecin; K Cymerman, K Cymerman, Indywidualna Specjalistyczna Praktyka Lekarska, Gdynia; M Dabrowska, A Ptak, Synexus SCM Sp z o o Oddzial w Warszawie, Warszawa; B Derlaga, E Laskowska-Derlaga, Spec.Gabinet Lekarski Internistyczno-Kardiologiczny, Tarnow; E Domanska, M Guziewicz, Centrum Medyczne CDS, Wroclaw; A Gieroba, E Zajac, SPZOZ, Lubartow; J Gniot, P Mroczkowski, SPZOZ w Pulawach Szpital Specjalistyczny, Pulawy; A Januszewicz, M Makowiecka-Ciesla, Instytut Kardiologii im. Kardynala St. Wyszynskiego, Warszawa; E Jazwinska- Tarnawska, P Ciezak, Synexus SCM Sp. z o.o., Wroclaw; J Jurowiecki, J Jurowiecki, NZOZ Przychodnia Morena, Gdansk; B Kaczmarek, A Pacholska, NZOZ Polimedica, Lodz; L Kaminski, L Kaminski, SP ZOZ w Przeworsku, Przeworsk; G Kania, K Tymendorf, NZOZ Przychodnia Zdrowia ZADEBIE, Skierniewice; A Karczmarczyk, R Kaliszczak, Indywidualna

Specjalistyczna Praktyka Lekarska, Szczecin; M Konieczny, E Benicka, KO-MED Marek Konieczny, Pulawy; R Korzeniak, W Borowski, NZOZ Specjalistyczna Przychodnia Lekarska Medikard, Plock; W Krzyzanowski, M Muzyk-Osikowicz, SPZZOZ Szpital Powiatowy im. M.Sklodowskiej-Curie, Ostrow Mazowiecka; W Kus, W Kus, Indywidualna Specjalistyczna Praktyka Lekarska, Lodz; J Lesnik, T Wierzykowski, NZOZ Kutnowski Szpital Samorzadowy Sp z oo, Kutno; J Lewczuk, M Stopyra-Poczatek, Wojewodzki Szpital Specjalistyczny we Wroclawiu, Wroclaw; A Lubinski, K Szymanska, Uniwersytecki Szpital Kliniczny im.WAM-Cen.Szpit.Weteran., Lodz; R Lysek, G Jaguszewska, Lecznice Citomed Sp. z o.o., Torun; L Matyszczak-Toniak, R Sznajder, R Wnetrzak-Michalska, A Kosmaczewska, Synexus SCM Sp z oo Oddzial w Katowicach, Katowice; S Mazur, A Chmielowski, Centrum Medyczne Medyk, Rzeszow; P Miekus, K Kosmalska, NZOZ Pro-Cordis Sopockie Centrum Bad. Kardiolog., Sopot; J Mosiewicz, W Myslinski, Samodzielny Publiczny Szpital Kliniczny nr 1 w Lublinie, Lublin; P Napora, D Biniek, NZOZ Centrum Badan Klinicznych, Wroclaw; J Nessler, B Nessler, Specjalistyczny Gabinet Internistyczno- Kardiologiczny, Krakow; K Niezgoda, A Nej, Elblaski Szpital Specjalistyczny z Przychodnia, Elblag; J Nowak, J Nowak, Gabinet Internistyczno-Kardiologiczny Dr n. med. Jacek Nowak, Libiaz; M Olszewski, M Olszewski, Szpital Praski p.w. Przemienienia Panskiego, Warszawa; D Podjacka, D Janczewska, NZOZ Kardiomed, Elblag; H Pogorzelska, H Pogorzelska, Instytut Kardiologii im. Kardynala St. Wyszynskiego, Warszawa; V Polaszewska-Pulkownik, E Bojanowska, Specjalistyczny Szpital Miejski im M. Kopernika, Torun; G Raczak, A Zienciuk-Krajka, NZOZ Centrum Medyczne Kardiorytm, Gdansk; H Rewinska, W Rozmyslowicz-Szerminska, Mazurskie Centrum Zdrowia Pro Medica, Elk; R Ronkowski, R Ronkowski, Regionalny Szpital w Kolobrzegu, Kolobrzeg; **W Ruzyllo**, B Norwa-Otto, Instytut Kardiologii im. Kardynala St. Wyszynskiego, Warszawa; D Sendrowski, D Sendrowski, Przychodnia Specjalistyczna Falck, Gdansk; J Spyra, J Spyra, Specjalistyczna Praktyka Lekarska Janusz Spyra, Ruda Slaska; M Szolkiewicz, A Malanska, NZOZ Eter-Med Sp. z o.o., Gdansk; R Turbak, R Turbak, NZOZ Zdrowy Checz, Linia; W Wrobel, P Muzalewski, Wielospec.SzpitalMiejski im.DrE.Warminskiego-SPZOZ, Bydgoszcz; A Wysokinski, J Kudlicki, Samodzielny Publiczny Szpital Kliniczny nr 4 w Lublinie, Lublin; M Zarebinski, R Krauze, NZOZ Starowka, Warszawa; M Zielinski, M Nawrot, Specjalistyczna Praktyka Lekarska, Chojnice.

Portugal- 180 patients 10 centers

F Matias, Cruz Vermelha Portuguesa- Sociedade de Gestão Hospitalar SA, Lisboa; J Correia, J Correia, Hospital de Santo Andre EPE, Leiria; V Gil, S Lopes, Hospital Fernando da Fonseca (Amadora Sintra), Amadora; J Madeira, D Maymone, Hospital de São Bernardo, Setúbal; D Martins, E Neves, Hospital do Divíno Espírito Santo, Ponta Delgada; P Monteiro, D Oliveira, Hospitais da Universidade de Coimbra, Coimbra; P Monteiro, A Leitao Marques, C Castro, Centro Hospitalar de Coimbra, Coimbra; A Salgado, A Gonçalves, H. Sao Marcos, Braga; O Santos, L Veiga Pais Nunes, H Sao Teotonio, Viseu; J Santos, D Soares, Hospital Infante D. Pedro S.A., Aveiro.

Romania- 410 patients 23 centers

P Albulescu, M Ciortea, Spitalul Clinic Judetean de Urgenta Ilfov, Bucuresti; E Apetrei, C Matei, Institutul de Boli Cardiovasculare Prof. Dr. C.C. Iliescu, Bucuresti; D Bartos, E Badila, Spitalul Clinic de Urgenta Floreasca Bucuresti, Bucuresti; C Bengus, V Ochean, Spitalul Judetean de Urgenta Sf. Pantelimon Focsani, Focsani; E Bobescu, B Doka, Spitalul Clinic Judetean de Urgenta Brasov, Brasov; F Bolohan, F Bolohan, Centrul Clinic de Urgenta de Boli Cardiovasculare al Armatei, Bucuresti; G Ciobotaru, M Andor, Centrul Medical Privat

Medicali's, Timisoara; I Coman, M Ghionea, Inst. Urgenta Boli Cardiovasculare Prof.Dr.C.C. Iliescu, Bucuresti; M Constantinescu, M Constantinescu, S.C. Medcon S.R.L., Buzau; M Creteanu, M Parasteac, Spitalul Judetean de Urgenta Sf. Ioan cel Nou Suceava, Suceava; M Cristea, M Anciu, Centrul Medical de Diagnostic si Tratament, Bucuresti; D Crisu, D Jemna, Consultmed SRL, Iasi; I Dobre, O Voicu, Spitalul Judetean de Urgenta Targoviste, Targoviste; D Dobreanu, I Sirbu, Spitalul Clinic Judetean de Urgenta Tg. Mures, Targu Mures; D Dragomir, S Jurca, CMDTA Dr. Nicolae Kretulescu, Bucuresti; L Iosipescu, L Costache, Spitalul Clinic Judetean de Urgenta Bacau, Bacau; B Minescu, D Serban, Spitalul Judetean de Urgenta Braila, Braila; C Pop, M Cozma, Cabinet Medical Individual de Cardiologie Dr. Calin Pop, Baia Mare; M Popescu, A Ardelean, Spitalul Clinic Judetean de Urgenta Oradea, Oradea; D Sipciu, P Plosca, S.C. Duo Medical S.R.L., Bucuresti; S Stamate, C Spinu, Spitalul Clinic de Urgenta Sf. Pantelimon, Bucuresti; L Topolnitchi, O Topolnitchi, Spitalul Judetean Sf. Gheorghe, Sfantu Gheorghe; M Tudoran, C Tudoran, Spitalul Clinic Judetean de Urgenta Timisoara, Timisoara.

Russian Federation- 1151 patients 66 centers

M Ruda, N Zhukova, FSBI Russian Cardiology Research and Production Complex, Moscow; G Arutyunov, T Chernyavskaya, Russian State Medical University, Moscow; M Ballyuzek, L Alexandrova, St-Petersburg Clinical Hospital of Russian Academy of Science, Saint-Petersburg; O Barbarash, A Bashkireva, MIH Kemerovo Cardiology Dispensary, Kemerovo; B Bart, V Larina, SBEU Russia National RMU n.a. N.I. Pirogov of MoH of RF, Moscow; D Belenky, Y Kosolapov, SBIH of Novosibirsk Region Clinical Emergency Hospital 2, Novosibirsk; S Berns, E Yukhno, SI SRI of Complex Problems of Cardio-Vascular Diseases of SB, Kemerovo; I Bokarev, T Khlevchuk, Moscow City Clinical Hospital 20, Moscow; G Chumakova, O Pokutneva, TSIH Altay Territorial Cardiology Dispensary, Barnaul; A Demko, A Masin, Dep. Clin. Hosp. on Station Kemerovo of OAO Russian Railway, Kemerovo; P Dovgalevsky, N Puchinyan, Saratov Institute of Cardiology, Saratov; O Drapkina, E Zyatenkova, First Moscow State Medical University n.a. I.M. Sechenov, Moscow; L Egorova, L Egorova, StP SHI Clinical hospital of St. Luka, Saint-Petersburg; V Esip, N Kirichek, St. Petersburg State Healthcare Institution Diagnostic Cent, St. Petersburg; A Filatov, I Soin, State healthcare facility Tula Regional Hospital, Tula; O Gilinskaya, E Valuyshkih, SI SRI of Physiology SB RAMS, Novosibirsk; M Glezer, S Valovyeva, SBHI City Clinical Hospital 59 of HD of city of Moscow, Moscow; S Golitsyn, T Kratskina, FSBI Russian Cardiology Research and Production Complex, Moscow; B Goloshchekin, I Laptev, St-Petersburg SIH City Hospital 15, St-Petersburg; N Gratsiansky, O Mazovets, SIH of Moscow City Clinical Hospital 29 n.a. Baymana, Moscow; Y Karpov, V Buza, FSBI Russian Cardiology Research and Production Complex, Moscow; Y Karpov, B Kosenko, Emergency Medical Care Hospital 1, Voronezh; V Khirmanov, I Kireenkov, All-Russian Center of Emergency and Radiation Medicine MCRS, St-Petersburg; A Khokhlov, O Sinitsina, Municipal MI Clinical Hospital 2, Yaroslavl; R Khokhlov, E Tsareva, Voronezh regional clinical hospital 1 Interregional cardio, Voronezh; O Khrustalev, A Khrustalev, Yaroslavl Regional SBHI Regional Clinical Hospital, Yaroslavl; V Kostenko, S Karabalieva, St. Petersburg SHI City Polyclinic 109, St. Petersburg; N Koziolova, E Polyanskaya, SHI Perm Regional Hospital of War Veteran's, Perm; O Kozyrev, O Kostenko, Smolensk State Medical Academy of Roszdrav, Smolensk; V Kuznetsov, A Rychkov, SRI of Cardiology of SB of RAMS br Tumen cardiology Center, Tumen; O Lavrova, L Tereschenko, Pavlov State Medical University of St.Petersburg, St. Petersburg; S Levashov, E Volkova, SBHI Regional Clinical Hospital 3, Chelyabinsk; R Libis, A Maslova, Orenburg State Medical Academy of RosZdrav, Orenburg; I Libov, Y Moiseeva, City Clinical Hospital named after S.P.Botkin, Moscow; A Lila, L Belousova, SBEI HPE NWSMU n.a.I.I.Mechnikov MoH RF, St.

Petersburg; Y Lukyanov, D Lamden, SEIHPE SPb SMU n.a. Pavlov affiliate 1 of FAHSD, St. Petersburg; K Nikolaev, A Nikolaev, SBIH of Novosibirsk Region City Clinical Hospital 19, Novosibirsk; I Nikolskaya, O Khromova, MBHI of Novosibirsk City Clinical Hospital 25, Novosibirsk; N Novikova, S Patrusheva, Central Clininical Hospital of Siberian branch of RAOS, Novosibirsk; E Panchenko, P Laguta, FSBI Russian Cardiology Research and Production Complex, Moscow; A Panov, R Nilk, FSI FC of Heart Blood and Endocrinology n.a. Almazov, St. Petersburg; E Polkanova, I Matveeva, SHI Center of Occupational Pathology, St-Petersburg; N Poluyanova, N Pikalova, FSI Outpatient Clinic 3 President of RF, Moscow; T Raskina, M Letaeva, SBHI of Kem. Regional Clinical Hospital for War Veterans, Kemerovo; A Rebrov, N Karoli, SEIHPE Saratov State Medical University, Saratov; M Repin, N Rodina, LLC Institute of Medical Investigations, St. Petersburg; I Shaposhnik, E Lebedev, City Hospital 1, Chelyabinsk; Z Shogenov, M Agirov, CityClinicalHospital81, Moscow; B Sidorenko, S Vorontsova, FSD ESMC of GMD of the president of RF Central Clinical Hospital, Moscow; I Sinitsina, V Orlov, M Golshmid, RMA of Post Graduate Education of MoH and SD of RF, Moscow; Z Sizova, N Lapidus, State Healthcare Institution of city of Moscow Cardiologic, Moscow; K Sobolev, S Erofeeva, City Clinical Hospital No.61, Moscow; E Suprun, D Dronov, Municipal Healthcare Institution Medicosanitary Unit 9, Omsk; N Tarasov, L Isakov, FGHI MSU of the MoIA of the RF for the Kemerovo Region, Kemerovo; S Tereshenko, I Kositsyna, Moscow State Medico-stomat. University City Hospital 68, Moscow; E Tikhonova, A Solovyev, JSC Med. Scient. Production Association Clinic Dvizhenie, Volgograd; A Timofeev, S Bulygin, MIH City Hospital 1, Barnaul; S Ustyugov, M Rossovskaya, MBHI City Clinical Emergency Hospital n/a N.S. Karpovich, Krasnoyarsk; A Vishnevsky, A Kirgizova, SPb SIH Pokrovskaya City Hospital, St-Petersburg; D Volkov, N Rodina, Medical Institute on Krestovsky, St. Petersburg; V Yakusevich, A Petrochenko, SHI Clinical Hospital for Emergency Medical Care n.a N.V. Solovyev, Yaroslavl; S Yakushin, N Nikulina, Ryazan Regional Clinincal Cardiology Dispensary, Ryazan; D Zateyshchikov, I Zotova, SBHI of city of Moscow City Hospital 17, Moscow; A Zateyshchikova, B Mankhaeva, SBHI City Clinical Hospital 51 of Hd of Moscow city, Moscow; S Zenin, O Kononenko, SBIH Novosibirsk Regional clinical cardiology Dispensary, Novosibirsk; G Zubeeva, I Motylev, Municipal Medicoprophylactic Institution City Hospital 33, Nizhny Novgorod.

Serbia- 277 patients 14 centers

S Apostolovic, D Djordjevic-Radojkovic, Clinical Center of Nis, Nis; V Celic, A Majstorovic, Clinical Center Dragisa Misovic, Belgrade; N Cemerlic Adjic, M Bjelobrk, Institute of Cardiovascular Diseases Sremska Kamenica, Sremska Kamenica; N Despotovic, P Erceg, Clinical Center Zvezdara, Belgrade; S Ilic, B Ilic, Institute for Treatment and Rehabilitation Niska Banja, Niska Banja; M Krotin, A Djokovic, Clinical Center Bezanijska Kosa, Zemun; V Miloradovic, I Djokic, Clinical Center Kragujevac, Kragujevac; P Otasevic, N Tasic, Dedinje Cardiovascular Institute, Belgrade; T Potpara, M Polovina, Clinical Center of Serbia, Belgrade; B Putnikovic, T Kalezic, Clinical Center Zemun, Zemun; P Seferovic, I Milinkovic, Institute of CV Disease Clinical Center of Serbia, Belgrade; D Tavciovski, Z Davicevic, Military Medical Academy, Belgrade; Z Vasiljevic-Pokrajcic, P Mitrovic, Clinical Center of Serbia, Belgrade; B Vujisic Tesic, **M Ostojic**, M Tesic, Institute of CV Diseases Clinical Center of Serbia, Belgrade.

Slovakia- 405 patients 15 centers

V Ambrovicova, I Ambrovic, CELL B s.r.o., Levice; A Banikova, A Banikova, Kardiomed s.r.o., Lucenec; A Dukat, V Kosmalova, Univerzitna nemocnica Bratislava Nemocnica Stare Mesto, Bratislava; K Dulkova, T Dulka, Kardiovaskularne centrum s.r.o., Bratislava; **T Duris**, L

Vankova, FNsP Nove Zamky, Nove Zamky; A Dzupina, M Dzupinova, Alian s.r.o., Bardejov; K Hatalova, R Hatala, Cardioconsult s.r.o., Bratislava; M Hranai, J Hofmanova, Kardiocentrum Nitra s.r.o., Nitra; V Kasperova, A Reptova, Univerzitna nemocnica Bratislava Nemocnica Stare Mesto, Bratislava; J Mazur, J Mazur, Kardioonkologia s.r.o., Dolny Kubin; D Pella, J Fedacko, Cardio D&R s.r.o., Kosice; L Ruffini, J Morsky, Nestatna kardiologicka ambulancia, Rimavska Sobota; M Slanina, J Kmec, FNsP J. A. Reimana, Presov; A Zachar, M Kokles, Univerzitna nemocnica Bratislava Nemocnica ak. L. Derera, Bratislava; P Zareczky, D Bollova, Cardio s.r.o., Galanta.

South Africa- 277 patients 15 centers

J Badenhorst, L Erasmus, Unitas Hospital, Lyttelton, Gauteng; M Basson, M Poynton, Tiervlei Trial Centre, Belville, W Cape; **A Dalby**, J Allman, Millpark Hospital, Parktown West, Gauteng; G Ellis, L Botha, Helderberg Clinical Trials, Somerset West Western Cape, W Cape; J Engelbrecht, M Mostert, Somerset West, W Cape; M Essop, T Nunkoo, Chris Hani Baragwanath Hospital, Diepkloof, Gauteng; M Gani, L Wilson, GCT- Mercantile CTC, Port ELizabeth, E Cape; Y Kelfkens, Y Kelfkens, Potchefstroom, NW; I Mitha, J Taljaard, Worthwhile Clinical Trials, Benoni, Gauteng; D Naidoo, Y Duki, Research Clinic, Durban, KZ-Natal; F Snyders, M Munnik, Wilgers Medical Consortium, Pretoria, Gauteng; P Soma, H Johnston, University of Pretoria Clinical Trial Unit, Pretoria, Gauteng; N van der Merwe, Y Goosen, Medi-Clinic Bloemfontein, Bloemfontein, Free State; L van Zyl, M le Roux, Clinical Project Research, Worcester; T Venter, L Wessels, Union Hospital, Alberton, Gauteng.

South Korea- 230 patients 23 centers

HJ Bae, MG Han, Seoul National University Bundang Hospital, Gyeonggi-do; JK Cha, DH Kim, Dong-A University Medical Center, Busan; BR Cho, DR Ryu, Kangwon National University Hospital, Gangwon-do; HH Choi, KS Hong, Chuncheon Sacred Heart Hospital, Gangwon-do; WS Chung, YS Oh, The Catholic University of Korea Seoul St. Mary Hospital, Seoul; SH Han, KH Lee, Gachon University Gil Hospital, Incheon; TJ Hong, HW Lee, Pusan National University Hospital, Pusan; MS Hyon, JW Jung, Soonchunhyang University Hospital, Seoul; HK Jeon, JM Lee, The Catholic University of Korea Uijeongbu St.Mary's Hospital, Gyeonggi-do; DH Kang, KJ Choi, Asan Medical Center, Seoul; CJ Kim, ES Jin, Kyung Hee University Hospital at Gandong, Seoul; DS Kim, JS Seo, Inje University Busan Paik Hospital, Busan; HS Kim, MJ Cha, Seoul National University Hospital, Seoul; JT Kim, MS Park, Chonnam National University Hospital, Gwangju; JH Kim, JH Park, Chungnam National University Hospital, Daejeon; JS Kim, SJ Park, Samsung Medical Center, Seoul; SH Kim, JB Seo, Seoul Metropolitan Government Seoul National University, Seoul; YJ Kim, MY Chun, Ewha Womans University Mokdong Hospital, Seoul; MH Lee, BY Joung, Severance Hospital Yonsei University College of Medicine, Seoul; SH Lee, DG Shin, Yeungnam University Hospital, Daegu; J Namgung, JJ Kwak, Inje University Ilsan Paik Hospital, Gyeonggi-do; SW Rha, JO Na, Korea University Guro Hospital, Seoul; SJ Rim, JY Kim, Gangnam Severance Hospital, Seoul.

Spain- 166 patients 14 centers

M Arcocha Torres, A Manzanal Rey, Hospital de Basurto, Bilbao, 48; J Blanco Coronado, I Puertas, Hospital Virgen del Mar, Almeria, 4; J Bruguera Cortada, P Cabero, H del Mar, Barcelona, 8; C Calvo, G Calvo, HCU de Santiago, La Coruna, 15; A de Arce Borda, A Asensio, Hospital de Donostia, San Sebastian, 20; E Diez Tejedor, M Pérez Guevara, HGU La Paz, Madrid, 28; J Gonzalez Juanatey, M Moure, HCU de Santiago, Santiago de Compostela, 15; A

Hernandez Madrid, A Delgado, HU Ramon y Cajal, Madrid, 28; V Lopez Garcia-Aranda, R Barquero, HU Virgen Macarena, Sevilla, 41; L Manzano, S Blanco Abril, Hospital Universitario Ramón y Cajal, Madrid, 28; J Merino, M Diaz-Pintado, H.G.U.La Paz, Madrid, 28; J Arias, M Fernandez, R Fernandez Alvarez, Policlinico de Vigo-Povisa, Vigo, 36; M Terns, M Dachs Delgado, CAP El Remei, Barcelona, 8; R Villuendas, L Astier, Hospital Universitari Germans Trias i Pujol, Barcelona, 8.

Sweden- 252 patients 16 centers
P Appelros, A Åkerberg, Universitetssjukhuset Örebro, Örebro; K Berndtsson Blom, R Andersson, Ladulaas kliniska studier, Skene; P Blomström, L Persson, Akademiska Sjukhuset, Uppsala; T Carlsson, A Stener Bengtsson, Hjärthuset AB, Varberg; S Dettmann, S Östberg, Mora lasarett, Mora; J Engdahl, L Karlsson, Länssjukhuset Halmstad, Halmstad; J Herlitz, L Winberg, Sahlgrenska Sjukhuset, Göteborg; **S Juul-Möller**, H Jernhed, Universitetssjukhuset MAS, Malmö; P Koskinen, E Håkansson, PharmaSite AB, Malmö; P Kozak, M Edlund, ProbarE, Lund; L Malmqvist, G Eriksson, Köpings lasarett, Köping; F Randers, J Moodh, Sahlgrenska Universitetssjukhuset Mölndal, Mölndal; A Rautio, M Johansson, Sensia Forskning, Luleå; F Rönn, C Sundholm, Norrlands Universitetssjukhus, Umeå; A Stenberg, A Gunnarsson, Lindesbergs lasarett, Lindesberg; J Thulin, M Broberg, Capio Citykliniken Lund, Lund.

Switzerland- 5 patients 1 center
T Moccetti, I Petrova Slater, Cardio Centro Ticino, Lugano.

Taiwan- 234 patients 15 centers
CC Cheng, WS Wu, Chi-Mei Medical Center - Yongkang, Tainan; CE Chiang, WC Yu, Taipei Veterans General Hospital, Taipei; FT Chiang, YW Wu, National Taiwan University Hospital, Taipei; CW Chiou, TC Yeh, Kaohsiung Veterans General Hospital, Kaohsiung; CH Hsia, YP Chen, Changhua Christian Hospital, Changhua; JL Huang, YF Chen, Taichung Veterans General Hospital, Taichung; CT Kuo, CL Wang, Chang Gung Memorial Hospital - Linkou, Taoyuan; WT Lai, TH Lin, Kaohsiung Medical University Chung-Ho Memorial Hospital, Kaohsiung; JT Lee, CC Cheng, Tri-Service General Hospital, Taipei; PY Pai, KH Lin, China Medical University Hospital, Taichung; KG Shyu, CZ Chiu, Shin Kong Wu Ho-Su Memorial Hospital, Taipei; WK Tseng, YF Pan, E-Da Hospital, Kaohsiung; KC Ueng, SC Lee, Chung-Shan Medical University Hospital, Taichung; JH Wang, WC Tsai, Hualien Tzu Chi Hospital, Hualien; HI Yeh, JY Kuo, Mackay Memorial Hospital - Tamsui, New Taipei.

Thailand- 115 patients 8 centers
K Jirasirirojanakorn, K Pornchaiyasit, Bhumibol Adulyadej Hospital, Bangkok; P Kaewsuwanna, W Sinthusopa, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima; S Kiatchoosakun, S Sriprasert, Srinagarind Hospital, Khon Kaen; P Laothavorn, P Bamrungpong, Phramongkutklao Hospital, Bangkok; D Piyayotai, A Sripracha, Thammasat Chalerm-Prakiat Hospital, Pathumthani; **P Sritara**, P Panpunuan, Ramathibodi Hospital, Bangkok; A Sukonthasarn, W Mekara, Maharaj Nakorn Chiang Mai Hospital, Chiang Mai; Y Vorasettakarnkij, E Puripun, King Chulalongkorn Memorial Hospital, Bangkok.

Turkey- 111 patients 17 centers
M Acikel, M Acikel, Ataturk University Medical Faculty, Erzurum; H Akilli, H Demir, Konya Necmettin Erbakan University Meram Faculty of Medicine, Konya; N Ata, N Ata, Osmangazi University Tip Faculty Hospital, Eskisehir; S Bayata, S Bayata, Izmir Ataturk Training and

Research Hospital, Izmir; N Cakmak, A Calik, Siyami Ersek Hospital, Istanbul; M Cayli, M Cayli, Adana Numune Training and Research Hospital, Adana; C Ceyhan, C Ceyhan, Adnan Menderes University Medical Faculty, Aydin; D Erdogan, D Erdogan, Suleyman Demirel University Medical Faculty., Isparta; C Ermis, C Ermis, Akdeniz Univesity Medical Faculty, Antalya; K Kabul, H Demir, GATA (Gulhane Military Medical School), Ankara; M Kanadasi, M Kanadasi, Cukurova University Medical Faculty, Adana; **A Oto**, A Oto, Hacettepe University School of Medicine, Ankara; O Turgut, I Tandogan, Cumhuriyet University Medical Faculty, Sivas; R Yalcin, R Yalcin, Gazi University, Ankara; F Yigit, F Yigit, Baskent University Medical Faculty, Adana; Z Yigit, Z Yigit, Istanbul University Cardiology Institute, Istanbul; M Zoghi, M Zoghi, Ege University Medical Faculty Hospital, Izmir.

Ukraine- 1148 patients 46 centers

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United Kingdom- 400 patients 31 centers

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United States- 3907 patients 336 centers

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