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► **To cite this version:**

Philippe Maury, Jean Benoit Thambo, Alice Maltret, Nicolas Combes, Sébastien Hascoet, et al.. Cohort profile: the ESC EURObservational Research Programme Atrial Fibrillation III (AF III) Registry. *European Heart Journal. Quality of Care and Clinical Outcomes*, 2021, 7 (3), pp.229-237. 10.1093/ehjqcco/qcaa050 . hal-03655993

HAL Id: hal-03655993

<https://hal.science/hal-03655993v1>

Submitted on 19 Jun 2023

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Cohort profile: the ESC EURObservational Research Programme Atrial Fibrillation III (AF III) Registry

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Keywords

Atrial fibrillation • Prospective • Observational • Non-interventional • EORP • Registry

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Aims

The European Society of Cardiology (ESC) EURObservational Research Programme (EORP)-Atrial Fibrillation (AF) III Registry aims to identify contemporary patterns in AF management in clinical practice, assess their compliance with the 2016 ESC AF Guidelines, identify major gaps in guideline implementation, characterize the clinical practice settings associated with good vs. poor guideline implementation and assess and compare the 1-year outcome of guideline-adherent vs. guideline non-adherent management strategies.

Methods and results

Consecutive adult AF patients (n = 8306) were enrolled between 1 July 2018 and 15 July 2019, and individual patient data were prospectively collected across 192 centres and 31 participating countries during the 3-month enrolment period per centre. The Registry collected baseline and 1-year follow-up data in the eight main domains: patient demographic/enrolment setting, AF diagnosis/characterization, diagnostic assessment, stroke prevention treatments, arrhythmia-directed therapies, integrated AF management, major outcomes (death, non-fatal stroke or systemic embolic event, and non-fatal bleeding event), and the quality of life questionnaire.

Conclusion

The EORP-AF III Registry is an international, prospective registry of care and outcomes of patients treated for AF, which will provide insights into the contemporary patterns in AF management, ESC AF Guidelines implementation in routine practice and barriers to optimal management of this highly prevalent arrhythmia.

Introduction

Atrial fibrillation (AF) and its complications pose a major burden to public health and healthcare costs.^{1,2} Currently, AF affects at least 3% of the general adult population^{1,3} and its global prevalence is anticipated to rise substantially in the next decades.^{1,4}

Recently, several key randomized clinical trials (RCTs) on rate and rhythm control^{5,6} and stroke prevention⁷ informed changes in the international guidelines on AF management.⁸ As reflected in the 2016 European Society of Cardiology (ESC) AF Guidelines, management of AF patients encompasses multiple domains, including identification and management of predisposing/underlying conditions, prevention of AF-related thromboembolism, rate and rhythm control and an active involvement of AF patients, and/or their carers.¹

Guideline-adherent AF management has been associated with improved patient outcomes.^{9,10} Nevertheless, numerous observational, large-scale AF registries (Table 1)¹¹ consistently show suboptimal adherence to AF management guidelines. These registries employed different methodologies to attenuate the limitations of observational studies,^{11,12} but all have been initiated (or even completed) before the 2016 ESC AF Guidelines publication, thus providing very limited sources for the assessment of 2016 ESC AF Guidelines implementation.

Table 1 Observational AF registries

Registry	Led by	Enrolment period	Size (n)	Design	AF cohort main features	Participating countries
^a BHS ¹³	ESC	2003–2004	5333	Prospective	ECG confirmed AF ≤ 1 year before inclusion; all-comers	35 ESC member countries
^a EORP-AF Pilot ¹⁴	ESC	2012–2013	3119	Prospective	ECG confirmed AF ≤ 1 year before inclusion; consecutive	9 EU countries
^a EORP-AF General Long-Term ¹⁵	ESC	2014–2016	11 096	Prospective	ECG confirmed AF ≤ 1 year before inclusion	27 ESC member countries
PINNACLE-AF ¹⁶	ACC	2008–2009	>121 000	Quality improvement	Office-based; outpatients	USA
GWTG-ARF ^{17, 18}	AHA	2013–	>20 000	Quality improvement	Inpatients	USA
^a J-RHYTHM ¹⁹	National	2009	7937	Prospective	Outpatients	Japan
^a RUSHIMI ²⁰	National	2011–2012	3304	Prospective	Community-based; consecutive	Japan (Kyoto)
Danish cohort ²¹	National	1996–	NA	Retrospective	Nationwide; consecutive	Denmark
Swedish cohort ²²	National	2005–	NA	Retrospective	Nationwide; all-comers	Sweden
Taiwan cohort ²³	National	1999–	NA	Retrospective	Nationwide; all-comers	Taiwan
GLORIA-AF ²⁴	Industry (Boehringer Ingelheim)	2011–ongoing	Target 56 000	Prospective, inception cohorts	Three overlapping phases, new-onset AF ≤ 3 months before inclusion, CHA ₂ DS ₂ -VASc ≥ 1	International
GARFIELD-AF ²⁵	TRL, UK (Bayer)	2009–ongoing	Target 57 000	Longitudinal (four prospective cohorts)	5 parallelly enrolled overlapping cohorts, new-onset AF ≤ 6 weeks, physician-judged risk of stroke	International
^a PREFER-AF ²⁶	Industry (Daichi Sankyo)	2012–2013	7243	Prospective	All-comers with AF diagnosed within ≤ 1 year, pacemaker/ICD AF diagnosis allowed	7 EU countries
^a ORBIT-AF I ²⁷	Industry (Jansen)	2009–2011	10 126	Prospective	Incident or prevalent AF, outpatients	USA
^a ORBIT-AF II ²⁸	Industry (Jansen)	2013–2015	13 785	Prospective	New-onset AF ≤ 6 months, outpatients	USA
^a BALKAN-AF ²⁹	SAFA	2014–2015	2712	Cross-sectional	Consecutive AF patients	7 Balkan countries

ACC, American College of Cardiology; AF, Atrial fibrillation; AHA, American Heart Association; ECG, electrocardiogram; BHS, EuroHeart Survey; EORP, EuroObservational Research Programme; ESC, European Society of Cardiology; EU, European Union; GARFIELD-AF, Global Anticoagulant Registry in the FIELD-Atrial Fibrillation; GLORIA-AF, Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation; GWTG, Get With The Guidelines programme using National Cardiovascular Data Registry; NA, not applicable; ORBIT-AF, Outcomes Registry for Better Informed Treatment of Atrial Fibrillation; PINNACLE, Practice Innovation and Clinical Excellence programme using National Cardiovascular Data Registry; PREFER-AF, Prevention of Thromboembolic Events European Registry in Atrial Fibrillation; SAFA, Serbian AF Association; TRL, Thrombosis Research Institute.

^aCompleted (otherwise ongoing).

Table 2 Specific objectives of the EORP-AF III Registry

Specific objectives
<ul style="list-style-type: none">• Assess the use of opportunistic or systematic screening to detect AF in daily practice.• Assess the modalities of AF documentation triggering AF treatment in clinical practice—e.g. whether only the guideline-recommended ECG documentation of AF triggers AF treatment or other methods (e.g. the handheld devices) are also considered diagnostic of AF.• Assess whether the diagnostic work-up of AF patients complies with 2016 ESC AF guidelines recommendations.• Evaluate appropriateness of treatment in AF patients in relation to the current 2016 ESC guidelines on AF, as well as the most recent ESC guidelines on other cardiovascular diseases management/prevention.• Evaluate the use of oral anticoagulation or non-pharmacological therapies for the prevention of AF-related thromboembolic events and assess the factors driving a particular choice.• Assess the use of antiarrhythmic therapies and factors driving a particular choice.• Evaluate the use of an integrated approach to AF management in clinical practice.• Obtain contemporary information on the major adverse cardiovascular and cerebrovascular events in AF patients.• Evaluate mortality and other outcomes in relation to therapeutic decisions including adherence to guidelines at 1 year.• Conduct comparisons with the dataset from previous EHS and EORP AF Long Term registry, to allow additional modelling information on time trends, modelling of prevalence/incidence, costs, healthcare utilization, and health economics, in the European population.• Assess progression of AF from paroxysmal (self-terminating) to persistent (non-self-terminating) AF and the impact of validated and less well-established risk factors for progression of AF.• Evaluate changes in the quality of life at baseline and at the 12-month follow-up visit, using a QoL Questionnaire (EuroQoL EQ-5D-5L).
Aims for immediate analysis
<ol style="list-style-type: none">(1) Analysis of the frequency of a complete diagnostic work-up concerning screening for AF, documentation of AF, underlying heart disease(s)/other conditions, clinical AF type, triggering factors, individual patient risk profile assessment, and consequences of AF.(2) Analysis of the frequency of guideline-adherent use of anti-thrombotic treatment, rate control measures, drugs in pharmacological cardioversion, electrical cardioversion, AF ablation, therapies for maintenance of sinus rhythm, and comprehensiveness of management of associated cardiovascular disease (particularly focusing on hypertension and coronary artery disease and systolic heart failure).(3) Analysis of the relationship between the management of AF and morbidity/mortality at 1 year.

AF, atrial fibrillation; ECG, electrocardiogram; EHS, EuroHeart Survey; EORP, EurObservational Research Programme; ESC, European Society of Cardiology.

From 2003 (the Euro Heart Survey¹³ and, subsequently, EurObservational Research Programme, EORP), the ESC has been prospectively observing the ‘real-world’ clinical management of AF patients and ESC AF Guidelines implementation in the member countries. Whereas the ESC EORP AF General Pilot¹⁴ (enrolling from 2012 to 2013) and AF General Long-Term Registry¹⁵ (enrolling from 2013 to 2016) provided valuable data pertaining to the respective time periods, the new ESC EORP-AF III Registry (enrolling from 2018 to 2019) was well-timed between the current 2016 and forthcoming 2020 ESC AF Guidelines, with the potential to optimally assess the uptake and implementation of the former and inform the latter by recognizing the barriers to guideline implementation and knowledge gaps that need to be addressed by targeted education programmes. In addition, a broad compatibility of the EORP-AF registries’ datasets will enable modelling of time trends in various aspects of the management and outcomes of AF patients.

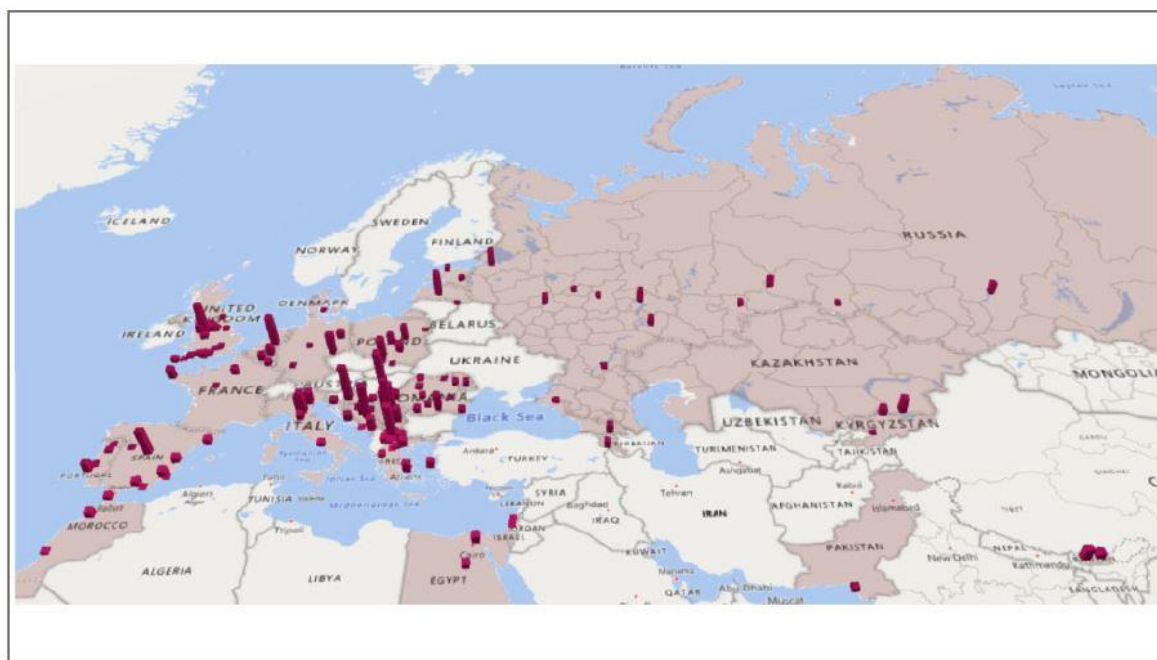
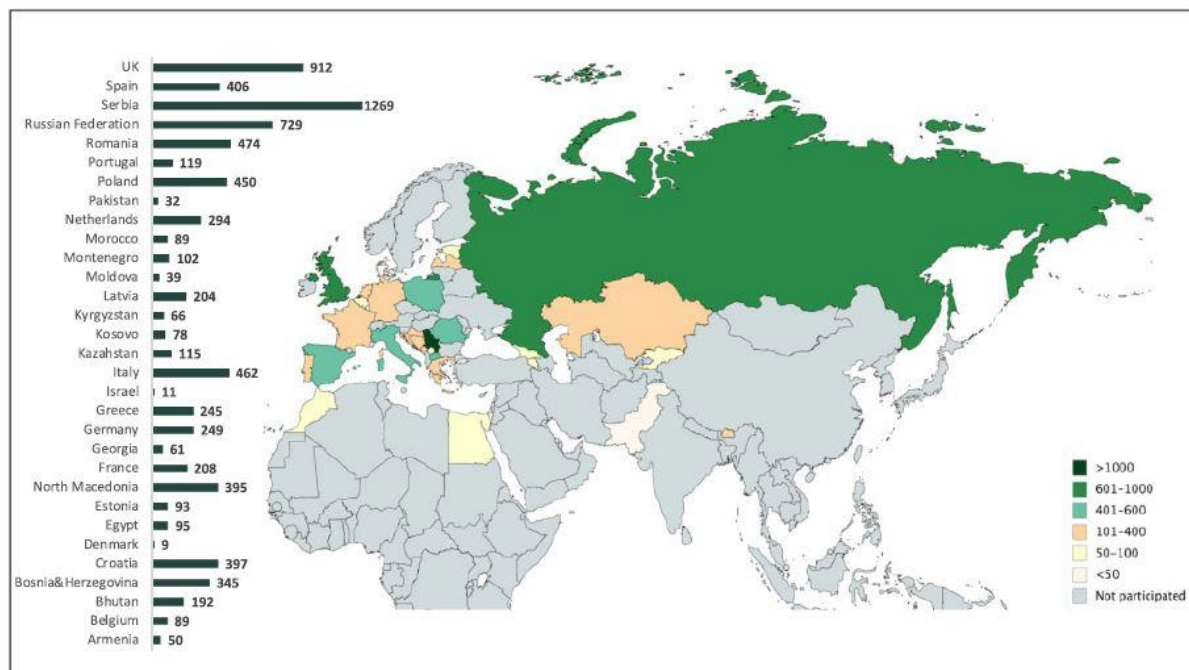
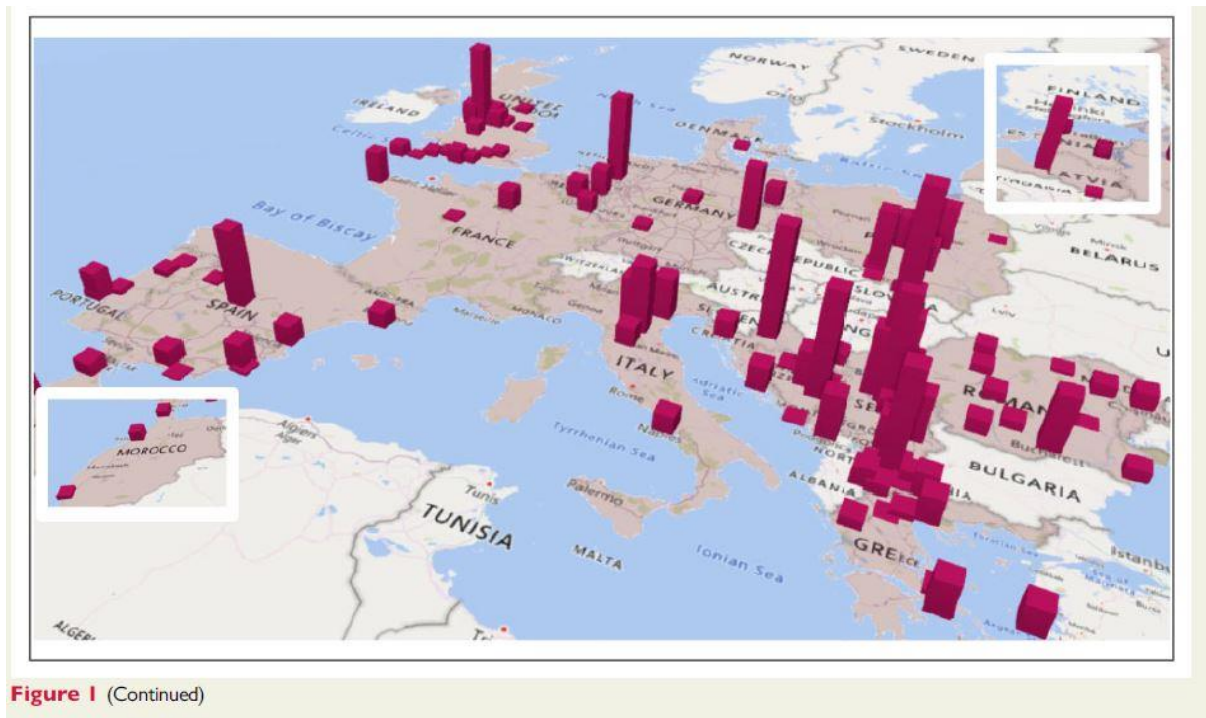


Figure 1 The ESC EORP-AF III Participating Countries and their colour-coded contribution (upper panel), centre distribution per country and proportion of patients included per centre (middle panel shows all participating centres and lower panel focuses on Europe). AF, atrial Fibrillation; EORP, EurObservational Research Programme; ESC, European Society of Cardiology.



Aim of the ESC EORP-AF III Registry

The general objectives of the ESC EORP-AF III registry are to identify contemporary patterns in AF management in clinical practice, assess their compliance with the 2016 ESC AF Guidelines, identify major gaps in the Guidelines implementation and characterize the clinical practice settings associated with good vs. poor AF Guidelines implementation, using the obtained information to improve the AG

Guidelines uptake and facilitate the guideline-adherent management of AF patients in routine clinical practice. In addition, the AF III Registry will assess and compare the 1-year outcome of guideline adherent vs. guideline non-adherent management strategies. The specific objectives of the EORP-AF III registry are listed in Table 2.

Quality of care interventions

Using an electronic case report form (eCRF), individual patient data were collected across eight main data domains including the enrolment setting, patient demographics, AF diagnosis and characterisation, diagnostic assessment related to AF, treatments during the enrolment visit and at discharge, integrated AF management, major outcomes at discharge, and the quality of life assessment at baseline, whereas the 1-year follow-up data will include all these domains except the enrolment setting and demographics. Since AF III Registry aims to capture AF management patterns in routine clinical practice, local AF management strategies were not pre-specified by the study protocol.

Setting

The ESC EORP-AF III registry is an international, prospective, longitudinal, multicentre, non-interventional, observational study including centres managing patients with AF. All 57 ESC member countries were invited to participate, and other countries worldwide were allowed to participate upon their request. Participating centres were appointed by the respective national coordinator, based on the centre technical suitability, profile (i.e. university/public/private, with/ without cardiac surgery and/or interventional cardiology), admission pathways for cardiac patients (cardiology wards/internal medicine wards), management facilities (e.g. the presence of dedicated arrhythmia clinic), and geographic localization.

Population and consent

The overall patient enrolment period in the study spanned from 1 July 2018 to 15 July 2019, but in each centre, patient enrolment was limited to three consecutive months within the study enrolment period. Participating centres were requested to consecutively enroll all eligible adult AF patients and plan a 1-year follow-up visit. All participating patients received detailed written information concerning the study and signed informed consent during the 3-month enrolment period per centre (counted from the first enrolled patient in the centre).

In total, 8306 patients were enrolled from 192 centres across 31 countries (Figure 1). Of 8082 patients included from ESC member countries, 60.3% were male, 91.6% Caucasian, 83.6% were enrolled by a cardiologist, and 36.5% were outpatients. The median age of the registry cohort was 69 years (interquartile range 61–77).

Patient identification

Potential participants were identified from outpatient clinics and hospitals managing AF patients and each patient was given a unique study number.

Start points

During the study (and centre) enrolment period, consecutive patients aged ≥ 18 years, with first-onset or previously documented AF were included. Patients were not required to be in AF at enrolment, but AF must have been electrocardiographically documented or the diagnosis of AF noted in the medical records in the 12 months before enrolment. Patients younger than 18 years, those with atrial flutter only and patients participating in ongoing RCTs were not included.

Baseline and follow-up data

Baseline data included the enrolment setting and patient demographic, AF diagnosis and characterization, AF-related diagnostic assessment (including concomitant risk factors/underlying conditions and stroke and bleeding risk), stroke prevention treatment at discharge, arrhythmia-directed (i.e. rate/rhythm control) therapy at discharge (including

interventions during the baseline visit/hospitalization), integrated AF management, major outcomes at discharge (death, nonfatal stroke or systemic embolic event, and non-fatal bleeding event), and the quality of life questionnaire. These data will be also collected at 1-year follow-up, thus providing information about treatment changes, occurrence of AF-related complications, and patients' outcome.

Data capture and storage

Data were manually entered by the participating physicians or data collecting officers in the registry-specific online eCRF that is accessible using the investigator's unique username and password provided and distributed by the EORP team. Collected patient data are anonymous. Only a unique code identifies patient in the EORP database, whilst patient-identifying data necessary to facilitate follow-up visit are only stored in the centre's local computers or as a paper copy of the Patient Log file, and not in the EORP central database. Anonymized data are stored in the registry-specific central database with limited access protected by individual encrypted and coded passwords. The EORP-AF III Registry database is stored at the EORP Department, European Heart House, 2035 route des Colles, 06903 Sophia Antipolis, France.

Data quality

The EORP-AF III registry database is designed, managed, controlled, and validated according to the ESC EORP standards. The EORP-AF III eCRF has numerous built-in auto cross-checks for data completeness and validity that automatically rises alerts in case of data incompleteness or inconsistency, thus enabling investigators to resolve such issues during data entering. In addition, data were regularly controlled and validated by the EORP-AF III Data Management Team, according to the Data Validation Plan. No formal source data verification will be carried out.

Endpoints and linkage to other data

Adherence to guidelines will be assessed at baseline and after 1-year follow-up, by analysing the use of guideline-recommended AF management strategies (also see Table 2). Reasons for poor guideline implementation will be captured from the replies to specific eCRF questions. Other endpoints including all-cause mortality, non-fatal stroke or systemic embolic events, non-fatal bleeding events, etc. will be recorded at baseline and 1-year follow-up visit. These endpoints will be directly entered in the eCRF, as adjudicated by the participating investigators and supported by pertinent medical records. A joint EORP AF Long-Term General and AF III dataset analysis is planned at a later stage.

Access to data

Direct access to the Registry dataset is limited to the EORP-AF III Data Management and Statistical Analysis teams. Country-specific datasets will be provided to the national cardiology societies/national coordinators for subsequent analysis of the country-specific data.

Conclusion

The EORP-AF III Registry is an international, prospective registry of care for and outcomes of patients treated for AF, which will provide insights into the contemporary patterns in AF management, ESC AF Guidelines implementation in routine practice and barriers to optimal management of this highly prevalent arrhythmia. The ESC has been prospectively observing routine clinical management of AF patients in the member countries since 2003, and the EORP-AF III Registry is well-timed to assess the implementation of the current and inform future ESC AF Guidelines by identifying barriers to guideline implementation and knowledge gaps that need to be addressed by targeted education programmes. Country-specific data will be provided to participating countries in order to facilitate insights into the country-specific barriers to AF guidelines uptake and guideline adherent management of AF patients, thus providing the opportunity for country-specific actions to increase guidelines implementation in practice. By asking questions about the guideline-defined domains of AF management, the registry will also contribute to the awareness of the ESC AF Guidelines at the individual physician level. A broad dataset compatibility across previous and current EORP-AF registries will enable modelling of time trends in various aspects of the management and outcomes of AF patients.

Acknowledgements

The EURObservational Research Programme (EORP) Oversight Committee members, the Registry Executive and Steering Committees. Data collection was conducted by EORP: Yue Song as Clinical Project Manager, Patti-Ann McNeill as Project Officer; Viviane Missiamenou and Sandrine Anglars as Data Managers. Statistical analyses were performed by Cécile Laroche. Overall activities were co-ordinated and supervised by Doctor Aldo P. Maggioni (EORP Scientific Coordinator). Special thanks to European Heart Rhythm Association.

Funding

This work was supported by the Abbott Vascular Int. (2011–2020), Amgen Cardiovascular (2009–2018), AstraZeneca (2014–2021), Bayer AG (2009–2018), Boehringer Ingelheim (2009–2019), Boston Scientific (2009–2012), the Bristol Myers Squibb and Pfizer Alliance (2011–2019), Daiichi Sankyo Europe GmbH (2011–2020), the Alliance Daiichi Sankyo Europe GmbH and Eli Lilly and Company (2014–2017), Edwards (2016–2019), Gedeon Richter Plc. (2014–2016), Menarini Int. Op. (2009–2012), MSD-Merck & Co. (2011–2014), Novartis Pharma AG (2014–2020), ResMed (2014–2016), Sanofi (2009–2011), Servier (2009–2021), Vifor (2019–2022).

Data availability

The data underlying this article are subject to an embargo of 12 months from the publication date of the article. Once the embargo expires the data will be available upon reasonable request to the EORP AF III Executive Committee Chair, with the approval of the EORP Oversight Committee.

Conflict of interest:

T.S.P. reports non-financial support from Pfizer, non-financial support from Bayer, outside the submitted work. G.Y.H.L. reports consultancy and speaker fees from Bayer, Bayer/Janssen, BMS/Pfizer, Biotronik, Medtronic, Boehringer Ingelheim, Microlife, Roche, Daiichi-Sankyo outside the submitted work. No fees received personally. G.B. reports personal fees of small amount from Medtronic, Boston, Biotronik, Boehringer, outside the submitted work. P.K. reports grants from NIHR, during the conduct of the study; grants and non-financial support from European Union, British Heart Foundation, Leducq Foundation, Medical Research Council (UK), and German Centre for Heart Research, from several drug and device companies active in atrial fibrillation and has received honoraria from several such companies, outside the submitted work. In addition, Dr Kirchhof is listed as inventor on two patents held by University of Birmingham (Atrial Fibrillation Therapy WO 2015140571, Markers for Atrial Fibrillation WO 2016012783). E.A. reports Speaker's fees from Biosense Webster. I.S. reports personal fees and non-financial support from Bristol Myers Squibb, personal fees from Pfizer, Bayer Pharma AG, non-financial support from Menarini Foundation, outside the submitted work. R.L. reports personal fees and non-financial support from Boston Scientific, personal fees and non-financial support from Medtronic, Biotronik, Abbott, and Boehringer-Ingelheim, grants from STRATEGMED II—project of the National Centre for Research and Development 'Prophylaxis and Treatment of Civilization Disease'—Non-invasive monitoring for the early detection of atrial fibrillation, outside the submitted work. L.F. reports personal fees from BMS Pfizer, personal fees from Boehringer Ingelheim, personal fees from Bayer, personal fees from Medtronic, personal fees from Novartis, outside the submitted work. A.P.M. reports personal fees from Bayer, personal fees from Fresenius, personal fees from Novartis, outside the submitted work. C.P.G. reports grants and non-financial support from Bristol Myers Squibb, grants, personal fees and non-financial support from Daiichi Sankyo, outside the submitted work. All other authors declared no conflict of interest.

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Appendix 1

AF III

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