**CONFIDENTIAL**

|  |  |
| --- | --- |
| **STUDY TITLE:**  The atrial FibriLlatiOn real World management registry  in the Middle East & Africa—Design and rationale  **CASE REPORT FORM** | |
| **PROTOCOL NO.:** | X9001174 |
| **SPONSOR:** | Pfizer Sponsored study |
| **COLLABORATOR:** | IQVIA |

**Version 2.0**

**Version Date 02Aug2018**

The text in red is for EDC platform programing purposes.

The subject number is automatically assigned when creating a new subject in the EDC platform.

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| **Selection criteria** |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| **Date of Visit (DD/MM/YYYY):** |  |  |  |
|  | DD | MM | YYYY |

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| **SUBJECT ELIGIBILITY** |

In order for the subject to be eligible for the study, he/she must meet ALL inclusion criteria. If the response is “No” to any of the inclusion criteria, the subject is not eligible to participate in the study.

|  |  |  |
| --- | --- | --- |
| **INCLUSION CRITERIA** | **Yes** | **No** |
| 1. All male or female patients aged 18 years and older at the date of inclusion.   **Age at inclusion in the study :** [Mandatory]   |  | | --- | |  | |  | |  |  |
| 1. Patient newly diagnosed (within the recruitment period (estimated to be 12 months) and 90 days before the baseline visit) with non-valvular atrial fibrillation (NVAF) and for whom treatment has started by the caring physician for the prevention of stroke / systemic embolism |  |  |
| 1. Signed informed consent   **Date of informed consent for data collection (DD/MM/YYYY):**   |  |  |  | | --- | --- | --- | |  |  |  | | DD | MM | YYYY | |  |  |

In order for the subject to be eligible the study, he/she must NOT meet the exclusion criterion. If the response is “Yes” to this exclusion criterion, the subject is not eligible to participate in the study.

| **EXCLUSION CRITERIA** | **Yes** | **No** |
| --- | --- | --- |
| 1. Severe psychiatric illness or other disease or circumstances that could compromise participation in the study. Patients are not to be enrolled if major difficulties with follow-up are anticipated, for example, patients with no valid residency permit or those planning to leave the country before the next scheduled follow-up |  |  |
| 1. Current participation in an interventional clinical trial |  |  |
| 1. AF with a generally reversible cause defined as non-cardiac surgery, post-cardiac surgery (AF within 3 months after surgery), hyperthyroidism, pulmonary embolism, pneumonia and acute myocardial infarction. |  |  |
| 1. Mechanical heart valves or valve disease expected to require valve replacement |  |  |
| 1. A medical condition other than AF for which chronic use of VKA/NOAC is indicated |  |  |
| Pregnant or Breast-feeding women. Pregnancy to be ruled out according to normal practice method of each site |  |  |

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| **BASELINE VISIT** |

### SUBJECT INFORMATION

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| **DeMOGRAPHICS** |

1. **GENDER:** [Mandatory]

Male

Female

1. **RACE:** [Mandatory]

Caucasian (including Arab)

Other Caucasian (non - Arab)

Asian

African (black African)

Hispanic / Latino

Unknown

Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **VITAL SIGNS** |

1. **HEIGHT (**cm)**:** \_\_\_\_\_\_\_\_\_\_\_ [Range: 50 – 220 cm][Mandatory]
2. **WEIGHT (**Kg)**: \_\_\_\_\_\_\_\_\_\_\_** [Range: 35.0 – 250.0 kg] [Mandatory]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of measurement (DD/MM/YYYY): [Mandatory] |  |  |  |  | Date of visit |
|  | DD | MM | YYYY |  |

1. BMI: \_\_ \_\_. \_\_ kg/ m2 [calculated]
2. **BLOOD PRESSURE AND HEART RATE AT REST:** [Mandatory]

Systolic (SBP): \_\_\_\_\_\_\_\_\_\_\_ mmHg [Range: 40 – 200 mmHg]

Diastolic (DBP): \_\_\_\_\_\_\_\_\_\_\_ mmHg [Range: 60 – 300 mmHg]

Heart Rate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ beats/ min

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of measurement (DD/MM/YYYY): [Mandatory] |  |  |  | Date of visit | |
| DD | MM | YYYY |
| DD | MM | YYYY |  |

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| **LIFESTYLE/ HABITS** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **SMOKING STATUS AT ENROLLMENT:**   Current smoker  If yes specify,   * Age of onset: ----------------   + - Cigars     - Water Pipe   + Cigarettes * How many cigarettes per day? Specify ------ * Pack/years: (calculated)   Former smoker  If yes specify,   * Age of onset: ---------------- * Age of termination:-------------   + - Cigars     - Water Pipe     - Cigarettes * In average how many cigarettes per day? Specify ------ * Pack/years: (calculated)   Non-smoker / Non passive smoker  Passive smoking (at home / other)   1. **Does the subject consume alcohol at enrollment?** No  Yes   If yes specify,   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Start date (DD/MM/YYYY): [Mandatory] |  |  |  |  | | DD | MM | YYYY |   How many units per week? Specify ------------------------- MEDICAL HISTORY AND RISK FACTORS  |  | | --- | | **MEDICAL History and RISK FACTORS** | |

Please mark if patient has any of the following medical history/ risk factors. Please mark all that apply

| No significant medical history / risk factors [list below disabled] | | |
| --- | --- | --- |
| 1. Stroke/ TIA (Transient ischemic attack) | No  Yes | If Yes, specify start date --/--/-- |
| 1. Venous Thromboembolism | No  Yes | If Yes, specify start date --/--/-- |
| 1. Congestive Heart Failure/ Left ventricular Dysfunction | No  Yes | If Yes, specify start date --/--/-- |
| 1. Coronary Arterial Disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Coronary surgery/ Stenting | No  Yes | If Yes, specify start date --/--/-- |
| 1. Carotid surgery/stenting | No  Yes | If Yes, specify start date --/--/-- |
| 1. Myocardial infarction | No  Yes | If Yes, specify start date --/--/-- |
| 1. Peripheral Arterial disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Peripheral vascular disease/ stenting/surgery | No  Yes | If Yes, specify start date --/--/-- |
| 1. Cerebrovascular Disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Valvular Diseases | No  Yes | If Yes, specify start date --/--/-- |
| 1. Bleeding History | No  Yes | If Yes, specify start date --/--/-- |
| 1. Hypercholesterolemia | No  Yes | If Yes, specify start date --/--/-- |
| 1. Hypertension | No  Yes | If Yes, specify start date --/--/-- |
| 1. Other Cardiovascular disease.   Please specify \_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |
| 1. Renal failure | No  Yes | If Yes, specify start date --/--/-- |
| 1. Chronic kidney disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Dialysis-dependent kidney disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Renal transplant | No  Yes | If Yes, specify start date --/--/-- |
| 1. Other Renal disease.   Please specify \_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |
| 1. Abnormal liver function | No  Yes | If Yes, specify start date --/--/-- |
| 1. Cirrhotic liver disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Other Liver disease   Please specify \_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |
| 1. Chronic obstructive pulmonary disease (COPD) | No  Yes | If Yes, specify start date --/--/-- |
| 1. Obstructive Sleep Apnea | No  Yes | If Yes, specify start date --/--/-- |
| 1. Asthma | No  Yes | If Yes, specify start date --/--/-- |
| 1. Other Respiratory disease   Please specify \_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |
| 1. Diabetes Mellitus | No  Yes | If Yes, specify start date --/--/-- |
| 1. Other Endocrine disorders   Please specify \_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |
| 1. Autoimmune disease | No  Yes | If Yes, specify start date --/--/-- |
| 1. Anemia | No  Yes | If Yes, specify start date --/--/-- |
| 1. Malignancy | No  Yes | If Yes, specify start date --/--/-- |
| 1. Any genetic factors considered to have an increased bleeding risk   Please Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_ | No  Yes | If Yes, specify start date --/--/-- |

1. **Medication contributing to risk factors**

Does the patient have any history of the following medication use predisposing to bleeding?

| 1. Antiplatelet agents | No  Yes | If Yes, specify start date --/--/-- |
| --- | --- | --- |
| 1. Nonsteroidal anti-inflammatory drugs | No  Yes | If Yes, specify start date --/--/-- |

1. **Calculated** [**CHA2DS2-VASc**](http://www.cardiosource.org/Science-And-Quality/Clinical-Tools/Atrial-Fibrillation-Toolkit.aspx)**stroke risk score: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [auto calculated based on the given variables]**
2. **Bleeding risk factors.** Please mark the factors applicable per patient

|  |  |  |  |
| --- | --- | --- | --- |
| **Modifiable bleeding risk factors** | | **Potentially modifiable bleeding risk factors** | |
| Hypertension (especially when systolic blood pressure is >160 mmHg) | No  Yes | Anemia | No  Yes |
| Labile INR or time in therapeutic range <60% in patients on vitamin K antagonists | No  Yes | Impaired renal function | No  Yes |
| Medication predisposing to bleeding, such as antiplatelet drugs and non-steroidal anti-inflammatory drugs | No  Yes | Impaired liver function | No  Yes |
| Current alcohol consumption (number of drinks/ week); Excess of alcohol consumption is defined as ≥8 drinks/week | No  Yes | Reduced platelet count or function | No  Yes |

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| **ATRIAL FIBRILLATION CHARACTERISTICS** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Date of diagnosis of atrial fibrillation (DD/MM/YYYY):** [Only month and year is mandatory, Day can be unknown] [if “date of baseline” is chosen date field inactivates] |  |  |  | **Date of baseline** |
| DD | MM | YYYY |  |
|  |  |  |  |

1. **Method of NVAF Diagnosis**

Electrocardiogram  Implantable Devices

Holter Monitor  Online/ Smart applications

Other, Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Family History of related diseases among first degree relatives**

NVAF:  Yes  No

Stroke:  Yes  No

Venous thromboembolism:  Yes  No

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| **LABORATORY ASSESMENTS** |

1. **INR History.** Please add here all the INR measurements done **during the diagnosis period** according to normal practice for patients taking Vitamin K Antagonists [dates and values below will allow for TTR to be calculated] [data will not appear in cases where VKAs are not used]

Not applicable (the patients is not receiving VKA treatment at baseline)

|  |  |
| --- | --- |
| **INR Value** | **Date of Measurement** (DD/MM/YYYY) |
|  | \_\_\_\_/\_\_\_/\_\_\_\_ |
| **[Add rows]** |  |

1. **TTR Data**

[Once the above data is entered, the below automatic calculations will show]

Rosendaal Method

|  |  |
| --- | --- |
| **Days Within Range** |  |
| **Total Days** |  |
| **% Days Within Range** |  |

|  |  |
| --- | --- |
| % in Range |  |
| **Total Number of Tests** |  |
| **Number of Tests in Range** |  |
| **% of Tests in Range** |  |

1. **Other Laboratory Assessments:** Please add here details of other significant laboratory assessments done during diagnosis period according to normal practice

Laboratory assessments not performed

|  |  |  |  |
| --- | --- | --- | --- |
| **Measurement** | **Value** | **Unit** | **Date (DD/MM/YYYY)** |
| RBC Count |  | 106/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Platelet count |  | 103/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| WBC count |  | 103/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant CBC results.  Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Creatine Kinase-MB |  | U/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Troponin I  Troponin T  (please enter test done as per normal practice) |  | ng/ mL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Sodium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Potassium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Calcium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant electrolyte results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| TSH |  | mU/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| FT4 |  | pmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| FT3 |  | pmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant thyroid function results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| B-type natriuretic peptide |  | pg/ mL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Creatinine |  | mg/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Estimated glomerular filtration rate [calculated according to Modification of Diet in Renal Disease Study (MDRD)] | | | |
| Aspartate Amino Transferase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Alanine Amino Transferase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Alkaline Phosphatase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Albumin |  | g/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Total Bilirubin |  | mg/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant liver function results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |

1. **Electrocardiogram assessment.** Please enter the results of the latest electrocardiogram assessment done as per normal clinical practice.

ECG not available

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of measurement (DD/MM/YYYY): [Mandatory] |  |  |  | Date of visit |
| DD | MM | YYYY |
|  |  |  |  |  |
| Results obtained:  Normal rhythm  Abnormal rhythm |  |  |  |  |

### MEDICATIONS SINCE DIAGNOSIS

### Antithrombotic Medications Treatments for Stroke prevention in patients with NVAF Since Diagnosis. Please capture all antithrombotic atrial fibrillation medications given since diagnosis (including those prescribed in the current visit).

| **ANTI-THROMBOTIC Therapy Class**  [Drop down menu] | **Drug name**  [Both compound and commercial names should be allowed] | **Frequency**  [Drop down menu] | **Total daily dose**  [Drop down menu] | **Start date**  (DD/MM/YYYY)  [full date mandatory] | **Stop date**  (DD/MM/YYYY)  [full date mandatory] | **Reason for discontinuing**  [Drop down menu] |
| --- | --- | --- | --- | --- | --- | --- |
| Oral Anticoagulant  Antiplatelet therapy |  | QD  BID  TID  QID  PRN  Other. (specify):\_\_\_ | \_\_\_\_\_\_\_  mg  units | \_\_\_\_/\_\_\_/\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing | Subject request  Adverse events (specify): \_\_\_\_  Unknown  Other (specify):\_\_\_ |
| Add rows  [Allow for 30 rows] |  |  |  |  |  |  |

1. **Other Concomitant Treatments Since Diagnosis.** Please capture any other medications taken from below significant categories for the 6 months before baseline.

|  |  |  |
| --- | --- | --- |
| **Treatment** | **Drug name**  [Both compound and commercial names should be allowed] [Drop down menu] | **Is this medication Ongoing at Baseline?** |
| Anti-arrhythmics | Amiodarone  Dronedarone  Flecainide  Propafenone  Ibutilide  Vernakalant  Other, Please specify: \_\_\_\_\_ | Yes  No |
| Lipid-lowering drugs |  | Yes  No |
| Beta-blockers | Bisoprolol  Carvedilol  Metoprolol  Nebivolol  Esmolol  Other, Please specify: \_\_\_\_\_ | Yes  No |
| Calcium channel blockers | Diltiazem  Verapamil  Other, Please specify: \_\_\_\_\_ | Yes  No |
| Cardiac glycosides | Digoxin  Digitoxin  Other, Please specify: \_\_\_\_\_ | Yes  No |
| Other Anti-hypertensive drugs (diuretics, , angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers) |  | Yes  No |
| Nonsteroidal anti-inflammatory drugs |  | Yes  No |
| Acetylsalicylic Acid |  | Yes  No |
| P2Y12 |  | Yes  No |
| Oral antidiabetic drugs |  | Yes  No |
| Insulin |  | Yes  No |
| Anxiolytics |  | Yes  No |
| Antidepressants |  | Yes  No |
| Glucocorticoids |  | Yes  No |
| Synthetic thyroid hormones |  | Yes  No |
| Oral contraception |  | Yes  No |
| Hormone replacement therapy |  | Yes  No |
| Bisphosphonates |  | Yes  No |
| Calcitonin |  | Yes  No |
| Selective estrogen receptor modulators. |  | Yes  No |
| Antifungals |  | Yes  No |
| Antibiotics |  | Yes  No |
| Add rows [Allow for 30 rows] |  |  |

### ADVERSE EVENTS

**DID THE SUBJECT REPORT ANY ADVERSE EVENTS DURING THE VISIT?**

No

Yes. Please complete the Adverse Events Log [If yes, the corresponding log will appear]

### HEALTHCARE RESOURCE UTILIZATION. Please enter only Healthcare resources associated with diagnosis of NVAF as per standard of care since NVAF diagnosis

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Did the patient undergo any laboratory assessments? | | | | No | | | | | | | Yes |
| If yes, please specify type and number of all laboratory assessments performed | | | | | | | | | | | | |
| Complete Blood Count | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Blood Chemistry | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Urine Analysis | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Other | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Unknown | | No | | | Yes | | |  | | | | |
|  | | | |  | | | |  | |  | | |
| Did the patient undergo any imaging exam? | | | | No | | | | | | | Yes |
| If yes, please specify type and number of all imaging tests performed: | | | | | | | | | | | | |
| X-Ray | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| ECG | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Echocardiogram | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Holter monitor | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Stress test | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Computed tomographic angiography | | No | | | Yes | | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Brain Computer Tomography | | No | | | Yes | | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Nuclear test | | No | | | Yes | | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Upper gastrointestinal endoscopy | | No | | | Yes | | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Lower gastrointestinal endoscopy | | No | | | Yes | | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Other, Please specify \_\_\_\_\_\_\_\_ | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Unknown | | **No** | | | **Yes** | | |  | | | | |
| Did the patient undergo any Surgical / non-surgical procedures? | | | | No | | | | | | | Yes |
| If yes, please specify type and number of all Surgical / non-surgical procedures performed: | | | | | | | | | | | | |
| Electrical cardioversion | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Ablation | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |
| Other, Please specify\_\_\_\_\_\_\_\_\_\_\_\_ | | No | | | Yes | | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Did the patient undergo any inpatient admission since NVAF diagnosis**  Including all‐cause hospitalization/ re-hospitalization, cardiovascular re-hospitalizations (AF related and non–AF related) | | | | No  Yes | |
| If yes, please describe all inpatient stays during diagnosis: | | | | | | |
| **Reason for hospitalization** | **Type of ward** | **Type of hospital** | **Admission date** | | **Discharge date** |
| Stroke (ischemic, hemorrhagic, etc)  Systemic embolism  Myocardial infarction  Bleeding events  Transient Ischemic Attack (TIA) | Coronary care unit (CCU) or  Cardiac Intensive Care Unit (CICU)  Supportive care  Other, please specify: \_\_\_\_\_\_ | Public  Private | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** | | **\_\_\_ / \_\_\_\_ / \_\_\_\_** |
| Add rows |  |  |  | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Did the patient undergo any outpatient visit?** | | No | | Yes | | |
| **If yes, report type and number of all visits performed:** | |  | | | |
| Emergency care visit | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Outpatient visit to general practitioner | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Outpatients visit to a specialist | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Other, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Did patient diagnosis include any other event of below categories which have impact on healthcare resources?** | | No | | Yes | | |
| **If yes, report type and number** | |  | | | |
| Surgery cancellation | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Surgery delay | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Patient refuses recommended treatment | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Events that require additional hospitalization or medical intervention | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Events leading to treatment not being completed (including adverse events related to drugs etc ) | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Other, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |

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| **FOLLOW UP VISIT** |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Date of Visit (DD/MM/YYYY):** |  |  |  |
|  | DD | MM | YYYY |

1. **WEIGHT (**Kg)**: \_\_\_\_\_\_\_\_\_\_\_** [Range: 35.0 – 250.0 kg] [Mandatory]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of measurement (DD/MM/YYYY): [Mandatory] |  |  |  |  | Date of visit |
|  | DD | MM | YYYY |  |

1. **BLOOD PRESSURE AND HEART RATE AT REST:** [Mandatory]

Systolic (SBP): \_\_\_\_\_\_\_\_\_\_\_ mmHg [Range: 40 – 200 mmHg]

Diastolic (DBP): \_\_\_\_\_\_\_\_\_\_\_ mmHg [Range: 60 – 300 mmHg]

Heart Rate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ beats/ min

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of measurement (DD/MM/YYYY): [Mandatory] |  |  |  | Date of visit |
| DD | MM | YYYY |

|  |
| --- |
| **LABORATORY ASSESMENTS** |

1. **INR History.** Please add here all the INR measurements done since last visit according to normal practice, only for patients taking vitamin K antagonist [dates and values below will allow for TTR to be calculated]

Not applicable (the patients is not receiving VKA treatment at baseline)

|  |  |
| --- | --- |
| **INR Value** | **Date of Measurement** (DD/MM/YYYY) |
|  | \_\_\_\_/\_\_\_/\_\_\_\_ |
| **[Add rows]** |  |

1. **TTR Data**

[Once the above data is entered, the below automatic calculations will show]

Rosendaal Method

|  |  |
| --- | --- |
| **Days Within Range** |  |
| **Total Days** |  |
| **% Days Within Range** |  |

|  |  |
| --- | --- |
| % in Range |  |
| **Total Number of Tests** |  |
| **Number of Tests in Range** |  |
| **% of Tests in Range** |  |

1. **Other Laboratory Assessments:** Please add here details of other significant laboratory assessments done since last visit according to normal practice. If more than one assessment per test is performed, please, report the most current one.

|  |  |  |  |
| --- | --- | --- | --- |
| **Measurement** | **Value** | **Unit** | **Date (DD/MM/YYYY)** |
| RBC Count |  | 106/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Platelet count |  | 103/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| WBC count |  | 103/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant CBC results.  Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Creatine Kinase-MB |  | U/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Troponin I  Troponin T  (please enter test done as per normal practice) |  | ng/ mL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Sodium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Potassium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Calcium |  | mmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant electrolyte results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| TSH |  | mU/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| FT4 |  | pmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| FT3 |  | pmol/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant thyroid function results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| B-type natriuretic peptide |  | pg/ mL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Creatinine |  | mg/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Estimated glomerular filtration rate [calculated according to Modification of Diet in Renal Disease Study (MDRD)] | | | |
| Aspartate Amino Transferase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Aspartate Amino Transferase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Alkaline Phosphatase |  | U/ L  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Albumin |  | g/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Serum Total Bilirubin |  | mg/ dL  Other, please specify: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |
| Other significant liver function results. Please specify test name: \_\_\_\_\_\_\_\_\_\_ |  | Please specify unit: \_\_\_\_ | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  Date of visit |

### HEALTHCARE RESOURCE UTILIZATION. Please enter only Healthcare resources associated with management of NVAF since last visit as per standard of care

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Did the patient undergo any laboratory assessments since the last visit? | | No | | | | | Yes |
| If yes, please specify type and number of all laboratory assessments performed | | | | | | | | |
| Complete Blood Count | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Blood Chemistry | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Urine Analysis | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Other | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Unknown | No | | Yes |  | | | |
|  | |  | | |  |  | | |
| Did the patient undergo any imaging exam since last visit? | | No | | | | | Yes |
| If yes, please specify type and number of all imaging tests performed: | | | | | | | | |
| X-Ray | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| ECG | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Echocardiogram | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Holter monitor | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Stress test | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Computed tomographic angiography | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Brain Computer Tomography | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Nuclear test | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Upper gastrointestinal endoscopy | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Lower gastrointestinal endoscopy | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Other, Please specify \_\_\_\_\_\_\_\_ | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Unknown | **No** | | **Yes** |  | | | |
| Did the patient undergo any Surgical / non-surgical procedures since last visit? | | No | | | | | Yes |
| If yes, please specify type and number of all Surgical / non-surgical procedures performed: | | | | | | | | |
| Electrical cardioversion | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Ablation | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |
| Other, Please specify\_\_\_\_\_\_\_\_\_\_\_\_ | No | | Yes | If yes, specify the number: |\_\_\_|\_\_\_|\_\_\_| | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Did the patient undergo any inpatient admission since last visit?**  Including all‐cause hospitalization/ re-hospitalization, cardiovascular re-hospitalizations (AF related and non–AF related) | | | | No  Yes | |
| If yes, please describe all inpatient stays since last visit: | | | | | | |
| **Reason for hospitalization** | **Type of ward** | **Type of hospital** | **Admission date** | | **Discharge date** |
| Stroke (ischemic, hemorrhagic, etc)  Systemic embolism  Myocardial infarction  Bleeding events  Transient Ischemic Attack (TIA) | Coronary care unit (CCU) or  Cardiac Intensive Care Unit (CICU)  Supportive care  Other, please specify: \_\_\_\_\_\_ | Public  Private | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** | | **\_\_\_ / \_\_\_\_ / \_\_\_\_** |
| Add rows |  |  |  | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Did the patient undergo any outpatient visit since last visit?** | | No | | Yes | | |
| **If yes, report type and number of all visits performed:** | |  | | | |
| Emergency care visit | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Outpatient visit to general practitioner | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Outpatients visit to a specialist | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Other, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Did patient diagnosis include any other event of below categories which have impact on healthcare resources since last visit?** | | No | | Yes | | |
| **If yes, report type and number** | |  | | | |
| Surgery cancellation | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Surgery delay | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Patient refuses recommended treatment | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Events that require additional hospitalization or medical intervention | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Events leading to treatment not being completed (including adverse events related to drugs etc ) | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |
| Other, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | If yes, number: |\_\_\_|\_\_\_|\_\_\_| | | |

### MEDICATIONS

1. **ANTITHROMBOTIC MEDICATIONS:**

Are there any changes in antithrombotic medications including changes in dosage since last visit?

No

Yes. Please complete the antithrombotic Medications Log [If the response is yes, the corresponding log appears]

1. **OTHER CONCOMITANT MEDICATIONS:**

Are there any changes in other concomitant medications including changes in dosage since last visit?

No other concomitant medications

Yes. Please complete the Other Concomitant Medications Log [If the response is yes, the corresponding log appears]

### ADVERSE EVENTS AND CLINICAL OUTCOMES

1. **DID SUBJECT REPORT ANY NEW ADVERSE EVENTS SINCE LAST VISIT?**

No

Yes. Please complete the Adverse Events Log [If yes, the corresponding log will appear]

1. **CLINICAL OUTCOMES.** Please add here if any of the following events has been experienced since last visit. Please complete the adverse events form in case of any of them marked as “yes” [Adverse events page to be open in case any below is marked as yes]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | **Date of diagnosis** |  | **Action taken with treatment** |
| Stroke | Yes | No |  |  |  |
| If yes, please specify the type of stroke:  Ischemic  Hemorrhagic  Unknown | | | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** |  | No change  Drug change  Drug discontinuation |
| Systemic embolism | Yes | No | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** |  | No change  Drug change  Drug discontinuation |
| Transient Ischemic Attack (TIA) | Yes | No | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** |  | No change  Drug change  Drug discontinuation |
| Myocardial infarction | Yes | No | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** |  | No change  Drug change  Drug discontinuation |
| ~~B~~leeding events | Yes | No |  |  |  |
| If yes, please specify the type of bleeding:  Major bleeding event  Clinically relevant non-major bleeding event  Minor bleeding event | | | **\_\_\_\_ / \_\_\_\_ / \_\_\_\_** |  | No change  Drug change  Drug discontinuation |

**Calculated** [**CHA2DS2-VASc**](http://www.cardiosource.org/Science-And-Quality/Clinical-Tools/Atrial-Fibrillation-Toolkit.aspx)**stroke risk score:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **END of Study**  **Study Completion/ Early Withdrawal** |

### SUBJECT INFORMATION

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **END OF STUDY DATE (DD/MM/YYYY):** |  |  |  |
|  | DD | MM | YYYY |

1. **REASON FOR END OF OBSERVATION:** Was the study completed according to protocol?

Yes

No [Following menu to appear]

If No, Please enter the date and reason for withdrawal:

Withdrawal of consent

Lost of follow-up

Death

Adverse events Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other reasons. Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | DD | MM | YYYY |

Date of subject withdrawal (DD/MM/YYYY):

|  |
| --- |
| **logs** |

[Items included in this section will be included at the end of the study visits and they will be completed each time that some additional information is available. In study visits the corresponding questions will refer the physician to the corresponding log]

### Antithrombotic Medications for Stroke prevention in patients with NVAF. Please capture all anti-thrombotic.

| **ANTI-THROMBOTIC Therapy Class**  [Drop down menu] | **Drug name**  [Both compound and commercial names should be allowed] | **Frequency** | **Total daily dose** | **Start date**  (DD/MM/YYYY)  [full date mandatory] | **Stop date**  (DD/MM/YYYY)  [full date mandatory] | **Reason for discontinuing**  [Drop down menu] |
| --- | --- | --- | --- | --- | --- | --- |
| Oral Anticoagulant  Antiplatelet therapy |  | QD  BID  TID  QID  PRN  Other | \_\_\_\_\_\_\_  mg  units | \_\_\_\_/\_\_\_/\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing | Subject request  Adverse events (specify): \_\_\_\_  Unknown  Other (specify):\_\_\_ |
| Add rows  [Allow for 30 rows] |  |  |  |  |  |  |

1. **Other Concomitant Medications.** Please capture any other medications taken from last visit and for the below significant categories. Please add as many rows as applicable

|  |  |  |  |
| --- | --- | --- | --- |
| **Treatment** | **Drug name**  [Both compound and commercial names should be allowed] | **Start date after Baseline**  **Ongoing from baseline**  **DD/MM/YYYY**  [Full date mandatory] | **Stop date**  **DD/MM/YYYY**  [Full date mandatory] |
| Antiarrhythmics | Amiodarone  Dronedarone  Flecainide  Propafenone  Ibutilide  Vernakalant  Other, Please specify: \_\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Lipid-lowering drugs |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Beta-blockers | Bisoprolol  Carvedilol  Metoprolol  Nebivolol  Esmolol  Other, Please specify: \_\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Calcium channel blockers | Diltiazem  Verapamil  Other, Please specify: \_\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Cardiac glycosides | Digoxin  Digitoxin  Other, Please specify: \_\_\_\_\_ | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Other Anti-hypertensive drugs (diuretics, , angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers) |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Nonsteroidal anti-inflammatory drugs |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Acetylsalicylic Acid |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| P2Y12 |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Oral antidiabetic drugs |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Insulin |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Anxiolytics |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Antidepressants |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Glucocorticoids |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Synthetic thyroid hormones |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Oral contraception |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Hormone replacement therapy |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Bisphosphonates |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Calcitonin |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Selective estrogen receptor modulators. |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Antifungals |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Antibiotics |  | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing from baseline | \_\_\_\_/\_\_\_/\_\_\_\_  Ongoing during this visit |
| Add rows [Allow for 30 rows] |  |  |  |

1. **ADVERSE EVENTS AND CLINICAL OUTCOMES.** All AEs and clinical outcomes from initial informed consent must be reported. [Log lines will be numbered by the system]

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Log N°** | **Adverse Event Name**  (One event per row.) | **Start date**  (DD/MM/YYYY) | **Stop date** (DD/MM/YYYY) | **Status at date of report or death** | | **Severity / Intensity** | **Causality to a suspect product(drop down according to Pfizer’s form)** | | **Last action taken with suspected product in response to the event (s)** | | **Concomitant medication or additional treatment given for this AE?** | **Is the event serious?** |
|  | **Stroke**  **Bleeding event**  **Transient ischemic attack**  **Myocardial infarction**  **Systemic embolism**  **Other, Please specify: \_\_\_\_\_\_\_** | **\_\_\_\_/\_\_\_\_/\_\_\_\_** | **\_\_\_\_/\_\_\_\_\_/\_\_** | | Recovered  Recovered with sequela  [if recovered or recovered with sequela] Specify. Recovery date: **\_\_\_\_/\_\_\_\_\_/\_\_\_\_**  Recovering  Not recovered  Unknown | Mild  Moderate  Severe | | **No**  **Yes**  **If Yes, Specify which suspect product (s): \_\_\_\_\_\_\_** | | Withdrawn permanently  Withdrawn Temporaily  Dose reduced  Dose increased  Dose not changed  Unknown  Not Applicable | **No**  **Unknown**  **Yes** | **No**  **Yes**  If yes, after completing this form, please print, complete and sign the SAE form and send to IQVIA within 24 hours [when chosen the next table options will appear]  **Initial report**  **Follow-up report** |

[Options showing when Serious is entered as Yes]

|  |  |  |  |
| --- | --- | --- | --- |
| **Log N°** | **Seriousness criteria**  (check all that apply)  (DD/MM/YYYY) | **Date Investigator / Investigational Staff became aware of SAE**  (DD/MMYYYY) | **Investigator Narrative** |
|  | Resulted in Death [if marked following will appear:]  Date of death: \_\_\_\_/\_\_\_\_/\_\_\_\_  Cause(s) of Death: \_\_\_\_\_\_  Was an autopsy performed?  Yes  No  Unknown  If Yes, what was the autopsy determined cause of death: \_\_\_\_\_\_\_\_\_\_\_\_\_ | **\_\_\_\_/\_\_\_\_/\_\_\_\_** |  |
| Life threatening  Hospitalization/ Prolongation of hospitalization, if marked  Date of admission: \_\_\_\_/\_\_\_\_/\_\_\_\_ Date of discharge: \_\_\_\_/\_\_\_\_/\_\_\_\_ |
|  |
|  |
| Persistent / significant disability / incapacity |
| Congenital anomaly / birth defect |
| Medically important event |