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### Table 00: Comments

- 1 The data was extracted from the GARFIELD-AF registry database on 28 JUL 2016
- 2 The data includes retrospective patients in cohort 1 and prospective patients in cohort 1, 2, 3, 4 and 5
- 3 The variable 'Congestive heart failure' was split into 'History of CHF' and 'Current CHF' in cohorts 3, 4 and 5. History of and/or current CHF were used to identify CHF in cohort 3, 4 and 5 patients (Table 6)
- 4 The variable 'Coronary artery disease' was split into 'History of CAD' and 'Current CAD' in cohorts 3, 4 and 5. History of and/or current CAD were used to identify CAD in cohort 3, 4 and 5 patients (Table 6)
- 5 The variable 'Other thromboembolism' is not recorded for patients in cohort 3, 4 and 5
- 6 The option 'None' was added in the CRF for the 'Chronic renal disease' field in cohort 3, 4 and 5. The percentages for the variable 'Moderate to severe CKD' are estimated assuming that patients with 'unknown' stage of CKD are without 'Moderate to severe CKD' (Table 6)
- 7 Table 7 describes the baseline treatment for stroke prophylaxis. For each treatment group identifier options are mutually exclusive. The option 'unknown' includes combination of treatments
- 8 Table 8 shows the baseline treatment for stroke prophylaxis with non mutually exclusive groups
- 9 Table 12 shows INR values and TTR for patients treated with VKA±AP at baseline. INR readings during the first year of follow-up were included in the analysis. Values less than 0.8 or greater than 20 were removed since these values may not be plausible. Patients on VKA±AP at enrolment but with fewer than three readings during the follow-up were excluded from the analysis. Patient-level TTR was estimated by linear interpolation according to Rosendaal et al (1993), using 2.0-3.0 as the target INR range. TTR was estimated using INR readings until discontinuation or interruption of VKA or the end of follow-up. In addition, TTR was estimated between two consecutive INR readings only if the interval did not exceed 90 days.
- 10 Tables 13 and 14 describe events during the first year of follow-up for patients in cohorts 1-4. Only the first occurrence of each event was taken into account.
- 11 Table 13 Congestive heart failure during the follow-up includes new congestive heart failure or worsening of pre-existing congestive heart failure.

**Table 01: Study population and enrolment information**  
**Full Analysis Dataset : ITALY**

|  |                       |
|--|-----------------------|
| Number of prospective patients (C1+C2+C3+C4+C5 ) | 2191                  |
| Number of enrolling sites                        | 56                    |
| Number of enrolling countries                    | 1                     |
| Enrolment period                                 | 07OCT2010 - 27JUL2016 |
| Duration of enrolment (months)                   | 69.7                  |

**Table 02: Patients by region, country, and cohort  
Full Analysis Dataset : ITALY**

| Region | Country | Cohort 1<br>Retrospective<br>patients<br>(N=391) | Cohort 1<br>Prospective<br>patients<br>(N=452) | Cohort 2<br>(N=529) | Cohort 3<br>(N=325) | Cohort 4<br>(N=468) | Cohort 5<br>(N=417) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--------|---------|--|--|---------------------|---------------------|---------------------|---------------------|--|--|
| Europe | Italy   | 391  | 452  | 529                 | 325                 | 468                 | 417                 | 2191   | 1774   |

**Table 03 : Demographic Characteristics  
Full Analysis Dataset : ITALY**

| Variable                              | Statistics      | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---------------------------------------|-----------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Sex, n(%)                             | n (missing)     | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                       | Male            | 213 (54.5)  | 257 (56.9)  | 281 (53.1)                   | 176 (54.2)                   | 245 (52.4)                   | 235 (56.4)                   | 1194 (54.5)  | 959 (54.1)   |
|                                       | Female          | 178 (45.5)  | 195 (43.1)  | 248 (46.9)                   | 149 (45.8)                   | 223 (47.6)                   | 182 (43.6)                   | 997 (45.5)   | 815 (45.9)   |
| Age at<br>Diagnosis<br>(Years)        | n (missing)     | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                       | Mean (SD)       | 72.8 (9.3)  | 73.7 (9.6)  | 73.5 (9.4)                   | 74.3 (9.2)                   | 73.0 (11.1)                  | 75.0 (9.9)                   | 73.9 (9.9)   | 73.6 (9.9)   |
|                                       | Median (IQR)    | 74.0 (68.0 to<br>79.0)                                    | 75.0 (68.0 to<br>81.0)                                  | 75.0 (69.0 to<br>80.0)       | 76.0 (69.0 to<br>81.0)       | 74.0 (67.0 to<br>81.0)       | 76.0 (69.0 to<br>82.0)       | 75.0 (68.0 to<br>81.0)   | 75.0 (68.0 to<br>80.0)   |
|                                       | Min to Max      | 30 to 92  | 25 to 94  | 18 to 97                     | 41 to 94                     | 18 to 95                     | 37 to 101                    | 18 to 101  | 18 to 97   |
| Age Group,<br>n(%)                    | n (missing)     | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                       | <65             | 68 (17.4)   | 69 (15.3)   | 81 (15.3)                    | 43 (13.2)                    | 87 (18.6)                    | 58 (13.9)                    | 338 (15.4)   | 280 (15.8)   |
|                                       | 65-74           | 134 (34.3)  | 144 (31.9)  | 163 (30.8)                   | 104 (32.0)                   | 151 (32.3)                   | 124 (29.7)                   | 686 (31.3)   | 562 (31.7)   |
|                                       | >=75            | 189 (48.3)  | 239 (52.9)  | 285 (53.9)                   | 178 (54.8)                   | 230 (49.1)                   | 235 (56.4)                   | 1167 (53.3)  | 932 (52.5)   |
| Time since AF<br>Diagnosis<br>(Weeks) | n (missing)     | 391 (0)   | 400 (52)  | 450 (79)                     | 259 (66)                     | 337 (131)                    | 354 (63)                     | 1800 (391)   | 1446 (328)   |
|                                       | Mean (SD)       | 62.78 (24.61)   | 2.41 (1.77)   | 2.55 (1.74)                  | 2.37 (1.71)                  | 2.18 (1.71)                  | 2.25 (1.79)                  | 2.36 (1.75)  | 2.39 (1.74)  |
|                                       | Median (IQR)    | 59.40 (41.10 to<br>85.10)                                 | 2.00 (0.80 to<br>4.00)                                  | 2.20 (1.00 to<br>4.20)       | 2.00 (1.00 to<br>3.50)       | 1.80 (0.70 to<br>3.40)       | 1.80 (0.70 to<br>3.80)       | 2.00 (0.80 to<br>3.80)   | 2.00 (1.00 to<br>4.00)   |
|                                       | Min to Max      | 26.1 to 104.2   | 0.1 to 6.0  | 0.1 to 6.0                   | 0.1 to 6.0                   | 0.1 to 6.0                   | 0.1 to 6.0                   | 0.1 to 6.0   | 0.1 to 6.0   |
| Race, n(%)                            | n (missing)     | 391 (0)   | 452 (0)   | 528 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2190 (0)   | 1773 (0)   |
|                                       | Caucasian       | 320 (81.8)  | 401 (88.7)  | 465 (88.1)                   | 318 (97.8)                   | 456 (97.4)                   | 408 (97.8)                   | 2048 (93.5)  | 1640 (92.5)  |
|                                       | Hispanic/Latino | 68 (17.4)   | 48 (10.6)   | 51 (9.7)                     | 7 (2.2)                      | 11 (2.4)                     | 6 (1.4)                      | 123 (5.6)  | 117 (6.6)  |
|                                       | Afro-Caribbean  | 1 (0.3)   | -   | -                            | -                            | -                            | 1 (0.2)                      | 1 (0.0)  | -  |

**Table 03 : Demographic Characteristics  
Full Analysis Dataset : ITALY**

| Variable     | Statistics          | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--------------|---------------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|              | Asian (Not Chinese) | -   | -   | -                            | -                            | -                            | 1 (0.2)                      | 1 (0.0)  | -  |
|              | Chinese             | -   | -   | -                            | -                            | 1 (0.2)                      | -                            | 1 (0.0)  | 1 (0.1)  |
|              | Mixed/Other         | 2 (0.5)   | 3 (0.7)   | 12 (2.3)                     | -                            | -                            | 1 (0.2)                      | 16 (0.7)   | 15 (0.8)   |
|              | Unknown             | -   | -   | 1                            | -                            | -                            | -                            | 1  | 1  |
| Region, n(%) | n (missing)         | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|              | Europe              | 391 (100.0)   | 452 (100.0)   | 529 (100.0)                  | 325 (100.0)                  | 468 (100.0)                  | 417 (100.0)                  | 2191 (100.0)   | 1774 (100.0)   |

**Table 04 : Care setting , Type of AF and Insurance  
Full Analysis Dataset : ITALY**

| Variable   | Statistics                                      | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--|---|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Care Setting<br>Speciality at<br>Diagnosis, n(%) | n (missing)                                     | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|  | Internal<br>Medicine                            | 82 (21.0)   | 114 (25.2)  | 139 (26.3)                   | 120 (36.9)                   | 120 (25.6)                   | 102 (24.5)                   | 595 (27.2)   | 493 (27.8)   |
|  | Cardiology                                      | 246 (62.9)  | 282 (62.4)  | 313 (59.2)                   | 170 (52.3)                   | 318 (67.9)                   | 283 (67.9)                   | 1366 (62.3)  | 1083 (61.0)  |
|  | Neurology                                       | 11 (2.8)  | 13 (2.9)  | 9 (1.7)                      | 5 (1.5)                      | 8 (1.7)                      | 9 (2.2)                      | 44 (2.0)   | 35 (2.0)   |
|  | Geriatrics                                      | 1 (0.3)   | 4 (0.9)   | 6 (1.1)                      | -                            | 1 (0.2)                      | 2 (0.5)                      | 13 (0.6)   | 11 (0.6)   |
|  | Primary<br>Care/General<br>Practice             | 51 (13.0)   | 39 (8.6)  | 62 (11.7)                    | 30 (9.2)                     | 21 (4.5)                     | 21 (5.0)                     | 173 (7.9)  | 152 (8.6)  |
| Care Setting<br>Location at<br>Diagnosis, n(%)   | n (missing)                                     | 390 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|  | Hospital  | 183 (46.9)  | 272 (60.2)  | 301 (56.9)                   | 179 (55.1)                   | 260 (55.6)                   | 250 (60.0)                   | 1262 (57.6)  | 1012 (57.0)  |
|  | Office  | 108 (27.7)  | 89 (19.7)   | 113 (21.4)                   | 56 (17.2)                    | 82 (17.5)                    | 82 (19.7)                    | 422 (19.3)   | 340 (19.2)   |
|  | Anticoagulation<br>clinic/thrombosi<br>s centre | 55 (14.1)   | 35 (7.7)  | 28 (5.3)                     | 34 (10.5)                    | 14 (3.0)                     | 6 (1.4)                      | 117 (5.3)  | 111 (6.3)  |
|  | Emergency<br>room                               | 44 (11.3)   | 56 (12.4)   | 87 (16.4)                    | 56 (17.2)                    | 112 (23.9)                   | 79 (18.9)                    | 390 (17.8)   | 311 (17.5)   |
|  | Unknown   | 1   | -   | -                            | -                            | -                            | -                            | -  | -  |
| Type of AF<br>Diagnosed,<br>n(%)                 | n (missing)                                     | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|  | Permanent                                       | 237 (60.6)  | 114 (25.2)  | 175 (33.1)                   | 122 (37.5)                   | 126 (26.9)                   | 144 (34.5)                   | 681 (31.1)   | 537 (30.3)   |
|  | Persistent                                      | 76 (19.4)   | 141 (31.2)  | 160 (30.2)                   | 58 (17.8)                    | 77 (16.5)                    | 81 (19.4)                    | 517 (23.6)   | 436 (24.6)   |
|  | Paroxysmal                                      | 63 (16.1)   | 70 (15.5)   | 87 (16.4)                    | 75 (23.1)                    | 115 (24.6)                   | 79 (18.9)                    | 426 (19.4)   | 347 (19.6)   |
|  | New   | 15 (3.8)  | 127 (28.1)  | 107 (20.2)                   | 70 (21.5)                    | 150 (32.1)                   | 113 (27.1)                   | 567 (25.9)   | 454 (25.6)   |

**Table 04 : Care setting , Type of AF and Insurance  
Full Analysis Dataset : ITALY**

| Variable               | Statistics              | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|------------------------|-------------------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Treatment              | n (missing)             | -   | -   | 325 (0)                      | 320 (0)                      | 458 (0)                      | 412 (0)                      | 1515 (0)   | 1103 (0)   |
| Costs, n(%)            | Public insurance        | -   | -   | 321 (98.8)                   | 320 (100.0)                  | 455 (99.3)                   | 404 (98.1)                   | 1500 (99.0)  | 1096 (99.4)  |
|                        | Private (insurance)     | -   | -   | 3 (0.9)                      | -                            | 2 (0.4)                      | 3 (0.7)                      | 8 (0.5)  | 5 (0.5)  |
|                        | Private (out of pocket) | -   | -   | 1 (0.3)                      | -                            | 1 (0.2)                      | 3 (0.7)                      | 5 (0.3)  | 2 (0.2)  |
|                        | Combination             | -   | -   | -                            | -                            | -                            | 2 (0.5)                      | 2 (0.1)  | -  |
|                        | Unknown                 | 391   | 452   | 204                          | 5                            | 10                           | 5                            | 676  | 671  |
| Treatment Sector, n(%) | n (missing)             | 1 (0)   | 1 (0)   | 333 (0)                      | 323 (0)                      | 468 (0)                      | 417 (0)                      | 1542 (0)   | 1125 (0)   |
|                        | In the public sector    | 1 (100.0)   | 1 (100.0)   | 320 (96.1)                   | 317 (98.1)                   | 452 (96.6)                   | 402 (96.4)                   | 1492 (96.8)  | 1090 (96.9)  |
|                        | In the private sector   | -   | -   | 13 (3.9)                     | 6 (1.9)                      | 16 (3.4)                     | 15 (3.6)                     | 50 (3.2)   | 35 (3.1)   |
|                        | Unknown                 | 390   | 451   | 196                          | 2                            | -                            | -                            | 649  | 649  |



**Table 05 : Vital signs and life style**  
**Full Analysis Dataset : ITALY**

| Variable                 | Statistics   | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--------------------------|--------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Height (cm)              | n (missing)  | 359 (32)  | 413 (39)  | 384 (145)                    | 263 (62)                     | 399 (69)                     | 370 (47)                     | 1829 (362)   | 1459 (315)   |
|                          | Mean (SD)    | 166.5 (8.5)   | 166.8 (8.6)   | 166.8 (9.0)                  | 166.1 (8.9)                  | 167.4 (9.2)                  | 166.9 (8.3)                  | 166.8 (8.8)  | 166.8 (8.9)  |
|                          | Median (IQR) | 166.0 (160.0 to<br>173.0)                                 | 167.0 (160.0 to<br>172.0)                               | 167.0 (160.0<br>to 173.0)    | 165.0 (160.0<br>to 172.0)    | 167.0 (160.0<br>to 173.0)    | 167.0 (160.0<br>to 173.0)    | 167.0 (160.0 to<br>173.0)                                      | 167.0 (160.0 to<br>173.0)                                      |
|                          | Min to Max   | 145 to 192  | 140 to 197  | 145 to 192                   | 140 to 189                   | 140 to 200                   | 137 to 188                   | 137 to 200   | 140 to 200   |
| Weight (kg)              | n (missing)  | 359 (32)  | 413 (39)  | 384 (145)                    | 263 (62)                     | 399 (69)                     | 370 (47)                     | 1829 (362)   | 1459 (315)   |
|                          | Mean (SD)    | 75.9 (13.8)   | 75.7 (14.2)   | 76.1 (15.5)                  | 76.0 (17.2)                  | 75.3 (14.4)                  | 76.2 (15.0)                  | 75.8 (15.1)  | 75.7 (15.2)  |
|                          | Median (IQR) | 75.0 (68.0 to<br>84.0)                                    | 74.0 (66.0 to<br>84.0)                                  | 75.0 (65.0 to<br>84.0)       | 73.0 (65.0 to<br>85.0)       | 75.0 (67.0 to<br>82.0)       | 75.0 (65.0 to<br>85.0)       | 75.0 (66.0 to<br>84.0)   | 75.0 (66.0 to<br>84.0)   |
|                          | Min to Max   | 44 to 133   | 39 to 130   | 42 to 148                    | 37 to 186                    | 34 to 140                    | 40 to 133                    | 34 to 186  | 34 to 186  |
| BMI (kg/m <sup>2</sup> ) | n (missing)  | 359 (32)  | 413 (39)  | 384 (145)                    | 263 (62)                     | 399 (69)                     | 370 (47)                     | 1829 (362)   | 1459 (315)   |
|                          | Mean (SD)    | 27.4 (4.5)  | 27.2 (4.6)  | 27.3 (4.7)                   | 27.4 (5.0)                   | 26.8 (4.4)                   | 27.3 (4.7)                   | 27.2 (4.7)   | 27.2 (4.6)   |
|                          | Median (IQR) | 27.0 (24.0 to<br>29.0)                                    | 26.0 (24.0 to<br>29.0)                                  | 27.0 (24.0 to<br>29.5)       | 27.0 (24.0 to<br>29.0)       | 27.0 (24.0 to<br>29.0)       | 27.0 (24.0 to<br>29.0)       | 27.0 (24.0 to<br>29.0)   | 27.0 (24.0 to<br>29.0)   |
|                          | Min to Max   | 17 to 49  | 15 to 48  | 17 to 56                     | 15 to 56                     | 10 to 53                     | 15 to 47                     | 10 to 56   | 10 to 56   |
| BMI Category,<br>n(%)    | n (missing)  | 359 (32)  | 413 (39)  | 384 (145)                    | 263 (62)                     | 399 (69)                     | 370 (47)                     | 1829 (362)   | 1459 (315)   |
|                          | <19          | 3 (0.8)   | 4 (1.0)   | 4 (1.0)                      | 5 (1.9)                      | 11 (2.8)                     | 9 (2.4)                      | 33 (1.8)   | 24 (1.6)   |
|                          | 19-<25       | 108 (30.1)  | 134 (32.4)  | 118 (30.7)                   | 75 (28.5)                    | 120 (30.1)                   | 102 (27.6)                   | 549 (30.0)   | 447 (30.6)   |
|                          | 25-<30       | 176 (49.0)  | 189 (45.8)  | 171 (44.5)                   | 123 (46.8)                   | 194 (48.6)                   | 176 (47.6)                   | 853 (46.6)   | 677 (46.4)   |
|                          | 30-<40       | 64 (17.8)   | 77 (18.6)   | 84 (21.9)                    | 53 (20.2)                    | 70 (17.5)                    | 78 (21.1)                    | 362 (19.8)   | 284 (19.5)   |
|                          | >=40         | 8 (2.2)   | 9 (2.2)   | 7 (1.8)                      | 7 (2.7)                      | 4 (1.0)                      | 5 (1.4)                      | 32 (1.7)   | 27 (1.9)   |
| Pulse (bpm)              | n (missing)  | 317 (74)  | 369 (83)  | 464 (65)                     | 285 (40)                     | 435 (33)                     | 377 (40)                     | 1930 (261)   | 1553 (221)   |
|                          | Mean (SD)    | 79.7 (14.3)   | 85.4 (18.8)   | 84.5 (17.9)                  | 84.8 (17.5)                  | 85.7 (23.4)                  | 85.1 (24.0)                  | 85.1 (20.6)  | 85.1 (19.7)  |
|                          | Median (IQR) | 78.0 (70.0 to<br>86.0)                                    | 82.0 (74.0 to<br>92.0)                                  | 80.5 (72.0 to<br>90.0)       | 84.0 (75.0 to<br>90.0)       | 80.0 (70.0 to<br>95.0)       | 80.0 (70.0 to<br>95.0)       | 80.0 (72.0 to<br>92.0)   | 82.0 (72.0 to<br>92.0)   |
|                          | Min to Max   | 52 to 180   | 50 to 170   | 44 to 155                    | 40 to 155                    | 40 to 192                    | 40 to 165                    | 40 to 192  | 40 to 192  |

**Table 05 : Vital signs and life style  
Full Analysis Dataset : ITALY**

| Variable                              | Statistics   | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---------------------------------------|--------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Systolic BP<br>(mm Hg)                | n (missing)  | 326 (65)  | 374 (78)  | 465 (64)                     | 288 (37)                     | 435 (33)                     | 379 (38)                     | 1941 (250)   | 1562 (212)   |
|                                       | Mean (SD)    | 137.3 (16.7)  | 134.9 (17.2)  | 135.5 (16.0)                 | 135.7 (17.0)                 | 134.3 (17.9)                 | 136.1 (17.9)                 | 135.3 (17.2)   | 135.1 (17.0)   |
|                                       | Median (IQR) | 140.0 (130.0 to<br>145.0)                                 | 135.0 (120.0 to<br>148.0)                               | 137.0 (126.0<br>to 145.0)    | 135.0 (125.0<br>to 142.5)    | 130.0 (120.0<br>to 143.0)    | 135.0 (125.0<br>to 145.0)    | 135.0 (125.0 to<br>145.0)                                      | 135.0 (125.0 to<br>145.0)                                      |
|                                       | Min to Max   | 90 to 224   | 90 to 200   | 80 to 190                    | 98 to 210                    | 80 to 197                    | 90 to 215                    | 80 to 215  | 80 to 210  |
| Diastolic BP<br>(mm Hg)               | n (missing)  | 326 (65)  | 374 (78)  | 465 (64)                     | 288 (37)                     | 435 (33)                     | 379 (38)                     | 1941 (250)   | 1562 (212)   |
|                                       | Mean (SD)    | 79.5 (10.0)   | 79.2 (10.3)   | 79.4 (9.2)                   | 79.5 (10.1)                  | 79.2 (10.4)                  | 79.9 (11.5)                  | 79.4 (10.3)  | 79.3 (9.9)   |
|                                       | Median (IQR) | 80.0 (74.0 to<br>85.0)                                    | 80.0 (70.0 to<br>85.0)                                  | 80.0 (73.0 to<br>85.0)       | 80.0 (70.0 to<br>84.0)       | 80.0 (70.0 to<br>85.0)       | 80.0 (70.0 to<br>90.0)       | 80.0 (70.0 to<br>85.0)   | 80.0 (70.0 to<br>85.0)   |
|                                       | Min to Max   | 50 to 120   | 50 to 116   | 40 to 110                    | 53 to 140                    | 50 to 116                    | 36 to 124                    | 36 to 140  | 40 to 140  |
| LVEF (%)                              | n (missing)  | 215 (176)   | 259 (193)   | 328 (201)                    | 252 (73)                     | 334 (134)                    | 304 (113)                    | 1477 (714)   | 1173 (601)   |
|                                       | Mean (SD)    | 55.1 (9.9)  | 54.0 (10.7)   | 53.0 (10.1)                  | 54.5 (9.6)                   | 54.7 (9.2)                   | 53.8 (9.5)                   | 54.0 (9.8)   | 54.0 (9.9)   |
|                                       | Median (IQR) | 55.0 (50.0 to<br>60.0)                                    | 55.0 (50.0 to<br>60.0)                                  | 55.0 (50.0 to<br>60.0)       | 55.0 (50.0 to<br>60.0)       | 55.0 (52.0 to<br>60.0)       | 55.0 (50.0 to<br>60.0)       | 55.0 (50.0 to<br>60.0)   | 55.0 (50.0 to<br>60.0)   |
|                                       | Min to Max   | 25 to 75  | 20 to 78  | 20 to 78                     | 20 to 76                     | 20 to 84                     | 20 to 76                     | 20 to 84   | 20 to 84   |
| LVEF Category, n<br>(missing)<br>n(%) | n (missing)  | 215 (176)   | 259 (193)   | 328 (201)                    | 252 (73)                     | 334 (134)                    | 304 (113)                    | 1477 (714)   | 1173 (601)   |
|                                       | <40%         | 16 (7.4)  | 26 (10.0)   | 33 (10.1)                    | 23 (9.1)                     | 24 (7.2)                     | 25 (8.2)                     | 131 (8.9)  | 106 (9.0)  |
|                                       | >=40%        | 199 (92.6)  | 233 (90.0)  | 295 (89.9)                   | 229 (90.9)                   | 310 (92.8)                   | 279 (91.8)                   | 1346 (91.1)  | 1067 (91.0)  |
| History of<br>Hypertension,<br>n(%)   | n (missing)  | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 467 (0)                      | 417 (0)                      | 2190 (0)   | 1773 (0)   |
|                                       | No           | 51 (13.0)   | 57 (12.6)   | 50 (9.5)                     | 44 (13.5)                    | 78 (16.7)                    | 68 (16.3)                    | 297 (13.6)   | 229 (12.9)   |
|                                       | Yes          | 340 (87.0)  | 395 (87.4)  | 479 (90.5)                   | 281 (86.5)                   | 389 (83.3)                   | 349 (83.7)                   | 1893 (86.4)  | 1544 (87.1)  |

**Table 05 : Vital signs and life style**  
**Full Analysis Dataset : ITALY**

| Variable                        | Statistics     | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---------------------------------|----------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|                                 | Unknown        | -   | -   | -                            | -                            | 1                            | -                            | 1  | 1  |
| Alcohol<br>Consumption,<br>n(%) | n (missing)    | 375 (0)   | 431 (0)   | 497 (0)                      | 296 (0)                      | 413 (0)                      | 348 (0)                      | 1985 (0)   | 1637 (0)   |
|                                 | Abstinent      | 186 (49.6)  | 206 (47.8)  | 278 (55.9)                   | 173 (58.4)                   | 215 (52.1)                   | 197 (56.6)                   | 1069 (53.9)  | 872 (53.3)   |
|                                 | Light          | 162 (43.2)  | 200 (46.4)  | 184 (37.0)                   | 97 (32.8)                    | 156 (37.8)                   | 117 (33.6)                   | 754 (38.0)   | 637 (38.9)   |
|                                 | Moderate       | 25 (6.7)  | 22 (5.1)  | 33 (6.6)                     | 23 (7.8)                     | 38 (9.2)                     | 31 (8.9)                     | 147 (7.4)  | 116 (7.1)  |
|                                 | Heavy          | 2 (0.5)   | 3 (0.7)   | 2 (0.4)                      | 3 (1.0)                      | 4 (1.0)                      | 3 (0.9)                      | 15 (0.8)   | 12 (0.7)   |
|                                 | Unknown        | 16  | 21  | 32                           | 29                           | 55                           | 69                           | 206  | 137  |
| Smoker, n(%)                    | n (missing)    | 388 (0)   | 441 (0)   | 508 (0)                      | 311 (0)                      | 442 (0)                      | 398 (0)                      | 2100 (0)   | 1702 (0)   |
|                                 | No             | 268 (69.1)  | 284 (64.4)  | 348 (68.5)                   | 217 (69.8)                   | 295 (66.7)                   | 273 (68.6)                   | 1417 (67.5)  | 1144 (67.2)  |
|                                 | Ex-smoker      | 97 (25.0)   | 124 (28.1)  | 130 (25.6)                   | 75 (24.1)                    | 117 (26.5)                   | 99 (24.9)                    | 545 (26.0)   | 446 (26.2)   |
|                                 | Current smoker | 23 (5.9)  | 33 (7.5)  | 30 (5.9)                     | 19 (6.1)                     | 30 (6.8)                     | 26 (6.5)                     | 138 (6.6)  | 112 (6.6)  |
|                                 | Unknown        | 3   | 11  | 21                           | 14                           | 26                           | 19                           | 91   | 72   |

**Table 06 : Clinical History**  
**Full Analysis Dataset : ITALY**

| Variable                                  | Statistics  | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---|-------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Congestive heart failure, n(%)            | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|   | No          | 313 (80.1)  | 383 (84.7)  | 442 (83.6)                   | 287 (88.3)                   | 402 (85.9)                   | 352 (84.4)                   | 1866 (85.2)  | 1514 (85.3)  |
|   | Yes         | 78 (19.9)   | 69 (15.3)   | 87 (16.4)                    | 38 (11.7)                    | 66 (14.1)                    | 65 (15.6)                    | 325 (14.8)   | 260 (14.7)   |
| Congestive Heart Failure NYHA Class, n(%) | n (missing) | 77 (313)  | 68 (383)  | 82 (442)                     | 37 (287)                     | 60 (402)                     | 62 (352)                     | 309 (1866)   | 247 (1514)   |
|   | I           | 10 (13.0)   | 16 (23.5)   | 8 (9.8)                      | 2 (5.4)                      | 2 (3.3)                      | 2 (3.2)                      | 30 (9.7)   | 28 (11.3)  |
|   | II          | 43 (55.8)   | 31 (45.6)   | 46 (56.1)                    | 22 (59.5)                    | 35 (58.3)                    | 39 (62.9)                    | 173 (56.0)   | 134 (54.3)   |
|   | III         | 24 (31.2)   | 18 (26.5)   | 27 (32.9)                    | 13 (35.1)                    | 22 (36.7)                    | 21 (33.9)                    | 101 (32.7)   | 80 (32.4)  |
|   | IV          | -   | 3 (4.4)   | 1 (1.2)                      | -                            | 1 (1.7)                      | -                            | 5 (1.6)  | 5 (2.0)  |
|   | Unknown     | 1   | 1   | 5                            | 1                            | 6                            | 3                            | 16   | 13   |
| Coronary artery disease, n(%)             | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|   | No          | 345 (88.2)  | 392 (86.7)  | 462 (87.3)                   | 285 (87.7)                   | 388 (82.9)                   | 346 (83.0)                   | 1873 (85.5)  | 1527 (86.1)  |
|   | Yes         | 46 (11.8)   | 60 (13.3)   | 67 (12.7)                    | 40 (12.3)                    | 80 (17.1)                    | 71 (17.0)                    | 318 (14.5)   | 247 (13.9)   |
| Acute coronary syndrome, n(%)             | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 324 (0)                      | 467 (0)                      | 415 (0)                      | 2187 (0)   | 1772 (0)   |
|   | No          | 359 (91.8)  | 408 (90.3)  | 487 (92.1)                   | 293 (90.4)                   | 408 (87.4)                   | 364 (87.7)                   | 1960 (89.6)  | 1596 (90.1)  |
|   | Yes         | 32 (8.2)  | 44 (9.7)  | 42 (7.9)                     | 31 (9.6)                     | 59 (12.6)                    | 51 (12.3)                    | 227 (10.4)   | 176 (9.9)  |
|   | Unknown     | -   | -   | -                            | 1                            | 1                            | 2                            | 4  | 2  |
| Carotid Occlusive Disease, n(%)           | n (missing) | 391 (0)   | 452 (0)   | 528 (0)                      | 320 (0)                      | 459 (0)                      | 413 (0)                      | 2172 (0)   | 1759 (0)   |
|   | No          | 361 (92.3)  | 416 (92.0)  | 481 (91.1)                   | 285 (89.1)                   | 393 (85.6)                   | 372 (90.1)                   | 1947 (89.6)  | 1575 (89.5)  |

**Table 06 : Clinical History**  
**Full Analysis Dataset : ITALY**

| Variable                                 | Statistics  | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--|-------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|  | Yes         | 30 (7.7)  | 36 (8.0)  | 47 (8.9)                     | 35 (10.9)                    | 66 (14.4)                    | 41 (9.9)                     | 225 (10.4)   | 184 (10.5)   |
|  | Unknown     | -   | -   | 1                            | 5                            | 9                            | 4                            | 19   | 15   |
| PE or DVT,<br>n(%)                       | n (missing) | 391 (0)   | 452 (0)   | 528 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2190 (0)   | 1773 (0)   |
|  | No          | 387 (99.0)  | 431 (95.4)  | 507 (96.0)                   | 315 (96.9)                   | 457 (97.6)                   | 407 (97.6)                   | 2117 (96.7)  | 1710 (96.4)  |
|  | Yes         | 4 (1.0)   | 21 (4.6)  | 21 (4.0)                     | 10 (3.1)                     | 11 (2.4)                     | 10 (2.4)                     | 73 (3.3)   | 63 (3.6)   |
|  | Unknown     | -   | -   | 1                            | -                            | -                            | -                            | 1  | 1  |
| Other<br>Thromboemboli<br>sm, n(%)       | n (missing) | 391 (0)   | 452 (0)   | 521 (8)                      | 0 (325)                      | 0 (468)                      | 0 (417)                      | 973 (1218)   | 973 (801)  |
|  | No          | 385 (98.5)  | 443 (98.0)  | 513 (98.5)                   | -                            | -                            | -                            | 956 (98.3)   | 956 (98.3)   |
|  | Yes         | 6 (1.5)   | 9 (2.0)   | 8 (1.5)                      | -                            | -                            | -                            | 17 (1.7)   | 17 (1.7)   |
| Systemic<br>Embolization,<br>n(%)        | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 324 (0)                      | 467 (0)                      | 417 (0)                      | 2189 (0)   | 1772 (0)   |
|  | No          | 388 (99.2)  | 441 (97.6)  | 514 (97.2)                   | 319 (98.5)                   | 458 (98.1)                   | 414 (99.3)                   | 2146 (98.0)  | 1732 (97.7)  |
|  | Yes         | 3 (0.8)   | 11 (2.4)  | 15 (2.8)                     | 5 (1.5)                      | 9 (1.9)                      | 3 (0.7)                      | 43 (2.0)   | 40 (2.3)   |
|  | Unknown     | -   | -   | -                            | 1                            | 1                            | -                            | 2  | 2  |
| Coronary Artery<br>Bypass Graft,<br>n(%) | n (missing) | 368 (0)   | 428 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2167 (0)   | 1750 (0)   |
|  | No          | 362 (98.4)  | 417 (97.4)  | 509 (96.2)                   | 314 (96.6)                   | 446 (95.3)                   | 401 (96.2)                   | 2087 (96.3)  | 1686 (96.3)  |
|  | Yes         | 6 (1.6)   | 11 (2.6)  | 20 (3.8)                     | 11 (3.4)                     | 22 (4.7)                     | 16 (3.8)                     | 80 (3.7)   | 64 (3.7)   |
|  | Unknown     | 23  | 24  | -                            | -                            | -                            | -                            | 24   | 24   |
| Stroke/TIA,<br>n(%)                      | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |

**Table 06 : Clinical History**  
**Full Analysis Dataset : ITALY**

| Variable                        | Statistics  | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---------------------------------|-------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|                                 | No          | 334 (85.4)  | 383 (84.7)  | 442 (83.6)                   | 296 (91.1)                   | 406 (86.8)                   | 378 (90.6)                   | 1905 (86.9)  | 1527 (86.1)  |
|                                 | Yes         | 57 (14.6)   | 69 (15.3)   | 87 (16.4)                    | 29 (8.9)                     | 62 (13.2)                    | 39 (9.4)                     | 286 (13.1)   | 247 (13.9)   |
| Stroke, n(%)                    | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                 | No          | 356 (91.0)  | 419 (92.7)  | 478 (90.4)                   | 309 (95.1)                   | 429 (91.7)                   | 394 (94.5)                   | 2029 (92.6)  | 1635 (92.2)  |
|                                 | Yes         | 35 (9.0)  | 33 (7.3)  | 51 (9.6)                     | 16 (4.9)                     | 39 (8.3)                     | 23 (5.5)                     | 162 (7.4)  | 139 (7.8)  |
| History of<br>Bleeding, n(%)    | n (missing) | 391 (0)   | 452 (0)   | 528 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2190 (0)   | 1773 (0)   |
|                                 | No          | 379 (96.9)  | 442 (97.8)  | 515 (97.5)                   | 315 (96.9)                   | 448 (95.7)                   | 408 (97.8)                   | 2128 (97.2)  | 1720 (97.0)  |
|                                 | Yes         | 12 (3.1)  | 10 (2.2)  | 13 (2.5)                     | 10 (3.1)                     | 20 (4.3)                     | 9 (2.2)                      | 62 (2.8)   | 53 (3.0)   |
|                                 | Unknown     | -   | -   | 1                            | -                            | -                            | -                            | 1  | 1  |
| Hypercholester<br>olaemia, n(%) | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 321 (0)                      | 455 (0)                      | 412 (0)                      | 2169 (0)   | 1757 (0)   |
|                                 | No          | 237 (60.6)  | 282 (62.4)  | 290 (54.8)                   | 201 (62.6)                   | 227 (49.9)                   | 251 (60.9)                   | 1251 (57.7)  | 1000 (56.9)  |
|                                 | Yes         | 154 (39.4)  | 170 (37.6)  | 239 (45.2)                   | 120 (37.4)                   | 228 (50.1)                   | 161 (39.1)                   | 918 (42.3)   | 757 (43.1)   |
|                                 | Unknown     | -   | -   | -                            | 4                            | 13                           | 5                            | 22   | 17   |
| Diabetes, n(%)                  | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                 | No          | 307 (78.5)  | 362 (80.1)  | 430 (81.3)                   | 262 (80.6)                   | 360 (76.9)                   | 331 (79.4)                   | 1745 (79.6)  | 1414 (79.7)  |
|                                 | Type I      | 4 (1.0)   | 5 (1.1)   | 6 (1.1)                      | 6 (1.8)                      | 4 (0.9)                      | 5 (1.2)                      | 26 (1.2)   | 21 (1.2)   |
|                                 | Type II     | 80 (20.5)   | 85 (18.8)   | 93 (17.6)                    | 57 (17.5)                    | 104 (22.2)                   | 81 (19.4)                    | 420 (19.2)   | 339 (19.1)   |
| Diabetes, n(%)                  | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                                 | No          | 307 (78.5)  | 362 (80.1)  | 430 (81.3)                   | 262 (80.6)                   | 360 (76.9)                   | 331 (79.4)                   | 1745 (79.6)  | 1414 (79.7)  |
|                                 | Yes         | 84 (21.5)   | 90 (19.9)   | 99 (18.7)                    | 63 (19.4)                    | 108 (23.1)                   | 86 (20.6)                    | 446 (20.4)   | 360 (20.3)   |
| Cirrhosis, n(%)                 | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 324 (0)                      | 466 (0)                      | 416 (0)                      | 2187 (0)   | 1771 (0)   |
|                                 | No          | 390 (99.7)  | 450 (99.6)  | 525 (99.2)                   | 318 (98.1)                   | 461 (98.9)                   | 413 (99.3)                   | 2167 (99.1)  | 1754 (99.0)  |
|                                 | Yes         | 1 (0.3)   | 2 (0.4)   | 4 (0.8)                      | 6 (1.9)                      | 5 (1.1)                      | 3 (0.7)                      | 20 (0.9)   | 17 (1.0)   |

**Table 06 : Clinical History**  
**Full Analysis Dataset : ITALY**

| Variable                     | Statistics  | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|------------------------------|-------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|                              | Unknown     | -   | -   | -                            | 1                            | 2                            | 1                            | 4  | 3  |
| Dementia, n(%)               | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 414 (0)                      | 2188 (0)   | 1774 (0)   |
|                              | No          | 383 (98.0)  | 447 (98.9)  | 517 (97.7)                   | 319 (98.2)                   | 462 (98.7)                   | 405 (97.8)                   | 2150 (98.3)  | 1745 (98.4)  |
|                              | Yes         | 8 (2.0)   | 5 (1.1)   | 12 (2.3)                     | 6 (1.8)                      | 6 (1.3)                      | 9 (2.2)                      | 38 (1.7)   | 29 (1.6)   |
|                              | Unknown     | -   | -   | -                            | -                            | -                            | 3                            | 3  | -  |
| Hyperthyroidism, n(%)        | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 317 (0)                      | 449 (0)                      | 405 (0)                      | 2152 (0)   | 1747 (0)   |
|                              | No          | 377 (96.4)  | 440 (97.3)  | 512 (96.8)                   | 312 (98.4)                   | 436 (97.1)                   | 397 (98.0)                   | 2097 (97.4)  | 1700 (97.3)  |
|                              | Yes         | 14 (3.6)  | 12 (2.7)  | 17 (3.2)                     | 5 (1.6)                      | 13 (2.9)                     | 8 (2.0)                      | 55 (2.6)   | 47 (2.7)   |
|                              | Unknown     | -   | -   | -                            | 8                            | 19                           | 12                           | 39   | 27   |
| Hypothyroidism, n(%)         | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 317 (0)                      | 448 (0)                      | 405 (0)                      | 2151 (0)   | 1746 (0)   |
|                              | No          | 363 (92.8)  | 422 (93.4)  | 488 (92.2)                   | 299 (94.3)                   | 393 (87.7)                   | 369 (91.1)                   | 1971 (91.6)  | 1602 (91.8)  |
|                              | Yes         | 28 (7.2)  | 30 (6.6)  | 41 (7.8)                     | 18 (5.7)                     | 55 (12.3)                    | 36 (8.9)                     | 180 (8.4)  | 144 (8.2)  |
|                              | Unknown     | -   | -   | -                            | 8                            | 20                           | 12                           | 40   | 28   |
| Vascular Disease, n(%)       | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 324 (1)                      | 468 (0)                      | 415 (2)                      | 2188 (3)   | 1773 (1)   |
|                              | No          | 325 (83.1)  | 367 (81.2)  | 450 (85.1)                   | 274 (84.6)                   | 387 (82.7)                   | 343 (82.7)                   | 1821 (83.2)  | 1478 (83.4)  |
|                              | Yes         | 66 (16.9)   | 85 (18.8)   | 79 (14.9)                    | 50 (15.4)                    | 81 (17.3)                    | 72 (17.3)                    | 367 (16.8)   | 295 (16.6)   |
| Moderate to Severe CKD, n(%) | n (missing) | 391 (0)   | 452 (0)   | 529 (0)                      | 325 (0)                      | 468 (0)                      | 417 (0)                      | 2191 (0)   | 1774 (0)   |
|                              | No          | 336 (85.9)  | 393 (86.9)  | 478 (90.4)                   | 275 (84.6)                   | 383 (81.8)                   | 326 (78.2)                   | 1855 (84.7)  | 1529 (86.2)  |
|                              | Yes         | 55 (14.1)   | 59 (13.1)   | 51 (9.6)                     | 50 (15.4)                    | 85 (18.2)                    | 91 (21.8)                    | 336 (15.3)   | 245 (13.8)   |

**Table 07 : Treatment for stroke prophylaxis  
Full Analysis Dataset : ITALY**

| Variable                       | Statistics  | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|--------------------------------|-------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| Baseline<br>Treatment,<br>n(%) | n (missing) | 389 (0)   | 442 (0)   | 528 (0)                      | 324 (0)                      | 465 (0)                      | 416 (0)                      | 2175 (0)   | 1759 (0)   |
|                                | VKA         | 316 (81.2)  | 329 (74.4)  | 395 (74.8)                   | 210 (64.8)                   | 164 (35.3)                   | 134 (32.2)                   | 1232 (56.6)  | 1098 (62.4)  |
|                                | VKA+AP      | 27 (6.9)  | 61 (13.8)   | 61 (11.6)                    | 32 (9.9)                     | 33 (7.1)                     | 26 (6.3)                     | 213 (9.8)  | 187 (10.6)   |
|                                | FXA         | 2 (0.5)   | 4 (0.9)   | 1 (0.2)                      | 27 (8.3)                     | 135 (29.0)                   | 171 (41.1)                   | 338 (15.5)   | 167 (9.5)  |
|                                | FXA+AP      | 1 (0.3)   | 3 (0.7)   | -                            | 2 (0.6)                      | 24 (5.2)                     | 21 (5.0)                     | 50 (2.3)   | 29 (1.6)   |
|                                | DTI         | -   | -   | -                            | 22 (6.8)                     | 23 (4.9)                     | 27 (6.5)                     | 72 (3.3)   | 45 (2.6)   |
|                                | DTI+AP      | -   | -   | -                            | 2 (0.6)                      | 3 (0.6)                      | -                            | 5 (0.2)  | 5 (0.3)  |
|                                | AP          | 32 (8.2)  | 30 (6.8)  | 48 (9.1)                     | 13 (4.0)                     | 47 (10.1)                    | 15 (3.6)                     | 153 (7.0)  | 138 (7.8)  |
|                                | NONE        | 11 (2.8)  | 15 (3.4)  | 23 (4.4)                     | 16 (4.9)                     | 36 (7.7)                     | 22 (5.3)                     | 112 (5.1)  | 90 (5.1)   |
|                                | Unknown     | 2   | 10  | 1                            | 1                            | 3                            | 1                            | 16   | 15   |
|                                | VKA±AP      | 343 (88.2)  | 390 (88.2)  | 456 (86.4)                   | 242 (74.7)                   | 197 (42.4)                   | 160 (38.5)                   | 1445 (66.4)  | 1285 (73.1)  |
|                                | FXA±AP      | 3 (0.8)   | 7 (1.6)   | 1 (0.2)                      | 29 (9.0)                     | 159 (34.2)                   | 192 (46.2)                   | 388 (17.8)   | 196 (11.1)   |
|                                | DTI±AP      | -   | -   | -                            | 24 (7.4)                     | 26 (5.6)                     | 27 (6.5)                     | 77 (3.5)   | 50 (2.8)   |
|                                | FXA/DTI     | 2 (0.5)   | 4 (0.9)   | 1 (0.2)                      | 49 (15.1)                    | 158 (34.0)                   | 198 (47.6)                   | 410 (18.9)   | 212 (12.1)   |
|                                | FXA/DTI+AP  | 1 (0.3)   | 3 (0.7)   | -                            | 4 (1.2)                      | 27 (5.8)                     | 21 (5.0)                     | 55 (2.5)   | 34 (1.9)   |
|                                | FXA/DTI±AP  | 3 (0.8)   | 7 (1.6)   | 1 (0.2)                      | 53 (16.4)                    | 185 (39.8)                   | 219 (52.6)                   | 465 (21.4)   | 246 (14.0)   |
|                                | AC          | 318 (81.7)  | 333 (75.3)  | 396 (75.0)                   | 259 (79.9)                   | 322 (69.2)                   | 332 (79.8)                   | 1642 (75.5)  | 1310 (74.5)  |
|                                | AC+AP       | 28 (7.2)  | 64 (14.5)   | 61 (11.6)                    | 36 (11.1)                    | 60 (12.9)                    | 47 (11.3)                    | 268 (12.3)   | 221 (12.6)   |
|                                | AC±AP       | 346 (88.9)  | 397 (89.8)  | 457 (86.6)                   | 295 (91.0)                   | 382 (82.2)                   | 379 (91.1)                   | 1910 (87.8)  | 1531 (87.0)  |



**Table 08: Treatment**  
**Full Analysis Dataset : ITALY**

|  | <b>Cohort 1<br/>Retrospective<br/>(N=391)<br/>(n %)</b> | <b>Cohort 1<br/>Prospective<br/>(N=452)<br/>(n %)</b> | <b>Cohort 2<br/>(N=529)<br/>(n %)</b> | <b>Cohort 3<br/>(N=325)<br/>(n %)</b> | <b>Cohort 4<br/>(N=468)<br/>(n %)</b> | <b>Cohort 5<br/>(N=417)<br/>(n %)</b> | <b>Total<br/>Prospective<br/>patients<br/>Cohorts 1 to 5<br/>(N=2191)</b> | <b>Total<br/>Prospective<br/>patients<br/>Cohorts 1 to 4<br/>(N=1774)</b> |
|--|---|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---|---|
| <b>Anti-platelet (non mutually exclusive groups)</b>       |   |   |                                       |                                       |                                       |                                       |   |   |
| Glycoprotein inhibitors                                    | -   | -   | 1 (0.2)                               | -                                     | -                                     | -                                     | 1 (0.0)   | 1 (0.1)   |
| ADP receptor/P2Y12 inhibitors                              | 7 (1.8)   | 12 (2.7)  | 12 (2.3)                              | 8 (2.5)                               | 21 (4.5)                              | 16 (3.8)                              | 69 (3.1)  | 53 (3.0)  |
| Cox inhibitors   | 3 (0.8)   | 9 (2.0)   | -                                     | 1 (0.3)                               | 2 (0.4)                               | 1 (0.2)                               | 13 (0.6)  | 12 (0.7)  |
| ASA  | 47 (12.0)   | 69 (15.3)   | 89 (16.8)                             | 41 (12.6)                             | 89 (19.0)                             | 52 (12.5)                             | 340 (15.5)  | 288 (16.2)  |
| <b>Anticoagulant drugs (non mutually exclusive groups)</b> |   |   |                                       |                                       |                                       |                                       |   |   |
| VKA  | 345 (88.2)  | 398 (88.1)  | 457 (86.4)                            | 242 (74.5)                            | 198 (42.3)                            | 161 (38.6)                            | 1456 (66.5)   | 1295 (73.0)   |
| FXa  | 5 (1.3)   | 15 (3.3)  | 2 (0.4)                               | 29 (8.9)                              | 160 (34.2)                            | 193 (46.3)                            | 399 (18.2)  | 206 (11.6)  |
| DTI  | -   | -   | -                                     | 24 (7.4)                              | 26 (5.6)                              | 27 (6.5)                              | 77 (3.5)  | 50 (2.8)  |
| Heparinoid   | 1 (0.3)   | 4 (0.9)   | 1 (0.2)                               | -                                     | -                                     | 1 (0.2)                               | 6 (0.3)   | 5 (0.3)   |
| Heparins   | 8 (2.0)   | 28 (6.2)  | 48 (9.1)                              | 39 (12.0)                             | 101 (21.6)                            | 60 (14.4)                             | 276 (12.6)  | 216 (12.2)  |

**Table 09 : Risk scores**  
**Full Analysis Dataset : ITALY**

| Variable                                      | Statistics   | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---|--------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
| CHADS2 Score                                  | n (missing)  | 381 (10)  | 443 (9)   | 519 (10)                     | 314 (11)                     | 461 (7)                      | 412 (5)                      | 2149 (42)  | 1737 (37)  |
|   | Mean (SD)    | 2.1 (1.1)   | 2.1 (1.1)   | 2.2 (1.2)                    | 1.9 (1.0)                    | 2.0 (1.1)                    | 2.0 (1.1)                    | 2.0 (1.1)  | 2.1 (1.1)  |
|   | Median (IQR) | 2.0 (1.0 to 3.0)  | 2.0 (1.0 to 3.0)  | 2.0 (1.0 to 3.0)             | 2.0 (1.0 to 2.0)             | 2.0 (1.0 to 3.0)             | 2.0 (1.0 to 3.0)             | 2.0 (1.0 to 3.0)   | 2.0 (1.0 to 3.0)   |
|   | Min to Max   | 0 to 6  | 0 to 5  | 0 to 6                       | 0 to 6                       | 0 to 6                       | 0 to 6                       | 0 to 6   | 0 to 6   |
| CHADS2 score<br>categories,<br>n(%)           | n (missing)  | 381 (10)  | 443 (9)   | 519 (10)                     | 314 (11)                     | 461 (7)                      | 412 (5)                      | 2149 (42)  | 1737 (37)  |
|   | 0            | 11 (2.9)  | 12 (2.7)  | 12 (2.3)                     | 11 (3.5)                     | 27 (5.9)                     | 16 (3.9)                     | 78 (3.6)   | 62 (3.6)   |
|   | 1            | 114 (29.9)  | 132 (29.8)  | 153 (29.5)                   | 93 (29.6)                    | 140 (30.4)                   | 130 (31.6)                   | 648 (30.2)   | 518 (29.8)   |
|   | 2            | 135 (35.4)  | 160 (36.1)  | 189 (36.4)                   | 142 (45.2)                   | 171 (37.1)                   | 158 (38.3)                   | 820 (38.2)   | 662 (38.1)   |
|   | 3            | 81 (21.3)   | 87 (19.6)   | 96 (18.5)                    | 49 (15.6)                    | 69 (15.0)                    | 73 (17.7)                    | 374 (17.4)   | 301 (17.3)   |
|   | 4            | 28 (7.3)  | 45 (10.2)   | 43 (8.3)                     | 11 (3.5)                     | 42 (9.1)                     | 24 (5.8)                     | 165 (7.7)  | 141 (8.1)  |
|   | 5            | 11 (2.9)  | 7 (1.6)   | 25 (4.8)                     | 7 (2.2)                      | 10 (2.2)                     | 10 (2.4)                     | 59 (2.7)   | 49 (2.8)   |
|   | 6            | 1 (0.3)   | -   | 1 (0.2)                      | 1 (0.3)                      | 2 (0.4)                      | 1 (0.2)                      | 5 (0.2)  | 4 (0.2)  |
| CHA2DS2-<br>VASc Score                        | n (missing)  | 381 (10)  | 443 (9)   | 519 (10)                     | 313 (12)                     | 460 (8)                      | 410 (7)                      | 2145 (46)  | 1735 (39)  |
|   | Mean (SD)    | 3.6 (1.5)   | 3.6 (1.5)   | 3.7 (1.5)                    | 3.5 (1.3)                    | 3.5 (1.5)                    | 3.5 (1.4)                    | 3.5 (1.5)  | 3.6 (1.5)  |
|   | Median (IQR) | 4.0 (3.0 to 4.0)  | 4.0 (3.0 to 5.0)  | 4.0 (3.0 to 5.0)             | 3.0 (3.0 to 4.0)             | 3.0 (2.0 to 4.0)             | 3.0 (3.0 to 4.0)             | 4.0 (3.0 to 4.0)   | 4.0 (3.0 to 4.0)   |
|   | Min to Max   | 0 to 8  | 0 to 8  | 0 to 9                       | 1 to 8                       | 0 to 9                       | 0 to 7                       | 0 to 9   | 0 to 9   |
| CHA2DS2-<br>VASc score<br>categories,<br>n(%) | n (missing)  | 381 (10)  | 443 (9)   | 519 (10)                     | 313 (12)                     | 460 (8)                      | 410 (7)                      | 2145 (46)  | 1735 (39)  |
|   | 0            | 4 (1.0)   | 8 (1.8)   | 4 (0.8)                      | -                            | 8 (1.7)                      | 7 (1.7)                      | 27 (1.3)   | 20 (1.2)   |
|   | 1            | 24 (6.3)  | 27 (6.1)  | 30 (5.8)                     | 20 (6.4)                     | 36 (7.8)                     | 19 (4.6)                     | 132 (6.2)  | 113 (6.5)  |
|   | 2            | 59 (15.5)   | 64 (14.4)   | 75 (14.5)                    | 48 (15.3)                    | 81 (17.6)                    | 74 (18.0)                    | 342 (15.9)   | 268 (15.4)   |
|   | 3            | 100 (26.2)  | 114 (25.7)  | 140 (27.0)                   | 93 (29.7)                    | 111 (24.1)                   | 106 (25.9)                   | 564 (26.3)   | 458 (26.4)   |
|   | 4            | 103 (27.0)  | 108 (24.4)  | 136 (26.2)                   | 99 (31.6)                    | 112 (24.3)                   | 117 (28.5)                   | 572 (26.7)   | 455 (26.2)   |

**Table 09 : Risk scores**  
**Full Analysis Dataset : ITALY**

| Variable                        | Statistics   | Cohort 1<br>Retrospective<br>patients<br>(N=391)<br>(n %) | Cohort 1<br>Prospective<br>patients<br>(N=452)<br>(n %) | Cohort 2<br>(N=529)<br>(n %) | Cohort 3<br>(N=325)<br>(n %) | Cohort 4<br>(N=468)<br>(n %) | Cohort 5<br>(N=417)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 5<br>(N=2191) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1774) |
|---------------------------------|--------------|---|---|------------------------------|------------------------------|------------------------------|------------------------------|--|--|
|                                 | 5            | 51 (13.4)   | 78 (17.6)   | 78 (15.0)                    | 38 (12.1)                    | 71 (15.4)                    | 58 (14.1)                    | 323 (15.1)   | 265 (15.3)   |
|                                 | 6-9          | 40 (10.5)   | 44 (9.9)  | 56 (10.8)                    | 15 (4.8)                     | 41 (8.9)                     | 29 (7.1)                     | 185 (8.6)  | 156 (9.0)  |
| HAS-BLED score                  | n (missing)  | 285 (106)   | 316 (136)   | 419 (110)                    | 259 (66)                     | 381 (87)                     | 310 (107)                    | 1685 (506)   | 1375 (399)   |
|                                 | Mean (SD)    | 1.3 (0.8)   | 1.4 (0.8)   | 1.3 (0.8)                    | 1.5 (0.8)                    | 1.5 (1.0)                    | 1.4 (0.8)                    | 1.4 (0.8)  | 1.4 (0.8)  |
|                                 | Median (IQR) | 1.0 (1.0 to 2.0)  | 1.0 (1.0 to 2.0)  | 1.0 (1.0 to 2.0)             | 1.0 (1.0 to 2.0)             | 1.0 (1.0 to 2.0)             | 1.0 (1.0 to 2.0)             | 1.0 (1.0 to 2.0)   | 1.0 (1.0 to 2.0)   |
|                                 | Min to Max   | 0 to 4  | 0 to 4  | 0 to 5                       | 0 to 4                       | 0 to 5                       | 0 to 4                       | 0 to 5   | 0 to 5   |
| HAS-BLED score categories, n(%) | n (missing)  | 285 (106)   | 316 (136)   | 419 (110)                    | 259 (66)                     | 381 (87)                     | 310 (107)                    | 1685 (506)   | 1375 (399)   |
|                                 | 0            | 35 (12.3)   | 36 (11.4)   | 43 (10.3)                    | 18 (6.9)                     | 48 (12.6)                    | 27 (8.7)                     | 172 (10.2)   | 145 (10.5)   |
|                                 | 1            | 157 (55.1)  | 155 (49.1)  | 225 (53.7)                   | 127 (49.0)                   | 166 (43.6)                   | 150 (48.4)                   | 823 (48.8)   | 673 (48.9)   |
|                                 | 2            | 69 (24.2)   | 96 (30.4)   | 123 (29.4)                   | 84 (32.4)                    | 114 (29.9)                   | 104 (33.5)                   | 521 (30.9)   | 417 (30.3)   |
|                                 | 3            | 20 (7.0)  | 26 (8.2)  | 26 (6.2)                     | 28 (10.8)                    | 44 (11.5)                    | 28 (9.0)                     | 152 (9.0)  | 124 (9.0)  |
|                                 | 4            | 4 (1.4)   | 3 (0.9)   | 1 (0.2)                      | 2 (0.8)                      | 7 (1.8)                      | 1 (0.3)                      | 14 (0.8)   | 13 (0.9)   |
|                                 | 5            | -   | -   | 1 (0.2)                      | -                            | 2 (0.5)                      | -                            | 3 (0.2)  | 3 (0.2)  |

**Table 10: Treatment at baseline by CHA2DS2-VASc score  
Full Analysis Dataset : ITALY**

| Cohort                 | CHA2DS2-VASc | VKA |      | VKA+AP |      | FXA |      | FXA+AP |     | DTI |     | DTI+AP |     | AP   |      | NONE |      | UNKNOWN |
|------------------------|--------------|-----|------|--------|------|-----|------|--------|-----|-----|-----|--------|-----|------|------|------|------|---------|
|                        |              | n   | %    | n      | %    | n   | %    | n      | %   | n   | %   | n      | %   | n    | %    | n    | %    | n       |
| Cohort 1 retrospective | 0            | 3   | 75   | -      | -    | -   | -    | -      | -   | -   | -   | -      | -   | -    | -    | 1    | 25   | -       |
|                        | 1            | 21  | 87.5 | -      | -    | -   | -    | -      | -   | -   | -   | -      | -   | 2    | 8.3  | 1    | 4.2  | -       |
|                        | 2            | 50  | 84.7 | 1      | 1.7  | 2   | 3.4  | -      | -   | -   | -   | -      | -   | 4    | 6.8  | 2    | 3.4  | -       |
|                        | 3            | 83  | 83   | 4      | 4    | -   | -    | 1      | 1   | -   | -   | -      | -   | 7    | 7    | 5    | 5    | -       |
|                        | 4            | 76  | 75.2 | 11     | 10.9 | -   | -    | -      | -   | -   | -   | -      | -   | 12   | 11.9 | 2    | 2    | 2       |
|                        | 5            | 41  | 80.4 | 5      | 9.8  | -   | -    | -      | -   | -   | -   | -      | -   | 5    | 9.8  | -    | -    | -       |
|                        | 6-9          | 32  | 80   | 6      | 15   | -   | -    | -      | -   | -   | -   | -      | 2   | 5    | -    | -    | -    |         |
| Cohort 1 prospective   | 0            | 4   | 50   | 1      | 12.5 | -   | -    | -      | -   | -   | -   | -      | -   | 2    | 25   | 1    | 12.5 | -       |
|                        | 1            | 19  | 73.1 | 2      | 7.7  | 2   | 7.7  | 1      | 3.8 | -   | -   | -      | -   | 1    | 3.8  | 1    | 3.8  | 1       |
|                        | 2            | 50  | 79.4 | 7      | 11.1 | -   | -    | 1      | 1.6 | -   | -   | -      | -   | 2    | 3.2  | 3    | 4.8  | 1       |
|                        | 3            | 84  | 75.7 | 13     | 11.7 | 2   | 1.8  | -      | -   | -   | -   | -      | -   | 10   | 9    | 2    | 1.8  | 3       |
|                        | 4            | 84  | 79.2 | 13     | 12.3 | -   | -    | -      | -   | -   | -   | -      | -   | 4    | 3.8  | 5    | 4.7  | 2       |
|                        | 5            | 56  | 73.7 | 13     | 17.1 | -   | -    | 1      | 1.3 | -   | -   | -      | -   | 5    | 6.6  | 1    | 1.3  | 2       |
|                        | 6-9          | 25  | 58.1 | 10     | 23.3 | -   | -    | -      | -   | -   | -   | -      | 6   | 14   | 2    | 4.7  | 1    |         |
| Cohort 2               | 0            | 2   | 50   | -      | -    | -   | -    | -      | -   | -   | -   | -      | -   | -    | -    | 2    | 50   | -       |
|                        | 1            | 22  | 73.3 | -      | -    | -   | -    | -      | -   | -   | -   | -      | -   | 4    | 13.3 | 4    | 13.3 | -       |
|                        | 2            | 57  | 76   | 5      | 6.7  | 1   | 1.3  | -      | -   | -   | -   | -      | -   | 8    | 10.7 | 4    | 5.3  | -       |
|                        | 3            | 109 | 77.9 | 17     | 12.1 | -   | -    | -      | -   | -   | -   | -      | -   | 7    | 5    | 7    | 5    | -       |
|                        | 4            | 102 | 75   | 19     | 14   | -   | -    | -      | -   | -   | -   | -      | -   | 13   | 9.6  | 2    | 1.5  | -       |
|                        | 5            | 57  | 74   | 10     | 13   | -   | -    | -      | -   | -   | -   | -      | -   | 8    | 10.4 | 2    | 2.6  | 1       |
|                        | 6-9          | 37  | 66.1 | 10     | 17.9 | -   | -    | -      | -   | -   | -   | -      | 7   | 12.5 | 2    | 3.6  | -    |         |
| Cohort 3               | 1            | 14  | 70   | 1      | 5    | 2   | 10   | -      | -   | 2   | 10  | -      | -   | -    | -    | 1    | 5    | -       |
|                        | 2            | 32  | 66.7 | 4      | 8.3  | 3   | 6.3  | -      | -   | 4   | 8.3 | -      | -   | 2    | 4.2  | 3    | 6.3  | -       |
|                        | 3            | 58  | 62.4 | 9      | 9.7  | 7   | 7.5  | -      | -   | 6   | 6.5 | 1      | 1.1 | 3    | 3.2  | 9    | 9.7  | -       |
|                        | 4            | 62  | 63.3 | 12     | 12.2 | 10  | 10.2 | 1      | 1   | 7   | 7.1 | -      | -   | 4    | 4.1  | 2    | 2    | 1       |
|                        | 5            | 21  | 55.3 | 6      | 15.8 | 5   | 13.2 | -      | -   | 2   | 5.3 | 1      | 2.6 | 2    | 5.3  | 1    | 2.6  | -       |

**Table 10: Treatment at baseline by CHA2DS2-VASc score  
Full Analysis Dataset : ITALY**

| Cohort  | CHA2DS2-VASc | VKA |      | VKA+AP |      | FXA |      | FXA+AP |      | DTI |      | DTI+AP |     | AP |      | NONE |      | UNKNOWN |
|---|--------------|-----|------|--------|------|-----|------|--------|------|-----|------|--------|-----|----|------|------|------|---------|
|   |              | n   | %    | n      | %    | n   | %    | n      | %    | n   | %    | n      | %   | n  | %    | n    | %    | n       |
|   | 6-9          | 12  | 80   | -      | -    | -   | -    | 1      | 6.7  | 1   | 6.7  | -      | -   | 1  | 6.7  | -    | -    | -       |
| Cohort 4  | 0            | 1   | 14.3 | -      | -    | 1   | 14.3 | -      | -    | -   | -    | -      | -   | 1  | 14.3 | 4    | 57.1 | 1       |
|   | 1            | 9   | 25.7 | 1      | 2.9  | 6   | 17.1 | -      | -    | -   | -    | -      | -   | 5  | 14.3 | 14   | 40   | 1       |
|   | 2            | 31  | 38.3 | 2      | 2.5  | 18  | 22.2 | 4      | 4.9  | 4   | 4.9  | 1      | 1.2 | 13 | 16   | 8    | 9.9  | -       |
|   | 3            | 40  | 36.4 | 10     | 9.1  | 40  | 36.4 | 4      | 3.6  | 4   | 3.6  | -      | -   | 8  | 7.3  | 4    | 3.6  | 1       |
|   | 4            | 47  | 42   | 8      | 7.1  | 28  | 25   | 6      | 5.4  | 9   | 8    | -      | -   | 11 | 9.8  | 3    | 2.7  | -       |
|   | 5            | 21  | 29.6 | 8      | 11.3 | 27  | 38   | 5      | 7    | 4   | 5.6  | -      | -   | 5  | 7    | 1    | 1.4  | -       |
|   | 6-9          | 11  | 26.8 | 2      | 4.9  | 15  | 36.6 | 5      | 12.2 | 1   | 2.4  | 2      | 4.9 | 4  | 9.8  | 1    | 2.4  | -       |
| Cohort 5  | 0            | -   | -    | -      | -    | 2   | 28.6 | -      | -    | 1   | 14.3 | -      | -   | -  | -    | 4    | 57.1 | -       |
|   | 1            | 10  | 52.6 | 1      | 5.3  | 5   | 26.3 | -      | -    | 1   | 5.3  | -      | -   | -  | -    | 2    | 10.5 | -       |
|   | 2            | 23  | 31.1 | 3      | 4.1  | 33  | 44.6 | 2      | 2.7  | 8   | 10.8 | -      | -   | 2  | 2.7  | 3    | 4.1  | -       |
|   | 3            | 34  | 32.1 | 5      | 4.7  | 43  | 40.6 | 7      | 6.6  | 4   | 3.8  | -      | -   | 7  | 6.6  | 6    | 5.7  | -       |
|   | 4            | 43  | 37.1 | 10     | 8.6  | 46  | 39.7 | 2      | 1.7  | 7   | 6    | -      | -   | 2  | 1.7  | 6    | 5.2  | 1       |
|   | 5            | 14  | 24.1 | 4      | 6.9  | 27  | 46.6 | 6      | 10.3 | 3   | 5.2  | -      | -   | 4  | 6.9  | -    | -    | -       |
|   | 6-9          | 6   | 20.7 | 3      | 10.3 | 12  | 41.4 | 4      | 13.8 | 3   | 10.3 | -      | -   | -  | -    | 1    | 3.4  | -       |
| Total<br>Prospective<br>patients<br>Cohorts 1 to<br>5 | 0            | 7   | 26.9 | 1      | 3.8  | 3   | 11.5 | -      | -    | 1   | 3.8  | -      | -   | 3  | 11.5 | 11   | 42.3 | 1       |
|   | 1            | 74  | 56.9 | 5      | 3.8  | 15  | 11.5 | 1      | 0.8  | 3   | 2.3  | -      | -   | 10 | 7.7  | 22   | 16.9 | 2       |
|   | 2            | 193 | 56.6 | 21     | 6.2  | 55  | 16.1 | 7      | 2.1  | 16  | 4.7  | 1      | 0.3 | 27 | 7.9  | 21   | 6.2  | 1       |
|   | 3            | 325 | 58   | 54     | 9.6  | 92  | 16.4 | 11     | 2    | 14  | 2.5  | 1      | 0.2 | 35 | 6.3  | 28   | 5    | 4       |
|   | 4            | 338 | 59.5 | 62     | 10.9 | 84  | 14.8 | 9      | 1.6  | 23  | 4    | -      | -   | 34 | 6    | 18   | 3.2  | 4       |
|   | 5            | 169 | 52.8 | 41     | 12.8 | 59  | 18.4 | 12     | 3.8  | 9   | 2.8  | 1      | 0.3 | 24 | 7.5  | 5    | 1.6  | 3       |
|   | 6-9          | 91  | 49.5 | 25     | 13.6 | 27  | 14.7 | 10     | 5.4  | 5   | 2.7  | 2      | 1.1 | 18 | 9.8  | 6    | 3.3  | 1       |

**Table 10: Treatment at baseline by CHA2DS2-VASc score  
Full Analysis Dataset : ITALY**

| Cohort               | CHA2DS2-VASc | VKA |      | VKA+AP |      | FXA |      | FXA+AP |     | DTI |     | DTI+AP |     | AP |      | NONE |      | UNKNOWN |  |
|----------------------|--------------|-----|------|--------|------|-----|------|--------|-----|-----|-----|--------|-----|----|------|------|------|---------|--|
|                      |              | n   | %    | n      | %    | n   | %    | n      | %   | n   | %   | n      | %   | n  | %    | n    | %    | n       |  |
| Total                | 0            | 7   | 36.8 | 1      | 5.3  | 1   | 5.3  | -      | -   | -   | -   | -      | -   | 3  | 15.8 | 7    | 36.8 | 1       |  |
| Prospective patients |              |     |      |        |      |     |      |        |     |     |     |        |     |    |      |      |      |         |  |
| Cohorts 1 to 4       |              |     |      |        |      |     |      |        |     |     |     |        |     |    |      |      |      |         |  |
|                      | 1            | 64  | 57.7 | 4      | 3.6  | 10  | 9    | 1      | 0.9 | 2   | 1.8 | -      | -   | 10 | 9    | 20   | 18   | 2       |  |
|                      | 2            | 170 | 63.7 | 18     | 6.7  | 22  | 8.2  | 5      | 1.9 | 8   | 3   | 1      | 0.4 | 25 | 9.4  | 18   | 6.7  | 1       |  |
|                      | 3            | 291 | 64.1 | 49     | 10.8 | 49  | 10.8 | 4      | 0.9 | 10  | 2.2 | 1      | 0.2 | 28 | 6.2  | 22   | 4.8  | 4       |  |
|                      | 4            | 295 | 65.3 | 52     | 11.5 | 38  | 8.4  | 7      | 1.5 | 16  | 3.5 | -      | -   | 32 | 7.1  | 12   | 2.7  | 3       |  |
|                      | 5            | 155 | 59.2 | 37     | 14.1 | 32  | 12.2 | 6      | 2.3 | 6   | 2.3 | 1      | 0.4 | 20 | 7.6  | 5    | 1.9  | 3       |  |
|                      | 6-9          | 85  | 54.8 | 22     | 14.2 | 15  | 9.7  | 6      | 3.9 | 2   | 1.3 | 2      | 1.3 | 18 | 11.6 | 5    | 3.2  | 1       |  |

**Table 11: Treatment at baseline by HAS-BLED score  
Full Analysis Dataset : ITALY**

| Cohort                    | HAS-BLED | VKA |      | VKA+AP |      | FXA |      | FXA+AP |      | DTI |      | DTI+AP |     | AP |      | NONE |      | UNKNOWN |   |
|---------------------------|----------|-----|------|--------|------|-----|------|--------|------|-----|------|--------|-----|----|------|------|------|---------|---|
|                           |          | n   | %    | n      | %    | n   | %    | n      | %    | n   | %    | n      | %   | n  | %    | n    | %    | n       |   |
| Cohort 1<br>retrospective | 0        | 33  | 94.3 | -      | -    | -   | -    | -      | -    | -   | -    | -      | -   | -  | -    | -    | 2    | 5.7     | - |
|                           | 1        | 144 | 92.9 | 3      | 1.9  | 1   | 0.6  | -      | -    | -   | -    | -      | -   | 4  | 2.6  | 3    | 1.9  | 2       |   |
|                           | 2        | 47  | 68.1 | 10     | 14.5 | 1   | 1.4  | -      | -    | -   | -    | -      | -   | 10 | 14.5 | 1    | 1.4  | -       |   |
|                           | 3        | 6   | 30   | 6      | 30   | -   | -    | 1      | 5    | -   | -    | -      | -   | 6  | 30   | 1    | 5    | -       |   |
|                           | 4-9      | -   | -    | -      | -    | -   | -    | -      | -    | -   | -    | -      | -   | 4  | 100  | -    | -    | -       |   |
| Cohort 1<br>prospective   | 0        | 32  | 88.9 | -      | -    | 2   | 5.6  | -      | -    | -   | -    | -      | -   | -  | -    | 2    | 5.6  | -       |   |
|                           | 1        | 135 | 88.8 | 8      | 5.3  | -   | -    | 1      | 0.7  | -   | -    | -      | -   | 3  | 2    | 5    | 3.3  | 3       |   |
|                           | 2        | 52  | 57.1 | 23     | 25.3 | -   | -    | -      | -    | -   | -    | -      | -   | 14 | 15.4 | 2    | 2.2  | 5       |   |
|                           | 3        | 9   | 34.6 | 12     | 46.2 | -   | -    | -      | -    | -   | -    | -      | -   | 3  | 11.5 | 2    | 7.7  | -       |   |
|                           | 4-9      | 1   | 33.3 | 2      | 66.7 | -   | -    | -      | -    | -   | -    | -      | -   | -  | -    | -    | -    | -       |   |
| Cohort 2                  | 0        | 33  | 76.7 | -      | -    | -   | -    | -      | -    | -   | -    | -      | -   | -  | -    | 10   | 23.3 | -       |   |
|                           | 1        | 207 | 92.4 | 7      | 3.1  | -   | -    | -      | -    | -   | -    | -      | -   | 4  | 1.8  | 6    | 2.7  | 1       |   |
|                           | 2        | 68  | 55.3 | 28     | 22.8 | 1   | 0.8  | -      | -    | -   | -    | -      | -   | 22 | 17.9 | 4    | 3.3  | -       |   |
|                           | 3        | 11  | 42.3 | 8      | 30.8 | -   | -    | -      | -    | -   | -    | -      | -   | 7  | 26.9 | -    | -    | -       |   |
|                           | 4-9      | -   | -    | 2      | 100  | -   | -    | -      | -    | -   | -    | -      | -   | -  | -    | -    | -    | -       |   |
| Cohort 3                  | 0        | 12  | 66.7 | -      | -    | 3   | 16.7 | -      | -    | -   | -    | -      | -   | -  | -    | 3    | 16.7 | -       |   |
|                           | 1        | 90  | 71.4 | 3      | 2.4  | 12  | 9.5  | -      | -    | 14  | 11.1 | -      | -   | -  | -    | 7    | 5.6  | 1       |   |
|                           | 2        | 39  | 46.4 | 22     | 26.2 | 7   | 8.3  | 1      | 1.2  | 5   | 6    | 1      | 1.2 | 5  | 6    | 4    | 4.8  | -       |   |
|                           | 3        | 13  | 46.4 | 5      | 17.9 | 1   | 3.6  | 1      | 3.6  | 1   | 3.6  | 1      | 3.6 | 5  | 17.9 | 1    | 3.6  | -       |   |
|                           | 4-9      | -   | -    | 1      | 50   | -   | -    | -      | -    | -   | -    | -      | -   | 1  | 50   | -    | -    | -       |   |
| Cohort 4                  | 0        | 14  | 30.4 | -      | -    | 13  | 28.3 | -      | -    | -   | -    | -      | -   | -  | -    | 19   | 41.3 | 2       |   |
|                           | 1        | 82  | 49.7 | 3      | 1.8  | 50  | 30.3 | 1      | 0.6  | 13  | 7.9  | 1      | 0.6 | 8  | 4.8  | 7    | 4.2  | 1       |   |
|                           | 2        | 28  | 24.6 | 14     | 12.3 | 34  | 29.8 | 12     | 10.5 | 4   | 3.5  | -      | -   | 19 | 16.7 | 3    | 2.6  | -       |   |
|                           | 3        | 9   | 20.5 | 11     | 25   | 14  | 31.8 | 5      | 11.4 | -   | -    | 1      | 2.3 | 4  | 9.1  | -    | -    | -       |   |
|                           | 4-9      | 2   | 22.2 | 1      | 11.1 | 2   | 22.2 | 3      | 33.3 | -   | -    | -      | -   | 1  | 11.1 | -    | -    | -       |   |

**Table 11: Treatment at baseline by HAS-BLED score  
Full Analysis Dataset : ITALY**

| Cohort                                    | HAS-BLED | VKA |      | VKA+AP |      | FXA |      | FXA+AP |      | DTI |     | DTI+AP |     | AP |      | NONE |      | UNKNOWN |
|---|----------|-----|------|--------|------|-----|------|--------|------|-----|-----|--------|-----|----|------|------|------|---------|
|   |          | n   | %    | n      | %    | n   | %    | n      | %    | n   | %   | n      | %   | n  | %    | n    |      |         |
| Cohort 5                                  | 0        | 12  | 44.4 | -      | -    | 11  | 40.7 | -      | -    | -   | -   | -      | -   | -  | -    | 4    | 14.8 | -       |
|   | 1        | 57  | 38   | 4      | 2.7  | 69  | 46   | 1      | 0.7  | 11  | 7.3 | -      | -   | 1  | 0.7  | 7    | 4.7  | -       |
|   | 2        | 28  | 26.9 | 15     | 14.4 | 45  | 43.3 | 5      | 4.8  | 5   | 4.8 | -      | -   | 6  | 5.8  | -    | -    | -       |
|   | 3        | 2   | 7.1  | 5      | 17.9 | 12  | 42.9 | 7      | 25   | 1   | 3.6 | -      | -   | 1  | 3.6  | -    | -    | -       |
|   | 4-9      | -   | -    | -      | -    | 1   | 100  | -      | -    | -   | -   | -      | -   | -  | -    | -    | -    | -       |
| Total Prospective patients Cohorts 1 to 5 | 0        | 103 | 60.6 | -      | -    | 29  | 17.1 | -      | -    | -   | -   | -      | -   | -  | -    | 38   | 22.4 | 2       |
| Total Prospective patients Cohorts 1 to 4 | 1        | 571 | 69.9 | 25     | 3.1  | 131 | 16   | 3      | 0.4  | 38  | 4.7 | 1      | 0.1 | 16 | 2    | 32   | 3.9  | 6       |
|   | 2        | 215 | 41.7 | 102    | 19.8 | 87  | 16.9 | 18     | 3.5  | 14  | 2.7 | 1      | 0.2 | 66 | 12.8 | 13   | 2.5  | 5       |
|   | 3        | 44  | 28.9 | 41     | 27   | 27  | 17.8 | 13     | 8.6  | 2   | 1.3 | 2      | 1.3 | 20 | 13.2 | 3    | 2    | -       |
|   | 4-9      | 3   | 17.6 | 6      | 35.3 | 3   | 17.6 | 3      | 17.6 | -   | -   | -      | -   | 2  | 11.8 | -    | -    | -       |
|   | 0        | 91  | 63.6 | -      | -    | 18  | 12.6 | -      | -    | -   | -   | -      | -   | -  | -    | 34   | 23.8 | 2       |
| Total Prospective patients Cohorts 1 to 4 | 1        | 514 | 77.1 | 21     | 3.1  | 62  | 9.3  | 2      | 0.3  | 27  | 4   | 1      | 0.1 | 15 | 2.2  | 25   | 3.7  | 6       |
|   | 2        | 187 | 45.4 | 87     | 21.1 | 42  | 10.2 | 13     | 3.2  | 9   | 2.2 | 1      | 0.2 | 60 | 14.6 | 13   | 3.2  | 5       |
|   | 3        | 42  | 33.9 | 36     | 29   | 15  | 12.1 | 6      | 4.8  | 1   | 0.8 | 2      | 1.6 | 19 | 15.3 | 3    | 2.4  | -       |
|   | 4-9      | 3   | 18.8 | 6      | 37.5 | 2   | 12.5 | 3      | 18.8 | -   | -   | -      | -   | 2  | 12.5 | -    | -    | -       |
|   | 0        | 91  | 63.6 | -      | -    | 18  | 12.6 | -      | -    | -   | -   | -      | -   | -  | -    | 34   | 23.8 | 2       |



**Table 12: INR values and time in therapeutic range (TTR) during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| Variable           | Statistics   | Cohort 1<br>Prospective<br>patients<br>(N=390)<br>(n %) | Cohort 2<br>(N=456)<br>(n %) | Cohort 3<br>(N=242)<br>(n %) | Cohort 4<br>(N=197)<br>(n %) | Total<br>Prospective<br>patients<br>Cohorts 1 to 4<br>(N=1285) |
|--------------------|--------------|---|------------------------------|------------------------------|------------------------------|--|
| TTR value,<br>n(%) | n (missing)  | 261 (129)   | 272 (184)                    | 179 (63)                     | 119 (78)                     | 831 (454)  |
|                    | <65          | 88 (33.7)   | 94 (34.6)                    | 77 (43.0)                    | 55 (46.2)                    | 314 (37.8)   |
|                    | >=65         | 173 (66.3)  | 178 (65.4)                   | 102 (57.0)                   | 64 (53.8)                    | 517 (62.2)   |
| TTR                | n (missing)  | 261 (129)   | 272 (184)                    | 179 (63)                     | 119 (78)                     | 831 (454)  |
|                    | Mean (SD)    | 71.8 (18.5)   | 69.2 (18.3)                  | 65.9 (22.0)                  | 64.3 (20.8)                  | 68.6 (19.7)  |
|                    | Median (IQR) | 73.3 (62.1 to 84.4)                                     | 71.4 (59.3 to 81.4)          | 70.2 (54.2 to 82.2)          | 68.0 (51.6 to 80.1)          | 71.4 (58.3 to 82.5)  |
|                    | Min to Max   | 0.0 to 100.0  | 0.0 to 100.0                 | 0.0 to 100.0                 | 0.0 to 100.0                 | 0.0 to 100.0   |
| INR value,<br>n(%) | n            | 4744  | 5467                         | 3610                         | 2517                         | 16338  |
|                    | 2-3          | 2840 (59.9)   | 3139 (57.4)                  | 2021 (56.0)                  | 1350 (53.6)                  | 9350 (57.2)  |
|                    | <2           | 1266 (26.7)   | 1710 (31.3)                  | 1141 (31.6)                  | 834 (33.1)                   | 4951 (30.3)  |
|                    | >3           | 638 (13.4)  | 618 (11.3)                   | 448 (12.4)                   | 333 (13.2)                   | 2037 (12.5)  |
| INR                | n            | 4744  | 5467                         | 3610                         | 2517                         | 16338  |
|                    | Mean (SD)    | 2.4 (0.7)   | 2.3 (0.7)                    | 2.3 (0.7)                    | 2.3 (0.7)                    | 2.3 (0.7)  |
|                    | Median (IQR) | 2.3 (2.0 to 2.7)  | 2.2 (1.9 to 2.6)             | 2.2 (1.9 to 2.6)             | 2.3 (1.9 to 2.7)             | 2.3 (1.9 to 2.7)   |
|                    | Min to Max   | 0.9 to 9.4  | 0.9 to 10.1                  | 0.8 to 16.0                  | 0.9 to 8.0                   | 0.8 to 16.0  |

**Table 13 :Event rates during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| Outcome                     | Cause                               | N    | Events | Event rate<br>/100<br>person-years | 95% CI         |
|-----------------------------|-------------------------------------|------|--------|------------------------------------|----------------|
| All-cause death             |                                     | 1774 | 65     | 3.87                               | (3.04 to 4.94) |
|                             | <b>Cardiovascular death</b>         | 1774 | 25     | 1.49                               | (1.01 to 2.20) |
|                             | <b>Non-Cardiovascular<br/>death</b> | 1774 | 23     | 1.37                               | (0.91 to 2.06) |
|                             | <b>Undetermined cause</b>           | 1774 | 17     | 1.01                               | (0.63 to 1.63) |
| Stroke/SE                   |                                     | 1774 | 15     | 0.90                               | (0.54 to 1.49) |
| Major bleed                 |                                     | 1774 | 19     | 1.14                               | (0.73 to 1.78) |
| Acute coronary<br>syndrome  |                                     | 1774 | 14     | 0.84                               | (0.50 to 1.41) |
| Congestive Heart<br>Failure |                                     | 1774 | 9      | 0.54                               | (0.28 to 1.03) |

**Table 14: Cause of death during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| Outcome                          | Cause                       | ITALY |        |       |
|----------------------------------|-----------------------------|-------|--------|-------|
|                                  |                             | N     | Events | %     |
| <b>Cardiovascular causes</b>     | Myocardial infarction       | 25    | 3      | 12.00 |
|                                  | Ischaemic stroke            | 25    | 2      | 8.00  |
|                                  | Congestive heart failure    | 25    | 6      | 24.00 |
|                                  | Sudden or unwitnessed death | 25    | 5      | 20.00 |
|                                  | Other                       | 25    | 9      | 36.00 |
| <b>Non-cardiovascular causes</b> | Respiratory failure         | 23    | 3      | 13.04 |
|                                  | Infection/sepsis            | 23    | 5      | 21.74 |
|                                  | Malignancy                  | 23    | 9      | 39.13 |
|                                  | Other                       | 23    | 6      | 26.09 |

**Table 15: Type of stroke during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset :ITALY**

| OUTCOME                                  | ITALY |        |      |
|--|-------|--------|------|
|  | N     | Events | %    |
| Stroke(not including systemic embolism)  | 1774  | 13     | 0.73 |
| Primary Ischemic Stroke                  | 1774  | 11     | 0.62 |
| <b>Primary intracerebral hemorrhage*</b> | 1774  | 2      | 0.11 |
| <i>Intracerebral</i>                     | 1774  | 1      | 0.06 |

**Table 16 : Mortality rate by CHA2DS2-VASc score during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| CHA2DS2-VASc | N   | Person-Years | Events | Event rate<br>/100<br>person-years | 95% CI          |
|--------------|-----|--------------|--------|------------------------------------|-----------------|
| 0            | 20  | 18.14        | 1      | 5.51                               | (0.78 to 39.13) |
| 1            | 113 | 104.82       | 1      | 0.95                               | (0.13 to 6.77)  |
| 2            | 268 | 250.36       | 6      | 2.40                               | (1.08 to 5.33)  |
| 3            | 458 | 437.82       | 13     | 2.97                               | (1.72 to 5.11)  |
| 4+           | 876 | 830.50       | 43     | 5.18                               | (3.84 to 6.98)  |
| Unknown      | 39  | 36.68        | 1      | 2.73                               | (0.38 to 19.36) |

**Table 17 : Stroke/SE rate by CHA2DS2-VASc score during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| CHA2DS2-VASc | N   | Person-Years | Events | Event rate<br>/100<br>person-years | 95% CI         |
|--------------|-----|--------------|--------|------------------------------------|----------------|
| 0            | 20  | 18.14        | 0      | -                                  | -              |
| 1            | 113 | 104.82       | 0      | -                                  | -              |
| 2            | 268 | 248.32       | 4      | 1.61                               | (0.61 to 4.29) |
| 3            | 458 | 436.82       | 1      | 0.23                               | (0.03 to 1.63) |
| 4+           | 876 | 827.03       | 10     | 1.21                               | (0.65 to 2.25) |
| Unknown      | 39  | 36.68        | 0      | -                                  | -              |

**Table 18 : Major bleeding rate by CHA2DS2-VASc score during the first year of follow-up Cohorts 1 to 4  
Full Analysis Dataset : ITALY**

| CHA2DS2-VASc | N   | Person-Years | Events | Event rate<br>/100<br>person-years | 95% CI         |
|--------------|-----|--------------|--------|------------------------------------|----------------|
| 0            | 20  | 18.14        | 0      | -                                  | -              |
| 1            | 113 | 104.69       | 1      | 0.96                               | (0.14 to 6.78) |
| 2            | 268 | 249.18       | 4      | 1.61                               | (0.60 to 4.28) |
| 3            | 458 | 436.99       | 2      | 0.46                               | (0.11 to 1.83) |
| 4+           | 876 | 824.90       | 12     | 1.46                               | (0.83 to 2.56) |
| Unknown      | 39  | 36.68        | 0      | -                                  | -              |