# 6 months versus 18 months dual antiplatelet treatment for patients underwent bioabsorbable polymer and abluminal coated DES deployment: NIPPON randomized study

Masato Nakamura, Raisuke Iijima, Junya Ako, Toshiro Shinke, Hisayuki Okada,Yoshiaki Ito, Kenji Ando, Hitoshi Anzai, Hiroyuki Tanaka, Yasunori Ueda, Shin Takiuchi, Yasunori Nishida, Hiroshi Ohira, Katsuhiro Kawaguchi, Makoto Kadotani, Hiroyuki Niinuma, Kazuto Omiya, Takashi Morita, Kan Zen, Yoshinori Yasaka, Kenji Inoue, Sugao Ishiwata, Masahiko Ochiai, Toshimitsu Hamasaki, and Hiroyoshi Yokoi, on behalf of the NIPPON investigators

# *COI Disclosure*

***Name of First Author : Masato Nakamura***

- Grants from Terumo  corp. Daiichi Sankyo and Sanofi KK outside the submitted work

- Honoraria from Terumo corp. Daiichi Sankyo KK, Astra-Zeneka KK, and Sanofi KK.

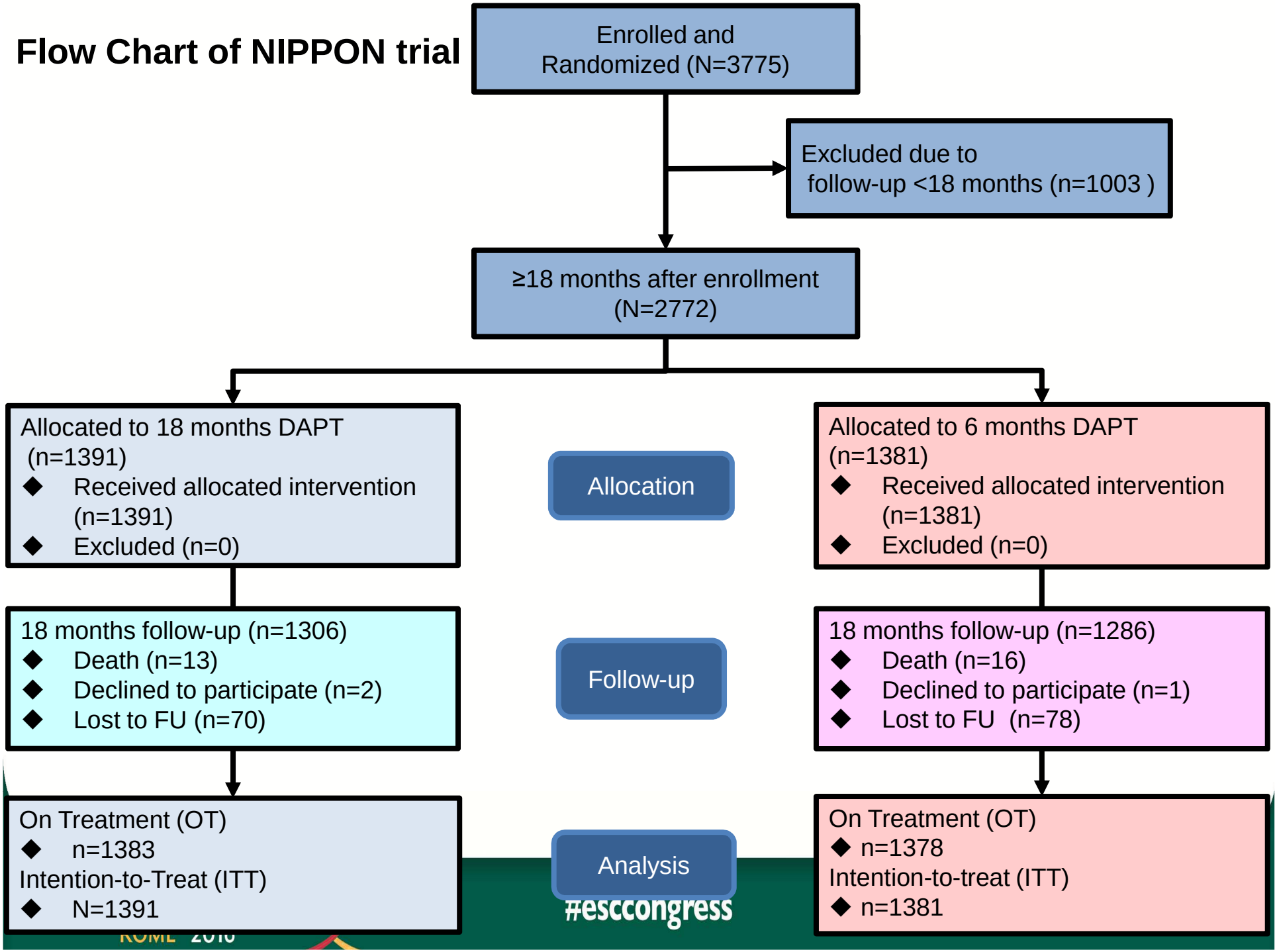
# Objectives

- **A combination of short DAPT and a newer DES should be able to minimize the incidence of thrombotic events and bleeding complications simultaneously**.

- **NIPPON trial is a multi-center randomized study to test the non-inferiority of 6 months DAPT compared with 18 months DAPT following NOBORI stent with bioabsorbable polymer and abluminal c**

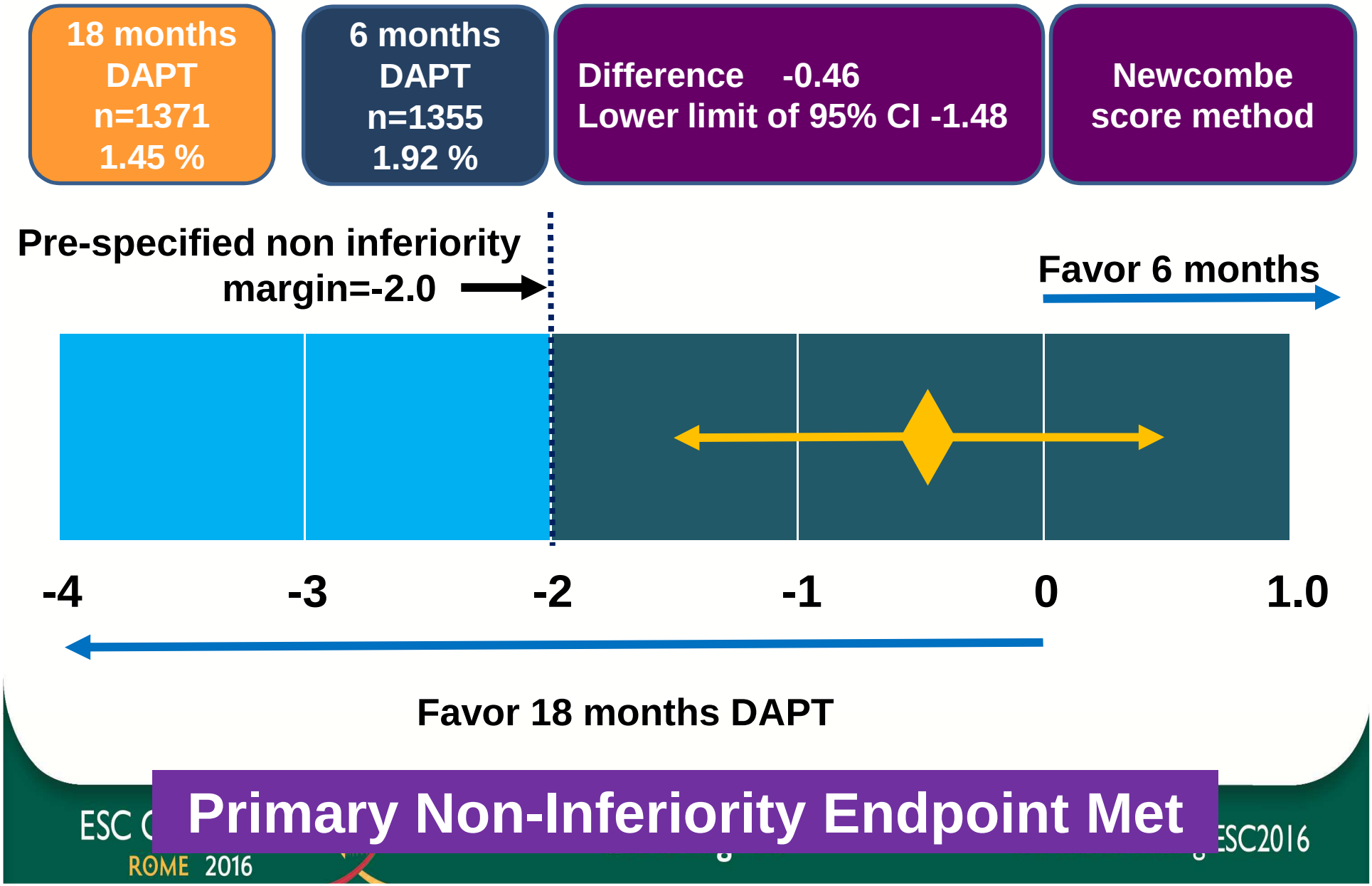
- **Clinical trial:NCT.01514227**

# Flow Chart of NIPPON trial



| | 18 months DAPT | 6 months DAPT |
|---|---|---|
| Target lesion coronary artery | | |
| Left main | 15 (1.1) | 4 (0.3) |
| Left anterior descending | 846 (60.8) | 822 (59.5) |
| Left circumflex | 317 (22.8) | 313 (22.7) |
| Right coronary artery | 426 (30.6) | 421 (30.5) |
| ACC/AHA classification | | |
| A/B1 | 283/523 | 294/489 |
| B2/C | 565/335 | 540/348 |
| Number of treated vessel | | |
| 1-vessel | 1189 (85.5) | 1215 (88.0) |
| 2-vessel | 179 (12.9) | 143 (10.4) |
| 3-vessel | 23 (1.7) | 23 (1.7) |
| Number of NOBORI stent per patient | 1.5±0.8 | 1.4±0.8 |
| Stent diameter (mean ± SD) | 3.0±0.4 | 3.0±0.4 |
| Minimum stent diameter | | |
| <3mm | 491 (35.3) | 498 (36.0) |
| ≥3mm | 897 (64.5) | 882 (63.9) |
| Total stent length (mean ± SD) | 20.3±5.0 | 20.1±5.1 |

# Primary endpoint (NACCE)



# Conclusion

6 months of DAPT was statistically non-inferior to 18 months of DAPT in terms of net adverse clinical and cerebrovascular events, including all cause death, Q-wave or non-Q wave MI, cerebrovascular events, and major bleeding.

However, the results need to be interpreted with caution given premature termination of enrollment, an open-label design with frequent crossover and a wide non-inferiority margin.

# Study limitation

- This was not a double-blind trial, as a result,  adherence of drug was problematic in the present study.
- This trial was not adequately powered due to lower event rate than anticipated and wide non-inferiority margin.
- Premature termination of the present study concomitant with the enrollment of relatively low risk subject suggest that the generalization of our results to high-risk patients requires caution.
- Antiplatelet therapy was mainly limited to clopidogrel in our study, so use of more potent antiplatelet agents may have led to different conclusions.
- The follow-up period may not have been long enough to draw conclusions about the optimum of duration of DAPT for patients with DES, because the DAPT trial demonstrated the benefit of prolonged DAPT for 30 months