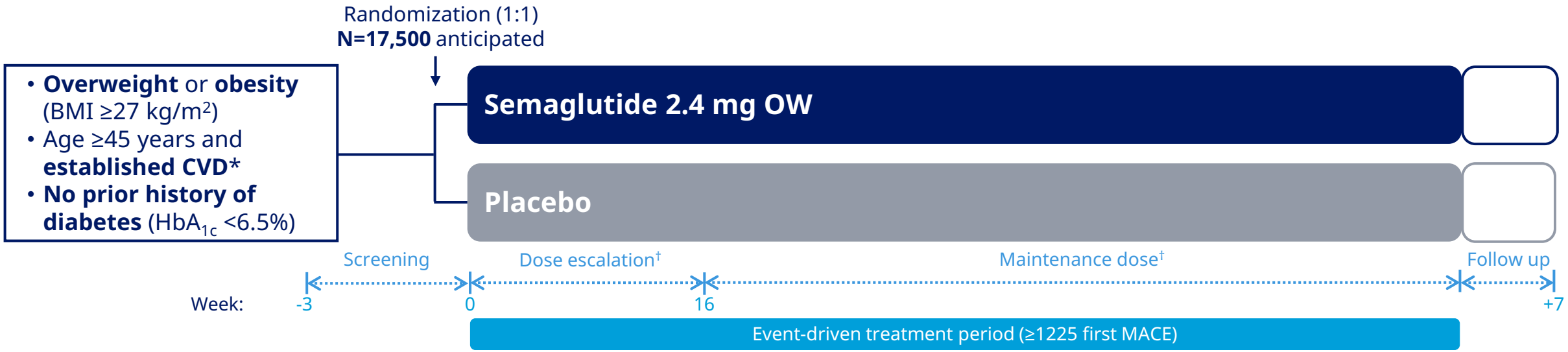
Trial design of SELECT



Estimated duration 59 months; mean follow-up ≈3 years and 8 months

Trial information

- Global trial involving multiple countries across Europe, the Americas, South America and Asia
- FPFV 24 Oct 2018
- Double-blind, placebo-controlled, superiority trial
- 90% power based on an assumed true risk reduction of 17% with semaglutide
- Assumed combined event rate: 2.0%

Key endpoints

Primary: Time from randomization to first occurrence of MACE (non-fatal MI, non-fatal stroke, CV death)

Secondary: Time from randomization to:
CV death; HF composite‡ and all-cause death

*Three-component MACE consisted of non-fatal MI, non-fatal stroke, CV death. *Established CVD: MI ≥60 days ago, stroke ≥60 days ago, or symptomatic PAD, NYHA Class IV excluded; †Dose escalation is from week 4 to 16 with intervals of 4 weeks, and maintenance dose is event-driven to end of treatment period.*
BMI, body mass index; CV, cardiovascular; CVD, cardiovascular disease; FPFV, first patient first visit; MACE, major adverse cardiovascular event; MI, myocardial infarction; NYHA, New York Heart Association; OW, once weekly; PAD, peripheral artery disease;SELECT, semaglutide effects on cardiovascular outcomes in people with overweight or obesity.

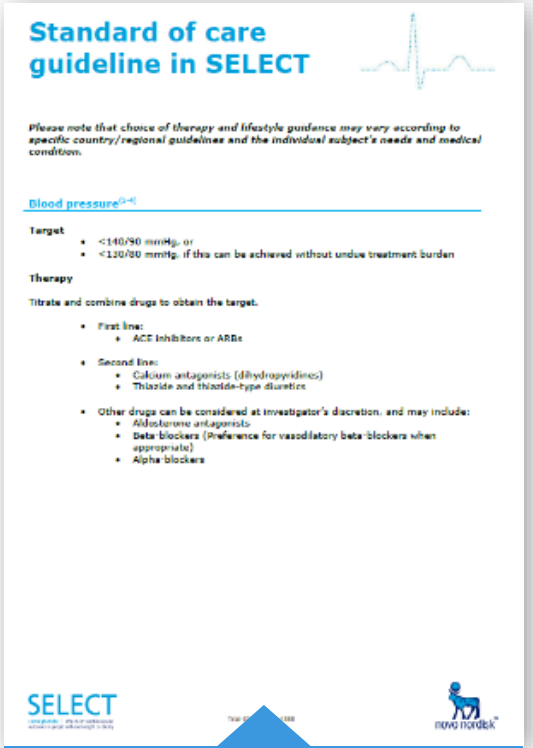
SoC for patients with CVD in SELECT

Adequate medical treatment

- Lipids
- Blood pressure
- Antiplatelet therapy
- Glycemic control for those developing T2D during the study

Healthy lifestyle guidance

- Heart healthy eating (including weight loss where appropriate)
- Increased physical activity
- Smoking cessation
- Limit alcohol consumption



Standard of care guideline in SELECT

Please note that choice of therapy and lifestyle guidance may vary according to specific country/regional guidelines and the individual subject's needs and medical condition.

Blood pressure[3-4]

Target

- <140/90 mmHg, or
- <130/80 mmHg, if this can be achieved without undue treatment burden

Therapy

Titrate and combine drugs to obtain the target.

- First line:
  - ACE inhibitors or ARBs
- Second line:
  - Calcium antagonists (dihydropyridines)
  - Thiazide and thiazide-type diuretics
- Other drugs can be considered at investigator's discretion, and may include:
  - Aldosterone antagonists
  - Beta blockers (Preference for vasodilatory beta-blockers when appropriate)
  - Alpha blockers

SELECT

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SELECT SoC guidance provided to all sites based on local CVD SoC Clinical Practice Guidelines

The emphasis of the SELECT trial is on SoC for CV risk reduction

CV, cardiovascular; CVD, cardiovascular disease; SELECT, semaglutide effects on cardiovascular outcomes in people with overweight or obesity; SoC, standard of care; T2D, type 2 diabetes.
Novo Nordisk. Data on file.