# HF-POLARIS

**zenagamtide** | effects on heart failure outcomes in people with obesity

# National Data Package

Italy

*National Leader:*



Maurizio Volterrani

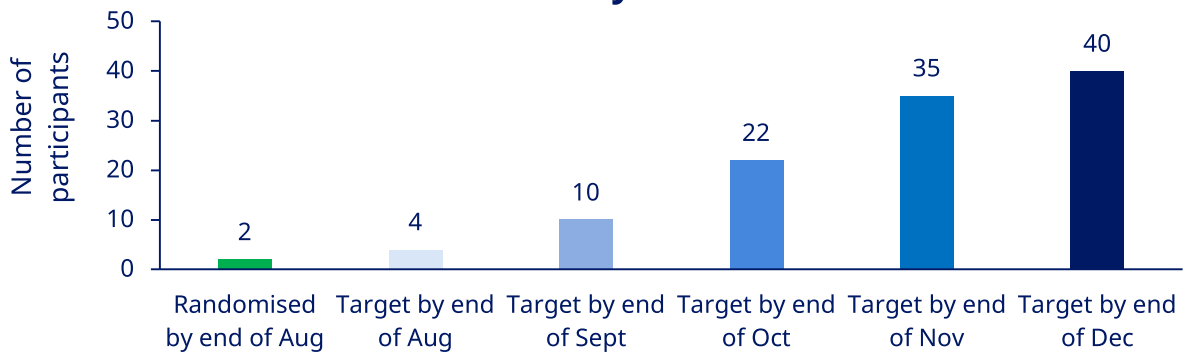
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# Participant overview

| Participant overview | Overall recruitment target | Participants screened | Participants randomised | Screen failure rate* | Off treatment |
|---|---|---|---|---|---|
| | N | N | N | % | N |
| Italy | 210 | 5 | 2 | 20 | 0 |
| Global | 5,610 | 1,064 | 438 | 46 | 12 |

**Forecasted*

## Participants randomised and recruitment target in Italy in 2026




## Screen failure reasons

| Screen failure reasons | Italy | Global* |
|---|---|---|
| | N (%) | N (%) |
| NT-proBNP (I7) | 1 (100) | 153 (38) |
| HF decompensation/ eGFR/UACR (I8) | 0 (0) | 104 (26) |
| Investigator discretion (E31) | 0 (0) | 22 (5) |
| $HbA_{1c}$ >10% (E12) | 0 (0) | 12 (3) |
| LVEF (I5) | 0 (0) | 12 (3) |
| Diabetic retinopathy (E10) | 0 (0) | 10 (3) |
| ICF process (I1) | 0 (0) | 8 (2) |
| BMI (I3) | 0 (0) | 8 (2) |
| Malignancy history (E22) | 0 (0) | 7 (2) |
| Insulin therapy (E11) | 0 (0) | 6 (2) |
| Other | 0 (0) | 64 (16) |

**Globally, 34 participants (13%) failed due to more than one eligibility criteria*
*BMI, body mass index; eGFR, estimated glomerular filtration rate; $HbA_1C$, glycated haemoglobin; HF, heart failure; ICF, Informed Consent Form; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal B-type natriuretic peptide.*

# Site-level data

Planned number of sites: 34

| Site* | PI | Participants, N | | | |
|---|---|---|---|---|---|
| | | Screened | In screening | Screen failed | Randomised |
| 3626 | Marco Metra | 1 | 0 | 0 | 1 |
| 3627 | Matteo Cameli | 3 | 1 | 1 | 1 |

**Only sites that have actively started recruitment are included*

*Notes*

# Notes

*What are the challenges you face or anticipate facing concerning:*



***Recruitment?***



***Retention?***



***Collaboration with other stakeholders?***

*Are there any challenges in other areas that you'd like to address in your action plan?*

*What actions or initiatives can you implement to help resolve these issues?*