Appendix F: An example of a CONSORT flowchart for reporting a population enrichment adaptive design (assuming enrichment was not done at an interim analysis)

ENROLMENT

Screened for eligibility
(n=)

Excluded (n=)
- Not meeting inclusion criteria (n=)
- Declined to participate (n=)
- Other reasons (n=)

Randomisation
(n=)

ALLOCATION

Group A
(n=)

Group B
(n=)

Subpopulation X (n=)
Received allocated intervention
(n=)
Did not receive allocated
intervention (give reasons) (n=)

Subpopulation Y (n=)
Received allocated intervention
(n=)
Did not receive allocated
intervention (give reasons) (n=)

Subpopulation X (n=)
Received allocated intervention
(n=)
Did not receive allocated
intervention (give reasons) (n=)

Subpopulation Y (n=)
Received allocated intervention
(n=)
Did not receive allocated
intervention (give reasons) (n=)

FOLLOW-UP

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Analysed (n=)
Excluded from analysis
(give reasons) (n=)
Overrun participants (n=)

Analysed (n=)
Excluded from analysis
(give reasons) (n=)
Overrun participants (n=)

Analysed (n=)
Excluded from analysis
(give reasons) (n=)
Overrun participants (n=)

Analysed (n=)
Excluded from analysis
(give reasons) (n=)
Overrun participants (n=)

Interim analysis

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Lost to follow-up (n=)
Discontinued
(give reasons) (n=)

Analysed
(n=)
Excluded from analysis
(give reasons) (n=)

Analysed
(n=)
Excluded from analysis
(give reasons) (n=)

Analysed
(n=)
Excluded from analysis
(give reasons) (n=)

Analysed
(n=)
Excluded from analysis
(give reasons) (n=)

Final analysis