

## Enrollment

Individuals assessed for eligibility (N)

- Excluded ( $X = X_1 + X_2$ )
- ◆ Not meeting inclusion criteria ( $X_1$ )
  - ◆ Declined to participate ( $X_2$ )
  - ◆ Other reasons ( $X_3$ )

Randomized ( $n=N-X$ )

## Allocation

Allocated to intervention IM\* ( $n/2$ )

- ◆ Received allocated intervention ( $n_1$ )
- ◆ Did not receive allocated intervention (give reasons) ( $n/2-n_1$ )

Allocated to intervention SC\*\* ( $n/2$ )

- ◆ Received allocated intervention ( $n_2$ )
- ◆ Did not receive allocated intervention (give reasons) ( $n/2-n_2$ )

## Follow-Up

Lost to follow-up (give reasons) ( $n_3$ )

Discontinued intervention (give reasons) ( $n_1-n_3$ )

Lost to follow-up (give reasons) ( $n_4$ )

Discontinued intervention (give reasons) ( $n_2-n_4$ )

## Analysis

Analysed ( $n_5$ )

- ◆ Excluded from analysis (give reasons) ( $n_3-n_5$ )

Analysed ( $n_6$ )

- ◆ Excluded from analysis (give reasons) ( $n_4-n_6$ )

\* IM: intramuscular injection  
\*\* SC: subcutaneous injections