

:- A group of patients taking the drug of interest is assembled and followed

:- A second group of patient (the control) with the same medical conditions, who are not taking the drug and who may receive alternative treatment, but who are otherwise matched as closely as possible with the cohort; may also be studied in parallel.

#### (4) Case - controlled Studies

:- Case controlled studies identify patients with the adverse effects to be studied and compare them with the sample, drawn from the cohort that give rise to the cases.