Ans:) Post marketing Surveillance (PMS)

:- It is also know as phase-IV clinical trials

:- It involves the various individual side effect and the new drug use and the other teratogenic and otm side effects of use which is variable on person to person and the geographical condation of the consumers.

:- These effects are collected by the pharmacovililance team or a board of the individual area of the drug where used.

:- Four types of Studies:-

(1) controlled clinical trials.

(2) Spontaneous or Voluntary reporting

(3) Cohost studies.

(4) Case-Control studies.

(1) Controlled clinical trials:-

Controlled clinical trials match treatment & control groups as

closely as possible, minimise bias through such methods as randomization and double-blinding & directly monitor patients for the duration of study

:- Controlled clinical trials are considered the most definitive method for evaluating a drug's efficacy and safety; but they are often costly or impractical in specific situations, &

:- for example when a drug's effects are rare or appear only after long-term use or a long latency period.

(2) Spontaneous or voluntary reporting:-

:- Voluntary reporting by physician and other health care providers, hospitals & consumers may act to alert FDA & pharmaceutical firms to possible adverse effects of drugs.

(3) Cohort studies:-

Cohort studies follow a defined group of patient for a period of time.

:- In this method, patients are not randomly assigned to groups, and there is no blinding.