Methods of post marketing surveillance

Phase IV Studies

Also known as post marketing surveillance trials involve the safety surveillance (pharmacovigilance) and ongoing technical support of drug after it receives permission to be sold.

- Phase IV studies may be required by regulatory authorities or may be undertaken by sponsoring company for competitive (finding a new market) or other reasons (for eg, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials).
- The safety surveillance is designed to detect any rare or long-term ADR over much larger patient population and longer time period than was possible during the phase I-III clinical trials.
- Harmful effects discovered by phase IV may result in a drug being no longer sold, or restricted

to certain uses: recent examples involve. cerivastatin, troglitazone, rofecoxib.

□ Purposes of clinical Studies in phase IV:

1. Address questions that arose during phase I to III, but which have not yet been completely answered or adequately addressed. These clinical trials include comparisons with other drugs, cost-effectiveness studies.

2. Continue clinical trials initiated in phase III.

3. Investigate interactions with food, drugs and environmental factors.

4. Expose more patients to new drug to confirm efficiency better understanding of safety (delayed effects, prolonged use effects) to quantify rates of nonadverse reactions.

5. Also drug should be evaluated in special patient like pregnant, nursing mothers, elderly

6. Determine whether the results obtained from tertiary care hospital during phase I and III can be confirmed in other hospitals.

7. Evaluate whether any rare but serious ADR occur.

8. Discover new indications that may be explored and developed in phase II and III discoveries may occur to serendipity.

9. Evaluate pattern of drug utilization in specific or general population.

10. Study the clinical characteristics of over dosage and the means of counteracting the problem.

11. Assess the costs of ADR to various sectors of society and possibly develop and approach to meet these costs.

Methods:

1. Descriptive studies
2. Cross-sectional studies
3. Case control studies

exposure to a drug or vaccine, pregnancy, ensured person.

- If the case and controls both come from the same population the results of the study are more easily validated.
- There is no randomization and blinding.
- Patients can be directly monitored to ensure they take the drug appropriately, and to observe drug effects.
- With less control, a larger cohort can be followed, but bias is thus increased.

□ [redacted]

- The term "controlled" refers to the trials that adhere strictly to a designed protocol.
- The purpose is to reduce the variability of many factors and biases that might influence the results.
- Control features include the double-blind procedure, where neither the patient, nor the

investigator is aware of which treatment the patient is receiving.

- The greater the number of factors of the study or trial design that are specified and the greater the control that is built into the study.
- Used to identify drugs beneficial as well as ADR.
- How often the effects occur (frequency).