NETWise
A Podcast About Neuroendocrine Cancer

Phases of Clinical Trials

Pre-Clinical Phase:
Does a new compound have a desired effect at a chemical level?

1. Computer modelling
2. "In Vitro" experiments: testing isolated chemicals in the laboratory
3. "In Vivo" experiments: testing in animals, such as mice or zebrafish

Phase 1 Trials:
Is the compound safe for patients to take?

- Small cohorts
- Primary Goal is to determine proper dosage and frequency of administration for further trials
- Identifing early signals of therapeutic activity is often a secondary goal

Phase 2 Trials:
Does the compound have the desired chemical effect in humans?

- Medium-sized cohorts
- Goal is to see if patients have anti-tumor response as measured against a defined endpoint

Phase 3 Trials:
Does taking the compound result in better patient outcomes?

- Large cohorts, often split and randomized into trial and control groups
- Goal is to see if clinical results are better than with existing treatments

FDA Approval

Phase 4 Trials:
Does data from use in the real world support the results of earlier trials? Are there any new adverse events which were not identified during drug development?

- Often based on data collected from clinicians

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