Concerns of Clinical trials

What is the issue?

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- Clinical trials are widely usedfor gathering data from bioequivalence studies.
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- In India for such clinical trials volunteers from poor and vulnerable sections of the society are being largely used.
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What is a bioequivalence study?

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- Bioequivalence is a term used to assess the expected comparison between biological equivalence of two proprietary preparations of a drug.
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- Bioequivalence studies, test the metabolism of generics in healthy subjects.
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- If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same.
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- For example if a X company produces a brand name generic drug A1 and Y company produces the same drug it need to prove its bioequivalence with the brand name drug for market standards.
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- The target of such study is to evaluate the therapeutic compatibility of tested drugs i.e. pharmaceutical equivalents or pharmaceutical alternatives.
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- The importance of bioequivalence studies is increasing due to the large growth of the production and consumption of generic products.
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Why clinical trial are used?

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- For finding out bioequivalence data volunteer subjects, generally healthy individuals but occasionally in patients are used.
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- For testing a drug usually Serum/plasma samples are obtained at regular intervals and assayed for parent drug concentration.
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- But these alone neither feasible nor possible to compare the two products of various means of use for instance if drug is to be consumed by inhaling etc.
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- Thus testing will be conducted to clinical trials at several different doses to derive expected results.
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What are the concerns with clinical trials in India?

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- The big problem plaguing clinical research is an over-representation of low-income groups among trial subjects.
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- Sometimes Clinical research organisations CROs recruit them selectively, exploiting financial need and medical ignorance.
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- Because these subjects are well-paid, and get no therapeutic benefit, their only reward from the trial is financial.
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- Such deception is a risk not only to volunteer health but also to society, because it can throw off the trial’s results.
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- Due to this unethical practises unsafe drugs can make their way into the market and safe drugs can get rejected.
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- Selectiveness in recruiting subjects for clinical trials leads to human rights violations and to bad science.
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What measures needs to be taken?

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- One potential solution is a national registry of trial volunteers, which will alert a CRO when someone signs up for two studies simultaneously.
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- So that regulators can create a system that anonymises each participant’s data.
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- Another option is to pay volunteers less, taking away the financial incentive to fudge their participation history.
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- Encouraging a wider cross-section of society to participate in research on human subjects will ensure that the burden not fall completely on the vulnerable groups.
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- Landmark amendments to the Drugs and Cosmetics Act in 2013 led to better protection of vulnerable groups such as illiterate people, but more regulation is needed to ensure truly ethical research.
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Source: The Hindu

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