

# Clinical Trial Terminology Demystified



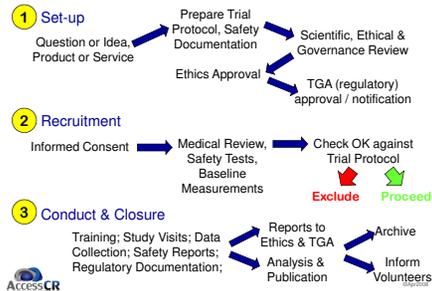
April 2008

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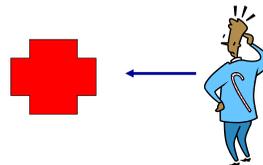
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## The Clinical Trial Process



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## Single centre

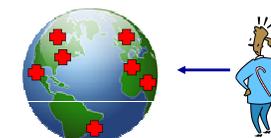


There is only one doctor running this study at only one clinic



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## Multi-centre

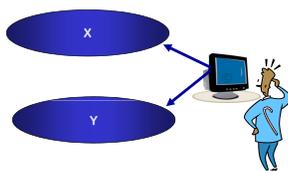


There is more than 1 doctor/clinic involved in this study.



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## Randomisation

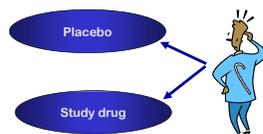


A computer will decide randomly whether you receive X or Y.



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## Placebo Control

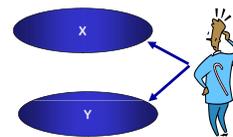


One group will receive a dummy that looks like the study drug, but doesn't have the active ingredient.



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## Open Label

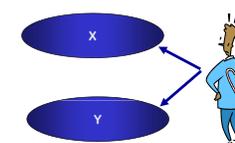


You and your doctor both know what treatment you are receiving, whether X or Y



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## Single Blind

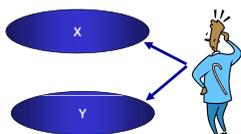


You don't know whether you are getting X or Y, but your doctor does



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## Double Blind

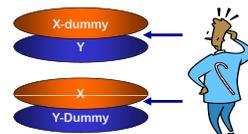


Neither you or your doctor know what treatment you are on, but your doctor can find out in an emergency.



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## Double Dummy

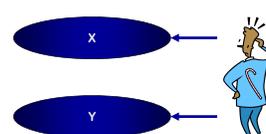


X and Y look different, so everyone gets something that looks like both, but one will be a dummy



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## Parallel Group

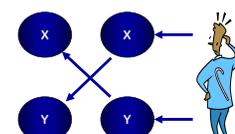


Patients receive only X or Y and both groups run at the same time



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## Crossover trial



At some time in the study, patients receive both X and Y and maybe more than once



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## Phase I

- First time in human
- Purpose:
  - understand drug metabolism
  - Relationship between structure and activity
  - mechanism of action
  - side effects associated with increasing doses
  - potentially early evidence on effectiveness
  - info to design phase II studies
- Healthy volunteer (usually), often male
- 20-80 pts, In-patient
- Paid



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## Phase II

- Often first time in patients
- Purpose:
  - obtain preliminary data on effectiveness for a particular indication or indications in
  - determine the common short-term side effects and risks
- 100-200 people
- Unpaid



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## Phase III

- Purpose:
  - gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.
  - provide an adequate basis for extrapolating the results to the general population and transmitting that information in the product labelling.
- 500 - 10,000 people



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## Phase IV

- Post marketing studies
- Purpose:
  - Additional safety
  - Health economic data
  - Understand "real-life" use
- Hundreds to thousands of people



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