

PHASES OF A CLINICAL TRIAL

0

PRE-CLINICAL

Lab – based research to tell if a treatment is useful and safe



1

SAFETY

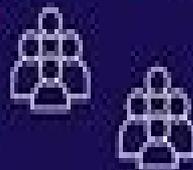
10 – 80 participants to assess effect of treatment in humans



2

SAFETY & DOSING

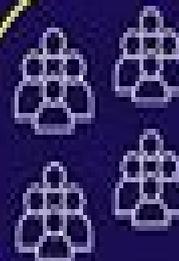
100 - 300 participants to evaluate safety & effective dose of treatment



3

SAFETY & EFFICACY

300 - 3000 participants to confirm benefit and safety of the treatment



4

POST-APPROVAL

Post-approval surveillance to evaluate long-term effects of treatment



Clinical Trials Explained

Judd E. Hollander



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