REGULATORY ISSUES IN INDIA

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PROCESS

- UNPREDICTABLE EARLIER
- NOW HAS TIMELINES
- LATEST NOTIFICATION
  - 1 MONTH AFTER 1ST PATIENT RECRUITED IN USA / EU
  - MOST AMMENDMENTS WILL REQUIRE ONLY NOTIFICATION IF FDA/EMEA APPROVED

CONTENT

- FOCUS ON TOXICOLOGY
- PHASE 1 STUDIES
- FOCUS ON SAEs
- FOCUS ON REPORTS SUBMITTED TO US/ EU
- CONSTANT FOCUS ON ANY DEATH

- NATIONAL DRUG CENTRE IS COMING UP TO LOOK AT AEs AND SAEs

PRINCIPAL INVESTIGATOR

- 1572 MODIFIED MORE STRINGENTLY, SPELLING OUT PERSONAL INVOLVEMENT OF PI
- DELEGATION OF KEY RESPONSIBILITIES NO LONGER POSSIBLE

ETHICS COMMITIES

- LAYS DOWN FORMAT OF STRUCTURE AND FUNCTIONING OF ECs TOUGHER THAN FDA
- ALSO STRESSES ON ON-GOING RESPONSIBILITY