

**SCIENTIFIC BASIS FOR
REGULATORY DECISIONS
ON MICROBICIDES**

**PRE CLINICAL
REQUIREMENTS**

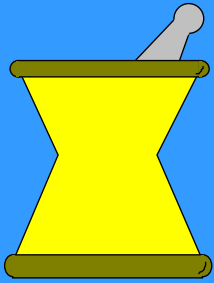
UNDP/UNFPA/ WHO WORLD
BANK SPECIAL PROGRAM
ON RESEARCH
DEVELOPMENT AND
RESEARCH TRAINING IN
HUMAN REPRODUCTION
DEPARTMENT OF
REPRODUCTIVE HEALTH

Members of the Pre-clinical requirements group

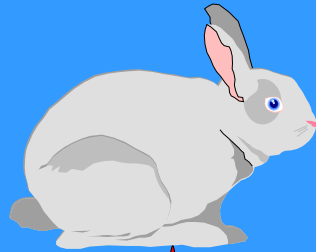
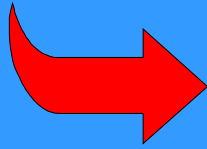
- Elof Johansson (Chair)
- Anne Marie Corner
- Virginie Ettiegne-Traore
- Polly Harrison
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- Tim Farley
- Elizabeth Bukusi

Pre-Investigational New Drug (IND) Consultation

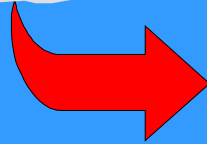
- Chemistry, Manufacturing and Controls (CMC)
- Good manufacturing practice (GMP)



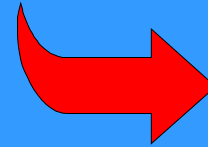
CMC/GMP



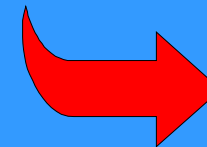
RABBIT IRR



GENERAL TOX



GENETIC TOX

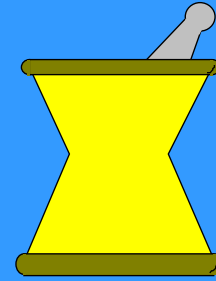


REPRO
TOX

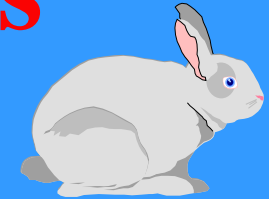


Phase I CMC “Expectations”

- Components
- Quantitative composition
- Description of manufacturing and packaging
- Acceptable limits and analytical methods (identity, strength, quality, purity)
- Stability (sufficient time to cover the duration of the trial)



Pre clinical requirements



1. A ten-day rabbit vaginal irritation study.



2. General toxicity studies

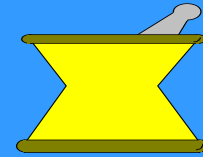
3. Genetic toxicity studies



4. Reproductive toxicity (segment one)



Transition Zone



- 1. Activity data (for the product)
- 2. Penile irritation studies and condom integrity studies (where applicable)
- 3. Segment two and three of reproductive toxicity studies
- 4. Hypersensitivity studies
- 5. Absorption, distribution, metabolism and excretion (ADME)



Prior to/ during phase III

- Carcinogenicity studies
- Long term toxicity studies

OTHER ISSUES

- Pharmacology
- Placebos
- Areas of disagreement
- Future directions

