Protocol after the ILSI/HESI International Act. Study  
(as of 2003)

- Preliminary test
  Period: 4 weeks
  Animals: wild type (non-Tg for rasH2)
  Purpose: Dose finding for 26-week study

- Carcinogenicity test
  Period: 26 weeks
  Group composition:
  GM: nega. con. group + 3 dose groups + posi. con. group
  wild type (non-Tg): nega. con. group + high-dose group. (crucial)
  Animal: 25/sex/group

Present protocol for the FDA application
(interview from people in US CROs & Pharmaceuticals)

- **Preliminary test**
  - Period: 4 weeks
  - Animals: wild type (non-Tg for rasH2)
    - 10 mice /sex/group + TK

- **Carcinogenicity test**
  - Period: 26 weeks
  - Group composition:
    - GM: nega. con. group + 3 dose groups + posi. con. group
    - wild type (non-Tg): no need (stated by FDA in DIA, 2005)
  - Animal: 25 mice/sex/group + TK
    - 15 mice/sex for positive control group (from Nov. 2009)