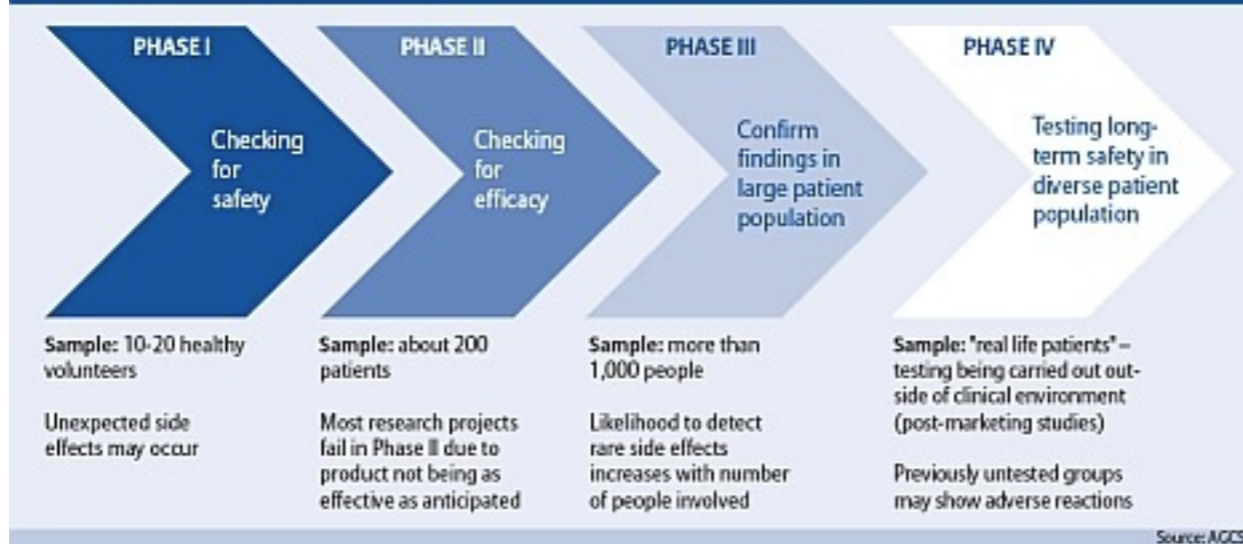


FDA approval for a drug : 3 Clinical Trial Phases



Ask Mish

WATCHING YOUR STEP – THE DIFFERENT STAGES OF CLINICAL DEVELOPMENT AND WHAT THEY EXAMINE



- For FDA approval 3 phases of the clinical trials must be passed:
- Phase 1: testing **safety** in **healthy volunteers**
- Phase 2: testing **efficacy** (dose levels) in **small group of patient volunteers**
- Phase 3: testing **efficacy and safety** in **larger group of patient volunteers**. Phase 3 is considered a definitive test for FDA.
- Phase 4: not necessary for FDA approval; is called post marketing survey and focuses on **long term safety** (e.g. Vioxx)

