The Drug Discovery Process

1. Research & Development
   - 3-6 years
   - Target identification
   - Compound screening
   - Lead identification
   - Ready to go
     • Compounds discovered through serendipity
   - Ready to go
     • Repurposing of FDA-approved drug or drug candidate

2. Preclinical Studies
   - 1-3 years
   - In vitro studies
   - POC efficacy testing in vivo
   - PK, TOX, safety pharmacology, etc.

3. Clinical Trials
   - 3-6 years
   - Phase I, II, III trials
   - Dosage & safety monitoring

4. Review & Approval
   - 1-2 years
   - Safety & efficacy evaluation
   - Approval & manufacture
   - Post-release monitoring

Figure 1
75th Anniversary