## Hit Discovery

- Discovery of chemical start points using various methods, including:
- Phenotypic (whole-cell)
- Screening against molecular targets
- Modification of existing compounds

# Lead optimisation

 Multi-parametric optimisation for potency, selectivity, physiochemical and pharmacokinetic properties, and nonclinical safety properties.

#### **Preclinical**

 Good manufacturing process (GMP) scale-up and good regulatory practice (GRP) toxicology

#### Clinical

- Phase 1: Pharmacokinetics and tolerability in healthy human volunteers.
- Phase 2: Proof of concept in patients.
- Phase 3: Large efficacy and safety study in patients.

### Registration

• Phase 4: Post-market surveillance.