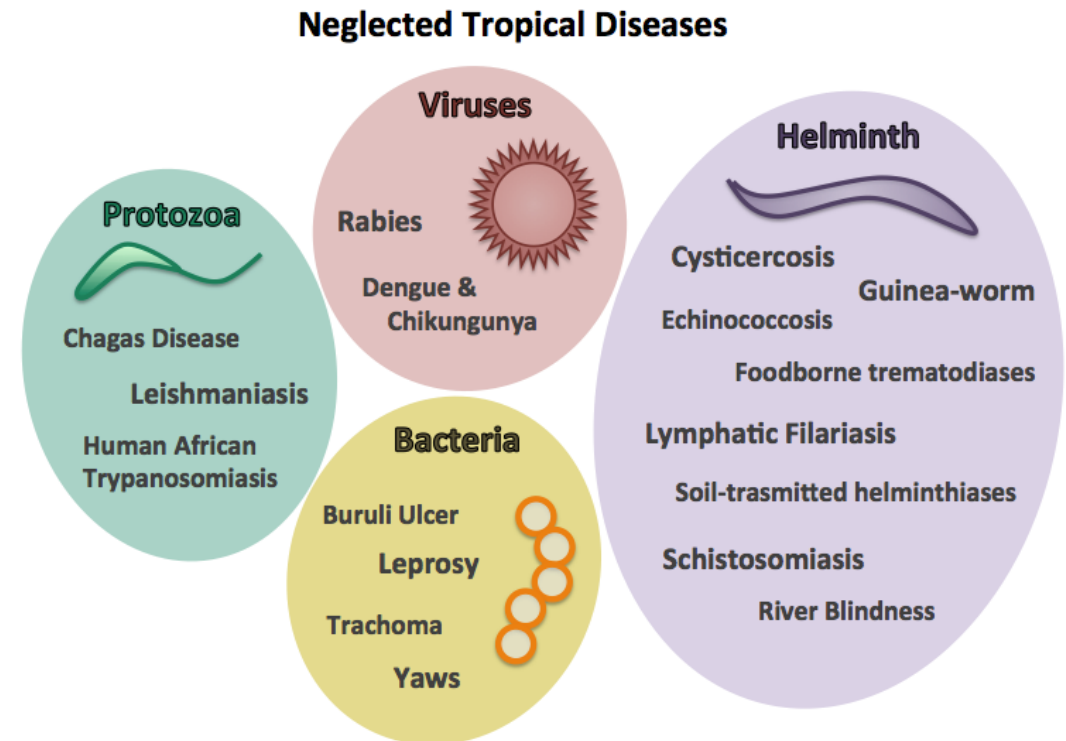


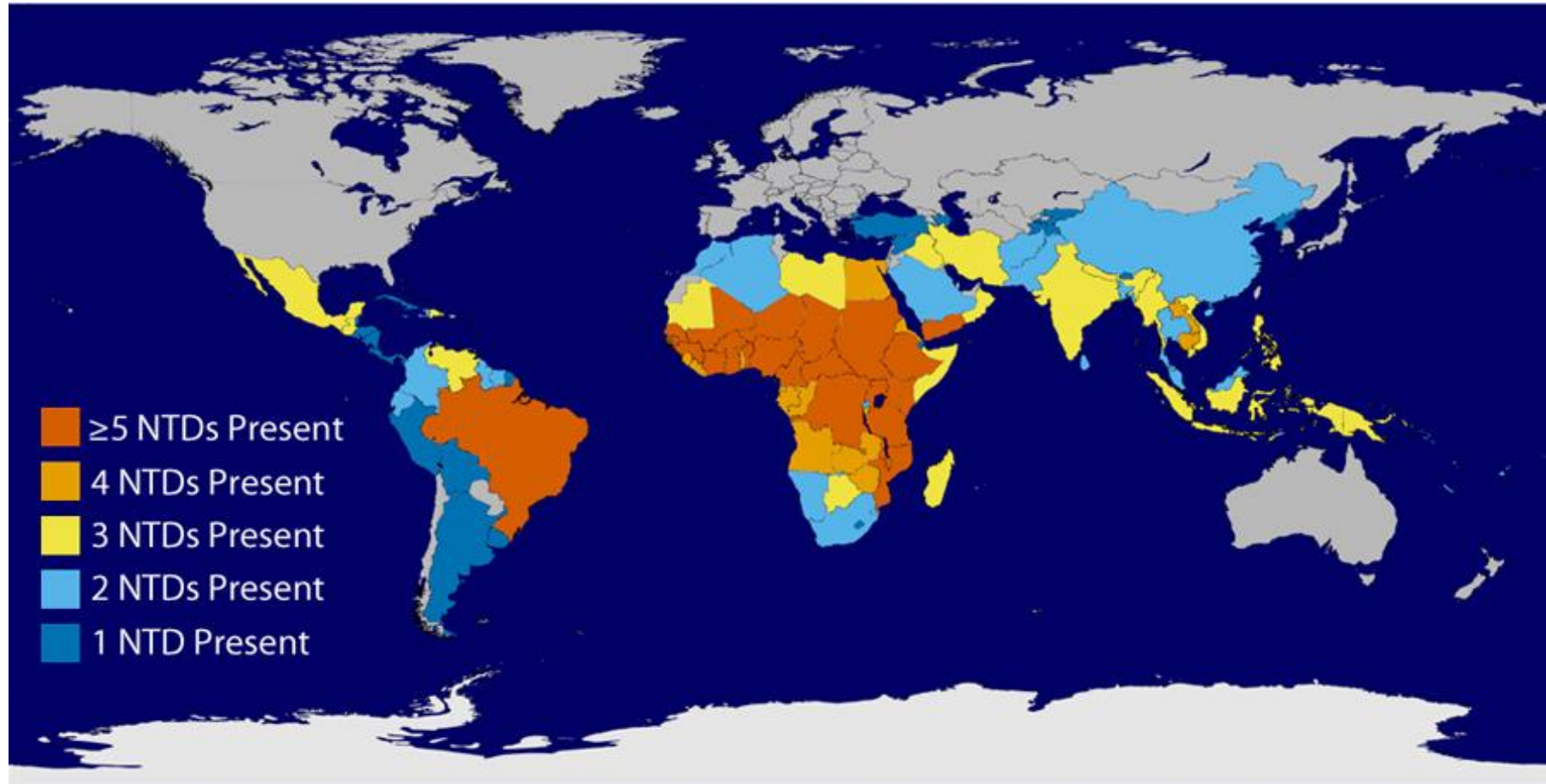
Drug Discovery for Neglected Tropical Diseases

NTDs: What Are They?

- Diverse group of infectious diseases
- Many are vector-borne
- Risk factors:
 - Poverty
 - Poor sanitation
 - Close contact with vectors
 - Underdeveloped medical systems



NTDs: Where Are They?



NTDs: What Is Their Impact?

- 11% of global disease burden
- 3 Billion people at risk
- 1.6 Billion people have at least one NTD
- 500,000 will die each year
- Patients face many challenges:
 - Pain and suffering
 - Stigmatization
 - Obstacles to growth



River Blindness (Onchocerciasis) patient, Cameroon

NTDs: How Are We Fighting Them?

- Preventative chemotherapy
- Innovative disease management
- Vector control
- Safe drinking water, sanitation, hygiene, education
- Veterinary science
- Government and philanthropy



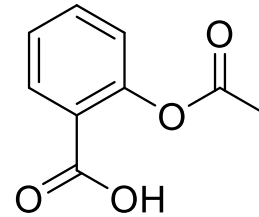
NTDs: Have We Been Successful?

- Only 2% of medical R&D funds
- 1% of approved NCEs
- Three Highlights:
 - New cases of Guinea-worm disease down 99% since 1989
 - 853 Million people treated with preventative chemotherapy in 2014
 - 77% decrease in reported HAT cases since 1999



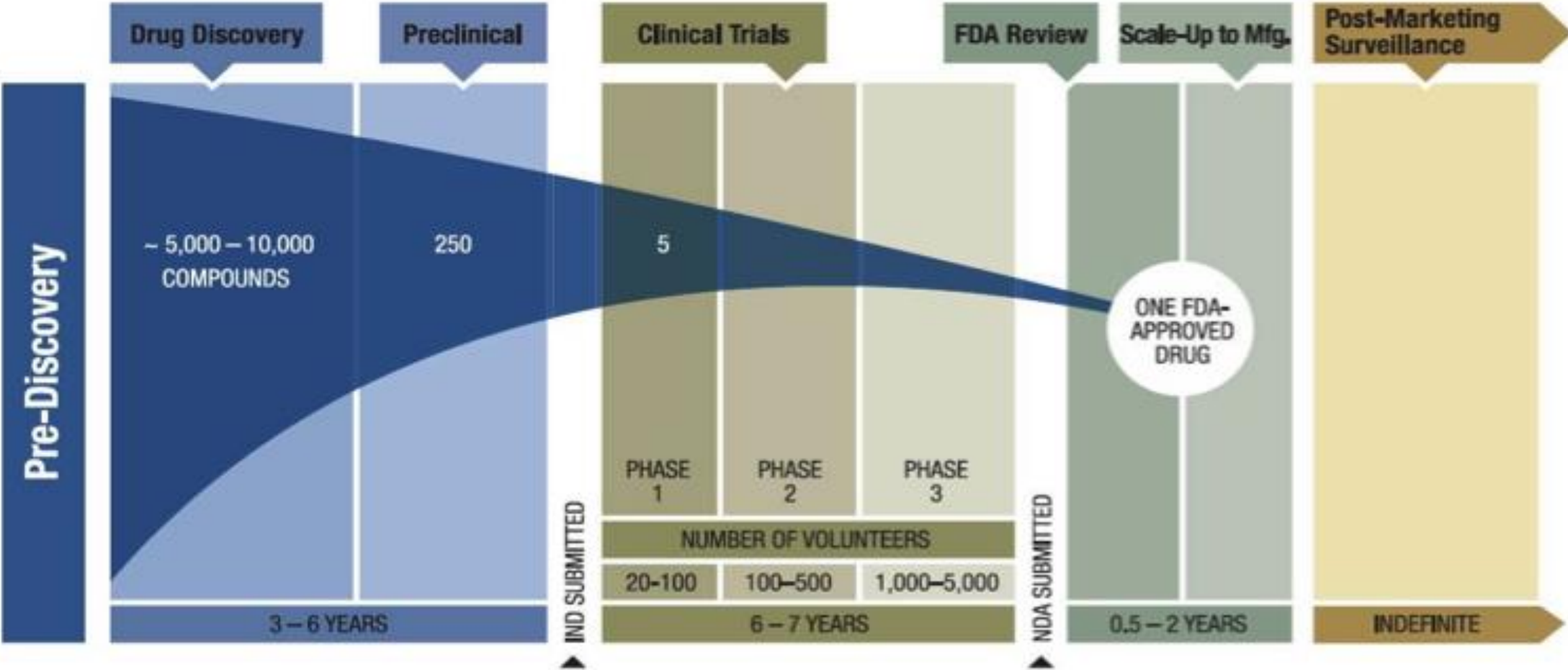
Drug Discovery: Aspirin

- Use chemical compound to modulate biological effect
 - reduce pain, inflammation
- Binds to an enzyme
 - Cyclooxygenase
- Originally derived from nature
 - Bark of the willow tree
- Has been used for at least 2400 years



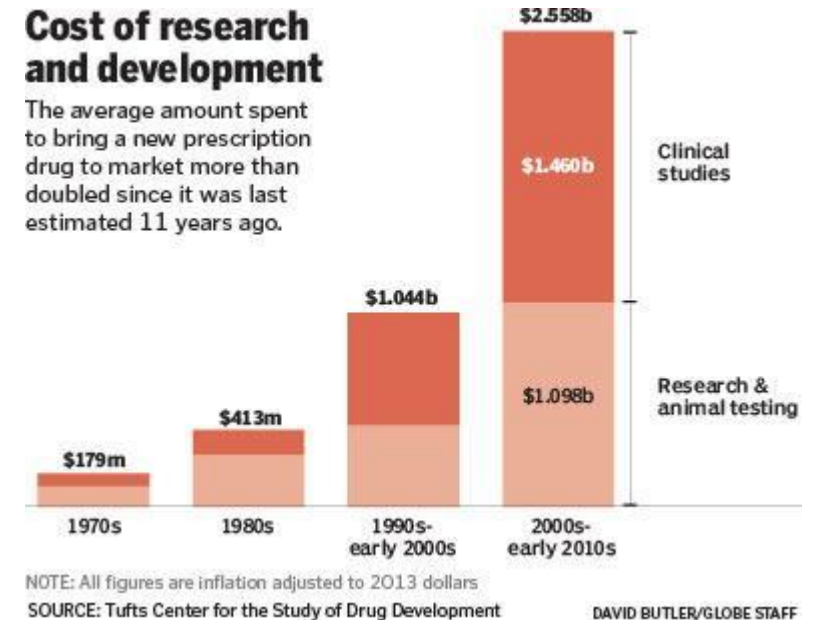
Willow tree

Drug Discovery and Development Timeline



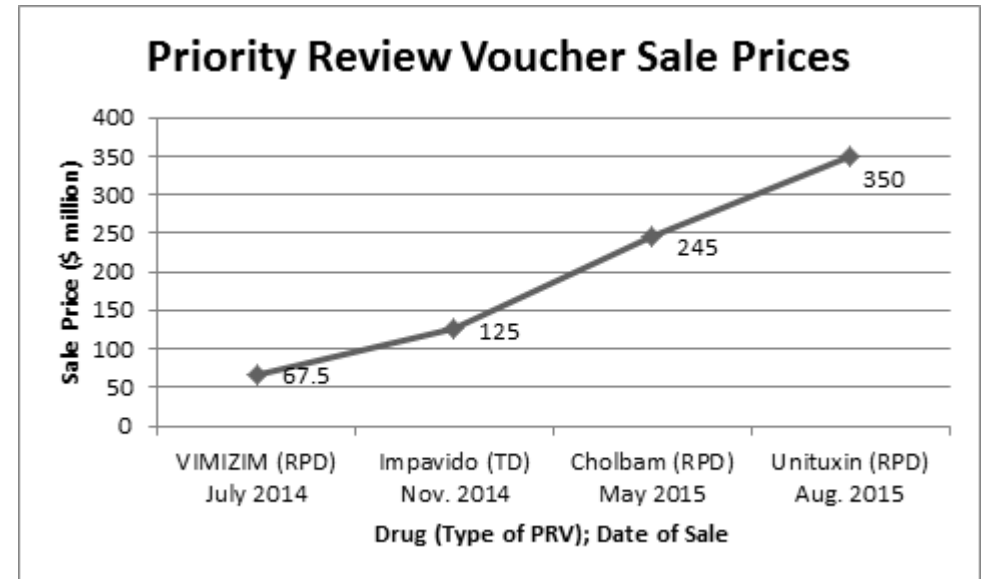
Cost of Drug Discovery

- \$2.6 Billion per approved compound
 - \$1.4 Billion out-of-pocket cost
 - \$1.2 Billion time costs
- Post-approval R&D adds even more cost
 - \$312 Million per drug
- Based on 106 drugs tested between 1995 and 2007
 - Global, not just U.S.
- **Obviously a huge hurdle for NTD drug discovery**



FDA Priority Review Vouchers

- First proposed in 2006
- Encourages companies to develop drugs for NTDs
- Rewards them with expedited review
- Vouchers can be used at any time or sold
- Very popular
- Has lead to 3 NTD drugs and 6 rare pediatric disease drugs



Challenges to Drug Discovery for NTDs

- What do you think makes NTD drug discovery especially difficult?
- Do you think the same regulatory process should be used for NTDs?