

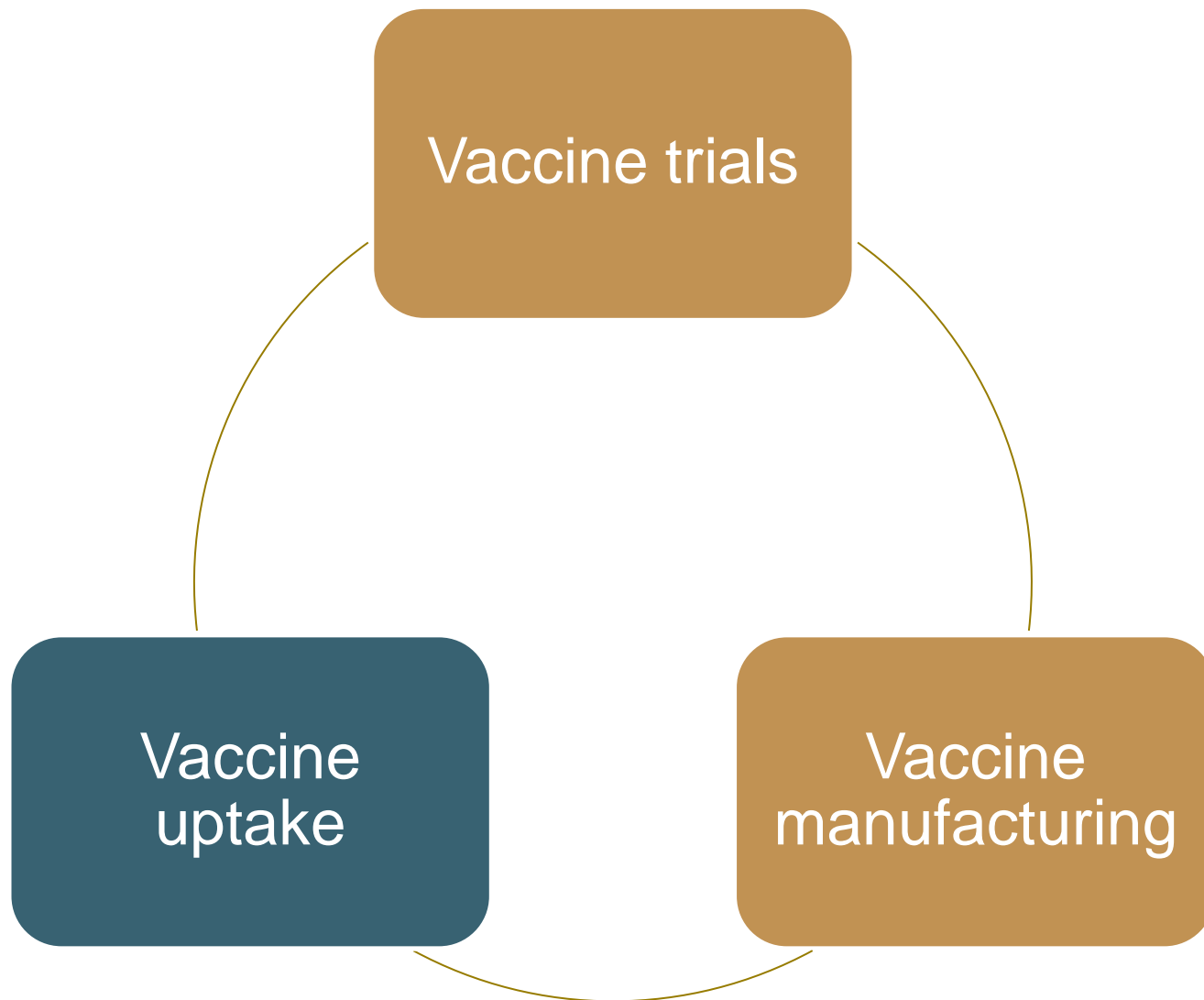
TB Vaccine Access to China

Opportunities & Challenges

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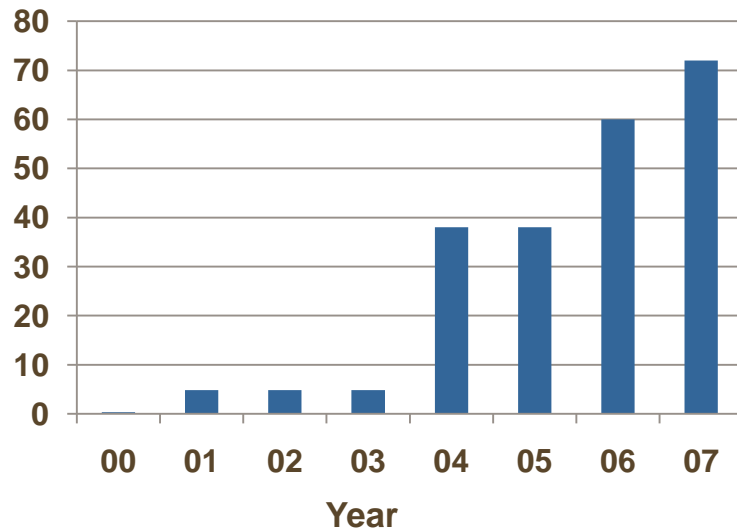
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Government support of TB

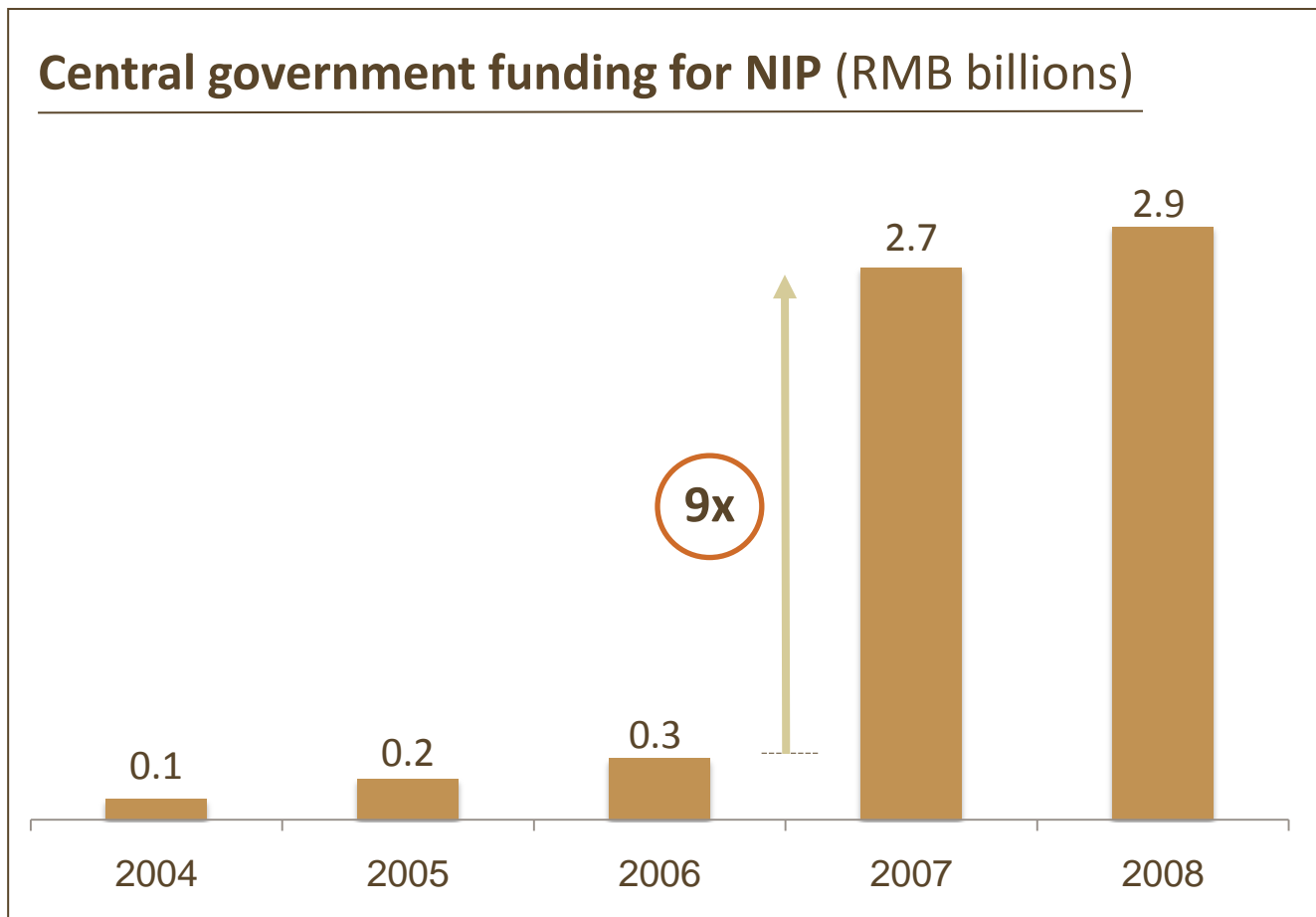
- Government's recognition of TB as a serious public health problem
- International commitment to tackle TB made by government

Amount (million US\$)



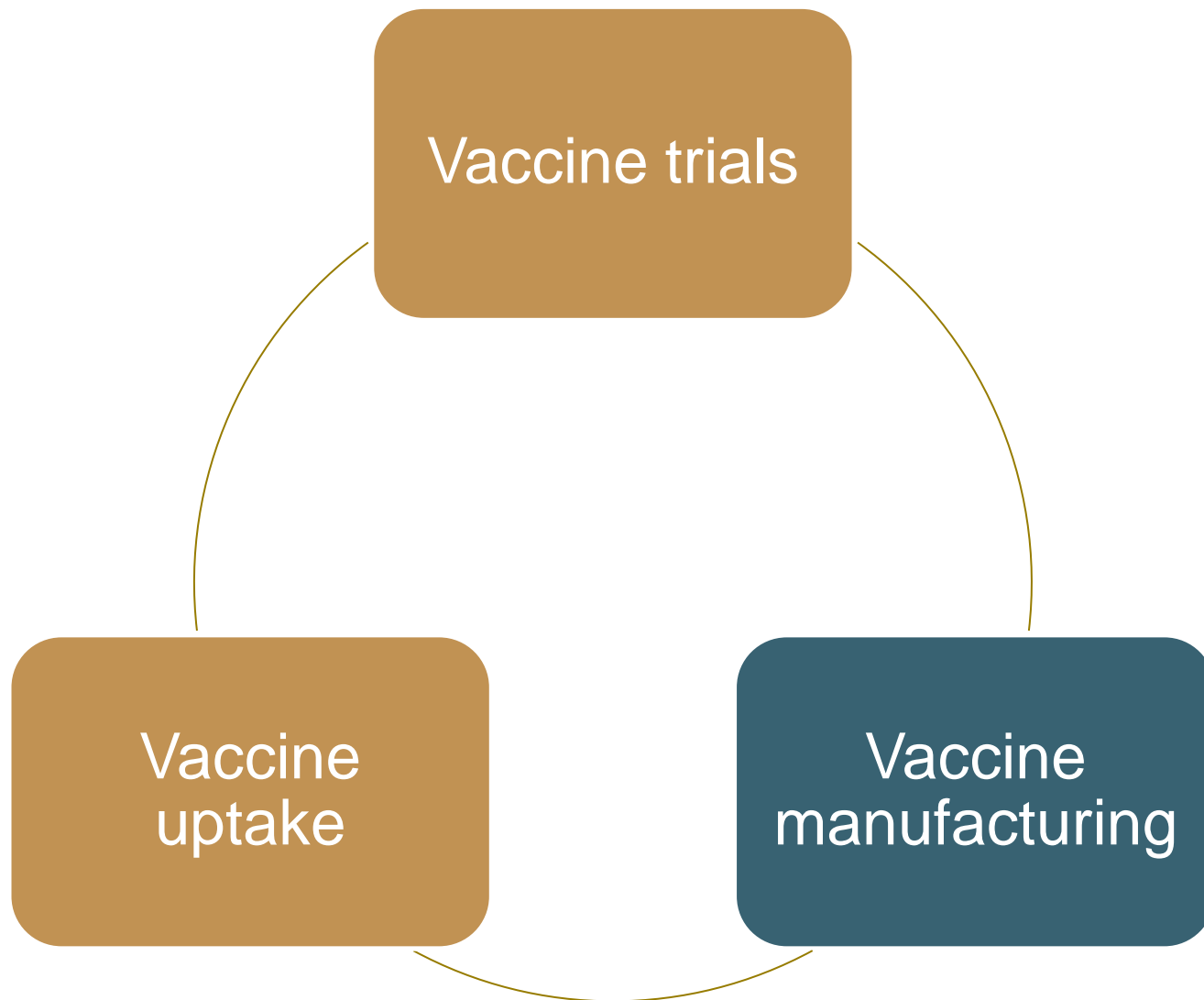
- Increased government funding for TB

Significant increase in Central government funding for National Immunization Program (NIP)



Vaccines are grouped into 2 categories

Category A: Provided free to citizens by the government	
Vaccines provided for the national expanded immunization program (EPI)	BCG, OPV, measles, hepatitis B, DT (children), DPTw (newborns)
Vaccines added by provincial governments based on local needs	Hepatitis A, MenCCV, MenA+C, measles + rubella, MMR, Japanese encephalitis
Vaccines for emergency immunization or group preventive vaccination organized by governments at the county level or higher	H1N1, leptospirosis, anthrax, hemorrhagic fever
Category B: Private market – supplied by local CDC and hospitals and paid by consumers	
Major source of profits for the vaccine producers and local CDCs (Preventive Health Service)	Varicella, rotavirus, HIB, influenza, hepatitis A + hepatitis B, yellow fever, meningococcal, typhoid, DPTA, IPV, HPV, pneumococcal vaccine



China's vaccine industry is well-developed and produces 800 million vaccine doses annually

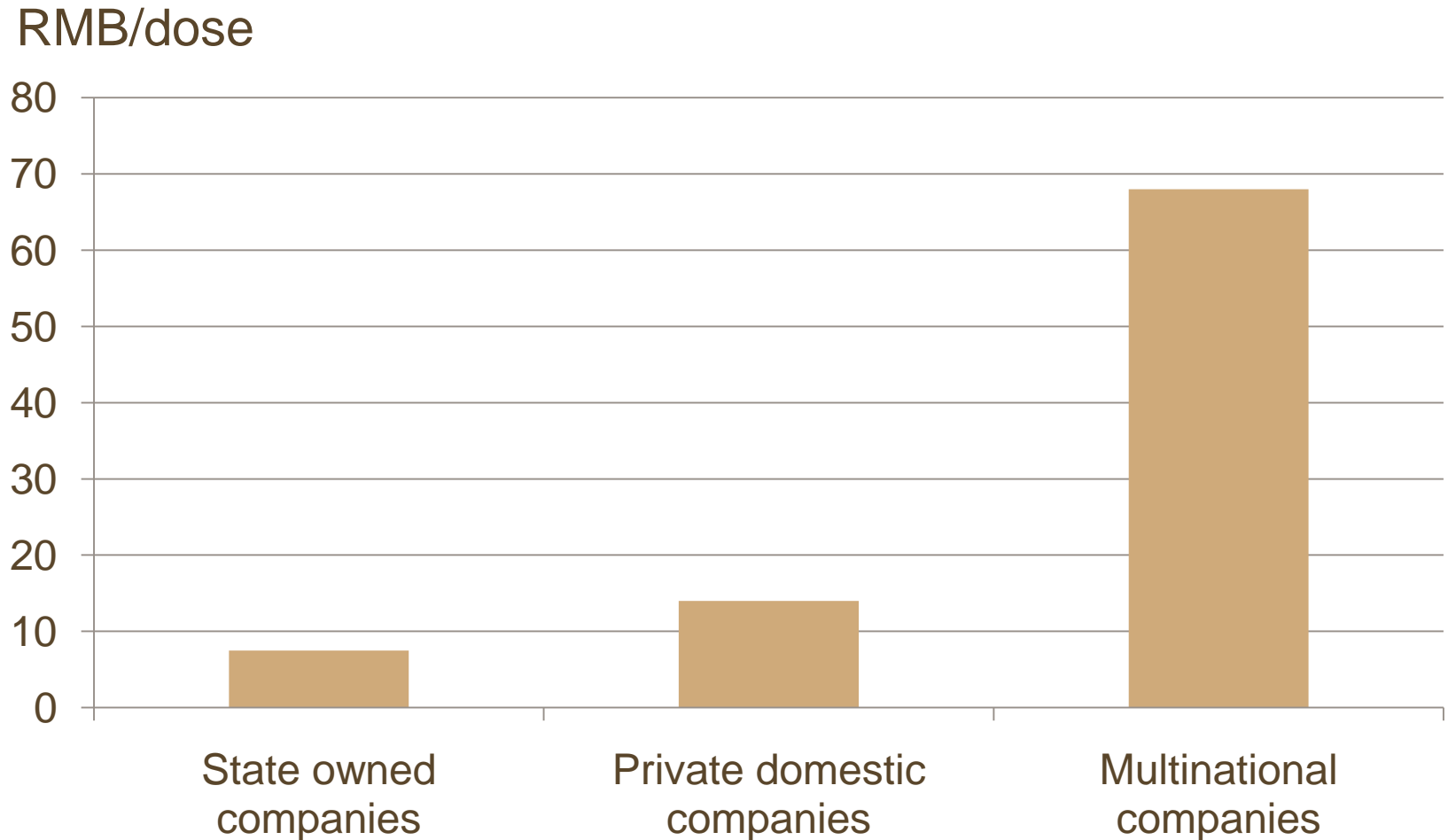
State-owned/ holding companies	Private enterprises or partially state-owned	Multinational corporation players
8	20+	5
<p>CNBG is largest vaccine player, with <u>60%</u> of the total market share (<u>90%</u> of Category A and <u>40%</u> of Category B vaccine markets).</p>	<p>High operation flexibility, low R&D capacity, operations maintained in particular areas</p>	<p>Strong marketing, emphasis on market incubation & branding, high prices. Sanofi Pasteur and GSK are the biggest players.</p>
<p>Vigoo  Tiantan </p> <p>BIBP  SIBP </p> <p>LIBP  CCBIP </p> <p>WIBP  CDIBP </p>	<p> Ealong Biotech</p> <p> Tianyuan Bio-Pharma  ChangSheng</p> <p> Aleph  Hualan</p> <p> WALVAX  Sinovac 北京科兴</p>	<p> GlaxoSmithKline 葛兰素史克</p> <p> Sanofi Pasteur The vaccines business of sanofi-aventis Group</p> <p> Wyeth  NOVARTIS</p> <p> MSD</p>

Chinese vaccine producers have marketed 49 vaccines to fight 26 infectious diseases.

Lower R&D

Higher R&D

Vaccine price by type of companies (2009)



Opportunities to engage Chinese manufacturers

- Chinese companies can access government funding for R&D
- >20 medium (25-75 mm doses) and small (<25 mm doses) size suppliers with strong scientific capabilities
- Significant competition for external funding and support
- May translate to favorable partnership terms
- Multinational companies are aggressively pursuing opportunities to establish partnerships with Chinese manufacturers

PATH Vaccine Programs in China

Japanese encephalitis (JE) Program:

- Partnering with Chengdu Institute of Biological Products in 2006
- To increase developing-country access to high-quality JE vaccine.

Malaria Program:

- Partnering with Shanghai Wanxing Bio-Pharmaceuticals in 2006
- To support the development of a pediatric malaria vaccine against *Plasmodium falciparum*

Rotavirus Program:

- Partnering with Wuhan Institute of Biological Products in 2007
- To develop a National Institutes of Health (NIH) human-bovine reassortant rotavirus hexavalent vaccine

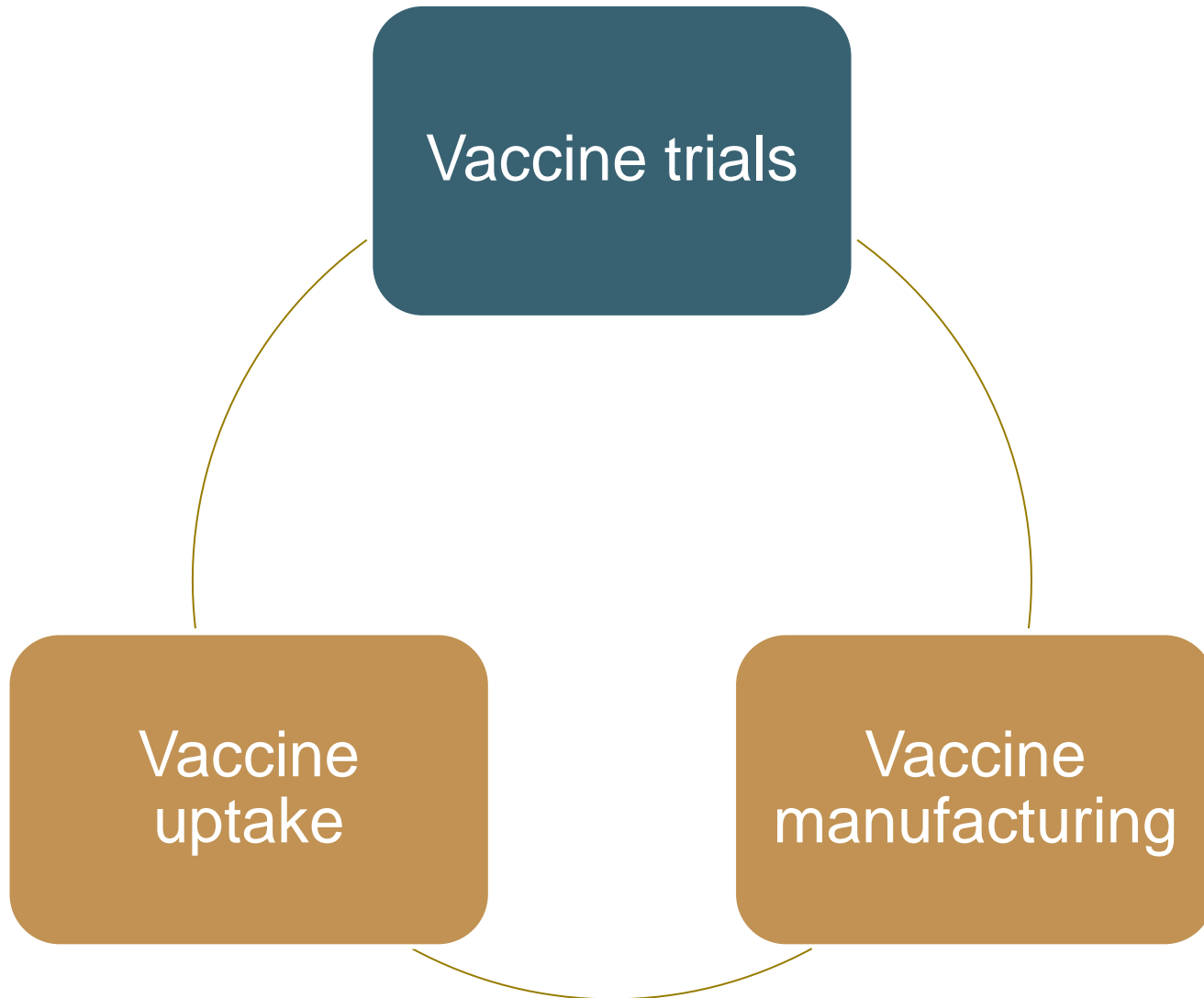
Pneumococcal Disease Program:

- Partnering with CDIBP in 2009
- To accelerate the development of safe, effective, and affordable vaccines against *S. pneumoniae*

Successful access: JE Vaccine

- Partnership between PATH and Chengdu Institute of Biological Products (CDIBP) – 2006-2009
- SA-14-14-2 is the most widely used JE vaccine in the world and the first internationalized Chinese vaccine
- Support to upgrade facility and improve product and quality control measures to int'l standards
 - Single dose instead of the 3 doses
 - Average price ~ 25 cents vs. 2 dollars of other products
 - Improved safety profile
- In 2009, **35.4 M JE vaccine doses** sold in 7 countries outside of China (95% in India); **97 M doses** sold in China

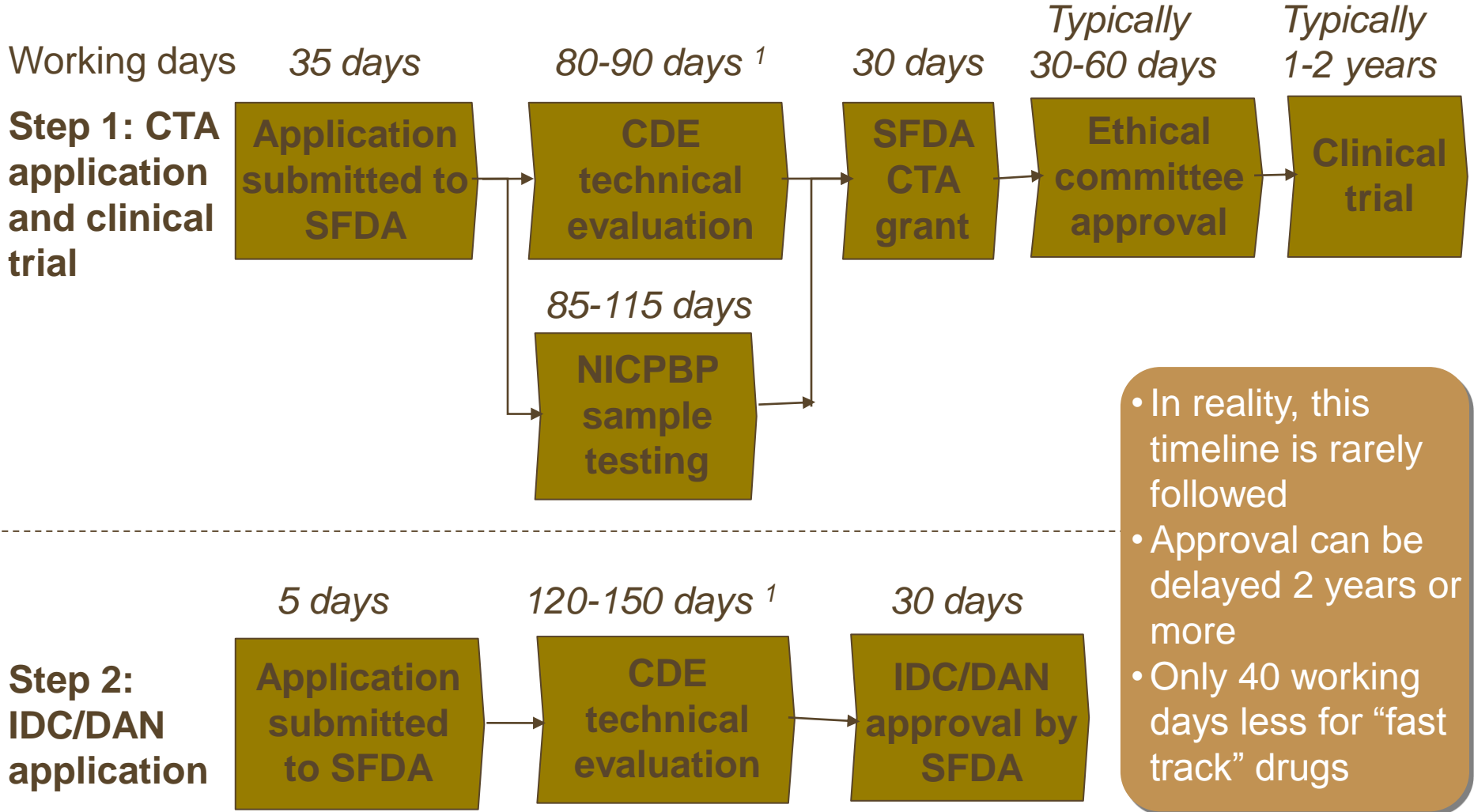




Bottlenecks in vaccine trials

- Vaccine has to be approved in originating country and a third country before trial application can be approved
- Tightening of regulatory procedures
- Increasing quality requirement on application dossier

Under ideal condition, it takes at least 3-4 years to approve a new vaccine



¹ Timeline depends on whether the drug qualify for “fast track”

Source: SFDA

But, with political commitment, approval can move much faster - H1N1 case

Reasons for fast development of H1N1 vaccine

“Three synchronizations”:

- **Regulatory and registration approval process and enterprise R&D were carried out simultaneously**
- **Government sampling and assessment and vaccine manufacturing were done at the same time**
- **Enterprise self QA/QC and government inspection were synchronized**

Swine
flu
outbreak

Human Swine flu was detected in Mexico, California and Texas in late March, 2009

WHO
H1N1
strain

On June 8, 2009, Hualan Biological Engineering, Inc attained WHO H1N1 strain, which 10 more enterprises obtained since then

Production
of vaccine

The whole process of R&D, pilot production, clinical trial, on-site inspections, registration and approval successfully completed on Sept. 2, 2009.

Requirements of study sites for phase 3 trials of TB vaccine

	Meet requirement?		
	Yes	Maybe	No
General: Infrastructure, commitment, stability	√		
Epidemiological			
High rates of TB			√
Ability to detect health events	√		
Good surveillance system to detect TB		√	
Clinical			
Accurate diagnosis of TB infection & disease		√	
Referral system for detection	√		
Immunology laboratory		√	

Conclusion

- Government support for TB and expansion of EPI bodies well for future uptake of a new TB vaccine
- Excellent opportunities for partnership with Chinese manufacturers in vaccine R&D → Low-cost, high-quality TB vaccine
- Major bottlenecks are in the regulatory area
- High-level political commitment, in-country intelligence, and early engagement are the keys to successful access

Thank You

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