



中國醫學科學院醫學生物學研究所
INSTITUTE OF MEDICAL BIOLOGY CHINESE ACADEMY OF MEDICAL SCIENCES

Application of Sabin-IPV in Eradication of Poliomyelitis

Shi Li

Institute of Medical Biology,
Chinese Academy of Medical Sciences
March 9, Taipei workshop

General Information of IMBCAMS



The first OPV(Dragee candy) was develop by Dr. Gu Fangzhou's team in 1962.

General Information of IMBCAMS

- Found in 1958.
- Involved in basic & applied researches in fields related to development of new vaccines for human infectious diseases.
- Large-scale production of series of polio vaccines, hepatitis A vaccines, EV71 Vaccine, etc.
- Postgraduates education of Peking Union Medical College.



Jiao Ling Road:
R & D center



Ma Jin Pu:
Industrialization
production base



Hua Hong Dong:
ABSL3/4 labs



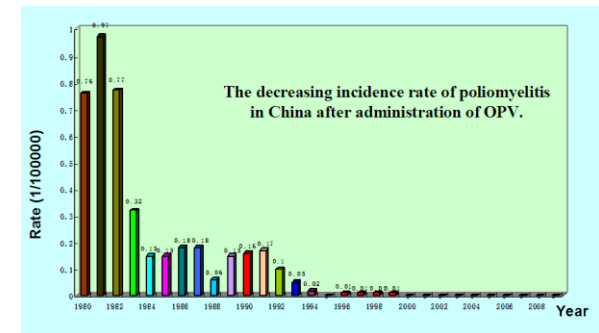
Yi Lu Cun:
Laboratory Animal
Center

Important position and function in disease prevention and control of national public health system



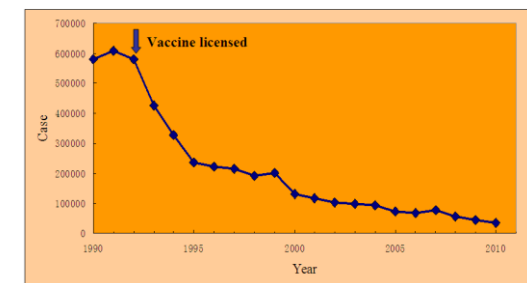
Make a great contribution to polio control and eradication and maintaining polio-free status in China.

- ◆ Over 6 billion doses OPV supplied since 1960s.
- ◆ WHO wrote a letter to compliment our contribution.



Play an essential role in controlling epidemics and reducing incidence of hepatitis A in China.

- ◆ Develop the 1st viral vaccine: HAV
- ◆ Over 200 million doses supplied since 1993.



The decreasing incidence rate of Hepatitis A in China after administration of Hepatitis A vaccine

Licensed vaccines

1992年
全球第一剂
甲型肝炎减毒活疫苗
获得新药证书和试生产文号
Live Attenuated HAV



1962年
中国第一粒
脊髓灰质炎减毒活疫苗糖丸
诞生
OPV(Dragee Candy)



2015年
全球第一剂
Sabin株脊髓灰质炎灭活疫苗(单苗)
成功上市
Sabin IPV



2015年
全球第一剂
肠道病毒71型灭活疫苗(人二倍体细胞)
获批上市
EV71 Inactivated Vaccine



2004年
中国第一剂
液体剂型脊灰减毒活疫苗
从这里走向全国
OPV



Sabin IPV



**“double lock”
attenuated strains + inactivation**



The Development of Sabin IPV

- **Started in 1983**
- **Got approval for clinical trials (phase I & II) in 2007**
- **Started phase I clinical trial in Aug. 2008**
- **Started phase II clinical trial in Jul. 2009**
- **Got approval for phase **III** clinical trial in Aug, 2011**
- **Finished phase **III** clinical trial in Oct., 2012**
- **GMP inspection was from May to Dec., 2014**
- **Licensed in Jan.14th, 2015**
- **WHO Prequalification Designing Initiated in 2015**



Phase III Clinical Trials

- Trial Plan: Random、Blind、Positive control

- Number: 1200 infants in 2 months old

- Group:

sIPV	600 infants	581 at end
------	-------------	------------

wIPV	600 infants	573 at end
------	-------------	------------

- Blood:

Before immunization

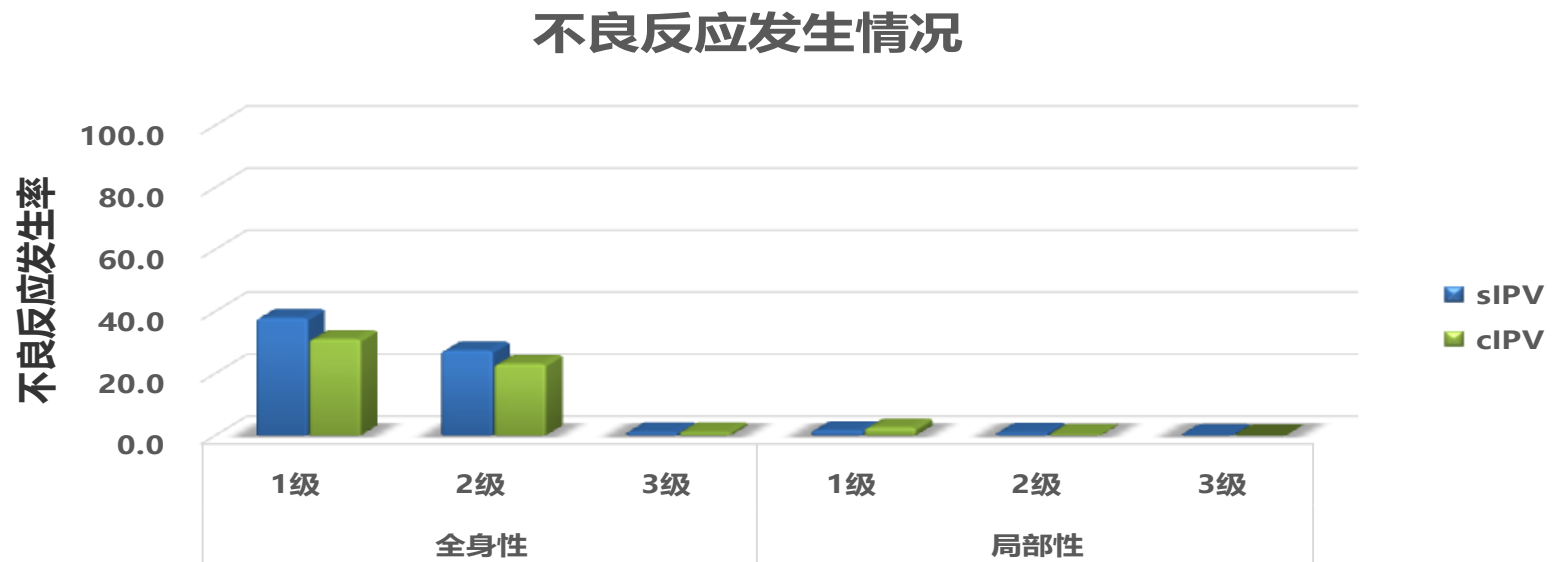
1 month after third dose

Lab. Test: Neutralizing antibody by NIFDC of China



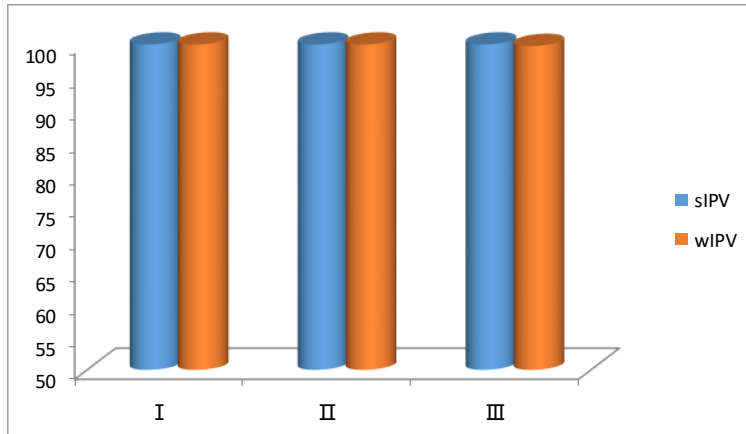
Summary in Clinical trials

Safety: No serious adverse events occur related to sIPV.

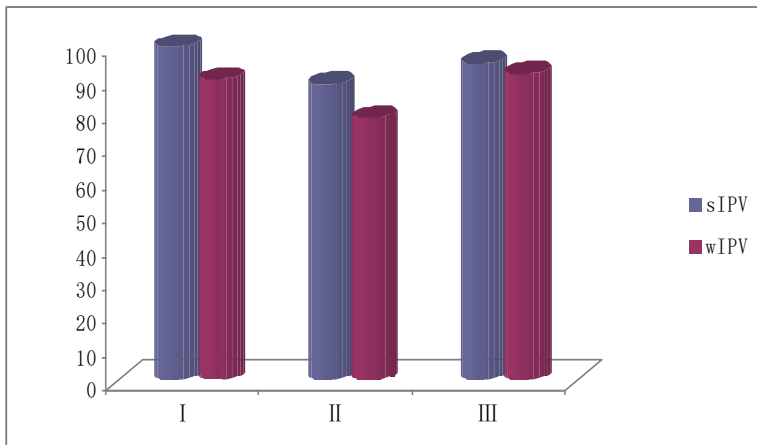


Guoyang Liao, et al. The Journal of Infectious Diseases, 2016,214,1728~1734.

Seroconversion Rates in Phase III Clinical trials



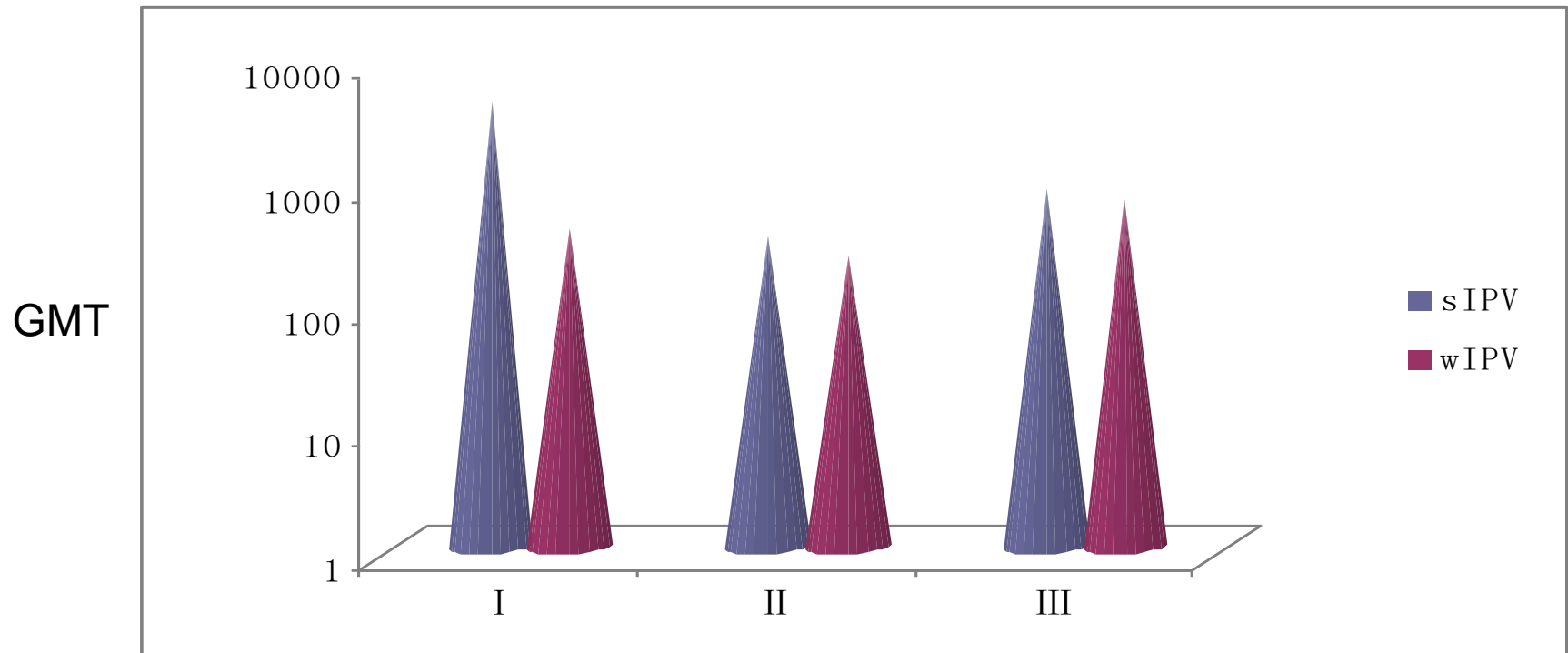
The seroconversion rate of anti-polioviruses types **I**、**II**、**III** in sensitive subjects after vaccination



The seroconversion rate of anti-polioviruses types **I**、**II**、**III** in non sensitive subjects after vaccination



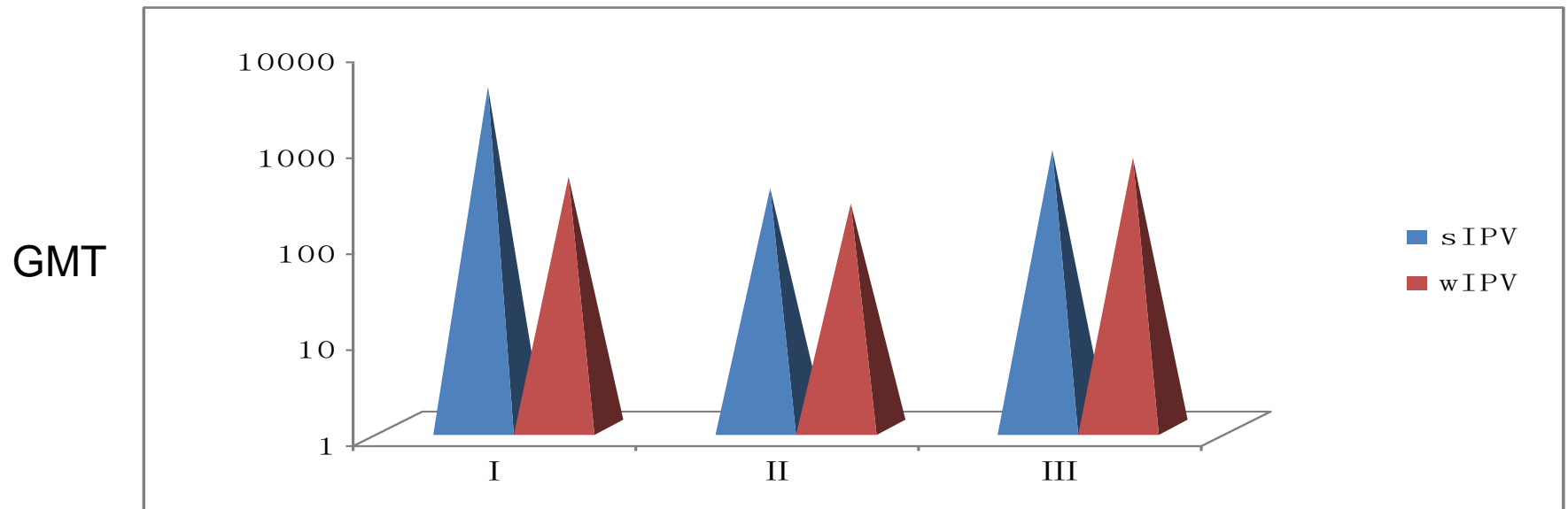
The GMT of anti-polioviruses types I、II、III in sensitive subjects after vaccination



Guoyang Liao, et al. The Journal of Infectious Diseases, 2016,214,1728~1734.

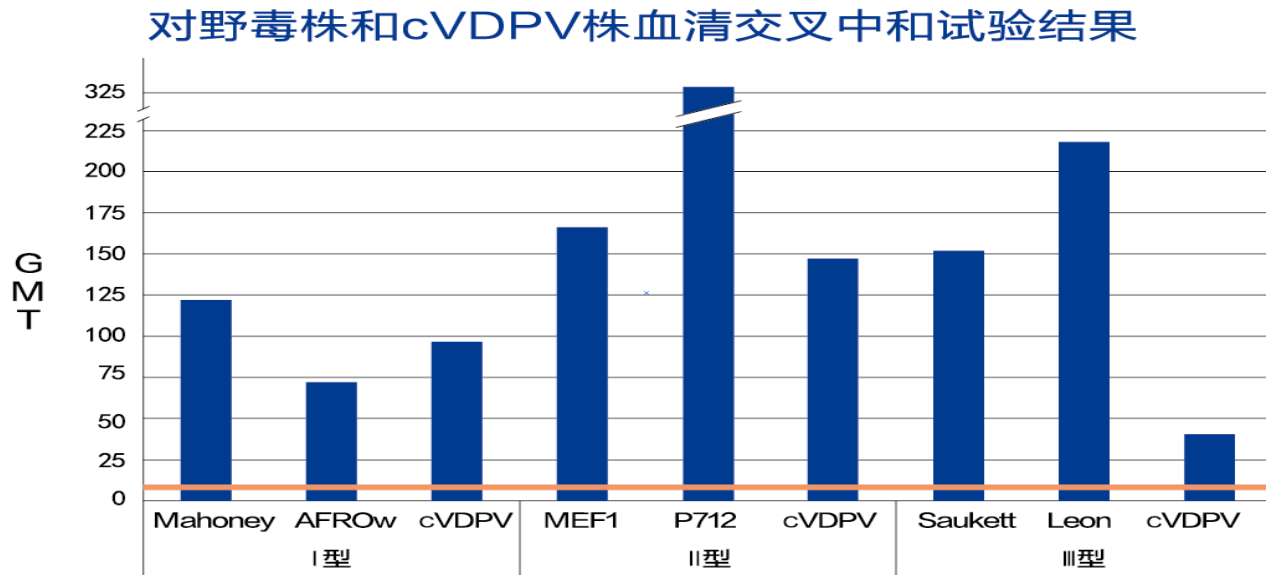


The GMT of anti-polioviruses types I、II、III in non sensitive subjects after vaccination



Guoyang Liao, et al. The Journal of Infectious Diseases, 2016,214,1728~1734.

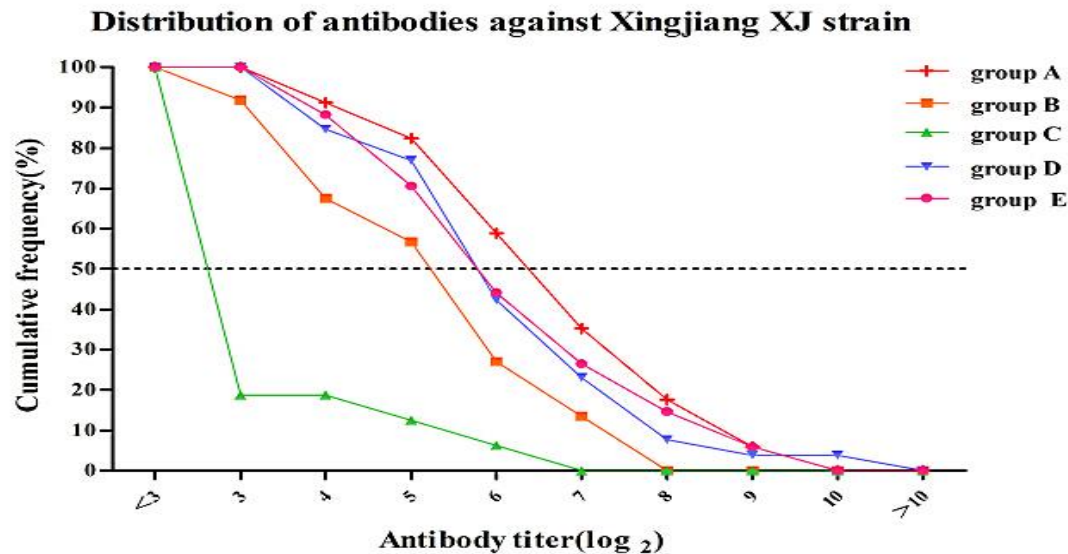
Cross Neutralization Test



Tested by US CDC

Cross Neutralization Test

c: Xinjiang XJ

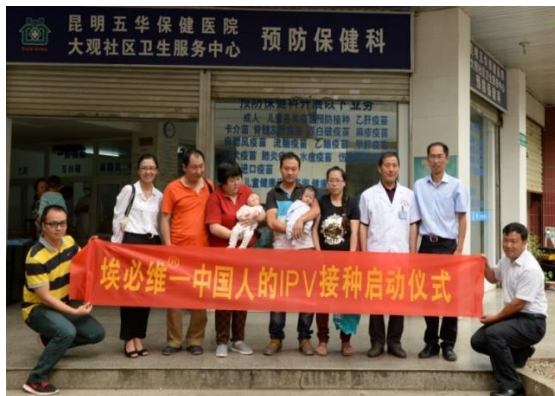


Tested by Chinese CDC

Inoculation of the 1st dose of Sabin-IPV 2015.7.1



Around 10 million doses supplied to domestic market until now



S-IPV Production Base (Phase II)



Progress – Kind Support by Gates foundation and DCVMN

The foundation will provide financial and technical support for the pursuit of WHO prequalification of sIPV.



S-IPV Production Facility (Phase II)

- **Total Investment: 350 million RMB**
- **Area:**
 - **4487.28 m²**
 - **First floor: two filling lines (Vials and prefilled syringes), clean utilities, packaging area;**
 - **Second floor: sIPV bulk production area;**
- **Capacity:**
 - **Vials (both single dose and 5-dose presentations): 40 million /year**
 - **Syringes: 20 million /year**
- **Designer: Eleventh Design & Research Institute of IT Co., Ltd (EDRI)**

Sabin IPV base 2 Foundation Stone Laying Ceremony



2016.8.25

Laying the foundation stone means that IMBCAMS has found the financial means to expand production of Sabin IPV, making this great vaccine available to more children.

—— Lance Rodewald
WHO Office in China

Inoculation of the 1st dose of Inactivated Enterovirus 71 vaccine (Human Diploid Cell) 2016.3.18

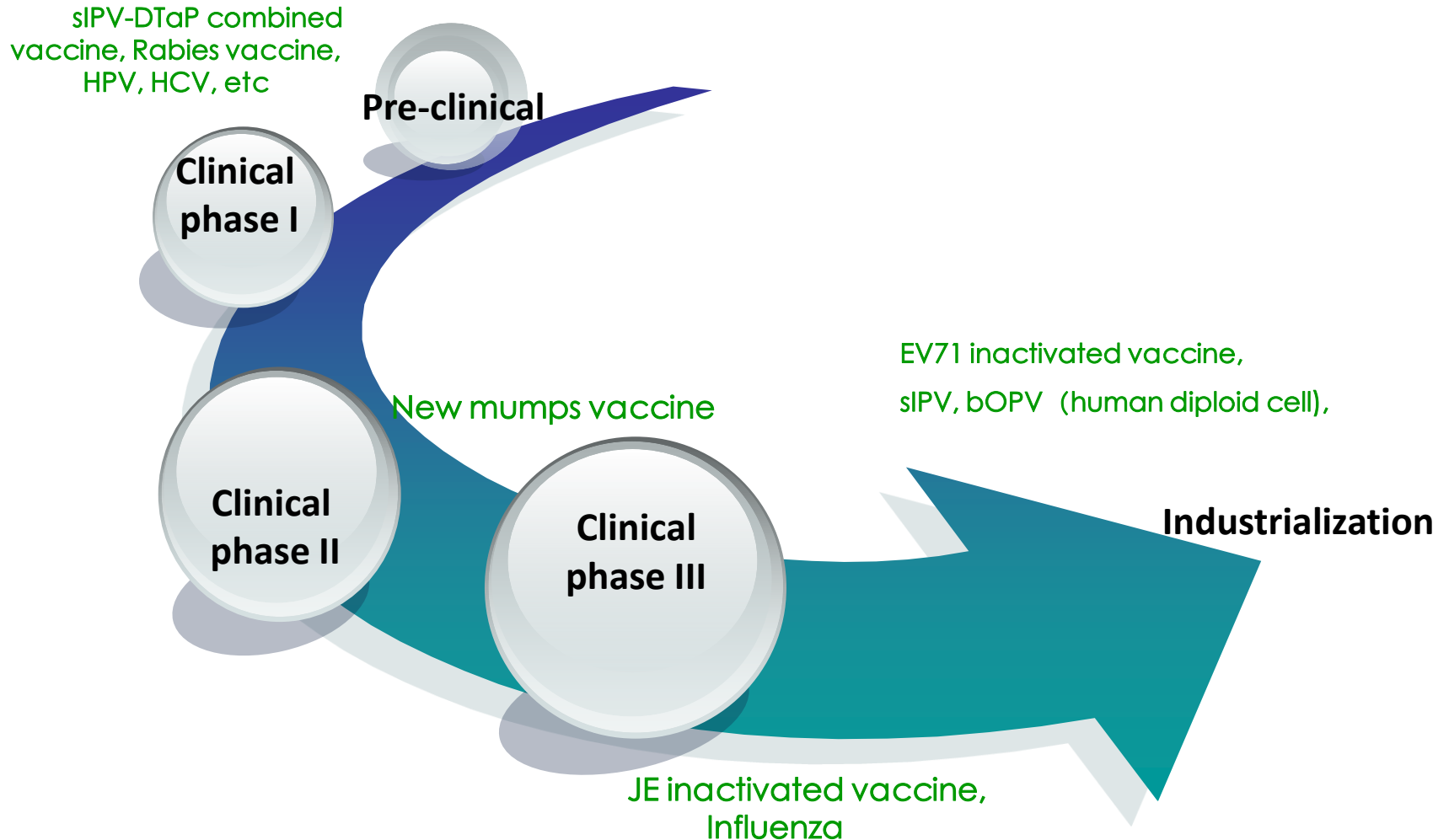


Around 4 million doses supplied to domestic market until now.





Innovation ability for sustained development of new vaccines





依偎一生

Stand by Life

责任为爱护航

Thank you for your time!