

中国国家药品监督管理局

National Medical Products Administration P.R.China

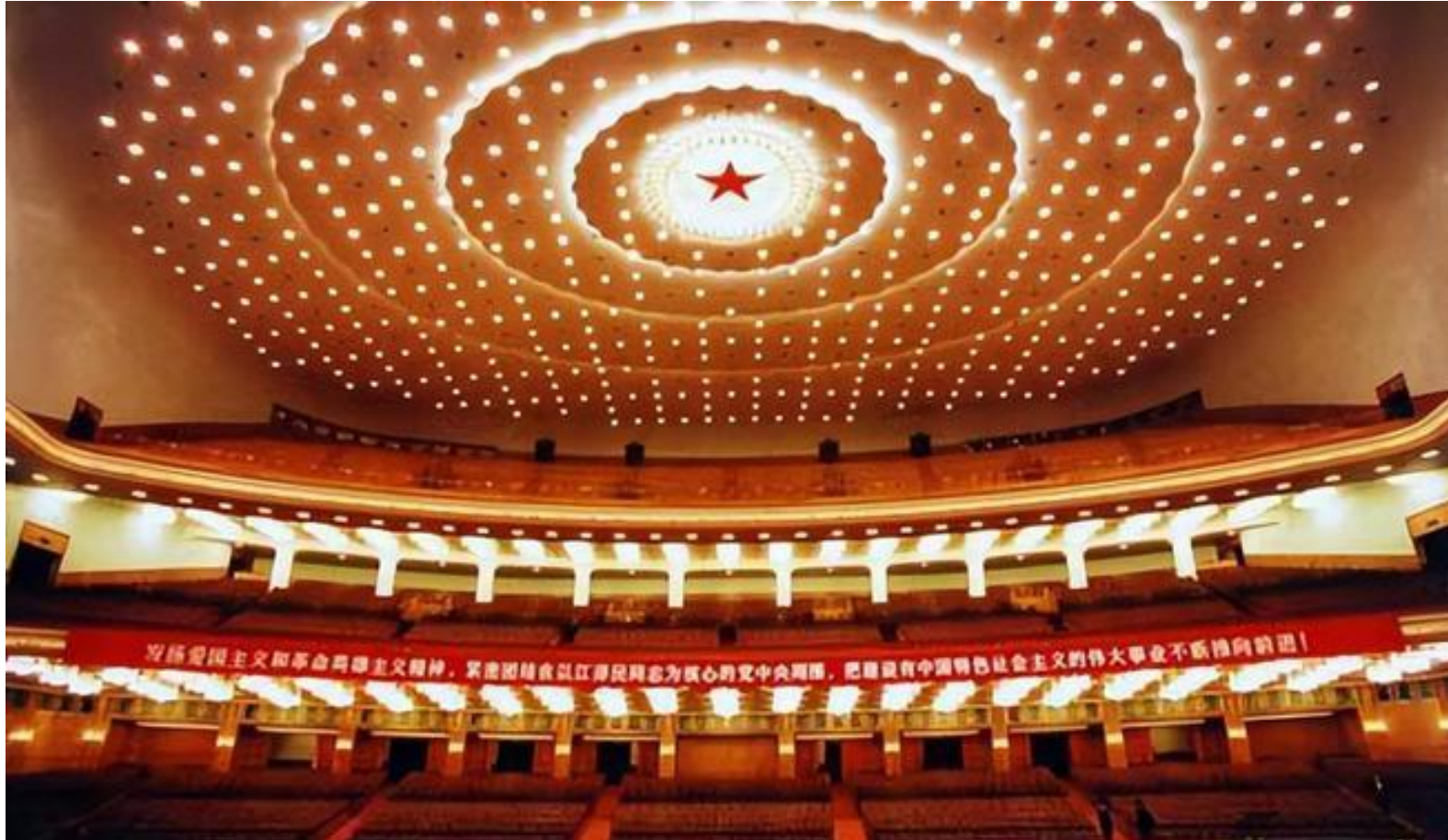
Progress of Medical Device Regulation in China

Dr. XU Jinghe

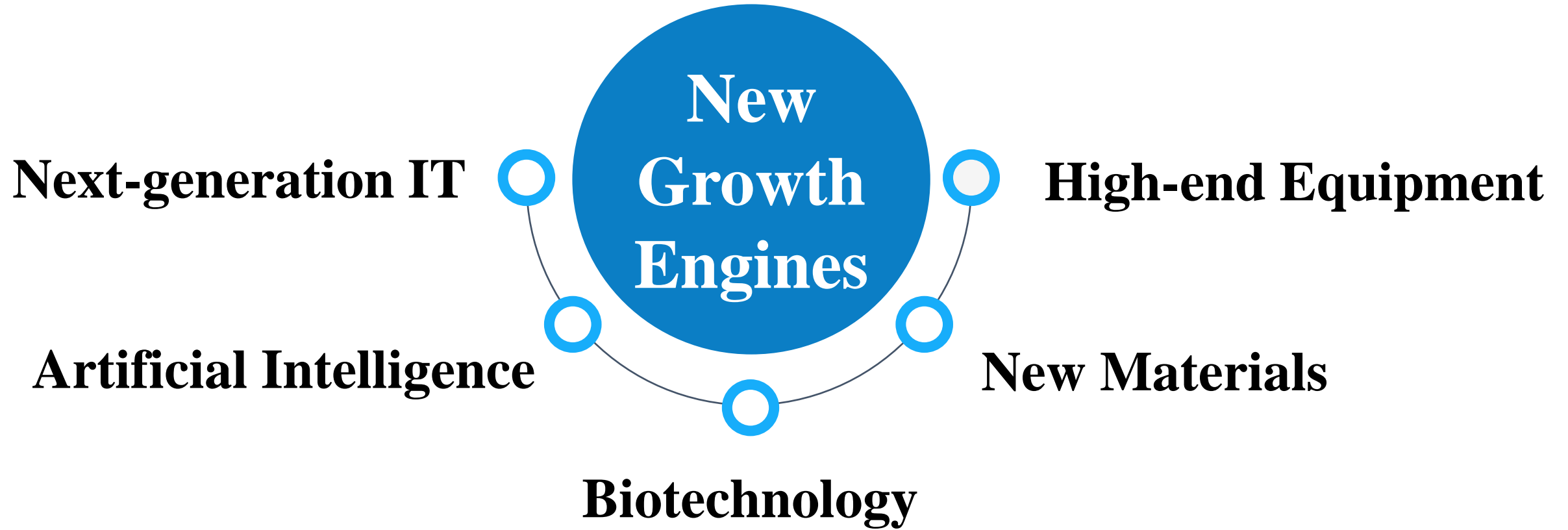
NMPA P.R.China

February 15, 2023





Paramountcy of Life
Put People First



30000+
MD manufacturers

1.2 million+
MD distributors

Operating
Revenue
179 billion+ USD

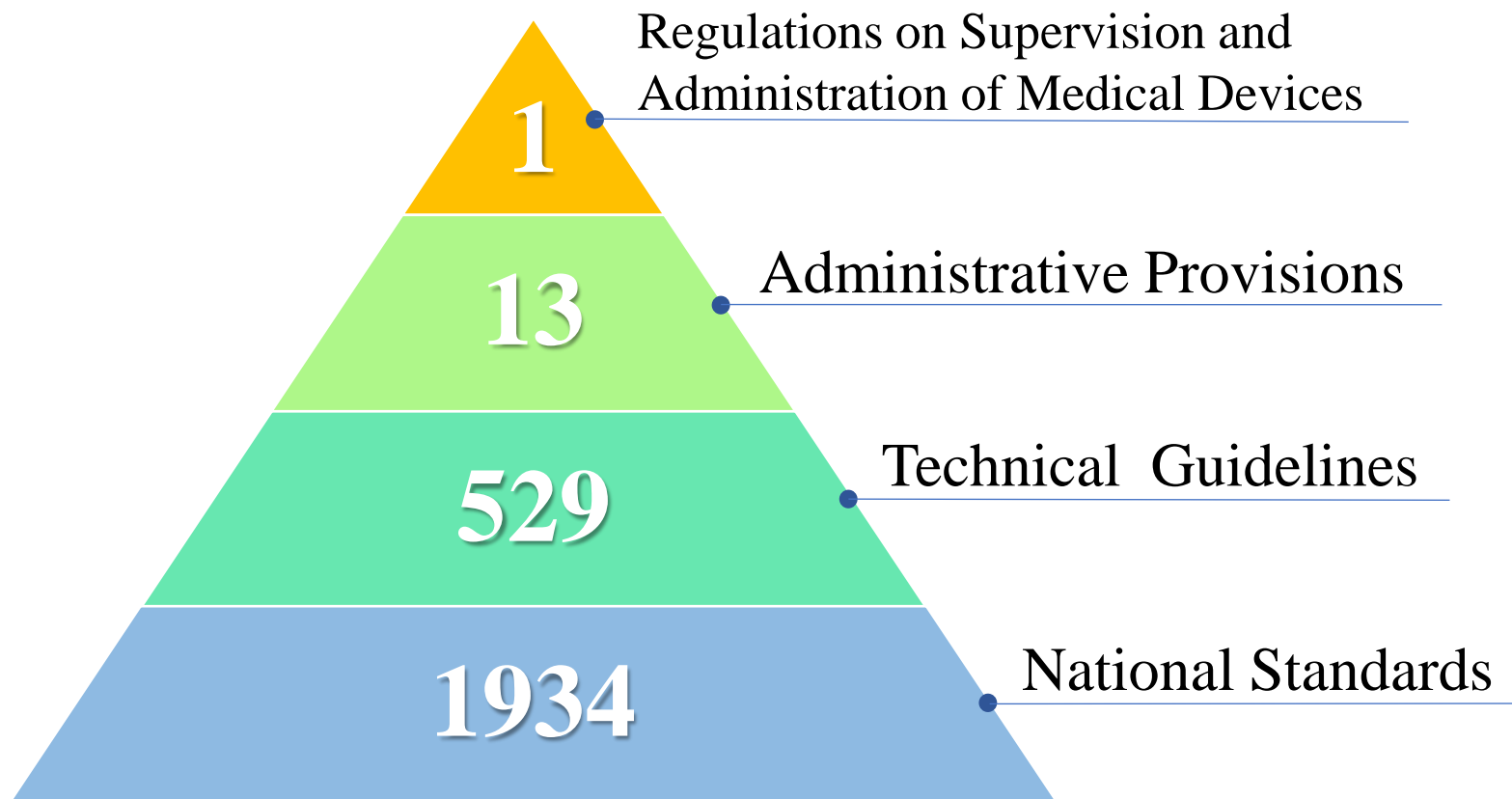
Compound
Annual Growth Rate
10%+

Import & Export
Amount
135 billion+ USD

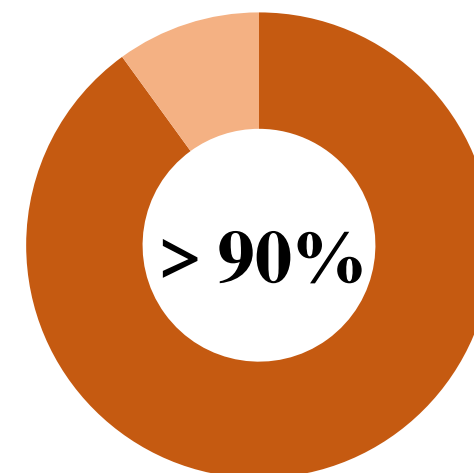
Main Tasks

1. to improve the system of regulation and standard
2. to deepen the reform of review & approval system
3. to strengthen the full life cycle regulation
4. to promote regulatory capacity building
5. to carry out international cooperation in regulation

1. to improve the system of regulation and standard



Consistency with international standards



2. to deepen the reform of review & approval system

- **191** innovative medical devices
- **129** products for clinically urgent needs

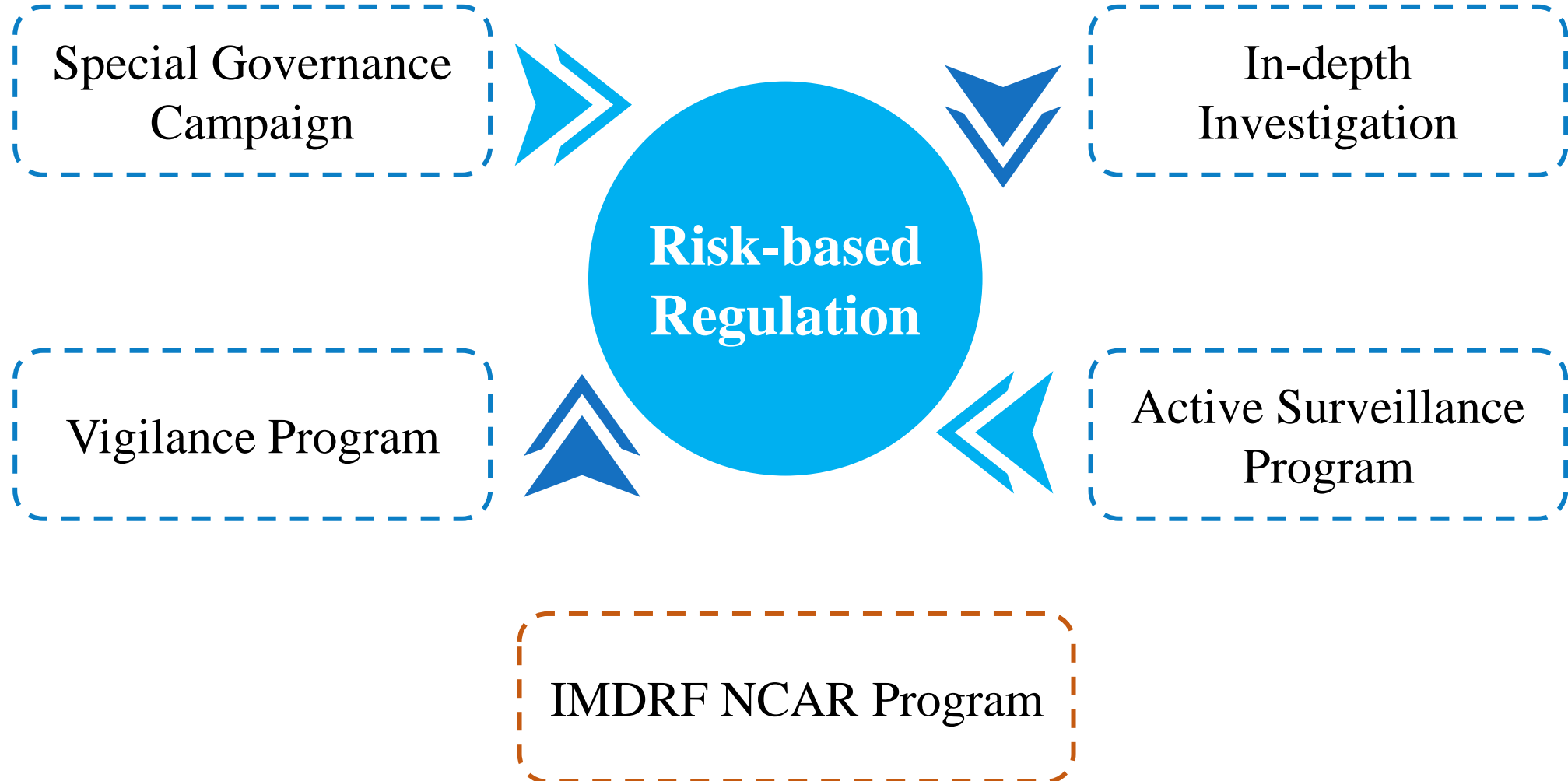


VenusP-Valve 经导管肺动脉瓣膜

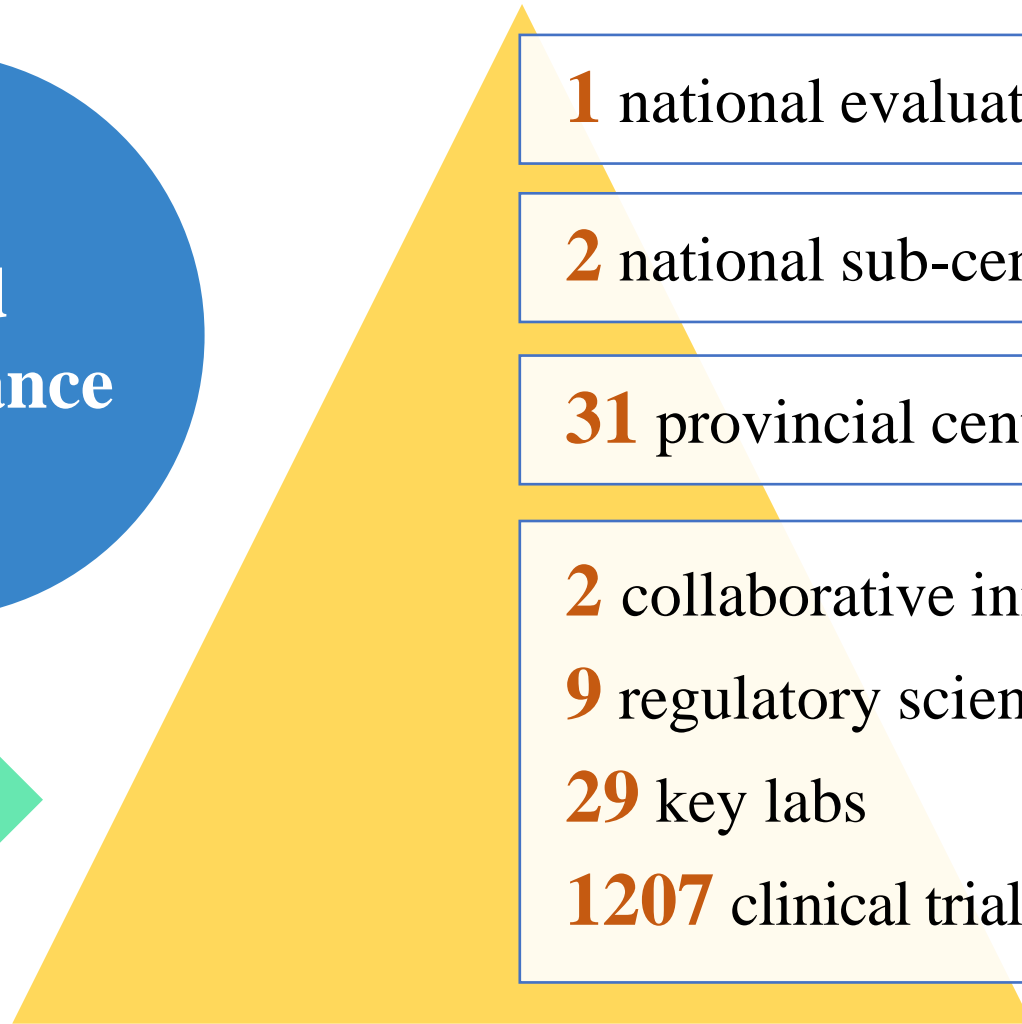
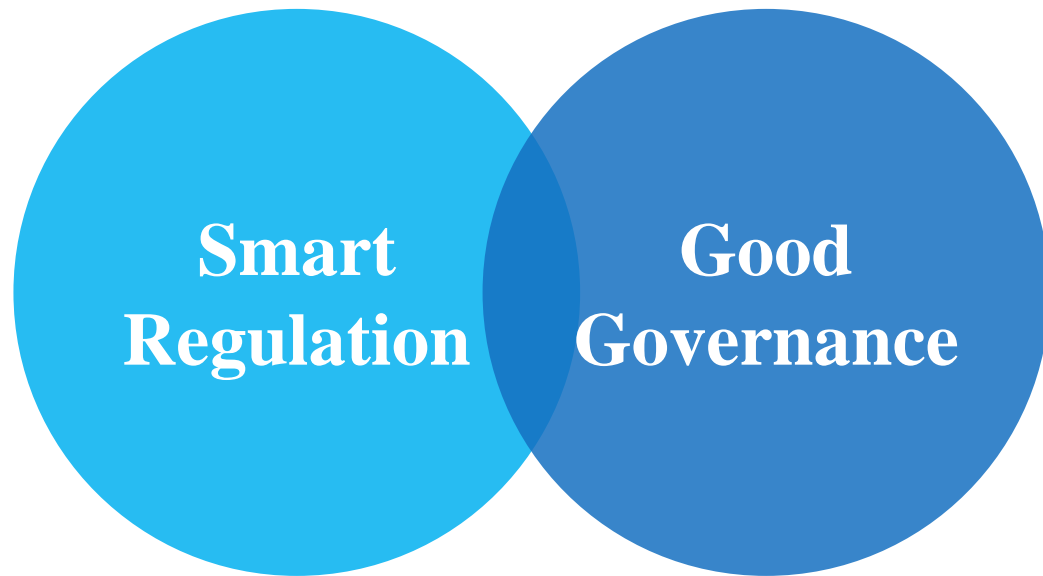


VenusP-Valve 经导管肺动脉瓣膜输送器

3. to strengthen the full life cycle regulation



4. to promote regulatory capacity building



1 national evaluation center

2 national sub-centers on evaluation

31 provincial centers

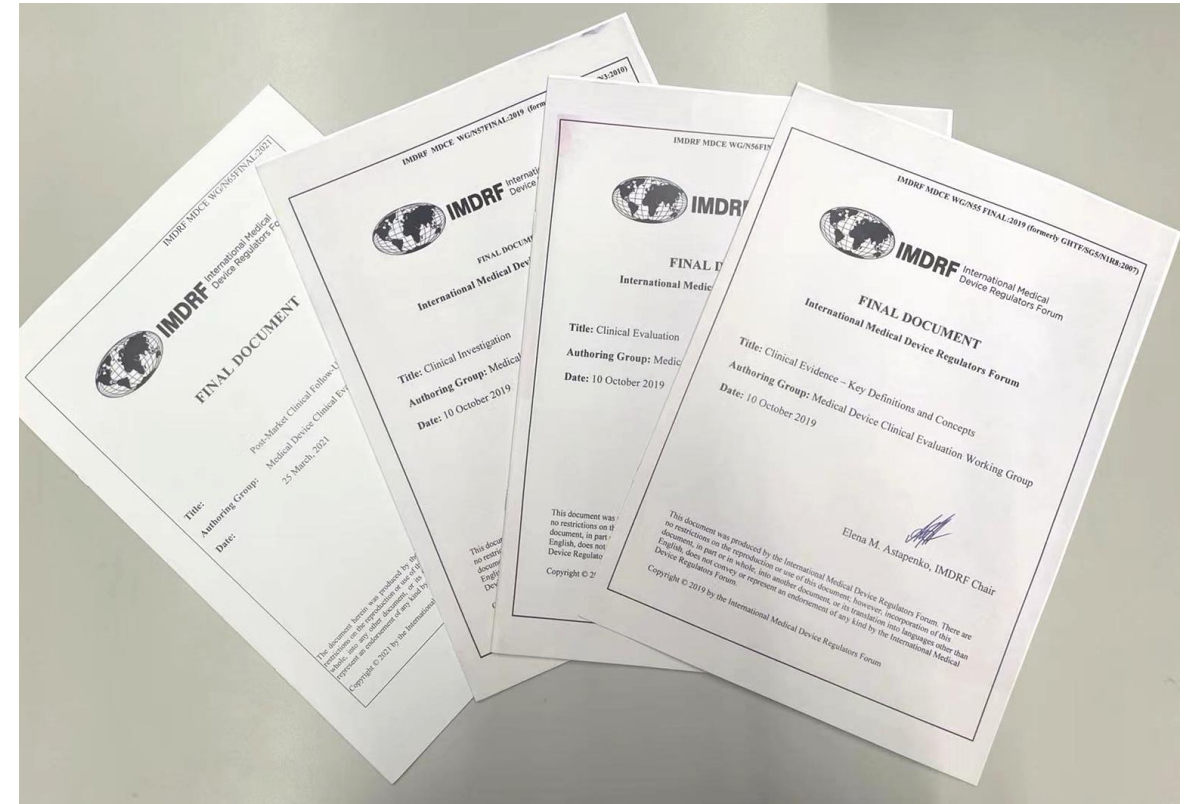
2 collaborative innovation platforms

9 regulatory science research bases

29 key labs

1207 clinical trial institutions

5. to carry out international cooperation in regulation



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Thank you

