

Partnerships, Policy and Regulation: Are these Factors Essential for IoT/M2M Business Success?

Dr. Li-Qun Xu

Chief Scientist

China Mobile Research Institute

Variety Services



OSS
Monitoring , Analytics,
Services

BSS
Billing , Clearing,
Access

**Network
Platform**

Custom NEs:

- GGSN
- SMSC
- HLR

IoT Network



GSM , TD-S , TD-LTE



**M2M Modules,
Devices,
Chipsets**

Design, develop and deploy product series for each vertical industry sector, including health, transport, finance, power, oil, and smart home, etc.

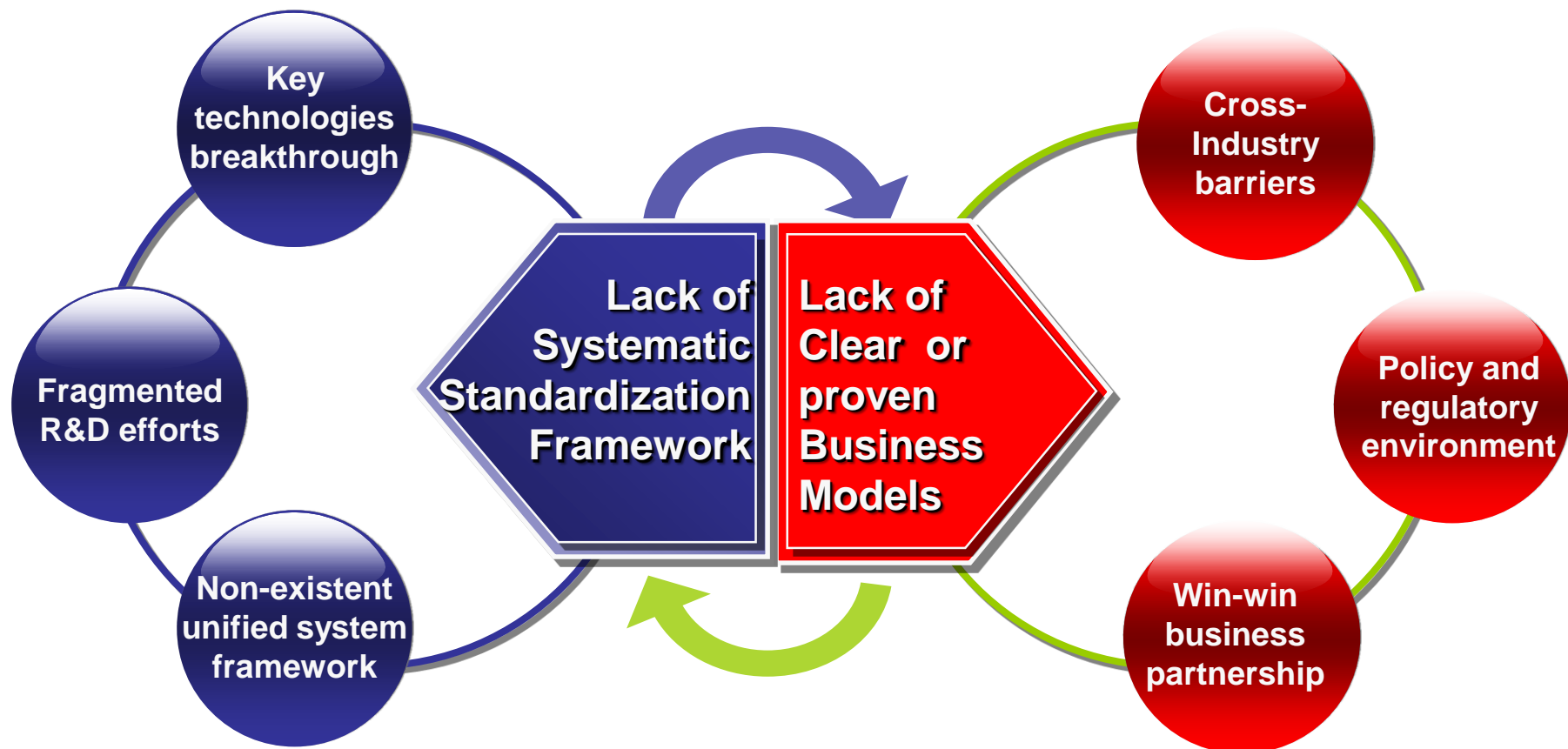
Build and operate nationwide, highly efficient, reliable, secure custom network specifically for IoT/M2M services delivery:

- Incorporate IoT services-specific NEs to provide exclusive **147 numbering segments** (Voice/data) and **10648 numbering segments** for data use only;
- Provide communication pipes (basic network services and VPN) as well as smart pipes (with additional Wireless M2M Protocols – WMMP) having the ability to manage terminal devices for customers.

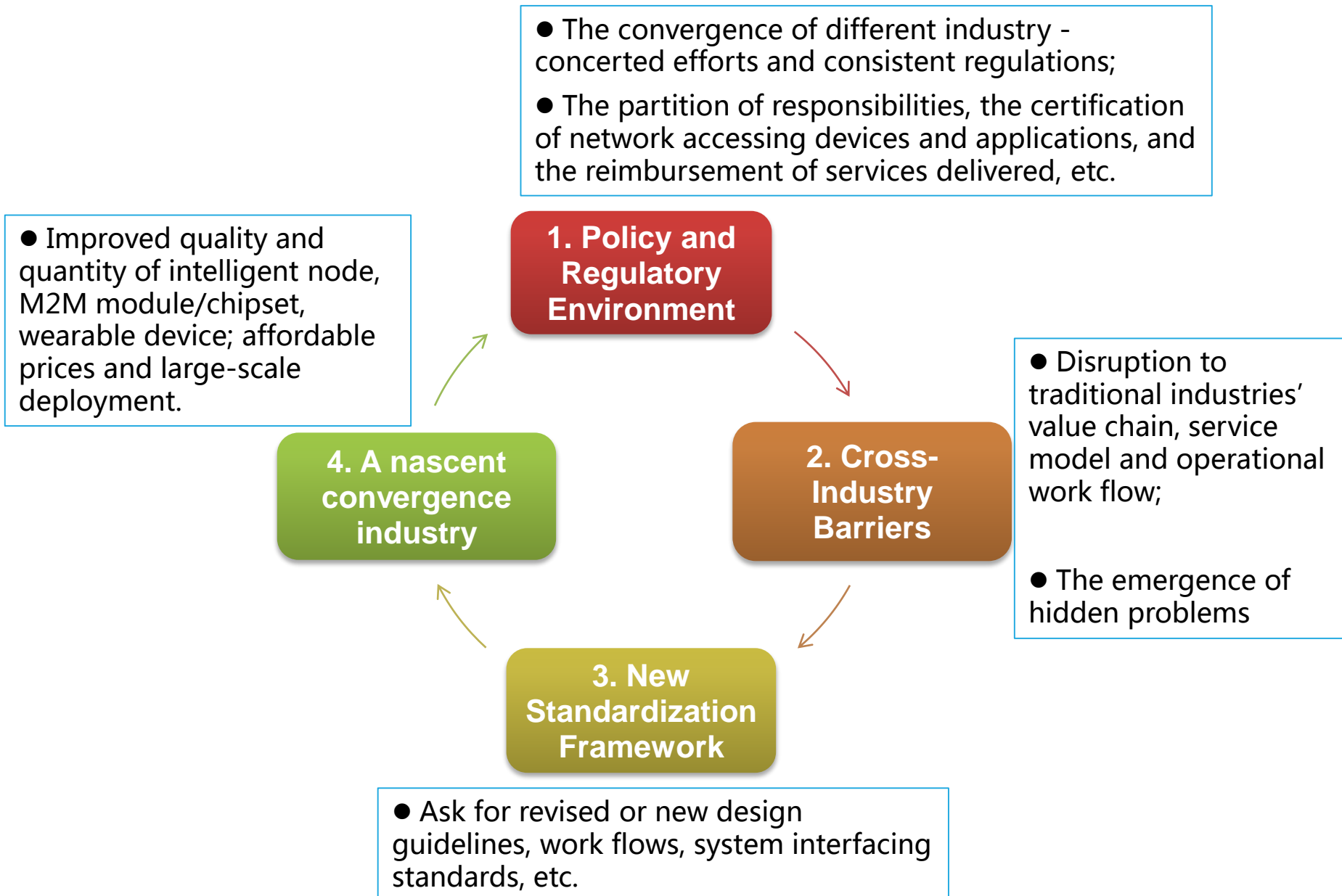
Design and develop M2M Chipset and Modules for general-purpose IoT industry applications; to integrate SIM card with communication modules to remotely monitor and administer M2M devices.

In 2013, the operation of “**China Mobile IoT Services Company Limited**” was formally launched to drive the growth of ever-important IoT services sector.

Main hurdles to overcome for the wide adoption of M2M technology and IoT services by traditional industries

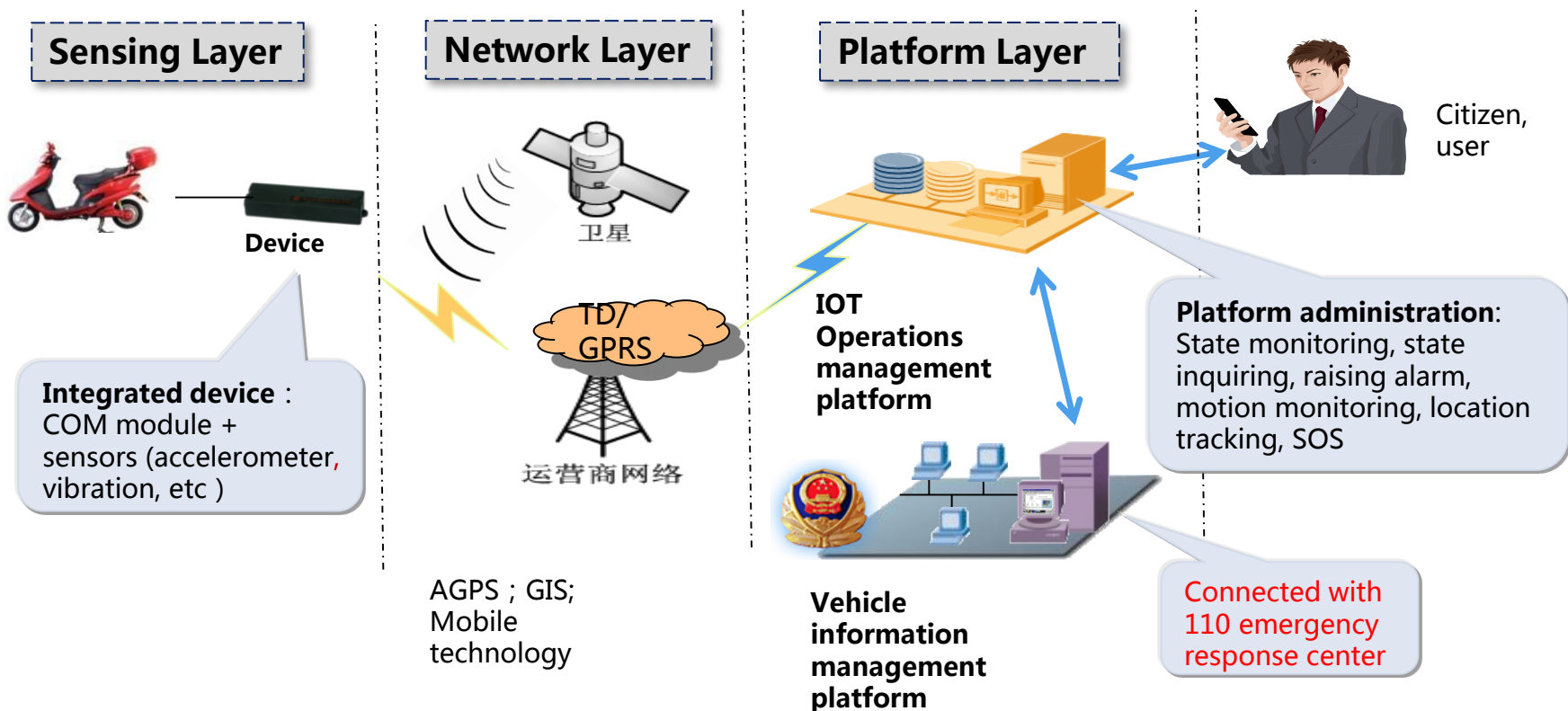


Some Key factors for IoT Services in China



“Electric Motorbike Guardian” Service:

- A real-time monitoring service for constantly positioning and tracking the status of an electric motorbike, by installing on the bike an **M2M module and multiple MEMS sensors**, incorporating GPS and wireless technology;
- The service is based on China Mobile’s custom IOT network, combined with a dedicated application platform.



1. Cross-industry regulatory system

- **MIIT** - regulating the design and manufacture of the motorbike, the networking service of the installed tracking device;
- **MoPS** – Motorbike road safety; register a theft case and the ensuing investigation by police force.

2. Industry barriers

- To install the anti-theft device on the motorbike, and **bundle** the device' s SIM card number with its owner' s mobile phone SIM card number;
- Traditional electrical motorbike production and use cycle include : Parts manufacture (including controller), assembly, retails, customer purchase, etc; traditional communication service is activated through retail outlets or Internet portals;
- Need to break traditional service model, for the pre-install and post-install markets, in which stage to install the device, and activate the service.

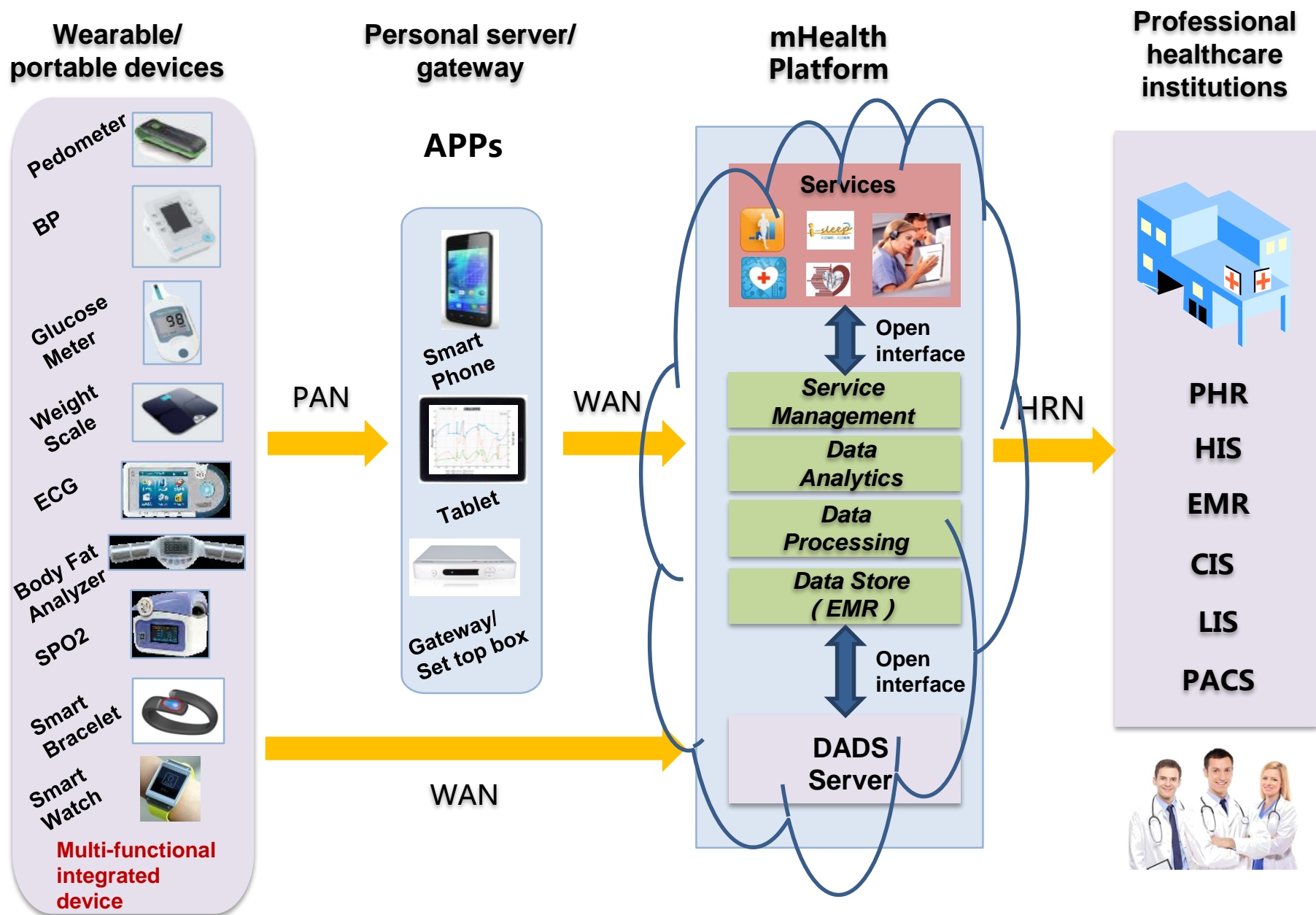
3. The industry is yet to mature

- The device **performs multiple functions** such as communication, location, detection of abnormal vibrations, and works in a tough environment. It currently adopts a module-based solution, the development is simple but the cost is relatively high.

4. Standardization and specification

- The **communication industry standards** apply to: communication functions of the device, application platform, network, protocols;
- The **MoPS stated specifications**: the integrated device, the interface between the application platform and **MoPS** system, etc.

System Architecture of mHealth Services



-- Remote Heart Health Monitoring System

- In close collaboration with a renowned **cardiovascular hospital** in China, we have designed and developed this ambulatory / home-based heart functions remote monitoring system, which is currently under clinic effectiveness test with five types of patients discharged from a hospital: **Hypertension, Diabetes, Pacemaker, Bypass Surgery and Stent Surgery.**
- By wearing and using devices for vital signs capture, in compliant with a doctor's **medication and activity prescription**, the data are uploaded to the cloud and are under surveillance and intervention by a **triage of services** of intelligent analytics, Call center nurses and doctors for a daily health status monitoring, irregular case detection, advice and call for hospital visit.



① mHealth products and services delivery need to be regulated by multi-agency concerted efforts:

In the US, the FDA and FCC signed an **MoU** in 2012, with a view to fostering effective collaboration in regulating the market of broadband and wireless medical equipments:

- ❑ FDA is mainly responsible for overseeing **mHealth devices and APPs** ;
- ❑ FCC is in charge of **provisioning spectrum** for wireless medical devices , so as to ensure mobile network has the ability to support mHealth services;
- ❑ For such a purpose, a special **professional team** is set up by FCC in 2014 to enlist advice and suggestions from experts in broadband and healthcare, to reinforce the supervision towards mHealth service delivery.

Chinese government would need to consider acts along similar lines.

② All partners in the mHealth eco-system should have clearly defined roles and responsibility :

- ◆ mHealth services **value chain** involves many players: healthcare provider, network operator, solution provider, system and (wearable) device vendor, etc.
- ◆ The **roles and legal responsibility** of each partner need to be specified by authorities overseeing healthcare and ICT industries.

③ New problems emerging:

◆ mHealth Apps and devices to be regulated ?

Mobile medical apps that undergo FDA review will be assessed using the same **regulatory standards** and **risk-based approach** that the agency applies to other medical devices.

□ **Class I devices:** The low-level risk. Need general controls (including adequate design controls, registration, device listing, adverse event reporting, and corrections and removals). Without the need for additional review of the market listing;

□ **Class II devices:** The middle-level risk. Manufacturers are required to submit premarket notification;

□ **Class III devices:** The high-level risk. The products are needed for pre-market approval and provide relevant clinical data.

◆ In China, these are still open questions at least for the time being :

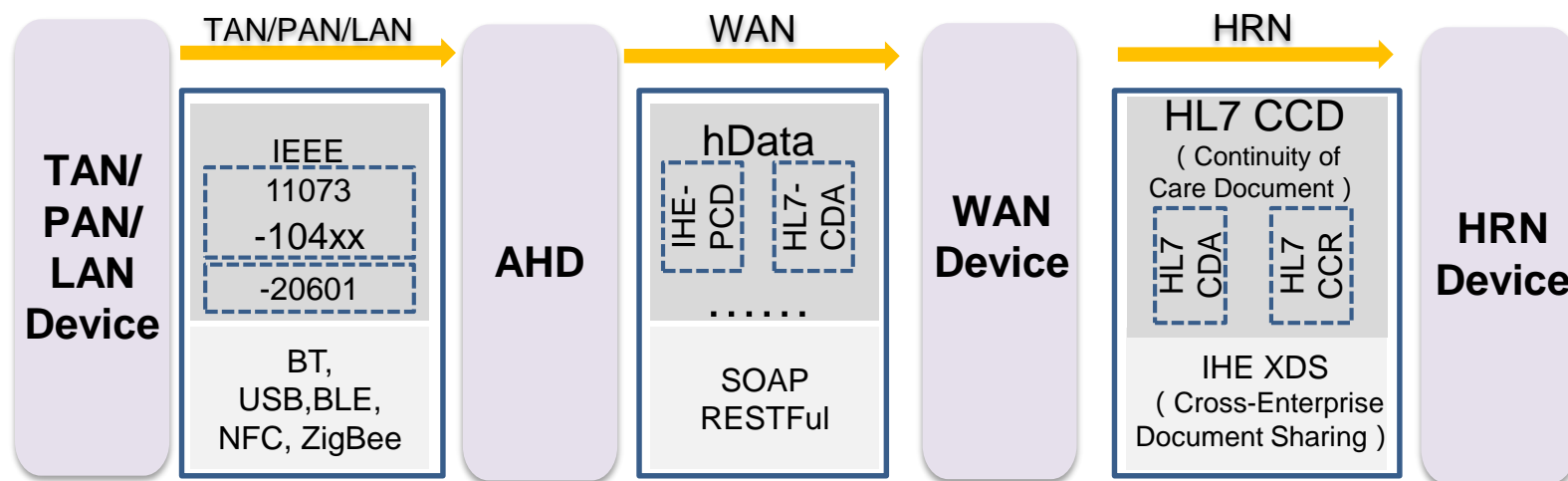
– An example: Sleep staging and Sleep Apnea detection apparatus certification

◆ Fee- or value-based charge model for chronic illness management and remote patient monitoring services are not clear.

◆ Reimbursement models for mHealth services are yet to be established, in respect of both social security insurance plan and commercial healthcare insurance system.

- Doctors have the concern that mHealth services may cause the diversion of their existing patients base.
 - ◆ According to the 2012 survey report from PwC :
 - Among doctors participating in the survey, 42% are worried that mHealth products and services would make patients more autonomous.
 - While for junior doctors (with less than five year clinic experience), an even higher percentage (up to 53%) are uneasy about the effects on patient that they may be out of control, with a 24% of the doctors, in particular, actively obstruct the patients from using mHealth Apps to manage their own health !
- In China, doctors in 3A graded hospitals already have unusually high overtime workload, the introduction of mHealth services will bring in extra work for them:
 - ◆ **CSU affiliated XiangYa hospital:** 1000 doctors, the number of consultation conducted 1.2 million annually on average, about 1200 for each doctor.
 - ◆ **No. 3 Hospital of PKU:** outpatient consultation 14,000 daily, there are currently 1464 hospital beds, the number of patients discharged from the hospital amounts to 79,076 in 2013, operations carried out 48,212.

- The need for new **clinic pathway** and **healthcare protocols** to guide different mHealth service delivery :
 - ◆ Healthy lifestyle promotion, chronic illness management , activity prescription, elderly care, remote monitoring and intervention, etc.
- Standards for **interface and inter-operability** between vitals capture devices and personal gateway and backend platform are to be established or improved.
 - ◆ Internationally, the CHA has been working to release comprehensive design guidelines for such purpose, but whether it will be adopted or not depends on the actual national case or market conditions ;
 - ◆ Certain further scenarios need to be included in industry or national standard, the existing standards may also need to be simplified or adapted.



- With the rapid advancement of ICT as well as sensors and electronics, the CHA has repeatedly introduced improved Design Guidelines for mHealth systems' interfaces, the device and system vendors adopted such guidelines are lacking, so are the devices passing the certification of the CHA.
- There is at present no widely adopted national design standards for mHealth systems in China. Notably, there are several standards bodies working towards this objective.

Medical devices certified by the CHA by May 2014

Devices	Passed certification tests (款)	TAN/PAN/LA Protocol				
		BT	BLE	USB	Zigbee	NFC
Glucose Meter	8	2	0	5	1	0
BP	7	5	0	1	1	0
SPO2	6	3	0	1	2	0

1. National bodies to coordinate a consistent regulatory policy

- To mark clearly the requirements and responsibility of each relevant government department for supervision ; delimit the scope of liability of each player in the end-to-end IoT service delivery process.
- To specify the standards and certification procedures to connect a device to a wireless network , as well as the charging model of an IoT application.

2. IT Industry alliance and GSMA to promote IoT/M2M among traditional industries

- Through pilots and demonstrator projects to showcase the positive impact of IoT/M2M to the traditional industries in terms of productivity, revenue growth, and cost reduction, etc.

3. Standards organizations and industry associations to work together to generate technical and service specifications

4. Device and system vendors to innovate and accelerate the maturity of the IoT/M2M industry

- To develop and manufacture more standards-compliant products through R&D investment to scale up the market.



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