



Memo on Medical Technology Artificial Intelligence (AI) in China

January 2019

Medtech AI in China

Executive Summary

- China has launched a nation-wide push to become the world leader in artificial intelligence (AI) by 2030. As part of this ambition, **the government is providing extensive support to the development of AI applications in the medical field**, which it hopes will tackle major issues plaguing China's healthcare system.
- Supported by central and local-level policy, **China's medical AI market is growing rapidly and is expected to reach RMB 20 billion (~USD 2.9 billion) by the end of 2018**. While the government has pledged specific support for its "national champion" internet giants, a host of traditional healthcare and emerging start-ups are also successfully pursuing wide-ranging opportunities.
- AI is already being widely used in China in the areas of medical imaging and clinical diagnosis support, health resource management, virtual assistants, patient health monitoring, and drug research and development.
- **China's medical AI industry currently lacks a regulatory framework**. Led by the National Medical Products Administration (NMPA), regulators and specific AI working groups under the National Institutes for Food and Drug Control (NIFDC) and Center for Medical Device Evaluation (CMDE) are in the process of creating classification catalogues, clinical trial guidelines and technical review documents to specifically regulate medical devices that integrate deep learning software.
- **China is currently experiencing a first wave of AI medical device applications, yet many devices are experiencing long approval waits due to the government's conservative approach to risk classification**. Existing classification and evaluation guidelines **classify any medical software with explicit diagnosis functions as Class III devices**.
- Thus far, no Class III AI medical devices have been registered in China. Some Class II AI medical devices have been successfully registered, yet these may only have an advisory/assistive role in medical diagnosis.
- Aside from the lack of unified industry standards for risk classification and evaluation, a range of other bottlenecks may complicate the growth of AI medical devices in China, including **issues surrounding the sharing of sensitive health data, legal liability and potential favoritism toward domestic companies**.

Introduction: China's AI Ambitions

The Chinese government has identified the development of artificial intelligence (AI) and related cutting-edge technology as a leading national priority. Its pursuit of AI is part of – and in many ways exemplifies – China's overall push to become the forerunner of technological development in the world. Technological innovation is seen as a new **source of**

economic growth and national power, and ultimately as the key to achieving the country's "rejuvenation." Consequently, the Chinese government has provided **unparalleled policy and financial support for the development of its AI industry**. In July 2017, the State Council released its strategic blueprint for AI, the *Next Generation AI*

Development Plan, which spells out China's goal to become the world's leading innovation center for AI by 2030, boasting a RMB 1 trillion (~USD 145 billion) AI core industry. The plan has been followed by several more specific AI policy documents that provide more concrete guidelines as to which AI technologies and sectors China could and should develop (see Appendix). Meanwhile, President Xi Jinping himself promoted the "deep integration of the Internet, big data, AI and the real economy"¹ in his report at the seminal 19th National Party Congress in October 2017, while March 2018 marked the second time AI was written into the

annual government work report presented by Premier Li Keqiang.

For China's policymakers, AI will not only be a key driver for economic growth but will also provide the country with an opportunity to be a global leader in a nascent form of technology and spearhead global technological advances. But perhaps most importantly, China's leaders recognize that AI forms the very basis of future technologies that will help transform Chinese society and solve critical societal issues. For this reason, **the development and application of AI in the healthcare industry has received particular attention.**

Overview: AI in Healthcare (MedTech)

The Chinese government identified healthcare as an area of particular promise in its national AI strategy, highlighting healthcare specifically as one of the key areas in which the application of innovative AI can help provide Chinese citizens with "personalized, diversified, high-quality services."² Recognizing that accelerating the advancement of AI could help China tackle some of its most difficult healthcare challenges, caused by a rapidly urbanizing and ageing population, the strategy document encourages "the use of new models and new methods of AI treatment," which includes everything from image-assisted diagnosis and surgical robots to intelligent hospitals and smart health monitoring systems.

¹ Xi Jinping's Report to the 19th National Congress of the Communist Party of China, Xinhua, October 2017 ([Source](#))

² Next Generation AI Development Plan, State Council, July 2017 ([Source](#))

High rate of misdiagnosis	Imbalanced distribution of medical resources/ large doctor supply & demand gap	Inaccuracy of early disease risk prediction	Inefficiency of drug R&D	Surgical imprecision
According to the Chinese Medical Association (CMA), China has an overall misdiagnosis rate of 27.8%. ³ AI-powered diagnosis assistance could significantly improve the accuracy and efficiency of medical diagnosis.	China suffers from a shortage of doctor resources (ca. 2.1 doctors per 1,000 patients) ⁴ , particularly in medical imaging and pathology departments. AI applications could increase the proportion of self-diagnosed patients and reduce the demand for doctors, while increasing the efficiency of doctors.	The combination of AI diagnosis technology and wearable device technology could allow for earlier disease risk prediction and intervention.	Deep learning and natural language processing techniques could greatly improve the efficiency of drug research and development, and reduce the production time and costs of pharmaceuticals.	Surgical robots will improve surgical precision and enable doctors to apply minimally invasive techniques more widely.

Key healthcare challenges that AI may be able to address in China

Over the past months, **various government departments have issued healthcare policies that specifically encourage the development and application of AI technologies in medical care** (see Appendix). At the national level, across the board, ministries ranging from the National Health Commission (NHC) to the Ministry of Industry and Information Technology (MIIT) have released measures that support the overall application of information technology in medical and public health services, while specifically promoting the application of AI in, for example, medical imaging, hospital resource management systems, wearable devices, and the Electronic Medical Records (EMR) system.

At the regional level, Guangdong province has taken the lead in pronouncing its support for AI applications in the medical space, publishing within two months this year two action plans that aim to expand the use of

AI and other cutting-edge technology in its public hospitals. Anhui provincial government has also shown its support of medical AI in a recent policy document.

Consequently, China's medical AI market has been growing rapidly. In 2016, it reached RMB 9.7 billion (~USD 1.4 billion) in size, growing by 40.7% to reach RMB 13 billion (~USD 1.9 billion) in 2017.⁵ **By the end of 2018 the market's value is expected to more than double to reach RMB 20 billion (~USD 2.9 billion).**⁶

With AI technologies highly supported and encouraged by the government, **AI is already being widely used in the medical field**, in particular in the areas of medical imaging and clinical diagnosis support, health resource management (e.g. electronic medical records), virtual assistants (e.g. chatdocs), patient health

³ 2018 Medical AI Technology and Application White Paper Internet Healthcare Industry Alliance, January 2018 ([Source](#))

⁴ *ibid.*

⁵ State Council article, July 2018 ([Source](#))

⁶ Smart Health: China Medical AI Industry Report, Philips/Caixin Healthpoint, July 2018 ([Source](#))

monitoring (e.g. wearables), and drug research and development.

The Chinese government is also providing targeted support to a select number of private companies. **China's first batch of four "national champions" in AI includes Tencent, which has been tasked with focusing on advancing computer vision for medical diagnosis.** In June 2018, the technology giant released its first AI-assisted medical diagnosis and treatment product, Tencent Miying, which had been developed by Tencent's AI laboratory in conjunction with several partners. Tencent Miying aims to create

an open platform to help support hospital information systems and achieve smart upgrades of online medical services.⁷

China's leading internet giants and traditional medical companies alike have been heavily expanding their business segments focusing on medical AI applications and products. At the same time, many startups have emerged, which have also been taking advantage of the rapidly growing market. **As of June 2018, a total of 89 medical AI startups in China had received a total of around RMB 21.9 billion (~USD 3.16 billion) in financing.**⁸

Current Regulatory Framework for AI Medical Devices



Much like the US and other parts of the world, **AI medical devices are still new in the Chinese market and therefore lack a robust regulatory framework thus far.** Yet, in recent months Chinese regulators, led by the National Medical Products Administration (NMPA), have focused their attention on drafting up policy documents and guidelines specifically for

medical devices that employ deep learning software. Two AI working groups established under the National Institutes for Food and Drug Control (NIFDC) and the Center for Medical Device Evaluation (CMDE) respectively are working on creating a classification catalogue, clinical trial guidelines and technical review documents specifically for AI medical devices.

A. Medical Device Categorization

According to China's latest *Medical Device Catalogue* (医疗器械分类目录)⁹, released by then-CFDA (now NMPA) in September 2017 and effective since August 1, 2018, AI software medical devices can fall into only two classifications in China:

- **Class II:** Software that **acts as a clinical reference** by analyzing images and data.
- **Class III:** Software that **automatically identifies** pathological changes and provides the basis and/or advice for clinical diagnosis or treatment, based on the nature of pathological changes including Computer Assisted Diagnosis (CAD).

⁷ Yicai article, June 2018 ([Source](#))

⁸ Smart Health: China Medical AI Industry Report, Philips/Caixin Healthpoint, July 2018 ([Source](#))

⁹ Medical Device Catalogue, CFDA, September 2017 ([Source](#))

It is important to note that **the current Medical Device Catalogue does not include provisions for new devices such as ones that employ deep learning software.** Ren Haiping, Director of the Optical Electronic Mechanical Device Laboratory under the National Institutes for Food and Drug Control (NIFDC), emphasized in August 2018 that **the 2017 Catalogue only categorizes existing medical device products on the market.**¹⁰ According to media reports, 11 companies are currently working with relevant government departments on drafting evaluation standards specifically for Class III AI medical devices, but these are yet to be released.¹¹

B. Medical Device Testing

Current regulations **require both Class II and Class III medical devices to be tested through clinical trials before registration and pass a technical evaluation.** As of now, the evaluation of AI software medical devices is determined according to the following three official documents:

- *Medical Device Software Registration Technical Evaluation Guidance Principle* (医疗器械软件注册技术审查指导原则)¹²
- *Medical Device Cybersecurity Technical Evaluation Guidance Principle* (医疗器械网络安全注册技术审查指导原则)¹³
- *Mobile Medical Device Registration Technical Evaluation Guidance Principle* (移动医疗器械注册技术审查指导原则)¹⁴

In the meantime, according to the 2017 Catalogue, any type of software that has diagnosis functions will be considered a Class III medical device, **which effectively means that any medical device that uses AI for medical imaging diagnosis purposes will be categorized as Class III.** Ren Haiping has also stated that new medical devices for which the risks are unclear will highly likely be placed in the higher risk category (Class III). Even devices that in the US have been classified and approved as Class II devices are therefore likely to be categorized as Class III devices in China.

For example, IDx-DR – the first and only FDA authorized retinal diagnostic software device – though approved by the FDA in April 2018 as a Class II device will likely be a Class III device in China.

According to some industry players, **the government is planning to release a new guidance principle for public comment that applies specifically to the evaluation of medical devices that make use of deep-learning assisted decision-making processes.**¹⁵ As of October 2018, the document had not been released yet.

Meanwhile, the NIFDC has been frequently quoted as saying it has made significant advances in testing AI medical devices. **The NIFDC has founded an AI Working Group under its Optical Mechanical and Electronic Medical Device Testing Office,** which has reportedly already accepted around 30 AI

¹⁰ Da Jiankang Pai Article, August 2018 ([Source](#))

¹¹ 21st Century Business Herald Article, August 2018 ([Source](#))

¹² Medical Device Software Registration Technical Evaluation Guidance Principle, CFDA, August 2015 ([Source](#))

¹³ Medical Device Cybersecurity Technical Evaluation Guidance Principle, CFDA, January 2017 ([Source](#))

¹⁴ Mobile Medical Device Registration Technical Evaluation Guidance Principle, CFDA, January 2018 ([Source](#))

¹⁵ Southern Daily Article, September 2018 ([Source](#))

products for testing.¹⁶ Its tests for AI medical devices are based on standard datasets it recently developed for diabetic retinopathy and pulmonary nodules, the former dataset having

only been completed in June 2018. The NIFDC is also working with 15 companies to develop a testing plan for pulmonary nodules.¹⁷

	Diabetic Retinopathy Standard Dataset	Pulmonary Nodules Standard Dataset
Number of Cases	6,372	623
Application (Diagnostic Decision)	Diabetic retinopathy stages Referral/ No need for referral Qualitative determination	Detection Classification Segmentation Sizing
Sub-Category Classification	a. 0-4 stage of diabetic retinopathy b. other oculi disease c. unidentified images	a. solid nodule b. part-solid nodule c. ground glass nodule d. solid/calcified pleural nodule
Source of Data	11 hospitals in 10 provinces	N/A
Medical Expert Validation	Marked by 15 medical experts selected from around the country	Marked by 20 experts selected from around the country, evaluated by 15 arbitration experts

Table of NIFDC's datasets used for AI medical device testing¹⁸

The Center for Medical Device Evaluation (CMDE) also formed an AI Working Group in 2017, which according to division director He Weigang has been tasked with creating a regulatory framework, including a clinical trial guideline and technical review guideline, for AI medical devices.¹⁹ The CMDE AI Working Group

is helping drive current discussions and plans for AI medical device guidelines, for example at the NMPA's recent conference on the application of AI in medical devices, co-hosted with the Chinese Society of Biomedical Engineering (see Appendix).²⁰

C. Medical Device Registration

Thus far, no Class III AI medical devices have been registered in China. It is expected that the first AI medical device will receive Class III approval in 2019, and that it will be a device produced by one of the 11 companies currently working with regulators on evaluation standards for Class III AI medical devices.²¹

Some Class II AI medical devices have been successfully registered in accordance with the newly effective 2017 *Medical Device Catalogue*. For example, on August 8, 2018, DNA Technology (点内科技) successfully obtained registration approval for its diagnostic image processing software from the Jiangxi Food and Drug Administration.²² Yet, since Class II devices may only have an

¹⁶ *ibid.*

¹⁷ VCBeat Article, September 2018 ([Source](#)). The 15 companies include JP Technology 健培科技, 12 Sigma 图兮深维, LinkDoc 零氟科技, YituTech 依图科技, Yunji Tech 云济科技, DeepWise 深睿医疗, Huiyiying 汇医慧影, InferVision 推想科技, QED Technique 雅森科技, DNA Biology 点内生物 and InsightMed 视见医.

¹⁸ *ibid.*

¹⁹ State Council article, July 2018 ([Source](#))

²⁰ NMPA announcement, August 2018 ([Source](#))

²¹ 21st Century Business Herald Article, August 2018 ([Source](#))

²² DNA Technology WeChat Post, August 2018 ([Source](#))

advisory/assistive role, this software device does not include advanced functions that could form the basis of a medical diagnosis. Due to the current tendency to classify AI devices as high-risk, many medical AI companies are reportedly planning to apply for Class II registration for their devices by reducing their AI components to meet the existing criteria for Class II devices and avoid being categorized as Class III.²³

Sun Lei, head of the CMDE, said in July 2018 that he **expects a large number of medical devices that employ deep learning to be filed for market approval in 2019** following

this year's flurry in investment and news headlines surrounding AI medical devices.²⁴ Yet, he also warned that there's still a long way to go for AI systems to be legitimately used in the country's healthcare system and emphasized that market approval usually takes at least a year.

Nevertheless, a number of **AI medical devices featuring deep learning are already being trialed in hospitals**. These are closely monitored by CMDE, which is in touch with the developers to keep track of their methodology, data collection and trial results ahead of their eventual application for market approval.²⁵

Looming Uncertainties

China's AI medical device industry is developing rapidly, boosted by ever-increasing government attention and enthusiastic industry investments. Opportunities abound as cutting-edge AI applications in medical devices are widely welcomed for their ability to address critical healthcare issues. Yet, industry players are still facing considerable bottlenecks as regulators try to catch up with the latest innovations and create the necessary regulatory framework to ensure the safety of AI-powered devices and software.

Recent activities by the NMPA, in particular the NIFDC, and the CMDE indicate that the beginnings of such a regulatory framework will be put in place very soon. But in the meantime, a lot of uncertainty remains regarding the commercialization process for AI medical devices and other related problem areas ranging from data sharing to legal liability issues:

Risk classification

The largest barrier standing in the way of widespread commercialization of AI medical devices at present is **the lack of unified industry standards and guidelines to evaluate and test the security of the devices ahead of market approval**. The approach of regulators to balancing the potential benefits against the risks of new AI medical devices will be crucial. Current evaluation guidelines strongly tend toward favoring the highest risk classification (Class III) for most devices that incorporate deep learning software. This conservative approach means that a large number of AI devices wait a long time to be approved, while some companies specifically tone down the diagnostics functions of their AI devices in order to try and qualify them as Class II devices.

Going forward, it will become **increasingly imperative for government bodies to work with industry players on defining what exactly constitutes "AI medical devices" and identifying plausible means to mitigate the risks associated with AI-powered diagnostic software**. A better understanding of the

²³ 21st Century Business Herald Article, August 2018 ([Source](#))

²⁴ State Council article, July 2018 ([Source](#))

²⁵ *ibid.*

practical risks of AI devices could lead to an expansion of the Class II category to include less risky diagnostic devices. One approach regulators could take to speed up the commercialization of crucial AI medical devices could be to **adopt a conditional approval mechanism for AI medical devices**. For example, extending the CMDE policy document principle²⁶ that allows for conditional approval of medical devices that are in clinical trials to include AI medical devices could help relieve this bottleneck.

Data sharing vs. data protection

Another major challenge for the development of AI medical devices is the availability and structure of data. Data sharing is essential to ensuring the wide (and safe) application of medical image-assisted diagnostic products. Datasets used to test the effectiveness and safety of AI products need to be fair, unbiased and drawn from a wide variety of hospitals and patients. **The development of robust datasets is currently limited due to underdeveloped resource sharing infrastructure between hospitals and the lack of standardized ways of structuring medical records.** The availability of such datasets determines the prospect of particular AI products. Regulators have taken some first steps to develop a better infrastructure for electronic medical records in hospitals²⁷ and standardize healthcare data sharing practices²⁸ across the country.

But at the same time, **the openness of data sharing will have to be balanced against the need to protect sensitive medical data.**

Under China's Cybersecurity Law and related implementation measures, a significant portion of data generated by medical devices may be subject to review and data localization requirements.²⁹ The NHC's recently issued trial regulations on the management of healthcare big data³⁰ re-emphasized that medical institutions must store healthcare data within China or apply for security evaluations should they transfer the data across China's borders. Such **cross-border data flow regulations and related provisions for "secure and controllable" data may hinder the development of datasets** or even create additional obstacles for the participation of foreign AI medical device players.

Ethical and legal liability issues

With the experimentation and commercialization of AI in medical decision-making, ethical concerns over letting algorithms decide complex disease diagnoses and treatment plans will inevitably increase. In addition, the problem of determining legal liability for injuries to patients may become another problem in the near future. International exchange and cooperation between regulators and industry could play an important role in defining China's approach to ethical and legal liability issues.

Foreign participation

It remains unclear to what extent China's overarching industrial goal of building an indigenous medical device sector may affect its openness to welcoming foreign AI medical device products into the market. The Chinese

²⁶ Basic Principles of Provisional Approval for Medical Devices in Urgent Clinical Needs (Draft for Public Comments, CMDE, April 2018 ([Source](#)))

²⁷ Notification on Promoting the Informatization of Medical Institution Through the Use of Electronic Medical Records, NHC, August 2018 ([Source](#))

²⁸ National Management Regulation for Healthcare Big Data Standards, Safety, and Services (Trial Version), NHC, September 2018 ([Source](#))

²⁹ Information Security Technology- Guidelines for Data Cross-Border Transfer Security Assessment (Draft), Standardization Administration of China, April 2017 ([Source](#))

³⁰ National Management Regulation for Healthcare Big Data Standards, Safety, and Services (Trial Version), NHC, September 2018 ([Source](#))

government's explicit designation of a "national champion" to lead the charge in efforts to commercialize AI-powered medical image assisted diagnosis is a clear sign of government intentions to build a support system that explicitly favors domestic companies.

Despite government intentions though, China's "national champion"-approach has a mixed record and even though Tencent has been pegged to become the market leader in AI-

assisted medical diagnosis, fierce competition among smaller companies and startups makes this far from a fait accompli.

While the Chinese AI medical device market currently shows no other clear signs of disadvantaging foreign players, in the future it may become important to encourage Chinese regulators to create an open environment for all players, regardless of nationality.

Appendix: AI Medtech Policy Database

Central level AI policies/documents

Policy/Event Name	Issuer	Policy/Event Summary	Link	Date
National level				
2017 Government Work Report 2017 年政府工作报告	State Council	First time AI is written into the annual government work report presented by Premier Li Keqiang at the National Party Congress: “We will accelerate R & D on and commercialization of new materials, new energy, artificial intelligence, integrated circuits, bio-pharmacy, 5G mobile communications, and other technologies, and develop industrial clusters in these fields.”	Xinhua link	Mar 5, 2017
Next Generation AI Development Plan 新一代人工智能发展规划	State Council	Blueprint for China’s AI development which lays out China’s ambitious goals for AI development: <ul style="list-style-type: none"> • By 2020, China’s AI core industry is to be worth 150 billion RMB • By 2025: China’s AI core industry is to be worth 400 billion RMB • By 2030: China’s AI core industry is to be worth 1 trillion RMB; and China is to become the world’s leading AI innovation center The plan highlights the application of innovative AI in healthcare to provide the public with “personalized, diversified, high-quality services.”: <ul style="list-style-type: none"> • Intelligent Medical Care: <ul style="list-style-type: none"> - Promote the use of new models and new methods of AI treatment, establish a rapid, accurate intelligent medical system. - Explore intelligent hospital construction, develop human-machine coordinated surgical robots and intelligent clinic assistants. - Pursue research and development on flexible wearable, biologically compatible physiological monitoring systems, research and development of human-computer collaboration intelligent clinical diagnosis and treatment programs. Achieve intelligent image recognition, pathology classification, and intelligent multi-disciplinary consultation. Intelligent Health and Elderly Care Systems:	State Council link	Jul 20, 2017

		<ul style="list-style-type: none"> - Strengthen community intelligent health management, achieve breakthroughs in big data analysis, Internet of Things, and other key technologies. - Research and develop health management wearable equipment and home intelligent health testing and monitoring equipment. - Promote changes in health management from point-like monitoring to continuous monitoring, from short process management to long process management. 		
<p>Three-Year Action Plan for Promoting Development of a Next Generation AI Industry (2018-2020)</p> <p>促进新一代人工智能产业发展三年行动计划（2018-2020 年）</p>	Ministry of Industry and Information Technology (MIIT)	<p>The Action Plan aims to promote the large-scale development of artificial intelligence (AI) in sectors including healthcare.</p> <p>The plan aims to develop auxiliary medical imaging diagnosis systems using artificial intelligence used in typical disease categories concerning the brain, lung, eyes, cardiovascular system, mammary glands, and bone diseases. By 2020, China aims to be able to diagnose more than 95% of the above typical disease categories using advance multi-model auxiliary medical imaging diagnosis systems.</p> <p>The plan also encourages the building of AI training resource databases to support advanced AI application in industries including healthcare.</p>	MIIT link	Dec 14, 2017
<p>2018 Government Work Report</p> <p>2018 年政府工作报告</p>	State Council	<p>Calls for the strengthening of next-generation AI R&D and application and promotes the advance of “Internet+” in many areas. Calls for the development of smart industries and an expansion of smart living, urging China to come closer to becoming a “country of innovators.”</p>	CPPCC link	Mar 22, 2018
<p>Artificial Intelligence Innovation Action Plan for Institutions of Higher Learning</p> <p>高等学校人工智能创新行动计划</p>	Ministry of Education (MOE)	<p>Calls for Chinese universities to become "core forces for the construction of major global AI innovation centers" by 2030</p>	MOE link	Apr 3, 2018

Healthcare policies/events related to AI

Policy/Event Name	Issuer	Policy/Event Summary	Link	Date
National level				
13th Five-Year Plan for Health and Health Science and Technology Innovation “十三五”卫生与健康科技创新专项规划	Ministry of Science and Technology (MOST)	A 13 th Five-Year Plan that promotes the acceleration of breakthrough technologies and applications to overcome key challenges in clinical diagnosis and treatment technologies: <ul style="list-style-type: none"> • Focuses on the development of medical artificial intelligence as well as precision medicine, early disease prediction, new detection and imaging technology and other cutting-edge technology research and development • Points out the specific direction for advancing the technological development of medical artificial intelligence, e.g. conducting research on medical big data analysis and machine learning. • Supports research on machine intelligence-assisted personalized diagnosis, precision treatment-assisted decision support system, assisted rehabilitation and care, and supports the development of smart medical care. 	MOST Link	May 16, 2017
Notification on Standards and Specifications for Nationwide Hospital Informatization (Trial Version) 关于印发全国医院信息化建设标准与规范（试行）的通知	National Health Commission (NHC)	A nationwide standard that sets mandatory standards for the informatization of Class II and above hospitals. It outlines the following details: <ul style="list-style-type: none"> • Requirements for software and hardware configuration, security measures, and new and emerging technology applications to serve clinical application and hospital management purposes. • Differential requirements for different levels of hospitals. • Tasks for the application of big data technology, cloud computing technology, artificial intelligence, and internet of things. 	NHC link	Apr 13, 2018
Notification on Carrying Out the Application of Innovative Projects Integrating Artificial Intelligence and the Needs of the Real Economy 关于开展 2018 年人工智能与实体经济深度融合创新项目申报工作的通知	Ministry of Industry and Information Technology (MIIT)	The Notification aims to select a group of projects that utilize Artificial Intelligence (AI) in sectors including healthcare . MIIT is collecting applications for AI projects with indigenous intellectual property including intelligent diagnosis systems for medical imaging and intelligent public service platforms for public healthcare services. Companies and research and development institutions can submit their applications by the end of May 2018. MIIT will release a catalogue of selected projects by the end of October 2018.	MIIT link	Apr 19, 2018

<p>Opinions on Promoting the Development of “Internet Plus Healthcare”</p> <p>国务院办公厅关于促进“互联网+医疗健康”发展的意见</p>	<p>State Council</p> <p>National Health Commission (NHC)</p>	<p>The Opinions call for increased use of information technology in medical services and public health services. The document stipulates the following means through which information technology can be incorporated into healthcare services:</p> <ul style="list-style-type: none"> • Support the development of internet hospitals affiliated to registered medical institutions. • Provide telemedicine services in primary level medical institutions with the support of artificial intelligence. • Develop clinical decision-making support system based on artificial intelligence technology. • Carry out mobile health monitoring pilots using smart medical devices. • Support the development of artificial intelligence healthcare technology, medical robots, large-scale medical devices, and emergency rescue devices. <p>On April 16, 2018, the National Health Commission (NHC) had hosted a press conference to introduce the then-upcoming Opinions on Promoting Development of “Internet Plus Healthcare,” which the State Council Executive Meeting approved in principle on April 12. At the time, details of the policy included:</p> <ul style="list-style-type: none"> • Allowing certified offline medical institutions to develop online subsidiaries providing telemedicine services. (NHC is currently in the process of drafting the scope of online diagnosis and treatment services and the standards to regulate them.) • Providing online family doctor services including health consultation, hospital transfer appointments, chronic illness follow-ups, and long-term prescriptions. • Utilizing the Internet to achieve remote medical insurance settlements. • Encouraging the development and application of new technology including artificial intelligence. 	<p>State Council link</p> <p>State Council Information Office link (Apr 16)</p>	<p>Apr 28, 2018</p>
<p>State Drug Administration Hosts First AHWP Technical Committee Meeting in Beijing</p> <p>亚洲医疗器械法规协调会（AHWP）2018 年第一次技术委员会会议在北京召开</p>	<p>State Drug Administration (SDA)</p> <p>China Association for Medical Devices Industry (CAMDI)</p>	<p>The SDA hosted the first technical committee meeting of the Asian Harmonization Working Party in Beijing in conjunction with the China Association for Medical Devices Industry (CAMDI). The committee discussed capacity building and the harmonization of regulations among its members in sectors including electronic labeling, in vitro diagnosis reagent supervision, post-market supervision, quality management system, and unique device identification. The meeting also discussed the use of frontier technologies in medical devices including artificial intelligence and 3D printing.</p>	<p>Official WeChat account of the National Medical Products Association (NMPA) link</p>	<p>May 11, 2018</p>
<p>Opinions on Promoting the High Quality Development of</p>	<p>National Health Commission (NHC)</p>	<p>The document outlines tasks to improve the quality of care in all areas. The opinions include the following measures:</p>	<p>NHC link</p>	<p>Aug 16, 2018</p>

<p>Medical Services Focusing on Protecting People's Health</p> <p>关于坚持以人民健康为中心推动医疗服务高质量发展的意见</p>		<ul style="list-style-type: none"> · Highlight the central role of medical staff in providing quality medical services. · Ensure that the salaries of medical staff reflect the technical value and intellectual property added according to their medical skills. · Promote the use of “internet plus healthcare” technology like AI and wearable equipment, and expand the use of digital medical records. · Implement an effective tiered medical system through collaboration between medical consortia, family doctors, general practitioners, and primary level medical institutions. · Build the capacity of county-level hospitals to increase the number of patients seeking consultation at the county level. · Reduce medical quality disparities between different regions, and among different levels of hospitals. 		
<p>Notification on Promoting the Informatization of Medical Institution Through the Use of Electronic Medical Records</p> <p>关于进一步推进以电子病历为核心的医疗机构信息化建设的通知</p>	<p>National Health Commission (NHC)</p>	<p>The document will ensure that at every diagnosis and treatment stage, Class III hospitals are connected through Electronic Medical Records (EMR). The notification highlights the need to protect information security and patient privacy when using EMR, requiring hospitals to store sensitive data such as patient information within China.</p> <p>The notification states that using EMR will help to achieve the following targets:</p> <ul style="list-style-type: none"> · Enhance capability to monitor diagnosis and treatment behavior of healthcare professionals. · Improve ability to control and evaluate medical service quality. · Facilitate the adoption of frontier technology including big data, cloud computing, blockchain, and robotics. · Encourage incorporating mature artificial intelligence technology into the EMR system to provide support to examination, pathological and imaging diagnosis, and assist clinical decision making. 	<p>NHC link</p>	<p>Aug 28, 2018</p>
<p>NMPA Hosts Conference on the Application of Artificial Intelligence in Medical Devices with the Chinese Society of Biomedical Engineering</p> <p>医疗器械创新与发展研讨会在京召开</p>	<p>National Medical Products Association (NMPA)</p> <p>Chinese Society of Biomedical Engineering</p>	<p>The NMPA jointly hosted a conference on the application of artificial intelligence (AI) in medical devices with the Chinese Society of Biomedical Engineering. The conference aimed to build consensus among regulators and academics on how to better regulate and manage AI in medical devices through discussions on the clinical applications of AI and the use of data and algorithms in AI medical devices.</p> <p>The AI Working Group established by the Center for Medical Device Evaluation was in attendance. Presenters included academic experts from Peking University, 301 Hospital, Chinese Academy of Sciences Institute of Automation, Peking Union Medical College Hospital, and the Chinese Academy of Sciences Shenzhen Institutes of Advanced Technology.</p>	<p>NMPA link</p>	<p>Aug 31, 2018</p>

<p>National Management Regulation for Healthcare Big Data Standards, Safety, and Services (Trial Version)</p> <p>国家健康医疗大数据标准、安全和服务管理办法（试行）</p>	<p>National Health Commission (NHC)</p>	<p>The trial regulation regulates the management and use of healthcare data generated in disease treatment, diagnosis, and health management processes. The NHC is in charge of supervising the standards, safety measures, and use of healthcare big data. Medical institutions and other relevant entities are mainly responsible for protecting data safety and privacy.</p> <p>The Regulation also requires medical institutions to store healthcare data on a secure server within China. Medical institutions need to apply for a security evaluation if they need to transfer the data across China's borders. The regulation also includes the following measures to manage healthcare data:</p> <ul style="list-style-type: none"> • The NHC will organize and supervise the drafting of healthcare big data standards. • The NHC will encourage medical institutions, research institutions, corporations, and industry associations to participate in the standard drafting process. • Medical institutions need to implement measures to protect the safety of healthcare big data, which includes data categorization, data backup, and data encryption. • Medical institutions need to ensure that key information infrastructure of healthcare big data is secure and controllable. • Medical institution need to strictly manage access to data and ensure traceability of data access. 	<p>NHC link</p>	<p>Sep 13, 2018</p>
<p>Management Regulation for Online Hospitals (Trial Version)</p> <p>互联网医院管理办法（试行）</p>	<p>National Health Commission (NHC)</p>	<p>The Regulation regulates the market entry qualifications and the operation of medical services provided by online hospitals. Medical institutions can set up online hospitals using their own registered physicians. Alternatively, they can partner with a third party to set up an online hospital to provide medical services using both their own physicians and physicians registered with other medical institutions. Online hospitals will be governed by the same regulations as regular medical institutions. The Regulation also includes a trial standard for online hospitals which includes requirements for services offered online, the personnel providing medical services, and infrastructure.</p>	<p>NHC link</p>	<p>Sep 14, 2018</p>
<p>Management Regulation for Telemedicine Services (Trial Version)</p> <p>远程医疗服务管理规范（试行）</p>	<p>National Health Commission (NHC)</p>	<p>The document regulates the basic personnel, equipment, and infrastructure requirements, as well as the operating procedures for telemedicine services. Telemedicine refers to both inter-hospital medial technical support and online medical consultations provided to patients. Platforms on which patients can seek consultations from physicians need to apply for approval as online hospitals. The regulation specified the procedure for conducting telemedicine, including patient consent, diagnosis decisions, and record keeping.</p>	<p>NHC link</p>	<p>Sep 14, 2018</p>

Regional level				
<p>Guangdong Province Action Plan to Promote “Internet Plus Healthcare” Development (2018 – 2020)</p> <p>广东省促进“互联网+医疗健康”发展行动计划（2018-2020 年）</p>	Guangdong Provincial Government	<p>In line with the State Council opinion on supporting the use of internet technology in healthcare, this Guangdong policy outlined specific targets, including the following:</p> <ul style="list-style-type: none"> • Build 56 county-level telemedicine medical imaging and electrocardiogram centers servicing county and community medical institutions by the end of 2019. • Ensure telemedicine services are available at all county-level medical institutions and community health service centers by 2020. • Reduce the percentage of emergency appointments at Class III hospitals. • Utilize the Internet of Things to carry out remote health monitoring. • Establish information connections between 20 provincial telemedicine centers and 56 county hospitals to provide telemedicine services by the end of 2018. • Expand the use of artificial intelligence in medical equipment to develop imaging, testing, diagnosis, and analysis equipment. • Ensure that county-level medical institutions and community health service centers have basic access to medical artificial intelligence technologies by 2020. <p><i>Analysis: Compared to the national policy, the Guangdong provincial policy includes more detailed goals to expand the use of internet technology at the primary level. The Guangdong government strategy will likely increase the demand for medical devices at the primary level, in particular for imaging devices, electrocardiographs, and mobile monitoring devices. The Guangdong government will also likely provide more support to the development of innovative medical devices that apply artificial intelligence technologies.</i></p>	NHC link	Jun 14, 2018
<p>Guangdong Province Action Plan for Deepening Integrated Public Hospital Reform</p> <p>广东省深化公立医院综合改革行动方案</p>	Guangdong Provincial Government	<p>The Action Plan outlines Guangdong’s reform tasks for the next two years. The plan aims to limit the growth of medical expenses to no more than 10% and to reduce individual healthcare cost contribution to less than 25%. Guangdong’s hospital reform will focus on a series of tasks including the following:</p> <ul style="list-style-type: none"> • Expand the use of domestically manufactured medical devices while encouraging public hospitals to set up application pilot centers for domestically manufactured devices. • Abolish medical consumable mark-ups by the end of 2018. • Support high-quality leading hospital development and create regional medical centers in the Pearl River Delta region. • Pilot an annual salary system for chief managers of public hospitals in Shenzhen, Zhuhai, Huizhou, and Dongguan in 2018, expanding the pilots to the rest of the province in 2019. 	Guangdong Government link	Jul 19, 2018

		<ul style="list-style-type: none"> • Allow the leading hospitals of a medical consortia to determine salary allocations for the rest of their consortium, while giving preferential treatment to general practitioners and public health doctors. • Build a province-wide public hospital health information platform and expand the use of electronic health records. • Expand the use of big data, cloud computing, internet of things, and artificial intelligence in public hospitals. 		
<p>Notification on Several Policies to Support Modern Medical Care and Medical Industry Development</p> <p>支持现代医疗和医药产业发展若干政策</p>	Anhui Provincial Government	<p>The document outlines the province's funding measures and policy incentives that support medical device innovation and the use of innovative technology in healthcare. The document incentivizes provincial regulators to:</p> <ul style="list-style-type: none"> • Draft an <i>Anhui Provincial Innovative Medical Device Catalogue</i> (安徽省创新型医疗器械产品目录) • Provide subsidies to products listed in the Anhui Catalogue that are worth around 10% of their market price and total no more than RMB 5 million (USD 728,194). • Provide support to projects that utilize innovative technology including smart healthcare, medical artificial intelligence, genetic testing, precision medicine, and medical big data, as part of the provincial new and emerging industry projects. • Set up a provincial investment fund to invest in the medical sector, including high-end medical devices. 	Anhui government link	Jul 18, 2018



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