RF Quarterly

Volume 1 • Number 2

Regulatory update for SaMD and AI product approvals in China

Hamish King, LLB, RAC

This article outlines the status of software as medical device regulation in China, with particular focus on medical software using artificial intelligence technology. The market approval pathways are reviewed, and key sticking points discussed. Recent regulatory updates in this fast-moving area are presented together with various product approval examples.

China's medical software regulatory framework

The term "medical device" is defined widely in China and will include many medical software products. The National Medical Product Administration, otherwise known as the NMPA, is China's medical products' regulator, including for medical software. The agency has taken various steps to develop a regulatory regime that responds to the unique complexities of regulating medical software products and particularly artificial intelligence (AI) medical products. For example, an online cooperation platform for furthering artificial intelligence medical devices[1] is managed by the NMPA and its technical review center, known as the Center for Medical Device Evaluation (CMDE). And, in March 2019, the NMPA established the AI Medical Device Standardization Unit, responsible for standardizing terminology, technology, and processes for development and quality assurance.

There has been an array of Chinese guidance issued in the last year relating to software as medical device (SaMD), including products using AI and machine learning (ML) technology. Following the early 2020 approval of the first AI product in China,[2] there has been a flurry of AI, ML, and SaMD product approvals in China. However, the regulatory landscape relating to SaMD, and specifically AI/ML products, is developing and fluid, and gaps remain.

The primary regulatory difficulties in China for AI and medical software products relate to their key strength – a rapid update cycle that can adapt or respond to data sets to evolve over time. That often conflicts with traditional regulatory frameworks that approve a product as safe and effective at a single point in time, requiring fresh approvals to any significant subsequent changes in the product. Another difficulty stems from the use of medical software on ubiquitous and relatively cheap mobile devices. That can lead to jurisdictional problems – such as whether mobile device functions should be considered within the software regulatory approval – and difficult questions about whether an application is a wellness function or not, with significant implications about whether it should be regulated as a medical device or not.

Software qualification

The threshold question when considering the regulatory approvals for selling Chinese medical software – including software using AI technology – is whether the product falls within the definition of medical device and is therefore regulated by the NMPA. The process of determining whether medical software is a medical device is known as software qualification.[3]

China is a member of the International Medical Regulators Forum (IMDRF) and the NMPA has members on the forum's AI medical device working committee.[4] SaMD is defined in IMDRF's N12 guidance as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[5] Although the NMPA has not adopted the N12 guidance, it is useful as a best practice guidance.[3]

NMPA's extensive classification catalog is the first step to determining whether medical software is regulated and what its relevant risk class will be: SaMD is allocated the code number 021.[6] Some example software categories are set out (see **Table 1**). The risk classes are defined as follows:

- Class I – Low risk
- Class II – Medium risk
- Class III – High risk

If a product does not readily fit within the parameters of the classification catalog, one may refer to the NMPA's rules for medical device classification document.[7] If it is still unclear, an application can be made directly to the NMPA, which takes 2-3 months.

For AI medical software, a recent draft guideline for classification has been released and public comment sought.[8] The draft specifies that, in medical-related fields, AI software can be roughly divided into four application directions according to its intended use:

- **Category 1 – Decision-support software**, used to assist medical decision-making, such as software for lesion identification and drug calculation;
- **Category 2 – Image/data processing software**, used for medical imaging and data processing, such as image segmentation and fusion, data calculation, and so on;
- **Category 3 – Analysis and data-mining products**, which involve the use of artificial intelligence algorithms to analyze and mine medical-related data and is expected to be used for software in drug

Table 1. Software categories in China's medical classification catalog[6a]

Software category	Example	Risk class
Treatment planning	Radiation therapy planning system software; radiotherapy contouring software; dental restoration design software, etc.	II/III
Image processing	Image archiving and transmission system software; endoscope graphic workstation software; digital ultrasound workstation software; CT image processing software, etc.	II
Data processing	Central monitoring management software; pregnancy hypertension syndrome monitoring software; ECG data management software, etc.	II
Decision support	Insulin injection calculation software; bone density computer-aided testing; computer-aided diagnosis software for lungs, ultrasound-aided diagnosis software for breasts, etc.	II / III
In vitro diagnostic	Chromosome analysis software; prenatal screening analysis software; Down syndrome prenatal screening analysis software, etc.	II
Rehabilitation training	Visual function training software for children with amblyopia; visual function inspection training software, etc.	II

[a]**Class I**, low risk; **Class II**, medium risk; **Class III**, high risk.

development, medical research, hospital nonmedical information management, and so on; and
- **Category 4 – Medical assistance products**, based on electronic medical records or patient main complaint information, in which natural language processing and other technologies are used to make logical inferences about a patient's disease conditions through published knowledge graphs and other forms of integrated data,[9] and are used only for nonmedical device purposes, such as hospital guidance and health consultation.

Categories 1 and 2 should be managed as medical devices, whereas categories 3 and 4 should, provided the software does not have a medical purpose, not be regulated as medical devices. This guideline, once implemented, will be an important development to support clarification of what AI products are regulated as medical devices in China. The draft guideline states that, in principle, medical software using AI technology is by default class III, because application is still in its infancy and clinical practical risks have not yet been fully evaluated.[8] However, the guideline also foreshadows that, as the regulator becomes more familiar with the technology, the risk class could be adjusted.[8]

Regulatory pathways

The approval pathways in China for medical software, including software using AI or ML, are substantially the same as for hardware or software/hardware combinations. Software that functions in conjunction with a physical medical device is called "software in medical device" or SiMD. It is reviewed together with the physical device in the NMPA approval processes and has the same risk classification as the hardware.

The China regulatory approval process takes 18 months from start to finish for risk class II products and 21 months for risk class III products in the author's experience. It also involves substantial registration and testing fees. One reason for the lengthy market approval process is that mandatory local testing is required for imported medical devices and in vitro diagnostic devices.

Local testing

Local testing requirements add further complexity for SaMD and particularly AI/ML products because there can be practical difficulties about what Chinese laboratories actually test.

The key document determining what will be tested in local testing is each product's product technical requirements (PTR). The PTR is annexed to the final NMPA certificate and is as important as the certificate. The PTR will often be requested by purchasers of the end-product.

The first draft of the PTR can be submitted to the local Chinese test lab for feedback and to allow the product to be imported exempt from customs duty, which can be as much as 20% of the product purchase price. Further revisions will be made following testing and submission to the NMPA.

In 2015, the NMPA issued guidelines outlining the testing requirements and submission documents.[10] An English translation of the software description document framework for that guideline is set out in **Table 2**. The submission requirements depend on the software safety level, which is different from the product's risk classification (although in practice, a class I product is likely to be of low risk and therefore, level A software). The software safety level is based on the severity of potential harm:[10]
- **Level A** – Not possible to cause any injury or harm;
- **Level B** – Possible to cause nonsevere harm or injury; and
- **Level C** – Possible to cause death or sever injury or harm.

Clinical trials and RWD-RWE

Furthermore, local clinical trials are by default mandatory for risk class II and III products.[11] Therefore, China requires clinical trials for risk class II and III SaMD, in addition to local testing unless:
- Applicants have sufficient overseas clinical data demonstrated, for example, in a multicenter clinical trial including full ethics approval; or

Table 2. Software description document framework[10]

Type of document	[Safety level[a]] Description	
Basic information		
Software identification	**A, B, C**	Defines product name, model and specification, revision number, manufacturer, and location
Safety level	**A, B, C**	Defines safety level, specify reasons for determination; original documents for levels B and C should be provided
Function and structure	**A, B, C**	Provides architecture diagrams and user interface diagrams (if applicable) in accordance with software design specification
Hardware topology	**A, B, C**	Based on physical topology, describes physical connection between software, computer, and medical device hardware
Operational environment	**A, B, C**	Explicit hardware configuration, software environment, and network conditions required for software operation
Application	**A, B, C**	Defines scope of application of software; describes country of origin of imported software
Contraindication	**A, B, C**	Clarifies contraindications or use restrictions of software, and describes country of origin of imported software
Registration history	**A, B, C**	Clarifies registration of software in China and country of origin
Implementation process		
Describe software development	**A, B, C**	Defines development language, tools, methods, as well as staff, time, workload, and code lines
Risk management	**A, B, C**	Provides risk management documents
Requirement specification	**A** **B, C**	Provides function and feature requirements Provides full text requirement specification
Lifecycle	**A** **B** **C**	Provides summary of development lifecycle plan Provides summary of development lifecycle, configuration management, and maintenance plans Provides summary of development lifecycle, configuration management, and maintenance plans, as well as design history document set index table
Validation and confirmation	**A** **B** **C**	Provides system test, user test plan, and report summary Summarizes verification activities of each development stage, provides plan and report of system test and user test Summarizes verification activities of each development stage; provides plan and report of system and user tests; and traceability analysis report
Defects management	**A** **B, C**	Describes defect management process and specifies total number of known defects and number of remaining defects Describes defect management process; defines total number of known defects and number of remaining defects; and lists known remaining defects
Update history	**A** **B** **C**	Specifies version naming rules and lists complete version, date, and type of previous software updates between current and previous registrations Specifies version naming rules and lists complete version, date, type, and specific update content of previous software updates between current and previous registrations Specifies version naming rules and lists complete version, date, type, and specific update content of previous software updates at time of previous registration, describe in detail changes in this revision vs earlier version
Clinical evaluation	**A, B, C**	Provide clinical evaluation data
Core algorithm		
Core algorithm	**A** **B, C**	Lists name, type, use, and clinical function of algorithm Recognizes mature algorithm; lists name, type, use, and clinical function of algorithm. New algorithm provides verification data of safety and effectiveness based on recognized mature algorithm.

[a]**Level A**, Not possible to cause any injury or harm; **Level B**, Possible to cause nonsevere harm or injury; **Level C**, Possible to cause death or severe injury or harm.

- They have detailed predicate device information of an NMPA-registered device to demonstrate substantial equivalence.

There are also some SaMDs that must provide clinical trial data to support their NMPA applications. That data may be obtained in clinical trials conducted outside of China, provided they are conducted in accordance with Chinese good clinical practice. Specifically, manufacturers of medical software using AI technology such as certain computer-aided detection, classification, and diagnosis functions, should support their product submissions with clinical trial data. A clinical trial can add 18 months or more to the regulatory approval timeline and cost hundreds of thousands of dollars, although timeline and cost are very product specific.

There are some promising recent developments relating to the NMPA's acceptance of real-world data and evidence (RWD and RWE), that is, data demonstrating function or use of the product in a clinical setting. In November 2020, the NMPA published a guideline on the use in medical device clinical evaluation (No. 77 of 2020),[12] following a consultation process begun with a draft guideline in December 2019.[13] An interpretation was also issued to explain key concepts.[14]

Although in trial version, the guideline has been implemented and permits applicants to draw on the RWE generated in their home country or other markets to reduce China clinical trial case numbers, thereby decreasing time and cost of a China clinical trial where required, or to do away with local China trials altogether for cases in which sufficient RWE has been gathered.

For AI and machine learning (ML) products specifically, NMPA issued a specific guideline in mid- 2019 on medical device software evaluation based on deep learning.[15] An agency presentation later that year further clarified the regulator's thinking on the topic.[16] For assisted decision-making software using deep learning, the NMPA stated it will use a risk-based method with increased emphasis on total lifecycle management.[16] Data collection and algorithm design will be closely scrutinised with clinical evaluation based on clinical trial. Data security – such as data anonymization, data backup and recovery, data interface, and interoperability – are also important factors for review. Additional product AI-ML product-specific guidelines are being considered to further clarify the position for manufacturers.

Other considerations for medical software

Cybersecurity

China's cybersecurity and personal information protection framework continues to develop, and this area is fast-changing from a regulatory perspective with numerous important potential further changes on the horizon.[17]

The key relevant regulation is the Cybersecurity Law of the People's Republic of China, which into effect on 1 June 2017.[18] A new civil code, effective 1 January 2021, expressly provides the right of privacy and personal information protection and is also relevant to medical software developers including of AI-ML products. A draft Personal Information Protection Law has also been issued to address data protection in a single law of general application.[17]

The cybersecurity law has a data localization requirement, so that critical data must be stored within China and not transmitted outside of China unless a security assessment is passed. Network operators, which would include hospitals, have specific obligations to monitor data leakage and loss of information. They also must seek consent for data collection of personal information.

In particular, genetic information is seen as highly sensitive, and must not be held by non-Chinese companies and is subject to close scrutiny by a special human genetics regulator.[19]

Networked software will require an additional self-assessment risk report regarding cybersecurity risks in the NMPA application.

Managing medical software update process

Medical software manufacturers have rapid development cycles, frequent changes to their software, and deliver updates by mass and rapid distribution. This poses specific challenges for registration frameworks, which are point-in-time. The difficulties are even greater for AI-ML products, which learn from the data with minimal human intervention (although it is often supplemented by human-in-the-loop interaction, which may mitigate some concerns). Therefore, product upgrade cycles need to be especially carefully managed for medical software products.

The solution adopted in China is to distinguish between minor and major software updates.[15] If the software update does not affect the safety or effectiveness of the product, such as text modifications of the user interface or bug fixes, then it will be considered a minor software update and managed through the quality management system. No notification to the NMPA is needed at the time of the change, although the agency will want to see certain documents at the product's next registration filing, such as a product change application or renewal application that includes a description of the software update, a regression test plan and report, and a description of new known remaining defects.

If the software changes affect the safety or effectiveness of the product, then it will be considered a major software update and trigger a requirement to submit a product-change application to the NMPA. Major software updates include adaptive software updates, such as a change in operating system, improvement software updates, and updates affecting users' clinical decision-making or personnel safety (including patients, users, and other related personnel).

If several types of software updates occur at the same time, the application materials should be submitted in accordance with the principle of higher risk, that is, if major software updates and minor software updates occur simultaneously, they will be handled as major software updates.

After the successful product-specific change, the NMPA does not issue a new certificate but a change note, which is to be used in combination with the original certificate, and the data in the NMPA database is updated. After the successful change, only the updated product can be sold in China.

For AI medical device software, major software updates are considered those affecting safety or efficacy of the software and will require a product change application submission.[15] If the software change does not affect safety or efficacy, it can be managed through the quality management system alone. If there are changes to the core algorithm, such as algorithm structure or flow, then it will be considered a major update. If there is a statistically significant change in algorithm performance, it will also be considered a major software update, but if there is no statistically significant change in algorithm performance, it will be considered only a minor update.

In addition, product version naming rules (often in the form X.Y.A.B.) should be carefully tracked because the NMPA will, in the author's experience, closely scrutinise version numbers against the version used in local testing. Total lifecycle management is also increasingly emphasized by the regulator as an ongoing requirement to track safety for users. This means medical software developers must develop a strong postmarket surveillance system.

Recent regulatory updates

The NMPA has issued numerous SaMD-relevant guidances recently (**Table 3**, p. 39). The regulatory changes have facilitated an increase in regulatory approvals of SaMD products. A selection of recent SaMD regulatory approvals by the NMPA is set out in **Table 4** (p. 39) extracted from the publicly available NMPA certificate database and translated from Chinese.[20]

About the author

Hamish King, LLB, RAC, is COO at Cisema, a contract research organization and turnkey regulatory affairs service provider for the Greater China market. He is currently based in Hong Kong where he specializes in NMPA registration of medical devices. King, admitted as a lawyer in New South Wales, Australia, and Hong Kong, was previously a solicitor with Magic Circle firm Linklaters and has 9 years' experience in the legal and regulatory fields. He graduated from the University of Sydney with BA honors degree and law degree. King has a close interest in the regulatory implications of digital healthcare and AI applications and is a member of RAPS (with RAC certification), APACMed, and a CFA Charterholder. He can be contacted at hamish.king@cisema.com.

Table 3. SaMD-relevant guidance issued by the NMPA[a]

Guidance	Date of issuance
Key points of medical device software evaluation based on deep learning https://www.cmde.org.cn/CL0030/19342.html	28 Jun 2019
Key points of software for CT-aided triage and evaluation of pneumonia (Trial) https://www.cmde.org.cn/CL0004/20526.html	05 Mar 2020
Guidelines for onsite inspection of independent software in medical device production quality management specification https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/gzwj/gzwjylqx/20200604162801601.html	04 Jun 2020
Guiding principles for technical review of medical device software (Draft for consultation of 2nd ed.) https://www.cmde.org.cn/CL0064/21039.html	05 Jun 2020
Draft guidelines for the technical review of medical device network security (2nd ed.) https://www.cmde.org.cn/CL0064/21612.html	8 Sep 2020
Guidelines for technical review of registration of CT-aided decision making software for pulmonary nodules https://www.cmde.org.cn/CL0004/22242.html	30 Dec 2020
Guidelines for technical review of registration of diagnostic software for diabetic retinopathy https://www.cmde.org.cn/CL0004/22242.html	31 Dec 2020
Key points of function evaluation of artificial intelligence software for image ultrasonic diagnostic equipment https://www.cmde.org.cn/CL0004/22243.html	31 Dec 2020
Guidelines for the classification of medical software products for artificial intelligence (Draft for comments) https://www.nifdc.org.cn/nifdc/bshff/ylqxbzhgl/qxzqyj/202104161101033302.html	16 Apr 2021

CT, computed tomography; **NMPA**, National Medical Product Administration; **SaMD**, software as a medical device.
[a]Guidelines are in Chinese only.

Table 4. Recent regulatory approvals of SaMD products by the NMPA[a]

Model name (description), registrant	Certificate date	(Class) Explanation
2021		
Sunkun AI (coronary artery CT images processing software) Yukun (Beijing) Network Tech.	23 Feb	**II.** For processing coronary artery CT images and displaying coronary artery calcification score.
iQMR-SW-P (MR images processing software) Medic Vision Imaging Solutions	18 Jan	**II.** For processing MRI images and improving signal-to-noise ratio of MRI images. Only for clinical reference.
2020		
Harmony (ophthalmology image management software Harmony) Topcon Healthcare Solutions	31 Dec	**II.** For reception, transmission, display, storage, measurement, and output of ophthalmic medical images and videos; and management of patient and diagnostic data, clinical information, and ophthalmic diagnostic instrument reports for clinical diagnosis and treatment.
myPKFiT for ADVATE (sparse sample PK profile and dosing software) Baxalta US	17 Nov	**III.** For hemophilia patients (>16 years; >45 kg). Individual coagulation factor FVIII PK parameter is estimated, based on coagulation factor VIII laboratory data and personal information, and preventive treatment (regular alternative treatment) dose calculated based on that parameter. Used by HCPs familiar with hemophilia treatment.[b]

Continued on next page

Table 4. *(continued)*

Model name (description), registrant	Certificate date	(Class) Explanation
2020		
Harmony (ophthalmology image management software Harmony) Topcon Healthcare Solutions	31 Dec	**II.** For reception, transmission, display, storage, measurement, and output of ophthalmic medical images and videos; and management of patient and diagnostic data, clinical information, and ophthalmic diagnostic instrument reports for clinical diagnosis and treatment.
myPKFiT for ADVATE (sparse sample PK profile and dosing software) Baxalta US	17 Nov	**III.** For hemophilia patients (>16 years; >45 kg). Individual coagulation factor FVIII PK parameter is estimated, based on coagulation factor VIII laboratory data and personal information, and preventive treatment (regular alternative treatment) dose calculated based on that parameter. Used by HCPs familiar with hemophilia treatment.[b]
InferRead CT Lung (CT-aided detection software for pulmonary nodules) Beijing Juixian Tech.	9 Nov	**III.** For display, processing, measurement, and analysis of chest CT images. Cannot be used as basis for clinical diagnosis and treatment decision making alone.
CoronaryView (coronary CT image processing software) Shanghai Xingmai Information Tech.	25 Sep	**II.** For importing, processing,[c] displaying, and basic editing operations, excluding auxiliary diagnostic functions.
MyoFlowQ-Lite (nuclear medicine heart image processing software) Beijing Bailingyun Biomedical Tech.	7 Sep	**II.** Used by nuclear medicine and submission doctors to display, process, archive, report, and transmit nuclear medicine heart images.
OsteoGram 2000 (bone densitometer) CompuMed, Inc.	7 Sep	**II.** For estimating bone mineral density and helping assess fracture risk and monitor bone mass changes.
AIDRscreening (diabetic retinal lesions eye image assisted diagnosis software) Shenzhen Siji Intelligent Tech.	7 Aug	**III.** For analysis of the colored eye image of adult diabetic patients, and to provide medical practitioners with supporting diagnostic recommendations for the visible retinal lesions of diabetes.
Mimics Medical (medical Image processing software) Materialise NV	15 Jun	**II.** Suitable for browsing, storage, transmission, display, and processing of medical images; not suitable for breast X-ray images.
HABMCMCN0003 (diagnostic support software) Hanalytics Pte Ltd	9 Jun	**III.** For displaying and processing MRI images. Based on analysis of T1WI, T2WI, and ce-t1wi MRI images, assists imaging doctors in classifying tumors[d] in children and patients >10 years.[e]
VSTP (medical and CT image processing software) Canon Medical Systems	15 Apr	**II.** For displaying, processing, and measuring CT, MR, and XA images.
syngo.CT Clinical Extensions (CT images analysis and processing software) Siemens Healthcare GmbH	30 Mar	**III.** For displaying, processing, measuring, and analysing CT images; vascular expansion function is used for display and measurement of vascular structure and lesions.
syngo.via View&GO (medical imaging processing software) Siemens Healthcare	12 Mar	**II.** Clinical function modules include patient information browsing; image viewing and tools.

MR, magnetic resonance; **CT**, computed tomography; **HCP**, healthcare provider; **XA**, x-ray angiography.

[a]Information from the publicly available NMPA certificate database; translated from Chinese. [b]Not suitable for patients with von Willebrand disease, who have produced FVIII neutralizing antibody (inhibitor). [c]Processing includes zooming; moving; four corner information; window adjustment; reset; calculating density value, length, and angle; deletion; coronary artery segmentation; manual editing of automatic segmentation results; automatic generation of mesh; and mesh cutting surface. [d]Includes gliomas, medulloblastomas, meningiomas, pituitary adenomas, acoustic neuromas, chordomas, and hemangioblastomas. [e]Gliomas, medulloblastomas, meningiomas, pituitary adenomas, acoustic neuromas, chordomas, and hemangioblastomas cannot be diagnosed on these results alone.

Disclaimer

This is content is not legal advice and should not be construed as such. Readers should seek specific advice relevant for their own situations.

Citation King H. Regulatory update for SaMD and AI product approvals in China. RF Quarterly. 2021;1(2):33-41.

References

1. [In Chinese] National Medical Products Administration and Centre for Medical Device Evaluation. Artificial Intelligent Medical Device Innovation and Cooperation Platform. http://www.aimd.org.cn/ Accessed 30 April 2021.
2. KeyaMedical website. DeepVessel FFR is approved for clinical use in China. https://www.keyamedical.com/deepvessel-ffr-approved-for-clinical-use-china/ Published 22 January 2020. Accessed 30 April 2021.
3. Asia-Pacific Medical Association Digital Health Committee Regulatory Working Group. Digital health regulation in Asia-Pacific: Overview and best practices. https://apacmed.org/digital-health-regulation-in-asia-pacific-overview-and-best-practices/ Dated 28 January 2021. Accessed 30 April 2021.
4. International Medical Device Regulators Forum. About IMDRF. http://www.imdrf.org/about/about.asp Not dated. Accessed 30 April 2021.
5. International Medical Device Regulators Forum, Software as a Medical Device (SaMD) Working Group. Software as a medical device: Possible framework for risk categorization and corresponding considerations. https://www.gmp-compliance.org/files/guidemgr/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf Dated 18 September 2014. Accessed 30 April 2021.
6. [In Chinese] National Medical Products Administration. List of classifications of medical devices. https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20170904150301406.html Dated 4 September 2017. Accessed 5 May 2021.
7. National Medical Products Administration. Rules for classification of medical devices. http://english.nmpa.gov.cn/2019-10/11/c_415411.htm Last updated 10 November 2019. Accessed 30 April 2021.
8. [In Chinese] Centre for Medical Device Standardization Administration, NMPA. Guidelines for the classification of medical software products for artificial intelligence (Draft for comments). https://www.nifdc.org.cn/nifdc/bshff/ylqxbzhgl/qxzqyj/20210416110103330 2.html . Dated 16 April 2021. Accessed 30 April 2021.
9. Ruan T, et al. QAnalysis: A question-answer driven analytic tool on knowledge graphs for leveraging electronic medical records for clinical research. https://bmcmedinformdecismak.biomedcentral.com/track/pdf/10.1186/s12911-019-0798-8.pdf Published 1 April 2019. Accessed 5 May 2021.
10. [In Chinese] National Medical Products Administration. Guidelines for technical review of medical device software registration (No. 50 of 2015).
11. https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20150805120001816.html Dated 5 August 2015. Accessed 30 April 2021.
12. King H. Initiating clinical trials in China: What foreign medtech companies need to do [updated]. RF Quarterly. March 2021;1(1):55-60.
13. [In Chinese] National Medical Products Administration. Technical guideline on real world data (RWD) used in medical device clinical evaluation (trial implementation) (No. 77 of 2020). https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20201126090030150.html Dated 26 November 2020. Accessed 30 April 2021.
14. [In Chinese] Center for Medical Device Evaluation, NMPA. Notice to publicly solicit opinions on the technical guidelines for clinical evaluation of real-world data for medical devices (Draft for Comments). https://www.cmde.org.cn/CL0101/20139.html Dated 13 December 2019. Accessed 30 April 2021.
15. [In Chinese] National Medical Products Administration. Interpretation of technical guidelines (trials) for the use of real-world data for clinical evaluation of medical devices. https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdylqx/20201130144911110.html Dated 11 November 2020. Accessed 30 April 2021.
16. 16 [In Chinese] Center for Medical Device Evaluation, NMPA. Key. points of medical device software evaluation using deep learning technology. https://www.cmde.org.cn/CL0030/19342.html Dated 28 June 2019. Accessed 30 April 2021.
17. PENG Liang, "Introduction to review points for decision-making medical device software using deep learning technology". Center for Medical Device Evaluation, NMPA. September 2019.
18. Luo D, Wang Y. China – Data protection overview. https://www.dataguidance.com/notes/china-data-protection-overview Dated November 2020. Accessed 30 April 2021.
19. [In Chinese] National People's Congress of PRC. Cybersecurity Law of the People's Republic of China. http://www.npc.gov.cn/wxzl/gongbao/2017-02/20/content_2007531.htm Dated 7 November 2016. Accessed 30 April 2021.
20. State Council of PRC. Regulations on management of human genetic resources. http://english.www.gov.cn/policies/latest_releases/2019/06/10/content_281476708945462.htms Updated 10 June 2019. Accessed 30 April 2021.
21. [In Chinese] National Medical Products Administration website. https://www.nmpa.gov.cn/ Accessed 5 May 2021.