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Legal Updates

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1. Top 10 Q&As on 2023 China Healthcare Anti-Corruption Initiatives

Authors: Aaron GU | Sophie SHI | Pengfei YOU | Duzhiyun ZHENG | Fengqi YU[1]

Recently, China's healthcare industry has been subject to a rigorous inspection and rectification initiatives focusing on anti-corruption. These initiatives have attracted widespread attention in the industry, and we have received numerous media and customer inquiries regarding such issues. Based on our observations, this round of anti-corruption initiatives is not short-term with respect to its duration or effect, but is intended to be an in-dept rectification project lasting for at least one year with inspections and enforcement to be carried out in a more regular manner at a later stage. The direct goal of these anti-corruption initiatives is to purge some entrenched, corrupt unlawful activities in China's healthcare industry, and the vision is to lead the industry towards healthier development. In response to the industry's various concerns, and in order to help the industry better understand the regulatory spirit and requirements and to assist companies in reassessing and planning their compliance plans, this article summarizes for our readers the key takeaways of this round of anti-corruption initiatives into "**10 Q&As**". (Please find the Chinese version of the 10 Q&As at the following link: 《*汉坤·观点 | 重磅：2023 年医药反腐热点"十问十答"*》.)

"Top 10 Questions" on the 2023 China healthcare industry anti-corruption initiatives:

1. What are the **background** and main **characteristics** of this round of anti-corruption initiatives in the healthcare industry?
2. What are the **regulatory focuses** on anti-corruption in the healthcare industry?
3. How should companies **react** to these anti-corruption initiatives?
4. What are the **legal consequences** for bribery?
5. What key compliance issues should **pre-IPO** healthcare companies pay attention to?
6. Is it still compliant to hold **academic conferences** in the medical field?
7. How can **medical representatives** conduct business activities compliantly?
8. What key compliance issues should companies be aware of when **interacting with industry associations and hospitals**?
9. What are the **causes** of and the **solutions** for corruption in the healthcare industry?
10. What are the **impacts on the industry** of this year's anti-corruption initiatives and the **suggestions to the companies for future development**?

[1] Shuwen Sun and Leyi Wang have contributions to this article.

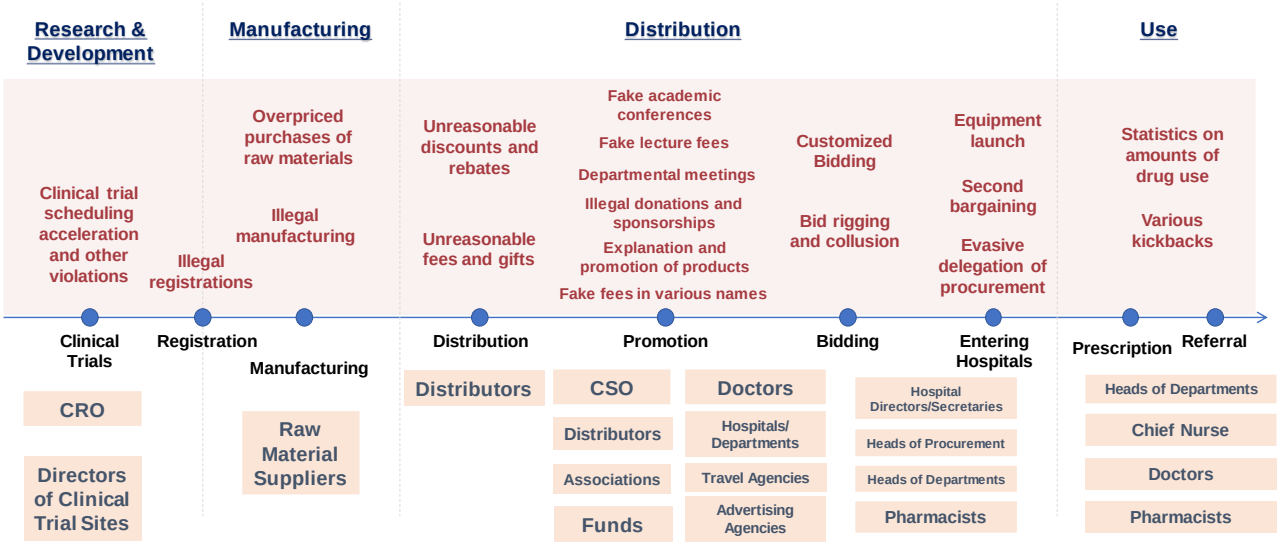
I. What are the background and main characteristics of this round of anti-corruption initiatives in the healthcare industry?

The healthcare industry has always been an industry subject to strict anti-corruption supervision and enforcement, and the determination shown this time is even greater than before. Based on our observations, the context of this round of anti-corruption initiatives are quite clear. At the beginning of 2023, President Xi Jinping emphasized at the second plenary session of the 20th Central Commission for Discipline Inspection (CCDI) that the situation of anti-corruption is severe and complicated, special rectification should be carried out on relatively prominent industry-specific and systemic corruption issues, forming a deterrent force that makes relevant subjects "dare not corrupt", a constraining force that makes relevant subjects "cannot corrupt", and an inspiring force that makes relevant subjects "not want to corrupt". Under the guidance of Xi Jinping's important speech, this round of anti-corruption initiatives in the healthcare industry is progressing in an orderly manner. On May 11, 14 national ministries and commissions jointly issued the *Key Points of Work on Rectifying Misconduct in the Fields of Medical Product Purchase and Distribution and Medical Services in 2023* ("***Key Work Points 2023***"), deploying the key issues for rectifying prominent corruption issues in the healthcare industry. On July 21, the National Health Commission held a video conference with nine ministries, including the Ministry of Education and the Ministry of Public Security, to deploy **a one-year-long nationwide concentrated rectification of corruption in the healthcare industry**. On July 28, the CCDI and the National Supervisory Commission (NSC) held a kickoff meeting to deploy the disciplinary and supervisory organs to coordinate the rectification work. According to the deployment, each province shall formulate local anti-corruption initiative plans and actively promote various concentrated rectification work.

In this round of anti-corruption initiatives in the healthcare industry, law enforcement has the following distinct characteristics, which deserve the attention of all types of industry participants. First, **the CCDI and the NSC** play an important role in this round of anti-corruption initiatives. Given that the CCDI and the NSC are relatively independent of the healthcare system in departmental status and functions, the involvement of the CCDI and the NSC and their cooperation in carrying out rectification work will expand the law enforcement capacity and enhance the effectiveness of law enforcement outside of key regulatory departments in the medical field, such as the National Health Commission. Second, the initiatives aim to achieve system-wide rectification **fully covering the healthcare industry**. The supervisory key issues of this round of anti-corruption initiatives cover the entire chain of manufacturing, distribution, sales, use, reimbursement in the healthcare industry, as well as regulatory departments, industry (academic) associations, health institutions, pharmaceutical and device companies ("**Healthcare Companies**"), and medical insurance funds. Third, this round of anti-corruption initiatives pays particular attention to **"key persons"** and **key positions**. While promoting the professional ethics of primary healthcare workers and other industry practitioners, this round of anti-corruption has focused on making critical breakthroughs on key issues involving the "key persons" and key positions, concentrating on investigating and closing a batch of corruption cases to make a noticeable impact. Fourth, this round of anti-corruption initiatives further clarifies the compliance requirements of the healthcare industry. For instance, the *Key Work Points 2023* require focusing on the supervision of various industry (academic) associations conducting activities related to the illegal transfer of benefits.

II. What are the regulatory focuses on anti-corruption in the healthcare industry?

The key issues of anti-corruption compliance in the healthcare industry cover the whole industry chain. We have summarized a corresponding compliance risk map as follows:



In addition, the *Key Work Points 2023* outline several key issues of supervision for the anti-corruption initiatives, which industry participants should pay attention to. The supervision key issues include but are not limited to the following:

- Improper intervention in **the administrative approvals** of the setting up of institutions, such as third-party medical examination institutions and aesthetic / dental institutions, and diagnosis and treatment subjects;
- **Industry (academic) associations** transfer improper benefits under the guise of academic conferences and donations;
- Healthcare companies, distributors, and medical representatives provide illicit benefits such as **kickbacks**;
- Medical institutions refuse or indirectly **refuse to implement centralized procurement results**;
- Doctors forcefully recommend third-party services such as **gene testing and external drug purchase**, illegally **take profits from prescriptions**, or improperly **refer patients**.

III. Question 3: How should companies react to these anti-corruption initiatives?

Despite the anti-corruption initiatives' focus on enforcement against "key persons" and key positions, we understand that healthcare companies remain key enforcement targets because, over the years, they continue to be major targets for inspection for wrongful practices with respect to the fields of medical services and medical procurement and sales. Therefore, we suggest companies proactively respond to these anti-corruption initiatives and actively realize compliance management in their business operations.

1. Company self-inspection

Firstly, companies can actively promote self-regulation and self-inspection to counter corruption and bribery. With law enforcement actions becoming more frequent and normalized, company compliance management becomes more critical in business operations. Hence, we suggest companies conduct compliance self-inspections, including but not limited to the following aspects:

- Spot and grasp risk points in projects and business models concerned in these initiatives in accordance with laws, regulations, and their existing internal control systems, which may help improve cooperation with and response to potential inspections and law enforcement;
- Recognize and take stop-loss actions against potentially non-compliant or high-risk businesses or projects. Companies should cease ongoing high-risk activities or projects in a timely manner and actively implement corrective measures; and
- Adjust and rectify business models with high compliance risks to avoid recurring non-compliance. This may assist in reducing future risks and losses.

Second, companies can actively conduct internal training against bribery and corruption. We suggest these trainings cover content and interpretation of relevant laws, regulations and policies of anti-corruption, anti-bribery, the relevant corporate internal control systems, as well as relevant "dos and don'ts" for employees in their daily business activities to avoid engaging in improper benefit transfers.

Third, companies can establish and improve internal control systems including relevant policies and standard operating procedures (**SOPs**). In addition to internal control documents regarding general business ethics and anti-corruption and anti-bribery requirements, companies also need to prepare separate standard procedures for certain sensitive daily business activities such as hospitality, interactions with healthcare professionals (**HCPs**), and holding or sponsoring academic conferences to prevent potential improper benefits transfer. Based on our experience, if the regulatory authorities uncover non-compliance during their inspections, they might examine the construction and execution of the company's internal compliance systems to determine whether such non-compliance stems from company-wide non-compliance or individual employees' wrongful behavior. Therefore, healthcare companies should also continually pay attention to key issues of anti-corruption and anti-bribery and improve corresponding policies and SOPs.

2. Cooperating with and responding to on-site investigations

We understand that regulatory authorities might conduct unexpected or unannounced on-site investigations on healthcare companies based on the leads or clues obtained regarding matters of anti-corruption and anti-bribery. If authorities carry out an on-site investigation, a company should:

- Arrange appropriate personnel to receive and courteously cooperate with the investigation carried out by the authorities;
- Provide the documents and information requested by the authorities without deliberately obstructing or destroying relevant materials;

- Answer the authorities' questions honestly, avoiding offering false or misleading responses as well as guesses or subjective conjecture;
- Arrange or hire specialized internal or external counsels to assist cooperating with and responding to the investigation and handle subsequent follow-ups.

3. Compliance in daily business operations

From a long-term perspective, with the deepening of the anti-corruption initiatives by the authorities, the anti-corruption regulation and enforcement on healthcare companies will become more "systematic, standardized, and normalized". The authorities will have more concrete and stricter requirements for the compliance management of healthcare companies. Therefore, healthcare companies should also adapt to the trend of tightening the compliance management, actively review and adjust their business models, daily business processes and employee behaviors, and ensure that the activities of the companies and employees comply with relevant laws, regulations, and internal control requirements.

IV. What are the legal consequences for bribery?

Bribery is an unlawful and even criminal act explicitly prohibited by Chinese law. Anti-corruption and anti-bribery are compliance baselines that all individuals and entities including companies and public institutions in the healthcare industry must abide by. Engaging in bribery not only could potentially trigger administrative liabilities, but if the thresholds for criminal charges are met, it could also trigger more severe criminal liabilities.

As for administrative liabilities, the authorities can investigate and penalize healthcare companies' bribery in the procurement and sales of drugs in accordance with the *Drug Administration Law.* Also, they could investigate healthcare companies' bribery behaviors in accordance with the *Anti-Unfair Competition Law*. The specifics are as follows:

Laws and Regulations	Wrongful Acts	Legal Consequences
Drug Administration Law Article 88 and Article 141	Giving monies or other improper benefits to person(s)-in-charge of medical institutions, drug procurement staff, physicians, pharmacists etc.	Include **confiscating illegal proceeds**, imposing **a fine of RMB 300,000 to 3 million**, **revoking qualifications**, and imposing a **lifetime ban on responsible personnel**.
Anti-Unfair Competition Law Article 7 and Article 19	Using bribes or other means to bribe employees of the counterparty, units or individuals entrusted to handle affairs, units, or individuals with authority or influence, to seek trading opportunities or competitive advantages.	Include **confiscating illegal proceeds**, **imposing a fine of RMB 100,000 to 3 million**, and **revoking business licenses**.

In terms of criminal liability, corporate bribery can potentially constitute different crimes depending on the

targets of the bribery. If court determines that the company engaged in criminal bribery, the corresponding criminal liability would include imposing a fine on the company; the directly responsible individual in charge of the company and other directly responsible individuals may be sentenced to fixed-term imprisonment or detention of not more than ten years, and imposed fines, etc. The crimes related to corporate bribery are as follows:

Bribery Target	Entity Crime	Individual Crime
State Functionaries, including but not limited to the authority and law enforcement officers, some public hospital doctors	A393 Crime of Offering Bribes by an Entity	A389 Crime of Offering Bribes
Close relatives or closely related individuals of (retired) State Functionaries	A390 Crime of Offering Bribes to Influential People	A390 Crime of Offering Bribes to Influential People
Entities, including public institutions (such as public hospitals) and state-owned companies	A391 Crime of Offering Bribes to an Entity	A391 Crime of Offering Bribes to an Entity
Employees of the distributors and other business partners	A164 Crime of Offering Bribes to Non-state Functionary	A164 Crime of Offering Bribes to Non-state Functionary

V. What key compliance issues should pre-IPO healthcare companies pay attention to?

Recently, the Shanghai Stock Exchange ("**SSE**") and the Beijing Stock Exchange ("**BSE**") respectively released their highlights on the regulatory compliance of sales and promotional activities carried out by pre-IPO healthcare companies. The stock exchanges emphasized the duty of intermediaries to verify key issues and to supervise issuers' full disclosure, thereby demonstrating their focus on compliance of sales and promotion activities of pre-IPO healthcare companies.

Stock Exchange	Major Aspects	Key Review Items
SSE	Compliance of Promotional Activities	■ Whether the promotional service provider has a valid business qualification and whether medical representatives have registered on the designated filing platform of the NMPA in accordance with the *Measures for the Filing Management of Medical Representatives (For Trial Implementation) ("**Trial Measures**")*.
		■ Whether the issuer, controlling shareholders, and actual controllers engage in commercial bribery or disguised benefit transfers through promotional activities.
	Authenticity and Completeness of Expenses Incurred in	■ Whether the frequency, number of participants, fee standards, and per capita expenses associated with promotional activities such as academic conferences,

Stock Exchange	Major Aspects	Key Review Items
	Promotional Activities	exhibitions, customer visits, and research consultations are reasonable, and whether the promotional service fees differ significantly from those charged by peer companies.
		■ Whether the issuer strictly follows the payment, settlement and reimbursement processes, and whether the various invoices and related supporting documents issued and obtained during the promotional activities are genuine, complete, and valid.
		■ Whether the issuer uses promotional activities to increase sales revenue by directly or indirectly channeling funds to customers.
	Effectiveness of Internal Control Systems Related to Promotional Activities	■ In cases where a third party is engaged in promotional functions, whether the issuer has established selection criteria for promotional service providers, and whether the design and implementation of related pricing mechanisms, assessment mechanisms, settlement mechanisms, and terminal sales management systems are sound and effective, and whether the division of responsibilities between the third party and the issuer's sales department is clear.
		■ In cases where the issuer conducts promotional activities itself, whether the issuer's approval and management measures for various promotional activities are standardized and effective, and whether the requirements for key sales personnel, salary levels, and fund flow are reasonable.
	Fairness of Related Transactions between Distributors, Promotional Service Providers, and the Issuer and its Affiliates	■ The time of incorporation, main services provided, cooperation history with the issuer, whether the distributor or promotional service provider exclusively serves the issuer, and whether there are abnormal changes in sales scale.
		■ Whether there are any related-party relationships between the distributor or promotional service provider and the issuer, its major affiliates, or former employees, whether the pricing of related transactions is fair, and whether there are abnormal fund flows or benefit transfers between the distributor or promotional service provider and the issuer or its major affiliates.
BSE	Soundness and Effectiveness of Internal Control Systems	■ Whether the issuer has sound and effective systems in place regarding the selection criteria, approval processes, service content, fee standards, and fee payment of distributors, and whether there are significant flaws in the design and implementation of anti-commercial bribery

Stock Exchange	Major Aspects	Key Review Items
	Authenticity and Reasonableness of Abnormal Promotional Business Occurrences Effective Supervision on Abnormal Fund Flows through Fund Flow Verification Sufficient Records of External Evidence	systems, as well as any instances of funds being misappropriated through illegal means.
		■ Conduct on-site visits to abnormal distributors, such as those established by related parties and former employees, as well as distributors of major service issuers, to assess their qualifications for academic promotion, their ability to fulfill contracts, and the commercial reasonableness behind their business relationship with the issuer.
		■ Examine the fund flows between the issuer and its controlling shareholders, actual controllers, directors, supervisors, major sales personnel, and other major related parties, as well as the fund flows between abnormal distributors and the issuer's clients and other suppliers, and identify any abnormal behaviors such as large cash withdrawals in the fund flows of relevant entities.
		■ Obtain evidence from end customers and relevant entities through external confirmations and interviews regarding the occurrence of commercial bribery, and conduct public channel inquiries to determine whether the issuer has been involved in obtaining customer orders through commercial bribery.

In addition, in February, the Shenzhen Stock Exchange ("**SZSE**") issued the *Report on The Supervision of Commercial Bribery-Related Issues of Healthcare companies Listed on SZSE*. The report listed certain major types of commercial bribery occur in the healthcare industry and mentioned the issue of high sales expenses for some listed healthcare companies. Over recent years, the stock exchanges have attached much importance to the compliance of the sales model and market promotion during the IPO review of pre-IPO healthcare companies. Not only should healthcare companies disclose information according to the rules, but the stock exchanges may also require intermediaries to look into and issue opinions on the legality and compliance of public tendering projects, commercial bribery and unlawful benefit transfers, and the implementation of internal control systems. The highlights released this time reiterate that, for pre-IPO healthcare companies, anti-corruption and anti-bribery have become a focus during IPO reviews, including the legality and compliance of sales promotion activities, the authenticity of expenditures, the effectiveness of internal control systems, the affiliated relationships, and fairness in transactions. The highlights issued not only clarify the key review issues of the stock exchanges for the sales and promotional activities of the pre-IPO healthcare companies but also provided guidance for their daily operational compliance. It also re-emphasizes the importance the securities regulatory authorities attach to anti-corruption and anti-bribery issues of healthcare companies.

VI. Is it still compliant to hold academic conferences in the medical field?

In the recent anti-corruption initiatives, the compliance requirements for medical academic conferences

have sparked significant industry-wide concerns. Amidst the upheavals of the initiatives, a number of medical academic conferences were either canceled or postponed, further raising concerns within the industry about the permissible space for medical academic conferences. In fact, **the compliance concerns surrounding medical academic conferences is indeed a key aspect of the ongoing anti-corruption initiatives**. For instance, the *Key Work Points 2023* explicitly propose the rectification of misconduct within industry associations and emphasizes the necessity of regulating various levels and types of industry associations that indirectly channel improper benefits under the guise of academic conferences. In the past, some healthcare companies often chose to collaborate with industry associations by co-hosting or sponsoring academic events held by them, for the purpose of serving as a protective "firewall" against potential corruption risks hidden behind such academic activities. The *Key Work Points 2023* pierces the veil of non-compliant academic conferences held by industry associations and highlights the great importance that regulatory authorities have attached to the corruption issues associated with academic conferences.

However, China's anti-corruption initiatives are directed towards penalizing illegal actions where improper benefits are funneled under the guise of academic conferences, rather than disrupting the organization of compliant academic activities. In fact, according to the *Notice on Further Strengthening the Regulation of Forum Activities*, jointly released by the State Administration for Market Regulation and nine other departments on August 7, and the *Questions and Answers on the Concentrated Rectification of Corruption in the Medical Field Nationwide*, issued by the Medical Emergency Administration Department of the National Health Commission on August 15, it can be observed that **regulatory authorities have consistently maintained a positive and affirmative stance towards the industry's compliant hosting of academic conferences**. Academic conferences serve as an excellent platform for efficiently gathering clinical experience and academic technical resources. They facilitate the exchange of medical professional knowledge, contribute to the professional growth of healthcare industry practitioners, and propel the advancement of medical science and technology. Hence, within the framework of legal regulations, healthcare companies, healthcare professionals, and various industry associations can certainly participate in, organize, and sponsor medical academic conferences as required.

In light of the new regulatory enforcement trends, companies should pay more attention to the compliance requirements associated with academic conferences, abandon any mentality of relying on luck or taking chances and, instead, proactively prevent bribery disguised as academic conferences. Regarding the compliance requirements of academic conferences, while laws and regulations have not outlined explicit standards, drawing from industry practices and our experience, the compliance management of academic conferences should encompass various aspects, including the **conference's objectives, lecture contents, speaker qualifications, audience qualifications, conference venues, catering arrangements, and lecture fee standards**. In our practice, we have also assisted many clients in formulating robust compliance management systems, which include reasonable lecture fee payment standards aligned with fair market value. These compliance standards can provide valuable insights into a company's internal compliance management as well as regulatory authorities' enforcement actions.

VII. How can medical representatives conduct business activities compliantly?

Medical representatives are professionals who represent drug marketing authorization holders (MAH) tasked with engaging in the conveyance, communication, and feedback of medical information within China[2]. Controversies surrounding medical representatives have been consistent and substantial due to the fact that, in the past, a significant number of medical representatives in China engaged in illegal activities such as "bribery-driven sales" and "providing kickbacks", failing to genuinely fulfill their responsibilities of communicating and conveying medical information. Since the implementation of the *Trial Measures* in December 2020, China's administration of medical representatives has transitioned towards a more standardized approach. However, based on our observations, the practical implementation of the *Trial Measures* has exhibited certain limitations. Under the new regulatory trend, we believe that **the regulatory requirements outlined in the *Trial Measures* will be implemented more effectively in the future**. Additionally, at present, the *Trial Measures* solely cover the administration of medical representatives who represent drug MAHs. We understand that the relevant regulatory framework may be further improved in the future to encompass the regulatory needs of medical representatives who represent medical device MAHs. According to the *Trial Measures*, the scope of compliant and non-compliant business activities conducted by medical representatives is as follows:

<table>
<tr><th colspan="2">Compliant Business Activities</th><th>Non-compliant Business Activities</th></tr>
<tr><td>Content</td><td>■ Drafting promotional plans and strategies for medical products;
■ Conveying related information of medical products to healthcare professionals;
■ Assisting healthcare professionals in the rational use of the company's medical products;
■ Collecting and conveying information on the drug clinical use and hospitals' needs.</td><td rowspan="2">■ Conducting academic promotion and other activities without filing;
■ Conducting academic promotion and other activities without the permission of the medical institution;
■ Undertaking medical sales tasks, such as collection, and handling sales-related documents;
■ Participating in the statistical count of drug prescriptions issued by doctors;
■ Providing donations, funding, and sponsorship directly to internal departments or individuals within medical institutions;
■ Misleading doctors in the use of drugs, exaggerating or misleading the effectiveness of drugs, hiding known drug adverse event information, or concealing adverse event information responded by doctors;
■ Other behaviors that interfere with or influence the rational clinical use of drugs.</td></tr>
<tr><td>Form</td><td>■ Communicating with healthcare professionals and medical staff directly at medical institutions;
■ Holding academic conferences and lectures;
■ Providing academic materials;
■ Communicating through internet or teleconferences;
■ Other forms permitted by the medical institution.</td></tr>
</table>

Furthermore, regulatory documents, including the *National Action Plan for Combating Corruption in*

[2] Article 2 of the *Administrative Measures for Filing of Medical representatives (for Trial Implementation)*.

Practices of Medical Institutions and Their Employees (2021 – 2024), stipulate that medical institutions should enhance their reception system for medical representatives, implementing the "three determinations and three existences" ("determined time, place and personnel", "the existence of appointment, procedure and record") approach to establish well-developed regulations. Medical institutions shall promptly remove individuals who enter into diagnosis and treatment areas in violation of regulations, and thoroughly investigate kickback issues within the institution.

Under the new regulatory enforcement trend, medical representatives should practice diligent compliance, closely following and adhering to the regulatory and compliance requirements in laws and regulations as well as internal management systems established by medical institutions. They need to transition from a **"product sales-oriented" approach back to a more orthodox "academic-profession-oriented" approach**, strictly adhere to filing, appointment reception, and other management requirements, eliminate any improper benefit transmission and conduct business activities in full compliance.

VIII. What key compliance issues should companies be aware of when interacting with industry associations and hospitals?

Regarding the interactions with industry associations. As we mentioned above, the *Key Work Points 2023* have pierced the veil and have explicitly emphasized the regulatory focus on non-compliant academic conferences held by industry associations. Therefore, healthcare companies should eliminate any misconception that industry associations may serve as a "firewall" or "white gloves" for improper benefit transmission. They should truly understand that academic activities are considered lawful and compliant only in the absence of any improper benefit transmission. In the future, when carrying out academic activities in cooperation with industry associations, companies should pay closer attention to the compliance requirements and consider implementing, for example, the following measures: (1) incorporating **anti-corruption and anti-bribery clauses** in cooperation agreements; (2) stipulating in advance that the company has **audit rights and other supervision and inspection rights** in respect of the conference in cooperation agreements; (3) **inspecting and supervising** the fulfillment of agreements and the authenticity, legality, and compliance of funds usage; (4) **taking proactive actions** in case any misconduct is identified during the conference, such as refusing to reimburse non-compliant activity expenses, terminating the agreement with the cooperating association, and blacklisting such association.

Regarding the interactions with hospitals. On the one hand, under the new regulatory enforcement trend, most hospitals will strengthen internal compliance management, and may refine and actively implement compliance management systems such as reception systems for medical representatives, drug purchase / admission procedures, and physician business management protocols. In response, healthcare companies should **proactively understand and cooperate with the hospital's corresponding management requirements**. Companies should also effectively **implement the requirements of their established compliance management system** during their interaction with the hospitals, encompassing a variety of aspects including but not limited to the requirements for gifts, visits, academic expenses, and communications. For example, when gifts are offered to healthcare professionals, the gifts should have a legitimate purpose and comply with all applicable regulations, policies, and rules, be presented transparently and openly, and with strict control over their nature, value, and frequency.

IX. What are the causes of and the solutions for corruption in the healthcare industry?

Corruption in the healthcare industry is a complex issue with multiple causes. On the one hand, medical and healthcare institutions and HCPs have much influence over prescriptions, treatment decisions, and the use of medical insurance funds, thereby holding significant influence over medical product purchase and distribution transactions. However, subject to various factors, the **base salaries of most HCPs are relatively low**, making it difficult for medical and healthcare institutions and HCPs to resist the lure of kickbacks, bribery, and profiteering. On the other hand, to **seek transaction opportunities and competitive advantage**, some healthcare companies tend to obtain admissions of their products into hospitals via kickbacks and bribery to heads of hospitals and HCPs. The wide-range practice of bribery has made it increasingly difficult for healthcare companies to compete solely based on the merit of safety, effectiveness, and innovation of their products, therefore has resulted in a negative impact on the healthcare industry. Also, such bad practices may cause the scenario of "**bad money drives out good**" in the healthcare industry, where non-compliant companies gradually squeeze compliant companies out of the market without bearing much risk of accountability and penalties. Such practices have also caused **the expenses of sales promotion and thereby price of drugs or medical devices to surge** dramatically.

Unlike anti-bribery and anti-corruption law enforcement in previous years, the current anti-corruption initiatives lay more emphasis on **"key persons" and key positions** in the healthcare industry. The regulatory authorities have focused on cracking down corruption both on the bribers, typically targeting healthcare companies, and especially on bribees, including the heads of hospitals and HCPs. This disruption of the existing benefit structure will address and alleviate a variety of issues:

- **Rooting out corruption in the healthcare industry.** By conducting law enforcement actions against medical and healthcare institutions, HCPs, and healthcare companies simultaneously, the regulatory authorities intend to weed out wrongdoing among both bribers and bribees and avoid pursuing a piecemeal approach. The regulatory authorities have also launched a sweeping drive with stronger enforcement and penalties than ever to deter non-compliant companies, medical and healthcare institutions, and HCPs from engaging in misconduct.

- **Restoring a fair market environment for medical product purchase and distribution transactions.** Eradicating bribery in the healthcare industry may allow the standard for product admission to hospitals to be refocused on the products' inherent effectiveness and safety. This is also to rebuild a relatively fair market competition environment to benefit compliant healthcare companies.

- **Reduce sales and promotion expenses.** According to the publicly disclosed financial reports of some listed healthcare companies, the proportion of sales and promotion expenses to the total expenses of many healthcare companies has exceeded 50%, which has aroused much concern from regulatory authorities. The crackdown of corruption and bribery may lead to changes in the methods of sales and promotion; therefore, such high proportions of sales and promotion expenses may no longer be necessary. The reduction of sales and promotion expenses may eventually reduce the total costs of products and contribute to a lower pricing of products, thus benefiting patients and serving the public good.

However, the intensive enforcement may solely focus on corruption itself and may not directly provide a rather feasible solution to the underlying causes of such corruption. So, in addition to the anti-corruption initiatives, policies and new measures are also necessary and may be carried out for resolving income issues of medical and healthcare institutions and HCPs, including but not limited to:

- **Encourage salary reform for HCPs.** In order to enhance income opportunities for HCPs, besides raising base salaries, it may also be feasible to encourage HCPs to earn legal and reasonable compensation through multi-site practices or other permissible practices.
- **Establish medical service fee standards scientifically.** Patients increasingly demand better medical services and, with such high incentives, cutting-edge medical technology has been developing rapidly. However, it is evident that the authorities' efficiency in adjusting the pricing of medical service fees can hardly keep pace with the development of medical technology, resulting in **hardly commensurate pricing for cutting-edge medical services** under the existing pricing system. Therefore, it would be practical to carry out a new standard to adjust the medical service fees that can promote fair pricing to align with the advancement of medical technology.
- **Encourage income (e.g., lecture fees) with fair market value.** Resulting from the initiatives, entities like hospitals and their departments, academic associations, and healthcare companies have suspended or terminated academic conferences where HCPs may be invited or may provide lectures or host a forum, in fear of compliance risks. The regulatory authorities explicitly state in the recently released *Questions and Answers on the Concentrated Rectification of Corruption in the Medical Field Nationwide* that they will continue to **actively encourage academic conferences and normal medical activities** in the healthcare industry. We understand that the HCPs, when engaged in serving academic lectures and courses, are somehow using their own knowledge and expertise and should be compensated for their lectures and courses as long as they meet fair market value. **Reasonable, fair, and legal compensation** for the labor of HCPs should still be **encouraged and advocated** and should not be banned completely for the slight possibility of becoming a channel for corruption and bribery.

X. What are the impacts on the industry of this year's anti-corruption initiatives and the suggestions for companies for their future development?

This one-year anti-corruption initiatives will have a far-reaching impact on the healthcare industry and the future business operations of healthcare companies. For the healthcare industry, with stricter anti-corruption and anti-bribery enforcement actions in the future, **a fairer market competition environment** may be restored for the medical product purchase and distribution transactions. Healthcare companies with stronger scientific research capabilities and products with better safety and effectiveness will more easily gain the favor of the market and admissions to hospitals. Meanwhile, diversified demands for medical technology from different patients may also promote the development of **commercial insurance** and **private hospitals**, thereby **establishing a new pattern of a healthcare security system that meets diverse level of medical demands**.

Healthcare companies may also face several significant changes in the future development of their

business operations:

- The compliance of healthcare companies in **conducting sales and promotional activities** is getting increasingly important. With the systematization, standardization, and normalization of anti-corruption and anti-bribery law enforcement actions, as well as the possible penalties for violating anti-corruption regulations becoming more severe, the compliance of healthcare companies will become a crucial foundation for their future business operations. Healthcare companies need to ensure their business models and sales activities of their personnel steer clear of legal risks like commercial bribery; also, the establishment and improvement of internal control and compliance systems will contribute to steady and healthy development of companies in the future.

- Medical representatives will focus more on **academic promotion** when conducting business activities. The initiatives is rigorously cracking down on methods of being admitted into hospitals through bribery and kickbacks. Consequently, representatives will invest more resources into **promoting medical knowledge** concerning the products and **educating target groups of patients** through various methods. This legitimate approach to academic promotion will benefit the popularization of medical knowledge.

- **Company development plans and budget plans** will be adjusted accordingly. The prohibition of commercial bribery of hospitals and HCPs may gradually lower unnecessary sales and promotion expenses and save funds in two aspects. Firstly, to obtain hospital admissions in a fair market competition environment, healthcare companies can **increase their investment in research and innovation** and obtain market recognition through safer and more effective products, which will also contribute to the development of more high-quality innovative drugs. Secondly, the decrease in sales expenses may **create space for lower product prices**. Such reduction of prices will eventually benefit patients and promote public welfare.

Conclusion

The healthcare industry is an integral component of the national economy and plays a crucial role in public health. This round of anti-corruption initiatives is expected to tackle underlying corruption issues in the entire industry and throughout its supply chain. This endeavor will be beneficial to enable fair competition amongst players in the market, promote healthy development of the healthcare industry, and improve public access to better medical services.

For each healthcare industry practitioner, this anti-corruption initiatives serve both as a challenge and a significant opportunity to gain a competitive edge based on the safety and effectiveness of their products, innovations in technology, and their commitment to internal compliance system development. It is our heartfelt wish that every dedicated participant in the healthcare industry may experience further growth in this fresh and more transparent industry environment.

2. China DCT Regulation and Implementation[3]

Authors: Aaron GU | Pengfei YOU | Duzhiyun ZHENG | Fengqi YU[4]

The concept of "patient-centered" has become the core guiding principle in current research and development ("**R&D**") of drugs. "Patient-centered" drug R&D refers to the process of drug discovery, design, implementation and decision-making based on the patient's point of view, with the aim of efficiently developing clinically valuable drugs that better meet the needs of patients. Decentralized Clinical Trials ("**DCT**") are a new type of clinical trial that embodies the "patient-centered" concept, providing new solutions and motivation for drug R&D activities for marketing registration purposes. According to the *latest Technical Guidelines for the Implementation of Patient-Centered Drug Clinical Trials (for Trial Implementation)* ("*Technical Guidelines for Implementation")* released by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**") on July 27, 2023, DCT refers to a new patient-centered clinical trial model, the implementation of which is not limited to the traditional on-site clinical trials. In simple terms, usually, DCT would be conducted using telemedicine as well as mobile or local medical care, allowing clinical trials to take place remotely while the subjects can remain at home.

Compared with traditional on-site clinical trials, DCT has several advantages. For instance, it significantly reduces the burden on the subjects, enabling them to participate even if they cannot visit the site in person. It also enhances the representativeness of the subjects and breaks the traditional limitations on the frequency of subject visits, thus gathering more comprehensive clinical data. Furthermore, DCT may reduce the errors caused by human intervention or data transcription, thus improving the quality of clinical trials. However, due to uncertainties such as the complexity of the new processes and technology operations, the practice of DCT may also present challenges such as the uniformity of clinical trial evaluation standards, data integrity, comparability of results, and operational standardization, etc.

DCT has already been practiced in some Western countries. As early as June 2011, Pfizer announced its first "virtual" clinical trial, aiming at conducting the first-ever randomized clinical trial under an investigational new drug ("**IND**") application that manages study participation entirely using electronic tools and allows patients to participate in the clinical trial regardless of their proximity to clinical sites[5]. The outbreak of the COVID-19 pandemic in early 2020 posed significant challenges to global drug clinical trials, but it also accelerated the rapid development of DCT. To address issues related to the conduction of clinical trials during the pandemic, the US Food and Drug Administration ("**FDA**") released the *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards* in March 2020, providing regulatory guidance for issues such as electronic signatures and remote monitoring in the conduction of DCT. Recently, the FDA also issued a draft guidance titled Decentralized Clinical Trials for Drugs, Biological Products, and Devices,

[3] For the Chinese version, please click 《*汉坤 • 观点 | 中国DCT(去中心化临床试验)的实施与监管*》.

[4] Leyi Wang and Shuwen Sun have contributions to this article.

[5] See *Pfizer Conducts First "Virtual" Clinical Trial Allowing Patients to Participate Regardless Of Geography*, https://www.pfizer.com/news/press-release/press-release-detail/pfizer_conducts_first_virtual_clinical_trial_allowing_patients_to_participate_regardless_of_geography.

which specifically focused on the compliance issues for implementing DCT. Moreover, some countries and regions such as the European Union, Canada, Denmark, and Sweden have also issued DCT-related guidance documents.

In China, although the practices are not yet abundant, the industry has been actively exploring the implementation of DCT in recent years. For example, in 2022, an expert consensus on the conduction of remote intelligent clinical trials was released to provide references for exploring DCT compliance in China. The development of DCT has also received support from regulatory authorities. In recent years, regions such as Beijing have been continuously encouraging DCT pilot projects in various policies. On July 27, 2023, after nearly a year of solicitation of public opinions, CDE formally released the three documents: Technical Guidelines for the Design of Patient-Centered Drug Clinical Trials (for Trial Implementation), Technical Guidelines for the Implementation of Patient-Centered Drug Clinical Trials (for Trial Implementation), and Technical Guidelines for the Benefit-Risk Assessment of Patient-Centered Drug Clinical Trials (for Trial Implementation). Among them, the Technical Guidelines for Implementation have provided crucial guidance for DCT compliance in China. Compared with its previous draft for public comments, the formally adopted Technical Guidelines for Implementation have more explicitly reflected the regulatory authorities' embracing openness while maintaining cautious supervision regarding the practice of DCT. It emphasizes that new models such as DCT may be adopted subject to evaluation by the sponsors, investigators, and clinical trial sites, and that such new models and new methods should be pre-set in the protocols and shall comply with regulations such as the Good Clinical Practice ("**GCP**") and shall be approved by ethics committees. New models and new methods shall not be blindly pursued without exploring their rationality, necessity, and feasibility.

To facilitate the recognition and management of legal risks in the implementation of DCT, the following section will, based on the Technical Guidelines for Implementation and other regulations closely related to clinical trials, explore and discuss the compliance and regulatory issues for conducting DCT in China. The key points cover various aspects including responsibilities of sponsors and investigators, electronic informed consent, telemedicine, drug distribution, privacy and personal information protection, and handling of safety incidents.

Responsibilities of sponsors and investigators

As a specific form of clinical trial, DCT shall, first and foremost, comply with a series of basic laws and regulations governing clinical trials, such as the *Drug Administration Law*, *Measures for the Administration of Drug Registration*, and the *GCP*. The *Technical Guidelines for Implementation* also emphasize that the *GCP*, the guidelines from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**"), and other relevant guidelines shall be followed. It highlights that clinical trials shall strictly follow relevant laws, regulations, the *GCP*, and ethical requirements. Therefore, in the process of DCT, the sponsors, the investigators, and other key participants shall strictly abide by their respective responsibilities under the above-mentioned laws and regulations.

As the primary responsible party in clinical trials, the sponsors should conduct a comprehensive and thorough evaluation of the design and operation of the clinical trials and should establish a sound quality management system. As the ultimate responsible party for the quality and reliability of clinical trial data

in drug registration, the sponsors should also pay attention to key issues such as the formulation of the protocols, the qualification and supervision of vendors, and the establishment of sound standard operating procedures ("**SOPs**"), to ensure the smooth conduct of the clinical trials and the successful progress of drug registration.

On the other hand, the investigators are responsible for the quality of the clinical trial and the rights and interests of the subjects. They should establish corresponding SOPs and quality management systems for the conduct of DCT and make contingency plans for potential challenges during the DCT process, such as handling safety incidents and addressing data transmission failures.

Electronic informed consent

Informed consent is an essential measure to safeguard the rights of the subjects and a prerequisite for their participation in clinical trials. In previous practice, sites and investigators usually would introduce and discuss the project face-to-face with the subjects and obtain handwritten informed consent from them. However, with the development of DCT, electronic informed consent may achieve broader application. The *Technical Guidelines for Implementation* explicitly state that electronic informed consent may be considered for clinical trials.

When implementing electronic informed consent, attention should be paid to the following matters. Firstly, regarding the effectiveness of electronic signatures, according to the *Electronic Signature Law*, electronic signatures are only recognized as legally effective and equivalent to handwritten signatures or seals when they meet certain criteria such as data exclusivity and controllability, and being capable of detecting changes in the electronic documents. To ensure the effectiveness of electronic informed consent, it is recommended to seek certification of the signature's validity from qualified electronic certification service providers. Secondly, the way of implementing electronic informed consent is crucial. By using multimedia resources, electronic informed consent has advantages in introducing the clinical trial information to the subjects in a way that is easier to accept. However, it may also raise the barrier for communicating with the subjects. Therefore, the T*echnical Guidelines for Implementation* emphasize that the investigators shall focus on real-time communication with the subjects and shall ensure the subjects' full understanding of the content under remote conditions. They can also provide assistance or offer traditional methods to the subjects who are not familiar with or unable to use electronic informed consent. In addition, the implementation of electronic informed consent shall also comply with the *GCP*, the *Personal Information Protection Law* and other regulatory requirements while adapting to the characteristics of DCT. Therefore, special attention should be paid to fully informing the subjects about the instruction on the digital medical technologies and other new technical methods used in the clinical trial, the scope of data collection, the risks and benefits from the clinical trial, the access and scope of use of the subjects' data, and other relevant information.

Telemedicine activity

Clinical drug trials are built upon diagnosis and treatment activities, which are also carried out between the research site, the investigators and the subjects (who are also medical institutions, doctors and patients). During the implementation of DCT, investigators may conduct research through a combination of

telemedicine and in-person visits. Consequently, these telemedicine activities shall also comply with regulations related to diagnosis and treatment, such as the *Administrative Measures for Internet-based Diagnosis and Treatment (for Trial Implementation)*, the *Administrative Measures for Internet Hospitals (for Trial Implementation)*, and the *Supervision Rules for Internet-based Diagnosis and Treatment (for Trial Implementation)*.

The key points of regulation for telemedicine activity include site qualifications, applicable scope of internet-based diagnosis and treatment, and quality control of diagnosis and treatment activities, among other aspects. For instance, in the process of conducting telemedicine activities for clinical trials, it is essential that the diagnosis and treatment activity are always provided directly by the doctors themselves, without delegation to artificial intelligence technology or clinical research coordinators ("**CRC**"). In recent years, the practice of CRC performing some responsibilities on behalf of doctors has led to increased risks in certain clinical trial projects, drawing attention from the industry and regulatory authorities. During the implementation of DCT, it is crucial to emphasize the doctors' responsibility and ensure the compliance of CRC involvement in the research. Additionally, the administration of online prescriptions must be stringent, prescriptions shall only be issued by the doctors and become effective after approval by pharmacists. Under no circumstances should any prescription drug be provided before the prescription is issued.

Drug delivery

With the development of DCT, the delivery of drugs for clinical trials will undergo more flexible changes. The *Technical Guidelines for Implementation* stipulate that, considering factors like drug safety and subjects' medication adherence, certain drugs can be directly delivered to the patient (Direct to Patient, DTP) in combination with some home visits (if necessary). To ensure the safety of subjects and the quality of the trial, the following key points should be considered:

- **Determine delivery methods based on specific characteristics of drugs.** When considering whether to adopt DTP, factors such as drug safety characteristics, storage conditions, routes of administration, and geographical locations of subjects should be carefully evaluated to control risks during drug delivery and usage. For example, drugs that require intravenous infusion or interventions by physicians are generally not recommended for DTP. On the other hand, drugs that are administered orally or self-administered, with a longer shelf life and can be stored at room temperature may be suitable for DTP.

- **Strengthen sites and investigators' responsibilities for drug administration.** According to *GCP*, investigators and clinical trial sites are always responsible for drug administration during the clinical trial. Changes in the clinical trial models should not lead to relaxed administration requirements for sites and investigators. Instead, they should reinforce drug administration practices by engaging qualified third-party drug distributors, providing subject training, conducting necessary home visits, devising appropriate plans for safety events, closely monitoring safety events, actively following up on drug usage by subjects, and strictly regulating the return of unused investigational drugs.

- **Strengthen the whole process of drug safety control.** Comply with or refer to the provisions of

the *Good Supply Practice* ("**GSP**"), the *Good Manufacturing Practice Appendix for Investigational Drugs*, *GCP* and other regulations related to investigational drugs and reference drugs for clinical trials. Ensure drug safety throughout the entire process of drug delivery and storage, including delivering the drugs to the subjects and storing them in the subjects' homes. Additionally, ensure that participants return any leftover drugs from the trials in a proper manner.

- **Conduct subject training.** In DCT, the significance of subjects is emphasized, and providing them with training is a crucial aspect of ensuring drug safety and maintaining the quality of clinical trials. Investigators should offer comprehensive training to subjects, covering various aspects such as drug usage methods, drug storage requirements, and countermeasures for safety events. Additionally, when providing drug guidance to subjects, investigators shall also adhere to the requirements stipulated in the trial protocol, such as implementing blinding studies.

Privacy and personal information protection

In recent years, privacy and personal information protection have emerged as significant concerns for regulatory authorities, which the industry shall pay significant attention to throughout the process of conducting DCT. This becomes particularly crucial in DCT when incorporating innovative technologies, methods, and models for collecting, storing, and processing subjects' personal information. The T*echnical Guidelines for Implementation* stress the significance of following privacy and personal information protection requirements throughout the entire process of DCT, which includes subject recruitment, trial data collection, drug delivery, data monitoring, and subject injury compensation. This shall be achieved through the compliant obtaining of informed consent, management of raw data, preservation data and data retrospectivity, data de-identification processing, administration of data access permission, and other approaches.

For example, the implementation of DCT may involve the use of innovative artificial intelligence technologies and devices for information collection, potentially involving various participants such as digital device suppliers. Therefore, when obtaining informed consent from subjects, investigators must thoroughly inform them about the privacy and personal information risks related to the use of digital technologies. This includes providing subjects with comprehensive information about the scope and methods of using the trial data and other personal information, whether the data will be shared or reused, and the corresponding measures for confidentiality. Additionally, investigators should pay special attention to regulatory requirements regarding data exports, sensitive personal information, and important data.

Safety data monitoring and reporting

To ensure subject safety in DCT, timely monitoring and reporting of safety data are essential. The *Technical Guidelines for Implementation* recommend prioritizing the use of digital technology platforms to monitor and report subjects' safety data in real time. This can be achieved through methods such as subjects' smartphone apps, remote visit platforms, or wearable devices to collect subjects' safety data and directly transmit it to investigators.

To prevent delays in data viewing and processing during remote monitoring, the guidelines emphasize the need for a robust mechanism to handle safety data. Investigators should consider factors such as the characteristics of the investigational drug and team resources to set appropriate frequencies for viewing and processing safety data. Furthermore, investigators should inform subjects beforehand about specific circumstances in which they may contact investigators directly through phone calls or other means in case of safety events. The data monitoring platform should also have a well-developed mechanism for promptly processing severe adverse events.

Communication and training

The *Technical Guidelines for Implementation* also outline certain specific requirements for communication and training among research participants. Since DCT involves the adoption of various innovative technologies and models, practices in this area are continuously evolving and being explored. Compared to more mature traditional on-site clinical trials, effective communication among research participants becomes even more crucial in addressing challenges during DCT implementation.

Firstly, sponsors, investigators, and other parties should strengthen communication with trial subjects, especially when employing remote methods like remote visits, timely and effective communication will greatly help in understanding their needs, building a trusting relationship, and facilitating the implementation of DCT. Secondly, communication between sponsors, investigators, and contract research organizations ("**CROs**") should also be enhanced to promptly stay updated on the trials' progress, make necessary adjustments in a timely manner, and ensure the smooth implementation of DCT. Additionally, research teams should communicate with regulatory authorities in a timely manner, especially when using new technologies and models. Sponsors should provide detailed explanations regarding the necessity, scientific rationale, and feasibility of incorporating certain new elements into the DCT in the clinical trial protocol. This should include basic information about the new elements, the purpose and scenarios of their use, evaluation and validation data, comparison trial data with traditional methods, risk assessment and mitigation measures, and other relevant details.

In addition, training for investigators and subjects is also essential for the successful implementation of DCT. Sponsors and investigators should provide comprehensive training to research staff on the methods of use, precautions, potential risks, and countermeasures for the various new technologies. This ensures that the trial is conducted properly and safely. Moreover, providing trial subjects with sufficient training will help them better understand the various new technologies and methods in DCT. It will also raise their awareness of potential risks and precautionary measures, enhance their adherence, and safeguard their rights and safety.

Conclusion

With the development of telemedicine and digital technology, the industry is actively exploring DCT, gaining increasing recognition and support from regulatory authorities. DCT is expected to provide trial subjects with improved research experiences, promote greater representativeness and diversity of clinical trial data, elevate the quality of clinical trials, and provide new avenues and impetus for innovative drug development. Despite the promising potential of DCT, it still encounters several challenges that need to be addressed

before it can become a dependable alternative to traditional on-site clinical trials. Areas requiring further experience and verification include participant responsibility, effective control of safety risks, proper administration of investigational drugs, and privacy and information protection.

The issuance of the *Technical Guidelines for Implementation* and other relevant documents indicate that regulatory authorities have attached great importance to the adoption and innovation of the "patient-centered" approach in drug development. It also demonstrates the regulatory authorities' proactive exploration of DCT supervision. The industry should pay attention to the *Technical Guidelines for Implementation* and other applicable regulatory requirements to effectively identify and control legal risks throughout the DCT process. We eagerly look forward to collaborative efforts between regulatory authorities and the industry to drive the successful implementation and advancement of DCT in China.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

If you have any questions regarding this publication, please contact:

Beijing	**Wenyu JIN**	**Attorney-at-law**
	Tel:	+86 10 8525 5557
	Email:	wenyu.jin@hankunlaw.com
Shanghai	**Yinshi CAO**	**Attorney-at-law**
	Tel:	+86 21 6080 0980
	Email:	yinshi.cao@hankunlaw.com
Shenzhen	**Jason WANG**	**Attorney-at-law**
	Tel:	+86 755 3680 6518
	Email:	jason.wang@hankunlaw.com
Hong Kong	**Dafei CHEN**	**Attorney-at-law**
	Tel:	+852 2820 5616
	Email:	dafei.chen@hankunlaw.com
Haikou	**Jun ZHU**	**Attorney-at-law**
	Tel:	+86 898 3665 5000
	Email:	jun.zhu@hankunlaw.com
Wuhan	**Jiao MA**	**Attorney-at-law**
	Tel:	+86 27 5937 6200
	Email:	jiao.ma@hankunlaw.com
Singapore	**Lan YU**	**Attorney-at-law**
	Tel:	+65 6013 2966
	Email:	lan.yu@hankunlaw.com