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Key Takeaways from China's Regulation on the Administration of Human Genetic Resources
《人类遗传资源管理条例》要点解读

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Life Sciences

On June 10, 2019, the State Council (China's chief executive agency) promulgated the long-awaited Regulation on the Administration of Human Genetic Resources (the "**Regulation**"), which will become effective on July 1, 2019. The Regulation supersedes the currently effective regulations and guidance on human genetic resources ("HGR").
2019 年 6 月 10 日，国务院颁布了业界期待已久的《人类遗传资源管理条例》（下称"**条例**"），该条例将于 2019 年 7 月 1 日生效，并取代有关人类遗传资源的现行法规和指南。

China issued its first regulation on HGR, the Interim Measures for Management of Human Genetic Resources in 1998 (the "**Interim Measures**"), which generally applies to international collaborations that involve the sampling, collection, research, development, trading, export and exit of HGR in China. Like the Regulation, the Interim Measures provided that "Foreign Parties" may not collect or use HGR in China on their own. Instead, these parties must enter into an international collaboration with a Chinese party to collect and utilize HGR. The Ministry of Science and Technology ("**MOST**") must approve the international collaboration.
中国于 1998 年颁布了首部有关人类遗传资源的法规《人类遗传资源管理暂行办法》（下称"**暂行办法**"），该法规广泛适用于涉及中国人类遗传资源的采集、收集、研究、开发、买卖、出口、出境。与条例类似，暂行办法不允许"外方"自行收集或使用中国人类遗传资源，而是要求这些外方与中方合作单位开展国际合作项目以采集并使用人类遗传资源。中国科学技术部（"**科技部**"）须对国际合作项目进行审批。

These requirements did not figure prominently into drug and medical device regulation regime in China for many years, until 2015 when MOST issued a Guideline on HGR that expanded the applicability of the Interim Measures to cover, among other areas, clinical trials that support drug and medical device marketing applications.
上述要求在许多年内都未显著被囊括在中国药品和医疗器械的法规体系中。直至 2015 年，科技部发布了一份有关人类遗传资源的服务指南，扩大了暂行办法的适用范围至更多事项，其中包括了为获得药品和医疗器械上市许可的临床试验。

Since that time, MOST has played a significant role in clinical trial regulation in China. According to statistics disclosed by MOST's Office of Human Genetic Resource Administration ("**OHGRA**"), which is responsible for HGR approvals, 85.7% and 7.8% of the 2,385 projects approved in 2018 were clinical trials intended to support marketing approval

of drugs and medical devices respectively. Therefore, it is not surprising that the Regulation focuses more on clinical trial regulation than the Interim Measures.
自彼时起，科技部在中国的临床试验管理中扮演了重要的角色。根据科技部下属人类遗传资源管理办公室（负责人类遗传资源审批，下称**“遗传办”**）披露的数据，在 2018 年获批的 2,385 个项目中，旨在支持药品和医疗器械上市许可的临床试验分别占 85.7% 和 7.8%。因此，条例相较暂行办法给予临床试验管理更多关注并不令人意外。

This note discusses and analyzes some initial takeaways of the Regulation, as well as the potential impact on drug and medical device companies conducting clinical trials in China. While there are still questions that need to be addressed in implementing regulations, the Regulation includes a number of important changes that are highlighted below.
本文将就条例的要点及其对在中国进行临床试验的药品和医疗器械公司的潜在影响进行讨论并做初步分析。虽然仍有些问题需要在实施细则中予以解答，下文将简述条例的一些重要变化。

Definition of Human Genetic Resources
人类遗传资源的定义

The Regulation adopts a definition of HGR that is similar to the one in the Interim Measures, but the Regulation further divides the definition into two components: the biological samples themselves (“**HGR Materials**”) and the associated data (“**HGR Information**”).
条例采纳了与暂行办法中的人类遗传资源相似的定义，但进一步将该定义分成了两部分：生物样本本身（**“人类遗传资源材料”**），及其相关数据（**“人类遗传资源信息”**）。

HGR Materials refers to genetic materials, such as organs, tissues or cells, which contain the human genome, genes and their products, and HGR Information refers to genetic information or data generated by using the HGR Materials.
人类遗传资源材料是指含有人体基因组、基因等遗传物质的器官、组织或细胞等遗传材料，人类遗传资源信息是指利用人类遗传资源材料产生的数据等信息资料。

Expanded Definition of Foreign Parties
外方定义的扩大

The Regulation officially adopts current practice and expands the definition of Foreign Parties by incorporating OHGRA’s broad interpretation that HGR requirements apply to both onshore or offshore entities established by foreign entities and individuals. Furthermore, the Regulation adds the concept of “actual control,” and deems foreign individuals and entities established or actually controlled by foreign entities or individuals to be Foreign Parties. In other words, not only all foreign-invested enterprises in China, but also domestic companies actually controlled by foreign shareholders (through a VIE structure, for example) could be considered Foreign Parties under the Regulation.
条例正式采纳了目前的实践并根据遗传办的扩张解释扩大了外方的定义，即人类遗传资源规定适用于外国组织和个人设立的境内或境外机构。此外，条例还增加了“实际控制”的概念，并将外国个人及外国组织或个人设立或者实际控制的机构均视为外方。换言之，不仅在中国的所有外商投资企业，被外国股东实际控制（例如通过 VIE 结构）的国内企业也可能被视为条例项下的外方。

Broader Regulation of Sampling and Biobanking
就采集和保藏的进一步规定

China has expanded the scope of the Regulation to cover not only the use and provision of HGR to Foreign Parties through international collaborations, but also specific requirements on the areas of the sampling and biobanking.
条例的适用范围有所扩大，不仅包括在国际合作项目中利用和对外提供人类遗传资源，还涵盖了对采集和保藏的具体要求。

The Regulation now prohibits Foreign Parties from independently sampling or biobanking any China HGR in China, and it adds an approval requirement for the sampling of certain HGR and biobanking of all HGR by Chinese parties. These restrictions appear to follow prior enforcement in this area. In 2018, MOST penalized a foreign-invested contract research organization for engaging in unapproved biobanking activities. Although the Interim Measures also contain the requirement of informed consent, the Regulation emphasizes it by, among other things, requiring the sampling party to obtain the written consent from the provider of HGR with a full, complete, true, accurate, non-misleading notice.
条例禁止外方在中国自行采集或保藏任何中国人类遗传资源，并对中方采集某些特定人类遗传资源和保藏所有人类遗传资源添加了审批要求。这些限制似乎呼应了之前在该领域的执法行动。科技部于 2018 年处罚了一家外资合同研究组织从事的未经批准的保藏活动。尽管暂行办法同样包含了知情同意的要求，条例对此予以强调，如要求采集方在取得人类遗传资源提供者的书面同意时的告知须全面、完整、真实、准确，不得误导。

The Regulation is not clear as to whether biobanking includes short-term storage of samples of laboratory testing. According to the statistics disclosed by the OHGRA, 78% of the 6.807 million samples from the 694 clinical trials conducted in China in 2018 were tested by foreign laboratories or foreign-invested laboratories in China. A broad reading of the Regulation could serve to restrict sample testing by foreign or foreign-invested/controlled laboratories in the future.
条例未明确保藏是否包括为实验室检测的目的短期储藏样本。根据遗传办披露的数据，2018 年在中国开展的 694 项临床试验中的 680.7 万份样本中，78%是由境外或外资实验室检测的。对条例的宽泛解释可能将限制今后境外或外资/外国控制的实验室进行样本检测。

Record-filing Procedure for Clinical Trials to Support Marketing in China
旨在支持中国上市许可的临床试验的备案流程

Arguably one of the most significant changes is the establishment of a record-filing (i.e., notification) procedure for international collaborations on clinical trials intended to support marketing approval of drugs and devices in China that do not transfer HGR Materials abroad. This record-filing procedure could reduce the wait time for qualifying trials, permitting them to start after the filing is complete, instead of waiting for an affirmative approval from OHGRA. However, it is not yet clear how this will work in practice.
条例中最重大的变化无疑是，为旨在获得药品和医疗器械在中国上市批准的、不涉及人类遗传资源材料出境的国际合作临床试验建立了备案制度。该备案制度可以减少合规试验的等待时间，允许其在备案完成后即开展，而无需等待遗传办的确认性审批。但目前尚不清楚该制度在实践中将如何运行。

To comply, the parties must submit, to the OHGRA, information as to the types, quantities and purposes of the HGR used prior to the commencement of the trials.
为遵守备案制度，合作方须在开展临床试验之前向遗传办提交拟使用的人类遗传资源种类、数量及其用途等信息。

The Regulation also does not appear to apply the record-filing procedure to investigator-led trials ("**ILTs**"), which could support marketing of drugs and devices in some respects. Other types of international collaborations remain subject to an approval procedure, similar to the one set forth by the Interim Measures and the Guideline. Sampling and biobanking activities by the Chinese parties under the international collaborations may still be subject to the aforementioned approval requirements added by the Regulation.
条例看似并未将该备案制适用于研究者发起的临床试验，虽然这些试验也可能在某些方面支持药品和医疗器械的上市。其余的国际合作项目仍需遵循类似暂行办法和服务指南中规定的许可制度。中方在国际合作项目中实施的采集与保藏活动，仍需适用上文所述的条例新增的审批要求。

Ethics Committee Approval
伦理委员会批准

The Regulation also requires that international collaborations receive ethics approvals from the respective country/region of both foreign and Chinese parties. This dual ethics committee approval requirement could cause delay. It is not clear whether foreign ethics committee approval is also required for record-filed trials.
条例要求国际合作项目必须通过中外双方各自所在国（地区）的伦理审查。这一双重伦理委员会批准要求可能会导致延误。条例并未澄清在备案制下的临床试验是否也需要外方伦理委员会的批准。

Provision of HGR to Foreign Parties
人类遗传资源的对外提供

Provision of HGR Materials and HGR Information to Foreign Parties is subject to different forms of review and pre-approval under the Regulation. This aspect is more restrictive than in the Interim Measures.
人类遗传资源材料和人类遗传资源信息的对外提供在条例下需要遵循不同的审查和批准流程。条例在这一方面相较暂行办法更具限制性。

In addition to the record filing, the provision of data to Foreign Parties or permitting uses of data by Foreign Parties requires submission of that corresponding data's copy to the OHGRA, and potentially a "security assessment" if such provision or permitting uses could impact the public health, national security or public interest of China. The Regulation does not provide further details on the submission of data or security assessment, and it is not clear how such requirements will work in practice.
除了备案之外，向外方提供人类遗传资源信息或者开放使用，需要向遗传办提交相应数据备份，以及在该提供或开放使用可能影响中国公众健康、国家安全和社会公共利益时，通过一项"安全审查"。条例并未进一步说明数据提交或安全审查的细节，尚不清楚这些要求在实践中如何执行。

Similar to current practice, MOST will require an export certificate before any exportation of HGR materials, which is separate from the master approval for international collaborations --

although both applications may be submitted at the same time. The China Customs Administration will check for the necessary exportation certificates at the border.
与现行实践类似，科技部要求任何人类遗传资源材料在出境前取得一份出境证明。该证明独立于国际合作项目的总体批件，尽管这两份申请也可以一并提交。海关总署将在边境核查必要的出境证明。

Information Sharing with Chinese Parties
与中方的信息共享

The Regulation requires that Foreign Parties should ensure the substantive involvement and full participation of Chinese parties in international collaborations. Records and data must be shared with the Chinese parties.
条例还规定了在国际合作项目中，外方应保证中方全过程、实质性的参与。记录和数据信息都应与中方分享。

Intellectual Property
知识产权

The Regulation retains the provision in the Interim Measures that parties should jointly apply for and own the patent rights arising from the results generated from international collaborations that utilize China HGR. However, the Regulation removes a requirement in the Interim Measures that, in the event of assigning or granting license to a third party, one joint owner should obtain approval and share benefits with the other joint owner, thus leaving it for the parties to contractually agree on their own as how to dispose of their rights (as provided under the Chinese Patent Law). The joint ownership requirement is still broad and its full implications are unclear.
条例保留了暂行办法中，合作双方应当共同申请并共有利用中国人类遗传资源开展的国际合作中产生成果的专利权。但是，条例删去了暂行办法中规定的，共有人中的一方在向第三方转让或许可实施该专利时，必须经过另一共有人的同意并分享所获利益这一要求，因此留待双方通过协议自行约定如何处置其权利（与专利法的规定一致）。这一共有权的要求仍十分宽泛，其整体含义尚不明晰。

The Regulation remains unchanged as to non-patented results of international collaborations. The parties may contractually agree on the rights to use, transfer and share such results. Otherwise, the default rule is that both parties have the right to use such results and may only transfer it to a third party upon both parties' consent, and the parties should share benefits generated from such transfer in accordance with their respective contributions.
对于国际合作项目项下专利以外的其他成果，条例的规定并未发生变化。合作双方有权通过协议约定该成果的使用权、转让权以及利益分享方法。若无协议约定，默认的规定即双方均享有使用权，但向第三方转让须经合作双方同意，所获利益按合作双方贡献大小分享。

The Regulation allows both parties to have the right to use HGR Information generated from the international collaborations.
条例允许双方使用国际合作项目产生的人类遗传资源信息。

Expanded Enforcement Powers for MOST
科技部执法权的扩大

The Regulation also officially enhances the authority of MOST and its provincial counterparts to conduct on-site inspections, question individuals from companies and the institutions, review and copy the relevant documentation and seize HGR (whether data or samples).
条例还正式扩大了科技部及省级科技部门的行政执法权力，以进行现场检查、询问公司和机构相关人员、查阅并复制有关资料、以及查封并扣押有关人类遗传资源（包括数据或样本）。

The Regulation specifies increased penalties for non-compliance, including warnings, disgorgement of illegal gains, confiscation of illegal HGR, fines up to about 10 million RMB (about 1,450,000 USD) or even more (5-10 times of illegal gains), and temporary (1-5 years) or permanent debarment of companies, institutions and responsible persons from further HGR projects.
条例细化并加强了各种违规行为对应的法律责任，包括警告、没收违法所得、没收违法人类遗传资源、上至 1000 万元人民币（约 145 万美元）或更高（5 到 10 倍违法所得）的罚款、以及暂时（1 到 5 年）或者永久禁止该公司、机构及负责人员将来从事人类遗传资源项目。

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Stakeholders should continue to monitor developments in this area, especially for implementation rules and guidance from MOST. If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our life sciences practice.
利益相关方应当持续关注这一领域的发展，尤其是科技部的实施细则与指南。若您对本文讨论的材料有任何疑问，请联络本所中国生命科学业务团队的以下人员。

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