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Why Europe, not America, may be Chinese sponsorsâ?? smartest move

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Most common mistake Chinese sponsors make is not considering EMA requirements early enough



It is estimated that by 2040 China-originated treatments will represent 35% of US FDA approvals. When marketing treatments beyond China, many sponsors opt for FDA approval as their pathway to the globe.

With potential delays due to personnel reductions in the FDA, trade tariffs and China labelled as a hostile territory by the Trump administration, Chinese sponsors may opt for a different route. Seeking marketing authorisation in Europe offers an attractive alternative to the FDA. Drug development regulatory requirements differ in the EU than in China so sponsors must meet different expectations when submitting Marketing Authorisation Applications (MAA) to the European Medicines Agency (EMA).

Why Europe is an attractive path to market

European geopolitics are stable with an open, cooperative environment for scientific research and development of new treatments. Recently the EMA has emphasised harmonising regulations across all EU member states with the goal of accelerating access to new treatments. Many EMA regulations align with global regulatory strategies. Centralised procedures mean that following a single review, the product has EU-wide access. EMA approval opens the door to market to over 450 million people in 27 EU countries, along with UK, Norway, Switzerland, Iceland and Liechtenstein.

Think Europe first

The most common mistake Chinese sponsors make is not considering EMA requirements early enough. This mistake, while understandable, often results in delays, additional expenses and even failure to get marketing authorisations. Issues can only be addressed early when the sponsor is aware of them. Chinese sponsors can benefit from working with a global CRO familiar with both EMA and CDE regulatory requirements. They can also avail of scientific advice from the EMA ahead of clinical trials and MAA. Seeking and following this advice does not guarantee a favourable outcome. However, one study found that applicants who sought and complied with scientific advice had an MAA success rate of 84% compared with 43% of those that did not get advanced advice.

Recent regulatory changes: Joint Clinical Assessments

The EMA's Joint Clinical Assessment rules already apply to oncology treatments and from June 2026 will apply to high risk medical devices.. These rules will become standard for rare disease treatments in 2028 and for all medicines in 2030.

Chinese sponsors need to meet the Population Intervention Comparator Outcome (PICO) requirements of joint clinical assessments (JCAs) with a clinical trial design focussed on health economic outcomes and patients' experiences. The single most important thing a Chinese sponsor can do is to consider Europe as part of their study design from the beginning. This will save resources in the long term rather than retrospectively adapting protocols. Retrofitting a trial design is almost always more expensive and less effective than being Europe-ready from the outset.

Mind the gap: Bridging studies and EU relevance

Many studies from China will have exclusively Chinese trial participants, yet the EMA expects a representative European population within the participant data. Sponsors should evaluate whether their existing data package is likely to meet EU expectations under ICH E5 and E17. When the pivotal data are exclusively Chinese, regulators usually expect additional analysis to demonstrate applicability to EU populations. Including EU patients in a global multi-regional clinical trial (MRCT) is the most efficient form of bridging. However, if this is not possible regulators may expect supplementary clinical pharmacology studies, pharmacokinetics bridging or supportive cohorts.

From China to the world via Europe

As emphasised throughout this article the single most important thing a Chinese sponsor can do is to plan their studies for EU regulators from the beginning. Doing so will avoid delays with unexpected – and thus, expensive – requirements later. While there are challenges to EMA MAA they are outweighed by the benefits. Partnering with a global CRO that understands EMA and CDE regulations significantly reduces those challenges.

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