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Including eCOA in a clinical trial in China

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With a large patient pool and growing pharma market opportunities, study sites in China are included in more and more clinical trials. According to Inspection reports provided to EMA (2000-2012)[1], the average number of findings per inspection was very similar in all geographical areas globally, including Asia.

However, data quality in clinical trials in Chinese hospitals is not always easy for sponsors to control due to regular issues with source data[2]. Some sponsors also struggle with later data entry than in non-Chinese sites.

> **"Including eSource solutions such as eCOA for Chinese clinical trials can increase data quality and reliability."**

Clinical trials in China are not yet as straightforward as they could be

Conducting a clinical trial in China is not yet as straightforward for US- and EU-based pharma companies as it could be. In a SCORR Marketing and Applied Clinical Trials report, language barriers as well as logistics and supply difficulties have been reported as the main constraints. [3]

According to the SCORR report, factors that make China less attractive for clinical trials include:

- Language barrier (51%)
- Logistics and supply difficulties (46%)

- Lack of sufficiently well-trained clinicians (41%)
- Data issues (31%)

> “Yet another of our clinical trials including sites in China has just finished recruitment and we observed again that the Chinese sites were very effective in patient recruitment and highly compliant with our eCOA solution.”
> *Björn Felber, Kayentis Project Manger*

How to avoid unnecessary complexity in clinical trials in China?

To avoid unnecessary complexity, it is important for CROs and Sponsors to choose vendors that have been able to adapt to the challenges of this specific geographical area.

- **Chinese import conditions** are currently being reinforced and may become more stringent in the future. Tablets or smartphones used for clinical trials need to have the Chinese CCC certification.

- **To avoid logistical issues,** an eCOA vendor with experience in China would ideally have an established partnership with a local provider for purchasing material that is produced specifically for Chinese markets. Preparing tablets locally and shipping only within China also avoids the risk of delayed delivery due to customs procedures.

- Tablets and smartphones used in China must have **the complete set of Chinese characters (hànzì).** With local purchasing this is guaranteed.

- When source data are transferred via 4G, **local connectivity is a must.**

The Chinese FDA is working hard to enhance the quality of clinical trials in China. eCOA can help to reach this aim but only if the provider can take care of the Chinese specificities.

Björn Felber, Kayentis Project Manager

Sources

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500178525.pdf
[2] http://www.appliedclinicaltrialsonline.com/running-clinical-research-china
[3] SCORR Marketing and Applied Clinical Trials China Clinical Trials Survey Report

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