Fact sheet

Quintiles medical device clinical evaluation

Shorten the timeline for product launches in China

Rely on Quintiles for a successful medical device launch

Navigating China's complex and fast-changing regulatory environment is a challenge for medical device companies. Regulation of devices ranges from comprehensive to sparse, depending on the market, the device and the national regulatory body in question. Medical device companies looking to succeed in China must find the right strategies to support faster commercialization. Trust our expertise to help you achieve a successful product launch – and make the most of rich medical device opportunities in the Chinese market.

Accelerating medical device development with the Clinical Evaluation Report

Clinical evaluation is the analysis of clinical data needed to establish the safety and performance of a medical device. Regulations outline three acceptable processes for medical device clinical evaluation in China: the traditional clinical trial; analyzing foreign pre-registration clinical trial data in either the origin country or license holder country with evidence of no racial difference; and the Clinical Evaluation Report (CER). Of the three, Quintiles' new CER process is the most efficient method for medical device clinical evaluation in China.

Speeding the process with equivalent device clinical data

The Clinical Evaluation Report establishes that a product:

- Meets performance standards under normal conditions
- Has acceptable risk compared to expected benefit
- And has performance and safety levels supported by evidence.

Using our regional and local expertise, **Quintiles is able to accelerate the Clinical Evaluation Report process** with data that shows a medical device is substantially equivalent to one that is already approved in China.

Our services are applicable to Class II/III medical device registration (and not applicable to IVD products).

*The World Bank, World Bank Open Data

QUINTILES®

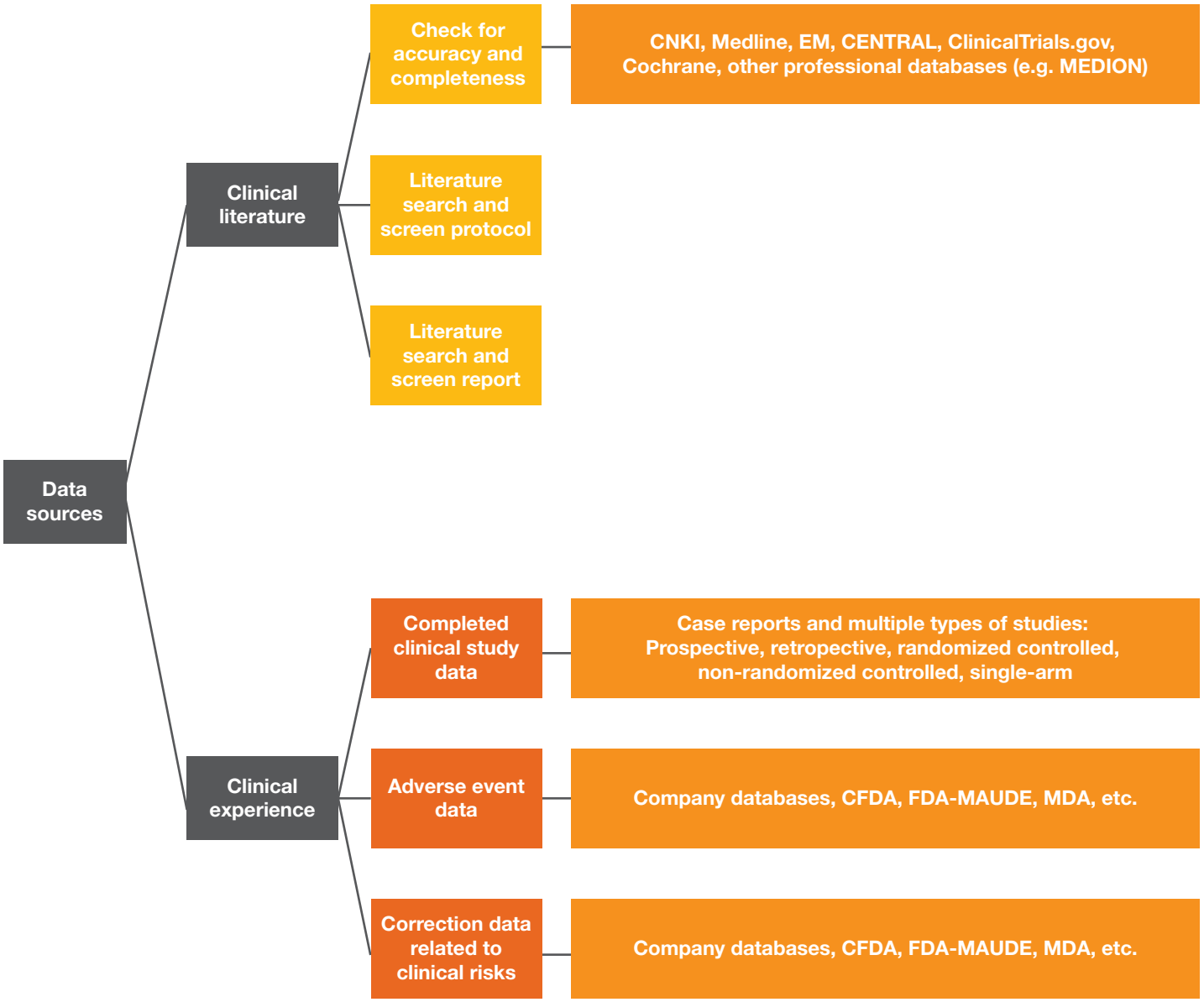
Improve your probability *of success*™

What is substantial equivalence (SE)?

If the difference between an application product and an approved equivalent product will not affect the safety and effectiveness of the application product, they can be considered substantially equivalent.

Trust Quintiles' Clinical Evaluation Report approach

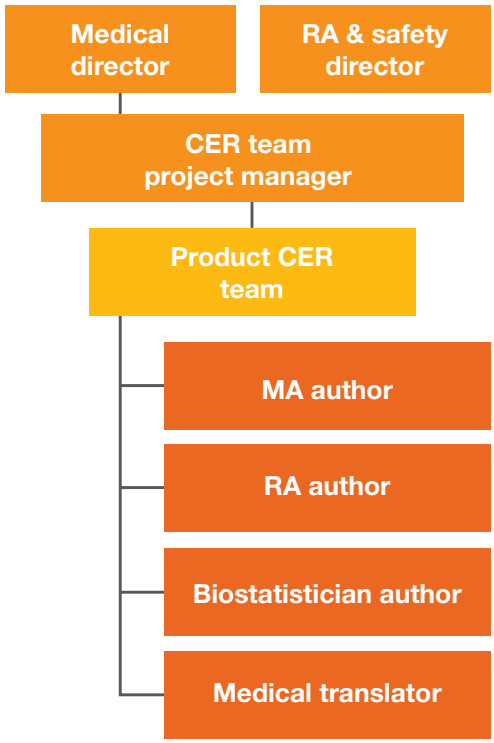
Our comprehensive analysis of multiple datasets can give you a **full report in 3 – 4 months.**



The Quintiles difference

Strong foundation	High quality	A record of integrity
• Our CER SOPs and templates are based on China's *Guideline for Medical Device Clinical Evaluation* (2015 Order 14)	• We've successfully passed CFDA formal examination • We have a strong understanding of CFDA requirements based on frequent communication with CMDE for different products • Our cross-functional internal reviews include Medical, RA, Bios and QC	• Literature search tool and record • Literature search and selection plan • Literature search and selection report • Data entry template • Experience data search and analysis report • Statistical analysis plan • Statistical analysis report • Clinical Evaluation Report

A cross-functional team of experts



When you're looking to launch a product, experience matters!

- **Medical Director:** Certified Physician with 4 years' pharma experience and 9 years' experience abroad
- **RA & Safety Director:** 12+ years RA experience
- **MA Authors:** Advanced degrees with an average of 4 years' MW experience
- **RA Authors:** An average of 5 years' RA experience
- **Bios Authors:** An average of 6 years' biostatistics experience
- **Medical Translator:** An average of 5 years' translation experience

Our smart approach to developing the Clinical Evaluation Report helps you achieve market launch faster. By bringing together the right experts, insights and tools, Quintiles works with you to improve your probability of success in the medical device market in China.

QUINTILES®

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