

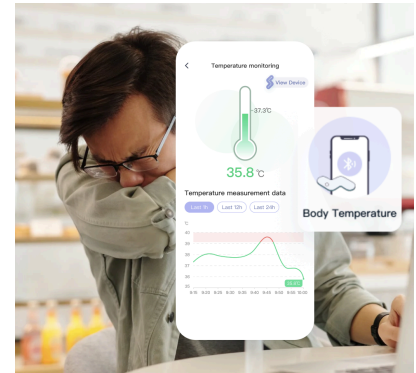
Luca: Conducting clinical trials in China



About Luca Healthcare

[Luca Healthcare](#) supports clinical research and healthcare through connected devices to manage patients at home and in remote settings, improve patient outcomes through disease diagnosis, and identify shifts in disease progression or exacerbations that require proactive interventions.

Relevant product: [LucaPlex® Remote Care](#) is recognized as a Class III product in China and is undergoing the national regulatory approval process.



Case study background

- Software as a medical device (SaMD) products that involve artificial intelligence (AI) are classified as Class III medical devices in China.
- Thus, the regulatory approval process is complex and requires clinical trial data, including representative patient populations to demonstrate usability.
- While Class II products can leverage data from other devices to demonstrate equivalence, Class III products require clinical trials.



National engagement

- Companies aiming to achieve medical device recognition are required to negotiate with the appropriate in-country regulatory body in advance of conducting a pivotal study.
- Although China is a single-payer healthcare system, the decision to list and utilize each product lies with hospitals and doctors, which may necessitate additional evidence.



Key takeaways

- ✓ All core studies for Chinese regulatory authorization must be conducted in China.
- ✓ Data generated in other countries can help demonstrate algorithm adaptability.



Strategy & approach

- Due to the limited number of qualified hospital sites in each geographic region that are required to be included in every clinical trial, Luca developers worked with clinical research partners to manage multi-site trials and coordinate data collection.
- Luca collaborated with a sponsor to develop a novel digital biomarker in partnership with regional hospitals. They validated the biomarker through an external validation study prior to submitting for regulatory approval.



“Access to large pools of patient data across many diseases makes China a great place to start validating algorithms, then export to the rest of the world.”

— **Echo Chen**

CEO, Luca Healthcare