

Medical Devices & Diagnostics

An Integrated, Best-in-Class Approach

From regulatory services through commercialization, our integrated team of experts leverages extensive experience and knowledge of medical writing, regulatory pathways, commercialization, and lifecycle management to provide the support you need to advance your program and help increase the probability of success. With the most experienced team of experts in regulatory services and market access, we are dedicated to achieving your success.

De-risking the Regulatory Process

With the introduction of several new guidance documents, the regulatory submission process is now more complex than ever. Compliance with these regulatory changes requires a robust team of qualified experts.

Our medical device team consists of:

- Experienced experts who have written hundreds of technical documents
- Experience with clinical/performance evaluations, spanning all classes of device
- Expert medical writers including, physicians, PhDs, nurses, and librarians
- Skilled staff to perform methodologically sound literature reviews supporting your clinical data

Innovative Pricing to Expand Market Access

Optimize value, positioning, and evidence synthesis across all stages of the reimbursement journey with Certara's Evidence and Access team.

Ensure success with:

- Strategy aligned with health authority and payer/HTA expectations to eliminate unnecessary data collection activities and deliver development programs efficiently
- Adaptive response to changing market dynamics
- Understanding of sources of data and evidence for historical comparators that improve value communication and capture

A Digital Umbrella for Stakeholder Engagement

Certara's BaseCase digital stakeholder engagement platform engages market access, medical affairs, advocacy and patient engagement, and commercial sales and marketing stakeholders with interactive, tailored, real-time data driven content across the product lifecycle.

Ensure success from Regulatory through Commercialization

[Learn more at certara.com/medical-technology](https://www.certara.com/medical-technology)

A decorative graphic on the right side of the page shows a profile of a human head in shades of blue. Overlaid on the head and extending to the right is a network of nodes (circles) connected by thin lines. Some nodes are larger and colored in red, yellow, or grey, while others are smaller and grey. The background is white with a subtle grid of lines.

Reduce risk and accelerate market access for medical devices and diagnostics with advanced technology, an integrated approach, and an experienced team.



About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 62 countries.

For more information, visit www.certara.com.