

Your Direct Line to Efficient and Economical  
**Medical Device &  
Diagnostics Studies**

**Exact experience. Reliable resources. Greater global reach.**

Keeping up with the quick advancement of today's medical device and diagnostics technologies requires specialized knowledge and studies designed to achieve shorter lead times at reduced costs. At DZS, we recognize and resolve these challenges every day.

Together, with the expertise of our scientific leadership team, we are your direct line to efficient and economical medical device and diagnostics studies. Our team provides customized clinical operations support for your trial and the unique patient populations you serve. Using our global expertise and flexible approach, we focus on increasing your study's efficiency, compressing timelines, and supporting your needs across the U.S., Europe, and Asia.

## Exact Experience

Get the job done right with a team of local and global experts with decades of device and diagnostics experience.



~40% of DZS studies conducted are device and diagnostics studies, with majority being Class II and III



Cardiovascular



Nephrology



Oncology



Pain



Rare and Orphan Diseases



Respiratory

## Reliable Resources

Bring your device and diagnostics technologies to market with experts who:

- Understand your clinical and regulatory strategy
- Develop and manage your study design
- Oversee your project management and monitoring
- Monitor your data management and statistical analysis
- Guide you through the regulatory submittal and compliance maze

### Clinical Development Services:

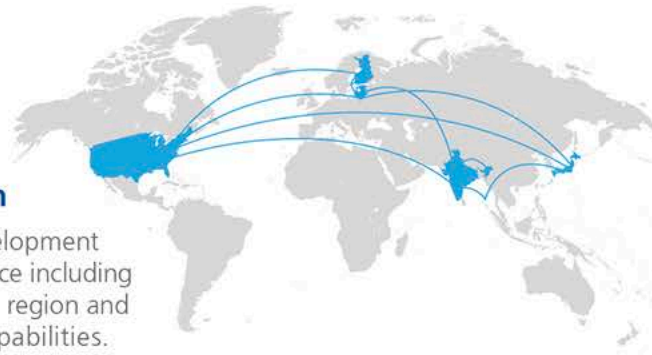
- Clinical study design
- Key opinion leaders and advisory board development
- Clinical evaluation reports (CERs)
- Meta-analyses
- Safety surveillance and observational programs

### Medical Device & Diagnostics Expertise:

- Class I-III
- Home use
- ICU-based
- Wound care

## Greater Global Reach

Support your product development with our worldwide presence including U.S., EU, MENA, and APAC region and a wide range of global capabilities.



## Recent Experience

- **Large, multinational, multiphased IVD projects (>30,000 samples)**

Developed the world's first fully automated and integrated testing platform for both blood grouping and donor disease screening

- **Multiple projects on unique IVD products across U.S. and Asia (>12,000 subjects/samples)**

Developed first fully automated urine chemistry analyzer/particle imaging device

- **Oncology diagnostic tools**

Novel photo-diagnostic tools utilized to screen and treat cancers

- **>15 additional medical device projects in the last three years in respiratory, ICU devices, and ophthalmology**

Many submitted to regulatory bodies globally



Clinical Development Strategy



Clinical Operations



Data Analytics



Pharmacovigilance & Risk Management



Medical Affairs

# The DZS Difference

Maximizing Efficiency Through Superior Service and Global Access



## Clinical Development Strategy

Access key advisers with experience in strategic planning for your drug, device or diagnostic, including project and end-point feasibility and protocol design. Our advisers also have the ability to provide regulatory strategy and representation.



## Clinical Operations

Collaborate with a global network of in-house resources and a team of clinical project management and clinical monitoring experts to select sites, determine feasibility, and manage and monitor your project from start-up to close-out.



## Data Analytics

Put data integrity at the forefront of your study with our clinical data management, medical coding, scientific writing, and biostatistics support and statistical programming teams.



## Pharmacovigilance & Risk Management

Improve the pre- or post-market surveillance of your therapeutics with a systematic approach to monitoring and risk management, including end-to-end case processing and reporting.



## Medical Affairs

Get support for your post-marketing activities and market access challenges with our experienced team. From real-world evidence trials and statistical models to health economics and market access strategies to IIT program development, we are here to help.

## Strategic Outsourcing Solutions

Ensure just the right fit for your organization and quality and timely delivery of your desired outcomes with our global short- and long-term contracts and a variety of staffing models.



**DZS** CLINICAL SERVICES

A WDB.G Subsidiary  
USA | Europe | Asia

Contact us for more information.  
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