ophthalmic device

Medpace is dedicated to helping our medical device clients bring products to market safely, effectively and efficiently. Our experience spans:

- Pre-market, post-approval and post-market studies
- National, regional and global device trials
- Single-center, first-in-human, and feasibility trials to multi-center, full-service pivotal trials as well as large-scale, post-market outcomes studies

Global Advantage

- Device offices in U.S. and Europe
- European authorized representative services
- Geographically diverse and multilingual employees understand local cultural environment and regulatory pathway

For more information about our medical device experience and services, visit our website at www.medpace.com/device, email us at info.mmd@medpace.com or contact us at one of our medical device offices below.

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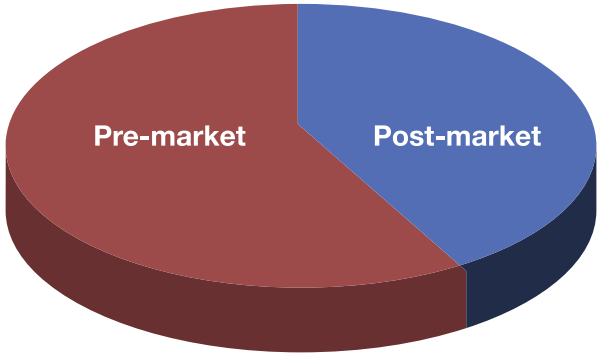
Experienced Ophthalmic Device Development

Medpace is your experienced partner in bringing innovative ophthalmic devices to market. We have conducted device studies in ophthalmology involving nearly 7,500 subjects across more than 160 sites globally for indications in presbyopia, myopia, glaucoma, age-related macular degeneration (AMD), diabetic macular edema (DME) and cataracts.

Almost equally divided between pre- and post-market studies, our ophthalmic device experience includes:

- Micro stents
- IOLs
- Corneal inlays
- Scleral implants
- Contact lenses
- Ultrasound guided cryogenic therapy

Ophthalmic Device Trials



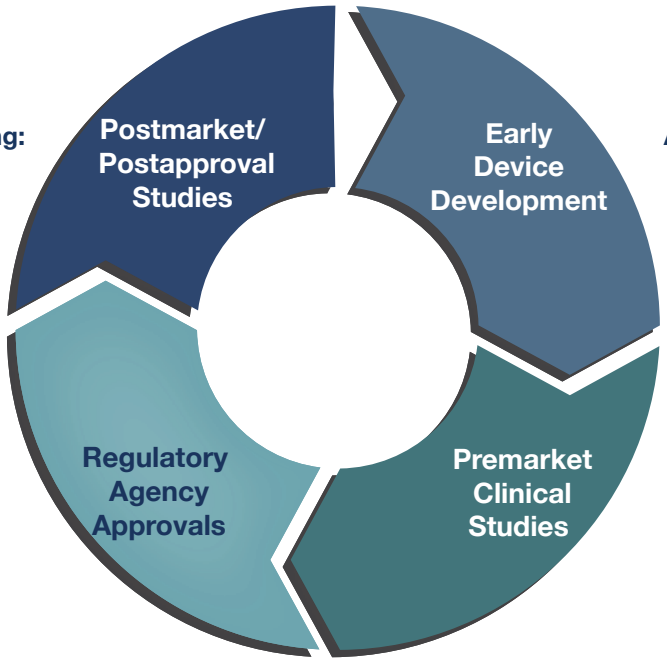
MEDPACE

Medical Device Services

Medpace provides pre-market, post-approval and post-market device trial management, including regulatory development, planning and submission support.

Full Service Clinical Trial offering:

- Clinical Operations
- Study Start-up
- Regulatory Submissions
- Data Management
- Biostatistics
- Safety/CEC/DSMB
- Medical Writing & Regulatory Affairs
- Quality Assurance



Additional services offered:

- Regulatory Strategy including:
  - Device classification
  - Notified body discussions
  - Pre-submission FDA meetings
- Clinical evaluation reports, Clinical literature review (EU)
- Technical files & design dossiers
- EU authorized representative services

Comprehensive Clinical Services

Clinical strategy development

Trial design including:

- Protocol
- Patient Consent
- Patient Information
- Investigator Brochure
- CRF
- Statistical

Trial management

- Clinical team management
- IRB/Ethics Committee submission
- Competent authority submission/notification
- Metrics and reporting
- CEC/DSMB management
- Episode adjudication

Site selection and qualification

Monitoring

- Site initiation
- Close out services

Data management

- Database development
- Data review and query management

Safety and risk management

- Safety and vigilance reporting
- Event management

Study report preparation

- Medical writing
- Data analysis

Device distribution services