CLINICAL SERVICES

MEDICEPT
Trusted Solutions, Rapid Response

Catering to start-up through large Medical Device, IVD, and Combination Products Sponsors, MEDIcept offers a right-sized, tailored approach to outsourcing clinical trials, from full-service CRO to a la carte functional support.

Our clients appreciate our deep therapeutic expertise, critical thinking, differentiated capabilities and nimble approaches.

CLINICAL STRATEGY & SUBMISSIONS

Our clinical team collaborates with regulatory experts to ensure that your trial is on target from the start. Our regulatory team ensures that MEDIcept is up to date on all global requirements.

TRIAL START-UP & MANAGEMENT

We utilize our site database, established relationships, and experienced selection process to ensure the right investigators are evaluating your product, activation and initiation proceeds efficiently, and that enrollment progresses smoothly.

SITE MANAGEMENT & MONITORING

Our expert project managers and monitors provide oversight to ensure site compliance with regulations, protocol, agreements, and IRB requirements.

DATA MANAGEMENT & BIOSTATISTICS

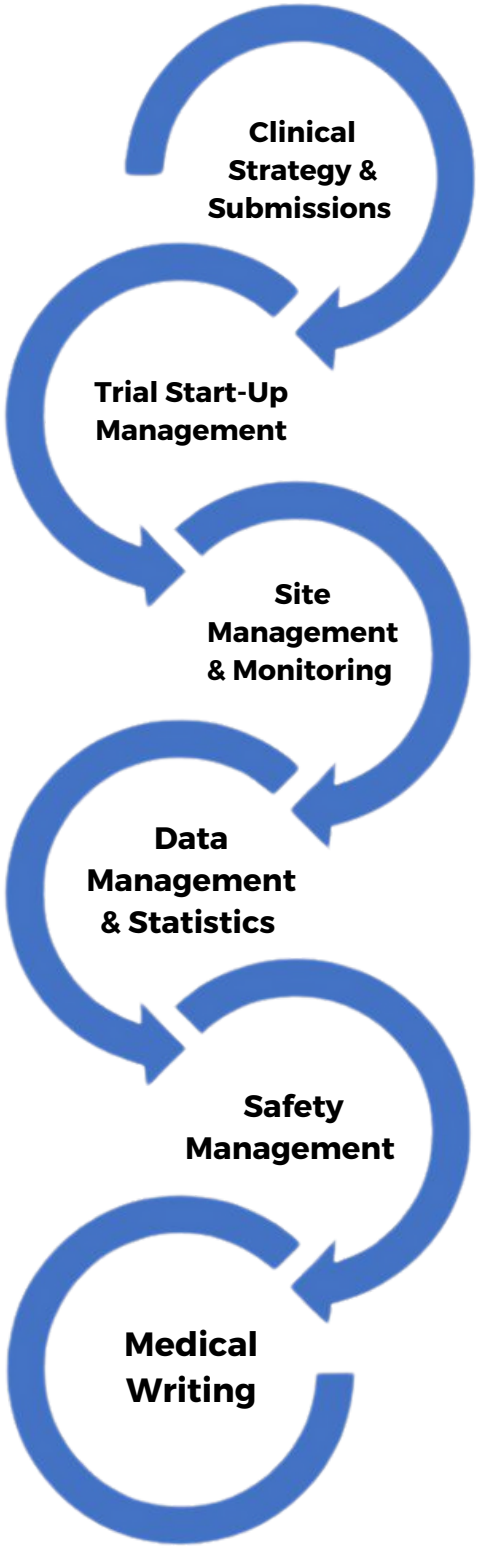
The MEDIcept data management team provides efficient development and validation of Clinical Systems and ongoing data review for faster database lock. Our expert statisticians are skilled in complex development and methodologies.

SAFETY MANAGEMENT

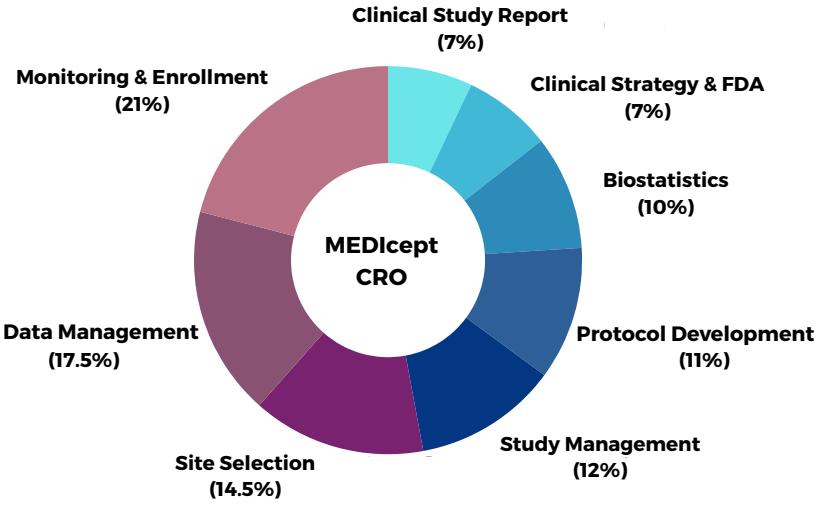
The MEDIcept team has a wide range of safety expertise, including safety committee (CEC and DSMB) management.

MEDICAL WRITING

We employ PhD/MD-level medical writers well-versed in all types of clinical document creation – from study protocols to clinical study reports.



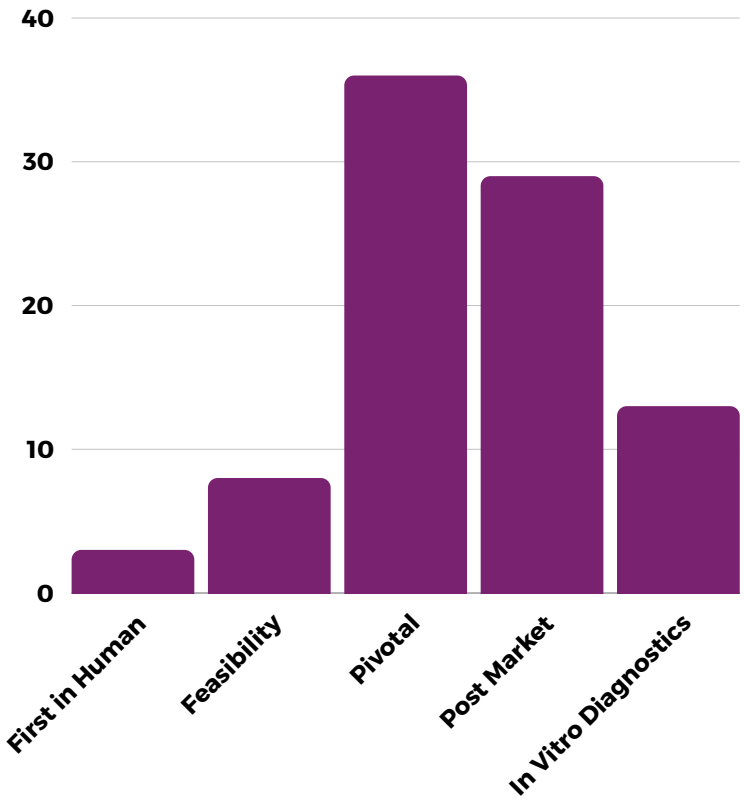
CLINICAL TRIALS BY FUNCTION



OUR CLINICAL TRIAL EXPERIENCE BY NUMBERS

12 countries (US, Canada, several EU countries, Australia, Mexico & Japan)
> 100 sponsors and products
> 150 trials
> 4000 sites
> 60,000 participants
> 42 Device and IVD Trial Submissions

TYPES OF DEVICE TRIALS



OTHER SERVICES

Decentralized Clinical Trials: Telehealth and Participant support, Remote Screening and Enrollment.

Vendor Management and Clinical System Solutions: Full clinical system ecosystem for EDC, eTMF, CTMS, ePRO, IxRS, eConsent, Safety. Strategic partnerships with trusted vendors such as laboratories, Imaging, Central Readers, and Centralized Equipment Providers to support trials.

Clinical Quality Audits: Internal and external sponsor, site, IRB, and vendor audits to assess compliance with regulatory standards and industry expectations (23 clinical audits); sponsor and site preparation for BIMO audits (15 BIMO audits); CAPA development and implementation.

Medical Affairs: Post market surveillance activities (49 post market surveillance plans/reports), clinical evaluation reports (58 CERs with 29 initials), literature search and reporting (49 literature searches for CER/PMS), data extraction and analysis (16 data extraction for PMS/CER), gap analysis, supporting publication writing.

THERAPY EXPERIENCE

- **Cardiovascular**
- **Orthopedics**
- **Endocrine**
- **Neurology**
- **Transplant**
- **OB/GYN**
- **Oncology**
- **Surgical**
- **Urology**
- **Mental Health**
- **And More...**