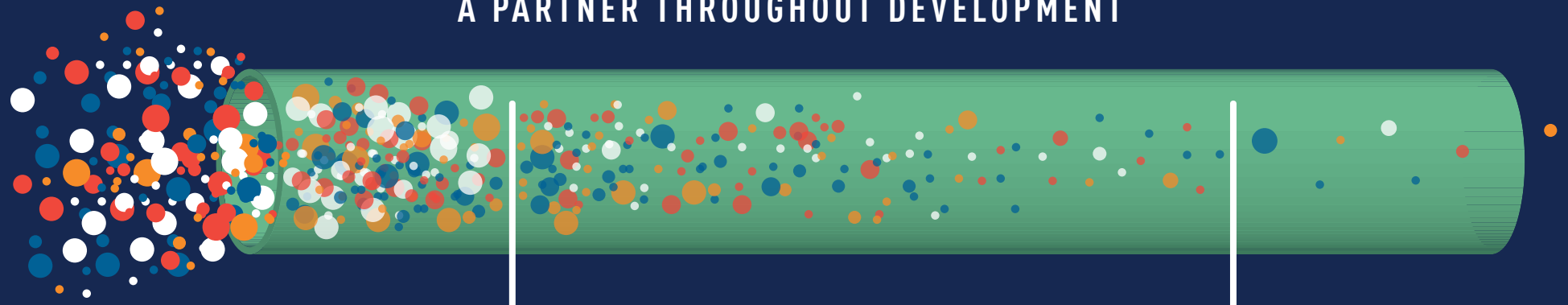
MEDPACE

GLOBAL REGULATORY AFFAIRS SERVICES

A PARTNER THROUGHOUT DEVELOPMENT



DISCOVERY | PRE-CLINICAL | PHASE I | PHASE II | PHASE III | POST-MARKETING

SME SUPPORT

- Clinical
- Regulatory
- CMC

STRATEGIC DEVELOPMENT

- Gap Analysis and Target Product Profile Development
- Clinical Synopsis Development
- Evaluation of Clinical Trial Design and Endpoints
- Fast Track and PRIME
- Breakthrough, RMAT and QIDP
- Orphan Drug Applications
- Pediatric Plans
- Accelerated and Conditional Approvals
- Clinical Development Plans

IND/CTA DEVELOPMENT

- M1-M5 Development
- IMPD & GMO Technical Dossiers
- Project Management
- SME & Regulatory Writing
- Publishing & Submission

REGULATORY AGENCY INTERACTIONS

- Strategy & Planning
- Meeting Requests & Briefing Documents
- Meeting Rehearsals and Facilitation
- Meeting Minutes and Follow-ups

APPLICATION MAINTENANCE

- SAE Reporting
- DSUR / PSUR Reporting
- US FDA Annual Reports
- IND & CTA Amendments
- Commitment Tracking

NDA/BLA/MAA DEVELOPMENT

- M1-M5 Development
- M2-M3 Review
- Project Management
- SME & Medical Writing
- Label Development
- Publishing & Submission

MEDPACE

GLOBAL THERAPEUTIC DEVELOPMENT EXPERTS

YOUR PARTNER TO FACILITATE THE DEVELOPMENT OF STATE-OF-THE-ART THERAPEUTICS

ACCELERATED EXPERIENCED INTEGRATED STRATEGIC SEAMLESS