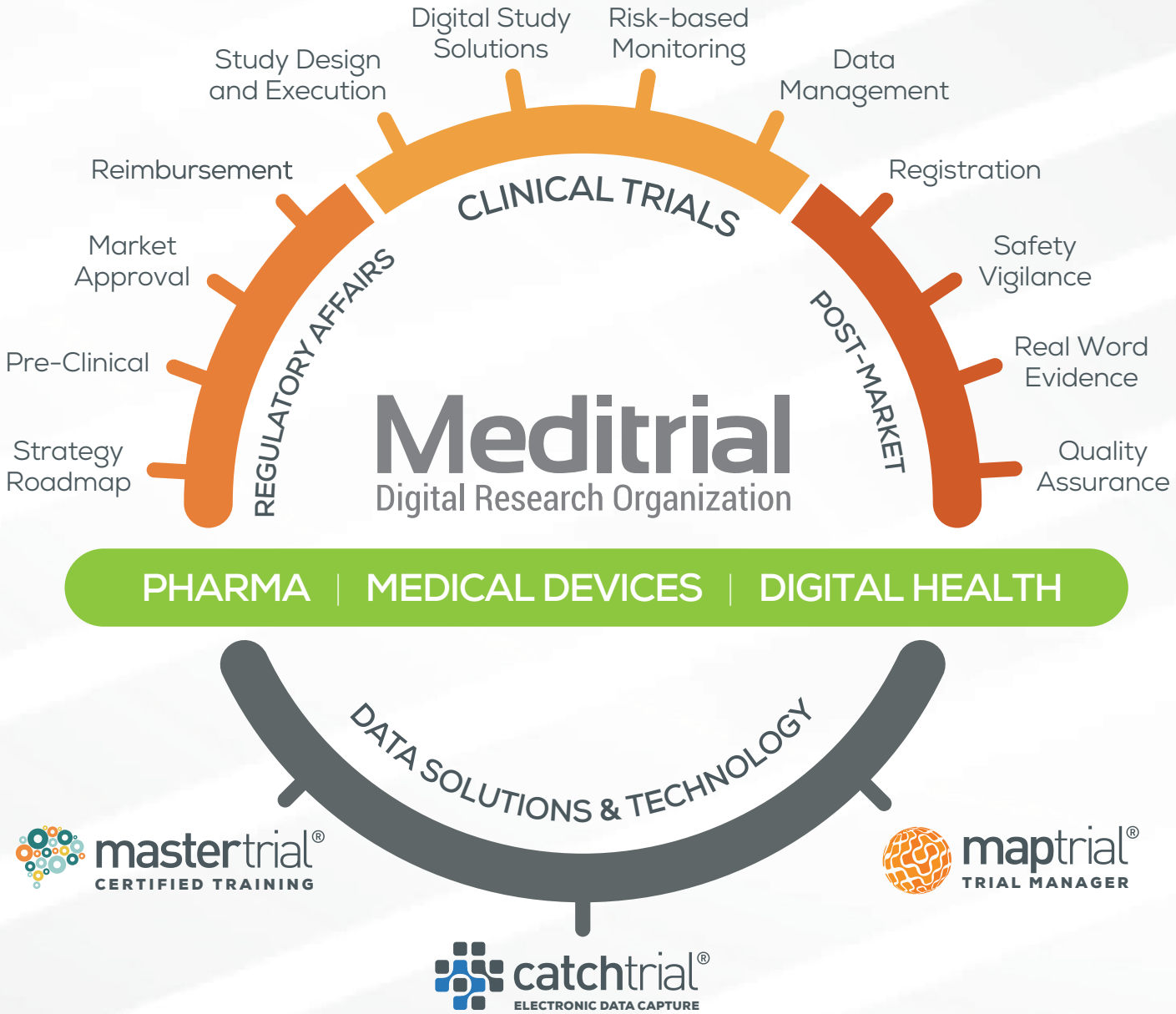

LIFE CHANGING
THERAPIES DESERVE
ACCELERATED ACCESS.
Meditrial
Digital Research Organization
THE RIGHT PATH.
THE RIGHT WAY.
NEW YORK | BERLIN | ZURICH | ROME | LONDON

MEDITRIAL IS DEDICATED TO **CLINICAL TRIALS,** MEDICAL **EDUCATION, REGULATORY, REIMBURSMENT** AND GLOBAL **MARKET ACCESS.**



Meditrial
Digital Research Organization

CERTIFIED ISO 9001:2015 COMPANY
CERTIFIED ISO 27001:2013 COMPANY
CERTIFIED ISO 13485:2016 COMPANY

CLINICAL TRIALS
DIGITAL PLATFORM
INFORMATION SECURITY
MEDICAL EDUCATION

TRIAL DESIGN

- Early Feasibility Studies EFS | FIH
- Pivotal | Randomized | Adaptive Trials
- Real World Evidence | Registries
- Clinical Study Design | Protocol
- Clinical Development Plan
- R&D Management Consulting
- Phase I-IV clinical trials
- Real worlds Studies

TRIAL EXECUTION

- Site Selection & Qualification
- Clinical Study Dossier
- Clinical Trial Submissions
- Full Clinical Trial Management

SITE EFFECTIVENESS

- Patient Recruitment
- Site Relationship
- Patient Retention
- Investigator Training
- On-site & Remote Monitoring
- GCP Inspections

SAFETY MANAGEMENT

- Vigilance Management
- DSMB & CEC
- Online Adjudication

EVIDENCE GENERATION

- Biostatistics & Analysis Plan
- Data Management
- Real Time Data Analytics
- Performance Management
- Medical Imaging Core Labs
- Value Based Outcomes

RUN SMARTER TRIALS

SOLUTIONS FOR YOUR DIGITAL TRIALS

catchtrial® ELECTRONIC DATA CAPTURE

Intuitive and user-friendly, Catchtrial allows doctors and patients real time access to online live data.

ePRO eConsent eCOA eSafety

PHARMA REGULATORY

- Due Diligence
- CMC activities
- Administrative/Quality/Safety Variations
- Centralized Procedure
- Decentralized Procedure
- Mutual Recognition Procedure
- eCTD submission and management
- Scientific Information according to NCA
- FDA meetings and submission
- IND submission
- Orphan drug, Breakthrough and
- Fast-Track Applications

MEDICAL DEVICE & IVD

- Global Regulatory Strategy
- Complete FDA Services
- US Agent
- Investigational device exemption (IDE)
- 510(k) | (PMA) | De Novo
- Reimbursement Services
- European MDR & IVDR Compliance
- EU CE Mark Consulting
- Clinical Evaluation
- Performance Evaluation
- European Authorized Representative
- UK Responsible Person

DISCOVER PHARMA SERVICES

MEDICAL DEVICE & IVD SERVICES

QUALITY ASSURANCE

- QMS | eQMS Setup and Support
- FDA QSIT, ISO 13485, ISO 9001
- GxP Audit, Gap-Analysis, Compliance Assessment
- Inspection readiness consultancy and support
- Quality system management
- Deviation and CAPA management
- EU MDR | IVDR Compliance
- Post-Market Surveillance

PRE-MARKET SERVICES

- Eudravigilance Registration
- Safety Management Planning
- European QPPV | Local QPPV
- Serious Adverse Event (SAE) Receipt
- SAE Management
- Case Narrative writing
- MedDRA coding
- Safety information medical review
- SUSARs/CIOMS preparation and follow up
- Safety information submission
- Periodic reports (DSUR and ASR)
- Data Base reconciliation
- Medical writing

POST-MARKET SERVICES

- Eudravigilance Registration
- European and local QPPV
- Pharmacovigilance System Management
- Case processing and reporting
- Quality Assurance
- PSUR preparation and submission
- PSMF management
- Signal detection
- Literature screening
- RMP preparation and management
- Patient support program

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DATA MANAGEMENT

- Data Management Plan
- CRF Design and Production
- Annotated CRF
- Database Design and Validation
- Data Entry Screens
- Remote Data Capture
- Programming and Validation of Data checks
- Query Management for paper-CRF and e-CRF
- Expert Coding using MedDRA
- CDISC-CDASH standards for data collection
- Laboratory Data Management
- Data Validation Plan
- Data Validation and Cleaning Programs
- Paper and electronic CRF Log and Tracking
- QC of CRFs/DCFs versus Database
- Database lock
- Preparation of tables for statistical analysis according to CDISC-ADaM
- Migration of database to CDISC-SDTM for submission
- Database Transfer according to Sponsor's requirements

CENTRALIZED BIOMETRICS

Today, immediate clinical data access and decision making are key to success. Meditrial combines exceptional expertise for data management with a proprietary software option for real life Electronic Data Capture (EDC).

Capture your trial data directly on an iPad with Catchtrial. With instant data validation, clean data is available in seconds allowing immediate decisions from anywhere in the world.

catchtrial®
ELECTRONIC DATA CAPTURE

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Meditrial
DIGITAL HEALTH SOLUTIONS

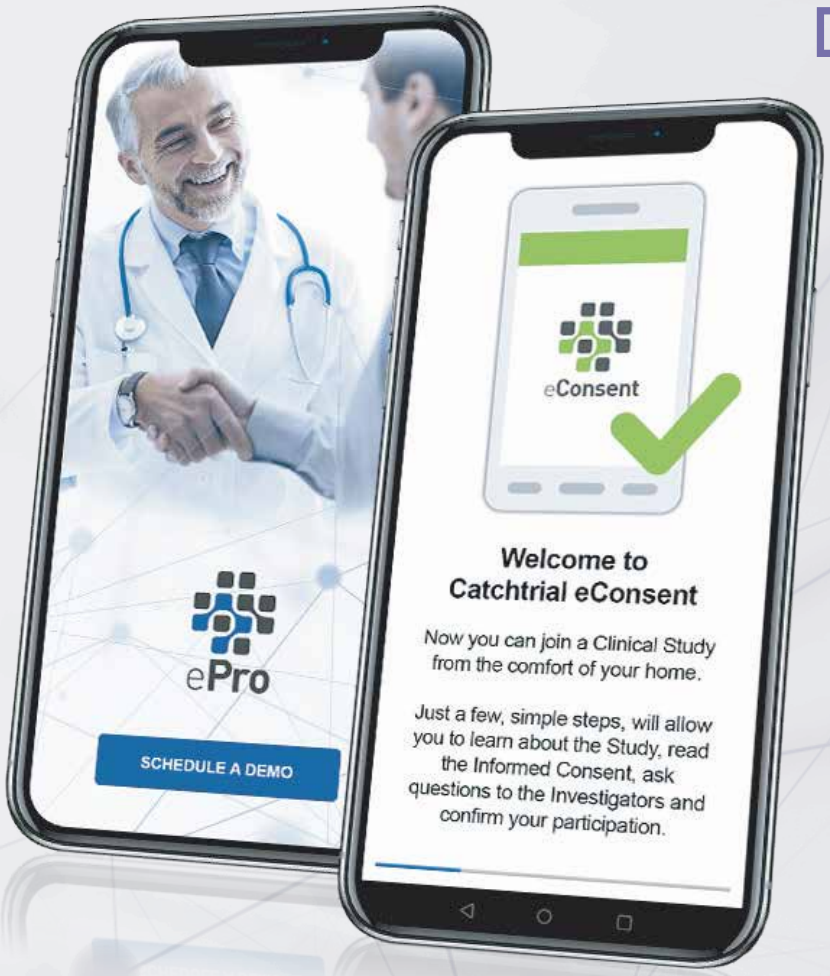
SCAN ME

STRATEGY AND REGULATORY SUPPORT
- SaMD intended use definition
- Classification determination
- Clinical Decision Support determination
- FDA Guidance and policy interpretation
- Q-Subs and meetings with Regulators
- Reimbursement Strategy

DATA AND ANALYTICS
- Identification of data sets for training algorithm
- Analytics
- Utilization of Catchtrial and other Meditrial digital tools

CLINICAL TRIALS WITH DIGITAL HEALTH TOOLS
- Study design
- Study execution
- Real world performance
- Demonstration of intended use and clinical utility

PRODUCT DEVELOPMENT
- MMA – customized app for clinical trials
- ePRO, eCOA, eConsent
- Cybersecurity and data integrity
- GMLP (Good Machine Learning Practices)



YOUR DOORWAY INTO THE DIGITAL HEALTH UNIVERSE

LANDSCAPE ASSESSMENTS & STRATEGIC PLAN

CLINICAL TRIAL REIMBURSEMENT SERVICES

CODING & PAYMENT INITIATIVES FOR NEW TECHNOLOGIES

STRATEGIC PLANNING FOR MARKET ACCESS

SCAN ME

Meditrial
Digital Research Organization

GLOBAL REIMBURSEMENT

Three of the most critical components in healthcare innovation are clinical trials, regulatory approvals and reimbursement—for both pharma, medical device and biotech products.

In digital health, regulatory and/or reimbursement processes are different. For example, revenues may often be augmented by a service with associated MRR/ARR for scale.

Meditrial helps customers to consider these issues early in the journey of maturing concepts to commercialization.

Our experts support the assessment, planning, and execution required to ensure unimpeded patient access to your innovation.

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YOUR **PARTNER** FOR **STRATEGIC DEVELOPMENT** AND GLOBAL **COMPLIANCE**

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