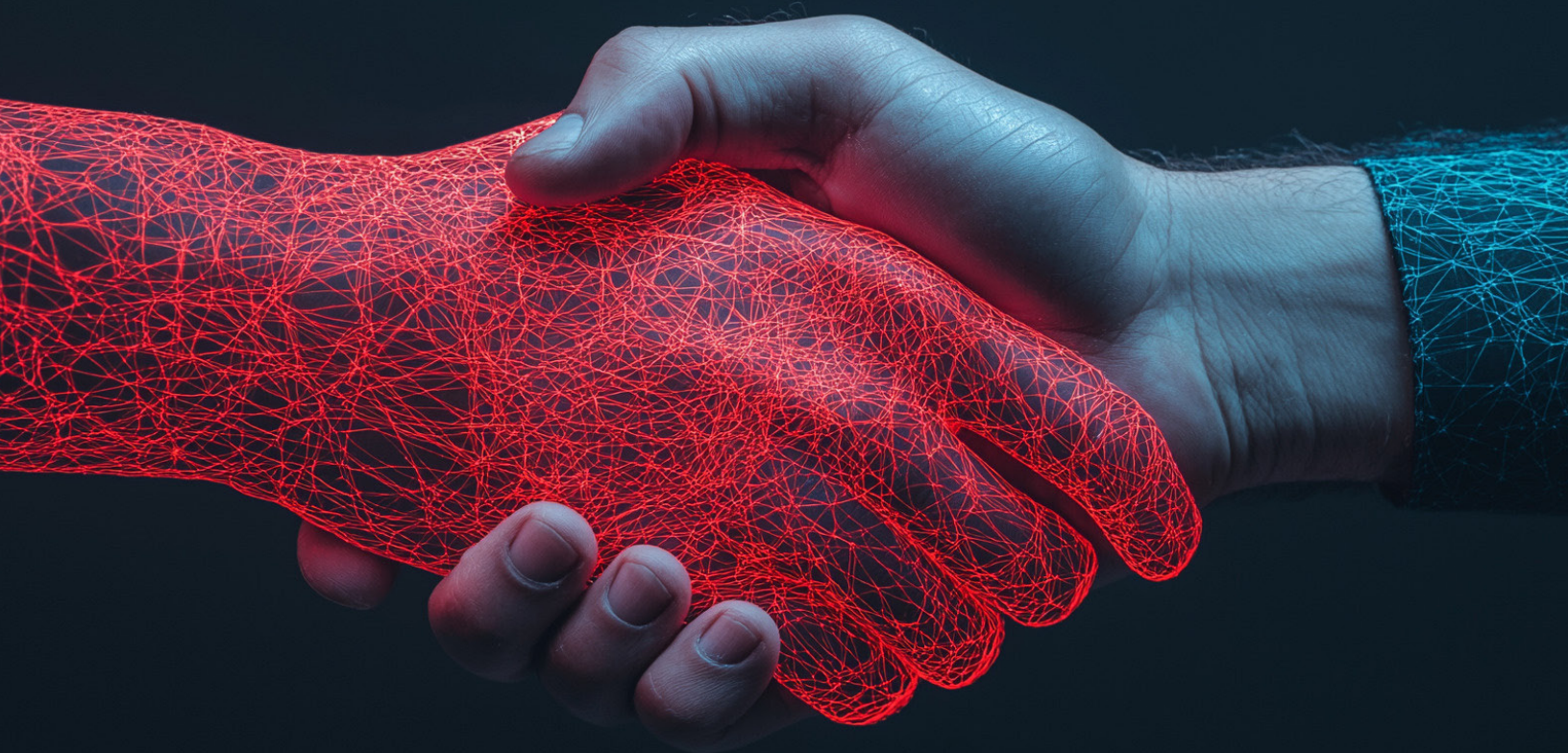




Total Enablement for Digital Health Technologies in Global Decentralized & Hybrid Clinical Trials

Regulatory, Operational, Digital,
End-to-End DHT Readiness

Your Partner for Global DHT Compliance, Deployment & Innovation

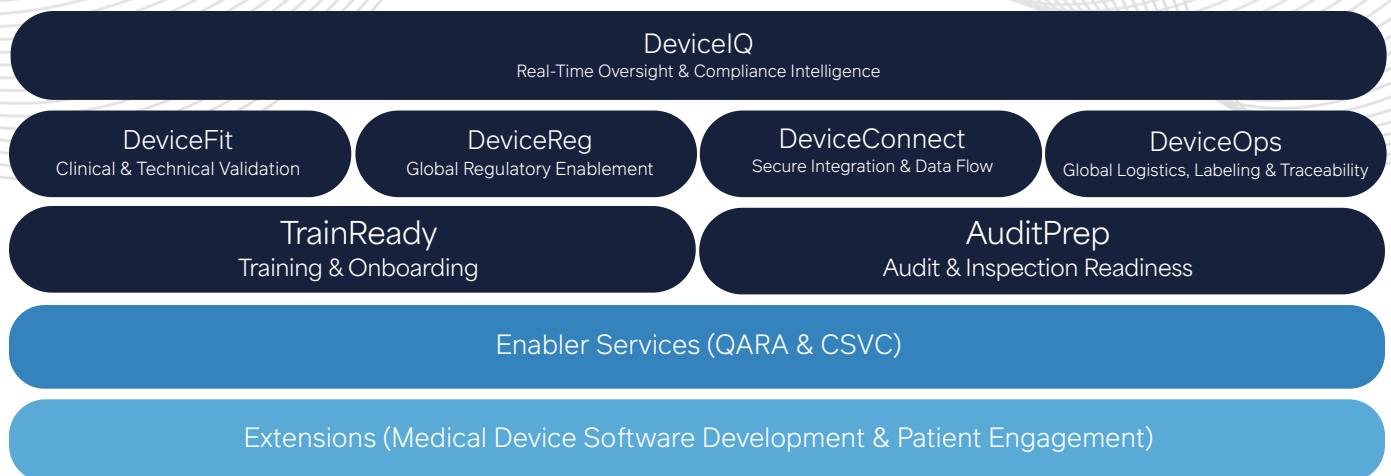
Decentralized and hybrid clinical trials rely on a growing ecosystem of Digital Health Technologies (DHTs)—including Point-of-Care (POC) devices, wearables, Biosensors, Digital Biomarkers and Software as a Medical Device (SaMD).

Deploying these technologies across regions introduces significant complexity: global regulatory classification, validation, logistics, integration, cybersecurity, AI/ML oversight, and inspection readiness.

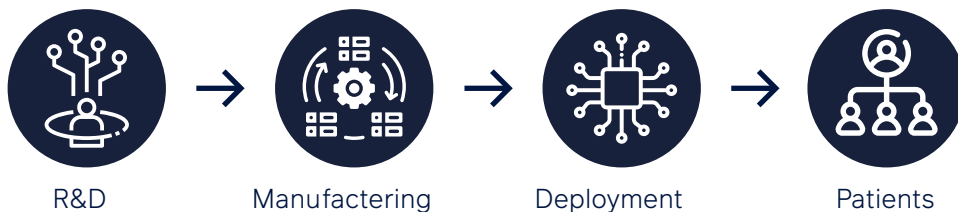
qointa Device360 is a modular, regulatory-grade service suite designed specifically to solve these challenges across the full DHT lifecycle.

Device360 integrates Real-World Data (RWD) and Real-World Evidence (RWE) to support digital endpoint justification, device suitability, population alignment, and regulatory defensibility — a crucial requirement in modern DHT-enabled trials.

It empowers sponsors, CROs, DCT platforms, and MedTech partners to deploy DHTs with confidence—ensuring compliance, data integrity, and regulatory alignment across all regions.

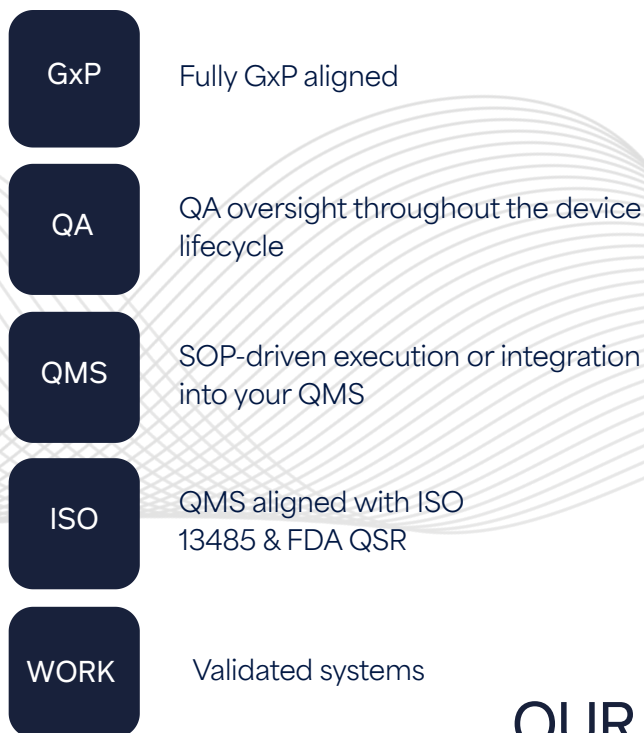


Device360 embeds regulatory-grade infrastructure across the device lifecycle, de-risking global trials.



Biopharma, CRO, MedTech, Wearables, Digital Health, Logistics, DCT Platforms

FROM REACTIVE TO REGULATORY READY IN 90 DAYS



Quick-start your DHT Compliance with our Off-the-shelf DHT, audit-ready QMS

Device360 creates a closed-loop compliance architecture for digital endpoints — combining regulation, validation, integration, data integrity, AI/ML governance, and RWE-supported performance insights.

OUR SERVICES

- 1 FIT-FOR-PURPOSE VALIDATION**
→ Technical, Clinical & Usability Validation
- 2 GLOBAL REGULATORY ENABLEMENT**
→ Classification, Documentation & Regulatory Strategy
- 3 COMPLIANT DEVICE DEPLOYMENT**
→ Global Labeling, Logistics & Country Readiness
- 4 INTEROPERABILITY & DATA FLOW**
→ Secure Integration, Metadata & Data Integrity
- 5 TRAINING & ONBOARDING**
→ Training, Certification & Adoption Readiness
- 6 INSPECTION READINESS**
→ Audit Preparedness, TMF Completeness & Documentation
- 7 REAL-TIME MONITORING & ALERTS**
→ Live Oversight, Risk Detection & Operational Performance

qointa for Life Sciences

Access the expertise of our
technology, validation, quality
and compliance professionals

**Choose the DHT specialists
trusted by global sponsors,
CROs, and MedTech innovators.**



End-to-End Compliance

Risk management, Usability, Data
Integrity & Privacy, Cybersecurity,
AI/ML governance,
RWE-supported evidence



Regulatory Aligned

EU MDR 2017/745, FDA 21 CFR,
11/820/812, ISO 13485, ISO 14971, IEC
62304, IMDRF SaMD, FDA DHT,
Framework, GDPR, HIPAA, FDA
PCCP, EU AI Act, ...



Global Scalability

Designed for multinational trials &
DCT platforms



Trusted Partner

Supporting sponsors, CROs, and
MedTech innovators worldwide

8 of top 20

pharmaceutical, medical
device clients served

100%

inspection-ready
deliverables

7

global regulatory
frameworks supported

50%

faster DHT deployment
with our regulatory-grade
framework Device360

30+

years combined expertise
in devices, clinical trials,
and digital health