

Govern the devices your trial relies on — before an inspector does.

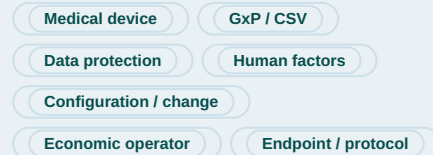
Phones, wearables, sensors and apps carry regulatory obligations the moment they touch your protocol. We find them early, control them, and prove it.

A device's regulatory status follows **what it does in the protocol**, not what it is called — so one handset can be medical-device software, a computerised system, a data processor and an economic-operator artefact **at the same time**. The obligations stack. Found late, they cost protocol amendments, retrospective validation, or data you cannot use. **"No obligation" is a conclusion you earn by assessing — never a starting assumption.**

THE PROBLEM

- "It's just a phone" is waved through at design — and becomes a finding at submission or inspection.
- Operator, importer and processor duties are **inherited by accident** at kitting, provisioning or a new country.
- An app or OS update silently moves a validated device across a perimeter, mid-study.
- EU MDR, the AI Act, FDA PCCP and GCP converge on the **same** connected device — on diverging timelines.

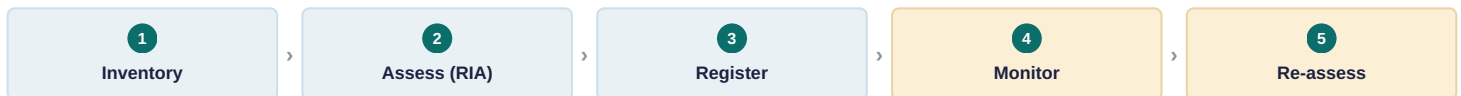
THE SEVEN PERIMETERS WE ASSESS



WHAT YOU RECEIVE

- A **controls decision** for every device & system — per stakeholder, per setup.
- A controlled, versioned **Trigger Register** — inspection-ready and kept alive.
- Endpoint **V&V / qualification** evidence built before pivotal data.
- Vendor qualification, QMS seam-ownership, and a complete **evidence index**.

OUR METHOD — ONE CONTROLLED LOOP, RUN UNTIL THE STUDY CLOSES

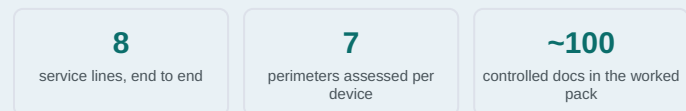


OUTCOMES WHEN YOU ASSESS EARLY

- **Fewer surprises at inspection** — "we assessed it and recorded why" beats "we believed it didn't apply."
- **Defensible endpoints** — evidence built before the data, not reconstructed after a challenge.
- **No duties inherited by accident** — operator and processor roles mapped before they trigger.
- **A living controls baseline** — updates, vendors and markets caught, not discovered.

WHY QUINTA

- 25+ years across eClinical, medical devices and digital health — buyer side and vendor side.
- The first **unified decision framework** that reads MDR, IVDR, the EU AI Act, FDA & GCP **together** — where they overlap, stack and diverge.
- Built on a **24-paper regulatory position series** and a structured Regulatory Impact Assessment method we run for you.
- Proportionate by design: a passive carrier closes in a short record; only real functions attract real work.
- A complete, **audit-tested delivery kit** — proven end-to-end on a worked engagement, so output is controlled and inspection-ready from day one.



Start with a Snapshot — a 2–3 week Regulatory Impact Assessment of your trial's devices.
rudiger@mail.com · +32 470 33 05 44 · qointa.com

Aligned to FDA DHT Framework · ICH E6(R3) · EU MDR 2017/745 · ISO 14971 · IEC 62304 · 21 CFR Part 11 · EU Annex 11
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