Accelerating Digital Health

For over a decade Gsap group provides a basket of services, that enable our digital health clients to have, all in one place, exactly what they need to drive their product development from concept to reality.

Gsap
Integrative Impact
A Family of Companies

QUALITY

- Quality system establishment according to **IEC 62304**
- Risk assessment according to **IEC 60601** (including interoperability)

REGULATORY

- Regulatory strategy (including for V&V testing)
- Clinical evaluation
- Regulatory submissions and communication (e.g. with FDA or EMA)
- Post-Marketing Surveillance (PMS) & Post-Marketing Clinical Follow-up (PMCF) plans

CLINICAL

- End to end CRO services
- Clinical study design, planning and monitoring
- Clinical validation

SOFTWARE

- Usability (according to **IEC 62366-1**)