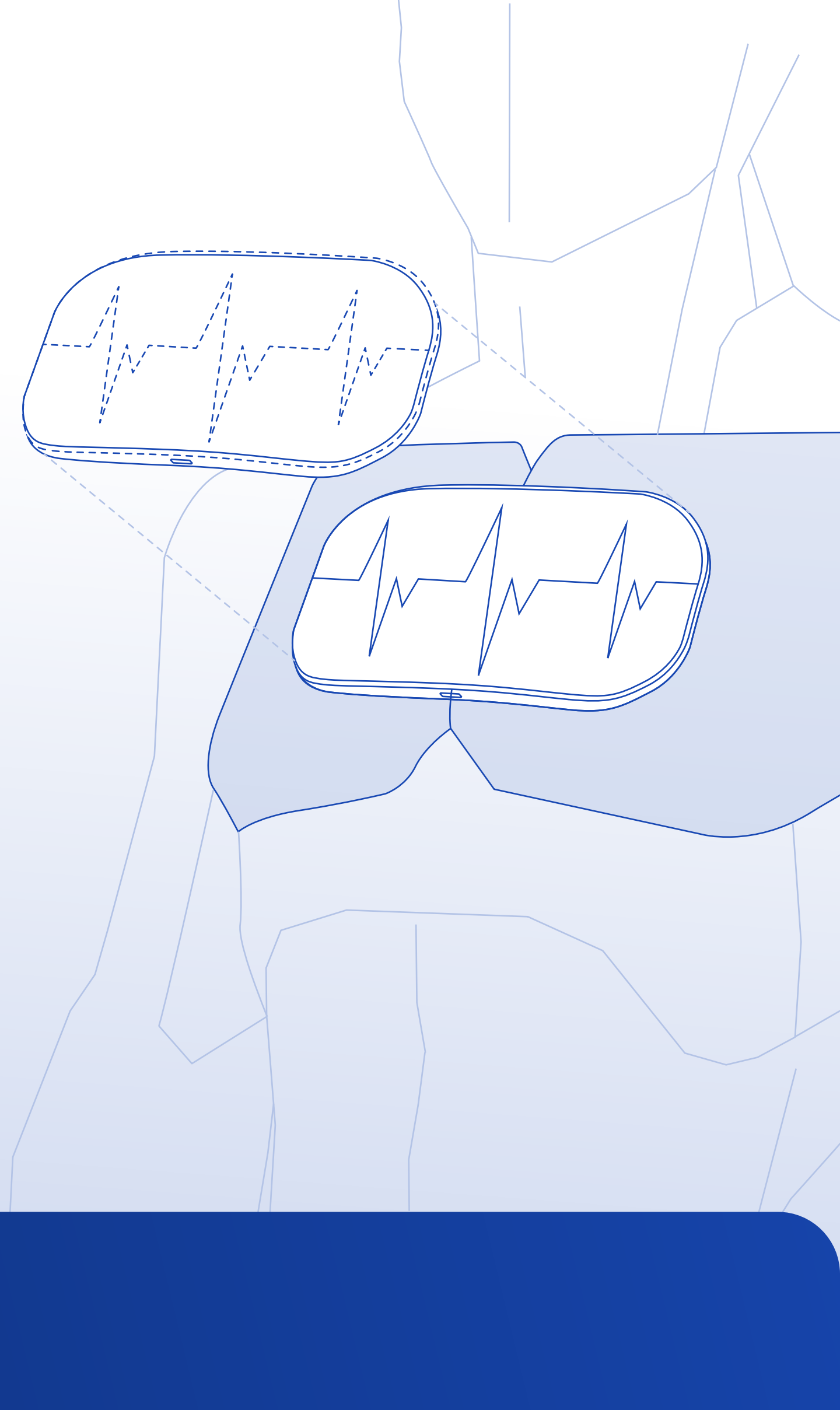


Your device has a twin. And it's changing everything.

Digital twins are virtual replicas of devices, systems, and patients. They are fed by real-time and simulated data. For MedTech companies, they unlock faster innovation and development, smarter operations, tighter regulatory-readiness, and a more predictable market performance.



THE MARKET OPPORTUNITY: WHY NOW?

Digital twins could unlock between \$60 billion and \$100 billion in annual value for the global MedTech industry.

*This estimate represents cumulative savings and revenue gains across design and R&D, manufacturing and operations, clinical trials and regulatory processes.

Lagging on precision and validation means falling behind. Digital twins support three of the most critical functions in MedTech today:



- Product innovation and development**
Accelerate device development and personalization. Reduce preclinical burden.
- Operations & manufacturing**
Prevent downtime. Build audit-ready processes at scale.
- Clinical & regulatory**
Accelerate trial timelines. Demonstrate value to payers. Monitor real-world outcomes.

INNOVATION & R&D LEADERS

Simulate fast. Validate early.

By creating virtual prototypes and simulating device performance in silico, design and product innovation teams can test diverse patient anatomies, refine trial protocols, and even replace traditional animal testing models. This means fewer physical iterations, earlier identification of risks, and faster paths to regulatory approval.

Use cases:

- In-silico prototyping
- Patient-specific modeling
- Trial simulation
- Animal testing replacement

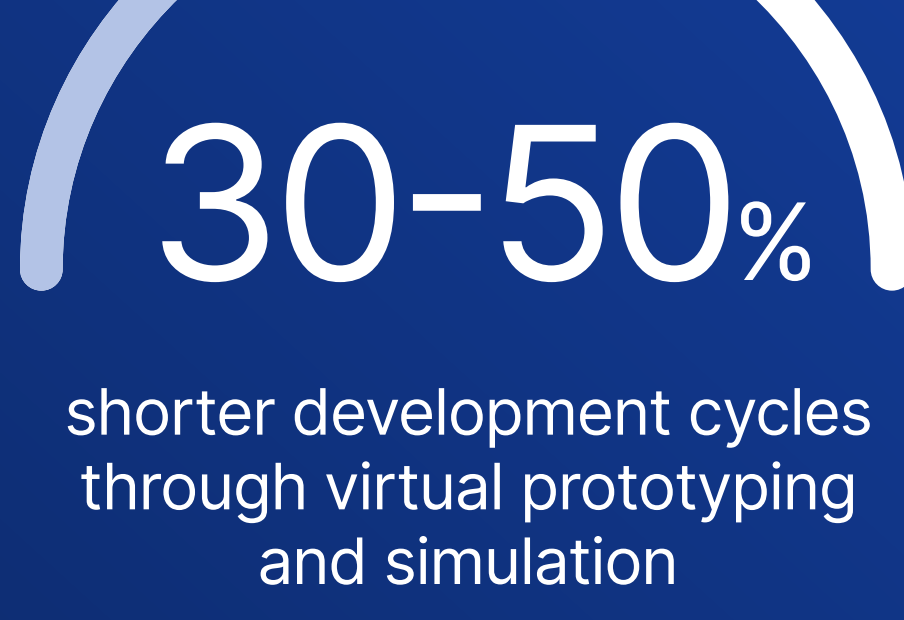
Typical development timeline for a medical device

3-8⁺ years

often longer for Class II & III devices

(SOURCE: JABIL)

The opportunity with digital twins:



shorter development cycles through virtual prototyping and simulation

(SOURCE: SIMQ)



35% lower R&D costs and 40% faster time-to-market

(SOURCE: SPRINGER NATURE)

Success spotlight: Virtonomy

Virtonomy, a Munich-based MedTech simulation company, is pioneering digital twins for medical device R&D, especially effective for virtual patient testing. Their platform creates realistic, **patient virtual environments** using rich clinical datasets, which allows manufacturers to test devices across various anatomies and conditions without the risk and cost of physical prototypes. The company already gained trust by Medtronic, Boston Scientific, Abiomed, and others.

Use cases:

01

By **simulating tricuspid valve replacement** by assessing anatomical fit and function in virtual patients, they completely eliminate early animal or cadaver testing.

02

By **optimizing cardiac catheter design**, testing navigation, tip alignment, and performance across diverse anatomies they managed to reduce costly iterations for their client.

03

By **conducting in-silico aortic valve bench tests**, simulating real-world performance and durability, they accelerated preclinical validation with higher efficiency.

OPERATIONS & DIGITAL TRANSFORMATION LEADERS

Unplanned downtime and failed audits could be prevented.

Operational inefficiencies like unplanned downtime, poor scheduling, and lack of real-time visibility are among the biggest drains on MedTech operations. In 2025, UK and European manufacturers are projected to lose more than £80 billion (approx. \$102bn) annually to downtime. Across industries, 80% of businesses have faced unplanned downtime in the last three years, with each incident lasting an average of four hours. Digital twins simulate production lines and processes in real time helping you de-risk every update and predict downtime.



Use cases:

Smart factory twins

QA simulation

Supply chain modeling

Integrated process + quality twins

Average cost of downtime across industries

\$260K

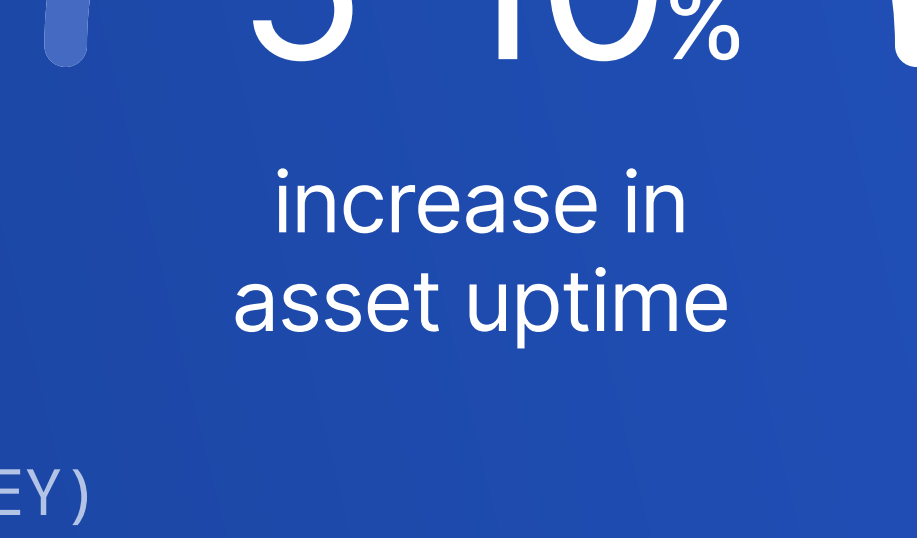
per hour

(SOURCE: GITNEX)

The opportunity with digital twins:



reduction in maintenance costs



increase in asset uptime

(MCKINSEY)

Success spotlight: Philips Healthcare

Philips Healthcare applied predictive analytics to create **virtual models of its MRI and CT systems**, shifting from reactive fixes to proactive, data-driven maintenance. For Philips, this was mission-critical, allowing them to address potential issues before they impact clinical operations. This boosted equipment reliability and ensured patients received timely, uninterrupted care.

By anticipating failures before they happened, Philips achieved:

30% reduction in equipment downtime

84% first-time fix rate, giving customers **136 extra hours of uptime** per system each year

20% of issues resolved proactively, often before users noticed a problem

CLINICAL & REGULATORY STRATEGY LEADERS

Prove value before launch. Improve outcomes after.

For clinical and regulatory leaders, success depends on generating high-quality data that demonstrates value to payers, supports regulatory submissions, and ensures ongoing patient safety. Yet in the 2025 Greenlight Guru Medical Device Industry Benchmark Report, **only 47% of medtech professionals whose products had already reached the market said they felt fully equipped to successfully manage clinical trials**.

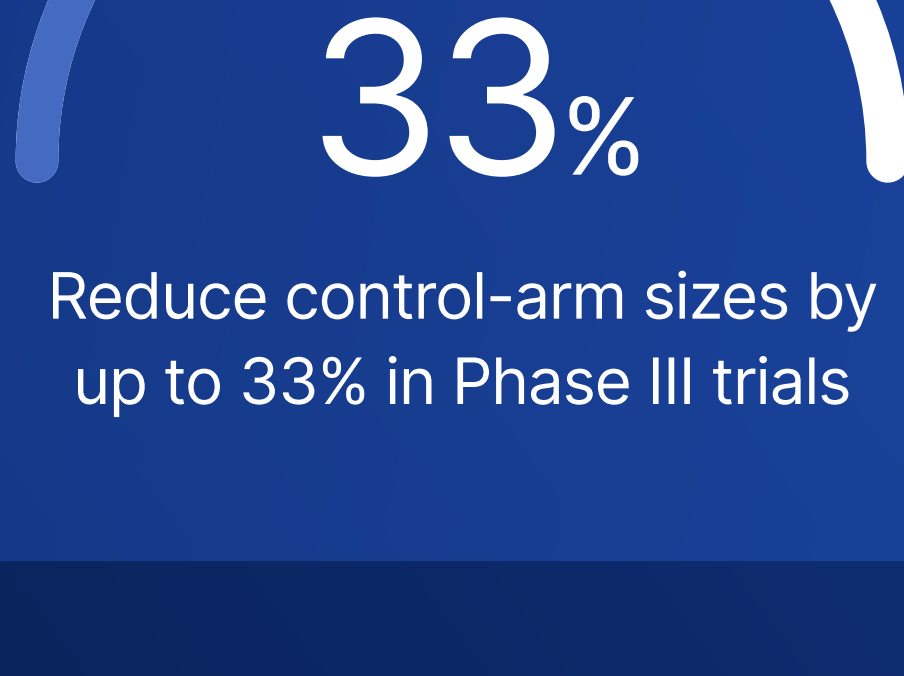
Digital twins help overcome uncertainties by:

- Providing new insights into patient outcomes through simulation
- Accelerating trial timelines
- Monitoring real-world performance after launch

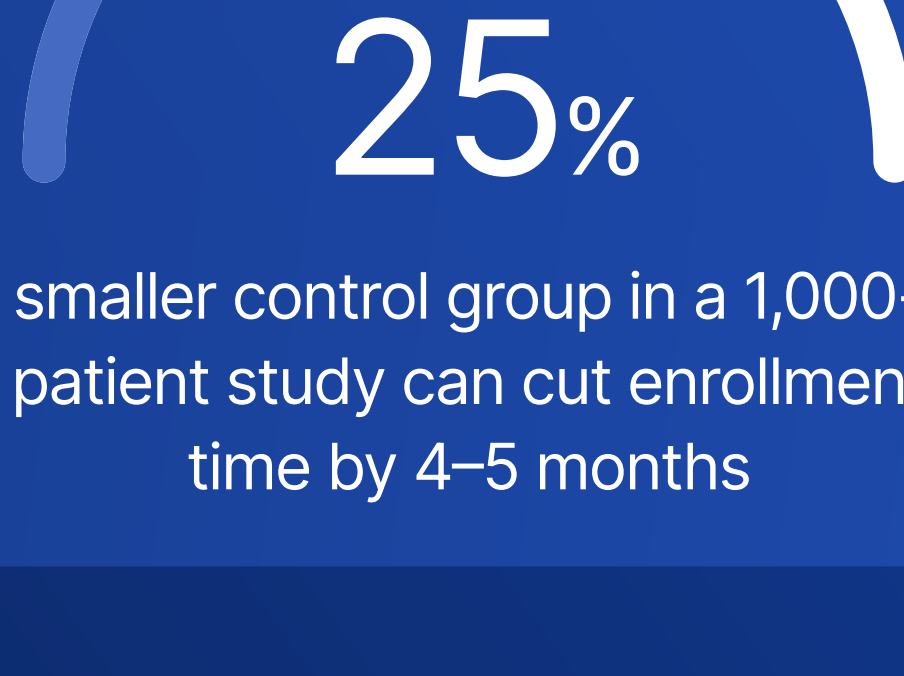
Trial preparedness

More than half of medtech teams with products already on the market say they were not fully prepared to run their clinical trials (Source: Greenlight Guru)

The opportunity with digital twins:



Reduce trial-arm sizes by up to 33% in Phase III trials



smaller control group in a 1,000-patient study can cut enrollment time by 4-5 months



reduction in nearly-arm size can save nearly a year in overall trial duration

(SOURCE: THE CONFERENCE FORUM)

Success spotlight: Digital twins in type two diabetes (T2D) clinical trial

In a randomized controlled trial for Type 2 Diabetes, researchers created **whole-body digital twins** of participants by combining clinical records, sensor data, and machine learning models. Each digital twin was used to **simulate how an individual patient would respond to dietary interventions**. Based on those simulations, the system then generated **personalized nutritional and health recommendations** with the aim of driving remission.

Results:

After one year, **73% of patients achieved T2D remission**, demonstrating the potential of digital twins to tailor trial interventions more effectively than one-size-fits-all designs.

The approach also provided **richer real-world evidence** that could support regulatory submissions and payer confidence by showing outcome predictability across diverse patient populations.

CHOOSING THE RIGHT PARTNER IS CRITICAL TO SUCCESS: HOW HTEC CAN HELP

HTEC is uniquely positioned to help MedTech companies use digital twin technology to personalize diagnostics, accelerate clinical trials, or launch next-generation medical devices. With deep expertise in real-world data, AI-driven analytics, and regulatory strategy, we support the full lifecycle—from model development and validation to implementation and market success.



Domain expertise in medtech

Understanding of FDA regulations, ISO standards, and manufacturing complexity



Scalable architecture

Ability to start small (e.g., one line or use case) and scale across the enterprise



Interoperability

Integration with your existing MES, ERP, PLM, and IoT systems



Simulation + AI capabilities

Not just monitoring, but predictive and prescriptive insights



Proven results

Case studies, ROI benchmarks, and customer references in regulated industries



Support for change management

Training, onboarding, and stakeholder alignment

HTEC helps you move from pilot to production and from potential to performance.

Get in touch