Franklyn Health

Your Device, Our Mission

A Contract Research Organisation (CRO) built for Medtech

About us

Who We Are

Franklyn Health is a **medtech-focused CRO** delivering end-to-end **clinical and regulatory solutions** for Medical Device and diagnostics companies worldwide.

We work exclusively with **small and midsize medtech innovators**, prioritising long-term partnerships and exceptional service.

From **strategy and study execution** to **final submission**, we help innovators generate the evidence they need to **launch, grow and stay ahead**.

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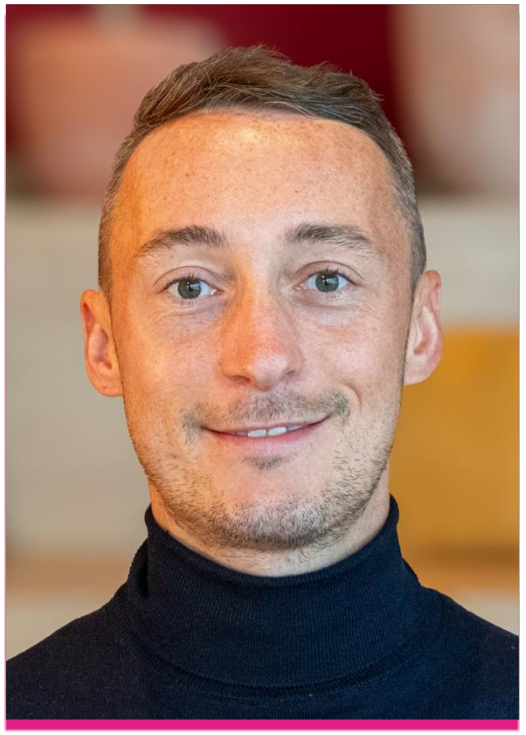
Our Leadership Team

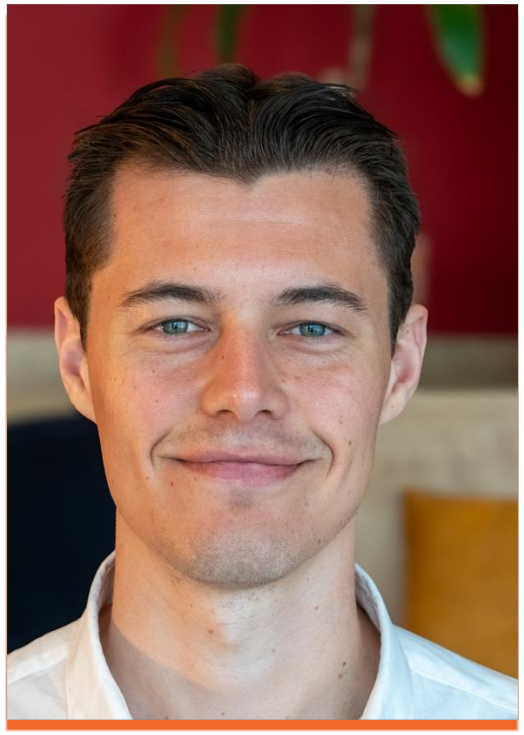


Rob Bedford

Co-founder, CEO & Head of Clinical Operations

Laura Van Vaeck

Co-founder, Head of Regulatory & Start-Up



Daniel Madsen

Co-founder & Finance Director

Michael Branagan-Harris

Senior Strategic Advisor

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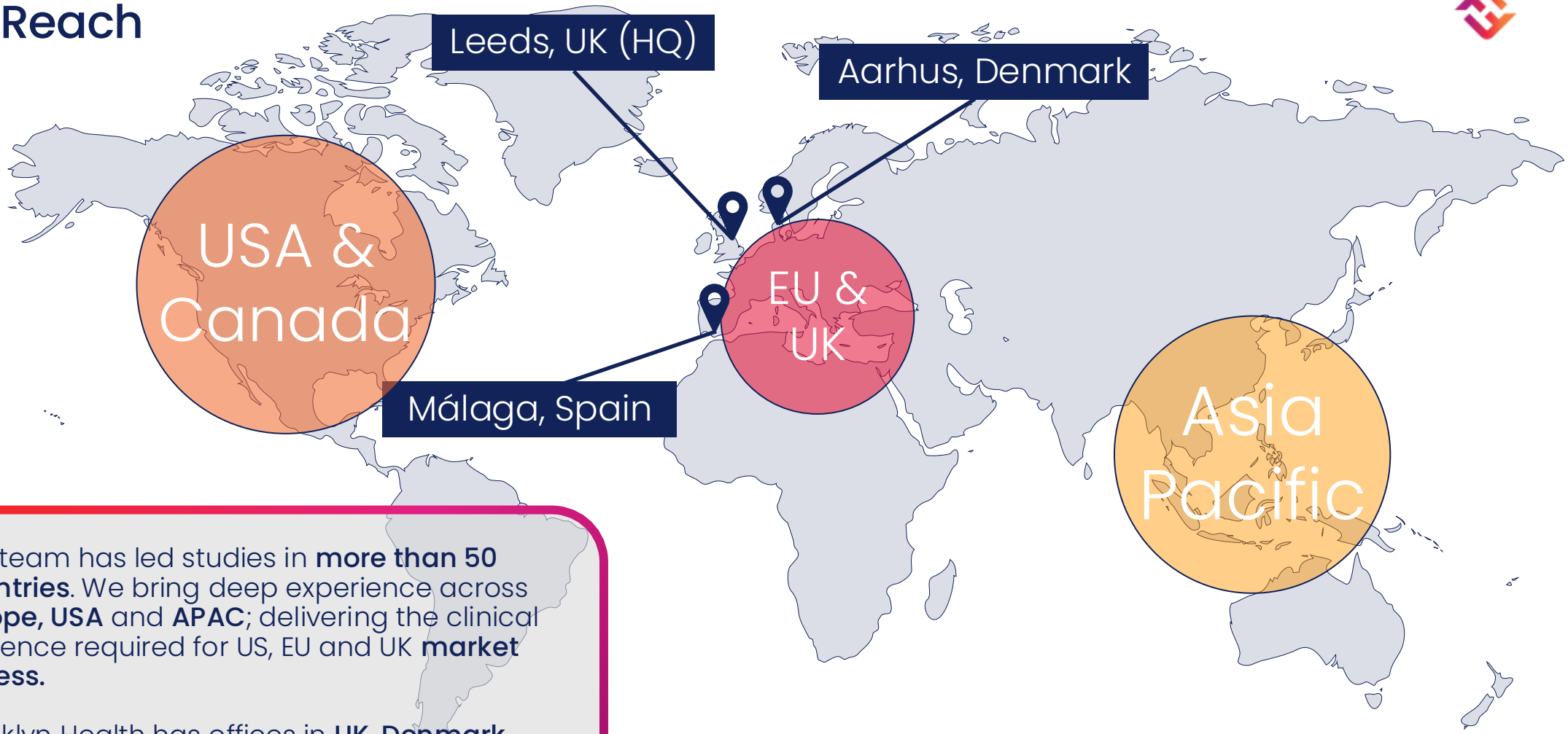
Global Reach



Our team has led studies in **more than 50 countries**. We bring deep experience across **Europe, USA** and **APAC**; delivering the clinical evidence required for US, EU and UK **market access.**

Franklyn Health has offices in **UK**, **Denmark** and **Spain**

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Why choose Franklyn Health?

Franklyn Health

Built for Medtech

- Specialists in EU MDR, UKCA and FDA (PMA, De Novo, 510k)
- Our team have spent their careers in devices
- We don't do Pharma or Biotech so your study is never a side project.

Outcomes-driven

- Our business model is to deliver successful outcomes, rather than maximise billable hours
- We want your trial to be a triumph, your device to succeed and to keep you as a client for many years

SMEs Only

- We work exclusively with small and midsize medtech manufacturers
- Your project is always a priority
- We will deliver with the accountability, responsiveness and hands-on reliability that large CROs can't match

Milestone-based Pricing

- Clear, milestone-based pricing aligned to delivery
- No opaque change orders or budget surprises
- You always know what you're paying for and why.

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Our Team's work in numbers

50+
EU and FDA protocols written

100+
Clinical Investigations Executed

25+
Devices Brought To Market

10,000+
Patients Enrolled To Date

Our team has successfully delivered trials for

QIAGEN
Johnson & Johnson MEDTECH
stryker
NOVARTIS Precision Medicine
ICON
DePuy Synthes
Smith+Nephew
abbvie diagnostics
IQVIA
labcorp

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Our Services

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Regulatory Strategy

- Define the optimal pathway to market
  - FDA: 510(k), PMA, De Novo
  - Europe: MDR/IVDR (CE/UKCA)
- Align scientific objectives with compliance requirements to reduce regulatory risk
- Health economics and market access planning

Study Design

- Develop frameworks balancing endpoints, feasibility and patient needs, with input from clinicians and key opinion leaders
- Ensure site-friendly designs that work in real-world clinical settings

Protocol Development

- Translate objectives into clear, practical protocols (Clinical Investigational Plan)
- Ensure compliance with FDA, MDR and IVDR requirements

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Our Services

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Regulatory & Ethics Submission

- Prepare and manage submissions to health authorities and ethics committees
- Secure timely approvals through region-specific expertise

Site Feasibility & Selection

- Identify and qualify high-performing sites and investigators
- Align site capabilities with study requirements

Contracting & Training

- Lead contracting and budget negotiations with sites
- Deliver comprehensive investigator and site staff training to ensure study readiness and compliance

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Our Services

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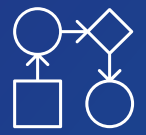
Project Management

- Oversee timelines, budgets and quality with dedicated Senior PMs
- Apply risk-based monitoring and resolve issues proactively
- Maintain eTMF and ensure continuous audit-readiness

Site Management

- Manage sites proactively to hit enrolment targets and deliver compliant, high-quality data
- Provide real-time insights into site and study performance



Vendor Oversight

- Integrate and manage specialist vendors (labs, imaging, logistics)
- Ensure accountability across all operational partners

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Our Services

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Data Management

- Design and validate eCRFs and study databases
- Ensure data integrity with QC and audit readiness

Biostatistics

- Develop statistical analysis plans aligned with regulatory expectations
- Provide interim and final analyses to support regulatory submissions, marketing and publications

Reporting

- Generate CSRs, CPSRs, CERs and PERs that support data transparency and dissemination
- Support notified body and FDA submissions with regulatory-ready outputs

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A CRO with Flexibility

You can choose a model which best fits your needs

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Full-service Model

- All-in-one solution: from clinical strategy to study execution and market approval
- Ideal for start-ups and scale-ups seeking end-to-end support
- Trusted by larger organisations for full study delivery

Functional Service Provision (FSP)

- Flexible support: project-based or time-based
- Pick the expertise you need: project management, study start-up, monitoring, regulatory functions...
- Seamless integration with your internal teams

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Ready to talk?

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Click here to book an intro call with our team.

linkedin.com/company/franklyn-health