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MediPath INNOVATION ROADMAP™

FROM INNOVATION TO IMPACT

From initial concept to international market access, the MediPath Innovation Roadmap™ guides you through every stage of MedTech commercialisation.



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Over the years, our Specialist Consultancy team at Medilink has worked with innovators across academia, industry and healthcare, helping them turn promising ideas into commercially viable, market-ready products.

Our work spans the whole innovation journey, from early market and competitor assessment, product positioning and health economics through to product development, clinical evidence, regulatory strategy, reimbursement and market access. Our aim throughout is to de-risk and accelerate innovation, helping innovators make the right decisions at the right time and avoid costly mistakes later in development.

One thing we have learnt is that great technology alone does not guarantee commercial success. Too often, product development happens in silos. Commercial advisers may understand the customer and market, while regulatory specialists focus on compliance and technical documentation. But decisions made early in development around intended purpose, product design, differentiation, claims and evidence can ultimately determine regulatory approval, adoption and commercial success.

That is why we created the MediPath Innovation Roadmap™, bringing commercial, technical, clinical, regulatory and market-access thinking together from the outset.

The MediPath Innovation Roadmap™ provides innovators with a flexible seven-stage framework for understanding where they are, where they need to get to and what needs to happen along the way. It helps identify gaps and risks early, supports better-informed development decisions and enables innovators to plan, cost and resource their R&D and commercialisation activities. This can also provide the structured development and commercial plan needed to support applications for public grant funding or to build a credible case for private investment.

For me, the real value of the MediPath Innovation Roadmap™ is that it helps take some of the guesswork out of MedTech innovation. Whether developing an initial concept, progressing through clinical and regulatory development, or preparing for international market access, it provides a structured way of looking at the whole commercialisation journey, helping innovators de-risk and accelerate development, make better decisions and focus resources where they can create the greatest value.

Patrick Trotter, PhD, MBA (Techmgmt)
Director of Specialist Consultancy
Medilink North of England

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ROADMAP™

MEDIPATH INNOVATION ROADMAP ™

MediPath Innovation Roadmap™ is a seven-step tool navigating innovation, de-risking R&D, strengthening plans, aligning expertise, and supporting investment decisions with real-world evidence.

STAGE 01

INNOVATION STRATEGY

- PROGRAMME INITIATION
- TOP-LEVEL INNOVATION STRATEGY
- PORTFOLIO PLANNING
- RESEARCH & DEVELOPMENT PLAN
- INITIATION OF NEW PRODUCT DEVELOPMENT PROJECT

STAGE 02

OPPORTUNITY ANALYSIS

- MARKET & COMPETITOR ANALYSIS
- UNMET NEED IDENTIFICATION
- CONVERTING NEEDS TO DESIGN INPUTS & OUTPUTS
- CONCEPT GENERATION, SELECTION & VALIDATION
- PRELIMINARY INTELLECTUAL PROPERTY ASSESSMENT

STAGE 03

PRODUCT DEVELOPMENT EARLY STAGE

- PRELIMINARY VALUE PROPOSITION
- INITIAL REGULATORY STRATEGY
- DESIGN HISTORY FILE & QMS DEVELOPMENT
- PRODUCT CLAIMS & LABELLING
- PROTOTYPING & PACKAGING

STAGE 04

PRODUCT EVALUATION

- PRODUCT CHARACTERISATION
- PRE-CLINICAL EVALUATION
- DESIGN FREEZE / DESIGN TRANSFER
- INTELLECTUAL PROPERTY APPLICATIONS & MAINTENANCE
- BIOLOGICAL SAFETY EVALUATION

STAGE 05

PRODUCT DEVELOPMENT CLINICAL

- CLINICAL INVESTIGATION PLAN & DESIGN
- INVESTIGATOR'S BROCHURE / SUPPLEMENTARY INFORMATION
- INSURANCE
- APPLICATIONS TO COMPETENT AUTHORITY FOR TRIALS
- CLINICAL TRIAL EXECUTION

STAGE 06

REGULATORY & QUALITY COMPLIANCE

- TECHNICAL FILE COMPILATION
- VERIFICATION & VALIDATION
- CLINICAL / PERFORMANCE EVALUATION REPORT (CER / PER)
- POST-MARKET SURVEILLANCE (PMS)
- NOTIFIED / APPROVED BODY SUBMISSION & REGISTRATION

STAGE 07

INTERNATIONAL MARKET ACCESS

- MARKET SEGMENTATION & PRIORITISATION
- INTERNATIONAL REGULATORY DOCUMENTATION & PROCESS
- REIMBURSEMENT & FUNDING PATHWAYS
- HEALTH ECONOMICS & VALUE DEMONSTRATION
- MARKET ENTRY STRATEGY

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STAGE 01

INNOVATION STRATEGY

A clear innovation strategy helps reduce commercial risk and maximise financial returns by aligning innovation with the organisation's vision and objectives.

It defines the markets the organisation wants to compete in, identifies potential product opportunities and establishes the resources, timescales and constraints that will shape future development.

Innovation Impact Matrix™



Programme Initiation

Start by understanding what the organisation has done to date, its current position and its future vision.

This establishes how innovation can contribute to the organisation's objectives and provides the strategic context for identifying and assessing potential development opportunities.

Portfolio Planning

Identify potential short-, medium- and long-term product opportunities and consider how they fit within the existing portfolio.

Products should complement the organisation's current offering while remaining sufficiently differentiated from competitors. Strategic tools such as Boston matrices, bubble diagrams and multigeneration product plans can help identify and compare potential opportunities.

Initiation of New Product Development Project

Use the innovation strategy and R&D planning process to provide clear direction for the initiation and prioritisation of new product development projects.

This enables selected opportunities to progress in a way that remains aligned with the organisation's wider strategy and commercial objectives.



Top-Level Innovation Strategy

Define the markets and market segments the organisation wants to compete in, together with the resources required and target timescales for launch.

Regulatory and reimbursement considerations and other constraints should also be considered to establish the parameters within which product development will need to operate.

Research & Development Plan

Translate the innovation strategy into one or more R&D plans containing the key activities and milestones required for successful commercialisation.

The plan should also establish the timelines and resources required, providing a structured route from strategic opportunity through to product development.

STAGE 01

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- Innovation activity is clearly aligned with the organisation's vision and objectives.
- Target markets, portfolio direction and development constraints are understood.
- Short-, medium- and long-term product opportunities are identified and prioritised.
- An R&D plan defines the activities, milestones, resources and timelines required for commercialisation.

COMMON PITFALLS

- Developing opportunities without a clear connection to company strategy.
- Failing to define target markets or adequately differentiate new products.
- Overlooking regulatory, reimbursement, resource or launch constraints.
- Progressing development without clear priorities or an R&D plan.

QUESTIONS TO CONSIDER

- What is our company vision, and how should innovation contribute to it?
- Which markets and market segments do we want to compete in?
- Where are the short-, medium- and long-term opportunities within our portfolio?
- What regulatory, reimbursement, resource and timescale constraints need to be considered?
- Which opportunities should we prioritise for new product development?

STAGE 02

OPPORTUNITY ANALYSIS

Opportunity Analysis builds the evidence needed to determine whether an innovation represents a viable product opportunity.

It considers the market and competitive landscape, unmet needs, differentiation and the generation and selection of commercially viable concepts, alongside an early assessment of intellectual property.



Market & Competitor Analysis

Identify and characterise the potential markets for the innovation, considering geographical areas, market segments and the actual accessible market.

Assess market and customer trends, alongside technology and regulatory trends and constraints. Competitor analysis should establish how the innovation can differentiate and add value through factors such as functionality, safety, clinical outcomes, supporting evidence or price.

Converting Needs to Design Inputs & Outputs

Evaluate, prioritise and segment user needs into sufficiently detailed and measurable requirements.

These can then be translated into design inputs and outputs that govern the performance and safety of the device and provide the basis for later verification and validation activities.

Preliminary Intellectual Property Assessment

Consider the intellectual property landscape alongside competitor analysis and emerging concepts.

An early assessment should explore potential patentability and freedom to operate, while recognising that protection may extend beyond patents to approaches such as design protection, trademarks and copyright. Identified IP barriers may also inform licensing decisions or modifications to the concept.



Unmet Need Identification

Define and validate the unmet need: the problem for which an effective solution is still required.

Market research approaches such as questionnaires, interviews and surveys can provide valuable insight, while techniques such as lead-user and ethnographic research can help uncover needs that end users may be unable to articulate directly.

Concept Generation, Selection & Validation

Use prioritised and validated needs as the basis for generating potential concepts and solutions.

Compare concepts against market and business needs, the market leader, key competitors and alternative concepts to select the strongest option. Leading concepts should then be validated with intended users, with findings informing iterative design improvements where required.

STAGE 02

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- A clearly characterised and accessible target market is identified.
- A validated unmet need and measurable user requirements are understood.
- The selected concept is differentiated, commercially viable and validated with intended users.
- Preliminary patentability and freedom-to-operate considerations are understood.

COMMON PITFALLS

- Developing a solution without sufficiently validating the customer or user need.
- Underestimating competitors or failing to establish meaningful product differentiation.
- Selecting concepts without benchmarking against market and business requirements.
- Overlooking the existing patent landscape or potential freedom-to-operate issues.

QUESTIONS TO CONSIDER

- Is it something the customer actually wants?
- Are there enough customers who want it?
- Can it be made and sold at a price that allows a sustainable profit?
- Can it be sufficiently differentiated from competitor offerings?
- Do we understand the intellectual property landscape and potential freedom to operate?

STAGE 03

PRODUCT DEVELOPMENT - EARLY STAGE

Stage 03 progresses the technical and commercial development of the product to a point where it can be evaluated and compliance with non-clinical regulatory requirements can be demonstrated.

This includes developing the business case for adoption, establishing the regulatory and quality framework, defining product claims and labelling, and generating functional prototypes suitable for evaluation and testing.



01 Preliminary Value Proposition

Develop the business case for adoption by understanding who influences procurement decisions and what matters to key stakeholders, including patients, healthcare professionals and payers.

Relevant quality indicators can help identify desirable outcomes and inform an evidence generation plan, ensuring that future evidence demonstrates the value needed to support adoption.

02 Initial Regulatory Strategy

Identify and prioritise target markets and determine the regulatory, technical documentation and clinical evidence requirements for each.

The regulatory strategy should consider the organisation's market priorities and existing market exposure, alongside factors such as local clinical practice, regulatory requirements and the evidence hurdles associated with different jurisdictions.

03 Design History File & QMS Development

Establish a fit-for-purpose Quality Management System (QMS) and begin documenting product development through the Design History File (DHF).

For medical devices, ISO 13485 provides the QMS framework, while ISO 14971 risk management and other relevant standards or common specifications should be identified so that compliance can be built into development and ultimately evidenced in the technical documentation.

04 Product Claims & Labelling

Develop draft product labelling covering areas such as the product description, intended purpose, intended users and populations, indications, claims, benefits and relevant warnings.

Labelling should be informed by user needs, design outputs, the value proposition, competitor products, clinical literature and applicable clinical guidance, and should remain aligned with the evidence generation plan.

05 Prototyping & Packaging

Develop functional prototypes guided by prioritised user needs and the selected concept, while identifying the test methods that will later demonstrate product performance and conformity.

Consider packaging, shelf life, sterilisation, storage conditions and manufacturing strategy early, including scalability, material selection and engagement with suppliers or contract manufacturers where appropriate.

STAGE 03

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- A clear, evidence-led value proposition supports the business case for adoption.
- Target markets and the initial regulatory route are defined.
- Product development is controlled through an appropriate QMS, risk management and design documentation.
- Functional prototypes, claims and labelling are sufficiently developed to support subsequent product evaluation.

COMMON PITFALLS

- Developing the product without adequately considering the needs of patients, healthcare professionals and payers.
- Leaving QMS implementation, risk management or regulatory planning until later in development.
- Finalising claims or labelling without ensuring that the evidence generation plan can support them.
- Developing prototypes without adequately considering future testing, packaging, sterilisation, manufacturing or scale-up requirements.

QUESTIONS TO CONSIDER

- What value does the product need to demonstrate to patients, healthcare professionals and payers?
- Which markets should be prioritised and what evidence will their regulatory pathways require?
- Are appropriate QMS, risk management and design controls being established early enough?
- Are the intended purpose, claims and labelling aligned with user needs and the evidence generation plan?
- Is the prototype suitable for evaluation, and have packaging, manufacturing and scale-up requirements been considered?

STAGE 04

PRODUCT EVALUATION

Stage 04 builds evidence that your product performs safely and as intended, using targeted preclinical evaluation to reduce development risk and prepare for clinical evaluation and regulatory approval.

It focuses on characterising the device, identifying applicable standards, testing performance and safety, refining the design and deciding whether to progress. Evaluation is iterative, with findings informing risk management, design freeze, transfer and potential intellectual property protection.



01 Preclinical Characterisation

Characterise materials, design and device performance using fit-for-purpose test methods, including benchtop testing and relevant preclinical models.

Select methods that reflect how the product will be used, and use preliminary screening to understand performance, safety and stability before committing to more extensive testing.

02 Standards & Specifications

Identify applicable formal or harmonised standards, common specifications and jurisdiction-specific regulatory requirements.

Consider electrical safety, biological evaluation, sterilisation and software requirements as relevant to the device. Align the testing strategy with the intended markets and check whether evidence or test methods will be expected.

03 Performance & Safety Evaluation

Generate proportionate evidence for performance, safety and stability, using appropriate testing alongside existing data, literature and scientific rationale where justified.

Document why the chosen approach is suitable and what it demonstrates. For software and other devices, supporting datasets can inform evaluation without automatically replacing the need for device-specific clinical evidence.

04 Iterate, De-Risk & Improve

Use early testing and formative human factors feedback to refine design, improve usability and labelling, reduce key risks and identify potential patentable improvements.

Address weaknesses through further development and repeat evaluation as needed. Consider the timing and cost of intellectual property protection as the design evolves.

05 Design Freeze, Transfer & Go / No-Go

Consolidate the evidence, resolve key risks and confirm design maturity to support design freeze, transfer and an informed Go / No-Go decision to progress into clinical evaluation.

Ensure the evaluation outputs can support verification, validation and technical documentation, and use this decision point before committing to more costly clinical development.

STAGE 04

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- Product performance, safety and stability are characterised against defined requirements, with appropriate standards and regulatory expectations addressed.
- Testing provides evidence to support verification, validation and future regulatory documentation, with appropriate use of existing data where justified.
- Key technical and usability risks are reduced through iterative testing, design improvements and feedback on draft labelling.
- Design maturity supports design freeze, transfer and an informed Go / No-Go decision on progression to clinical evaluation.

COMMON PITFALLS

- Testing that is not linked to defined requirements, applicable standards or the expectations of the intended regulatory markets.
- Overlooking existing data, literature or scientific rationale that could justify reducing the need for additional testing.
- Freezing the design or progressing towards clinical evaluation before significant technical and usability risks have been addressed.
- Treating product evaluation as a one-off activity, without using findings to refine the device, its labelling and the testing strategy.

QUESTIONS TO CONSIDER

- Have we defined what must be proven before clinical evaluation and which standards apply to our device and markets?
- Are our test methods representative, robust and defensible, with existing data and literature considered where appropriate?
- Have iterative testing and user feedback resolved key performance, safety, stability and usability concerns?
- Have evaluation activities identified design improvements or intellectual property that should be protected?
- Are we ready for design freeze, transfer and an informed Go / No-Go decision to progress?

STAGE 05

PRODUCT DEVELOPMENT - CLINICAL

Stage 05 develops the clinical evidence needed to substantiate product claims, demonstrate value and support regulatory approval, reimbursement and market adoption.

It brings together clinical investigation design, regulatory & ethics preparation, study delivery and evidence translation. The aim is to generate clinical and health economic data that address the intended purpose, benefit-risk profile and value proposition for patients, healthcare professionals and payers.



01 Define the Clinical Evidence Strategy

Establish the evidence required to support the intended purpose, claims, benefit-risk profile and value proposition, considering regulatory, clinical and health economic requirements.

Clarify what patients, healthcare professionals and payers need to see, and use these priorities to guide evidence generation throughout the clinical development programme.

02 Design the Clinical Investigation

Define the study design, patient population, sample size, endpoints and follow-up, informed by a draft clinical evaluation plan and developmental Clinical Evaluation Report (CER).

Consider suitable comparators, the number of study sites and the timing of review points, ensuring the investigation can address both clinical and health economic objectives.

03 Prepare for Regulatory & Ethics Approval

Develop the clinical investigation documentation and submission strategy for the relevant regulatory and ethics bodies.

Prepare the clinical investigation plan, investigator's brochure, participant information and consent materials, alongside the required governance documentation. Plan the application process for the intended market and address the applicable requirements before the study begins.

04 Plan & Enable Study Delivery

Identify suitable clinical centres, clinical research organisations (CROs) or healthcare partners, and plan recruitment, monitoring, documentation and data management.

Confirm responsibilities, resources and timelines across the study team. Ensure participant protection and appropriate insurance are in place, with arrangements that support reliable study delivery and the collection of usable evidence.

05 Analyse, Publish & Translate the Evidence

Analyse clinical and health economic outcomes and plan for peer-reviewed publication.

Translate the findings into clinical evaluation, regulatory, reimbursement and market-access activities. Establish the publication strategy before the study is completed, so that the resulting evidence can support the benefit-risk assessment, strengthen the value proposition and inform market adoption.

STAGE 05

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- Clinical evidence requirements are clearly defined and aligned with the intended purpose, product claims and benefit-risk profile.
- The investigation addresses clinical, regulatory and health economic needs, with appropriate study design, patient numbers, endpoints and follow-up.
- Regulatory, ethics and governance requirements are addressed, with capable delivery partners and appropriate arrangements for participant protection.
- High-quality evidence supports the value proposition and can be translated into clinical evaluation, reimbursement and market-adoption activities.

COMMON PITFALLS

- Unclear or insufficient endpoints, inappropriate study design or patient numbers that cannot adequately address the evidence requirements.
- Incomplete or poorly prepared regulatory and ethics submissions, with insufficient attention to the documentation and governance needed.
- Delays caused by unsuitable sites, recruitment challenges, unclear responsibilities or inadequate preparation for study delivery.
- Clinical, health economic and commercial evidence needs are considered separately, leaving important gaps for reimbursement or market adoption.

QUESTIONS TO CONSIDER

- Does the planned evidence support our intended purpose, claims and benefit-risk profile?
- Will our study generate evidence that is valuable to patients, healthcare professionals, regulators and payers?
- Are the study design, patient numbers, endpoints and follow-up appropriate for our objectives?
- Are we prepared for regulatory and ethics submissions, site readiness, participant protection and study delivery?
- How will we analyse, publish and use the evidence to support regulatory approval, reimbursement and market access?

STAGE 06

REGULATORY & QUALITY COMPLIANCE

Stage 06 brings together the technical, clinical and quality evidence needed to demonstrate regulatory conformity and place the device on the market.

It focuses on finalising the technical documentation, verification and validation, clinical or performance evaluation, post-market surveillance planning, and the conformity assessment and registration process, all supported by an effective Quality Management System.



01 Technical File Compilation

Compile and finalise the technical documentation within the Quality Management System, bringing together the evidence demonstrating that the device meets applicable regulatory requirements.

This includes device and design information, manufacturing controls, risk management, verification and validation evidence, labelling, and clinical or performance evaluation, with clear document control and traceability throughout.

02 Verification & Validation

Complete and document verification and validation activities to demonstrate that design outputs meet the defined design inputs and that the final device meets user needs and performs as intended.

Test protocols, reports and resulting data should provide objective, traceable evidence supporting the device's safety, performance, claims and regulatory requirements.

03 Clinical / Performance Evaluation Report (CER / PER)

Finalise the Clinical Evaluation Report (CER), or Performance Evaluation Report (PER) for an IVD, by bringing together the available clinical evidence to demonstrate safety, performance and clinical benefit.

Evidence may include clinical investigations, relevant scientific literature and other supporting data, with any remaining evidence gaps identified and addressed through appropriate post-market activities.

04 Post-Market Surveillance (PMS)

Develop the Post-Market Surveillance plan defining how the manufacturer's device safety and performance will be monitored throughout its lifetime.

This includes methods for collecting and analysing post-market information, such as user feedback, incident reporting and literature reviews, with findings feeding back into risk management, clinical evaluation and the technical documentation.

05 Notified / Approved Body Submission & Registration

Where required, submit the completed technical documentation, CER/PER and QMS evidence to the relevant Notified Body or Approved Body for conformity assessment.

Following successful assessment, or self-declaration where applicable, complete the required device registration with the relevant authority before placing the product on the market.

STAGE 06

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- Technical, clinical and quality documentation provides clear, traceable evidence of regulatory conformity.
- Verification and validation demonstrate that the device meets its requirements and performs as intended.
- Clinical or performance evaluation supports the device's safety, performance and benefit-risk conclusion.
- Conformity assessment, registration and appropriate post-market arrangements are in place for market placement and ongoing compliance.

COMMON PITFALLS

- Inconsistencies or poor traceability across technical documentation, risk management, clinical evidence and the QMS.
- Incomplete verification or validation evidence, or testing that does not adequately support product requirements and claims.
- Clinical evidence gaps that are not clearly acknowledged or addressed through appropriate post-market activities.
- Entering conformity assessment with incomplete or poorly structured documentation, resulting in requests for clarification or additional evidence.

QUESTIONS TO CONSIDER

- Is the technical documentation complete, controlled and traceable to the applicable regulatory requirements?
- Have all required verification and validation activities been completed and documented?
- Does the CER/PER adequately support safety, performance, clinical benefit and the product's claims?
- Is there an appropriate PMS plan for monitoring safety and performance following market placement?
- Are the applicable conformity assessment and registration requirements understood for the intended market?

STAGE 07

INTERNATIONAL MARKET ACCESS

Stage 7 turns regulatory readiness into sustainable commercial and clinical impact by prioritising international markets and aligning regulatory, reimbursement, value and market-entry strategies.

It brings together market selection, adaptable regulatory documentation, funding pathways, health economic evidence and practical market entry. The focus is on matching the product to local healthcare needs, demonstrating its value and planning how adoption can grow beyond the initial launch.



01 Market Segmentation & Prioritisation

Systematically assess and rank international markets using Medilink's proprietary methodology, considering healthcare system structure, regulatory complexity, reimbursement maturity, procurement pathways and commercial opportunity.

Balance accessibility, risk and likely speed to adoption, and sequence entry so that resources are focused on markets with a credible route to funding and growth.

02 International Regulatory Documentation & Process

Develop a regulatory strategy that allows technical documentation and evidence to be adapted across target markets.

Identify local classification, submission and evidence requirements, assess where existing approvals may support access, and plan ongoing post-market obligations. Maintain an approach that reduces duplication while addressing the specific expectations of each jurisdiction.

03 Reimbursement & Funding Pathways

Identify reimbursement systems, funding mechanisms, coding, health technology assessment (HTA) requirements and payer evidence needs in each target market.

Map the roles of payers, procurement teams and healthcare providers, and clarify how coverage, payment or purchasing decisions are made. Align the evidence and commercial approach with a realistic route to funded adoption.

04 Health Economics & Value Demonstration

Demonstrate market-specific value through clinical and health economic evidence on outcomes, costs and resource use.

Tailor the value proposition to local care pathways, comparators and system priorities, using appropriate economic analysis. Address evidence gaps through further studies or real-world evidence, and communicate the benefits clearly to clinicians, payers and procurement teams.

05 Market Entry & Scale-Up Strategy

Develop a practical go-to-market plan covering partnerships, distribution, pricing and stakeholder engagement.

Consider early adopter sites or pilot programmes to demonstrate fit within clinical workflows and strengthen the evidence base. Define the investment and steps needed to expand beyond initial market entry and achieve sustainable commercial growth.

STAGE 07

HOW MEDIPATH SUPPORTS YOU

WHAT SUCCESS LOOKS LIKE

- Target markets are prioritised with a clear, evidence-based rationale that balances access, risk, commercial opportunity and potential for adoption.
- Regulatory documentation and evidence can support efficient submissions across markets, with local requirements and ongoing obligations addressed.
- Credible reimbursement and funding pathways are identified, supported by health economic evidence that demonstrates value within the target healthcare system.
- A practical market-entry and scale-up plan supports early adoption, sustainable commercial growth and measurable clinical and economic impact.

COMMON PITFALLS

- Pursuing markets without clear priorities, or relying solely on distributor interest, perceived market size or opportunistic partnerships.
- Underestimating differences in regulatory requirements, reimbursement systems, procurement processes or ongoing compliance obligations between markets.
- Using insufficient clinical or health economic evidence, or a value proposition that does not reflect the target market.
- Launching without a clear route to funding, suitable local partners or a practical plan for scaling beyond initial entry.

QUESTIONS TO CONSIDER

- Which international markets offer the best opportunity for our product, and what supports that choice?
- Which regulatory requirements apply in our target markets, and how can we adapt our existing documentation and evidence?
- What reimbursement, funding, HTA or procurement pathways can support adoption in each priority market?
- What health economic evidence is needed to demonstrate value to local payers and healthcare systems?
- Who are the right partners, and what is our practical market-entry and scale-up strategy?

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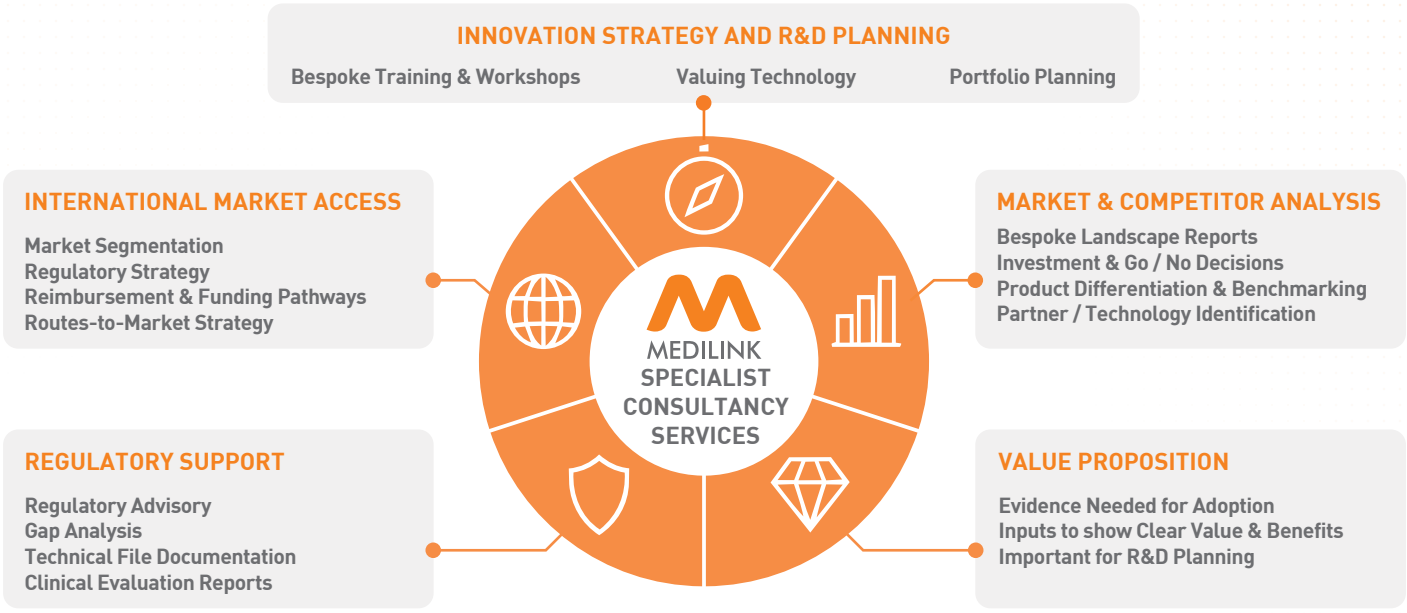
MEDILINK SPECIALIST CONSULTANCY

Helping innovators turn great ideas into commercially successful, market-ready products.

Medilink Specialist Consultancy supports innovators across academia, industry and healthcare to de-risk development, accelerate routes to market and maximise commercial potential.

The **Medilink Specialist Consultancy Team** provides end-to-end support aligned with the MediPath innovation roadmap, helping organisations navigate the journey from early-stage innovation through development, evidence generation, regulatory compliance, market access and commercialisation. The examples below highlight some of the typical areas where our specialists can add value, with support tailored to the specific needs, challenges and stage of each innovation.

Our multidisciplinary team's support includes:



Patrick Trotter
PhD, MBA (TechMgmt)
Director of Specialist Consultancy



Stefanie Read
MSc
Principal Specialist, Regulatory & Commercialisation



Rashmi Raju
PhD
Regulatory & Market Access Manager



MARKET AND COMPETITOR ANALYSIS

Medilink conducted a thorough market and competitor assessment regarding the opportunities for ClotProtect's small molecule to attenuate blood loss. The work was conducted with considerable insight including identifying types of clinical need, which could represent commercial opportunities. The assessment also analysed existing types of solution with their benefits and limitations including clinical risks.

Professor Helen Philippou
CEO, ClotProtect Therapeutics Ltd

SPECIALIST CONSULTANCY

The Innovation and Commercialisation team at Medilink work with us to provide 'lie of the land' assessments covering market opportunity, competitor analysis, regulatory and market access / reimbursement considerations. This input has been hugely beneficial and has allowed us make informed investment decisions and has helped de-risk our future pipeline.

Chris Yates
CEO, Abingdon Health

CLINICAL EVALUATION REPORTS

Medilink have authored a number of clinical evaluation reports for our family of class III implantable tissue regenerative products and we have been delighted in the speed and quality of the service and reports, which have also satisfied the notified body. We look forward to continuing our relationship with Medilink"

Wayne Austin
Managing Director, Ceramisys Ltd

REGULATORY SUPPORT

Medilink have provided exceptional support throughout our product development journey. Their expertise in regulatory strategy, product labelling, risk management, technical documentation, clinical evaluation, and post market surveillance has been invaluable. In a remarkably short period of time, their contributions have significantly accelerated our route to market. Their support is greatly appreciated."

Dr Rebecca Allam
CEO, PreActiv

INTERNATIONAL MARKET ACCESS

The comprehensive consultancy services provided by Medilink, including in-depth market research, insights into the market's healthcare settings, reimbursement pathways, and regulatory processes, have been invaluable in supporting our new market entry strategy. We highly recommend Medilink's services to any healthcare business seeking to expand internationally.

Sonia Neary
MD and Co-Founder, Wellola

WORKSHOPS & TRAINING

The Medilink Innovation and Commercialisation and Regulatory course was fantastic with relevant content bespoke to our request for training. The interactive content and innovation management tools will help us manage and optimise our portfolio. The learnings gained from this course have upskilled our entire team. Great course!"

Mark Taylor
Head of Innovation, South Tyneside and Sunderland NHS Trust

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