Transforming Triage and Acute Care: Go-To-Market Strategy for Novel Triage Diagnostic Devices

Strategic insights to support research, development and rapid market entry

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Abbreviations

AAC - Accelerated Access Collaborative
AI - Artificial Intelligence
ARPH - Advanced Research Projects for Health
CDC - Centers for Disease Control and Prevention
CE - Conformité Européenne (European Conformity marking)
CE-IVD - CE-marked In Vitro Diagnostic
CLIA - Clinical Laboratory Improvement Amendments
CMS - Centers for Medicare & Medicaid Services
CTAS - Canadian Triage and Acuity Scale
ED - Emergency Department
EDL - Essential Diagnostics List
EEA - European Economic Area
EIC - European Innovation Council
EIT - European Institute of Innovation and Technology
EMS - Emergency Medical Services
ESI - Emergency Severity Index
EU - European Union
EUL - Emergency Use Listing
EVA - Early Value Assessment
FDA - Food and Drug Administration (US)
GP - General Practitioner
GPO - Group Purchasing Organization
HRA - Health Research Authority (UK)
HTA - Health Technology Assessment
ICRC - International Committee of the Red Cross
ICU - Intensive Care Unit
IDAP - Innovative Devices Access Pathway
IEC - International Electrotechnical Commission
IRAS - Integrated Research Application System
ISO - International Organization for Standardization
IVD - In Vitro Diagnostic
IVDR - In Vitro Diagnostic Regulation (EU 2017/746)
LMIC - Low- and Middle-Income Countries
MDR - Medical Device Regulation
MHRA - Medicines and Healthcare products Regulatory Agency
MSF - Médecins Sans Frontières (Doctors Without Borders)
MTFM - MedTech Funding Mandate
MTS - Manchester Triage System
NCD - National Coverage Determination
NEMSIS - National Emergency Medical Services Information System
NEWS2 - National Early Warning Score 2
NGO - Non-Governmental Organisation
NHS - National Health Service
NICE - National Institute for Health and Care Excellence
NIH - National Institutes of Health
NIS - NHS Innovation Service
POC - Point of Care
POCT - Point-of-Care Testing / Triage
QMS - Quality Management System
Q-Sub - Q-Submission (FDA pre-submission programme)
SOM - Serviceable Obtainable Market
STeP - Safer Technologies Program
TCET - Transitional Coverage for Emerging Technologies
UK - United Kingdom
UKCA - UK Conformity Assessed
UN - United Nations
US - United States
WHO - World Health Organization

Executive Summary

There is a substantial commercial opportunity in developing novel diagnostic technology that can alleviate pressures and pain points in early clinical decision-making processes across emergency and acute care settings.

- Healthcare systems face increasing pressure from rising emergency demand, ageing populations, workforce shortages and diagnostic delays, creating a **need for rapid, accurate and portable point-of-care (POC) triage diagnostics that support earlier clinical decision-making.**
- The competitive landscape reveals a **gap between equipment-intensive hospital POC analysers and narrow, disease-specific rapid tests**. **Novel technology should be positioned to bridge this gap** through broad, physiology-based triage panels delivered from single finger-prick samples with smartphone-enabled analyses.
- **Emergency departments (EDs) are identified as the primary entry market** , where faster diagnostic decisions can reduce admissions, improve patient flow and alleviate overcrowding. Longer-term expansion opportunities include ambulances, urgent care, community healthcare, pharmacies and care homes.
- The **United States offers the largest commercial opportunity**, while the **UK provides a strategically attractive market** where strong clinical and economic evidence could enable NHS-wide adoption through a centralised healthcare system.
- Key differentiators of novel technology should include **consolidation of multiple biomarkers into one test, elimination of dedicated laboratory equipment, simple workflows, digital integration and triage-oriented risk stratification** rather than disease-specific diagnosis.
- A **global market access strategy is proposed**, centered on generating a **single evidence package that can be adapted for regulatory and reimbursement requirements** across the UK, US, EU and WHO, reducing duplication and accelerating adoption.
- Market adoption should follow phased regulatory, clinical and commercial pathways in each jurisdiction, with **success dependent on demonstrating clinical effectiveness, health-economic value, improved patient flow, and robust real-world evidence** to support widespread implementation.

This whitepaper outlines the clinical need, market opportunity, competitive positioning, and global regulatory and commercial strategy for the technology, presenting a roadmap for its adoption as a novel point-of-care triage diagnostic across major healthcare markets.

Clinical Need for a Novel Triage Diagnostic Device

Healthcare systems are facing sustained pressure on emergency care capacity. Population growth and rapid aging have increased chronic disease, multi-morbidity and acute exacerbations, driving higher demand for urgent and emergency care. Emergency triage functions as the system's front door control point - governing clinical prioritisation, resource allocation and overall patient flow. The triage settings differ in staffing, protocols and downstream actions, but share a common challenge: **clinical decisions are often made with limited objective diagnostics at first contact[1, 2].**

The convergence of rising demand, diagnostic delays and resource constraints has created a growing unmet need for emergency triage and diagnostic tools that are fast, accurate, portable and operationally simple. Triage is increasingly expected to function not only as prioritisation, but as a decision-enabling layer that supports escalation, redirection or immediate treatment and safe discharge[1,2].

Emergency triage occurs increasingly across multiple environments, including:

- Urgent care / on-site in hospitals,
- Care homes,
- Community pharmacies or healthcare centres,
- At-home diagnostic / self-evaulation modalities.

Operationally, the triage burden intensifies when uncertainty is high and decisions are time-sensitive[3].

Currently, triage in any setting remains heavily reliant on clinical judgement plus basic observations, with laboratory confirmation often arriving too late to support early decisions. This contributes to:

- Conservative disposition (long observation or admission),
- Avoidable ED utilisation,
- Downstream congestion[1, 2].

Representative comparison of settings in need of a triage platform or service

	Emergency Department (ED)	On-site hospital / ambulances	Pharmacy	Care Homes
Primary Goal	Identify life-threatening conditions and prioritise care	Manage flow; treat urgent non-emergency cases	Screen minor ailments; refer to higher care if needed	Detect acute deterioration early; decide to treat onsite or escalate
Common System	5-level acuity scales (e.g., MTS, ESI, CTAS)	Streaming + clinical assessment	Clinical pathways / "pharmacy first" protocols	Observation and assessment; escalation protocols; GP/remote clinical input
Staffing	Specialist triage nurses/doctors	Nurses, GPs or specialised clinicians	Pharmacists, trained staff	Care staff, visiting clinicians, remote medical oversight
Action Taken	Stabilise or prioritise treatment	Treatment on site or redirection to ED/GP	Advise, supply, prescribe, or refer	Monitor onsite, escalate to GP or transfer to ED

For a portable, microfluidics-based diagnostic or triage platform utilising whole blood as sample, the value proposition is:

1. **Reduced time to actionable clinical decision,**
2. **More accurate early identification of high-risk patients,**
3. **Reduced avoidable ED utilisation / patient admission where appropriate,**
4. **Reduced dependency on central laboratory infrastructure in constrained environments,**
5. **Measurable improvements in flow metrics (length of stay, boarding, left-without-being-seen proxies).**

Emergency Triage Demand by Care Delivery Setting

Emergency departments (EDs) represent the most direct, throughput-anchored entry point[1]. Distributed healthcare / diagnostic hubs could follow once the device is established and its benefits are well proven. Community settings and care homes could also benefit from the technology by reducing unnecessary hospital transfers, as long as the device is easy to use and supported by clear protocols[4].

Most Likely Adoption Scenario: High-Acuity / High Throughput Front Door Setting (EDs)[1, 2]

Representative Settings: Hospital EDs, major urgent care and emergency units, ambulance services

Primary Unmet Need: ED congestion is highly sensitive to time-to-decision. Disposition depends on laboratory confirmation; delays drive conservative triage and increased observation / admission, prolonging length of stay. Boarding further reduces functional triage capacity.

Where Rapid Diagnostics / Triage Fit: Highest value in high-volume, high-uncertainty presentations where earlier objective risk stratification enables escalation or safe discharge.

Adoption Outlook: High; strong potential for early adoption due to clear throughput and economic linkage.

Alternative / Expansion Scenario: Distributed, Low-Infrastructure Diagnostic Hubs[2]

Representative Settings: Ambulance services, community pharmacies or clinics, field / surge hospitals

Primary Unmet Need: Escalation and destination decisions are often made without objective diagnostics, leading to risk-averse referral / conveyance or delayed escalation or misdiagnosis.

Where Rapid Diagnostics / Triage Fit: As a referral-quality and conveyance decision tool, provided the solution / technology is robust, simple and fast in low-infrastructure environments.

Adoption Outlook: Medium; strong policy tailwinds in some markets but higher workflow variability and governance requirements.

Alternative / Expansion Scenario: Chronic Care Environments with Episodic Acute Events (Care Homes)[2, 4]

Representative Settings: Care homes / nursing homes, hospital geriatric units or services, residential long-term care

Primary Unmet Need: Diagnostic scarcity on-site increases uncertainty, atypical presentation and frailty of patients complicated clinical judgment. Avoidable transfers to hospital or escalation are anchored in policies in several systems.

Where Rapid Diagnostics / Triage Fit: As a transfer avoidance and early escalation tool, especially for infection risk and cardiopulmonary syndromes.

Adoption Outlook: Medium; heavily dependent on operational simplicity, clear escalation protocols and evidence that use of the technology reduces avoidable conveyance without delaying necessary care.

The Fit of the Technology for ED Rapid Diagnostics / Triage is Informed by Data

NHS England categorises emergency care into Type 1 (major ED events), Type 2 (single-specialty emergencies) and Type 3 (lower-acuity minor injury units). Collectively, Type 1 and Type 2 ED admissions make up ~60% of total emergency care instances, almost all of which could benefit from rapid, point-of-care results readout[5].

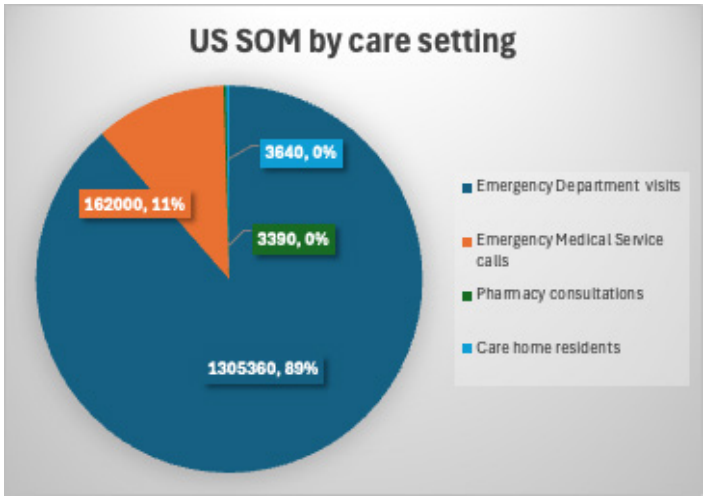
Over 80% of reported point-of-care triage technology use is concentrated in high-acuity syndromes including acute coronary syndromes (41%), sepsis (14%), trauma (12%), critical illness (10%) and undifferentiated presentations (5%)[2].

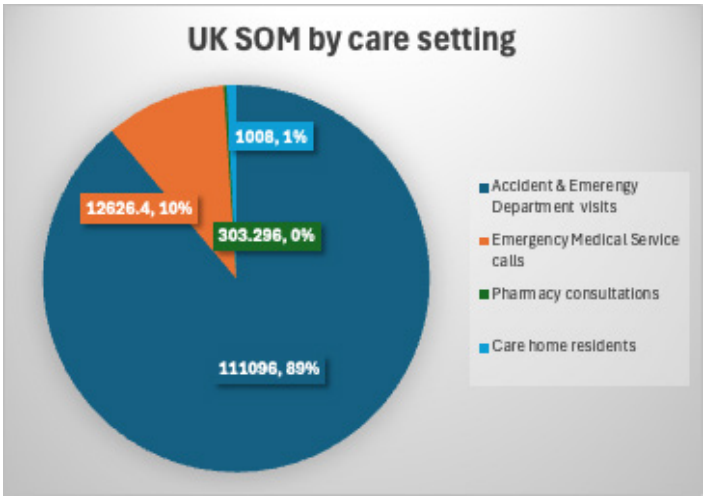
Serviceable Obtainable Market (SOM) Analysis

There is a substantial opportunity for novel diagnostic / triage technology across emergency and acute care settings, with EDs representing the primary entry market as delays in diagnostic decision-making directly contribute to admissions, ED overcrowding and over-use or resources[1]. Here, we present a SOM analysis of the US and UK markets, which are most appropriate for this technology.

The US is the largest and most attractive near-term market, with approximately 155.4 million ED visits annually, of which around 17.8 million result in hospital admissions, alongside more than 54 million emergency medical service activation, and a large long-term care population[6-8].

In the US, the large scale of the healthcare system translates to a substantial market opportunity. Based on approximately 155.4 million annual ED visits, approximately 93 million visits are eligible for the novel point-of-care triage (POCT) diagnostic technology. Accounting for serviceability and setting a conservative 2% penetration rate, the US market alone could support roughly 1 million tests annually within five years. This figure increases further when considering additional opportunities in emergency medical services (EMS), community healthcare centres and long-term care settings.





In the UK, the opportunity is smaller in absolute terms but remains substantial and easier to access due to the more integrated nature of the healthcare system. From approximately 30.8 million annual ED attendances, around 18.5 million are eligible for the novel POCT diagnostic technology. Accounting for serviceability and setting a conservative 1% penetration rate, the UK market could support 90,000 - 110,000 tests per year within five years[9-12].

While the UK SOM is smaller, there is an urgent clinical need in the UK for rapid triage diagnostic modalities, as the NHS faces acute operational pressures such as ED overcrowding, delayed diagnostics and poor four-hour target performance. This need can suppport evidence-led adoption of the technology, if clear benefit is demonstrated[13].

In Summary:

- **The US offers the largest commercial opportunity and fastest route to meaningful scale-up.**
- **The UK represents a smaller but strategically attractive market where strong clinical and economic evidence could facilitate system-wide adoption through a centralised national healthcare system.**

Competitive Landscape in POC Diagnostic and Triage Technologies

Competitive landscape analysis reveals a clear gap between high-performance but equipment-intensive hospital POC systems and narrow, indication-specific rapid tests deployed in community settings. **Successful novel POC diagnostic / triage technologies will bridge this gap by delivering a broad, physiology-based test panel from a single finger-prick sample on a disposable test card, interpretable electronically.**

The competitive landscape to the proposed / hypothetical technology can be segmented into four categories:

1. Direct Competitors: Multi-parameter POC Blood Analysers

This segment comprises established hospital-based platforms such as the Abottt i-STAT, Siemens epoc, Nova Stat Profile, Radiometer AQT90 Flex, Abbott Piccolo Express or PixCell HemoScreen. These systems provide many of the same analytes as the proposed novel technology, including electrolytes, blood gases, inflammatory or cardiac biomarkers or full blood counts. However, clinicians often require multiple instruments and analyte cartridges to obtain a full clinical picture. These platforms are well validated and already integrated into hospital workflows but require dedicated equipment, QMS, maintenance contracts and trained operators, limiting their use away from hospital settings.

The proposed technology should differentiate itself by consolidating fragmented tests into a single disposable microfluidic card using a low-volume finger-prick sample and robust data analysis and integration capability.

2. Use-case-specific Competitors: Community and Oncology Triage Platforms

In comparison with these modalities, the proposed technology should offer a broader biomarker panel. Deploying one technology that is operationally simple would allow its use both in hospital settings and at home or in pharmacies, presenting multiple market opportunities.

A new generation of portable diagnostic modalities including LumiraDX, 52North Health Neutrocheck and PocDoc demonstrated increasing demand for finger-prick testing outside of acute care hospital settings. These technologies are currently applied for focused use cases such as infection, cardiovascular disease or oncology applications, and typically directed at at-home or in-pharmacy use. While they validate the feasibility of portable diagnostics and smartphone-enabled workflows, they remain indication-specific.

3. Indication-Specific Competitors & Current Standard of Care

Many existing rapid tests (e.g., BD Veritor, Quidel Sofia, Abbott i-STAT) answer single clinical questions (i.e., presence of infection) and are in practice combined with clinical monitoring and use of scoring systems (e.g., NEWS2 or MTS). The evidence generated by these portable system is almost always validated by central laboratory infrastructure as the default triage pathway. These approaches are deeply embedded in clinical practice, making their performance the primary comparator when evaluating a novel diagnostic / triage modality.

Rather than replacing existing clinical scores, the technology should be designed to augment and support early clinical decision-making by providing objective, multi-marker physiological data at the point of triage. This would enable earlier risk stratification across multiple potential conditions instead of focusing on one diagnosis at a time.

4. Enablers and Competitors in Data Structures and Management

The proposed technology should be inherently aligned with this trend through smartphone-native infrastructure, enabled digital results capture, AI- or machine learning-based results interpretation capabilities and being able to readily integrate into existing clinical information management systems without requiring middleware or proprietary hardware or software solutions.

Data and its effective management is of increasing value in medical systems. Companies such as iSTOC, Flowify AI, BBI / Novarum, Abingdon Health, TestCard, opTricon, and Qassay expand the possibilities of card and reader-based tests by augmenting the analysis with a smartphone-based reader, AI-enabled analysis, image analysis, connectivity, cloud analytics, and integration with electronic health records. Rather than competing directly on diagnostics, they provide digital infrastructure that can support third-party assays.

Overall Strategic Positioning of the Technology

The competitive landscape analysis highlights a gap between high-performance point-of-care systems designed for hospitals and rapid tests used in community settings that target only specific conditions. Novel technology should be **positioned to fill this gap by delivering a broad, physiology-based triage panel from a single finger-prick sample on a disposable microfluidic card,** with capabilities to readout and analyse results through a smartphone-enabled application.

Key differentiators should include

- **consolidation of multiple tests into one assay,**
- **elimination of dedicated hardware,**
- **a simple finger-prick workflow,**
- **triage-oriented risk categorisation rather than disease-specific diagnosis,**
- **scalable digital infrastructure.**

These characteristics make the technology particularly well suited to emergency departments, ambulances, urgent care, oncology outreach, community care, and low-resource settings where existing platforms are impractical or unavailable[2]. **Successful adoption, however, will depend on demonstrating that it improves clinically meaningful outcomes such as reducing time to decision, avoiding unnecessary admissions, improving patient flow, and identifying high-risk patients earlier, while integrating seamlessly into existing workflows**[14].

Strategy for Market Adoption

In this report, we present a roadmap to adoption of a point-of-care diagnostic modality in four systems: United Kingdom, United States, European Union and the World Health Organisation. We can think of these four systems as playing different roles within a larger global sales model. The UK and US are high-credibility markets where strong evidence and adoption provide powerful validation of MedTech devices[15, 16]. The EU offers breadth, with one regulatory approval offering numerous national opportunities[17]. The WHO is a global amplifier, which does not replace national approvals, but can turn robust evidence into a global standard in low- and middle-income countries and humanitarian settings[18, 19].

Although there are intrinsic differences between the four pathways, the four routes share common principles:

All treat point-of-care diagnostic / triage technologies as in-vitro diagnostics (IVD), governed by device regulations.

All expect a robust quality management and risk management systems, aligned with norms including ISO 13485 (quality), ISO 14971 (risk), IEC 62304 (software), IEC 62366- 1 (usability).

All require robust analytical and clinical performance evidence, appropriate to the claimed intended use.

Coherent Global Go-to-Market Strategy

A substantial risk for MedTech companies with ambition to enter multiple markets is generating fragmented, country-by-country bodies of evidence, addressing multiple questions asked by regulators and payers. This can lead to increased logistical and financial burden and delays in market access. MedTechs can avoid this by deliberately designing single evidence backbones that can be readily adapted to each pathway.

Define a Precise, Intended Use Statement

Define a single, precise intended use statement for single scenarios, then map how each region's wording needs to differ based on regulations (e.g. labeling nuances for FDA vs IVDR). Each trial and/or pilot should specifically address one conceptual question.

Develop Universal Clinical Study Design

Develop a global clinical study protocol that can be implemented in different countries. Use common clinical endpoints that satisfy MHRA, IVDR, FDA and WHO needs:

- Consistent target population (e.g. adults with suspected serious infection in ED).
- Consistent clinical role (supporting triage, admission decisions).
- Consistent key outcomes (turnaround time, impact on decisions, resource use).

Have clear inclusion and exclusion criteria for statistical evidence. From this dataset, country-specific tables and figures can be generated without further studies. Include a mix of geographies if possible (eg. add region-specific sub-analyses).

Re-use Manufacturing Evidence

Analytical validation, stability, robustness, and manufacturing controls can be universal for many countries. Design stability and robustness testing to cover:

1. Temperature and humidity range relevant for high- income EDs and for LMIC and humanitarian environments.
2. Shipping and storage profiles that satisfy both hospital supply chains and potential home use later.

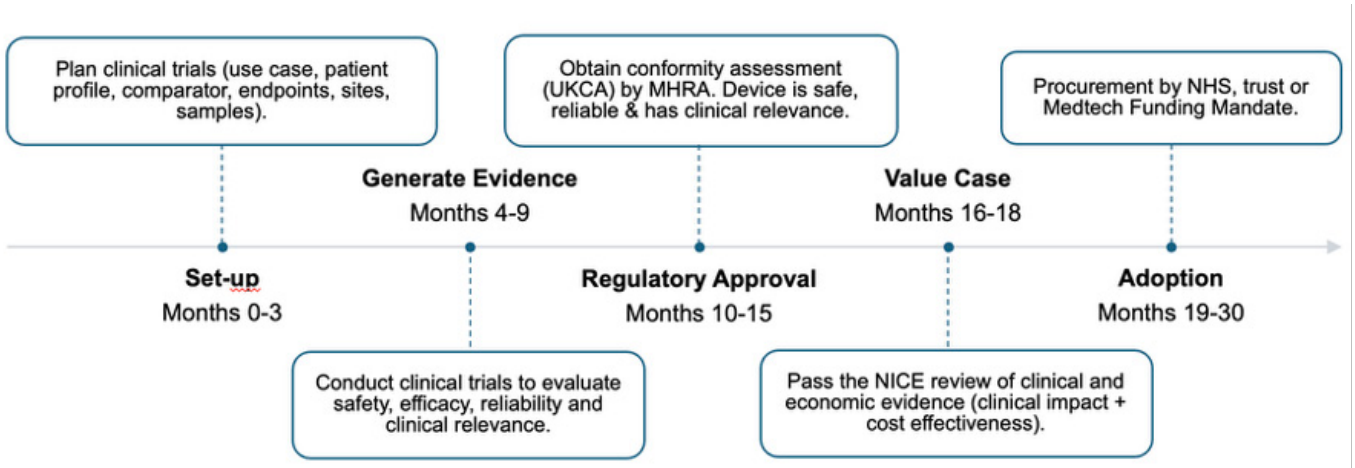
This allows for one core analytical package to be submitted to MHRA, FDA, IVDR Notified Bodies and WHO, with only minor tailoring.

Roadmap to Adoption in the United Kingdom

In the UK, success of emerging medical technologies is ultimately measured by the NHS procuring and routinely use the technology. The regulatory pathway in the UK has three main pillars:

1. Regulatory approval using UKCA (UK Conformity Assessment) by the MHRA[20]
2. Value case evaluation by NICE (National Institute for Health and Care Excellence)[21]
3. Adoption and dissemination within the NHS[22]

Here, we present a five-stage approach to address the above pillars.



(ideal, accelerated timeline)

Phase 1: Early Engagement and Classification

Focus on clearly defining the technology's intended use case and target patient population, alongside establishing appropriate comparators and clinical endpoints, including current standards of care (such as vital signs, biomarkers, and clinical scoring systems) and key outcomes like time to decision, admission rates, ICU escalation, mortality, and antibiotic use[23]. Suitable trial sites should be selected based on strong emergency or acute medicine services and established research infrastructure. Regulatory and ethics preparations should confirm the technology's classification as an in vitro diagnostic (IVD) device and its likely risk category, map relevant UK regulations and standards, establish a quality management system (QMS), complete a Health Research Authority (HRA) approval through IRAS (Integrated Research Application system for NHS-based studies, and engage with the MHRA early in development[20]. In parallel, access accelerators such as the NHS Innovation Service should be engaged to identify evaluation sites, funding opportunities, and strategic partners. Technology could also be assessed for eligibility under the Innovative Devices Access Pathway (IDAP)[15], an MHRA, NICE, and NHS England programme designed to accelerate regulatory and market access for high-impact medical technologies addressing unmet clinical needs.

Phase 2: Evidence Generation

A clinical study should be conducted within the NHS to generate evidence of the technology's analytical and clinical performance, including its safety, reliability, precision, reproducibility, and stability in emergency and acute care settings. This should be supported by comprehensive technical documentation and a QMS, alongside the development of a health-economic model assessing impacts on emergency department flow, admissions, and ICU utilisation. The overall aim is to produce a robust, NHS-relevant evidence base demonstrating that the device is safe, reliable, and effective in real-world clinical practice[23, 24].

Phase 3: Regulatory Submission and UKCA Marking

The technology should complete its technical documentation, including performance evaluation, risk management, usability, and labeling requirements, before undergoing quality management system (QMS) and technical documentation audits by an Approved Body. It should then seek UKCA marking through the MHRA or an Approved Body and may also pursue CE marking (European Conformity) under the IVDR via an EU-based Notified Body, which is currently recognised in Great Britain under transitional arrangements.

Phase 4: Building a Value Case for NICE Engagement

The economic case for the technology should align with NHS priorities, including improving emergency departments' throughput and target performance, reducing admissions and length of stay, and optimising the use of intensive care resources. An appropriate NICE engagement route should be identified, either through a standard MedTech evaluation or an Early Value Assessment (EVA) if evidence is still emerging. If the technology demonstrates clinical effectiveness and cost savings, the long-term goal should be NICE guidance supporting inclusion in the MedTech Funding Mandate (MTFM) and wider adoption through the Accelerated Access Collaborative (AAC) and regional Health Innovation Networks.

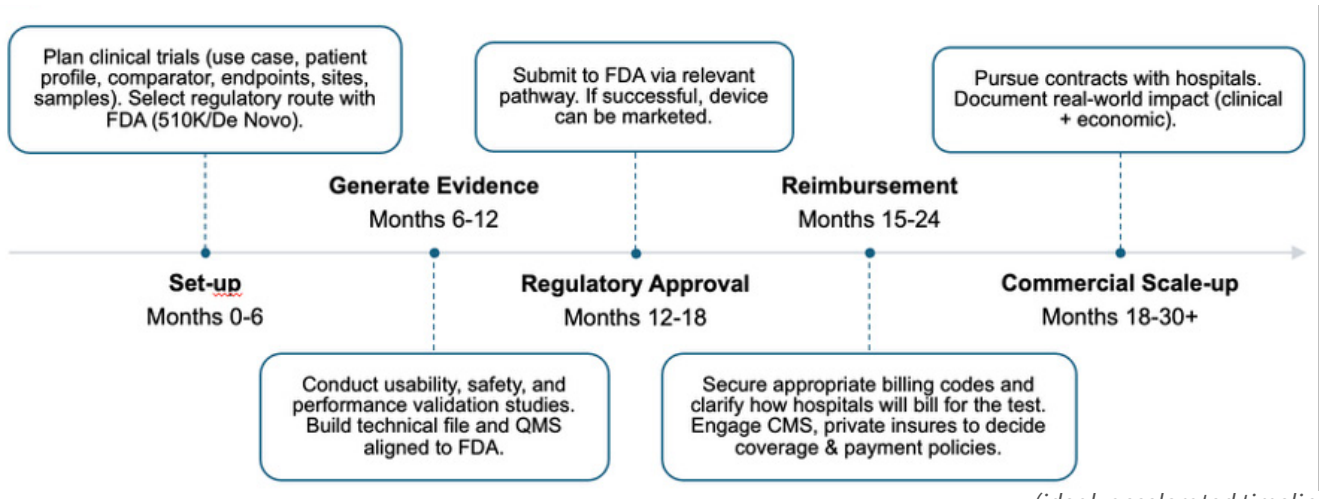
Phase 5: Adoption, NHS Dissemination, Post-Market Evidence Extension

Following regulatory approval and evaluation milestones, the focus should shift to commercialisation and implementation by engaging commissioners and procurement teams, running pilot deployments in selected NHS Trusts with appropriate training and support, and collecting real-world evidence to support post-market surveillance and clinical follow-up requirements. The health-economic model should be refined using NHS data, while opportunities to expand the technology into other care settings, such as acute medical units and urgent care centres, should also be explored.

Roadmap to Adoption in the United States

In the US, Food and Drug Administration (FDA) clearance is necessary, but not sufficient to bring a MedTech device to market[25, 26]. After selecting an appropriate regulatory route, the technology requires robust analytical and clinical data from US-style ED settings[27]. Once cleared, the focus shifts to coverage and payment decisions by private insurance companies, hospitals themselves and group purchasing organisations (GPOs)[28]. The US adoption pathway revolves around two milestones:

1. Regulatory approval from the FDA[25]
2. Coverage and payment decisions by payers (insurers, GPOs, hospitals)[28]



(ideal, accelerated timeline)

Phase 1: Q-Submission Preparation

Preparatory activities should define the technology's intended use, target patient population, comparators, and study endpoints, while selecting trial sites with strong emergency or acute care research infrastructure. Regulatory planning should clarify the likely FDA classification as a moderate-risk IVD, determine the most appropriate pathway - either 510(k) for devices substantially equivalent to existing products or *De Novo* for novel technologies without a suitable predicate, and initiate the FDA Q-Submission process to obtain early feedback on study design, endpoints, and regulatory strategy.

Phase 2: Evidence Generation

Depending on the selected regulatory pathway, the technology should undergo usability, safety, and performance studies that meet FDA requirements for emergency and acute care settings. In parallel, an early value proposition should be developed for US payers, focusing on reducing avoidable admissions, optimising ICU utilisation, and improving emergency department throughput. Technical documentation, quality management processes aligned with FDA Quality System Regulations, and clear labeling and instructions for use tailored to emergency and acute workflows should also be established.

Phase 3: FDA Submission and Clearance

The technology should finalise and submit its FDA regulatory dossier, including pooled analytical and clinical evidence, clinician-focused labeling, and risk and usability data. Following submission, any FDA queries and required bridging studies should be addressed promptly. FDA clearance would permit marketing in the US and provide important external validation for regulators, global health organisations, and investors.

Phase 4: Reimbursement, Coding, Early Adoption

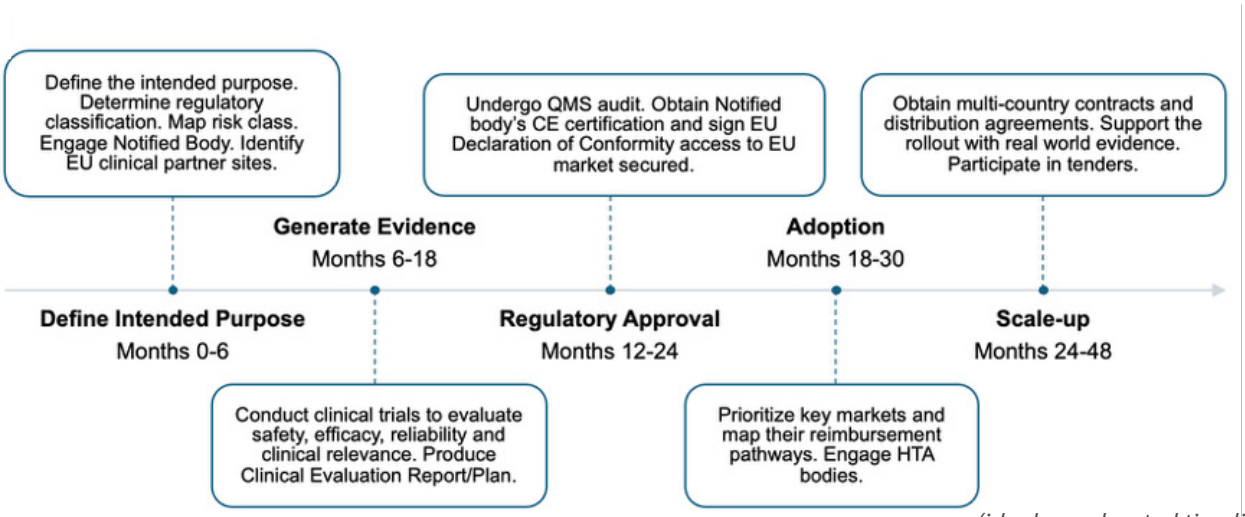
After FDA clearance, efforts should focus on securing reimbursement pathways by engaging with CMS and private insurers to establish appropriate billing codes and coverage arrangements. Early implementation partnerships with academic medical centres and integrated delivery networks should generate outcomes and resource utilisation data, while demonstrating impacts on emergency department throughput, bed occupancy, and ICU use. Where appropriate, eligibility for FDA programmes such as Breakthrough Device designation or the Safer Technologies Program (STeP) should also be explored.

Phase 5: Commercial scale-up

Commercialisation should focus on securing access through Group Purchasing Organizations and hospital formularies, while using US real-world evidence to strengthen the value proposition for public and private payers. Ongoing post-market surveillance and additional studies should support potential label expansions, including use in community pharmacy settings under CLIA or as over-the-counter self-tests.

Roadmap to Adoption in the European Union

The EU healthcare market is highly segmented with country-specific, distinct regulatory agency and adoption pathways for medical products and technologies. However, all technologies must obtain a CE marking under IVDR (Regulation EU 2017/746) from centralised Notified Body, an independent organisation designated by an EU / EEA country to carry out conformity assessments for specific regulations[29]. After seeking CE-IVD marking, companies need to tailor market access strategies for their selected priority markets[30]. Here, we summarise the path towards CE-IVD marking. Notably, this timeline may be longer as compared to the UK and the US market adoption timelines.



(ideal, accelerated timeline)

Phase 1: Define Intended Purpose, Classification and Partnerships

The technology should define its intended purpose and confirm whether it falls under the Medical Device Regulation (MDR) or IVDR, ensuring the quality management system is aligned accordingly. An experienced Notified Body should be engaged to determine the appropriate risk classification and conformity assessment route, while 2–3 European pilot sites should be identified to support clinical performance and usability studies.

Phase 2: Generate Clinical and Analytical Performance Data

A Clinical Evaluation Plan and Clinical Evaluation Report should be developed to demonstrate scientific validity, analytical and usability performance, and clinical effectiveness in relevant European settings. This phase should also establish comprehensive risk management documentation and plans for post-market surveillance and, where appropriate, post-market clinical follow-up.

Phase 3: CE Marking

The technology should finalise its technical documentation, including device description, manufacturing information, performance evidence, risk management, labeling, and surveillance plans, before undergoing Notified Body review and quality management system audits. Successful assessment will enable issuance of an EU Declaration of Conformity, application of the CE mark, and access to the EU and EEA markets.

Phase 4: National Health Technology Assessment and Reimbursement Decisions

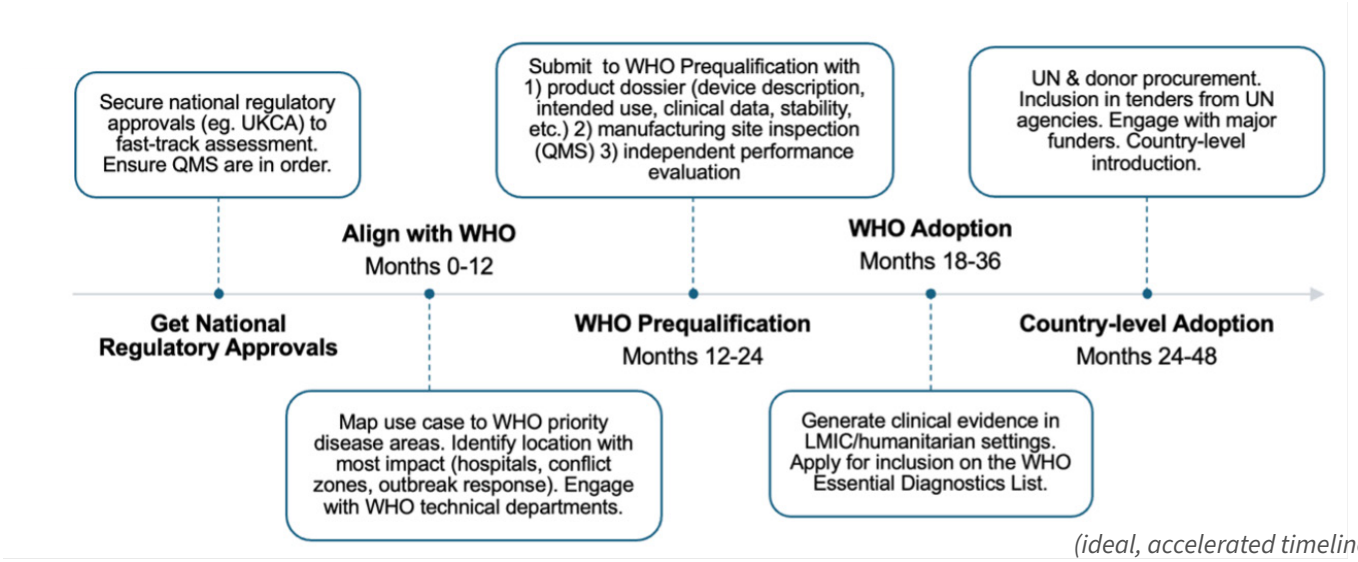
Following CE marking, market access efforts should focus on national health technology assessment and reimbursement processes, prioritising key European markets based on clinical need and innovation readiness. The technology's value proposition should be adapted to local reimbursement structures, while partnerships with procurement teams and participation in tenders and framework agreements should support market entry.

Phase 5: National Adoption and Scale-Up

Wider adoption should be driven through engagement with European projects, professional societies, and key opinion leaders to support guideline inclusion and routine use. Multi-country contracts and distribution agreements should be secured, while ongoing IVDR-compliant post-market surveillance and real-world evidence generation should be used to refine indications and support long-term growth.

Roadmap to Adoption via the World Health Organisation

While the WHO does not replace national regulators, it strongly influences procurement in low- and middle-income countries[18, 19]. **If WHO reviews the proposed device / technology and lists it as a priority diagnostic modality (for example on the Essential Diagnostics List), it becomes easier for donors and UN agencies to procure these devices.** This typically comes **after at least one stringent approval** (i.e. UKCA, CE, FDA), since the **WHO is not a regulator itself.** Instead, it shapes norms, lists and donor purchasing decisions[18]. In the context of blood-based, POC diagnostic systems, this opens up avenues in establishing the company in international outbreak or emergency response efforts[31, 32].



(ideal, accelerated timeline)

Phase 0: Secure National Regulatory Approvals

The technology should obtain, or make substantial progress towards, recognised regulatory approvals such as CE marking, FDA clearance, and UKCA marking, as these can support an abridged WHO prequalification assessment. A robust quality management system aligned with ISO 13485 requirements should also be established.

Phase 1: Align Use Case with WHO Priorities

The technology's use cases should be mapped to WHO priority areas, including sepsis, antimicrobial resistance, emergency care, and pandemic preparedness, with a focus on settings where it could have the greatest impact, such as district hospitals, humanitarian contexts, and outbreak responses. Early engagement with WHO technical departments should identify the most appropriate pathways, including WHO Prequalification, Emergency Use Listing, and potential future inclusion in WHO guidelines or the Essential Diagnostics List.

Phase 2: WHO Pre-Qualification Application and Dossier

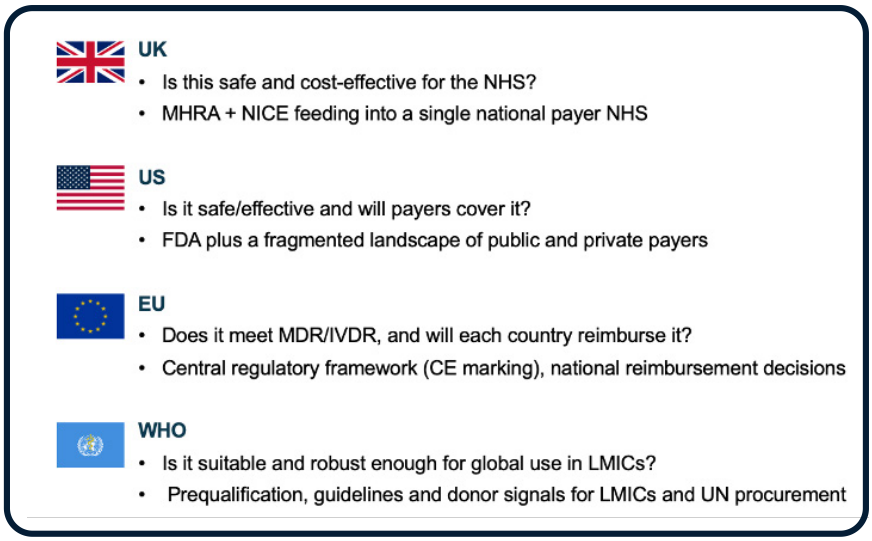
The technology should submit a pre-submission application for WHO pre-qualification and prepare a comprehensive product dossier containing device information, intended use, analytical and clinical evidence, environmental robustness data, quality management documentation, and independent performance evaluations, ideally incorporating evidence from low- and middle-income countries.

Phase 3: WHO Adoption

Programme-level evidence should be generated in low-resource and humanitarian settings to demonstrate impacts on triage, treatment timeliness, mortality, and referral decisions. This evidence can support inclusion in WHO guidelines and applications for listing on the WHO Essential Diagnostics List or other priority device frameworks.

Phase 4: UN, Donor and Country-Level Adoption

Following WHO prequalification and, ideally, guideline or Essential Diagnostics List inclusion, the technology should pursue procurement opportunities through UN agencies and major global health funders while implementing national or regional rollouts to generate early success stories and operational learning. Ongoing performance monitoring and field feedback mechanisms should support maintenance of WHO prequalification and future product updates.



In Conclusion

In the UK and EU MHRA and Notified Bodies are key regulators who handle safety and performance review, while NICE, national HTA bodies and member countries payers control reimbursement and adoption. UK is currently closely aligned to EU rules, with future divergence possible. Compared to the UK with NHS reaching from research labs to EDs, US market adoption is more fragmented. In the US, FDA manages clearance of an IVD, but CMS and private insurance decide coverage and payment and individual hospitals adoption. Uniquely, the WHO pathway links regulatory clearance to cross-country pooled procurement and to leading donors, including Unitaid and The Global Fund, making it uniquely powerful for low- and middle-income market access.

The evidence required to obtain clinical approval varies between countries and healthcare ecosystems. However, four common pillars of evidence can be identified where benefits have to be demonstrated and supported by robust clinical evidence in all systems.

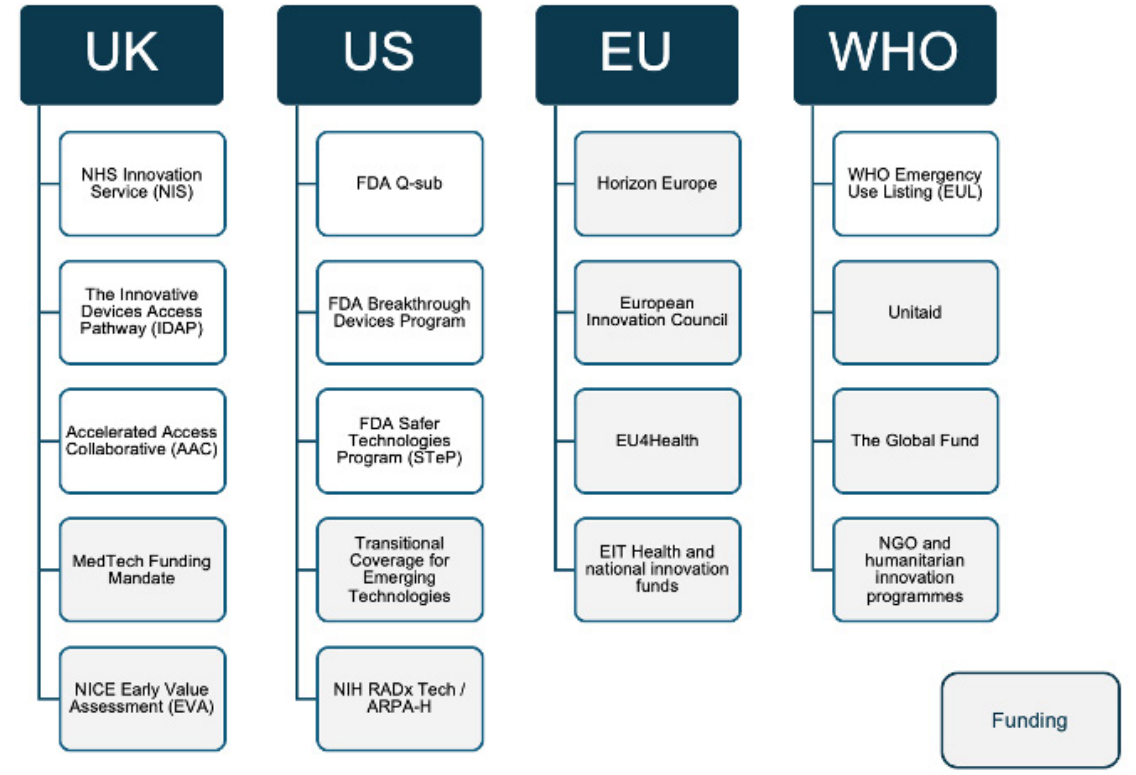
1. Clinical - ED / acute studies showing impact on decisions, timing and key outcome proxies
2. Economical - Device saves money to healthcare systems
3. Analytical - Accuracy, precision, stability and robustness across conditions
4. Quality management - Technical standards including ISO 13485 (quality), ISO 14971 (risk), IEC 62304 (software), IEC 62366- 1 (usability)

Access Accelerators

In addition to the core regulatory and reimbursement pathways, emerging MedTechs are advised to liaise and interact with access accelerators - programmes that can aid validation and adoption. These don't replace the need for robust evidence or formal approval process, however they can provide:

- early funding support,
- structured advice,
- access to network including connections to evaluators,
- access to network of key opinion leaders,
- in some cases faster or more predictable reimbursement routes.

Here, we present selected access accelerators with capability to support adoption of a MedTech in the UK, US, EU and WHO ecosystems. Notably, these accelerators are mostly non-dilutive and will not require equity or financial returns.



UK Access Accelerators

- **NHS Innovation Service (NIS)** - helps innovators understand stages from idea to adoption and access tailored support across MHRA, NICE and NHS partners.
- **Innovative Devices Access Pathway (IDAP)** - a joint pilot between MHRA, NICE, NHS England and devolved HTA bodies. It offers an integrated, enhanced pathway for a small number of transformative devices that meet critical NHS needs, combining early regulatory and HTA advice with a clearer route to NHS use.
- **Accelerated Access Collaborative (AAC)** - national partnership that streamlines and accelerates adoption of innovative treatments and diagnostics.
- **MedTech Funding Mandate (MTFM)** - policy commitment to get selected NICE-approved, cost- saving devices and diagnostics to patients more quickly, with an expectation that commissioners fund their use.
- **NICE Early Value Assessment (EVA)** - fast, early assessments that allow time- limited NHS use of promising technologies while further evidence is generated.

US Access Accelerators

- **FDA Q- Submission (Q- Sub)** - voluntary process that allows sponsors to request structured feedback and meetings with FDA outside formal submissions, improving study design and pathway selection.
- **FDA Breakthrough Devices Program** - voluntary programme that offers expedited review for devices that provide more effective diagnosis or treatment of serious conditions.
- **FDA Safer Technologies Program (STeP)** - a voluntary programme for devices that are expected to meaningfully improve safety, for conditions that are less serious than those eligible for Breakthrough status. It provides many of the process benefits of Breakthrough, without being a separate route to market.
- **CMS TCET (Transitional Coverage for Emerging Technologies)** - introduces time-limited national Medicare coverage for selected Breakthrough devices, using existing NCD (National Coverage Determination) and coverage with evidence development tools to expedite access.
- **NIH RADx/ARPH** - can provide non- dilutive funding and testbeds for novel diagnostics.

EU Access Accelerators

- **Horizon Europe** - funds collaborative research and innovation projects to improve diagnosis, monitoring and treatment, often including multi- country studies and implementation work.
- **European Innovation Council (EIC)** - offers a mix of grant and equity funding for high-impact innovations, including MedTech and diagnostics.
- **EU4Health** - supports stronger, more resilient health systems, with calls that can fund uptake and evaluation of innovative technologies.
- **EIT Health and national innovation funds** - provide pilots, support and capital for healthtech scale-ups across Europe.
- **Germany's DiGA Fast Track** and **France's Forfait** can provide temporary reimbursement while evidence is collected.

WHO-linked Programmes and Accelerators

- **WHO Emergency Use Listing (EUL)** - inclusion on the list expedites availability of IVDs in public health emergencies.
- **Unitaid** - catalytic funder that uses market- shaping grants to accelerate access to diagnostics and other health products in low- and middle-income countries.
- **The Global Fund and World Bank-linked programmes** - finance large-scale procurement and healthcare system investments that can embed new diagnostics into routine care.
- **NGO and humanitarian innovation programmes (e.g. MSF, ICRC)** - run innovation and field-testing programmes that adapt and evaluate tools for challenging environments, including conflict zones and fragile health systems.

While not replacing formal approvals, these programmes can shorten time to meaningful adoption as well as improve the chances of reimbursement. The list above is not exhaustive but highlights the most relevant access accelerators for an emerging MedTech that wants to access markets across the UK, US, EU and global health (WHO).

In Conclusion:

For an emerging MedTech, the priority should be to select a small number of programmes in each geography that align with the device's stage of development and strategic markets.

Conclusions and Takeaways

1. Need for Novel Technology

Healthcare systems face a growing need for rapid point-of-care triage diagnostics that improve early decision-making, reduce diagnostic delays, and alleviate pressure on emergency care.

2. Entry Markets for the Novel Technology

Emergency departments are the highest-value entry market, with the US offering the greatest commercial opportunity and the UK providing a strategically attractive, evidence-driven adoption pathway.

3. Scope for Novelty and Positioning

Emerging technology should be positioned to bridge the gap between complex hospital POC analysers and single-purpose rapid tests through a broad, smartphone-enabled, finger-prick triage platform.

4. Ensuring Commercial Success

Commercial success will depend on demonstrating both clinical benefit and health-economic value, including improvements in patient flow, admissions, and resource utilisation.

5. Coordinated Global Strategy Streamlines Adoption

A coordinated global regulatory and evidence-generation strategy can streamline approvals, support reimbursement, and accelerate adoption across the UK, US, EU, and WHO pathways.

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