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WELCOME TO:

# How to Successfully Enter and Drive Growth in the UK

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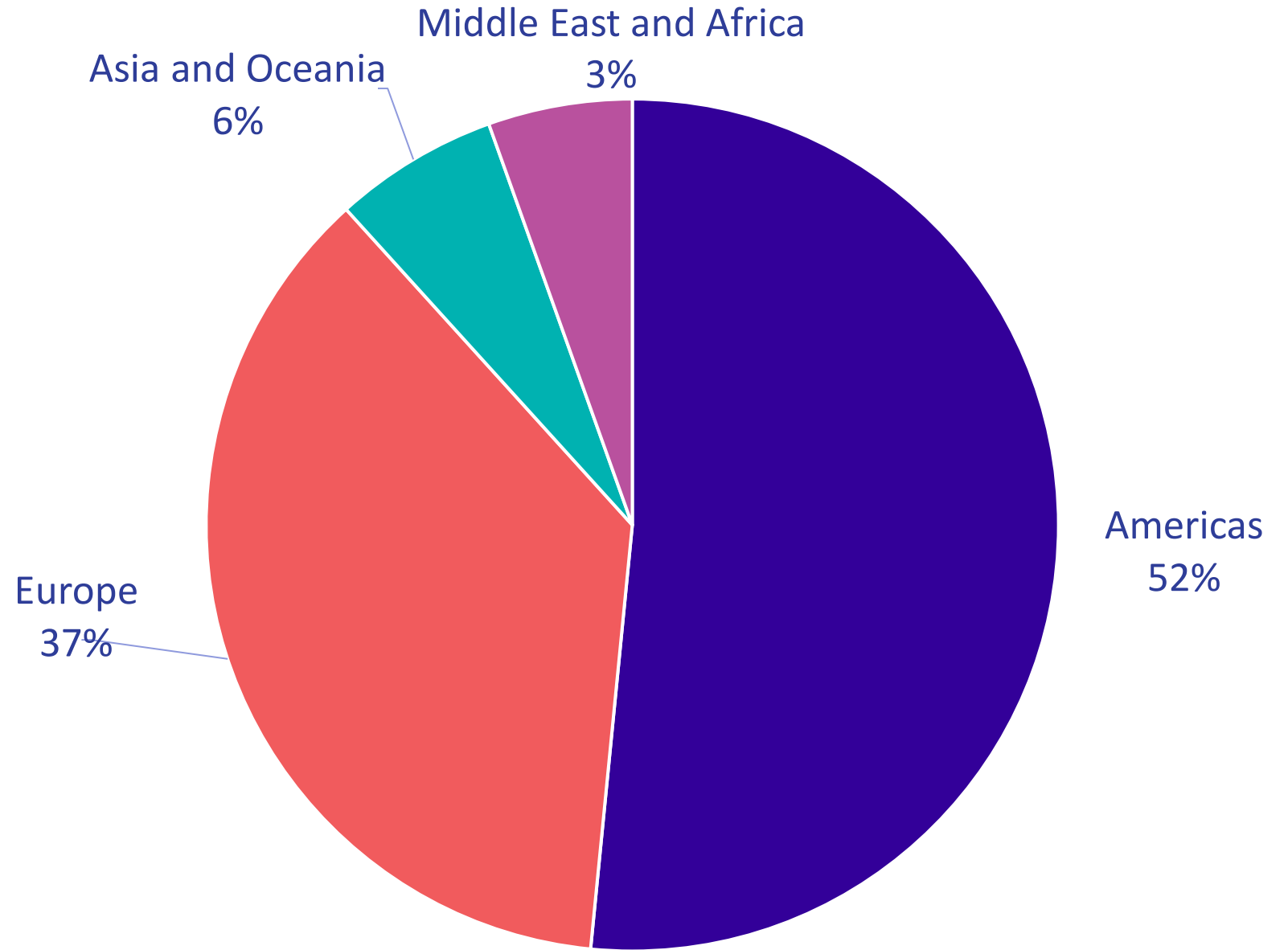
**Craig MacInnis**  
Co-Founder and Co-CEO



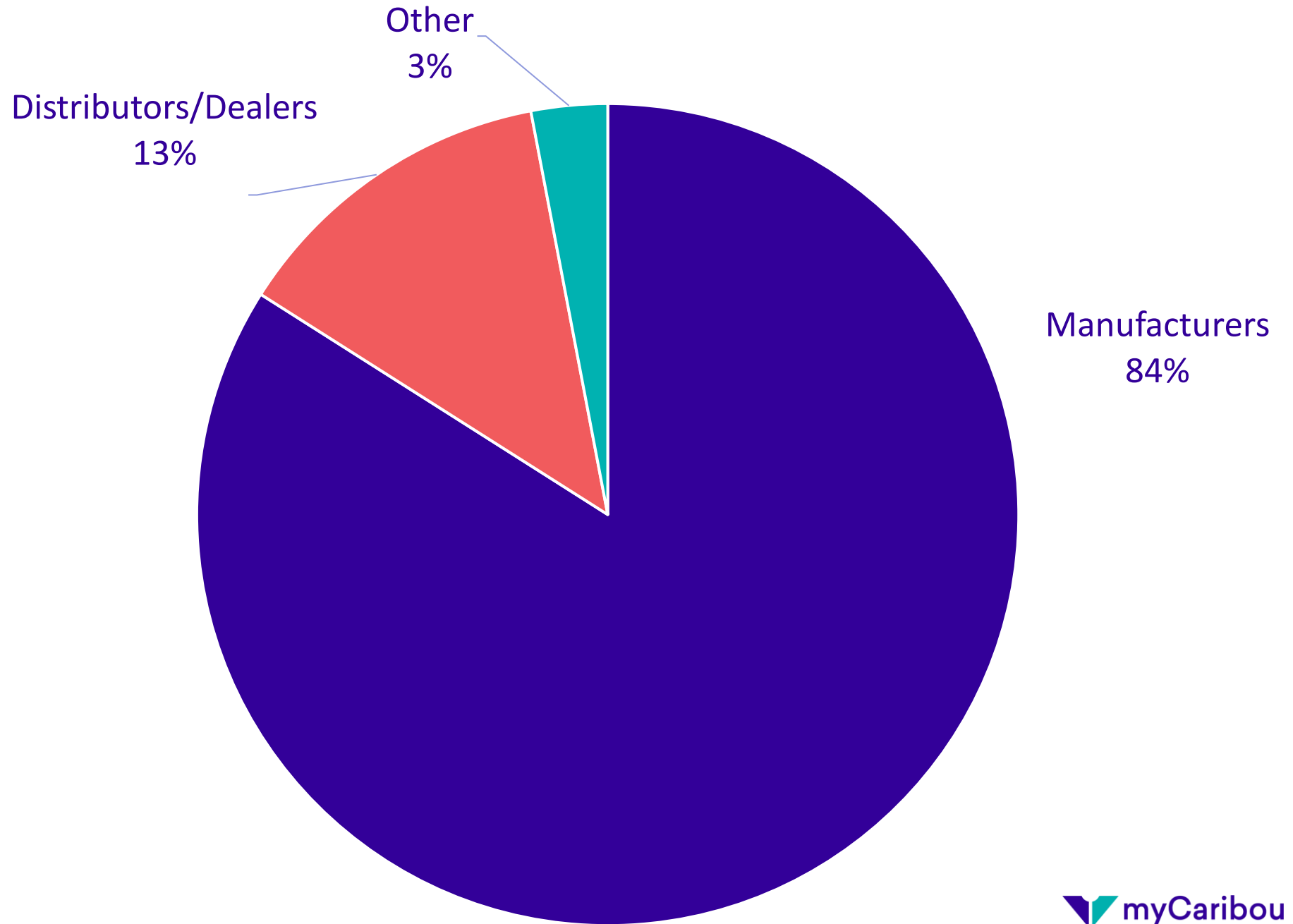
# The world's only global partnering platform for the medtech industry.

1. Grow sales by 20%+ by managing and collaborating with your existing partners and replacing your current failing partnerships
2. Reduce costs by \$200,000+ annually
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# Registrations



# Registrations





**Alison Woodhouse**  
Director, Head of Responsible  
Business  
Lexington



**Michael Latham**  
Associate Director  
Lexington



**Phil Brown**  
Director, Regulatory & Compliance  
ABHI

POLL



# Entering the UK MedTech Market

- **Lexington Health and the Association of British HealthTech Industries** July 2023



# Today's Presentation

1. About Lexington Health and the ABHI
2. Introduction to the UK healthcare system
3. NHS and the UK Med Tech market
4. UK Med Tech Market dynamics
5. MedTech Adoption Process
6. Regulatory Considerations
7. The changing landscape: social value in NHS procurement
8. How to get your communications approach right
9. Questions and Answers





Shape Tomorrow<sup>x</sup>

# About Lexington Health

# Lexington's Health Expertise

- At the forefront of healthcare public affairs, PR and communications
- Experience from the highest levels of Government, the media and health policy
- Experience of working across the UK and internationally, running integrated campaigns and communications projects in the UK, the US and beyond for clients in the life sciences.
- We support clients to **understand** key challenges, **engage** with influential decision makers and ultimately **leverage** opportunities for commercial success.

## Our current clients include:



# How we can help



Profile raising and executive thought leadership



Crisis communications, media training and issues management



Integrated public affairs and political engagement



Building campaigning coalitions and brokering partnerships



Paid social and digital campaigns



Brand or product campaigns



Creating insight-led collateral – data, reports, case studies



HCP and PAG engagement



Strategic counsel



Monitoring and research



ABHI



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## About the ABHI

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Phil Brown  
Director, Regulatory & Compliance

# ABHI & OUR OFFER



## Engagement to Shape Policy

With government, NHS, ALBs, patient & clinical organisations



## Expertise in Regulation

Addressing MDR, IVDR, UKCA, digital, standards and policy



## Deep NHS Relationships

Working at national, regional and city level



## Networking Opportunities

With peers, partners and key influencers across industry & system



## Insight, Intelligence & Resources

Enabling planning for issues impacting you and the industry



## Supporting Trade & Export

With the EU, US and RoW opportunities

### OUR MEMBERSHIP

420+ 75% SME  
>80% of the industry  
value  
Peer to Peer  
Networks

### OUR TEAM

Deep HealthTech  
Industry Experience  
8 Strong Leadership  
Team

### INTERNATIONAL

Help >250  
companies annually  
US Accelerator  
Programme  
UK Pavilions

A woman in a dark suit stands on a stage, gesturing with her hands as she presents to an audience. The audience is seated in rows of chairs, mostly in silhouette. A large screen in the background displays the text "Shape Tomorrow" with a small 'x' mark to its right. The room has a modern, wood-paneled wall and recessed ceiling lights. The overall lighting is dim, with a warm, orange glow from the right side of the frame.

Shape Tomorrow<sup>x</sup>

# The UK healthcare system

# Introduction to the UK Health System

- National Health Service (NHS) is the publicly funded healthcare system in the United Kingdom
- Provides comprehensive healthcare services to residents of England, Scotland, Wales, and Northern Ireland
  - each country has its own structure, policies, and decision-making processes
- Funded through taxation and provides healthcare services that are **free at the point of delivery**
- Service provision is split into the following areas:
  - Primary care
  - Secondary care
  - Emergency care
  - Mental health services
  - Public health services





National bodies

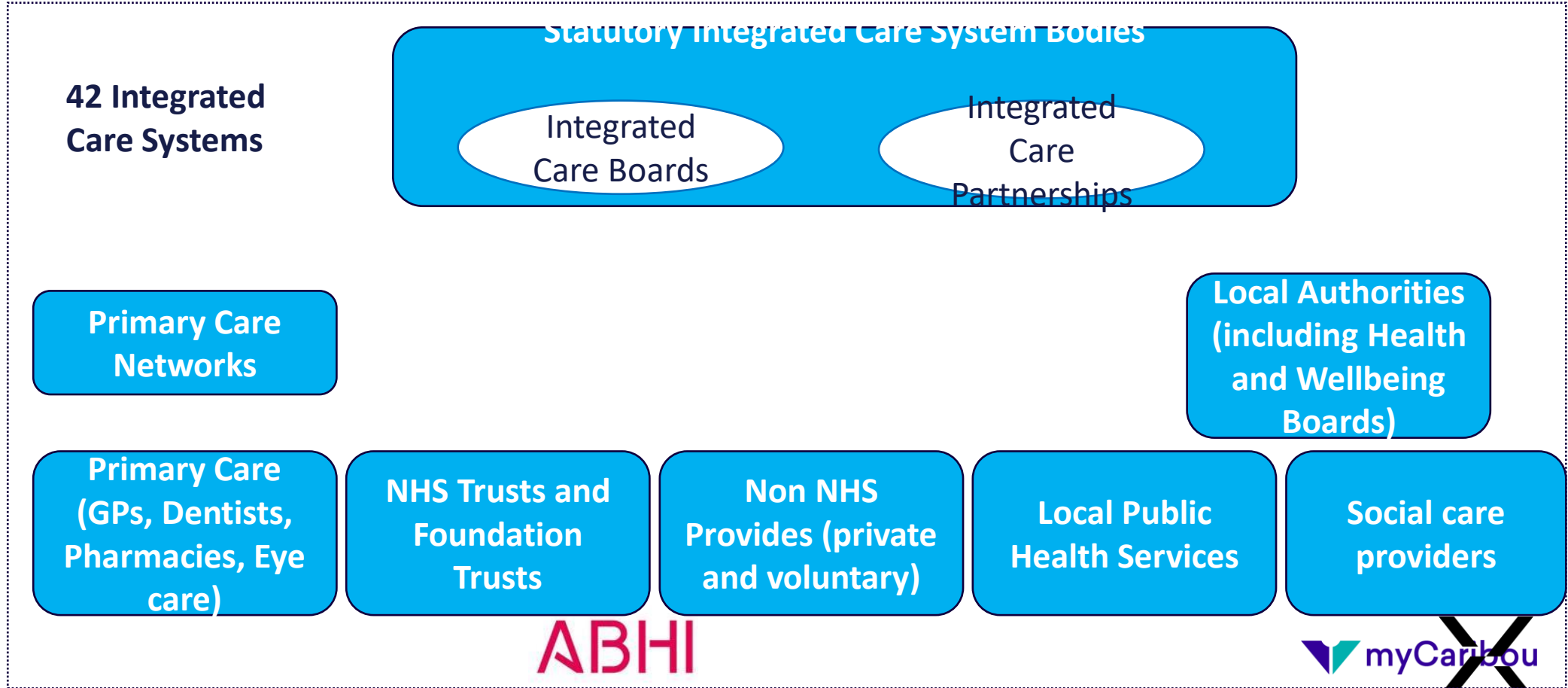
Care Quality Commission

Department for Health and Social care

NHS England  
including Health Education England, NHs Digital

NHS England Regional Teams

ICS/  
Regional level



Local/  
place level

Service Providers

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# NHS and the UK MedTech market

## Strengths

- Thriving MedTech eco-system
- Established routes to market
- Robust and world-leading regulatory framework
- Access to a skilled workforce and thriving research base

## Weaknesses

- Highly competitive
- Financial pressures
- Hospital beds crisis
- Workforce pressures and staffing crisis
- Brexit uncertainty

## SWOT Analysis

## Opportunities

- Growing healthcare expenditure and increased recognition of value of collaboration
- Focus on bi-lateral trade opportunities
- Support for digital transformation

## Threats

- Bureaucracy
- Delay in the introduction of innovative technologies
- Regulatory Compliance
- Reimbursement challenges
- Intellectual property protection



# UK Med Tech Market Dynamics

Relative NHS spend by medtech product type

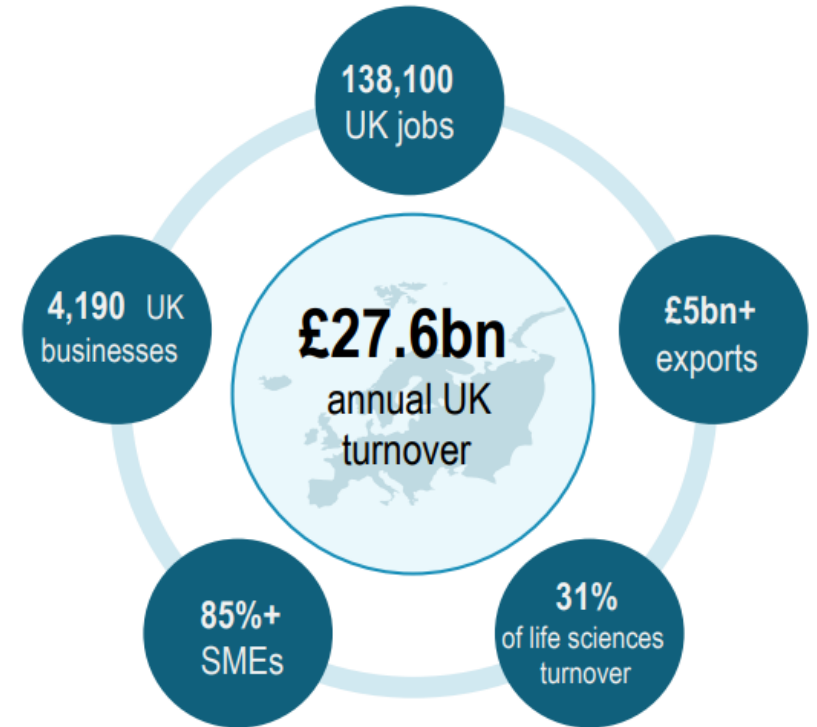
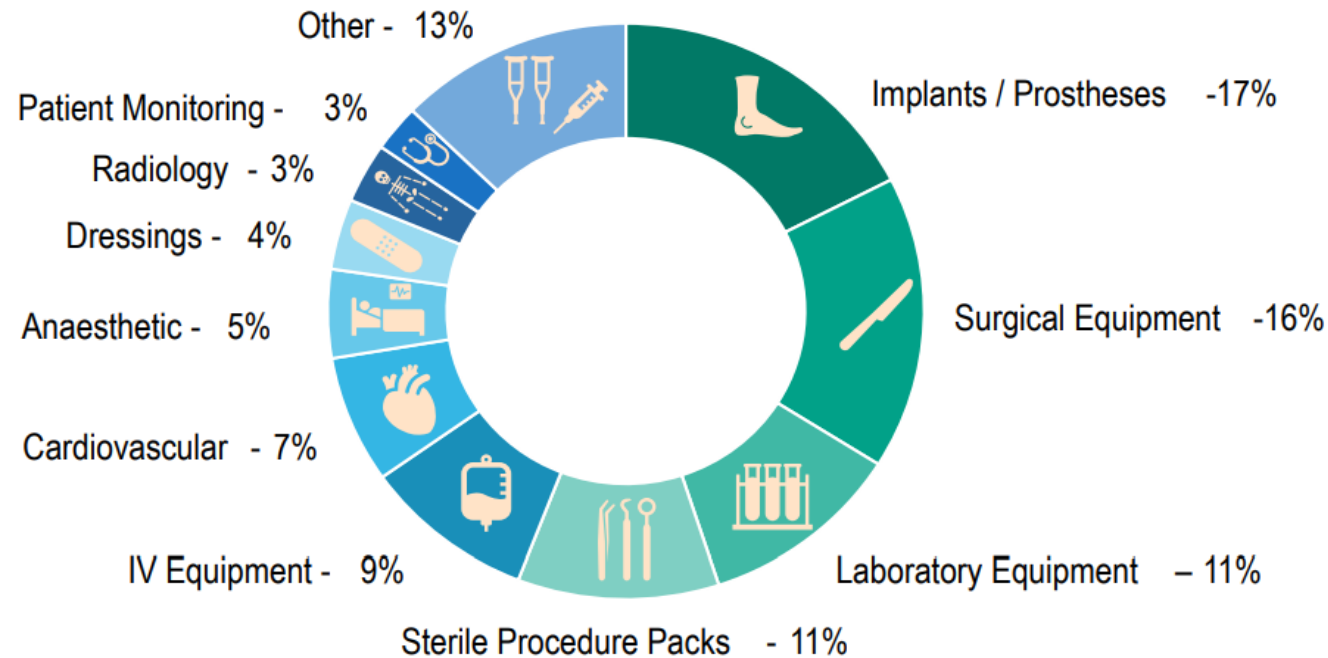


Figure 3: The top ten medtech product types by spend, 2021.<sup>9</sup>

UK Government MedTech Strategy, 2023

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# Med Tech Adoption Process



**NIHR** | National Institute for Health Research

**ABHI**



Clinical Practice Research Datalink

Accelerated Access Collaborative



Medicines & Healthcare products Regulatory Agency



**NICE** National Institute for Health and Care Excellence



*The***AHSN***Network*

**ABHI**

Scottish Medicines Consortium



# Current Regulatory Situation

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## A Progressive Standstill...

- › Recognition of the European CE Mark and certification granted under the Medical Device Regulation (EU-MDR) and In-Vitro Diagnostics Regulation (EU IVDR)
- › UK Medicines and Medical Devices Act (2021); “... *making the UK an attractive place to do business ...*”
- › UK regulation based on MDD/IVDD/AIMDD (2002 Statutory Instrument); update rather than repeal...
- › Practical and pragmatic consideration of EU MDD/IVDD/AIMDD transitions and continuation of ‘standstill’
- › 2021 Consultation (950+ responses) focused on ‘conservative’ EU alignment, to ensure patient safety and product supply
- › UK involvement in IMDRF activities, including MDSAP
- › Recognised system-wide capacity issues
- › Change in Government policy?

# Current Regulatory Situation

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## A Progressive Standstill

- › 2022 Industry provocations, particularly with product supply (ultimate patient safety) and UK attractiveness – UK an overall 3% of a global Healthtech market
- › Life Sciences Council proposals on ‘Innovation, Recognition and Capacity’
- › McLean review on ‘Pro-Innovation Regulation’
- › Government Policy shift towards ‘recognition and reliance’
- › Requirement for new consultation in October
- › Current practical activities;
  - Cooperations across stakeholders (McLean recommendations)
  - Plugging the gaps with recognition
  - Possibilities with Capacity, including with UK Conformity Assessment Bodies (UK CABs)
  - Innovation pathways (IDAP, Horizon Scanning & Innovation Office/Scientific Advice)

# DELIVERABLES (MHRA WORKSTREAM)

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Ten proposals covering how, what, when to deliver:

## Innovation

- Ambitious routes for innovative HealthTech (including but not limited to Innovation Devices Assessment Programme (IDAP)).

## International

- Domestic assurance routes that will allow recognition of approvals in other, trusted jurisdictions (eg FDA) and immediately release capacity constraints.

## Capacity

- Tangible solutions to the ongoing regulatory system capacity challenges

# McLean Review

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› 8 Recommendations;

– Capacity

- Collaboration across Government Agencies
- CERSI implementation
- Two-way Secondments
- Closer ties between MHRA and CABs

– Innovation

- IDAP
- Learning from ILAP
- Horizon Scanning





# Current Regulatory Situation

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## A Progressive Standstill

- › Connections to be made;
  - UK Conformity Assessment Bodies
  - UK Responsible Person and Economic Operators
  - UK Trade Bodies
- › Pitfalls to avoid;
  - Do not forget to consider 'sustainability targets'
  - Considering regulatory practice in isolation
  - Neglecting full consideration of timelines
- › Opportunities to look for;
  - Integration of regulatory processes from innovation to patient
  - Less burdensome UK patient access
  - Innovation opportunities through IDAP
  - Northern Ireland?

# Social Value in NHS procurement

Adopting UK central government's Social Value Model has been a key change to procurement since April 2022, with a mandatory 10% social value weighting on all procurement.

NHS England and Integrated Care Boards need to ensure their goods and services are assessed against five key themes:



Fighting climate change  
COVID-19  
*(compulsory in all tenders)*

recovery



Wellbeing



Equal opportunity



Tackling economic

inequality



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# NHS Net Zero Supplier Roadmap

The NHS aims to become the world's first net zero national health system – eliminating 'direct' emissions by 2040 and 'indirect' emissions by 2045.

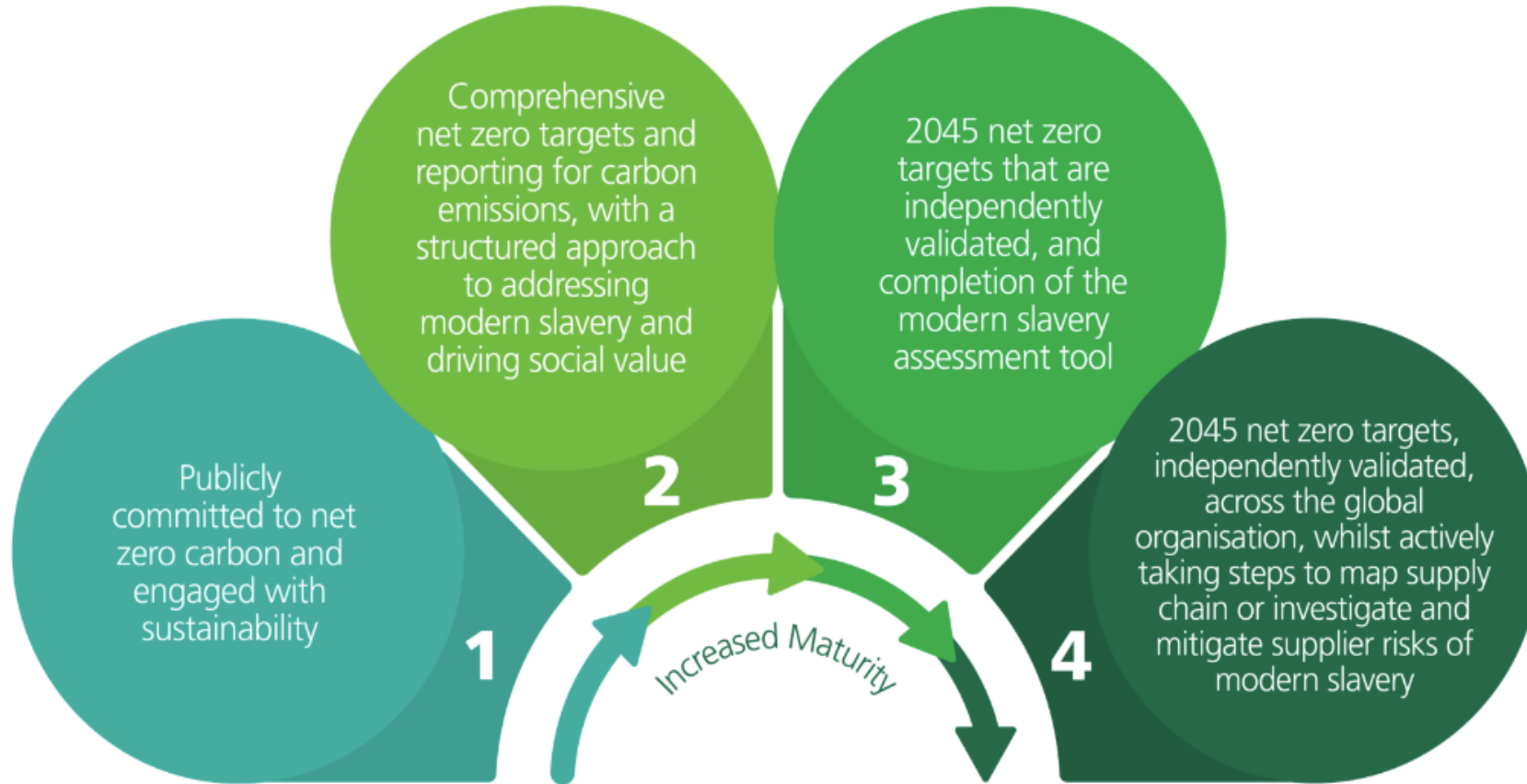
Over 60% of NHS carbon emissions are generated by the supply chain. Therefore...

2023	2024	2025	2026	2027	2028	2029	2030
<b>From April 2023:</b> all suppliers of NHS contracts over £5m/yr must publish a Carbon Reduction Plan (CRP) for their UK Scope 1 and 2 emissions and a subset of scope 3 emissions as a minimum							
<b>From April 2024:</b> CRP requirement extended to <b>all</b> procurement							
				<b>From April 2027:</b> all suppliers need to publish a CRP that includes <b>global</b> emissions, aligned with the NHS's net zero target			
					<b>From April 2028:</b> new requirements to provide 'carbon footprinting' of individual products supplied to the NHS		
						<b>From January 2030:</b> NHS will no longer purchase from suppliers that have not aligned with its move towards net zero carbon.	



# Evergreen Sustainable Supplier Assessment

## Summary of Maturity Criteria



[england.nhs.uk/evergreen](https://england.nhs.uk/evergreen)

June 2023

NHS 'Evergreen' supplier assessment tool will determine progress in reduced carbon emissions to qualify for NHS contracts from 20230



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# How to get your communications approach right

- Define and align your value proposition , creating resonant and targeted messaging
- Establish your evidence base
- Develop advocates and key opinion leaders
- Identify areas of best practice and opportunities for engagement
- Demonstrate need and replicability
- Engage with regions and local systems - ICSs/AHSNs
- Start small and prove the concept
- Develop a partnership approach - solve, don't sell – aligned with local and national strategies



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# Questions and Answers

# Thank you for attending!

## Contact Information for the presenters:

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- Phil Brown - phil.brown@abhi.org.uk
- Craig MacInnis - craig.macinnis@cariboumed.com

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# myCaribou Resource Library

Stories and insights from industry experts.

## Market Entry Sessions:



## Building Stronger Medtech Partnerships:

Accelerate your Growth with Better Partner Selection

Why Manufacturer & Distributor Partnerships Fail So Often

Creating Stronger Medtech Partnerships to Increase Growth

Establishing Key Performance Indicators (KPIs)

How to Avoid the Management Pitfalls of Medtech Partnerships



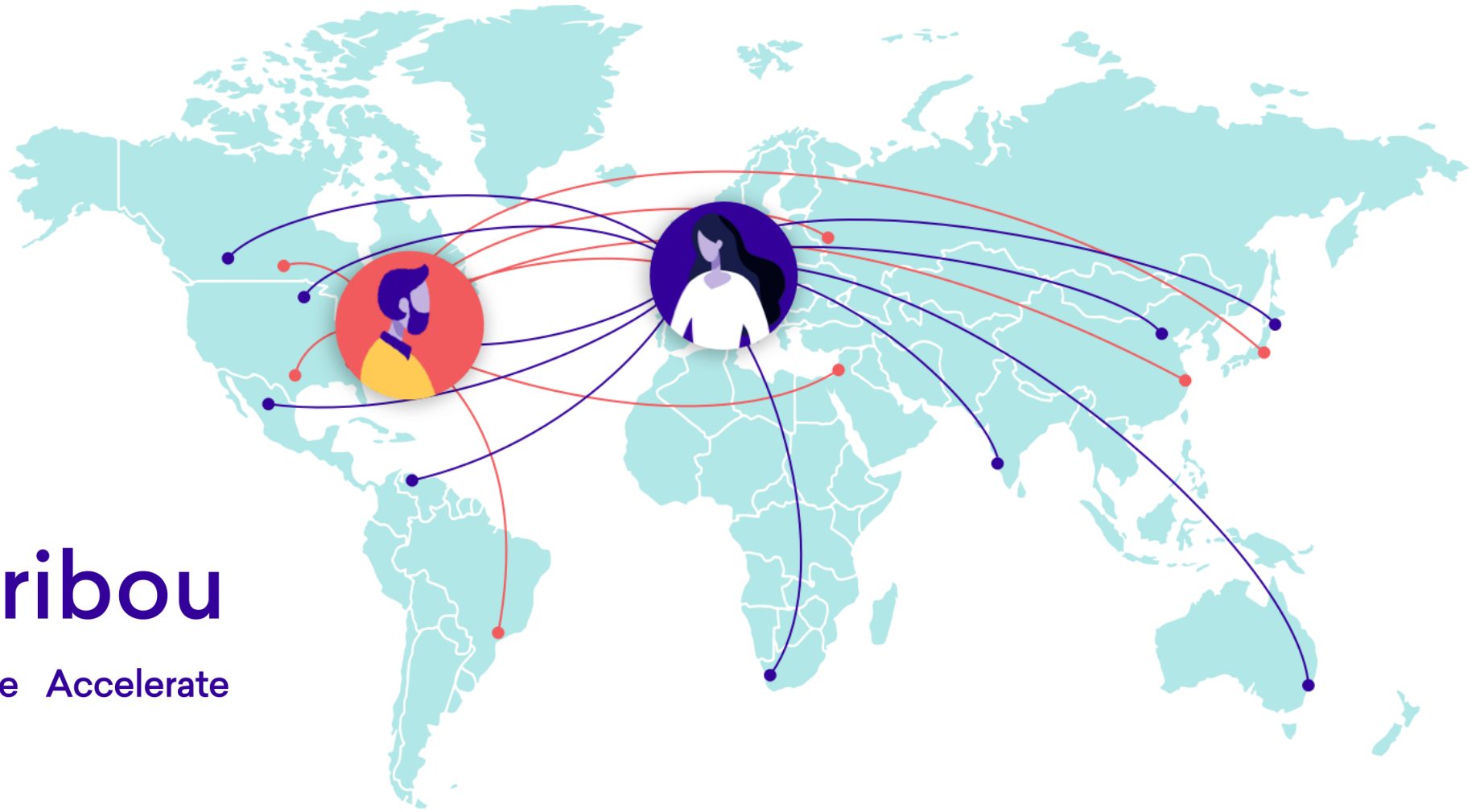


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