UK HEALTHTECH REGULATORY SURVEY

October 2022

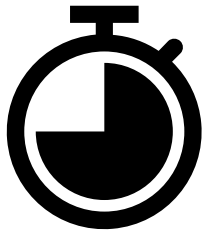
Evnia
To Strive • To Seek • To Find

Association of British HealthTech Industries (ABHI) Survey

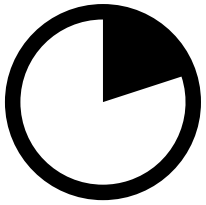
- The Association of British HealthTech Industries (ABHI) is the leading health technology association in the UK with >330 members
- ABHI's latest membership survey was published in October 2022
- Context of the Survey: Current status & development of the UK sovereign HealthTech regulatory system

Evnia
To Strive • To Seek • To Find

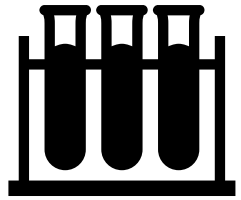
Key statistics



Three quarters of the Health Technology industry currently believe that the UK will no longer be seen as a priority internationally



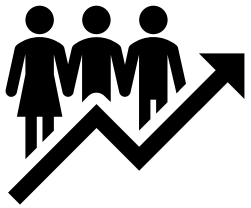
One in five products are expected to be removed from the market over the next five years and one in ten companies are halting all innovation activity.



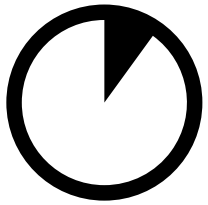
67% of the HealthTech industry expects a delay in bringing innovation to the UK, rising to 86% in those manufacturing in vitro diagnostic medical devices.

Evnia
To Strive • To Seek • To Find

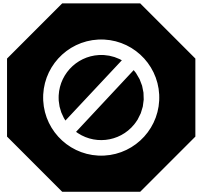
Key statistics



Only 17% of companies believe that the UK is taking an ambitious approach in the development of a sovereign system.



One in 10 companies foresee the UK developing a best-in-class regulatory regime.

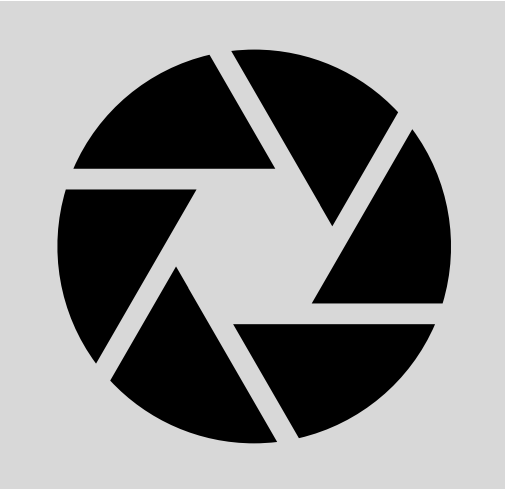


19% of companies are unable to engage early with their Approved Body on new technologies.

90% of companies have seen their regulatory costs increase over the last 12 months, and for 20% the increase has been by over 50%.

Evnia
To Strive • To Seek • To Find

Key Recommendations

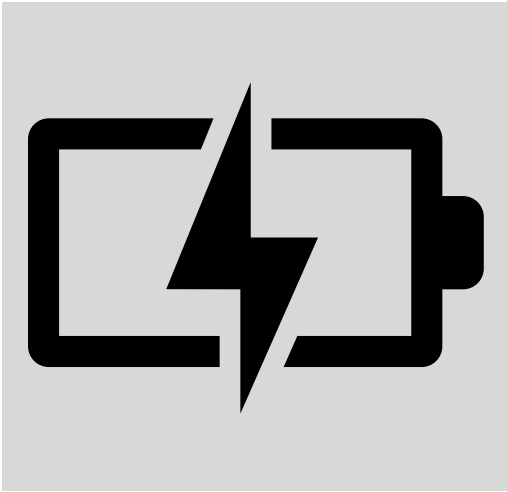


Reduce ongoing uncertainty

- Immediately providing the legislative amendments for transitionary arrangements committed to within the Government's UKCA consultation response.
- Working with industry throughout the development of the UK system to ensure that aligned messaging on reassurance can be provided even whilst the longer-term uncertainty remains.
- Providing a comprehensive UK roadmap of activities and milestones to develop UK regulatory infrastructure.

Evnia
To Strive • To Seek • To Find

Key Recommendations

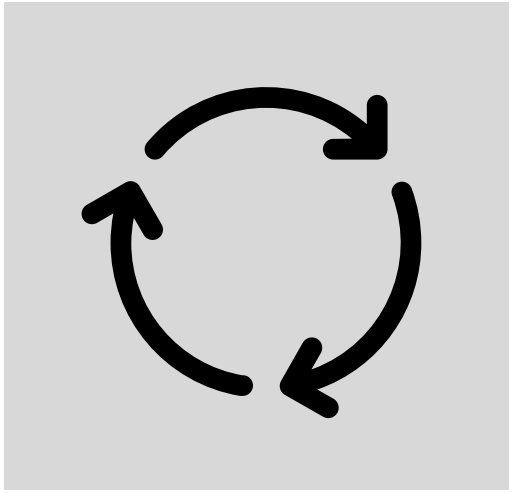


Overcome capacity constraints and reduce the cost burden

- Limiting costs for the designation of Approved Bodies.
- Prioritising the development of domestic assurance routes that will allow recognition of approvals in other, trusted jurisdictions such as those within the MDSAP and ACCESS consortium. This would also allow the reduction of the scope of operations for our own Assessment Bodies.
- Provide both the resource and political impetus to MHRA to increase UK regulatory ambition and enable the development of systems such as those based on the principles of Outcome Based Cooperative Regulation (OBCR).

Evnia
To Strive • To Seek • To Find

Key Recommendations



Ensure appropriate focus and support for the development of innovative technologies

- Developing an ambitious Innovation Devices Assessment Programme (IDAP) that supports clinical need, availability and choice.
- Developing new support programmes for HealthTech clinical investigations and performance studies.

Evnia
To Strive • To Seek • To Find


Evnia
To Strive • To Seek • To Find