Diagnosing data difficulties: The challenges facing MedTechs in the UK and Ireland



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Introduction

The global MedTech industry is rebounding from the pandemic, with Europe very much playing its part in the resurgence.

Although companies in orthopaedics and cardiovascular medicine took a hit from the cancellation of non-urgent procedures and outbreaks of new Covid-19 variants in 2021/2022, others thrived. Global professional services consultancy EY reports that overall the medical technology industry revenues were up by 6.3% in 2020 with "the pandemic often acting as a driver rather than a constraint". In the first half of 2021, the big MedTech companies' revenues were up 30% on the same period in 2020.

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> > EY, Pulse of the Industry databook, 2020

Many successful MedTech businesses and organisations were start-ups just a few years ago, built on proprietary technology, and it is this innovative drive that fuelled the success of the MedTech sector throughout the first year of the pandemic. In 2020, the European Patent Office saw a 2.6% increase in MedTech filings, amounting to more than 14,200 applications, many from European companies. There is every reason to believe this trajectory will continue, particularly given the growth in financing for the sector (as reported for H2 2020 and H1 2021 by EY) and the push towards data-driven healthcare in major organisations such as the NHS. The steady expansion of the MedTech sector in the British Isles means it now employs more than 100,000 people in the UK and 40,000 in Ireland.

The shift to data-driven care, however, presents challenges as well as huge opportunities. It means devices must be capable of generating and sharing data with health IT systems so other devices, solutions, clinicians and researchers can use it to improve procedures and outcomes or to reduce costs and save time.

Devices cannot stand on their own and expect to gain acceptance. They are typically softwarepowered and need companion applications, making data preparation and interoperability essential. This is a complex task because MedTech data must now comply with the data standards used by the major healthcare providers and regulators.

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In the NHS, for example, any solution must comply with the mandatory data standards Health Level Seven[®] (HL7[®]) International V2 and FHIR[®] which govern interoperability. MedTech companies need to be well-versed in all the standards and their protocols, including HL7 International, ASTM International, DICOM (Digital Imaging and Communications in Medicine) Standard Committee, and IHE (Integrating the Healthcare Enterprise).

The entire MedTech industry is also highly regulated. In Europe it must comply with privacy, record-keeping and formatting requirements of the new EU Medical Device Regulation (EU MDR), for example. Further challenges will also arise for companies with in-vitro technology following the introduction of the EU In Vitro Diagnostics Regulation (EU IVDR) in May 2022.

It is against this background that InterSystems conducted research among 100 senior figures at MedTechs in the UK and Ireland to explore attitudes around the use of data and the challenges of interoperability. The research examined the specific pain-points that these organisations experience, along with the difficulties of regulation and data management. Those surveyed included owners, directors and chief data and information officers, with a focus on businesses with annual revenues in excess of €5 million.

About the research

The research surveyed 100 senior figures from companies in UK and Ireland.



49% of companies are in digital health, with a company revenue from less than £5 million to £30 million (36% in UK and 62% in Ireland)



42% are in the medical devices sector, with a revenue from less than £5 million to £30 million (52% in the UK and 32% in Ireland)



9% are in vitro diagnostics, with a revenue of between £5 million and £30 million

(12% in the UK and 6% in Ireland)



Key findings:



Ireland

78%

70%

100% of surveyed companies say they have a data interoperability strategy, but 70% of those in the UK and 78% in Ireland admit they still struggle to make data interoperable with healthcare data standards 52%

42%

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52% of surveyed companies in the UK and 42% in Ireland use, or plan to use a database management system to achieve interoperability



UK 30% 28%



30% of surveyed companies in the UK and 28% in Ireland that use a data platform say it's not currently up to the job



The challenges of achieving interoperability

The scale of the challenge facing MedTechs in the UK and Ireland is apparent in the headline findings. Despite all having interoperability strategies, 70% of those surveyed in the UK and 78% surveyed in Ireland admit they find it difficult to make data interoperable with healthcare data standards used by the major healthcare providers.

The most frequently cited problem is keeping up with constantly evolving requirements of healthcare IT systems. More than half of the polled companies in Ireland (52%) and more than four-in-ten polled in the UK (42%) say this is their biggest challenge.

Healthcare organisations and standards bodies frequently update their requirements to meet new operational, security and privacy demands. The EU MDR, which came into force in May 2021, has added to the burdens of data management. Devices in Class II under this directive face a far stricter set of regulations, for example. In the UK, a new conformity standard for medical devices is scheduled for implementation next year.





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The research went on to reveal a number of obstacles facing MedTechs on their path towards achieving interoperability. These include:

Shortage of the necessary skills in-house

(cited by 36% of respondents in Ireland and 34% in the UK)

In other words, the results found more than a third of MedTechs surveyed in the two countries lack the necessary experience of healthcare culture, data, and standards. This is unlikely to improve quickly, given the continuing unfulfilled demand for data talent. A <u>report</u> by the UK government in May 2021 found employers were looking to fill 234,000 roles that required hard data skills, while in Ireland, developers and data scientists were consistently among the <u>roles in shortest</u> <u>supply</u>. It is increasingly tough to find developers with an intimate understanding of healthcare systems, interoperability, and regulatory compliance.



A data platform that is not up to the job

This is a real barrier to progress, cited by 30% of those surveyed in the UK and 28% in Ireland. When platforms fail to deliver, the data scientists are forced to spend more time on data-drudgery. The research found, for example, that 79% of the data scientists across organisations polled in the UK and Ireland have to devote at least a quarter of their time to organising and cleaning data, rather than addressing interoperability or driving forward product development and innovation.

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Failing to consider interoperability properly when starting the business

This is a problem for 26% of UK MedTechs surveyed, and 14% in Ireland. While many companies possess energy and entrepreneurial talent, they also need to set off with healthcare data standards and interoperability requirements at the forefront of their strategy. Without a focus on these aims, they run into real difficulties when it comes to data-sharing and achieving scalability.

The research found that while fewer respondents in Ireland had neglected interoperability when they started up, more of them said such challenges were a barrier when they reached the point of pushing for growth and uptake. This was reported by 44% of respondents in the region, compared with 32% in the UK.





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Everyone has an interoperability strategy, but does it work?

Every company questioned in the research said it has an interoperability strategy with the results highlighting the different approaches used by different organisations.

The top choice for resolving the interoperability challenges that MedTechs come up against is a database management system – used by 52% of UK respondents and 42% in Ireland. This is followed by a unified data platform (selected by 40% in the UK and 32% in Ireland).

Other solutions in use to achieve interoperability include:



Open-source technologies (selected by 36% in the UK and 28% in Ireland)



Cloud-native technologies (selected by 32% in the UK and 30% in Ireland)



Third-party integration platforms (selected by 28% in Ireland and 20% in the UK) While companies in the MedTech industry are deploying, or plan to deploy, a variety of techniques and technologies to give them the necessary interoperability, the research contains one very stark finding. Three-in-ten companies surveyed in the UK (30%) and more than a fifth surveyed in Ireland (22%) admit their current data platform is not capable of facilitating interoperability with current healthcare data standards. It is little wonder then, that so many MedTechs find they are left behind when it comes to gaining acceptance.









Conclusion:

This research confirms that despite being part of a dynamic and entrepreneurial medical technology sector, many companies in the UK and Ireland continue to face very significant challenges with data interoperability. This continuing struggle to achieve compliance with standards such as HL7® V2 and FHIR® severely inhibits growth for many companies at a time when their healthcare provider customers are eager to use data and digital technology to improve outcomes and efficiency.

Although all companies surveyed say they have interoperability strategies, the majority clearly find it difficult to make their data usable within the major healthcare providers' systems. Many solutions on the market lack the advanced data platform technologies and in-house skills to address significant interoperability problems, so the survey's findings are not surprising.

For a solution to be successful, it is necessary to pull data from multiple sources, some of which will use legacy standards and others which will operate to new requirements. New products that include the capability to support older standards, other APIs, and non-standard interfaces increase the ability to fit into any architecture, making them more desirable in a competitive marketplace

Resource and time constraints mean that achieving this level of interoperability swiftly and cost-effectively on their own is often beyond the capabilities of many MedTech companies, especially in their early stages of development. However, a solution does exist. InterSystems IRIS for Health is a comprehensive data platform which encompasses interoperability, the ability to orchestrate multiple interfaces, high-speed data storage, and "in-flight" data transformation. It is uniquely purpose-built for health data.

InterSystems has specifically engineered IRIS for Health to facilitate the seamless integration of proprietary data with the masses of pre-existing clinical data, achieving full compliance with current mandatory data standards, such as HL7[®] V2 and FHIR[®].

InterSystems IRIS for Health relieves data scientists of many of the burdens of cleaning and preparing data and allows companies to address a far greater number of interoperability use cases. MedTech organisations can enhance these capabilities further with the ability to provide real-time analytics, such as insight into usage patterns and performance. These insights and measurements are the fuel for the future of data-driven care and transformational gains in efficiency.

The user-friendly sophistication of InterSystems IRIS for Health and its support for cloud-based implementations means it is the ideal platform to help power the growth and scale of innovative MedTech companies in the UK and Ireland.

Find out more >



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