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Game changing technologies: Horizon Scan of Wearable Devices for Patient Remote Monitoring of Vital Signs in Health Care

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Conflicts of Interest

No conflicts of interest to declare.

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Abstract

Background:

Wearable devices enable remote monitoring of key health indicators, supporting chronic disease management, rehabilitation, and vital sign tracking. This report focuses on wearables with real-time monitoring capabilities, which may improve early detection, diagnosis, clinical decisions, and reduce healthcare burden. Recent endorsements by NICE and inclusion in the UK's 10-year Health Plan[1] highlight their transformative potential. However, challenges remain around accessibility, development, and regulation. This horizon scan provides an overview of current innovations and gaps in wearable healthcare technologies across the emerging (innovation and preclinical), transitional (clinical trials), and imminent horizons (on the market). The scope of this report covers global developments with focus on the UK and on applications for remote monitoring of vital signs.

Methods:

Searches were conducted in March 2025 across bibliographic databases (Embase, IEEEXplore, INAHTHA), funding portals (CORDIS), clinical trial registries (ClinicalTrials.gov and ICTRP) and patent databases (Espacenet and Patentscope). Retrieved records were deemed eligible if they included wearable technologies with application in the prevention, diagnosis, prognosis, or treatment response of health conditions and diseases across the three priority areas (remote monitoring of vital signs, chronic disease management and rehabilitation). A pilot sample from each data source was dual-screened to develop large language model (LLM) prompts. The LLM was then applied to remaining records, with predicted includes and a random 10% of excludes manually reviewed. Data were subsequently extracted using semi-automated methods, and summarised to indicate technology readiness levels, their disease area and intended purposes.

Results:

The searches retrieved 5,125 records after deduplication, of which 208 were relevant to the scope of the current priority area. Remaining records were either excluded or identified as relevant for the other two priority areas. Across bibliographic databases (Embase and IEEE Xplore), 119 records were included, while 14 clinical trials, 4 funding projects and 71 patents (Patentscope and Espacenet) were included. A third of records identified in this horizon scan described technologies within the emerging horizon. Cardiovascular disease, and remote monitoring of heart rate and respiratory rate were the most common indications. Watches were the predominant type of wearable being developed. From devices that were named, the majority were marketed as consumer devices.

Conclusions:

This horizon scan highlighted the ongoing expansion of wearable devices with remote monitoring capabilities. While some devices were clearly marketed, others lacked regulatory clarity. Limited UK-based early-stage research suggests development may be occurring in contexts less relevant to the NHS. Key challenges include transparent reporting and clinical validation to guide effective implementation of transformative wearable technologies.

Background

The global wearable technology market was valued at USD 53.1 billion in 2023, and with a compound annual growth rate (CAGR) of 26.8%, has been projected to grow to USD 951.7 billion by 2035 (Market Research Future, 2025[2]). Within the UK, the wearable technology market size was estimated at USD billion 2.65 in 2023, and is expected to grow from USD 3.48 billion in 2024 to 47.59 by 2025 with a CAGR of 26.8% (2025-2035).[3] The exponential growth is driven by rapid advancements in data science, electronics, materials science, telecommunication, and the incorporation of additional technologies like virtual reality, artificial intelligence (AI), and the Internet of Things (IoT).[2,4] Furthermore, alongside the growing healthcare demands of the ageing population, the upsurge in accessibility of technologies and societal awareness of health and wellbeing, healthcare application is predicted to be the biggest growing wearable technology sector.[4-6] In a more focused analysis of the global wearable healthcare devices market, the sector was valued at USD 47.5 billion in 2024, and is expected to reach USD 137.4 billion by 2034, with a growth rate of 11.2%.[7]

In healthcare, a wearable device is described as a portable electronic technology that can be worn non-invasively on the body or attached to clothing, and contains sensors to monitor vital physiological, physical and biochemical parameters which indicate health and well-being.[8-10] Since the inception of wearable hearing aids in the 1970s, the types of wearables devices being developed and on the market has become diverse, to include smartwatches, tattoos, lenses, glasses, earbuds, necklaces, smart patches, smart bracelets/bands, smart rings, and wearable robots.[9,11,12] Additionally, we will consider implantable devices, which are placed inside the body by surgery or injection. While not universally considered part of the wearable technology spectrum, they are often integrated with wearable technology, enabling accurate monitoring or internal drug delivery.[12,13] Physiological parameters that can be measured include: temperature, electrocardiography, sleep, blood pressure, pulse, heart rate, oxygen saturation, and respiratory rate, while examples of biochemical parameters include glucose, lactate, cortisol, electrolytes, dopamine, ions, and biomarkers in human biofluids like sweat, saliva, interstitial fluids, and tears.[9,14-17] The measurement and real-time monitoring of these parameters may provide a useful role in healthcare for preventive, diagnostic, therapeutic, and prognostic purposes, as well as for the early detection and identification of disease-related risks. Thus, the potential use and application of wearable devices in health care is diverse.[18] They can be classified based on their roles and applications e.g., health and safety monitoring, disease diagnosis and treatment, chronic disease management, and rehabilitation.[19]

In recent years, NICE has recommended the implementation of wearable medical devices in the NHS. For example, in the remote monitoring of Parkinson's disease[20] and in continuous glucose monitoring for type 1 diabetes.[21] Five wearable devices that monitor and record symptoms of Parkinson's disease were recommended in 2023 because they provide an objective and accurate assessment, enabling better-informed treatment decision by clinicians. Additionally, these devices may help reduce the length and number of clinic appointments

required and thus free up NHS resources.[20] For type 1 diabetes, the NHS is rolling out next-generation wearable sensors which can feed data in real time to an automatic insulin pump for optimal delivery of insulin. Patients with type 1 diabetes are subsequently less likely to experience complications such as disabling hypoglycaemia, strokes and heart attacks.[22]

Despite wearable technologies having the potential to revolutionise both inpatient and outpatient care, several limitations of implementing them in health care have been highlighted. For the user, barriers include accessibility associated with costs and socioeconomic status, and a requirement for some level of knowledge to operate and adhere to the use of the devices as well as understand the risks and benefits.[9] Additionally, the accuracy, sensitivity and clinical validity of wearable devices will impact the durability and robustness of the devices in clinical practice.[9] In addition, issues surrounding data storage, patient privacy, standardisation, and regulatory frameworks remain major challenges to the adoption of wearable devices in healthcare.[9,23,24]

The Medical Devices Regulations 2002[25] is the legal framework in the UK for the identification of devices which have an intended medical use as stated by their manufacturer, for ensuring both consumer safety and device effectiveness. Medical devices are given a safety risk by the Medicines and Healthcare products Regulatory Agency (MHRA), with devices considered low risk (Class I) e.g., spectacles, requiring the least oversight; whilst high risk devices (Class III) e.g., pacemakers, require greater insight into their safety and efficacy.[26] However, not all wearable devices available on the market are regulated under this framework, and are instead classed as consumer devices, facing less scrutiny regarding safety, security, and health inequity issues.[26] As such the majority of commercially-driven, consumer-facing wearable devices (such as those for fitness or wellness related purposes) have no publicly available data published to indicate their level of accuracy and validity.[27,28] Meanwhile, MHRA-regulated wearable devices, certified as effective in clinical populations, may be commercially accessible, despite not being evaluated for use in the general population.[26] It is therefore essential that policies remain adaptable to the rapidly evolving landscape of wearable technologies, provide clear guidance to manufacturers and enable protection of their end-users.[29,30]

Nonetheless, in terms of market access strategy, pre-market approval as a consumer device may face fewer barriers and be easier to obtain.[26] Gaining regulatory approval as a medical device can be a time-intensive process, causing delays and unsustainable costs, particularly for small and medium enterprises.[26] Moreover, the increasing advancement of wearable technologies suggests some devices may already reach the threshold of what authorities may deem a medical device.[28]

In July 2025, the UK government published the NHS 10-year Health Plan for England, which proposed wearables as one of five potentially transformative technologies that will be integral to improving healthcare.[1] With the aid of embedded AI algorithms to analyse data, the plan states wearables will help to detect early disease, predict adverse events and provide

personalised coaching. By 2035, wearables are proposed to become standard in preventative, chronic and post-acute NHS treatment.[1] Access to these devices is also proposed to include all NHS patients, with free provision in areas with the highest health needs and deprivation.[1] As part of the government's healthcare model, wearables will enable virtual care to take place in real-time, providing patients with insights into their health and access to clinical teams at home, which can enable improvement in self-management and timely interventions for better overall health.[1] Gaining early insight into emerging wearable technology innovations in healthcare is therefore crucial to help anticipate future trends, and inform the development of responsive, forward-looking regulatory strategies that enable safe and effective development and integration of wearable devices in healthcare.

This report focuses on one of three priority areas of wearable devices highlighted by our stakeholders: specifically, wearable devices for the remote patient monitoring of vital signs. This enables continuous, real-time monitoring of vital signs within and outside conventional healthcare settings. The data are transmitted remotely, which allows continuous data sharing and monitoring between patients and healthcare providers.[31] This function enables the collection of real-world patient health data during activities of daily living, which may assist in the early detection of health deterioration, decision-making by health care practitioners on diagnosis and treatment pathway, and improve patient outcomes.[31-33] Additionally, wearable remote monitoring devices may reduce the number of healthcare visits required and enable patients to make the necessary lifestyle adjustments to prevent further health issues.[33]

Aim

The overall aim of this research is to provide a comprehensive overview of the latest progress and remaining gaps in the research pipeline of innovative wearable devices in health care. By using horizon scanning methods, the project will deliver reports, interactive dashboards, and technology radars for three priority areas across wearable devices, identified during consultation with our stakeholders.

Project objectives:

- Identify and describe innovative wearable remote monitoring devices across the MedTech development pipeline for application in health care and to provide strategic insights and foresight, which may address key issues in healthcare policy and regulation.
- Map the trends of innovative remote monitoring wearable devices being developed across the health technology landscape including disease areas, target population, country, vital signs monitored, and maturity of a technology for market access.
- Indicate wearable remote monitoring devices which implement the use of AI, pose a higher risk to patients, or more likely to face regulatory hurdles.

Methods

The following sections describe horizon scanning methods undertaken to achieve the objectives of this project.

Scope

The framework for this horizon scan including type of innovation, population, sources and interest holders is outlined in Table 1 below.

Table 1. The scope of the horizon scan for wearable technologies in healthcare

Item	Description
Horizon	Across the MedTech development pathway from initial concept to recently-approved devices ready for implementation into healthcare: therefore the emerging (innovation and preclinical), transitional (clinical trials) and imminent (on the market) horizons will be searched.[34]
Innovation	New technology or new application of existing technology
Population	Global with focus on the UK
Data sources	The following patent and funding databases will be searched to identify relevant technology across the emerging horizon: • CORDIS • Patentscope • Espace The following trial registries and bibliographic databases will be searched to identify relevant technology across the transitional and emerging horizons: • International Clinical Trials Registry Platform (ICTRP) • ClinicalTrials.gov • Embase • IEEEXplore
Interest holders	• Government departments and policy makers to inform strategic planning and regulatory foresight of innovative technology for improving public health. • Regulators and health technology assessors to ensure relevant clinical efficacy and safety evidence, as well as cost effective evidence for decision-making, is generated. • Funders, accelerators and catapults to ensure the appropriate support and investment is available for game changing

	technologies that can boost public health and economic development. • SMEs, patient groups and charities to ensure the relevant guidance and support for innovations that address unmet needs can obtain market access and reach underserved populations.

Search Strategy

An information specialist in collaboration with the researchers in the team developed and ran the searches. Searches were performed to identify wearable technology devices in generalist, source-specific and "other topic" databases as follows: Embase (OVID), IEEEXplore, The International Network of Agencies for Health Technology Assessment (INAHTA), ClinicalTrials.gov, the International Clinical Trials Registry Platform (ICTRP), CORDIS, Espace and Patentscope. As there is potential for multiple applications of a single technology, all three priority areas (remote monitoring of vital signs, chronic disease management, and rehabilitation) were searched simultaneously in the bibliographic databases, while distinct search terms were applied in the clinical trial registries, funding and patent databases; then results were pooled for each data source. The full search strategy is available in Appendix A.

Bibliographic databases

Published literature searches were conducted in three databases: Embase (OVID) [Embase <1974 to 2025 March 17>], IEEEXplore (searched March 17th 2025), and INAHTA (searched March 19th 2025). The search strategies were designed in Embase (OVID) using EMTREE subject headings and keywords and translated across the databases where possible. Prior to conducting the full search, search terms were tested for sensitivity and specificity via a pilot search then tailored to each database to account for differences in indexing, search fields and controlled vocabularies. Some searches faced limitations caused by variations in indexing, limited controlled vocabulary and limited search functionality. No published search filters were used. The search was limited by year, specifically 2022–2025 to capture most recently reported technologies near-market, and by journal publication type. All search results were downloaded to EndNote and de-duplicated using EndNote software.

Clinical Trials

Searches in the clinical trial registries Clinicaltrials.gov and ICTRP were conducted on 18th March 2025 for all three priority areas. Search terms were adapted to each registry's search functionality. Due to more limited search functionality, comprehensive searches could not be conducted and was therefore restricted to combinations of keyword terms only such as "wearables AND remote monitoring". Full details of the search are available in Appendix A. The search was limited by date (2022-2025) but not limited by trial phase or language.

Funding

CORDIS comprises a database of the EU's research and innovation funding programmes. Searches for funding were conducted on 18th March in CORDIS with a start of 2022-01-01 for all three priority areas. Keyword searches were conducted using focused terms from the main search strategy: full details of this search are available in Appendix A.

Patents

Patentscope and Espacenet, run by World Intellectual Property Organization (WIPO) and the European Patent Office respectively, provide access to published patent applications from granting offices worldwide. Searches for patents were conducted on 18th March in Patentscope [1975–current] and Espacenet with the date limited to 2022-2025. Espacenet does not permit a date filter to be applied, therefore records retrieved prior to 2022 were excluded during screening. Searches were adapted to patent-specific fields and controlled vocabularies where appropriate. Title and abstracts were limited to English language but no country restrictions were applied. Limitations of this search included incomplete abstract information and variations in terminology across patent databases.

Screening

All records identified in the searches were retrieved and input into either an Excel spreadsheet (CORDIS, Espacenet, Patentscope and INAHTA) or Covidence (Embase, IEEEXplore and Clinicaltrial.gov) for screening. Information screened included: titles, abstracts, summaries, objectives, and keywords if available. In Covidence, a separate project was created for trial registry records due to their different characteristics compared with bibliographic records.

A pilot screen of the records comprising 10% (or 100 records, if lower) from each database search was carried out by two independent reviewers using predefined eligibility criteria - detailed below. Any discrepancies were resolved through discussion, or consultation with a third reviewer. After pilot screening, all records in Covidence were exported into an Excel spreadsheet.

Automation of screening

To help reduce the number of records manually screened, a LLM (GPT-4o-mini) was applied, accessed via the OpenAI Application Programming Interface.[1]

Step 1: We drafted LLM prompts based on the inclusion criteria for this scan and refined them based on the manually screened pilot data. We developed prompts with the primary aim of high sensitivity (identification of true positives), while also considering precision (fraction of false positives; also called positive predictive value). These parameters were calculated from

[1] https://openai.com/index/gpt-4o-mini-advancing-cost-efficient-intelligence/
https://platform.openai.com/docs/models/o4-mini

the output of the pilot screen and prompts were refined and evaluated iteratively. We adapted prompts for each specific data source, using one of the bold text options as applicable:

*"You are a researcher screening **[references/clinical trial registry entries/patents/funding records]** for inclusion in a literature analysis. The inclusion criteria are the following: Any reference that describes wearables used on humans, for prevention, diagnosis, prognosis, or treatment response of health conditions such as diseases, impairments, or disability. Devices must be wearable, eg. biosensors worn on the body or attached to clothing, in case of implants worn invasively, or as sensors within fabrics. Examples of wearables include, but are not limited to, smart watches, tattoos, lenses, glasses, earbuds, necklaces, smart patches, smart bracelets/bands, smart rings, exoskeletons, wearable robots, or virtual reality and immersive technology. Included reference should describe wearables being tested for health-relevant functions such as remote monitoring of vital signs, support of rehabilitation, chronic disease management, or measuring other health-related data on patients. Exclude all references describing review articles, multiple conference proceedings, protocols, software development, materials development, and other papers reporting no results on wearables on humans. Answer YES if the article is relevant to the inclusion criteria or unclear. Answer NO if it is not. Then reproduce the exact context from the paper that contained the information on which basis you made the decision. Here is the text of the article: [..]"*

Results on the pilot data showed high sensitivity (>0.98) on all data sources (full results are presented in Appendix C).

Step 2: We then applied the LLM to the remaining unscreened records. To validate the LLM output, all the records that were predicted to be included, plus a random sample of 10% excluded by the LLM, were manually screened by a single reviewer, blinded to the LLM prediction. Any queries over records during single screening were discussed amongst the team to reach a consensus.

For bibliographic data, nine records were falsely excluded by the LLM. Subsequently, to mitigate the risk of missing relevant references and biasing the horizon scan outcome, we conducted additional screening of likely relevant evidence. To retrieve missing relevant unscreened bibliographic records, we used a prioritisation tool developed within the Innovation Observatory, Artificial Intelligence Document Organiser and Classifier, to re-rank the remaining records excluded by the LLM based on their predicted similarity to previously included records.[35] Likely relevant records were subsequently screened until a sustained pattern of consecutively excluded records was encountered, indicating that further screening was unlikely to yield additional includes. All remaining clinical trial registry entries, patent and funding records were screened due to a high miss-rate of the LLM. Full results for this second step of automation are reported in Appendix C.

Step 3: We continued screening the whole trial registry, funding, and patent datasets due to the relatively small numbers of records and concerns of missing relevant technologies. For trial registry entries, the LLM falsely excluded three records in the random sample. However, full evaluation of the LLM predictions against manual screening results revealed high sensitivity (>95%) on all datasets. Full results are shown in Appendix C.

The number of records searched, retrieved, and screened for eligibility were recorded using an adapted Preferred Reporting Item for Systematic reviews and Meta-Analyses (PRISMA) diagram.[36]

Eligibility criteria

During the screening of titles and abstracts/summaries retrieved during the searches, records were included if they met the inclusion criteria and none of the exclusion criteria as listed in Table 2. To be identified as relevant for remote monitoring of vital signs, the first three criteria all had to be met.

Table 2. Eligibility criteria

Inclusion criteria	Exclusion criteria
• Wearable devices that can be worn on the body, attached to clothing or implanted in the body, and able to capture vital sign parameters which were able to be monitored remotely by a healthcare professional; AND, • Vital signs included (but were not limited to) heart rate, heart rate variability, blood pressure, oxygen saturation, breathing rate, temperature, electrocardiogram (ECG), and blood glucose; AND, • Remote monitoring or reference to the transmission of data from the wearable to another person had to be explicitly stated. • The full device did not need to be the focus of the record; records presenting a component of a device (e.g., a material or algorithm) were eligible if the component was tested or demonstrated within the context of a full device. • Improvements to existing devices or new applications for existing technologies were also included. • Devices could be worn intermittently or continuously. • Studies involving healthy participants.	• Review articles and compilations of papers, abstracts or conference proceedings. • Records where the abstract or summary concluded that the technology was ineffective or not a viable substitute for current standard of care, as these were not considered 'game changing technologies'.

Semi-automated data extraction and quality assurance

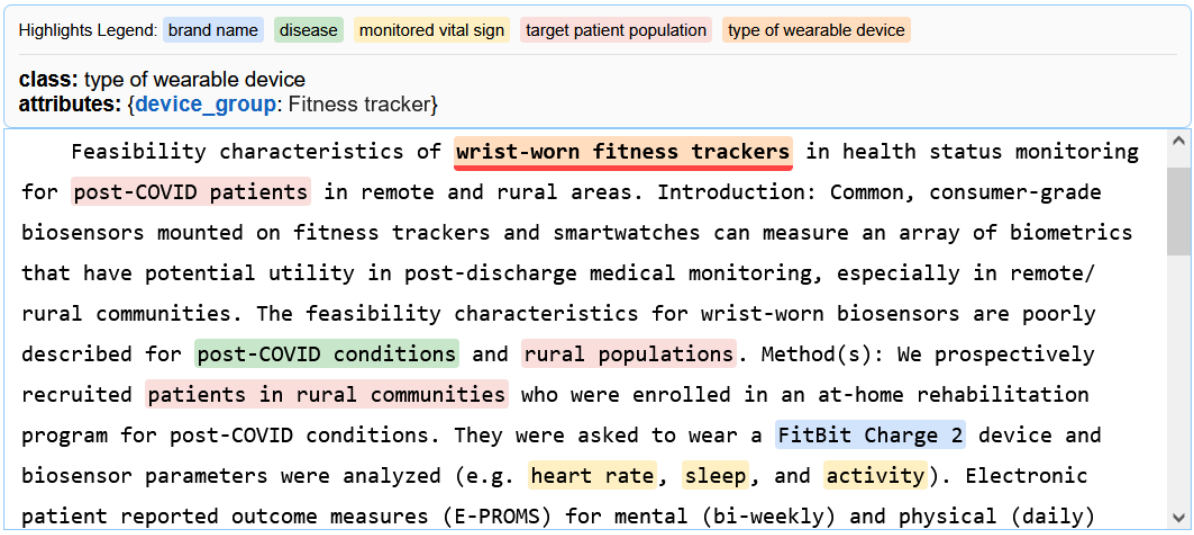
Bibliographic sources

Data were extracted from all included bibliographic records into an Excel spreadsheet. In total, three researchers were involved in single-extracting data from each publication, supported by an LLM. Items extracted included: *Device name; Target population; Disease area; Country; Vital signs monitored; Type of device including implantable devices; TRL; intended purpose; and AI use.*

The LLM Google Gemini-2.5-flash[2], accessed via the LangExtract[3] Python library, was applied to semi-automate data extraction in a human-in-the-loop process. Extractions were grounded in each source context, allowing only verbatim extractions and thus mitigating the risk of hallucinations.

We first evaluated the performance of zero-shot data extraction using manually extracted data from 20 records as gold standard. Results showed high sensitivity (1.0 for most variables; the lowest was 0.92) but variable precision, reflecting frequent false positives where the LLM extracted unspecific terms (e.g., "patients") that reviewers deemed insufficient. False negatives, which impact sensitivity, were rare but occurred when extracted information was incomplete or implicit in the source text. See Appendix D for full evaluation results and an extended description.

To enable safe use of AI, a semi-automated workflow was introduced, where the LLM pre-extracted information into spreadsheets and provided highlighted source contexts e.g., for brand, disease, vitals signs, with outputs clearly marked for human reviewers to verify and edit (Figure 1). This process combined automation with manual oversight, improving efficiency while reducing misclassifications.



[2] https://deepmind.google/models/gemini/flash/ (last accessed 20/08/2025)
[3] https://pypi.org/project/langextract/ (last accessed 20/08/2025)

Figure 1. Semi-automated data extraction using Google gemini-2.5 flash and LangExtract

ClinicalTrials.gov

All National Clinical Trial numbers (NCT) of trials included from trial registries were input into the ClinicalTrials.gov search query and a CSV file with the following data fields was created: *NCT Number; Study Title; Study URL; Acronym; Study Status; Brief Summary; Study Results; Conditions; Interventions; Primary Outcome Measures; Secondary Outcome; Measures; Other Outcome Measures; Sponsor; Collaborators; Sex; Age; Phases; Enrolment; Funder Type; Study Type; Study Design; Other IDs; Start Date; Primary Completion Date; Completion Date; First Posted; Results First Posted; Last Update Posted; Locations; Study; Documents; Funding; Patents.*

Funding

The funding projects retrieved from the searches encompassed total costs, EU contribution costs, and start/end dates. The country co-ordinating the projects was found by manually searching the project on the CORDIS website.

Data Analysis

Technology development characteristics

A narrative summary and graphical representation of technologies identified from included records were constructed, focussing on the geographical location of the development, the type of device, target disease area as categorised by NICE,[37] target patient population, age group, and use of AI. For bibliographic records investigating more than one wearable device, the devices were grouped as one technology, and the intended purpose (treatment, diagnosis or management) was assigned to each.

Technology readiness levels

Assessment of the maturity level of each technology identified was conducted by evaluating the development of the technology against the technology readiness levels (TRLs).[38,39] Technologies assigned TRL 1-3, 4-7 and 8-9 can be mapped to the emerging, transitional and imminent horizons respectively.[34] TRLs were assigned to each record if possible, based on the information retrieved from the searches. If the technology name was stated, researchers conducted a manual search of the product website, as well as the MHRA, FDA and EMA regulatory websites for any relevant information indicative of the TRL and if regulated as a consumer of medical device. If the technology was already marketed but a different application e.g., disease indication, was being tested, the TRL was assigned according to the study record included in this report. For bibliographic records investigating more than one wearable device, the devices were grouped as one technology and a single TRL was applied. Technology radars which provide a graphical representation of the TLRs of identified technologies were generated.

International Patent Classification

The technical field and application to which all identified patents pertained to were summarised by pooling all the International Patent Classifications (IPCs) assigned to each patent. The IPC is a hierarchical system of language-independent symbols, organised into sections, classes,

subclasses and groups, for each technical field, enabled the number of patents at each level to be summed for graphical representation.

Missing data

Any information that was not stated in the title, abstract, summary of the record, or was unretrievable from the developer's website, was stated to be not reported (NR) and treated as missing.

Results

Weak signal selection

Of the 5125 records, retrieved from searches after deduplication, 208 records met inclusion criteria and none of the exclusion criteria for the remote monitoring of vital signs. The flow of records through the record retrieval and screening processes to identify relevant technologies is presented in the adapted PRSIMA diagram in Figure 2. The weak signal selection reported here serves to identify wearable devices within the emerging (innovation and preclinical), transitional (clinical trials) and imminent (on the market) horizons, which may hold most potential for significant future impact in enabling the remote monitoring of vital signs.

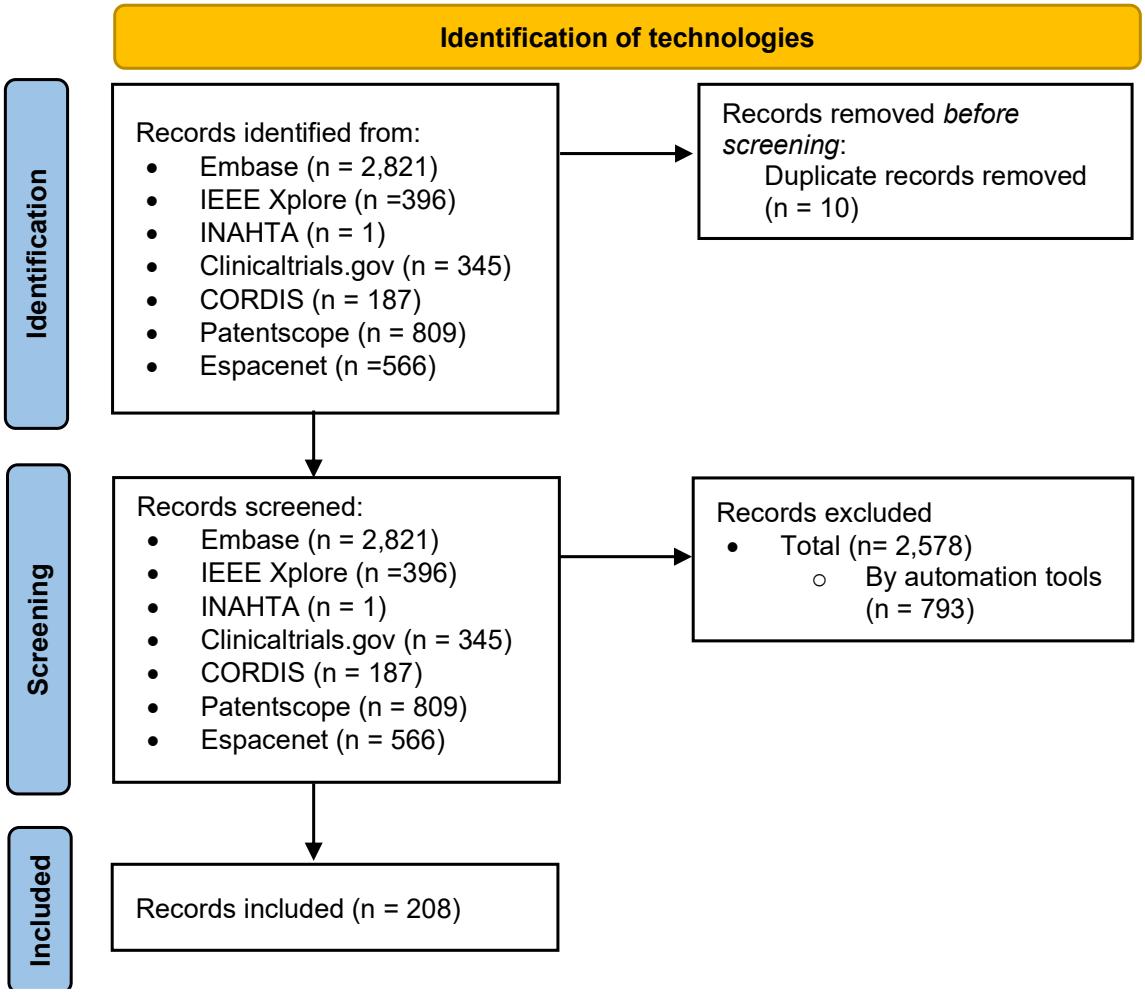


Figure 2. PRISMA 2020 flow diagram for identification of wearable technologies showing the number of records at each stage

Single source of information characteristics

The number of records included and stratified by data source searched is shown in Figure 3. Across bibliographic databases (Embase and IEEE Xplore) 119 records were included, while 14 clinical trials (ClinicalTrials.gov), 4 funding records (CORDIS) and 71 patents (Patentscope and Espacenet) were included. No records were included from INAHTA.

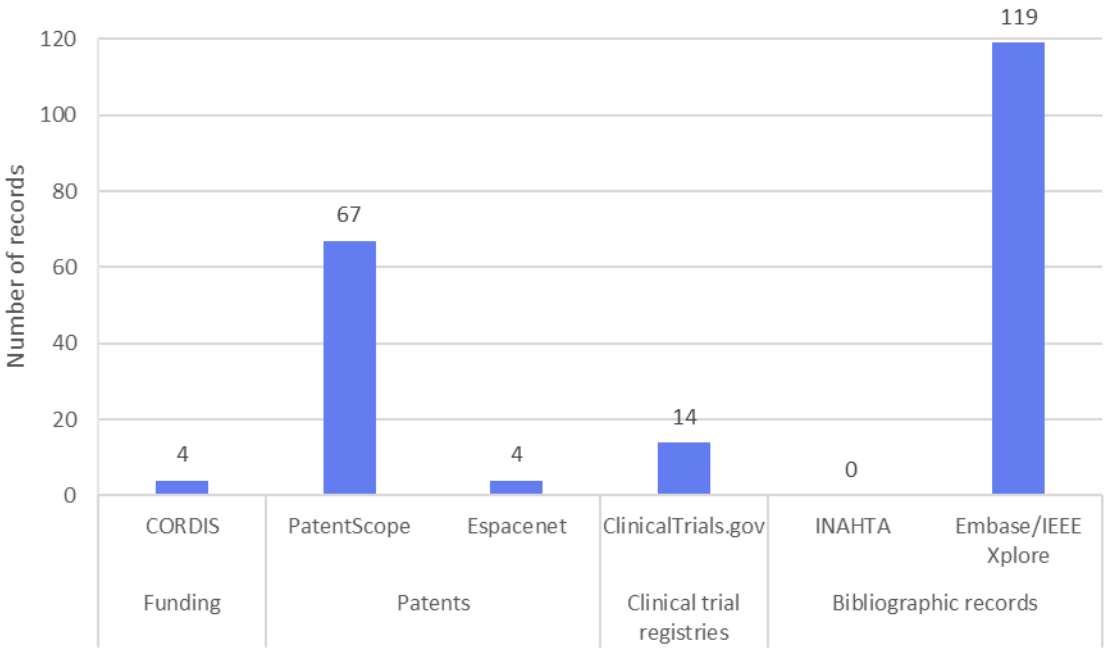


Figure 3. Number of records included for remote monitoring of vital signs from each data source searched.

Funding

Overall, four relevant funding projects were identified from CORDIS (Table 3). These projects, ranging from approximately 1.7 to 22 million Euros, are co-ordinated in Turkey, the Netherlands, Bulgaria and France. Two of the four projects, ARCHANGEL and ADAPTE, state that AI was used, the latter using an AI-driven emotion recognition algorithm to help with remote continual monitoring of patient's emotional status. Collectively, the projects identified aim to develop and implement wearable devices that can help improve the speed of diagnosis, inform treatment strategies and support preventive measures, particularly in the context of chronic disease and postnatal care. These initiatives reflect a growing emphasis on leveraging real-time data and personalised monitoring to intervene earlier and more effectively in patient health trajectories.

Table 3. Funding projects identified from CORDIS relevant to wearable devices for remote monitoring of vital signs

Grant agreement ID	Title, acronym	Keywords	Total cost, €	EU contribution, €	Start date	End Date	Co-ordinated by
101068646	Heart Attack Monitoring Patch (HAMP)	AC Electrokinetic, wearable, biosensor, wireless communication	NR	148,478.40	6/16/2022	6/15/2024	Turkey
101095792	New remote non-invasive monitoring solutions for ensuring the health of mothers and babies before and after birth (Newlife)	eHealth, remote healthcare, medical sensors, ultra-sound monitoring, smart textile, artificial intelligence, pregnancy monitoring, risk birth, premature birth, medical data acquisition and data sharing	22,048,506	6,162,183.02	01/01/2023	12/31/2025	Netherlands
190185304	Advanced Remote Continuous patient Health mANaGemEnt SoLution (ARCHANGEL)	A.I. decision support, digital biomarkers, Digital services, telemedicine, Patient care	3,480,000	2,436,000.00	08/01/2023	7/31/2025	Bulgaria
190129251	A novel and accurate emotion recognition system for real-time and continuous patient monitoring in psychiatry (ADAPTE)	Emotion tracking, eco-friendly hydrogel, diagnosis, convolutional neural network, mood disorders, digital health therapeutics, wearable, EEG, dry electrodes, emotion recognition, continuous patient monitoring	3,568,155	2,497,708.00	11/01/2023	10/31/2025	France

Abbreviations: NR, not reported

Patents

Patent records identified in the horizon scan reflect the earliest stages of innovation, representing conceptual ideas or initial prototypes rather than fully developed or clinically validated technologies. Across the included 71 patent records, the assigned country codes for 63 of these records showed China, India and the USA to be the top three countries where patent applications were filed or grated (Figure 4). Of the remaining eight records, four were assigned 'WO' and four were assigned 'EP', indicating WIPO and the European Patent Office.

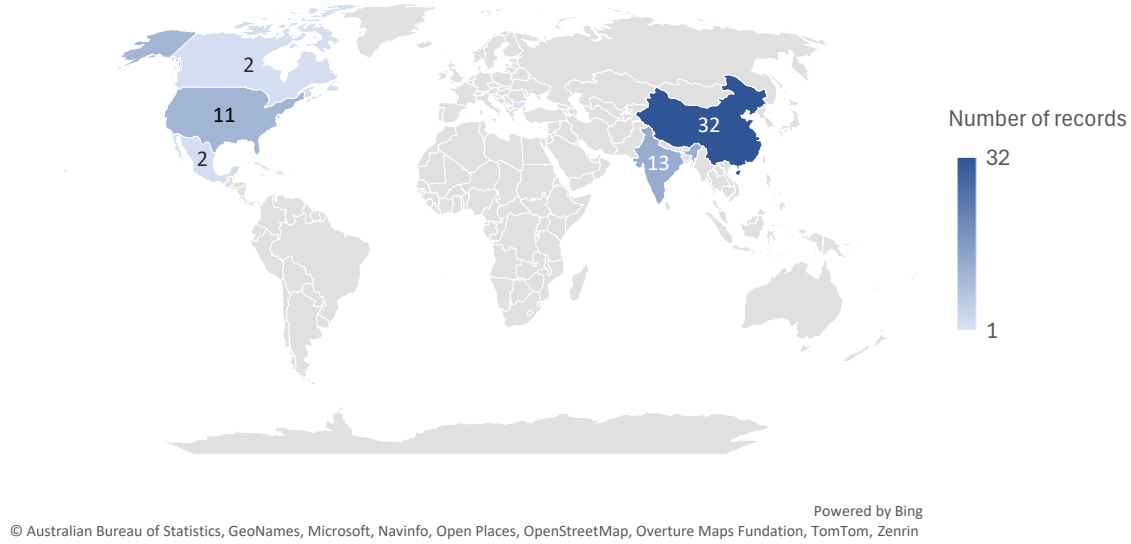


Figure 4. Locations of where patent applications were filed or grated

To characterise the technical fields and applications the included patents aligned to, all 71 relevant patents were pooled and grouped according to their allocated IPC subclass (See Table 5 in Appendix B). The most commonly assigned class with 168 IPC symbols was A61, representing inventions within the field of "Medical or veterinary science; hygiene". Within this class, the majority (162/168) of patents were further assigned to the subclass for "Diagnosis; surgery; identification" (A61B). Within this subclass the majority (150/162) were labelled in the group for inventions "Measuring for diagnostic purposes" (A61B 5/00). The top nine subgroups pertaining to the invention's specific application within this subclass, are displayed in Figure 5.

Figure 5 Bubble chart showing the nine highest occurring International Patent Classification (IPC) symbols for subgroups in the A61B 5/00 group reported by included patents (measuring for diagnostic purposes. Footnote a: the higher-level description of this subgroup was 'Measuring temperature of body parts'

The second most common class with 61 IPC symbols was G16 representing inventions within the field of "Information and communication technology [ict] specially adapted for specific application fields". Within this class, the majority (55/61) were further assigned to the subclass for "Healthcare informatics, i.e. information and communication technology [ict] specially adapted for the handling or processing of medical or healthcare data" (G16H). The top nine groups and subgroups assigned to the inventions in the latter subclass are displayed in Figure 6.

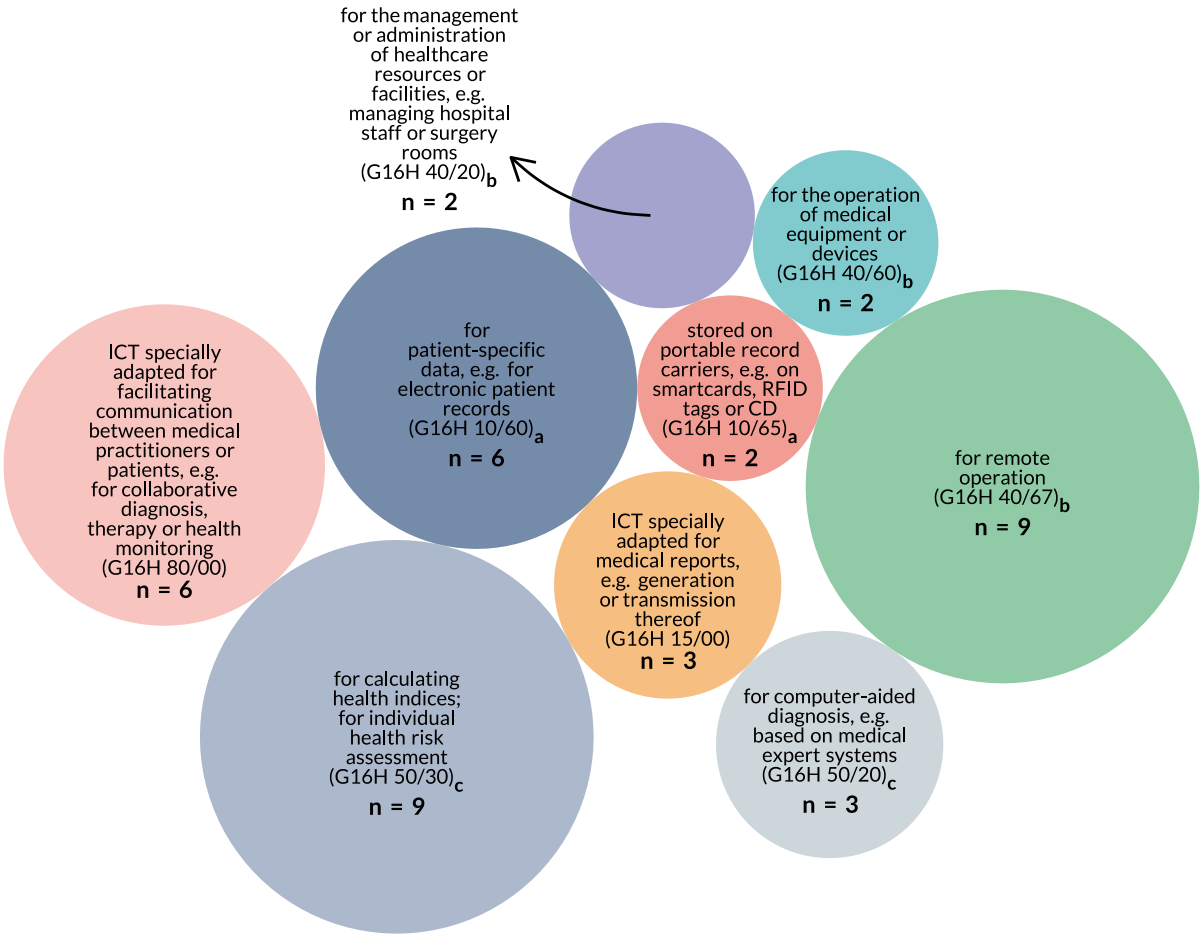


Figure 6 Bubble chart showing the nine highest occurring International Patent Classification (IPC) symbols for groups and subgroups in the G16H (Healthcare informatics, i.e. information and communication technology [ict] specially adapted for the handling or processing of medical or healthcare data) subclass reported by included patents. Higher level description of those with a footnote: a, ICT specially adapted for the handling or processing of patient-related medical or healthcare data; b, ICT specially adapted for the management or administration of healthcare resources or facilities; ICT specially adapted for the management or operation of medical equipment or devices; c, ICT specially adapted for medical diagnosis, medical simulation or medical data mining; ICT specially adapted for detecting, monitoring or modelling epidemics or pandemics.

The third most common class cited with 29 IPC symbols was H04 representing inventions with "Electric communication technique". Within this class, the majority (26/29) were further assigned within the subclass, H04W, representing "Wireless communication networks". Within the latter subclass, the majority (20/26) were assigned to the following group for application in "Services or facilities specially adapted for wireless communication networks" (H03W 4/00). The top five subgroups indicating the specific application of inventions listed under H03W 4/00 are displayed in Figure 7.

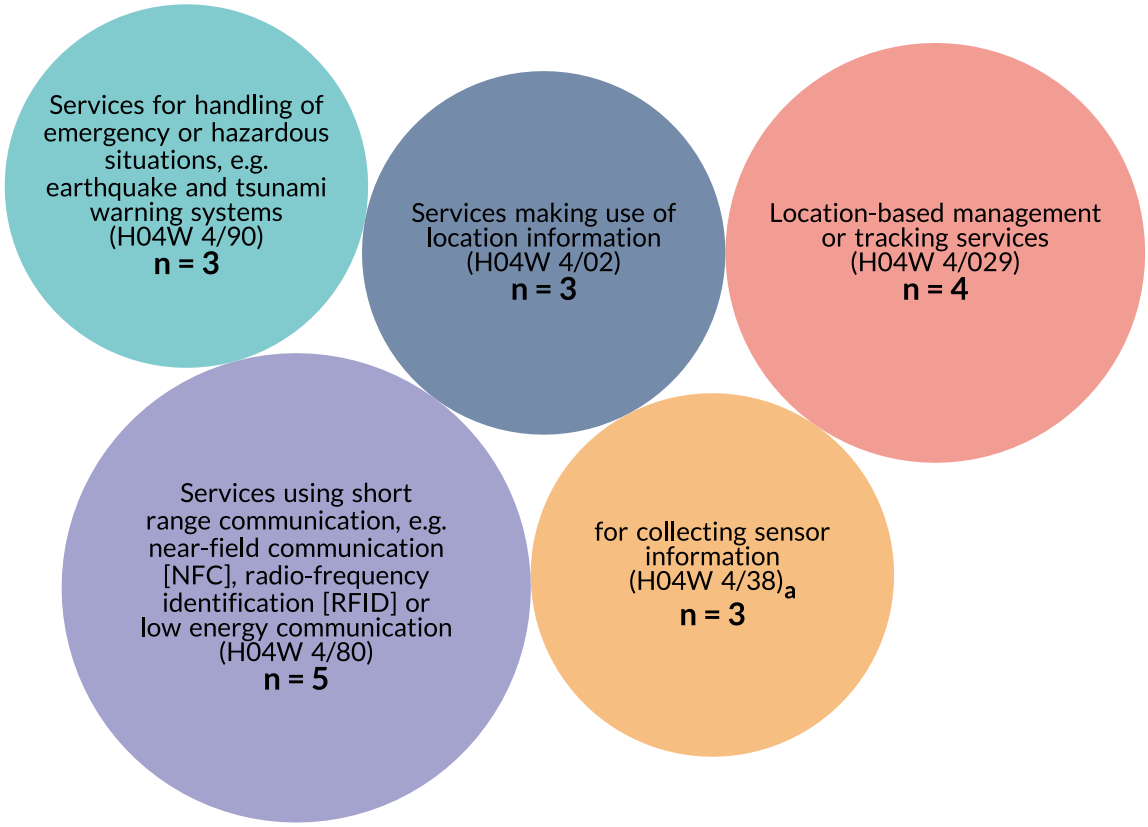


Figure 7 Bubble chart showing the five highest occurring International Patent Classification (IPC) symbols for subgroups in the H04W 4/00 group reported by included patents. Footnote a: Higher level description of this subgroup is 'Services specially adapted for particular environments, situations or purposes'

Trial registries

A total of 14 clinical trial records were categorised into the remote monitoring of vital signs category, which are reported in Table 4. Across all included trials, four trials were stated to be investigating application of consumer devices available on the market. Most trials included had US sponsors (7/14, 50%) indicating their dominance in the field of clinical validation of wearable devices, while two trials had UK sponsors. All trials targeted adults and older adults. The most common disease areas were respiratory conditions (5) and cancer (3). Ten device names were extracted; seven of these were consumer devices such as Apple watch, Fitbit and Oura Ring. The most common type of wearable type reported was a watch (4/14 trials, 28.6%) but most types were not reported (8/14 trials, 57.1%). The most common vital measured was heart rate and respiratory rate/activity, both measured in 7/14 (50%) trials. AI was implemented in two out of the 14 trials. Most technologies were described as intended for management (11/14, 78.6%), with two of these also intended as a treatment, and one as a preventative. Only three technologies did not focus on management and instead were aimed with diagnostic intent (21.4%). For the ten trials that were not testing consumer devices, most were assigned TRL 6 (8/10, 80%), with the other two assigned TRL 7.

Table 4 Clinical trials investigating wearable devices for the remote monitoring of vital signs

Title and accession number	Country of sponsor/ developer	Start date	Study status	Disease area	Brand name/ type of device	Vitals monitored	AI used?	Intended purpose	TRL
Adaptive, Real-time, Intelligent System to Enhance Self-care of Chronic Disease. NCT03643692	UK/NR	2/26/2019	Completed	Diabetes and other endocrinal, nutritional and metabolic conditions	ARISES/ NR	NR	N	Management	6
Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting. NCT04362631	US/NR	4/24/2020	Completed	Respiratory conditions	NR/NR	Temperature; heart rate; respiratory rate/activity	N	Diagnosis	6
EvALuation of ECG Transmission and AI moDels Using Apple Watch ECGs and Symptoms Data Collected usiNg a Mayo iPhone App. NCT05324566	US/US	5/5/2021	Completed	Cardiovascular conditions	Apple watch/ watch	ECG	N	Management	CD
It is Possible to Continuous Monitor Vital Signs in Patients Discharged a Rehabilitation Center - An Observational	Denmark/ NR	10/14/2019	Completed	NR	NR/NR	Oxygenation monitoring; heart rate; respiratory rate/activity;	N	Management	6

Feasibility Study. NCT05345626						blood pressure			
Study to Remotely Monitor Activity in Transgender Cancer Survivors. NCT05391217	US/NR	2/1/2023	Recruiting	Cancer	NR/NR	NR	N	Management	6
Effect of a Home-based, Supervised Prehabilitation With Wearable Technology for Patients With Non-small Cell Lung Cancer Before Lung Resection: a Single-arm, Prospective Study. NCT05608759	China/NR	11/1/2022	Unknown	Cancer	NR/NR	NR	N	Management and treatment	6
Remote Assessment of Lung Disease and Impact on Physical and Mental Health. NCT05630599	UK/NR	7/26/2021	Unknown	Respiratory conditions	NR/NR	Respiratory rate/activity; oxygenation monitoring; heart rate	N	Management	6
Wearable Assisted Viral Evidence (WAVE) Study A Decentralized, Prospective Study Exploring the Relationship Between Passively-collected Data From Wearable Activity Devices and Respiratory Viral Infections. NCT06207929	US/US	1/21/2024	Completed	Infections	Apple Watch; Fitbit; Garmin/ watch	Heart rate	N	Diagnosis	CD

A Program of Care in Chronic Obstructive Pulmonary Disease Involving Virtual Pulmonary Rehabilitation, Integrated Care and Remote Clinical Monitoring After Discharge From a Recent Exacerbation: Mixed-Methods Study on Feasibility. NCT06253013	US/US	9/15/2023	Recruiting	Respiratory conditions	Hyfe Smart-watch; FitBit Versa 2/ watch	NR	N	Management and treatment	CD
Early Detection of Clinical Deterioration Using an Integrated Remote Monitoring System in Lung Cancer Patients Receiving Cytotoxic Chemotherapy. NCT06479005	Belgium/Finland	7/1/2024	Not yet recruiting	Cancer	Oura Ring/ ring	NR	N	Management	CD
Determining the Feasibility of Digital Interventions for Adults with Treatment-Resistant Depression. NCT06732089	US/NR	12/16/2024	Recruiting	Mental health, behavioural and neurodevelop-mental conditions	NR/ watch; ring	Heart rate; respiratory rate/activity; temperature; electrodermal activity (skin conductance)	N	Management	6
WeArable TeChnology DaTa DriVen DigitAl HealTh COachINg (ACTIVATION)- a Mixed-methods Study. NCT06752772	Singapore/ NR	8/6/2024	Recruiting	More than 3	NR/NR	NR	N	Management and prevention	7

COR-INSIGHT: Optimizing Cardiovascular and Cardiopulmonary Outcomes with AI-Driven Multiplexed Indications from the COR ECG Wearable. NCT06763549	US/NR	11/16/2024	Enrolling by invitation	Cardiovascular conditions; Sleep and sleep conditions; Respiratory conditions	COR 1.0; COR 2.0/NR	Respiratory rate/activity; heart rate; heart rate variability; oxygenation monitoring	Y	Diagnosis	7
Early Prediction of Acute Exacerbations of COPD Using Wearable and Portable Remote Monitoring Technology with AI/ML Empowered Platforms: a Prospective Clinical Study. NCT06802003	Canada/NR	5/22/2025	Recruiting	Respiratory conditions	NR/ wristband; ring	Respiratory rate/activity; heart rate; heart rate variability; oxygenation monitoring	Y	Management	6

Abbreviations: CD, consumer device; N, no; NR, not reported; Y, Yes

Bibliographic sources

Bibliographic records offer peer-reviewed, evidence-based insights into the areas of research and development that are gaining academic traction and can serve as a useful source for assessing the maturity and credibility of technologies. In this horizon scan a total of 119 records, including six clinical trial protocols, were identified as relevant studies reporting wearable devices with application in the remote monitoring of vital signs.

Conditions and diseases

The number of records which reported wearable devices categorised by the condition or disease area the device is indicated for is shown in Figure 8. The most common target disease areas were cardiovascular conditions (23/119) and respiratory conditions (17/119), while less commonly reported conditions included those regarding digestive tract, musculoskeletal or urological conditions. However, the target condition or disease was not reported for 21% (25/119) records and therefore it remains uncertain as to whether these technologies have been developed for a specific indication and represent some of these latter conditions or whether they are used for multiple conditions.

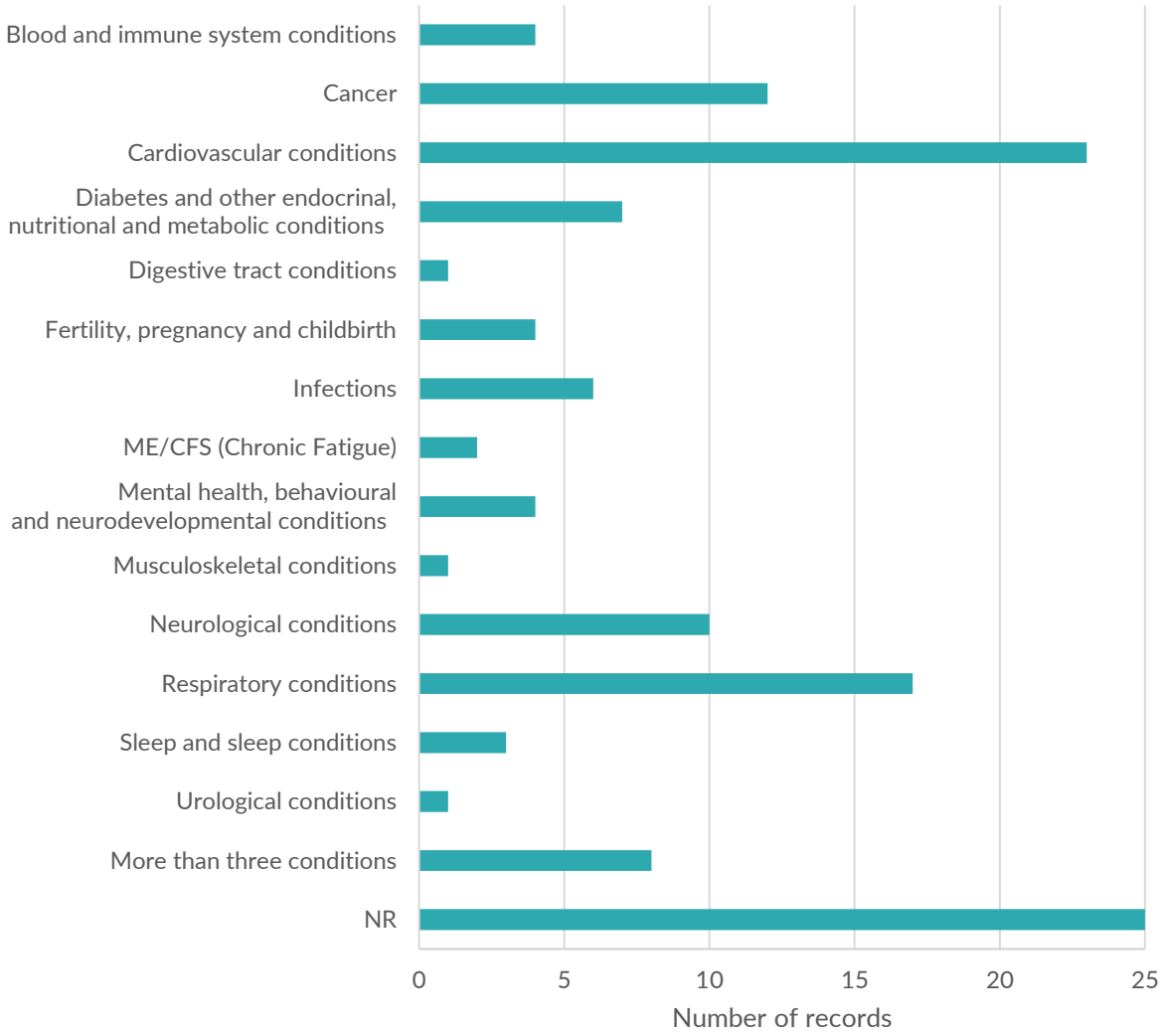


Figure 8. Number of technologies by condition or disease area

Abbreviations: ME/CFS, myalgic encephalomyelitis or chronic fatigue syndrome; NR, not reported

Target population

Just over half of the records (71/119, 59.7%) studied the technology in a defined patient population and 4.2% (5/119) of records investigated the technology in healthy subjects; the remaining records did not specify the patient population the technology was being studied or intended for. The age of the target population the technologies were intended for was reported by 39/119 records (32.8%), while 80 records did not report a target age for the technology (Figure 9). The most common age range reported was older adults, which was an identified population age in 17.6% of records (21/119).

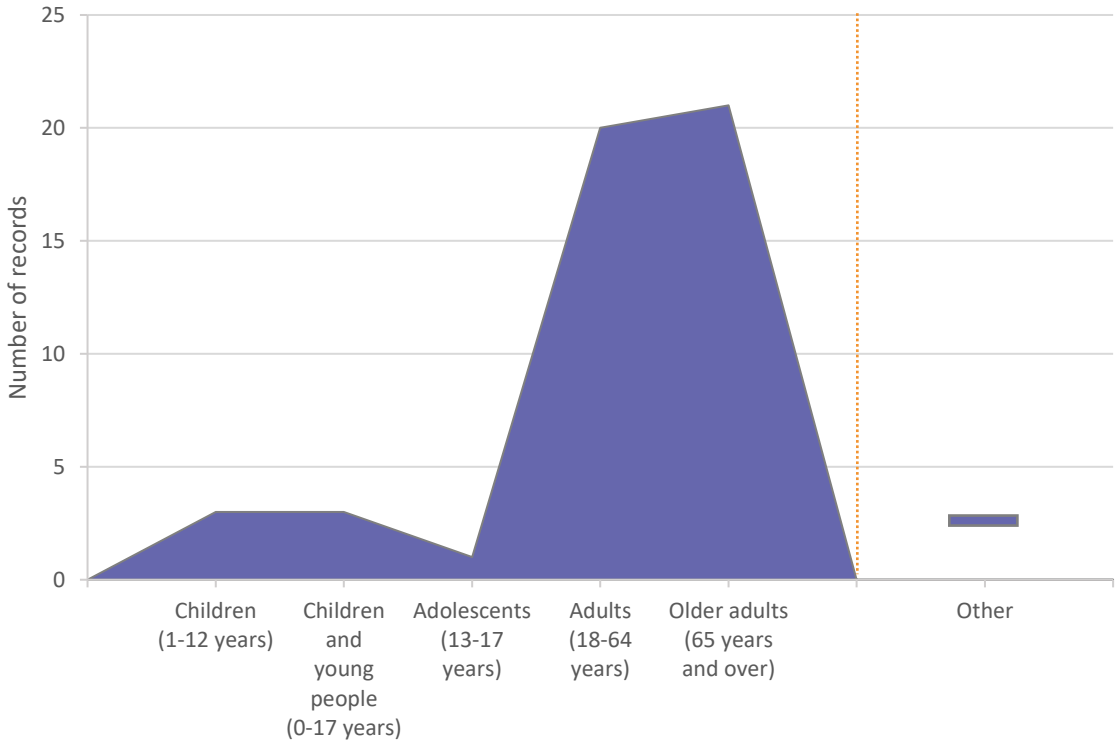


Figure 9. Number of technologies identified for each target population

Type of wearable and implantable devices

The most common type of wearable was a watch. The type of wearable was reported in the abstract by 66/119 records (55.5%), while 53 records did not specify the type of wearable being studied (Figure 10Figure 9). No records describing implantable devices were identified.

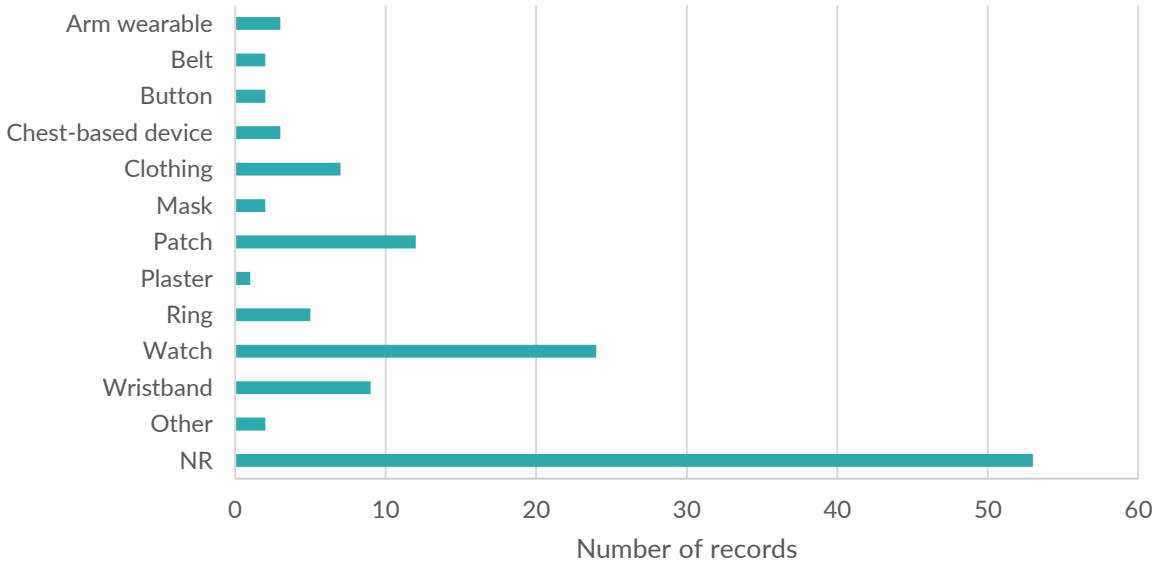


Figure 10 Types of wearable devices reported by included bibliographic records

Vital signs monitored

Of all the included records, the most common vital signs stated to be recorded by a wearable were heart rate (64/119, 53.8%) and respiratory rate/activity (40/119, 33.6%) (Figure 11).

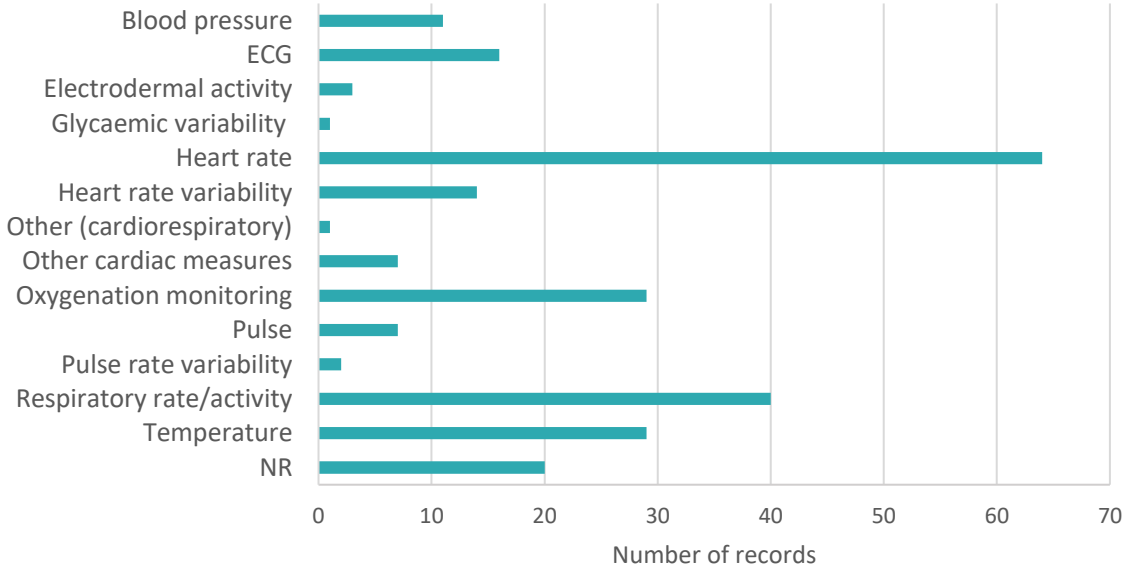


Figure 11 Vital signs reported by included bibliographic records

AI

The number of records that stated to implement AI was 14/119 (11.8%) Three of these records focused on more than three conditions, followed by respiratory conditions (3), cardiovascular conditions (2), blood and immune system conditions (2), and other disease

areas (4) (Figure 12). Across the 14 devices identified, machine learning algorithms were used to enable identification and analysis of patient activities and vital signs to predict physical and psychological function and decline. These devices were proposed to enable scalable remote monitoring systems that can assist physicians to intervene more promptly and make more informed treatment decisions. Furthermore, several wearable devices with AI enabled digital coaches were described, with the potential to help delay the onset or worsening of chronic diseases and promote a healthy lifestyle.

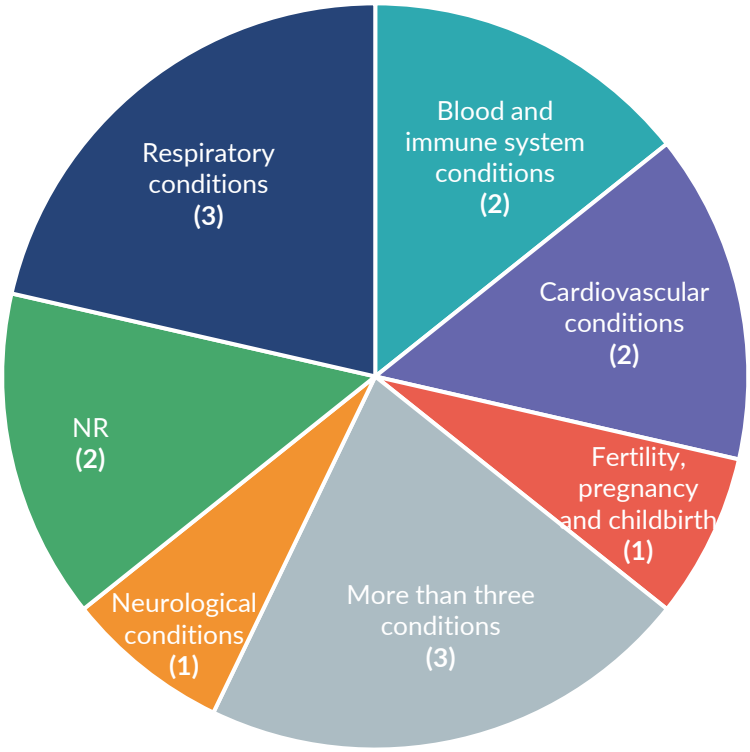


Figure 12 Disease areas of the bibliographic records that implemented AI

Named devices

The brand name of the device under development was reported in the abstract by 50/119 records (42%) (see Appendix B: Table 6). There were 35 consumer devices, of which the most common were Fitbit (15/35) and Apple Watch (7/35) (Figure 13). There were 27 other, named, non-consumer technologies. Four of these are FDA approved; two of these are still being tested in different indications. Two of these are CE-certified and two approved by the MHRA. The remaining were either not approved, or not enough information could be found to make a decision on whether they were.

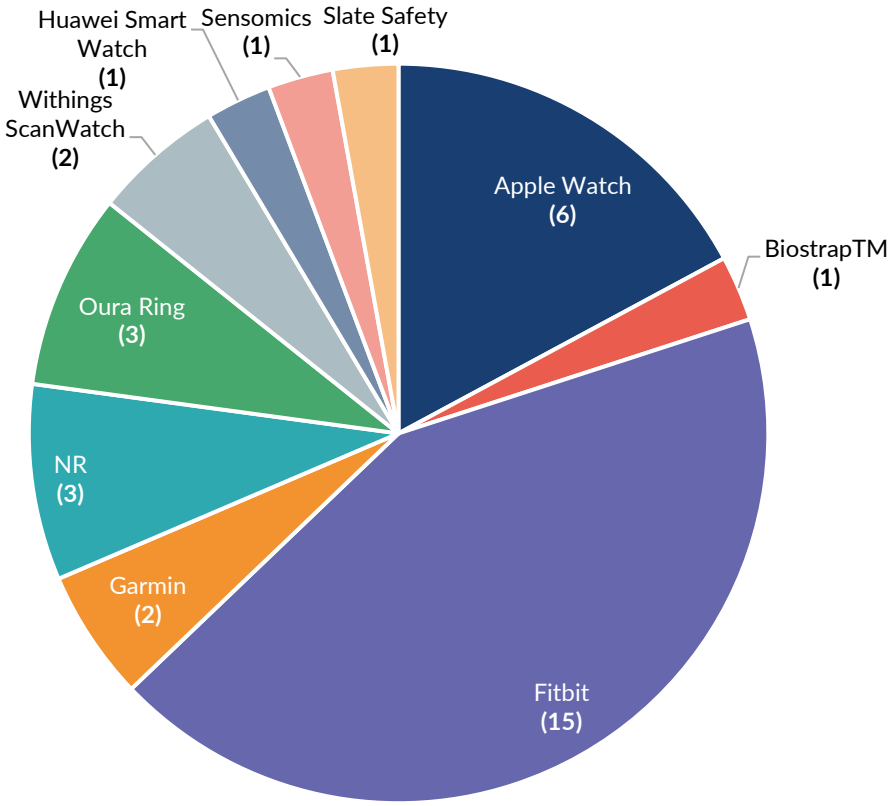


Figure 13 Names of wearable consumer devices used for remote monitoring of vital signs

The consumer devices found mainly focused on the cardiovascular conditions area (11) (Figure 14). Unlike other consumer devices, Fitbit devices were used in respiratory conditions (4) and neurological conditions (2) areas.

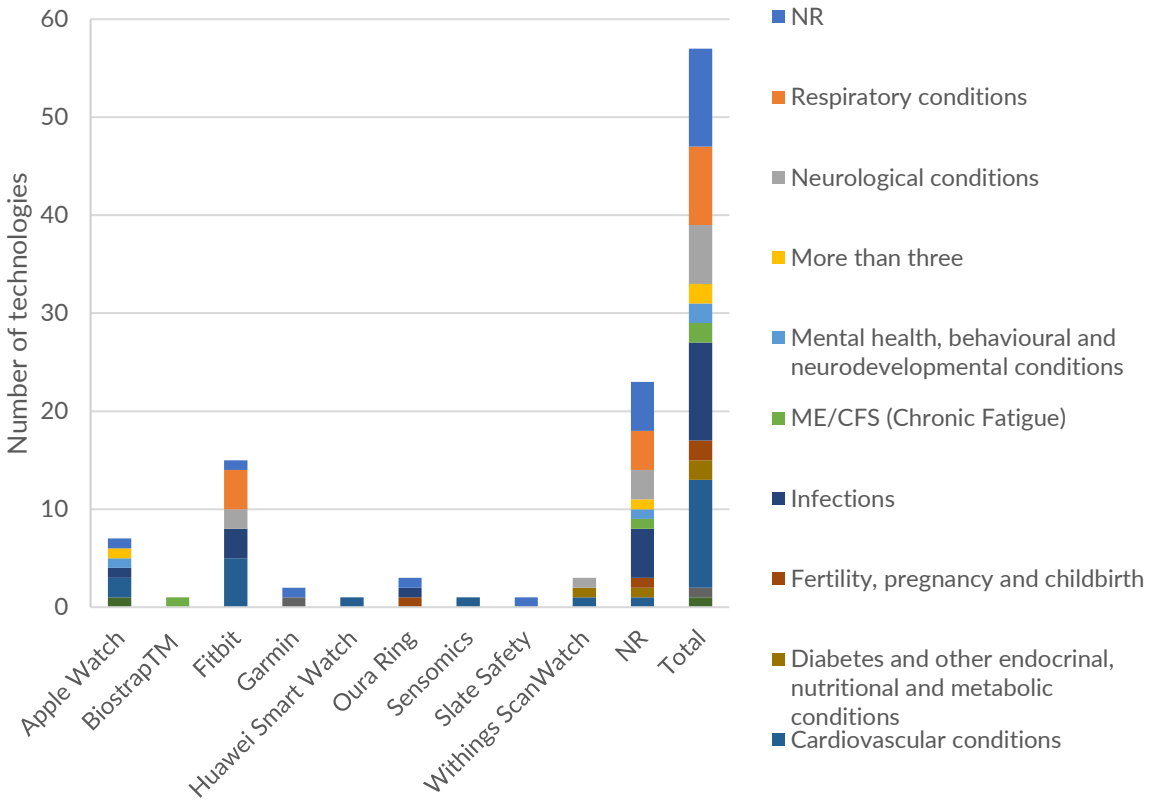


Figure 14 The disease areas of the consumer devices used for remote monitoring of vital signs

The most common developer country was the US (33), with only two named devices being developed in the UK. The developer locations of named wearable devices (47/119 records) identified in bibliographic abstracts are displayed in Figure 15.

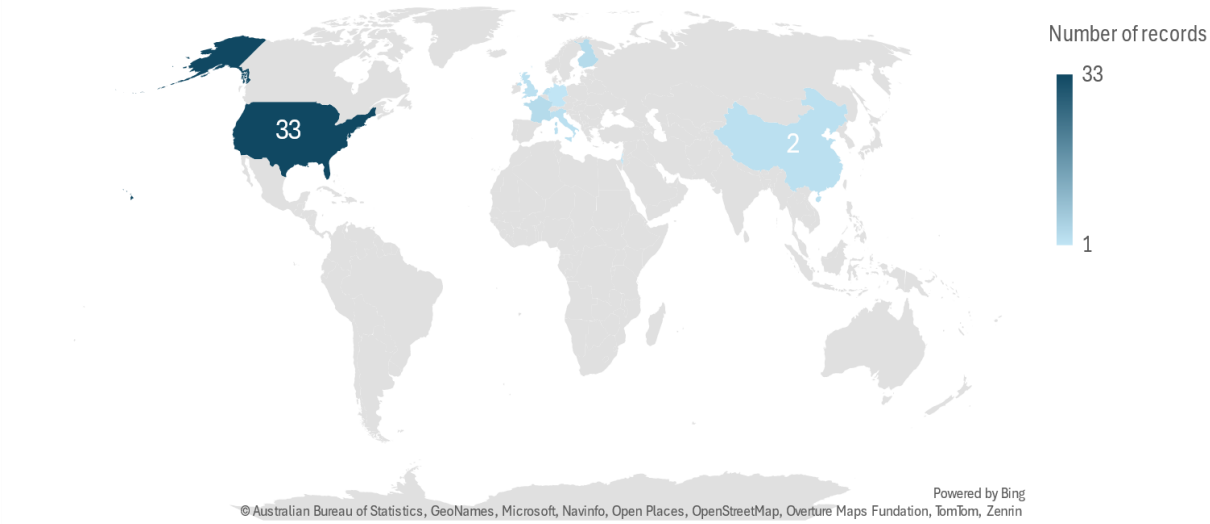


Figure 15. Developer locations of named wearable devices identified in bibliographic records

Technology readiness levels

Within the 119 records identified, 91 technologies were assigned an individual TRL (Figure 16). The consumer device label was given to 35 technologies that were a commercially available general-purpose wearable, such as a Fitbit or Apple Watch, not regulated as a medical device, but used within the study for health-related purposes. Therefore, these were not assigned a TRL. Most of the technologies were found to be in TRL 6 (48/91, 52.7%), with only 31.9% (29/91) in earlier stages of development (TRL 2-5), and 8.8% (8/91) in or passed the regulatory stages (TRL 8-9).

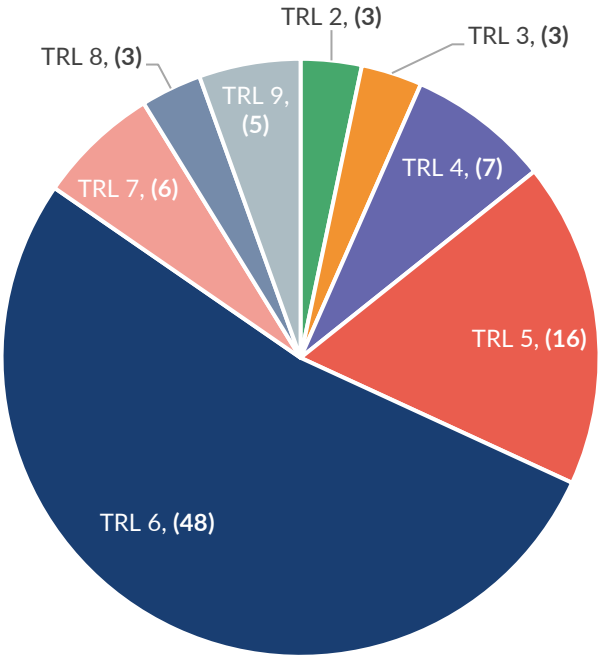


Figure 16 TRLs of technologies (n = 97)

Technologies in earlier stages of development (TRL 2-5), were mostly reported without a disease area (Figure 17). The seven technologies in later stages of development (TRL 8-9) were in the disease areas of cancer, respiratory conditions, cardiovascular conditions, diabetes and other endocrinal, nutritional and metabolic conditions, digestive tract conditions, or not reported.

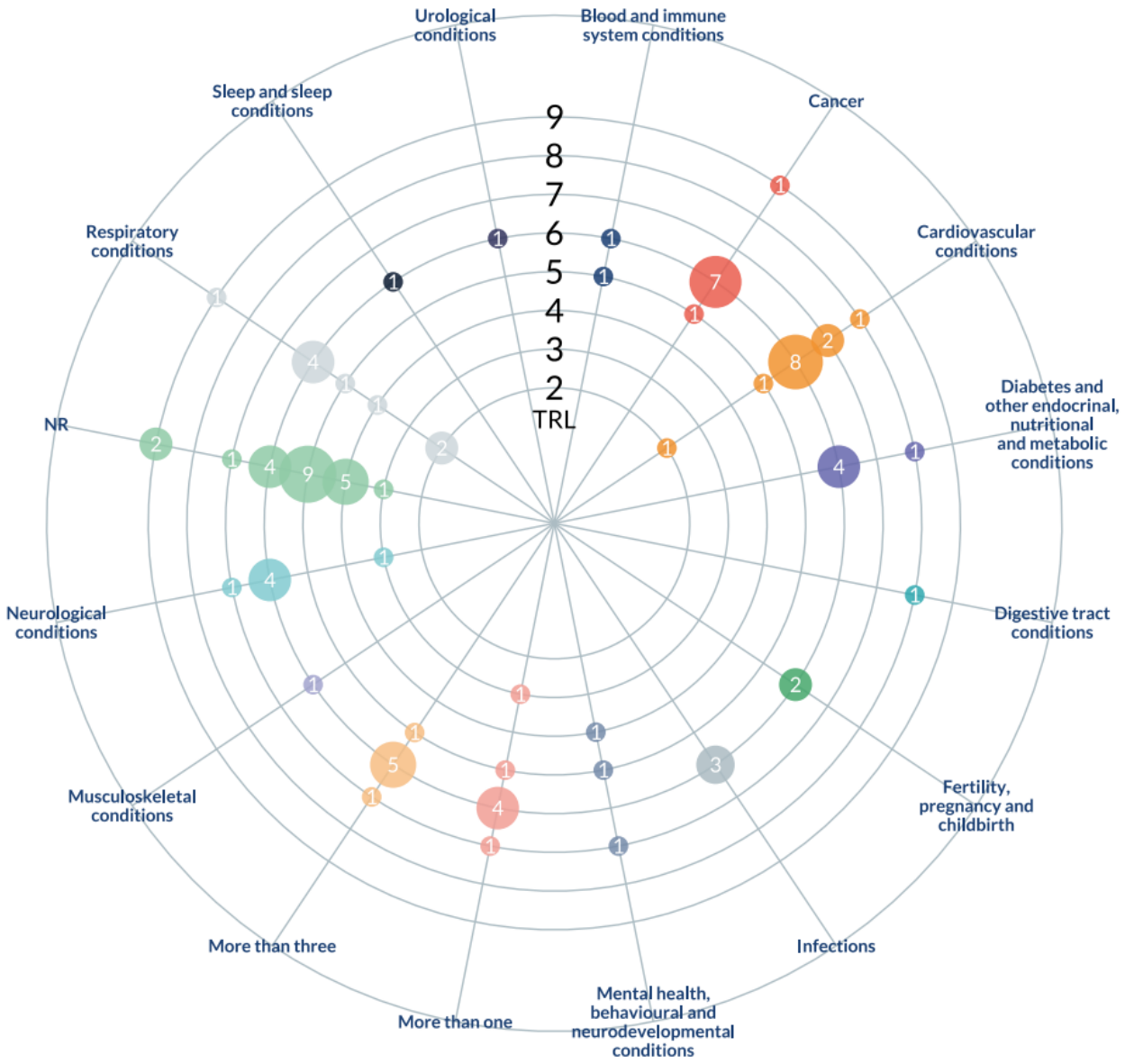


Figure 17 Technology radar to represent technologies by disease area

Abbreviations: NR, not reported

The eight types of wearables in later stages of development (TRL 8-9) were a button, a patch, a wristband, a watch, or not reported (Figure 18).

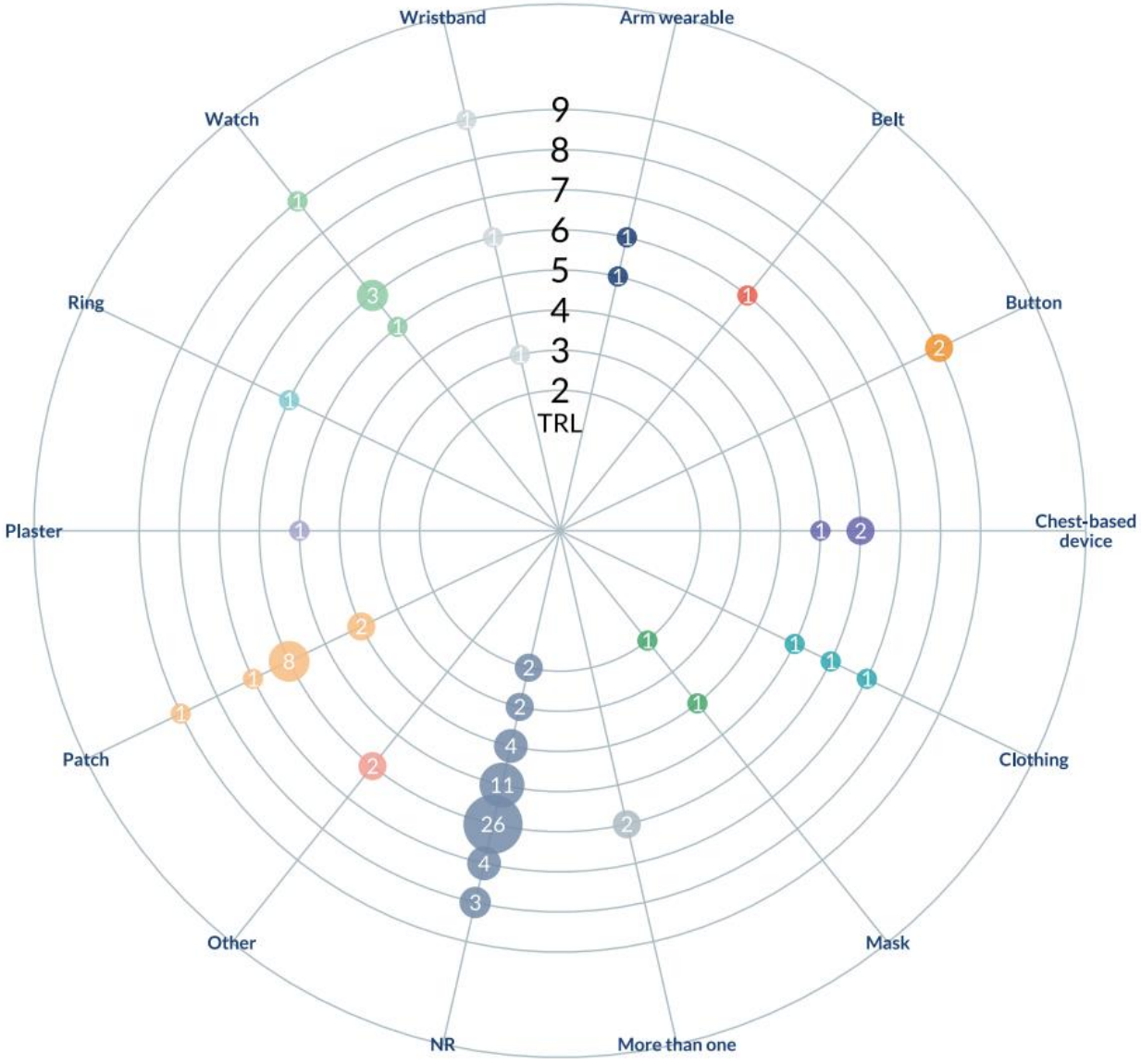


Figure 18 Technology radar to represent technologies by wearable type

Abbreviations: NR, not reported

Intended purpose or outcome

Most records focused on management (113/119, 95%), with eight, six and one also targeting treatment, diagnosis, and prevention, respectively (Figure 19). Only six records did not focus on management, with five aimed solely at diagnosis and one at prevention.

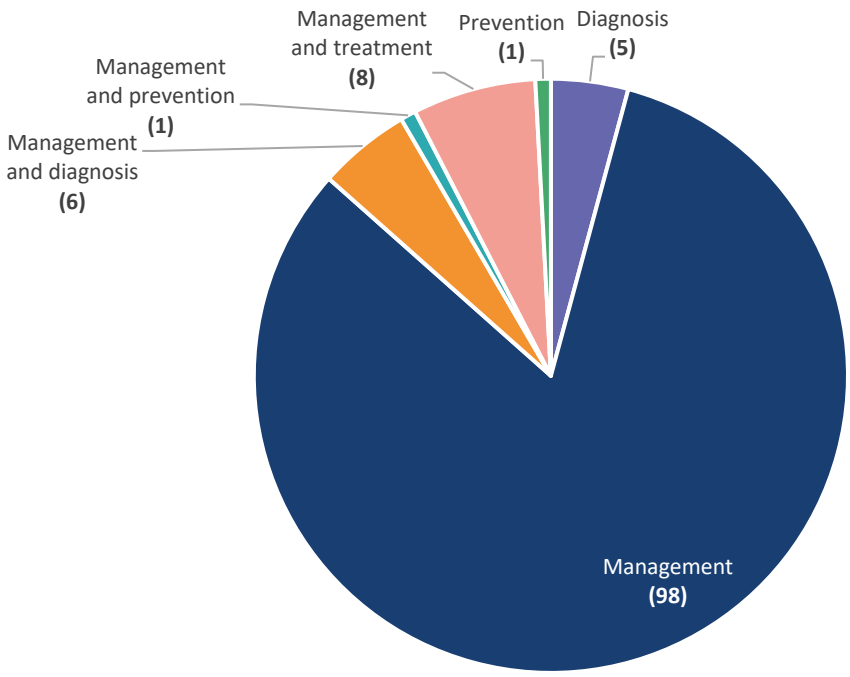


Figure 19 Intended purpose of wearable technologies per bibliographic record

Reporting of missing data

Any information that was either not stated in the information retrieved from searches, or was unretrievable from the product website, was stated to be not reported and included in the analysis.

Risk of bias and quality of evidence

The risk of bias and quality of evidence was not performed due to the lack of supporting information for each record retrieved to enable a clear and justifiable judgment to be made.

Implications and Recommendations

During this horizon scan for wearable technologies for remote monitoring of vital signs in the MedTech development pathway, 208 records were identified, including patents, funding projects, clinical trials and bibliographic records. Collectively, these included records described the global development of wearable technologies in the emerging, transitional and imminent horizons, which can help provide a more forward-looking and greater understanding of the innovation trajectories in this specific field of MedTech.

Most of the records identified were sourced from bibliographic databases and patent registries; a third of records describing technologies within the emerging horizon, indicates this field of MedTech is still expanding and being explored by developers. Given that clinical trials often demand substantial funding and institutional support — and considering that many of the identified wearables are consumable devices — the accessibility and motivation to pursue

formal clinical validation may be constrained. Furthermore, the lack of records related to funded projects supporting the development of wearable technologies also suggests a broader gap in financial and infrastructural support for developers in this space. Additionally, while some technologies in the latter stages of development were clearly identified as being marketed as consumer or medical devices, the regulatory pathway for some technologies was unclear.

Across the emerging horizon, China, India and the USA were the top three countries where patent applications were filed or grated. The most frequently stated classification associated with included patents pertained to inventions measuring physiological parameters, with cardiovascular measuring capabilities being a common theme. As the NHS 10-year plan sets out cardiovascular disease as one the top clinical priorities, alongside mental health, frailty and dementia,[1] the appropriate support and development of such technologies may contribute to helping to remotely monitor this target patient population and those at risk. Additionally, one funding project described the development of wearables patches for detection of heart attacks. However, no patents or funding projects were identified in the UK, which may indicate such early-stage development is being initiated in populations and healthcare systems not translatable or transportable to the UK. Furthermore, the low number of funding projects aimed at the development of wearables may indicate a lack of funding support available in this field across Europe. However, as this was the only data source for funding searched, future horizon scans should consider including other databases including those covering a wider geographical scope.

Across the transitional and imminent horizon (clinical trial registries and bibliographic records), the most common applications in terms of vital signs were remote monitoring of heart rate and respiratory rate or activity, these being valuable measurements for detecting clinical deterioration. The most commonly identified type of wearable device identified was a watch, likely due to its widespread acceptance and practical design for non-invasive monitoring of vital signs. While less frequent examples included belts, masks, and clothing. In line with some of the priority topics highlighted by NICE[40] and the UK Government,[1] the most common disease areas for application were cancer, cardiovascular disease and respiratory conditions. Although there were some signs of development of wearable technologies within neurological, mental health and musculoskeletal conditions, promoting development of wearables in these areas might be considered useful to support unmet needs in other top priority areas. Furthermore, the dominance of US sponsors may skew innovation towards US-based priorities and patient populations and highlights the needs to incentivise domestic sponsorship.

Most technologies were studied in adults and the majority were focused on the management of a disease or condition. Due to a range of ethical, physiological and logistical challenges, such as obtaining informed consent, and designing clinical trials that are tailor to children's developmental and physical needs, that lack of studies in infants, children and adolescents is unsurprising. However, it is important that the population medical devices are validated in are transparently reported and appropriately considered, ensuring that data drawn from adult populations is not inappropriately generalised to younger populations. Furthermore, fewer devices being aimed at treatment, diagnosis or prevention, may indicate there are missed

opportunities for early detection and intervention measures. This may reflect challenges to pursuing diagnostic or therapeutic validity and as such may limit their clinical impact.

In terms of maturity, most technologies were at mid-stage TRLs, with more than half of the non-consumer devices at TRL 6, indicating most technologies identified have had been tested in an operational environment regarding their clinical effectiveness and safety. This highlights a bottleneck of technologies which have not been proven in real-world healthcare settings. Advancing technologies into this latter stage can require significant technical and financial investment and suggests a need for targeted support to help developers to meet regulatory and reimbursement standards, for successful adoption and acceptance of wearable medical devices into healthcare.

Technologies in earlier stages of development (TRL 2-5), were mostly reported without a disease area, which is expected as newer technologies may not yet have defined or tested applications. Just over half of the named wearable devices in this horizon scan were identified as consumer devices, the remaining either being classified as medical devices by the MHRA or FDA, or with an unknown status. Developers of these named devices were most commonly located in the US, with only two devices being developed in the UK. Additionally, only a couple of clinical trials were identified to have UK sponsors. Taken together, this may further implicate evidence generation is occurring in populations and healthcare systems irrelevant to the health technology appraisal process in the UK. Additionally, the large majority of wearables marketed as consumer devices, may highlight further the growing rate of such devices being used in healthcare. This raises important questions about the clinical validity and reliability of such devices in medical contexts.

In alignment with fast evolving MedTech and healthcare priorities, the UK Government announced the Software and AI As A Medical Change Programme in 2022 to ensure regulatory requirements for these integral components was clear to manufacturers and that the public and patients are protected.[29] Surprisingly, only a relatively small proportion of technologies captured across funding, clinical trials and bibliographic records reported the use of AI. It is essential that developers are made aware of their responsibility to ensure transparent reporting and clear ownership of AI usage in the research and development of wearable medical devices. Despite nearly 90% of bibliographic records did not explicitly reference AI in their titles or abstracts, it may be reasonable to infer that a significant proportion of these studies involve AI-enabled functionalities within the wearable devices themselves. This reflects a broader trend in digital health research including wearable devices, where AI is increasingly embedded in device architecture enabling activity recognition, vital sign analysis, predictive modelling, and personalized feedback.[40] Thus while the integration of AI may not be the primary focus or explicitly acknowledged in bibliometric analyses reported here, it is increasingly becoming a foundational component in wearable devices, potentially leading to an underestimation of its true adoption within this field. Furthermore, patents identified in this horizon scan were commonly assigned to the subclass covers cross-sectional aspects of computer, information or communication science with medical or healthcare science, and includes technologies such as

electronic health records, telemedicine, AI-driven diagnostics, and wearable monitoring devices.

In the NHS 10-year plan, remote monitoring in peoples' homes away from healthcare setting is a key theme. As such, the plan presented a case study from South Korea's National Smart hospital which has rolled out "smart hospital models" that include the use of remote monitoring tools.[41] The smart hospitals are reported to reduce stress amongst staff, improve patient satisfaction and overall delivery of healthcare. It will therefore be imperative that wearable devices with remote monitoring applications can be adapted if needed and implemented effectively into the UK healthcare system. In alignment, NICE have recently published the NICE HealthTech programme manual to help guide the methods and processes required for evaluation of HealthTech products.[30] Additionally, within the first 3 years of the 10-year NHS plan expansion of hospital at home programmes and of NICE digital programmes for consideration of medical-grade wearables have been proposed.[1]

Some healthcare practitioners believe that remote patient monitoring will add to their workload as the volume of data collected would necessitate a time-consuming process to determine what information is essential and what is unnecessary.[33] In addition, the patient's electronic medical records do not always incorporate the collected data, especially because data normalisation is challenging and complex due to manufacturers' diversity. Even with planned development to improve the device's interoperability, it remains challenging to link the data to the patient's actual electronic medical records, as systems do not grant third-party developers access to patients' data for security reasons.[33,2] Furthermore, challenges ahead may include rapidly changing technology trends and consumer preferences.[2] Ensuring that patients are engaged with early on in development may help with implementation and acceptability of devices.

Limitations of the data and horizon scanning processes used

Owing to the resources available and time constraints, full texts were not retrieved for bibliographic records. Subsequently, this limited the retrieval of all potentially relevant and supporting information, as well as the capacity to assess risk of bias and certainty of evidence. Furthermore, while information for named technologies was retrieved from developer websites, when possible, required information was not always accessible or clearly reported. As a result, this may limit the accuracy, transparency and depth of the derived results and conclusions stated here. Furthermore, the horizon scan is restricted to a defined number of data sets and does not include soft intelligence sources. Additionally, judgement of TRLs were based on information retrieved and available during the project, which may therefore be subject to bias. Although implantable devices, in certain contexts, can be found integrated alongside wearable devices, during this horizon scan no implantable devices were identified. This is likely due to the search strategy not specifying "implantable" within the search terms used and therefore future scans should develop a strategy focused on these devices. Lastly, in this horizon scan a semi-automated approach was used for screening and data extraction. While the process involved significant human input to ensure quality assurance, it contributed to the validation of using a LLM in horizon scanning methods.

Conclusion

This horizon scan highlights the rapid growth and transformative potential of wearable technologies in healthcare, particularly for remote monitoring of vital signs. While advancements in data science, electronics, and AI have driven innovation, challenges remain in accessibility, regulatory clarity, and clinical validation. The findings underscore the need for transparent reporting, robust regulatory frameworks, and targeted support for early-stage development to ensure the safe and effective integration of wearables into healthcare systems. Addressing these gaps will be critical to realising the full potential of wearable devices in improving patient outcomes and reducing healthcare burdens.

Other information

Registration and protocol

Not applicable.

Competing interests

None.

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Appendix A: Searches

Bibliographic databases

Embase <1974 to 2025 March 17

#	Query	Hits
1	exp wearable device/	21056
2	(wearable adj (technologi* or devic*)).ti,ab,kw.	9481
3	wearable*.ti,ab,kw.	38725
4	(smart adj (device* or glasses or watch* or finger* or jewellery or belt* or ring* or sock* or shoe* or bracelet*)).ti,ab,kw.	2724
5	"IOT".ti,ab,kw.	7444
6	(IOT adj2 device*).ti,ab,kw.	1491
7	or/1-6	56830
8	Remote sensing/	19066
9	Telemetry/	22592
10	(monitor* adj2 (wearable* or remote or digit* or home or tele*)).ti,ab,kw.	25435
11	((remote or mobile or digital*) adj (health* or care or sens*)).ti,ab,kw.	36070
12	(mhealth or m-health).ti,ab,kw.	11602
13	or/8-12	92448
14	vital sign/	38646
15	((cardi* or pulse or temperature* or respir*) adj2 (variab* or monitor*)).ti,ab,kw.	50960
16	(heart adj2 (rate or beat* or monitor* or rhythm* or variab*)).ti,ab,kw.	285685
17	or/14-16	363196
18	Chronic disease/	215463
19	(chronic disease adj2 (monitor* or manag*)).ti,ab,kw.	6966
20	((chronic or long-lasting or long lasting or noncommunicable) adj (diseas* or condition* or ailment* or illness* or disorder*)).ti,ab,kw.	201612
21	or/18-20	339238
22	exp Rehabilitation/	534179
23	rehab*.ti,ab,kw.	342040
24	or/22-23	719462
25	7 and 13 and 17	1394
26	7 and 21	1194
27	7 and 24	5364
28	(systematic review or review).pt.	3329725
29	(editorial or letter).pt.	2181486
30	28 or 29	5511211
31	25 not 30	1231
32	26 not 30	941
33	27 not 30	4652

34	limit 31 to (human and yr="2022 - current")	560
35	limit 32 to (human and yr="2022 - current")	384
36	limit 33 to (human and yr="2022 - current")	2014

IEEEXplore

#	String	Hits
1	("Index Terms":wearable device) OR ("All Metadata":wearable NEAR/2 (technology or device)) OR ("All Metadata":smart NEAR/2 device)	44720
2	("Index Terms":remote sensing) OR ("Index Terms":telemetry) OR ("All Metadata":monitor adj2 (wearable or remote or digit or home or tele))	69605
3	("Index Terms":vital signs) OR ("All Metadata":cardio NEAR/2 (variable or monitor)) OR ("All Metadata":pulse NEAR/2 (variable or monitor)) OR ("All Metadata":temperature NEAR/2 (variable or monitor))	6726
4	((((Index Terms:wearable device) OR (All Metadata:wearable NEAR/2 (technology or device)) OR (All Metadata:smart NEAR/2 device))) AND ((Index Terms:remote sensing) OR (Index Terms:telemetry) OR (All Metadata:monitor adj2 (wearable or remote or digit or home or tele)))) AND ((Index Terms:vital sign) OR (All Metadata:cardio NEAR/2 (variable or monitor)) OR (All Metadata:pulse NEAR/2 (variable or monitor)) OR (All Metadata:temperature NEAR/2 (variable or monitor))) You Refined By: Year: 2022-2025	8
	Filter Applied: 2022 - 2025	8
5	("Index Terms":chronic disease) OR ("All Metadata":chronic disease NEAR/2 (monitor* or manag*)) OR ("All Metadata":chronic NEAR/2 (disease or condition or ailment or illness or disorder))	5682
6	(((Index Terms:chronic disease) OR (All Metadata:chronic disease NEAR/2 (monitor* or manag*)) OR (All Metadata:chronic NEAR/2 (disease or condition or ailment or illness or disorder)))) AND ((Index Terms:wearable device) OR (All Metadata:wearable NEAR/2 (technology or device)) OR (All Metadata:smart NEAR/2 device))	346
8	Filter Applied 2022 - 2025	137
9	("Index Terms":rehabilitation) OR ("All Metadata":rehab)	14521
10	(((Index Terms:rehabilitation) OR (All Metadata:rehab))) AND ((Index Terms:wearable device) OR (All Metadata:wearable NEAR/2 (technology or device)) OR (All Metadata:smart NEAR/2 device))	904
11	Filter Applied 2022 - 2025	295

The International Network of Agencies for Health Technology Assessment (INAHTA)

Line	Query	Hits
21	#18 AND #14	1
20	#17 AND #14	1
19	#16 AND #15 AND #14	0
18	#13 OR #12	399

17	#11 OR #10 OR #9	956
16	#8 OR #7	22
15	#6 OR #5 OR #4	67
14	#3 OR #2 OR #1	8
13	rehabilitation	368
12	(rehabilitation)[mh]	167
11	(chronic AND (disease or condition or ailment or illness or disorder))	762
10	(chronic disease AND (monitor OR manage))	32
9	(chronic disease)[mh]	393
8	(cardio or pulse or temperature) AND (variability OR monitoring)	18
7	(vital signs)[mh]	5
6	(remote AND (sensing OR monitoring))	53
5	(telemetry)[mh]	19
4	(remote sensing)[mh]	11
3	((wearable AND (device or technology)))[abs]	7
2	(wearable AND (device or technology))Title]	2
1	wearable device[mh]	1

Clinical trials registries

Clinicaltrials.gov

((wearables OR "wearable device" OR "wearable technology" OR "smart device") AND ("remote monitor" OR telemonitor OR "home monitor" OR e-health OR "mobile health" OR m-health OR mhealth OR "digital health") AND (cardio OR cardiac OR "heart rate" OR "heart beat" OR "heart rhythm" OR temperature OR pulse OR respiratory OR "respiratory rate" OR breathing OR "breathing rate"))

(wearables OR "wearable device" OR "wearable technology" OR "smart device" OR "digital device") AND ("chronic disease" OR "chronic disorder" OR "longstanding disease" OR "longstanding disorder" OR "longstanding illness")

(wearables OR "wearable device" OR "wearable technology" OR "smart device" OR "digital device") AND (rehabilitation OR rehabilitate)

Field searched: Other terms

ICTRP

((wearables OR "wearable device" OR "wearable technology" OR "smart device") AND ("remote monitor" OR telemonitor OR "home monitor" OR e-health OR "mobile health" OR m-health OR mhealth OR "digital health") AND (cardio OR cardiac OR "heart rate" OR "heart beat" OR "heart rhythm" OR temperature OR pulse OR respiratory OR "respiratory rate" OR breathing OR "breathing rate"))

(wearables OR "wearable device" OR "wearable technology" OR "smart device" OR "digital device") AND ("chronic disease" OR "chronic disorder" OR "longstanding disease" OR "longstanding disorder" OR "longstanding illness")

(wearables OR "wearable device" OR "wearable technology" OR "smart device" OR "digital device") AND (rehabilitation OR rehabilitate)

Funding

CORDIS

(remote monitor AND wearable AND vital sign) startDate=2022-01-01

(wearable AND chronic disease management) startDate=2022-01-01

(wearable AND rehabilitation) startDate=2022-01-01

Patents

Patentscope (WIPO) (1975 – current)

(EN_TI:(wearable OR "smart device" or "smart watch" or (wearable NEAR ring* or device)) OR EN_AB:(wearable* OR "smart device" or "smart watch" or (wearable NEAR ring* or device))) AND (EN_TI:(vital NEAR sign* OR (cardi* or pulse or temperature or respir*)) OR EN_AB:(vital NEAR sign* OR (cardi* or pulse or temperature or respir*))) AND DP:[01.01.2022 TO 31.03.2025]*

(EN_TI:(wearable OR "smart device" or "smart watch" or (wearable NEAR ring* or device)) OR EN_AB:(wearable* OR "smart device" or "smart watch" or (wearable NEAR ring* or device))) AND (EN_TI:(chronic NEAR (diseas* or condition* or illness* or ailment*)) OR EN_AB:(chronic NEAR (diseas* or condition* or illness* or ailment*))) AND DP:[01.01.2022 TO 31.03.2025]*

(EN_TI:(wearable OR "smart device" or "smart watch" or (wearable NEAR ring* or device)) OR EN_AB:(wearable* OR "smart device" or "smart watch" or (wearable NEAR ring* or device))) AND (EN_TI:(Rehab*) OR EN_AB:(Rehab*)) AND DP:([01.01.2022 TO 31.03.2025])*

Espacenet

ta all "wearable" AND ta all "remote monitoring" AND ta all "vital signs"

ta all "wearable" AND ta all "chronic disease"*

ta all "wearable device" AND ta all "rehab*"*

Appendix B: Patents and named technologies

Table 5 All International Patent Classification (IPC) symbols from included patent records and their count

IPC symbols	Count	IPC symbols	Count	IPC symbols	Count
A41D 13/12	1	A61G	1	G16H 10/60	6
A41D 27/00	1	A61G 10/02	1	G16H 10/65	2
A41D 27/20	1	A61H 9/00	1	G16H 15/00	3
A42B 3/04	1	A61J 1/00	1	G16H 20/10	1
A44C 5/00	1	A61J 7/04	1	G16H 20/13	1
A44C 5/02	1	A61M	1	G16H 20/30	1
A61B	3	C12M	1	G16H 40/20	2
A61B	8	G01C 21/00	1	G16H 40/60	2
A61B 3/10	1	G01K 1/024	1	G16H 40/63	1
A61B 5/00	42	G01K 13/20	1	G16H 40/67	9
A61B 5/01	5	G01P 15/00	1	G16H 50/00	1
A61B 5/02	1	G06F	1	G16H 50/20	3
A61B 5/0205	27	G06F 16/174	1	G16H 50/30	9
A61B 5/021	6	G06F 16/25	1	G16H 50/50	1
A61B 5/022	1	G06F 18/213	1	G16H 50/70	1
A61B 5/024	12	G06F 18/241	3	G16H 50/80	1
A61B 5/053	1	G06F 18/25	2	G16H 80/00	6
A61B 5/08	5	G06F 21/44	1	G16Y 10/60	1
A61B 5/11	10	G06F 21/62	2	G16Y 20/10	1
A61B 5/113	1	G06K 7/14	1	G16Y 20/40	1
A61B 5/117	2	G06N 3/045	1	G16Y 40/10	1
A61B 5/145	14	G06N 3/0464	1	G16Y 40/20	1
A61B 5/1455	3	G06N 5/022	1	G16Y 40/50	1
A61B 5/256	1	G06Q	2	H04L	1
A61B 5/265	1	G06Q 10/0631	1	H04L 67/12	1
A61B 5/268	1	G06Q 30/00	1	H04N	1
A61B 5/27	1	G06Q 50/26	1	H04W	2

A61B 5/28	1	G07C 9/00	1	H04W 4/02	3
A61B 5/282	1	G08B 15/00	1	H04W 4/029	4
A61B 5/291	1	G08B 21/02	5	H04W 4/18	1
A61B 5/296	1	G08B 21/04	2	H04W 4/20	1
A61B 5/318	3	G08B 21/24	1	H04W 4/38	3
A61B 5/33	2	G08B 25/01	2	H04W 4/80	5
A61B 5/332	2	G08B 25/04	1	H04W 4/90	3
A61B 5/363	1	G08B 25/08	1	H04W 84/06	1
A61B 5/369	2	G08B 29/18	1	H04W 84/12	1
A61B 5/384	1	G08C 17/02	1	H04W 84/18	2
A61B 90/90	1	G16H	5	H05K	1

Table 6 Technology brands and/or names, whether they have been approved as medical devices, and who by, or if they are consumer devices. Those highlighted in blue have been approved but are being tested in a different indication.

Device brand and/or name	Count	Approved?
Apple Watch	6	Consumer device
Apple Watch 7	1	Consumer device
Aventusoft LLC Hemotag	1	No
Biobeat	1	Not enough information
BioIntelliSense BioButton	2	FDA
BiostrapTM	1	Consumer device
Bora band	1	CE-certified/EU
Current Health Inc.	1	Not enough information
DEXCOM G6	1	MHRA
EmbracePlus	1	FDA
Empatica E4	1	Discontinued
Ethera	1	Not enough information
Fitbit	5	Consumer device
Fitbit Charge 2	1	Consumer device
FitBit Charge 2 device	1	Consumer device
Fitbit Charge 3	1	Consumer device
Fitbit Charge HR	1	Consumer device
Fitbit Inspire 2	1	Consumer device
Fitbit Inspire 3	1	Consumer device
Fitbit Inspire HR	1	Consumer device

Fitbit Sense	1	Consumer device
Fitbit Versa 2	2	Consumer device
FlexNIRS	1	No
Freestyle Libre	1	MHRA
Garmin	1	Consumer device
Garmin Fenix 6 Pro	1	Consumer device
Huawei smart watch	1	Consumer device
INSPIRA	1	Not enough information
Leo	2	Not enough information
OMNI	1	Not enough information
Oura Ring	2	Consumer device
Oura ring Gen 2	1	Consumer device
Philips Biosensor	1	Not enough information
Philips Healthdot	1	CE-certified/EU
PneumoWave Respmeter	1	Not approved
Respeck	1	Not enough information
Sensomics	1	Consumer device
Sibel Health ANNE Sleep	1	FDA
SISTINE 3.0	1	Not enough information
Slate Safety (SS) wearable physiological monitoring system	1	Consumer device
Spire RPM system	1	Not enough information
VitalConnect VitalPatch	1	FDA
VITAL-ECG	1	Not enough information
Withings ScanWatch	2	Consumer device
YouCare	1	Not enough information

Appendix C: Automation Methods (Screening)

Step 1: Results on prompt-development datasets

Data	Sensitivity	Precision	Manual inclusion rate
Bibliographic records	0.98	0.76	60%
Trial registry entries	1.00	0.87	74%
Patentscope	0.98	0.83	75%
Espace	1.00	0,96	95%
Funding	1.00	0.5	21%

Note: Prompts were refined iteratively, with the main focus on increasing sensitivity (to detect all relevant records). The biggest challenge during this step was condensing the broad inclusion and exclusion criteria of this horizon scan into a well-performing and concise prompt. The final prompt text is shown in the main report.

Step 2: Results on validation sets (all records predicted as included by the LLM + 10% randomly sampled excludes)

	Bibliographic records (N=2198)	Trial registry entries (N=192)
True Positives	1074	85
False Negatives	9	2
True Negatives	87	11
False Positives	1028	94

Evaluation scores based on actual screened data (including 10% randomly sampled excludes)

	Bibliographic records (N=2198)	Trial registry entries (N=192)
Sensitivity	0.99	0.97
Precision	0.51	0.47
Miss-rate in random sample	0.09	0.15

Extrapolated sensitivity scores across full dataset. Assuming randomly sampled excludes are representative of unscreened records, we multiplied the number of False Negatives by a factor of 10 to estimate sensitivity across the whole dataset.

	Bibliographic records	Trial registry entries (see final numbers below)
Sensitivity	0.92	0.81*

*These extrapolated numbers do not represent final results, since the full dataset was manually screened later

Step 3: Full screening results (if applicable)

For CORDIS and Patentscope, the random sample did not include any False Negative predictions by the LLM. However, due to the small number of total records in these datasets, we proceeded to assess them for eligibility. LLM performance on the fully screened datasets are shown below.

Full Screening	**CORDIS (N=187)**	**Trial registry entries (N=345)**
True Positives	55	88
False Negatives	3	4
True Negatives	108	132
False Positives	21	121

	CORDIS (N=187)	**Trial registry entries (N=345)**
Sensitivity	0.95	0.96
Precision	0.72	0.42

Note: the extrapolated sensitivity for trial registry entries was 0.81, while the final, actual sensitivity was much better at 0.96. While the initial random 10% sample of excluded records contained 2 false negatives, the fully-screened dataset with the remaining 90% of excluded articles only contained two further false negative records. This is likely due to chance, because the overall number of false negatives was low.

Appendix D: Automation Methods (Data Extraction)

Step 1: Evaluation of one-shot data extraction with Google gemini-2.5-flash and LangExtract

We define

- 'True Negatives' as instances where no information was available in the source text, and the LLM correctly extracted nothing
- 'True Positives' as instances where relevant information was available, and the LLM correctly extracted all information required to reproduce the human's extraction
- 'False Negatives' as instances where relevant information was available, but the LLM extracted none or only partially complete information
- 'False Positives' as instances where human reviewers did not extract relevant information, but the LLM extracted something

	Disease Area	Target Population	Brand name	Type of Wearable	Vitals monitored	Country
True Negative	3	0	10	0	1	18
True Positive	12	3	10	8	14	0
False Negative	1	0	0	0	1	0
False Positive	4	17	0	12	4	1
Sensitivity	**0.92**	**1.00**	**1.00**	**1.00**	**0.93**	**Not Applicable**
Precision	**0.75**	**0.15**	**1.00**	**0.40**	**0.78**	**0**

Discussion of incorrect predictions:

False negatives appeared in two extraction contexts. Once, the information extracted by the LLM was partially correct. In the second instance, information was implicit and the LLM failed to extract the correct source context.

False positives appeared more often. As the LLM was constrained to extracting verbatim, it could not hallucinate new information. In this research context, False positives were caused mostly by the LLM extracting unspecific information in cases where human reviewers made no extraction. For example, extracting 'patients' as Target Population where humans sought and were unable to find more detailed information about demographic variables such age.

We therefore decided to implement a semi-automated data extraction workflow, to expedite the process of identifying and checking data, while keeping human screeners in the loop to detect misclassifications. This process is described in more detail in Step 2.

In the following, we show the prompts used to implement data extraction.

This is the general instruction, to ground the LLM's extraction in source context

```
"Extract diseases, target patient populations, brand names, type of wearable device,
monitored vital signs in order of appearance.
Use exact text for extractions. Do not paraphrase or overlap entities.
Provide meaningful attributes for each entity to add context."
```

These are the definition of the variables for data extraction, with an example provided for context. This exact example was used as 'training' data for each record.

```
examples = [
    lx.data.ExampleData(
        text="Evaluation of physical health status beyond daily step count using a
wearable activity sensor. Physical health status defines an individual's ability to
perform normal activities of daily living and is usually assessed in clinical settings
by questionnaires and/or by validated tests, e.g. timed walk tests. These measurements
have relatively low information content and are usually limited in frequency. Wearable
sensors, such as activity monitors, enable remote measurement of parameters associated
with physical activity but have not been widely explored beyond measurement of daily
step count. Here we report on results from a cohort of 22 adult individuals with
Pulmonary Arterial Hypertension (PAH) who were provided with a Fitbit activity monitor
wristband (Fitbit Charge HR, United States) between two clinic visits (18.4 +/- 12.2
weeks). At each clinical visit, a maximum of 26 measurements were recorded (19
categorical and 7 continuous). From analysis of the minute-to-minute step rate and
heart rate we derive several metrics associated with physical activity and
cardiovascular function. These metrics are used to identify subgroups within the
cohort and to compare to clinical parameters. Several Fitbit metrics are strongly
correlated to continuous clinical parameters. Using a thresholding approach, we show
that many Fitbit metrics result in statistically significant differences in clinical
parameters between subgroups, including those associated with physical status,
cardiovascular function, pulmonary function, as well as biomarkers from blood tests.
These results highlight the fact that daily step count is only one of many metrics
that can be derived from activity monitors.Copyright &#xa9; 2022, The Author(s).",
        extractions=[
            lx.data.Extraction(extraction_class="disease", extraction_text="Pulmonary
Arterial Hypertension", description="The disease or health condition that affects the
patients described in the text", attributes={"disease_group": "Pulmonary Arterial
Hypertension"}),
            lx.data.Extraction(extraction_class="target patient population",
extraction_text="adult individuals", description="Description of the patients
including their age group and other demographic data", attributes={"disease_group":
"Pulmonary Arterial Hypertension"}),
            lx.data.Extraction(extraction_class="type of wearable device",
extraction_text="wristband", description="The wearable device used by the patients",
attributes={"device_group": "wristband"}),  # TID = three times a day
            lx.data.Extraction(extraction_class="monitored vital sign",
extraction_text="heart rate", description="A patient vital sign measured by the
wearable device", attributes={"device_group": "wristband"}),
            lx.data.Extraction(extraction_class="brand name",
extraction_text="Fitbit", description="The brand or company name that produced the
wearable device", attributes={"device_group": "wristband"}),
            lx.data.Extraction(extraction_class="country", extraction_text="United
States", description="The country where a device was produced, sold, or the
nationality of patients that used it."),

        ]
```

```
    )
]
```

Step 2: Semi-automated data extraction

This step included pre-extracting information into a spreadsheet and visualising data in source contexts to support their review.

For each included record, we pre-extracted relevant context for each data extraction variable into a spreadsheet, pre-ceding the extraction with '>>>> LLM:' to ensure that screeners are aware of automation content. Screeners were required to review the content and remove the LLM mark.

To expedite review, screeners were provided with colour-coded versions of the source texts. This enabled them to quickly access and comprehend LLM extractions.

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