



# Rising adoption of healthcare wearables in clinical study design

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## Introduction

Healthcare wearables are technology that can be worn and used to collect biological, physiological or behavioural patient data (1).

Common forms include watches, headbands, patches, straps, cuffs, and other monitoring sensors (2).

Patient data collected using wearables can be gathered in-clinic or in a real-world setting, allowing for the transition from single measurements at predefined timepoints to continuous streamed data (3).

As a result, there is increased interest by Pharma and MedTech manufacturers in the use of wearables to assess real-world outcomes, in addition to or as a replacement to traditional in-clinic measures (4).

## Methodology

An advanced search was conducted on the clinicaltrials.gov portal to identify all studies that were registered on the platform between 01/01/2000 and 31/05/2023.

A keyword search was applied to identify studies that included the term 'wearable' in the study details. No additional filters were applied.

Results were exported to an Excel database:

- **Study start date** was used to count the number of registered studies that included wearables to collect patient data in each year, between 2000 and 2022. 2023 was excluded since it had only partial data for the year
- **Interventions data** were used to count the application of wearables across different intervention types, including device, behavioural, drug, diagnostic test, procedure, dietary supplement, combination product, biological, genetic, and other interventions
- **Condition data** were used to analyse the disease, disorder, injury, health issue or health risk that was being studied. Studies were assigned to categories including cardiology, neurology, health and wellbeing, musculoskeletal, mental health, oncology, and other conditions
- **Primary outcome data** were used to understand the type of data that was being collected using wearable technology. Firstly, the primary outcomes were reviewed to determine if they were collected using a wearable or not. Endpoints collected via a wearable were assigned to one of the following categories – mortality, morbidity event, clinical status, symptom, function, health-related quality of life (HRQoL) or healthcare resource use. An additional non-clinical category was created for studies that assessed the validity, reliability, or performance of the wearable. Analysis was conducted on trial data from the year 2022, as it represents the most recent complete dataset for a single annual year

## Objectives

This study assessed the maturity of the field of healthcare wearable application to clinical study design. The aim was to answer the following four questions about clinical study design:

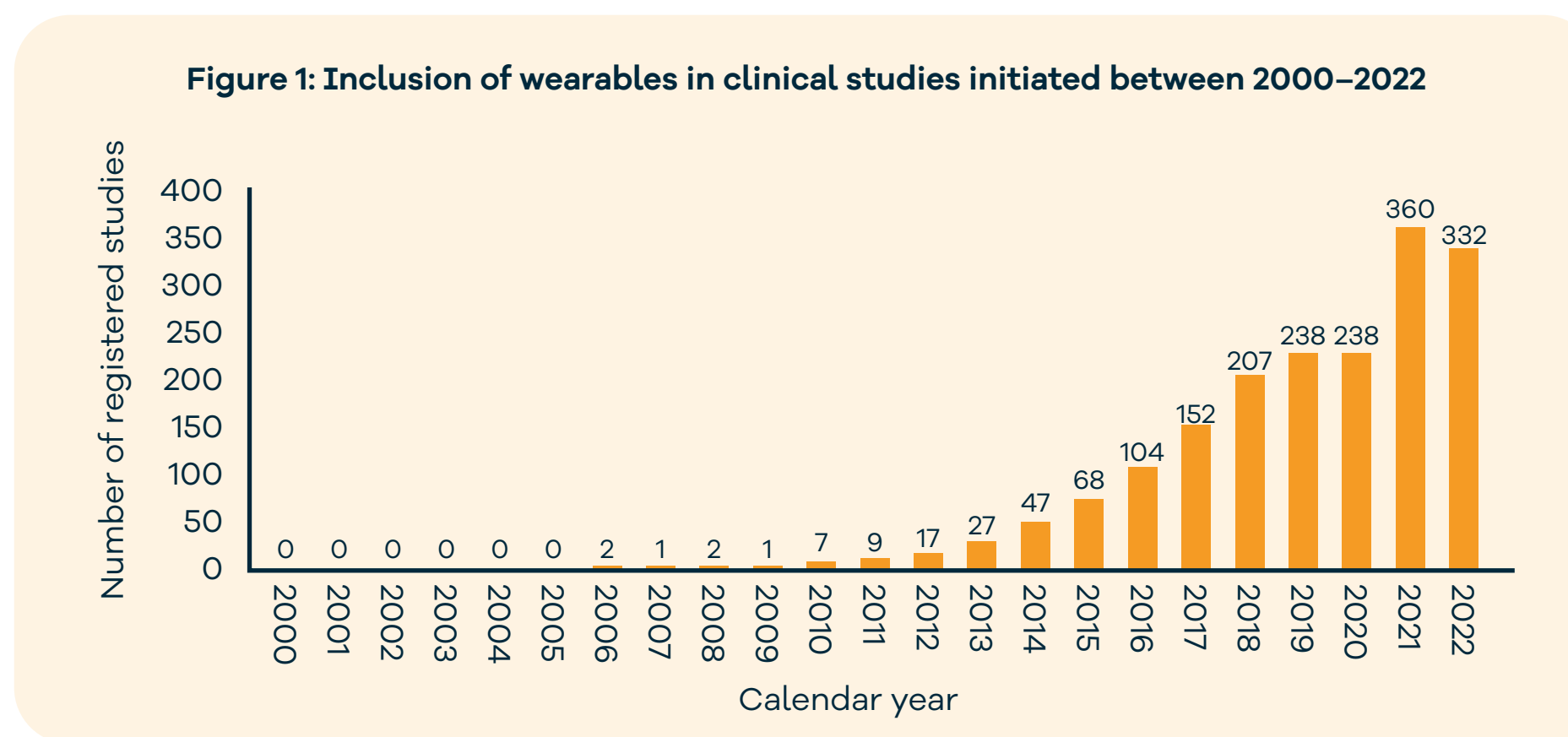
- 1 Has the adoption of wearables changed over time?
- 2 Which therapeutic areas have wearables in the study design?
- 3 Which categories of intervention have wearables in the study design?
- 4 What type of endpoint data is being collected via wearables?

## Results

A total of 452,947 studies were registered on clinicaltrials.gov between 01/01/2000 and 31/05/2023. A total of 2,015 studies contained the keyword 'wearable' and were included for further analysis.

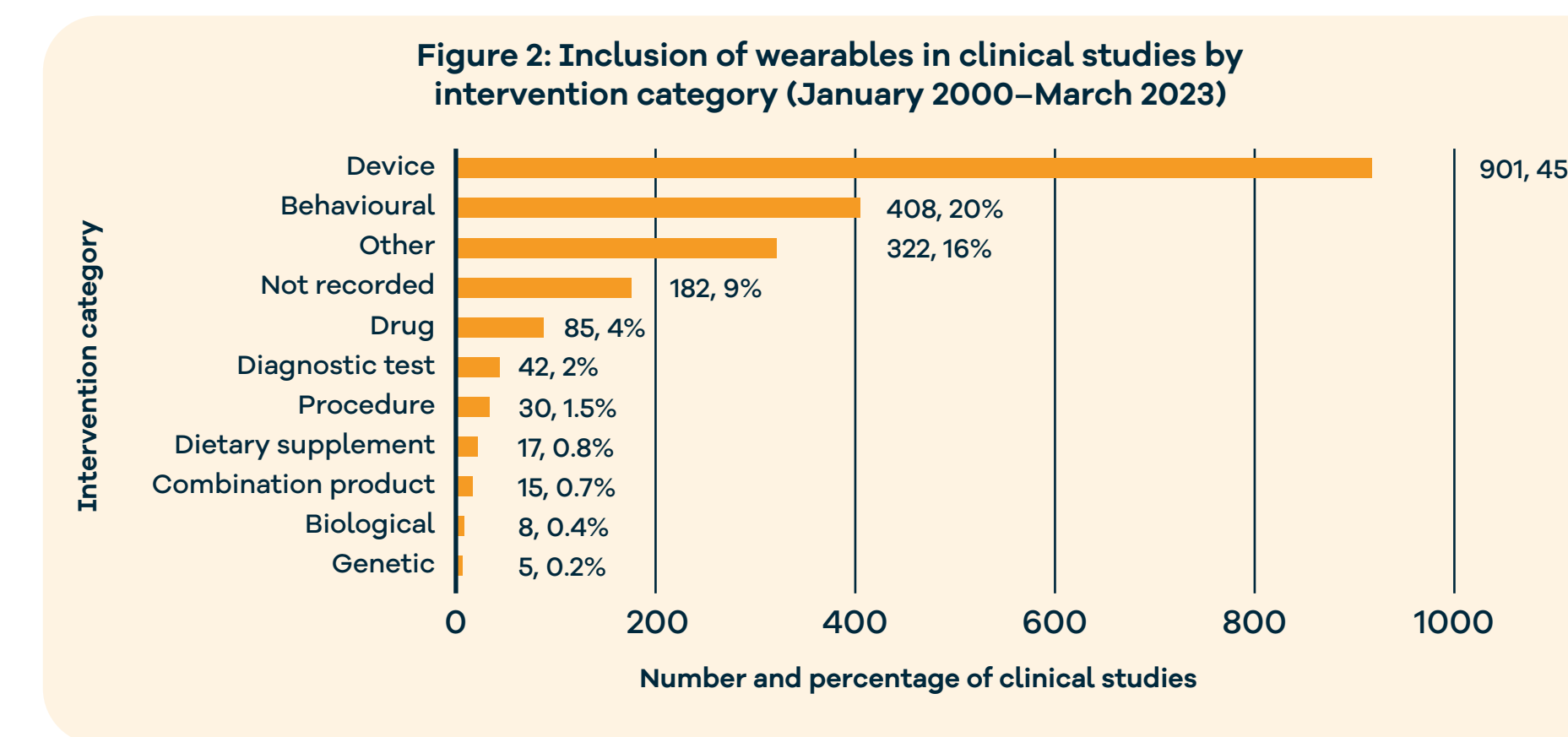
### Temporal application of wearables

Figure 1. illustrates an increase in the frequency of clinical studies that were initiated between 2000–2022 and used a wearable in the study protocol. The year 2023 was excluded since there was only partial data for the year.



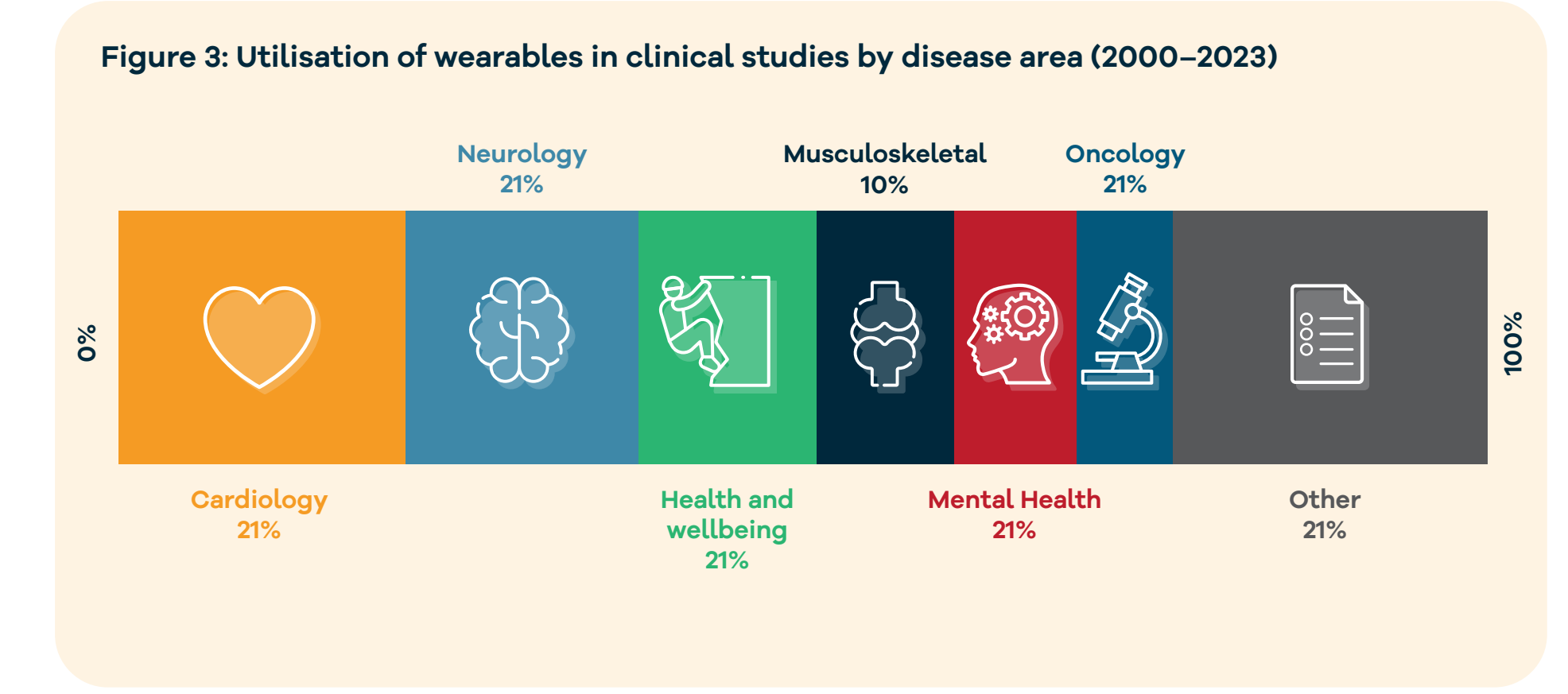
### Application of wearables to intervention categories

Figure 2 illustrates that device (45%), behavioural (20%), and other (16%) interventions accounted for most clinical studies that included use of a wearable. Drug, dietary supplement, combination product, biological and genetic interventions combined to account for 6% of the registered studies. 9% of studies did not record an intervention category.



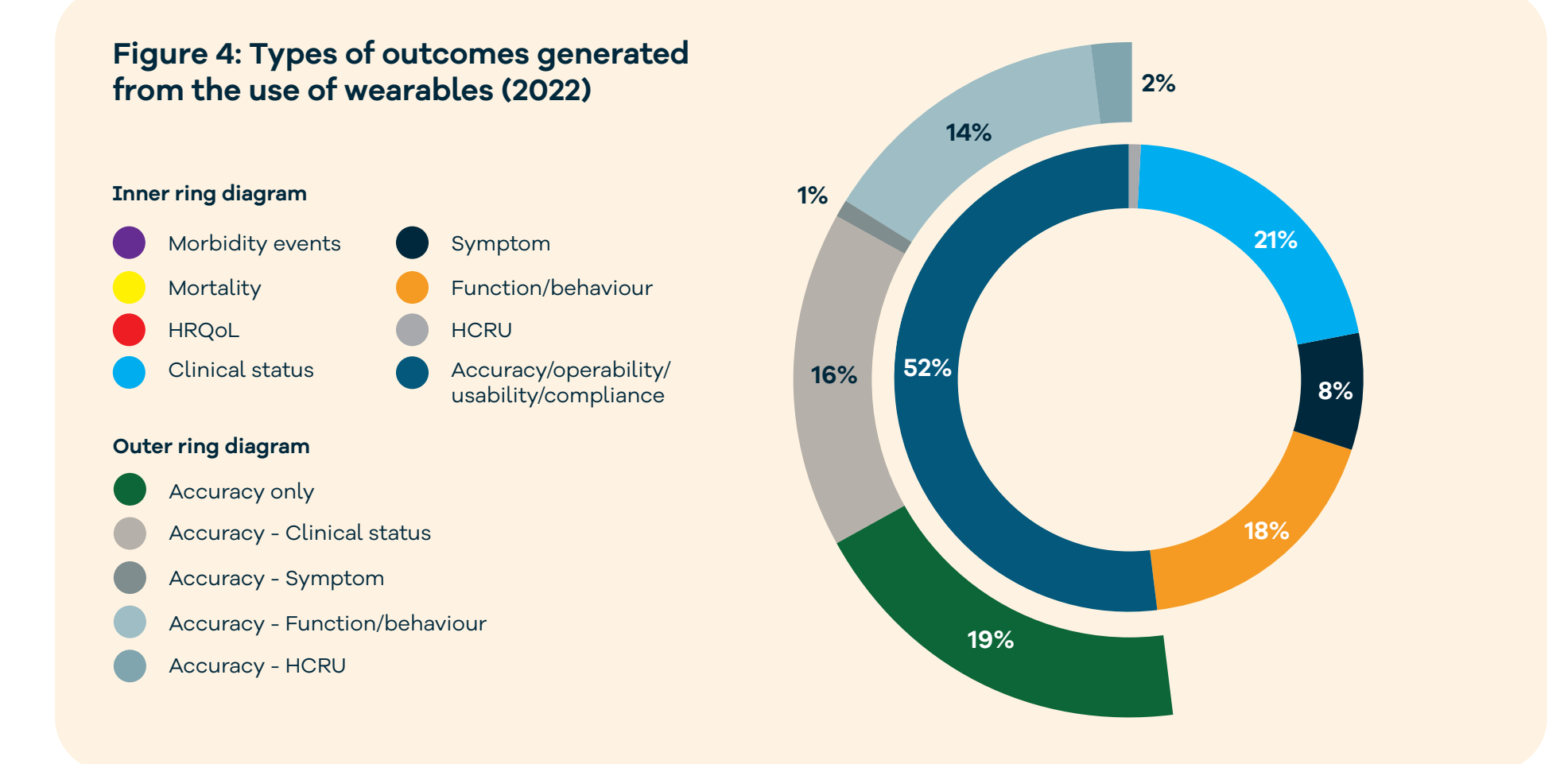
### Application of wearables to different conditions

Figure 3 illustrates that wearables have been utilised across a range of conditions, with the most frequent application to cardiology (21%), neurology (17%), health and wellbeing (13%), musculoskeletal (10%), mental health (9%) and oncology (7%).



### Primary outcome data collected via wearables

Figure 4 illustrates that in 2022, primary outcome data were collected using wearables across the following categories of outcome: Accuracy/operability/compliance (52%), clinical status (21%), function/behaviour (18%), symptoms (8%), healthcare resource use (1%), mortality (0%), and HRQoL (0%). Dual measures were observed in the accuracy category, where data were collected to explore the accuracy of the wearable in measuring clinical status (16%), symptoms (1%), function/behaviour (14%) and healthcare resource use (2%).



## Conclusion

Over the past two decades, there has been a substantial rise in the adoption of healthcare wearables into clinical study design, suggesting a paradigm shift in clinical research, where wearables offer a valuable method of data collection that supplements traditional in-clinic methods. Wearables have been applied to trial design with the highest frequency by manufacturers who are developing devices or behavioural interventions. Wearables have been less frequently used in clinical study designs for drug, diagnostic test, procedure, dietary supplement, combination product, biological, and genetic product development.

A broad range of therapeutic areas have applied wearable technology; cardiology had the greatest focus, perhaps because wearables can continuously measure metrics such as heart rate and blood pressure, but applications in neurology are also manifold and included monitoring sleep, cognition, and movement. However, generation of primary outcome data related to accuracy/operability/compliance of wearables demonstrates the current focus is upon meeting the regulatory requirements to attain marketing authorisation/CE marking, rather than on more patient-focused outcomes.

### References

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### Abbreviations

- CE: Conformité Européenne  
HCRU: Healthcare resource use  
HRQoL: Health-related quality of life