

# Status of the Art on Global Clinical Trials of Patient-Managed Digital Medical Devices (pDMDs): 2023 Original Data Analysis from Multiple Sources

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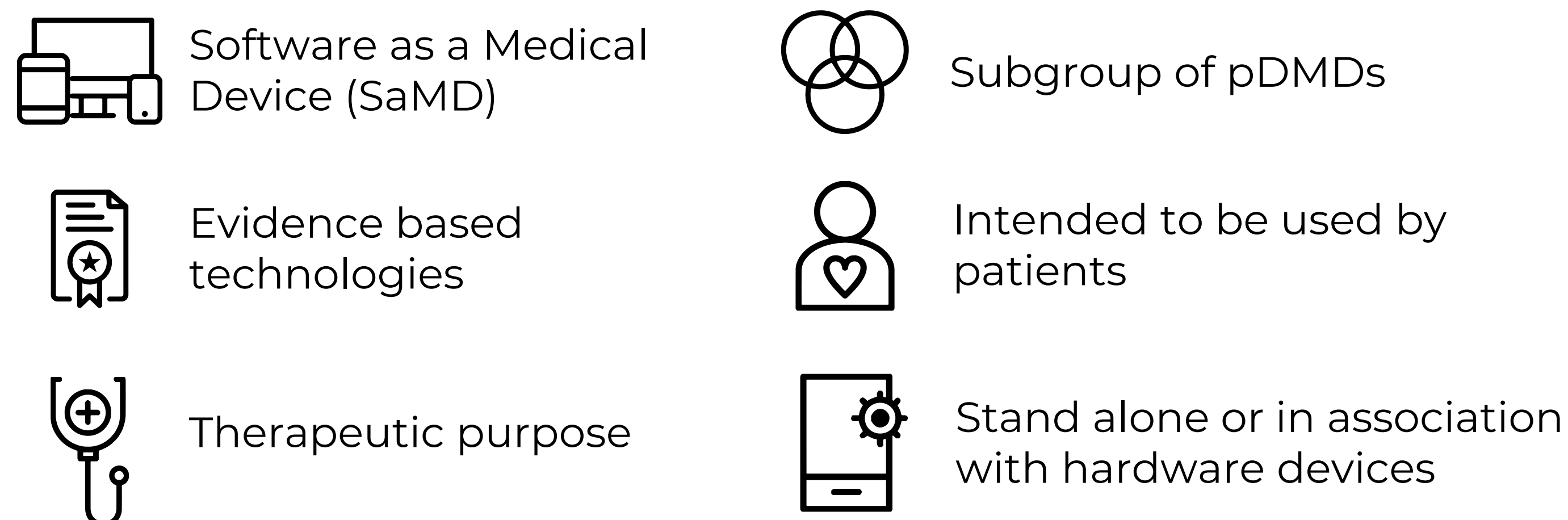
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## OBJECTIVES

Digitalisation is now part of our everyday life, and just as digital devices are reshaping our lifestyle in many ways, the healthcare sector is also set to undergo profound change. In this context, **patient-managed Digital Medical Devices (pDMDs)**, including those with therapeutic purpose known as **Digital Therapeutics (DTx)**, bring the promise to revolutionize our approach to treatments. The aim of this work is to **provide an overview** of this new segment of the healthcare industry.

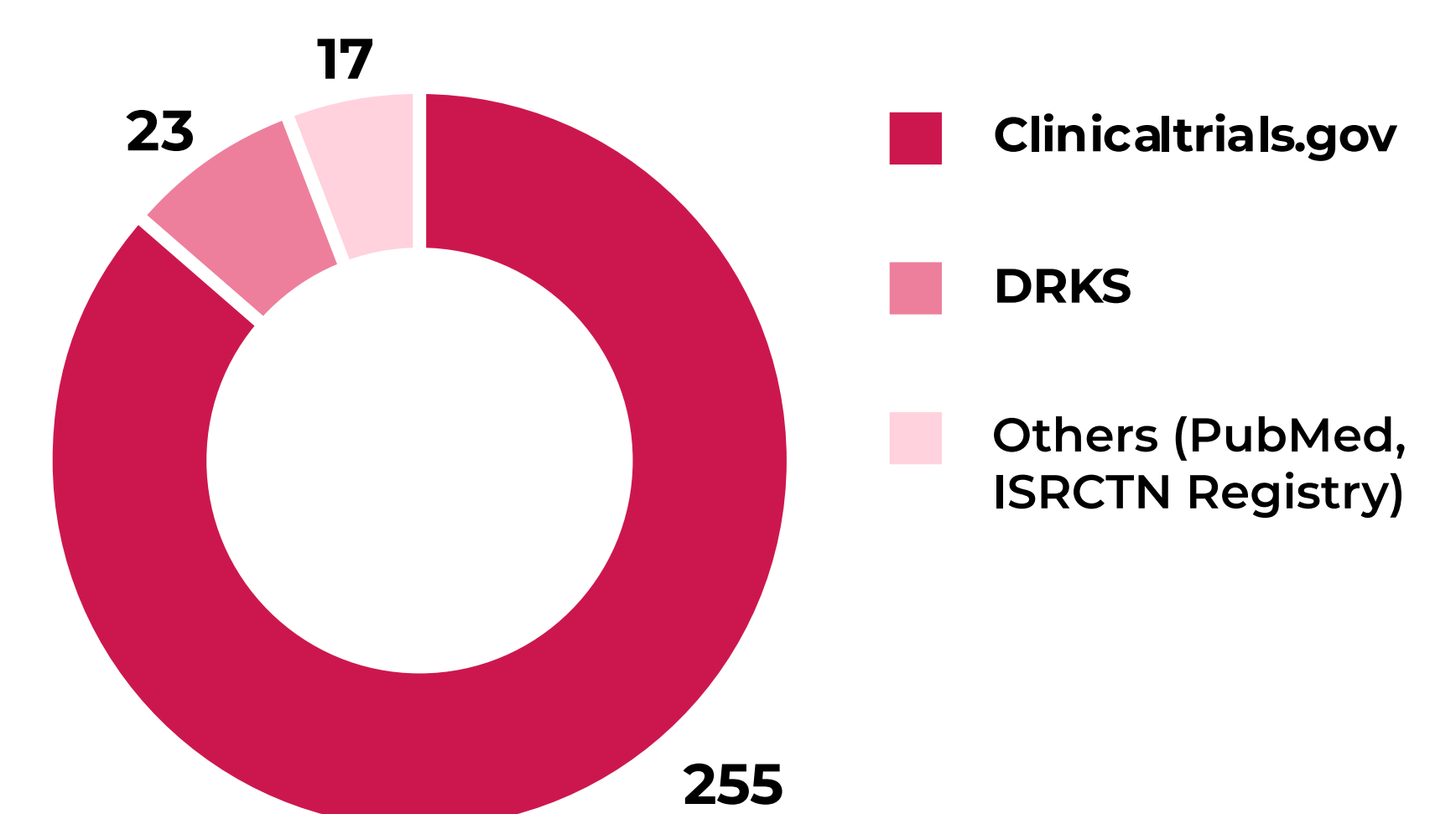
### Digital Therapeutics(DTx)



## METHODS

A Microsoft Excel database was created and populated with data from continuous desk research. The most relevant online **clinical trials repositories** were consulted (e.g., clinicaltrials.gov [1], DRKS [2]), identifying **992 trials**. After analysing each individual technical data sheet, pDMDs with therapeutic function (Digital Therapeutics, **DTx**) were separated from ordinary wellness apps, resulting in **295 studies** referring to **236 technologies**. Characteristics such as **technology, country of study and therapeutic area** were then analysed.

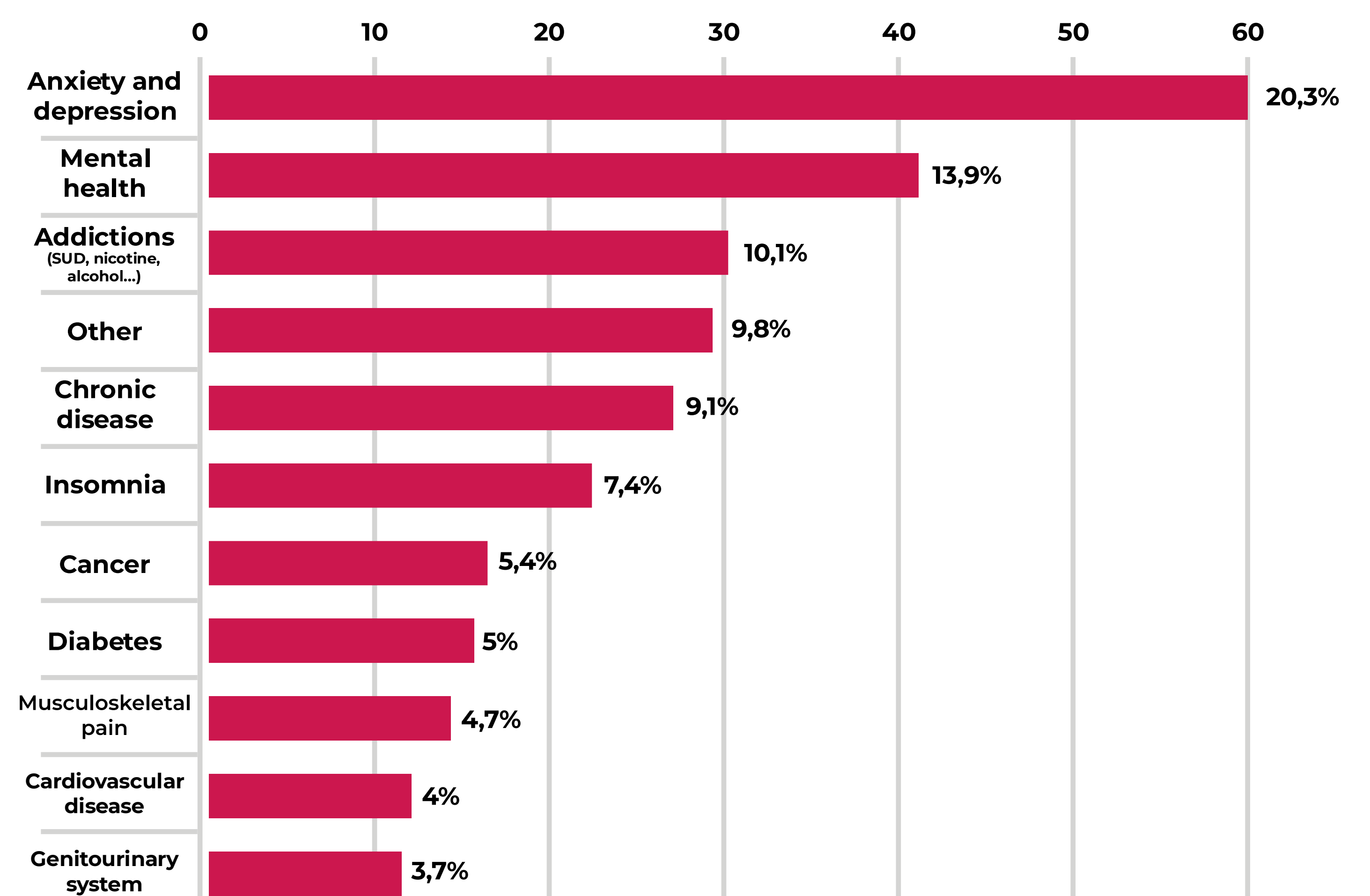
### Sources



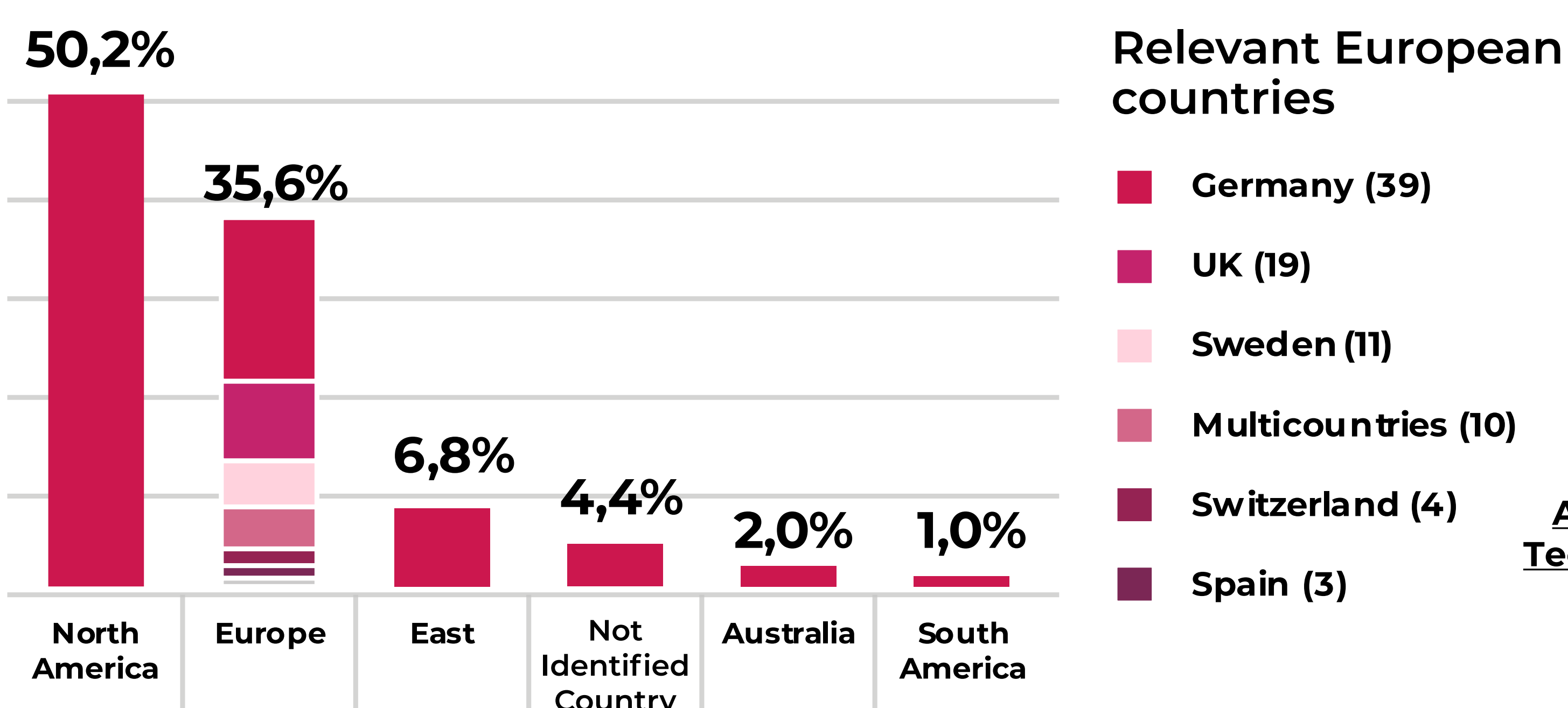
## RESULTS

The analysis revealed that **69.9%** of the considered trials concern **mobile applications**, 13.2% on web-based platforms, and 7.5% on videogames. Over **50%** of the digital therapies encompass **cognitive behavioural therapy (CBT)**, mental disorders (mainly **anxiety and depression**) being the most investigated diseases and covering **30%** of the studies. The **USA**, accounting for over 50% of the trials, are the most prolific country, while **Germany** emerged as the European leader with over 40 studies, followed by the UK with 19 studies.

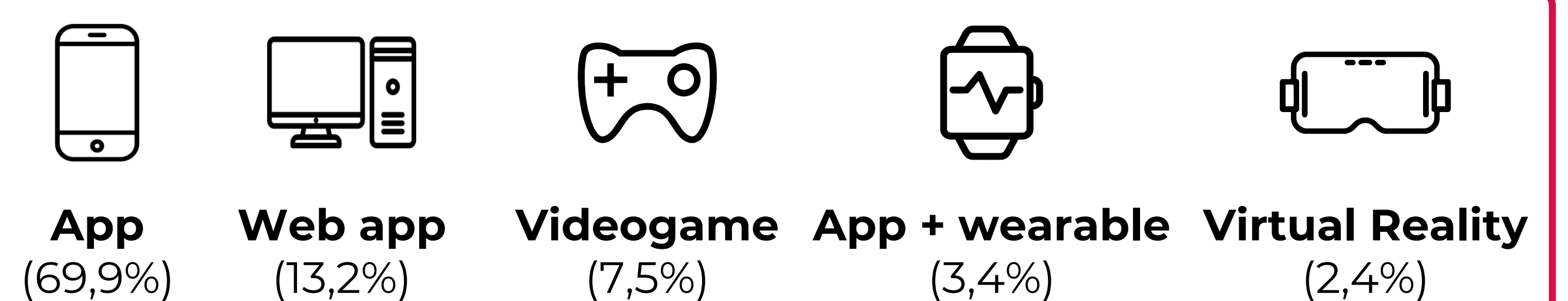
### Therapeutic areas - Number of DTx clinical trials



### Geographical analysis - DTx clinical trials

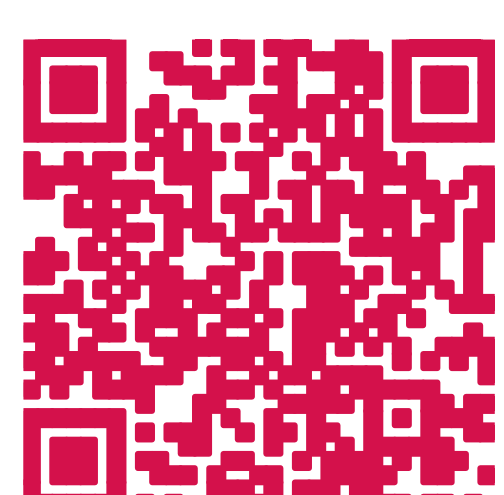
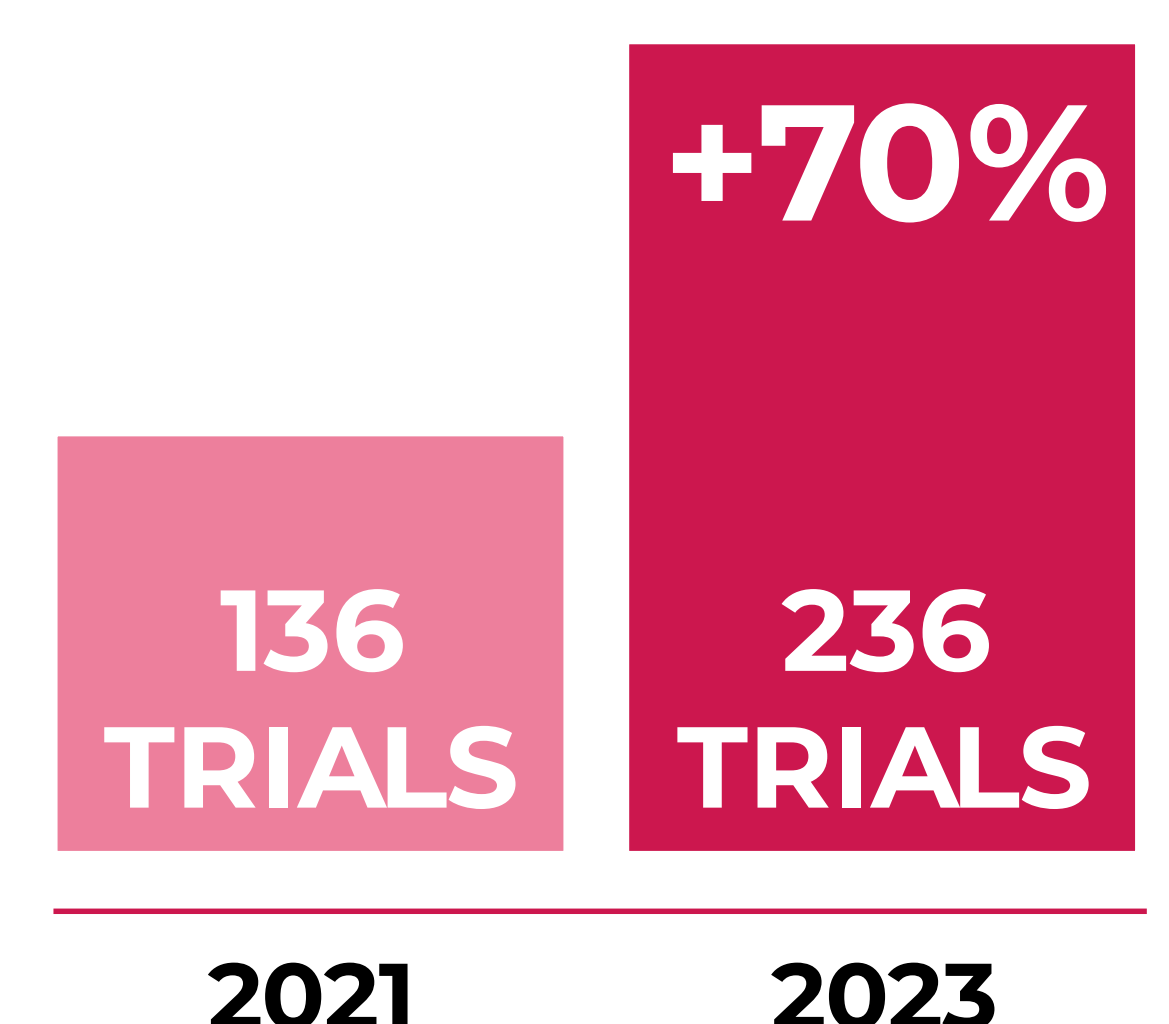


### Analysis of Technological devices



## CONCLUSION

Compared to a similar analysis relying on early **2021** data [3], our research highlights a **70% growth in clinical trials**, suggesting that pDMDs development has a positive trend, and their adoption will impact our future. To our knowledge this is the **first technology infrastructure focused on DTx Monitoring** tracking main features of this **fast-growing market**, able to help Pharma Corps, startups, Institutions, and all stakeholders working and collaborating more efficiently, by collecting and sharing info on pDMDs, including DTx, for human health.



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## REFERENCES

- [1] National Library of medicine, ClinicalTrials.gov, available at <https://clinicaltrials.gov/>
- [2] German Clinical Trials Register, Deutsches Register Klinischer Studien, DRKS, available at <https://drks.de/search/en>
- [3] Santoto et al. Terapie digitali: una revisione degli studi clinici Ric&Pra 2021;37(3):112-116