

A Comprehensive Evaluation of Clinical Studies in Digital Therapeutics: Uncovering Trends and Potential Implications

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Background

- Digital Therapeutics (DTx), a subcategory of digital-health, provides evidence-based software-driven therapeutic interventions to prevent, manage, or treat various diseases or disorders.
- It can be used as a standalone therapy or in conjunction with more conventional treatments like in-person therapy or pharmacological treatment. It can also be used with certain hardware or other sensory or mechanical devices. The treatment depends on the collection and processing of digital measurements. Because of the digital nature of the methodology, data can be collected and analysed as both a progress report and a preventative measure.
- Chronic diseases have created a need for comprehensive disease management solutions that are best enabled by digital technologies.
- At the European level, no specific legal regulation exists on DTx while the European Medicines Agency and the European Commission are starting exploring these solutions. On national level, the new German Digital Healthcare Act (DiGA) regulates specific requirements for the use of DTx. Important factors such as quality, security and data protection must be proven with scientific evaluation. France is moving forward to implement a similar legal act like Germany. In the USA, the Food and Drug Administration has an active pre-certification program in place since 2017 on DTx.
- Our current analysis of trials aimed to assess the trends in DTx indications and its end-usage scenarios.

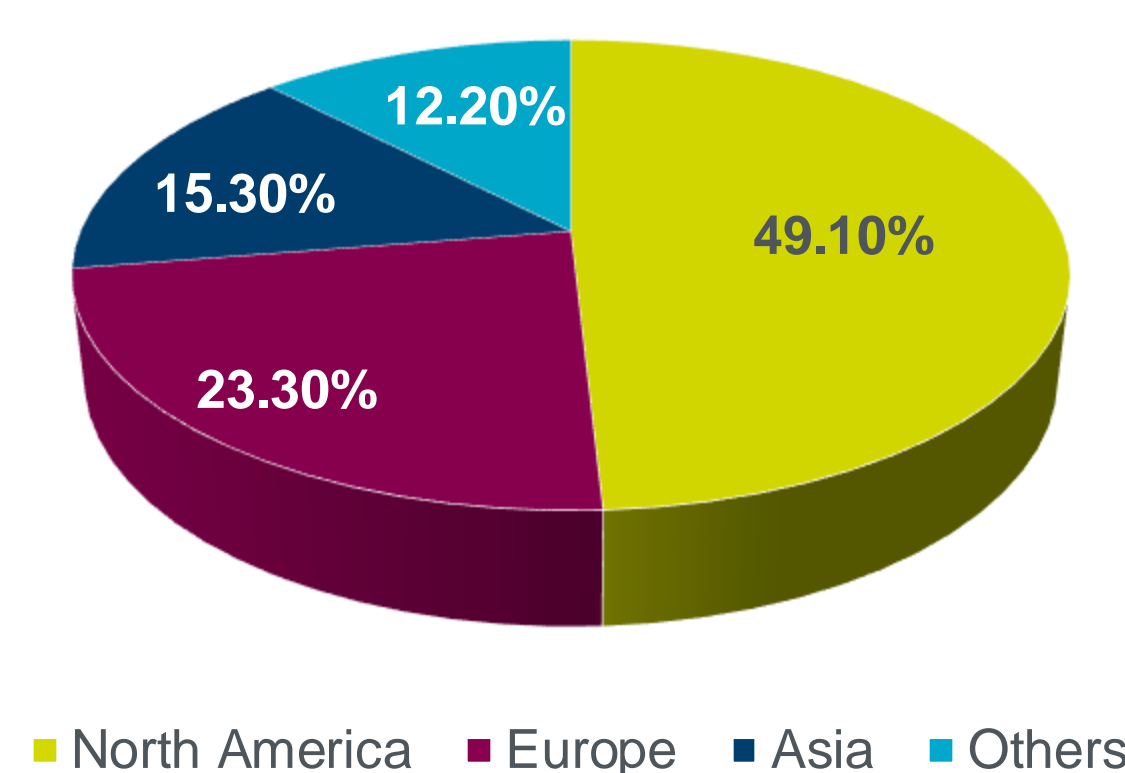
Methods

- A comprehensive search was performed to identify all trials published at the ClinicalTrials.gov site in the last 10 years on DTx. A total of 1,556 trials were retrieved and screening was performed to find the relevant trials. The included trials were categorized based on regions, disease areas, primary endpoint, status of trial, year for conducting the trial and the type of trial. The trends in trials being conducted in certain geographic regions and new disease areas of focus were also analyzed.

Results

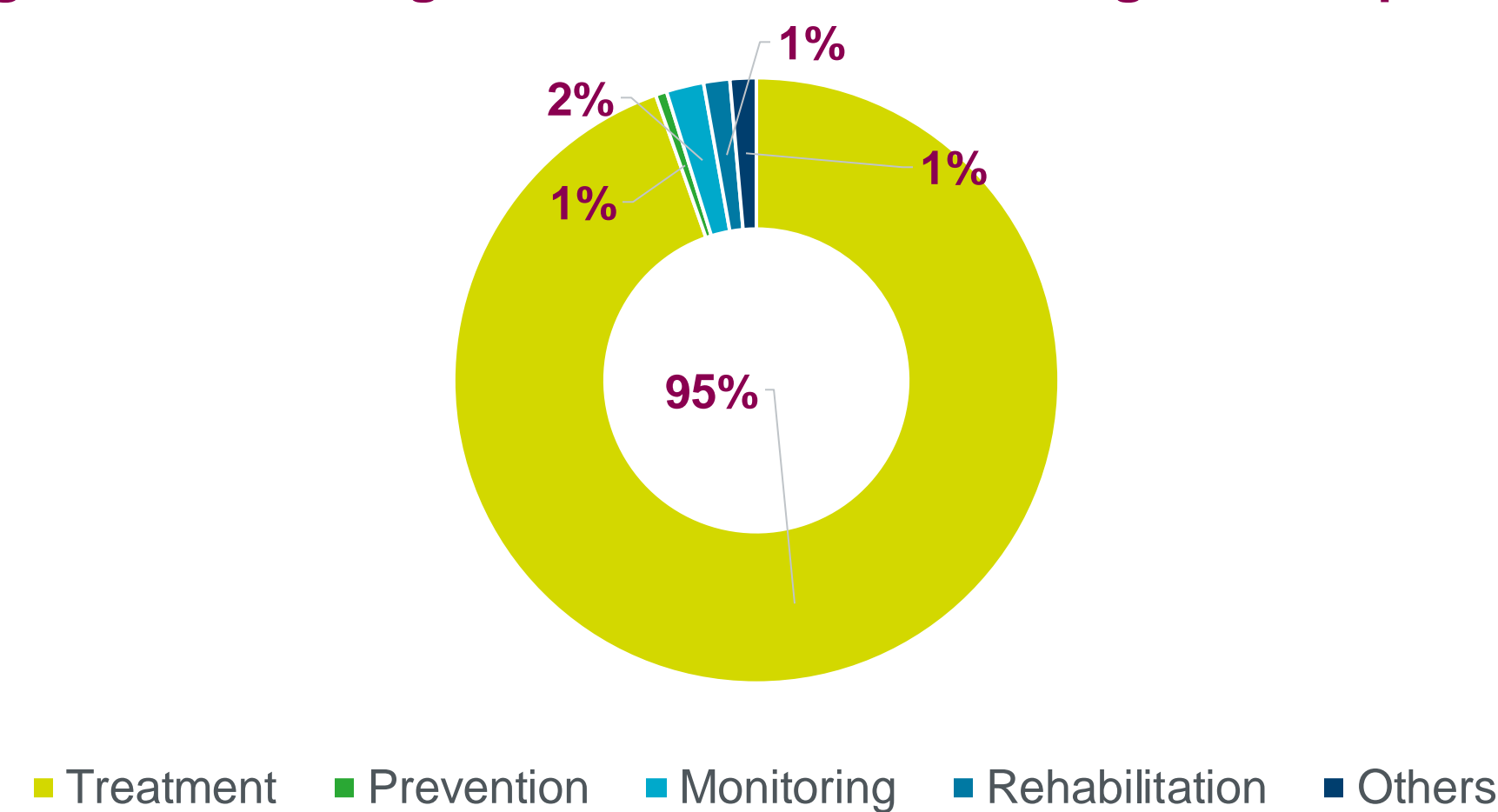
- A total of 1,556 records were identified from ClinicalTrials.gov site. Of these, following screening, 352 trials were included in this study.
- Most studies were identified from the North America (49.1%), followed by Europe (23.3%) and Asia (15.3%; **Figure 1**).
- Of 352 trials, 280 (79.5%) were randomized controlled trials (RCTs) and the remaining 72 (20.5%) were nRCTs.
- It was also observed that 69.3% of trials were conducted by academic/government institutions and the remaining 30.7% were company sponsored. Over the period of last 10 years, it was observed that more and more trials have been conducted by academic or government institutions. The 76.6% of the ongoing trial were conducted by academic/government institutions as compared to 61% of completed trials.
- Most of the included trials were parallel group (74.1%), followed by single arm trial (19.3%) and others (6.5%).

Figure 1. Geographic distribution of trials on digital therapeutics



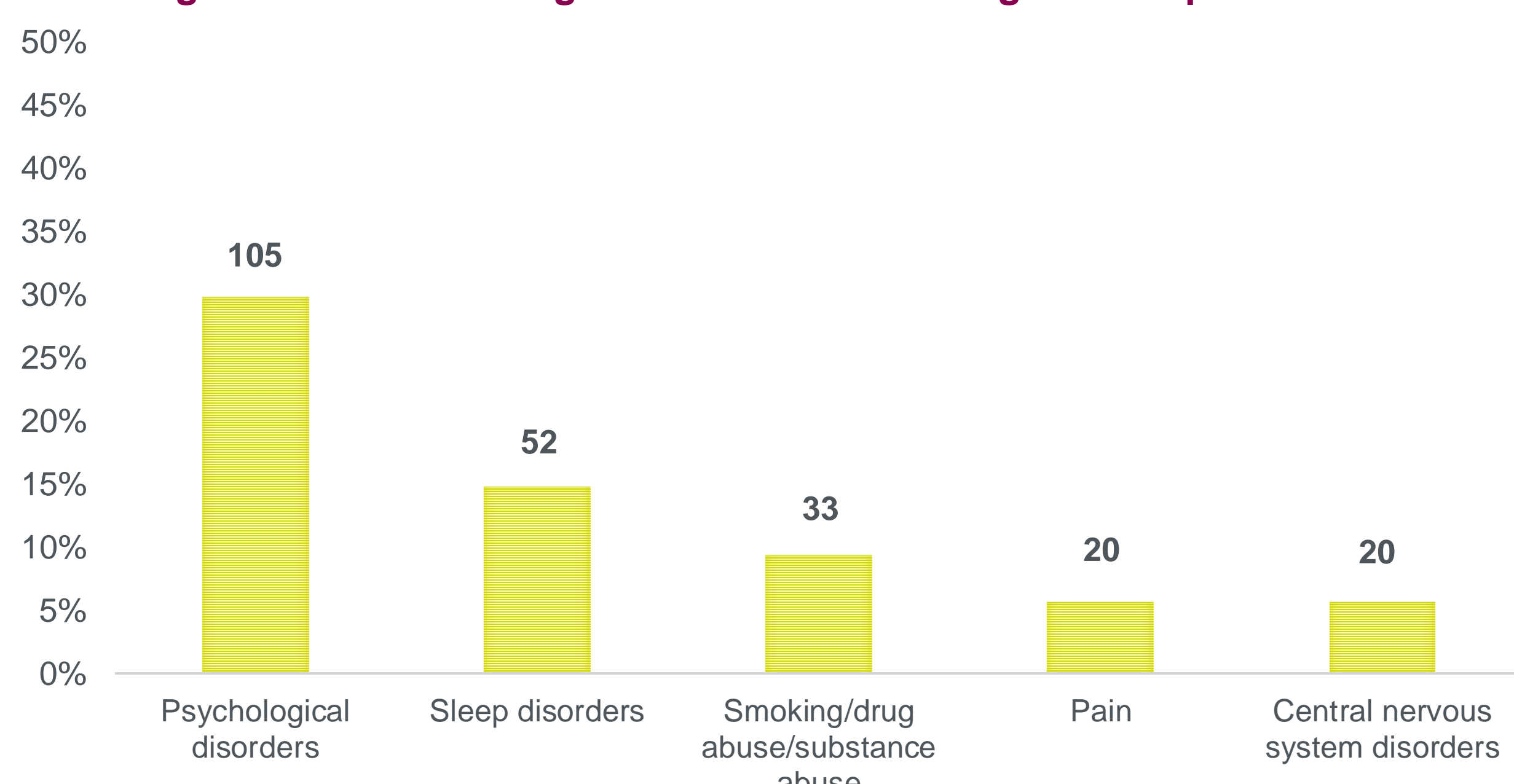
- Majority of the trials considered treatment (94.6%) as end-usage scenario. The other end-usage scenarios were reported to be rehabilitation, monitoring, prevention and others (**Figure 2**).

Figure 2. End-usage scenarios of trials on digital therapeutics



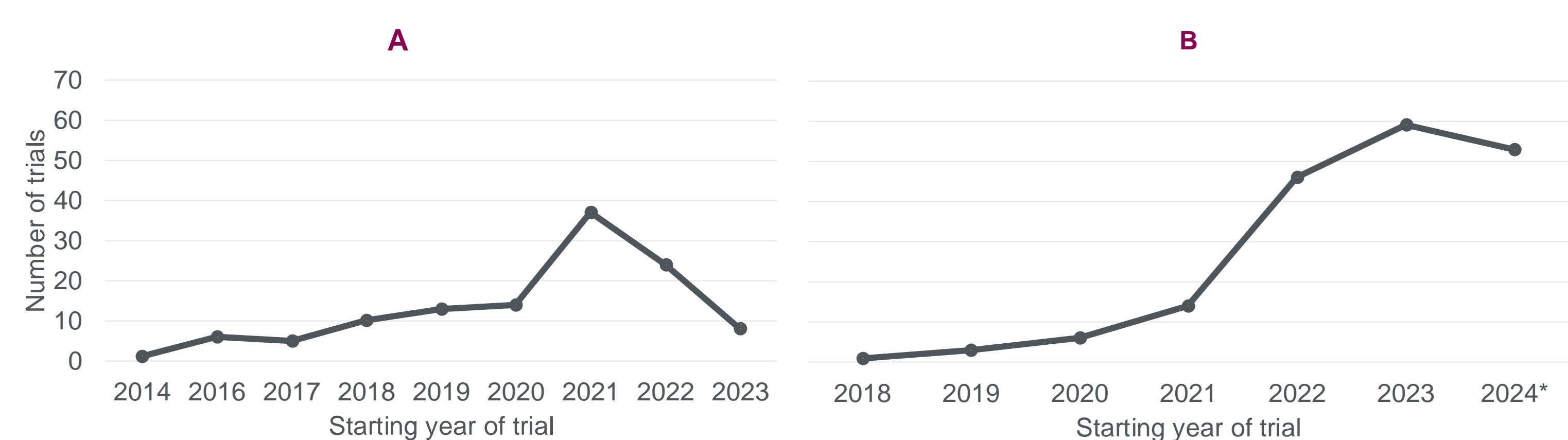
- The top five diseases (psychological, sleep and central nervous system disorders, smoking/drug abuse, and pain) of DTx trials belonged to the neuropsychological domain (**Figure 3**).

Figure 3. Disease categorization of trials on digital therapeutics



- The study found that there was an increase in the number of trials from 2014 to 2024 and majority of trials being conducted during 2021-2024 period.
- In **Figure 4**, it can be observed that higher number of trials started in recent years as compared to the earlier years.

Figure 4. Trends in number of trials on DTx in last 10 years for: A. Completed B. Ongoing trials



Abbreviations: DTx, digital therapeutics. **Note:** Two trials are not yet started. *First six months data only.

- Of the included trials, 184 were ongoing while 118 were completed (50 trials were either terminated/withdrawn or the status was unknown). The study identified that there has been an increase in trials being conducted in Europe (ongoing trials: 28.8% versus completed trials: 18.6%). Also, in general, these trials have increased over the period of last decade.
- The ongoing trials were majorly being conducted on diseases such as psychological disorders, sleep disorders, smoking/drug abuse/substance abuse and cancer.
- The new disease areas of interest for DTx, which were not taken into consideration in the completed trials, were found to be eating, eye, endocrinal and metabolic disorders (**Table 1**).

Table 1. Disease distribution of ongoing and completed trials

Disease area/name	Ongoing trials (184), n (%)	Completed trials (118), n (%)
Arthritis	1 (0.5)	1 (0.8)
Autism	2 (1.1)	2 (1.7)
Central nervous system disorders	8 (4.3)	8 (6.8)
Cancer	10 (5.4)	2 (1.7)
Cardiovascular disorders	5 (2.7)	2 (1.7)
Eating disorders	6 (3.3)	-
Endocrine disorders	8 (4.3)	4 (3.4)
Eye disorders	1 (0.5)	-
Gastrointestinal diseases	3 (1.6)	1 (0.8)
Gynecological disorders	-	2 (1.7)
Infections	-	2 (1.7)
Kidney diseases	1 (0.5)	-
Liver diseases	1 (0.5)	1 (0.8)
Metabolic disorders	6 (3.3)	2 (1.7)
Psychological disorders	53 (28.8)	37 (31.4)
Bone disorders	-	1 (0.8)
Pain	13 (7.1)	6 (5.1)
Respiratory disorders	3 (1.6)	2 (1.7)
Skin diseases	1 (0.5)	1 (0.8)
Sleep disorders	28 (15.2)	17 (14.4)
Smoking/drug/substance abuse	16 (8.7)	16 (13.6)
Suicide	4 (2.2)	1 (0.8)
Others	14 (7.6)	10 (8.5)

Note: Two trials are not yet started

Conclusions

- Digital therapeutics work through various means, such as cognitive behavioral therapy delivered digitally, remote monitoring and adjustment of treatment and personalized interventions based on patient data.
- Significant involvement of government agencies in trials evaluating DTx is an indication of favorable policy shaping in the domain in near future.
- The increasing trend of trials being conducted in Europe could also be associated with recent advancements.
- Behavioral, neuropsychological, and metabolic disorders are key disease areas for DTx with increasing interest in other indications like oncology and gastrointestinal/renal disorders.
- Ensuring data privacy and security, gaining regulatory approval, integration into existing healthcare systems, reimbursement and payment models, and demonstrating long-term efficacy are few challenges of using DTx.

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