Trends In Clinical Trials For Digital Health Technologies

Orkisz A[1], Kloc K[1], Rémuzat C[2], François C[3], Toumi M[3]
[1]Creativ-Ceutical, Cracow, Poland; [2]Creativ-Ceutical, Paris, France; [3]Faculté de Médecine, Laboratoire de Santé Publique, Aix-Marseille Université, Université de la Méditerranée, Marseille Cedex, France

BACKGROUND

- Digital health technologies (DHT) are gaining an attention among various stakeholders, including healthcare providers, consumers/patients, payers and health industry, as valuable ways to enhance healthcare management efficiencies.
- However, to successfully reach the market and gain funding, they need to prove their effectiveness as for other health technologies, which may represents a significant challenge due to specificities associated with digital solutions.

OBJECTIVES

- The aim of this study was to analyse current trends in clinical trials conducted for DHT.

METHODS

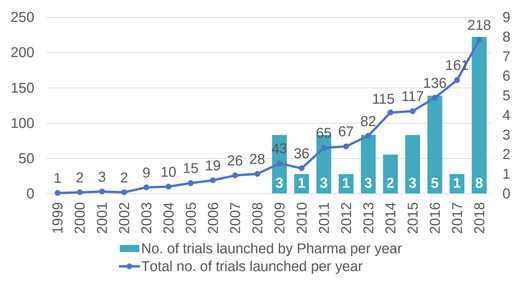
- Clinical trial designs for DHT were retrieved from clinicaltrials.gov records. Trials were identified using free search terms “digital health”, “eHealth”, “telehealth”, “telemedicine”, “artificial intelligence”. The search did not include any time limits and the search cut-off date was 23rd of May 2019.
- For all identified digital health trials, study characteristics were analysed including, study design, sponsor, purpose and location.

RESULTS

Number of trials

- In total, 1317 trials for DHT were identified. The first record for such trial was dated 1999 and since then, the number of new trials increased exponentially, reaching 218 in 2018. (Fig. 1)

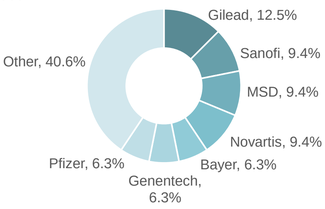
Figure 1. Number of trials launched per year



Trial sponsors:

- Despite increasing interest of pharmaceutical industry in DHTs, trials sponsored by the industry accounted only for a fraction of all digital health trials (3%). Most of them (97%) were sponsored by universities, research institutes and medical centres.
  - First trials for DHTs conducted by pharmaceutical companies launched in 2009 and since then on average 3 new pharma-led trials had been launching each year. However, in the last 3 years a significant increase in this field can be noted. (Fig. 1)
  - The key pharmaceutical companies involved in clinical trials for DHT were Gilead Sciences, Sanofi, Merck Sharp and Dohme Corp., and Novartis. (Fig. 2)

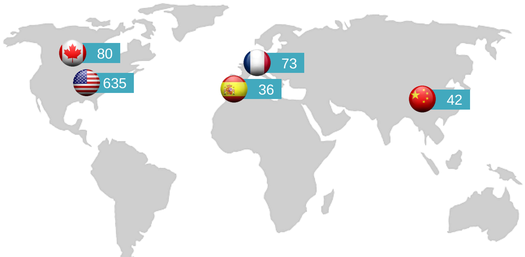
Figure 2. Key pharmaceutical companies involved in clinical trials for DHT



Trial location

- Significant majority of studies was launched in the USA (635), totalling to approximately the same as in all other countries together. Canada (80) and France (73) were the second and the third most common locations for digital trials, respectively. China (42) and Spain (36) closed the top 5 of locations with highest number of trials (Fig. 3). Other countries with >20 trials were Scandinavian countries, UK, Netherlands and Italy.

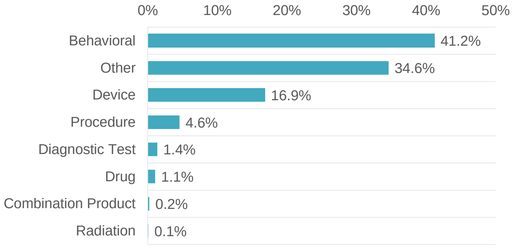
Figure 3. Top 5 locations with highest number of digital health trials



Intervention types

- Types of DHTs investigated in the trials were often classified as “behavioural” (41.2%) and “device” (16.9%), but sometimes also not specified (“other”, 34.6%). Other, less common categories were procedure (4.6%) and diagnostic test (1.4%), while trials with DHT accompanying drug therapy accounted for 1% of trials. (Fig. 4)

Figure 4. Split of trials based on intervention type



General study design & development phase

- Interventional study design (INT) dominated in trials for DHT (86%) where most often participants were assigned to parallel arms (61.7%), or less often to single groups (16.2%). Observational approach (OBS) was used for 14% of trials and cohort assignment was most often used for such trials (7.3%). (Fig. 5)
- 79% of INT trials was reported as randomized, 6% as non-randomized and for the remaining 15% of trials information on randomization was not available. (Fig. 6)
- Over a half of INT trials (63.6%) did not include any masking. Among blinded INT trials for DHT, single-blinded trials were almost three times more common than double-blind trials (24.4% and 6.8%, respectively). (Fig. 7)
- The average enrolment was over 2,300 participants, however, the median enrolment was 130.
- Only 9% of INT trials (n=117) had development phase assigned and among them almost 1/3 was Phase III, followed by Phase II and I/II in similar shares (approx. 1/4 each), and Phase IV (nearly 1/5 of trials). (Fig. 8)

Figure 5. Split of trials based on overall design, n=1,317[1]

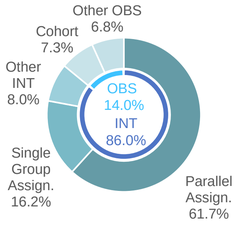


Figure 6. Split of trials based on randomization, n=1,132[2]

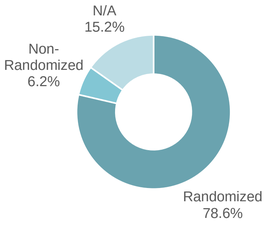


Figure 7. Split of trials based on masking, n=1,132[2]

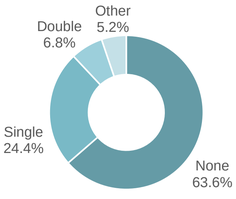
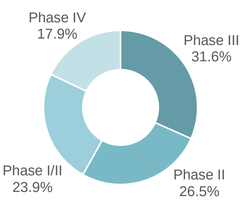


Figure 8. Split of trials based on development phase, n=117[3]



1. All trials; 2. Only interventional trials; 3. Only trials with development phase assigned.

CONCLUSIONS

- The fact that digital technologies are relatively new and emerging healthcare domain is reflected in clinical trials records. The number of trials for DHT has increased exponentially since 1999 and most of them have been conducted by scientific institutions; however, increasing interest of pharmaceutical industry could be noticed.
- Most of DHT trials were interventional studies with random assignment to parallel arms, and with relatively large study samples; thus had a design which is considered as the gold standard. However, they often use open-label approach which indicates on difficult blinding of DHT.
- Issues with controlling confounding factors in trials may become important challenge for successful adoption of DHT, as decision-makers could question the reliability of study outcomes. Therefore, developers should early engage in partnerships with experienced academics or medical centres to generate the most appropriate evidence to demonstrate well the added value of DHT.

ISPOR 2019, Copenhagen, Europe, November 2-6 2019. PNS310.