Results. A total of 100 unique biosimilar medicines in 136 clinical trials were included in the MInD since April 2017. Of these, 44 percent of biosimilars are currently EMA-approved (Nov 2021). Adalimumab was the reference medicine with the most unique biosimilars identified (12%). Seventy-two percent of the biosimilars in MInD were indicated for non-oncology conditions, twenty percent for oncology condition and eight percent for both.
There were 46 biosimilars unapproved, which were in active development. Of these biosimilars 17.4 percent are indicated for an oncology condition, 78.3 percent for non-oncology conditions, and 4.3 percent for biosimilars for both. Aflibercept was the reference product with the most (eight) biosimilars in active development.
There were 56 individual clinical trials in the MInD that list a biosimilar in development. For 26 trials, the primary completion date (PCD) was prior to 2021, whilst 28 trials listed a PCD post-2021, and 2 PCD's were unavailable
Conclusions. Our analysis identified high levels of active clinical development for biosimilars. The majority of biosimilars being developed are indicated for non-oncology conditions, with many in trials due to readout in the near future. Early identification, monitoring and reporting of biosimilars allows for expedited patient access and benefits, including cost-savings for health services.

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PP19 Reimbursable Health Apps (DiGA) In Germany: Which Factors Impact The BfArM's Assessment And Directory Listing? – Updated Research

Janika Drews (janika.drews@iqvia.com),
Doreen Bonduelle and Dr Johanna Schuller

Introduction. Since May 2020, reimbursement can be requested for Digital healthcare applications (DIGAs) in Germany. The prerequisite for reimbursement is a listing in the Federal Institute for Drugs and Medical Devices (BfArM) DiGA-directory, granted after successful completion of an assessment process. In June 2021, IQVIA first evaluated the BfArM's decision-making and identified criteria that may positively impact a directory listing. In November 2021, the research was updated to consider the latest developments.
Methods. Published information for each app in the DiGA-directory was qualitatively compared according to pre-specified criteria by two independent reviewers. With no data available for denied apps, only DiGAs with permanent or preliminary listings were compared.
Results. By 26 November 2021, twenty-four apps had received a positive assessment. Permanently listed apps (n=6) focused on health status improvements and/or patients' health competency. None claimed to improve patients' quality of life. Results from at least one randomized controlled trial (RCT) showed efficacy with medium or strong significant effect sizes (Cohen's d > 0.4) versus standard of care (SOC). For preliminarily listed DiGAs (n=18), final results of positive care effects were not yet provided, but applications included study designs for RCTs including definitions of primary endpoints. The BfArM accepted the trial designs to be suitable to measure an app's positive effects on health care within twelve months after listing. Since the last analysis, no preliminarily listed apps have been granted permanent DiGA-status. Evaluation periods were extended by up to five months for three apps. With none of the trials for preliminary apps being completed, possibilities for assessment remain limited. Claims for either medical benefit and/or patient-relevant structural/procedural improvements do not seem to impact the type of listing.
Conclusions. Updated research confirmed previous findings. For a DiGA-directory listing DiGA, the (planned) provision of RCT data seems to be gold standard. Medium to strong effects on the improvement of health status compared to SOC appear to be important for a permanent listing. Evaluation periods of five preliminarily listed apps are expected to be completed in December 2021, allowing for further analyses in the future.

PP20 Effectiveness And Safety Of Autogenic Training As A Treatment For Medical Conditions

Yolanda Alvarez-Perez (yolanda.alvarezperez@sescs.es),
Amado Rivero-Santanta, Lilisbeth Perestelo-Perez,
Andrea Duarte-Diaz, Vanesa Ramos-García,
Alezandra Torres-Castaño, Ana Toledo-Chávarri,
Nerea González-González, Leticia Rodríguez-Rodríguez,
Carlos González-Rodríguez and Pedro Serrano-Aguilar

Introduction. Autogenic training consists of reaching a state of deep relaxation through mental representations of physical sensations in different parts of the body. It is a promising technique for improving the psychological well-being of people with chronic diseases, but there are no clinical practice guidelines recommending the use of autogenic training in this population. The aim of this work was to identify, critically evaluate, and synthesize the available evidence on the safety and effectiveness of autogenic training in the prevention and treatment of medical conditions.
Methods. We conducted a systematic search for systematic reviews and randomized controlled trials (RCTs) in MEDLINE, Embase, CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials. The selection and assessment of risk of bias of the included studies was carried out independently by two reviewers.
Results. A total of 2,420 references were identified after eliminating duplicates. Of these, 141 were selected for reading the full text, and 13 systematic reviews and 18 RCTs were included. Compared with no intervention or delayed treatment, autogenic training significantly reduced levels of anxiety and depression as well as some physical symptoms (e.g., headaches and atopic dermatitis).
Conclusions. Autogenic training could be useful for improving the psychological well-being and physical symptoms of patients with

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