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

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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

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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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chronic health conditions and as an additional element in multicomponent intervention programs. However, these conclusions are not definitive due to the low number of studies available for each health condition and their high or unclear risk of bias.

PP21 Efficacy And Safety Of Aromatherapy: An Overview Of Systematic Reviews

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Introduction. Aromatherapy is the field of herbal medicine that uses essential oils distilled from flowers, roots, and herbs and other plant compounds to promote physical and psychological well-being. Essential oils are absorbed into the body in different ways, with the inhaled and topical routes being the most widely used. The aim of this review was to critically evaluate and synthesize the available scientific evidence on the efficacy and safety of aromatherapy for the management of any therapeutic indication. This report was requested by the Spanish Ministries of Health and Science and Innovation.
Methods. An overview of systematic reviews (SRs) was performed. The MEDLINE, Embase, CINAHL, and PsycINFO databases were searched for literature published from January 2006 to August 2021. SRs reporting the efficacy and safety of aromatherapy were included. We applied no restrictions in terms of administration route or essential oil used. Two reviewers independently performed screening and selection, data extraction, and quality assessment.
Results. We included 74 SRs covering a wide variety of populations and settings. The most reported outcome was anxiety, followed by pain, and the most commonly used essential oil was lavender. Fifteen SRs reported mild adverse events with aromatherapy. Only 11 SRs assessed the certainty of evidence using the GRADE approach. Aromatherapy reduced heart rate and likely reduces anxiety and breathing rate in patients with cardiovascular diseases. Aromatherapy probably also reduces pain in women with primary dysmenorrhea. Additionally, it may reduce blood pressure, acute pain, subjective stress, and the need for antiemetic drugs after surgical procedures. However, the evidence was very uncertain regarding the effect of essential oils on anxiety, pain, and quality of life in patients with cancer, anxiety and pain after a caesarean section, and dental anxiety.
Conclusions. Aromatherapy may be useful for managing psychological and physical symptoms in different settings. However, the conclusions of this review are not definitive because of the moderate to high risk of bias in many of the primary studies included in the SRs.

PP22 A Lifecycle Approach To The Use Of Real-World Evidence In HTA Submissions And Resubmissions: A Decade's Experience

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Introduction. Health technology assessment (HTA) bodies worldwide recognize the importance of real-world evidence (RWE) in addressing uncertainties around the effectiveness of new drugs at the time of launch and as part of resubmissions. We assessed the use and acceptability of RWE by analyzing HTA recommendations.
Methods. We analyzed 24,841 HTA reports, including original submissions, resubmissions, extensions of original indications, and renewals, published from January 2011 to October 2021 from more than 100 HTA agencies across 37 countries.
Results. Our analysis showed that 3,820 (15%) reports mentioned RWE. Between 2011 and 2021 there was an eight-fold increase in the use of RWE, from 4 percent in 2011 to 34 percent in 2021. RWE was most commonly included in HTAs in oncology (26%) and endocrine and metabolic diseases (13%). The main areas supported were effectiveness (40%), safety (38%), and epidemiology (35%). RWE supplemented evidence on survival and quality of life as well as resource utilization, proxy comparators, and utility. Based on an analysis of the 1,474 reports that mentioned RWE, effectiveness was mainly supported by cohort (22%) and observational studies (13%), safety was mainly derived from pharmacovigilance data (9%), and epidemiology data were collected from registries (23%). The top five HTA bodies mentioning RWE in their reports were from France, Germany, Poland, and the United Kingdom (n=2). RWE was most accepted when it supported safety and epidemiological considerations, and to a lesser extent when it was used for effectiveness aspects or understanding management pathways.
Conclusions. The inclusion and acceptability of RWE in HTA recommendations varies between HTAs according to their data requirements and assessment methods. While it is not always specified how RWE was considered, there is a clear tendency for its increased use and acceptability, albeit not in all areas. Greater use of and transparency around RWE are likely to continue as multiple RWE initiatives emerge globally.

PP23 Lost In Translation? The Differences In The Use Of Real-World Evidence Across Key Markets

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