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A Mixed Methods Review of Endpoint Measures Utilized in Adult ADHD Medication Clinical Trial Design

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OBJECTIVES/GOALS: To evaluate the clinical trial designs of stimulant medications approved for the treatment of adult Attention-Deficit/Hyperactivity Disorder (ADHD) and identify discrepancies between safety and efficacy outcome measure criteria. METHODS/STUDY POPULATION: There are 24 stimulants currently approved and marketed for the treatment of adult ADHD: 12 amphetamine (AMP)-based and 12 methylphenidate (MPH)-based formulations. A mixed methods review of clinical trials that have evaluated the safety and efficacy of these drugs will be performed using qualitative and quantitative data, including inclusion and exclusion criteria, primary and secondary outcome measures, manufacturer recommendations, and package inserts, as well as FDA recommendations for industry. After compiling a list of clinical trials for each of the 24 drugs, this information will be analyzed for themes and trends in the assessment of safety and efficacy with particular attention paid to differing criteria between individual drugs and/or the two subclasses of prescription stimulants. RESULTS/ANTICIPATED RESULTS: The FDA has published recommendations for ADHD medication clinical trial design, including suggested outcome measures utilizing validated assessment tools. However, the FDA notes that these assessments may be altered to fit study populations and indicate that other primary and secondary endpoint measures may be acceptable. As such, efficacy assessments for these drugs may vary greatly, and the specific criterion selected for each drug's study population and outcome measures may suggest more specific indications and usage conditions for optimal efficacy. DISCUSSION/SIGNIFICANCE: Regulatory officials consider AMP- and MPH-based stimulants equivalent therapeutic options for the treatment of ADHD. A study of clinical trial criteria reveals that differing mechanisms have been used to evaluate safety and efficacy. This discrepancy may have implications that affect clinical decision-making and patient experiences.

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An Investigation on the Activity of Repurposing Already Marketed Drugs for New Indications from 2015 to 2021.

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OBJECTIVES/GOALS: To examine the prevalence of new indications for existing drugs conducted by non-originator companies from 2015 to 2021 and determine how many could qualify for 505(b)(2) under the Food, Drug, and Cosmetics Act. METHODS/STUDY POPULATION: A search within Clinicaltrials.gov was conducted to identify phase 3 drug interventional studies completed from 2015 to 2021. Results were categorized by funding source and industry sponsored studies were further separated into originator- and non-originator companies using dailymed.com. An in-depth review of 2018 was conducted to understand the nature of the studies including indication, dosage form, and route of administration. RESULTS/ANTICIPATED RESULTS: According to clinicaltrials.gov, a total of 7148 phase 3 studies were conducted between 2015 and 2021. Most of these studies were funded by industry (4447, 66.21%), followed by other (2428, 33.97%), NIH (266, 3.72%), and government (62, 0.87%). In-depth examination of the studies completed in 2018 (n=1077) revealed similar pattern in that most were funded by industry (674, 62.58%) followed by other (356, 33.05%), NIH (43, 3.99%), and government (10, 0.93%). Some studies were funded by more than one type. Of the industry-sponsored studies, 623 were funded by originator companies and 51 by non-originator companies. A total of 49/674 of the industry sponsored studies were for new indications, with 42 studies conducted by originator companies and 7 conducted by non-originator companies. DISCUSSION/SIGNIFICANCE: The 505(b)(2) is a way for manufacturers to add new indications to drugs by non-originator companies. In 2018, 49/674 studies were conducted to pursue new indications with few, 7/49, conducted by non-originator companies. The product development landscape reveals few opportunities for entities pursuing the 505(b)(2) pathway for new indications.

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Basic Researcher Interviews to iDentify Gaps to Enabling Translation (BRIDGE Translation)

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OBJECTIVES/GOALS: Despite expanded interest in translational research, barriers in funding, infrastructure, staffing, training opportunities, and interdisciplinary collaboration still remain. Our goal was to interview basic science researchers to identify research barriers and potential areas for improvement. METHODS/STUDY POPULATION: After receiving an IRB determination for a quality improvement study, 15 New Jersey-based principal investigators (PIs) from various departments and at various stages of their careers were virtually interviewed one-on-one by a trained medical student and asked a series of standardized questions about their subjective experiences with their institutions' research processes, training and mentoring, interdisciplinary collaboration, and intellectual property. The interview was then transcribed to complete an anonymous, standardized REDCap form. Qualitative data analysis was performed to identify common themes, barriers, and gaps in conducting translational research as reported by the PIs. RESULTS/ANTICIPATED RESULTS: Of the 15 PIs, 4 (27%) were assistant professors, 6 (40%) associate professors, and 5 (33%) professors. 5 (33%) joined the institution less than 5 years ago. The most common barrier was translational research funding. Time needed to navigate administrative and regulatory processes and access to clinical collaborators were other common barriers. One PI noted leaving the institution due to difficulty accessing clinicians and patient samples. PIs with extensive training or who reported successfully conducting translational research noted fewer barriers. Suggested solutions included programs and grants to link basic scientists with clinicians, a streamlined IRB process, and better staffing to support research. DISCUSSION/SIGNIFICANCE: The findings suggest a need to increase grant funding for translational research. Improving support staffing and minimizing administrative barriers would also be helpful. Improving the dissemination of available resources, grants, and guidance on administrative processes may further decrease barriers.

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