residents of the state of Michigan or the local county surrounding MM (Washtenaw County), using US Census tract data to provide context for these findings. RESULTS/ANTICIPATED RESULTS: MM patients who received EA treatments were more likely to come from neighborhoods that showed markers of high SES compared to residents of the state of Michigan but not Washtenaw County. This includes the proportion of persons living in poverty (12.5% EA / 13.4% Michigan / 12.4% Washtenaw) and education in the form of a bachelor's degree or higher (32.2% / 30.6% / 57.2%). This varied by the disease being treated. Oncology patients were more likely to be from areas with less poverty and more education (12.4% / 76.8%) than the EA average. EA patients being treated for infectious diseases were from areas with more poverty and less education (13.5% / 26.7%). DISCUSSION/SIGNIFICANCE: Patients treated at Michigan Medicine using treatments obtained through the EA pathway came from areas that were, on average, more affluent than residents of the state of Michigan as a whole. This finding warrants more research to ensure equitable access to these therapies for patients in disadvantaged neighborhoods.

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Examining Participant Representation in Atopic Dermatitis Clinical Trials from 2011-2022

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OBJECTIVES/GOALS: This study seeks to comprehensively evaluate the extent to which participants in clinical trials (CT) for Atopic Dermatitis (AD) accurately mirror the demographics and characteristics of the broader AD-affected populations. We will achieve this objective by analyzing data from AD CTs spanning the years 2011 to 2022. METHODS/STUDY POPULATION: We examined completed trials for 10 FDA approved treatments for AD, utilizing data sourced fromclinicaltrials.gov [http://clinicaltrials.gov]. In light of the increased number of AD clinical trials over the past decade, we tailored our search parameters to encompass all trials related to approved treatments from 2011-2022. To assess the characteristics of the participant population in these trials, information including inclusion and exclusion criteria, age, location, sex, and disease severity were collected for each trial. Furthermore, race and ethnicity data were also extracted and analyzed. Additionally, comparisons were drawn between trials completed before and after April 2017, when the FDA began requiring that researchers publish race and ethnicity data toclinicaltrials.gov [http://clinicaltrials.gov]. RESULTS/ANTICIPATED RESULTS: Across 67 CTs examined, 45% of trials were restricted to adult patients, 28% were restricted to pediatric patients, and 27% included both. 77% of CTs occurred in urban settings and 23% occurred in rural settings according to the The Economic Research Service definition. 36% of CTs included mild-to-moderate AD patients, and 64% of CTs included moderate-to-severe AD patients. Race distribution of CTs revealed 67% White, 14% Black/African American, 16% Asian, and 3% others. 13% of participants identified as Hispanic or Latino. With further analysis, we will determine whether there is a difference in ethnic distribution between trials completed before and after April 2017, when the FDA started requiring race/ethnicity data to be submitted. DISCUSSION/SIGNIFICANCE: The findings highlight a significant concern in AD CTs: the insufficient representation of Black and Asian populations. The findings emphasize the need for a more inclusive selection process that accurately reflects the diversity of patients. Failing to do so could undermine the assessment of treatment effectiveness in such populations.

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A Comparison of Regulatory Mechanisms for the Approval of Herbal Medicines

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OBJECTIVES/GOALS: To compare the herbal medicine (HM) programs of the U.S. to those of different countries–including the European Union, South Korea, China, and India–and to examine each regulatory body's process for obtaining market approval for HM drugs. METHODS/STUDY POPULATION: The European Union, South Korea, China, and India's respective HM regulatory programs were examined and compared to the U.S. FDA's HM process. These specific regulatory bodies were chosen based on the country's long history with HM and/or the robustness of their existing HM review processes. International HM programs were researched using official government websites and journals published by independent, external research institutions that were accessed via USC's library services. Data regarding the efficacy of HM policies such as HM IND approval rates, number of marketed HM drugs, and establishment of unique HM sectors will be collected. RESULTS/ANTICIPATED RESULTS: Investigational New Drug (INDs) applications regarding HM from each country will be categorized and displayed according to their approval status in order to provide insight on a HM program's efficiency. Results also included a table displaying common challenges for approval for HM drugs across federal regulatory bodies. If applicable, effective solutions implemented to address some of these obstacles that proved to be effective will also be displayed in the form of a table. DISCUSSION/SIGNIFICANCE: Tables displaying the collective flaws of international HM programs and the resulting regulatory solutions can provide clearer guidance for companies seeking to submit HM INDs and for the U.S. FDA seeking to develop improved HM regulations.

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A Multi-Institutional Look at Single-Patient Expanded Access Submissions

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OBJECTIVES/GOALS: Physicians can request the clinical use of investigational products for their patients through an FDA pathway called Expanded Access (EA). Most evaluations of EA focus on the FDA submission only. We sought to evaluate these requests through

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the full academic medical center process. METHODS/STUDY POPULATION: Through the Transforming Expanded Access to Maximize Support and Study grant, we reviewed regulatory records for single-patient EA requests at four institutions (Duke University, University of Rochester, University of Michigan, and University of Texas Southwestern) which occurred between June 1, 2021 and February 28, 2023. Key data was collected, including the investigational product requested, submission and approval dates, urgency of request, and indication for treatment. Descriptive statistics were performed with Microsoft Excel. RESULTS/ANTICIPATED RESULTS: A total of 405 EA requests were identified, of which 319 (78.8%) were for drugs, 59 (14.6%) for biologics, and 27 (6.7%) for medical devices. The majority were characterized as non-emergency (60.7%), but the proportion of emergency to non-emergency cases varied considerably when stratified by year, with a peak in emergency cases in 2020. The most common products included therapies for COVID-19 and Mpox. Median time to obtain all approvals for treatment was 7 days for emergency cases and 28 days for non-emergency. The FDA review took the least time, with a median of 1 day in non-emergency cases. Full board approval from an institutional review board in non-emergency cases was 7 days. DISCUSSION/SIGNIFICANCE: These results generally align with previous reports on EA submissions received by the FDA. The timelines for the EA process represent an important benchmark both for treatment planning and institutional improvement.

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Regulatory Lens of a QA/QC Project Manager

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OBJECTIVES/GOALS: The primary purpose of the QA/QC Project Manager (PM), appointed under the NCATS UL1 administrative supplement award, is to facilitate quality and timely NCATS prior approval submissions preventing study start delays. Other goals include supporting these projects' IRB applications and monitoring to ensure data quality and compliance. METHODS/STUDY POPULATION: At the Indiana CTSI, the QA/QC PM is assigned to the Regulatory Knowledge and Support program (RKS) and functions as a unique regulatory service provider. Through monitoring, auditing, and personalized consultations, the IN CTSI QA/QC PM provides study teams with regulatory, GCP, and other compliant study conduct insights while managing NCATS prior approval and RPPR submission quality and timeliness. In contrast to many CTSAs, this role is uniquely situated within RKS and provides QA/QC support through a regulatory lens. The Indiana CTSI QA/QC PM serves on the CTSA QA/QC Lead Team collaborating with NCATS and other CTSA QA/QC personnel. The Lead Team engages with NCATS to host monthly/quarterly meetings and participate in a discussion forum of NCATS and other CTSA QA/QC personnel. RESULTS/ANTICIPATED RESULTS: Not all CTSAs employ the QA/QC PM as regulatory support and the role and skill sets at each CTSA vary, yet the collaborative nature of these individuals across the CTSAs facilitates sharing of resources and knowledge. While prior approval and RPPR submissions vary widely, the QA/QC PMs can rely on their counterparts for guidance complying with the same regulations and policies within unique research settings and institutional nuances. The IN CTSI QA/QC PM, in collaboration with the QA/QC Lead Team, provided quality assurance revisions to the NCATS prior approval instructions which were adopted and published by NCATS January 2022 for implementation at all CTSAs. Ongoing, quality control efforts are accomplished through education, monitoring, and regulatory consultations. DISCUSSION/SIGNIFICANCE: As the research environment evolves, the QA/QC PM responsibilities shift in response to needs within RKS and NCATS. The versatility of the position enables QA/QC to occur at all stages of a study. QA/QC strategies aim to facilitate communication, quality NCATS prior approval and RPPR submissions, and compliance with proposed study conduct.

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Addressing the Regulatory Needs and Challenges of Academic Researchers by Creating a One-Stop Shop Web Portal

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OBJECTIVES/GOALS: To identify challenges faced by academic researchers in accessing online regulatory information and/or tools to advance their research work to develop a free, publicly accessible, interactive web portal that provides regulatory support. METHODS/STUDY POPULATION: The Regulatory Knowledge and Support core of the Southern California Clinical and Translational Science Institute interviewed five local research professionals. These interviews guided the development of a Qualtrics survey, consisting of multiple responses and open-ended questions, submitted to our local institutional review board (IRB). After receiving IRB approval, the survey was disseminated via email, newsletters, flyers, and presentations targeting researchers at academic institutions and members of clinical and translational science hubs. Survey data will be used to identify the challenges academic researchers face in finding regulatory resources and to compile the types of regulatory information or tools they would find helpful for their research. RESULTS/ANTICIPATED RESULTS: According to the interviews, researchers with extensive involvement in clinical trials found regulatory resources easily accessible compared to those with less experience. Additionally, they all stated having a colleague or regulatory specialist whom they can consult about regulatory requirements. Insights from these initial interviews confirmed the need to obtain a comprehensive view across research professionals. Anticipated results will show the challenges in accessibility, source, and type of regulatory resources researchers typically encounter. It is also anticipated that researchers will share what kinds of resources they would find most useful for their work. Ultimately, the information and tools identified as essential by survey takers will be collected and incorporated into the web portal. DISCUSSION/SIGNIFICANCE: Academic researchers find navigating through regulatory hurdles persistently challenging when translating their work from bench to clinic, especially since academia is typically resource-constrained. Findings from this study will allow the creation of a web portal for researchers that is broadly accessible and meets their regulatory needs.

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Analysis of Clinical Outcome Assessments in Clinical Trials for Huntington's Disease

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OBJECTIVES/GOALS: Examine the use of Patient-Reported Outcomes (PRO) in Huntington's Disease (HD) clinical trials (CT) and compare across time and sponsor types. METHODS/

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