

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.

509

### Regulatory Lens of a QA/QC Project Manager

Rachel Bennett<sup>1</sup> and Christine Segó Caldwell<sup>2</sup>

<sup>1</sup>Indiana University and <sup>2</sup>RKS Program Manager, Indiana University School of Medicine

**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.

510

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

Karen Manrique and Eunjoon Pacifici

University of Southern California

**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.

511

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

James Kim and Nancy Pire-Smerkanich

University of Southern California

**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/**