regulations, while more advanced regulations cover adverse event reporting and premarket requirements. DISCUSSION/SIGNIFICANCE OF IMPACT: Cosmetics, supplements, and homeopathic products lack transparency regarding safety and quality requirements. This project establishes a benchmark for cosmetic product regulation, addressing a historic gap in oversight. The benchmark supports regions with less developed regulatory policies to enhance cosmetic safety and quality standards.

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Incorporating user feedback to enhance OpenRegSource – A researcher's portal to regulatory information

Karen Manrique and Eunjoo Pacifici
University of Southern California

OBJECTIVES/GOALS: This study aims to gather user feedback from clinical research professionals on the usefulness and relevance of regulatory resources found on a new regulatory web portal, OpenRegSource, to enhance its usability, thereby advancing this project from the initial to the full implementation phase of the implementation science framework. METHODS/STUDY POPULATION: The Regulatory Knowledge and Support core of the Southern California Clinical and Translational Science Institute developed a regulatory web portal called OpenRegSource to help researchers gain basic regulatory information prior to professional and/or paid consultation. Before publicly launching, a virtual focus group (FG) composed of 21 members of the local clinical research workforce was given two weeks to explore the web portal and answer three surveys. Two other research professionals also gave feedback outside of the focus group. The user feedback data was analyzed and discussed by the web portal project team. Updates were then made accordingly. Once the portal was launched, a plan was implemented to collect usage metrics and additional feedback for continuous improvement. RESULTS/ANTICIPATED RESULTS: Of the 21 FG participants, 20 completed the feedback survey specifically for their experience with the web portal. 65% (13/20) said the number of resources was just right. 90% (18/20) found the resources to be very relevant to their respective topics. 85% (17/20) found the resources very useful and somewhat useful to their daily work activities. 75% (15/20) found the organization of the portal to be good or very good. 85% (17/20) found it very easy and somewhat easy to navigate the web portal. 90% (18/20) found the portal to be effective in providing its audience with a basic understanding of regulatory requirements. 95% (19/20) found the portal useful for novice research professionals. 85% (17/20) found the web portal useful overall. Participants were also able to provide commentary feedback for specific pages. DISCUSSION/SIGNIFICANCE OF IMPACT: Obtaining stakeholder input during the development of a resource or tool is essential to ensure the final product meets user needs and is effectively utilized. In this case, involving the feedback of clinical researchers will help improve OpenRegSource to better facilitate the advancement of their work.

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Improving the compliance of informed consent documentation for expanded access patients

Elias Samuels, Misty Gravelin, Ellen Champagne, Dorsa Haj Ghaffari and Jeanne Wright
Michigan Institute for Clinical & Health Research

OBJECTIVES/GOALS: The informed consent (IC) process is similar between clinical trials and expanded access (EA), which allows clinical use of investigational products outside studies. Physicians face unique barriers to IC in clinical environments. This project assesses IC documentation, identifies potential barriers, and evaluates efforts to improve compliance. METHODS/STUDY POPULATION: This is a continuous quality improvement project. To assess the compliance of IC processes for EA patients, informed consent documents signed by EA patients in 2023 were collected and reviewed against institutional standards. Five components of each form were evaluated, and the number and type of noncompliant documentation were tracked. Five physicians who provided EA treatments in 2023 were interviewed and the transcripts were analyzed to identify barriers to physician's and teams' IC processes. Efforts made to address these barriers and improve the compliance of informed consent documentation are being tracked and trends in compliance are being evaluated. RESULTS/ANTICIPATED RESULTS: Sixty seven (67) signed informed consent documents for EA treatments were systematically reviewed and 34% were found to be compliant in all key aspects assessed. Analyses of interview notes, transcripts, and memos identified barriers to informed consent processes for expanded access treatments, including the infrequent or irregular occurrence of EA treatments making it difficult for care teams to develop and maintain their understanding of IC process and resources. Efforts made to improve compliance by pre-populating available information into informed consent documentation and removing unnecessary boxes in these forms may have driven improvement in compliance with further efforts underway. DISCUSSION/SIGNIFICANCE OF IMPACT: This project evaluated the compliance of IC documentation for EA treatments and identified drivers affecting physicians' IC processes for these patients. Different strategies to improve the compliance of IC documentation were evaluated and potential best practices for EA support were identified.

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Application of public health theory to advance the diffusion of plain language summaries (PLS) in clinical research

Araksi Terteryan[1] and Nancy Pire-Smerkanich[1,2]
[1]University of Southern California and [2]Southern California Clinical and Translational Science Institute

OBJECTIVES/GOALS: Diffusion of innovations (DoI) posits that new health-related ideas spread through communities over time and across stages of adoption. We will apply DoI to understand a paradigm shift toward seeing participants as partners in clinical research, specifically through delivery of plain language summaries of results. METHODS/STUDY POPULATION: The return of results in lay language (plain language) to clinical trial participants represents a paradigm shift in the EU and now the USA. We will conduct a systematic review of the implementation of "lay summaries" or "plain language summaries" in different jurisdictions to understand current regulatory influence. We will then review PLS samples and published studies to determine the rate of adoption by industry and non-pharmaceutical company sponsors. Using the DoI framework, groups will be placed in an adopter category. Finally, we will employ an implementation science approach to understand the diffusion process and the translation to participants, laying the groundwork for a culture of change in medical product development. RESULTS/ANTICIPATED RESULTS: Our search on PubMed using key terms "Diffusion of Innovation" and "Plain Language Summary" did not produce any relevant results in the context of clinical trials in

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