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

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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

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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

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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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the USA, which illustrates a gap in the literature and application of this theory in this context. In the future analyses, we will examine factors influencing the adoption stage and outcomes, such as regulatory action, what best practices have been defined/implemented (if any), culture shifts in the context of clinical research, health communications, and inclusion of patient voices in clinical research. Our analysis will include a network analysis to evaluate characteristics that influence adoption of PLS in clinical research. We hope to identify who is at the forefront of innovation and why. DISCUSSION/SIGNIFICANCE OF IMPACT: Novel application of DoI theory will help lay the groundwork for a culture of change in patient-focused drug development, specifically for the dissemination of results to patients. In future studies, we plan to develop a tailored framework for the inclusion of PLS as part of a paradigm shift in the patient-focused drug development process.

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Plain language summaries (PLS): Practices, limitations, and strategies

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OBJECTIVES/GOALS: This literature review examines the current landscapes of plain language summaries (PLS), which are used to make research accessible to nonexpert audiences. It aims to identify gaps in their implementation by focusing on challenges related to consistency, accessibility, and quality across fields. METHODS/STUDY POPULATION: A systematic search was conducted using databases such as PubMed and Google Scholar, employing key search terms like "plain language summaries," "scientific communication," "health literacy," "patient education," "knowledge translation," "accessibility in research," "public engagement," "layperson," and "lay summaries." Literature from multiple sources (pharmaceutical companies/industry, nonprofit organizations, private–public partnerships, and government) was compared to assess the gaps in current PLS best practices. RESULTS/ANTICIPATED RESULTS: Search results yielded 95 articles. Of those, 37 articles fit the criteria, highlighting critical gaps in PLS implementation for clinical research. Preliminary findings suggest a lack of standards and guidelines, as well as a need for more research on the effectiveness of PLS for improving knowledge transfer and patient engagement. Key limitations were identified for investigator-initiated trials (IITs). A best practice table, comparing recommendations from each group of sources, was developed with suggestions for writing effective PLS. While there is consensus on some principles (i.e., importance of simplicity), differences emerge regarding optimal length and the use of layperson glossaries and graphics. The table aims to serve as a guide for creating effective and standardized PLS across fields. DISCUSSION/SIGNIFICANCE OF IMPACT: There are limited PLS best practice resources tailored for IITs. These findings could lead to more practical tools and a streamlined approach to enhance communication strategies for lay audiences. This would benefit trial participants and community members who rely on this information and bridge the gap between scientific communities and the public.

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Mental health care for patients with potential decision-making capacity compromise: Challenging Ontario's mental healthcare legislation

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OBJECTIVES/GOALS: How do we care for a patient whose mental health is deteriorated such that their decision-making capacity may be compromised? The high-potency opioid crisis in Ontario demands that we provide effective care for the affected population. We must also avoid patients having a subjective experience of coercion and must protect their human rights and dignity. METHODS/STUDY POPULATION: Ontario's legislation governing mental health care will be explored: the Ontario Mental Health, Healthcare Consent, and Substitute Decisions Acts. We will identify best practices/learning across locales. Patients who have been involuntarily treated/confined will be welcomed to voice what the law should contain. International strategies for: coercion reduction practices, advanced care directives, less prohibitionist care culture, and supports for social determinants of health (SDH) may also help Ontarians. Patients, family members, law enforcement, judiciary, community agencies, and healthcare professionals will be invited to contribute via focus groups to drafted mental health care legislative improvements. Thus, we ensure law enforces patient-defined quality care and practical workflows. RESULTS/ANTICIPATED RESULTS: We hope to emerge from our focus group consultation with draft legislative and procedural edits for Ontario's mental healthcare laws to ensure that the laws protect human rights and that the laws reflect patient-defined needs. We must ensure controls are in place to de-risk power imbalances and limit the incidence of potential procedural misuse. We intend to design legislated procedures to ensure that people don't get inappropriately involuntarily confined/treated. We will incorporate the perspectives and lived experiences of patients who have experienced involuntary treatment and/or involuntary medical confinement (locally in a focus group(s)) and internationally (in literature) to inform this legislative development. DISCUSSION/SIGNIFICANCE OF IMPACT: We will learn from engaged stakeholders about how to shape Ontario's legislation to support quality mental health care. We hope to identify and draft legislation improvements that voice what patients and their families' value, drafts informed by evidence-based best practices and informed innovation. Via inclusion, we create a policy that serves.

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An international comparison of the efficacy of regulatory mechanisms regarding traditional medicines (TM)

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OBJECTIVES/GOALS: To identify the most impactful regulations regarding the approval and marketing of TMs in the U.S., E.U., Japan, Australia, China, and India enacted between the years 2000 and 2022. To explore TM-related regulations in new countries, Japan and Australia, for their novel regulatory approaches in

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