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Goldilocks analysis: Translational implications of post-approval FAERS data on safety labeling of PD-1 inhibitors

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OBJECTIVES/GOALS: To evaluate the incremental value of post-approval adverse event reporting and population exposure in characterizing a drug's safety profile, using PD-1 inhibitors as a model class to assess how continued clinical experience enhances safety knowledge. METHODS/STUDY POPULATION: Using PD-1 inhibitors as a model, we are exploring FDA Adverse Event Reporting System (FAERS) database to capture real-world post-marketing safety information on drugs in this class approved by FDA since 2014. Findings from FAERS will be compared with the safety profile in the initial package insert used for FDA approval for each of the drugs. The nature of novel adverse events will be characterized and compared with the extent of exposure as determined through the use of marketing databases (e.g., IQVIA, Cortellis). We seek to identify relationships between the observation of novel adverse events and levels of population exposure. We will explore whether the safety experience with older products in this drug class could be predictive of safety outcomes in newer class candidates. RESULTS/ANTICIPATED RESULTS: The findings would aim to inform the development of a "Goldilocks" approach (the value of incremental exposures), to explore how post-marketing exposure impacts changes in the safety profile of drugs in this class. Results will be used to explore whether a particular level of post-approval exposure is predictive of the occurrence of novel adverse events, excluding idiosyncratic events, among PD-1 inhibitors. DISCUSSION/SIGNIFICANCE OF IMPACT: The study will guide the understanding of the incremental value of additional population exposure to refining the safety profile within a class of well-defined drugs and may inform a systematic approach towards consistent class labeling.

Education, Career Development, and Workforce Development

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Training the next generation of clinical research nurses

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OBJECTIVES/GOALS: To evaluate an undergraduate nursing externship revised to integrate the updated International Association for Clinical Research Nursing (IACRN) curriculum, designed to strengthen knowledge, skills, and career readiness for the specialty of clinical research nursing (CRN). METHODS/STUDY POPULATION: A 192-hour, 8-week summer externship was conducted at the Rockefeller University (2022–2025), accepting two rising junior nursing students annually. The curriculum included lectures on clinical research principles and processes, IRB observation, informed consent simulation, a mock IRB, and rotations in bionutrition, pharmacy, bioinformatics, and laboratory processing. Externs also completed the Collaborative Institutional Training Initiative on Good Laboratory Practice and lab safety modules. Program evaluations included a pre- and post-test, a 30-item knowledge exam to assess understanding of clinical research concepts, as well as ratings by the mentors across professional competencies, and open-ended questions to obtain feedback from the externs. RESULTS/ANTICIPATED RESULTS: Externs' knowledge scores rose from pretest averages of 58–70% to post-test scores of 73–86%, a gain of ~20 points. Surveys revealed an improved understanding of research processes, particularly in areas such as informed consent and protocol design. Hands-on activities, lab processing, dietary simulation, and pharmacy were most valued. Mentors consistently rated externs as "Good" to "Excellent" in terms of professionalism, adaptability, and teamwork. Externs reported a greater interest in CRN careers and a deeper appreciation for the specialty's breadth. DISCUSSION/SIGNIFICANCE OF IMPACT: This externship, which embedded updated IACRN competencies at the undergraduate level, successfully enhanced knowledge and understanding of the field. Its innovative, replicable model demonstrates how early exposure can expand the clinical research nursing pipeline and prepare future CRN leaders.

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Development and implementation of training in best practices for study documentation: A new resource for the research workforce

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OBJECTIVES/GOALS: To develop and implement a new course to fill an identified gap in the present IU School of Medicine Clinical Research Staff Education program, enhance data accuracy, and minimize audit findings. The goal was to provide a robust and thorough training on study orientation, source documentation, and adhering to ALCOA+ principles to clinical research staff. METHODS/STUDY POPULATION: A 90-minute presentation titled Best Practices for Study Documentation, or Level 1.5 because it fills the gap between the currently offered Level 1 and 2 courses, was developed by monitoring team members with input from the Director of Research Staff Education. A pilot session was presented to senior research staff for feedback prior to launch. The 90-minute presentation was designed with interactive polls to assess attendees' research and documentation experience at the start and to maintain engagement throughout the session. Attendees receive a post-course evaluation survey along with a certificate of attendance. The course is offered every two months. Completion of Level 1 training is a prerequisite and aimed at those who are three to six months of starting in research at Indiana University School of Medicine. RESULTS/ANTICIPATED RESULTS: Results from the post-course evaluation survey described Best Practices in Study Documentation as engaging, informative, and valuable for new and experienced research staff. Many learners reported increased confidence, improved understanding of documentation and regulatory requirements, greater awareness of the