

Taking Preemptive Action with Monthly Compliance Newsletters for Oncology Clinical Trials

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Background

- ❖ The UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC) Data and Safety Monitoring Committee (DSMC) includes both the DSMC Monitoring Office and the DSMC Education and Training Office (ETO). The DSMC is responsible for monitoring and auditing of interventional institutional and NCI clinical trials for data validity, trial conduct, and safety reporting. The DSMC reviews all protocol violations (PV) as well as consent and privacy incidents (PI) that occur for all oncology trials to ensure that a root cause analysis has been completed, and a corrective and preventative action (CAPA) plan is implemented. The HDFCCC DSMC tracks PVs and PIs to identify trends and develop training and other strategies to improve compliance.

Goals

- ❖ Develop a simple teaching tool to educate HDFCCC clinical research staff members about recurring PVs and PIs to reduce incidence and improve overall protocol compliance.

Solution and Methods

- ❖ The DSMC ETO has developed a monthly newsletter (“DSMC Recipe for Compliance”) for circulation to the UCSF HDFCCC clinical research staff since 2022. These newsletters present PV and PI trends based upon IRB submissions from oncology interventional trials. The monthly newsletter template includes: (1) Selected PV or PI, (2) Action taken, (3) Reminders for prevention, (4) Resources (i.e., Guidelines), (5) Training, (6) Suggested CAPA, and (7) Reference Link (which includes a hyperlink to previous similar PVs reported and their CAPAs). This information is provided to inform all study teams and help mitigate future compliance issues through resources such as retraining courses, guideline reviews, and other educational initiatives. Additionally, these newsletters provide visual data trends on PVs and PIs reported and compliance issues identified during DSMC monitoring visits on a quarterly basis.

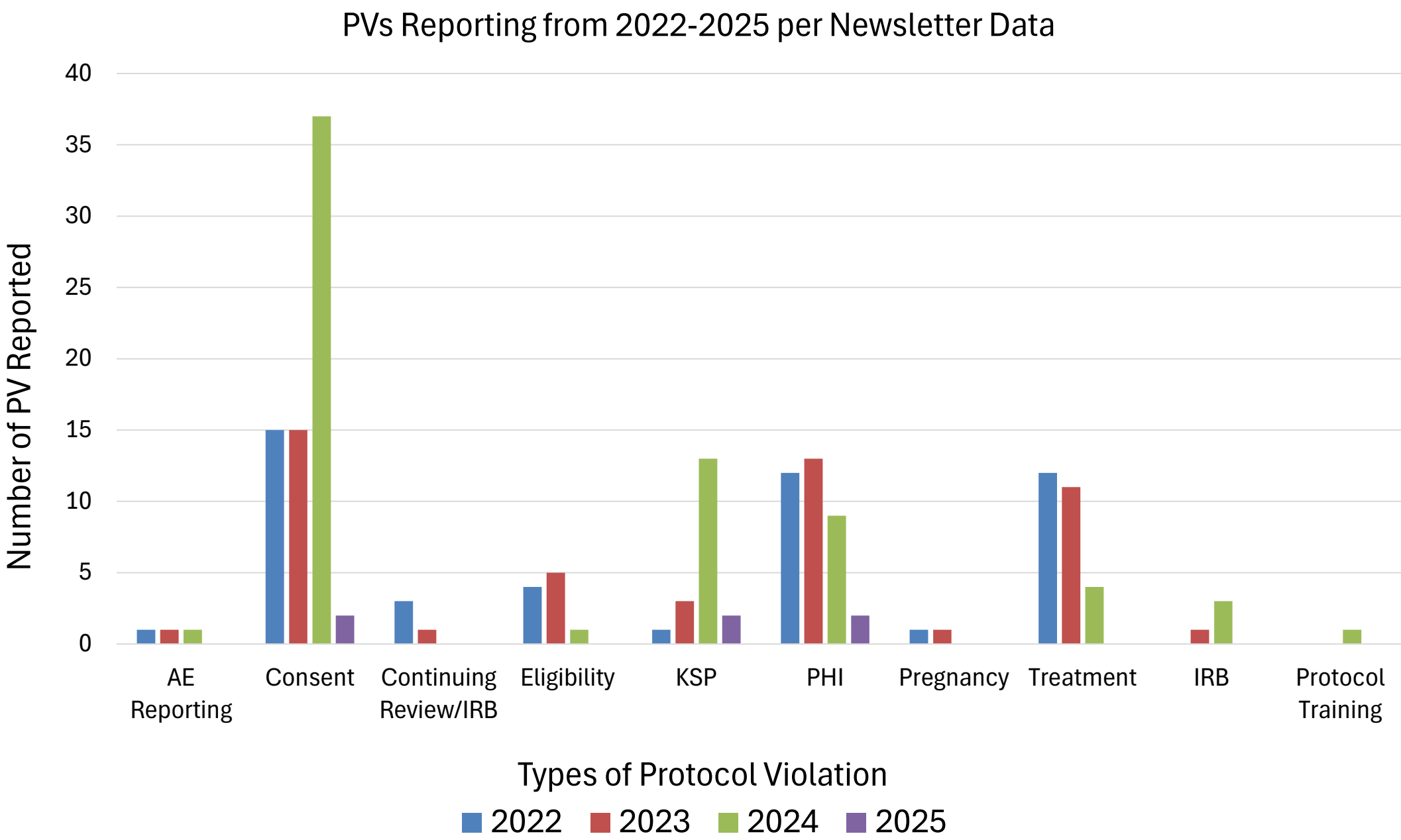
Lessons Learned and Future Directions

- ❖ Future directions include the continuation of quarterly data trend reports from PVs, PIs, and the DSMC monitoring visit reports to track compliance issues trends. Additionally, feedback will be solicited from study teams on how this newsletter can be improved to better capture helpful compliance information.

Outcomes

- ❖ The newsletter has identified the following common PVs and PIs reported by oncology trials since inception from April 2022 to February 2025.

Type of Protocol Violation Listed in the Newsletter	Years ‘DSMC Recipe For Compliance Newsletter’ Issued			
	Apr-Dec 2022	Jan-Dec 2023	Jan-Dec 2024	Jan-Feb 2025
AE Reporting	1	1	1	0
Consent	15	15	37	2
Continuing Review / IRB	3	1	0	0
Eligibility	4	5	1	0
KSP	1	3	13	2
PHI	12	13	9	2
Pregnancy	1	1	0	0
Treatment	12	11	4	0
IRB	0	1	3	0
Protocol Training	0	0	1	0



- ❖ The data indicates that the compliance issues highlighted in the newsletter have been practical for study teams in reviewing effectiveness of CAPAs and working towards improving study procedural compliance rather than noting specific compliance documentation.