<table>
<tr><td colspan="2">Amendment Training SOP (PM-9) Audit
Conducted Q1 FY 2024
[Previous audit conducted Q2 FY 2023 – those results in green]

73 protocol amendments reviewed (25 major amendments* / 14 minor amendments / 34 administrative amendments)
66 protocol amendments reviewed (28 major amendments* / 35 minor amendments / 3 administrative amendments)</td></tr>
<tr><td colspan="2">Random selection of 73 [66] out of over 700 [127] amendments approved between May 1, 2023 – September 30, 2023

Training records were available for 34 (15 major/12 minor/7 admin) amendments (47%)
[42 (17 major/22 minor/3 admin) amendments (63%)]

• There was adequate training documentation for 21 (4 major/11 minor/ 6 admin) amendment (29%)
[29 (8 major/18 minor/3 admin) amendments (44%)]
• Training was conducted (out of 34 [42] with documentation):
○ via email for 26 (10 major/10 minor/6 admin) (76%)
[33 (13 major/17 minor/3 admin) amendments (79%)]
○ in person for 3 (2 major/ 1 admin, done during SIV) (10%)
[3 (2 major /1 minor) amendments (10%)]
○ via email and in person for 4 (3 major/1 minor) (12%)
[8 (4 major /4 minor) amendments (19%)]
• Training tool was used for 3 (all major) (10%)
[3 (1 major /2 minor) amendments (7%)]
• Training log was used for 10 (7 major/ 2 minor/ 1 admin) (29%)
[13 (7 major /6 minor) amendments (31%)]</td></tr>
<tr><td>Overall Findings
(major/minor)</td><td>• Amendment training records were not located for 39 (10 major/ 2 minor/ 27 admin) amendments (53%)
[24 (11 major /13 minor) amendments (36%)]
• Of the 34 (14 major/ 12 minor/ 7 admin) 42 (17 major /22 minor/3 admin) amendments that had training records available for review:
○ Amendment training documentation was not adequate or late for 11 (32%) [9 (21%)] major, / 1 (3%) [4 (10%)] minor and 1 (3%) admin</td></tr>
<tr><td>Detailed Findings</td><td>• “Read Receipt” return emails or primary training email were not available in regulatory files.
• Amendment training was conducted more than 5 business days after the amendment IRB approval.
• Only training log was available in regulatory files without specifying the process used to communicate amendment changes.
• Training documentation did not specify who is responsible for action items and in what timeframe.</td></tr>
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* Major amendments include but not limited to changes to eligibility, study design, drug administration, dose, study procedures, study related risks, informed consent document and/or requirement for reconsent.