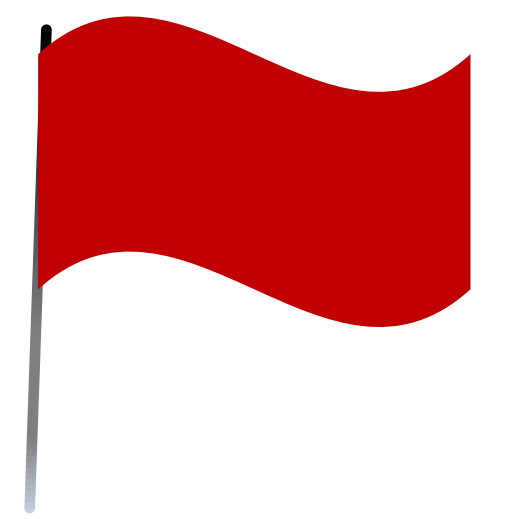


Different Last 4 of ID Provided: A Red Flag for the Professional Subject?



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OBJECTIVE To examine if subjects that do not provide a last four of social security number or other ID at one or more visits, or provide a different last 4 of ID at a visit, are more likely to present at multiple sites or change study indications. **METHODS** We looked at data within a subject registry that reports on a subject's history by searching for identifiers provided at previous visits. We pooled data for all subjects entered from January 2012 until November 2023 - specifically matching subject visits that were considered Virtually Certain (greater than 1 in 10M due to chance) and Probable (between 1 in 1M and 1 in 10M due to chance). Data was broken down into three groups for last four of ID reported: "1234-1234" (same last 4 of ID between visits), "1234-XXXX" (unreported last four of ID at either visit), or "1234-4321" (different last four of ID between visits). We specifically looked at whether visits within each group occurred at a different site or for a different indication. We also compared these rates to subjects who provide matching or non-matching initials (labeled "ABC-ABC" and "ABX-XYZ" respectively). **RESULTS** Of 158,829 matched entries that occurred within this timeframe, 25% (38,992) of these matches included a non-matching last four of ID or a non-reported ("XXXX") last four of ID. We chose 3 months at random to sample from for accuracy of this flag. For these 3 months, to our knowledge, 15% of subjects with mismatched last 4 of ID were continued in the study (however it is possible we were left out of the loop on some sponsor correspondence on the remaining cases). For subjects who present to multiple sites and change indications between visits, it is significantly more likely that the last four of ID is not provided (11.0%, vs 9.4%, p<0.0001) or provided differently at the next presentation (21.0% vs 9.4%, p<0.0001). ABC-XYZ occurs 31.0% of time (often because one site will put ABC and another A-C). This is not a specific enough red flag and often from the site user incorrectly entering one of the initials (no middle initial, hyphenated last name, etc.). On the contrary, only 8.7% go 1234 to 4321, almost always coming from the subject themselves and therefore a better indicator of possible deception. **DISCUSSION** Certainly, site user error or non-collection of last 4 of ID may contribute to these findings. However, when subjects change their last 4 of social security or other ID, this may be a surrogate for attempted deception by a professional subject. Flagging these subjects, especially those who provide a different last 4 of social security or other ID is a valid way for a subject registry to alert investigators and Sponsors to potentially problematic subjects prior to randomization. Based on a small sampling of site/sponsor handling of subjects flagged for mismatched last 4 of ID, our flag appears to be accurate, but we cannot quantify with certainty exactly how accurate.

BACKGROUND

Duplicate and professional subjects are a significant problem in clinical trials, particularly in studies with subjective endpoints, such as in CNS or pain.¹

Data integrity is compromised when professional subjects purposely deceive with regard to inclusionary symptoms, excluded conditions, adherence to investigational product or previous study participation.² There are subject registries that use partial identifiers to track duplicate and professional subjects across sites and sponsors. However, duplicate and professional subjects may choose to falsely report these partial identifiers or not report them at all (typically last four of ID), in an attempt to game the system and not be caught with a history of exclusionary conditions.³

METHODOLOGY

Our subject registry collects subject-authorized Initials, DOB, Sex, Height and last 4 of Social Security Number (SSN) or other ID and compared with identifiers provided at previous visits. We looked at pooled data for all subjects entered from January 2012 until November 2023 - specifically matching subject visits that were considered Virtually Certain (less than 1 in 10M due to chance) and Probable (between 1 in 1M and 1 in 10M due to chance). Data was broken down into three groups for last four of ID reported: "1234-1234" (same last 4 of ID between visits, our Green Flag group), "1234-XXXX" (unreported last four of ID at either visit, our Yellow Flag group), or "1234-4321" (different last four of ID between visits, our Red Flag group).

We specifically looked at whether visits within each group occurred at a different site or for a different indication. We also compared these rates to subjects who provide matching or non-matching initials (labeled "ABC-ABC" and "ABX-XYZ" respectively) and examined findings related to subjects presenting to different sites or for different indications, independent of Last Four of ID reporting.

To check the accuracy of this flag, we selected 3 months at random to see if subjects were actually excluded from the study. For these 3 months, to our knowledge, 15% of subjects with mismatched last 4 of ID were continued in the study (however it is possible we were left out of the loop on some sponsor correspondence).

We also examined instances of patients changing indications between visits or visiting different sites regardless of ID presentation.

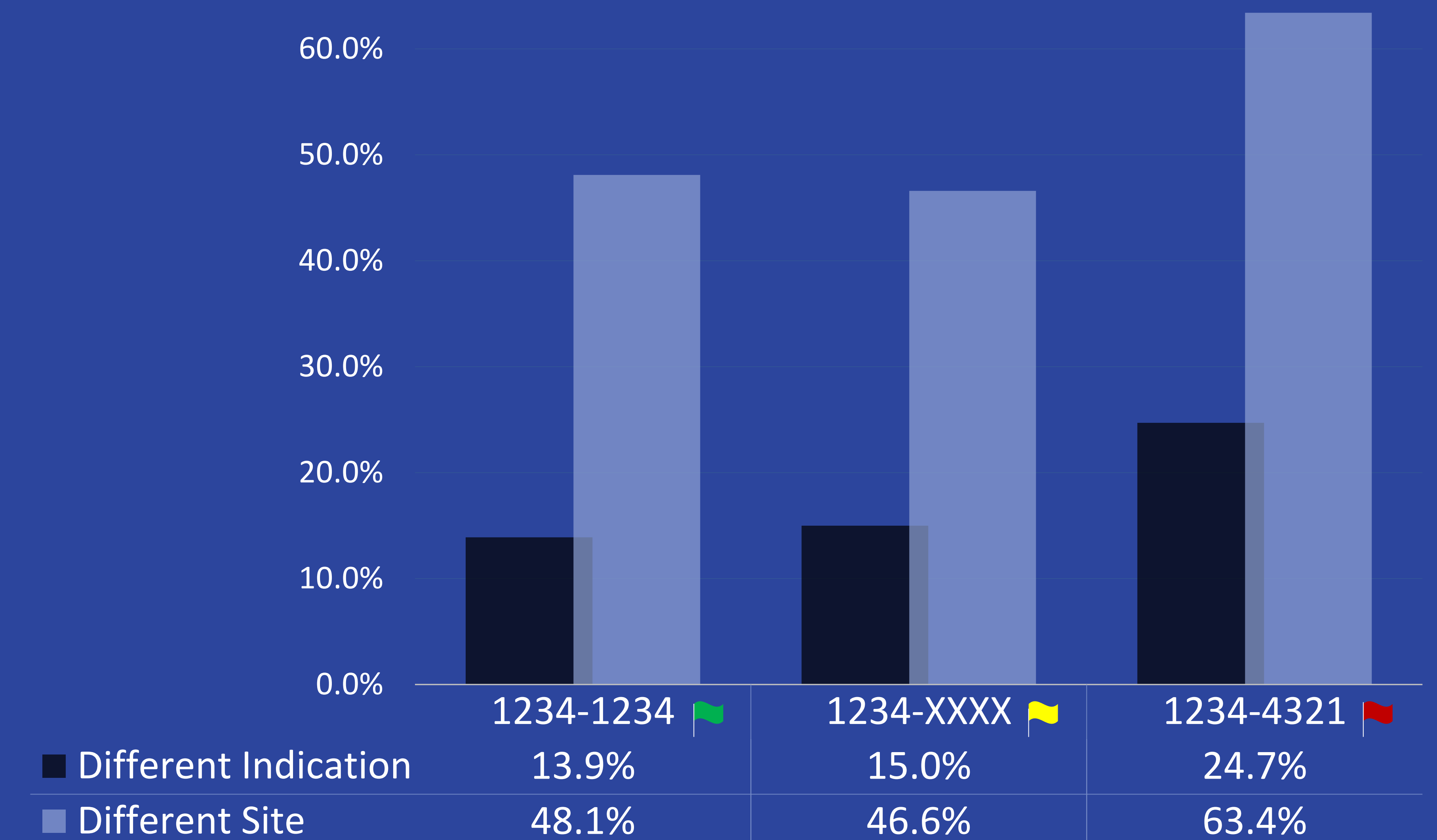
ANALYSIS

Of 158,829 matched entries that occurred within this timeframe, 25% (38,992) of these matches included a non-matching last four of ID or a non-reported ("XXXX") last four of ID.

- In the "1234-1234" group, 13.9% (n=16,680) of the time, the match was for a different indication and 48.1% (n=57,683) of the time, the match was at a different site.
- In the "1234-XXXX" group, 15.0% (n=3,773) of the time, the match was for a different indication and 46.6% (n=11,703) of the time, the match was at a different site.
- In the "1234-4321" group, 24.7% (n=3,424) of the time, the match was for a different indication and 63.4% (n=8,787) of the time, the match was at a different site.

For subjects who present to multiple sites and change indications between visits, it is significantly more likely that the last four of ID is not provided (11.0% vs 9.4%, p<0.0001) or provided differently at the next presentation (21.0% vs 9.4%, p<0.0001).

Indication and Site Changes for Subjects Reporting Same vs. Divergent Last Four of ID to a Subject Registry



SUPPLEMENTARY FINDINGS

Changing Initials: Differing initials, e.g. ABC-XYZ, occurs 31.0% of time (often because one site will put ABC and another A-C). This is not a specific enough red flag and often from the site user incorrectly entering one of the initials (no middle initial, hyphenated last name, etc.). On the contrary, only 8.7% go 1234 to 4321, almost always coming from the subject themselves and therefore a better indicator of possible deception.

Changing Indications/Diagnoses: Subjects may present to a different site or for a different indication, regardless of ID reporting. We found that in cases where a subject went to the same site, they presented with a different indication 8.53% of the time. This number jumps up to 21.64% when presenting to a different site.

CONCLUSIONS

- While site user error or non-collection of last 4 of ID may contribute to these findings, subjects who change their last 4 of SSN/other ID may be a surrogate for attempted deception by a professional subject.
- Our flag for a subject changing last 4 of ID appears to be a valid way for a subject registry to alert investigators and Sponsors to potentially problematic subjects prior to randomization.
- A related finding - that subjects who go to different sites present with a different indication over 20% of the time - is an area for further study, as frequently changing diagnosis/indication is very likely a marker for a professional subject.

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