

Are your SF Ratios Increasing?

The Serial Screener, A Variant of the Professional Subject

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Abstract: Objective: To present the case history of a Serial Screener and discuss steps that might be taken to detect such persons and mitigate the effect that they and other professional subjects may have on clinical trial enrollment and outcomes. **Background:** Methods: Duplicate and professional subjects are a significant problem in clinical trials, where they can affect subject safety and data integrity. CTSdatabase, one of several commercially available subject registries, detected a man who has been to at least 13 different sites at least 29 times in 4 years, and for 7 different indications, including schizophrenia, migraine and shift work disorder. We will present a case history. **Results:** In late 2024, CTSdatabase reported a professional subject screening for a Shift Work Disorder study who had presented 29 different times, often in the same week, to a remarkable 15 different sites over a span of 5 years. The majority of presentations were screening or prescreening for schizophrenia, but he also screened for a Migraine study and prescreened for studies of Bipolar Affective Disorder and Borderline Personality Disorder as well as Healthy Volunteer and vaccine studies. The outcome of all these pre-screenings are unknown. However, every study he screened for resulted in a screen failure. **Conclusion:** This subject should have known that he would be tracked by our registry as he signed an authorization each time and would presumably have been notified if he showed up elsewhere. We propose that the motivation of this subject was to sign consent and collect stipends, even if it was soon discovered that he was not an appropriate candidate for the study: A Serial Screener.

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
- These prospective subjects can change their presentation or magnify their symptoms as they go from site to site.
- Duplicate subject registries, such as CTSdatabase, are available to detect such subjects at screen, before they can adversely affect study data integrity.
- We have found that in studies of persons with schizophrenia, the duplicate subject issue is most pronounced, with these subjects often accounting for more than 10% of screened subjects.²
- Per Getz (2019), CNS studies saw the most significant increases in screen failure (SF) rates, increasing from 30% in 2012 to 57% in 2019.³

OBJECTIVE

To present the case history of a Serial Screener and discuss steps that might be taken to detect such persons and mitigate the effect that they and other professional subjects may have on clinical trial enrollment and outcomes.

METHODOLOGY

A subject registry (CTSdatabase) was integrated into screening procedures for a Shift Work Disorder study to facilitate eligibility assessment, in accordance with the study protocol. Following informed consent, which was IRB-approved, the subject's partial identifiers were entered into the registry to obtain a report detailing past visits. A matching algorithm then identified Virtually Certain (less than 1 in 10 million odds to occur by chance) match history and the site printed the Match Report.

The registry then sent the site and Sponsor team an email detailing the protocol-specific exclusions (i.e., "Dear Dr Jones: This subject appears to meet Exclusion #3: "Lifetime history of or presentation consistent with schizophrenia or any other psychotic disorder; Bipolar I or II disorder, or borderline, antisocial, or narcissistic personality disorder..."")

Visit Date: 26-Feb-2025

Protocol: DEV-TEST-1

Site: Test Site 1

Subject Number: XXX-111

STUDY CRITERIA NOT MET

- The following eligibility criteria have been flagged. Randomization may not occur without prior Sponsor approval:
- Washout Violation: Active in Age-Related Cognitive Decline, Adjustment Disorder, ADHD Study
 - Indications Found: Age-Related Cognitive Decline, Adjustment Disorder, ADHD, Schizophrenia, Migraine
 - Prescreen Visits found that may violate washout, investigation pending.
 - Potentially misreported identifiers: Last 4 of ID

Search Parameters

Initials: KPM

Date of Birth: 11-Nov-99

Sex: M

Height: 175.26 cm

Virtually Certain Matches | Identifiers matched closely enough that the odds are less than 1 in 10 million to occur by chance

Visit Information			Identifiers Reported			Site Information		
Initial Visit	Indication	Last Status	Initials	DOB	ID Match	Site Name	Site Zip	Site Phone
26-Feb-2025	Age-Related Cognitive Decl	*	KPM	11-Nov-99	●	Test Site 1	91403	618.990.2871
09-Jul-2024	PS - Schizophrenia	SF 20-Aug-2024	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
21-Jun-2024	PS - Schizophrenia	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
05-Jun-2024	PS - Schizophrenia	SF 05-Jun-2024	K-M	11-Nov-99	●	ABC Research	90703	562.248.3800
01-May-2024	PS - Schizophrenia	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
30-Apr-2024	PS - Schizophrenia	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
22-Apr-2024	PS - Schizophrenia	PS Fail 22-Apr-2024	KPM	11-Nov-99	●	LA Site	90660	562.628.8801
07-Sep-2023	PS - Schizophrenia	*	KPM	11-Nov-99	●	Bellflower Site	90706	562.249.6956
27-Apr-2023	PS - Schizophrenia	EOS 02-Aug-2023	K-M	11-Nov-99	●	Long Beach Site	90807	562.548.8530
25-Apr-2023	PS - Schizophrenia	SF 25-Apr-2023	KPM	11-Nov-99	●	Glendale Site	91206	688.255.5796
19-Apr-2023	PS - Schizophrenia	SF 13-Dec-2024	KPM	11-Nov-99	×	Orange Site	92668	714.289.1100
09-Mar-2023	PS - Bipolar	*	K-M	11-Nov-99	×	CNS Site	92845	866.267.8742
03-Mar-2023	PS - Schizophrenia	SF 03-Mar-2023	KPM	11-Nov-99	●	123 Research	91845	616.303.6130
09-Jan-2023	Schizophrenia	SF 09-Jan-2023	K-M	11-Nov-99	●	ABC Research	90703	562.248.3800
09-Jan-2023	PS - Schizophrenia	*	K-M	11-Nov-99	●	ABC Research	90703	562.248.3800
09-Oct-2022	Migraine	SF 06-Oct-2022	K-M	11-Nov-99	●	Newport Site	92660	949.752.7910
08-Sep-2022	PS - Schizophrenia	*	KPM	11-Nov-99	●	Santa Ana Site	92705	866.478.8391
22-Aug-2022	Schizophrenia	SF 22-Aug-2022	KPM	11-Nov-99	●	XYZ Research	92805	714.999.6668
17-Jun-2022	Schizophrenia	SF 06-Jul-2022	KPM	11-Nov-99	●	XYZ Research	92805	714.999.6668
28-Mar-2022	PS - Healthy Normal	*	K-M	11-Nov-99	×	CNS Site	92845	866.267.8742
13-Jan-2021	PS Borderline PD	*	KPM	11-Nov-99	●	Santa Ana Site	92706	866.478.8391
12-Jan-2021	PS - Vaccine	*	K-M	11-Nov-99	●	Los Alamitos Site	90720	714.827.3657
12-Jan-2021	PS - Vaccine	*	KPM	11-Nov-99	●	Los Alamitos Site	90720	714.827.3657
18-Dec-2020	PS - Migraine	*	KPM	11-Nov-99	●	Riverside Site	92503	951.374.1190
23-Sep-2020	PS - Bipolar	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
22-Sep-2020	PS - Bipolar	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
03-Mar-2020	PS - Bipolar	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742
27-Jan-2020	PS - Bipolar	*	K-M	11-Nov-99	●	CNS Site	92845	866.267.8742

Figure 1 (or RESULTS): Redacted Match Report for Subject Screening for a Shift Work Disorder Study

DISCUSSION

Most of the prior presentations for this potential Shift-Work Disorder subject were for schizophrenia, but he also screened for a Migraine study and prescreened for studies of Bipolar Affective Disorder, Borderline Personality Disorder, Healthy Volunteer and vaccine studies. The outcome of all the pre-screenings are unknown. However, every study he screened for resulted in a screen failure. Of note, this subject should have known he would be tracked as he signed a registry authorization at each visit. Are the numbers of such Serial Screeners increasing? If so, they could be partially responsible for increasing SF ratios and certainly affect the speed and costs of conducting clinical trials.

CONCLUSION

- This professional subject screened or attempted to screen 29 times, often in the same week, to a remarkable 15 different sites for 6 different indications over a span of 5 years.
- We propose that the motivation of this subject was to sign consent and collect stipends, even if it was soon discovered that he was not an appropriate study candidate.
- CNS Studies have seen a dramatic increase in SF ratios over time.
- Such "Serial Screeners" increase SF ratios and may adversely affect the costs of conducting clinical trials.

REFERENCES

1. Shiovitz TM, Bain EE, McCann DJ, et al. Mitigating the Effects of Nonadherence in Clinical Trials. J Clin Pharmacol. 2016; 56(9): 1151-1164.
2. Steinmetz CB, Shiovitz TM, Steinmiller BL, Trout, LC. Prescreen Use of a Subject Registry in a Large Site Network. CNS Summit 2023, November 8-11, 2023, The Encore, Boston.
3. Getz K. Can Recruitment and Retention Get Any Worse? Applied Clinical Trials. 2019; 28 (12): 12-13.

