Bombshell: New Release of Pfizer Confidential Documents. “10,000 pages out of a cache of over 450,000 of Pfizer-BioNTech vaccine-related data”

Description

On March 1, the eagerly awaited new installment of Pfizer’s documents was made publicly available thanks to the recent judicial ruling. 10,000 pages out of a cache of over 450,000 of Pfizer-BioNTech vaccine-related data, which the FDA relied upon to grant Emergency Use Authorization, can now be reviewed.

The first wave of documents was released last November, following a FOIA request from the plaintiff group, Public Health and Medical Professionals for Transparency (PHMPT), made up of over 30 scientists, medical professionals and academics, led by **Dr. Peter McCullough** and represented by **Aaron Siri**, of Siri & Glimstad LLP.

Last December, I wrote an investigative report for TrialSite News reviewing Pfizer’s cumulative analysis of vaccine adverse events, a shocking 38-page document, which was part of the first wave of released records. The document revealed over 1228 deaths occurring after the administration of the Pfizer BioNTech vaccine with 42,086 individuals (cases) reporting 158,893 vaccine adverse events, many of which were serious, within a 3-month period.

Up until January, the FDA has been fighting a legal battle not to release the data, in breach of FOIA law. The agency ‘dragged their feet’ and was willing to only produce 500 pages a month- meaning the public would have to wait 75 years to see all the documents. On 6 January, district judge, Justice Mark Pittman ordered the FDA to publicly release all the Pfizer documents within 8 months at a rate of 55,000 pages a month.

The following is a summary of my findings after an initial review of the plethora of papers in a limited space of time.

The Case Report Forms (CRFs)

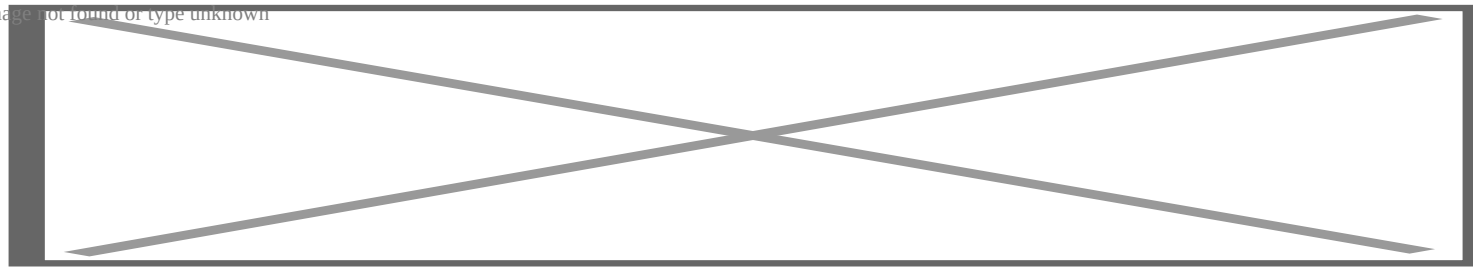
A Case Report Form (CRF) is a printed or electronic document used in clinical trial research to capture standardised clinical data from each patient including adverse events. It’s a critical part of the clinical

trial process and plays an important role in pharmacovigilance.

The majority of CRFs released originated from various trial sites run by Ventavia, one of the clinical research groups contracted by Pfizer to conduct the Covid-19 vaccine trials. The company is currently facing a law suit brought by Brook Jackson, the former Ventavia regional director, turned whistle-blower, who provided The BMJ with a preponderance of internal company documents and photos which revealed the Pfizer contractor's poor laboratory management; their compromising of data integrity and patient safety. Ms Jackson will be talking exclusively with *TrialSite News* in an upcoming interview about this matter. Readers may remember that Facebook literally fact checked *The BMJ* for reporting on this incident. They had no reason to censor the medical journal's article indicating the possibility of programmatic algorithmic bias.

The errors and anomalies

Subject # 11281009 was part of Pfizer's phase 2/3 trials in the healthy population. This cohort were deemed eligible by the clinical judgement of the investigator in meeting the criteria of 'healthy.'



One can see evidence below that this participant was far from healthy, when reviewing their general medical history. The participant was a type 2 diabetic; suffered from angina and had a cardiac stent placement following a myocardial infarction (heart attack).

It's puzzling how a trial investigator from Ventavia would identify this participant as healthy and include them in the trial. There were other participants who I came across, who were included in these phases of the trials (on the healthy population) who had an extensive list of conditions as part of the general medical history. How much pressure was exerted by the sponsor (Pfizer) on the contract research organization and participating trial sites enrolling vaccine trial participants?

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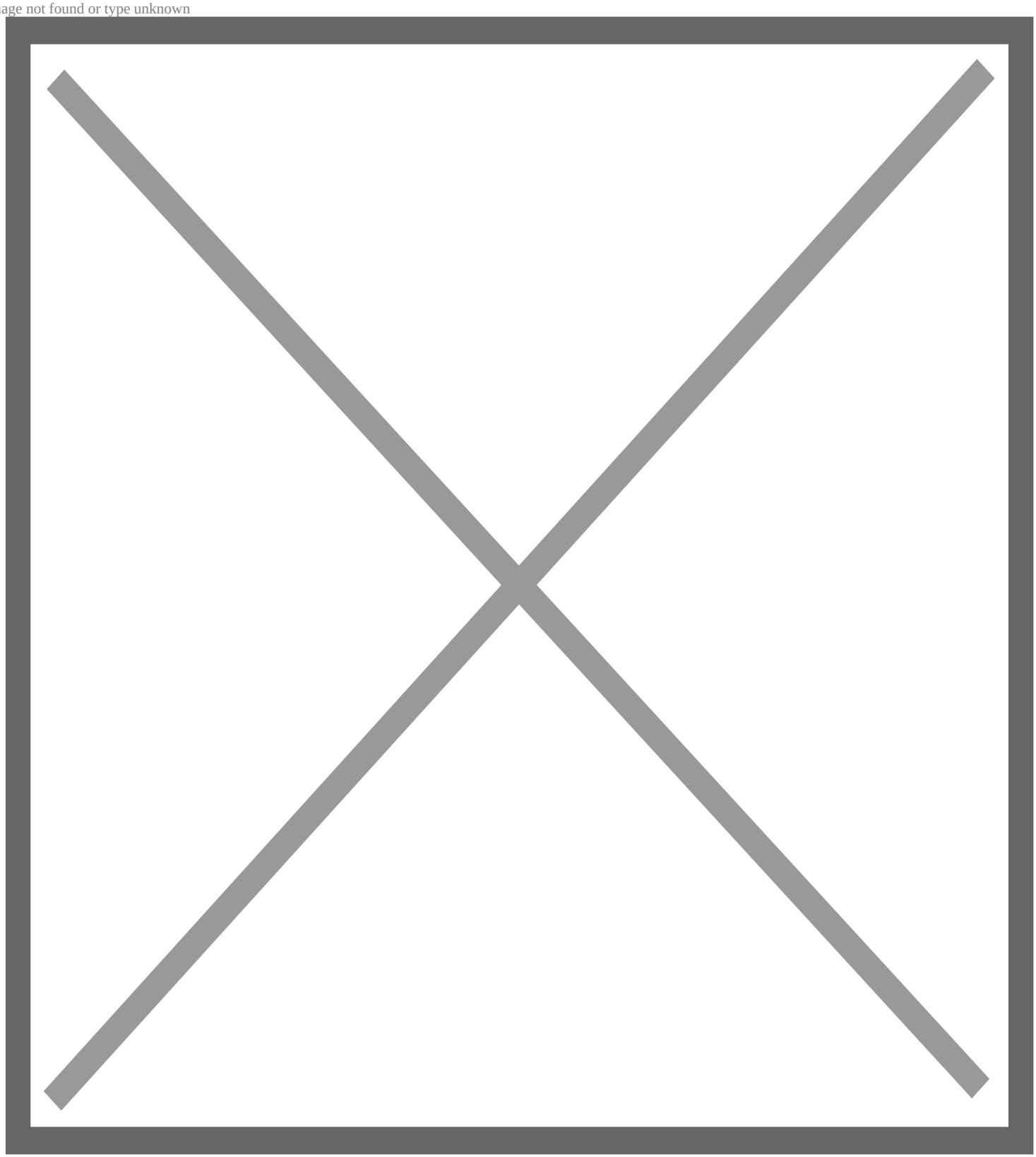

Another CRF for this participant reveals an adverse event of myocardial infarction (heart attack) requiring hospitalization, noted as serious; however, the serious adverse event (SAE) number was left

blank (see screenshot below). Later, a SAE number was entered but it's surprising that the clinical research associates would make such significant data reporting errors such as this. Were SAE numbers left blank a common occurrence at Ventavia trial sites? Again, what type of pressure were the CROs, and sites exposed to?

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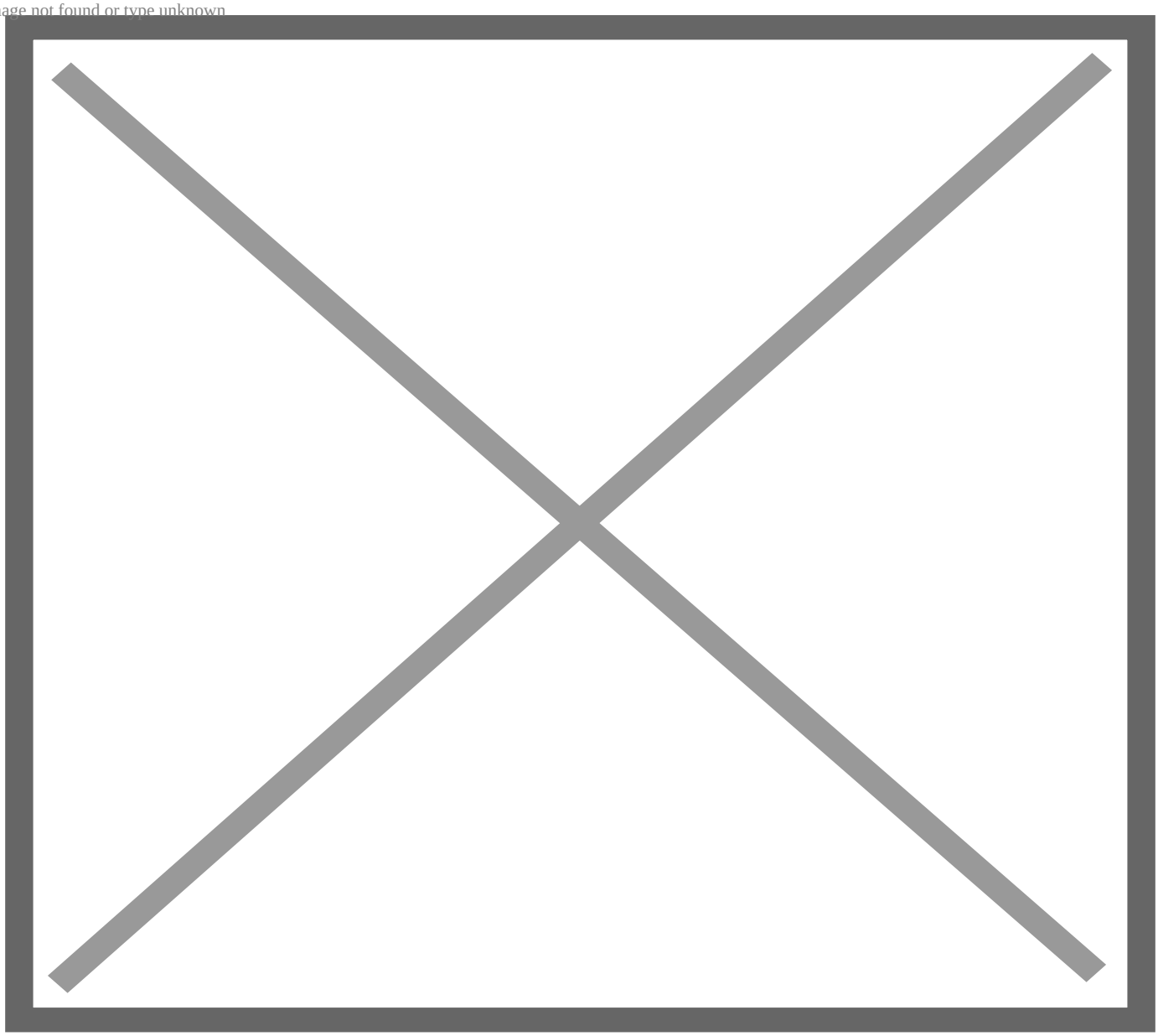

Another note-worthy point are the start and end dates of these SAEs. The myocardial infarction start date is recorded on 27October with the end date on very next day, which happens to be the start date of pneumonia (see screenshot below).

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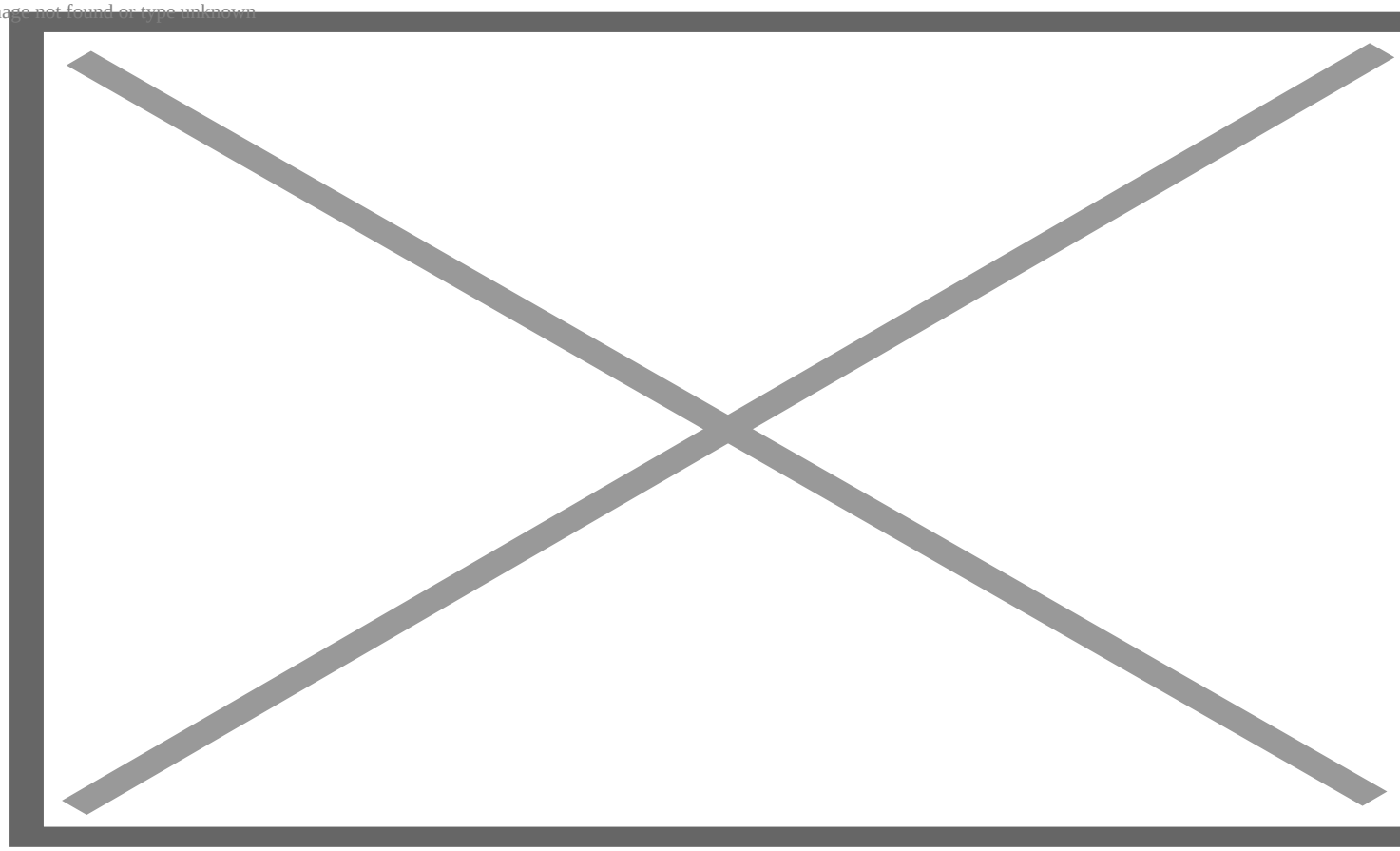

Interestingly, the myocardial infarction outcome is recorded as ‘recovered/resolved’ (see screenshot below) with the entered end date recorded only one day after the start date. This is unusual as a CRF reveals that the participant was hospitalized because of the event (see earlier screenshot).This anomaly raises doubt as to the accuracy of these recorded dates, potentially violating ALOCA-C clinical site documentation guidelines for clinical trials. That is the data must be:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete

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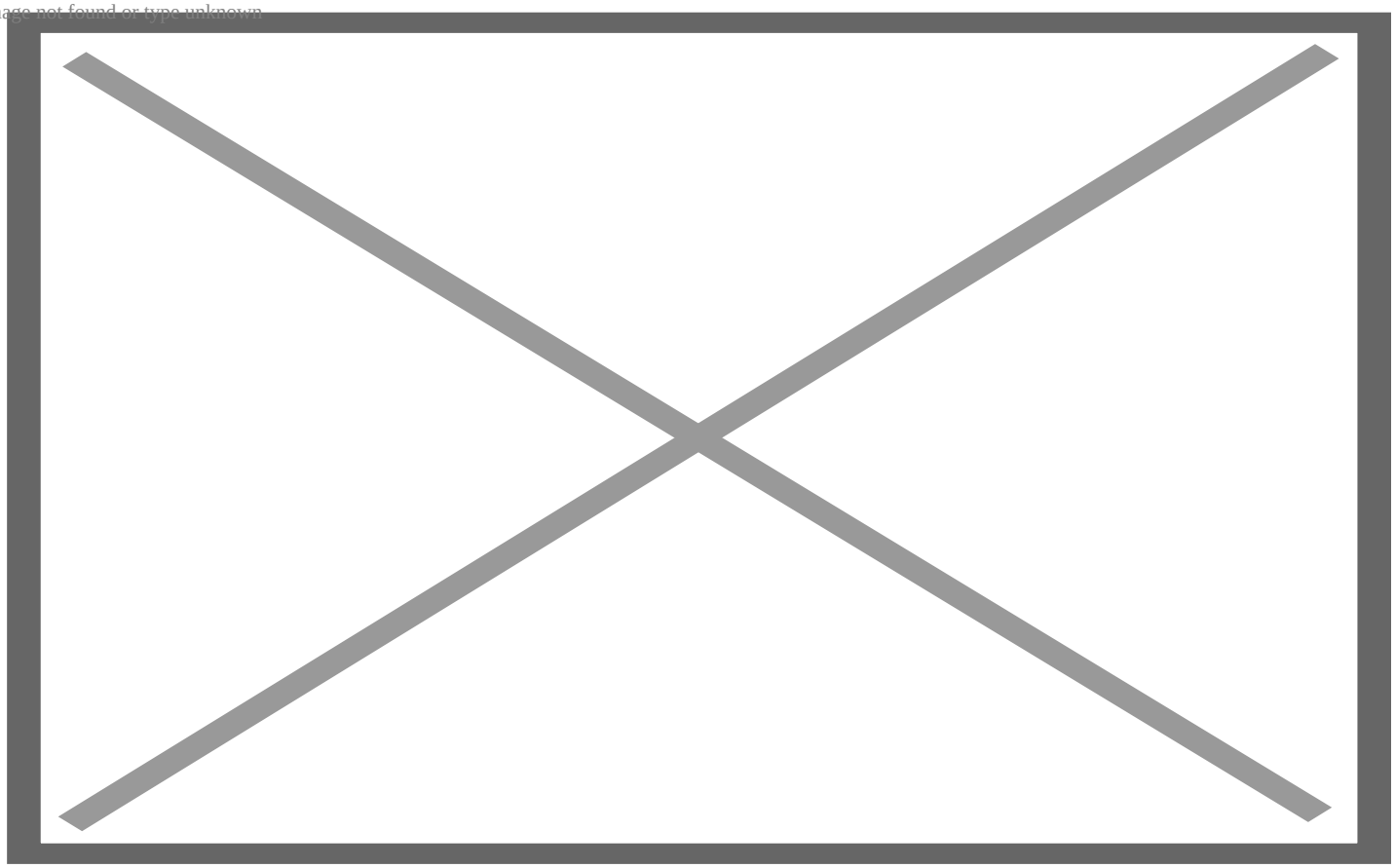

For the SAE of pneumonia, we can again see below that trial investigator, Salim Boguermouth entered ‘ *potential COVID-19 related pneumonia should have triggered a Covid illness visit*.’ The fact this was an open query evidence that the protocol was not consistently followed.

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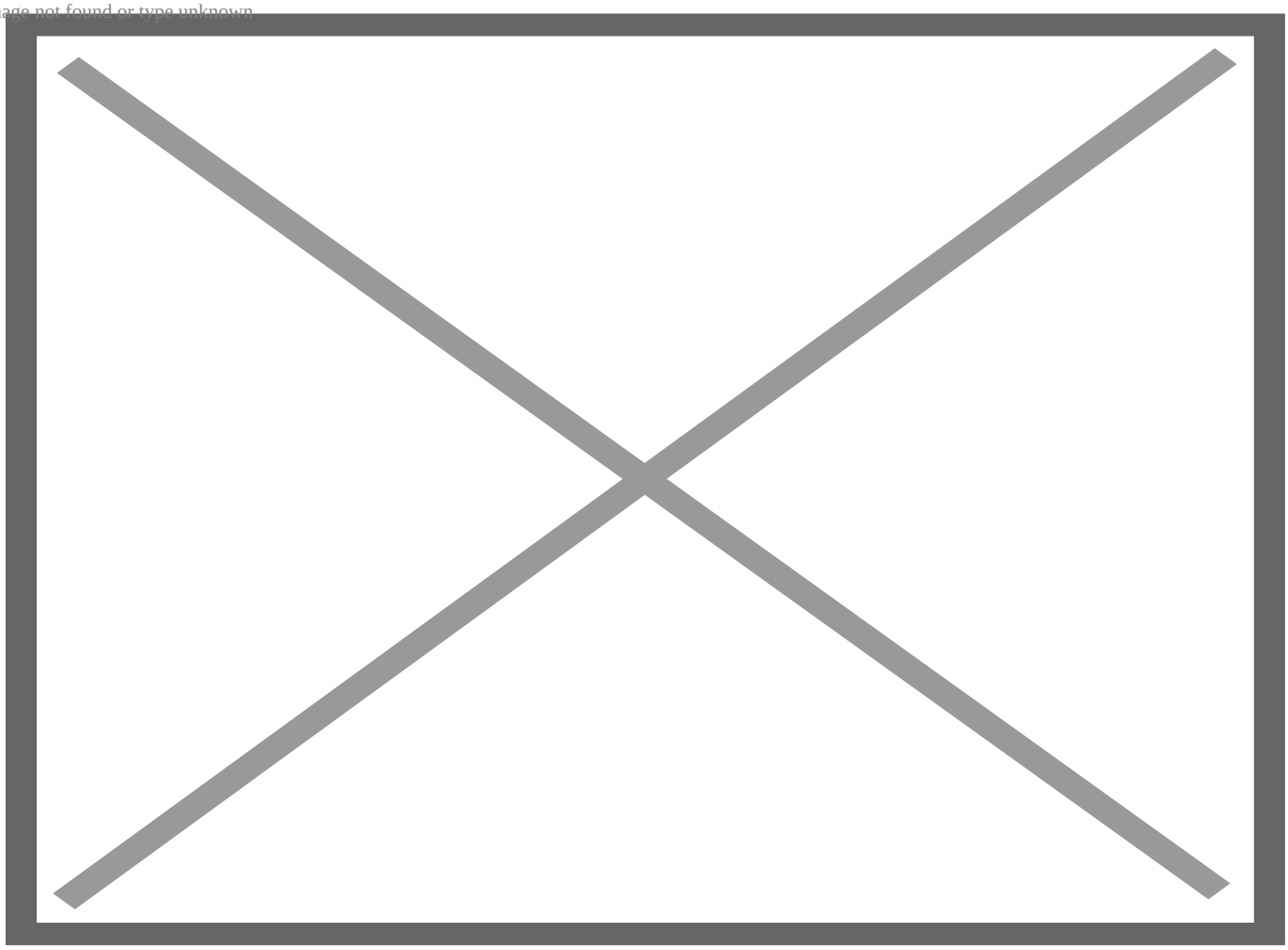

Another investigator opens the same query, declaring that the AE term of pneumonia should be updated to Covid Pneumonia. The response back is interesting as it simply states '*site has not been made aware that it was Covid pneumonia. Per PI (principal investigator) pneumonia is related to an infection, therefore the term cannot be updated as such*.' This response seems to satisfy the query and it's closed. No other questions were asked; no investigations appear to be made. (See screenshot below)

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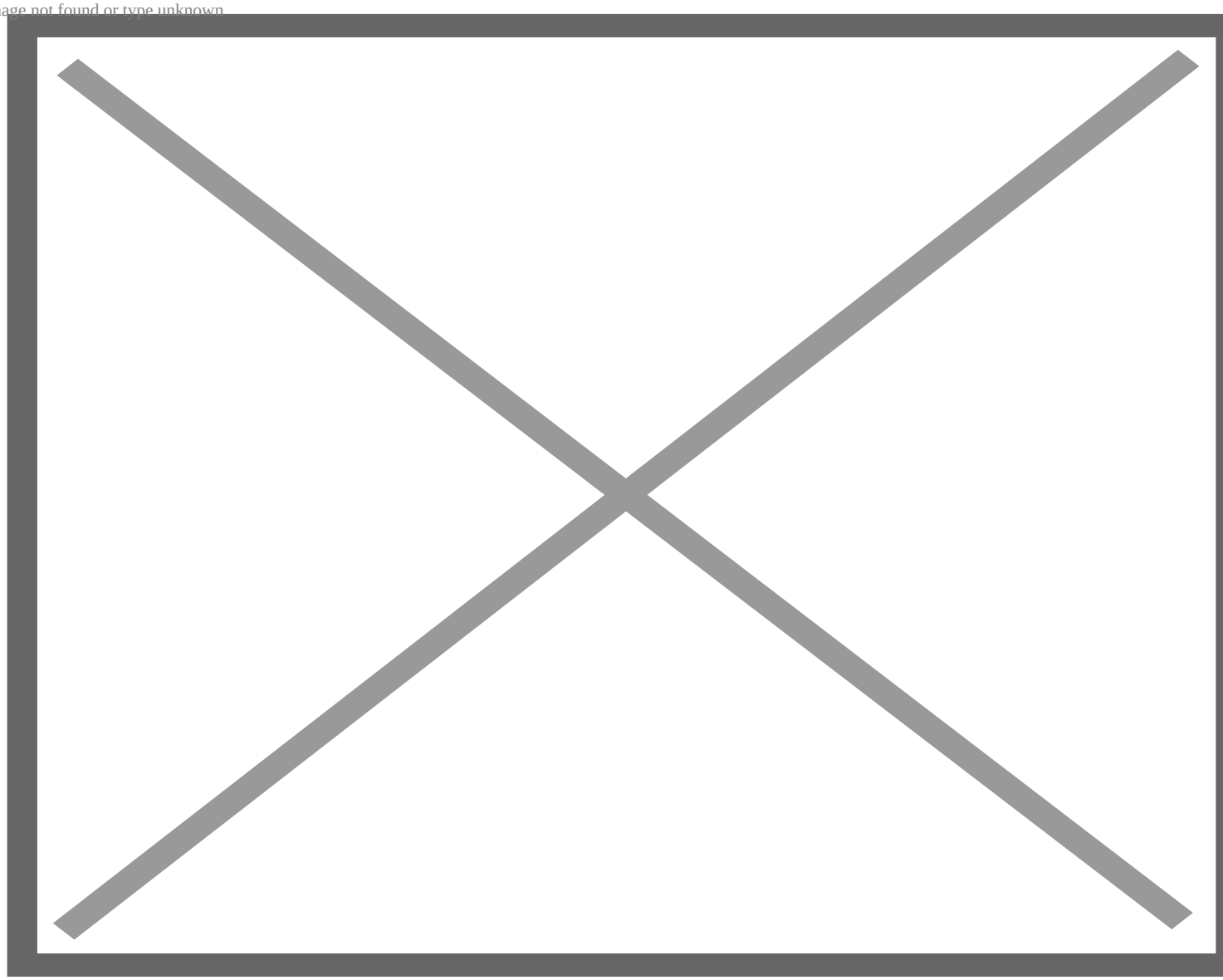

Within Pfizer's protocol (section 8.2.4), enhanced COVID-19 (antibody dependent enhancement potentially caused by the vaccine) was on their watchlist, which indicates that they had some concern about this condition. It's important to note that **unblinded** teams were reviewing cases for severe COVID-19 and reviewing AEs for additional potential cases.

'In Phase 2/3, the unblinded team supporting the DMC, including an unblinded medical monitor, will review cases of severe COVID-19 as they are received and will review AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups.'

Inadvertently, this could have led to bias, as the unblinded teams would have been aware which participants were assigned the placebo and those who received the vaccine. They might have been under pressure by the sponsor for the trial to go a certain way and for events like ‘Covid Pneumonia’ to be classified simply as pneumonia.

Given the FDA’s non-binding guidance to manufacturers of covid-19 vaccines urging them to devise a method to allow volunteers in their studies’ placebo arms to receive the vaccine, in October 2020-Pfizer’s trial participants assigned to the placebo were later offered the vaccine.

This would have triggered the unblinding of the participant and everyone else involved. Given close to half of the participants would have received the placebo in phase 1/2/3 of the trials, it’s fair to say that a significant portion of those would have been assessed as eligible for the actual vaccine. The data collected on those participants would have been completely unblinded. This raises an important issue where unblinded studies (observational) as opposed to double-blinded (where both the participant and those administering the treatment are blinded) are subject to substantial biases which can significantly affect data integrity.

A systematic review study was conducted and published in the *International Journal of Epidemiology*, in its conclusions, it stated: *‘This study provides empirical evidence of* ***pronounced bias due to lack of patient blinding*** *in complementary/alternative randomized clinical trials with patient-reported outcomes.’*

However, according to Pfizer’s clinical trial protocol, its trials (which are still in progress) are not double blinded but ‘observer-blinded’ where sponsor staff, study managers, clinical research associates and those who are involved with ‘*ensuring protocol requirements*’ are unblinded.

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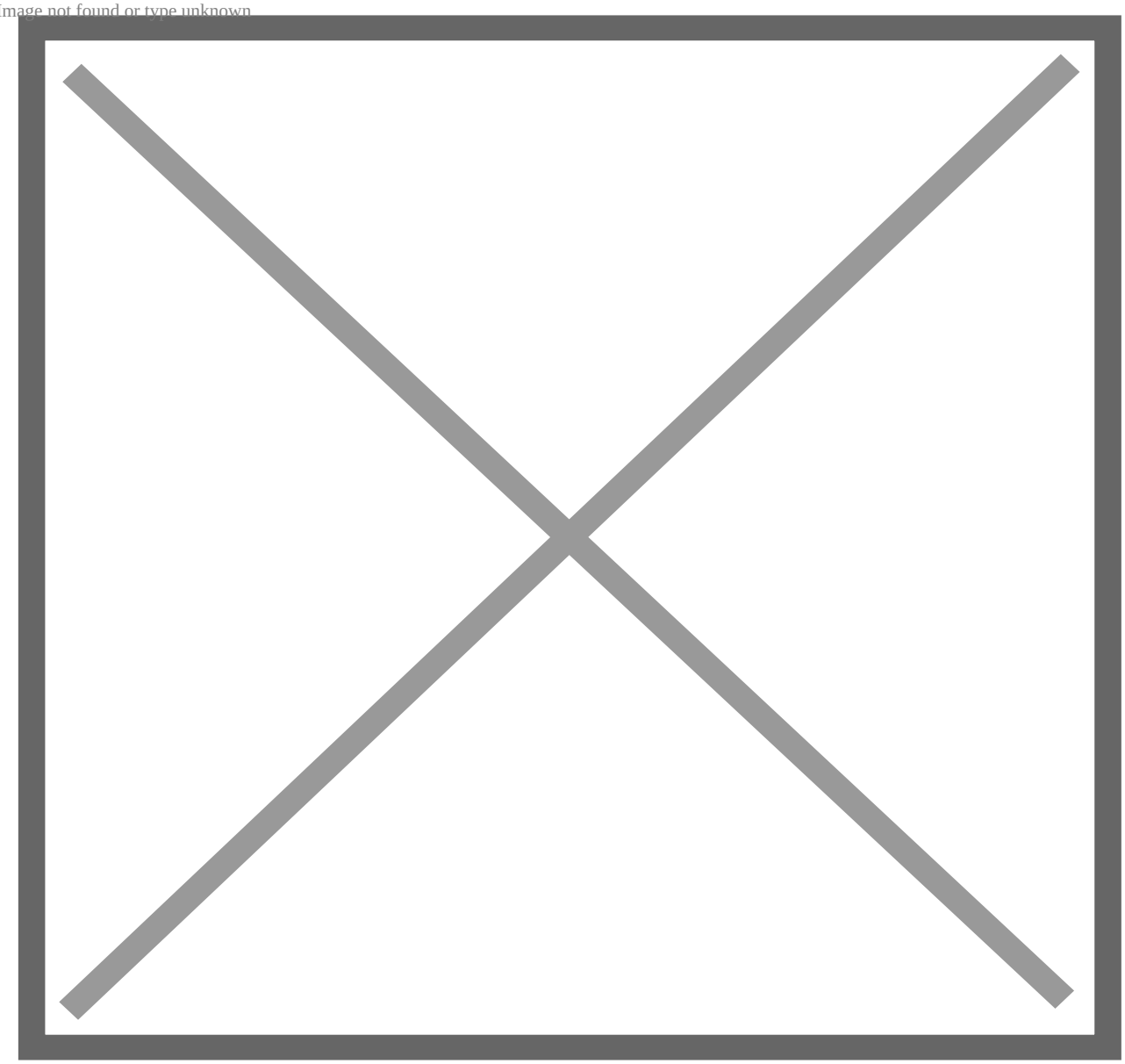

By Pfizer essentially unblinding the vaccine trials for what at least some experts refer to as a novel gene therapy product, did they establish a new precedent? In an interview with the British Medical Journal (BMJ), Steven Goodman, associate dean of clinical and translational research at Stanford University said “by allowing unblinding it will set as de facto standard for all vaccine trials to come and that is dangerous.”

Perhaps one of the most significant errors and anomalies found on the CRFs for subject #11281009 is the one below, which astonishingly reveals the participant’s death being recorded before a ‘Covid ill’ visit. Of course, it’s impossible for a study subject to die and then visit and participate in the clinical trial.

The clinical investigator makes note of this by writing *'There cannot be a date later than date of death. Please remove data from the COVID illness visit and add cough and shortness of breath as AEs (adverse events).'* What kind of pressure was being exerted here?

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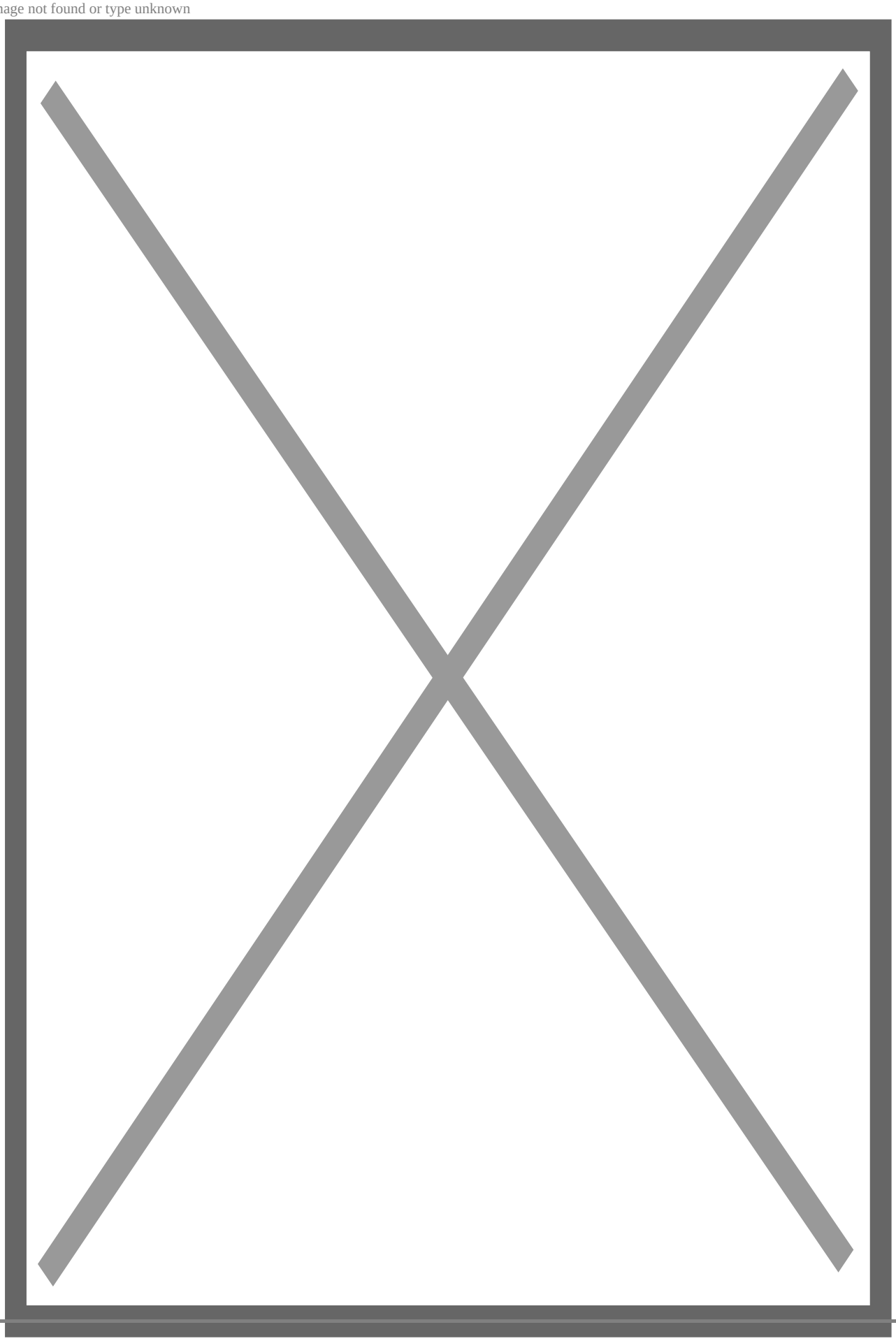

Subject # 11281014

This participant was enrolled at the same Ventavia site (1085). The participant was administered the first dose of the blinded treatment on July 31 and the second dose was administered on August 27 (outside the 3-week window protocol).

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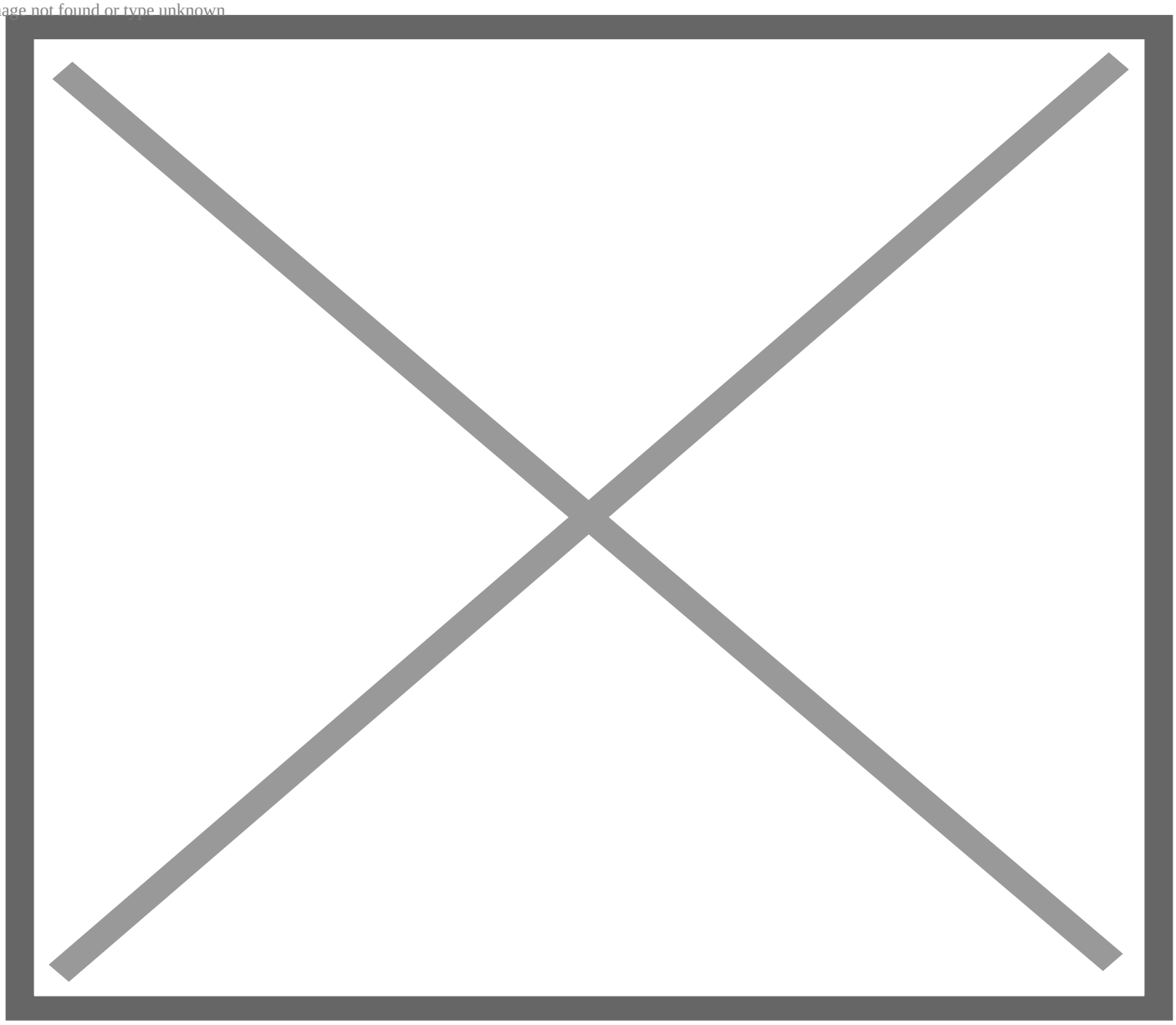

The screenshot above shows when the second dose was given. At this point this author would like to raise an area of concern given that close to every CRF reviewed at the standard entry for line 10 includes the term: '*The protocol specified observation period'* has been entered, with some CRFs stating '*30 minutes*.' This is in reference to the timeframe period which the subject is observed by trial staff after being administered the treatment. It's worth noting that 30 minutes is the minimum amount of time that the subject should be observed after treatment. For the majority of the CRFs to simply state what appears an automatic entry for line 10 is cause for concern, raising the question that perhaps

participants were not observed for adequate amounts of time, thus putting their safety at risk. This backs up what Brook Jackson, the Ventavia/Pfizer whistle-blower has stated in numerous interviews.

What's unusual about the CRFs for this subject is that they reveal that this participant had a serious fall, the following day on **August 28** after the second dose was given, resulting in them being hospitalized. (See screenshot below)

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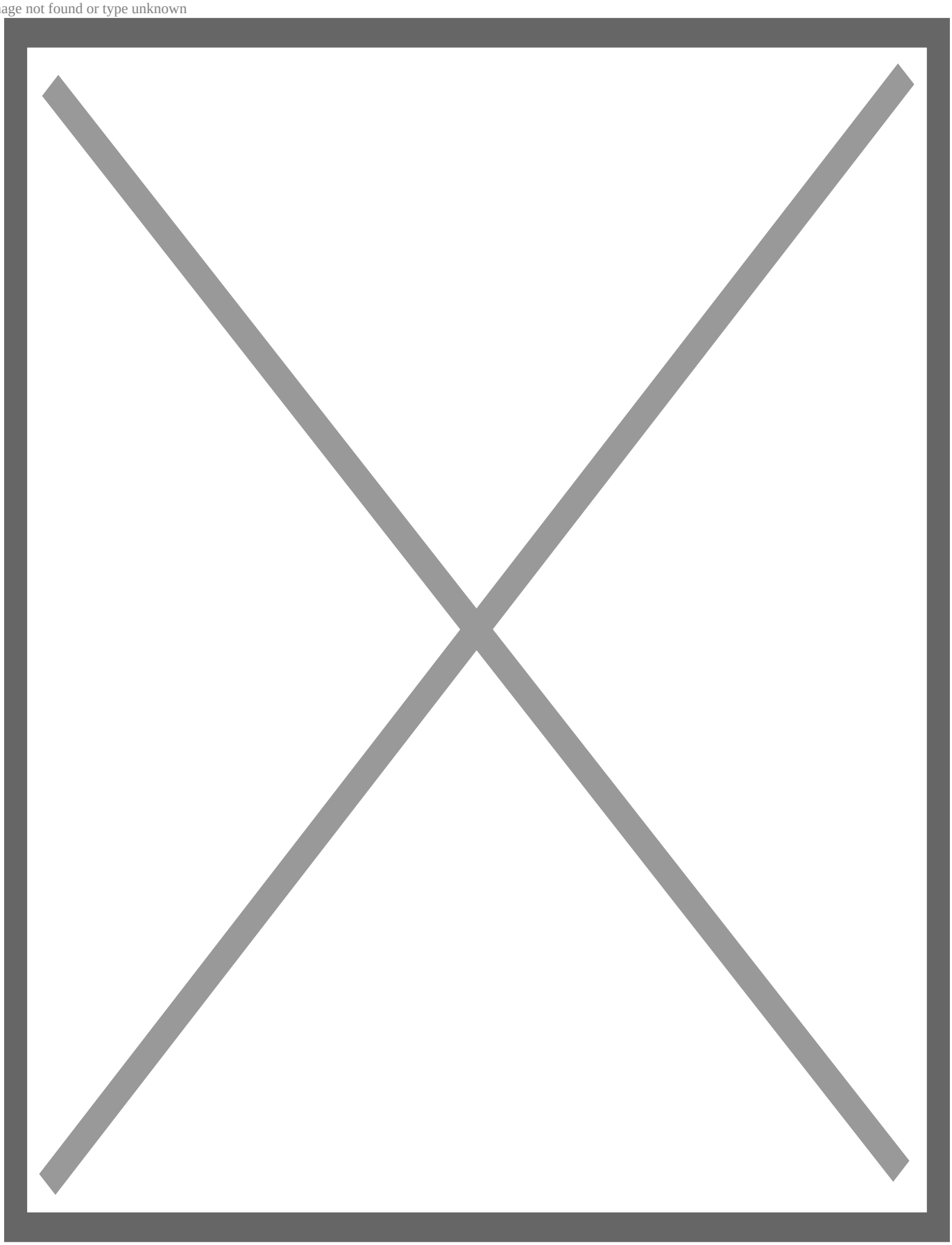

The fall caused facial lacerations, which was recorded as a separate AE but were not reported as serious, even though the toxicity grade level assigned was 2 and the participant was hospitalized for 26 days, see below.

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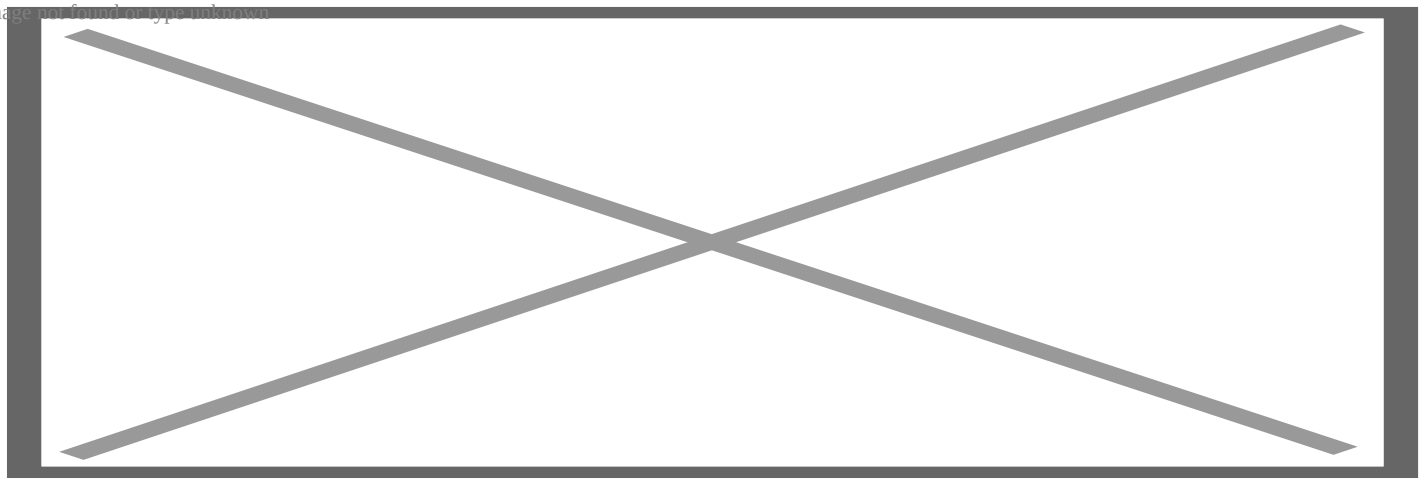

Screenshot below shows AE report for facial lacerations.

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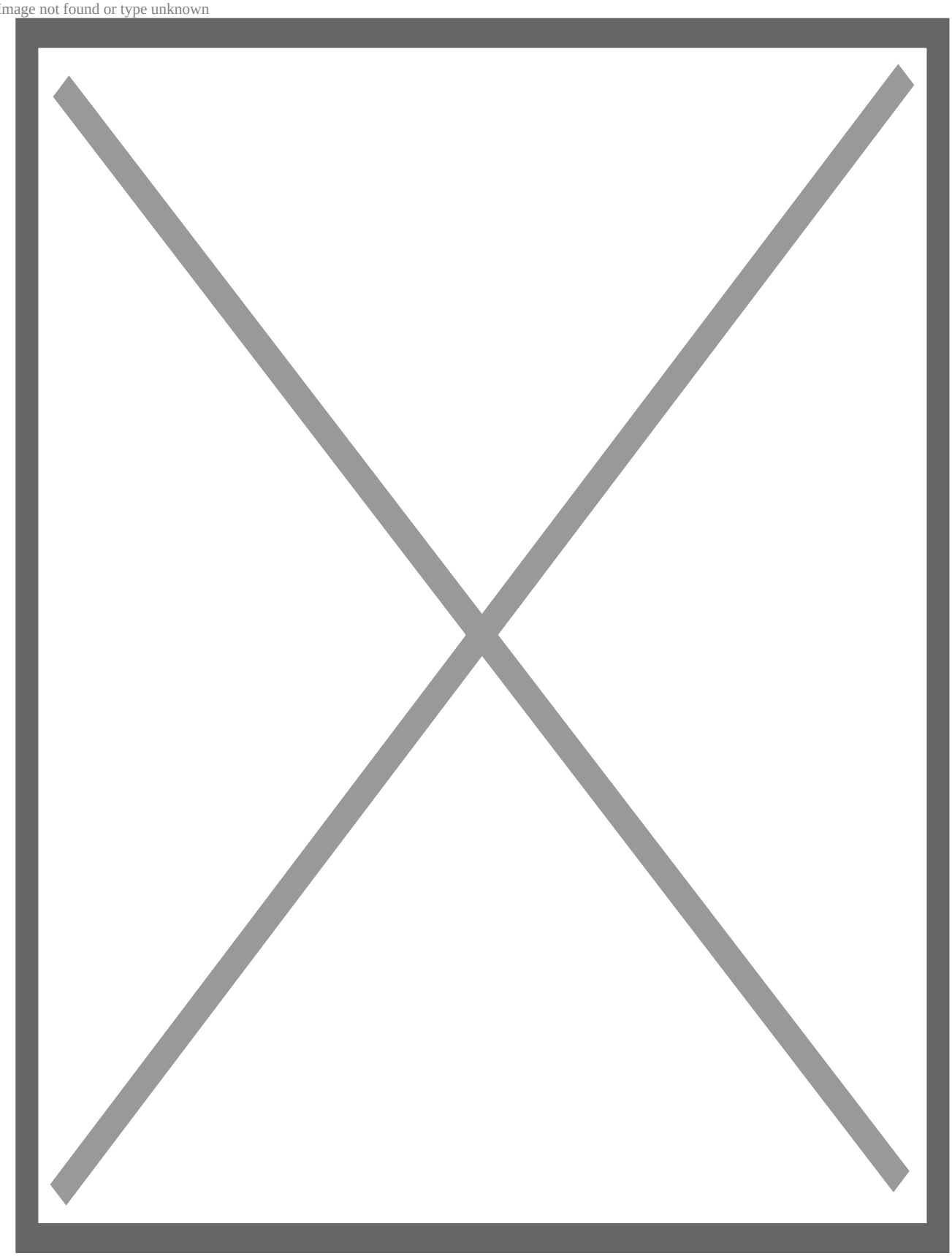

Line 9 includes an unusual anomaly stating the event is ‘NOT RELATED’ to the study treatment but ‘Hypotension’ but in the AE report form for the ‘Fall’ (see screenshot below) it’s due to ‘fall.’

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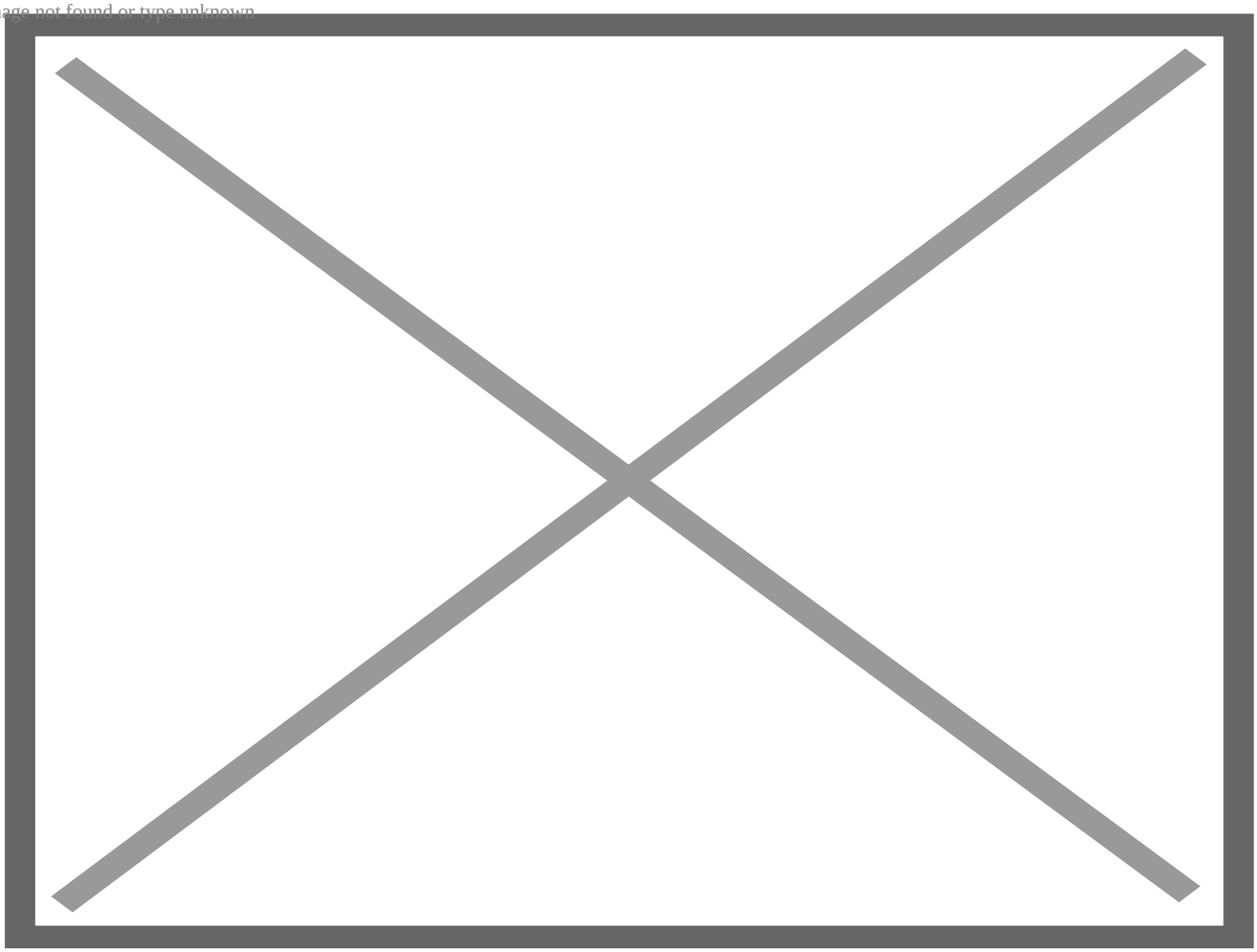

Screenshot below shows missing SAE number for ‘Facial lacerations.’

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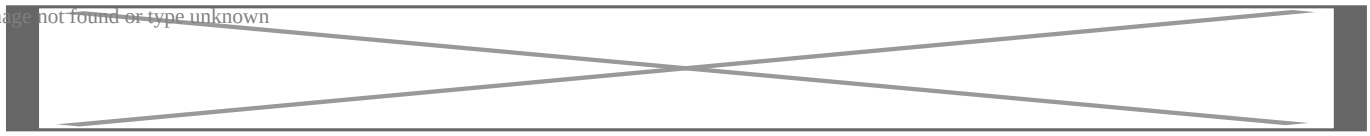

This was flagged by a trial investigator, see below

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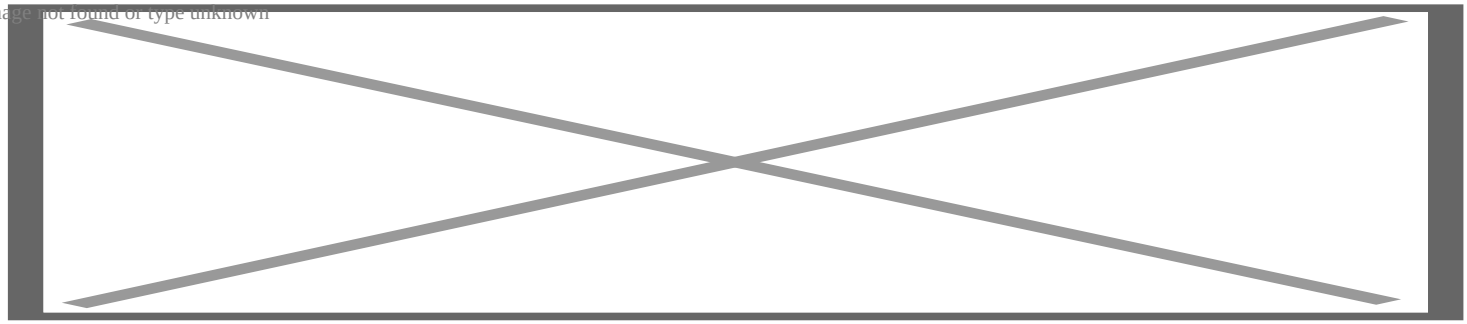

For these two SAEs the Ventavia staff share both events were due to ‘other reasons’ and not related to the study treatment. However, doubts can be raised over the credibility of this information given the fall and facial lacerations were intrinsically related. So, if facial lacerations were due to ‘hypotension’ then the fall should be due to that too.

It’s note-worthy that the fall happened the day after the second treatment dose was given, which at least raises the question of causality.

It’s also concerning that the screenshot below shows how AER #2020337848 (this number referenced in line 15 of the AE report above for the fall) ‘*the causality was recorded as RELATED in SAE form however reported as NOT RELATED on AE CRF*’

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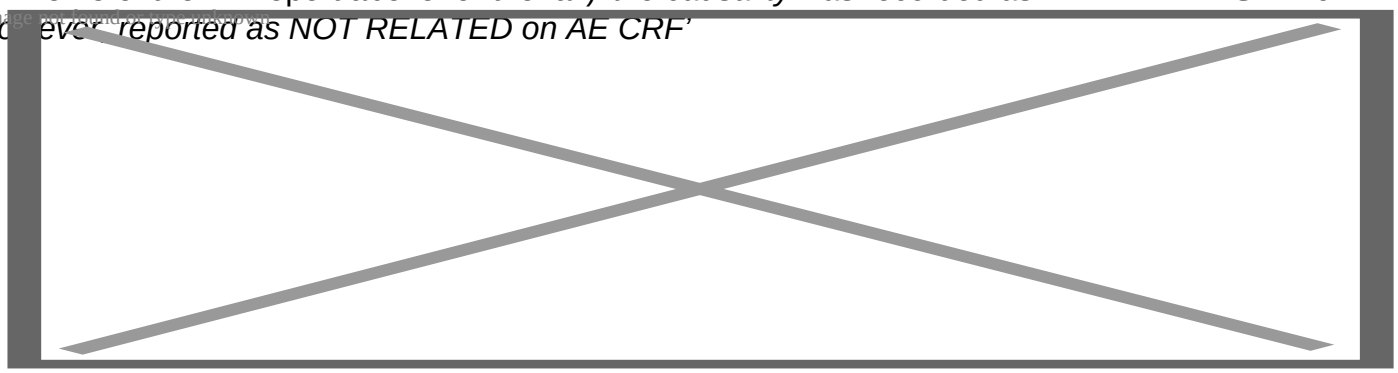

Subject #11281103

The general medical history for this female participant shows no evidence of impaired kidney function (such as hypokalaemia and kidney stones).

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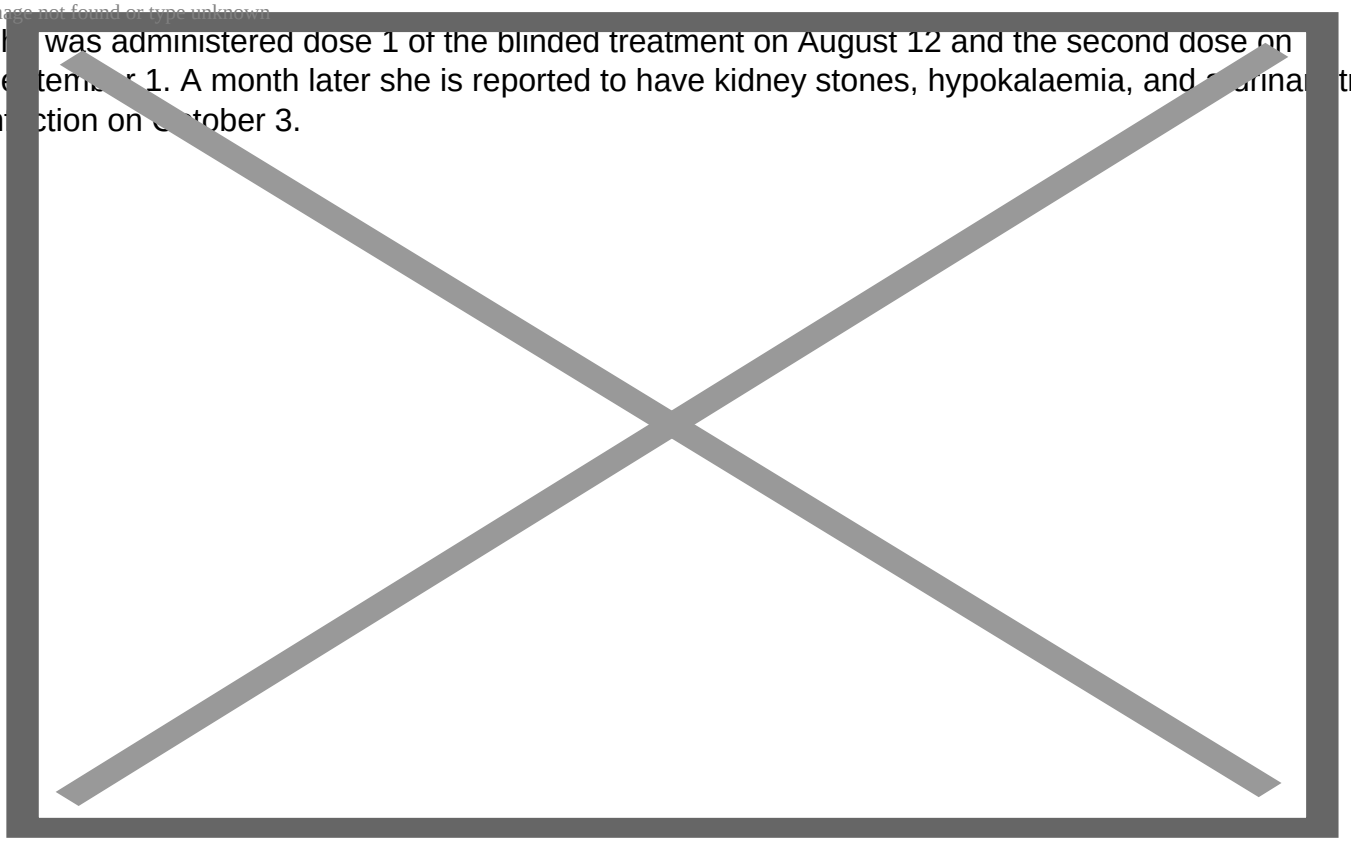
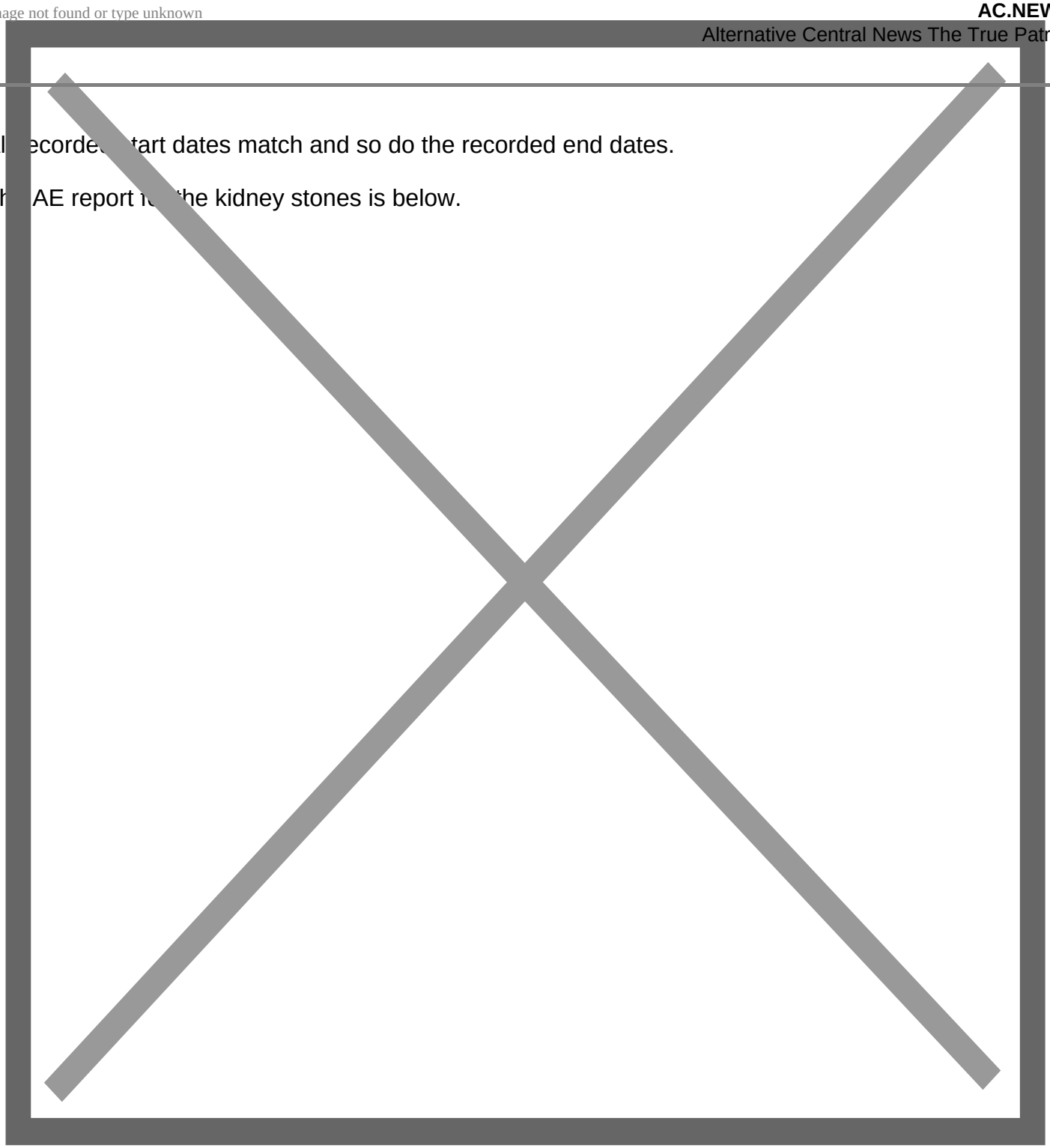
She was administered dose 1 of the blinded treatment on August 12 and the second dose on September 1. A month later she is reported to have kidney stones, hypokalaemia, and a urinary tract infection on October 3.



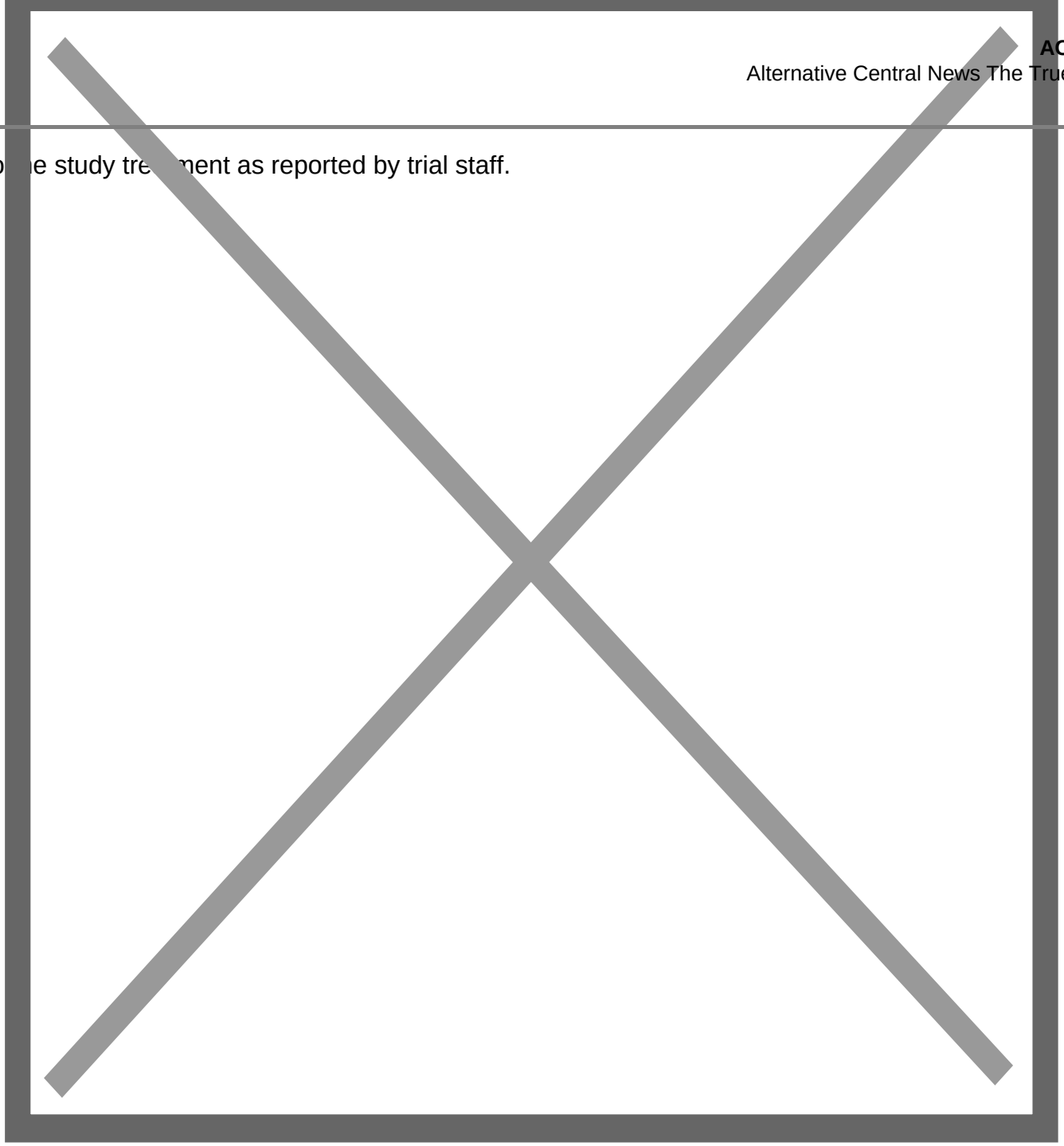
Al recorde tart dates match and so do the recorded end dates.

Th AE report fo the kidney stones is below.



The line 9 entry shows '*this event is due to other…renal calculus'* and for the AE of severe hypokalaemia (see below) the event is attributed to '*hypokalaemia*.' Both events are 'NOT RELATED'

to the study treatment as reported by trial staff.



Given this participant had no previous history of impaired renal function before taking part in the trial and the fact that kidney stones along with renal function impairment have been reported as side effects of the Pfizer-BioNTech vaccine- it's highly questionable why these AEs were not investigated further in relation to them being related to the study treatment, especially when they arose just one month after the second treatment dose.

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Th

W en l king through the CRFs for participant, subject # 10851246, an AE report is l ged w th '*Ex osure d ring pregnancy'* entered for the adverse event. This term is given whe a *femal pa icipant is f nd to be pregnant while receiving or after discontinuing study in vention.'*

A query is made about the SAE number being left blank for this participant at another Ventavia site (1085).

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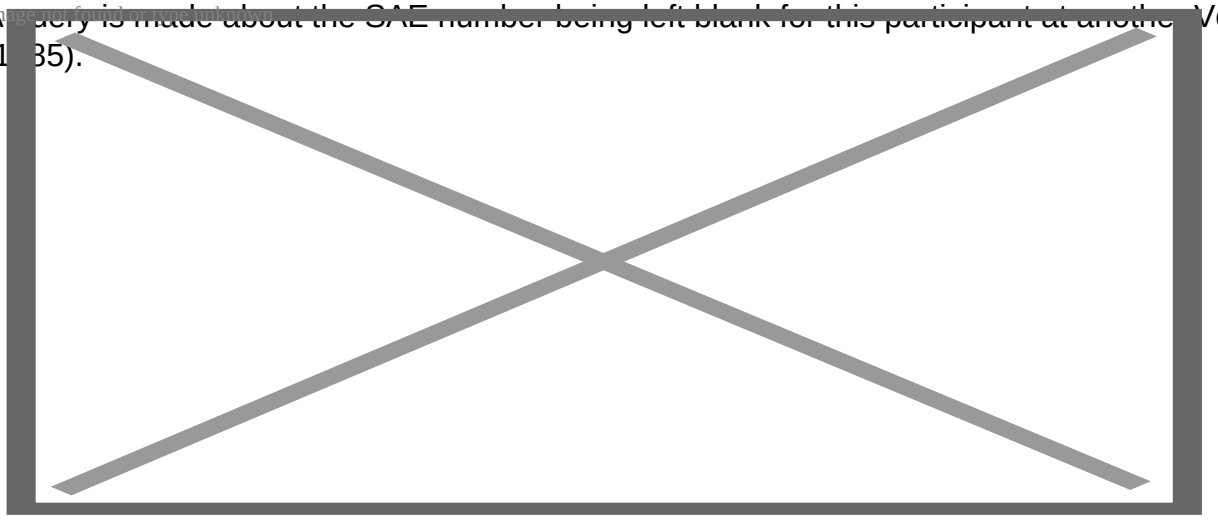

For Subject #10851216, a serious adverse event number is left blank regarding a ‘left leg fracture’ after a fall.

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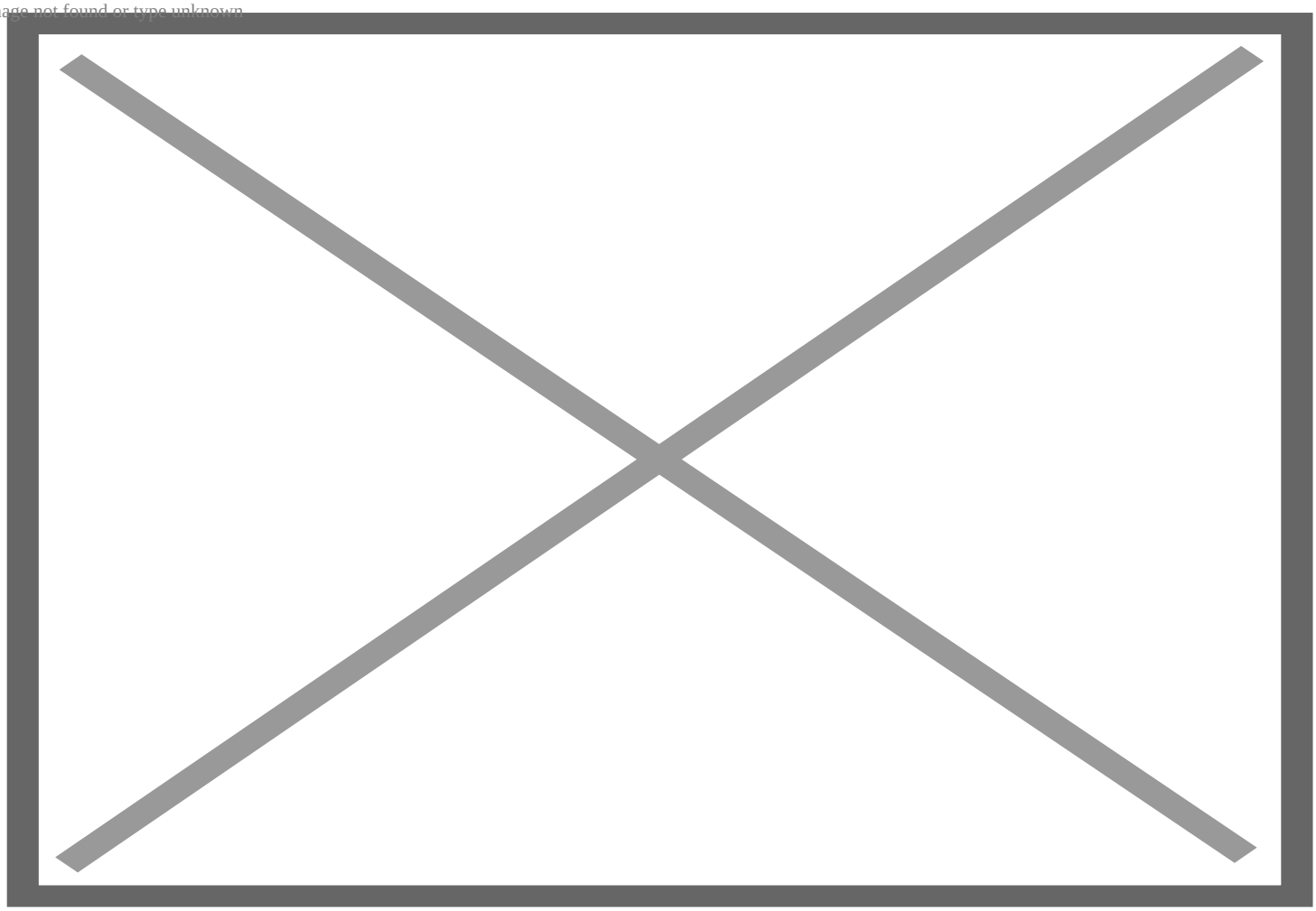

At Ventavia site #1085 there seems to be a pattern of leaving SAE numbers left blank.

The missing barcodes

In the process of writing this report, this author not only reviewed thousands of CRFs, but also encountered lots of entries of missing barcodes for samples collected from participants, such as the one below. This suggests a serious possibility that sufficient evidence reveals a pattern of questionable Ventavia trial site data at best, perhaps compromised in more worse case scenarios.

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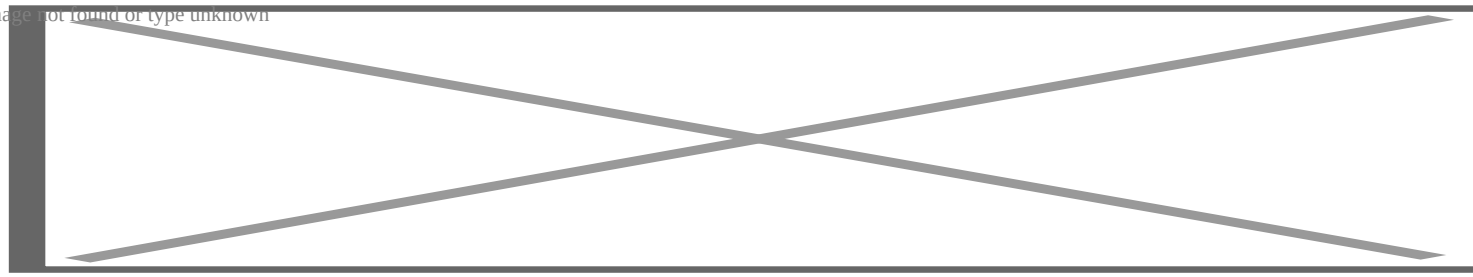

All the evidence gleaned over a limited time appears to back up whistle-blower Jackson's claims of poor trial site data management and raises questions as to how Ventavia conducted the Pfizer clinical trials. The errors and anomalies in the CRFs also allude to her claims that the clinical research associates were not trained adequately, with many having had no prior clinical experience history. If such egregious findings are true at these sites, could they manifest at other trial sites around North America and beyond?

It's worth pointing out that the FDA conducted inspections of only 1% of the clinical trial sites.

By Sonia Elijah

Featured image is from TrialSite News

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Date Created
03/18/2022