Why we should do more than just talk about fraud

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Be honest now, how many of you have implemented systematic methods such as checks, algorithms or reviews, to ensure your data is not unintentionally biased, intentionality tweaked, deliberately skewed or even purposely invented?

Not many in my experience. Personally, I have done quite a bit of this, but in bits and pieces and I'll be the first one to admit that I don't think I've done enough on my watch.

We sometimes talk about risks for bias, we mention fraud over a coffee with a colleague. Most likely though as something that happens in other companies, something we have read about, something that happens to others whilst at the same time confirming to ourselves that this luckily doesn't happen in *our* trials.

Signals for bias, tweaking, skewing and fraud are different from the typically used quality parameters. In fact, it might even be the very opposite signs we should be looking for, i.e., things being "too good" rather than "bad" and I very seldom see any structured checks looking for these things, or hear it being discussed.

It is important we realize that this *does* happen, all the time. On different levels, sure, but it still imposes a risk to your trials. Fully invented patients *do* happen; we know that, maybe not that often, but probably more common that we would like to think. And what about the more subtle things? Tweaking the medical history to make the patient eligible, the "it does not matter" change to avoid the protocol deviation, or just actions in good faith that end up biasing the results. How many have measures in place to look for these things?

Here are my top 5 things we should be looking at:

1 Changes benefiting the site: Not the number of changes as a (intended) quality measure but the trigger, context and implications of the change. Do the changes make the patient eligible instead of not? Does the change make the data compliant with the protocol?

2 Data being too normal: Does the data have a natural variance and distribution? Basic statistics can tell what "real" data looks like (including natural variance from entry mistakes, badly measured BP etc.). Run statistical checks on your data, looking for deviations from the expected pattern. Every time I have seen this done thoroughly, something strange pops up.

3 To good to be true: Are all typical quality parameters shinning green? No PDs, no queries, no late data entry, no SDV findings? Apologies to the truly great sites out there, but "too good" is a more worrying indicator than "too bad". Have a closer look. If it really is true? Happy days! Hang on to that site.

4 Time-points data: Timestamps can tell us a lot, both system timestamps and entered timepoints. Correlate timepoints for assessments, sampling and procedures over time and also across patients over time. What is supposed to have happened at the same time at the site? Is it practically feasible that the activities happened as stated or are things too regular? Same thing for system timestamps.

5 Home diaries – completion behaviours: Honestly, I am a strong believer that most patients really try their best. But device set-up, limited training, misunderstandings etc., can lead to behaviour or habits that can skew results (see presentation on patient behaviour on triticon.com/resources, for some examples of patient behaviour).

We spend so much time and money on our trials, we do all kinds of validation, QC, checks and oversight to ensure what we define as quality of our data (primarily checking that the data matches the "source"). Investing a little effort in ensuring that the data (and source) is 'true' is an obvious thing to do. It's *not* complicated, it doesn't have to be much or take a lot of time, but it can make a tremendous difference.

About TriTiCon

TriTiCon provides expert consultancy for all aspects of Clinical Data Handling. From strategy, organization and vendor selection to system implementation and process development.

TriTiCon combines the 3 Tiers of Subject Matter Expertise, Strategic Understanding and Project Management to fit the needs of each specific situation or company stage.

TriTiCon is not a CRO but can help sponsors with clinical trial set-up and execution, supporting everything from vendor selection and contracting, to set-up, operations and oversight.

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