**Grey highlight is being repeated/replied to 😊**

[11:26 AM] Raunig, Dave

I am not sure how the site can be more accurate but more biased.  It seems contradictory

[11:27 AM] Goldmacher, Greg

**Raunig, Dave (Guest)**

I am not sure how the site can be more accurate but more biased. It seems contradictory

That liver lesion that the site called, but BICR didn't, in my hypothetical example, was probably real, that's what I mean by more accurate

[11:28 AM] Angela Becker

**Raunig, Dave**

I am not sure how the site can be more accurate but more biased. It seems contradictory

Do you think this is related to the site being more accurate from a patient care perspective but more biased in their application of RECIST criteria / assessment based entirely on imaging

[11:28 AM] Raunig, Dave

You cannot  be "on the whole" more accurate but more biased.

like 1

[11:29 AM] Wim Vos

what was the delay of the BICR read as compared to the local read?

[11:29 AM] Miguel Murillo

While it is obvious that sponsors cannot influence sites or central readers, there is also some degree of oversight. In this regard, is there any measure that the sponsor can implement to prevent/correct anomalous biases or to detect them in time, beyond training? Thanks

[11:29 AM] Raunig, Dave

It will be hard to say based on the censoring

[11:30 AM] Goodman, James

**Raunig, Dave**

You cannot be "on the whole" more accurate but more biased.

Agree.  We need to disambiguate what we mean by the term "accurate."

[11:31 AM] Raunig, Dave

When the ICR knows that it is confirming progression, the ICR is already biase.

like 1

[11:31 AM] Raunig, Dave

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[11:31 AM] Antoine IANNESSI

What the panellists  think about the confirmation of PD design set for this study. And what are the lesson learned regarding site/central discrepancy management during COPD.

[11:32 AM] Ilovich, Ohad

Dave, I don't think BICR would be aware that they are confirming progression. COP should bump a scan to be read first in line to accelerate timelines without the radiologists knowing that they got bumped or why they got bumped.

[11:34 AM] Raunig, Dave

To be quite fair for clinical information, the protocol, imaging charter and FDA guidance specifies that clinical  information that is not pre-specified for release is  not given to the reader.  If the site is allowed to have clinical information to be "more accurate" then the central reviewers should also have that information to be a fair comparison.

[11:35 AM] Raunig, Dave

Power cannot accommodate bias

[11:35 AM] Guenther Brueggenwerth

@Greg: Why have re-read when error is detected - probably adjudication decision would be more straight fwd

[11:36 AM] Angela Becker

Do you agree that separating decisions about continuing treatment from requiring imaging to continue until progression is confirmed by BICR is a good approach to mitigate risk of lost BICR PD events (while leaving decision about treatment with the PI)?

like 1

[11:36 AM] Goldmacher, Greg

**Guenther Brueggenwerth**

@Greg: Why have re-read when error is detected - probably adjudication decision would be more straight fwd

Maybe both primary readers missed the new lesion, so no adjudication was performed

[11:37 AM] Guenther Brueggenwerth

exactly, if they missed it first time they might miss it at re-read again

[11:37 AM] Goldmacher, Greg

**Guenther Brueggenwerth**

exactly, if they missed it first time they might miss it at re-read again

Yep, they might. No way for this to be perfect

[11:37 AM] Raunig, Dave

If errors are equally distributed between treatment arms, then hazard ratios are very robust to increases in variance (Dodd et al). HR  is not robust to bias

[11:37 AM] Ira Smalberg

What were the BICR adjudication rates?  Were any BICR readers identified as being "out of range" by the adjudicator, requiring retraining, etc.?

[11:37 AM] Tatiparthi, Arun K

To Panel - Can the discordance (b/t PI and BICR) be challenged even when BICR didn't trigger an adjudication?

[11:38 AM] Guenther Brueggenwerth

**Tatiparthi, Arun K**

To Panel - Can the discordance (b/t PI and BICR) be challenged even when BICR didn't trigger an adjudication?

Great question: do we ave some measure of readers performance here?

[11:38 AM] Ira Smalberg

This bias seems to be partially related to the philosophical emphasis and harmonization of when to call a new lesion...do you call a new lesion prospectively or retrospectively when they first appear even if they are only one pixel and not when a reasonable radiologist would first call the lesion.

like 2