Risk of Bias (RoB) Corpus Annotation Guideline Infographic

- These instructional placards provide guidance to RoB assessors on how to perform RoB span annotation for randomised controlled trials (RCT) full-texts.
- These placards are designed and adapted using RoB 2: a revised tool and are complementary to RoB 2 and should be used in tandem with the original guidance document in case of confusion or conflict.

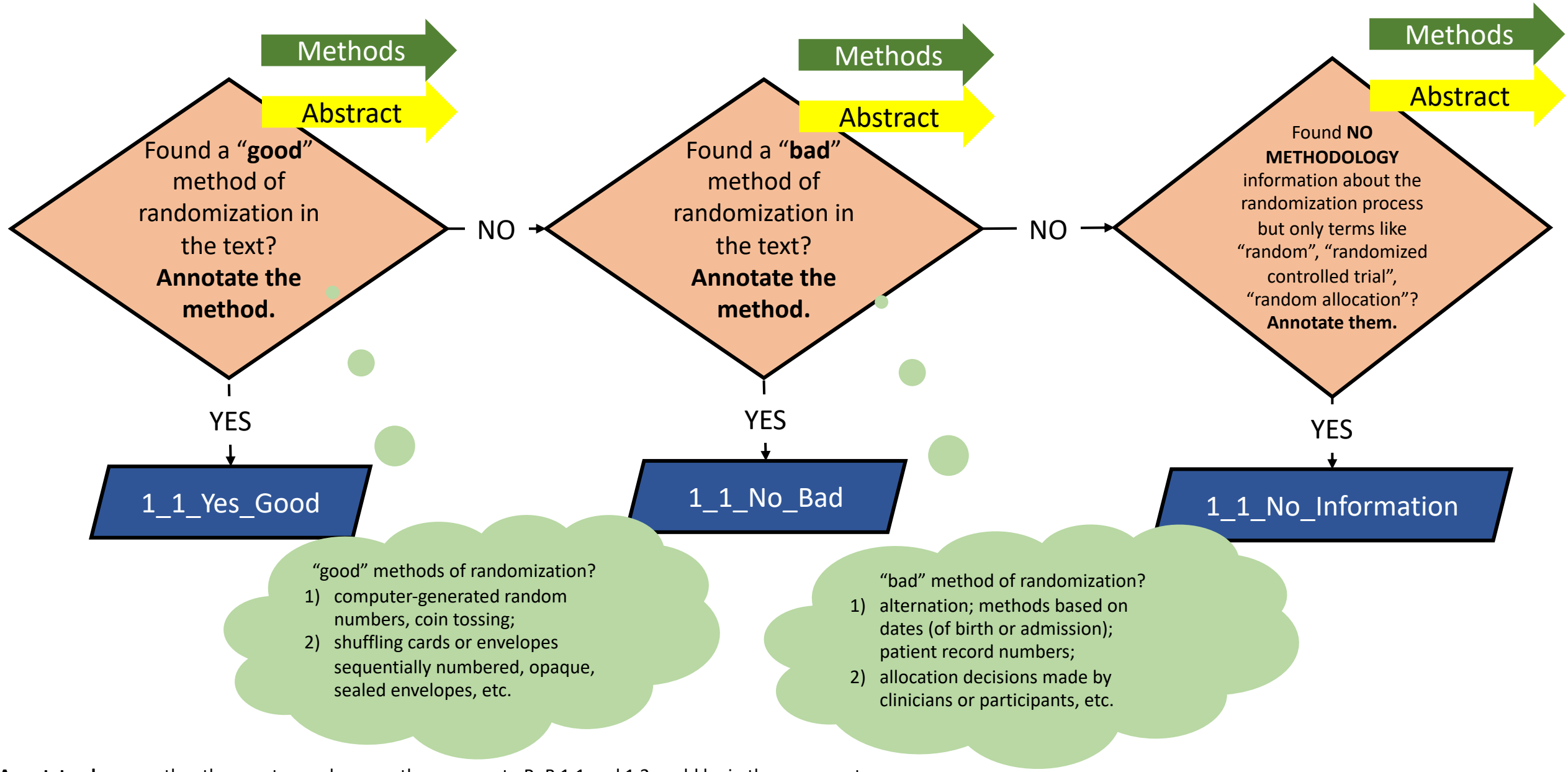
General Instructions

- Try to annotate the most informative sentence you find for answering a signalling question, but if you need to make two or more annotations for a signalling question, mark multiple sentences (within the instructed full-text (green arrow) region – Results section, methods section, etc.) and use the judgment which is appropriate for these sentence individually.
- **! Flowchart rating is not possible with the software we use, PAWLS. So, if it is inevitable to mark the information in the flowchart because it was not found elsewhere, mark the flowchart caption. But keep flowchart annotations as a last resort.**
- Whenever no text annotation is found for a signalling question, “No Information” will be assumed.

Domain 1

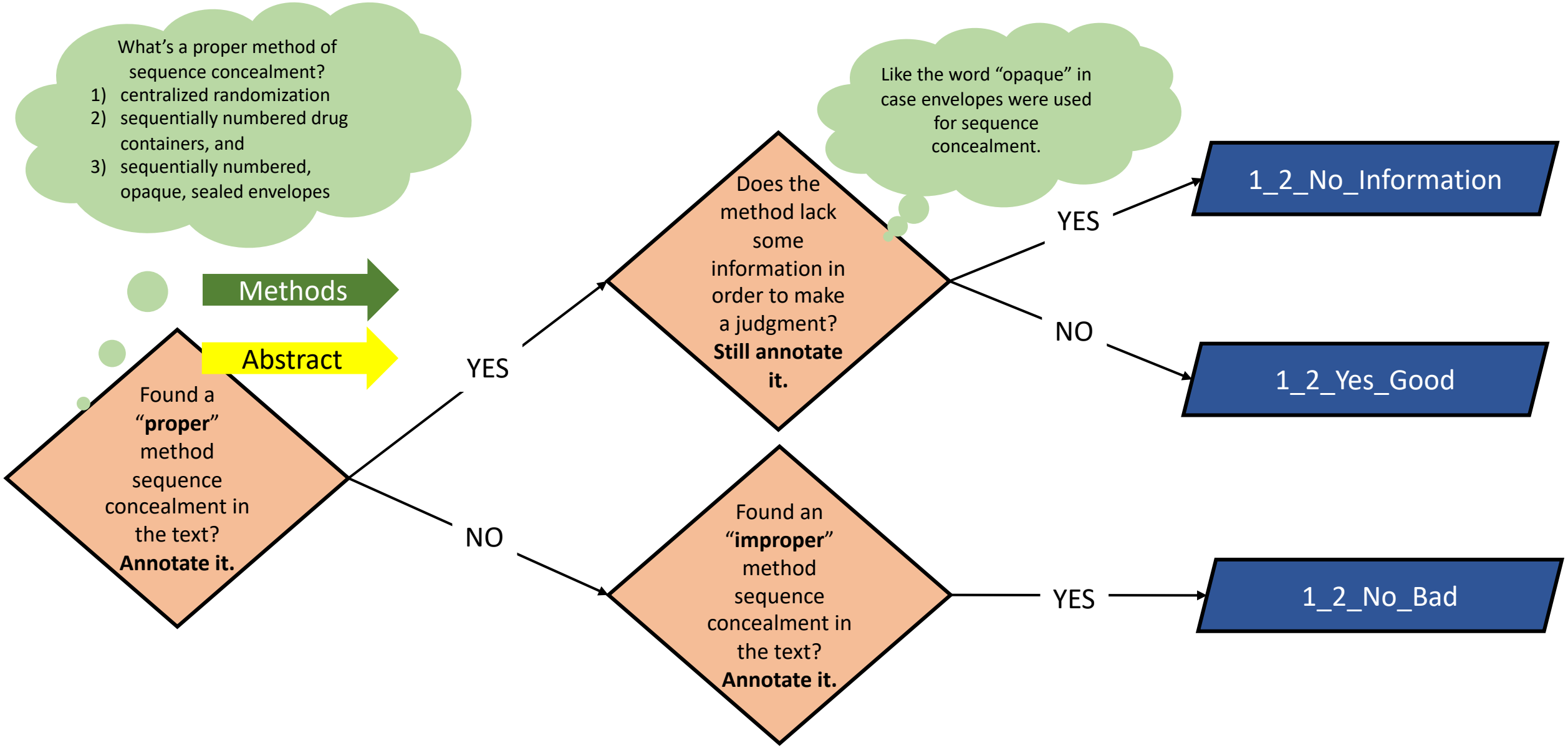
Risk of bias arising from the randomization process

RoB 1.1 Was the allocation sequence random?



Annotate phrases rather than sentences because the answers to RoB 1.1 and 1.2 could be in the same sentence.
Green arrow = which section to find these text evidence
Yellow arrow = If the information is not found in Methods section, look for it in the abstract

RoB 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?



Annotate phrases rather than sentences because the answers to RoB 1.1 and 1.2 could be in the same sentence.

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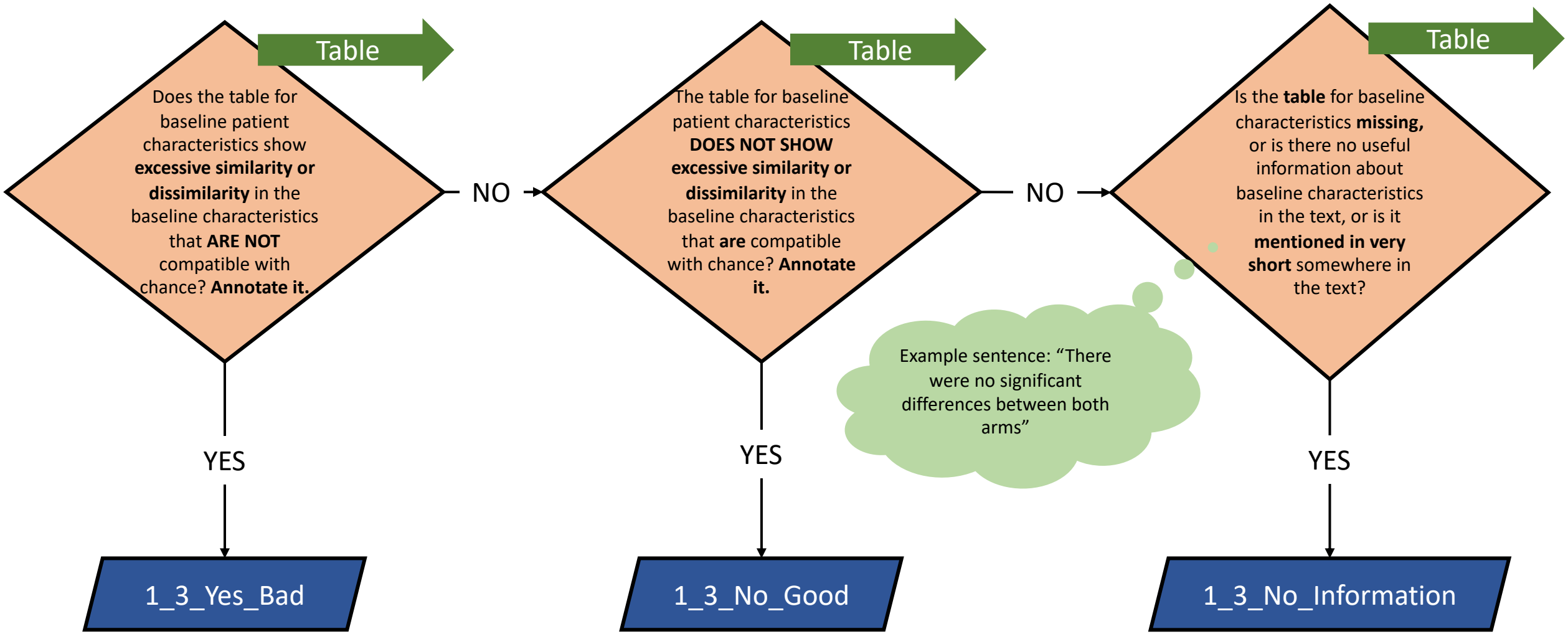
Yellow arrow = If the information is not found in Methods section, look for it in the abstract

RoB 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?



Green arrow = which section to find these text evidence

NOTE: Please annotate the full table including the caption

Domain 2

Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

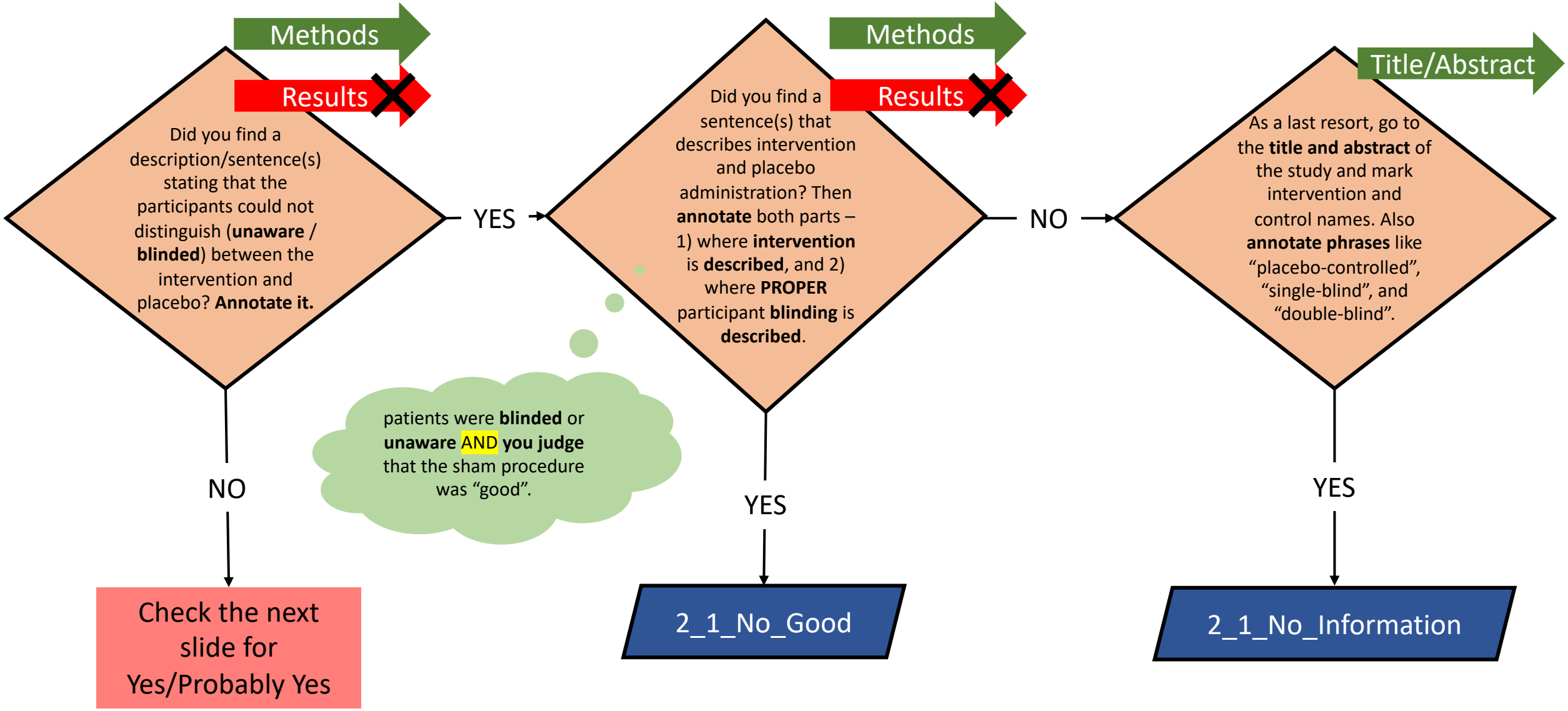
General definitions

Deviations from the intended intervention are defined as any unintentional changes that may have occurred in the intervention being studied due to the trial context.

Dropouts, on the other hand, refer to participants who withdrew from the study or were lost to follow-up.

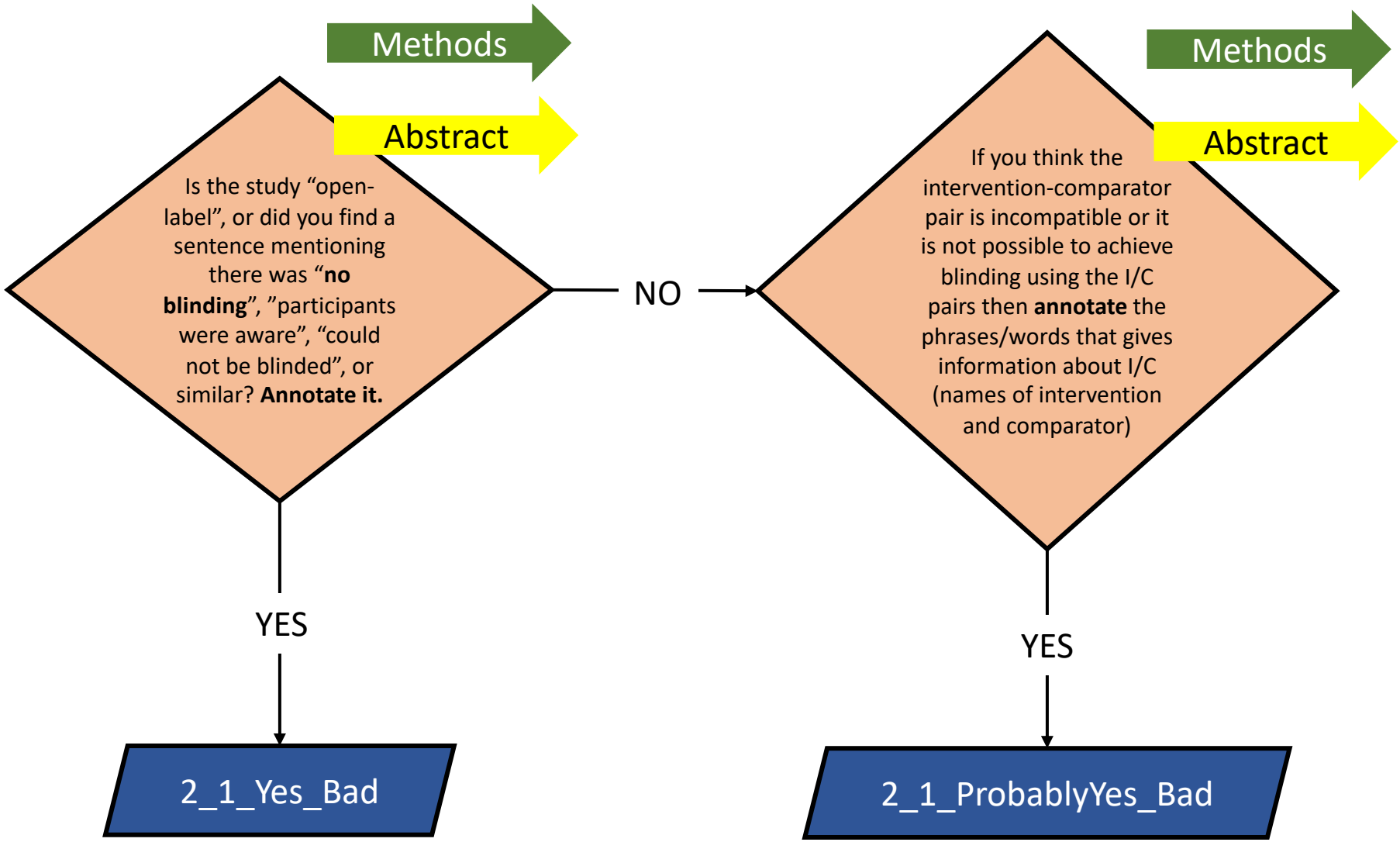
Note: With PAWLS (our annotation software), you cannot annotate images (and hence **flowcharts**) – discuss this point while training the new annotators.

*RoB 2.1: Were **participants** aware of their assigned intervention during the trial?*



Annotate full sentences if not otherwise specified to annotate only phrase.
Green arrow = which section to find these text evidence
Red arrow = which section to NOT go to.

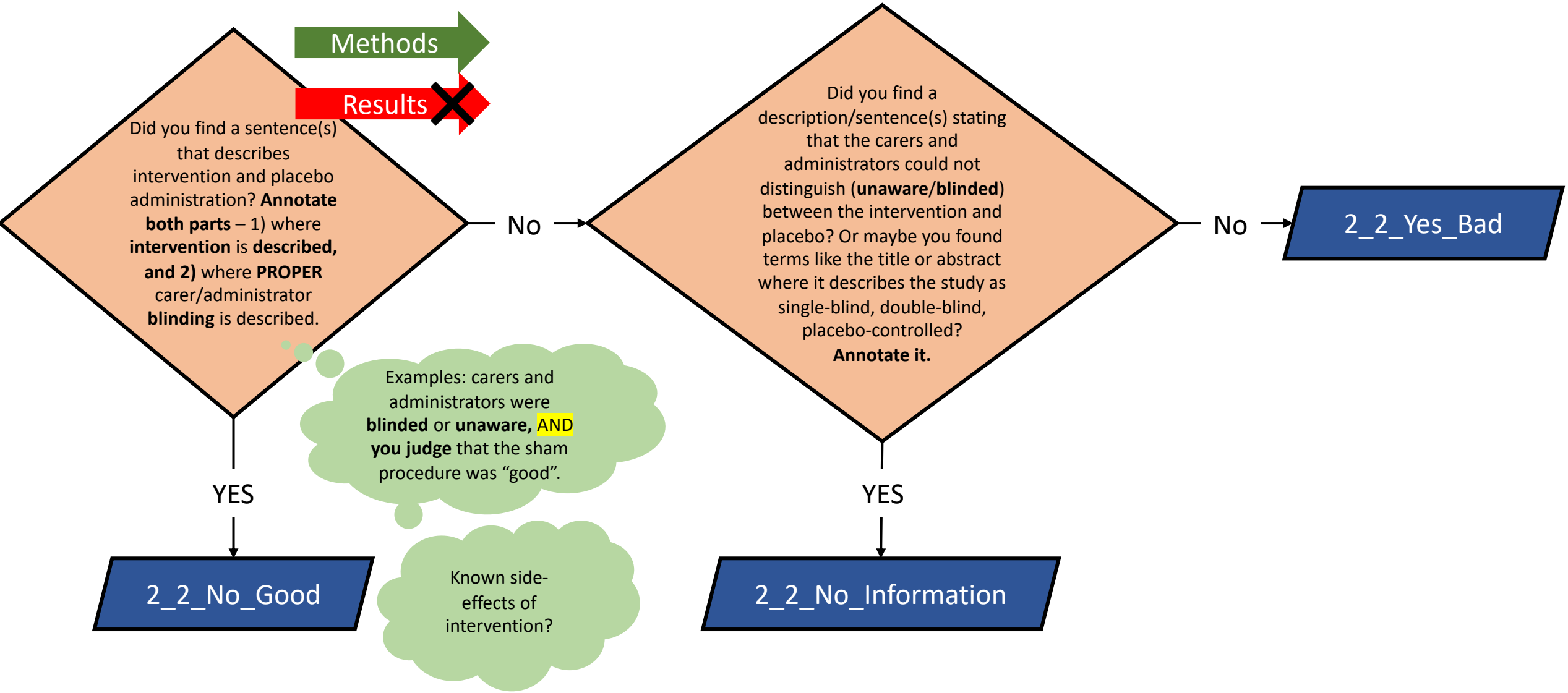
*RoB 2.1: Were **participants** aware of their assigned intervention during the trial?*



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence
Yellow arrow = second preferred section after the green arrow.

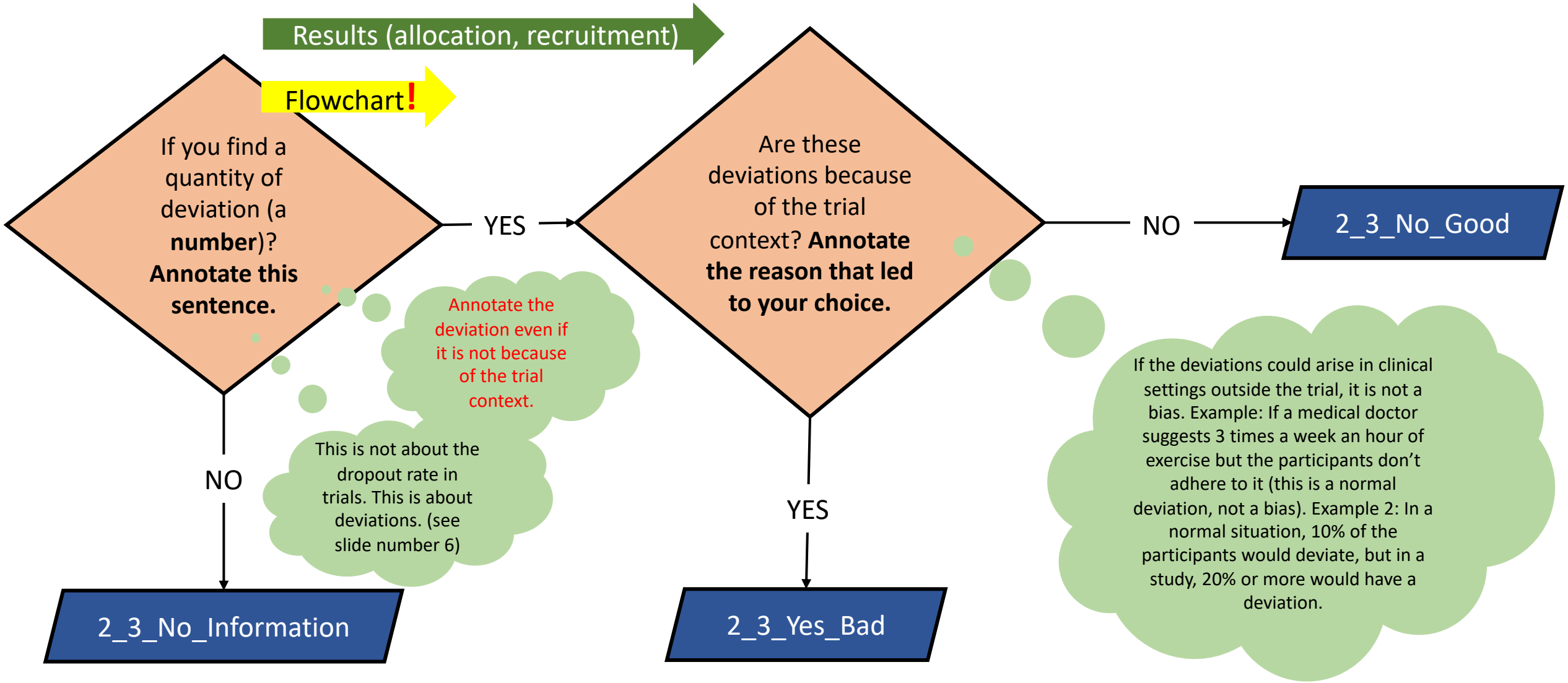
List down intervention-comparator pairs where blinding cannot be achieved. (Tip for adding to the paper.)

RoB 2.2: Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?



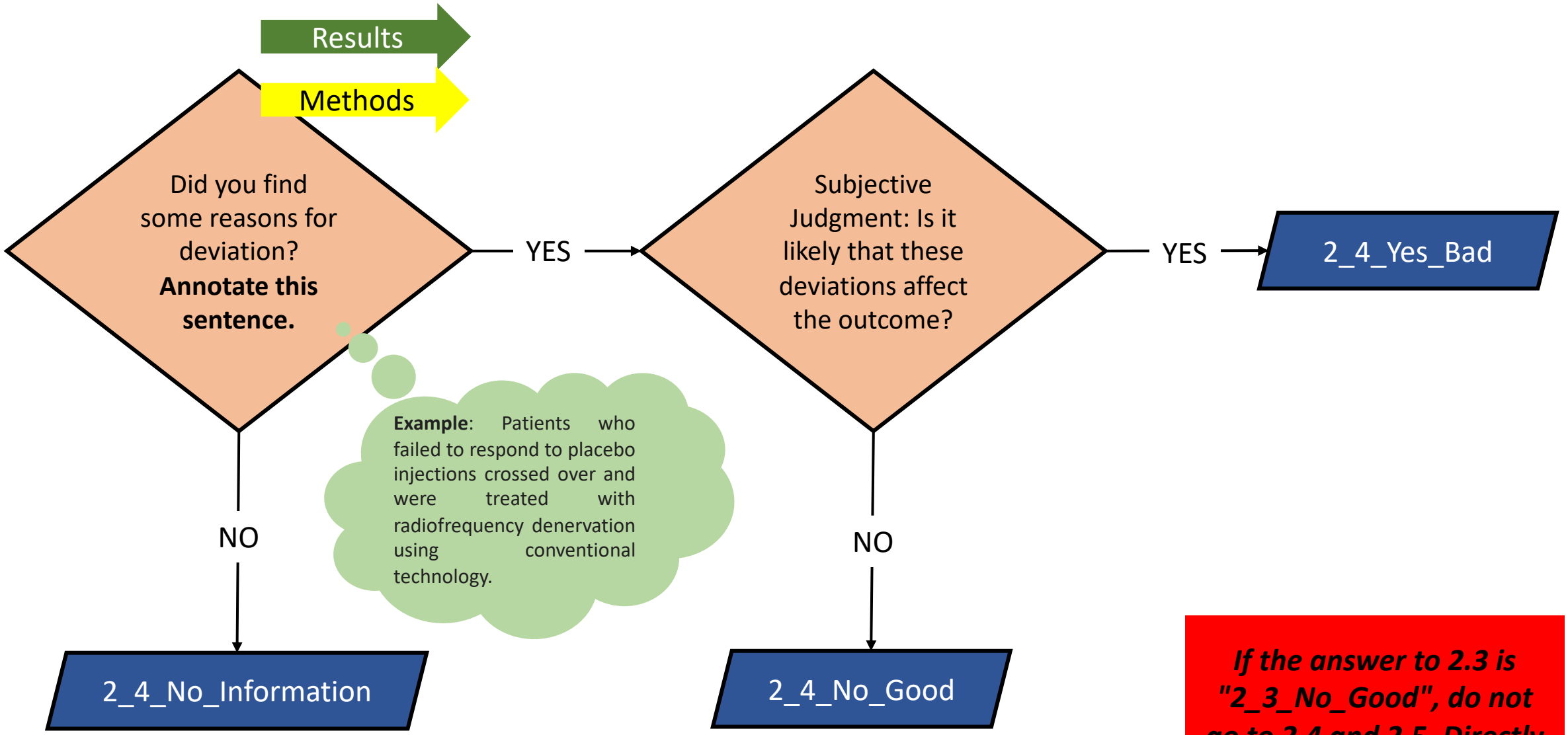
Annotate full sentences if not otherwise specified to annotate only phrase.
Green arrow = which section to find these text evidence
Red arrow = which section to NOT go to.

RoB 2.3: Were there deviations from the intended intervention that arose because of the trial context?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence
Yellow arrow = If you do not find it in the Results section, mark it in the Flowchart

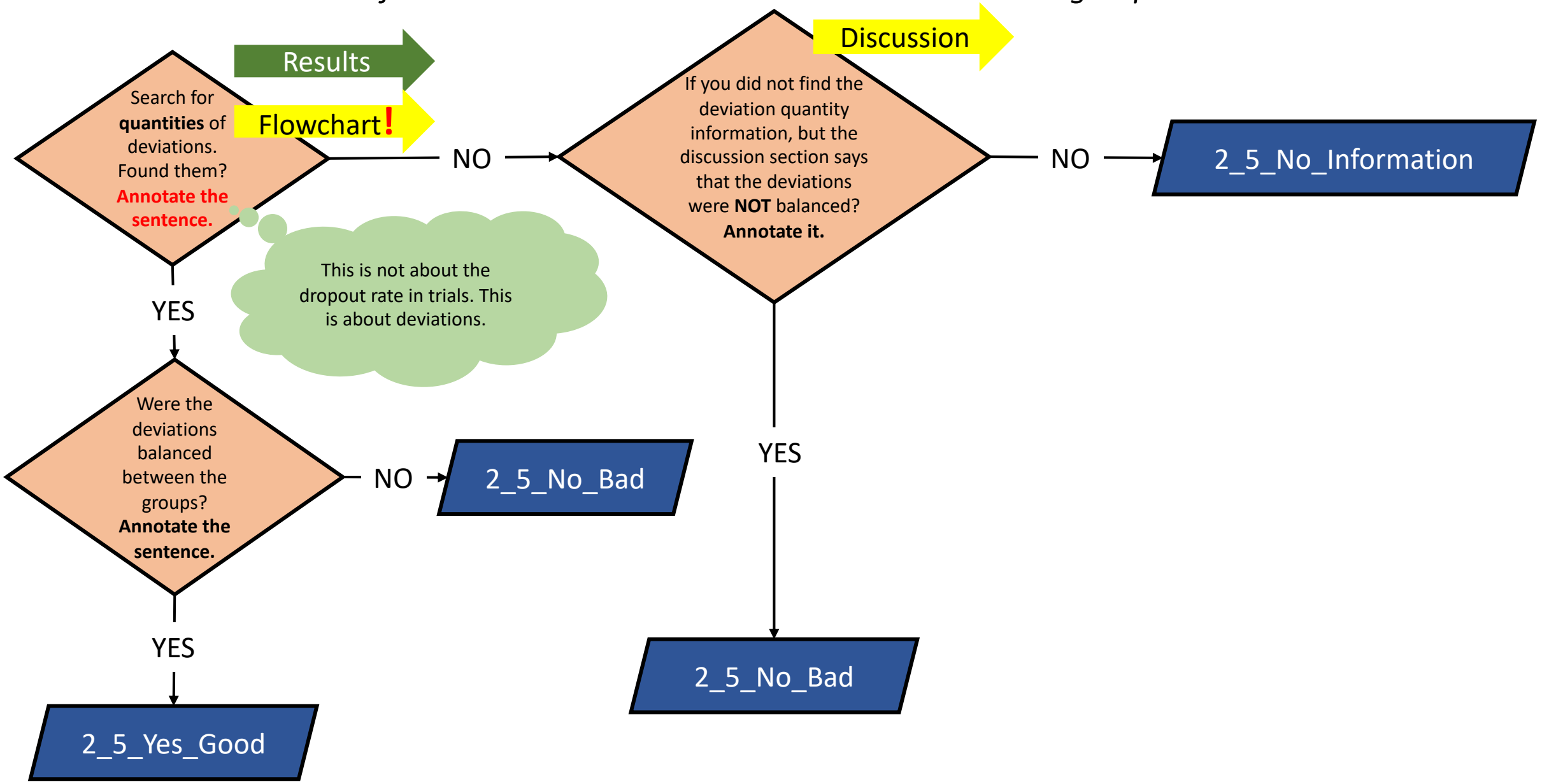
RoB 2.4 Were these deviations likely to have affected the outcome?



If the answer to 2.3 is "2_3_No_Good", do not go to 2.4 and 2.5. Directly skip to question 2.6.

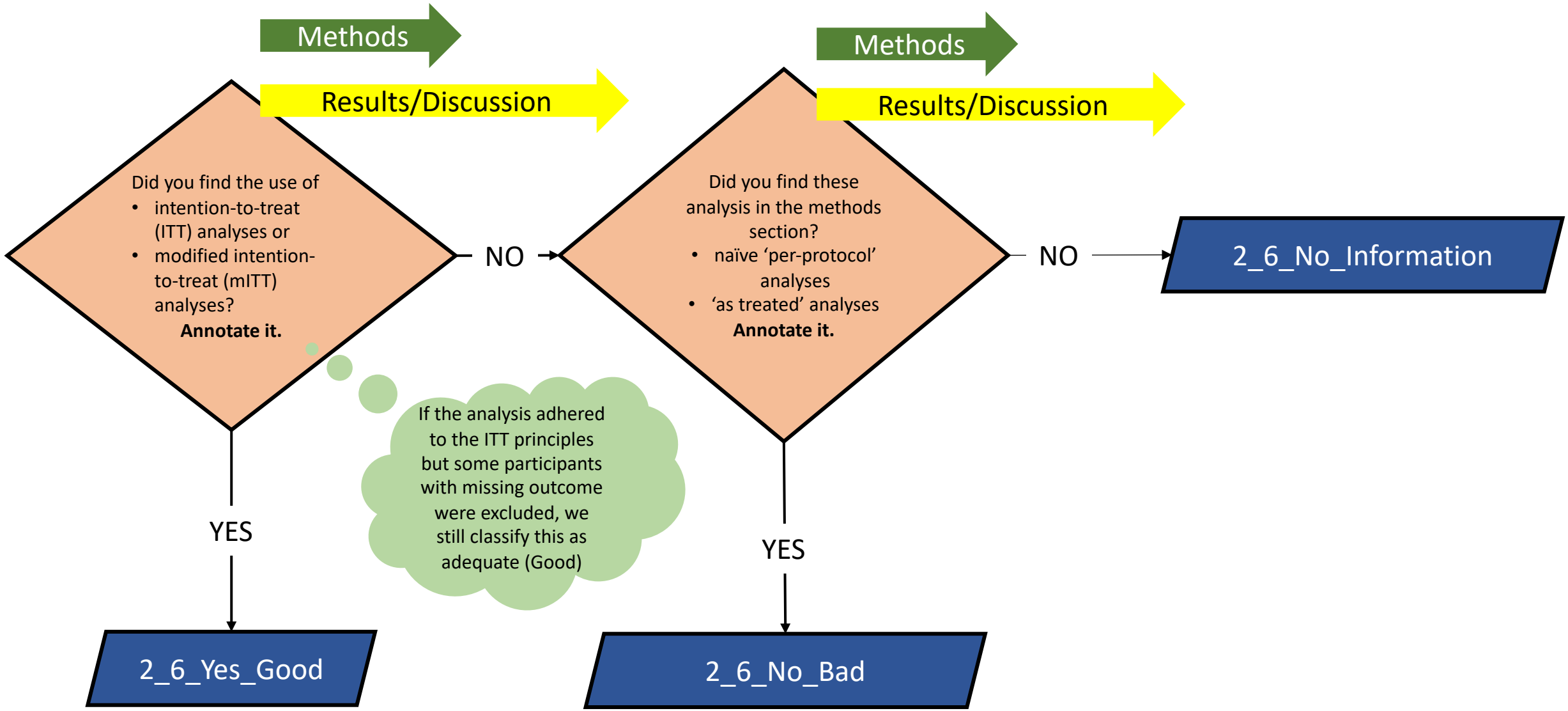
Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence
Yellow arrow = If you do not find it in the Results section, mark it in the Methods

RoB 2.5: Were these deviations from the intended intervention balanced between groups?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence
Yellow arrow = If enough information is not found in the Results section, mark it in the Flowchart

RoB 2.6: Was an appropriate analysis used to estimate the effect of assignment to intervention?

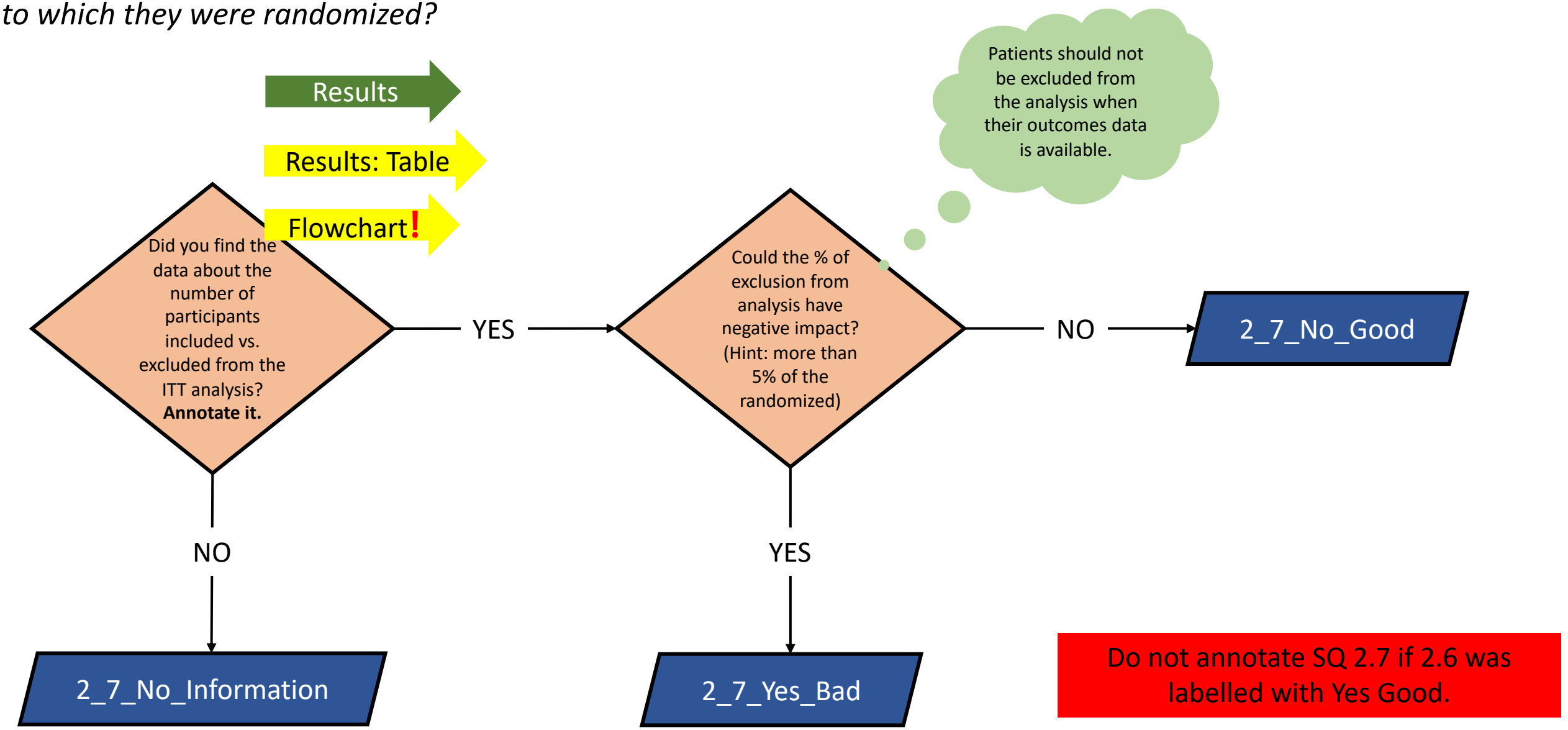


Annotate full sentences if not otherwise specified to annotate only phrases.

Green arrow = which section to find these text evidence

Yellow arrow = If information is not found in the Results section, mark it in the Results/Discussion

RoB 2.7 Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

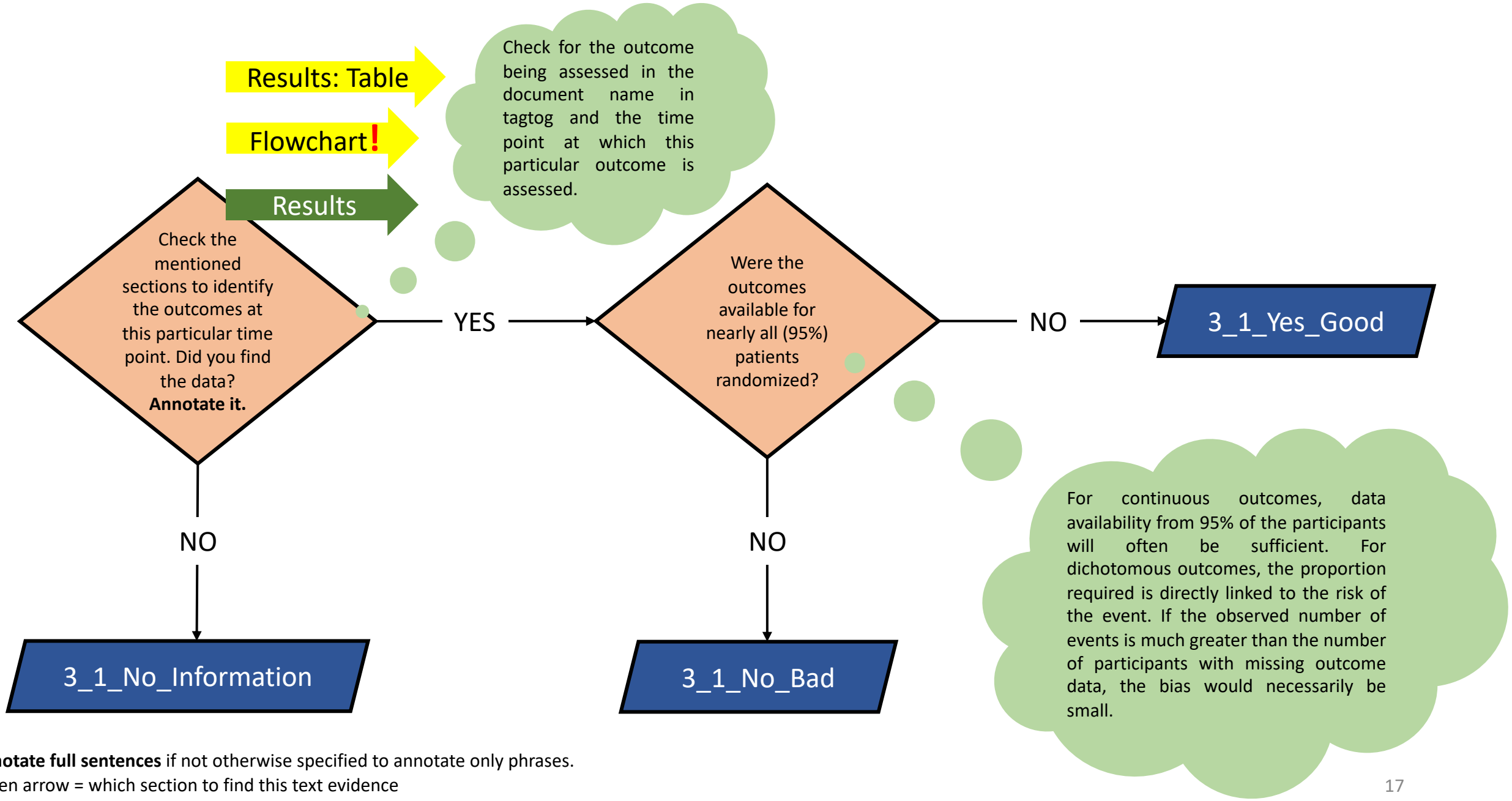


Do not annotate SQ 2.7 if 2.6 was labelled with Yes Good.

Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence
If the information was not found in the Results section, only then go to the flowchart. Any annotations in the flowchart should mark all the content of the flowchart box

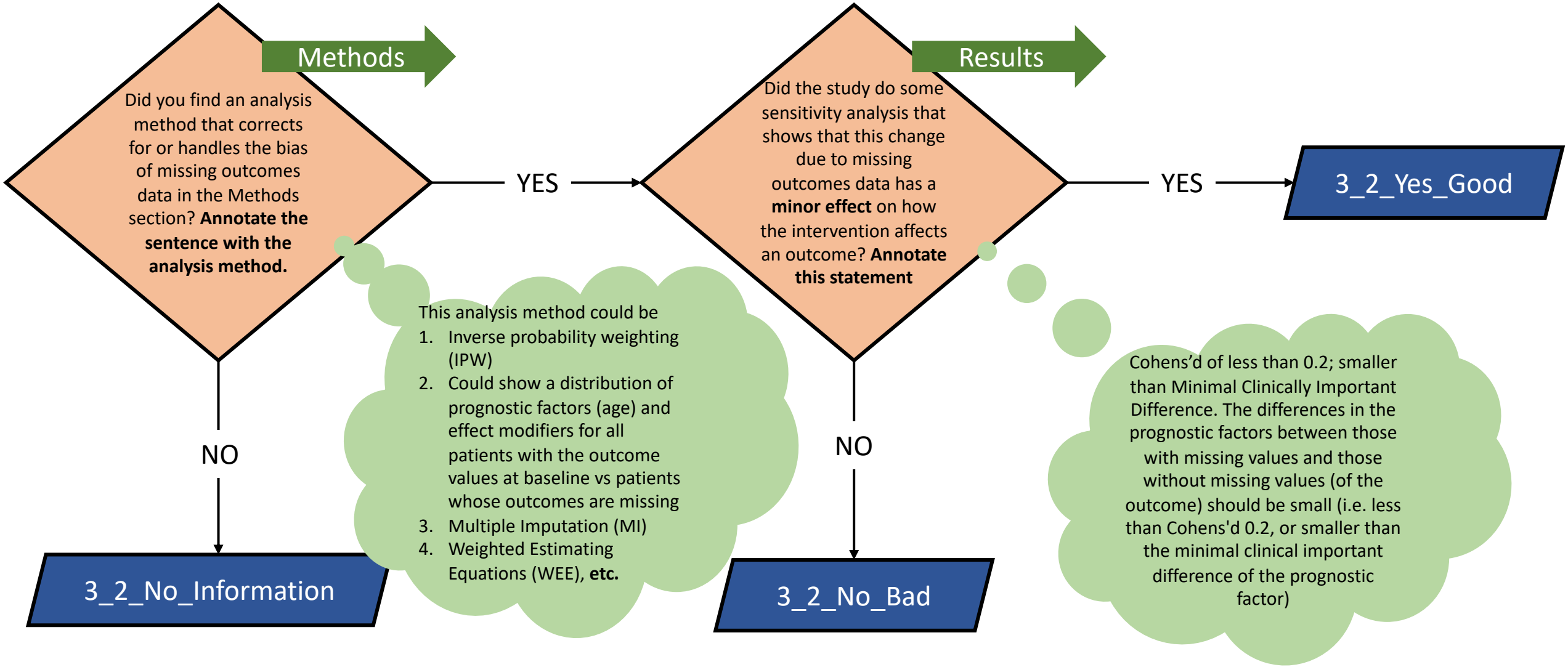
Domain 3
Risk of bias due to missing outcome data

RoB 3.1 Were data for this outcome available for all, or nearly all, Participants randomized?



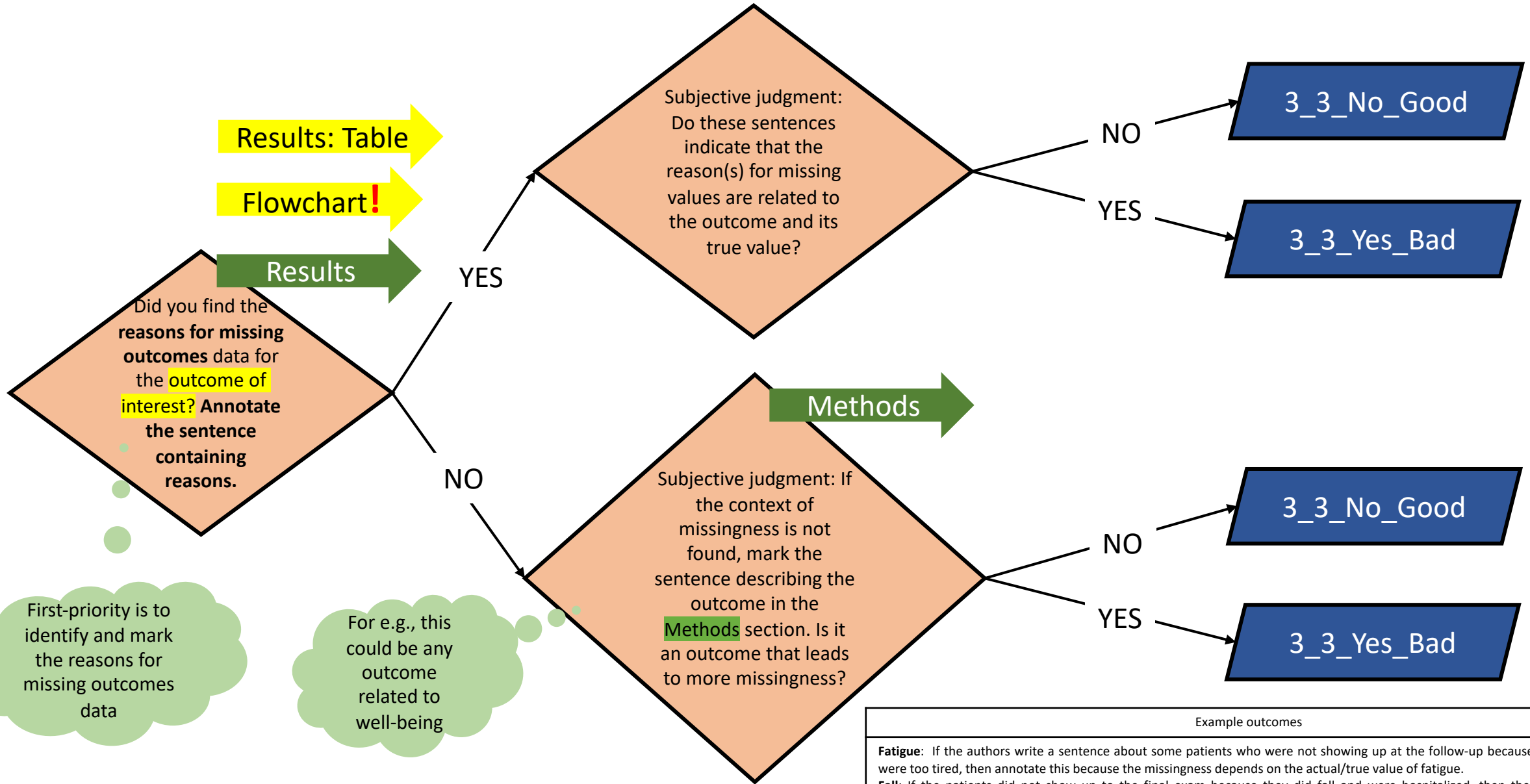
Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence
Yellow arrow = If the information was not found in the Results, then look for in the Results: Table

RoB 3.2 Is there evidence that the result was not biased by missing outcome data?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

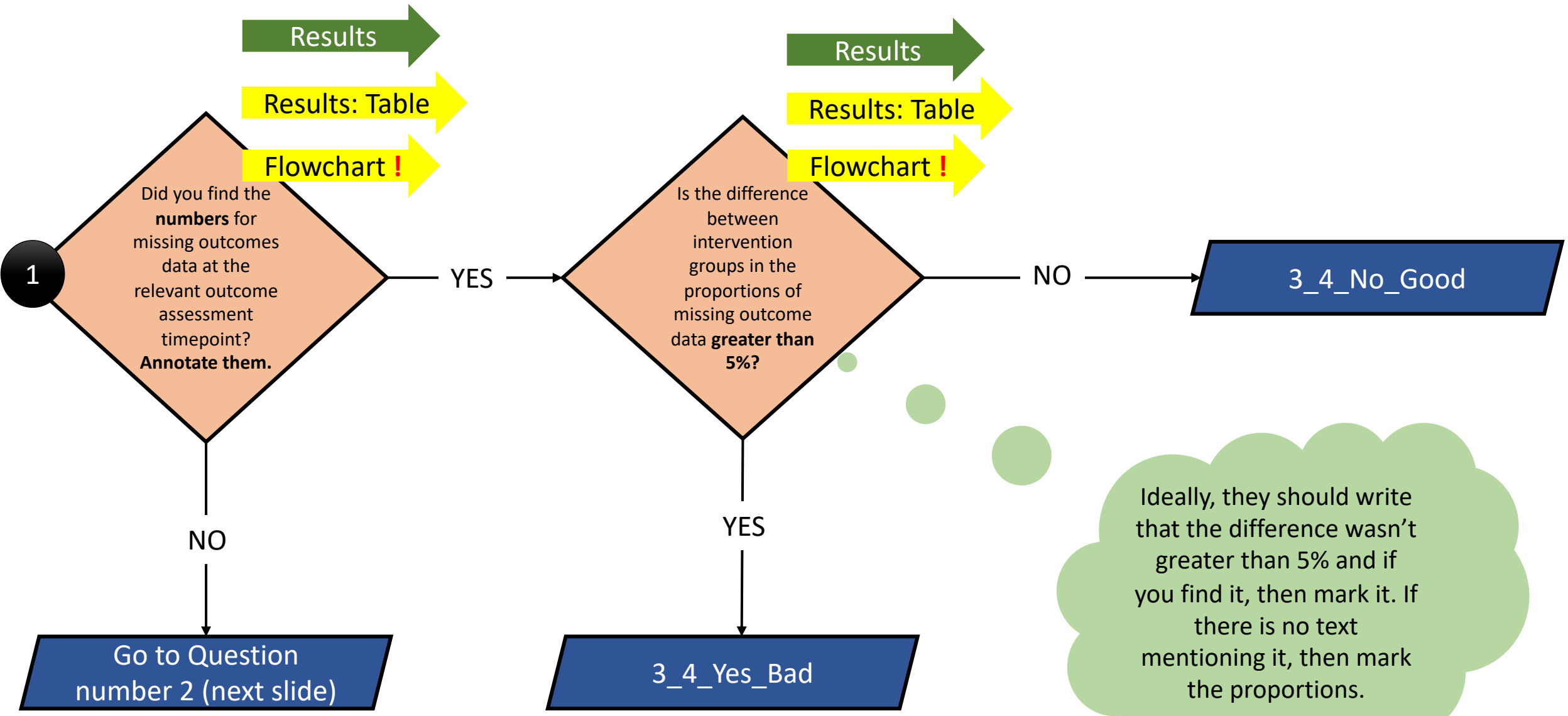
*RoB 3.3 **Could** missingness in the outcome depend on its true value?*



Example outcomes
Fatigue: If the authors write a sentence about some patients who were not showing up at the follow-up because they said they were too tired, then annotate this because the missingness depends on the actual/true value of fatigue. **Fall**: If the patients did not show up to the final exam because they did fall and were hospitalized, then the outcome fall - missingness depends on the true value. Assessors should reflect on the label the reason for missingness. Probably different labels are used, e.g., for the outcome fatigue, a possible explanation would be "exhaustion"?

Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

RoB 3.4 Is it likely that missingness in the outcome depended on its true value?



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Green arrow = which section to find these text evidence

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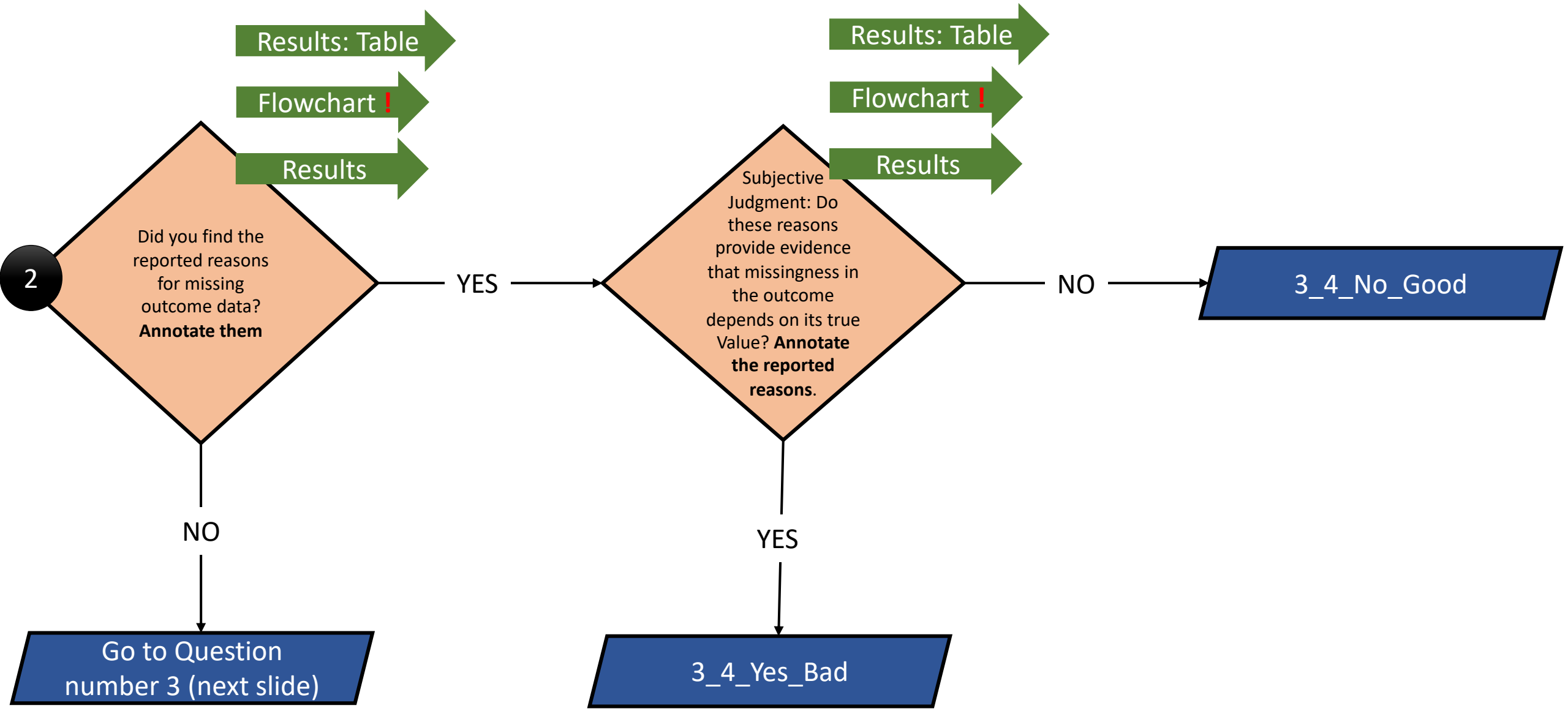
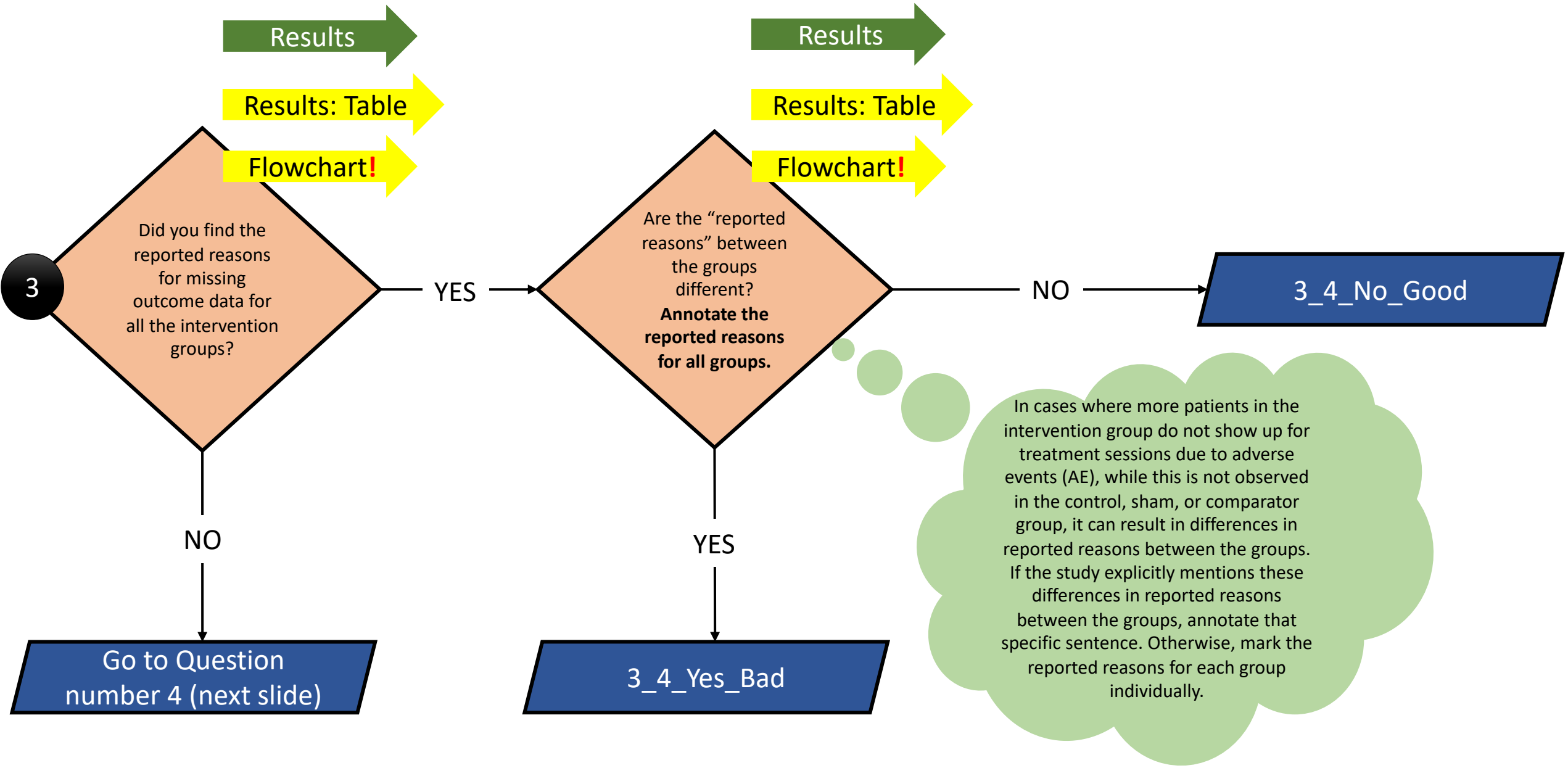


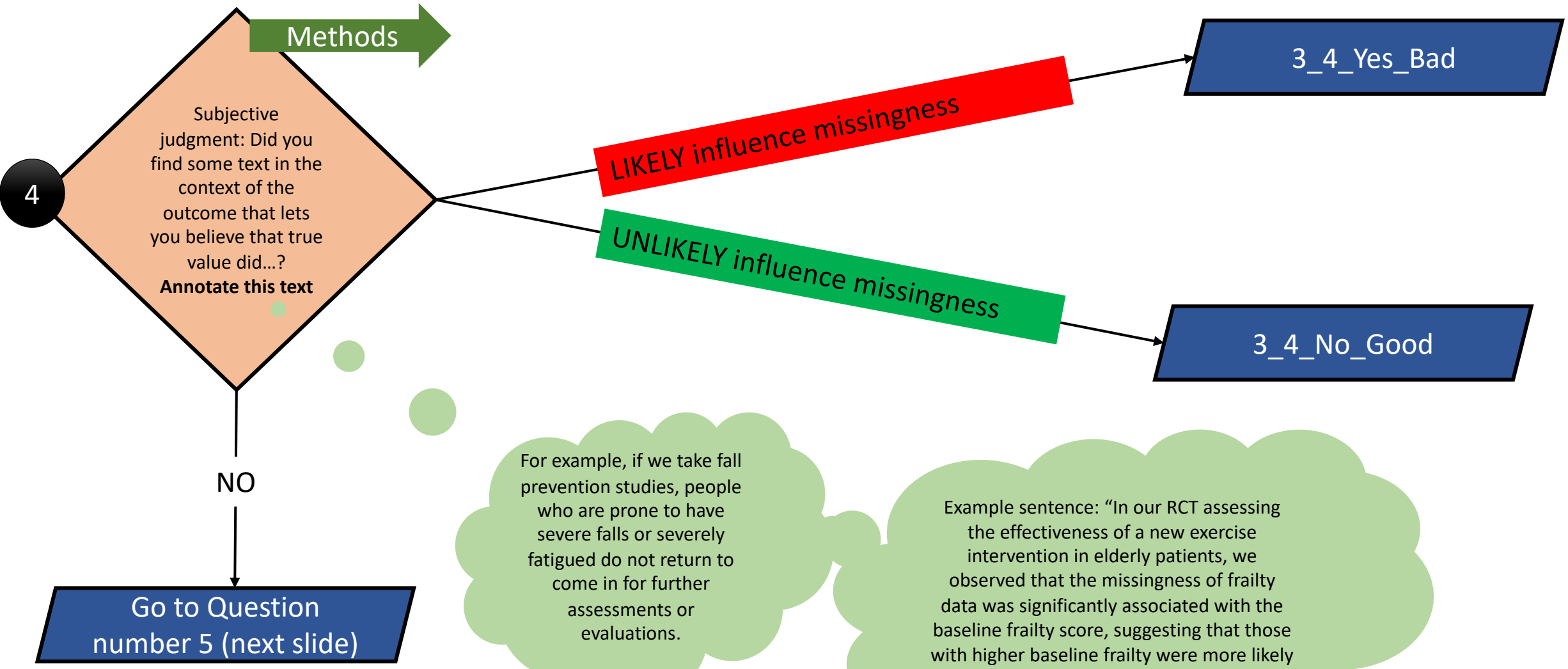
Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

RoB 3.4 Is it likely that missingness in the outcome depended on its true value?



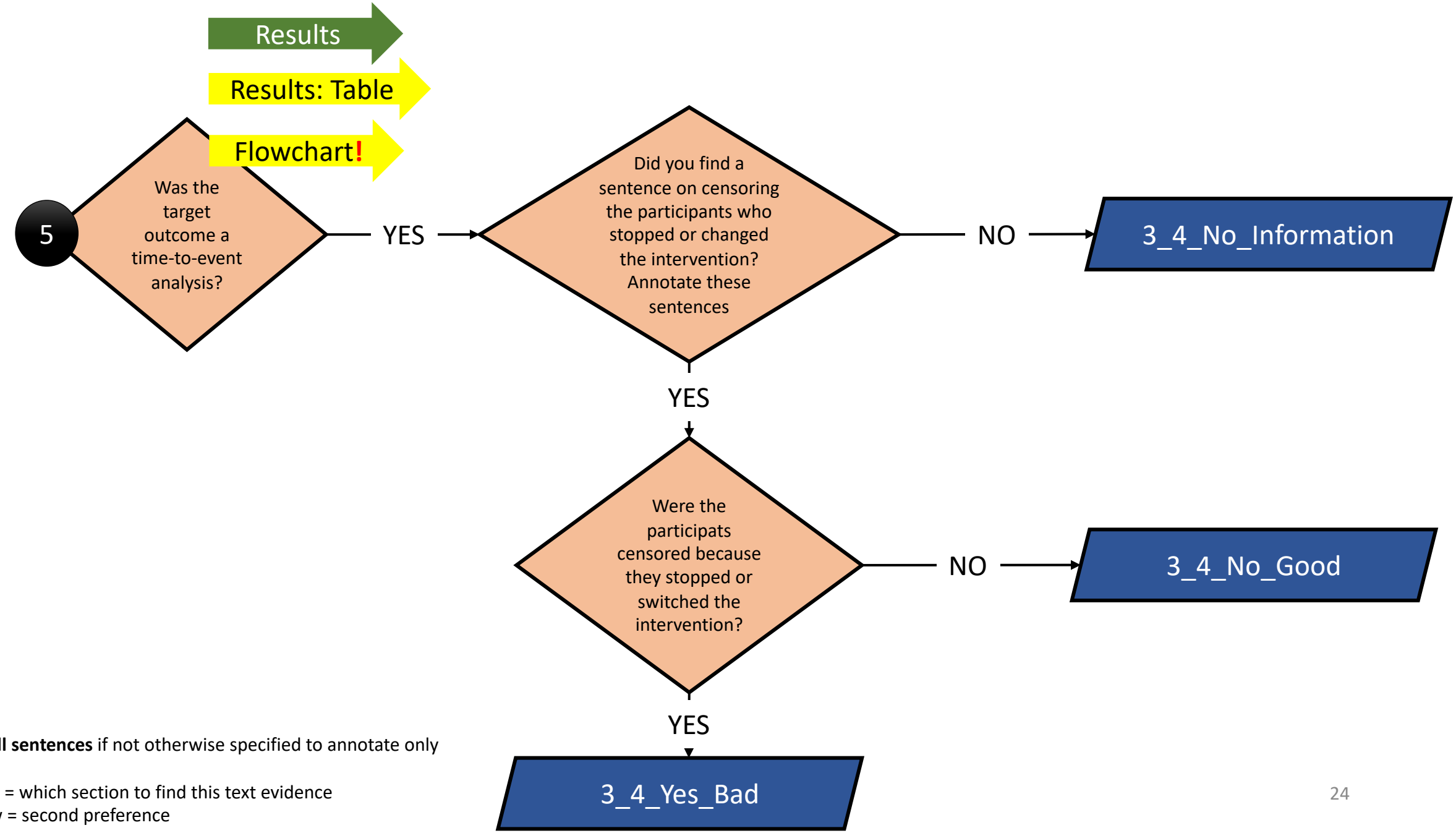
Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence

RoB 3.4 Is it likely that missingness in the outcome depended on its true value?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

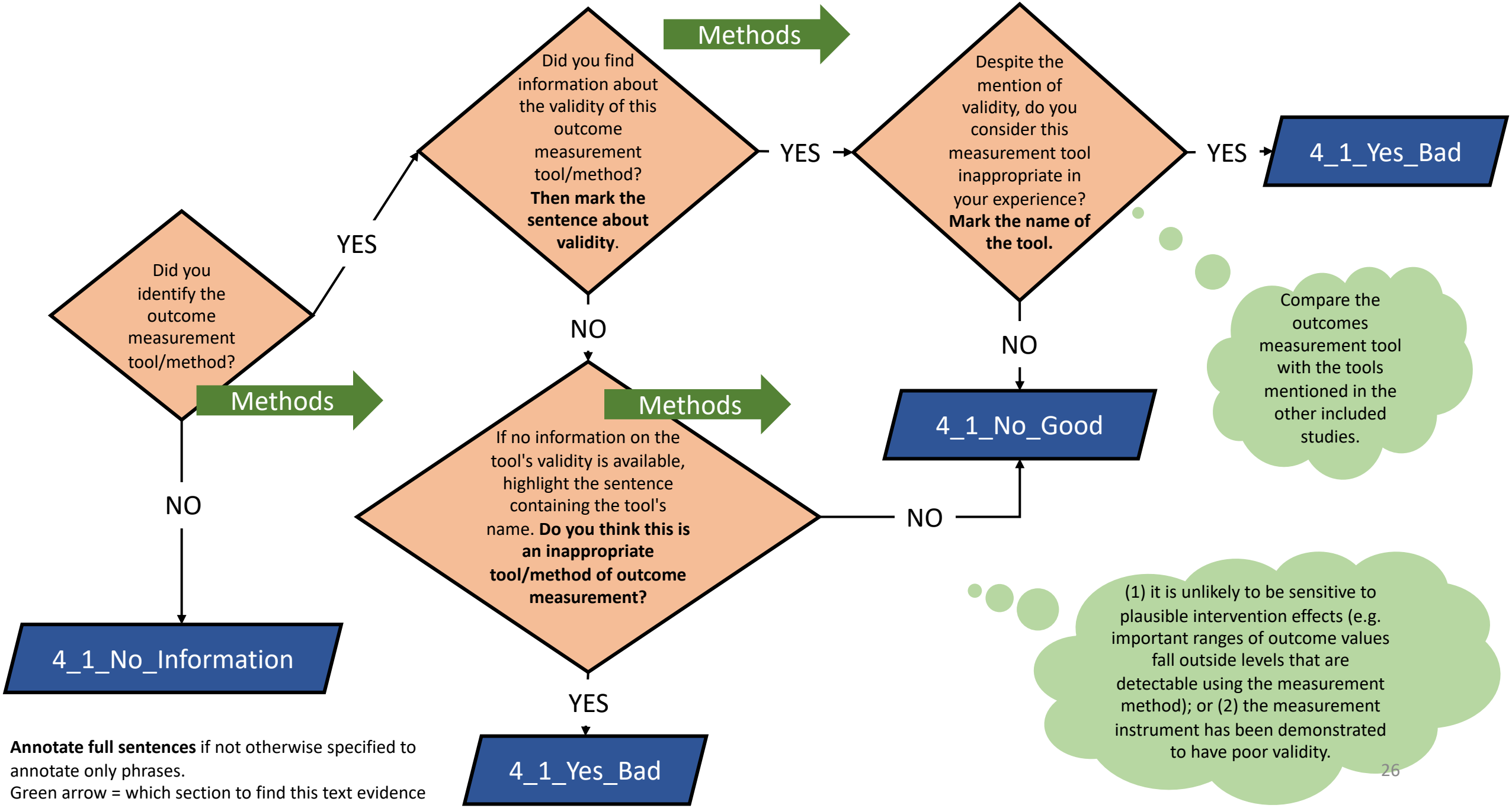
RoB 3.4 Is it likely that missingness in the outcome depended on its true value?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence
Yellow arrow = second preference

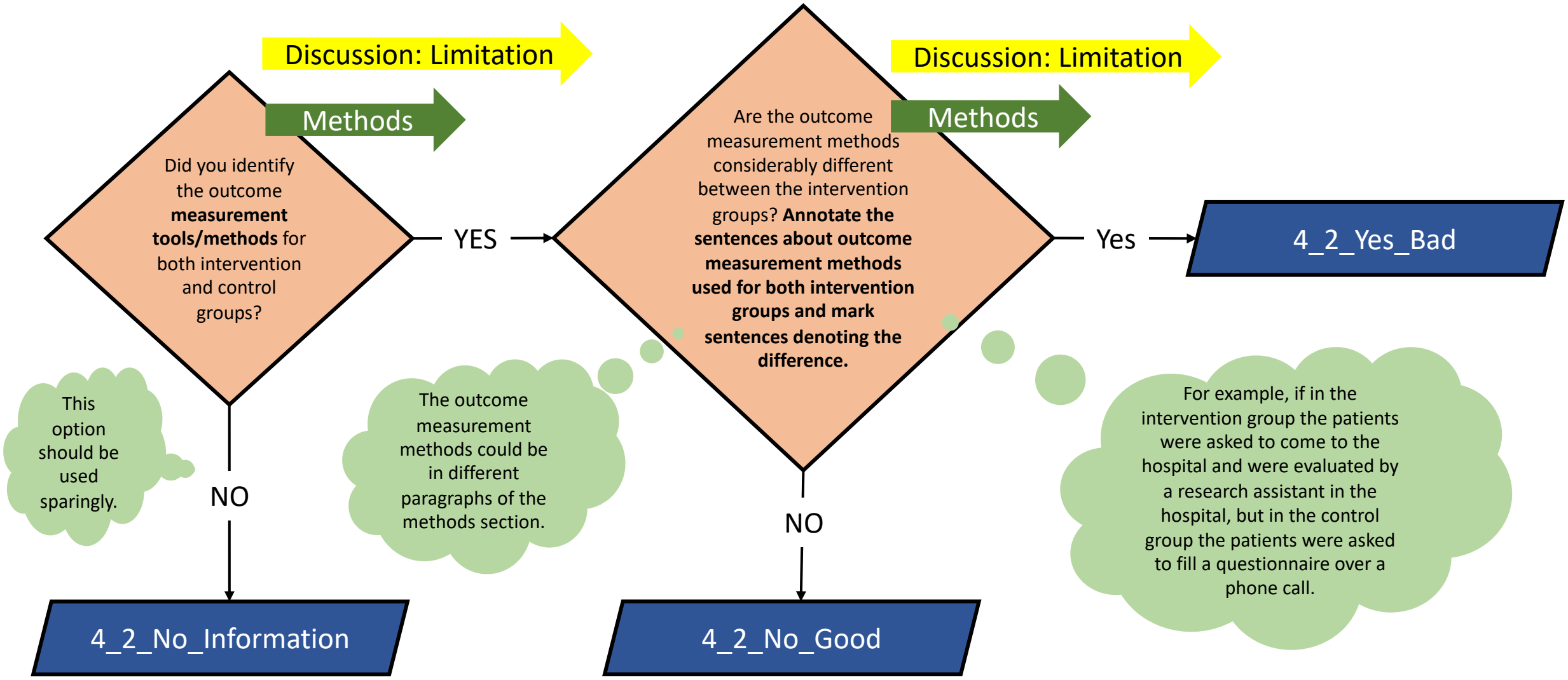
Domain 4
Risk of bias in measurement of the outcome

RoB 4.1 Was the method of measurement of the outcome inappropriate?



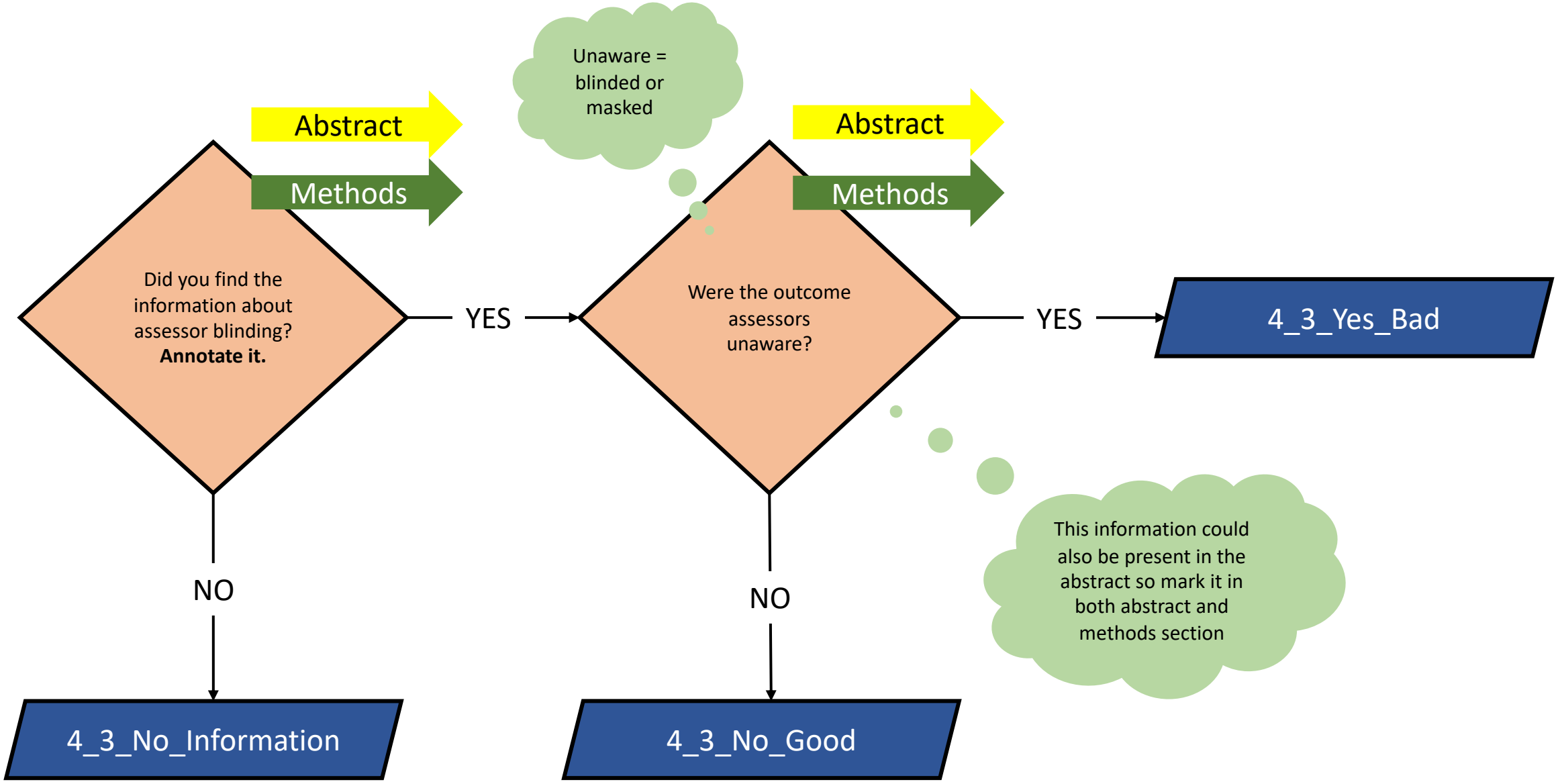
Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence

RoB 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence

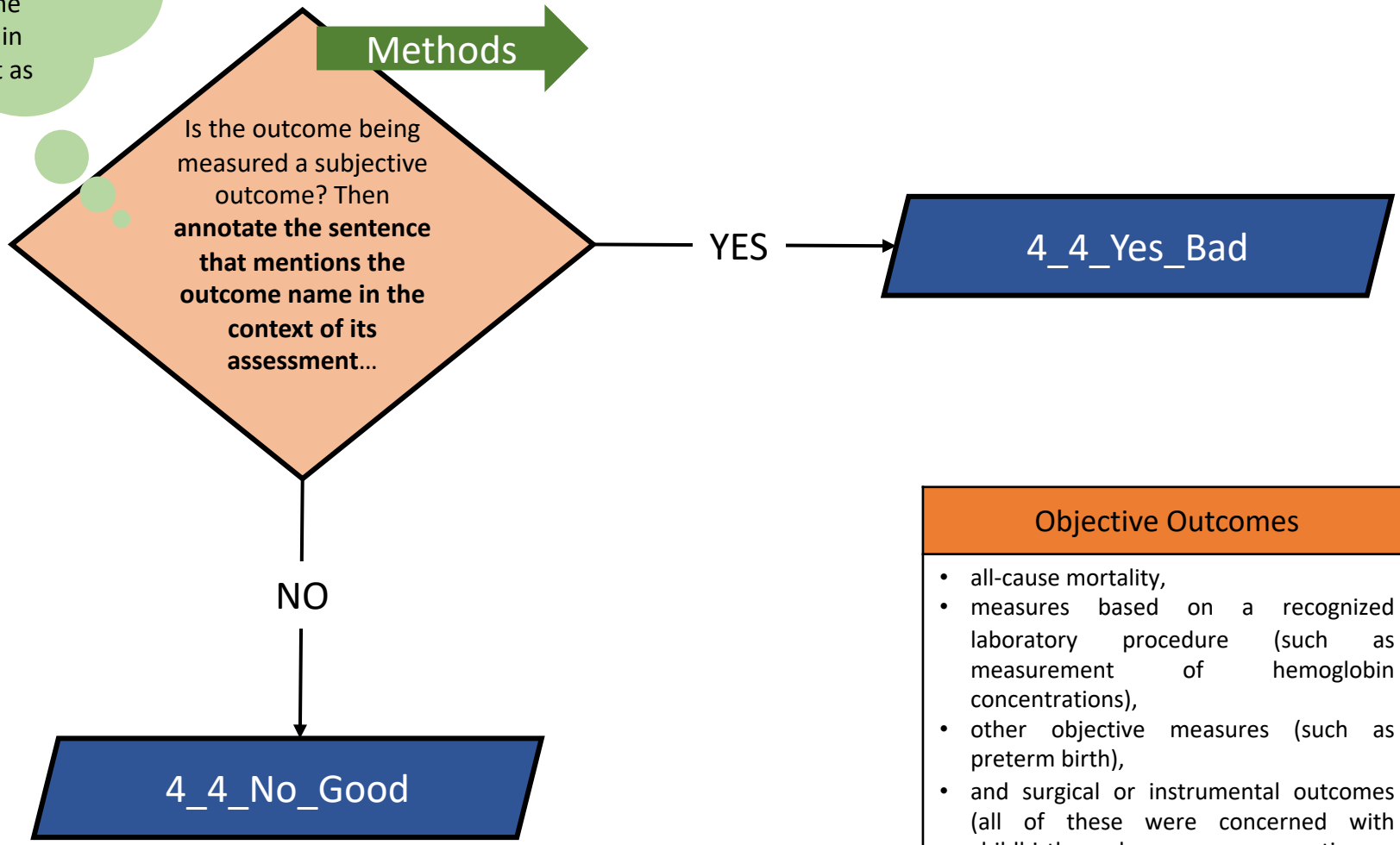
RoB 4.3 Were outcome assessors aware of the intervention received by study participants?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence
Yellow arrow = second preferred section after the green arrow.

RoB 4.4 Could assessment of the outcome have been influenced by knowledge of intervention received?

For Objective and mortality outcomes (check examples in the table)…. **Annotate the sentence** with the outcome name where it is mentioned in terms of its assessment as well.

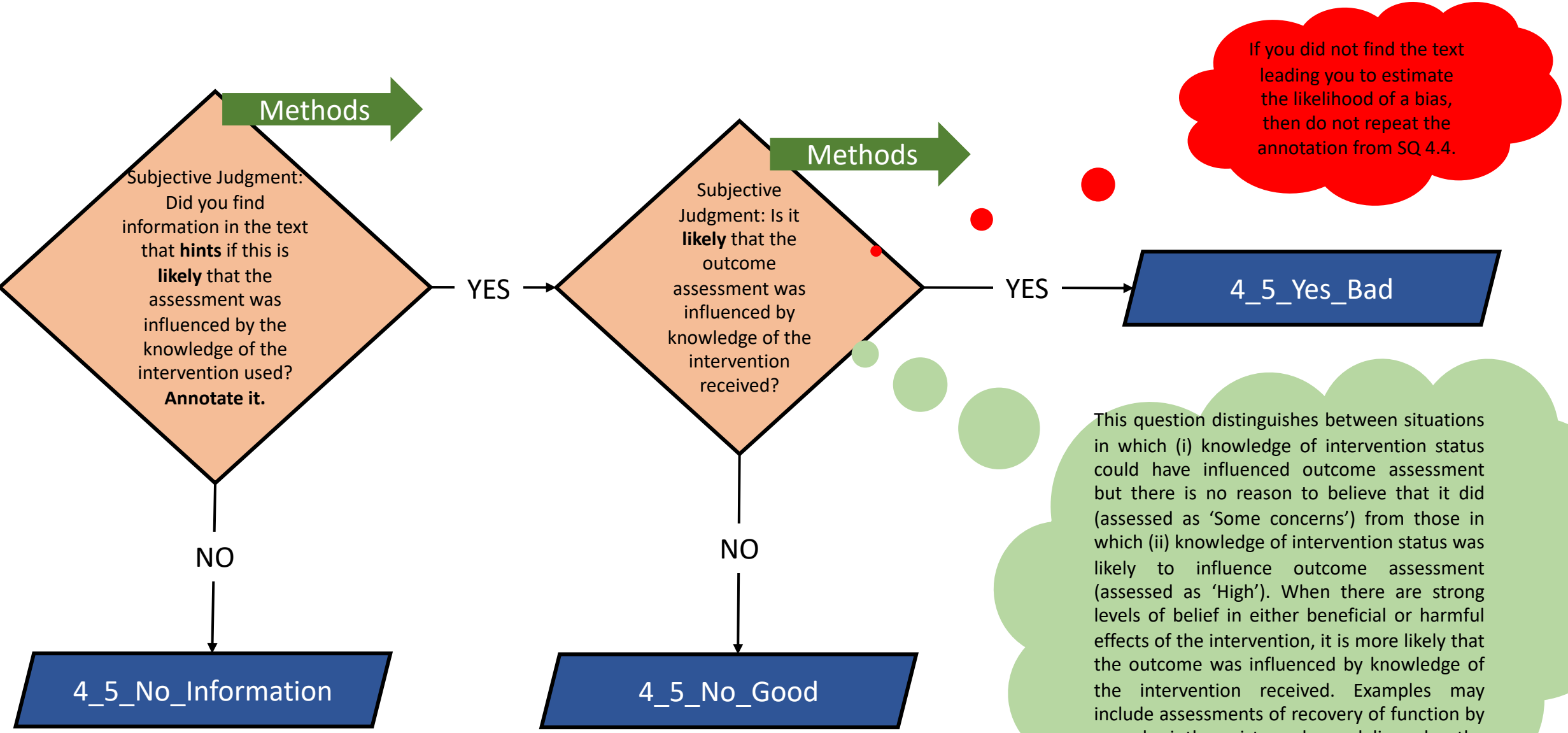


Objective Outcomes	Subjective Outcomes
• all-cause mortality, • measures based on a recognized laboratory procedure (such as measurement of hemoglobin concentrations), • other objective measures (such as preterm birth), • and surgical or instrumental outcomes (all of these were concerned with childbirth, such as caesarean section or instrumental delivery).	• patient-reported outcomes, • the physician assessed disease outcomes (such as vascular events, pyelonephritis, or respiratory distress syndrome) • Measures combined from several outcomes, and • withdrawals or study dropouts

Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2267990/pdf/bmj-336-7644-res-00601-el.pdf

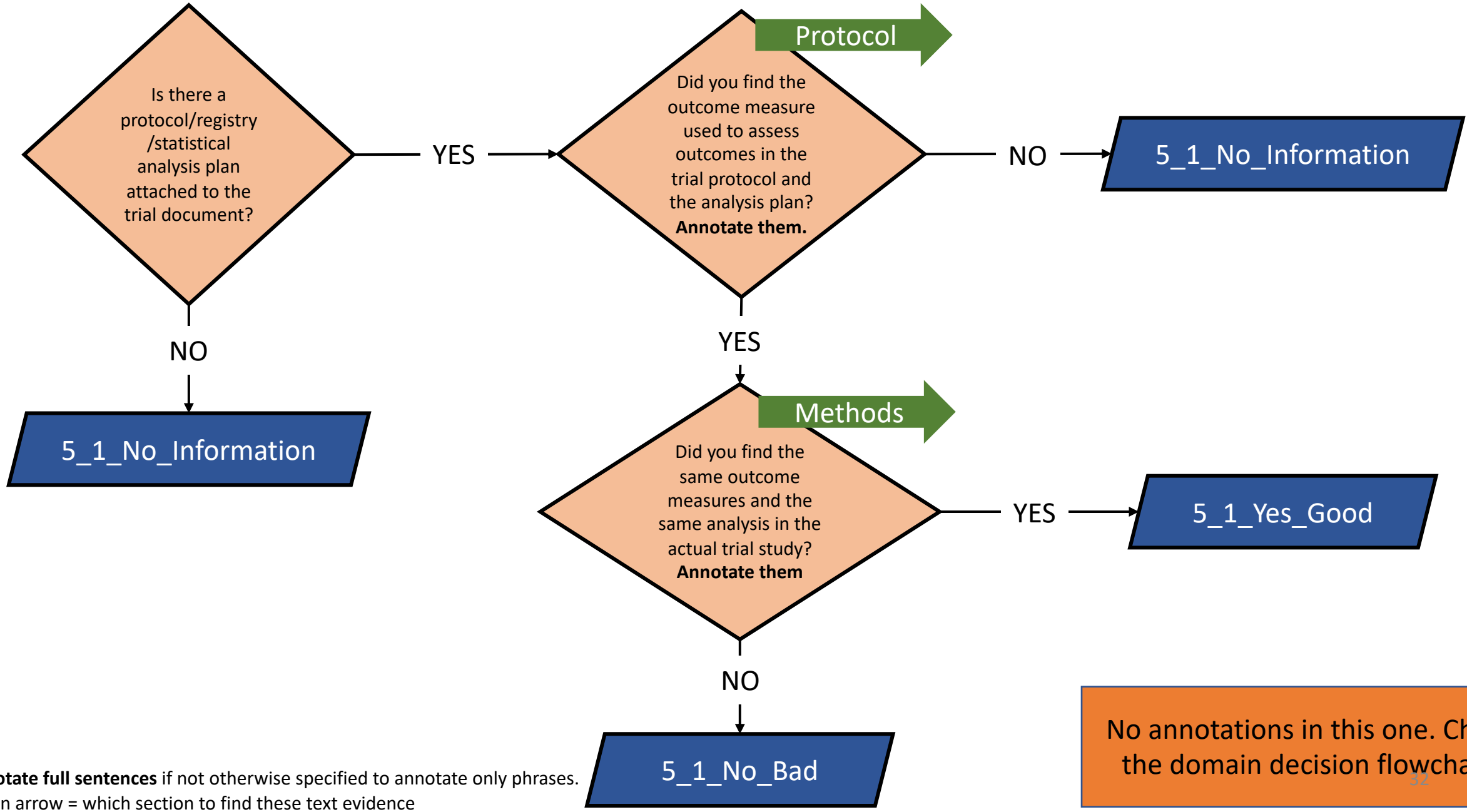
RoB 4.5 Is it likely that the assessment of the outcome was influenced by knowledge of the intervention received?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence
Yellow arrow = second preferred section after the green arrow.

Domain 5
Risk of bias in selection of the reported result

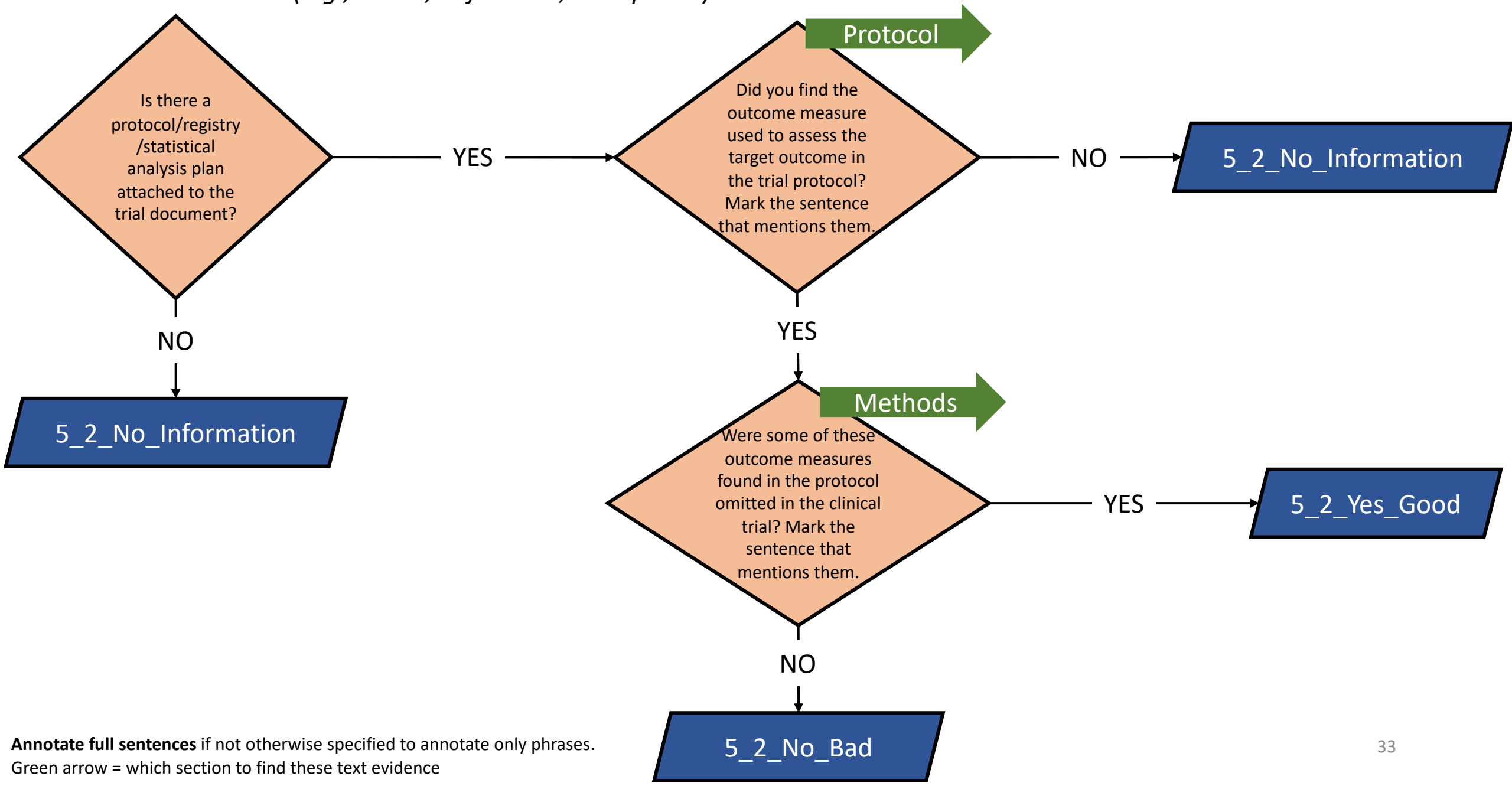
RoB 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

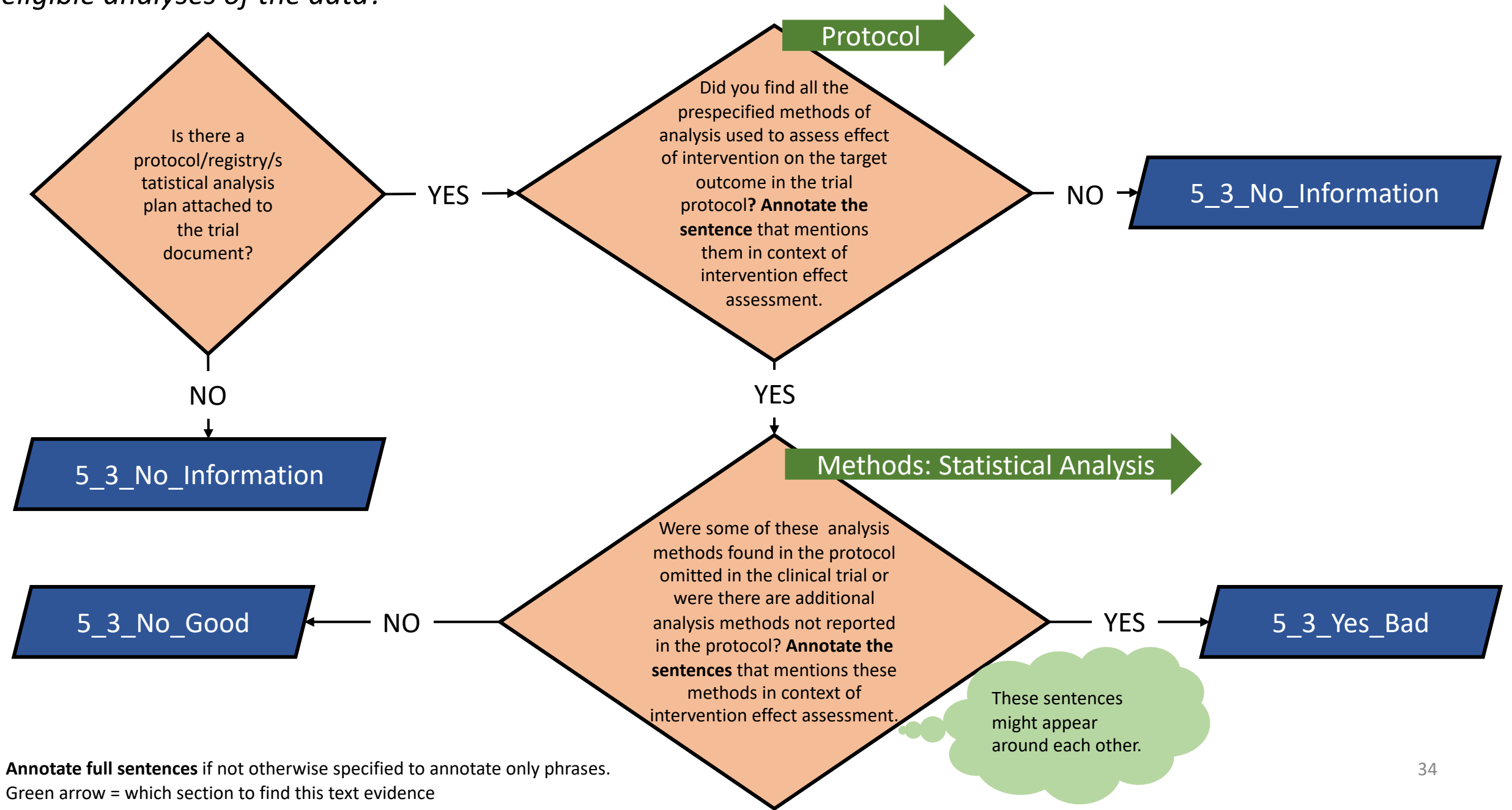
No annotations in this one. Check the domain decision flowchart.

RoB 5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (e.g., scales, definitions, time points) within the outcome domain?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find these text evidence

RoB 5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?



Annotate full sentences if not otherwise specified to annotate only phrases.
Green arrow = which section to find this text evidence

Bibliography

- Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng H-Y, Corbett MS, Eldridge SM, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019; 366: l4898.
- Sterne JA, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng HY, Corbett MS, Eldridge SM, Emberson JR. RoB 2: a revised tool for assessing risk of bias in randomised trials. bmj. 2019 Aug 28;366.
- Wood L, Egger M, Gluud LL, Schulz KF, Jüni P, Altman DG, Gluud C, Martin RM, Wood AJ, Sterne JA. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. Bmj. 2008 Mar 13;336(7644):601-5.