Handling Subjects Clinical Trials participation to inform future analyses involving trials-based care (Work Group 3)

Working Group

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Questions Entertained…

- Primary question: Recommendations about collecting information about innovative clinical trials that can be used to test differences between patients on trials or SOC and guide future risk adjustment

- Stating the obvious, falling out of the expected center-specific survival analysis (CSA) has considerable impact for the center

- From a center perspective: do clinical trials provide quality, risk or both?

- Many different types of clinical trials (observational, interventional) is it possible to distinguish these from data on CIBMTR forms?

Working Group Recommendations

1) The data about clinical trial participation seems to partially exist

2) The committee would like to see if (using the existing data) whether trial participation impacts the center spp outcome measurement

3) Most speculated that it would make a material impact

Further considerations

- The committee felt that it did exist was quite definitive in the suggestion that using the existing data would be helpful. Also, suggestion about publication depending on the quality of the data.

- There was some bias that the number of phase I studies (that might diminish a center outcome result) was minimal

- Further discussions around the quality provided in clinical trials might *improve* outcomes and *increase* center outcomes

- This resulted in a discussion of how centers might game the system by enrolling large numbers of patients who are complex