

- *Why carry out this study?*
- Overall survival as the primary endpoint of the DAC-016 study was not met and decitabine was not approved by the FDA in acute myeloid leukemia (AML).
- Though pre-specified, the log-rank test could be considered not optimal to assess the observed survival difference because of the non-proportional hazard nature of the survival curves.
- Wilcoxon test is considered more powerful as it assigns more weight to earlier events. Wilcoxon test indicated significant increase in survival for decitabine versus treatment choice.
- *What was learned from the study?*
- It should be possible to ex-ante include different test options in a statistical analysis plan making their respective use dependent on the proportionality of hazard rates.
- In the future an adaptively-weighted log-rank test might be appropriate because it maintains optimality at the proportional alternatives, while improving the power over a wide range of non-proportional alternatives.

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