



EMIF Deliverable 8.3: Evaluation of liver function tests in placebo groups from existing clinical trials to try to determine factors that influence the natural history of liver function tests

Executive summary

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The pooling of placebo data across industry studies demonstrated that this approach was possible within the constraints of data privacy and corporate information security, an approach that could be replicated for future studies.

Pooled placebo data revealed the natural history of aminotransferase changes in study participants in an era when both occult and overt fatty liver disease is at least moderately prevalent in trial populations. These data may inform thresholds for detection of potential hepatotoxicity in this population, enhancing the ability to preserve the safety of study participants and robustly assess the safety of novel therapies.

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