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Methods to enrich clinical trial evidence by real world evidence conceptually explained

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Real world evidence is more and more recognized by both regulatory as well as health technology assessment agencies as can be seen by different guidelines from EMA, FDA, NICE and other agencies. Methodology to use real world evidence is new and still in development. It can be used to enrich single arm studies and can be useful for oncology when the majority of patients cross-over to active treatment, or for modelling of plateau effects in immune oncology, among others. The conceptual idea behind methods like propensity scoring, matching adjusted indirect comparisons, simulated treatment comparison, disease risk modelling will be presented which can be used to enrich clinical trial data by real world evidence, both supporting long term extrapolation for NICE and other HTA agencies and supporting single arm trial information, as well as validating findings by treatment switch algorithms. Examples will be provided, together with frameworks to select the appropriate methodology.

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