# $GDOLPXPDE %LRVLPLODU $GDOLPXPDE DGEP 3KDUPDFRNLQHWLFV LQ +HDOWK\ 3HUVRQV DQ 'HWHUPLQH 3KDUPDFRNLQHWLF 6LPLODULWLHV

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assess the impact of switching treatment from Humira to adalimumab-adbm on PK using a Population Pharmacokinetic (PPK) approach.

## Conclusion

Using intensive PK data from the phase 1 investigation in healthy subjects, a PPK model was first built (NCT02045979). In patients with active RA, PPK models were created separately for the phase 3 base study (NCT02137226) and its extension study (NCT02640612). PPK models for adalimumab were established based on the treatment of healthy volunteers and RA patients with adalimumab-adbm and Humira. Adalimumab clearance was found to be influenced by weight and anti-drug antibodies. The PK of adalimumab-adbm and Humira were quite similar. Humira's effect on clearance was predicted to be 1.02 times that of adalimumab-adbm (*i.e.* Humira has 0.02 greater clearances). In the phase 3 extension research, the effect of treatment arms (switching) on clearance was assessed to be 1.00 and 0.997, respectively, for the Humira:Humira:BI and Humira:BI:BI arms, compared to the BI:BI:BI arm (BI refers to adalimumab-adbm).

The PPK method was used to demonstrate PK similarities between adalimumab-adbm and Humira in patients with active RA. When moving from Humira to adalimumab-adbm at week 24 or 48, the PK of adalimumab was also similar.

## References


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