

ntraocular use of biologics

- The intraocular use of biologicals has revolutionised the treatment of blinding diseases, especially in our ageing population.
- Preclinical development is hampered by anti-drug antibodies (ADAs) that form in animal models against human candidate medicines. ADAs limit development of products designed for longer duration of action.
- The PK-Eye[™] replicates the human clearance times of intraocular protein medicines.
- The PK-Eye[™] makes it more feasible to determine intraocular clearance times, dose escalation PK effects and stability profiles of biologicals during preclinical development.

The PK-Eye[™] replicates the human clearance times of biologics

- Biologics such as antibody based medicines and other proteins are large, charged molecules that are NOT permeable through the back of the eye (RCS pathway).
- Aqueous outflow is through the front of the eye (anterior chamber) and is the primary means of
 mass transfer in the eye needed to nourish the cornea and lens.
- Protein-based medicines primarily clear from the front of the eye (anterior pathway) due to aqueous outflow. Large molecules diffuse more slowly than small molecules in the vitreous.



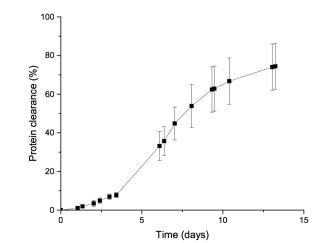
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Intraocular injection of an antibody drug

As the protein drug diffuses within the vitreous, it also clears anteriorly due to aqueous outflow

□ Using simulated vitreous (SV), the PK-Eye[™] shows the clearance half-life (T_{1/2}) for ranibizumab (Lucentis[®]) is very similar to what is observed in humans.

Ranibizumab dose of 0.5 mg, 50 uL	
The PK-Eye™ (SV)	Humans
8.0 ± 3.1 days	7-9 days



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