

Update on Fluvax[®]

Inactivated Influenza Vaccine (Split virion)

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based on material provided by Seqirus (a CSL Company)

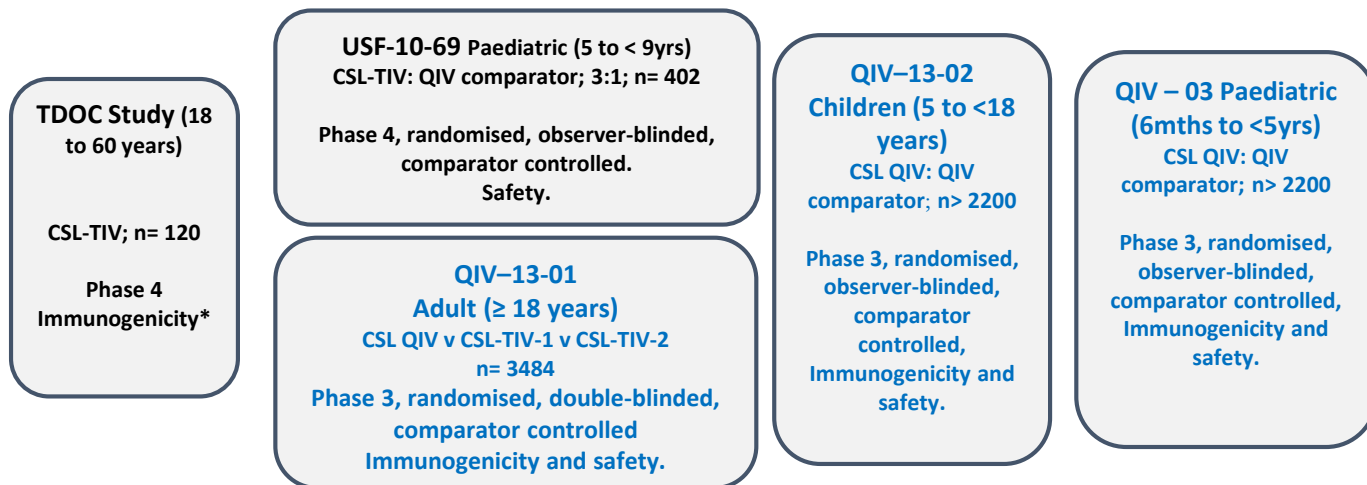
Scientific Investigation Conclusions

- Standard method of manufacture results in more residual lipid and RNA components than other licensed influenza vaccines
- Lipid-mediated delivery of fragmented viral RNA induced a stronger than expected pro-inflammatory signal in *in vitro* assays
- Mechanism believed to be responsible for the febrile reactions observed in some young children

Increasing the levels of the splitting agent sodium tauro deoxycholate (TDOC) for B strain, significantly reduced lipid levels and release of pro-inflammatory cytokines

Key to addressing the increased reactogenicity

QIV Clinical Development Plan



*CPMP Note for Guidance on Harmonisation of Requirements for Influenza Vaccines (CPMP/BWP/214/96)

Findings from clinical studies

- TIV Immunogenicity study:
 - ✓ B strain in TIV split at 1.5% TDOC in healthy adults met CHMP immunogenicity criteria
 - ✓ Introduction of 1.5% TDOC for splitting B strains (within registered conditions) in commercial product from 2014

- In 2015 paediatric study (USF 10-69):
 - ✓ CSL TIV fever rates observed in the study are lower than CSL TIV historical experience in this age group
 - ✓ similar to that reported for competitor vaccines
 - ✓ Commencement of paediatric studies