



## Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140

Donnelly, L., Curran, R., Morrow, R., Kett, V., Andrews, G., Malcolm, K., ... Shattock, R. J. (2009). Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140. *Retrovirology*, 6(S3), 156. DOI: 0.1186/1742-4690-6-S3-P156

**Published in:**  
Retrovirology

### Queen's University Belfast - Research Portal:

[Link to publication record in Queen's University Belfast Research Portal](#)

#### General rights

Copyright for the publications made accessible via the Queen's University Belfast Research Portal is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

#### Take down policy

The Research Portal is Queen's institutional repository that provides access to Queen's research output. Every effort has been made to ensure that content in the Research Portal does not infringe any person's rights, or applicable UK laws. If you discover content in the Research Portal that you believe breaches copyright or violates any law, please contact [openaccess@qub.ac.uk](mailto:openaccess@qub.ac.uk).

Poster presentation

Open Access

## PII-II. Stable lyophilised gel vehicles for vaginal administration of recombinant C-clade HIV-1 trimeric CN54gp140

L Donnelly\*<sup>1</sup>, RM Curran<sup>1</sup>, RJ Morrow<sup>1</sup>, VL Kett<sup>1</sup>, GP Andrews<sup>1</sup>, RK Malcolm<sup>1</sup>, AD Woolfson<sup>1</sup> and RJ Shattock<sup>2</sup>

Address: <sup>1</sup>School of Pharmacy, Queens University Belfast, Belfast, UK and <sup>2</sup>St George's University of London, London, UK

\* Corresponding author

from AIDS Vaccine 2009  
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, 6(Suppl 3):P156 doi:10.1186/1742-4690-6-S3-P156

This abstract is available from: <http://www.retrovirology.com/content/6/S3/P156>

© 2009 Donnelly et al; licensee BioMed Central Ltd.

### Background

With an effective vaccine being sought for the prevention of HIV transmission, current focus is upon a mucosal vaccine strategy providing protection at the viral point of entry. The full potential of these vaccines can only be realised with the development of successful delivery systems which are also capable of providing an environment conducive to antigen stability. Previously, rheologically structured vehicles (RSVs) were formulated to include the recombinant C-clade HIV-1 envelope protein CN54gp140, and intra-vaginal immunisation in rabbits induced significant systemic IgG and specific IgG and IgA in genital tract secretions. However, CN54gp140 stability within these aqueous formulations remains a concern. Here we investigate the formulation of CN54gp140 within modified lyophilised RSV matrices as a means of providing enhanced protein stabilisation.

### Methods

RSV formulations were prepared comprising mucoadhesive (polycarboxophil, sodium carboxymethylcellulose) and vaginal fluid absorbing (polyvinylpyrrolidone) components. Using rheological analyses in combination with dispensing studies, formulations having appropriate flow properties were chosen for lyophilisation. *In vitro* release testing of the lyophilised CN54gp140 formulations were investigated in PBST, and following prolonged storage at 37°C the antigenicity of CN54gp140 from the lyophilised RSVs were analysed by ELISA. The antigen CN54gp140

stability profiles of these formulations were compared to the original aqueous RSV.

### Results

CN54gp140 was found to be uniformly distributed within the lyophilised products and exhibited a sustained release profile over an 8 hour period during which the lyophilised 'tablet' underwent complete dissolution in the surrounding media. While recovery of CN54gp140 from the aqueous RSV diminished over 9 days, lyophilisation showed no loss in CN54gp140 antigenicity over 67 days storage.

### Conclusion

Formulation of CN54gp140 within a lyophilised gel matrix is shown to have a stabilising effect on the antigen while preserving its sustained release capacity. Such a mucosal vaccine delivery system may offer numerous advantages including ease of use, long-term stability and cold chain avoidance.