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Poster abstract submission

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Poster title

Evaluation of monoclonal antibodies as potential standards for harmonisation of bacterial vaccine immunoassays

Poster abstract

Antimicrobial resistance (AMR) poses a critical global health challenge, driving the need for innovative diagnostics, therapeutics, and vaccines. As part of the Medicines and Healthcare products Regulatory Agency's (MHRA) Global AMR Innovation Fund (GAMRIF)-funded programme, we aim to support bacterial vaccine development through the creation of biological standards that enable robust immunological assessment. Accurate measurement of antibody responses in human serum is essential for evaluating immunogenicity and efficacy of bacterial vaccines. Currently, World Health Organisation (WHO) reference standards for immunoassay calibration are derived from pooled convalescent or vaccinee sera, requiring large volumes from multiple donors. This approach presents logistical and biochemical challenges, including variability between batches and difficulties in sourcing equivalent material for replenishment. We are conducting a proof-of-concept study centred on the Diphtheria antigen toxin (DAT), for which a WHO polyclonal standard and established human serology assays are already available. To reduce reliance on pooled human serum, we are developing an alternative approach using recombinant monoclonal antibodies as surrogate reference materials. Twelve antibodies, each targeting distinct epitopes and exhibiting diverse affinity and functional profiles, have been expressed in ExpiCHO cells. These will be combined to assess binding and functional activity in a mixed format.
Recombinant reference materials offer several key advantages: they are theoretically unlimited, fully characterized, and capable of supporting global standardization and harmonization of serological and functional assays. By assembling a panel of monoclonal antibodies that reflects a spectrum of clinical responses (undetectable, low, medium, high), we aim to determine whether recombinant mixtures can replicate the bioactivity of pooled plasma. Successful validation of this strategy could enable the development of sustainable, reproducible reference standards, reducing dependence on human-derived materials and improving assay comparability across laboratories. This work represents an important step toward innovation in vaccine standardisation and antimicrobial resistance mitigation.

Research topic

Vaccines

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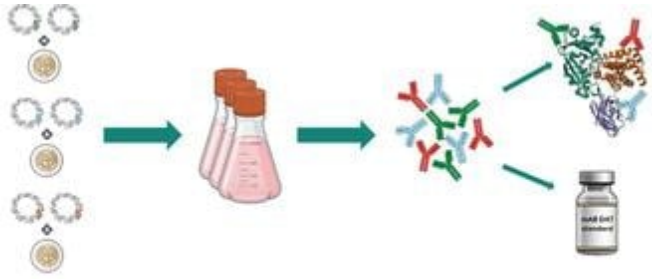

Figure 1 – expression of monoclonal DAT antibodies as a physical standard material using ExpiCHO cells