

Veeda UK awarded the MHRA Phase I Supplementary Accreditation.

Veeda UK today announced that it is been awarded Supplementary accreditation for conducting clinical pharmacology Phase I Trials in Europe by the Medicines and Healthcare products Regulatory Agency (MHRA)

The Accreditation Scheme was introduced in 2008 following the review of the TGN-1412 incident and provides formal guidance on the standards expected in a unit conducting First In Human Trials. There are two levels of assessment – Standard which shows the company as competent to perform most Phase I studies and Supplementary which indicates the centre has demonstrated they have the necessary experience, robust systems in place and highest standards maintained for the conduct of FIH trials and in particular those involving drugs that would require risk review from the EAG (Expert Advisory Group)

In order to be awarded Supplementary level accreditation the Phase I Units concerned have to undergo stringent inspection by the MHRA with a particular emphasis on investigator competence and the implement of all safety procedures.

The voluntary accreditation process provides clinical trial volunteers and sponsors with additional reassurance and confidence that the Veeda Phase I Unit meets the very highest of industry safety standards. The award further confirms the quality standards that Veeda delivers and enables the unit to continue to carry out clinical trials at all levels of complexity.

Dr Maurice Cross, Group Medical Director said

After the tragic outcome of the study carried out at the Northwick Park Unit in London, the UK MHRA introduced stringent new standards for Phase I Units wishing to perform First-into-Man studies of those new molecules which are classed as being 'high risk'. Units which successfully pass this accreditation scheme are increasingly being chosen as the places of choice to perform these studies in preference to non-accredited units as the 'comfort-factor' for clients substantially increases. It is much to the credit of the Plymouth Unit and its staff that we have become included in this elite group.