Update: The EVERREST team supports wider inclusion of pregnant women in clinical trials research

Over the past 18 months, the EVERREST team has developed a set of definitions and grading criteria for pregnancy-related adverse events in obstetric clinical trials of therapeutics. As a result of this work, led by Dr Rebecca Spencer (Clinical Research Fellow, Fetal Medicine, UCL) and EVERREST co-ordinator Dr Anna David (Reader in Obstetrics and Fetal Medicine at UCL), 18 terms have now been included in to the Medical Dictionary for Regulatory Activities (MedDRA).

During a clinical trial of a new drug, patients who receive the drug are carefully monitored for any untoward medical occurrence. These “adverse events” are graded for their severity to allow comparison between trials. MedDRA is a clinically validated international medical terminology dictionary that is used by regulatory authorities in the pharmaceutical industry to evaluate adverse events in clinical trials.

The need for an internationally recognised set of definitions and grading criteria for pregnancy-related adverse events in obstetric clinical trials of therapeutics was identified early in the EVERREST project. To address this need, the team convened a working group to develop definitions and criteria of adverse events, based on national and international guidelines. The working group comprised specialists in obstetrics, fetal medicine and neonatology, as well as representatives of the pharmaceutical industry. Definitions and grading criteria were proposed and discussed at a workshop in Barcelona in May 2015, before being presented to MedDRA’s Maintenance and Support Services Organisation and included in version 19.0 of the dictionary in March 2016.

Inclusion of the new fetal adverse events by MedDRA is an important step in supporting future clinical trials in obstetrics and promoting the inclusion of women, and particularly pregnant women, in clinical research. A key objective of the European Commission FP7-funded EVERREST project is to conduct a Phase I/IIa clinical trial to investigate whether localised maternal gene therapy can increase blood flow to the womb in cases of severe early-onset Fetal Growth Restriction and thereby improve fetal growth. The proposed clinical trial is scheduled to start in 2017.

Please see www.everrest-fp7.eu or email everresttrial@ucl.ac.uk for further details.