In the highly-charged environment of emergency care, the treatment of premature babies carries additional uncertainty and risk. In cases of neo-natal shock – an acute state with inadequate circulatory function and oxygen delivery in the newborn – immediate intervention is required to raise the blood pressure, but doctors may be called to act without understanding precisely what is causing the problem, or even how to accurately assess circulatory failure in such immature infants. Licensed drugs are available for adults, but until now clinical trials have not been conducted on infants in order to establish optimum dosages.

Neo-Circ is a part of the EU’s response to new legislation which will shortly require all new drugs to be trialled on infants. Europe’s leading neo-natal specialists are working together with experts in America to redefine neo-natal shock and show how existing drugs can be used in novel ways.

PUSHING THE BOUNDARIES OF MEDICINE

Prof Heike Rabe, project coordinator for Neo-Circ, has first-hand experience of the uncertainties in neo-natal care and the difficulties in establishing which cases to prioritise. Currently, the infant’s blood-pressure is the most widely

THE FRIGHTENING FACTS:

Normal blood pressure in newborns, especially premature babies, is CRITICAL TO DEVELOPMENT.
Without treatment, low blood pressure carries a HIGH RISK OF BRAIN INJURY.
Impaired blood flow to critical organs will cause BRAIN DAMAGE.
used measure of circulatory failure, but there is increasing evidence that taking an ultrasound reading of blood flow velocity within the Superior Vena Cava in the body gives a far more accurate assessment.

Today, Dopamine is normally the first line treatment for infants in neo-natal shock. Dobutamine tends to be used as a second line treatment, but Prof Rabe and her colleagues are committed to showing that this could be the best drug treatment if dosages adapted to premature babies were available. By establishing an agreed definition of neo-natal shock and a range of dosages applicable to Dobutamine, Neo-Circ hopes to radically change the prospects of each baby treated.

WORKING WITH NEW COLLABORATORS – THE EXPERIENCE OF A PRIVATE PAEDIATRIC HOSPITAL IN ROMANIA

Dr Adrian Toma of the Life Memorial Hospital in Bucharest is a neonatologist with a special research interest in neo-natal care who is bringing vital expertise to the project. At the same time, he and other staff at his private hospital are set to take big steps forward in the level of neo-natal and maternal health care that they can offer patients. As one of 13 clinical recruitment centres for the project they are quickly building up new clinical data and widening their range of experience.

He had been involved with planning this project right from the beginning of the proposal, but says that it’s still a learning curve when it comes to applying for EU funding. “It’s not difficult, but you need to have the best proposal and experience of the procedures if you are to succeed. With this first project now underway, we are much better placed to pursue further EU-funded projects.”

Romania is not the only example; Hungary and Turkey are also part of the project. Dr Toma is delighted to be building new contacts with scientists in these countries and in Germany, as well as extending the ones he already had elsewhere.

ACHIEVING INTERNATIONAL RECOGNITION

This collaborative research has such significant potential thanks to the range of expertise offered by 18 participants representing different types of hospitals and SMEs. Their combined experience and the volume of data accumulated through the 13 recruitment centres means that this clinical trial can justify its findings in the face of the toughest international scrutiny.

With American involvement, the results of Neo-Circ will be acknowledged by the Food and Drug Administration (FDA), without replica research being done in the USA; a feature which saves a huge amount of resources but also underlines the scientific weight of the project.

CONFIRMING THE VITAL STRENGTHS OF EU-FUNDED RESEARCH

As highlighted by Dr Toma, good research outcomes take years of careful collaboration, but projects such as Neo-Circ point to the enormous benefits of ongoing work with an increasing range of partners. Prof Rabe brings her own connections to bear through the European Society for Paediatric Research and this leads on to a wider network of EU experts.

She stresses the value of having both public- and private-funded hospitals involved who together contribute a bigger quantity of significant data. Further down the line, it ensures too that all patients, wherever they are treated, get the benefit of the latest expertise.