ACTA Trial of the Year Awards, May 20 2016.

Acceptance speech by Professor Jonathan Morris AM, Chief Investigator of the winning PPROMT Trial

"It is an indeed a great honour for me to accept this award on behalf of so many colleagues who contributed to the PPROMT study. I feel remarkably humbled that our study has been recognized in this way. Not only because this is the inaugural award from ACTA but also because of the quality of the other finalists and also that there are so many other distinguished clinical trial leaders here this morning who have contributed to the health and wellbeing of people across the world through their clinical trial findings. Australia truly does lead the world in the design, completion and implementation of clinical trials.

I just want to talk briefly about the study, then research followed by what I have learnt

The PPROMT study arose because two of the investigators, in casual conversation, discovered their approaches to the management of women with ruptured membranes in pregnancy were diametrically opposed. In Adelaide the thinking was that after 34 weeks, newborn outlook was so good, continuing the pregnancy would place the baby at risk of infection, such that early planned birth was advisable. In Sydney the approach was to wait for labour to commence whilst monitoring for signs of infection. The study addressed an issue in which there had been practice creep - if a woman's waters broke beyond 34 weeks it has become normal practice to advocate early planned birth. Indeed such austere bodies as RCOG and ACOG stated this in guidelines although conceding this was based on “limited and inconsistent scientific evidence”. It is a clear example of unsubstantiated practice change.

So we designed a study and tested whether one form of management was better than another. The study ran over 9 years, 1839 women provided their consent in 11 countries across the world. Women with ruptured membranes after 34 weeks were allocated to early planned birth within 24 hours or to a “wait and see” approach.

Our findings contrary to recommendations were that early birth is more harmful to babies. Babies born after early planned birth were more likely to develop respiratory problems, require support on a ventilator, go to the newborn intensive care and spend more time in there. Mothers were more likely to have a caesarean section. As an accompanying editorial said in The Lancet we found that “it pays to wait”.

The findings of this study will mean that waiting will prevent hundreds of Caesarean sections, hundreds of days less babies spend in newborn intensive care.

So, as I have said, I am extremely humbled to receive this award.
But today is not about me and one clinical trial it is to celebrate clinical trialists and all clinical trials.

You see if we want a great health care system, yes we need hospitals and equipment, but to provide for an ever improving health system - we need research

If we want to get subsidized medicines onto the PBS, yes, we need a highly functional PBAC (which we do have, I have sat on the Economic Subcommittee), but to know which medicines we need to list – we need research

If we want consistency in practice and reduce unwarranted variation, yes, we need high quality clinical practice guidelines but to establish what is best practice- we need research

You see it is clinical trials not clinical services that will effect most change
It is the application of trial findings not the application of technology that will guide a reduction in variation.

So I finally want to reflect on three strengths and three things that I have learnt we need to improve as a result of the PPROMT study.

Firstly the willingness of those who at a time of anxiety in their pregnancy were prepared to consider involvement in the study is a great and fundamental requirement for such a study.
Secondly the importance of a Network and the IMPACT network was instrumental in ensuring the study was funded and commenced in Australia.
Thirdly the great strength of international collaboration. That our study was chosen as a portfolio study by the NIHR's CRN in the UK was essential in getting us to our target recruitment.

What could be improved?

We still have a way to go to mainstream our clinical research and fully embed it within our health system. Clinical trials are the obvious focal point for this to occur. It would be fabulous if in studies such a PPROMT that even at 2am when women were to present with ruptured membranes they were not told what would happen but: "Ah, there is a study suitable for you to consider" regardless of with whom the initial contact is made. It is important to note that it is not the patient that is suitable for our studies, but we have studies suitable for people such as them to consider.

Secondly our health system needs to invest in a portfolio of priority studies to which we really want the answers. Prioritisation that is not the result of academic whim or fuelled by commercial gain, but studies that researchers, the community, industry and those in health care delivery agree we want the answers to.

Thirdly we need to unite researchers with policy makers so findings do not simple sit in The Lancet or New England Journal of Medicine but can be rapidly incorporated into practice for real benefit.

I am encouraged by the activity in the clinical trial space - we are seeing real improvements in ethics and governance , collaboration is replacing competition, ACTA has helped unite networks and given them an added sense of purpose. Australian has a proud history of high performing clinical trial activity. That has occurred in the absence of a cohesive strategy. We now are on the cusp through ACTA of a real step change in our productivity, an opportunity to improve health and generate wealth.

So finally I would like to acknowledge the clinical trial coordinators who make such trials happen, and I am thrilled that Diana Bond the PPROMT clinical trial coordinator is here today to receive this award with me. But most importantly again I do want to acknowledge our community who offer their participation in the hope that others, and not necessarily themselves, may benefit in the future. There are arguably no greater examples of acts of generosity within health.

Many thanks ACTA for the honour of this inaugural award and happy international trials day to you all."