(Towards)

a framework for industry led research using the NNRD

Kate Costeloe

Queen Mary, University of London

Barts and The London
School of Medicine and Dentistry

NDAU
Neonatal Data Analysis Unit

Conflict of Interest

- Consultancy work for Micregen Ltd.,
- Distant past…. Support for attending scientific meetings…… Chiesi, Danone etc.
- Activities supported by ‘Unrestricted Funds’ from pharmaceutical, equipment manufacturers and infant feeding companies

Why collaborate with industry?

- Need for safe efficacious medicines and ‘foods’
- Industrial companies have the technical expertise
- We have whole population complete detailed data
- Constructive, ethical, transparent collaboration is essential

How might the NNRD help to accelerate the development of medicines and feeds?

- Baseline data to support good research programmes: demonstrating need
- Data to support good study design
- Data collection
- Post-marketing surveillance
- Assessing generalisability of study results geographically and over time

Plan

- Describe first examples of collaboration
- Consider models
- Feedback?
- An opportunity for us all to get a sense of how to proceed

OPTI-SURF

Optimising surfactant delivery for preterm babies born below 37 weeks gestation in the UK, using national data from the National Neonatal Research Database

- Funder Chiesi
- Units opt-in with an opt out at patient level
- NDAU receives a fee for data extraction
- Study set up costs and per patient costs are contracted and paid directly between Chiesi and Neonatal Units
- Benchmark for such studies?

- Development of tool (PREMII) for a clinician reported outcome of overall function of extremely preterm infants suitable for clinical trial use
- The proposal is to use NNRD data for retrospective validation
- Neonatal units approached about study with an ‘opt out’ for use of their data
- Neonatal units receive no money
- NDAU receives a fee for data extraction
- This has stimulated discussion around conditions for data release

- Do the hospitals providing the data gain any reward?
- Specifically for this study the ‘tool’ will be available free to non-commercial users
- …. and in general……..

Any commercial company requesting data:

- How should we confirm company credentials? Medical Industry Accredited?...
- All purposes for which the data are to be used must be clear; the protocol should go to the NDAU Board before the REC
- There must be a robust data sharing agreement
- Agreement in place that the data are used only for the requested purpose(s)
- Agreement that ALL results will be published

This is an opportunity to consider how to proceed

- Funding models: recompense to NNUs?
- Levels of consent at NNU and patient level: opt in/out, when is explicit patient level consent needed?
- Conditions of data release to industry
- Dissemination of results: peer review / company and/or NDAU website

Thank you