

WP 1.7: Ethical, social and cultural processes of translational research

1. WP (related WPs, MG contact persons): WP 1.4b,1.5,1.6; MG: Gorm Greisen and Per Sangild

2. Key involved personnel, their institution, mail address (project leader + main study site underlined): Gorm Greisen, Prof., Neonatology, Copenhagen University Hospital, Gorm.Greisen@regionh.dk (5%) Lene Koch, Prof., Prof., Ct. Med. Sci. Tech. Studies, Univ. Copenhagen, leko@sund.ku.dk (5%) <u>Mette N. Svendsen</u>, Ass. Prof., <u>Ct. Med. Sci. Tech. Studies</u>, Univ. Copenhagen, mesv@sund.ku.dk (15%) Mie S. Dam, PhD stud, as above + Copenhagen Univ. Hospital, mda@sund.ku.dk (100%) Per Sangild, Prof., Clinical and Experimental Nutrition, NEXS, Univ. Copenhagen, psa@life.ku.dk (5%)

3. Main aim and sub-aims:

With the overall purpose of exploring the ethical, social and cultural processes of translational research in NEOMUNE this work package sets out to map the moral reasonings and organizational frameworks that are mobilized and affect possibilities for translation between animals and infants in experimental and clinical research settings in Denmark, Holland and China. The following research question is guiding the enquiry: What moral reasonings are mobilized and what social responsibilities are negotiated in NEOMUNE activities and how do these reasonings and negotiations form the translational activities of NEOMUNE?

4. Background and a central hypothesis:

Dialogue between experimental animal studies and clinical studies in Europe and China is a critical component of achieving both scientific and clinical goals in NEOMUNE. However, prior social science studies on translational medicine have shown that the relationship between laboratory and clinic is often complicated by unexpected results, epistemic disagreements and differences in experimental cultures of biologists and clinicians trying to make sense of cross-species comparisons. In NEOMUNE the international context may further complicate the translational processes.

We hypothesize that different sets of norms and practices shape translational processes and set out to study how this happens in NEOMUNE, focusing on the interface between clinical and laboratory studies in Denmark. This study will enable analyses of the moral reasoning and social responsibilities negotiated in the translational activities of NEOMUNE.

5. Key analyses and methods:

Overall WP 1.7 takes a qualitative approach to the scientific activities in NEOMUNE, drawing methodologically and theoretically on anthropology, sociology and public health. The study of moral reasonings and social responsibilities actualized in NEOMUNE will be undertaken trough multi-sited ethnographic fieldwork where NEOUMUNE activities are situated. This is primarily:

- NEOMUNE project meetings
- The Danish perinatal pig laboratory at the University of Copenhagen (5 weeks)
- Neonatal intensive care units at hospitals in Denmark (5 weeks)
- The data collection methods are participant observations and open-ended semi-structured interviews (approx. 20) primarily with researchers and clinicians involved in NEOMUNE

6. Expected results:

By an investigation of the collaborations between the experimental pig studies and randomized clinical trials in NEOMUNE, WP 1.7 will enable analyses of how negotiations and trade-offs between clinical, scientific, economic and political rationales take place. The WP will result in three scientific publications and the facilitation of cross-disciplinary reflection on the concept and practice of translational medicine thereby contributing to the social robustness of the NEOMUNE centre.



NEOMUNE research platform – work package synopses

7. Estimated time frame	r										n – – –			
Task	2013				2014			2015			2016			
Planning, protocol	х	х												
Fieldwork (data collection)		х	х	х	х	х								
Modelling a biological system: a sensitive human patient				х	х	Х								
Bovine colostrum – the familiar, foreign and natural								х	х	х				
Managing multiple responsibilities										х	Х	х		
Publication(s)								х		х		х		L

8. Estimated budget from NEOMUNE: 1.6 mio DKK

PhD scholarship for Mie S. Dam.

9. Estimated budget from elsewhere:

0.5 mio DKK by co-financing from collaborating partners with salaries paid from elsewhere.

10. Additional comments:

- NEOMUNE contains different interfaces between species, nations, scientific disciplines and public and private partnerships, more than may be covered in one Ph.D. project.
- While WP 1.7 takes a specific focus on the relationship between animal laboratory and human clinic, it only covers the role of industry and the general public in relation to this specific part of the translational processes.
- We will attempt over the course of the project to apply for supplementary funding that will enable analyses of many other aspects and allow maximal translation from basic biological research, over clinical studies to applied effects at the societal and commercial levels.
- The PhD stud. in this project will be based formally at Copenhagen Univ. Hospital, but the daily work place will be at the work place of the main supervisor, Centre for Medical Science and Technology Studies.
- As the NEOMUNE project unfolds with studies in Netherlands and China and around the world, the WP may also incorporate separate analyses of the international translational and cultural dimensions of NEOMUNE topics. These parts are predicted to require additional funding and personnel.