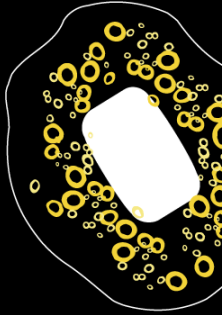


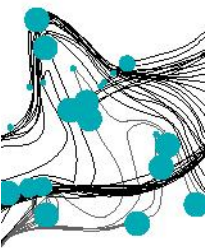
Exploring possibilities for patient involvement in translational molecular medicine: dialogue as a means to enhance ethical reflection



Lieke van der Scheer
Marianne Boenink
Simone van der Burg
Elisa Garcia Gonzalez

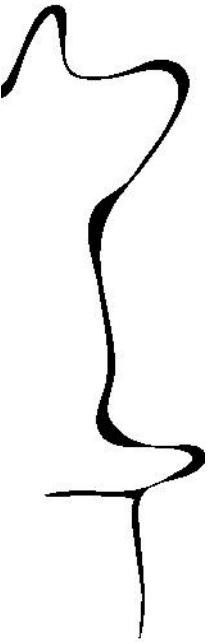
Funded by Centre for Society & the Life Sciences & CTMM

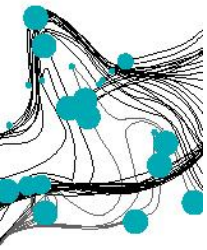




Outline

1. - overview of recent literature on patient involvement,
- difficulties in establishing patient involvement in scientific research.
2. - reasons for determining possibilities for patient involvement in Translational Research
- research questions
3. How insights from the literature can be used in our research project

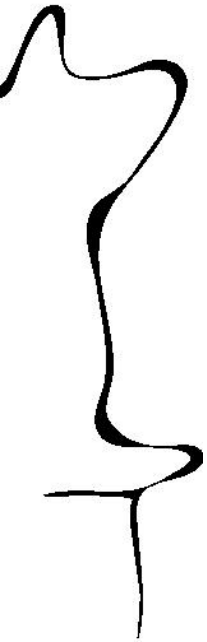


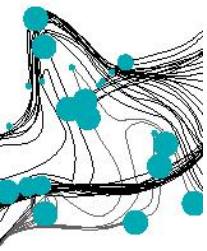


LITERATURE

SUCCESS STORY 1: AIDS ACTIVISTS IN AIDS RESEARCH

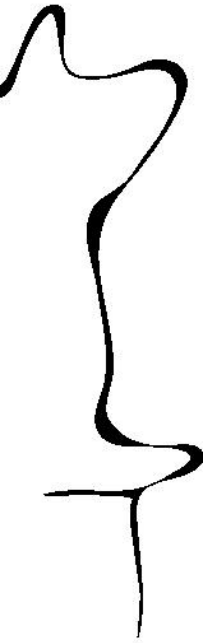
- Aids activists in the United States provide an example of lay participation in biomedical research. (Epstein, 1996)
- RESULTS:
 - the arguments published in scientific journals and presented at formal scientific conferences
 - new pathways for the dissemination of medical information;
 - voice and vote on review committees helped determine which studies receive funding;
 - changes in the very definition of AIDS to incorporate the HIV-related conditions that affect women
 - establishment of new regulatory and interpretive mechanisms by the FDA
 - shifts in the balance of power between competing visions of how clinical trials should be conducted

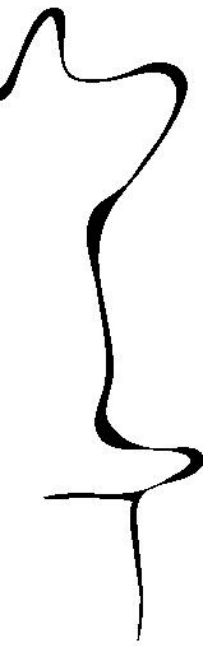
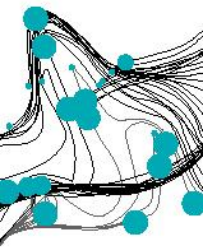




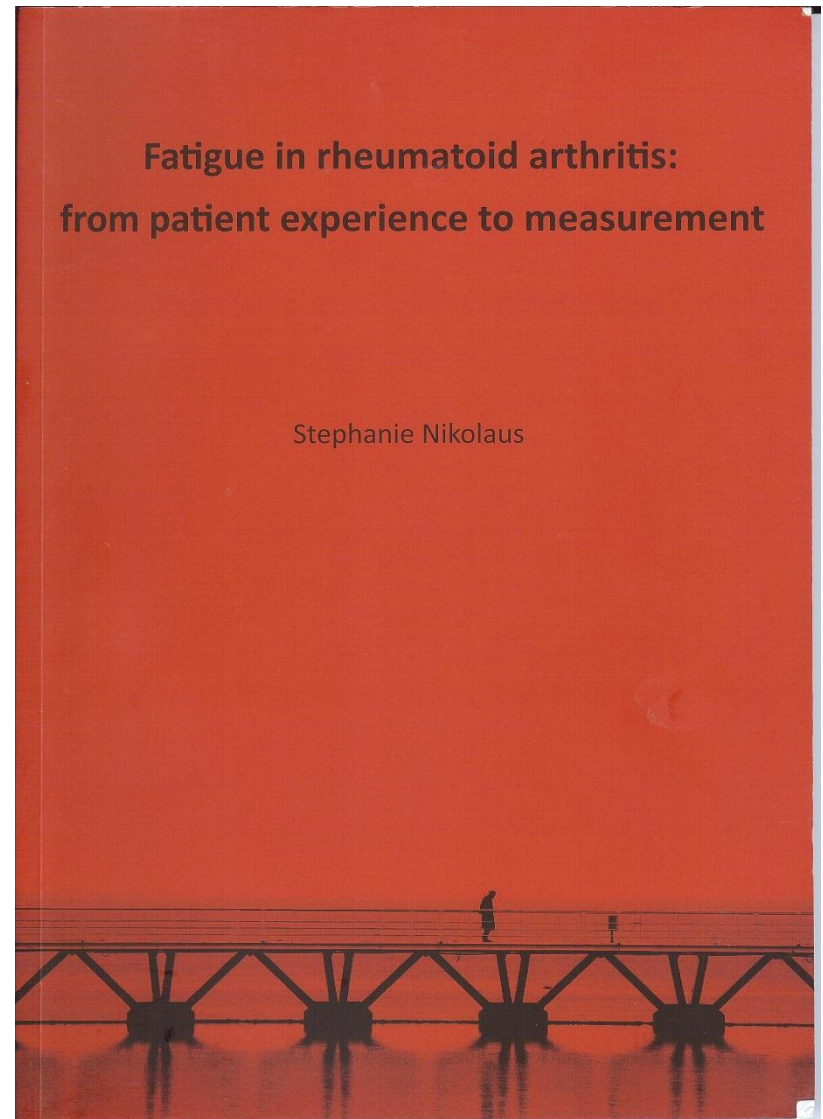
Success story 2: The OMERACT experience

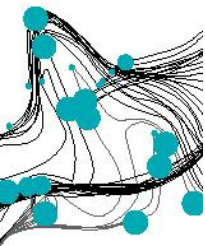
- Biennial conference OMERACT: Outcome Measurement in Rheumatology Clinical Trials
- Started in 1992
- 2002 OMERACT 6: workshop “patient perspectives on the RA core set”
 - No attention for Fatigue, Well being, disturbed sleep etc in RA core set
 - No adequate description of those problems
 - No measuring instrument for fatigue, Well being, disturbed sleep etc
 - No effective treatment
 - Researchers did not realize impacts.





- Researchers accepted patients as a discussion party about outcome measurements.





Success story 2: The OMERACT experience

- Development from patient **representation** to patient research **partner**:
 - Progress since OMERACT 6 on **including patient perspective** in rheumatoid arthritis outcome assessment.

Kirwan, J, Heiberg T, Hewlett S, Hughes R, Kvien T, Ahlmen M, Boers M, Minnock P, Saag K, Shea B, Suarez-Almazor M, Taal E. J Rheumatol. 2003 Apr;30(4):868-72

- Patients and professionals as **research partners**: challenges, practicalities, and benefits.

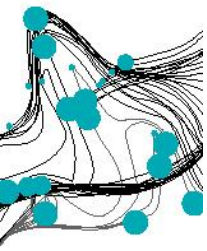
Kirwan JR, Ahlmen M, de Wit M, Heiberg T, Hehir M, Hewlett S, Katz PP, Minnock P, Quest EM, Richards P. J Rheumatol. 2005 Nov;32(11):2246-9

Hewlett, S, de Wit, M, Richards P, Quest E, Hughes R, Heiberg T, Kirwan J. University of the West of England, Bristol, United Kingdom. Arthritis Rheum. 2006 Aug 15;55(4):676-80.

- Results:

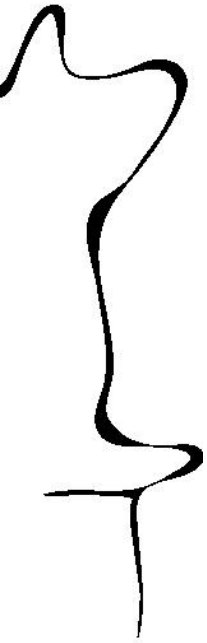
- Refining research questions
- New outcome measurements
- Empowerment of involved patients





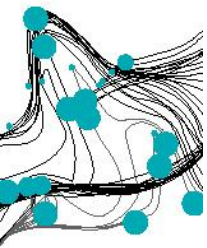
ON WHAT DO THESE SUCCESSES DEPEND?

- The patient group is well defined
- The patient group is well organized
- Patients are competent / well trained / patients have expertise in research methods
- In Aids research: groups with a history of gay activism pursuing civil rights and civil liberties.



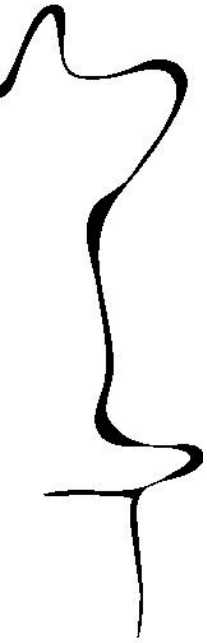
- Maxime: patient participation should be developed.

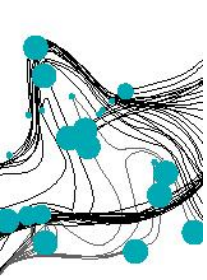




Development of patient participation

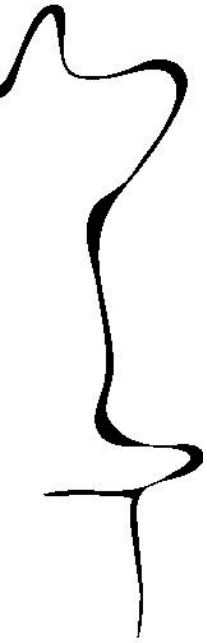
- Netherlands Organisation for Health Research and Development (2006) *Guide Patient Participation in Scientific Research*.
- Abma, Broerse (2007) “*Right of say in science. Patient participation; theory and practice*” (Zeggenschap in Wetenschap. Patientenparticipatie in theorie en praktijk)
- Dutch Advisory Committee on Health Research (2007) “*Patient participation in health care research*”.
- Netherlands Organisation for Health Research and Development. (2009-2013) Funding patient participation projects; €2.700.000

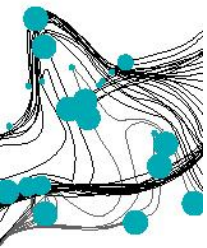




REASONS PUT FORWARD IN FAVOR OF PATIENT PARTICIPATION:

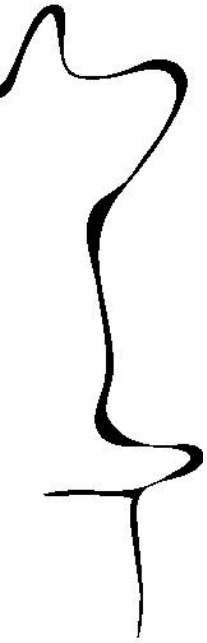
- People's right to participate in decisions that will (eventually) affect their lives
 - The idea of democratization of scientific research as a public good
 - Improvement of care
 - Commitment of user community is indispensable when solutions are to be successfully implemented
 - Lay or local knowledge is indispensable for an appropriate problem definition and design of solutions
 - Enlargement of basis, to legitimize
- arguments for societal and patients' influence on emerging technologies

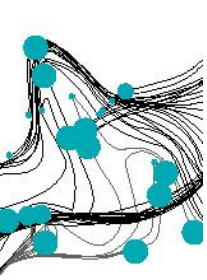




Obstacles

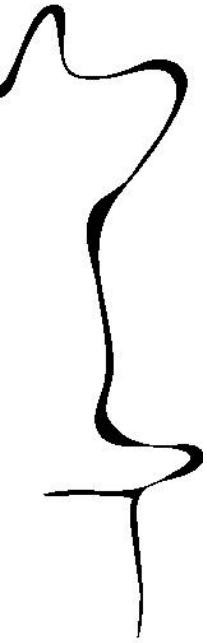
- Trappenburg , 2008 Enough is enough. About health care and democracy (in Dutch)
- Elberse et al, 2010 Patient–expert partnerships in research: how to stimulate inclusion of patient perspectives. *Health Expectations*, 14
- Verhoeff et al, Good Intentions, Stubborn Practice: A critical appraisal of a public event on cancer genomics, *International Journal of Science Education*, Part B 2011





OBSTACLES TO PARTNERSHIP IN DECISION- MAKING ON BIO-MEDICAL RESEARCH

- Patient participation is not that easy to establish.
 - Researchers do not experience a Sense of urgency
 - Financing structures and procedures
 - Characteristics of the biomedical research model
 - Reduction and specialization
 - Shared views, norms values among professionals -> **A Regime**
 - Characteristics of the patient community according to researchers
 - They lack knowledge, objectivity, competency in formulating, self confidence and empowerment etc

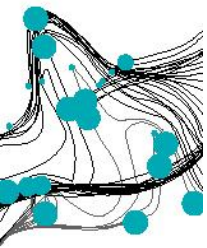


Caron-Flinterman et al. Patient participation in decision making on biomedical research: changing the network. Science, Technology and Human Values 32: 339-368 (2007)



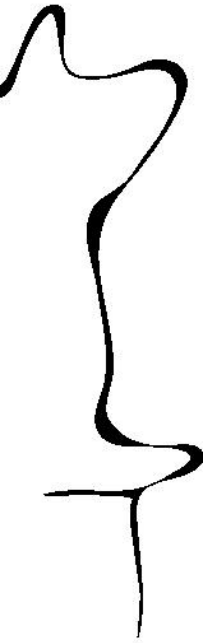
S.NET October 22-25 2012

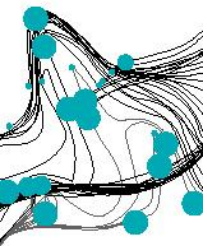
Exploring possibilities for patient involvement in translational molecular medicine:
dialogue as a means to enhance ethical reflection 11



Obstacles

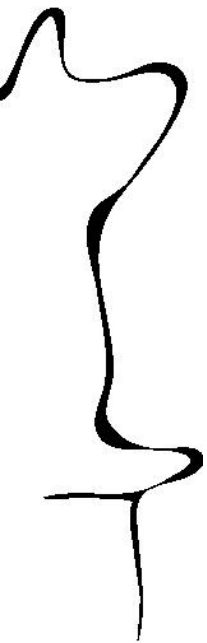
- researchers and patients
 - may not speak the same language
 - may not share all values
 - researchers may be numerically superior
- proto professionalism of patients
 - support and training of patients to acquire skills
 - problem of representation
 - both risk of confinement by researchers and loss of recognition by patients' rank and file
- stubbornness of the scientific practice (regime)
 - researchers don't like political or moral influence
 - patient or lay participation may corrupt scientific results

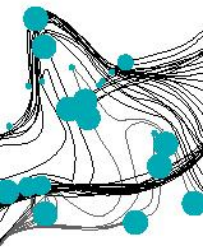




WHY???

- **WHY to determine whether patient engagement in translational research may be useful DESPITE all problems?**



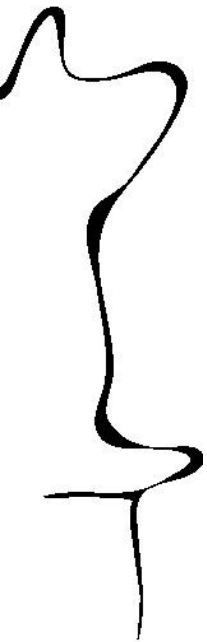


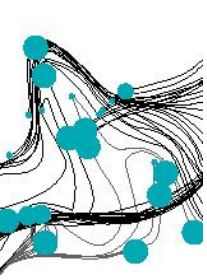
THE (OR RATHER: A) TRANSLATIONAL GAP

- *Even if*
 - all project goals are met and deliverables produced,
 - *MTA* thoroughly maps efficacy, sensitivity, specificity, cost-effectiveness etc, and predicts high scores,

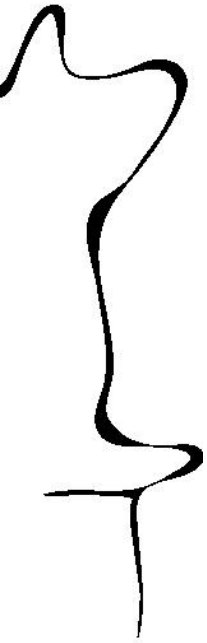
Successful introduction and practical application may not appear, or technologies may be used for different purposes

- **Examples:**
 - Anti-fertility vaccines
 - DNA-diagnostics for breast cancer, Huntington's Disease
 - Nanopil for screening colon cancer
 - Telecare systems





HOW TO EXPLAIN THIS?

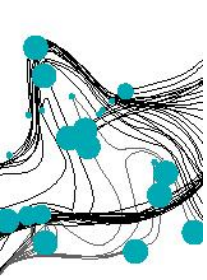


- Technologies usually do much more than they are intended to do
 - ‘side effect’ – or rather additional effects
 - Impacts on patients’ lives (sometimes very mundane, but nonetheless important)
- Technologies are more than devices: socio-technical practices
 - Devices need users with specific roles & responsibilities, specific material settings, routines, et c ...
 - Do they fit with existing practices?



HOW TO ANTICIPATE SUCH ADDITIONAL EFFECTS? 1

- One big problem:
 - Characteristics of the patient community according to researchers
 - They lack knowledge, objectivity, competency in formulating, self confidence and empowerment etc
 - However: in the eyes of researchers
 - **Credibility** of stakeholders / patients



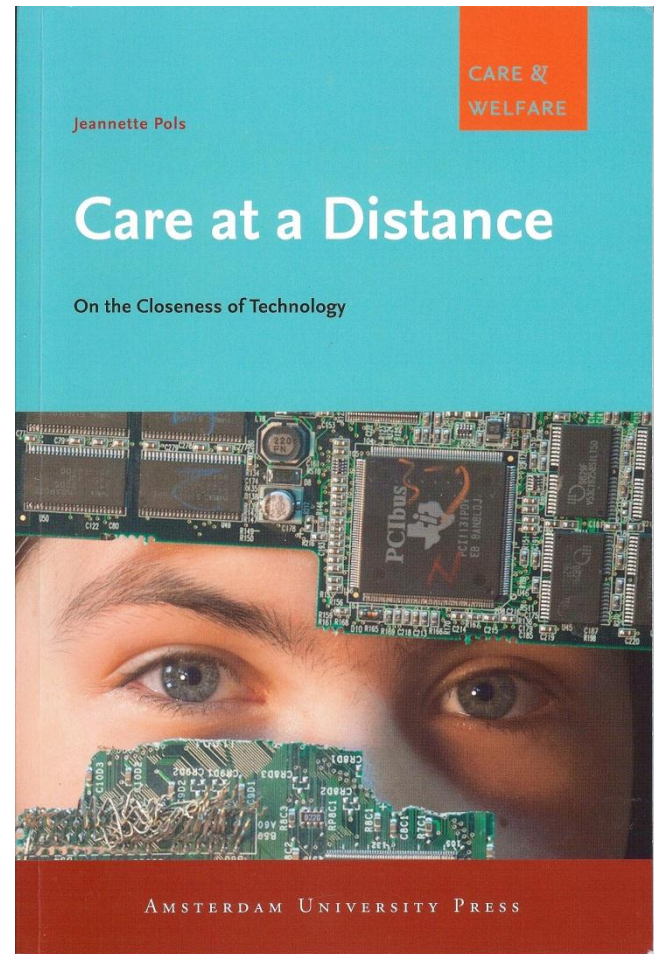
How to anticipate such additional effects? 2

Jeannette Pols:
Rehabilitate practical knowledge

- Explicit knowledge
- Know-how
- Know-now

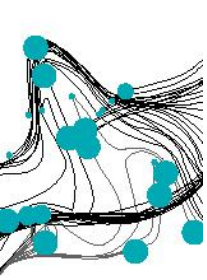
So we're not (only) interested in the framing of the issue by researchers,

But particularly in patients's know-how and know-now.

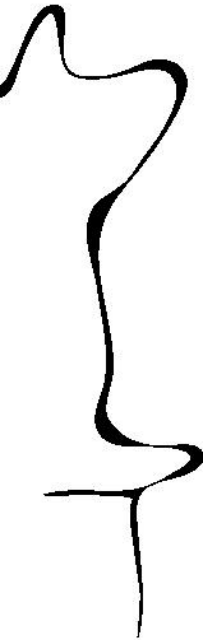


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Exploring possibilities for patient involvement in translational molecular medicine: dialogue as a means to enhance ethical reflection

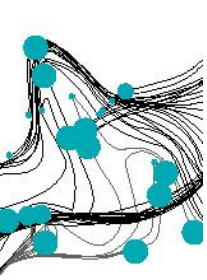


HOW TO ANTICIPATE SUCH ADDITIONAL EFFECTS? 2



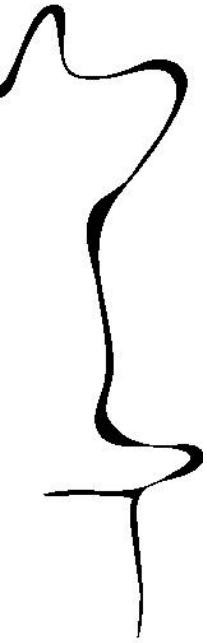
- Qualitative research to open up the 'Black Box' of a new technology to identify possible obstacles, unforeseen effects
 - Observing science **in action**, reconstructing assumptions, determining the configuration of patients
 - Observing current diagnostic **practice**, determining concerns, contrasts between old and new
 - Observing patients' **lives, routines & values**
- To determine patients' know-how and know-now.
- Asking what needs to change in current practice for a new technology to work, how will it configure patients?
- For all stakeholders, but we are particularly interested in patients





QUESTIONS

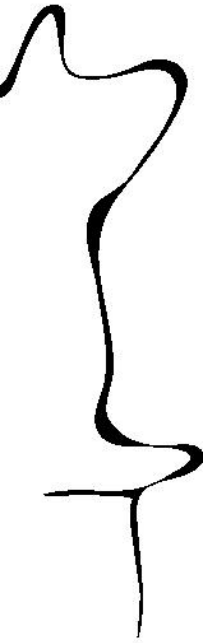
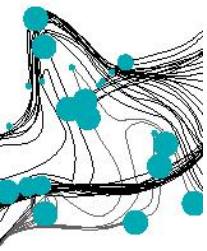
DETERMINING WHAT AN EMERGING TECHNOLOGY DOES
APART FROM ITS GOAL / WHAT IT IS SUPPOSED TO DO



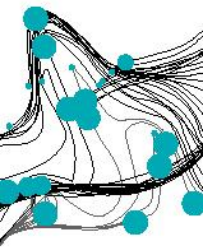
- What do patients need to do to make a technology work?
- Which are essential skills ?
- Which (material & organizational) conditions are necessary?
- Are patients supposed to perform particular roles?
- Are patients obliged to specific responsibilities?
- How are patients supposed to relate to professionals, devices, other people?

- How does all this fit with their current routines, practices, values?



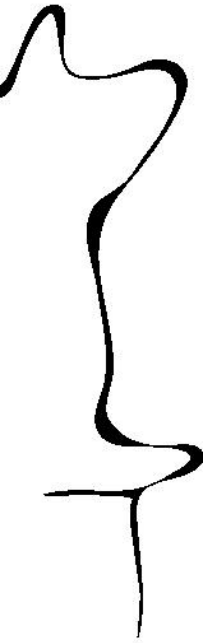


- By conducting ethnographic qualitative research we believe to identify possible obstacles, unforeseen effects.
- Ultimately: development of empirically and theoretically documented recommendations on the feasibility and the added value of patient involvement in translational research, in particular in research funded by CTMM.



THANK YOU FOR YOUR ATTENTION!

QUESTIONS, COMMENTS?



Lieke van der Scheer

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S.NET October 22-25 2012

Exploring possibilities for patient involvement in translational molecular medicine: dialogue as a means to enhance ethical reflection²¹