12th IAS-STS Annual Conference of the Institute for Advanced Studies on Science, Technology and Society (IAS-STS), Graz – Austria, 6th-7th May 2013

Category: Life Sciences/Biotechnology

The translation of synthetic biology medical devices into medical practice – Guiding the process

Anna Genske[1], Bernice Elger[2], Sabrina Engel[3]

Synthetic biology is a vastly growing research field encompassing, amongst others, the redesign and reassembling of natural components to form highly controllable biological circuits. Applications of synthetic biology are numerous. A very new and promising branch of research in synthetic biology focuses on the design of novel strategies for the treatment of a variety of human diseases such as cancer, type-II-diabetes and gout. Translation of these novel strategies into medical practice, especially with regards to first-in-human (FIH) trials, raises a variety of ethical but also policy concerns. These include but are not limited to subject recruitment, informed consent, harm minimisation and uncertainty of risks. While inherent to any first-in-human trial, they become more pronounced in relation to novel technologies.

We will highlight the broader ethical and policy issues raised by first-in-human trials of new synthetic biology applications. Such trials are highly likely to be conducted within the next decade. However, it is remarkable that existing policy recommendations in the field of synthetic biology do not address ethical issues and safety concerns with regard to FIH trials involving medical applications of synthetic biology at all. Hence, we will address these issues and describe a way to provide researchers, RECs and policy makers with more thorough and more specific guidance for decision making with regard to synthetic biology FIH trials.

Contact details:

Anna Genske
Doktorandin
Anna.genske@unibas.ch

Prof. Dr. Bernice Elger
b.elger@unibas.ch

Dr. ETHZ Sabrina Engel Glatter
Sabrina.engel@unibas.ch

Institut für Bio- und Medizinethik (IBMB)
Universität Basel
Bernoullistrasse 28
4056 Basel

Tel. 061 267 17 85
Fax 061 267 17 80
Webpage: http://ibmb.unibas.ch/

[1] PhD candidate at the Institute for Biomedical Ethics, University of Basel, Switzerland
[2] Head of the Institute for Biomedical Ethics, University of Basel, Switzerland
[3] Post-Doc researcher at the Institute for Biomedical Ethics, University of Basel, Switzerland