NOTE #4

Technology transfer as a form of Responsible Research and Innovation (RRI)

By Maria Salvato

RRI IMPLEMENTATION IN BIOSCIENCE ORGANISATIONS

GUIDELINES FROM THE STARBIOS2 PROJECT

Andrea Declich with the STARBIOS2 partners

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On 18 February 2019 the STARBIOS2 Consortium held a workshop on "Technology Transfer as a form of Responsible Research and Innovation" to showcase RRI efforts at the University of Maryland, Baltimore, Maryland, USA. The following is a brief presentation of this theme and, particularly, of the difficulties encountered and the solutions attempted in the implementation of Technology Transfer.

The University sees its mission as creating knowledge for the benefit of society, with Technology Transfer as the transmission of that knowledge to the public. To begin with, the university makes great efforts to educate the public about its discoveries and to assist its faculty in patenting and licensing their inventions. Technology transfer takes many forms, but three concrete examples of Technology Transfer are given here: 1) the transfer of a cholera vaccine to a company that could market it to the public; 2) the engagement of local people with AIDS by University sociologists and medics to help them manage their diseases; and 3) the transfer of technology from wealthy countries to resource-poor countries half-way around the globe. These examples illustrate both obstacles and solutions.

Infrastructures created to assist in technology transfer

To promote technology transfer, the university created infrastructures such as an Office of Public Engagement, an Office of Technology Transfer (OTT), and an Institute of Clinical Translation and Research (ICTR).

For public engagement, the University produces a number of newsletters and brochures describing faculty discoveries in lay language. It holds educational seminars open to the public and has specific programs to educate school children about research (The CURE Project, Internships, and Summer Medical School). An area that needs improvement is the involvement of more faculties in STEM education; so more salary and promotion incentives are needed to insure faculty participation.

The OTT helps faculty members patent and license their inventions. Unfortunately most faculties do not want to take time outside their research laboratories to file provisional patents and to interface with marketing officers. A solution would be for universities to compensate faculty to file provisional patents, and to arrange for faculty to share in more of the income from licensing arrangements. The OTT sponsors classes in Entrepreneurship for ~12 graduate students a year. This educational effort is extremely valuable and could be expanded to educate more students, post-docs and faculty. The ICTR is another element of the University's infrastructure that promotes technology transfer by giving grant money to faculty for pilot studies that could lead to translation of research. The ICTR also creates core laboratory facilities that help develop research projects so they are more easily transferred to Contract Research Organisations. The University President's office has expanded its marketing of University inventions to the Biotech industry that is growing in Maryland. As public funding wanes and private funding increases, more faculties will look towards industry collaborations to fund their research.

Technology Transfer of a cholera vaccine

In the 1980's, Dr. James Kaper at the University of Maryland made genetic modifications to virulent ***Vibrio cholera*** in order to create a live-attenuated vaccine against cholera (Herzog, 2016). A single oral dose could confer 90% protection from severe cholera diarrhoea that annually afflicts as many as 4 million people around the world. With the help of a senior colleague who had industry connections, Dr. Michael Levine, the vaccine was marketed to a Swiss company.

Unfortunately, some of the biggest markets for such a vaccine, Europe and Australia, passed laws against the sale of "genetically modified organisms" (GMOs) and the market for this cholera vaccine shrank. For a time, the vaccine was only given away ***gratis*** by the World Health Organisation, and by 2004 it was no longer economically feasible to produce. The vaccine sat for years in cold storage, but cholera outbreaks in war-torn regions of the world caused the demand for this vaccine to resurge. In 2009 it was licensed to PaxVax in San Diego and in 2016 it was issued an FDA license. The lessons from this story are: 1) laboratory inventions do not go anywhere without marketing; 2) the resistance of popular beliefs (like anti-GMO sentiments) must be overcome by educating the public; 3) one must be patient and persistent to bring a vaccine to the people.

Health care delivery to the neighbourhood adjacent to the University

The University of Maryland School of Medicine sits next to a neighbourhood gripped by poverty, crime, and disease: 12 % of the adult population is HIV+, and 80% of the HIV+ people are Hepatitis C positive; the average annual income is $17,000 per family; 34% of the people believe AIDS was manufactured in a laboratory, and most of the population prefers to use "alternative medicine" (mysticism and herbs) (Temoshok & Wald, 2008). The University has created programs of job assistance, childcare, healthcare delivery, and spaces for public engagement, but it faces enormous obstacles. For example, although an estimated 30,000 individuals in a city of 600,000 people are HIV+, only 5,000 have agreed to medical treatment. The University tries to reach people through their churches, to promote HIV testing and treatment, and to create mental health and social programs. All these programs are small in comparison to the immense need but they do serve as beacons of hope.

Technology transfer from affluent to resource-poor countries

The University has many global programs in surveillance and health care delivery. Professor Claire Fraser, Director of the University's Institute of Genome Science and new President elect of the AAAS, provided a vaccine to Kenya for a disease that was decimating cattle. The funding obstacle was overcome by obtaining small private funding that later attracted World Bank funding. A similar effort to bring a Lassa vaccine to Nigeria was described by Professor Salvato, a member of the STARBIOS2consortium. The Nigerians want their own people trained in vaccine production, and they have money available for building an institute and paying teachers, but they still need more clinics to screen for disease, train technicians, medics and project managers, biosafety committees, animal care facilities, human subjects monitoring, and a better system for data storage and sharing. Such an effort will resemble the Argentinian effort to manufacture their Argentine Haemorrhagic fever vaccine. With a seed stock from the US Army and some US technical training the people of Argentina were able to achieve independent vaccine production in approximately 5 years (Ambrosio et al., 2018).

Professor Vittorio Colizzi, Director of the University of Rome and Principal organizer of the STARBIOS2 consortium spoke of epigenetic studies in Italy and Africa to monitor the effects of specific plant diets on miRNA expression and disease resistance. He described the difficulty of convincing subjects to volunteer for his studies. He also mentioned problems of ethically handling private information, and problems with making big data openly accessible. A core issue of technology transfer to Africa is the lack of academic infrastructure and trained personnel. All the members of the STARBIOS2consortium have training programs that recruit young medics and scientists from Africa. The developing countries problems in technology transfer are complex, but those with vision must be empowered to lead the political and scientific actors in a mutually agreeable strategy.

ABOUT THE STARBIOS2 GUIDELINES

This guideline aims to help readers formalize and trigger structural change aimed at introducing appropriate RRI-related practices to their own organisations. This is not a series of prescriptions, but an itinerary of reflection and self-interpretation addressed to different actors within the biosciences. To support this itinerary of reflection and self-interpretation, the document provides...

- a description of a general RRI Model for research organisations within the biosciences, that is a set of ideas, premises and "principles of action" that define the practice of RRI in bioscience research organisations,
- some practical guidance for designing interventions to promote RRI in research organisations in the Biosciences, putting into practice the RRI Model,
- a set of useful practices in implementing the structural change process,
- and information on particular STARBIOS2 cases and experiences, as well as materials, tools and sources, are also provided in the Appendix and in the Annex.