



Workshop on Biomedical Innovation and the Public

March 13-14, 2014

Venue: JNU Convention Centre, New Delhi

Organized by Centre for Studies in Science Policy, Jawaharlal Nehru University, New Delhi & King's College, London, United Kingdom

WORKSHOP REPORT

The advancements in science and technology are touching and transforming all facets of life in the contemporary world. One such endeavor is the field of biomedical innovations which holds great promises for the future in the form of regenerative (stem cell therapy and tissue engineering) and personalized medicine (pharmacogenetics, bioinformatics and genetic engineering). The promises of the future are almost always accompanied by the concerns regarding the ethical, legal, and social uncertainties and challenges associated to such technologies. In an attempt to navigate between these currents in the streams of biomedical innovation, the Centre for Studies in Science Policy (CSSP), Jawaharlal Nehru University, New Delhi in collaboration with King's College, London organized a two day workshop on *Biomedical Innovation and the Public* on 13-14 March

2014. The two day workshop invited experts from different sections of society to deliberate on the issues of linkages between biomedical innovation and governance with a focus on the consumers. Experts for the meeting involved international and national scientists, policy makers, medical practitioners, Non Governmental Organizations, and academic researchers. The aim for involving such a diverse range of participants was to create hybrid forums for engagement and dialogue on issues of biomedical innovations.

The two day workshop, in between the inaugural and concluding session was organized under six major themes which include Responsiveness of Biomedical Innovation Models to Consumers, Open Access and Biomedical Innovation: Trends, Issues and the Way Forward, Role of Patient Organizations /Stakeholders in Governance of Biomedical Innovation, Public/ Private Partnerships in Biomedical Innovations: Trends and Issues, Case Studies of Regenerative and Personalized Medicine and Cross-Cutting Panel Discussion.

In the inaugural address, Prof. Pranav Desai, Chairperson, Centre for Studies in Science Policy, JNU explicated the aims and motives behind the workshop as well as the larger context of the CSSP-King's project on *State Strategies and Governance in Global Biomedical Innovations: The Impacts of India and China*. Prof. Desai contemplated the need for a broader outlook on the issues of transnational governance of these innovations with a focus on transparency, affordability and inclusivity, funding structures, regulatory bodies and consideration of socio-economic disparities. Prof. Alex Faulkner, project representative from King's college, London presented the agenda and project report.

In the session *Responsiveness of Biomedical Innovation Models to Consumers*, participants deliberated on the strategies envisaged in various biomedical innovation models in order to address the question of responsiveness to health consumers. Dr. Parthasarathi Banerjee, National Institute of Science Technology and Development Studies (NISTADS), India, in his talk tried to explain the reasons behind the lack and inefficiency of regulatory mechanisms to promote biomedical innovations in India. He proposed to move from inter and intra firm analysis to much broader institutional aspects of biomedical innovation to address the governance gap. Prof. Alex Faulkner, School of Global Studies, Sussex University, in his presentation elucidated different models they employed to study the political economy of global stem cells therapy market. In the open discussions, questions were raised about the power dynamics involved in global-local, public-private, doctor-patient relationship, asymmetry of regulatory frameworks, transparency at various levels, 'real' demand and 'manufactured' demand, and information and awareness among the consumers.

The session *Open Access and Biomedical Innovation: Trends, Issues and the Way Forward*, discussed the meanings, trends and issues in open access innovation models from the perspectives of industry, academia and policy makers. Zakir Thomas, Council for Scientific and Industrial Research (CSIR), New Delhi, in his talk on the Open Source Drug Discovery

(OSDD) movement in India tried to explain the delinking of innovation cycle from patents. Questioning the relevance of patents in promoting innovation, he explicitly described the OSDD initiative as a common property resource model, aiming for inclusive, rapid and accessible drug development. Mamta Mishra and Prof. HariBabu, Department of Sociology, Central University of Hyderabad, from their experiences of interviews with practitioners of OSDD initiatives charted out the ground realities and challenges of this initiative. Dr. Anup Kumar Das, CSSP, presenting the scientometrics analysis of Open access journals in India proposed the need to promote linkages between open access, open innovation and open science data. Taking a different strand Mr. Manoj Vimal, Centre for Studies in Science Technology and Innovation Policy (CSSTIP), Central University Gujrat, presented his findings from case studies of two genetic testing institutes in Gujrat and their relationships with patients/consumers. This session in the open discussion phase contemplated on the issues of free ridership, motivation for the participants of the OSDD initiative, and the elements of nationalism, gender, and inclusion being associated to it as a moving forward vision.

The third main theme entitled *Role of Patient Organizations/Stakeholders in Governance of Biomedical Innovation* explored the space, role, representation and advocacy strategies of patient and civil society organizations in the governance of biomedical innovation. Dr. Poonam Bala, fellow at Cleveland University, talked about the role of state in channeling certain innovation pathways. Taking cases of surrogacy, telemedicine and biotechnology, she discussed the ethical and social aspects of technological intervention in the biomedical field in relation to framing of women as consumers/patients. Broadening the previous strand further, Dr. Parvathi Iyer, CSSTIP, Central University Gujrat, talked about the role of patient organizations as hybrid forums in deliberating about the gaps in governance systems of pharmaceutical innovations. Dr. Duraiswamy Navaneetham and Prasanna Kumar Shirol, from the Foundation for Research on Rare Disease and Disorder (FRRDD), Bangalore, through various case studies, illuminated the need for R&D and Investment for drug discovery and diagnostics on rare diseases. They proposed that a focus on personalized medicine development in this field can prove beneficial for a large section of population which gets marginalized through dominant trends of drug development.

The second day of the workshop began with the session on *Public/ Private Partnerships in Biomedical Innovations: Trends and Issues*. Here, different dimensions of collaboration between state, public universities and research institutes, national and international private firms and research institutes were discussed. Dr. Bhaskar Vyas and Dr. Rupa Dave from Total Potential Cell, Vadodara, Gujrat, by taking examples from Indian value system and western value system tried to highlight the role of ethics in medical profession in relation to stem cell therapy. Simultaneously, they raised questions about the meanings and mechanisms through which the recent Indian Council of Medical Research (ICMR) guidelines for stem cell research (2014) have been developed. Harpreet Singh, ICMR,

Delhi delivered a talk on the public-private partnership in relation to genomic research in India. Here, he projected a lot of potential in this field for India provided a mechanism to integrate various stakeholders and institutions at the central and local level is developed. Prof. Indira Ghosh, School of Information Technology (SIT), JNU, recollected her experiences of working with private as well public sector while talking about the immense possibilities and challenges of handling huge amount of bioinformatics data. She argued that bioinformatics has become the communicator between biotechnology and Information Technology, the challenge is to analyze and manage this data for use for the betterment of society rather than control or protect it. Taking examples of the Genome Valley (first bioscience cluster in India) and analyzing it through the framework of Global Innovation Networks (GIN), Nimita Pandey and Prof. Pranav Desai, CSSP, explicated the phenomenon of newly emerging global-local platforms creating new purviews and models of R&D off shoring, knowledge production, and value-chain creation. Rahul Mongia, CSSP, in his presentation tried to locate the position of Indian pharmaceutical industry for vaccines in terms of their technological capabilities.

The fifth theme of the workshop, *Case Studies of Regenerative and Personalized Medicine* emphasized on the specific cases of biomedical innovation and the challenges these specific cases highlight for the broader governance of emerging technologies in society. Dr. Geeta Shroff of NU Tech Mediworld, through her own experience as a physician demonstrated different cases of treatment through stem cells therapy. She urged for a better, robust and democratic governance framework to support stem cell research as well as therapy in India so that this biomedical innovation can be access by larger sections of society. Prof. Dinesh Abrol and Nidhi Singh, Institute for Studies in Industrial Development (ISID), New Delhi, taking the case of Tuberculosis in India, mapped the system of innovation of pharmaceutical industry in the country. Prof. Alex Faulkner, Sussex University, presented the case of framing of bioinformatics in global health policy, genomics policy and medical policy. He highlighted the tensions in different framings of bioinformatics in relation to consumer/patient, data privacy, policy positioning of bioinformatics as niche/platform and lack of focus on defining risks and health/disease norms. Through the analysis of scientific publications in the field of cancer research, Rajesh K. and Prof. Pranav Desai, CSSP, showed the status of cancer innovation system in India. The session touched upon many ethical and social aspects of stem cell therapy through open discussion.

The session *Cross-Cutting panel discussion* engaged the experts and other participants to take a detour of the two-day workshop and think out loud on the main emerging themes to be taken further for policy suggestions. Professor Aditya Bharadwaj, from the Graduate Institute Geneva, emphasized the crucial role played by the hybrid forums (like this workshop platform) in order to rethink the notions of innovations, the public and their mediation through the notion of consumer/patients. He argues that the boundaries of public and private are very much overlapping, mutually-shaped, and constantly shaped by

the changing contexts in which science and technology operates. There is a need to engage with the promissory value of innovation in order to think about the relationship between innovation and the public in a more practical sense. Dr. Yatish Agarwal, Safdarjung Hospital, New Delhi, extended the Chair's thoughts by giving examples of the hype associated to highly advanced technologies such as stem cell therapy and personalized medicine. He emphasized on the need look at the alternative medical practices (such as Ayurveda) as well to address the issues of affordability and social inclusion. Stressing on the need to rethink the existing models of Big Pharma and High cost and high benefits which have proven to be exclusionary and skewed to the interests of certain sections of society, Prof. Dinesh Abrol, visiting Professor at CSSP, highlighted the need for new models which are democratic, innovative and inclusionary. Stating examples from the OSDD model Prof. Abrol expressed hope for a new beginning. Adding to this Prof. Pranav Desai argued for organizational innovations to take into account the issues of market failure.

The global-local context of science, technology, innovation and policy emerged as another major theme of reflection in the cross-cutting panel. Panelists agreed that rather than conforming solely to the global standards and requirements the policies and models should try to look inwardly on the local needs. In that regard, Prof. R.N.K Bamezai, School of Life Sciences, JNU, indicated for the devising of mechanisms through which broader public and institutions can remain vigilant of the public-private partnership, makes good use of the resources already available in the country in a more participatory manner for the betterment of society. Questions about the participatory exercises prevalent in the country for regulatory decision-making were raised by various participants taking the case of recent Indian Council of Medical Research (ICMR) guidelines which raises serious objections on the practice of stem cell therapy. Participants argued for a context-specific, inclusive, well-defined guidelines developed by a rigorous participatory mechanism and enabled by a feedback mechanism from different stakeholders. Participants agreed on the need for mobilization of larger public on issues of biomedical innovations (such as stem cell therapy) in order to combat power relations and hierarchies in developing of these innovations for larger social good.

In the concluding session Prof. Pranav Desai and Prof. Alex Faulkner extended their thanks to the participants, with the wishes to take the dialogue of this hybrid forum further in the form of policy suggestions which can play a significant role in shaping the landscape of biomedical innovation in India and the United Kingdom.

Prepared by **Poonam Pandey**, Ph.D. Student, CSSP/SSS/JNU

Workshop Photos (Photo Credit: Dr. Anup Kumar Das, CSSP/SSS/JNU)







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Biomedical Innovation and the Public

March 13 - 14, 2014

Committee Room, Convention Centre, Jawaharlal Nehru University, New Delhi

Programme

| March 13, 2014 (Thursday) | |
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| 9.30 – 10.30 | Registration & Tea |
| 10.30 - 10.40 | Welcome Address – Pranav N. Desai , CSSP, JNU |
| 10.40 - 11.00 | Key Note Address – Alex Faulkner , University of Sussex |
| Session 1 11.00 - 13.00 | Responsiveness of Biomedical Innovation Models to Health Consumers Chair – Bhaskar Vyas , Total Potential Cell, Vadodra Alex Faulkner , University of Sussex Geeta Jotwani , ICMR, New Delhi Parthasarathi Banerjee , NISTADS, New Delhi |
| 13.00 – 14.00 | Lunch |
| Session 2 14.00 – 16.00 | Open Access and Biomedical Innovation : Trends, Issues and the Way Forward Chair – R. N. K. Bamezai , School of Life Sciences, JNU Zakir Thomas , CSIR, New Delhi Mamta Mishra and Haribabu E. , HCU, Hyderabad Anup Kumar Das , CSSP, JNU Manoj Vimal , Gujarat Central University, Gandhinagar |
| 6.00 – 16.30 | Tea |
| Session 3 16.30 – 18.00 | Role of Patient Organisations/different Stakeholders in Governance of Biomedical Innovation Chair – Dinesh Abrol , ISID, New Delhi Poonam Bala , University of Edinburgh Parvathi Iyer , Central University of Gujarat, Gandhinagar Duraiswamy Navaneetham , Foundation for Research on Rare Diseases and Disorders, Chennai Prasanna Kumar Shirol , Organization for Rare Diseases India, Bangalore |
| 19.00 | Workshop Dinner |

| March 14, 2014 (Friday) | |
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| Session 1 10.00 - 12.00 | Private/Public partnerships in Biomedical Innovations: Trends and issues Chair – Alex Faulkner , University of Sussex Bhaskar Vyas & Rupa Dave , Total Potential Cell, Vadodra Harpreet Singh , ICMR, New Delhi Indira Ghosh , SIT, JNU, New Delhi Nimita Pandey and Pranav N. Desai , CSSP, JNU Rahul Mongia , CSSP, JNU |
| 12.00 - 12.15 | Tea |
| Session 2 12.15 - 14.00 | Case Studies of Regenerative and Personalised Medicine Chair – Parthasarathy Banerjee , NISTADS, New Delhi Alex Faulkner , University of Sussex Dinesh Abrol and Nidhi Singh , ISID, New Delhi Geeta Shroff , NU Tech Mediworld, New Delhi Rajesh Kalarivayil and Pranav N. Desai , CSSP, JNU |
| 14.00 - 15.00 | Lunch |
| Session 3 15.00 - 17.00 | Cross Cutting Panel Discussion: Biomedical Innovation and Public Policy – Issues and Challenges Chair – Pranav N. Desai , CSSP, JNU Parthasarathy Banerjee , NISTADS, New Delhi Dinesh Abbrol , ISID, New Delhi R.N.K. Bamezai , School of Life Sciences, JNU Geeta Jotwani , ICMR, New Delhi Geeta Shroff , NU Tech Mediworld, New Delhi Alex Faulkner , University of Sussex |
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