Abstract: How Governance-Free Zones Emerged in Ethical Science Organizations: Research Breakdowns and Resilience in Translational Cancer Medicine
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Objectives This paper explores how governance-free zones emerged in ethical, responsible science organizations, in what manner subsequent resilience (Cf. Lebel et al 2006; Carpenter et al 2001) occurred where labs and science communities underwent disturbances but managed to retain well-functioning controls and structures of governance, and why the Institute of Medicine (hereafter, IOM) 2012 Guidelines on translational omics worked in this context. The research questions are (a) whether self-regulation is enough to address research breakdowns in paradigm shift (Kuhn 1962) conditions, (b) what science policies should look like to address ethical and innovative scientists and science organizations. The framework is based on autonomy, public oversight, boundary choice, and process independence and truth (Resnik 2008; Williamson, 1980, Dwarkin 1988). For this purpose, I conduct retrospective study showing the defined causes of research failures in the translational cancer medicine field, especially in the discovery and preclinical phases conducted in academic settings. Cancer/ cancer-biomarker research provides a favorable source, since misconduct that led to subsequent peer-reviewed scientific paper retraction is statistically smaller than the general trend in the life science and biomedical fields as revealed by Fang et al (2012, hereafter, the general trend) (cancer / cancer biomarker 0.513: general trend 0.674. p-value 0.0001. Period: 1977-2012.5).

Background: Translational medicine and omics-based biomarkers are expected to play a critical role in predicting clinical outcomes and disease diagnostics. However, several types of failures in the discovery/preclinical phases have caused delays for sound translation to clinical settings. Nevertheless, scientific paper retractions due to model confirmation failure and data integrity issues sharply declined before and in 2012.

Methodology: Classify and codify "reasons" of research failures that led subsequent peer-reviewed scientific paper retraction. Once assuring that cancer research is not following the general trend, conduct structured case analysis. Data: peer-reviewed scientific paper retraction posted at PubMed from 1977-May 2015; Official disclosure at journal retraction notices.

Findings: Among reproducibility failures (0.249. CI: 0.126-0.371), pure scientific ones caused by model confirmation/ lock down failures occupy roughly 16.7% (Period: 1977-May 2012). The majority was due to data integrity issues (0.687), among which 33% were troubled by incomplete raw data, unclear/ misallocation of responsibilities, together with untraceable records. More than half were outside of primary investigators' (PIs') direct control. Structured case analysis shows that, once self-regulated PIs restored their control in their profession and accepted external governance, they resumed adding high impact contributions to scientific success and integrity.

Conclusions: Appropriate science governance will be realized by boundary choices focusing on scientific autonomy, knowledge specificity, complexity and possible harms to others. In this sense, the IOM 2012 worked by allocating responsibilities among related parties, recommending a confirmatory model to be completed before publication, and transparent and sustainable data release. It has stimulated ethically motivated academic scientists through enhancing publication standards. Optimal law and science ethics policies would be ones that stimulate professional self-regulation while retaining external review and enforcement.

Keywords-self-regulation, scientific autonomy and external governance, science ethics, translational omics, cancer/ cancer-biomarker research.