How governance-free zones emerged in ethical science organizations: Research breakdowns and resilience in translational cancer medicine

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Abstract:

Objectives This paper aims to explore how governance-free zones emerged in ethical, responsible science organizations. For this purpose, we conduct retrospective study showing the defined causes of research failures in the translational cancer medicine field, especially in the discovery and preclinical phases. By understanding how breakdowns occur in ethics and research practices, I expect to provide clues for placing bioethical issues upon common ground. We will also uncover those labs that subsequently exhibited resilience, where labs and the science communities they belong to underwent disturbances but managed to retain well functioning controls and structures of governance.

Science research is performed in globally collaborative manner, while the resultant medicine is delivered in local regulatory contexts. As our focus is on the discovery and preclinical phases, we pursue the objective with global science governance in mind. 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 life science and biomedical research as revealed by Fang et al (2012) (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 after 2012. This suggests that transparency policies and data sharing protocols by the National Research Council 2012 guidelines and Institute of Medicine initiative have had salutary effects. This ongoing success indicates it is good timing to conduct retrospective study in order to understand how and why the new guidelines are delivering improved research outcomes.

Methodology: Classify and codify "reasons" of research failures that led subsequent peer-reviewed scientific paper retraction. Control data mishandling and errors including those related to coordination failure. Data: peer-reviewed scientific paper retraction posted at PubMed from 1977-May 2015.

Findings: Among reproducibility failures, that certainly existed in the field (0.249. CI: 0.126-0.371), pure scientific ones caused by model confirmation/ lock down failures (Cf. Kuhn 1962) occupy roughly 16.7% (Period: 1977-May 2012). The majority was due to data integrity issues (0.687). Among them, data misalignment due to system issues were less than 10 %. Thirty three percent were troubled by incomplete raw data or unclear responsibility. More than half were suspected of being generated by misconduct, outside of the primary investigators' (PIs') direct control. Once self-regulated PIs restored their autonomy and focused on their core research activities, they resumed adding high impact contributions to scientific success and integrity.

Conclusions: While transparency policies have been working, the true resilience occurred when self-regulated scientists restored autonomy in their profession, as well as accepted external governance. Optimal law and bioethics policies would be ones that stimulate professional self-regulation.

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