

## **Pharmaceutical research and development: A key informant assessment of whether an "open-science" model could improve clinical research in terms of quality and efficiency**

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**Abstract:** The average cost to develop each new pharmaceutical drug is approximately \$1 billion or more and takes 12-15 years from laboratory concept to an approved drug on the shelf at the local pharmacy. There is concern that the high cost and extended timelines required for pharmaceutical research and development (R&D;) is not sustainable in the long term, as pharmaceutical companies question the value of investing \$1 billion against an uncertain future revenue stream. The high cost of R&D; contributes to the high cost of pharmacotherapies to consumers, where one recent estimate projects that annual global spending on pharmaceuticals will exceed \$1.2 trillion by 2016.

Spending over \$1 trillion on pharmaceuticals each year is a burden on global health resources. Therefore, reducing the cost of pharmaceuticals could have a tremendous impact on patients' access to healthcare. A potential source of cost reduction is to improve efficiency in pharmaceutical R&D; while protecting patient safety and maintaining or improving research quality. If savings in pharmaceutical R&D; could be passed on to consumers, this would result in lower pharmaceutical prices and healthcare costs worldwide.

One concept proposed to improve R&D; efficiency and quality is to make the process more transparent and collaborative where researchers, even those from competing pharmaceutical companies, could more freely share information on their research designs, processes and outcomes. This concept, "open-science" R&D; (OSRD), differs from traditional R&D; approaches that typically are more secretive and less collaborative. To explore whether OSRD could be a viable and beneficial alternative to current pharmaceutical R&D; practices, key informants from academia, industry, and regulatory agencies were interviewed using a qualitative, semi-structured questionnaire. While the key informants were concerned that for-profit pharmaceutical companies would not voluntarily embrace OSRD, the results also revealed that, 1) OSRD may be more efficient and therefore better in terms of R&D; costs, 2) many OSRD-type activities are already in place, 3) more transparency is probably inevitable, and 4) senior leaders, including those in industry, are open to exploring opportunities for broad transparency and collaboration such as those envisioned in OSRD.

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