Critical oncology trial data remains hidden

July 28 2022

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Despite a commitment from the pharmaceutical industry in 2014 to improve data transparency, more than half of the clinical trials that led to the United States Food and Drug Administration approving anticancer medicines over the past 10 years are not available for independent scrutiny, a multi-national study led by Flinders University has found.

The authors say the commitment needs revisiting as it was designed to help restore confidence in evidence-based medicine and ensures data can be used for further research into the safety and efficacy of medicines.

To determine the current level of transparency in oncology trial data, the team looked at what proportion of clinical trials underpinning the registration of recent anticancer medicines were eligible for sharing with qualified researchers.

Published in the journal *JAMA Oncology*, the audit found of the 304 trials which backboned the registration of 115 anticancer drugs over the last 10 years, only 136 (45%) had individual patient data available for sharing.

Concerningly, for three of the globally top-selling anticancer drugs (nivolumab, pembrolizumab, and pomalidomide), 90% of the trial data was unavailable. Alone, these medicines generated over US$30 billion in revenue in 2020.

In Australia, two of these medicines (nivolumab and pembrolizumab) are the costliest antineoplastic (chemotherapy) drugs for the Australian taxpayer, costing the government over $800 million via the Pharmaceutical Benefits Scheme in 2020-21.

Study senior author Dr. Ash Hopkins, an NHMRC Investigator Fellow and leader of the Clinical Cancer Epidemiology Lab at Flinders University, says the most common reason provided for the lack of transparency was that the collection of long-term follow-up data was still ongoing.

"This is the same reason given by Pfizer and Moderna for the clinical trial data on their respective COVID-19 vaccines not currently being available," says Dr. Hopkins.

"However, this excuse disregards any commitment to data transparency. Ongoing follow-up is of course needed, but it should not hinder the release of the key data that is implicated in the global release of medicines to tens of thousands of people."

Study lead author Natansh Modi, an NHMRC Ph.D. candidate in the Clinical Cancer Epidemiology Lab at Flinders University, says while the need for the ongoing verification of clinical trial claims is one of the pillars of data transparency, he adds it is only one of several important benefits of data sharing.

"Evidence indicates that independent data requests are most often occurring to unlock insights into the risks and benefits of medicines in unexplored patient groups," says Modi.

"This aspect of research upholds the social contract that the industry enters into with trial participants, whereby they are told their participation will allow for further research to maximize the benefit to society."

"If the data isn't made available it can't be put to good use. Trial participants and their families deserve better."

The team is calling on the pharmaceutical industry to explicitly state in their transparency policies that trial data underpinning drug approvals will be available for independent investigation as soon as they are registered.

"Emerging policies drafted by the pharmaceutical industry offer an unparalleled opportunity to advance evidence-based medicine, support decision-making, and protect the community," says Modi.

"It is time that global regulators, governments, and journals establish

mandates for data transparency on all major trials investigating registered medicines. Their purpose must be to protect and maximize public health and ensure the contributions of trial participants and their families reach their full potential."

More information: Ash Hopkins et al, Audit of Data Sharing by Pharmaceutical Companies for Anticancer Medicines Approved by the US Food and Drug Administration, *JAMA Oncology* (2022). DOI: 10.1001/jamaoncol.2022.2867

Provided by Flinders University